Leaflet-based and Internet-based information about medicines for consumers

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Acknowledgements

This long and awkward journey has been one of the greatest challenges I have faced. The inspirational words of Friedrich Nietzsche (for me) offer an ironic reflection on the experience of doing a PhD:

> *"And with that, forward on the path of wisdom, with bold step and full confidence! However you may be, serve yourself as your own source of experience! ... for in any event you possess in yourself a ladder with a hundred rungs upon which you can climb to knowledge. You have it in your hands to achieve the absorption of all you experience – your experiments, errors, faults, delusions, passions, your loves and your hopes – into your goal without remainder ... no honey is sweeter than that of knowledge ... the clouds of affliction hovering over you will yet have to serve as udders from which you will milk the milk of your refreshment"* Friedrich Nietzsche (1878) *Human All Too Human: A book for free spirits. Section five: Tokens of Higher and Lower Culture.* Translated by R.J. Hollingdale (1986). Cambridge University Press, Cambridge: (pp 134-5)

Abstract

This thesis reports four studies that evaluated the usefulness of written medicines information provided as a leaflet, and on the Internet, for improving people's understanding about medicines. Three of the studies used mixed methods. Study one used two methods. A systematic review evaluated 36 randomised trials that examined the effectiveness of leaflet-based medicines information for changing knowledge, attitudes and medicines-taking behaviours. Two sequential workshops enabled stakeholders to input into the review aims, and then give feedback on the findings. The review concluded that leaflet-based information can improve knowledge, but there was no evidence that it can change attitudes or behaviour. Study two analysed ten websites that contained information about medicines and found considerable variation in their quality, content, and design. Study three examined the usability and readability of five sites sampled from Study two. Fifteen participants were randomly allocated to use one site, to locate and explain information about the safety and efficacy of the medicine. Their performance was measured using four concurrent methods: observation, online tracking, thinking aloud, and User Testing. The design of the sites and how their content was written impeded participants' performance on the task. Evidence-based recommendations were derived for improving the sites' design. Study four was a pilot of an intervention for redesigning Internet-based medicines information, including a crossover study design and tools for measuring the outcomes. Thirty participants viewed both the original and revised web pages in a random and counterbalanced order to see if the redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information. The study design and limited redesign of the webpages may not be appropriate for a full RCT. Applying User Testing to the evaluation of websites appears to be original, and using a mixed methods approach has been beneficial to the research. Improvements are needed to leaflet-based and Internet-based medicines information to make it easier to read and understand. This could make written medicines information more useful for medicine users, enabling them to make an informed choice about taking medicines, or be better informed about their safety and efficacy.

Table of contents

Figures

Tables

Abbreviations used in this thesis

- CHD – Coronary heart disease
- CMI – Consumer medicines information
- CTA – Concurrent think aloud
- CRUK – Cancer Research UK
- DTC – Direct-to-consumer
- EBM – Evidence-based medicine
- EU – European Union
- GP – General practitioner
- HCI – Human Computer Interactions
- HDL – High density lipoprotein
- HON Code – Health On the Net Code of Conduct
- HSR – Health Services Research
- HTA – Health Technology Assessment
- HTML – HyperText Markup Language
- IBMI – Internet-based medicines information
- IT – Information technology
- LDL – Low density lipoprotein
- LUTO – Leeds University Testing Organisation
- NHS – National Health Service
- NSAID – Non-steroidal anti-inflammatory drug
- OTC – Over-the-counter
- PC – Personal computer
- PDF – Portable document format
- PIL – Patient information leaflet
- POM – Prescription-only medicine
- PPI – Patient package insert
- PSSUQ – Post Study System Usability Questionnaire
- RCT – Randomised controlled trial
- RTA – Retrospective think aloud
- SIMS – Satisfaction with Information about Medicines Scale
- TPB – Theory of Planned Behaviour
- URL – Universal resource locater
- WMI – Written Medicines Information

Chapter one
Background

1.1.Introduction

Medicine users need sufficient information about medicines (Raynor *et al.*, 2007a). This information should be useful to enable them to understand and appreciate how to effectively take medicines, and to understand the risks and benefits in doing so (Raynor, 2007). Written medicines information (WMI), also known as consumer medicines information (CMI), is normally provided as leaflet-based information accompanying medicines, and is also available on the Internet. This thesis evaluates the usefulness of leaflet-based and Internet-based medicines information (IBMI) for aiding people's understanding about taking medicines. It does not seek to identify the circumstances in which WMI can be useful – this is a wider question that would necessitate examining the social context in which WMI is provided.

In the European Union (EU), WMI is provided as a patient information leaflet (PIL) accompanying both prescription-only medicines (POM) and over-the-counter (OTC) medicines (see 1.2.2). Coulter (1998) has proposed that if WMI is evidence-based and presented in an acceptable and useful format, this could enable the medicine user to be an active decision maker in her or his healthcare. Other means to support medicine users to take their medicines as prescribed include counselling, simplified dosing, and medication charts (Haynes *et al.*, 2008). These interventions are necessary because, while medicines are the most commonly provided health care intervention by the *National Health Service* (NHS) in the UK (Anonymous, 2002a), not all people take their medicines as intended (Haynes *et al.*, 2008). This is a worldwide public health issue that could have life-threatening risks, as well as negating the effectiveness of treatment (World Health Organisation (WHO), 2003).

There has been a call in the UK for an increase in public awareness of the availability of PILs in different formats (Medicines and Healthcare Products Regulatory Agency, 2005). The Internet offers an alternative resource for information on healthcare and medicines

information, known as e-health (see 1.3). IBMI is a category of e-health and is introduced in 1.4.

The following is a short overview of the work presented in this thesis. Study one (Chapter three) evaluated the role, value and effectiveness of PILs, as research of secondary data. This study was part of an *Health Technology Assessment* (HTA) Report (Raynor *et al.*, 2007a) that was commissioned by the *NHS R&D Health Technology Assessment Programme*. This project was based on a systematic review. Medicine information stakeholders provided input into the aims, and the conclusions of the review through two workshops.

The three other studies in this thesis were primary research that evaluated IBMI. Study two (Chapter four) assessed the design features, quality, and general and specific content of a sample of sites with information about the medicine *simvastatin*. Study three (Chapter five) examined the usability and the readability of the information contained in a sample of these sites. A series of evidence-based recommendations for improving the design of IBMI sites were derived. Study four (reported in Chapter six) was a pilot study of an intervention for redesigning Internet-based medicines information, including a crossover study design and outcomes measure tools. These could be used in a full trial evaluating whether redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information. The precise aims and objectives of the work reported in this thesis are presented in detail in 1.6.2. The following four sections provide an overview of the concepts and research base underpinning this thesis.

1.2. Written medicines information (WMI)

This section provides an introduction to PILs, which are examined in Chapter three. There is an overview of PILs in a wide context: the provision of WMI in the EU (and associated problems); the need for WMI to be readable (understandable) to be useful; WMI enabling the medicine user to make an informed decision; and the links between provision of WMI and the pharmaceutical industry. Several of these concepts are also relevant to IBMI. Firstly there is a brief overview of the PIL.

1.2.1. The patient information leaflet

The main mode of providing WMI is the PIL. This is a sheet of paper with written information, usually accompanying all medicines in the EU; see Figure 1 for an example of a PIL. Raynor *et al.* (2007a) have proposed that the PIL has two functions:

(i)   To enable an informed decision to be made about taking medicines, and

(ii)   To enable the patient to take and use the medicine effectively and safely.

These functions are examined in greater detail in section 1.2.6. The PIL is available to varying degrees and in different formats throughout the world. It is useful to look at three reported examples from around the world as a point of reference for PILs in the present-day EU.

In Australia CMI is required by law to provide information in English that is easily understood, to accompany all medicines (Koo *et al.*, 2003). In Belgium, patient package inserts (PPIs) have accompanied medicines (to varying degrees) since 1964, preceding EU legislation (Vander Stichele, 2004). There is no legal stipulation for WMI to accompany medicines in the USA, but a computer-generated leaflet (if available), can be printed by the pharmacist to accompany the medicines (Raynor *et al.*, 2007a).

Reviewing factors that determine the use of WMI, Koo *et al.* (2003) have categorised these as:

1. Relating to the leaflet: for example, the readability of its content (see 1.2.5), and the presentation of the information on the leaflet; and

2. Relating to the medicine user: for example, their health literacy (see 1.2.4), the role of caregivers, the medicine user's demographics, etc.

Two observations are drawn from this. Firstly, that the relationship between the leaflet and person is similar to that of user and website. Secondly, that the readability and presentation of the leaflet is dependent on how it is designed (see 1.5.2). This can equally apply to IBMI, and underlies the examination of IBMI in Studies two and three in this thesis.

Figure 1: Abridged example of a patient information leaflet

SIMVASTATIN

Read this leaflet carefully before you start taking this medicine.

- You may need to read this leaflet again.
- If you have further questions, speak to your doctor or your pharmacist.
- Do not share this medicine with others as it could harm them.

1. What Simvastatin is and what it is used for?

Simvastatin (also known as "statin".) is a medicine that lowers lipids. They work by lowering lipids (fats) such as cholesterol and triglycerides in your blood. Simvastatin Tablets are recommended for patients with high cholesterol and triglyceride levels, and for patients with cardiovascular diseases (heart and blood vessels diseases) and/or diabetes mellitus with either high or normal cholesterol levels.

2. Before you take Simvastatin

Do not take Simvastatin:

- If you are allergic to simvastatin, or any similar medicines.
- If you have liver problems.

Take special care:

Simvastatin can cause muscle problems. This risk is greater in higher doses and for certain patients. You should also tell your doctor if you:

- Have medical conditions including allergies;
- Have kidney problems;
- Are over 70 years of age;

3. How to take Simvastatin Tablets

Do not take more than what was prescribed by your doctor. If you take too much, go to the nearest hospital casualty department or tell your doctor immediately. Do not take two doses at once if you miss a dose.

4. Possible side effects

The following side effects are rare (between 1 in 1000 and 1 in 10,000 people are likely to be affected):

- **Nervous system disorders: headache, dizziness, numbness or loss of sensation in the arms and legs,**
- Gastrointestinal disorders: sickness, constipation, diarrhoea, flatulence.
- Hepato-biliary disorders: liver disease (possibly presenting as yellowing of the eyes and/or skin, itchiness of the skin, dark colored urine, pale colored stools),
- Skin and subcutaneous tissue disorders: hair loss, rash, itchiness,
- Musculoskeletal, connective tissue and bone disorders: muscle damage (see below),
- Allergic reaction to Simvastatin Tablets. The allergic reaction may include some of the following: swelling of the face, tongue or throat (in which case you should contact your doctor immediately), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, flushing, difficulty in breathing, or tiredness.

Speak to your doctor immediately if you have muscle aches and pains, tenderness, weakness, or cramps.

5. Storing Simvastatin Tablets

Do not take simvastatin after the expiry date.

[Based on the Dexcel Pharma *simvastatin* PIL accessed online in May 2008 at

http://emc.medicines.org.uk/emc/assets/c/html/DisplayDoc.asp?format=original&documentid=19028]

1.2.2. The provision of paper-based WMI in the European Union

The provision of WMI has been subject to legislation in Europe since the mid-1960s

(Vander Stichele, 2004). The development and existence of PILs and their content, in

member states of the EU, was regulated by Article 6 of the 1992 EU directive (92/27/EEC) (Council Directive, 1992), fully implemented in 1999. This made it a legal obligation for a comprehensive information leaflet to accompany all licensed medicines, (POM and OTC) in EU member states.

The 1992 Directive has now been superseded, with revised legislation stipulating the specific information to be contained in a leaflet. Directive 2004/27/EC of the European parliament and of the council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (European Commission, 2004), set out five obligatory items of information for PILs in the EU (see also Figure 1):

   (i)   What the medicine is and what it is used for;

   (ii)   Before you take or use the medicine;

   (iii)   How to take or use the medicine;

   (iv)   Possible side effects; and

   (v)   Storage of the medicine.

The mandatory headings for each section, were laid out in a document by the Quality Review of Documents (QRD) Group of the EU in 2005 (Quality Review of Documents Group, 2005).

The 2004 Directive allows the inclusion of some non-promotional information about the benefits of taking a medicine. How balanced the perspective of the risks and beneficial effects of taking a medicine is could have implications for people's intentions to take a medicine. Bersellini and Berry (2007) examined this using a hypothetical scenario and found provision of a benefit message increased participants' intention to take a medicine.

Research in the UK has shown that EU legislation may not yet be providing full benefit to patients. For example, a telephone survey in 1999 of 215 people who were dispensed medicines at three UK pharmacies found one third of medicines did not have a leaflet. When the leaflet was available, 83% of participants noticed it; and of those who did so, 40% reported reading at least some of it, and around 21% said they read all of it (Raynor and Knapp, 2000). This study was updated in 2003 by Raynor *et al.* (2005); and again in

2006 by Raynor *et al.* (2007b), when 97% of 456 respondents reported noting the insert. Of those receiving a medicine for the first time (122 people), 87 (71%) reported reading it. However, nearly two thirds of those receiving a repeat prescription had not read the PIL on that occasion (Raynor *et al.*, 2007b). So, despite the inclusion of the PIL being legislated for, a large number of people receiving long-term medicines in the UK did not read the information accompanying it, other than when they first received the medicine.

1.2.3. The relationship between information provision and health

It can be reasonably assumed that a key purpose of providing WMI will be to have a beneficial effect on the medicine taker's health, by encouraging him/her to adapt their health-related behaviours. However, it is important to critically examine the plausibility of this relationship.

There appears to be no evidence that clearly shows a direct relationship between provision of health information on (any) health-related behaviour. Rosenfeld and Morville (2002) have provided the example of the simplistic information model where 'black magic' occurs between the person asking a question and receiving an answer. They have criticised this as a mechanistic view of how people search for information, where it wrongly assumes that the individual is predictable in behaviour and rational in motivation. The same problem underlies the notion that giving information (the stimulus) will lead to a change in someone's health (the response). This ignores mediating variables: how the person processes the information, as well as environmental factors acting on the health and well-being of the individual.

The *Theory of Planned Behaviour* (TPB) (Ajzen, 1991) seeks to explain individual behaviour in terms of underlying intentions, rather than as a direct response to stimuli. TPB proposes that an individual forms an attitude towards an object, based on his beliefs, which then shape her or his intentions to behave in a particular way. The individual's attitude then shapes his intentions to behave in a particular way. It is this intention that solely and directly determines her or his behaviour. It follows that the effect of WMI on behaviour

(e.g. taking the medicine as instructed) is mediated by an attitude change, and not a direct stimulus-response relationship.

For the reasons above, providing WMI probably does not have a direct impact on the medicine taker's health. This is reflected by EU legislation, which does not seek to change health-related behaviour, but legislates for readable information (see 1.2.5). This thesis examines the readability of IBMI: if the information can be read and understood, this could enable the medicine user to make an informed choice about her or his medicine-taking behaviour. One role of WMI will be to (potentially) enable the medicine user to make an informed choice, and is examined in 1.2.6.

1.2.4. Health literacy

Koo *et al.'s* (2003) categorisation of aspects determining WMI use highlighted that one of the factors attributable to the individual user was their health literacy. This is an important public health phenomenon said to represent:

> "The cognitive and social skills which determine the motivation and ability of individuals to gain access to understand and use information in ways which promote and maintain good health ... health literacy is critical to empowerment" (World Health Organization (WHO), 1998), pp10.

Speros (2005) proposed that an individual's health literacy is dependent upon her or his literacy (reading and computational levels) and health-related experience. In this respect, an individual's need for WMI may vary in relation to her or his state of health. However, a high level of health literacy in the general public will not be enough for them to make an informed choice, and safely and effectively take the medicine. As Raynor (2008a) has noted, usable information that people can interpret and understand is as important for their understanding about their health and healthcare.

1.2.5. Readability and medicines information

The readability of written text refers to its understandability (Ley and Florio, 1996). The *US Pharmacopoeia* has proposed that usable medicines information is that which can be understood (Hartzema *et al.,* 1999). Adding to this, the *Communication Research Institute of Australia* have defined usable medicines information as that which is understandable, easy

to find, and appropriately acted upon (Sless, 2001). The usability of WMI will to an extent depend upon its perceived role. For example, Grime *et al.* (2007) have noted that WMI can encourage compliance or enable decision making, depending on whether one is a patient or a doctor (see also 1.2.6.).

The readability of information has typically been assessed using a formula. Bailin and Grafstein (2001) have proposed that the use of readability formulae is attractive because it offers an apparently objective and quantifiable evaluation of the difficulty of reading written material. An example of a readability formula is the *Flesch Reading Test* (Flesch, 1948) which measures sentence length (the number of words), and word length (the number of syllables) to calculate a reading ease scale which ranges from 0 (unreadable) to 100 (very easy to read). Other examples, based on similar principles include the *Fog Index* (Gunning, 1968), and the *Simple Measure of Gobbledygook* – SMOG (McLaughlin, 1969). An evaluation using a readability formula of US Medication Guides providing information about prescription medication found that none met the national recommendation for a reading level of 6th to 8th grade. This led to the conclusion that the reading level requirement should be reduced to make WMI in the USA more understandable to all sections of the community (Wolf *et al.*, 2006).

The rationale for examining the readability of WMI is that if the medicine user can understand the information (having found it) this would enable her or him to make an informed, evidence-based choice about their treatment. While it is important to examine whether WMI is understandable for the above reason, the usefulness of 'readability formulae' is questionable, as it may be neither necessary nor sufficient to examine this. Bailin and Grafstein (2001) have proposed that existing readability formulae do not measure what they purport to, because there is no set criterion that comprises a universal, unified concept of readability. Friedman and Hoffman-Goetz (2006) have indicated that the main difficulty with readability formulae is the reliance on word and sentence length, which ignores the effects of reader motivation, design and graphics on readability and comprehension. There is also the problem that the readability score for text will be the

same whether it is written forwards or backwards (Raynor, 2005): clearly someone would not be able to understand information when it is written backwards.

Article 59(3) of the 2001 EU Directive (2001/83/EC) (European Commission, 2001) stipulated that paper-based medicines information should be the subject of consultation with target groups to ensure it is legible, clear and easy to use. This can be interpreted to mean that the information must be understandable for the medicine users. This legislation has paved the way for the user testing of all medicine information leaflets produced by manufacturers and supplied in all packets of medicines in the EU (European Commission, 2004). User Testing of the content of a leaflet is a performance-based method for testing readability, devised in Australia (Sless and Wiseman, 2004). The performance being measured is the behaviour of the person reading the leaflet, specifically their ability to find and then understand precise information (see 5.2.1). The examination of the readability of the web pages by the research reported in this thesis adopts the User Test, legislated by the EU for evaluating the readability of PILs. IBMI sites are not regulated in a similar way, but there remains a need for them to be easy to use, and for the information they contain to be understandable.

Dickinson *et al.* (2001) compared a leaflet based on EU guidelines (Council Directive, 1992) with a leaflet based on best practice in information design, on a sample of 40 adults aged 55-85 years (Dickinson *et al.*, 2001). They found that the 'best design' leaflet was more understandable than the EU leaflet as well as demonstrating that user testing (see 5.2.1) provides a means for examining if a person understands the information. The review by Raynor and Dickinson (In press) of best practice in information design derived the following set of recommendations for writers of WMI. The expectation is that applying such recommendations to the design of not only PILs, but also IBMI, can make the information easier to comprehend. The recommendations are based around four themes:

- **Words:**

Choose short, familiar, everyday words of few syllables, which are concrete rather than abstract. Minimise jargon, and provide an explanation if technical terms are used. Use

different voices for different messages: an active voice to explain or warn; an imperative voice to relay instructions; do not use a passive voice. Use short sentence length of 15-20 words, with simple grammar. Convey attitude and meaning in a relaxed, straightforward style. Use positive phrasing, unless warning not to do something. Use an appropriate, conversational tone, e.g. 'we' and 'you'.

- **Type:**

Use a large font to maximise legibility. Use colour sparingly, and try to have black print on white paper to maximise contrast and legibility. A conventional typeface that is familiar is best, and bold fonts are more legible. There is no consensus on the use of serif or sans serif font.

- **Lines**

Left justification (non-justified text) is easier to read. Have 8-12 words per sentence: more or fewer hinders reading. Have short paragraphs. Do not wrap words around graphics.

- **Layout**

Bullet points can help to organise text. To emphasise words, use bold lower-case text, because words in capitals or italic are harder to read. Have plenty of white space, i.e. the absence of print. Use short headings that stand out. Have a clear organisational structure to aid finding information. Pictures or graphics do not necessarily improve documents; therefore they need to be used with care. Numbered lists should be used for sequences or lists of instructions. Page column breaks should not split sections. A table of contents will be helpful with a long document.

A study interviewed 40 patients using a questionnaire to evaluate understanding of the information in a random selection of PILs and found that although most information was well understood, information about drug interactions and contraindications was not (Gustafsson *et al.*, 2005).

The *EU Guideline on the readability of the label and package leaflet of medicinal products for human use (1998)* (European Commission Directorate-General III, 1998) proposed that the

side effects of a medicine should be categorised according to frequency, and described using verbal terms in WMI; for example, the risk of having a side effect that is 'very common' represents a risk greater than 10% numerically. However, there is consistent evidence showing people do not accurately interpret a verbal risk descriptor (see 3.5.5). It has therefore been proposed that the EU rescind the use of verbal risk descriptors until there is greater evidence to support them (Berry et al., 2003c). The evidence base, from which this argument is derived, forms part of the first empirical study of this thesis (see 3.5).

1.2.6. The role of WMI

It is as important to understand the purpose of WMI, i.e. what is it used for in the context of social relations, as well as whether or not it works. WMI can be considered to inform the patient and to enhance the shared decision-making process between the medicine user and health professionals. WMI can also be seen to be a means for facilitating compliance. However, compliance reflects a paternalist doctor-patient relationship (Parsons, 1951), where it is believed that the doctor 'knows best' and that the patient should comply (agree to the doctor's instructions) without question. Non-compliance (and its synonym non-adherence) can then be seen as negative behaviours. However, these may not be helpful concepts because they make no distinction between those who take some or none of their medications, and do not explain motivations relating to a patient's medicine-taking behaviour (Wride et al., 2007). A further criticism of compliance is that it suggests that the provision of WMI directly impacts on a person's medicine-taking behaviour, which has been shown to be problematic, (see 1.2.3).

The development of the ethos of increased patient involvement in their care (from the 1980s onwards) saw the choice-making informed consumer as being central to UK health policy (Huntington et al., 2007). The philosophy and practice of patient-centred medicine arising from this is marked by mutual participation, whereby responsibility for patient care is shared between the patient and doctor (Mead and Bower, 2000). Giving information about medicines provides an opportunity for the medicine user to be an equal partner in the doctor-patient relationship. Ratzan (2007) has proposed that this has great potential for

public health, because the 'informed patient' will be the basis for a healthier society, because she or he can contribute to her or his healthcare. However, there are arguments why this is may not be achievable (see below).

The World Health Organisation (WHO) (2003) has distinguished between 'adherence' to medication or any other regimen, which is a behaviour, and 'compliance', a passive act which does not require the medicine user's agreement. In the UK, the *Medicines Partnership* program has stated a need for concordant relations between healthcare professionals and patients (Medicines Partnership, 2005), whereby decision making is shared between the two parties. This reflects an active role for the patient seeking to process knowledge to aid decision making, rather than passively complying. Pound *et al.* (2005) have proposed that this process requires patients and doctors to be equal partners in treatment decisions. The process of concordance can (in part) be supported by the provision of tailored, clear, accurate, accessible, and sufficiently detailed information (Medicines Partnership, 2005). Therefore WMI, either paper-based or Internet-based, remains necessary for medicine users to be equal partners. However, this will only benefit people who are able to read. One way of providing information about medicines to people who cannot read includes the use of pictograms. (This is not examined in this thesis). The two other means to support concordance are prescribing consultations involving patients as partners; and patients being supported in taking medicines (Medicines Partnership, 2005).

WMI can then enable the individual to make an informed choice about taking medication or not. As such, it should be pivotal in enabling concordance. But Raynor and Britten (2001) have argued that current WMI may undermine concordance because it arrives too late for patients, i.e. only after they open the medicine package. Aarnio and Raitoharju (2007) refer to as the concept of time specificity, where there is a need for having information about medicine in a short time-frame. Raynor and Britten (2001) have also noted that the information is only about the medicine, so there is no information about alternative treatment options; and the information is not balanced because of its focus on negative aspects (for example, side effects). It has been noted above that although it

appears logical, providing information with the aim of changing behaviour may not have an effect at all (Ferner, 2003).

A qualitative synthesis of previous research found that medicines users did not take their medicines because of concerns about taking them (Pound *et al.*, 2005). This contradicts theories of compliance which attribute this to a failing on the part of the patient. Interviewing women receiving hormone replacement therapy, Henwood *et al.* (2003) found there were constraints on the women becoming informed patients (through accessing the Internet): their lack of health literacy skills for finding and appraising information; reluctance on the part of the General Practitioner (GP) to facilitate the person to have an equal role in the process; and many patients not wanting to have responsibility for finding information, instead uncritically accepting their GP's decisions. Whether medicine users will be empowered to use WMI to make informed choices about taking their medicines (or not), this does not negate the need to evaluate WMI.

Matters are complicated by disputes surrounding the issue of concordance. Some have cast doubt on the value of the term concordance, arguing it is synonymous with adherence or compliance (Aronson, 2007a), and therefore presents no difference or benefit to the patient. The response to this has been that concordance refers to a process of negotiation between doctor and patient, while compliance/adherence refers to the patient's medicine-taking behaviour (Bell *et al.*, 2007). However, in a convincing argument, (Aronson, 2007b) has highlighted how, in the treatment of a critically ill patient, there is no scope or need for negotiation. Whether this is a semantic debate about a sociological label, or a more fundamental debate on the relationship between doctor and patient, does not negate the need for trustworthy, evidence-based WMI.

These points indicate that WMI has a potential role as a means for aiding compliance, and/or shared decision making. Raynor *et al.* (2007a) evaluating the role and value of WMI for patients, and health professionals, have found that these stakeholders have different perceptions of the role and value of WMI. Some patients felt WMI had an empowering role to facilitate their involvement in their treatment, and so they valued information that

was condition-based and personalised; particularly when it provided information about alternative treatments. In comparison, professionals saw WMI as a tool to lead to patient compliance with treatment; valuing short and simple information, as they thought that more complex information might overwhelm the patient.

Newby *et al.* (2001) conducted a telephone survey of 786 people, and a follow-up in-depth interview with a random sample of 58 of those participants. They found that medicine users reported wanting advice about how the medicine works for the condition, and the reason for taking the medicine, to enable them to make a treatment choice. With this information available online, e-health could be seen by medicine users as an empowering tool enabling them to make shared decisions with their GP. However, this hope may be forlorn, when considered in relation to Henwood *et al.*'s (2003) finding that there are constraints on people becoming Internet-empowered shared decision makers (see above).

The work reviewed in this section highlights a potential tension between the WMI as devised by pharmaceutical companies and what it is used for by patients. The purpose of WMI is not evaluated in this thesis. Examining the purpose of WMI can provide insight on what it is used for by medicine users, whether or not it meets their needs, and whether or not they value WMI. This, however, does not consider if users understand the information. It is perhaps not difficult to appreciate that before the person can use WMI in a particular way (i.e. act upon reading it), they must first have understood the information. Therefore it is argued that it is first necessary for research to determine if WMI (leaflet or Internet-based) is easy to read and understand.

1.2.7. The pharmaceutical industry and WMI

The most important sponsor of medical research worldwide, and the principal generator of WMI, is the pharmaceutical industry (Collier and Iheanacho, 2002). The pharmaceutical industry also produces direct-to-consumer (DTC) drug advertising; in 2008 the only places in the world where DTC advertising was legal was in New Zealand and the USA. In 2001 regulatory guidelines (European Federation of Pharmaceutical Industry, 2001) for DTC on the Internet came into force in the EU, limiting the information available to technical details and further information for health professionals.

It is important to distinguish between WMI and DTC advertising. WMI accompanies the medicine, whilst DTC advertising promotes the product (medicinal drug) to potential consumers. Some have sought to blur the barriers between the two concepts, with calls to use DTC advertising as a means to meet medicine users' demands for better information (Holmer, 1999). This proposal has been criticised on the grounds that profit will become more important than the actual information (Alper, 1999).

There is no evidence that DTC advertising can improve health. This was the conclusion of a systematic review of four studies evaluating the impact of DTC on health-seeking behaviour and other related outcomes (Gilbody *et al.*, 2005). There is evidence that DTC is not understandable to a large number of people. A study evaluating the readability of DTC magazine advertisements in the USA, using a readability formula, concluded that the material was written at a level only a college student or graduate would understand (Kaphingst *et al.*, 2004). This would probably make the information difficult to understand for the vast majority of the public who would not have been educated to that level. However, this finding is based on a readability calculation, which may be an invalid measure of the understandability of written information (see 1.2.5). Instead a user test would be required to examine how understandable this information actually was. While DTC advertising is not permitted in the EU, the Internet makes this information available to EU residents, as well as the prescription drugs it advertises.

1.3. Overview of e-health

DTC advertising is one element of healthcare information available on the Internet, known as e-health. Three studies in this thesis evaluate IBMI, a specific type of e-health. This section provides an overview of e-health, looking first at the Internet in general and then issues of relevance to e-health. These issues are also relevant to IBMI, covered in 1.4.

1.3.1. The Internet and the World Wide Web

The Internet and World Wide Web ('the web') are terms often used interchangeably, although they are not the same: the web is a service available on the Internet. (This thesis will use the term 'the Internet'). To access the Internet, three pieces of hardware are

necessary: a computer, a telephone or cable connection to the Internet, and web browser software to enable the user to navigate the Internet. The two most commonly accessed browsers are *Microsoft Internet Explorer* (*www.microsoft.com/window/ie*) and *Mozilla Firefox* (*http:// www.mozilla.com/firefox/*) (source: *http://en.wikipedia.org/wiki/Image:Webapps.svg* accessed September 2008). Pages on the web are held on servers, i.e. computers permanently connected to the Internet which send, store or receive information, and are identified by a unique name, a uniform resource locator (URL): for example, *http://www.bbc.co.uk*.

In the UK there are approximately 38 million Internet users, more than 62% of the population (http://www.internetworldstats.com/stats9.htm, Accessed November 2007). Eysenbach and Köhler (2003) estimated that approximately 4.5% of all searches on the Internet (worldwide) are health-related. While less than one tenth of these relate to medicines (Eysenbach and Köhler, 2004), this is still a vast number of searches when it is considered that in February 2007 nearly seven billion searches were performed worldwide (*http://www.tmcnet.com/usubmit/2007/07/12/2778610.htm*, Accessed November 2007).

Several functions have been noted for interactive health care applications, (a definition that includes the Internet), including to relay information, and to enable informed decision making, both of which are commonly cited reasons for providing WMI (Robinson *et al.,* 1998). The interactive nature of the Internet is important to note, because Berry (2006) has argued that the Internet could personalise large amounts of medicines information to individuals: for example, where a medicines user enters details about her or his medicines and receives information that is specifically tailored.

1.3.2. Internet search engines
Search engines are a tool for finding information available on the Internet. The individual searches by typing a word or phrase, which retrieves a list of sites with information relevant to that search. This may be helpful when an individual seeks information about a medicine but does not know the URL of an IBMI site. Constraints exist on what the individual can find, however, and this will structure the web use experience of the

individual (Seale, 2005). Beyond the individual's Internet proficiency, two technical aspects of search engines determine what can be found: indexing, and ranking.

Indexing of web pages involves assigning keywords to the sites, which aid their retrieval using a search engine (if the site's URL is not known). This carries immense power because, to exist as a website, it has been argued, is to be indexed by a search engine (Introna and Nissenbaum, 2000). Search engine databases are either directory based, where pages are manually submitted (for example, *Yahoo!*™), or they are created by a 'spider' automatically searching the Internet. It is not, however, transparent how a spider works (Introna and Nissenbaum, 2000).

After a site is indexed, it can then be ranked. There is competition to receive a high ranking. Introna and Nissenbaum (2000) have suggested that, as search engines display sites in blocks of ten, website designers covet ranking in the first ten to 20 positions. This becomes more important when it is considered the search strategies the public use (see 1.3.5). The way that search engines rank sites is not disclosed (Seale, 2005), which means the process of ranking is not transparent.

This lack of transparency can be seen to give search engine companies an element of power. Because it is argued that search engines' indexing and ranking of websites has a political feature over and above a technological dimension this will constrain the information the Internet user can and cannot find (Introna and Nissenbaum, 2000), including information about medicines.

1.3.3. e-health

Eysenbach (2001) has defined e-health as a form of health service and information delivered and/or enhanced through the Internet and related technologies. e-health encompasses a range of websites, including support group sites offering individuals a forum for discussing health issues; Government-developed websites providing information as fact sheets; pharmaceutical company sites providing (and promoting) product information; and media sites, providing health news (Sillence *et al.*, 2006). To this list can be added advocacy group websites, which promote patients' and relatives'

interests (Jørgensen and Gøtzsche, 2004), and non-industry developed IBMI. Whatever the type of site, Eysenbach (2001) proposes that e-health should enhance quality and be: efficient, evidence-based, empowering, encouraging, educating, enabling, extending the scope of health care, ethical, and equitable. It may be asked if it is possible or realistic to expect e-health to be able to meet all these features. Furthermore, this list does not address the accessibility of the Internet to the public, which will also determine whether or not e-health is beneficial (see 1.3.4).

There are a couple of points to note when evaluating the Internet. Because it is not a static medium, research findings cannot reflect the possibility for changes in their content over time. Furthermore, evaluators of the Internet need to be aware that a website cannot be assessed as if it is a leaflet (Eysenbach, 2002). This is because it can be assumed that people may be accessing more than one website, whereas if they have a leaflet in their hands, they will only look at that. (It remains possible that some people will look at more than just the leaflet in their hands). Furthermore, a website requires navigating, and this requires the person to have a level of proficiency in using the Internet, whereas a leaflet only requires the person to read it.

The patient making an informed decision about healthcare treatment (see 1.2.6) can do so using information accessed from the Internet. McMullan (2006) proposes that the Internet could facilitate patient-centred interaction between the patient and health professional, by opening access to information for the patient. Kivits (2006) has suggested that the person using the Internet to become an informed patient is (in part) taking responsibility for his or her health. The potential benefits from Internet use may be attractive to those patients who want to be more informed about their healthcare and take an active role in decision making. However, not everyone will want to, or have the resources to adopt this role (Raynor *et al.*, 2007a). Furthermore, if the person accessing e-health looks at information which contradicts that given by their healthcare professional, or if the information discusses alternative treatment options to those offered by their healthcare professional, and the person acts on this, there is the potential for them to incur a health problem.

1.3.4. Public access to e-health

It is important to consider who usually accesses e-health; their rationale for accessing e-health, and socioeconomic factors determining access. Knowing who does and does not access e-health could inform public health attempts to improve access to health information and could aid the tailoring of sites to the intended audience.

Demographics of e-health users

The evidence shows that individuals may have differing information needs dependent upon their state of health and well-being or disease progress. A study of 50 young Finnish people (mean age 27 years) with or without a health condition found that women who were pregnant and men or women with diabetes accessed the Internet more often and viewed e-health more often than non-pregnant women, including e-health sites (Eriksson-Backa, 2003). Cotten and Gupta (2004) interviewed 385 people in the USA and found that those who accessed e-health were in general healthier, younger, had a higher socioeconomic status, and were educated to a higher level than those who did not. Alternatively the Pew Internet and American Life Project, a nationwide US survey examining the impact of the Internet on households, found those with poorer health made more frequent use of health information on the Internet, compared to those in better health (Houston and Allison, 2002). Inequalities in access to the Internet are referred to as the 'digital divide'. It highlights that those who are most disadvantaged, and more likely to have the poorest health in developed countries, have least access to the Internet (Brodie *et al.*, 2000). This reflects the broader observation by Hart (1971) that the provision of good medical care varies inversely with the needs of the population ('the inverse case law').

Dolan *et al.* (2004) distributed a questionnaire to 851 patients in an affluent and a deprived general practice in Wales, and found that older patients (> 55 years) had significantly less access to the Internet than younger patients; while younger patients (24-54 years) were significantly more likely to use the Internet for accessing healthcare information. In time the difference is likely to be reduced as the current older generations decline, because younger people are (on the whole) Internet literate. However, the digital divide will probably not be resolved, and so universal access to e-health will not be realised. A

telephone survey in Finland of 714 medicine users similarly found that more young respondents than older participants reported accessing IBMI (Närhi, 2007). Huntington, Nicholas *et al.* (2007) examined use of the *NHS Direct (http://www.nhsdirect.nhs.uk)* and *BBC Health (http://news.bbc.co.uk/health)* websites in a sample of 923 people (who were predominantly male, in full-time employment, and aged 25 to 52). Around one quarter reported accessing *NHS Direct*, while one fifth visited the *BBC Health* web pages.

As a whole, these studies have increased our understanding about e-health, who accesses it, and the socio-economic factors determining people's access to it. However, they have tended to be based on either large random samples, or small purposive samples, fitting their quantitative or qualitative design respectively. Each approach is beset with its own advantages and problems (see 2.5.1). In general it is difficult to gather a sample of participants in any survey that reflects the wider population. The sampling frame used by several of the studies was not representative of everyone that accesses e-health; therefore the external validity is limited. Firstly the results may be a product of respondent bias; i.e. it is not certain that what a respondent in a survey says reflects their actual Internet behaviour. This can also explain apparently contradictory findings: for example, those of Cotton and Gupta (2004) and Houston and Allison (2002). A common limitation of much research is that participants may be self-selecting and therefore more motivated to take part than those who do not. This again will constrain the generalisability of the findings, because the sample will not be a true reflection of everyone who uses e-health.

Motivation for accessing e-health

It is important to know the reason(s) for people accessing e-health. These may be varied because the Internet offers a number of potential benefits for health information seekers: widespread access to health information, the potential for interactive communications, tailored information, facilitation of interpersonal interaction, and the potential for anonymity (Cline and Haynes, 2001).

A study of *Best Treatments (http://besttreatments.bmj.com/btuk/home.jsp)* a UK-developed site offering condition-based information for patients and doctors, (Anon, Unpublished)

conducted individual interviews and group discussions to evaluate if the site helped the public make choices and enabled them to share decision making with their doctors. Respondents reported that they trusted the site because it was explicitly evidence-based, linked to the *British Medical Journal*, and used the same information source as *Clinical Evidence (www.clinicalevidence.com)*, a website aimed at health professionals. Participants reported feeling more comfortable discussing treatment issues with their doctor after using the site. A second study found this site scored high for readability, making the information easy to understand (Kamel Boulos, 2005).

In general, e-health is well received by the public. A series of focus groups examining UK and US adolescents' perceptions and experiences of online health information, found the Internet can empower adolescent users by offering personalised healthcare information, which increases the salience of the information (Gray *et al.*, 2005). If this is reflected in general, e-health may have a valuable role in informing adolescents (who may not regularly access a GP). A three week online questionnaire survey of users of *NHS Direct (http://www.nhsdirect.nhs.uk/)*, the *NHS* website, providing information about health, illness and health services; received 42 replies (25 from men). Most commented that they liked the convenience and anonymity of the Internet for health information (Williams *et al.*, 2003). However, the very small number of self-selected respondents makes this finding difficult to generalise. By comparison, Nicholas *et al.* (2002) conducted an online questionnaire on the *NHS Direct* website which recruited 3,374 respondents. They identified four broad reasons given for accessing the site, with people saying that they wanted information:

(i)   About a condition when they or a relative were ill; so as to know what to do;

(ii)   About a condition when they thought they were ill, so as to know what to do;

(iii)   About avoiding illness;

(iv)   About the NHS.

A web-based questionnaire of 1,103 Internet users found they reported accessing e-health in preference to other sources of information, because it provided advice on sensitive or stigmatising issues, and it offered the opportunity to self-diagnose. They also preferred its ability to be a social-support mechanism (Sillence *et al.*, 2007a).

A focus group session evaluating young people's perspectives on using the Internet to obtain health information and resources found the quality of access to the Internet was felt to be as important as having access to it, if not more so (Skinner *et al.*, 2003). Four factors affected the reported quality of access:

- **Privacy** – searching for personal or sensitive topics without intrusion;
- **Gate-keeping** – access being blocked or restricted;
- **Timeliness** – access when required and for as long as needed;
- **Functionality** – the personal computer (PC) operating adequately (Skinner *et al.*, 2003).

While this study examined the views of young people, factors influencing access may be different for the rest of the general public: for example, it may be dependent on gender, ethnic background or socio-economic status.

In summary, these findings suggest that the public favour e-health when it: (i) is explicitly evidence-based; (ii) is easy to understand; (iii) offers personalised healthcare information; (iv) offers convenience and anonymity re sensitive issues; and (v) is easy to access. However, the validity of some of these findings can be questioned as they were acquired from small studies with samples that are not representative of everyone who uses e-health.

1.3.5. Searching for healthcare information on the Internet

It is important to know how people conduct searches on the Internet for healthcare and medicines information, because this will impact on what people do and do not find (and then read). Eysenbach and Köhler (2002) sought to examine the techniques that the general public used to retrieve and assess health information on the Internet. They conducted focus group sessions with 21 participants (five males, mean age 37 years), and usability tests and semi-structured interviews with a further 17 participants (six males, mean age 38

years) in Germany. None of the participants reported using a medical portal as the starting point for their searches. Instead they used a search engine and looked at only the first few links on the page. When the researchers observed the participants using the sites, they noted that the participants did not look for information about the source of the site, i.e. 'about us' sections, disclaimers, or disclosure statements to ascertain the source of information. However, the same participants when interviewed said that they would look for this information in the future to assess the credibility of a site. The authors noted that the study had no consequences for the participants, and so they may not have conducted the search as thoroughly or with as much motivation as someone with an illness. While this reflects the possibility that people (may) have differing information needs dependent on their current health status, there has been little research examining the impact of disease progress on the amount of, or quality of, information sought.

Goldner (2006) randomly telephoned 2,038 adults in the USA to examine whether a person's health status determined what information was sought. Sixty-three percent of respondents said they looked for information on disease or medical conditions (the most commonly searched term), but only 34% of people looked for information on 'drugs', the fifth most commonly searched for health-related term. Respondents with a disability or medical condition were significantly more likely to have searched for information about 'medical conditions' or 'treatments', compared to 'healthy respondents'; but there was no difference for searching for information online regarding 'healthy lifestyle' issues.

1.3.6. The quality, trust, and reliability of e-health

Because incomplete or inaccurate information on the Internet can potentially have a bearing on the health and well-being of an individual (Eysenbach *et al.*, 2002), it is important for e-health users to be able to adequately assess the trustworthiness of the sites. The general public need high quality information about health, prevention, detection and treatment of disease in order to be able to manage their health (Ratzan, 2007).

Research has sought to identify standards for evaluating the quality of healthcare websites. A systematic review of 79 studies assessing the quality of e-health found five recurring criteria, that are features of the Internet site (Eysenbach *et al.*, 2002). They were:

- **Technical criteria:** for example, disclosure of authorship, or e-mail contact details;
- **Design features:** for example, layout of the site;
- **Readability:** based on sentence/word length and complexity;
- **Accuracy:** the concordance between information and best evidence;
- **Completeness/comprehensiveness:** of the information covered.

Adams *et al.* (2006a) has similarly noted that reliability is a property of (Internet-based) healthcare information; (see below for a further discussion of the reliability of e-health). Therefore the quality or reliability of information is external to the person.

Eysenbach *et al.* (2002) found that the majority of the 79 studies (70%) reported that the quality of e-health was a problem. However, the authors warned that the prevalence data for inaccurate or incomplete web information that was reported in the studies was difficult to interpret, and thus compare. They also warned that it was not likely to be generalisable or representative.

Eysenbach and Diepgen (1998) have proposed that the variability of the quality of information available on the Internet limits its use as a credible source, where information can still harm even if not necessarily false. Furthermore, research has found that consumers have difficulty finding complete and accurate information (Berland *et al.*, 2001). Risk and Petersen (2002) have suggested that the quality of an e-health site could be measured by whether or not the site has a positive effect on the person's health outcomes, quality of life, or clinical end points. However, this argument takes a 'black box' approach to understanding the role of information on people's health, ignoring how the person processes the information (see also 1.2.3).

Suggested ways for the public to assess the quality of e-health

There are many recommendations on how the general public should assess the quality of e-health sites. A review by Wilson (2002) identified five competing approaches to

assessing English language sites that are available to the consumer: codes of conduct, quality labels, user guidance systems, filtering tools, and 3rd party certification.

- Codes of conduct make recommendations for the development and content of the websites – for example, the *Internet Healthcare Coalition's e-health Code of Ethics* (*http://www.hi-europe.co.uk/files/1998_9/codeofethics.htm*) – placing the emphasis for the assessment of quality on the user of the site. This may be unrealistic if web users do not have the time and skills to commit to this process.

- Quality labels on a site, displayed as a logo on a site, show that it meets a pre-determined criterion – for example, the *Health on the Net Code of Conduct (HON Code)* (*http://www.hon.ch/HONcode/Conduct.html*), (see Appendix two). The responsibility lies with the site developer to ensure the site meets the criterion, and with the user to check for a logo, which assumes that the user will know to check for this. The site offers a *HON Code* toolbar which can be downloaded to check the accreditation status of the website currently accessed. Again the responsibility lies with the user to be aware of the logo and the toolbar. Breckons *et al.* (2008) published an evaluation of the quality of websites containing information about complementary medicines, the aim of which was to compare the performance of different evaluation instruments. They concluded that the *HON Code* did not correspond with other tools' ranking of site quality.

- User Guidance systems allow users to check if a site and its content meet standards – for example, *DISCERN* (*www.discern.org.uk/discern_instrument.php*), (see Appendix two). Again the burden is on the user to assess the site, and likewise assumes the user will be adept at this task.

- Filtering tools enable users to set criteria for automatically accepting or rejecting sites – for example, *OMNI*, now *Intute: Health and Life Sciences* (*www.intute.ac.uk/healthandlifesciences*). This places little demand on the consumer as the assessment has been conducted by a reviewer, although the user would have to be proficient in using the tool.

- Third party certification displays logos (for a fee) to show that the site meets a set of standards for content – for example, *MedCertain (http://www.hi-*

europe.co.uk/files/2000/medcertain.htm). Again there is no burden on the consumer, (although knowledge and awareness of this system would be necessary).

These initiatives have been criticised for having general limitations, placing a great burden on the providers and seekers of IBMI, having development costs and, because they are English-language based, not meeting the needs of users in the developing world (Risk, 2002).

The importance of e-health being trustworthy

Sillence and Briggs (2007) propose that trust is the process of seeking and acting upon advice, with associated risks. Trust is therefore a cognitive process internal to the individual, (unlike quality, which is a feature of the site or leaflet). Thiede (2005) has noted that health information needs to be trustworthy and understandable for the average healthcare user. The potential danger is that if the information is not trustworthy or understandable, the person may act inappropriately upon reading it, and endanger her or his health. However, similar to the point made above about the quality of the information, any relationship between untrustworthy information and negative health consequences is indirect, for the reasons explained in 1.2.3.

Most people seeking medical care do not have the same level of knowledge of medicine as healthcare professionals. Therefore, Clark (2002) has argued that trustworthy information is vital because it redresses the vulnerability of the patient as a health consumer. The trust placed in a website is pertinent to the Internet in general and not just e-health. For example, Resnick and Zeckhauser (2002) examined how users of the popular auction website *eBay* assessed the trust of buyers and/or sellers, and found evidence that users do so based on the buyer's or seller's online reputation.

How the public assess the quality of e-health

This section has identified a range of formal methods for the public to use to assess the quality of e-health. However, the evidence shows that people (largely) do not adopt such approaches. For example, research has found that consumers do not always look for the

source of information as evidence of the credibility of a website (Eysenbach and Köhler, 2002).

How the public assess the trustworthiness of e-health

It is important to understand how people assess the trustworthiness of e-health. Sillence *et al.* (2007c) observed 15 women (mean age 49, 41-60 years) looking for online information about the menopause. They found that the women's judgement of whether the websites were trustworthy (or not) was based on their look and feel; e.g. whether or not the site referred to the source of the evidence, or how up-to-date it was. Observing 13 people (six female, age range 33-68 years) interacting with an e-health site, Sillence *et al.* (2007b), found that participants' impression of mistrust was based upon the visual design of the site, while trust was based on the option to personalise information. (Sillence *et al.*, 2007a) conducted an online survey to record how people reported searching for health information and judging its trust. From 1,480 responses, they found that the three trust markers that were considered most important were: the ease of use of the site, advice from a knowledgeable source, and advice from an expert source. These studies suggest that the general public use methods for assessing the trust of a website that are more makeshift than the suggested formal methods listed above.

Sillence *et al.* (2006) devised the Staged Model of Trust for web-based health advice as a way of explaining the process by which the public develop trust in e-health. It proposes that those who access e-health analyse the trust of the information to different depths, depending on when they access it. At an early stage people use heuristics (cognitive shortcuts) to make a cursory analysis of trust, based on the look and feel of the site: for example, whether the balance of text and graphics is visually appealing, if the site has social identity cues that signal that it will be of interest, the number of adverts it has, whether the site features branding of its image, and the layout and navigation of the pages. In the longer term, people's engagement with websites is based on the credibility of the content and the ability to personalise the content: e.g. sites that are interactive, and have user-generated content.

This model predicts:

(i)   How people assess the trustworthiness of information, and

(ii)   How reliable their assessment will be.

These studies have improved our understanding about how people assess the trust of e-health, and acts as a frame of reference for the examination of how people assess the trust of IBMI sites in Study three (see Chapter five). Future studies of the assessment of trust of e-health could recruit from a wider sample; e.g. more men, and younger and older people, to broaden understanding of this process in other groups.

How the public assess the reliability of e-health

The *Oxford English Dictionary Online* defines 'reliable' as:

> *"that may be relied upon; in which reliance or confidence may be put; trustworthy, safe, sure"* (http://www.oed.com/ accessed online May 2009).

Reviewing the concept of reliability with regards to e-health, Adams (2006a) has argued that the literature deals with this in a clear-cut manner, promoting professional expert criteria, for example, looking for the presence of a quality seal or comparing the information with a checklist to the detriment of the individual's situation. Instead of adopting such 'formal' techniques, she has suggested that people construct the reliability of information acquired from a website by cross-referencing with other sources: for example, a GP, friend or family member, or another website (Adams, 2006b). However, it can be argued that people should not depend on only cross-referencing material to assess a website's reliability. It is possible that a person could find different sources of health information providing the same incorrect information. While this replication may appear to give the information greater credibility, it would only be repeating incorrect information. Information like this could be potentially dangerous for the medicine user to conclude that the repeated information is therefore reliable. People accessing e-health need to be able to assess the absolute reliability of the information on a website, rather than the relative reliability between sites.

Concluding remarks on the quality, trust, and reliability of e-health

Because of the open nature of the Internet, e-health cannot be regulated (Bonaccorso and Sturchio, 2002). Therefore the possible impact of poor site quality remains a concern, and may (at the very least) provide people with inaccurate, inconsistent, or incomplete information. At worst it could have indirect detrimental consequences for the health and well-being of the medicine user, if they act on the information. It is therefore important that research examines the quality of information, as this can highlight when it is incomplete, inadequate or incomprehensible.

The trustworthiness (or not) of the websites may not necessarily deter people from using the Internet. As Wofford *et al.* (2005) have argued, regardless of its endorsement or not, patients will use the Internet to learn about their healthcare. Furthermore, Kivits (2004) has noted that the idea of the online health information seeker is ambiguous, because that person may actually be searching for information for friends or family, and not for her or himself.

By highlighting the (potential) impact of the quality of websites, this has necessitated an analysis of the quality of IBMI as a possible determinant of their usefulness. A range of assessment tools are available, and principles from the following two will be used to guide the content analysis (Study two reported in Chapter four):

- The *HON Code*,
- Recommendations from the *DISCERN* website.

The reasons for applying aspects of these tools are:

(i)   The *HON Code* seal shows sites meeting its quality criteria. This may be reassuring to the Internet user who recognises what it stands for, and may spare the person from assessing the quality; and

(ii) Both enable users to assess the 'quality' of the sites, therefore are potentially empowering (albeit to the competent user). Filtering tools are not used because there may be an issue of their ease of use; which is a separate (but related) research question to that examined in this thesis.

1.3.7. Personalisation of e-health sites

Medicines users have indicated that they would value receiving personalised information about medicines via the Internet (Howarth et al., 2000), yet no known study has examined the worth of personalised IBMI. Jones et al. (2006) have examined the benefits of personalising information about cancer treatment on PCs. They randomised 400 people starting radiotherapy treatment to one of eight groups based on three binary factors: personalised or general information; information from a PC or from a booklet; and additional anxiety management information or no such information. Patients receiving the personalised information felt it informed them more than the general material, and they were more likely to share this with friends and family. This is likely to be a robust finding despite 43% of the participants being computer naïve at the start of the study. As the authors note, this would have affected their performance with the PC, but should not have impacted on the benefits from the personalised information.

1.4. Overview of Internet-based medicines information (IBMI)

Having reviewed e-health, the focus now shifts to IBMI. In this thesis it is considered that a site which provides information solely or primarily about a medicine is an IBMI site. Sites that provide general information about a range of treatments, where the information about medicines is not the main focus, are not considered to be an IBMI site. Sites that have been developed by a pharmaceutical company to provide information about a medicine are not excluded from the definition of IBMI, even though medicine users have reported disinclination to access pharmaceutical developed sites (see 1.4.2). It is considered that this is not a reason to not evaluate these websites, because they are aimed at the general public, and some people will access them. It is important that all IBMI (and e-health) websites are easy to use, and have understandable and trustworthy content.

1.4.1. Medicine users access to IBMI

People are known to search for IBMI after being prescribed medication, e.g. see the literature review by Morahan-Martin (2004). A survey of 1,322 people found that 54% accessed the Internet for information about prescribed medication (Nicholas et al., 2003). In the *Pew Internet and American Life Project*, researchers found that 40% of Internet users

searched for IBMI; and of those who reported doing this, adults (50-64 years), and experienced Internet users (six or more years' experience) were more likely to do so (Fox, 2005). Focus groups in Australia found that medicine users reported using limited strategies to search for IBMI, i.e. typing the name of the medicine into a search engine, and not looking beyond the first page of links (Peterson *et al.*, 2003). This corresponds with the limited techniques people are seen to use for searching for information about healthcare in general (see 1.3.5).

While it is known that people look for IBMI after being prescribed a medicine, the precise reason for doing so remains unclear. It has been suggested that this could be because WMI accompanying medicines is not felt to match medicine users' needs (Sidhu *et al.*, 2006). More work is needed to answer why people use this medium to access WMI, and this is explored in research reported in Chapter five. The better our understanding of how and why medicines users access IBMI, the better evidence designers of IBMI will have to tailor it in a way that will benefit the user.

1.4.2. Medicine users' views on IBMI

Focus group studies have assessed medicines users' opinions about IBMI. An Australian study found that, on the whole, respondents regarded the Internet as a beneficial and convenient source of WMI, in spite of doubts about the quality of the information (Peterson-Clark *et al.*, 2004). Many of the participants reported concerns about the credibility of the site, preferring government or professional health care sites to pharmaceutical sites, while some respondents spoke of concerns about the quality of the information, and described a range of different quality assessment strategies (Peterson *et al.*, 2003).

1.4.3. The content and quality of IBMI

Huh and Cude (2004) investigated the content and presentation of risk information for prescribed medicines on direct-to-consumer drug websites. Using a sample of 60 sites, they found that almost all sites (59/60) presented both benefits and risk information

anywhere on the site, and half of those sites displayed the benefits information in a larger font than the risk information.

Sidhu *et al.* (2006) found that, in comparison to paper-based WMI, IBMI had incomplete and inaccurate information. This could have implications for people who cross-reference IBMI against PILs to assess the reliability of its content. An analysis of 150 websites providing information about popular complementary and alternative medicines found that over 95% omitted important information: drug interactions or contraindications, for example (Walji *et al.*, 2004). An evaluation of the content of 208 websites covering *St John's Wort*, used different websites' recommendations (*HoN Code*; and *e-Health Code of Ethics*), as well as a question based on the subjective experience of the authors. It found that the majority inconsistently reported information about *St John's Wort* (Martin-Facklam *et al.*, 2002).

1.4.4. General appraisal of previous research of IBMI

In general the findings have been derived from focus groups and content analyses. These designs can be considered less dependable than those using direct methods of examination. There is the potential for a discrepancy between respondents' reported use of IBMI and their actual use. Research using focus groups, like that using interviews or questionnaires, gathers opinions, and does not directly observe behaviour (see 5.2). Respondents may voice socially acceptable opinions in a sterile context; for example, participants may feel social pressure to comply with the opinions of other respondents. In considering these shortcomings, this thesis concurs with the suggestion of Bessell *et al.* (2002) that e-health research should use well-designed, controlled studies, and not be based on anecdote and opinion. However, the trade-off between ecological validity and internal validity is a common consideration when examining lab-based studies of behaviour. Lab-based studies of the Internet may not truly reflect how people interact with websites in the real world. However, a real-world study observing how someone interacts with a website would have less experimental control, and so the results can be less insightful. It may be more important for a study to be able to control for extraneous variables, even if that leads to reduced external validity.

The content analyses of IBMI sites to date have largely focused on assessing the quality of the sites, and in particular the presence or absence of markers of trust. This is an important facet to examine, but it is not the only feature of IBMI sites that is important. Less has been said about the nature of the medicines information content (for example, how the risk of a side effect is presented) or sites' features (for example, the presence of a table of contents). The medicines information content is important to examine because this is the reason why people access the sites. The design features of the site are important to examine because this impacts on the usability of the sites (see 1.5.2), and therefore should also be examined. This thesis considers that an evaluation of the quality, content and design features of an IBMI site is a valuable and necessary basis for examining usability.

Previous research has been limited because it has not examined the person using IBMI, i.e. whether or not the sites are easy to use, or if their content is understandable (Nicolson, 2007). Only a usability study can do this. For example, Kaufman et al. (2003) used a 'cognitive walkthrough model' to assess the usability of a home-based telemedicine system for 25 diabetic patients, and found it to have problems. The lack of research evaluating the usability of IBMI (and e-health sites), is an important deficit; forming a basis for the research question examined in this thesis. It is therefore essential that the evaluation of IBMI is placed firmly on the research agenda (Nicolson, 2007).

1.5. The theoretical framework underpinning this research

This section examines the role of theory in this thesis, and explains the theoretical framework employed. Firstly arguments are examined for conducting research with and without theoretical input, as a base for understanding the role of theory in this thesis.

1.5.1. The value of theory

McLaren (1998) has argued that the starting point for scientific investigation is theory; i.e. the research question is derived from a theory. For example, in a study by Bergus et al. (2002), the theory of the information-order effect guided the researchers to ask if the order in which risk and benefit information on a leaflet was provided affected the person's decision to take a medicine. (It was not). Theory is beneficial to research because it

provides a structure to guide the course of research. A theory can then be considered practical; offering a framework from which to organise data, a structured direction on which to devise new research, and an explanation for events and patterns (Melnyk and Handfield, 1998). A theory allows a hypothesis to be made in advance of the data collection; thereby researchers can make a prediction that can explain the data, rather than look for potentially spurious explanations after the data has been gathered. The predictive quality of a theory enables the development of a research question seeking to examine a process or mechanism linking the stimulus and response being measured. However, despite its potential benefits, Brazil *et al.* (2005) have noted that the incorporation of theory has largely gone unrealised in Health Services Research (HSR).

Theory-driven research can also be problematic. Mellenbergh *et al.* (2003) have argued that theory-driven research can only be an approximation to reality. This is because theory can sometimes assume an abstract nature, and so its relevance to the real world becomes blurred. A second problem is that theory-driven research can obstruct the progress of research when it primarily seeks to test a theory (Greenwald *et al.*, 1986). Thus the real world problem may be viewed as less important than the theory being examined.

The converse of theory-based research is results-driven (or data-driven) research, where a stimulus and a response are measured. This can show a correlation between measures, but it cannot explain why they are supposedly related as there is no hypothesised process (theory) linking the two events. The research question is derived from previous findings. This approach is problematic because results-driven research cannot explain data out-with the sample it was drawn from (Mellenbergh *et al.*, 2003).

Research does not always have a theoretical basis. Often it is practical in nature, being based on a problem or need in the 'real world' that is legislated for, e.g. EU legislation for the user-testing of leaflets (see 1.2.5). These points are reflected in the discussion of mixed methods research (see 2.3).

The basis for the research conducted in this thesis is that there is a need to know if WMI (leaflet or on a web-based) is useful. The research is not theoretically driven, but has a framework guiding the analysis of the outcomes measured. The theoretical framework underpinning this work is now explained.

1.5.2. The theory underpinning this thesis

This thesis presents work predominantly based in cognitive psychology and human computer interactions (HCI) research, which reflect the theoretical interests of the author. A component of the first study utilised to a lesser extent, a medical sociology framework.

Theory considered but not adopted by this thesis

At the outset of this thesis, competing theories from Cognitive Psychology and HCI were considered for providing the theoretical framework for this thesis; e.g. The Technology Acceptance Model (TAM), (Davis, 1989) and (Davis *et al.*, 1989). This developed from Ajzen's (1991) Theory of Planned Behaviour (see also 1.2.3). TAM predicts the intention to use IT is determined by the individual's perceived usefulness of the IT to benefit her or him in some way; and that it would require little effort to use it (Davis, 1989). This model was rejected because it examines intention to use, and not actual use, which is the focus of this thesis.

Theory from Medical Sociology

Dixon-Woods' (2001) patient information discourse model proposes that there are two different (but not distinct) styles of patient information: 'patient education' and 'patient empowerment'. The professionally oriented 'patient education discourse' was considered rooted in the biomedical model, where the patient who lacked knowledge about their medicines required education to bolster her or his competence, The 'patient empowerment discourse' driven by consumer advocacy considered information as the entitlement of the individual and as a means for realising patient choice and autonomy (Raynor *et al.*, 2007a).

Theory from Cognitive Psychology and Human Computer Interaction

Cognitive Psychology proposes that behavioural reactions to a stimulus are best understood by mediating cognitive processes; whereby behaviour results from how the

information has been processed. The research in this thesis examines the cognitive

processes facilitating the user's interface (interaction) with IBMI. Theory from Cognitive

Psychology and HCI research are applied to offer insight into how the design of IBMI sites

can determine how easily the information can be accessed and understood.

The psychology of knowing and understanding

The primary outcome measure of the systematic review of the effectiveness of WMI (in

Study one) is 'knowledge'. The outcome measure of the User Test questionnaire (in

Studies three and four) is 'understanding'. These are (probably) distinct cognitive

processes. The purpose of this section is not to present a lengthy review of this extensive

area, but to briefly examine them, to enable the reader to distinguish between them.

The noun 'knowledge' has a vast number of definitions. The *Oxford English Dictionary*

Online provides over ten definitions, which include:

> *"acknowledgement or recognition of the position or claims; to become aware of; the fact*
> *of knowing a thing, state, etc., acquaintance with a fact; perception, or certain*
> *information of, a fact or matter; acquaintance with ascertained truths, facts, or*
> *principles; information acquired by study"* (http://www.oed.com/ accessed online
> November 2008).

The basis for this thesis examining understanding of WMI as an outcome measure follows

from EU policy (see 1.2.5). What does it mean to 'understand'? The *Oxford English*

Dictionary Online provides a range of definitions of the word 'understand'. These include:

> *"to comprehend, to apprehend the meaning or import of, to grasp the idea of; to*
> *comprehend by knowing the meaning of the words employed; to grasp as a fixed or*
> *established fact or principle, to have knowledge of, to know or learn, by information*
> *received; to take or accept as a fact, without positive knowledge or certainty; to get as*
> *an impression or idea, to believe; to have knowledge or information, to learn, of*
> *something"* (http://www.oed.com/ accessed online November 2007).

From these definitions, it is noted that the process of knowing appears to require less effort

than understanding. This can be related to Craik and Lockhart's (1972) model of levels of

information processing, where information that is processed at a deep level is found to be

meaningful to people, unlike information processed at a shallow level. It follows that a

consequence of this is that the person may know information about their medicines, but not necessarily understand it.

Mazur (2000) has asked how exactly is 'understanding' to be defined and measured? And Edwards *et al.* (2006) have noted that examining understanding at a level greater than the mere recall of information requires a complex assessment. These points can be seen as a challenge for research measuring patient understanding (of WMI) as an outcome measure. While it is important to recognise this, this does not have a bearing on the examination of understanding in this thesis, because the EU stipulated user test (see 5.2) is adopted.

Understanding and cognitive load

One role of WMI is to enable people to understand how to take their medicines safely and effectively (see 1.1). This can be seen to suggest that WMI is (in part), a set of instructions.

Understanding instructions, it has been argued, is difficult if multiple elements of the information interact, whereby individuals must assimilate these elements simultaneously which produces an excessive demand on working memory, i.e. a high 'cognitive load' (Marcus *et al.*, 1996). An example would be learning the grammar of a foreign language which requires the individual to relate each word to the other in a sentence to be able to put them in the grammatically correct order (Sweller *et al.*, 1998).

There are two types of cognitive load. Intrinsic cognitive demands are faced by an individual's working memory due to the inherent characteristics of the material, i.e. what is to be understood. Extrinsic cognitive demands are faced by an individual's working memory from the way the material is presented (i.e. its design features), or the activities required by the person interacting with the material (Sweller *et al.*, 1998). Intrinsic cognitive load can be changed by providing information in an understandable format, extrinsic cognitive load results from how the material is presented, and so changing the way it is designed can partly lessen cognitive demands.

The theory of cognitive load has implications for the way WMI (either paper-based or Internet-based) is designed, because it will determine the cognitive demands faced by the

individual, and thereby can facilitate ease of understanding information. To adapt a proposition made by Carlson *et al.* (2003), by identifying the cognitive mechanisms involved in assimilating IBMI and the design features of an IBMI site that are most important, this can increase knowledge about how to design IBMI to be as useful (easy to use and reliable) as possible.

Distributed cognition

The classical view of cognition is that it is a set of mental processes within the individual. The theory of distributed cognition, however, proposes that cognition is a process of coordinating distributed internal representations (for example, memory) and external representations (for example, written instructions) (Horsky *et al.*, 2003). This theory, developed from anthropological studies of how knowledge is shared between people, was applied to Information Technology (IT) to examine how the interaction between airplane pilots and IT in a cockpit enables the pilot to compute and remember the correspondence between airspeed and wing configuration (Hutchins, 1995).

The Distributed Information Resources Model (Wright *et al.*, 2000), adapted from the theory of distributed cognition, seeks to understand what information is necessary to carry out a task and where the information should be stored. The model entails six abstract information structures which can be represented either internally as cognitive processes within the IT user, externally in the IT, or distributed between both resources (Wright *et al.*, 2000).

The design features of Internet sites are of central focus to HCI research; which aims to produce usable computer software and hardware (Olson and Olson, 2003); seeking to understand and support human interaction with technology (Carroll, 1997).

The following examples of internal and external information representations are based on the work of Wright *et al.* (2000) as applied by Horsky *et al.* (2003). In the study reported in Chapter five, they are applied to code participants' behaviours and online actions in the usability study.

- **State:** refers to the current set of resources (for example, information displayed on screen) and is an external representation only.

- **Internal and external plans:** internal plans are sequences of actions based on system knowledge (for example, when the individual employs prior knowledge to use a website without the need to refer to instructions). External plans are sequences of actions that are performed to achieve a goal, which rely on, for example, a help page of a site.

- **Goal:** an outcome formed by the user (for example, information sought). This is an internal representation only and differs from a plan because it refers to the outcome alone, and not the process used to achieve the outcome.

- **Affordances:** possible next actions (for example, a drop-down menu). This is external to the IT alone.

- **History:** an external history provides a visible record of actions undertaken (for example, previous URLs accessed). An internal history is the recall of previous states (for example, recognition of where information is when it is not displayed).

- **Action-effect relations:** this is the causal relation between an action and an effect (for example, the recollection of the consequences of an action [internal], or an onscreen warning when an action is about to be committed [external]).

In addition to the six categories above, Horsky *et al.* (2003) added two further categories of internalised knowledge:

- **Knowledge about medicines:** refers to current or previous specific and general knowledge about medicine (for example, the person relates information to her or his knowledge or experience of taking medicines).

- **Conceptual system knowledge:** refers to knowing how to use a site (for example, a sequence of actions required to complete a task).

This model was applied to evaluate a medical information system for physicians ordering patients' medication, and found that the configuration of the system placed undue demands on the user (Horsky *et al.*, 2003).

This theory can account for how the design features of an IBMI site have the potential to lessen the cognitive demands on the individual interfacing (interacting) with the site. Thus the properties (design features) of IBMI sites (in theory) can potentially store information externally, thereby reducing the user's cognitive load because she or he does not have to actively recall this when using the IBMI site. As a result, the user can focus on trying to understand the information.

The structural design of a website represents its information architecture. Rosenfeld and Morville (2002) propose information architecture has the following concepts underpinning it:

(i)   Information is the link between data (facts) and knowledge (known facts);

(ii)   Information architecture refers to the structure, organisation, and labelling of information; and

(iii)   The information should be easy to find by browsing, searching, and asking.

Individual factors still play a role in determining the individual's level of understanding of WMI. Accounting for ways to reduce cognitive load for understanding WMI, the Pharmacokinetics Communication Model (Morris and Aikin, 2001) contend that individual differences as well as design features of WMI (the authors' focus was on PILs and not IBMI), will determine the users' comprehension of WMI. The three personal factors are: motivation to read the information (including time and effort given); opportunities they have to read the information (including available time), and their ability to process the information (including literacy levels).

The psychology of design

The information architecture of an IBMI site will determine whether or not the person interfacing with a site is able to find information or not. This necessitates an evaluation of the design features of sites. As Norman (1988) has noted; applying psychological principles to poorly designed objects can make them more usable, and therefore reduce the demands (cognitive load) for the user to remember large amounts of information.

Preece *et al.* (2002) have devised a set of design principles, based on understanding of cognitive processes, that suggests how knowledge of how people process information can be applied to website design to make the site easier to use. These offer a means for evaluating the usability of websites in relation to their features. The six design principles, with examples of implications provided by Preece *et al.* (2002) are presented below. Examples (by the thesis author) of the possible effect of IBMI design impacting on participants' use of it are related to these.

(i)   Attention

This refers to the processing of information on the site. The information should be salient when needs be, so it can be more easily processed. Cluttered information should be avoided, because it makes excessive demands on attention; and the site should be made as plain as possible (for example, like *Google*™), to make it easy to use. Evidence of the design of the IBMI sites affecting users' attention would be, for example, if participants complain about cluttered information being a distraction.

(ii)   Perception

This relates to the perception of text and graphics on the site. The use of icons can enable their meanings to be easily distinguished; and it is important to ensure that text is legible and distinguishable from the background. Evidence of the design of the IBMI sites affecting users' perception would be, for example, if participants click on icons for finding information.

(iii)   Problem-solving

This refers to the provision of support for using the sites. It is suggested to provide additional information to aid those who wish to understand how to interface more effectively. Evidence of IBMI sites problem-solving capabilities would be, for example, if participants use a further information resource or access online help.

(iv)   Memory

This is in relation to the retrieval of information on the site. It is recommended to not overload users' memories with complicated task procedures; and to (aim to) draw on users' recognition rather than recall of information, as the former is more effective for retrieving information. Evidence of the design of the IBMI sites impact on users' memory

would be, for example, if participants are able to recognise the site features once familiar with them.

(v) Learning

The focus here is on supporting the user of the site. Interfaces should encourage exploration and provide guides to allow users to select appropriate actions. Evidence of the design of the IBMI sites impact on learning would be, for example, if users are able to quickly explore the site with ease.

(vi) Reading

This relates to reading the site's information. It is best to aim for large text without affecting formatting. Evidence of problems with reading the IBMI sites would be, for example, if users struggle to read the information because of the text font size.

In Chapter five these design principles are utilised to code verbal protocols, because it is considered that this can provide an insight into the cognitive processes that the individual is using when interfacing with the site.

It is contended in this thesis that the principles of attention, perception and problem-solving are relevant to the content of a website: for example, how information is presented on screen can have different demands on attention, whether or not information is provided as an icon can influence perception, while an option to access 'help information' can support problem-solving. The latter three principles (memory, learning and reading) can be relevant to design features of a website. For example, a site that enables recognition of information on how to use it, rather than requires the information to be recalled, can reduce demands on memory.

A site designed to encourage the user to freely navigate it may enable the person to learn to use it with ease; and a site with a text size change option may be easily read. It is necessary to analyse the content and design features of IBMI sites, as these may impact on how readable and easy to use they are; and therefore ultimately how useful they are to the medicine user. Each principle necessitates focusing on IBMI sites' content and design in

relation to their usability: for example, cluttered text (with little 'white space') may impact on the accessibility of IBMI, by appearing off-putting to the reader.

An example of research examining the effect of information designed in different formats is by Edwards *et al.* (2006). They conducted a randomised controlled trial (RCT) examining four different ways of presenting risk information on the *Best Treatments* website. They looked at the effect on reducing decision conflict (recorded on a scale, which measures a persons confidence or uncertainty about whether or not a choice is right for them). 508 individuals were shown the information numerically, graphically, as anchored information, or as a combination of the three. A fifth group acted as a control and received the standard information from the *Best Treatments* website. The study found no difference between the interventions, but qualitative feedback indicated that information presented as a bar chart was more favourable than the other graphical formats.

Usability research principles

The theory of distributed cognition predicts that the design features of IBMI sites will impact on their ease of use for people finding and understanding information about medicines (i.e. usability). This section introduces the principles guiding usability research. An overview of research methods for examining usability is presented in 5.2.

The ethos of usability and user testing is to examine the usability of the site, or the understandability of the information. It does not examine the knowledge or expertise of the user. The aim therefore is for designers to adapt the site/information to make it more easy to use or understandable, as opposed to the user having to adjust to the site and its information. Nielsen (1993) has proposed that the usability of a website can be changed by adapting it to have the following features:

- **Learnability**, where the system is easy to learn;
- **Efficiency**, allowing for a high level of productivity;
- **Memorability**, so the user does not have to relearn the system on separate occasions;

- **Low possibility of errors,** or if errors are possible, they should be easily recoverable. A similar concept is 'safety' to ensure the prevention of serious errors (Preece *et al.*, 2002);

- **Satisfaction,** because the system is deemed to be pleasant to use.

Preece *et al.* (2002) add the following:

- **Effectiveness to use,** i.e. how well a system does what it is supposed to;

- **Utility,** the system provides the correct function to allow users to do what they have to do.

Norman and Panizzi (2006) have argued that the major goal of usability-testing for computer-based information is to discover major problems which could result in user errors and thereby frustrate the user. This assertion further highlights the importance of the design of IBMI sites in facilitating their ease of use.

1.5.3. Concluding remarks

The role of theory in this thesis is to provide a framework for the evaluation of:

(i)   The quality and trustworthiness of information,

(ii)   The information content, and

(iii)   The design features of the sites.

The evaluation of these three concepts to an extent reflects criteria drafted by Tweddle *et al.* (1998) for evaluating a cancer information website. Rogers (2004) has argued that theory derived from studies examining cognition in a laboratory cannot be applied simply. She notes that cognitive processes underlying HCI in the real world are 'messy'; unlike the neat uniformity of cognitive processes measured in a laboratory. This does not negate the use of laboratory -derived theory, but provides a reminder of the limits of the generalisability of usability study findings. Nevertheless there remains a need to understand the cognitive processes of the person interfacing with a website. This thesis contends that laboratory -based research enables these processes to be examined in a

controlled environment, where there is less chance of extraneous variables biasing this investigation.

Drawing from these disciplines, three concepts are used to underpin the evaluation of IBMI: if the information is trusted; if its content (information about medicines) is understandable; and if the design of the site makes it easy for the user to navigate the page(s). Each of these concepts has a theoretical rationale, which is explored below.

Trust

An assessment of the trustworthiness of IBMI is important for determining if they are reliable and trustworthy. There is the possibility (though far from straightforward), that Internet users accessing poor quality information may, as a consequence, act in a way that is detrimental to their health (see 1.2.3). The trust markers of the IBMI sites will be examined in two ways: firstly in the analysis of IBMI content reported in Chapter four, and secondly in Chapter five by assessing whether participants displayed evidence of considering the trustworthiness of the site they used.

Content

This thesis examines if the information about medicines on IBMI sites is understandable; therefore the readability of the content of these sites is measured. Readability of leaflet-based (but not Internet-based) WMI and its measurement have been defined by EU legislation. Understanding will be measured by participants' explanation of the information, which is a proxy measure of their understanding of it or not, and is reported in Chapters five and six.

Design features

Because extrinsic cognitive load is determined by the way that information is presented, this highlights the consequences that the design of IBMI sites (and probably also leaflets) can have for understanding its content. Poorly designed IBMI sites may not be easy to use, and therefore the individual may be less able to locate the specific information sought. The way an IBMI site is designed can make it more or less easy to use, irrespective of the users' underlying Internet skills; impacting on the cognitive demands on the person accessing it.

These points necessitate the need to examine the ease of use of the site in relation to its design. These are measured by participants' verbal protocols, their online actions, and their observed behaviours when interfacing with the sites in the study reported in Chapter five, and by using indirect methods in the study reported in Chapter six.

What can the theory potentially reveal?

The following applied example anticipates what the data may tell in relation to the theoretical framework. The participant has a goal to find information to explain a question about taking a medicine. The state is the onscreen display, i.e. the homepage of the site, presenting a range of affordances for the participant, including a search bar, links to external sites, and links to different sections of the same web page. An online help page provides an external plan to support the participant. Clicking on a link opens an external page, and acts as an external action-effect letting the participant know she or he entered a new site. Recognising this, the participant shows conceptual system knowledge. Closing the link, she or he scrolls down the page reading the content, and then identifies the information to answer the question.

1.6. Aims, objectives, and outline of thesis

1.6.1. Overall aim

This thesis evaluates leaflet-based and Internet-based WMI, to examine if they are useful for aiding people's understanding about taking medicines.

This is an applied piece of research, drawing on theories (see 1.5.2) and methods of others (see the methods section of each study). The contribution of this thesis to knowledge seeks to be two-fold: (i) knowledge of WMI, and in particular IBMI; and (ii) the use of mixed methods to examine WMI.

1.6.2. Specific aims and objectives

Study one: an evaluation of the effectiveness of written medicines information

(i) To examine medicine users' opinions about written information for individual medicines

This study was patient centred, giving WMI stakeholders the opportunity to express their opinions about WMI at two workshops, at the beginning and end of a research project.

- The aim of the first workshop was to elicit stakeholders' perceptions of key issues regarding WMI, so that these could be taken into account when shaping, planning and executing the systematic review, thereby enabling it to be user-centred.

- The primary aim of the second workshop was to elicit views about the review findings from the stakeholders involved in workshop one, in order to make interpretation of the findings and the conclusions drawn user-centred.

(ii) To evaluate the effectiveness of WMI

The systematic review of effectiveness sought to examine the evidence for paper-based and Internet-based WMI changing medicine users' knowledge, attitudes and behaviours relating to taking medicines.

- How effective is WMI about individual medicines in improving patients' knowledge and understanding of treatment, and improving self-management of illness and health outcomes?

Study two: an evaluation of the quality, content and design features of websites with information about medicines

An evaluation of the quality, content and design features of a sample of IBMI sites provided a basis for the subsequent evaluation of the usability of the (same) sites and the readability of their information.

- To determine how frequently the most popular IBMI sites in the UK and USA are accessed.

- To compare the quality, content and design features of the IBMI sites.

Study three: an evaluation of the usability and readability of websites with information about medicines

A purposive sample of IBMI sites from Study two were tested for their ease of use and the readability of their information by people who take medicines.

- To assess participants' prior experience of WMI and IBMI.

- To examine how participants searched for information about medicines using an Internet browser.

- To examine the ease of use of the sample of IBMI sites.

- To examine if the information on the sites was understandable.

- To determine participants' views on the ease of use of the sites; readability of the information; and if they will access the Internet again to find information about medicines.

Study four: a pilot examining the appropriateness of the design and methods for a full RCT evaluating changes to web pages with information about medicines

The final study was a pilot to examine the appropriateness and feasibility of using a repeated measure with counter balance study design, an intervention for redesigning web pages containing information about medicines, and tools for measuring the outcomes. These could be used in a full trial to evaluate whether redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information.

- To pilot an intervention based on content and general content formatting.

- To pilot a repeated measures with counter balance design.

- To pilot a set of proposed tools for measuring participants' ability to locate and understand specific information about medicines on a website.

Overall discussion of the findings, limitations and implications of the research in this thesis

The discussion chapter brings together:

- A summary of the four studies.

- A discussion of the limitations of the research reported in this thesis.

- An examination of how the findings in this thesis add to the knowledge base.

- A discussion of the implications arising from the research in this thesis.

- Concluding remarks regarding WMI.

This thesis uses mixed methods in three of the four empirical studies and this method is examined in detail in the following chapter.

Chapter two
The methodological foundations of the research

2.1.Introduction

The research reported in this thesis mixes qualitative and quantitative methods, to gather a fuller picture of WMI. This chapter examines methodological issues that underpin mixed methods: the different paradigms and epistemologies that underlie research; the problems associated with mono-methods and the rationale for using mixed methods; the possibility of pragmatism as the epistemological basis for mixed methods research; and procedures for using mixed methods. There is an appraisal of mixed methods research, and then it is explained how these methods are applied to the research reported in this thesis.

2.2.Research paradigms

The concept of research paradigms, conceived by Kuhn (1962), seeks to explain how science is conducted, and specifically, how developments in science arise. Breaking this concept down, Creswell (2003) talks of 'three elements of enquiry', i.e. three stages that combine to form the process of conducting research:

1) The philosophical assumptions that underlie knowledge claims; e.g. what it is possible to know, and what knowledge is. This can be broadly considered to be epistemology (the theory of knowledge), although this has a more specific meaning in philosophy.

2) Strategies of inquiry, i.e. they are general procedures regarding the research design, based upon knowledge claims; i.e. broad methodological paradigms, such as positivism, postpositivism or constructivism.

3) Methods: specific procedures for collecting and analysing data.

These three elements highlight how the method(s) available to a researcher are grounded in a distinct methodological paradigm, which follows from a specific philosophical

outlook. The consequence of this process for Creswell (2003), is that research can be exclusively quantitative or qualitative (mono-methods), or a combination of both (mixed). Figure 2 highlights this in pictorial form. The difference in approaches to research (methodology), and the methods that researchers use, result from the different philosophical positions that researchers take regarding knowledge (see Table 1).

Figure 2: Overview of the three research paradigms, including sub types
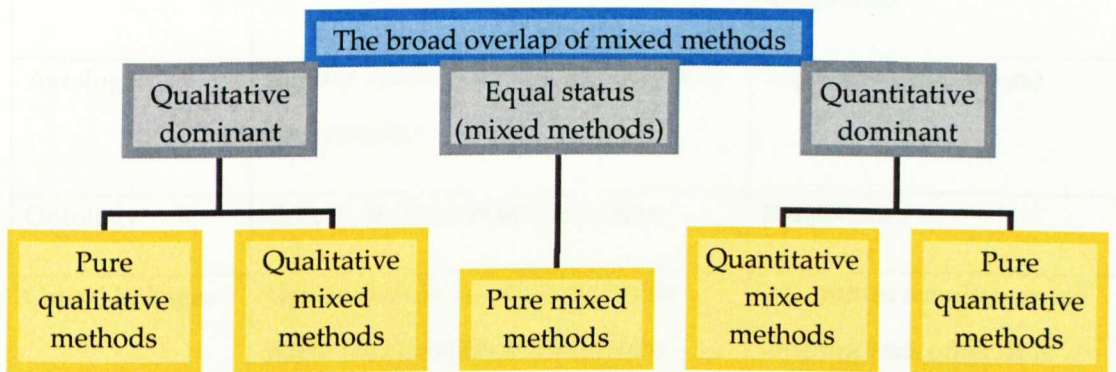
Adapted from Johnson *et al.* (2007), pp 124

Creswell (2003) discusses the epistemological paradigms of postpositivism and constructivism; pragmatism; and advocacy/participatory research. The latter seeks to combine research with a (political) agenda in seeking reform, addressing social issues and involving the public's collaboration. This approach is not discussed, as it is not relevant to the research in this thesis. Pragmatism is examined in 2.4.

In the social and behavioural sciences, two mono-methods have been dominant: quantitative and qualitative research. The positions are presented in Table 1 as polar. But as Johnson and Onwuegbuzie (2004) acknowledge, they share several features: they are based on empirical observations, each incorporate methods that safeguard their inquiry from bias, and they both provide defensible assertions.

Table 1: Comparisons of postpositivist and constructivist paradigms

Paradigm	Postpositivism	Constructivism
Methods	Primarily quantitative	Qualitative
Logic	Primarily deductive	Inductive
Epistemology	Modified dualism. Findings are probably objectively 'true'	Subjective point of view. Knower and known are inseparable
Axiology	Inquiry involves values, but they may be controlled	Inquiry is value-bound
Ontology	Critical or transcendental realism	Relativism
Causal linkages	There are some lawful, reasonably stable relationships among social phenomena. These may be known imperfectly. Causes are identifiable in a probabilistic sense that changes over time	All entities simultaneously shaping each other. It is impossible to distinguish causes from effects.

Adapted from Tashakkori and Teddlie (1998), pp 23

2.2.1. Quantitative research paradigms

Quantitative research is grounded in the philosophy of postpositivism, which holds that social phenomena can usually be reduced to their constituent parts, and measured to derive reasonably stable relationships (Tashakkori and Teddlie, 1998). Postpositivism is a descendant of positivism, the philosophical tradition that formed the basis for modern day science.

Quantitative research has an objective, naïve realistic outlook on the world, and seeks to develop lawful cause and effect links (Baum, 1995). Broadly speaking, this approach attempts to observe and measure social phenomena in the same way that a scientist

observes and measures natural phenomena (Bowling, 2002); and considers that findings are probably objectively true (Tashakkori and Teddlie, 1998). It is primarily quantitative, and uses controlled conditions, measuring the outcomes, and analysis (usually) by statistical methods (Malterud, 2001). It uses the hypothetico-deductive method of analysis, which seeks to derive a logical conclusion from a premise (Fuller, 2003). The research is therefore theory driven, where a tentative hypothesis (initial prediction to explain the phenomenon) is tested, and the data gathered either supports or refutes this.

2.2.2. Qualitative research paradigms

Qualitative research has its basis in the constructionist paradigm which seeks to understand, rather than measure or reduce phenomena, recognising the importance of context (Baum, 1995). Qualitative research focuses on interpreting, and analysing textual data (Malterud, 2001). This position views the meanings that individuals attribute to a situation as being constructed, which directs research attention to interpreting others' meaning of the world (Creswell, 2003). Here knowledge is derived through an inductive analytic approach, where the codes are derived from the data itself (Draper, 2004). Thus a researcher induces a general statement from a limited number of observations. This is data driven research, where a theory explaining the phenomenon that has been examined emerges from the data set. (There are also many examples of qualitative work that are driven by theory). Fuller (2003) has proposed that this method can be considered to hold the future to hostage; because knowledge is derived through a limited number of examples, and it would only take one (future) negative example to negate this.

2.2.3. Paradigm wars and Communities of Practice

The postpositivist paradigm, with its emphasis on the quantifiable, has led to a number of important scientific discoveries (Flynn, 2006). However, quantitative research has been criticised for ignoring how science and its methods are socially constructed (Flemming et al., 2008), and that its findings are not valid as they do not reflect the real world. By comparison, qualitative research has been criticised for being too small scale, and impossible to generalise from, because its data are said to represent little more than interpretations and anecdotes (Flemming et al., 2008). Not only are there problems with

using either of the mono-methods, it is also argued that they are incompatible. Tashakkori and Teddlie (1998) have reported how some commentators have argued that the quantitative and qualitative positions are 'incommensurate' (i.e. incompatible) because their differences are so fundamental. It is therefore impossible for researchers to enquire about questions that are both quantitative and qualitative. The idea of incompatibility came to a head in the social and behavioural sciences with the 'Paradigm wars' of the 1970s-1990s (Tashakkori and Teddlie, 1998) when the contrast between proponents of the dominant postpositivist paradigm, and constructivism disputed the merits of the other.

For Kuhn (1962), the day-to-day work of science (normal science) represents puzzle solving, where scientists conduct the business of working on problems. It is contrasted with revolutionary periods in science where the dominant paradigm is overthrown in favour of a new paradigm to explain phenomena. Normal science can be seen to be reflected in the idea of Communities of Practice. Denscombe (2008) notes that the concept of 'Communities of Practice' presents the work of science and research as a collective process of shared activity between colleagues. This replaces the idea of supposed conflict between paradigms; and instead looks upon the acquisition of knowledge (the process of research) as a social activity where knowledge is pooled. For Denscombe (2008), Communities of Practice permit mixed methods research, because there is no clear distinction between practice and research, therefore enabling researchers not only to have awareness of the knowledge and skills of another paradigm, but also to be able to practise it.

Denscombe (2008) has proposed that Communities of Practice can explain the methodological choices made in mixed methods research. This dispenses with the idea that decisions are either solely individual or rational; and instead recognises that social factors can underlie the methodological choices of the researcher. In Studies three and four the readability of IBMI is examined by the method of 'User Testing'. EU law (see 1.2.5) legislates that this is the sole means for examining the readability of PILs, and therefore represents an example of a social factor underpinning the direction of research.

2.3. The rationale for mixed methods

The problems associated with either of the mono-methods can provide a rationale for combining quantitative and qualitative methods; i.e. mixed methods research. This section examines the rationale to do so from the perspective of the benefits this offers, as well as a response to the criticisms of the individual mono-methods.

First it is important to be clear upon a definition of mixed methods. Johnson, Onwuegbuzie and Turner (2007) interviewed leading methodologists in mixed methods research who constructed 19 separate definitions of mixed methods research. From this they have offered a definition of mixed methods research as an intellectual and practical synthesis of quantitative and qualitative research to offer the most complete, balanced and useful results.

Figure 3 (from Johnson and Onwuegbuzie, (2004) shows how mixed methods research fits in between the quantitative and qualitative paradigms at either end of this spectrum (numbers1 and 8). The six categories in between (numbers 2 to 7) are examples of research that mixes methods to varying degrees and at different stages in the research process.

There are several reasons for using a mixed methods approach, which seeks to overcome the problems of adopting a mono-method. Firstly Creswell (2003) has argued that research can better understand problems by converging quantitative and qualitative data rather than adopting a mono-method. Both quantitative and qualitative research examine problems that are guided by their methods: i.e. the research questions themselves are based on what they measure and how they measure. In mixed methods research the question drives the methods, and not vice-versa (Greene, 2008). Therefore the researcher is not constrained because she or he can adopt tools from quantitative or qualitative research to examine the question. The notion that the question/problem precedes the method is important from a practical perspective. The Health Development Agency in the UK has contended that failing to examine health inequalities because of philosophical or methodological differences cannot be justified, because these are considerable problems that need to be addressed (Kelly and Swann, 2004).

Figure 3: Typology of mixed methods research
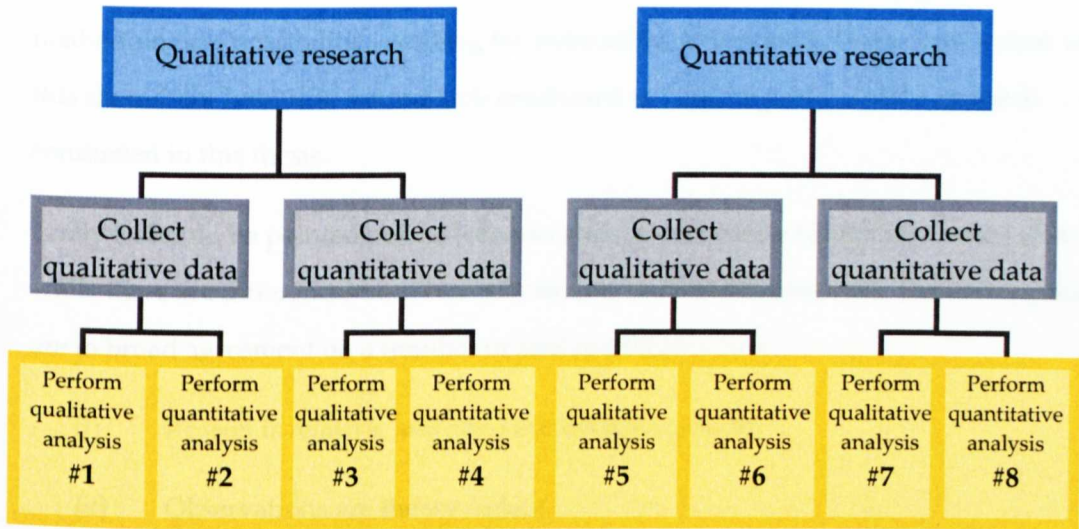
Secondly, following on from a point made in section 2.2, quantitative and qualitative research share several tenets. At a broad level, both seek to understand and improve human conditions (Sale *et al.*, 2002). Furthermore, Abushaba and Woelfel (2003) have proposed that all data, i.e. quantitative and qualitative, have both an objective and subjective component. They cite the argument that numbers can be allotted to qualitative data in a survey, and numerical data gathered in a quantitative study can be analysed in a subjective or qualitative manner.

Thirdly, Sale *et al.* (2002) acknowledge the argument made by commentators that, because there appears to be no way of reconciling the quantitative-qualitative debate, one should not focus upon choosing between epistemological stances, as this will not help in getting the research done. Instead they argue, the phenomena being investigated should be clearly labelled with regard to the method being used. Thus a phenomenon can be labelled and measured one way for a qualitative study, and in a separate way for a quantitative study. These different labels they propose, add value to each other.

Fourthly, Abushaba and Woelfel (2003) have proposed that combining the two approaches will cancel out to some extent their respective weaknesses (see 2.2.1 and 2.2.2). Similarly, Johnson and Onwuegbuzie (2004) have argued that epistemological and methodological

pluralism (in educational research) can increase researchers' epistemological and methodological possibilities, making for more effective research. There is no reason why this should not hold true for research conducted in HSR, in particular the research conducted in this thesis.

Lastly it should be pointed out, as Johnson and Onwuegbuzie (2004) have noted, that while there are differences between quantitative and qualitative work, the two approaches are in broad agreement on a number of philosophical points:

(i)   Reason is relative, and can vary between people;

(ii)   Observations are theory-laden;

(iii)   Evidence does not always determine a theory, because more than one theory can fit a set of data;

(iv)   There are alternative ways of explaining data;

(v)   Because of the problem of induction, evidence can only be probabilistic;

(vi)   Research is a social enterprise, so researchers are affected by the beliefs, values and attitudes of communities; and

(vii)   Inquiry is value-laden because researchers cannot avoid their values affecting what is examined and how it is interpreted.

2.4.Pragmatism and mixed methods

The epistemological bases for quantitative and qualitative research are positivism or postpositivism, and constructivism, respectively. Mixed methods research does not yet have a similar base in epistemology. Johnson *et al.* (2007) note that some commentators consider that pragmatism can act as the philosophical basis for mixed methods research, by providing an epistemological justification, and a logic for mixing methods.

Tashakkori and Teddlie (1998) propose that pragmatists consider the research question they are investigating is more important than the methods they use, or the worldview underpinning it. Thus the method follows from the question, rather than the question

being based on the methods, as can be the case with mono-methods. This opens up the possibility of mixed methods research examining a wide range of questions, as it is not constrained by the methods that it can use. Tashakkori and Teddlie (1998) suggest that a pragmatic approach avoids the metaphysical concepts that are associated with the mono-method, offering a practical, applied approach to research.

Creswell (2003) cites the adage that lies at the heart of the pragmatist philosophy: that truth is what works at the time. From this he argues that mixed methods research draws on quantitative and qualitative methods because this works to provide the best understanding of the research problem, compared to using a solely quantitative or qualitative approach. The upshot of this approach for Creswell (2003) is that the researcher is not constrained by one paradigm and one broad way of collecting and analysing data, and so has freedom to mix different methods to try to answer a research question. Denscombe (2008) has proposed that pragmatism is sometimes considered to mean expedient; a commonsense way for justifying an 'anything goes' approach to conducting research. However, he notes this is not the philosophical meaning of pragmatism and provides examples of mixed methods research that are based on this approach.

While this approach can offer much potential to mixed methods research, it has several weaknesses, according to Johnson and Onwuegbuzie (2004). A pragmatic approach to research can favour applied research to the detriment of basic research, as the former produces more immediate and practical results. Similarly Johnson and Onwuegbuzie (2004) have noted that pragmatism may offer incremental change, but not a more fundamental, structural change to society. This can probably also be applied to the discipline of HSR.

2.5. Procedures for using mixed methods
Having provided the rationale for conducting mixed methods research, and the epistemological basis for it, the focus now turns to an examination of procedures for conducting mixed methods research.

2.5.1. Sampling

Sampling is of importance to the social and behavioural sciences in general and not just mixed methods research. Sampling is the method of taking a sub-section of a population that is being examined. How a sample is selected will impact on the results of a study, as well as the researcher's ability to generalise their findings to the wider population, i.e. its transferability.

Teddlie and Yu (2007) have referred to four broad techniques for sampling: probability, purposive, convenience, and mixed methods. Probability sampling is used in quantitative-based research to derive large numbers of people picked from the population at random, who will be representative of as many people as possible. Purposive sampling is used in qualitative research to select units of investigation (e.g. people or websites) specifically for the information they can provide. Convenience sampling is used to gather people who are easily accessible, and willing to take part in research. Mixed methods sampling combines both probability sampling (to increase the external validity), and purposive sampling (to increase the transferability of the findings).

Mixed methods research sampling, represents an overlap between quantitative and qualitative methods. As Teddlie and Yu (2007) explained, mixed methods sampling employs both probability and purposive sampling with the aim of being both representative, and having information rich cases. They note that there is no widely accepted typology for mixed methods sampling strategies. However, drawing on the literature, they offer the following guideline for a sampling procedure for mixed methods research:

1. The sampling strategy should follow the research question, and will usually involve both probability and purposive sampling.

2. There should be adherence to the assumptions of using a probability sample or a purposive sample.

3. The strategy should be sufficient to answer the research question; ensuring the data are both representative, and that there is saturation.

4. The sample should have credibility and internal validity, so that clear inferences can be made.

5. The strategy must be ethical, feasible and efficient.

6. The sample should permit the generalisability or transferability of the results (Teddlie and Yu, 2007).

Collins *et al.* (2007) have reviewed the minimum sample size recommendations for most common quantitative and qualitative research designs. For the research designs carried out in this thesis, Collins *et al.* (2007) suggest that the minimum sample sizes should be the following:

- Focus groups have between 6 and 12 participants;

- Case studies have between 3 and 5 participants;

- Experimental studies (trials) have a minimum of 21 participants per group.

These are only recommendations, and sample size calculations depend on many factors. It needs to be asked therefore if these are reliable estimates. The recommended range for focus groups appears to be feasible. Too few participants may be a barrier to maintaining a discussion, while too many participants may not enable everyone to give their responses. The numbers cited for a case study appear to be reliable, as long as data saturation is reached in the case studies; i.e. no new findings emerge after the nth study. However, the recommendation of as few as 21 participants per arm in a trial is far too low. In reality trials are usually conducted with many more participants, so that they are adequately powered to be able to detect a meaningful and statistically significant difference between the interventions.

2.5.2. Decisions determining mixed methods

Creswell *et al.* (2007) have reported a decision matrix for determining a mixed methods design (see Figure 4). This shows that decisions have to be made regarding four concepts for determining a mixed methods design. Implementation refers to whether the different

methods are conducted sequentially, or concurrently. Priority relates to whether one mono-method or both are given precedence in terms of analysis and data collection. Integration of the data can occur at any one of three stages, or in combination. Lastly Creswell *et al.* (2007) ask whether a theoretical perspective is operating explicitly or not.

Figure 4: Decision matrix for determining a mixed methods design

Implementation	Priority	Integration	Theoretical perspective
No sequence concurrent	Equal	At data collection	Explicit
		At data analysis	
Sequential: qualitative first			
	Qualitative	At data interpretation	
Sequential: quantitative first			Implicit
	Quantitative	With some combination	

Adapted from Creswell *et al.* (2007), pp 171

The adoption of strategies for using mixed methods reflects the rejection of the separate mono-methods. For example, quantitative research uses the process of deduction; while qualitative research adopts an inductive method. Morgan (2007) notes that mixed methods research does perceive this dichotomy; instead the logic is based on abduction, where there is a moving back and forth between theory and data. Thus the researcher can derive a theory from observation, and then test the theory (for example, by using a RCT). This point is crucial to mixing research methods, because it explains the grounds for interchange between different methods, rather than the adoption of one approach and the rejection of the other.

Section 2.2 highlighted that a key distinction between quantitative and qualitative research was the objective nature of the former, and the subjective nature of the latter. Morgan (2007) has argued that there is not such a clear distinction, because research cannot solely be one or the other. He proposes that, instead, most researchers exhibit 'intersubjectivity', whereby they move back and forth being objective and subjective. This view can be extended to provide a means to overcome the problem of quantitative and qualitative research being incompatible, which makes it impossible to mix methods (see 2.2). Thus the mixed methods researcher can accept that there is a 'single real world', and that individuals have their own personal and unique interpretations of it.

2.5.3. The different strategies for using mixed methods

Creswell (2003) has broadly classified the methods by the type of implementation strategy they adopt: sequential or concurrent. Within each of these are three sub-categories.

Sequential

Creswell (2003) discusses three types of sequential strategies, where one method follows the other:

1. Explanatory: this has an initial (dominant) quantitative study, with a follow-up qualitative component; and is used to aid the understanding of the initial quantitative data. This is a straightforward design, but can take a lot of time to conduct.

2. Exploratory: this has an initial (dominant) qualitative study feeding into a follow-on quantitative study; and is used to provide the elements of an emerging theory for testing. This is a useful design when the researcher is building a new instrument, but can also be time-consuming to conduct.

3. Transformative: the sequence and priority of methods can alternate in this design, to best suit the theoretical perspective of the researcher. This has the same strengths and weaknesses as the previous designs. However, little has been written on this, and so it is not well guided.

Concurrent

Likewise Creswell (2003) discusses three types of concurrent strategies, where both methods are conducted simultaneously:

1. Triangulation: this uses two different methods within a single study, to confirm, corroborate, or cross-validate findings. This strategy involves gathering different data on the same phenomenon from different methodological perspectives (quantitative and qualitative), to obtain the most adequate account of it (Malterud, 2001), and can highlight when results do or do not converge. It is, however, not easy to conduct, as it requires a great effort to examine the same phenomena with separate methods.

2. Nested design: in this approach one predominant method has a smaller (less dominant) method embedded within it. This method allows the researcher to gain a broader perspective from using different methods, rather than using a different predominant method. This is advantageous because the researcher can use different methods simultaneously in one data collection phase, and it offers the chance to explore different perspectives. However, this is a poorly understood method, and not easy to conduct.

3. Transformative: this takes on the design features of either the triangulation or the nested methods, to best suit the theoretical perspective of the researcher. This has the same strengths and weaknesses as the individual designs that it borrows from.

2.5.4. Transferability of the knowledge gained from mixed methods research

Research seeks not only to answer the research question, but also to contribute to wider knowledge. In quantitative research, this relates to the generalisability of the research; where it is held that the findings are universal and can be applied to other similar situations. Qualitative research rejects notions of generalisability, because its focus is on the specific context of the research. Thus no attempt is made to apply the results to a larger level. Mixed methods research by comparison seeks to ensure that the findings are transferable, distinguishing between the mono-methods. As Morgan (2007) notes, instead

of querying whether or not the findings are universal, mixed methods research seeks to examine the transferability of the findings; thereby taking the knowledge gained from one method in one setting, and applying it to a different setting.

2.6. Appraisal of mixed methods methodology

Section 2.5 has (in part) highlighted the potential benefits of adopting different procedures for using mixed methods research. However, several commentators have noted reasons for being cautious about adopting a mixed methods approach. Those that are most pertinent to the research conducted in this thesis are now examined.

Mixed methods research has aligned itself with the philosophy of pragmatism, in an attempt to lend it the same credibility that postpositivism and constructivism give to quantitative and qualitative research, respectively. But is this necessary? Johnson *et al.* (2007) have proposed that mixed methods research should distinguish itself by not having a guiding philosophy, but instead be self-reflexive, and contribute to discussions on the philosophy of science. The concept of 'Communities of Practice' appears to provide a practical and realistic description of how the business of research is conducted day-to-day. The researcher is not faced with the necessity to reflect on matters of the philosophy of science, or making a choice between paradigms, and so can concern him or herself with the design and conduct of research that is valid and reliable.

Furthermore, mixed methods research has sought to distinguish itself from mono-methods by being driven by the question and not the method. This is very much a feature of contemporary research. It is commonly the case that the research question will have been defined at the outset by the funding body, and researchers compete to win a tender for conducting the project. The successful applicants, depending on the research question, may then have scope to choose the methods to examine the question.

Mixed methods research is an emerging discipline, compared to quantitative and qualitative research. Collins *et al.* (2007) have cited four methodological issues that remain to be resolved:

(i) The challenge for sampling to be conducted to enable the research to be representative;

(ii) The difficulty in generating findings that are 'legitimate', i.e. credible and transferable;

(iii) The challenges of integrating quantitative and qualitative data, with regard to the relative weight given to quantitative and qualitative data and how to integrate them; and

(iv) The problems that arise when there is an apparent discrepancy between qualitative and quantitative data.

This uncertainty in mixed methods research methods and the underpinning methodology can be contrasted with the stability of the mono-methods. The consequence for this thesis is that it is that it is adopting a developing methodology that may be seen as less reliable than either mono-method. This presents a challenge for the validity of research conducted in this thesis to be safeguarded, and offers a potentially novel methodological approach to examining WMI.

2.7. The application to this thesis

This thesis reports applied research seeking to answer a real world problem, driven by the research question, and not a particular methodology. It uses a mixed methods approach to provide the best means for answering the research question. Adopting a mixed methods approach will be invaluable because it will provide a more comprehensive picture of the usefulness of WMI, in particular IBMI. Thus it will be possible to examine not only what features of IBMI sites facilitate or impair their efficient use; but also to gain an understanding of why they do so. This will therefore necessitate record quantitative and qualitative data simultaneously, at stages in the research in this thesis.

The mixing of methods to examine questions relating to WMI represents a novel approach to examining this area of research. There is no known example of such research in this area

to act as a template to guide this; and so this makes the conduct of this research in a valid and reliable manner a challenge.

Mixed methods are used in three of the four research studies in this thesis.

- Study one: the examination of the effectiveness of WMI and the examination of the views of WMI stakeholders represents the combination of primary research using qualitative methods, and secondary research using quantitative methods. The first workshop enables stakeholders to input into the aims of the systematic review. The follow-up workshop provides an opportunity for stakeholders to feed back on the findings of the review.

- Study three: utilises a triangulation of concurrent quantitative and qualitative methods to examine the readability and usability of IBMI. This is complemented by a sequential explanatory component: a post-study interview with the participants, to gather their opinions on the readability and usability of the website. It is considered that the use of concurrent methods is essential for examining the usability and understandability of IBMI sites as it will highlight problems that the person has when using the website and at the same time bring to light the participants' perceptions of the reasons for their having problems. This will be conducted by measuring participants' ability to find and understand specific information on the IBMI sites, and simultaneously observing their actions while interacting with the websites as they think aloud (see 5.2). By triangulation of this data, it will enable a picture to be developed of what features of the site are easy to use or not, and why they are so.

- Study four: the User Test task is the main focus of this study, followed by a sequential explanatory post-study questionnaire for examining the ease of use of the site, and the participants' satisfaction with using it. As with Study three, this provides an opportunity to examine participants' explanations for their interactions with the web pages, but by using different methods (see 6.5.2).

2.8.Conclusion

This chapter has explored the methodological issues that underpin the four studies reported in this thesis; and explained how the methods are mixed in each of these studies. The next chapter reports the first empirical study. This study mixes focus groups research with a systematic review of trials to evaluate the effectiveness of paper-based information about medicines.

Chapter three
Study one: evaluating the effectiveness of written medicines information

3.1.Introduction

This chapter reports research of secondary data that evaluated the effectiveness of WMI as a leaflet (usually) accompanying medicines. This study formed part of a *Health Technology Assessment (HTA)* report by Raynor *et al.* (2007a), and has recently been updated for a *Cochrane Review* by Nicolson *et al.* (2009). The author of this thesis was an author on both the *HTA* report and the *Cochrane Review*, and his role on these projects is set out in Appendix one.

This chapter is based on the updated Cochrane Review. The inclusion criteria of the Cochrane Review differed from the original *HTA* report in that it evaluated trials that used medicine user participants, but not trials conducted with general public participants. As a consequence, the *Cochrane Review* excluded trials that examined the impact of information about the risk of a side effect presented in different ways to the general public. These trials were included in the *HTA* report (which included trials recruiting non-medicine users), and are reported in this chapter.

This chapter also reports the findings from two multi-stakeholder workshops that formed part of the *HTA* review project. The first workshop informed the aims and objectives of the review. The themes that emerged from this workshop were compared to themes in previous reviews of WMI, conducted by Nicolson *et al.* (2006b); and this work is referred to in this chapter. The second workshop enabled the stakeholders to feed back on the findings of the review, so that the conclusions of the report could reflect their comments. An examination of methods issues surrounding the review (see 3.7.2) were presented by Nicolson *et al.* (2006c) at the *International Social Pharmacy Workshop* conference.

This is the first of three studies in this thesis to utilise mixed methods (see 2.7). The workshops, using qualitative methods, ran sequentially before and after the quantitative systematic review of effectiveness. This chapter now examines the methods underpinning a systematic review, which is the dominant research method adopted in this chapter.

3.2. Systematic reviews

The evaluation of WMI is conducted by a systematic review synthesising the best available evidence from previous research. The systematic review process is closely linked to evidence-based medicine.

3.2.1. Evidence-based medicine

Evidence-based medicine (EBM) is a modern approach to medical practice which explicitly uses high quality evidence to make decisions about the healthcare of individual patients (Sackett et al., 1996). This evidence is essential for healthcare professionals to ensure that they use effective, efficient, and up-to-date practice. Many healthcare professionals, however, do not have the time to locate, appraise and assimilate the vast quantities of evidence (Earle and Weeks, 1999). To overcome this, the evidence is often disseminated to professionals by means of a systematic review.

At the forefront of systematic reviewing in healthcare is the *Cochrane Collaboration*. This provides up-to-date information on the effectiveness of healthcare treatments (Grimshaw, 2004), through the development of systematic reviews and meta-analyses, published on the Internet in the *Cochrane Library* (*http://www.thecochranelibrary.com*). The *NHS Health Technology Assessment (HTA)* (*http://www.ncchta.org/*) and the *National Institute for Health and Clinical Excellence (NICE)* (*http://www.nice.org.uk/*) are UK based organisations that produce evidence based guidance for clinical and healthcare professionals, derived from systematic reviews. The *HTA* (in part) produce research examining the effectiveness of healthcare treatments (*http://www.ncchta.org/* accessed online May 2008). NICE produce national guidelines on public health, health technologies, and clinical practice (*http://www.nice.org.uk/* accessed online May 2008).

3.2.2. Randomised Controlled Trials (RCTs)

Much of EBM is based upon findings from systematic reviews of RCTs, which are considered to be the best evidence for the effectiveness of an intervention, (discussed in greater detail in the following section). This section examines what safeguards are in place to ensure that potential bias in a trial of WMI leaflets is reduced. These principles informed the conduct of the systematic review.

- Selection bias can occur when participants are allocated to the intervention or control (Moher *et al.*, 1999). The allocation of participants to the intervention has two components: the generation of allocation, and then the concealment of the allocation process (Khan *et al.*, 2001). Random allocation of the participants to the intervention or control groups can be adequately carried out if the sequences are unpredictable; by using a computer program, or a random numbers table (Jüni *et al.*, 2001). In a trial of WMI, participants then have an equal chance of receiving the experimental leaflet or control leaflet. The second part of the process is the concealment of allocation from the experimenter so that she or he cannot subvert the allocation process. This is adequate if it cannot be foreseen which intervention each individual has been assigned to, e.g. by putting the name of each intervention ('experimental leaflet' or 'control leaflet') in sealed opaque numbered envelopes (Moher *et al.*, 1999).

- Detection bias occurs when the outcome assessor allows knowledge of what intervention the participant received to affect her or his measurement of the outcome (Moher *et al.*, 1999). This can be minimised by concealing knowledge of whether the participant received the 'experimental leaflet' or 'control leaflet' from the outcome assessor. (It is not possible to conceal the type of information from the participant or the treatment provider (Jüni *et al.*, 2001)).

- Attrition bias refers to the loss of participants to follow-up, and bias in the occurrence and handling of deviation from the protocol (Jüni *et al.*, 2001). This can be controlled by conducting an intention-to-treat analysis, where participants'

outcome measures are still analysed when they drop out of the trial. All measures should be recorded for the participants, so that there is a complete set of data, and when there is not, the number of people who were lost to follow-up should be recorded so that this can be taken into consideration when analysing the results (Khan *et al.*, 2001).

3.2.3. The rationale underpinning a systematic review

A systematic review is a means for synthesising primary research, providing a robust summary of the best available evidence. Cook *et al.* (1997) note that a systematic review:

(i)   Clearly states its aims and objectives as a focused question;

(ii)   Aims to be comprehensive in the identification of studies relevant to the review;

(iii)   Has explicit inclusion criteria;

(iv)   Rigorously assesses the quality of the methods used by the research;

(v)   And often (though not always) provides a quantitative summary statistic.

A systematic review uses these scientific methods to minimise bias and error (University of York NHS Centre for Review and Dissemination, 2001). This contrasts with a 'traditional narrative review' which does not attempt any of the five steps above, and so is prone to bias and error. Systematic reviews benefit EBM, because they constantly update the evidence on the effectiveness of treatments, preventing the unnecessary reproduction of research while ensuring that the best available evidence is kept up-to-date.

A systematic review of RCTs is widely perceived as the 'gold standard' for evaluating the effectiveness of an intervention (Sackett *et al.*, 1996); placing it at the peak of the hierarchy of evidence. The hierarchy of evidence is not accepted by all within pharmacy practice research (or HSR); for example, Harding and Taylor (2006) repeat an argument by some researchers to reject the hierarchy in favour of criteria based on the quality and robustness of the evidence, whether from qualitative or quantitative research. Such arguments are rejected in this thesis because the RCT is widely accepted to be the most rigorous method for evaluating the effectiveness of an intervention. The RCT equally distributes

confounding and extraneous variables between the intervention and control groups, so that the only difference between groups is the intervention. Therefore any differences that exist between the intervention and control groups on the outcome measures can be attributed with greater confidence to the intervention differences.

Meta-analysis is a statistical technique for pooling the results of different studies to produce an overall summary estimate and confidence interval (University of York NHS Centre for Review and Dissemination, 2001). This increases the sample size and therefore the power of the combined studies, making a significant effect more detectable (Mulrow, 1994), and the conclusion more certain. The Cochrane Collaboration logo depicts a meta-analysis of seven trials evaluating the effectiveness of corticosteroids for reducing complications when given to women who were expected to give birth prematurely (Antes and Oxman, 2001). Only two of these individual trials found statistically significant results in favour of this treatment. But when pooled, the sample size and power increased and a statistically significant effect was discovered (Mulrow, 1994).

Meta-analysis is a valuable tool in the systematic reviewer's arsenal, but it is not always necessary. Petticrew (2001) has noted that systematic reviews do not automatically warrant a corresponding meta-analysis, as a narrative synthesis of studies may be more appropriate and, perhaps all, that is possible.

A systematic review provides a basis for primary research by enabling researchers to identify which research questions have already been answered, so as not to needlessly replicate previous research; and to identify limits and gaps in the evidence base. The *Medical Research Council* funding body requests that a systematic review precedes any proposed new primary research (Glasziou *et al.*, 2006).

3.2.4. The limitations of systematic reviews

Systematic reviews have limitations. There may be publication bias in the studies. Publication bias occurs because journals may only be willing to publish results with positive outcomes, thus holding back findings which dispute the evidence base (Wormald and Oldfield, 1998); for example, small trials which are inconclusive or have negative

results are less likely to be published. Poor reporting of the methods used in a trial can mask inadequate methods, and thus cast doubts on the validity of the results (Wormald and Oldfield, 1998).

Systematic reviews are not wholeheartedly embraced because they can produce unclear findings. For example, Petticrew (2003) has noted that they are often unable to find specific evidence in favour of an intervention. Furthermore, Waters and Doyle (2002) have noted that a systematic review can only reflect the evidence from primary studies, which immediately constrains the conclusions it derives.

3.3. Examining the views of stakeholders about WMI

The first workshop gave stakeholders an opportunity to shape the aims and objectives of the *HTA* funded project, before the systematic review was conducted. Data was gathered by recording and analysing the themes which developed during the discussions.

3.3.1. Aims and methods of the first stakeholder workshop

The aim of the first workshop was to gather stakeholders' opinions about the importance and purpose of WMI, through group work. The workshop ran for four hours with a structured format of presentations, group work and feedback. The participants were nine medicine users, four representatives of *NHS National Patient Organisation* groups, four project collaborators, and 12 project members; (see Table 2 for further details). A broad range of stakeholders was recruited to ensure that the opinions of different stakeholders were all represented (Rowe and Frewer, 2000). The sample of medicine users were identified through the local *Expert Patient Programme*. The sample of *National Patient Organisation* groups and project collaborators were picked because of their close working relations with the team that developed the report.

The workshop followed a structured format of group work and feedback, with presentations by project staff. (See Appendix three for the programme of this and the feedback workshop). The numbers of consumers, collaborators, and project staff were balanced between five groups for the table discussions. The objectives of each activity were explained to the groups at the beginning of the tasks. At each group, one project

member per group facilitated the activity, supporting the flow of discussion and reflecting on pertinent points made by the participants. A second project member recorded on paper the key comments made. Audio recording of the group discussions were not possible because of the close proximity of each group, which may have lead to individual group conversations being less audible. Because no audio record was kept, it was not possible to determine which comments related to which of the stakeholders recorded on paper.

We asked the participants to consider five points for discussion, framed as questions. These were:

(i)   To provide examples of good and bad medicine information leaflets.

(ii)   To describe what they feel are the most important things about medicine information leaflets.

(iii)   To state what they feel the role (purpose) of medicine information leaflets is.

(iv)   To state what they think makes medicine information leaflets effective.

(v)   To state what they think makes medicine information leaflets valuable to them.

At the end of the activity, there was a discussion of this task between all the groups. A project member recorded the main points arising from each group on a flip-chart.

The author categorised the records for each group's discussions into overarching themes. For example, comments about 'type size of patient information leaflets' and 'the flimsy paper they are printed on' were considered to be categorically similar and condensed as 'visual presentation'. A PhD supervisor (who also worked on the project) checked the derived themes against the workshop records, and differences were reconciled by discussion.

The groups were given 25 minutes to discuss the first point, and 55 minutes to discuss the remaining four points in one exercise.

Table 2: Characteristics of participants in the first workshop

Nine consumers of medicines
• The medicine users were from a city in the north of England.
• Their mean age was 63 years (range 50-77), five were male and all participants were retired.
• They had personal experience of a range of medical conditions, and were currently prescribed a mean of 6 medicines (range 2-11).

Four representatives of National Patient Organisation groups
• Diabetes UK.
• Multiple Sclerosis Trust.
• Asthma UK.
• Arthritis UK.

Four project collaborators
• www.patient.co.uk.
• NHS Direct Online.
• Association of the British Pharmaceutical Industry (ABPI).
• Medicines and Healthcare products Regulatory Agency (MHRA).

3.3.2. Themes discussed in the workshop

What are good and bad medicine examples of information leaflets?

The participants mainly focused on negative examples of leaflets; speaking about difficulties of readability (for example, tiny print and flimsy paper making the leaflet difficult to read), complicated content and the use of over-technical language. It was noted that delivery of the information comes too late, i.e. after the medicine has been prescribed and dispensed. Stakeholders spoke of how too much information can be overwhelming and, if it was not understandable, they said it can be frightening.

What is most important about medicine information leaflets?
Participants highlighted the importance of readability: for example, the size of the text, and the provision of meaningful information for them. They identified information about dosage and ingredients; when/how long to take it; the likelihood of it being successful; side effects (for example, how likely they are); and factors relevant to their personal medical condition (as opposed to any other condition for which the medicine is taken), as being important.

What is the purpose (role) of medicines information?
It was felt that a role of WMI was to provide practical information on how to take the medicine effectively, and its potential side effects and interactions. They felt information should complement but not replace a consultation with a doctor or other healthcare specialist. They also indicated the information should inform them of the purpose of the treatment in relation to their specific diagnosis, as well as what condition the medicine is treating.

What makes medicines information effective?
Stakeholders considered information would be more effective if it was available during the consultation with a health professional. They felt that non-technical information written in plain language was most effective. They also indicated that the content of the information was important, such as whether it provides basic information about what the medicine contains.

What makes medicines information valuable?
Participants indicated they valued information when it enabled them to make an informed choice; was reassuring and reduced concern, conflict and anxiety about whether the medicine was the right one for them; and when it gave them confidence in taking medicines.

3.3.3. Discussion
The themes generated by the workshop underlined the aims of the systematic review. As a primary research exercise, the workshop provided an invaluable insight into consumers of

medicines' (and the other stakeholders') feelings about WMI. For example, workshop participants spoke of wanting information about medicines that is understandable.

The participants wanted information to be available during the consultation, rather than only after they receive the medicine and read the insert. It remains to be seen if IBMI could meet this need. The participants also reported they would like to receive information providing personalised and treatment specific information, which may again be possible with IBMI.

Stakeholders' comments about what makes the information valuable appear to suggest that they value the information for providing a purpose rather than what it is: a legally sanctioned piece of information accompanying a medicine.

3.4. A comparison of workshop and review themes

As a secondary exercise, we compared themes covered in previous reviews of medicines information leaflets with the themes that emerged from the workshop. The aim was to compare how far the themes emerging from previous reviews of medicines information leaflets reflected the current priorities and concerns of those who use medicines information (and attended the initial workshop). These findings would be used to feed back into the aims of the systematic review.

3.4.1. Methods

Previous reviews were identified from searching Medline and Embase from 1970 to October 2004 for:

(i)   Systematic reviews, meta-analyses, or narrative reviews of studies of the effectiveness of patient information leaflets about medicines; and

(ii)   Reviews of research on patient information leaflets for medicines information in a 'wider context'.

Non-systematic reviews were included in the search because there were no known previous systematic reviews which specifically focused on the effectiveness of patient information leaflets. The following sources were excluded:

(i)   Book chapters or university degree theses;

(ii)   Reviews of the actual patient information leaflets (rather than reviews of

        primary research);

(iii)   Reviews (of any design) evaluating patient information leaflets as one of a

        range of interventions to improve patient compliance that could not be

        separated from the overall synthesis.

The themes which emerged from the comparison of the previous reviews and the

workshop were related to categories of 'patient education discourse' (Dixon-Woods, 2001)

(see 1.5).

3.4.2.   Themes discussed in the previous reviews

Five reviews of research of WMI meeting the inclusion criteria were found: (Morris and

Halperin (1979), Arthur (1995), Buck (1998), Kenny et al. (1998), and Koo et al. (2003).

A brief overview of how the five reviews were conducted and what they found is

presented in Table 3.

There was variation in how the reviews were conducted. Two did not report methods

(Arthur, 1995, Morris and Halperin, 1979) while one mentioned only the search strategy

(Kenny et al., 1998). One review reported its objectives, search strategy, data extracted and

data synthesis (Buck, 1998); and one stated its search strategy, inclusion and exclusion

criteria and data synthesis (Koo et al., 2003). No reviews were considered to have been

conducted in a systematic way; (see 3.2.3 for the criteria of a systematic review). Two

meta-analyses (Haynes et al., 2002, Roter et al., 1998) evaluated a range of interventions to

improve patient compliance (including 'written materials'). Because patient information

leaflets for medicines was a minor aspect of these papers, and could not be separated from

the overall synthesis, these were not included.

In summary, the reviews reported some important points, but because they were not

systematically derived, their usefulness as reports of robust evidence is limited. Points

from the review to note were: WMI has the potential to impact positively or negatively on

users (Koo et al., 2003), but patients want and use WMI (Kenny et al., 1998). Morris and

Halperin (1979) and Arthur (1995) both reported studies that found that providing WMI did not increase adherence. Buck (1998) noted limitations in the information that the leaflets provide.

Table 3: Summary of previous reviews of patient information leaflets

Article	Methods stated	Conclusions
Morris and Halperin (1979) 'Effects of written drug information on patient knowledge and compliance: a literature review.'	None	• Adequate patient information leaflets alone will not aid compliance.
Arthur (1995) 'Written patient information: a review of the literature.'	None	• Few studies have evaluated patient information leaflets. • There is little research on the impact of patient information leaflets on consumers.
Buck (1998) 'Providing patients with written medication information.'	Objectives; search strategy; data extracted; data synthesis.	• Patient information leaflets can serve as a useful addition to verbal counselling. • Some patient information leaflets are limited in the information they provide.
Kenny et al. (1998) 'A PIL for every ill? Patient information leaflets (PILs): a review of past, present and future use.'	Search strategy.	• Patient information leaflets have been poorly written. • Patients want medicines information leaflets and use them.
Koo et al. (2003) 'Factors influencing consumer use of written drug information.'	Objectives; search strategy; inclusion and exclusion criteria; data synthesis.	• Patient information leaflets have positive and negative impacts on consumers.

Table 4: Comparison of themes emerging from the MILK workshop, with themes in the literature

Themes arising in workshop:	Morris and Halperin 1979	Arthur 1995	Buck 1998	Kenny et al. 1998	Koo et al. 2003
Language (e.g. readability or understandable)	✓	✓	✓	✓	✓
Visual presentation (e.g. print font, paper size, illustrations)	✓	✓	✓	✓	✓
Patient reactions (e.g. satisfaction, anxiety, etc)	✓	✓		✓	✓
Complement consultation	✓		✓	✓	✓
Source (e.g. web available)			✓	✓	
Medicine use (e.g. emergency contact information. beneficial effects, dose administration)			✓		✓
Medicine side effects			✓		
Explanation/rationale for taking the medicine			✓		
Condition specific or patient relevant				✓	✓
Need to be evidence-based				✓	
Timing					✓
Informed choice and autonomy					
Themes not arising in workshop:	**Morris and Halperin 1979**	**Arthur 1995**	**Buck 1998**	**Kenny et al. 1998**	**Koo et al. 2003**
Compliance/ behaviour change	✓	✓			✓
Recall		✓			
Multi-language			✓		
Availability of information			✓		
The information needs of caregivers of people taking medicines					✓
Psychological models to explain patient information leaflets					✓

3.4.3. Comparison of themes from the workshop and previous reviews

No review addressed all the themes arising from the workshop. The more recent reviews reflected a greater number of workshop themes than the older reviews, suggesting a probable temporal trend of increased professional sensitivity to consumer issues, by both primary research and the review authors.

Workshop themes most often reported in the reviews were 'language' and 'visual presentation' (which are cognate themes) and appear to reflect the patient education discourse model, because the latter has a focus on design features (see Table 4). The workshop themes less often reflected in reviews, ('patient-relevant information', and 'timing'; or not reflected at all, 'informed choice and autonomy'), and can be mapped on to the 'patient empowerment model', because the information allows patients to play a more active role in making decisions about treatment and managing their health (Dixon-Woods, 2001).

3.4.4. Discussion

Comparing the themes arising from workshops and previous reviews identified evidence of an apparent mismatch between what current medicine users consider important regarding WMI and what past research focused on. Considered in relation to Dixon-Woods' (2001) patient information discourse model, it suggests that there has been a change in the direction of WMI research from being based on 'patient education' to focusing on 'patient empowerment'. This exercise crystallised the need for research of WMI (PIL or IBMI), including that in this thesis, to be patient-centred.

3.5. Systematic review of trials evaluating the effectiveness of WMI

3.5.1. The aim of the effectiveness review

The aim was to systematically review RCTs evaluating the effectiveness of paper-based or Internet-based WMI for changing knowledge, attitudes and behaviour related to taking medicines.

3.5.2. Search methods

Twelve electronic databases were searched: *Medline, Embase, Cochrane Library, CINAHL, Digital Dissertations, HMIC, Index to Theses, ISI Proceedings, Pharmline, PsychINFO, Sociological Abstracts, and Web of Science,* for published and grey literature from 1970 to October 2004 on the effectiveness of WMI. This was augmented by searching the table of contents of six electronic journals, and checking the reference lists of published reviews.

3.5.3. Inclusion criteria for study inclusion in the review

Inclusion criteria were based on study design, participants, interventions, and outcome measured.

Types of studies

- RCTs published in English language from 1970 onwards;

- RCTs that provided the intervention group with written information and compared this to a control group receiving no intervention or a second intervention group receiving a different version of written information.

In the protocol it was anticipated that there would be an absence of RCTs, and so including non-randomised controlled trials, and controlled before and after studies was considered. However, as the RCT represents the most robust form of evidence of effectiveness (see 3.2.3), and a sufficient number of RCTs for the review were found, no other type of study design was included.

Usability testing studies and studies of the readability of WMI were excluded.

Types of participant

- Studies of medicine takers, or informal carers of any age were included;

- Trials examining the presentation of the risk of a side effect on the general public were included (see also 3.1).

Types of intervention

- Written medicines information was defined in terms of the EU categories of information, (see 1.2.2);

- Studies providing WMI for POM or OTC medicines were included;

- Studies providing WMI that was leaflet or Internet-based were included.

Studies examining the following types of information were excluded:

- Information designed to inform decisions about taking a drug;

- Condition-based leaflets containing brief information about medicine;

- General information about treatments for the public;

- Information solely using icons;

- Information about non-drug forms of contraception or alternative medicines.

Types of outcome

Four types of outcome data were extracted:

- Treatment-related knowledge;

- Treatment-related attitudes;

- Treatment-related behaviours;

- Treatment-related health outcomes.

Two reviewers independently extracted descriptive information and outcome data. Differences were reconciled by discussion and authors were contacted for missing data.

3.5.4. Collection and analysis of the data

The thesis author sifted the title and abstracts of the references on Endnote. One PhD supervisor checked a random sample of 10% of the references. The author and two PhD supervisors independently assessed each paper that was retrieved for consideration for inclusion, and agreement was reached by discussion.

Trials were categorised according to the comparison between the intervention and the control:

- Trials examining the absolute effectiveness of WMI for changing knowledge, attitudes, and behaviour: these trials isolated the effectiveness of written information by comparing WMI versus nothing; or WMI and spoken information versus spoken information alone. Trials that compared WMI versus WMI and spoken information were not included, because they isolate the effect of additional spoken information, and not written information.

- Trials examining the relative effectiveness of different ways of presenting WMI for changing knowledge, attitudes, and behaviour: these trials compared WMI versus WMI.

- Trials examining the relative effectiveness of different ways of presenting information about the risk of a side effect for changing knowledge and attitudes. (These trials did not measure behaviour as an outcome, and most enrolled non-medicine takers).

The data from each of these categories were grouped together for knowledge, attitudinal and behavioural outcomes, and presented in a descriptive way to highlight the effect of WMI on each of these outcomes. This method was undertaken because it was anticipated (at the outset of the project) that a statistical synthesis would not be possible.

When inferential statistics, and/or probability values (p-values) were not reported in papers, but sufficient raw data was available (such as group data, means or standard deviations), statistics were calculated. For categorical data a chi-square test of association was conducted. Similarly, when data was aggregated across groups to fit the purpose of the systematic review, their statistics and p-values were recalculated by using a chi-square test. For example, in trials where participants received both written information or not, and spoken counselling or not; the data was aggregated over those receiving spoken counselling or not to isolate the effect of receiving WMI or not.

The author and one supervisor independently assessed the quality of trials, following guidelines written by the University of York NHS Centre for Review and Dissemination (2001) and Verhagen *et al.* (1998). Trial quality (see 3.2.2) was considered for:

- Adequacy of randomisation, which seeks to control for selection bias;
- Concealment of allocation, which seeks to control for selection bias;
- Blinding, which seeks to control for detection bias; and
- Reported loss to follow up, which seeks to control for attrition bias.

The quality of the information in the leaflet was examined in two ways:

- The EU categories of information to be contained in a leaflet (see also 1.2.2).
- Two categories were devised for evaluating presentational aspects of the leaflet: (i) 'easy to read', indicated by the absence of complex words or unexplained jargon; and (ii) 'good layout', indicated by headings being separate from the main text.

It was also noted if the intervention was developed from an explicit theory or evidence-base and if the leaflet was available in the report (or subsequently obtained from the authors).

The author and one a supervisor independently extracted data from all included studies, using a standardised form. Differences were reconciled by discussion, or in conjunction with a second supervisor. When papers had missing data or incomplete information about the conduct of the trial, we contacted the authors.

3.5.5. Results

Description of the trials

Thirty six trials enrolling 8,270 participants met the inclusion criteria. The trials were reported in 31 papers. (See Appendix four for the full references of these papers). Four papers (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b) reported nine trials in total. Twelve papers reported the source of funding of the trial. Pharmaceutical companies sponsored three trials (Desponds *et al.*, 1982, Labor *et al.*, 1995, Vesco *et al.*, 1990). The trial by Peveler *et al.* (1999) received funding from both a UK Government research council and pharmaceutical company. The other papers that

reported funding received it from a national funding body. The remaining papers did not declare the funding source.

The trials were conducted in nine countries: nineteen in the UK; eight in the USA; two in Belgium; two in Canada; and one each in Finland, France, Hong Kong, Switzerland and Turkey. The earliest trial was published by Clark in 1972, and the most recent in 2004 by Knapp. The mean length of follow-up in the 32 trials that clearly reported it was 25 days. This ranged from same day follow up in 13 trials to 111 days (Pope et al., 1998).

Description of participant demographics

Seventeen trials reported participants' age, which was on average 43 years: this ranged from 16 to 88 years. Twenty-nine trials reported how many participants were male, on average 40%. One trial (Little et al., 1998), examined WMI for the contraceptive pill (and therefore enrolled only women). Excluding these 636 women, the average number of male participants was 44%. Two trials reported the ethnic background of participants (Morris and Kanouse, 1982, Vander Stichele et al., 1992). Overall, 69% of the 333 participants in these trials were from a non-white background; although none of the 74 participants in the trial by Vander Stichele et al. (1992) were from a non-white background.

Ten trials enrolling 911 participants in total reported withdrawal: 131 people in total withdrew. This ranged from none (Clark and Bayley, 1972, Knapp et al., 2004) to 56 (37%) (Labor et al., 1995). The average rate of withdrawal was 14%.

Description of the intervention (WMI content)

Nineteen trials provided information for medicines for long-term conditions: five for non-steroidal anti-inflammatory drugs (NSAIDs); and nine for cardiovascular medicines. Five trials provided information about a medicine to treat an acute condition. One trial provided information about medicines used to treat a chronic condition (methyldopa for high blood pressure), and an acute condition (ampicillin for bacterial infection). (For the list of these trials, see Appendix five).

Ten of the 13 trials that examined perception of the risk of a side effect used information about a hypothetical antibiotic. The other three trials provided information about a real medicine.

The information provided ranged from minimal information to a well detailed document. Twenty-nine trials either published a full or partial copy of the WMI intervention, or the authors later provided a copy on request. The information in the interventions was matched to the five content categories recommended by the 1998 EU Directive. A considerable amount of heterogeneity in the content of the WMI between trials was noted.

The information in the leaflets was compared with the five EU recommended content categories. Most trials provided WMI about 'possible side effects' (see Table 5). Over half (19) the trials WMI mentioned 'what this medicine is and what it is used for', and 'how to take the medicine' (18). Less than half the leaflets in the trials (12) gave information relevant to 'before taking the medicine', while less than one quarter (6) provided storage information. Six trials provided information pertaining to all five categories: (Gibbs *et al.*, 1989, Peveler *et al.*, 1999, Regner *et al.*, 1987, van Haecht *et al.*, 1991, Vander Stichele *et al.*, 1992, Vesco *et al.*, 1990). elve of the 13 trials examining perception of risk (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry, 2004, Berry *et al.*, 2004, Knapp *et al.*, 2004) only provided information about 'possible side effects'.

No trials were found that had examined the effectiveness of IBMI when this review was conducted in 2005, or when it was updated in 2007. Ten trials reported that the design of the WMI was theory driven or evidence-based: see below. The remaining trials did not explain why the WMI intervention was designed as it was. It is unclear if the design of these trials interventions was based on theory or evidence.

Table 5: Specific content of the trials interventions

EU content category	Trials comparing:			Total
	Absolute effectiveness of WMI (	Relative effectiveness of WMI presentation	Presenting side effect risk descriptor	
What medicine is and what it is used for	14	4	1	19
Before taking the medicine	10	2	0	12
How to take the medicine	12	6	0	18
Possible side effects	13	4	13	30
How to store	5	1	0	6

The following trials reported a theoretical basis for the intervention:

- Baker *et al.* (1991): *Plain English Campaign* involved in WMI design.

- Bergus *et al.* (2002): information-order effect.

- Dodds (1986): recommendations of *Drugs and Therapeutic Bulletin*, 1981.

- Dolinsky *et al.* (1983):theory of read-organise-attend.

The following trials reported an evidence-base for the intervention:

- Arthur and Clifford (1998): based on the *Flesch reading levels test* (Flesch, 1948).

- Clark and Bayley (1972): intervention based on results from questionnaire.

- Desponds *et al.* (1982) based on the findings of Bellantuono et al. (1980) and Greenblatt and Shader(1978).

- Gibbs *et al.* (1989): intervention had been previously piloted by George et al. (1983) and Gibbs et al. (1987).

- Labor *et al.* (1995): revised in a pilot study, and using Flesch reading levels test (Flesch, 1948).

- Strydom and Hall (2001a): intervention had been previously piloted, by Strydom *et al.* (2001b).

Description of the outcome measures

Trial measures were categorised into one of three generic outcomes: knowledge, attitudes, or behaviour. No trials were found that measured the effect of WMI provision on a health outcome, and no trials that reported an adverse effect from giving WMI to the participants.

Twenty-nine trials, reported in 24 papers, measured knowledge (see Appendix five). The measure varied between trials, and included knowledge about the medicine, recall of medicines information, or estimation of the probability of a side effect.

Seventeen trials, reported in 13 papers, measured an attitude (see Appendix five). Again the method differed between trials, and included satisfaction with information, or intention to comply with or favour the treatment.

Nine trials measured behaviour as an outcome (see Appendix five): for example, adherence to treatment recommendations. Nineteen trials examined two or more of the categories of outcome measures. No trials measured a health outcome. The results for each of the three outcomes across the different intervention categories were pooled.

Description of the categorisation of included trials

Trials were categorised in terms of what they compared the intervention to:

- 20 trials examined the absolute effectiveness of WMI i.e. comparing the effectiveness of WMI against nothing: (Arthur and Clifford, 1998, Baker et al., 1991, Clark and Bayley, 1972, Dodds, 1986, Dolinsky et al., 1983, Gibbs et al., 1989, Johnson et al., 1986, Kumana et al., 1988, Little et al., 1998, McBean and Blackburn, 1982, Morris and Kanouse, 1982, Peura et al., 1993, Peveler et al., 1999, Pope et al., 1998, Regner et al., 1987, Robinson et al., 1986, Savas and Evcik, 2001, Strydom and Hall, 2001a, Vander Stichele et al., 1992, Vesco et al., 1990).

- 6 trials examined the relative effectiveness of WMI presentation: i.e. comparing the effectiveness of different ways of presenting WMI: (Clark and Bayley, 1972, Desponds et al., 1982, Dolinsky et al., 1983, Labor et al., 1995, Little et al., 1998, van Haecht et al., 1991).

- 13 trials, reported in eight papers examined the relative effectiveness of the presentation of information about the risk of a side effect: i.e. comparing the effectiveness of different ways of presenting information about a side effect: (Bergus *et al.*, 2002, Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004)

3 of the above trials compared the effect of more than one way of presenting WMI, and no information, and so are included in both the absolute and relative effectiveness categories: (Clark and Bayley, 1972, Dolinsky *et al.*, 1983, Little *et al.*, 1998).

Trial quality

Reporting of the methods was frequently incomplete; and when trials reported the methods clearly, they often highlighted inadequate methods. Eleven of the 36 trials (31%) reported a process of randomisation that was considered adequate. A further 11 trials randomisation process was confirmed to be adequate after contacting the authors. The remaining 14 trials either failed to report their randomisation method, or reported it in an unclear manner (that could not be discounted as inadequate). Seven trials reported a method of concealing allocation. This was judged adequate in five of the trials (14%). The trial by Pope *et al.* (1998) randomised by coin tossing, thus concealment was not possible. In the trial by Knapp *et al.* (2004), the paper explicitly stated that concealment was not adequate. The eleven trials by Berry and colleagues did not report how concealment of allocation was conducted. From further information received from the authors, we judged their method as inadequate. The remaining 18 trials either did not report concealment of allocation, or reported it in an unclear way.

Eight trials (22%) adequately masked the outcome assessor to the intervention, while 15 did not. It was not possible to judge whether or not this was adequate in the remaining 13 trials, as it was not clearly reported. Twenty trials enrolling 3,472 participants in total reported loss to follow-up. This ranged from no loss to follow-up in 12 trials that were

followed up on the same day, to 67 (67%) (Robinson *et al.*, 1986). The average rate of loss to follow-up was 19%.

Results from trials examining the effect of WMI provision on knowledge

Thirty-five trials measured a knowledge based outcome. As predicted in 3.5.4, a meta-analysis could not be conducted, due to the heterogeneity of outcome measures for knowledge. There were four main categories of knowledge outcome:

(i)   Knowledge about the medicine or recall of medicines information;

(ii)   Recognition or recall of side effects;

(iii)   Estimation of probability or likelihood of a side effect; and

(iv)   Judgement of the risk of a side effect or health risks.

- **The absolute effectiveness of WMI**

Twelve trials evaluated the absolute effect of WMI on knowledge; i.e. the effectiveness of WMI to improve knowledge compared to no information, (see Table 6 for an overview of trials examining the absolute effectiveness of WMI provision). Six trials found a statistically significant effect favouring WMI for improving knowledge (Arthur and Clifford, 1998, Clark and Bayley, 1972, Johnson *et al.*, 1986, Little *et al.*, 1998, Robinson *et al.*, 1986, Savas and Evcik, 2001).

Four trials (Dolinsky *et al.*, 1983, Kumana *et al.*, 1988, McBean and Blackburn, 1982, Strydom and Hall, 2001a) found no difference in improvement in knowledge for those given WMI or not. Of these four trials, McBean and Blackburn (1982) did not report statistical significance, and this could not be calculated from the available data. Dolinsky *et al.* (1983) compared two different WMI leaflets against no leaflet. They did not find any significant differences in knowledge outcome between the three groups.[1]

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[1] They however did not report individual statistical comparisons between the three interventions and it was not possible to calculate.

Table 6: Summary of the 20 trials examining the absolute effectiveness of WMI provision

Study	Participants and length of study	Intervention vs. control	Outcomes
(Arthur and Clifford, 1998) *J Adv Nurs*	80 medicine takers mean age 54 years, 27% male. Followed up for 8-12 weeks.	• Leaflet-based information about one of 12 NSAIDs and spoken information • Spoken information alone	• Knowledge
(Baker et al., 1991) *Br J Clin Pharmacol*	125 medicine takers mean age 52 years (20-83), 63% male. Followed up for 2 weeks.	• Leaflet-based information about one of 16 drugs covering four groups: glyceril trinitrate sublinguinal (GTS) tablets; ß-blocker; warfarin; or digoxin and spoken information • Spoken information alone	• Knowledge • Attitude
(Clark and Bayley, 1972) *Am J Public Health*	366 medicine takers age 21-77 years, 49% male. Followed up for 1-3 days.	• Information sheet about warfarin • No WMI • Programmed instruction information booklet about warfarin • No WMI	• Knowledge
(Dodds, 1986) *Pharm J*	68 medicine takers mean age 28 (16-81), 23% male. Followed up for 3-5 days	• Leaflet-based information about one of 11 antibiotics • No WMI	• Knowledge • Behaviour
(Dolinsky et al., 1983) *Am J Hosp Pharm*	271 medicine takers. Length of follow up unclear.	• Short paragraph leaflet about methyldopa or ampycillin • No WMI • Readable leaflet about methyldopa or ampycillin • No WMI	• Knowledge • Behaviour
(Gibbs et al., 1989) *Br J Clin Pharmacol*	719 medicine takers >16 years, 36% male. Followed up for 12 weeks.	• Leaflet-based information about one of 3 drugs: ß-blocker, NSAID, bronchodilator • No WMI	• Knowledge • Attitude
(Johnson et al., 1986) *JAMA*	34 medicine takers mean age 58, 80% male. Followed up for one month.	• Leaflet-based information about digoxin or propranolol • No WMI	• Knowledge
(Kumana et al., 1988) *Diabetes Res Clin*	111 medicine takers mean age 57, 37% male. Followed up for 3 months.	• Leaflet-based information about hypoglycaemic drug • No WMI	• Knowledge

Study	Participants and length of study	Intervention vs. control	Outcomes
Pract			
(Little *et al.*, 1998) *Brit Med J*	366 medicine takers mean age 27 years (21-31), 0% male. Followed up for 3 months.	• Evidence-based summary leaflet about the oral contraceptive pill • No WMI • Traditional leaflet about the oral contraceptive pill • No WMI	• Knowledge
(McBean and Blackburn, 1982) *Can Pharm J*	155 medicine takers mean age 56. Length of follow up not reported.	• Leaflet-based information about NSAID • No WMI	• Knowledge • Attitude • Behaviour
(Morris and Kanouse, 1982) *J Behav Med*	249 medicine takers mean age 52. Followed up for 3 months.	• Leaflet-based information about thiazide diuretic • No WMI	• Knowledge • Behaviour
(Peura *et al.*, 1993) *Int J Pharm Pract*	500 medicine takers, 27% male. Followed up for 17 days.	• Electronically produced leaflet-based information about digoxin and spoken information • Spoken information alone	• Knowledge
(Peveler *et al.*, 1999) *Brit Med J*	213 medicine takers mean age 45 (21-83), 27% male. Followed up for 3 months.	• Leaflet-based information about dothiepin • No WMI	• Behaviour
(Pope *et al.*, 1998) *J Rheumatol*	72 medicine takers mean age 48 (35-62), 31% male. Followed up for 111 days.	• Leaflet-based information NSAID and spoken information • Spoken information alone	• Knowledge
(Regner *et al.*, 1987) *Drug Intell Clin Pharm*	48 medicine takers. Followed up for 17 days.	• Leaflet-based information about digoxin and spoken information • Spoken information alone	• Knowledge
(Robinson *et al.*, 1986) *Psyc Quary*	100 medicine takers. Followed up for 14 days.	• 1 to 2 page information sheet specific to the class(es) of medication on which they were being discharged and standard education.	• Knowledge • Behaviour

Study	Participants and length of study	Intervention vs. control	Outcomes
(Savas and Evcik, 2001) *Scand J Rheumatol*	70 medicine takers mean age 50 (28-73). Followed up for 7-10.	• Spoken information alone	• Knowledge
(Strydom and Hall, 2001a) *J Intellect Disabil Res*	57 medicine takers median age 36, 63% male. Followed up for 8 weeks.	• Leaflet-based information about NSAID and spoken information • Spoken information alone	• Knowledge
(Vander Stichele et al., 1992) *Post Market Surveill*	74 medicine takers age 52-70, 49% male. Followed up for 8 weeks.	• Leaflet-based information about one of 8 mental health drugs and spoken information • Spoken information alone	• Knowledge
(Vesco et al., 1990) *Eur Respir J*	40 medicine takers mean age 43, 75% male. Followed up for 8 days.	• Leaflet-based information about β-blocker or ACE inhibitor • No WMI	• Behaviour
		• Leaflet-based information about theophylline • No WMI	• Behaviour

The remaining two trials (Gibbs et al., 1989, Pope et al., 1998) found a statistically significant effect favouring both WMI and no information, depending upon the outcome measured. Gibbs *et al.* (1989) found that significantly more participants receiving written information gave the correct answer to questions about the medicine, for four of nine questions (p<0.05). However, more people who received no WMI (73%) knew the name of the medicine compared to those who received WMI (66%), (p<0.05). Pope *et al.* (1998) found a statistically significant effect for two of the eleven knowledge outcomes: one favouring WMI, and one favouring no information; (both p<0.05). Morris and Kanouse (1982) did not test for statistical significance.

Four trials (Baker *et al.*, 1991, Dodds, 1986, Little *et al.*, 1998, Peura *et al.*, 1993) examined participants' recall of information about the medicine that they received. Dodds (1986) found that participants given WMI had significantly higher endpoint recall of the information than those receiving no intervention.

Little *et al.* (1998) used a factorial RCT design to compare the effectiveness of an experimental evidence-based summary leaflet, a standard leaflet and no leaflet, on women's knowledge of an oral contraceptive. In addition to receiving one of the three interventions above, participants were also randomised to be asked questions or not by a healthcare professional. A questionnaire designed specifically for the study was validated for face-, content- and construct-validity. For the purposes of the systematic review, the results were aggregated over those asked the questions or not, and it was found that those receiving the experimental leaflet correctly answered more questions about oral contraceptives (33%) compared to those receiving no leaflet (17%), (p<0.05). However, there was no significant difference in the number of questions correctly answered by those receiving the standard Family Planning Association leaflet (24%) or no information (19%). Baker *et al.* (1991) and Peura *et al.* (1993) only found significant differences (p<0.05) in recall for half of the questions they asked participants.

Six trials (Baker *et al.*, 1991, Gibbs *et al.*, 1989, Morris and Kanouse, 1982, Peura *et al.*, 1993, Pope *et al.*, 1998, Regner *et al.*, 1987) examined participants' recall of the information about

a side effect. The trials by Baker *et al.* (1991), Gibbs *et al.* (1989), Peura *et al.* (1993), and Regner *et al.* (1987) found that participants had significantly greater recall of the information when they received WMI, than when they received none. Gibbs *et al.* (1989) found 38% of participants receiving WMI had an awareness of side effects (aggregated over all study drugs), compared to those receiving nothing, 15% (difference p<0.001). Morris and Kanouse (1982) found participants given WMI named more side effects at follow-up compared to the control group, but also more incorrect side effects. However they did not report statistical significance and this could not be calculated from the available data. The trial by Pope *et al.* (1998) found a statistically significant effect for two of the eleven knowledge outcomes: one favouring WMI, and one favouring no information. They found that participants who received spoken information alone, listed more side effects than those who had received additional WMI, (p<0.05); but there was no significant difference between the groups for the number of correct side effects named.

- **The relative effectiveness of different WMI**

Four trials measured the relative effectiveness of presenting WMI in different ways for a knowledge outcome (see Table 7 for an overview of all trials examining the relative effectiveness of WMI provision).

Clark and Bailey (1972) found that participants receiving a programmed WMI instruction booklet had a significantly greater understanding of the drug than those receiving the standard information (p=0.008). Aggregating the results of the trial by Little *et al.* (1998), no significant difference was found between those receiving the evidence-based summary leaflet (33%) and those receiving the standard leaflet (24%) for answering questions correctly about oral contraceptives. Dolinsky *et al.* (1983) did not find any significant differences between the WMI in their trials. Desponds *et al.* (1982) did not report statistical significance, and the raw data was not available to calculate the p-value.

Table 7: Summary of the 6 trials examining the relative effectiveness of WMI provision

Study	Participants and length of study	Interventions compared	Outcomes
(Clark and Bayley, 1972) *Am J Public Health*	366 medicine takers age 21-77 years, 49% male. Followed up for 1-3 days.	• Information sheet about warfarin • 'Programmed instruction' information booklet about warfarin	• Knowledge
(Desponds et al., 1982) *Schweiz. Med. Wochenschr*	268 medicine takers mean age 60 years, 43% male. Followed up for 2-3 days	• Experimental WMI (with more text) providing information about one of four benzodiazepine drugs • Manufacturer WMI providing information about one of four benzodiazepine drugs	• Attitude
(Dolinsky et al., 1983) *Am J Hosp Pharm*	271 medicine takers. Length of follow up unclear.	• Short paragraph leaflet about methyldopa or ampicillin • Readable leaflet about methyldopa or ampicillin	• Knowledge • Behaviour
(Labor et al., 1995) *Drug Inf J*	150 medicine takers mean age 43 years. Followed up for 1 day.	• 5 types of leaflet-based information about an antihistamine, varying by complexity and scope of the information	• Attitude
(Little et al., 1998) *Brit Med J*	366 medicine takers mean age 27 years (21-31), 0% male. Followed up for 3 months.	• Evidence-based summary leaflet about the oral contraceptive pill • Traditional leaflet about the oral contraceptive pill	• Knowledge
(van Haecht et al., 1991) *Patient Educ Couns*	366 medicine takers mean age 38 years (14-82), 55% male. Length of follow up unclear.	• 2 types of leaflet-based information about an NSAID, varying by experimental or traditional leaflet design	• Behaviour

- **The effect of the presentation of side effect risk information on knowledge**

Thirteen trials (reported in eight papers) compared the effect of different ways of presenting information about a side effect on a knowledge outcome, (see Table 8 for an overview of trials examining the presentation of side effect risk information). Twelve of these studies were conducted as part of a series of trials by Berry and colleagues which presented participants with a hypothetical, but realistic situation relating to taking a medicine. Berry *et al.* examined the effects of giving information about a side effect as a written verbal descriptor, recommended by EU Guidance (see 1.2.5): for example, 'common' or 'rare', or as a percentage, on a set of outcomes that were consistently measured and statistically examined:

(i)   Estimate of probability of a side effect occurring (Berry *et al.*, 2002a, Berry *et al.*, 2003b).

(ii)   Estimated likelihood of a side effect occurring (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004).

(iii) Judgement of side effect/health risk from a side effect occurring (Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004).

Two trials found that participants who were given descriptive information significantly over-estimated the probability of a side effect occurring, compared to those given numeric information Berry *et al.*, 2002a, Berry *et al.*, 2003b). Probability was measured by asking the participants to estimate it as a percentage. Participants significantly over-estimated the likelihood of a side effect occurring when given descriptive information compared to numeric information (Berry *et al.*, 2003b). Likelihood was measured by asking the participants to estimate it on a Likert scale (from 1-6). Participants presented with information about a side effect as a percentage estimated the risk of a side effect to be higher than those receiving the side effect as a frequency (Berry *et al.*, 2002a).

Table 8: Summary of the 13 trials examining the effectiveness of different ways of presenting risk of side effect information

Study	Participants and length of study	Interventions compared	Outcomes
(Bergus et al., 2002) *J Gen Intern Med*	217 members of the general public mean age 39 years, 35% male. Length of follow up unclear.	2 types of leaflet-based information about aspirin: • Risk then benefit information • Benefit then risk information	• Attitude
(Berry et al., 2002a) trial 1 *Int J Pharm Pract*	268 members of the general public age 18-55 years, 0% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as a frequency • Presented as a percentage	• Knowledge
(Berry et al., 2002a) trial 2 *Int J Pharm Pract*	114 members of the general public age 18-70 years, 48% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as numerical probability • Presented as descriptive probability	• Knowledge • Attitude
(Berry et al., 2002b) trial 1 *Psychol Health*	976 members of the general public age 18-70 years, 46% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as mild side effects • Presented as severe side effects	• Knowledge • Attitude
(Berry et al., 2002b) trial 2 *Psychol Health*	592 members of the general public age 18-70 years, 48% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as positive benefits from side effects • Presented as unknown benefits from side effects • Presented as no benefits from side effects	• Knowledge • Attitude
(Berry et al., 2002b) trial 3 *Psychol Health*	515 members of the general public age 18-70 years, 45% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as prevention of side effects, contact GP re side effects, or no statement on the control of side effects • Presented as prevention contact GP re side effects • Presented as no statement on the control of side effects	• Knowledge • Attitude
(Berry et al., 2003a) trial 1 *Psychol Health*	95 members of the general public age 18-60 years, 46% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented in a personal style • Presented in an impersonal style	• Knowledge • Attitude

Study	Participants and length of study	Interventions compared	Outcomes
(Berry et al., 2003a) trial 2 *Psychol Health*	100 members of the general public age 18-60 years, 39% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented in a personal style • Presented in an impersonal style	• Knowledge • Attitude
(Berry et al., 2003b) trial 1 *Psychol Health Med*	120 members of the general public age 18-80 years, 48% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as a verbal descriptor • Presented as a percentage descriptor	• Knowledge • Attitude
(Berry et al., 2003b) trial 2 *Psychol Health Med*	360 members of the general public age 18-75 years, 54% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Presented as 'common' • Presented as 'rare' • Presented as '2%: 2 out of 100' • Presented as '0.02%: 2 out of 10,000'	• Knowledge • Attitude
(Berry, 2004) *Psychol Health Med*	188 members of the general public age 18-70 years, 42% male. Length of follow up 1 day.	Information about the risk of a side effect from ibuprofen: • Presented as a verbal descriptor • Presented as a percentage descriptor	• Knowledge • Attitude
(Berry et al., 2004) *Patient Educ Couns*	136 members of the general public age 20-50 years, 0% male. Length of follow up 1 day.	Information about the risk of a side effect from hypothetical antibiotic: • Written for the self • Written for a child	• Knowledge • Attitude
(Knapp et al., 2004) *QSHC*	120 medicine takers mean age 63 (35-74) years, 63% male. Length of follow up 1 day.	Information about the risk of a side effect from simvastatin or artovastatin: • Presented as a verbal descriptor • Presented as a percentage descriptor	• Knowledge • Attitude

Participants more often over-estimated the probability of a side effect occurring when it was designed for a parent of a child, rather than for an adult (Berry *et al.*, 2004); and when there was no information about control of side effects (Berry *et al.*, 2002a).

Individuals were found to judge the likelihood of a side effect to be significantly higher when presented with the risk verbally rather than numerically (Berry *et al.*, 2002a, Berry, 2004, Knapp *et al.*, 2004).

In a trial measuring participants' judgement of side effect risk, participants given impersonal information made a significantly greater judgement of side effect risk, compared to those given personal information (Berry *et al.*, 2003a).

Participants given WMI that described the risk of a side effect to be as 'common' judged the risk to be significant higher than those told it was 'rare' (Berry *et al.*, 2003b). Participants told that the risk was rare judged the risk to be significant higher than participants receiving one of two numerical values (Berry *et al.*, 2003b).

- **Summary of the effect of WMI on knowledge**

The large heterogeneity of the outcome measures precluded a statistical synthesis of the results being conducted, and so it was difficult to make firm conclusions regarding the effectiveness (or not) of WMI to change knowledge. The following points can be made:

(i) Six of 12 trials found that people receiving WMI had significantly greater knowledge about the medicine than people receiving no WMI. Two of the twelve trials also found this effect for some outcomes, but also found a significant effect favouring no leaflet provision.

(ii) Two of four trials found that people receiving WMI had significantly greater recall of information about a medicine compared to people receiving no WMI. The two other trials found a significant effect favouring WMI, but not for all outcomes measured.

(iii) Three of four trials found that participants had significantly better recall of information about side effects when they received WMI than when they did not.

(iv)   The results varied between trials examining the effectiveness of presenting WMI in different ways; but tended to show that the experimental intervention either improved knowledge or made no significant difference.

(v)   Two trials found that participants significantly overestimated the probability of a side effect from taking a medicine when presented with verbal information compared to numerical data about the risk of the adverse event.

(vi)   Three trials found that participants significantly overestimated the likelihood of a side effect from taking a medicine when presented with verbal information compared to numerical data about the risk of the adverse event.

Results from trials examining the effect of WMI provision on attitudes

Seventeen trials (reported in 13 papers) measured an attitude outcome. Unique outcomes were measured and so again the results could not be statistically pooled. There were four main categories of attitude outcome:

(i)   Satisfaction with the information given;

(ii)   Perceived health or side effect risk;

(iii)   Intention to comply with or favour treatment;

(iv)   Rating of side effect severity.

• **The absolute effectiveness of WMI**

Three trials (Baker et al., 1991, Gibbs et al., 1989, McBean and Blackburn, 1982) examined the attitudes of those given written information or not, specifically for their levels of satisfaction with the information provided. Baker *et al.* (1991) gave all participants spoken information, and the intervention group received additional WMI. They found that significantly more participants receiving WMI thought that the information received was easy to understand (90%) compared to those receiving spoken information alone (33%). Likewise, significantly more participants (84%) receiving additional WMI felt the information received was useful (or extremely useful), compared to 33% of participants who received spoken information alone.

Baker *et al.* (1991) also found participants given the additional WMI reported significantly less worry about the medicine than those not given the WMI: 53% compared to 25% (p<0.05). Participants, who did not receive the WMI, were more likely to feel that information could be improved (64%) than those who received it (27%), which was again statistically significant.

Gibbs *et al.* (1989) found a statistically significant association between participants' levels of reported satisfaction and whether or not they received WMI. 401 of 419 people receiving WMI said that they were satisfied or completely satisfied, a greater proportion than those giving the same reply that did not receive WMI, 235 of 300 (p<0.001). McBean and Blackburn (1982) similarly reported that participants who received WMI in their trials expressed greater satisfaction with the information provided. This trial did not test for statistical significance, and did not report sufficient data to be able to calculate a p-value.

- **The relative effectiveness of different WMI**

Two trials (Desponds *et al.*, 1982, Labor *et al.*, 1995) compared the effect of presenting WMI in different ways on attitudes. Desponds *et al.* (1982) evaluated experimental PIL that had more text than manufacturer PIL, less medical terminology, and included precautions about side effects, including addiction. They compared this to a manufacturer's PIL that contained more information on the therapeutic effect, no mention of action to take in the event of accidental overdose or that the medicine required a prescription. They found that participants given the experimental WMI said that they felt the text to be easy to understand (P<0.01), complete (P<0.05), and had a lot of new information (P<0.05). They found no difference in participants' views about the information being considered 'easy to read' or 'interesting'.

Labor *et al.* (1995) examined the effect of five different leaflets, which varied according to the wording ('professionally worded', 'simply worded', or 'normally worded'); and number of information topics provided (two, seven or twelve). They found that significantly more participants who received written 'normal' worded information of seven topics felt the number of topics, and the complexity of the information in the leaflet,

was 'about right'. Participants who received information that was professionally worded and had two items, most often felt that the information left them feeling 'confused', 'unsure', 'doubtful', 'overwhelmed', or 'foolish', which was a significant result.

- **The effect of the presentation of side effect risk information on attitudes**

Twelve trials (reported in eight papers) examined participants' attitudes about the way a side effect risk was presented. Eleven trials were conducted by Berry and colleagues. These trials measured one of four outcomes:

(i)   Satisfaction with information (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004);

(ii)   Perceived health or side effect risk (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004);

(iii)   Intention to comply with or favour treatment (Bergus *et al.*, 2002, Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004); and

(iv)   Rating of side effect severity (Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Knapp *et al.*, 2004).

Trials measuring satisfaction with information about side effects consistently found that participants significantly favoured numerical information over verbal information (Berry *et al.*, 2002a, Berry *et al.*, 2003b, Berry, 2004, Knapp *et al.*, 2004). Further trials examining the effect of: providing personal information (Berry *et al.*, 2003a); mild side effect information (Berry *et al.*, 2002b); information about the positive benefits of side effects (Berry *et al.*, 2002b); information offering encouragement to take the correct dose (Berry *et al.*, 2002b); information presented in a specific numerical manner (0.02%) (Berry *et al.*, 2003b); and as information aimed at a parent (Berry *et al.*, 2004), all found numerical information was favoured significantly more than verbal information.

People have been shown to perceive the risk of a side effect from taking a medicine to be significantly greater when presented with: verbal information (Berry *et al.*, 2002a, Berry, 2004, Knapp *et al.*, 2004); information reporting severe side effects (Berry *et al.*, 2002b);

information presenting unknown benefits of side effects (Berry *et al.*, 2002b); no statement on the control of side effects (Berry *et al.*, 2002b); information about the side effect presented in an impersonal manner (Berry *et al.*, 2003a); and information for the parent of a child (Berry *et al.*, 2004).

Bergus *et al.* (2002) found that people, who received information about the likelihood of a side effect occurring after receiving information about the benefits, favoured the treatment less than participants who received information about the risk first. This effect was statistically significant.

Trials consistently found that participants had a significantly greater intention to take the medicine when risk information was presented numerically, rather than verbally (Berry *et al.*, 2002a, Berry *et al.*, 2003b, Berry, 2004, Knapp *et al.*, 2004). Furthermore, participants were significantly more likely to report an intention to take the medicine when the information reported mild side effects (Berry *et al.*, 2002b) or positive benefits of side effects (Berry *et al.*, 2002b), or similarly when the risk of a side effect was presented as a specific numerical figure (for example, 0.02%) (Berry *et al.*, 2003b), or the risk of a side effect was presented in a personalised manner (Berry *et al.*, 2003a), and when information was aimed at parents (Berry *et al.*, 2004).

Participants who received verbal descriptor information anticipated the risk of a side effect to be significantly greater than those who received numerical information in four trials (Berry *et al.*, 2002a, Berry *et al.*, 2003b, Berry, 2004, Knapp *et al.*, 2004). Participants who received information about severe side effects (Berry *et al.*, 2002b); and information aimed at parents of children (Berry *et al.*, 2004), anticipated the risk of a side effect to be significantly greater than those who received numerical information.

- **Summary of the effect of WMI on attitudes**

Again the inability to derive a summary statistic has made it difficult to draw firm conclusions regarding the effectiveness of WMI to change attitudes relating to medicines taking. Nevertheless, several trials repeatedly found similar effects from the presentation

of the risk of a side effect either numerically or descriptively, which were statistically significant, and from these, the following points are made:

(i)   Four of four trials found that participants presented with numeric data about the risk of a side effect were significantly more satisfied compared to participants presented with descriptive information about the risk of a side effect.

(ii)   Three of three trials found that participants perceived the risk of a side effect to be greater when presented with verbal (rather than numeric) side effect information.

(iii)   Four of four trials found that participants had a statistically greater intention to comply with taking the medicine when information of the risk about a side effect was presented numerically than descriptively.

(iv)   Four of four trials found that participants estimated the risk of a side effect to be significantly greater when receiving descriptive information compared to those who received numeric information.

Results from trials examining the effect of WMI provision on behaviour

Ten trials (reported in nine papers) measured behaviour as an outcome. They did so in different ways and so the results could not be combined in a meta-analysis. The main type of behaviour measured was compliance to treatment.

- **The absolute effectiveness of WMI**

Eight trials compared the effect of participants receiving WMI or not, on a measure of behaviour. Six trials (Dodds, 1986, McBean and Blackburn, 1982, Peveler *et al.*, 1999, Robinson *et al.*, 1986, Vander Stichele *et al.*, 1992, Vesco *et al.*, 1990) examined compliance with instructions. Compliance was measured in four ways.

Four trials measured compliance by counting tablet count, to see if the number remaining to be taken corresponded with the number that the medicine taker was prescribed to have taken up to that point. Dodds (1986) found that participants given WMI complied significantly more often with taking the medicine than those who did not receive WMI.

Robinson *et al.* (1986) measured adherence by tablet count along with clinician's judgement and patient interview, and found a small significant difference favouring written information. Vesco *et al.* (1990) found no significant difference between those receiving the written information or not. McBean and Blackburn (1982) did not report a probability value, and for those receiving WMI or not, the differences were small.

Two trials monitored when the tablet container was opened, as a proxy measure of the person taking the medicine. In the trial by Peveler *et al.* (1999), the outcome of self-reported continuation of the medication after 12 weeks was aggregated over those groups receiving counselling or no counselling. No statistical difference was found between participants receiving a medicines leaflet or no intervention at six months. Similarly Vander Stichele *et al.* (1992) found no difference between the group receiving WMI and the group receiving none.

Dodds (1986) was the only trial to examine self-reporting of compliance (by questionnaire and interview); and found that participants receiving the WMI scored significantly higher than those receiving no WMI. Vesco *et al.* (1990) was the only trial to measure adherence as a physiological measure; by measuring blood levels of theophylline (the active ingredient in the study drug). They found a very small difference between the intervention and control group on a whole, but this was not statistically significant. In contrast they found that significantly more people receiving WMI reported a side effect ($p<0.05$).

In the two trials that did not measure compliance, Morris and Kanouse (1982) examined participants' reporting of a health problem, while Dolinsky *et al.* (1983) measured the participants' application of the information. Morris and Kanouse (1982) found that those receiving WMI reported slightly more problems. (This study did not test for statistical significance). Dolinsky *et al.* (1983) reported no significant difference between those given one of two WMI interventions and those receiving no intervention in correctly applying the information about the two study drugs. However, they did not report individual statistical comparisons between groups.

- **The relative effectiveness of different WMI**

Van Haecht *et al.* (1991) found no significant difference in the number of participants who reported reading the leaflet thoroughly when they received the experimental WMI (with improved readability and layout), or the standard leaflet (without improved readability and layout). Dolinsky *et al.* (1983) reported no significant difference between those receiving either of the two WMI interventions for correctly applying the information.

- **Summary of the effect of WMI on behaviour**

The inability to statistically synthesise the results has compromised the ability to make firm conclusions regarding the effective of WMI on behaviour. It therefore cannot be said if WMI is effectiveness for encouraging the medicine user to comply with instructions about taking a medicine, or if the provision of WMI affects side effect reporting.

- Two of six trials found compliance was significantly greater for those who received the WMI than those who had not.

3.5.6. Discussion

The review highlighted that the trials as a whole poorly reported how they were conducted; e.g. the randomisation process was unclearly reported (or not reported at all) in around 40% of the trials. The poor conduct of previous research had provided a firm basis for recommending improved standards of research examining WMI. The poor conduct of the trials is further examined in 3.7.2.

As anticipated, there was great heterogeneity amongst the outcome measures of the trials, and so a meta-analysis could not be conducted. Because no overall summary statistic of the effectiveness of written medicines information could be derived, this made it difficult to provide clear evidence to indicate if WMI is effective for changing knowledge, attitudes and behaviours relating to medicine taking. No trials reported adverse effects from the provision of WMI.

Because attitudes are difficult to quantify, and difficult to compare when they are not quantified (Littlewood *et al.*, 2005), and because there was considerable heterogeneity in the way that attitudes were measured as an outcome by the trials; it is concluded that the

review found no convincing evidence of the effectiveness of WMI (compared to none) for changing attitudes. Likewise no convincing evidence of the effectiveness of WMI (compared to none) was found for increasing the medicine user's adherence with treatment instructions. The lack of evidence that provision of WMI increases compliance to taking the medicine is not necessarily a disappointing result, because the person receiving information may make an informed decision not to take a medicine (Raynor *et al.*, 2007a).

There was some evidence to show that provision of WMI can improve aspects of knowledge. For example, two trials found that participants receiving WMI had significantly better recall of information about a medicine (than participants receiving none). Two further trials found this, but not consistently across all outcomes measured. Three of four trials found that participants receiving WMI had better recall of side effect information than participants receiving none.

The evidence showed that the way that the risk of a side effect is presented impacts on readers' knowledge and attitudes. For example, a numerical description of the risk of a side effect was consistently shown to lead to a more accurate estimation of the probability of likelihood of side effects, compared to verbal risk descriptor information, as stipulated by the *1998 EU Directive* (European Commission Directorate-General III, 1998). There was similar evidence for the effect on attitudes. Participants presented with numeric information about the risk of a side effect were significantly more satisfied; and had a greater intention to comply with taking the medicine compared to participants presented with verbal descriptor information.

Conversely, participants presented with verbal descriptor information about the risk of a side effect perceived the risk of a side effect from taking a medicine to be greater and anticipated the risk of a side effect to be significantly greater as compared to those presented with numerical information.

The content, length and layout of the information, and the way it was provided, differed between trials. The majority of studies were found to have adopted atheoretical or non-

evidence-based interventions, and outcomes unique to that trial. Durand *et al.* (2008) examining trials in a systematic review of patient decision aids, similarly found a lack of theoretical input in the interventions. Research of an intervention whose design is atheoretical or not evidence-based can be problematic because it essentially examines a stimulus-response relationship. Findings from such trials can still have an important and relevant impact on practice. However, because they only show a correlation, they cannot explain why the intervention was effective or not. This is not helpful in aiding the understanding of what makes WMI effective or not for changing knowledge, attitudes and behaviours.

The average age of participants in the trials was 43 years of age. However, most people who take medicine long term, and have most need for WMI, are older. Therefore the participants in these studies may not have been representative of everyone who takes a medicine and needs WMI. A large number of the trials had follow-up periods of one week or less; and thirteen trials followed up participants only for one day. Doubt can be cast as to whether trials of such length offer a reliable indicator of the long-term effects of providing WMI, because many people relying on WMI take medicines for chronic conditions over a long period of time.

The review reported in this chapter was the first to systematically gather and analyse previous research of WMI; and generate recommendations based on these findings. Berry (2006) made recommendations for how WMI should be presented, based on a non-systematic review of studies of information giving. Not all studies included in this review were RCTs and the information was not for medicines alone; therefore the inclusion criteria and the conclusions differed from that of this study. Nevertheless there was some overlap between the findings of Berry's (2006) review and the review reported in this chapter.

- The risk of a side effect from a medicine should be framed both positively and negatively, so as not to make the information biased either by being persuasive, or appearing threatening; for example, the evidence shows that when information is

framed positively (e.g. emphasising a 95% survival rate rather than a 5% chance of mortality), people are more likely to choose the treatment.

- Care should be taken in how information about risk is portrayed, because the perception of risk can be determined by producing it as a relative risk rather than as an absolute risk: for example, the evidence shows that a reduction from 10% to 5% risk of harm described in absolute terms as a 5%, or relatively as a 50%, will be perceived and favoured differently.

- Providing information in a personal manner: for example, saying 'your symptoms' rather than the impersonal 'the symptoms' can make people more satisfied with the information and so WMI should be tailored in such a way. Providing further support for the personalisation of information; Jones *et al.* (1999) have shown that when participants were randomised to receive general computer-based information, personalised computer-based information (providing details about their medical record) or information in a booklet, they most often favoured the personalised format.

- Important information should be presented at the start of the information, because the order effect shows that information provided at the beginning of a leaflet is more easily remembered and is probably perceived to be more important, than when it is presented elsewhere.

- Medicine users should be encouraged to actively process information about risk, because the evidence shows when people do so, their estimate of the risk improves, as does their satisfaction with the information, compared to passively reading the information.

3.5.7. Implications of this research

The findings of the systematic review have implications for the provision of WMI, and future research evaluating this. These are set out in set out in Table 9 below.

Table 9: Evidence-based recommendations for WMI

Problems and recommendations arising from this study
1. **The effectiveness of WMI:** evidence from individual trials suggests that WMI can be effective for changing knowledge. There is no evidence that WMI is effective for changing attitudes or behaviours, or that it has any adverse effects when provided.   • **Recommendation:** provision of WMI is justified because it can improve knowledge, and does not have adverse effects.
2. **Poor reporting of trial conduct:** several trials were poorly conducted, and several reported poorly how they were conducted.   • **Recommendation:** future trials evaluating WMI should apply recognised standards to their design, conduct and reporting.
3. **Atheoretical interventions:** trials commonly used unique outcome measures.   • **Recommendation:** future trials of WMI should evaluate interventions that have a clear rationale, being either theory-driven or evidence-based.
4. **Heterogeneous outcomes:** trials commonly used unique outcome measures.   • **Recommendation:** future trials evaluating WMI should use consistent and validated outcome measures that will facilitate a statistical analysis.
5. **Length of follow-up:** there was variance in the length of follow-up and a number of trials only followed up for one day.   • **Recommendation:** it may be useful to identify an optimal length of follow-up for trials of WMI.
6. **Evidence gap:** no previous trials had evaluated IBMI.   • **Recommendation:** there is a need for the evaluation of IBMI.

3.6. Stakeholders' feedback on the project findings

3.6.1. Aims and methods of the second stakeholder workshop

The aim of the second workshop was for stakeholders to reflect on the findings of the project, and offer feedback. The workshop followed a similar format to the first, and was composed of the same attendees as the first workshop, except for one person, a medicine user who could not attend.

3.6.2. Stakeholder feedback on the results of the systematic review

The group work activities generated useful discussions regarding the findings of the review. Stakeholders were initially asked what findings they hoped would have arisen from the review. The rationale for doing this was because of the threat of hindsight bias, i.e. where people claim to have known the effect in advance (Trout, 2002). This is a powerful effect because people given information retrospectively claim this was inevitable in hindsight (Fischoff, 2003).

The stakeholders hoped that the evidence would support the importance and packaging of WMI, make the information more understandable, and highlight the importance of focusing on positive aspects instead of negative aspects of information. There was disappointment that the findings from the effectiveness review were largely inconclusive; and stakeholders called for future research of better quality, perhaps using a different non-RCT study design. They were disappointed at the lack of research into the effectiveness of IBMI. Stakeholders were surprised that WMI was valued by participants who had been interviewed in the studies examining the role and value of WMI (see 1.2.6); and yet it was not clearly understood if WMI was effective (for changing knowledge, attitudes and behaviour). This led some to wonder why information should be given if it was not effective.

The stakeholders made a number of important observations throughout the discussions about the research in general. Firstly they did not distinguish between spoken and written information, which was not reflected in the previous research. Secondly they queried some of the outcomes that trials measured: e.g. 'compliance', and anxiety about taking the medicine. With the latter they felt that having increased anxiety about taking a medicine

would not necessarily be a negative outcome from reading the WMI, which was the opposite to the conclusion to a trial measuring this.

Stakeholders were asked to recommend priorities for future research and they made a number of suggestions, including future research focusing on understanding as an outcome, and the need to investigate how the *Medicines Guide* website and *NHS Direct* deal with WMI.

3.6.3. Discussion

The stakeholders were surprised that the review did not find clear evidence of the effectiveness of WMI; and that no research had examined the effectiveness of IBMI. They disagreed with some of the outcomes that had been measured by the trials, e.g. measures of compliance. The stakeholders again stated the need for evaluating the 'understandability' of information by research. The findings of this workshop not only crystallised the conclusions of the systematic review; but have reinforced the aim of evaluating IBMI in this thesis.

3.7. Discussion of the strengths and limitations of the studies

3.7.1. Stakeholder workshops

The workshops were valuable in helping to define the aims and then conclude the findings of the systematic review. The first workshop gave the stakeholders, including medicine users, the chance to input into the goals of the project at the outset. The second workshop gave the stakeholders the opportunity to give feedback on the results, for how the findings and conclusions could impact on WMI, and what that would mean to medicine users.

The workshops were of great importance, but had restrictions. The key limitation of the workshops was the inability to analyse the medicine users' verbal protocols. This could not be done for two reasons. Firstly no audio recording of the discussions in the individual groups at either workshop could be made (see 3.3.1). Secondly, the discussion groups were mixed between the participants representing the different stakeholder constituencies: *National Patient Organisation* groups, project collaborators, and project members. Therefore the comments and thoughts of the medicine users alone could not be isolated. This

constrained the analysis and may have detracted from specific opinions of the medicine users by their not being picked up. However, by aggregating the views of all stakeholders together, this can be seen as having enabled a stronger synthesis of all participants' viewpoints.

The sample of medicine users was not representative of everyone who takes medicines long-term: e.g. none were under 50 years of age, and none were from an ethnic minority group. Nicolson *et al.* (2006b) have acknowledged that this probably impacted on the issues that were and were not raised by the medicine users at this workshop.

3.7.2. Systematic review

The systematic review reported in this chapter represents the first systematic retrieval and analysis of research evaluating the effectiveness of WMI. By highlighting problems with previous WMI research conduct, as well as gaps in published WMI research, this has provided a firm evidence base for future research to examine WMI (both leaflet and Internet-based) using more rigorous methods, outcome measures that are patient-centred, and better designed interventions. The lack of research evaluating IBMI has reinforced examining it in this thesis. This review of the effectiveness of WMI had limitations based on the poor quality of several of the included trials, and doubts regarding the usefulness of RCT-based research for examining WMI. Doubts about its research question being answerable or not are raised first.

Examining the effectiveness of WMI

The aim of the review was to examine the effectiveness of WMI for changing knowledge, attitudes and behaviour related to taking medicines. However, it can be suggested that it is not straight forward to answer the question 'Is WMI effective for improving an outcome' because there is not one but two questions to answer here: (i) has WMI ever been shown to be effective for improving an outcome; and (ii) if it has been shown to be effective, when and where did this occur. Arguing this point, the systematic review can be said to have undertaken the first question, but not the second. The second question would have required a sub-group analysis, but this was not possible because a meta-analysis was not possible to conduct.

The poor quality of previous trials evaluating WMI

In countries where PILs are legislated for, research evaluating them has to provide minimal patient care, i.e. WMI. Thus at the very least, research will examine the effect of a standard PIL against an experimental one. Therefore there has been a rise in trials comparing the presentation of different types of WMI; and demise of trials examining the comparison of WMI against no intervention. Nevertheless, this thesis contends that the inclusion of these categories of trials was beneficial. It is not enough to only know if WMI is effective. It is also important to compare different ways of presenting WMI, to find out the most effective.

The review was hampered by the poor reporting of trial conduct (see 3.5.6), and there is reason to doubt the adequate conduct of some of the trials. Most papers did not report how the trials concealed allocation, and when further information was received from authors, it was clear that a number of these trials did not adequately conceal it. Because this is the greatest source of overestimation of treatment effects (Jüni *et al.*, 2001), doubt is cast on the reliability of these trials results. The discovery that several of the included trials were poorly conducted is a standard finding of many systematic reviews.

The trials largely used outcome measures that were unique to that trial. This made it impossible to combine and compare results statistically; although this is neither a pre-requisite of a systematic review, nor an uncommon outcome when conducting one.

Interventions were often heterogeneous, but it was only possible to categorise by intervention and control for descriptive purposes alone. Nearly one quarter of the trials compared WMI to no intervention which does not reflect practice in the real world, where EU regulation has determined that information should accompany the medicine. (These trials were conducted before this legislation came into place.) A degree of heterogeneity is acceptable (and inevitable) in systematic reviews, but the extent of heterogeneity in the interventions and outcomes of the trials meant it was impossible to combine the results because they were so different.

Several trials (for example, Berry *et al.* (2002a) or Berry *et al.* (2003a)), enrolled non-medicine users as participants, providing them with a hypothetical scenario about taking a medicine and one of two (or more) types of side effect risk descriptor. An argument can be made that testing medicines information on people who do not take the medicine cannot be generalised to medicine users – for example, because the emotional state of the person reading the information may play a role. This is an important point and probably beyond doubt for some types of information (for rare conditions, for example). But in defence of this method, it is important to recognise the assertion that processes underlying understanding of WMI for most people most of the time, like other cognitive processes, are (presumably) universal. The series of trials by Berry and colleagues examined the general public's understanding of the presentation of information about the risk of a side effect from taking a medicine. The study by Knapp *et al.* (2004) examining the same outcome in people taking simvastatin for high cholesterol, found no differences in the results from the previous studies conducted in the general public. One conclusion that can be drawn from this finding is that because there was no difference between people with a condition and the general public, it is valid to examine some WMI on the general public using hypothetical scenarios.

The trials by Berry and colleagues have made important findings that aid our understanding of how people evaluate the risk of a side effect from the way the information is presented. They are, however, limited by (arguably) being 'black box studies' that examine an input and output. It is argued that they have found a correlation, but are not able to explanation for why people overestimate the risk of a side effect. One way that this could be overcome would be to record participants' verbal protocols (see 5.2.3) to enable an insight to be made on their cognitive processes.

It is important to consider the context of time in relation to the trials; in particular the conduct of the RCTs being relative to when they were carried out. The *CONSORT Statement* (Begg *et al.*, 1996) has changed the quality of reporting of trials since its inception, and this may explain the poor quality of many of the older trials. Poor reporting of trial methods can be due to constraints in publication space even when the methods

used may have been adequate. Therefore it cannot be said with certainty that the trials were poorly conducted; only that their conduct was poorly reported.

Reporting of the source of funding of the trial was not reported by the majority of trials. This is relevant as there is clear evidence that funding is a source of bias in research (for example, see Lexchin *et al.* (2003)). There is no reason to question whether the results in the included trials were related to the funding source; but the lack of transparency over funding, does not inspire confidence on this point.

The usefulness of the RCT for evaluating WMI

The systematic review was based on the best available evidence, i.e. RCTs. However, some commentators have suggested that the RCT study design is inappropriate for evaluating the effectiveness of information, (a criticism not unique to that design). It has been argued that the RCT design may not reflect the typical uses of an information system in day-to-day practice (Heathfield *et al.*, 1998). Similarly, RCTs are noted to be poor for understanding issues pertaining to system use (Kaplan, 2001); which has implications for the examination of the effective use of IBMI (as well as PILs). The RCT has been an invaluable tool for determining the effectiveness of drug treatments, for example, but IT is not similar to a drug (Heathfield *et al.*, 1998). The assimilation of information requires active cognitive processing, while the intake of a drug is largely autonomic.

The effectiveness review sought to evaluate *if* WMI was effective; not *how* or *why* it works. In spite of the criticisms raised above, the RCT when conducted correctly remains the study design most capable of determining if an intervention is effective, with the least bias. Therefore it was appropriate to include RCT-based evidence alone for examining the question. The inability of the project to highlight *if* WMI was effective was (probably) not due to the inclusion of RCTs alone, but rather the poor quality of their conduct. The findings do not provide evidence to reject the RCT for evaluating the effectiveness of WMI. While not all evidence in pharmacy research is garnered from an RCT, some is (Bond, 2006). Evidence produced by using this method can justify its use. For example, the series of trials by Berry and colleagues, which have been well conducted and have derived

consistent results, are evidence for this. Despite the problems noted with it; the RCT remains a rigorous means for exploring if WMI (both paper-based and Internet-based) 'works'.

The issues arising from the review have prompted consideration about the optimum study design for evaluating the ease of use and understandability of IBMI. An examination of home healthcare technology called for a better need to understand the usability of such a system (Kaufman *et al.*, 2003); while it has been argued (in general) that there is a need to gain insight into the 'black box' to understand why interventions are successful or fail (Hulscher *et al.*, 2003). This may be pertinent to WMI, as information can be seen as a sum of specific points rather than as a whole, and so it will be important to know which aspects of the information are more (or less) effective than others.

3.8. Concluding remarks

The research presented in this chapter conducted the evaluation of leaflet-based WMI, by secondary research. Using sequential focus groups to enable stakeholders to prime the review and feed back on its findings had led to the following conclusions being drawn:

- Evidence from individual trials suggests that WMI can be effective for improving knowledge relating to medicine taking;

- There was no clear evidence to show that leaflet-based WMI is effective for changing attitudes and behaviours relating to medicine taking;

- There was no evidence to suggest that the provision of WMI has an adverse effect for its readers;

- The way information about the risk of a side effect is presented will impact on the readers' understanding of the information;

- Many of the trials that examined the effectiveness of WMI were poorly conducted. Future research should be conducted more rigorously;

- No trials examining the effectiveness of IBMI were found.

The outcomes of this study represent the first set of findings in this thesis. They also impacted on the direction of the remainder of this thesis. Finding no trials examining IBMI has solidified the focus on evaluating IBMI in the remaining studies. The remaining three studies evaluate IBMI, examining its content and design to see if it is easy to use and understand, and if evidence-based changes can make it easier for medicine users to navigate redesigned web pages and understand its information. The next chapter reports the first study to evaluate IBMI: presenting an audit of the quality, content and design features of a sample of sites. This serves to identify a sample of websites whose usability is examined in the study reported in Chapter five.

Chapter four
Study two: evaluating the quality, content and design of websites with information about medicines

4.1. Introduction

The systematic review reported in Chapter three found no trials that examined the effectiveness of IBMI. This chapter reports an evaluation of the quality, content and design features of a sample of IBMI sites, and forms the base for evaluating the usability of the same sites, reported in Chapter five. Part of this study was presented at the *EACH International Conference on Communication in Healthcare* (Nicolson *et al.*, 2006a).

No known studies to date have evaluated the content of IBMI against the EU directed categories of WMI (European Commission, 2004), or specific content recommendations (Quality Review of Documents Group, 2005). The value of doing this is that it provides a checklist for auditing the content of IBMI. We know that medicine users consider information about safety and efficacy issues to be essential (Dickinson and Raynor, 2003), therefore it is important to have a clear understanding of the specific information that IBMI sites contain, and in particular if they correspond with users' wants.

The systematic review in Study three found that understanding of the risk of a side effect varies depending upon whether it is presented as a numerical value, e.g. greater than 10%; or as a verbal risk descriptor, e.g. very common. Therefore it is important to examine how sites present information about the risk of a side effect.

This study (and the study reported in Chapter five) examines websites which have information about *simvastatin*[2] (a medicine). This is used for treating hypercholesterolemia (high cholesterol), i.e. too much fat and oil in the arteries. It lowers cholesterol in two

122

ways: (i) decreasing low density lipoprotein (LDL, known commonly as 'bad cholesterol'), and triglycerides; and (ii) modestly raising high density lipoprotein (HDL). The combined level of LDL and HDL is total serum cholesterol. Epidemiological evidence shows a causal relation between total serum cholesterol and atherosclerosis (the narrowing and hardening of the walls of the arteries over time), which can result in coronary heart disease (CHD) and other atherosclerotic diseases, such as ischaemic stroke (Clark, 2003). By reducing total serum cholesterol and LDL, *simvastatin* is effective in lowering the risk of CHD (The Scandinavian Simvastatin Survival Study Group, 1994).

Simvastatin is a commonly prescribed medicine in primary care. For example, in the last quarter of 2001, 3.5 million prescriptions of *statin* were made in the UK, and *simvastatin* was the most frequently prescribed *statin* (Anonymous, 2002b). It is normal that the person prescribed *simvastatin* will be expected to stay on it for the rest of her or his life, because high cholesterol is a chronic condition in most people.

Examining data from the *Doctors Independent Network*, DeWilde *et al.* (2003) found prescription of *simvastatin* was more common in patients younger than 64 years, and that more men than women were prescribed it, although this difference disappeared after adjusting for age and severity of disease. The points in this section highlight that prescribing of *simvastatin* is common, and that the efficacy of *simvastatin* is well established in reducing the risk of CHD.

As with any medicine, *simvastatin* has adverse effects. In a review of the risks and benefits of *statin* treatment, Clark (2003) notes that its use is not advisable for certain patients (for example, those with liver or muscle disease), and that interactions with other drugs (for example, *warfarin*) are possible. It is imperative that someone taking this medicine does not take grapefruit juice: the interaction between *simvastatin* and grapefruit juice can increase the amount of *simvastatin* in the blood stream. Another side effect that can be unpleasant and harmful for the person taking a *statin* is muscle weakness.

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[2] Brand names for *simvastatin* include *Simvacor* and *Zocor*. Another member of the *statin* family is *rosuvastatin* (brand name *Crestor*).

Many people do not take *simvastatin* long term, despite its effectiveness. Reasons for this include the side effects above, as well as the inconvenience of taking a medicine daily for the rest of one's life. Furthermore, because high cholesterol is a condition without symptoms (before the onset of a stroke or heart attack), there are no tangible benefits for the person taking a statin. A cohort study in Canada of older adults (greater than 66 years) found 25% discontinued *statin* therapy within six months of starting, and less than half of the patients continued treatment after two years (Jackevicius *et al.*, 2002).

For the reasons above, *simvastatin* is an appropriate subject for the information examined in this chapter. Information about its effectiveness, side effects, and how to take it safely, can support the medicine taker; enabling him or her to take the medicine effectively, as well as make an informed decision about taking it or not.

4.1.1. Aims

The aims of this study were:

(i)   To identify a purposive sample of commonly accessed websites providing information about *simvastatin*, which will be evaluated in the usability study; and

(ii)   To compare the quality, content and design features of the sample of websites.

4.2. Content analysis

This study uses a content analysis method to evaluate IBMI. Berelson (1952) has defined a content analysis as a *"research technique for the objective, systematic, and quantitative description of the manifest content of communication"* (pp 18). As such it can allow for the systematic evaluation of the content of a variety of media; from newspapers to websites. In this thesis the content analysis provides a preliminary analysis of a sample of websites to be examined in the usability study described in the next chapter.

4.2.1. How to conduct a content analysis

Drawing on Weare and Lin's (2000) procedures for conducting a content analysis of websites, five practical issues are discussed.

- A sample of messages is selected from a pre-defined population. How the sampling frame is defined is an important first step, because it determines the scope of sites which will be retrieved for the analyses. There are several competing methods, each with their own merits; including sampling by Internet address, using a sample retrieved from a search engine result, and conducting a purposive sample (Weare and Lin, 2000).

- The unit of analysis is identified. This refers to the objects of the study (Graneheim and Lundman, 2004). In this study they are quality indicators; specific medicines information and general site content, and the design features of the site.

- A categorisation scheme is devised whereby messages can be validly and reliably classified. As with a systematic review, this scheme is devised *a priori*, so as to not introduce bias.

- Coders are trained to code a sample of the messages. As with a systematic review, there is greater reliability if two people independently code a sample of messages. They then compare their coding for inter-rater agreement. Methods include taking a simple percentage agreement, whereby a specified percent of difference between the two assessors coding is accepted; to more elaborate schemes using a statistical calculation – for example, Cohen's Kappa (Lombard *et al.*, 2002). When coders do not agree, disagreement may be reconciled with the intervention of a third party.

- The data is analysed and interpreted.

4.2.2. Strengths and limitations of a content analysis

Any content analysis has strengths and limitations.

Strengths

Kondracki and Wellman (2002) have noted strengths of conducting content analyses:

- Content analyses can be used to track messages over time, comparing them at different points;

- Content analyses are unobtrusive, as there is no interaction between the subject and researcher;

- Content analyses can use any material that is archived, expanding its potential sample; and

- Content analyses are usually inexpensive.

Limitations

Kondracki and Wellman(2002) have also noted limitations of conducting content analyses:

- Depending on the sampling procedure, the conclusions of content analyses may not be generalisable,

- While identifying relationships between variables, content analyses cannot explain them, nor attribute causation;

- A content analysis can be time-consuming to properly conduct.

4.3. Methods

4.3.1. Inclusion criteria

The inclusion criteria for the websites were:

(i)   English language;

(ii)   Providing information about *simvastatin*;

(iii)   Professionally developed (for example, by a healthcare authority or pharmaceutical company).

Sites were excluded if:

(i)   Registration was required, as this may put people off accessing them in the short term;

(ii)   Content was only about the condition (hypercholesterolemia) and did not include information about the medicine;

(iii)   The site was a portal (providing links to other sites) and did not present information of its own.

4.3.2. Search strategy

Medicine users have reported finding IBMI by using a search engine; in particular *Google*™ because it is straightforward to use, and *Yahoo!*™ because it often appears as a default page when accessing personal emails (Peterson *et al.*, 2003). Therefore to replicate a search

strategy medicine users might employ, and because the most frequently accessed search engines used when this study began in January 2006 were *Google*™ and *Yahoo!*™ (Source:*http://www.alexa.com/* accessed January 2006); these two search engines were used to search for sites. The phrase *'simvastatin'* was searched on both sites, because medicine users have reported finding information about a medicine by typing its name (Peterson *et al.*, 2003). There is evidence to show that users of the Internet rarely open any link found after the first ten from a search for healthcare information on the Internet (Eysenbach and Köhler, 2002). The first 50 sites provided on both search engines were examined, which more than covered this. Language was limited to English, the language of the two reviewers, and no other limits were set.

To maximise the possible IBMI sites available for analysis, the search was augmented from two other sources: web page links to medicines information sites on the *Patient.co.uk* website; and websites reviewed in two content analyses of information for commonly prescribed medicines: Hatfield *et al.* (1999) and Doupi and van der Lei (1999), (see Appendix six). These two analyses were found by conducting a search on *Embase* and *Medline* for analyses of IBMI sites (from 1995 to 2005). Four content analyses studies were found in total, but two, one of asthma education (Croft and Peterson, 2002), and one of *St John's Wort* (Martin-Facklam *et al.*, 2002), did not have their websites considered, because they did not relate to *simvastatin*.

To summarise, the search for IBMI was conducted using three sources:

(i)   Sites identified from *Google*™ and *Yahoo!*™, using the phrase *simvastatin* (limited to the first 50 sites on each search engine);

(ii)   Web page links to medicines information sites on the *Patient.co.uk*™ website; and

(iii)   Websites reviewed in two content analyses of information for commonly prescribed medicines by Hatfield *et al.* (1999) and Doupi and van der Lei (1999), (see Appendix six).

Two reviewers (the author and a research colleague) independently evaluated the sites for inclusion in January 2006.

A decision was made to analyse a criterion sample of the ten most commonly accessed IBMI sites, for the purpose of analysing the most commonly accessed websites with information about medicines. The decision to look at the top ten sites was made on the basis of knowledge about the public's search strategies. Medicine users have reported that they do not look beyond the first page of links (usually ten) on a search engine (Peterson *et al.*, 2003). Medicine users have also noted a difference in material presented by US and UK health websites: *"American and English web sites sometimes gave conflicting information"* (Interview T29 Transcript *DIPEx.org www.DIPEx.org* Accessed: July 2006). For this reason, the sample of ten sites was divided between the five most frequently accessed IBMI sites, developed in the USA and UK.

From the sample of websites found, the most frequently accessed sites were identified by using the *Alexa.com (http://www.alexa.com/)* website. This provides data for the frequency of access to websites, called 'reach' data. The mean number of people accessing each website that met the inclusion criteria over a three-month period was obtained by typing their *URL* into the search bar on the *Alexa.com* website (in April 2006) to ascertain this data.

4.3.3. Descriptive review of websites

A qualitative description was made of aspects of the site: the brand name of the drug; the appearance of the homepage (for example, if it had pictures or icons); and any navigational steps required to locate the information about *simvastatin*. Because this was a descriptive process and did not include an analysis, this was performed by one reviewer, the author. Recommendations for design principles (see 1.5.2) were applied to inform:

(i)   If the layout appeared cluttered, (impacting on attention);

(ii)   If the site used icons (to aid perception); and

(iii)   If the text was legible and distinguishable from the background.

Preece *et al.* (2002) have noted that sites that are cluttered with information can place great demands on the user's attention (see 1.5.2) and have provided the example of *Google™* as a

site that is judged to be clutter free. The reviewer used this as a benchmark for assessing which sites were considered to be cluttered, and which were not.

The specific location of the search bar was noted (if one was available), because medicine users have reported using search engines (featuring search bars) to find WMI (Peterson *et al.*, 2003). The way that side effect risks were described (if at all), was noted because understanding has been shown to differ depending on whether it is numerical or verbal (see 3.5.5). Information was extracted from the web pages in May and June of 2006.

4.3.4. Coding frame

Referring to a standardised protocol (see Appendix seven), the same two reviewers who considered the sites for inclusion, assessed the general and specific content data of the websites and their design features in January and February 2006. The reviewers recorded if each website had corresponding content and design features, and made an assessment of the site's quality, on a standardised form (see Appendix eight). Differences in decisions were reconciled by discussion.

The features of the IBMI sites being checked were divided into five categories:

- **Design attributes:** the features of the site which pertain to its use. For example, whether there were links to external sites, whether or not the site had a search bar. Nine design attributes were assessed (see Appendix seven).

- **Quality:** indicators of the quality of the information and its source. These were derived from recommendations of the *HoN Code*, and the *Discern* handbook (see Appendix two). Examples included noting if the site made reference to scientific evidence to justify claims (and provide the source). Eight indicators of quality were assessed (see Appendix seven).

- **Medicine information content:** the information about the medicine provided by the site. In total, fourteen aspects of medicine information content were checked (see Appendix seven). The content to be checked was derived from:

(i) The *1998 European Commission Directorate-General III directive* for categorisation of information to be contained in a medicines information leaflet (European Commission Directorate-General III, 1998); and

(ii) Recommendations on medicines package leaflets (Quality Review of Documents Group, 2005).

- **General site content:** the non-medicines information on the site. Eight items of content, including whether the site promoted a pharmaceutical product, or if it disclosed its rationale, were assessed (see Appendix seven).

- **Piloting the User Test:** as a precursor for the usability study reported in the next chapter, each site's content was examined to see if it provided indicative information to answer ten factual questions (see Appendix sixteen). These ten questions were adopted from a User Test used by *LUTO Research Limited (www.LUTO.co.uk)* for assessing the readability of a paper-based *simvastatin* leaflet. The ten questions were designed to largely reflect the safety and efficacy issues that pharmacists consider to be essential information about *simvastatin*. For example, the indicative information to answer the question 'Is there specific food or drink you should avoid when taking *simvastatin*?' was grapefruit or grapefruit juice. This task identified the sample of sites that met the criteria of having the indicative information to answer all ten questions, and could therefore be evaluated in the usability study reported in the next chapter. IBMI sites that did not provide indicative information to answer to all ten questions were considered 'incomplete' and not included in the final usability study, because it would be unethical to ask participants to look for information which was not available.

For each site the total number of design attributes, quality indicators, and content items it had were tallied.

4.4. Results

4.4.1. What the search found

Searching *Google*™ returned over 850,000 web links, and on *Yahoo!*™ over 500,000 when the search was conducted in January 2006. It was not possible to determine the level of duplication. Fifty-eight websites (see Appendix six) were considered for inclusion:

- 38 sites were found from the first 50 sites on both search engines;
- 15 sites from previous analysis by Hatfield *et al.* (1999) and Doupi and van der Lei (1999); and
- Five sites were from links on the *Patient.co.uk*™ website.

Thirty-three sites met the inclusion criteria (see audit trail in Table 10). Three of four sites (*Medicine Net, Druginfonet,* and *Rxlist*) evaluated by one of the reviews (Hatfield *et al.,* 1999) met the inclusion criteria. Five of 14 sites (*Healthtouch Online, DrugInfoNet, Mayo Clinic, Medicine Net,* and *RxList*) evaluated by the other review (Doupi and van der Lei, 1999), met the inclusion criteria.

The most common reasons for sites not meeting the inclusion criteria were: it was a portal to other sites (seven sites); or did not provide information about *simvastatin* (six sites). These sites were found in the general content analyses that looked at general information about medicines. Appendix nine shows the reason for exclusion of all sites.

The earliest site available was *US Food and Drug Agency* (*http://www.fda.gov*), first developed in April 1993 (Source:*http://www.alexa.com/* accessed April, 2006). Considerably more people accessed the US developed sites. The five most frequently accessed US, and UK developed IBMI sites are in Table 11. The only UK site with a similar level of access to any US site was *Net Doctor*.

4.4.2. Descriptive review of websites

Typing *simvastatin* in the search engines returned links to pages with specific information about *simvastatin,* and not any of the ten sites' homepages. Five sites (*Medicine Net, Rxlist, Medicine Guides, Net Doctor,* and *Drugs.com*) provided information for the *Zocor* brand; two did not specify a brand (*Best Treatments* and *Patient UK*); and one each provided

information about the *Simvacor* (*Electronic Medicines Compendium*) and *Crestor* (*US Food and Drug Agency*) brand. The *Mayo Clinic* site provided information for *Vytorin* (a drug combining a cholesterol absorption inhibitor and *statin*). The *Medicine Guides* site also provided information for this brand, as well as information about the *Zocor* brand.

Table 10: Audit trail of IBMI sites considered for inclusion

Audit trail of IBMI sites	
Sites identified using search strategy	38
Sites identified from previous analyses	15
Sites identified from *Patient.co.uk*	(12*) 5
Total sites considered for inclusion	58
Sites excluded for not meeting inclusion criteria	22
Sites not able to be fully accessed	2
Sites duplicating information from other site	1
Total sites excluded	25
Total sites included	33
Purposive sample of sites analysed	10
• 5 most accessed UK IBMI sites for *simvastatin*	
• 5 most accessed US IBMI sites for *simvastatin*	

*Seven sites were duplicated from the search strategy; thus only five new sites were found.

Most home pages were cluttered with a mass of links to other websites, or to pages within the same IBMI site (see Appendix ten). Five sites had icons, but this was largely limited (for example, having only a printer icon). *Patient UK* displayed different icons highlighting the types of information available (for example, 'information leaflet' or 'medicines'), when the name of the drug was typed in the search bar. One site (*Electric Medicines Compendium*) provided the information as a Portable Document Format (PDF) only. It also provided

Summary Product Characteristics information, which is more extensive information about the drug, not written in plain English (because it is designed for health professionals), and submitted by the medicine manufacturers as part of the licensing process.

Table 11: Five most often accessed US, and UK developed Internet-based medicine information sites

Internet-based Medicines Information Site and *URL*	Reach*
US websites	
MedicineNet http://www.medicinenet.com/script/main/hp.asp	494.0
US Food and Drug Agency http://www.fda.gov/	490.5
Mayo Clinic http://www.mayoclinic.com/	403.5
Drugs.com http://www.drugs.com/	397.0
Rxlist http://www.rxlist.com/	303.0
UK websites	
Net Doctor http://www.netdoctor.co.uk/	270.0
Patient UK http://www.patient.co.uk/	86.5
Best Treatments http://www.besttreatments.co.uk/	19.5
Electronic medicines compendium http://emc.medicines.org.uk/	7.4
Medicine Guides http://medguides.medicines.org.uk/	5.7

*Mean over 3 months per million people accessing the Internet

Figure 5 shows a screenshot of a frequently accessed website with information about medicines *Mayo Clinic (http://www.mayoclinic.com/)*. Appendix ten provides screenshots of all ten sites analysed.

Figure 5: Screenshot of an example of a website with information about medicines

Four US sites homepages contained advertisements for pharmaceutical products; the *US Food and Drug Agency* did not contain adverts. Two UK sites featured sponsorship: *Net Doctor* promoted treatments for stopping smoking, and coping with erectile difficulties; and *Patient UK* advertised mobile telephone networks.

Three sites did not provide information about the risk of a side effect: *Patient UK, Best Treatments*, and *Medicine Guides*. The remaining sites provided this information, as a verbal description. Only one site (*Patient UK*) provided comments from users about the experience of taking the medicine, and its effects. For a complete description of all ten websites, see Appendix eleven.

4.4.3. Design of the IBMI sites

There was little difference in the range of sites' web-design characteristics (see Table 12). More than half of the sites had seven or more features: the rest had five or six. All sites

provided a link whereby users could make direct contact with the site (see Table 13), and similarly all sites provided links to external sites.

The *Medicines Guide* was the only site not to have a search bar. Of those that did, it was most often at the top middle of the screen, thus prominently displayed to attract the user. The *RxList* site had four search bars. Its most prominent search bar *'search for a drug name'*, was displayed at the top centre of the home page.

Seven sites ran an email list, allowing users to correspond. The *Medicines Guide* was the only site to provide the opportunity to personalise information. The *'My medicines'* box allowed users to enter the dosage of the medicine, their age and sex, to receive more personally relevant information, dependent upon these variables. However, this option was not immediately visible, and therefore could be missed by the user. (This function was no longer available on the site in April 2008). Only two sites (*Mayo Clinic* and *Medicines Guide*) provided a text size change function. Three sites did not provide an instruction or help page: *Net Doctor*, *Patient UK*, and *US Food and Drug Agency*. Four sites provided a table of contents: *Drugs.com*, *Medicine Guides*, *Best Treatments*, and *Mayo Clinic*.

Table 12: Number of design, quality and content characteristics of the IBMI sites

IBMI site	Design (9 characteristics)	Quality (8 indicators)	Medicine information content (14 markers)	General content (8 markers)
Medicine Net	7	8	6	4
US Food and Drug Agency	5	4	6	5
Mayo Clinic	8	8	11	6
Drugs.Com	8	7	11	6
Rxlist	7	5	12	4
Net Doctor	5	7	6	3
Patient UK	5	5	11	3
Best Treatments	8	5	4	4
Electronic medicines compendium	5	4	10	4
Medicine Guides	8	6	12	5

4.4.4. Quality of the IBMI sites

There was large variation in site quality. Two sites (*Mayo Clinic* and *Medicine Net*) had all eight quality indicators; a further five sites met five or fewer quality indicators (see Table 12). All sites presented a specific date when their *simvastatin* information webpage was last updated (see Table 14); Wald, Dube, and Anthony(2007) refer to this as the site's currency. Three IBMI sites had updated the page within three months of the date of assessment (*Medicine Net, Drugs.com* and *Best Treatments*), (see Appendix eleven). *Net Doctor* and *Medicines Guide* updated the page between 13 and 24 months before it was accessed (January-February 2006), while *Electronic Medicines Compendium* had not been updated in more than two years before it was accessed. Only four sites reported when the site was first developed (*Mayo Clinic, Medicine Net, Medicines Guide* and *Patient UK*).

Table 13: Design features of the IBMI sites

Web-design characteristics	Number of sites with characteristic
Links to external page	10
Contact site link	10
Search bar	9
Printer friendly option	9
Contains pictures	8
Instructions or help page	7
Interactive facilities	7
Table of contents	4
Text size changeable	2

Table 14: Quality of the IBMI sites

Quality indicators	Number of sites with indicators
Specific date of last update	10
Funding source stated	9
Disclaimer	9
Statement of confidentiality/privacy	9
Reference to evidence	6
Authorship	6
Advertising policy	6
Date site developed	4

Six sites provided details of authorship. All sites (except *RxList*) reported sponsorship. *Patient UK* was the only site not to display a confidentiality or privacy statement. Six sites referred to evidence, but only *Best Treatments* and *RxList* presented the references to articles. *Medicine Net* provided links to further information and evidence. Four sites: *Mayo Clinic*, *Medicine Net*, *Net Doctor*, and *Drugs.com* were accredited by the *HoNCode*.

4.4.5. Medicine information content of the IBMI sites

Information about medicines on the sites varied greatly; ranging from as few as four items (*Best Treatments*), to 12 items (*Medicines Guide*, and *RxList*), (see Table 12). All sites provided some information about 'what the medicine is' and 'side effects' (see Table 15). Two sites (*Medicine Net*, and *Best Treatments*) did not provide information about 'before taking a medicine'; and two sites (*Net Doctor*, and *Best Treatments*) did not provide information on how to take the medicine. Three sites (*Net Doctor*, *Best Treatments*, and *US Food and Drug Agency*) did not provide storage information. *Best Treatments* provided only broad condition-based information about hypercholesterolemia, and lifestyle and drug

137

treatments for the condition. It did not offer the same level of information about medicines as the other sites.

Table 15: Medicine information content of the IBMI sites

EU recommended headings	Number of sites with content
	Specific content items
'What the medicine is'	10
'Side effects'	10
Notify GP if side effects occur	7
'Before you take'	8
Interaction with other drugs	8
'How to take'	8
Action to take if miss a dose	6
Action to take if overdose occurs	5
Consequences if drug not taken	2
'Storage'	7
Other items	
Information about hypercholesterolemia	9
Complementary or alternative treatments (for example, dietary)	7
Information about impact on quality of life	1
Experiential comments	1

Overall the provision of information relevant to taking the medicine was variable. Eight sites provided information about the possibility of interactions with other medicines – *Best Treatments* and *Patient UK* did not. Seven sites stated that the medicine user should notify their GP if side effects occur. Six sites mentioned what to do if the medicine user missed a dose. Only two sites (*Mayo Clinic* and *RxList*) spoke of the consequences if the user chose not to take the medicine. Conversely seven sites provided information about treatments to complement taking the medicine (for example, dietary changes), or alternative treatments.

All sites provided information about hypercholesterolemia, except the *US Food and Drug Agency* site. Only the *Medicines Guide* provided information about the impact on quality of life when taking the medicine.

4.4.6. General site content

The general content of the sites varied. Four sites (*RxList, Medicine Net, Mayo Clinic,* and *Drugs.com*) promoted a pharmaceutical product. A further three sites (*Medicines Guide, US Food and Drug Agency,* and *Electronic Medicines Compendium*) had links to pharmaceutical companies, but did not promote a pharmaceutical product. The *RxList* was the only site not to declare its purpose.

Three sites provided explicit information that could potentially enable the medicines user to share decision making with a healthcare professional (see Table 16). For example, *Mayo Clinic* encouraged the medicine user to reflect on several questions when taking the medicine. *Best Treatments* explained how to use the research to support decisions about which treatment to opt for. *Drugs.com* raised points the individual should discuss with her or his GP before taking the medicine.

Three sites (*Mayo Clinic, RxList,* and *Medicines Guide*) gave answers to frequently asked questions. All sites were judged to be written in plain English language (by the two reviewers). Only *Drugs.com* and *US Food and Drug Agency* provided a translation of information about the medicine into another language (Spanish). For both sites, this option was not clearly available. *Patient UK* provided translations for some condition-based information into foreign languages.

Table 16: General content of the IBMI sites

Content on site	Number of sites with content
Medicines information written in plain English	10
Site content written in plain English	10
Purpose/rationale of site stated	9
Promoting a pharmaceutical product	4
Site developed by a pharmaceutical company but not promoting a pharmaceutical product	3
Information enables shared decision making	3
Provides answers to FAQs	3
Offers translations in other languages	2

4.4.7. Piloting the User Test

Only five sites provided indicative information to all ten User Test questions (see Appendix twelve and Table 17): *Mayo Clinic, RxList, Medicines Guide, Electronic Medicines Compendium,* and *Drugs.com.* All sites provided examples of side effects, explained the benefits of taking *simvastatin,* and provided information about lifestyle changes needed whilst taking the drug. All sites except *US Food and Drug Agency* reported the danger of too much cholesterol, explaining the benefits of lowering cholesterol. Six sites explained what action to take if a dose was missed. Not all sites provided information about what action to take if the medicines user suffered muscle pain from taking the drug, a potentially serious side effect. Likewise not all sites noted that the user should not take grapefruit juice when taking *simvastatin.*

Table 17: Indicative information to answer the User Test on the IBMI sites

Specific questions	Number of sites with information
Why should you take simvastatin?	10
Please name three unwanted outcomes from taking simvastatin	10
Can you name me at least two lifestyle changes you should make whilst taking simvastatin?	10
Is it okay to drink alcohol when taking simvastatin?	9
What effect could having too much cholesterol in your blood have on your body?	9
If you are pregnant or considering becoming pregnant, should you take simvastatin?	9
Is there specific food or drink you should avoid when taking simvastatin?	7
Suppose you are taking Erythromycin, an antibiotic, and the doctor starts you on simvastatin. Is it okay to take it?	7
Suppose you take Simvastatin and you find that your joints start to ache. What should you do?	7
What should you do if you forget to take simvastatin?	6

4.5. Discussion

4.5.1. Overview of main findings

The modest search found a large number of links to IBMI sites through search engines.

This may be surplus to the needs of medicines users, when it is considered that people

rarely look beyond the first page of links when searching for healthcare information

(Eysenbach and Köhler, 2002). Because of the power of search engines to promote popular sites and constrain the promotion of others (Introna and Nissenbaum, 2000), and the public's use of limited search strategies, this will probably impact on what they do and do not find.

Information found on the Internet is a product of the search strategy adopted: where the person searches for information (using a portal or a search engine, for example) will determine what is found (Adams, 2006b). This study found that typing *simvastatin* into the search engines led directly to a specific page with information about the drug *simvastatin* on the site, bypassing the homepage. This potentially made the homepage redundant, and therefore if it had any important information about a medicine on that page that it is not repeated elsewhere, it may never be viewed by the person accessing the site. This can be considered to represent what Eysenbach and Diepgen (1998) refer to as a 'context deficit', whereby information can be harmful, even though not false. It is therefore important for site designers to ensure that this information is repeated elsewhere on the site.

The design of IBMI sites

There was little difference between the design features of the sites. All provided links to external sites, and all provided a contact link. Most sites had external links, either on the home page or on the web page with information about *simvastatin*. This may benefit medicine users; because some people cross-reference this information(Adams, 2006b). However, links may also distract the user. Many of the sites' home pages were cluttered with links, which may make it difficult for the user to navigate the site and process information. *Electronic Medicine Compendium* was the only site to provide links to external sites on a page devoted solely to links (and clearly labelled '*links*'). Links to external sites that have little or no relevance to people's information needs when accessing the site, may distract their search.

Nine sites provided a search bar thereby enabling the individual to search for any medicine, by typing the name in the search bar. This is a useful design feature because users can access information by typing the name of the drug, rather than navigating

complicated menus (which they may not have the skills or the confidence to negotiate). Paradoxically it may be a redundant feature of the sites. As noted before, when medicine users type the name of a drug into a search engine, they are normally taken to a specific web page on a site and bypass its homepage, and so they may fail to see the search bar on this page. Most sites lacked a table of contents which may be a missed opportunity to optimise the interactive nature of the Internet.

A site with a printer-friendly option allows the user to print the information for later use. Printing from a web page itself can sometimes result in text at a margin being cut off. One site (*Electronic Medicines Compendium*) provided the WMI in a PDF format. However, this format fails to utilise the interactive nature of the Internet. Most sites did not take advantage of technological features of the Internet, such as the option to change text size; thereby missing an opportunity to aid medicines users with visual impairments. On Internet browsers, readers can increase the font size from the 'View' drop-down menu; therefore this may not be a detrimental issue to the person who is aware of this. However, if the person accessing the site does not know this, she or he may not get the most benefit from using the website.

Only the *Medicines Guide* site provided the option to personalise information. This could easily be missed by the person accessing the site, as this was contained within an introductory section that medicine users may perceive as irrelevant and therefore ignore. This was limited to specifying the sex of the medicine user, and the type of medicine, therefore offering little scope for personalising. Only two IBMI sites provided foreign language translation (Spanish) reflecting the US origins of the sites; but neither site presented this option explicitly; for both sites this was found by chance. A Spanish translation would probably not be helpful to many people from ethnic minorities in the UK, whose first language would reflect their Asian or Eastern European ancestry. The *Welcome to NHS Direct Online* website (*http://www.nhsdirect.nhs.uk/*) provides translation facilities in a number of Asian and African languages, for some information, but not medicines (when accessed in April 2006)

The quality of IBMI sites

The number of quality indicators that sites featured varied, with two sites having only half of the eight items. Websites can be updated daily; therefore it was good that all sites declared how recently they had been updated. However, three sites last updated the information more than one year before the site was accessed. Information which has not been updated regularly could quickly become out-of-date and may not be considered credible by a medicine user.

Nine of the ten websites provided a disclaimer, and confidentiality and privacy information. The availability of this information may encourage people to access these sites. Medicine users have reported not trusting websites developed by pharmaceutical companies (Peterson *et al.*, 2003). Therefore it may be reassuring to people accessing the sites that nine of them reported details of sponsorship. This could enable the person accessing the site to make a choice about whether or not to read and trust the information, based on this knowledge.

Nearly half the sites did not refer to evidence to support claims made about the medicine. This is not helpful for people who specifically look for evidence-based information, and may deter them from accessing the site. It is important to note that the sites may have provided evidence-based claims, but they did not provide reference to this.

The content of IBMI sites

The sites provided inconsistent information. This reflects the finding of an evaluation of leaflet-based WMI that found the provision of important information – for example, action to take if missing a dose, or the warning about the risk of an interaction with another medicine – was variable(Gustafsson *et al.*, 2005).

Few sites were judged to have provided information explicitly intended to enable shared decision making. All WMI can have the potential to enable shared decision making because it can change someone's level of knowledge about a medicine. The crucial point about the definition in the study reported in this chapter was that the site had to provide content that explicitly sought to enable shared decision making, rather than merely inform

the person. Participants in the stakeholder workshop (see 3.3.2) spoke of wanting WMI that would complement the consultation with the doctor, and that would enable them to make an informed choice. By providing detailed information about medicines, medicine users could be better informed to be a more equal partner in the decision-making process. However, the social circumstances underlying concordant relations between the doctor and the patient are as important: for example, the differences in the power and knowledge held by the doctor and patient. Therefore the information on a site (or leaflet) alone may not be enough.

Respondents in the workshop (see 3.3) strongly felt that condition-based information was an important component of WMI. *Best Treatments* was the only site to provide information on treatment options – for example, advice on changing lifestyle – as well as medicines information. Nine sites provided information explaining how *simvastatin* lowers cholesterol to reduce the risk of having a heart attack or stroke. This is important because it outlines the purpose and benefits of taking the medicine.

All sites provided information about 'what the medicine is', and 'side effects'. This information could enable the medicine user to have a balanced picture of the risks and benefits of taking the medicine, to make an informed decision about taking the medicine.

Several sites did not provide specific information about the medicine: for example, what action the medicine user should take if they overdose, the consequences of missing a dose, or the impact on quality of life. This is not only a missed opportunity, but could have potentially serious consequences for the medicine user. An analysis of the content of a random sample of leaflets by Raynor *et al.* (2007c) similarly found variation in the presence of this information, which could have serious implications for the medicine user depending on WMI alone.

Only one site (*Patient UK*) reported the experiences of people taking the medication. This is information that participants in the workshop stated they would value, and so in this respect it is disappointing that most sites did not provide this material. Few sites provided

information about the impact of taking the drug on the quality of one's life, again not providing information medicine users have said they want.

Information about the risk of a side effect is particularly sought by medicines users (Raynor *et al.*, 2007a). Sites provided information only as a verbal descriptor. This is a less than effective means for communicating the risk of a side effect (Berry *et al.*, 2003c), and may therefore be of limited use to people accessing those websites. An analysis of pharmaceutical websites by Davis *et al.* (2007) similarly found that the sites presented a verbal description of the risk of a side effect that was ambiguous and inconsistent.

Only half of the sites provided indicative information to answer ten safety and efficacy questions (chosen for the User Test). While sites provided information complying with the recommended EU categories, some provided in a cursory and not specific form. This information can be seen as useful, if not essential to the user, and yet not all sites provided it. The omission can be considered an oversight on the part of the writers of IBMI site content, if the User Test reflects information priorities of medicine users.

Websites and the pharmaceutical industry

No pharmaceutical company websites were in the five most frequently accessed US or UK developed sites. However, four sites, all US developed, promoted a pharmaceutical product; and a further three sites (*Medicines Guide, US Food and Drug Agency*, and *Electronic Medicines Compendium*) had input from the pharmaceutical industry, but did not promote a pharmaceutical product. This finding may reflect medicine users preferring government or professional developed websites to pharmaceutical company websites (Peterson *et al.*, 2003), but the reason remains to be clarified. It also reflects a conclusion reached by Raynor *et al.* (2007a) examining the role and effectiveness of WMI: medicine users have in broad terms expressed reservations about trusting information provided by pharmaceutical companies. Medicine users' doubts about the trustworthiness of information provided by pharmaceutical websites may not be unfounded. For example, an evaluation of 51 sites, the majority developed by Turkish pharmaceutical companies, found that most did not

meet quality guidelines for IBMI set by the Turkish Pharmaceutical Manufacturers Association (Yegenoglu *et al.*, 2005).

4.5.2. Comparison with previous findings

Two sites evaluated in this study (*Medicine Net* and *Rxlist*) were examined by Hatfield *et al.* (1999), who assessed the quality of IBMI for commonly prescribed medicines. They found *Medicine Net* had no search function when the analysis was conducted (before 1999). The study reported in this chapter found the same site had a search bar, prominently placed on the homepage. Hatfield *et al.* (1999) were unable to locate references to evidence when they analysed the site. The current analysis found that the site had supplementary reading called '*Suggested reading by our doctors*', which provided evidence about the drug, although it did not provide a reference for the evidence. There was no difference between evaluations of the *Rxlist*. The differences between the findings of Hatfield *et al.* (1999) and this study highlight the transient short-lived nature of Internet sites.

The study reported in this chapter has found variability in site content which mirrors previous content analyses of IBMI. Doupi and van der Lei (1999) examined whether 14 sites offering information about general prescribed medication conformed to a quality criterion, and found this was patchy. Other content analyses – for example, Croft and Peterson (2002) examining sites with asthma education, and Martin-Facklam *et al.* (2002) assessing sites with information about *St John's Wort* – have similarly reported variation in the content and quality of sites.

Sidhu *et al.* (2006) analysing the content of websites providing information on *NSAID analgesics*, found they had incomplete and inaccurate information. The present study has similarly found incomplete information on sites (for *simvastatin*), but did not assess the accuracy of the information. However, the omission of important information about not taking grapefruit juice, or the dangers of *erythromycin* interacting with *simvastatin*, presents an inaccurate account of the drug which could have serious consequences.

Previous research has found that some sites that displayed the *HoNCode* accreditation symbol did not match the criteria for displaying this (Croft and Peterson, 2002). This could

be a cause for concern, as people who saw the insignia may have assumed that the quality of the site was assured, (if they recognised what it was). Of the ten sites that had their design features, quality and content examined in this study, four were found to display the *HoNCode* accreditation symbol; (*Mayo Clinic, Medicine Net, Net Doctor,* and *Drugs.com*). All met the criteria for this accreditation. A study of 100 sites providing information on the treatment of fever in children, found that only 14 displayed the *HoNCode* insignia (Fallis and Frické, 2002). The current study has found a greater proportion of accredited sites than previously reported. However, the *HoNCode* is only one means for assessing the quality of an e-health website, and different measures, (e.g. *Discern*) may have produced different results for the assessment. Furthermore, the quality of a website does not necessarily relate to its trustworthiness. Therefore; this does not automatically mean that the sample in this study was any more trustworthy than other content analyses, or that the quality of IBMI in general has improved.

Dickinson and Raynor (2003) propose that an ideal source of WMI would have the following eight features. This is used as a checklist to assess the usefulness of the IBMI sites.

(i) Accurate and up-to-date: while all sites reported when they were last updated, three last updated the information more than one year before it was accessed (in early 2006).

(ii) Able to be personalised or customised: only one site had a (limited) personalisation option.

(iii) Available in different levels of detail at different times: the only site to offer different levels of information was *Best Treatments*, which provided the same information written for either a patient or a doctor.

(iv) Available at the consultation: this was not examined in this study.

(v) Balanced in reporting of adverse and beneficial effects: the sites have in general, provided a balanced reporting of beneficial and adverse effects.

(vi) Accessible in language, format and tone: the ten sites were considered (by the two reviewers) to be written in plain English, which may make them

understandable to the medicine user. Whether or not the information is understandable can only be tested by a performance-based study, such as the User Test reported in Chapter five.

(vii) Linked to other reliable sources of information: most sites had links to external sites, which could benefit medicine users looking for information from more than one source. However, presenting links to external sites that have little or no relevance to the medicines information searched for may be irrelevant or distracting to medicine users accessing the site(s).

(viii) Provide information about the condition as well as the treatment: most sites provided varying degrees of condition information.

Most of the sites therefore provided some of the features that Dickinson and Raynor (2003) recommended. These features alone will not make the sites useful to the medicine user. The ease of use will impact on whether or not the user will be able to find specific information; and the wording of the content will determine whether or not the information is understandable. These issues are examined in the next chapter.

4.5.3. Consideration of study limitations

The inclusion criteria impacted on what IBMI sites were found and therefore counted in the results; a different set of criteria would have found a different number of sites, and excluded some of the sites that were analysed. By considering for inclusion professionally developed sites, including those by a pharmaceutical company, this does not necessarily reflect the real world choices of medicine users who largely do not trust information from this source. However, it can be said that there is ambiguity regarding the role of the pharmaceutical industry and IBMI. For example, the *Medicines Guide* and *Electronic Medicines Compendium* were developed by *Datapharm Communications*; a 'not for profit' company set up by the Association of the British Pharmaceutical Industry (http://medguides.medicines.org.uk/about.aspx#support accessed October 2008). Furthermore, the *Medicines Guide* website reported receiving financial support from 30 pharmaceutical companies (http://medguides.medicines.org.uk/about.aspx#support accessed October 2008). There could have been grounds to exclude these sites on the basis

of their pharmaceutical links. However, these sites were in the sample of top five UK developed sites accessed. It is not known if people accessing these sites recognise their pharmaceutical industry links, and if so, still chose to access them.

Sites that required registration were excluded (because this may put people off accessing them in the short term). However, people interact with websites in different ways in the short and long term. Sillence *et al.* (2006) Staged Model of Trust has shown that in the long term, people engage with websites that offer personalised content, interactivity, updated content, and user-generated content. It may be that people who have accessed a website over a long period of time would not be deterred from registering to it. This criterion may have lead to some sites being omitted. Furthermore, because sites requiring registration may often be those that offer personalisation (Sillence *et al.*, 2006), this can account for why none were found.

There were shortcomings with the search strategy. While identifying a large number of sites; the search introduced bias by considering sites for inclusion from the reviews by Hatfield *et al.* (1999) and Doupi and van der Lei (1999), and the *Patient UK* website, and not sites linked from elsewhere. It was an unnecessary step to consider sites from different sources because the content analysis of the sites focused only on the five most commonly accessed UK and US developed sites; that were found by the search engines. Using the search engines to find sites was a better method: it identified more sites, and reflects how medicine users search for IBMI. Weare and Lin (2000) have similarly stated that sampling by the search engines is beneficial because it is relatively quick and inexpensive, and it reflects the way that medicine users search the Internet.

In this study the ten sites that were the subject of the analysis were drawn from the *Alexa Web Search* 'reach' data. This was not a representative measure of how many people accessed the sites specifically for information about *simvastatin*, but rather a record of the number of people accessing the sites as a whole. The *Alexa* site did not offer the level of specificity where it would be known how many people accessed specific pages about *simvastatin* only. Thus *Yahoo! Health*™ was ranked the most frequently accessed site,

because this took into account everyone accessing any web page on *Yahoo.com*™, and not necessarily the *Yahoo! Health*™ pages relating to information about a *simvastatin* alone. This was similarly the case for the *about.com* site. Because of the exaggerated figure for people accessing the information about *simvastatin* on these two sites, they were excluded from the analysis. Constructing a perfect sampling frame for Internet sites (of any content), is probably impossible; and wholly depends on the purpose of the research.

A range of different sampling strategies could have been used in place of the purposive sample; e.g. a random sample of the 33 web pages that met the inclusion criteria, or web pages that represented typical cases. These sampling frames may have derived different results to those found here; and so the findings of this study are not necessarily transferable to all other e-health and IBMI sites. However, this study sought to analyse the most commonly accessed websites with information about *simvastatin*. The sampling frame offered an indicator of how many people, on average over three months, have accessed the sites. Despite these drawbacks it is considered that the purposive sampling frame served its pragmatic role.

A further limitation of the *Alexa Web Search* 'reach' data was that it is not broken down by country, so there is no indication of how many people from the UK accessed a given site. Therefore the sample of IBMI sites is not necessarily representative of those accessed by people in the UK. This would require a different method which was not available when the study was conducted.

Analysis of the content of IBMI sites can be difficult. The Internet has been likened to a *'moving target'* (Berland *et al.*, 2001), because it is constantly evolving; a point which presents a challenge to research (Weare and Lin, 2000). Evaluation of the same site at different times can be difficult, and several sites have changed their features since they were analysed for this study. For example, the *Medicines Guide* site is no longer a pilot, and has increased its content, while *Best Treatments* now requires people to subscribe to it.

This study was conducted two years before Breckons *et al.'s* (2008) reported finding limitations of the *HON Code* (see 1.3.6), and so this finding could not have impacted on the decisions to apply the principles from the *HON Code* (along with the *DISCERN* website) for assessment of the sites' quality. However, it was not an aim of the content analysis to compare different tools for assessing an IBMI site's quality.

The readability of the IBMI was conducted by two researchers who applied good practice principles. However, they may not have been the most suitable people to judge this: the person best placed to comment on the readability of the information is the end user. The readability of the information for the medicine user will be more apparent after the usability study reported in the next chapter.

4.5.4. Implications

- There was variation in the quality and content of the sites. Medicine users should be aware that they will find more or less information, of greater or lesser quality, depending on the site they have accessed.

- This study did not examine if the sites provided information about the benefits of taking *simvastatin*, other than if it reported why it should be taken and the consequences if not. Future analysis of IBMI content could examine what information about benefits is and is not provided.

- Sites need to clearly state when they are, and are not, evidence-based; e.g. by providing references to evidence.

- Typing the name of the medicine into the search engine often returns pages dedicated to that specific medicine rather than the homepage of the sites. The homepage may then be a redundant feature to many people. However, this may remain a reassuring design feature, allowing the person accessing the site to more easily access information about more than one medicine on the same site.

- Providing information as a 'printer friendly option' will enable users to print off for later reading. However, providing information in PDF file format alone may make the site less appealing to the individual because it does not offer the potential interactive nature of an HTML web page.

- Only one site was found to offer an option to personalise information. This may have been a product of excluding sites that require registration.

4.6. Concluding remarks

This study has found a large number of websites containing information about medicines by using a limited sample frame. This number may be surplus to the needs of many medicine users, because we know that most people do not look beyond the first page of links when searching (see 1.4.1). There was little difference between the design features of the sites. Several sites' homepages were cluttered with links, and this may have a negative effect on some people interfacing with them. Of the most frequently accessed sites, only one provided the option to personalise the information. This option was limited and may be missed by users. There was variability in the quality markers of the sites. This may or may not be an issue, depending on whether or not users look for these features.

There was inconsistency in the medicines information on the sites, and several sites did not provide detailed information. Furthermore, of the ten most frequently accessed websites, only half provided information on ten important safety and efficacy issues. The usability and readability of these sites is examined in the next study, reported in Chapter five.

Chapter five

Study three: evaluating the usability and readability of websites with information about medicines

5.1. Introduction

The previous study examined quality indicators, content, and design features of five IBMI sites. The study reported in this chapter follows this by observing people interacting with these websites to determine if the sites were easy to use and if their information was readable. Participants were asked to think aloud while using these sites, and at the same time a computer programme recorded their online actions and verbal protocols. A User Test questionnaire was administered to determine the readability of the information.

This study used a mixed methods design, as set out in 2.7, to identify when a participant was able to navigate a site with ease to find and understand its content, and to provide insight into their perceptions of these difficulties from their concurrent verbal protocols. This work was complemented by gathering participants' opinions on the sites. This study was presented at the *Health Services Research and Pharmacy Practice* conference (Knapp *et al.*, 2008, Nicolson *et al.*, 2008a).

5.1.1. Theoretical framework for the study

The theoretical framework of this thesis was outlined in 1.5.2. The following is a summary of some relevant aspects.

The framework of distributed information resources (Wright *et al.*, 2000) was applied to code the observations and online actions data from the usability study. The coding framework was:

- **State**: information displayed onscreen.

- **Plans**: actions based on knowledge, internal to the person or external to the website.

- **Goal:** an outcome formed by the user.

- **Affordances:** possible next actions.

- **History:** internal to the person and external to the website.

- **Action-effect relations:** the causal relation between an action and an effect.

- **Knowledge about medicines:** individuals' knowledge or experience of taking medicines.

- **Conceptual system knowledge:** a sequence of actions required to complete a task.

The design principles of Preece *et al.* (2002) were based on an understanding of cognitive processes, and were applied to code the participants' verbal protocols. They are:

(i) **Attention:** online information should be salient when it needs to be, for easy processing. Cluttered information making excessive demands on attention should be avoided.

(ii) **Perception:** icons can enable meanings to be easily distinguished.

(iii) **Problem-solving:** information on the site to aid interacting with the website more effectively should be included.

(iv) **Memory:** Internet users should be able to recognise rather than recall information, as the former is a more effective method of retrieval.

(v) **Learning:** websites should encourage active learning by the user.

(vi) **Reading:** aim for large text without affecting formatting if the text is a struggle to read.

5.1.2. Aims

The aim was to identify common features of a sample of websites containing information about *simvastatin* which facilitated, or were a barrier to, locating and understanding the information about medicines. A set of evidence-based recommendations for the design of IBMI will be derived from these findings. The aim is to apply these to a site in the final study to examine if they improve readability.

The specific aims were:

(i) To examine how medicine users searched for information about medicines on the Internet;

(ii)   To examine whether the design of IBMI sites helped or hindered medicine users to locate specific information about taking medicines; and if the information was understandable.

(iii)   To understand how medicine users assessed the trust of the sites;

(iv)   To record the participants' thoughts and feelings about the usability of the sites, and the understandability of sites' content.

5.2. User Testing and usability research

The research in the last two studies (this chapter and Chapter six) largely employs User Testing and usability research to examine the ease of use of the sites and the readability of their content.

5.2.1. Examining the readability of IBMI with a User Test

Readability formulae are insufficient for examining the understandability of information (see 1.2.5). The method for assessing the readability of PILs is largely interpreted to be the User Test (European Commission Directorate-General III, 1998). This study applies the method of User Testing to IBMI sites. Because this method is currently used for evaluating only leaflets, the literature has only focused on User Testing of PILs. User Testing examines the information and not the user; a principle that also underlies usability research. A User Test requires the individual to use the information as it is intended to be used. The observer notes how the participant uses it and what problems she or he has, to find out what is wrong with it, and not merely confirm that it works (Sless and Wiseman, 2004). A User Test seeks to examine:

(i)   If the user can easily find key information, and

(ii)   If the user can express the information in his or her own words (Raynor, 2005).

The insistence on expressing the information in his or her own words requires that the individual explains the information in a way that shows that it was understandable.

Participants in User Tests are recruited from the target group for the medicine, although they are not actually taking the medicine themselves (Raynor, 2005). It is assumed that participants bring no prior knowledge to the test, as it aims to mimic the situation of a first

time medicine user. They are given a scenario to consider: for example, they have been prescribed *simvastatin* for the first time, and are asked to read the leaflet to find out about it. Using the PIL, they are asked to find information to answer a number of factual questions in a User Test. Usually 12 to 15 questions are asked, as this is a sufficient number to identify problems (Blenkinsopp, 2005). The questions are asked in a random order, rather than the order in which the required information appears on the leaflet, to make less obvious the position of the answers.

As a benchmark, at least 90% of participants must be able to find information to answer the questions; and of those who do, 90% must be able to understand it (Raynor, 2005). These thresholds are applied to PILs in EU legislation (European Commission, 2004).This is an iterative process, whereby the PIL is modified and retested until it reaches the 90%/90% pass mark (Anonymous, 2005). The information participants are asked to find reflects all five EU categories for WMI, particularly safety and compliance issues (Raynor, 2007).

User Testing PILs determines if the information can be found and understood. This is a performance-based test in contrast with the readability formulae (see 1.2.5). However, the review of literature reported in the background chapter (1.4) failed to find any previous studies that had conducted a User Test of IBMI. Because User Testing was designed for evaluating PILs and not IBMI, this presents three issues. Firstly, User Testing has not been validated for this medium; secondly, this method alone does not provide the means for assessing whether the participant can use the site with ease to find the information (before trying to understand it); and thirdly, a distinction between evaluating the readability (i.e. understandability) and the ease of use of a site is necessary.

5.2.2. Examining the ease of use of a website with a usability study

To examine how participants navigate a site to find the information, and what difficulties they have in doing so requires a usability study. Usability studies can be broadly categorised as indirect or direct in their design (Nielsen, 1993).

Indirect study design

Indirect methods measure the user's interactions in a (sometimes) concealed manner: for example, studying Internet activity by logging file use. This approach can offer a reduction in the bias associated with observational methods (see below), but there is an ethical concern about invasion of privacy; and although this method documents activity, it cannot explain it (Norman and Panizzi, 2006).

- **Interviews**

Interviews indirectly explore the reasons why people act as they do, permitting the interviewer to interact with and react to the interviewee, clarifying matters as and when they arise (van Teijlingen and Forrest, 2004). Problems can arise if interview bias occurs, where the interviewer steers the interview in a certain direction, either knowingly or not (van Teijlingen and Forrest, 2004). Furthermore, because an interview is indirect, it does not study how the user interacts with IT in real time (Nielsen, 1993). As a means for recording user reflections in conjunction with a direct method, this may offer a reliable means for gauging usability. However, there will be the drawback that the findings may not be generalisable to other populations.

- **Focus groups**

Focus groups facilitate the expression of like-minded people's ideas and experiences (Kitzinger, 1995). They can be problematic if participants express only 'socially desirable' views (van Teijlingen and Forrest, 2004). Furthermore, testing information in a group environment can obscure individual (mis)understanding and (in)comprehension (Shrensky and Sless, 2005), therefore valuable data may never be recorded. A further problem with this method is that of self-selection: those most likely to give feedback will be the most dissatisfied with the system, and the most vocal users; therefore the findings will not be representative of all users of the system (Nielsen, 1993).

Direct study design

Direct methods measure users interfacing with IT in real time. This can be a demanding process for both observer and participant.

- **Observation and online tracking**

Observation is one means whereby participants use the computer system as they would in their normal user environment, without interference (Nielsen, 1993). This is done by making a detailed observation of behaviour, and watching and recording what people say and do. However, this method may prompt changes in the behaviours or actions of those being observed, i.e. the 'Hawthorne Effect' (Mays and Pope, 1995), which can lead to bias. Tracking the actions of the person using a website can offer a reliable measurement. Mouse tracking can be used as a proxy for following the attention of the user, because there is a close (but not perfect) correlation between visual gaze and attention (Norman and Panizzi, 2006). Computer software (for example, *Macromedia Captivate™*) tracks online activities by recording all onscreen actions and instantly creating a flash simulation.

5.2.3. Think aloud and verbal protocols

The 'think aloud' method requires the user to express her or his thoughts that arise during a task. This approach contrasts with asking them to describe or explain how she or he solved the task retrospectively (Ericsson, 2002), because this could lead to biased justification of task performance in hindsight. An alternative is to ask the user to report what she or he did at the end of a task. This allows the participant to complete the task without the distraction of interrupting their cognitive processes by explaining their actions in real time (Norman and Murphy, 2004). This method is problematic if the participant cannot later retrieve the reasons for their actions.

Concurrent think aloud (CTA) requires the participant to think aloud during a task, while retrospective think aloud (RTA) allows the individual to carry out the task in silence, and then verbalise his thoughts afterwards on viewing a recording of their task performance (van den Haak *et al.*, 2003). A comparison of CTA and RTA for evaluating an online library, found that both methods detected a similar number of problems, but differed in how these problems were detected: CTA highlighted more observable problems in the participants' actions, while RTA discovered more verbalised problems (van den Haak *et al.*, 2003).

The think aloud method is central to the evaluation of the usability of IBMI in this thesis, because verbal expressions generate a source of direct data for thought processes involved in the task (Jaspers *et al.*, 2004), referred to as verbal protocols (Ericsson and Simon, 1980). The insight that this method gives into the user's thought processes makes this an invaluable method for examining usability. Thinking aloud, it is noted, can be difficult to do because of its unnaturalness, as (i) it slows the user's performance, becoming less representative of their actual behaviour, and (ii) it can influence the user's problem-solving behaviour because they are verbalising their thoughts (Nielsen, 1993), which may introduce bias, and make the outcomes less valid.

There are benefits and disadvantages to both the CTA and RTA methods. The research in this thesis will adopt CTA for the following reasons. Verbal expression of thoughts has been shown not to significantly disrupt cognitive processes (Ericsson and Simon, 1998), a commonly held criticism of 'introspective methods'. If gathered and interpreted correctly, the method offers a valid and reliable insight into the user's cognitive processes during a task (Ericsson and Simon, 1980). Because the user voices her or his cognitive processes at the time of acting, she or he later avoids rationalising her or his actions (Nielsen, 1993); giving the method high face validity (van den Haak *et al.*, 2003).

5.2.4. 'Discount usability'

Nielsen (1993) has proposed that researchers should apply the concept of 'discount usability engineering' to usability studies. These are simpler methods that reflect practical design situations, based on the argument that they can be almost as successful as theoretically driven usability studies (which demand greater money and expertise to conduct), for identifying problems with IT usability. This approach does not seek perfection in research, but rather to identify usability problems, using four techniques below (Nielsen, 1993).

- Observing users in an unobtrusive way allows them to work as they normally would, without interference.

- Devising a scenario to reduce the demands of the usability test.

- Simplified thinking aloud allows the observer to determine *why* as much as *what* a participant is doing.

- Observation notes suffice because discount usability is not aiming for perfection and therefore video recording of sessions is not necessary.

The sample size in usability testing is a contentious issue. Nielsen (1993) proposed that a usability-test can be conducted with as few as five participants. This has been challenged by Faulkner (2003) who found that, while a five-participant study can identify major problems, a usability-test with 20 participants has far less variance in results, and does not miss subtle errors that a smaller study would. While this is important to note, it ignores practical considerations: for example, time and financial resources available for conducting the study. Furthermore, the evidence shows that a study with five participants has a 90% probability of getting within 24% of the true mean level of problems identified. This would be an acceptable level of accuracy for many usability studies (Nielsen, 1993).

5.2.5. Concluding remarks on usability research

There is a need to understand how people use a website to access and understand information about their medicines effectively. Usability research will have an increasingly important role in identifying problems with the safe and productive use of e-health as it continues to grow (Kaufman *et al.*, 2003). The position of this thesis is that it is essential to conduct a usability study for evaluating participants' use of IBMI sites in conjunction with a user-test examining the readability of its content. Internet-based information is not the same as paper-based information; therefore a User Test alone is insufficient. The first goal of research of IBMI should be to examine how the user locates and draws on the information, because the ease of use of a site will precede the user's attempts to understand its information (Nicolson, 2007).

A usability test will be employed to evaluate the features of the IBMI sites which potentially facilitate or impede locating and understanding of information. This will provide actionable data, indicating what needs improving (Rubin *et al.*, 2001) and offering recommendations on how to make IBMI sites more effective. Because of financial

constraints in this PhD research project, the tenets of discount usability have been adopted for the design of the usability study in this thesis.

5.3. Methods

5.3.1. Research ethics application

Research ethics approval for this study was obtained from the University of Leeds, School of Healthcare, Educational Research Ethics Group in June 2006.

5.3.2. Participant criteria for inclusion and exclusion

The inclusion criteria for participants were:

- People who had taken a POM or OTC medicine in the previous year.

- People with prior experience of using a website, (because participants with no web experience would have required extensive training before conducting the tests).

People were excluded if:

- They were under 30 years of age, as they may have less experience of taking medicines and therefore value less the importance of this study.

- They were current members of the medical or healthcare professions; or conducting any form of research.

5.3.3. Recruitment of study participants

The participants in this study were drawn from a convenience sample. Participants were recruited in person (by the author) from a busy pharmacy in a Leeds suburb. Recruitment took place over the course of seven visits (lasting around three hours each) between August 2006 and February 2007. Pharmacy customers were approached by the author and asked:

    (i)   If they could use the Internet;

    (ii)   Their age (if there was doubt that they may be under 30 years of age);

    (iii)   Whether they had taken a prescribed or OTC medicine in the last year.

Those who answered yes to all three questions were given a verbal overview of the study and invited to take part. Because of the large volume of people approached in a relatively short period of time, the author was unable to keep a record of how many people in total

were asked if they would take part. Finding people who met the inclusion criteria and showed an interest in the project was a lengthy process. Many people were not recruited because they were unable to use the Internet. Most participants who could use the Internet (in general younger adults in employment), said they would be unable to come to the University to take part in the study.

Thirty people meeting the inclusion criteria verbally agreed to take part in the project and gave contact details. They were given full information about the nature of the study, verbally, and in writing (see Appendix thirteen). They were asked to return a signed consent form (see Appendix fourteen), and a short questionnaire (see Appendix fifteen). After the study completion they were given a £10 gift voucher as a token of appreciation.

Six participants withdrew from the study, and six who did not respond to telephone calls or emails for more than one month were considered lost to attrition. One person agreed a study date, but did not appear nor return the consent form or questionnaire. Seventeen people returned the questionnaire and completed the consent form. Around the time of collecting from the 12th participant, it was noted that 'data saturation' had been reached; i.e. no new concepts were emerging from the data (see 5.3.6 for further details). For this reason it was decided not to run any studies after the 15th (at which point equal numbers of participants had viewed each of the websites used in the study).

5.3.4. Conducting the usability study

The study was conducted one-to-one in the University of Leeds, School of Healthcare. Each participant sat at a work station. The author sat adjacent to the participants, to observe their interaction with the Internet, and to be able to ask them the User Test questions (see below). A computer programme, *Macromedia Captivate*™ recorded the user's on-line activities and vocalisations. The author noted the outcomes for the three tasks, and made notes of the participants' actions when using the IBMI sites. Participants were instructed to 'think aloud' during all tasks and wore a microphone to record their vocalisations, concurrently saved with their online actions by *Macromedia Captivate*™.

Internet search for information about simvastatin

Participants were asked to open *Internet Explorer*™ and find any site providing

information about *simvastatin*. They were given no further details. This also enabled the

participant to get used to the PC configuration if need be.

User Test

Participants were assigned to use one of the five IBMI sites from the content analysis (see

Table 18) that contained the indicative information to answer the questions in this study.

To minimise the risk of selection bias (see 3.2.2), participants were allocated to one of the

five websites randomly. Participants were not permitted to search for and explain

information using the site that they found in the search task, unless they had been

randomly allocated to use it. The randomisation process was conducted at a remote site as

follows: the names of each website were written on pieces of card, placed in one of 15

sealed opaque envelopes, shuffled and then numbered to conceal allocation. The author of

this thesis opened the next numbered envelope in the sequence directly before the study

session with each participant.

Table 18: IBMI sites examined in the usability study

IBMI SITES	URL
• *Mayo Clinic*	*http://www.MayoClinic.com/*
• *Drugs.com*	*http://www.drugs.com/*
• *RXlist*	*http://www.rxlist.com*
• *Medicines Guide*	*http://medguides.medicines.org.uk/pilot/*
• *Electronic Medicines Compendium*	*http://emc.medicines.org.uk/*

The participants were asked to imagine a scenario where they had been prescribed

simvastatin for the first time. The User Test had ten questions answerable using

information on the site; and one further question asking participants to assess the

trustworthiness of the site they had used. They were asked to explain the information in their own words, a proxy measure for understanding the information. If it was thought that a participant was reading verbatim from the screen, they were asked to turn away from it to give their answer. The participants were taken straight to the web page for *simvastatin* rather than the site's homepage, because medicines users have reported finding information using a search engine (Peterson *et al.*, 2003), which usually provides a link to the specific medicine's web page, and not the homepage of the IBMI.

The User Test was adapted from one used by the *LUTO Research Ltd* for assessing the usefulness of a paper-based WMI; providing a tool for measuring finding and understanding the information. (This has been validated for examining leaflets, but not IBMI sites). Ten questions of practical importance for taking *simvastatin* were piloted on the ten sites in the previous study, see 4.4.7. Usually 12-15 questions are asked in a User Test (1993), but because participants were also asked to 'think aloud', this was reduced to ten questions, to lessen task demands. These questions were designed to require information which reflected all five EU categories for medicines information, particularly safety (side effects) and compliance issues. Figure 6 provides an example of the rationale for questions in the User Test.

Figure 6 Example of the rationale for a set of questions in the User Test

Respondents on the *DIPEx* website (*http://www.DIPEx .org/*) have talked about side effects from taking statins; cough, some hair loss and vivid dreams (Interview HA22 Transcript *www.DIPEx.org*, Accessed July 2006); and the importance of diet change to maintain a low cholesterol level when taking a *statin* (Interview HA21 Transcript *www.DIPEx.org*, Accessed July 2006). These concerns of people taking a *statin* are the basis for five User Test questions (see Appendix sixteen for the User Test).

If participants were unable to find the indicative information, the author intervened at three points:

1. The participant was reminded that this was a test of the website and not his or her knowledge or skills, as recommended by Nielsen (Blenkinsopp, 2005);

2. If participants had difficulties after the first prompt, the author offered to repeat the question.

3. If the participant still failed to find the information at this point, they were directed to it by the author.

This enabled data on the understandability of the information to still be gathered, even when the information could not initially be found. This ability for the author to be responsive to problems occurring during this research is considered a strength of conducting qualitative research (Johnson and Onwuegbezie, 2004). For scoring the User Test in this circumstance, the participant received 0 for finding the information. In addition to these prompts, if the participant was silent for a length of time (e.g. more than ten seconds), they were reminded to keep talking aloud.

Examining participant assessment of the trustworthiness of the sites
Immediately after completing the User Test, participants were asked if they thought the information was trustworthy or not, and their reason for their answer.

5.3.5. Outcome measures
The Internet search, User Test, and trustworthiness assessment had separate outcome measures:

Internet search
This task had five measures:
  (i)   The search strategy and search term participants used;
  (ii) The URL of the site opened, and how the site was entitled on the search engine (if found by a search engine);

(iii)   How many search results pages were viewed, and the position of the link on the page that it was opened (for example, third link);

(iv)   How long they searched for the information; and

(v)   Participants' responses to the question 'Why did you search for information this way?' at the end of this task.

User Test
This task had four measures:

(i)   Participants' successful location of the indicative information to answer each question. This was measured by the participants showing where the information was located on the web page. Finding the correct information received a score of one mark, noted by the observer on the User Test form. The inability to find the information received a score of 0.

(ii)   Participants' understanding of the information to answer the User Test was measured by their explanation of the information in their own words, verbatim transcribed on the verbal protocols. A correct explanation received a score of one mark, noted by the observer on the User Test form. An incorrect explanation or the inability to explain the information received a score of 0.

(iii)   Participants' online activities for navigating IBMI sites, denoted by (a) verbal protocols, and (b) online actions, recorded by *Macromedia Captivate*™;

(iv)   Observed problems and ease of use when interfacing with IBMI sites.

Participants' assessment of the trustworthiness of the sites
This task had three measures:

(i)   Whether the participant said if they thought the information was trustworthy or not;

(ii)   Participants' reported reasons for considering if the information was trustworthy or not; and

(iii)   Participants' reported strategies for assessing trust.

5.3.6. Data analysis

Two methods of data analysis were used for the usability tasks: emergent themes for the search strategy; and a-priori codes for the analysis of the usability data (online actions and observations), and the User Test data.

Internet search

Participant's search strategy was analysed, and details of the site that they had opened were noted. Analysis of their online actions, observed behaviours, and responses to the question at the end of the task was based on Grounded Theory (Glaser and Strauss, 1967), where the themes emerged from the data. The analysis was made by the author alone. This is a common approach to analysing qualitative data, where the researcher is considered the instrument of research, using his or her judgement as the data collection and analysis processes are intertwined (Bradley *et al.*, 2007). The author examined the transcripts and noted themes consistently raised by several participants, and themes made by only one or two participants. The themes were iteratively categorised, until no new categories were found to emerge from the transcripts. The quotes presented in the results section are examples of the consensus and atypical themes that emerged during the task. Examples of these are provided in Figure 7 below.

Figure 7: Examples of consensus and atypical themes that emerged

1. Examples of iteratively derived themes that emerged from remarks made by the participants.

    "That's down to inexperience err, really, because I've never been taught computer skills, I've what I've picked up myself from manuals" (Participant #7).

    "That's the way I always search for information basically. I'm a Google man; in fact it's a verb now: to Google, isn't it?" (Participant #19).

    This was categorised as 'previous experience determining search strategies' because the participants were relating their search strategies back to previous actions.

2. Examples of remarks made by participants that typified the broad consensus.

> *"It's just the way that it's presented and the form that it's presented, it does seem to be well researched"* (Participant #6).
>
> *"I can't see a site called MayoClinic.com err being able to put up a website like this without it being, erm, correct"* (Participant #16).
>
> This was categorised as 'reasons for trusting the website'.
>
> 3. Example of a remarks made by a participant that was untypical of the broad consensus.
>
> > *"Well yes I would have imagined they would have erm, revised it a bit more recently than that. This is obviously an old ... this is old information, isn't it? There must have been something more up-to-date than this?"* (Participant #10).
> >
> > This was categorised as 'reason for trusting the website'.

Analysis of the User Test and ease of use

The author analysed the User Test by counting the number of participants who could find, and then explain the indicative information to answer each question. The results for locating the information were scored as 0 = no and 1= yes, as used by Dickinson *et al.* (2001). For example, the indicative information to answer the question 'name three unwanted effects from taking *simvastatin*' was any three from muscle wastage or pain, constipation, wind, flu-like symptoms, and headache. If the participant highlighted where these answers were on the page, they received a point. If they were then able to explain the indicative answer, they received a further point, making this a performance-based test.

For each question a comparison was made between how many participants did or did not find and explain the information. Examples of participants failing to locate, and/or explain the information were more important for this analysis, because they indicated problems with the ease of use of the IBMI site(s), making them less useful to users.

A random sample of 20% of User Test scores were independently scored by a PhD supervisor, who has considerable experience of conducting User Test studies. The scores had a 97% agreement rate. This was much greater than 80% agreement that Miles and

Huberman (1994) have considered to be a reasonable level of reliability. This was a satisfactory indicator that the scores were reliable and so there was no need for a second scorer to check the remaining User Test scores.

The analysis of the usability data (observations, verbal protocols and online actions) was conducted using a set of a priori developed codes (see 5.1.1.). This is a deductive approach to conducting data analysis that utilises a framework to analyse the data (Bradley *et al.*, 2007). This method was chosen because it is said to be both valid and reliable (Pope *et al.*, 2000).

The verbal protocol data were analysed, as recommended by Ericsson and Simon (1984), by segmenting the verbal protocols and then encoding them; ensuring the encoded categories correspond to the verbalisations to assure validity and reliability. The process of verbal protocol analysis had the following stages:

(i)   The author played back the *Macromedia Captivate*™ recordings and transcribed the verbal protocols in full.

(ii) Participants' online activities were noted; and observation records added.

(iii) The records were segmented at a question level for each participant; thus giving 150 potential examples for coding; ten for each of the 15 participants.

(iv) Participants' verbal protocols were coded for questions where they were unable to find, or explain, the indicative information to answer the User Test. It was presumed these were examples where the sites were not easy to navigate and the information not understandable.

(v)   The data were indexed with the *a priori* codes (see 1.5.2), and more than one code could be applied to the observations, verbal protocols and online actions of each segment.

(vi) Example of an a-priori coded verbal protocol:

·*"There's a problem here, because my joints do ache because I have arthritis. But I saw something earlier on, hmmm; now then. Other medical problems, di-dum; I'll see if I can find it again. I thought I saw something about joints as I was scanning past, now here: side effects of this medicine; joint pain"* (Participant #12).

This was coded as internal history because the participant referred to information that she had seen when navigating the page.

Online actions and observations were analysed using the distributed information resources model (Wright *et al.*, 2000), as a framework. Verbal protocols were analysed using the model of design features aiding cognitive processes (Preece *et al.*, 2002) as a framework. The author used these frameworks to code and analyse the verbal protocols, online actions, and observations for all questions where participants were unable to find the indicative information to answer the User Test.

A second researcher independently coded a sample of these records, and the separate codings were compared. The two assessors discussed the coding scheme and reconciled differences in coding. This was again much greater than the 80% agreement and the author's coding was therefore considered reliable (when compared to that of an experienced usability tester), and the remaining coding was not checked.

Participants' assessment of quality
The analysis was the same as for the Internet search strategy task (see 5.3.5).

5.3.7. Conducting the interview
The post-study interview gave participants the chance to express opinions about the site, the information, and the tasks, and whether they valued the site and its content. The interview was conducted immediately after the usability study, to minimise disruption during the task and to make it easier to recall the reasons for actions.

The questions (see Appendix sixteen) were influenced by the concepts of usability (see 1.5.2). The question 'Did you feel it was easy to use the site?' related to 'learnability'; 'Did you feel the site was pleasant to use?' asked about levels of satisfaction with using the site; and 'Did you feel the site was helpful for finding the information?' related to efficiency. Participants were asked whether they felt the information was understandable; which complemented the objective User Test results. Because of doubts over whether or not the thinking aloud task disrupts processing (see 5.2.3), participants were asked if it had affected their performance.

The interview took a semi-structured format. The last question let participants introduce issues not previously discussed; and for the author to follow-up observations made during the usability study and issues raised by the participant. Using a semi-structured technique allowed flexibility in the interview (Britten, 1995, van Teijlingen and Forrest, 2004).

Outcome data
The outcome data were:

(i) Participants' opinions, both typical and uncommon, about the usability of the site, and the readability of its content.

Interview data analysis
Although this was a semi-structured interview, no *a priori* framework for the analysis was used. Participants' remarks were transcribed in full. The analysis of this data was the same as for the search task (see 5.3.6), based on Grounded Theory (Glaser and Strauss, 1967), where the themes emerged from the data. The analysis was made by the author alone. The themes highlighted the main issues that arose when participants interacted with the web pages.

Reporting the interviews
All interview extracts are quoted verbatim, with pronunciation and grammatical errors deliberately left in. A series of dots indicate an elapse of time when the participant was silent; or a deliberate gap in the verbal protocol where the individual spoke either about an irrelevant matter, or about person specific or sensitive information. When the researcher interjected, this was mentioned in parentheses. Participants are distinguished by the number they received for the study, and the site that they were randomised to for the User Test task.

5.4. Participant demographics
Participant demographics, their previous and current use of medicines, and experience of accessing e-health and IBMI were assessed using the 22 item questionnaire (see Appendix fifteen), designed specifically for this study. Questions about medicines and medicine taking were based on those used in the 2003 *MORI* 'Medicines Use Questionnaire' (Market

& Opinion Research International for Medicines Partnership, 2003). Questions about previous use of IBMI were devised to assess participants' feelings about the quality of the sites, the readability of their content, and the ease of use of their design features.

Participants' ages ranged from 37 to 70 years with a mean age of 54 years (see Table 19). There were more male than female recruits and only three participants were from an ethnic minority group. Their education level varied; seven were graduates, while four had completed their education by the age of 16 years. Five participants were retired. Twelve participants had been taking medicine(s) for more than one year. Most participants were currently taking two or more medicines, and five were taking a *statin*. All participants recounted seeing PILs accompanying medicines. Most said they read them 'always' (7 participants) or 'sometimes' (5 participants). One person said they never read the information. When asked why they read the leaflets, several said they wanted to know about possible side effects, which was the most commonly read section of the leaflet. Most read the information for practical information about taking the medication: for example, what it is for, and how to take it. No participants strongly agreed with the phrase 'they get enough information about their medicines', although most tended to agree. Most participants (11) said that they valued medicines information from different sources, and the same number felt it was good to have more than one source of medicines information.

Eleven participants who had five or more years' experience of Internet use were considered highly experienced; only one participant had less than three years' experience. Ten participants accessed the Internet daily; and fourteen had access at home. The majority accessed health or medicines information on the Internet, using a variety of sources: for example, three participants reported accessing the NHS Direct website. Seven participants said they looked for e-health because it was convenient (quick and easy to access). One person reported searching for information online when no leaflet accompanied their medication. All said they found the website by using a search engine.

Half the participants felt e-health sites were easy or very easy to use; the rest felt they were neither easy nor difficult. Most felt the information was useful or very useful; three felt it

was not. Only one third of the participants said they wondered about the accuracy of the information. Several participants said they would check the information with a health professional, or another site. Two thirds of the participants said they would access IBMI in the future, again citing convenience and cross referencing the information as reasons for doing so. Those who said they would not, felt they already received enough information from health care professionals, and queried the trustworthiness of online information.

Table 19: Characteristics of the 15 participants

Characteristics			
Sex		**Age**	
Male 9 Female 6		Mean 54 Range 37-70	
Participants per ethnic group			
White: 12	Mixed: 2		African: 1
Number of medicines taken		**How long taking current medicines**	
Participants		Participants	
>6	3	>12 mths	12
2-5	9	<12 mths	2
1	3	short-term course	1
How long used Internet for		**Current Internet use**	
Participants		Participants	
>5yrs	11	Every other month	0
3-5 yrs	3	Monthly	0
1-3 yrs	1	Weekly	5
<1 yr	0	Daily	10

5.5. Results of search task

5.5.1.   Internet search for information about *simvastatin*

The key results are in Figure 8 below. Themes that emerged during this task are defined in Table 20.

Figure 8: Summary of participants' search strategies

- Participants spent a mean 106 seconds searching (range: 31-239 seconds).

- No participant looked beyond the 5th link on the first page of search results.

- 14 participants typed 'simvastatin'. One typed 'simvastatin – drug for cholesterol'.

- 14 participants accessed the site via a search engine; one searched using the NHS Direct portal.

- The most frequently accessed site, opened six times, was the medic8.com site; with a page entitled 'Simvastatin – a Patient's Guide'.

- No participants opened a pharmaceutical company developed website, or a site with 'amateur input'.

Search strategy used

Most participants searched by typing *simvastatin* into a popular search engine. Three

examples were observed where participants used a different approach (see Table 21); and

these are important to note. One participant searched on the NHS Direct website,

(*www.nhsdirect.nhs.uk*); explaining that he did so because of previous experience, and

because he trusted the site to give good information (see Figure 10:). The second case was

where a participant searched the University intranet; (Participant #17 *Medicines Guide*). The

third example was where a participant specified the search, typing 'simvastatin – drug for

cholesterol'. She explained when she searches for artists on the Internet; she clarifies the

search with the word 'artist'. Hence she said:

> "The word simvastatin, I know we know it's a drug name, but it could, erm, it could be
> anything. So if I just give the computer a reminder that it's the drug, that the word is
> for the drug that I am looking for, I thought it might help it" (Participant #3,
> Medicines Guide).

Another participant expressed she would specify the search to UK only sites.

Participants gave several reasons for using a particular search engine (see Figure 9:).

Figure 9: Examples of reasons given by participants for the search engine they used

(i) **Familiarity**: *"One of the sites I work on is Yahoo! for my emails…. so I tend to use that more"* (Participant #8, *RxList*);

(ii) **Popularity**: *"they (Google) are the biggest search engine"* (Participant #12, *Mayo Clinic*);

(iii) **Ease of use**: *"Google is usually the easiest"* (Participant #2, *RxList*);

(iv) **Perceived helpfulness**: *"If you haven't got the right information …if you haven't got that code ww dot and things like that, erm, then using a search engine… and then just put the name of the thing, see what it hands out to ya…it could hand out lots of things which aren't relevant and a lot of things that are relevant"* (Participant #1, *Mayo Clinic*);

(v) **Free access**: *"it's (Google) always given me good results before, and it's, it's free"* (Participant #5, *Drugs.com*).

Table 20: Themes emerging from the search task

Emergent themes	Examples
Search strategy used	Talks about the reason for the search strategy used.
Previous experience	Experience aids use of site.
Assessment of quality and trust	How quality would be assessed; doesn't know how to assess quality; reasons for trusting site or not.
Understandable information	Does or does not understand the information
Information content	Talks about the content: side effects or how to take medicine, information relating to the condition and whether it is valued or not.

Table 21: Summary of participant search strategies

Participant, date of study, sex (m/f)/age	Time spent searching (seconds) Summary of search strategy used, any problems encountered, and site found
Participant #8, 18/10/2006 F/46	77 seconds Typed *simvastatin* in *Yahoo*™ search engine. Opened 4th link 1st page *http://www.medicinenet.com*

Participant, date of study, sex (m/f)/age	Time spent searching (seconds) Summary of search strategy used, any problems encountered, and site found
Participant #2, 19/10/2006 M/48	48 seconds Typed *simvastatin* in *Google™* search engine. Opened 1st link 1st page *http://www.trustedmeds.com*
Participant #3, 25/10/2006 F/68	213 seconds Typed *simvastatin – drug for cholestorol* (misspelled) in *Google™* search engine. Clicked on recommendation *did you mean 'Simvastatin - drug for cholesterol?'* Opened 1st link 1st page *http://www.drugs.com*
Participant #5, 1/11/2006 F/44	56 seconds Typed *simvastatin* in *Google™* search engine. Opened 2nd link 1st page *www.medic8.com*
Participant #7, 8/11/2006 M/70	154 seconds Typed *simvastratin* (misspelled) in URL. Accessed *Google™* toolbar browser by chance. *Google™* results page states *'Your search did not match any results'*. Clicked on *'did you mean simvastatin?'* link and then *'select similar pages'* link. Opened 2nd link 1st page *http://www.druginfonet.com*
Participant #1, 8/11/2006 M/48	229 seconds Typed *simvastatin* in *Google™* search engine. Opened 3rd link 1st page *http://www.drugdigest.org*
Participant #12, 10/11/2006 F/56	113 seconds Typed *simvastatin* in *Google™* search engine. Opened 5th link 1st page *http://www.medic8.com*
Participant #11, 21/11/2006 F/62	239 seconds Typed *simvastatin* in URL. No results, and clicked on *info@simvastatin.com* link. Put off by picture of chemical structure of *simvastatin*, and looked for help from the observer. Recommended to type *simvastatin* in *Google™* search bar. Opened 5th link 1st page *http://www.medic8.com*
Participant #6, 30/11/2006 M/45	77 seconds Typed *simvastatin* in *Google™* search engine. Opened 1st link 1st page *http://www.nlm.nih.gov*
Participant #10, 10/01/2007	31 seconds

Participant, date of study, sex (m/f)/age	Time spent searching (seconds) Summary of search strategy used, any problems encountered, and site found
M/59	Typed *simvastatin* in *Google™* search engine. Opened 1st link 1st page *http://www.medic8.com*
Participant #13, 25/01/2007 M/37	103 seconds Typed NHS in *Google™* search bar and retrieved NHS Direct website. Typed *simvastatin* into the search bar. Opened 1st link 1st page Hyperlipidaemia and lipid-lowering medicines *http://www.nhsdirect.nhs.uk/articles/article.aspx?articleId=202&sectionId=24580*
Participant #17, 12/02/2007 F/59	121 seconds Typed *simvastatin* in the search bar on the University intranet homepage. Clicked on link called *'Cardiovascular Research Institute at Leeds'* (*www.cristal.leeds.ac.uk*). Redirected to home page and encouraged to search again. Opened 1st link 1st page *http://www.medic8.com*
Participant #18, 15/02/2007 M/54	48 seconds Typed *simvastatin* in *Yahoo™* search engine. Opened 3rd link 1st page *http://www.wikipedia.org*
Participant #16, 16/02/2007 M/55	45 seconds Typed *simvastatin* in *Yahoo™* search engine. Opened 1st link 1st page *http://www.nlm.nih.gov*
Participant #19, 22/02/2007 M/59	43 seconds Typed *simvastatin* in *Google™* search engine. Opened 1st link 1st page *http://www.medic8.com*

Previous experience

Some participants' search strategy was determined by their previous experience of Internet use. For example, typing the name on the URL bar, one participant explained it by accident: *"That's down to inexperience"* (Participant 7, *Electronic Medicines Compendium*); and another by design: *"I always look for the website address first"* (Participant #11, *Drugs.com*).

Figure 10: Example of searching for information using *NHS Direct*

Participant #13, *Electronic Medicines Compendium*:
> "Okay. What a would normally do, erm, yes okay, is get to Google. We just go to NHS search engine. And there probably in this case I'll just try on the NHS website; okay". [Online action: types NHS into Google search bar on tool bar]. "Erm, okay on this website I know you've got this erm, 24 hour nurse-led telephone advice service, yeah(?) ... Erm I think that's what I need okay. Erm; then when I get there; okay obviously there are quite a number of, erm, submenus [uh-huh], so what I'll probably try and do is, erm ... I'm trying to get particular information on a medicine, the simvastatin, yes(?) Okay so maybe let me see, 'health encyclopaedia, common health questions, self-help guide'. Okay now I've looked, I suppose the specific drug that I want; I'll probably just try and eh, go via the search engine". [Online action: types simvastatin into the search bar]. "So I'll just type in sim-va-sta-tin. I suppose it I'll probably try and go... if there's any information I'm hoping it should come out, okay yeah. Well here I've probably got most of the information that I need for simvastatin, yeah? Okay the information; what one was to know just probably what the drug is for and ... Okay the ... ...I can see the information that I'm getting"

[Online action: clicks on the first link:
http://www.nhsdirect.nhs.uk/articles/article.aspx?articleId=202&sectionId=24580
(entitled Hyperlipidaemia and lipid-lowering medicines: Treatment)]

[Author – Why did you search for the information this way?]

Participant #13, *Electronic Medicines Compendium*:
> "I thought probably I would do ... get better results if I was to search the NHS website [comparing site to Google], probably I'd get information from lots of other websites, yeah, and I'd probably end up getting... ... But I suppose I think I, because I've used the NHS website before I want specifically to that website and the information that I find there"

Assessment of quality and trust

Participants were not asked about their judgement of the quality or trustworthiness of the site at this point because it may have primed them ahead of the question about the trustworthiness of the site used in the second task, therefore biasing results. Observing their behaviours suggested that some participants may have assessed site quality, although not by using a recognised method. For example, no participants opened sites labelled as sponsored links, and several showed discernment in what information the search engine said the sites covered. One noted:

"Now let's see if some of them look more reliable than others. 'Cause there's lots of stuff on, which is why I don't normally use it. Ooh heck! Medicine plus drug information simvastatin. Du-dum; erm. Zocor, ...contraindications, ... healthy, ... if it's anything, it looks more official than the others" (Participant #12, Mayo Clinic).

She reacted to seeing a link to *Wikipedia*, saying *"Erm, Wikipedia is not reliable, I know that FOR A FACT, ...through experience"* and further noted how *"some of them (links on Google) look more reliable than others"* (Participant #12, Mayo Clinic).

Looking at the site labelled *'Simvastatin: a Patient's Guide'* and noting the url (*www.medic8.com*), a participant said: *"Err; but 'Simvastatin a patients guide' might give me it. To me 'medic8' means it's probably biased anyway, because it's probably some company"* (Participant #19, Drugs.com). He still opened the link despite these doubts. A further five people opened this link, making it the most commonly accessed site. Nine different websites were opened in total (see Table 21).

Readability

The *www.medic8.com* site appealed to participants because it stated that it provided information for the patient. One participant said: *"that looked to me as if it was aimed at THE patient"* (Participant #12, Mayo Clinic). Another participant made a distinction between information for a patient or a doctor:

> *"Well erm I chose a patients guide because I would normally be a patient if I was receiving it ... Erm I'd certainly not want to read what a doctor reads because I wouldn't understand it."* (Participant #10, Electronic Medicines Compendium).

The medicine users appeared to want basic information that they could build upon. For example, explaining why he opened the link to *Wikipedia*, a participant said:

> *"I use Yahoo! and I know that Wilkipedia is the next stage where I go because that's like, if you want to call it; it's an encyclopaedia, it's the basic one. And then I go back and I say well what else do we want to look at?"* (Participant #18, RxList).

Information content

Links labelled 'side effects' provoked immediate reactions: *"Side effects, ... sounds interesting; tells you about side effects"* (Participant #8, RxList); *"it mentions side effects ... so I'm just going to see what effects are on there"* (Participant #2, RxList); and *"SIDE EFFECTS! ...*

Right, let me have a look at, ... side effects, what shall I watch for while using simstatin" (Participant #1, *Mayo Clinic*). Participants were equally interested in finding out beneficial effects of the drug, noting: *"it may do more harm; well I want to know what it does first"* (Participant #3, *Medicines Guide*); and *"the one that immediately looks interesting is the one that tells you it's a cholesterol lowering drug, which is used to prevent stroke or heart attack"* (Participant #11, *Drugs.com*).

It was important for the site to mention the name of the medicine, as there were reservations about a link (*www.lesscholesterol.co.uk/*) labelled 'Cholesterol and health'. The participant said: *"cholesterol levels and cholesterol lowering agents, so err it doesn't actually say simvastatin in the, err, actual information here"* (Participant #6, *Medicines Guide*).

Other points raised

The quantity of available information surprised participants. One asked, *"Gosh; does every sort of drug have this information?"* (Participant #11, *Drugs.com*. Another said: *"Drug uses, uh wow! What can I see here from the web; side effects, drug uses, interactions, warnings, recalls, for patients, from medical authorities; ....wow! There's so much!"* (Participant #1, *Mayo Clinic*).

The search was seen in a broader context of information provision, where a participant would seek information if it was not provided by his GP:

> *"I wanted to know that the medication, erm suited the application of my complaint. Err, you don't always get a full erm, description of the side effects from your GP. I always look now to see what the side effects might be in terms of whether it would make me feel drowsy when I'm driving, etc etc."* (Participant #16, *Mayo Clinic*).

5.6. Results of the User Test

This section presents a summary of the results of the User Test. Analysis of the participants' online activities and verbal protocols is presented to explain why they did or did not find indicative information. The verbal protocols highlighted when the information was adequately explained, or not, (as a proxy measure for understanding the information). These results have been categorised according to the concepts arising from the theories in Chapter one.

5.6.1. Summary of the results of the User Test

The results for locating and explaining the indicative information are in Table 22. There were four questions where the indicative information was located by less than 80% of participants (questions 1, 2, 5 and 7), and two questions (7 and 8) where fewer than 80% of participants understood the answers. Ten participants failed to explain adequately what to do if side effects were experienced; most stating to seek advice, but failing to mention to stop taking the medicine. Just fewer than 80% of participants understood what effect having too much cholesterol in your body could have, mentioning blocked arteries, but not that it could lead to a heart attack or stroke. Aggregating the results by IBMI sites for all ten questions; indicative information was not found for the minimum 80% of the time, by participants using three IBMI sites: *RxList*, *Medicines Guide*, and *MayoClinic*. Information was understood at least 80% of the time by participants using all sites except *MayoClinic*.

5.6.2. Reasons for failing to locate and understand the information

Site layout (state)

It seems that participants struggled or were unable to find the indicative information due to site layout. This was most evident for answering the first few questions, as participants became accustomed to the layout of the site. For example, some participants were unaware that they could scroll beyond the initial screen shot (on different sites) to the indicative information (see Figure 11 for example).

Sites with a clutter of links (see Figure 12 for example) made effective processing difficult, because they distracted the user's attention: for example, participants clicked on links to external sites: "*I'll try that. I'll just press on cholesterol levels* (clicks on link to *e.cholesterollevel.info*, see Figure 12) ... and *I'm now clicking on 'dramatically reduce cholesterol levels'*" (see Figure 13) (Participant #5, *Drugs.com*). These are also examples of the use of affordances. This strategy was not helpful to the participant because the information needed to answer the questions was on the initial site.

Table 22: Number of participants per IBMI site who found/understood the information

Question		RxList	Medicines Guide	Drugs.com	Mayo Clinic	Electronic Medicines Compendium	%
1) Why should you use simvastatin?	Located	2	2	1	3	3	73*
	Understood	2	3	3	3	3	93
2) Please name three unwanted effects from taking simvastatin	Located	1	1	3	0	1	40*
	Understood	3	3	3	3	2	93
3) Is it okay to drink alcohol when taking simvastatin?	Located	2	3	3	2	3	87
	Understood	3	3	3	1	3	87
4) What should you do if you forget to take simvastatin?	Located	3	2	3	3	2	87
	Understood	3	3	3	1	3	87
5) Is there specific food or drink you should not have when taking simvastatin?	Located	3	3	3	0	2	73*
	Understood	3	2	3	3	3	93
6) Suppose you are taking Erythromycin, an antibiotic, and the doctor starts you on simvastatin. Is it okay to take it?	Located	2	2	3	2	3	80
	Understood	3	2	3	1	3	80
7) What effect could having too much cholesterol in your blood have on your body?	Located	2	2	2	1	3	67*
	Understood	3	2	2	1	3	73*
8) Suppose you take simvastatin and you find that your joints start to ache. What should you do?	Located	3	3	2	2	3	87
	Understood	1	1	1	1	1	33*
9) Name me two things you can do to improve your health while taking simvastatin	Located	3	2	2	3	2	80
	Understood	3	3	3	3	2	93
10) If you are pregnant or considering becoming pregnant, should you take simvastatin?	Located	2	3	3	3	3	93
	Understood	3	3	3	3	3	100
Total by site	Located	23	23	25	19	25	
	Understood	27	25	27	20	26	

* Questions where less than 80% found or explained the information

Figure 11: Example of a site (*Medicines Guide*) where a participant failed to scroll beyond the initial screen shot
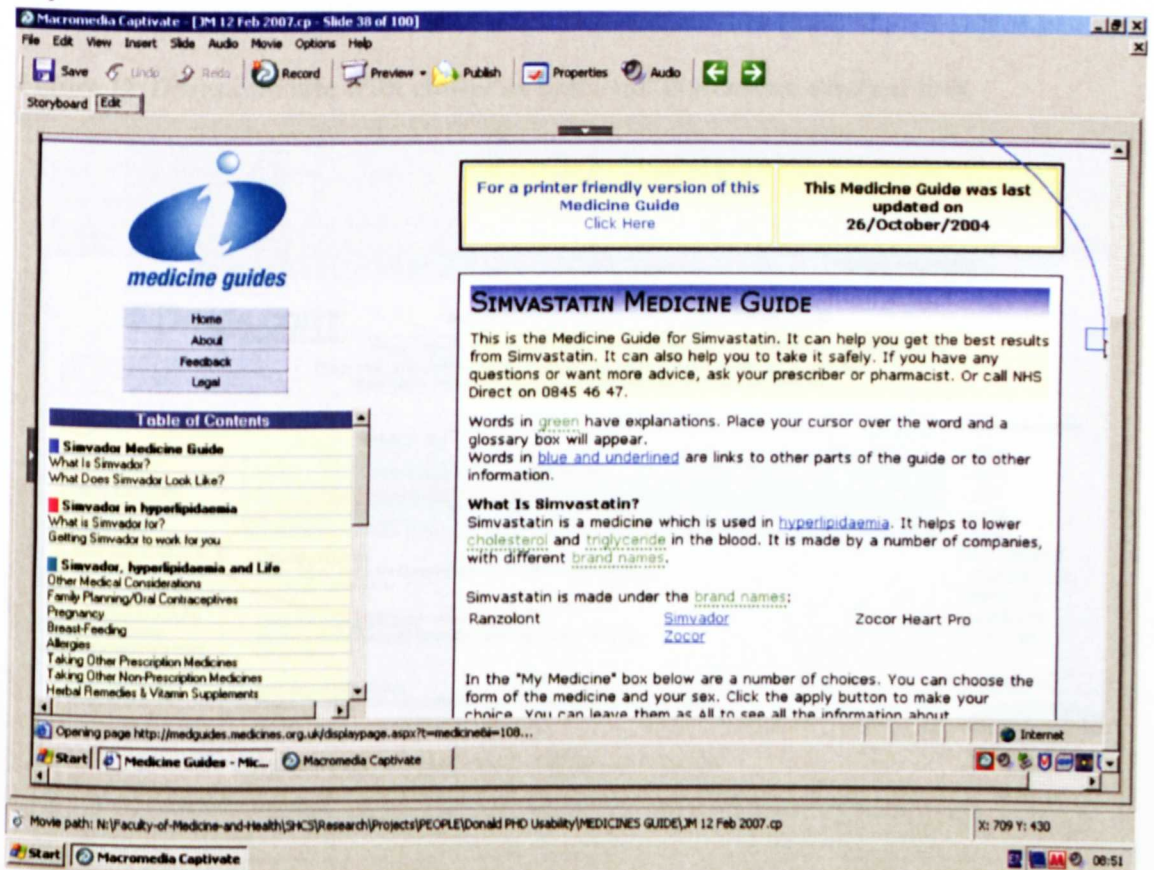
The site design of the *RxList* site caused problems as participants commonly failed to notice the link to the side effects page, designed to look like a file tab (see Figure 14). This hampered their initial navigation of the site, as they should have clicked on the link to access the page with the indicative information to answer the second question. When later asked if he noticed this feature, a participant said: *"No I didn't (laughs). It was right in front of me!"* (Participant #2, *RxList*).

Problem solving and the use of affordances

Participants regularly engaged in problem-solving techniques, when the pages did not appear to them to provide the information sought. (The adoption of problem-solving techniques was evident from analysing their verbal protocols). This resulted in them using affordances to find the information, clicking on external links, for example (see Figure 12

and Figure 13). This strategy rarely helped because they failed to recognise when they opened external links as there was no indication given on the website.

Figure 12: *Drugs.com* **site with clutter of links and distracting external link**
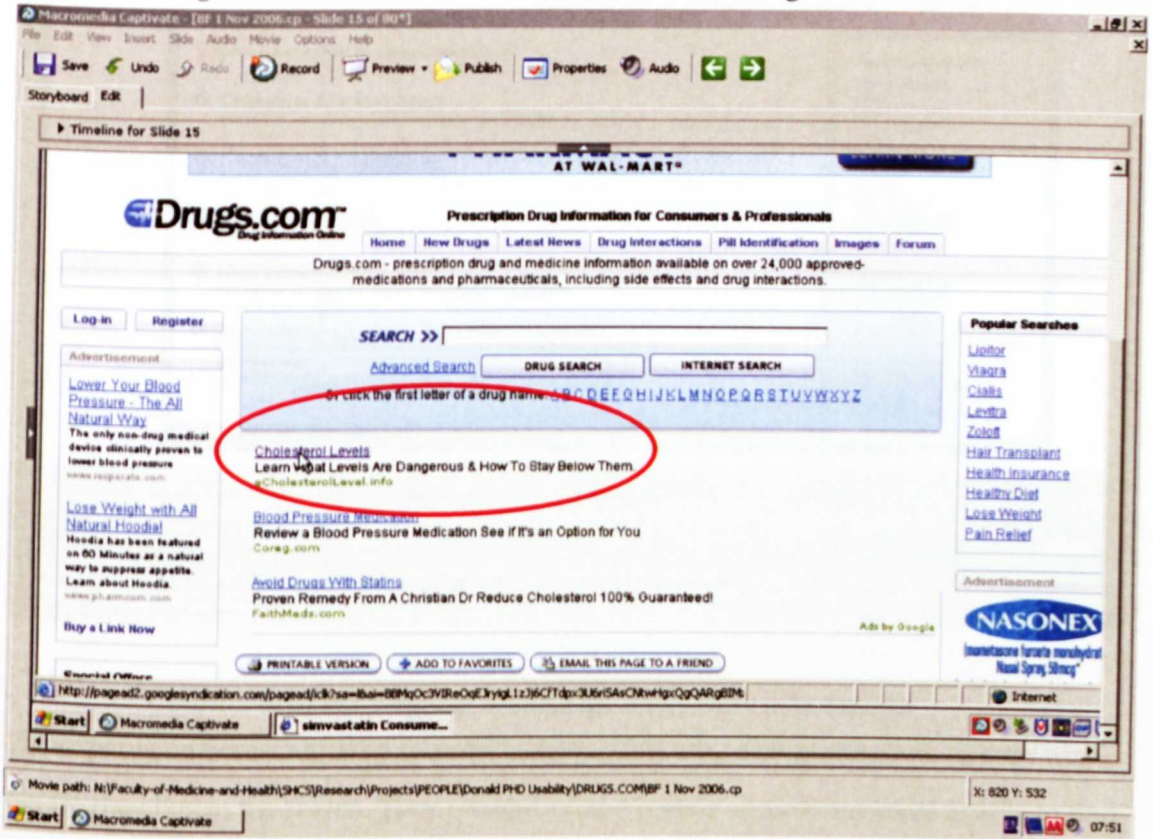
Several participants who were unable to find the indicative information were prepared to use a search engine, for example: *"Just wondering whether to look in a general, put the name into a search engine again, and try to find something a bit more...."* (Participant #2, *RxList*).

Some features could have impacted positively on participants' search strategies: for example, a table of contents containing hyperlinks. But when they were available, these were rarely noticed (see Figure 15), and participants commonly did not use them.

Unable to find the indicative information to answer the final question, a participant using the *Drugs.Com* site clicked control F to use the 'find' search function, typing 'pregnancy'. However, the site only had the word 'pregnant' so 'pregnancy' was not recognised. Put off by this, he was prepared to search on another website.

Figure 13: External page from activation of link on the *Drugs.com* site
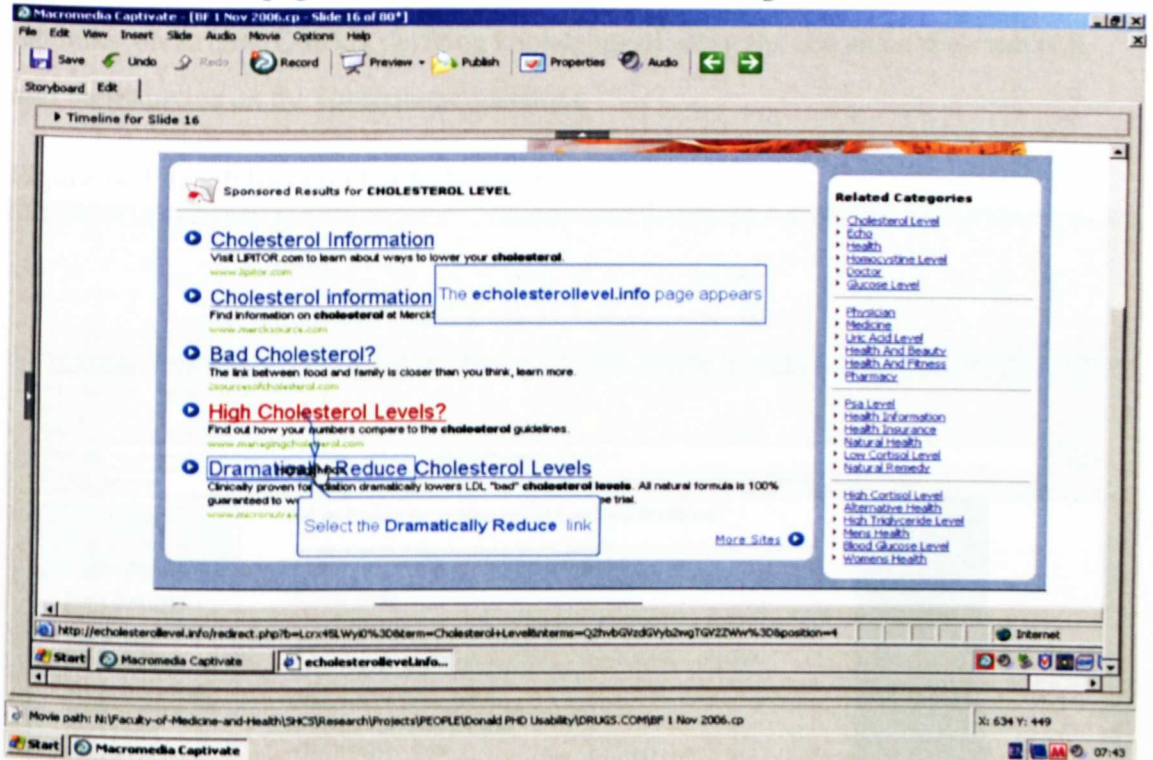
Conflict between personal knowledge and online information

Participants on occasions were recorded saying what they thought that the answer was before they began the search. They recognised the correct answer but were unable to find it online, highlighting a mismatch between site content and the individual's prior knowledge and expectations, which may have made it difficult to find the indicative information. Examples of this are in Figure 16. When answering the question 'Why should you use *simvastatin?*' a participant clicked *'What is simvastatin for?'* on the table of contents on the *Medicines Guide* site, but did not find the answer there. These examples highlight the discord between the information online and the user's knowledge and resulted in failure to find the information.

5.6.3. Reasons for finding and understanding the information

Learning

Most participants quickly got used to navigating the site, and were usually able to find the information after the second question. At the point of navigating the site for a few questions, participants may have recognised where to find the answer, and become

accustomed to certain design features for locating the information (for example, the 'file tab links' on *RxList*). Quickly deriving knowledge of using the site aided their use of it, and their success on the subsequent questions.

Figure 14: File tab links on the *RxList* site
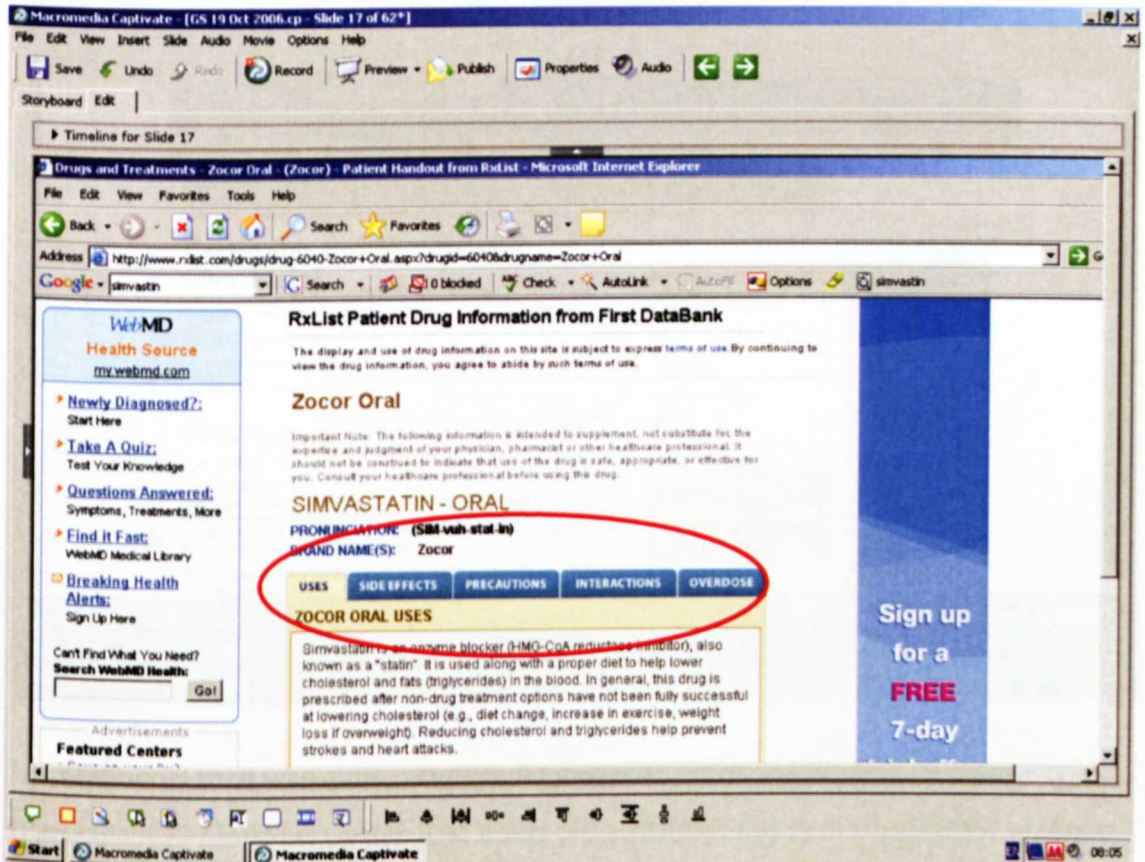
5.6.4. Did participants trust the information?

Following the completion of the User Test, participants were asked whether or not they felt the information was trustworthy.

Reasons for trust

More participants said they felt the information was trustworthy than not. The appearance of the site was important: for example, *"It's just the way that it's presented and the form that it's presented, it does seem to be well researched"* (Participant #6, *Medicines Guide*). The name of the site was important too. For example: *"Mayo Clinic, I would take notice of that; yeah, yup"* (Participant #12, *Mayo Clinic*). Another person using this site showed similar trust:

"I can't see a site called Mayo Clinic.com err being able to put up a website like this without it being, erm, correct. … I'd have to take it that that is a site that looks as if it hasn't been made in the bedroom" (Participant #16, *Mayo Clinic*).

Figure 15: Example of a missed table of contents on the *MayoClinic* site
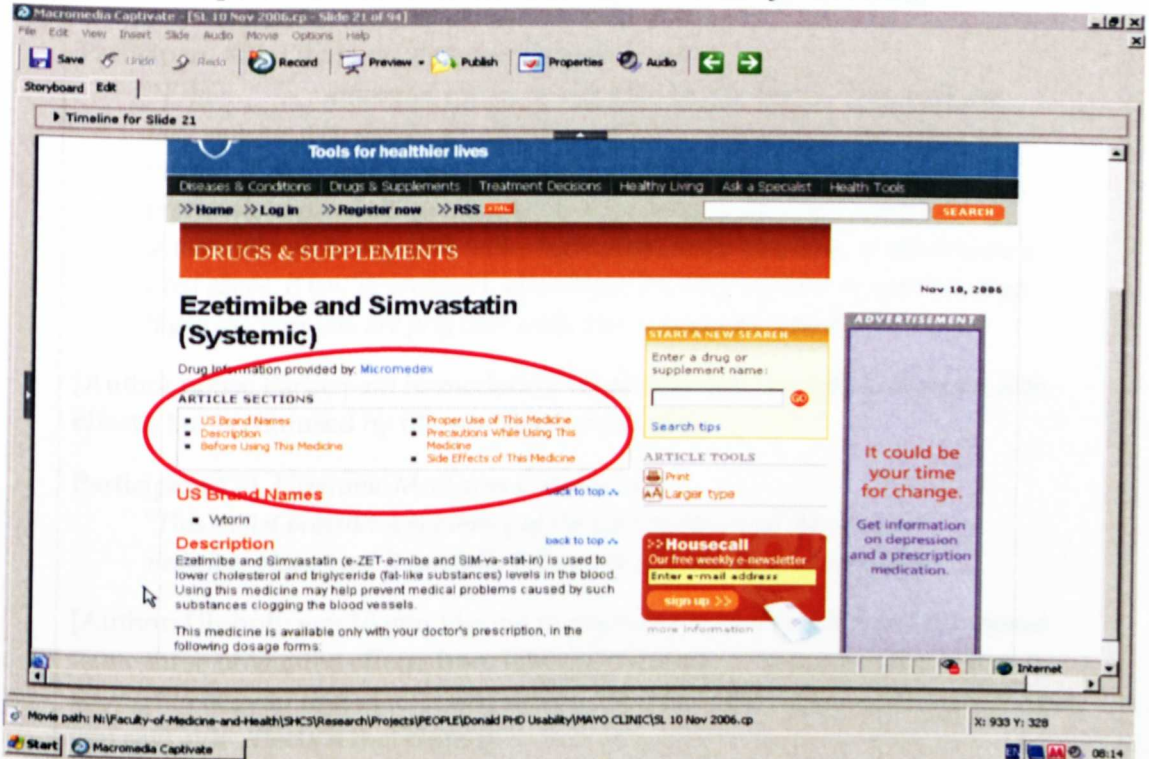
Unconditional trust was quite common: for example, *"Huh; you've got to trust somebody"* (Participant #3 *Medicines Guide*). And it was felt a site could be both trustworthy and not, depending on who found it:

> *"I'd trust this information on this screen if it were prescribed by the doctor… If I found it by myself, I wouldn't trust it, nuuh; I would check it out"* (Participant 7, *Electronic Medicines Compendium*).

Figure 17 highlights two examples where the same site was both trusted and not. Sites developed by healthcare organisations would be trusted by the participants: *"If I've got to take this tablet, I would like to, erm, go onto a website and check that that medicine is on a website like NHS direct, or Mayo Clinic"* (Participant #7, *Electronic Medicines Compendium*). However, lying behind this point may be a contradiction: while participants said they would trust *NHS Direct*, only one person used the site for the search task.

Figure 16: Examples of the conflict between personal knowledge and online information

Example one:

Author: "Please name three unwanted effects from taking simvastatin"

Participant #10, *Electronic Medicines Compendium*:

"Erm, ...unwanted effects, so this must be side effects. Erm, well, are they patients who should not take these tablets? Erm, well; if, erm, there's a number of cases here where people are not to take them. People who have previously suffered allergic reaction to a medicine containing simvastatin. If you are allergic to any of the other ingredients in the medicine, of which there's a list above; if you're pregnant, planning to become pregnant or breast feeding. If you discover you are pregnant while taking simvador which is..."

[Author notes: Participant immediately recognises this is a question about side effects, but is confused by the wording on the site].

Participant #10, *Electronic Medicines Compendium*:

"This leaflet provides a summary of the information available on your medicine; please read it carefully before you start to take your medicine."

[Author: Uh-huh; would you like me to remind you of the question? It's please name three unwanted effects from taking simvastatin. I think you were, you seemed to be; you first of all when you had started, I think you were correct when you said side effects if that helps?]

Participant #10, *Electronic Medicines Compendium*:

"Ah so it's really about side effects and not erm, reasons not to take. Right erm, ... this could possibly be it ... you should check with your doctor before, ... ah no that's before, not after. You have unexplained muscle pain, tenderness or weakness. Is this what we're referring to here? This list? ... ...It does, well if it is, it seems to be before, in which case it is badly worded. So it's not an after ... If this is a side effect, it should have been worded 'after taking these tablets', not 'before taking these tablets'"

Example two:

Author: "Name me two things you can do to improve your health while taking simvastatin"

Participant #5 *Drugs.com*:

"... It doesn't seem to say whether, what say, you should have lifestyle changes or anything like that; although it does say where I can get more information, but it just says your pharmacist. I was expecting it to say lifestyle changes somewhere; ... changing your diet, whatever. But it doesn't seem to; it may just be me ... it tells you what you should avoid, the alcohol; but I was expecting it to have something about exercise, and something like changing your diet, but there's nothing that I can see; ... 'cause we've all heard what

> you're supposed to do to lower your cholesterol, and I can't see it anywhere. ...
> Maybe it's just me! (Laughs)".

[Author redirects her to answer on the page].

Participant #5 *Drugs.com*:
> "Aaah; well it's not very obvious! It's on a very; ... it's under how should I
> take simvastatin. Now if it were me, I wouldn't put it there. I'd have put it on
> it's, err, you know; a low fat, low cholesterol diet in a box on its own, because I
> actually felt I didn't see that scrolling up and down."

Figure 17: Example of trust and distrust of the same site

Example one:
Author draws the participant's attention to the date the *Electronic Medicines Compendium* was last revised as a quality marker (last updated in June 2003). "Now that you've seen it was last updated in 2003, does that change your thoughts about it?"

Participant #13, *Electronic Medicines Compendium*:
> "Okay; my assumption is, if there's no any other revision that has taken place.
> I'd only be worried if, let's say, I'm talking about information that is more than
> ten years old. Okay, probably that's when I would; probably but if it's three
> years old, like; probably there isn't going to be much change since then. But I
> am sure this is the date it become effective, isn't it? Okay, so it means this
> information is effective from; okay say it is useful from June 2003 up to now so
> for me I would still be comfortable with it, yeah. But probably if it is ten years
> old or say maybe, ...there some other website with more updated information,
> okay but then I would believe that honestly, okay, the people that run the
> Internet that are responsible for manning it and posting this information; they
> should actually be aware of this, probably take out the information that they
> know"

Example two:
Author: "This leaflet was last updated in June 2003. Is that at all important to you?

Participant #10, *Electronic Medicines Compendium*:
> "Well yes I would have imagined they would have erm, revised it a bit more
> recently than that. This is obviously an old ... this is old information, isn't it?
> There must have been something more up-to-date than this?"

Some participants wanted the site to be as up-to-date as possible: for example, *"Oh it says 06/08/05. ... Erm, I think I'd search the medical directory"* (Participant #18, *RxList*). When

asked how recently a site would need to have been updated to be trusted, a participant said:

> "Hard to say but I'd have to at least feel it's been updated in the last three or four months. Though if I was researching something that was very new which was, you know, just come on the market or something; I'd maybe want something a bit closer to hand, a couple of weeks or a month maybe" (Participant 19, Drugs.com).

The last reported update was vague for some:

> "It tells you two things: it tells you there's nothing more been found out about simvastatin since it was updated on the 26th of October 2004; or it could tell you they haven't bothered doing anything about it since the 26th of October 2004" (Participant #17, Medicines Guide).

Pharmaceutical company websites

Participants commonly did not trust the websites linked to industry. For example, it was remarked:

> "Err note from our sponsors; drugs information online. I'd have to take it with a pinch of salt. I tend to think anything sponsored by a drugs company is going to have, err, their own slant on it" (Participant 19, Drugs.com).

This was reflected in another comment:

> "Err; RxList the Internet drug use index. Who produces it? That's what my question would be. It's from First Data Bank. I would go onto First Data Bank and found out who it is, and I would look at a few other drugs just to see what else they do" (Participant #18, RxList).

The objectivity of the sites was questioned: *"you're taking the word of the, err, manufacturer on his product; which he could be, he can be biased, can't he?"* (Participant #7, Electronic Medicines Compendium); and:

> "I suppose if you were cynical you could say the drugs company would want you to take their drug, and therefore they would not put in a lot of things that they think that might stop you taking it" (Participant #11, Drugs.com).

This mistrust extended to advertising:

> "Because if you look at the top, it's talking about breast cancer (the top banner says: 'breast cancer: dispel the myths) so you're looking at all this and I'm trying to think is this a drugs company site or what is it?" (Participant #11, Drugs.com).

Lay user assessment of trust

When asked if they thought the sites were trustworthy, participants were often unaware of how to assess this: for example, *"How long is a piece of string?!! Well I wouldn't know whether it is trustworthy or not"* (Participant #17, *Medicines Guide*). Instead they spoke of ways to assess trust which did not correspond with recommended methods for assessing the reliability of the websites (see Figure 18).

Some participants were wary of trusting a US developed site. One asked:

> *"Is it an American site?" (Speaking about the Mayo Clinic website).* [Author – It is] *"Is that why it comes out, err, err; is that why it's erm, designed that way?"* [Author – I don't know. I don't think that would.] (Participant #1, *Mayo Clinic*).

Another offered:

> *"Mayo Clinic, I would take notice of that; yeah, yup. If I was really seriously wanting information, from there, then I would also cross-reference it with something like British Medical thing-a-me-bob, because the American and the Brits may have a slightly different opinion"* (Participant #12, *Mayo Clinic*).

The failure to recognise quality assessment seals

Medicine takers appeared naïve to 'recommended' quality assessment tools, in particular the *Health on the Net Code of Conduct (HONcode)* seal. For example, on being shown the *HONcode* emblem, a participant remarked:

> *"No I didn't notice it; I haven't heard of it. Is it just specifically for websites then? ... Aaah! And that's so to speak a kite mark symbol to say this is a fairly reliable, trustworthy site... Actually well that's kind of reassuring then, but I've not heard of that"* (Participant #11, *Drugs.com*).

Another participant said:

> *"What's that HoNcode thing, I've never seen before? ... Health on the Net, HoN? That's Health on the Net presumably? And the HoNcode is some sort of thing they've signed up for... Ah that would be something I've learned today then. Yes to look at the whole website and see what the HoNcode things is!"* (Participant 19, *Drugs.com*).

While this was novel to the participants, they immediately appreciated it:

> *"I, I see that it's accredited to the some sort of H-O-N, I suppose that means honours code, I don't know; but I'd haven't a clue what that meant... unless I clicked on it ... I think it does give it utmost respect... It tells you that somebody whose erm, drawn up some sort of code of conduct, has checked this information and this site complies to the*

Code of Conduct that's been strictly set up by some medical foundation in America presumably" (Participant #16, Mayo Clinic).

Figure 18: Examples of lay user methods for assessing trust

- **Cross-referencing**

Participant #6, Medicines Guide

> "If I were looking for information, I wouldn't just take it from this site; I'd probably go to another one as well and just compare the level of information ....that each one provides. If I found that this one gave me more information or that the information provided was, was better then, you know, maybe two or three others that I've tried, then I'll probably come back to this one"

- **Site appearance**

Participant #16, Mayo Clinic

> "It looks very professional; lots of links, lots of information..."

Participant #18, RxList

> "Err, sometimes you can tell just by the way it's written"

Participant #7, Electronic Medicines Compendium

> "You can generally tell, erm, well, well if you stray off the reputable websites; you're going to get yourself into a load of quacks who're selling all sorts of wonderful remedies... Like the left leg of a toad and all that stuff enhanced my life amazingly".

- **Site ranking**

Participant #16, Mayo Clinic:

> "Err the only thing I'd ask about the site is if it's on the top ten of the search ... Because to scroll through one hundred recommended sites for information; if it's down at number 50 or 60, it's not going to get used as much as if it's up near the top".

[Author – So you would trust one that's used very often?]

Participant #16, Mayo Clinic:

> "I would trust that, yeah"

Information from health professional

Participants would check the information with a healthcare provider to determine if it was trustworthy:

> "Erm, the only way that someone who is not a medic would know whether it is trustworthy is sort of getting a reaction from somebody, a doctor. Going to a doctor and saying 'I've been advised by such and such a website that this is the case; is this correct?' If the doctor said this was right, I would have an indication this is trustworthy; but not, not from my own, erm knowledge" (Participant #2, RxList).

This cross-referencing of the information went beyond a check mechanism, hinting at the importance of the doctor-patient relationship. Another participant said: *"I'd look at this first, but then I would probably go back and discuss it with her (GP)"* (Participant #5, Drugs.com).

5.7. Interview findings

Eleven themes emerged from the interviews and are defined in Table 23 below. For the purpose of the analysis and presentation of the results, exemplars are provided. The themes have been aggregated over the five questions.

Table 23: Themes emerging from the User Test interviews

Emergent themes	Examples
Design features	Liked layout; design features were help or hindrance.
Perceived information wants/needs	Wants more/less information.
Previous experience	Experience aids use of site.
Information content	Talks about the content: side effects or how to take medicine, information relating to the condition and whether it is valued or not.
Information from health professional	Prefer to receive information from GP/Pharmacist.
Paper-based information	Prefers information (or not) from leaflets; compares IBMI to WMI.
Understandable information	Does (or does not) understand the information
Appeal of technology	Novelty of the Internet.
Access to IBMI	Place of access, reasons for current/future access (or not).
Pharmaceutical company websites	Would distrust pharmaceutical company developed website.
Patient/family relevant information	Information relevant to participant or family/friend.

5.7.1. Design features

Whilst some participants commented positively on the usefulness of the site in relation to its design features, most were critical. The points raised about tables of contents (see Figure 19) reflect this well. Some participants felt tables of contents (when noticed) were helpful; but most failed to notice them throughout the task, until directed to them by the author. Several participants felt that making the table more noticeable would benefit site users.

Figure 19: Examples of participants' comments (opinions) on tables of contents

- **A useful feature**

Participant #3, *Medicines Guide*:

> *"I haven't come across one of these (indicating to the table of contents) before and it made it much easier".*

- **A missed feature**

Participant #6, *Medicines Guide*:

> *"... and the colour coordinated menu headings, erm which I didn't realise at first, but once I, I, it occurred to me to use that it did, it was easier searching for things just by scrolling up and down and on the right hand side, just looking for the coloured headings".*

- **Make a more prominent feature**

Participant #11, *Drugs.com*:

> *"Actually looking now I can see, and I would have, I would have just gone back to there (indicating to the table of contents) ... maybe if that had been a little bit more bold, I might have picked that out sooner".*

Participant #6, *Medicines Guide*.

> *"... you could probably make these a bit more like hyperlink (indicating to the links on the table of contents). I know that you get like a little pointer there when your cursor over it, err, but possibly if it underlined and you know that you are actually clicking on that line, and just things like that. ... And as I said earlier, probably open up a new window when you do".*

The layout of the site and the white space (absence of text) aided navigation for some participants: for example,

> *"I like the idea of two blank bits down the side. I like this idea of space here because it doesn't, it's not all information in your face right across the A4 piece of paper ... If you*

have a big block and you read it all, sometimes it doesn't all go in" (Participant #16, *Mayo Clinic*).

This was reflected by the comments of a participant who, having navigated the *Drugs.com* site, preferred the lower half of the page below the initial screen shot, which was free of the clutter of hyperlinks which dominated the top half:

> *"That's a good, the second half of that page is good in, once you get beyond the top of it, it does just actually simply tell you stuff. That's why, not being distracted by the pictures, you're just being told stuff"* (Participant 19, *Drugs.com*).

Although a printer-friendly option was rarely noticed, when participants were shown it, most valued it. The notion arose of being able to print facilitating empowerment. For example, a participant considered printing out the information to show her husband's GP:

> *"Erm, if I thought there was something affecting my husband's health that I thought this drug might ... be affecting his health; I would print this off to take into the GP as I have done before with things"* (Participant #17, *Medicines Guide*).

There was a wish for symbols or pictures on the sites, and the lack of pictures in particular was noted. For example, a participant who had initially queried the lack of pictures on the site, when shown a picture of the medicine at the bottom of the website page, responded:

> *"Yeah; hmmm. I would have thought that would have been better up at the top ... if you had it at the top, err you would see it there and you would, you might also click on the link. Whereas there, as it's set up, you wouldn't necessarily get down as far as that; scroll down to the bottom of the page ... because you might think it's another drug, unrelated drug"* (Participant #8, *RxList*).

The search bar was unnecessary for completing the tasks as all indicative information was on the site. But there was a desire for a search bar similar to the 'find' function (Control F) to help users locate information:

> *"It would have been great to have had a search on it where we could put in the word pregnant. Because in a sense you were asking basic questions so I could have had one that said forbidden foods, another could have said side effects; and it just would have done them out in point form. That would have made it easier... there are most probably what, a hundred key words on the site. So you could put pregnancy or pregnant and if you click that, it would just come up 'do not take it if pregnant'. That would make it easier."* (Participant #18, *RxList*).

5.7.2. Perceived information needs

Some participants did not want too many options on the site. For example:

> *"I don't want to be going back and making it larger when I want to look the*
> *information up. I don't want to be sorting out the print. Next you'll be telling me if I*
> *want it italic, an this an t'other. All I'm interested in is finding out what this drug*
> *does"* (Participant #1, *Mayo Clinic*). For this participant the content of the site
> was what mattered; not its design features.

The amount of content was important, and some participants did not want too much:

> *"Sometimes to just find the one thing you want, there is a massive amount of*
> *information and it's not always easy just to find two or three facts when finding fifty*
> *thousand others ... I sometimes think you can have information overload"*
> (Participant #11, *Drugs.com*).

The amount of content would become a problem if the medicine user took multiple drugs:

> *"It's only two pages isn't it, so it's ... I mean, I take, I take err, a number of drugs err;*
> *...and I'm slightly asthmatic and I also take four different, erm, drugs for epilepsy, to*
> *prevent epilepsy...I don't read them every time, but I, I read them occasionally"*
> (Participant #10, *Electronic Medicines Compendium*).

This highlights two important points: the potential negative accumulative effect of
information for various medicines; and the value of concise information.

The interactive nature of IBMI appealed to the information needs of participants:

> *"Maybe there should be links to other sites ... Or even a blog. Because the other thing*
> *is; is there any way to come back to this? ... Is there any way you can actually say to*
> *them, look I'm taking simvastatin and this is happening to me; am I mad?"*
> (Participant #18, *RxList*).

Participants spoke of a need for balanced information, relating this to concerns about the

potential for information to provoke worry:

> *"It's sort of a balance between you ought to be aware of it, and then some people*
> *become walking encyclopaedias ... they become nothing but ... how many side effects*
> *they might have, and this, that, and the other. And I'm trying to sort of find a balance*
> *... And when you go on the Internet, you have everything that is, erm; very serious*
> *and very rare!"* (Participant #12, *Mayo Clinic*).

For others, information was empowering; providing a balance in the doctor-patient

relationship:

"I'm not a cyberchondriac or anything like that ... but, I'm going to check up on all of that ... Oh doctors are getting plagued by them now. (laughs). You see, a GP knows a little about a lot, so a guy comes in who's got a specific complaint; he's learned up on it on the web, hasn't he? He knows more about it than the doctor does. And he's telling the doctor what treatment he should be getting! (Laughs) It can be a bit of a national phenomenon really; but they've tagged it cyberchondriacs" (Participant #7, Electronic Medicines Compendium).

Medicine users might be prompted by an item on television programs to seek further information about medicines:

"Let's use 'This Morning', let's say. If they had something it tends to be if they had something about health and I haven't heard it properly and I want to go on it, then I click a bit like that" (Participant #12, Mayo Clinic).

5.7.3. Previous experience

The ease of use of the site was determined in part by participants' previous experience of Internet use. A participant who considered himself a novice felt the site was easy to use:

"Somebody who's experienced with a computer should handle that no problem, and err, as I say; I haven't been on computers long, so I got that easy enough, didn't I?" (Participant #7, Electronic Medicines Compendium).

Participants' intention to access IBMI in the future was also related to previous experience of using the Internet, with one in particular put off accessing IBMI because her PC was inadequate: *"I mean my computer is a bit like the cart and horse! It's quicker to drive down to the chemist than to go on the Internet. (Laughs)"* (Participant #12, Mayo Clinic).

5.7.4. Information content

Participants considered IBMI useful if there was specific information about medicines. For example:

"... it told you why you were taking the medicine; what possible side effects which is what would be useful to me, erm, ...an just helpful things about, you know changing your lifestyle and ... improve your health and your cholesterol; things like that" (Participant #6, Medicines Guide).

Accessing the Internet would also be useful for condition-specific material and information about alternative treatments.

Participants would be put off by sites with commercial interests, and some would look for information elsewhere on the Internet for a more balanced perspective of the pros and cons of taking the medicine. For example, it was offered:

"If there is any, erm ... a discussion group ... So I'm getting a different perspective from the, from the company that make this. They say, oh it's quite safe. These are the possible side effects, full stop; but when you go on a, on a website that says, this is what is happening to people that are taking it and we feel there is not enough research being done into it, that's something I look for as well. It gives a different perspective from the manufacturer... So I'd look for something that, erm, doesn't appear to be linked to the product in any way but they're just giving, you know, information about that, err, particular product" (Participant #6, *Medicines Guide*).

5.7.5. Information from health professional

It was felt IBMI would be useful when medicine users wanted more information and could not talk to their GP. But rather than just balancing perceived gaps in GPs' knowledge, IBMI was seen as offering medicine users the opportunity to study information before a hospital or GP appointment:

"I've just had an operation and before I went into hospital I was err, messing around on the Internet and looking at all sorts of things to do with it ... printing stuff off and also giving me something for when I went to the clinic; something to sort of talk about and ask questions about, whereas you know, if I hadn't used the Internet, for that, I wouldn't have thought of certain questions, and you know, doctors don't always remember to tell you everything (laughs). 'Cause I do like to know about things beforehand" (Participant #8, *RxList*).

All things said; while IBMI was valued as an additional source of information, it would not replace a doctor's advice: *"But at the end of the day, erm I would have to trust my doctor to give me, you know the ultimate advice on any condition"* (Participant #2, *RxList*).

5.7.6. Leaflet-based information

For some participants, IBMI was felt to be more useful than leaflet-based information. For example:

"It's easier to read than the little slip you get inside the pack which is in tiny writing and several different languages; and it takes forever to get through the English bits, and then it's all full off 'talk to your GP about this, talk to your GP about that'; it doesn't go into detail, which this site does. There is more detail in this than there is on the pack inserts" (Participant #5, *Drugs.com*).

IBMI convenience was valued, compared to print information:

> "*If you just wanted to know 'oh gosh how many am I supposed to take today' and you could just go to like an index or something and click on something and it brought you to that bit, then that would probably be as quick as finding the information in a book ... you can go to another site perhaps if that site didn't answer your question ... On the whole this is better for getting more information definitely, because if you have a question on the book, it's not going to be answered probably*" (Participant #11, *Drugs.com*).

Some participants still preferred paper-based materials:

> "*You can have a booklet in your bedside cabinet and you can pick it up and look at a page if you want to... when you have got a booklet and somebody tells you you've got some disease, you can actually, your family worry, so you can actually give them the booklet that's been given to you that's specific to the type of illness you have*" (Participant #11, *Drugs.com*).

5.7.7. Understandable information

Medicine users valued IBMI content for being understandable. For example: "*Well it's, it's basic and down-to-earth, which is what you want. It, it tells you what you want simply and clearly; ... the idiot's guide to simvastatin (laughs)*" (Participant #3, *Medicines Guide*).

Another participant offered:

> "*It was, err, straightforward and it wasn't, it was written in reasonable English. It wasn't written in a way that sort of makes you think what does this mean. It, it's straightforward, it's easy to understand*" (Participant #2, *RxList*).

Having the headings as questions was valued: "*They're (the headings) in as questions which are, erm, questions are more stimulating than simple statements*" (Participant #10, *Electronic Medicines Compendium*).

Although the content was largely felt understandable, some participants were confused, by the word 'hypercholesterolaemia', for example. It was thought a glossary could help in these situations:

> "*There's that bit about the HMV, err, HMC-COA reductor base co-inhibitor; I wouldn't have minded a bit more on that. Like ... like these little green things; what are they called? ... I wouldn't have minded something like that.*" (Participant is referring to the hyperlinks to a glossary). [Author – So are you saying you would have

preferred if those words had, they were maybe defined in a glossary?] "Yeah, yeah"
(Participant 19, *Drugs.com*).

In situations where the medicine user was confused with the wording of the information, they considered they would approach a pharmacist for an explanation.

While it was recognised that IBMI could be beneficial by offering WMI before the medicine was dispensed, it was felt that if the content was not understood, these benefits would disappear:

> *"it's okay having it (IBMI access) in a GPs surgery, but erm, if you can't even understand it in your GPs surgery, so he's gonna take up more time talking to you through this thing what he's got on his screen, and at the end of it you're not going to be able to say to your GP, well you couldn't print me off a copy of that, could you?"*
> (Participant #1, *Mayo Clinic*).

Information may not be intrinsically easy to understand for medicine users, but participants felt it had to be so from necessity:

> *"... because after you have what they call 'an event', or a myocardial infarct which I had, you have to assume, you become nearly PhD level in cardiac affair ... because they drive you mad, and if you don't understand it you don't survive ... Strange thing"*
> (Participant #18, *RxList*).

5.7.8. Appeal of technology

Some participants found modern technology appealing, and so would access IBMI in the future: *"Yeah I think it's just, it's the thing today, isn't it? It's what most people do; use the Internet for anything and everything really"* (Participant #8, RxList). The ability to purchase medicines via the Internet made IBMI all the more important:

> *"You can even order; you can even order prescription drugs off the Internet from other countries, so if you do that and you miss out your doctor, you certainly need to know what you're doing in terms of the information about that drug"* (Participant #16, *Mayo Clinic*).

5.7.9. Access to IBMI

Accessibility was regularly discussed. It was felt that IBMI should be available during the consultation:

> *"That would be great you know, having my GP looking it up ... like side effects, right, this-that, and he's got it all lying in front of ya, and a can, a can just turn round and say can a have a copy of that?"* (Participant #1, *Mayo Clinic*).

A similar point was made about the want for access to IBMI in a pharmacy before the prescription was dispensed.

Some, though not all, older participants spoke of how they actively use the Internet:

"I think I'm one of these 'silver surfers' ... The majority of people now who have retired use the Internet ... I've used it about nine years ... I got it about ten years, and I've always found it a great aid for all sorts of things" (Participant #17, *Medicines Guide*).

Not everyone would want to immediately access IBMI after a diagnosis. Some spoke of needing time to come to terms with illness first:

"I think at the time you go away if you're told something if it's a serious sort of illness, that you need to get your head round that before you start reading about things; but you would probably come to that later" (Participant #11, *Drugs.com*).

5.7.10. Pharmaceutical company websites

The medicines users were wary of accessing sites selling pharmaceutical products:

"At least this is free of pop-ups or interference or pestering you to buy stuff. I mean that's the other thing I really hate, is the people, they're hassling you all the time to get ten thousand of these tablets from Hong Kong, you know, five pence a piece or whatever" (Participant 19, *Drugs.com*).

The neutrality of pharmaceutical sites was again doubted (see also 5.6.4): *"If the drugs are put on by drugs companies, they have a commercial interest to some extent, haven't they? ... So that would slightly worry me"* (Participant #11, *Drugs.com*).

5.7.11. Patient/family relevant information

Several participants would search for information for themselves or others, explaining they had done this before:

"I have been trying to find a certain amount of information about my brother's illness, 'cause my brother's got a very rare ... erm, degenerative illness ... and I've been looking once or twice to see if I can find anything about that on the computer" (Participant #10, *Electronic Medicines Compendium*).

5.8. Discussion

5.8.1. Review of the main findings from the usability study

This section draws on the findings of the usability studies, relating them to the theoretical base for the study, and previous research.

How did medicine users search for online information about medicines?

The findings solidify understanding of how people search for IBMI. Most participants typed *'simvastatin'* into a search engine (*Google™* or *Yahoo!™*), because of its familiarity, ease of use, and popularity, which reflects the findings of focus groups (Peterson *et al.*, 2003). Furthermore, only one participant searched using the *NHS Direct* site, reflecting a previous finding that people searching for information generally do not use medical portals (Eysenbach and Köhler, 2002). Medical portals, including *NHS Direct*, appear to remain an under accessed resource for searching for information about medicines, in comparison with the prominent use of popular search engines by the general public. Further research should examine the determinants and barriers of access to medical portals for search purposes.

One participant typed more than the name of the medicine alone, specifying *'simvastatin – drug for cholesterol'*; the other 14 typed only the medicine name. This reflects what participants said in a focus group when asked how they searched for IBMI (Peterson *et al.*, 2003). No-one in the present study looked beyond the first page of links on a search engine, which Eysenbach and Köhler (2002) and Peterson *et al.* (2003) have similarly found.

The findings in this study do not reflect the finding of Toms and Latter (2007) (2007) that participants searching for information about medicines opted to specify the search strategy, and looked at an average of 5.4 pages. This may reflect the demographics of the participants in Toms and Latter's (2007) study: 71% were 21-35 years of age, and 50% were students. The students may have had better search skills, and therefore opened more pages. It may also reflect a difference in the task demands and instructions given to the participants. Nevertheless, the fact that the participants in the study reported in this chapter did not look beyond the first pages of links suggests that many IBMI sites may be potentially redundant, depending on how they are ranked (see 1.3.2), if few people access them.

Toms and Latter (2007) also found that participants made three considerations when opening a website:

(i) If the information met their expectations;

(ii) An assessment of the quality of the information; and

(iii) If the information was understandable.

Comparing this to the present study, participants reported assessing the quality of the information, and said whether or not the information appeared to be understandable was a reason for their opening the link. Some spoke vaguely about the information meeting their expectations, (although they were not asked this). For example, one participant saw a mention of side effects, and said she first wanted to know about the actions of taking the medicine.

Participants were not asked at this point in the study to make an assessment of the site they had opened – this may have primed them for being asked about the assessment of trustworthiness of the site they used for the User Test. Still in some cases participants appeared to have assessed the quality of the sites when they were asked how they searched for the information. Most participants spent little time searching before opening a link, and appeared to give little or no consideration to accessing the quality of the site. No participant used a recommended approach for assessing quality. Instead untested methods were employed, trusting sites with 'official appearance', for example, and relying on previous experience. Participants saw the site for a short period of time, (at most a couple of minutes), so they may have used heuristics based on visual appeal to make the short-term decisions about the trust of such sites, as predicted by the stage model of trust for Web-based Health Advice (Sillence *et al.*, 2006). The most commonly accessed site, labelled '*Simvastatin – A Patient's Guide*', appealed to medicine users because it featured the word '*Patient*' in the title, therefore distinguishing the information from that for doctors, and giving medicine users the impression that the information would be understandable to them.

What influenced medicine users finding the IBMI sites easy to use?

The analysis indicated that sites with a mass of text and hyperlinks were difficult to navigate. For example, sites with a clutter of hyperlinks were not easily navigated at the beginning of the task, suggesting that participants were distracted by the links. The stage model of trust (Sillence *et al.*, 2006) predicts users will exit sites with a cluttered homepage. This was not an option for participants in this study as they looked at only one specific site; and so the findings of this study cannot corroborate this.

Participants sometimes struggled to find information that they anticipated was the answer to the User Test question. The problem was not participants' knowledge, because their answer (expressed via verbal protocols) was more often than not correct. Rather the barrier was that the information on the site did not match their knowledge and expectations. Had this been better written to reflect users' knowledge, they may have found it. The Information Resources Model (Wright *et al.*, 2000) would suggest that the problem lies not with the user, but with the site. Therefore the content needs to be written to reflect users' knowledge and expectations. This could make locating the information easier for the user.

The three participants who used the *Electronic Medicines Compendium* site, on which information was available as a PDF, appeared to have little difficulty using it. Nielsen (2003) recommends that PDFs should not be used for online reading because they can be less easy to read than an HTML page, and so should only be printed off. It is unclear why participants in this study were able to navigate the PDF with little difficulty. This may have been because it was only two pages in length; or it may be that the participants (older adults) were better able to navigate PDFs, which do not have distracting links or pop-ups.

Did medicine users find IBMI understandable?

The majority of participants adequately explained the information suggesting they understood it. These scores were consistent across all sites, except the *Mayo Clinic* site, where participants correctly explained the answers slightly less often. The purpose of this study was not to compare results between sites, but to aggregate them. Doing so found

common examples where the sites as a whole did not convey the information in a way that was understandable: for example, only one third of participants understood the information about what to do if they experienced muscle pain (a possibly fatal side effect of *simvastatin*). For example, the sites may not be useful for the person seeking to become better informed about medicines.

Participants' comments about the understandability of the information were largely favourable (despite the difficulties), other than for the use of medical terms. Information was considered useful because it explained why to take the medicine and its benefits, side effects from taking it, and condition based information. The last topic is particularly valued in leaflet-based WMI by medicine users (Raynor *et al.*, 2007a); as is the importance of having expert knowledge about conditions (Raynor *et al.*, 2004). Few people reported difficulties with the language used.

Medicine takers valued IBMI because they perceived that it explained information that GPs did not provide clearly, and that it filled gaps in GPs' knowledge. For some people, IBMI may have an empowering element in preparation for a GP's appointment, reflecting Dixon-Woods' (2001) analysis of discourses in provision of patient information, whereby information is useful when it empowers the patient.

Participants spoke of the information in relation to the medicine user's emotional state. Some felt that the presence of too much information could lead to undue worry. However, this is not to suggest the information was not wanted by them. Raynor *et al.* (2007a) have argued that WMI may provoke anxiety, and medicine users want for WMI, are separate matters. Others valued information for helping them to find out if they had genuine side effects as opposed to irrational fears about their health.

How did medicine users assess the trustworthiness of IBMI?

Shon and Musen (1999) have labelled sites that have the *HoNcode* seal to be 'HONoured'. Participants in the usability study did not recognise 'HONoured' sites; i.e. they failed to notice when the sites displayed the *HoNcode* seal. If this finding is a reflection on the general public, this seal for quality assurance may be under utilised. However, the trust

that people have for such websites may not be adversely affected if they fail to recognise the seal. This view is suggested because Shon *et al.* (2000) found no significant difference in their participants' perception of the credibility of information on a website based on whether or not it featured a fictitious logo stating approval from an invented physician organisation.

Breckons *et al.* (2008) compared the performance of different instruments for evaluating the quality of websites with information about complementary medicines, and found that the *HONcode* did not correspond with other tools' ranking of site quality. If the *HONcode* does assess quality in a different way to other tools, people's failure to recognise the seal may not be so much of a problem.

The participants were on-the-whole aware of the need to assess the trustworthiness of the sites. However, the methods they described for assessing trust did not reflect recommended ways for assessing the quality of a website (see 1.3.6). Some participants said they would give unconditional trust to whatever site they found. This may be considered risky if the information is not accurate, and it could have potentially dangerous consequences for the health and well-being of these participants if they act on it.

Other participants spoke about websites that were 'reputable'. This can suggest that the appearance of the website is an important factor in determining whether or not it is trusted. For example, Peterson-Clark has noted that both pharmacists and the general public consider 'professionalism' to indicate if a site is of good quality (Savage, 2008). When participants in the usability study perceived a site to have a commercial interest, they considered this to indicate it was not trust worthy. For example, they spoke of distrust for industry related websites, and some extended this view to sites with advertising. This reflects comments made by medicines users in the study by Peterson *et al.* (2003); and GPs and pharmacists by McCaw *et al.* (2007).

Several participants spoke of wanting to cross-reference the information with other sites. Adams (2006b) conducted an ethnographic study of 18 web users in the Netherlands, and

noted that they cross-referenced the material they found. She has proposed that people searching for health information (both online and through paper-based resources) construct the reliability of information by cross referencing; therefore 'reliability' is the process whereby information is pieced together from different websites. This is an important proposition, but the method may be insufficient to gauge trust. It is not inconceivable that individuals could consistently find material that is not trustworthy and, if they follow Adams assertion, they may erroneously conclude that the information is reliable. This thesis contends that cross-referencing information to make a judgement on its trustworthiness, or quality, is not enough: those accessing IBMI need to be able to judge the absolute trustworthiness or quality of a site.

Participants trusted a site because of its professional appearance and recognisable name. This suggests they adopted a heuristic approach, i.e. using cognitive shortcuts to analyse trust, and again reflects the model of Sillence *et al.* (2006) for understanding how people trust e-health websites.

Would medicine users access IBMI again?

Respondents said they would access IBMI again to expand on information not given by GPs, reflecting a finding that Dutch patients searching the Internet for information about pain control do so because they have a need for additional information (de Boer *et al.*, 2007). Participants said they wanted access to IBMI in a GP surgery or a pharmacy. Reservations about promotional IBMI would prompt medicine users to consider looking to discussion sites to get other medicine users' perspectives, for information about side effects, for example. Medicine users said they would access IBMI for specific content (for example, content-based information), reflecting a finding of the focus groups reported in Chapter three. While IBMI appealed to many participants, they would give greater weight to their GP's advice. Conducting a focus group to gauge patients' opinions about e-health websites, Stevenson *et al.* (2007) have proposed that the Internet offers a means for reinforcing the doctor-patient relationship. The findings of the study reported in this chapter lend weight to a common observation that the advice of GPs remains paramount

over WMI. IBMI will not replace it, but it can be a useful additional source of information; expanding on information or offering a second opinion.

5.8.2. Strengths and limitations of the study

Search task and User Test

These tasks had limitations, some noted by the participants in their interviews. Some may have treated the search task as a time test, therefore biasing their results. This was not its aim, nor were they given this instruction.

If a participant was unable to find the information, they were directed to the answer by the researcher, (for the reason explained in 5.3.4); and so it can be considered that these participants' User Test results were to some extent a product of the participant-observer interaction. Kaufman *et al.* (2003) have noted that researchers in usability studies are also participants, interacting with the 'real participants'. Tweddle *et al.* (2000) used this approach in a similar usability study of a website with information about cancer healthcare.

It was explained in 5.3.4 that there were practical reasons for the researcher to sit beside the participants. However, this could have been distracting, and it may have been better for the researcher to have left the room, leaving participants alone to have conducted the search unaided. Had this happened, several participants may have struggled to have found an appropriate site. Participants could have been given a set time for the task, so they could have accessed any number of sites (and perhaps compared them for trust). This could have provided an improved insight into whether or not participants disengage from sites with a clutter of links. Some participants commented that they would have searched differently at home, looking at other sites to cross-reference the trustworthiness, for example. This was not permitted within the study protocol.

The User Test task began immediately after participants were shown the IBMI site. They did not have the opportunity to read through the site first to become accustomed with its layout before being asked to find the indicative information. Prior reading is normally encouraged for a User Test of a PIL. If participants had this opportunity, it would have

given them an advantage with using the IBMI sites and they may have displayed fewer problems than found here. This may tell less about the ease of use of IBMI, which was the purpose of this exercise.

The User Test (deliberately) asked questions in an order that did not match with the information on screen, which participants noted, and felt unnatural. This impacted on participants' navigation of the sites. For example, a participant noted that the User Test task did not reflect how she searched for information normally:

> "I think the thing is when you're coming in cold and you're doing an exercise, you're looking at it almost like an exam paper. If you ... turn your own computer on to look up simvastatin, it's a totally different thing. You're doing it for your own benefit and you're trying to find out as much information ... If I wanted to know about simstatin, I would have started at page one and scrolled right the way through" (Participant #17, Medicines Guide).

The non-sequential order of the questions was necessary. Had the indicative information on the site followed in sequence, it would have probably been less of a challenge for the participants to find it, and would have said less about the ease of use of the site. Nonetheless, most participants displayed confidence navigating the site after the second question, reflected by fewer errors in finding the indicative information. This suggests that they quickly acquired conceptual system knowledge of the site; therefore the site was easy-to-learn.

In the interview, some of the participants said they would have preferred to use a site of their own choice, rather than the site they were assigned to. This was not permitted within the study protocol as participants were randomly allocated to one of the five sites. An alternative method would have been to have purposively allocated participants to a website based on their demographics, so that equal numbers of similar participants were assigned to each website. However, this could only have been done with an *a priori* list of participants. This was not possible because recruitment to the study was concurrent with the running of the study.

Several participants felt the question about IBMI being 'pleasant to use' was an unfamiliar concept. Instead they stressed the seriousness of the information, especially for a person with the condition. It may have been better to have worded the question differently.

Most participants found thinking aloud unnatural, saying that it slowed their performance or that made it difficult to focus. Some found it complicated searching, but they either became used to it, or felt they would after a time: for example,

> "Erm, trying to remember to, to read and talk at the same time and to look for information is quite hard. After a period of time I'm sure it is something you would get used to, but when you're not used to doing something like that" (Participant #8, RxList).

Not all participants felt thinking aloud was difficult. Some had no problem doing this, as it was normal for them: for example, a currently employed sales representative and a retired teacher who referred to talking as a skill he had maintained in retirement.

It is unavoidable that a study conducted under controlled conditions will have less ecological validity, but it was thought essential that the study was conducted in a controlled, rigorous manner, to increase the reliability of the findings. As Ericsson and Simon (1998) have noted; to study covert thinking requires a non-reactive setting where thinking can be reproduced under controlled conditions. The study was considered a low risk situation for participants (even for the five participants currently taking *simvastatin*), presenting no threat to their health and well-being. Participants may then have been less motivated to find the information, making less effort compared to someone prescribed *simvastatin* for the first time, as they were asked to imagine.

The participants

People who are extroverted or who have firm beliefs may be more keen to be interviewed than others (van Teijlingen and Forrest, 2004). This is the problem of self-selection, and it means that the participants in this study are not representative of everyone who uses the Internet and take medicines. However, it is unclear if enrolling such people affected the results. Extroverted people may be no better or worse at navigating websites and completing User Tests than non-extroverts. It would have benefited the study to have

enrolled more people from minority ethnic groups, who may have a poor command of English; therefore making the readability of the information even more important to assess. (However, their level of English may have posed difficulties for running the study).

This study sought to examine the website and information, and not the participant, which are foundations of User Testing and usability testing (see 5.2). However, it could not be discounted that participants' experience and knowledge of medicines, and Internet proficiency, impacted on how easily they could use the sites, and how easily they understood the information. Thus it was not just the design of the website, but also the individual differences between participants that determined how easily they navigated the site and answered the questions. This corresponds with the theory of Distributed Information Resources (Wright *et al.*, 2000) which indicates that it is the interaction between the internal information of the user and the external information of the website that determine how easily it can be navigated and its information understood. Therefore participants' previous knowledge and experience probably impacted on their ability to navigate the site and understand its content. If the ease of use and readability was a product of website design alone, it could be expected that every participant using it would have had the same results when using it. This was not the case and so there is evidence to suggest that individual differences were operating.

The sample of participants was not representative of everyone that accesses IBMI or takes a medicine; this therefore limits the transferability of the study findings. Firstly, the participants were on average 54 years of age. Younger and older people will have different Internet use proficiency, as well as different needs for IBMI. Secondly, the five participants taking *simvastatin* during the trial were able to find and explain on average more information (8.6 and 8.8 respectively), than all participants (7.7 and 8.3). They may have had an advantage when looking for and explaining the indicative information compared to those who were not taking this medicine. To overcome this, an inclusion criterion could have been set for all participants to have either taken *simvastatin* or all not. However, recruiting participants to this study was challenging, and therefore this limit was not set.

Assessing understanding

Participants were asked to explain the information to indicate that they understood it. Understanding and explaining are not easily defined: there is no one accepted account of what an 'explanation' is (Trout, 2002). It is necessary to consider whether participants' explanations were evidence of understanding, or mere paraphrasing of the information. For some of the answers it was sometimes impossible to say anything other than the answer (for example, 'to lower the amount of cholesterol and fats in your blood' to answer the question 'why should you use simvastatin?'); yet in other cases there was greater scope for paraphrasing.

Some participants may have struggled to find the indicative information to answer the questions because they did not understand the questions rather than the website content. In these circumstances, the online information may not have been at fault. (This may be a moot point as no participants asked for clarification of the questions).

Scoring the User Test

When participants did not find the information, they were directed to it, and asked to explain it. However, if someone failed to find the information in everyday life, help may not be available to lead them to the information, and so they could not then understand it. Giving participants who failed to find the information the chance to explain it means the results overestimate understanding. However, an aim of this study was to examine if the IBMI content was understandable. Therefore, it was necessary to give participants the chance to explain the information even when she or he could not find it. The User Test could have been scored for finding alone, or not finding alone. It was considered if help given was reflected in the score, this would give a misleading overall score for finding the information. Therefore scoring was only made for finding alone, or not finding; and a descriptive record was kept of participants requiring support to find the information.

The majority of participants had increased confidence in navigating the site by the third question, evident by their reduced inability to find the information. This was unlikely due to site features, and more likely an effect of the task requirements. Most had by this point

navigated through the whole of the site, and so may have noticed the information often (when scrolling) to recognise where it was. This may have been an effective 'method', because recognition is more effective for retrieving information than recall.

Examining trust

The researcher's interactions with the participants likely biased their judgements of the *HONcode* symbol. For example, participants who did not notice the *HoNcode* symbol, (if it was displayed on the site), were purposively led to it by the researcher, so as to gather their opinions about it. The researcher used different cues at this point, e.g. "does that change your thoughts about it?" and "Is that at all important to you?", and these may have impacted upon the participants' responses, and therefore findings. Furthermore the researcher used the terms quality, trust, and reliability interchangeably on occasions during interviews without a clear rationale for doing so, although they are not the same concepts: see 1.3.6 for separate definitions of quality, trust and reliability. By using one term or other, this will have determined to some extent participants' perception of the question, and shaped their responses. For example, participants on the whole did not recognise the *HON Code* seal, but still spoke of the importance of the websites being trustworthy. This suggests that the 'quality' of a website for consumers does not correspond with its 'trustworthiness'. Therefore using these terms synonymously likely led participants to engage with them in different ways, and so prompt different responses dependent upon what term they were asked about. If this study were to run again, it would be imperative not to repeat this error so as not to introduce error into the findings.

Using Macromedia Captivate ™

Macromedia Captivate ™ tracking of the cursor movements was portrayed as a uniform flow rather than the jittery movements displayed by the participants during the tasks. This was not problematic as the aim of the study was not to perform a fine grain analysis of precise online actions. The programme remained an invaluable tool for keeping an objective record of the participants' online actions and verbal protocols.

This study used psychological methods to examine how participants search for IBMI, and the usability and readability of available IBMI. It was conducted under 'laboratory conditions', which can call into question the validity of the results. This level of stringency was imperative for the study to ensure reliability. Previous focus group work has provided insight into how people search for IBMI. However, dissonance between respondents' comments in the focus groups and their actions cannot be discounted. Therefore by providing robust observational evidence of how medicine users searched for information about medicines, the findings above have reinforced and expanded on the focus group findings.

5.8.3. Implications

The recommendations in Table 24 were produced by identifying the main problems with the sites' design that impacted on the participants using them in the study (see results, 5.6). From these, the author devised one or more recommendations for resolving each problem. The recommendations aim to make IBMI sites as useful as possible for people, by making them easy to navigate them, and their content easy to understand. The recommendations (not in order of importance) are relevant to designers, providers, and researchers of IBMI, as well as medicine users. The recommendations may have particular relevance for sites that have been developed with amateur input: if their developers seek to have an evidence-based design, it may improve the appearance of their sites and persuade more people to access them.

Table 24: Evidence-based recommendations for the design of IBMI sites

Problems and recommendations arising from this study
1. **Tables of content:** when available, participants rarely used table of contents; and often appeared not to notice them. • **Recommendation:** sites could encourage people to use a clearly identifiable table of contents with hyperlinks to different sections on the pages.

2. **Navigating lengthy web pages:** at times participants experienced difficulty in navigating lengthy web pages, and between web pages of several pages.

   - **Recommendation:** sites should ensure that they are designed to be easy to navigate. This could be achieved by enhancing their information architecture, e.g. by the inclusion of left-hand navigation, sub-headings and/or a flow chart; and with the addition of symbols and pictures to make the site more pleasant and easy to use.

3. **Information that is difficult to locate:** at times participants had difficulty locating specific information when the content of the site appeared to not correspond with their knowledge; and some wanted to locate specific information by searching for keywords on a website.

   - **Recommendation:** content should be written to reflect medicine users' expectations about the information available on the site, and be understandable to as many people as possible.

   - **Recommendation:** it may be useful to have headings in the form of questions, or have a frequently asked questions (FAQs) section.

   - **Recommendation:** a 'find bar' may enable locating a keyword/phrase, by reducing cognitive demands when searching, and to make the site appealing to use.

4. **No warning of online consequences:** it was not always clear to the participants when they left a site, or tabbed down a page.

   - **Recommendation:** sites should provide explicit warnings when users leave it or tab down, so that they are aware of their consequences.

5. **Examples of when information was felt to be useful:** some participants felt that the information was useful when it explained why to take the medicine, the benefits and side effects from taking it, and when it provided information about the condition.

   - **Recommendation:** sites should ensure that they provide information explaining

why to take the medicine, the benefits and side effects from taking it, and condition based information.

6. **Clusters of links were distracting**: some participants were distracted by clusters of links on the sites; e.g. accidentally clicking on them, or exiting the site because they were off-putting.

   - **Recommendation**: sites should try to avoid clustering hyperlinks on the homepage, so that users are less distracted and do not accidentally click on one, or exit the site because they are off-putting.

7. **The trustworthiness of sites**: at times participants were largely unaware of how to reliably assess the trust of health websites; and often used untested methods, e.g. gauging trust on the professional appearance of a site.

   - **Recommendation**: sites should aim to ensure that their content is accurate and complete to make it as trustworthy as possible.
   - **Recommendation**: sites that are considered to have a 'professional appearance' are often regarded as trustworthy by users; therefore if sites display features and markers that reinforce this image, they may earn users' trust.

8. **Medicine users' search strategies**: participants did not look beyond the first page of links when searching for a site with information about medicines.

   - **Recommendation**: links on the first few pages (at least) of search engines should be to good quality sites.
   - **Recommendation**: it may be useful for descriptive information about a site on a search page to be written in a way that could reassure the general public: for example, by citing the word 'patient' to indicate that the information is intended for 'the patient'.

9. **The general layout of IBMI sites**: sites with a mass of text and links distracted some users from navigating the pages with ease.

   - **Recommendation**: it may be useful for IBMI sites to avoid cluttered text and

> masses of links, and make pertinent information easily identifiable. This could
>
> make it easier for some medicine users to navigate the pages and find the
>
> information they want.

The findings of this study also have implications for recommended future research, reported in Table 25. These suggestions in part arise from the limitations of this having been a lab-based examination of how easy to use IBMI sites were.

Table 25: Recommendations for research arising from this study

The recommendations
1. An important next step would be to examine the public's use of IBMI in natural environments; e.g. when and why people access these sites. This may necessitate the development of novel methods.
2. Future research could examine if medicine users appreciate and benefit from having access to IBMI when receiving a prescription at the GP surgery, or before dispensing a prescription in a pharmacy; and if they feel IBMI enabled her or him to make an informed decision about taking the medicine.
3. Future research should examine the usability and the readability of IBMI with other population samples, and in particular people from ethnic minorities, and people with special needs. The transferability of the findings was limited because the participants were not representative of all medicine takers.
4. Future research should examine perceived barriers to accessing healthcare portals because this study found that participants did not use a recognised healthcare portal to search for information about medicines.

5.9.Concluding remarks

This exploratory study has analysed the ease of use of a sample of IBMI sites and the readability of their content. Four methods were used concurrently, with a follow-up interview. Using mixed methods to evaluate IBMI was a beneficial and innovative approach, but also a challenge to operationalise.

The design of the sites, and how their content was written, impacted on the ease with which people located and understood the information. Examining in real time how people search online for information about a medicine has revealed that the search strategies used may not be reliable, and that what a person does and does not find is largely determined by search engines. This reinforces our knowledge of how people search for information about medicines online, by providing robust observational evidence to complement previous findings from focus groups. The way a website is described on a search engine may determine if the person opens the link to it or not. From these findings a series of evidence-based recommendations for improving the design of IBMI sites has been derived. It remains to be seen if implementing these recommendations can make it easier for people to find and understand specific content on an IBMI site.

The next chapter reports a study that piloted (i) a repeated measure with counter balance study design, (ii) an intervention based on changing the content and general content formatting for redesigning web pages containing information about medicines, and (iii) the proposed tools for measuring the outcomes. This study sought to determine the appropriateness and feasibility of these three points for use in a full trial evaluating whether redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information.

Chapter six

Study four: a pilot examining the appropriateness of the design and methods for a full RCT evaluating changes to web pages with information about medicines

6.1. Introduction

The study reported in Chapter five examined the usability of a sample of IBMI sites, deriving a series of recommendations on how their design could be improved to make them easier-to-use and their information more understandable. This chapter reports a study piloting the appropriateness and feasibility of using a repeated measures with counter balance study design, an intervention for redesigning web pages by changing the content and general content formatting, and the proposed outcome measures tools. These are examined for use in a later RCT that could seek to evaluate whether redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information.

Employing a mixed methods approach (see 2.7), the readability and usability of the web pages were examined by triangulation of methods; with participants' opinions on the pages complementing this. This study was reported at the *International Social Pharmacy Workshop* conference in July 2008 (Nicolson *et al.*, 2008b).

6.1.1. The *CancerHelp UK* website

This study sought access to pages from a website with information about medicines in order to trial the evidence-based recommendations made in the previous study (see 5.8.3). Based on existing research contacts, a working relationship was developed with *Cancer Research UK* (CRUK), a UK-based charity dedicated to cancer research. Following negotiations about what changes would be possible; CRUK provided a set of web pages

with information about analgesics (painkillers) on the *CancerHelp UK* website *http://www.cancerhelp.org.uk/* that could be redesigned and trialled. This was beneficial to CRUK, as they wanted an evaluation of the ease with which people could locate and understand information on the web pages with information about painkillers. Examining a website that provided information about treatments for people living with cancer shifted focus from the previous studies that had looked at websites with information about *simvastatin*, but was made for the practical reason of third party connections. This had the advantage of seeing if the recommendations from 5.8.3 could be generalised to another type of site and information.

The content of the three web pages examined in the intervention were for pain controlling medication; specifically:

- *Types of Painkillers* page
  (http://www.cancerhelp.org.uk/help/default.asp?page=5976);

- The page with information about *Ibuprofen*
  (http://www.cancerhelp.org.uk/help/default.asp?page=28429); and

- The page with information about *Co-codamol*
  (http://www.cancerhelp.org.uk/help/default.asp?page=28422).

Had the site contained information about *simvastatin*, it could have been included in studies two and three of this thesis because it was professionally developed, not a portal site, provided medicines information, and did not require registration.

The *CancerHelp UK* website was accessed by around 25 in every million Internet users on the week ending 5 April 2008 (Source:*http://www.alexa.com/* accessed April 2006). These pages provide important information about drugs to reduce pain, some of which are available OTC, (i.e. without prescription). Analgesics are also given to people with conditions other than cancer. People living with cancer, their friends, relatives and caregivers, may all access the *CancerHelp UK* site.

The web pages with information about specific drugs on the *CancerHelp UK* website were developed in around 2000 and the general pain control pages in 2004. The pages are updated annually. The pain control pages had been last updated in March 2007. In *CancerHelp UK* the updating of the pages follows a set agenda: all information is updated annually, but if important new information about a drug changes in-between, ad-hoc changes can be made.

At an interview with the head of the *CancerHelp UK* website and a *CancerHelp UK* web page developer, 26 July 2007, the following main principles guiding the writers of the website were identified:

- The developers write everything in plain English, write in the second person, write in the active tense, avoid medical jargon and make text as easy to read as possible, and 'bullet' information to make it stand out.

- For categorising side effect information, they are grouped by frequency as 'common', 'occasional' and 'rare' with an attempt to quantify them with a frequency where possible. The writers try to avoid the use of percentages to describe the risk of a side effect, where possible.

- The web pages are not formally tested, but their readability is sometimes examined using lay reviewers.

In general the information is user-led; therefore the content has been developed in terms of what people have asked for. The pain control section was developed because there was information about the cancer treatments, but not how people coped with pain. Because it is a heavily used website, they receive lots of feedback. The *CancerHelp UK* writers use the information gained from the CRUK nurse telephone helpline (This information was acquired from an interview with representatives of *CancerHelp UK*).

6.1.2. Previous evaluations of websites with information about cancer

Previous studies examining the usability and readability of web-based information about cancer overlap with this study. Using various readability formulae to measure the

reliability of 55 websites with information about cancer, Friedman *et al.* (2004) found that two thirds of the sites had a high readability score, i.e. they required high levels of literacy for reading; and sites that were easier to read were more often those developed by non-profit organisations. While there are problems with using readability formulae (see 1.2.5), the high level of literacy required to read the majority of these sites suggests they would not be accessible to people with low levels of literacy. Tweddle *et al.* (2000) assessed the usability of the *CancerHelp UK* website, using methods similar to those in the usability study (see 5.3.4), and found that participants who had little or no confidence of using a PC, were able to easily use the site.

6.1.3. Using a repeated measures study

This trial adopted a repeated measures design, i.e. a crossover study design. Fuchs and Hippius (2007) used a crossover design to examine leaflet-based information, and found that participants using a redesigned leaflet were significantly better at locating and explaining information than when they used an original leaflet. No trials appeared to have used this design for evaluating the redesign of IBMI web pages. The main reason for using this study design was that participants receive both the intervention and the control, and therefore it eliminates between person differences (see add cross ref to 6.2.1.), a common criticism of a parallel RCT. This however introduces other problems, and these are reviewed below (see add cross ref to 6.2.2.).

6.1.4. Overall aim of this study

The overall aim of this study was to pilot the appropriateness of (i) a repeated measure with counter balance study design, (ii) making content and general content formatting changes alone to the webpages, and (iii) the proposed tools for measuring the outcomes: User Test Questionnaire; participants' satisfaction with the medicines information was measured by Horne's (2001) *Satisfaction with Information about Medicines Scale (SIMS)*; and participants' judgement of the ease of use of the pages measured by Lewis's (1992) *Post Study System Usability Questionnaire (PSSUQ)*. These could be used by a future trial evaluating whether redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information.

The study had three stages:

(i)   Interviews with e-health stakeholders to gather their comments on perceived strengths and limitations of the selected *CancerHelp UK* web pages;

(ii)   Dissemination of the recommended changes to the design and wording of the *CancerHelp UK* pages for the intervention; and

(iii)   The pilot study to examine (i) the appropriateness of using a crossover study design to evaluate whether or not redesigned web pages containing information about medicines improved participants' ability to locate and understand specific information; the appropriateness of the intervention, making changes to the content and general content formatting as an intervention for redesigning web pages containing information about medicines; and (iii) the validity of the proposed outcome measures; for use in a potential full trial.

6.2. Intervention studies of repeated measures with counterbalance

This study used a repeated measures (or crossover trial) design in which participants received both interventions. Therefore it was the sequence in which they received the intervention that they were randomised to because of the need to counterbalance the order of presentation (Elbourne *et al.*, 2002). The purpose of this section is to explore the strengths and weaknesses of this design, and proposed solutions to the potential issues. For issues pertaining to the running of an RCT, see 3.2.2.

6.2.1.   The strengths of a repeated measures design

The repeated measures study design is beneficial for two reasons. Firstly, because the same participants receive both interventions, this removes any differences between the participants in the two groups which might determine the outcome (Armitage and Hills, 1982). Any extraneous variables will be the same across both groups; therefore there is a greater chance that any difference in outcome for each variable can be attributed to the

intervention and not between group differences. Secondly it increases statistical power. As the participants act as their own control, this increases precision of the estimate of the treatment effect given the same number of participants as a parallel study (Sibbald and Roberts, 1998). In effect this doubles the number of people taking part in a crossover trial (Armitage and Hills, 1982). As the statistical power of a trial increases, the chance of not finding an effect when it actually exists (Type II error) decreases.

6.2.2. The weaknesses of a repeated measures design

The repeated measures design is weakened by the potential for a 'carryover effect', which can bias intervention effects (Senn, 2001). There are two variants of this which are relevant to this study: a learning effect, and a fatigue effect. A learning effect is when, for example, information provided in the first intervention is retained and affects the outcome during the second intervention. To minimise this there should be a washout period (no treatment) between the intervention stages (Sibbald and Roberts, 1998). The learning effect is a concern for many repeated measures studies, (although probably not drug trials). This design has been successfully implemented in an evaluation of information giving. Fuchs and Hippius (2007) evaluated original and revised versions of paper-based leaflets using this design and found significant differences in favour of the revised leaflets for finding and understanding information.

It can be argued that there may be no reason that the learning effect should differ for the order of the intervention in a study of information giving (Knapp, personal communication). If this assumption is true, any carryover effect would be the same regarding the order of the intervention, and therefore the effect would be cancelled. The carryover effect can be controlled by counterbalancing the order in which participants receive the interventions.

The second issue is the potential effect of fatigue on participants viewing the second set of pages (regardless of what version this is), which may determine their outcome more than the pages being viewed. Again a washout period can provide respite before they view the second set of pages.

6.2.3. Practical considerations for running the repeated measures design

The difficulty of the carryover effect was identified as a potential problem for running the study, and was addressed as follows. Methods to minimise this were to randomise participants (i) to receive alternate sets of questions in the User Test for the two versions of the web pages in different orders, and (ii) to view the pages in alternate orders. A 'washout period' (five minute break) between viewing the versions of the pages was used in an attempt to reduce this, as well as reducing potential fatigue

6.3. Stage one: Recording e-health stakeholders' recommendations

6.3.1. Aims

To conduct interviews with stakeholders in order to gather their comments on perceived strengths and limitations of the web pages, in relation to their ease of use, and the readability of their content.

6.3.2. Methods

Ethics application

A research protocol was submitted to the University of Leeds, School of Healthcare, Educational Research Ethics Group in July 2007 and approval was granted for all stages of this study.

Recruitment and demographics of stakeholders

An e-health stakeholder was operationally defined as someone with a professional interest in, or personal experience of, using an IBMI site. All stakeholders were given spoken and written information about the study (see Appendix seventeen), and were asked to return a signed consent form (see Appendix eighteen).

Professional stakeholders were sampled from critical-cases, to enable the gathering of specialist information. Five interviews with professional stakeholders were conducted. Those recruited were: the head of the *CancerHelp UK* website and a *CancerHelp UK* web page developer (interviewed together); an experienced HCI researcher; a community pharmacist; a health information expert; and a patient information expert. For each professional stakeholder interview conducted, a medicine user interview was also conducted with a participant who had taken part in the previous usability study; (an

example of convenience sampling). This was done to ensure that there were an equal number of interviews for the two groups of stakeholders, but were not matched on any other variables. None of the medicine users reported having a cancer-related illness when they previously completed the demographic questionnaires for Study three.

Individual interviews were conducted to gather the views of stakeholders on the pages, (except for the CRUK representatives who were interviewed together for practical reasons). The informed consent of all participants was sought before the study, and anonymity was assured. This study distinguished between the comments of professional and medicine user stakeholders, and maintained their anonymity by referring to them only by their assigned participant number and the date on which they were interviewed. This was done because the participant information sheet guaranteed that the participants' feedback would be anonymised to ensure that no comments could potentially be attributed to a stakeholder, and therefore potentially deter someone from taking part in the interview.

Interviews were conducted in person with the *CancerHelp UK* participants and the pharmacist (for practical reasons). A *Dictaphone*™ was used to record these interviews, and the participants looked at printouts of the web pages; having looked at the site before the meeting. The remaining interviews with stakeholders were conducted by telephone with the interviewee simultaneously accessing the Internet to view the web pages. The interviews were recorded using *Re-Tell*™ and saved using the *Audacity*™ software program.

The interviews were based on four statements for agreement or disagreement in the *Post-Study System Usability Questionnaire (PSSUQ)* (Lewis, 1992) (see Appendix twenty-two). They were based on the following statements: (i) It was easy to find the information on these pages to answer the questions; (ii) I am satisfied with how easily I found the information on these pages to answer the questions; (iii) the information on the pages was easy to understand; and (iv) the information on the pages was organised clearly. Participants were asked to use their expertise and/or experience to assess the pages. The

interviews were conducted in July and August, 2007 and lasted no longer than 30 minutes each.

Outcomes

The outcomes were participants' comments on the strengths and limitations of the pages, and recommendations on how to improve them.

Data analysis

The recorded outcome measures (reported strengths, limitations and recommendations) were transcribed (not verbatim). The key points from each interview were extracted, and the overall themes were categorised in relation to the concepts that have underpinned the primary research in this thesis: (i) quality, (ii) content, and (iii) design features. The discussions with the medicine users led to the iterative development of a fourth category: consideration of the information needs of the target audience. From the discussions, general recommendations on how to improve the ease of use of the web pages, and the understanding of their content were made.

6.3.3. Key findings from interviews with professional stakeholders

The following points emerged from the discussions with the professional stakeholders.

Design features

Professional stakeholders considered that the design of the web pages impacted on their ease of use, and they reported having difficulty navigating the site, because specific information (for example, about particular medicines) was not easy to access: *"People looking for information about specific drugs have to dig quite deep"* (P1, 23 July 2007). Because of the vast information architecture, they felt users could easily lose their way going up and down the various paths. It was felt that the URL (see Figure 20) was not conducive to finding the information, as it did not say, for example, *'Cancerhelp.org/pain'* which may be more intuitive for people using the site.

The stakeholders thought the links on the top banner (*Home, Site Map, Search, Glossary*), and the crumb links, did not immediately appear to resemble links (see Figure 20). They felt these features would not be clear or helpful to people using the site if they were not

familiar with banner or crumb links. In particular, one stakeholder reported having difficulties using the *'Menu for this topic'* link; because it was unclear that he had moved to it. Links for tabbing down at the top of the *'Side effects of painkillers'* page, were unclear; so, although something happened, the user was still on the same page which caused confusion (see Figure 21).

Figure 20: Unhelpful URL and unclear crumb links
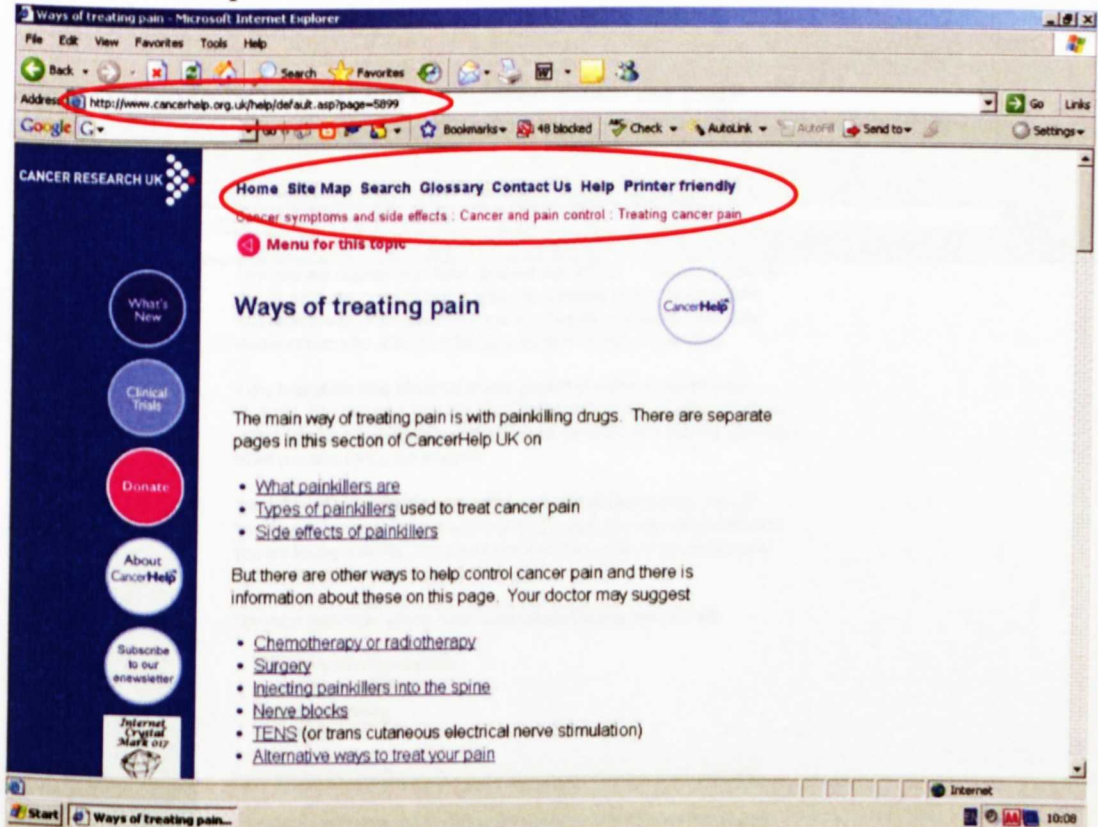
Content

Specific information was praised: for example, the *'What are painkillers'* pages stating that the patient should not suffer in silence, but talk to their doctor honestly and openly. It was felt that it was written with empathy, stressing other people's similar experiences. The pages were further praised for making clear the need to take painkillers regularly, not to expect painkillers to provide continuous pain relief immediately, and for covering the concept of the *'analgesic ladder'*. It was felt the pages were written in plain English.

Some problems with the layout of the content were raised. All stakeholders had difficulty navigating the pages, and particularly felt that specific information (for example, for particular medicines) was quite deep within the site. It was felt that the hierarchy of the information layout, in particular the headings, did not make it clear that there was more information about painkillers underneath it. Furthermore, it was felt that the pages may not be helpful if users were looking for specific information about individual painkillers, because this was not available.

Figure 21: No indication of having tabbed down the page
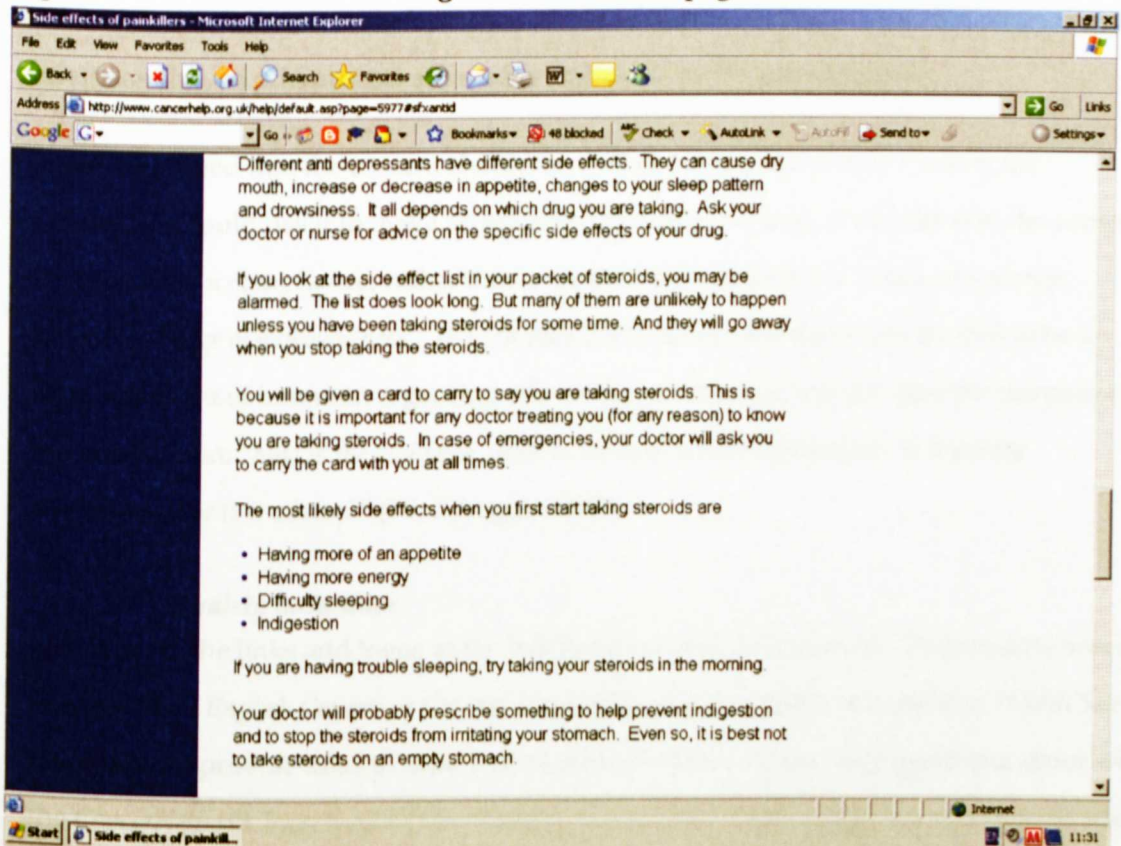
It was remarked that the content did not account for people who only occasionally visit the pages:

> *"There is a narrative fallacy within the pages, (that people will read all of it): where in fact people may dip in and out of the pages and could miss crucial information"* (P1, 23 July 2007).

People doing so may not notice when particular content had been updated, or may fail to see crucial information elsewhere on the site if only looking at specific pages.

A specific criticism of the *'Types of painkillers'* page was that it stated that opioids were also called narcotics, which was felt may be unnecessary information for the patient, as well as cause for undue worry. The site explained the *NSAID* acronym, but participants failed to notice this. The *'Types of Painkillers'* page contained limited information about paracetamol, but the stakeholders did not notice this. It was observed that the pages did not mention pharmacists as a source for information about medicines. It was felt that the pages should advise on this, as pharmacists are readily accessible to the general public.

It was suggested that the content should be written so that the person reading the information could use it to make an informed decision. Instead, it was felt that the content was based on a compliance, rather than a concordance framework: *" non-compliance becomes a 'badge of awkwardness'"* (P1, 23 July 2007). It was felt that there needed to be a clear statement of intention regarding whom the information was for, and the purpose of the information: *"who is the audience, what is the intention of information, is it purely informational or is it advice?"* (P5, 7 August 2007).

Quality assurance

The value of the links and logos in the left-hand column were queried. Participants noted how the *Plain English Campaign Crystal Mark*, *Most Popular Health Site* and *Best Health Site* logos did not provide links to information defining them. There were questions about why the *CancerHelp UK* logo (beside the *'Treating Cancer pain'* title) was there, as it did not add to the page, by acting as a link, for example. A similar point was made about the *'Best'* and *'Most Popular Health Site'* award logos in the left-hand column. It was proposed that the logos are *"badges of clarity…People who don't understand the badges may feel stupid"* (P1, 23 July 2007).

It was also noted that the site mentioned *'NHS Information Partners'*, providing a link to *NHS Direct*, which may be problematic for the *CancerHelp UK* website, as it could potentially lose traffic to another site. It was asked:

"It's unclear why this should happen. Is the link to NHS Direct an endorsement by CRUK of all the information on NHS Direct? How do CRUK feel about potentially losing traffic to another site?" (P5, 7 August 2007).

This may be a helpful link for the reader if they are willing to look at additional sources of information. However, if the person does not want information from an external link; it may be an unnecessary distraction, especially if they are unable to navigate back to the *CancerHelp UK* pages.

6.3.4. Key findings from interviews with medicine user stakeholders

The following points arose in the discussions with medicine users. The themes which developed from these discussions led to the development of a fourth category: consideration of the information needs of the person with cancer.

Site design

The information was largely felt to be very easy to locate, and the features of the site useful for accessing it. For example, some participants said the information was *"very easy to get at"* (P1, 13 August 2007); and the site *"very easy to use"* (P2, 14 August 2007). In particular it was noted:

"I've just gone onto search, typed in painkillers and the ways of treating pain has come up; what are pain killers, types of pain killers. It explains everything and I just found it particularly useful" (P2, 14 August 2007).

The functions at the top of the page were noticed by the participants and they found them useful: *"as soon as you put the web page up, you notice the headlines, and even the red section, the pink section at the top, there seems to be plenty of options"* (P4, 14 August 2007). The information was succinct and clear for the medicine users, with the large print being particularly valued. It was as one participant said: *"easy on the eye, not cluttered... with the headings... done in nice size type"* (P4, 14 August 2007). However, clicking on the bullet point hyperlinks (for example, on the *Types of painkillers* page) led to confusion because tabbing down the page was not apparent.

Content

The medicine users felt the content to be informative, and aspects of it were felt to be enlightening. For example, one participant considered the general public (including himself) was under a misconception on treating pain: *" I always thought there was a level you would reach where the painkiller wouldn't do any good, but the information on the pages laid that fear to rest"* (P3, 14 August 2007). The pages were felt to tackle a similar misunderstanding, where some people may think that if they get a painkiller and the pain stops that they are cured: *"Obviously it's not curing it; it's just dealing with the pain. But most people could understand it"* (P3, 14 August 2007).

The information was felt to be of practical benefit for the medicine users, by explaining the importance of taking painkillers regularly:

> *"The importance of taking them (painkillers) regularly... stood out for me... You know, and why you should take them regularly. To get to a certain level of the drug in the body, the importance of taking painkillers at a certain time and the importance of taking them regularly, every four or six hours"* (P5, 20 August 2007).

The warning about constipation was noticed and it was felt it was well explained.

> *"One thing they've put on here which is good is, if your doctor gives you this drug; make sure he gives you something for constipation. It's good that it reminds you to drink plenty of fluids and increase the fibre in your diet, vegetables and stuff like that. And so they've went way beyond what a drug is. They've put ways for you to stop being constipated and things like that"* (P5, 20 August 2007).

All medicine users said they felt the information was understandable. One noted, *"I understand a lot more; I mean I don't have cancer, but I have something I do need to take painkillers for"* (P1, 13 August 2007). Another participant suggested this was because of how it was written:

> *"It's put down in laypeople understanding. They've not used a lot of difficult words which sometimes if you read a lot of difficult long words which you can't relate to, you turn off; you look elsewhere"* (P5, 20 August 2007).

The language was considered understandable to the medicine users because there was little jargon, and the content was felt to have been designed for a layperson to read. Links to words were valued (for example, 'Chemotherapy') as this helped explain what the words

meant. Medicine users liked the way that the site spelled out very long medical words phonetically, because if they had trouble with it, they might have skipped by it. Respondents also felt it important that if readers wanted further information, the pages should give terms they could search for elsewhere.

As with the professional stakeholders, several medicine users failed to notice the definition for what NSAIDs were. One noted: *"They used the word NSAID, which I know of, but they have not put that anywhere. They've not written it out in full and then in brackets NSAIDs"* (P5, 20 August 2007).

Quality assurance

Medicine users only recognised the logos on being directed to them by the interviewer; and did not question their function. The author waited until the last question ('Is there anything about the site I haven't asked you, which you'd like to mention?') to see if participants noticed this. The last question allowed participants to raise their own points, and for the author to follow up on observations made during the task. None of the medicine user stakeholders noticed the logos; therefore the author directed their attention to it to get their views. For example, asked if she wondered about the logos in the left hand column, a participant said she had not, and thought:

> *"Oh that's good, I just presumed I was looking at a very good website. I didn't consider what they were. I just assumed they had won an award because they were the most informative"* (P2, 14 August 2007).

Another participant said:

> *"Well if people see something like them, the most popular one to go to, it makes them feel what they're going to look at is well done and they're going to get lots of information, which hopefully they want"* (P5, 20 August 2007).

When they tried clicking on the logos to no avail, expecting to get an explanation about them, several felt the information should have been available. For example, it was remarked:

"It doesn't actually say what they are; there must be a lot of health sites. Maybe it should have said if this was for a site about the control of pain. Maybe it ought to have said that" (P1, 13 August 2007).

The logos left some participants with more questions than answers:

"I clicked on it but nothing's coming up. I thought they were patting themselves on the back or that. And also it's 2006 which puts it a year behind. I would probably think myself that erm, this is just a recommendation they've given themselves; this most popular health site. So it is pretty misleading. It looks a little self-congratulatory doesn't it? When I saw the most popular health website, I thought this was an accolade they'd given themselves" (P3, 14 August 2007).

The currency of the pages was not an issue for another participant who felt if the site displayed an award for 1998, that would have suggested it was a bit dated, but not for 2006.

A participant when asked what he thought the *2006 Best Health Site* award meant said: *"well I would guess it's a highly used web page.* (He then tried to run the cursor over logo). *No it doesn't give you an explanation. That does seem a bit odd really"* (P4, 14 August 2007). The lack of information about the award and the inability to click on the logos to find an explanation was therefore troublesome for some, but not all, medicine users. It was also said: *"Well it just says Best Health Site 2006. If it was me, I don't think I'd want to click on them; I think it's quite clear what they mean"* (P5, 20 August 2007).

Consideration for the target audience

Several participants thought the pages showed empathy for the person with cancer, feeling they would place high value on the web pages. For example,

"I am sure if you were concerned about having cancer yourself, or having a relative or a friend who had cancer, and you went to this website, I'm sure you would be so honed in on what you are looking for you would find it easy" (P2, 14 August 2007).

In conjunction with this thought, participants raised doubts about the validity of their comments because they did not have cancer: *"it's one of these situations where if you were unfortunate enough to be in this situation, you would probably be in a better situation to give a response"* (P4, 14 August 2007). Another offered;

"Maybe if I'd got cancer or I had a relative who had cancer and I was stressed, it wouldn't be as easy. I think that's something you have to think about on these websites. People may be looking because they have cancer or have a friend who has cancer. Because I don't, I was looking at it from a different position" (P2, 14 August 2007).

6.3.5. Discussion: stage one

Findings

The findings of this exercise have highlighted medicine users' favourable opinion of the *CancerHelp UK* web pages, which mirrors a finding by Tweddle *et al.* (2000). This exercise also found a difference with the stakeholder group's comments, which to an extent reflects a previous finding that patients and pharmaceutical specialists had conflicting attitudes about medicines (Ramström *et al.*, 2006). In this study medicine users were far more positive in their remarks about the site than the professional stakeholders. There are three possible explanations for finding this difference. Firstly, they may genuinely not have experienced any problems with the site. This cannot be discounted as no formal observation of the participants using the site took place. However, none of the medicine users appeared to recognise the accreditation logos (see Figure 22) as a quality marker or thought to click on it for further information before they were shown it, suggesting the pages were not as useful as they could have been. Secondly, they may have felt intimidated to be overly critical of a recognisable charity website.

The third reason is that their level of critical insight may differ from the professional's. The professional stakeholders, (perhaps to a lesser extent the pharmacist), work in a role which demands critical thinking coupled with a well-developed academic knowledge of issues relating to healthcare information. Whereas the medicine user's knowledge and interest is arguably less academic, and more practically orientated in terms of seeking to learn about their medicines from such sources. Thus they may have been less critical in their approach to it. Professional stakeholders by comparison offered a more academic critique of the content, criticising, for example, the pages' failure to adapt a concordance framework, and the need for taxonomy by condition. Sillence and Briggs (2007) have noted a difference between professionals' and patients' evaluation of e-health. They explained this as being

due to professionals not having the same concerns as people with genuine health concerns, who may look for support and empathy, beyond mere medical content.

Figure 22: Accreditation logos that were missed by medicine users
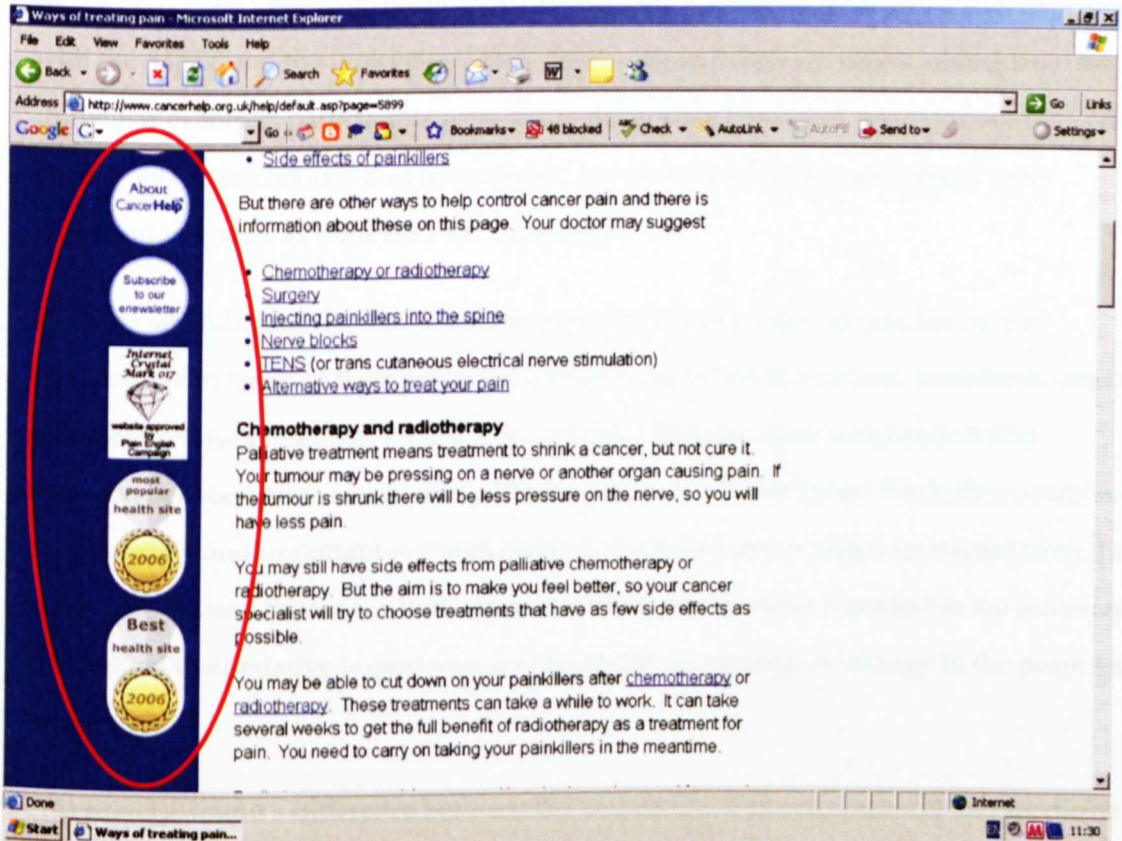
Methods

The method of individually interviewing each stakeholder was beneficial because it allowed responses to be documented and analysed separately. This was in contrast to the stakeholder workshops (reported in Chapter three) where it was not possible to distinguish between professional and medicine users' responses.

Eight interviews were conducted by telephone, with participants sat at a PC. Therefore there was no observation of the user's problems. Criticisms of indirect methods for gathering usability data were discussed in 5.2.2, and are not repeated here. However, the aim of this part of the study was to document stakeholders' views about the ease of use of

the web pages, and the readability of their content. The interview method enabled this and provided a rich source of data; therefore it was considered a useful method.

At the end of the interview, participants had an opportunity to raise issues that they had with the pages, and the interviewer took the chance to follow up issues arising from the study. For example, participants were led to the quality logos and asked to comment on them. This has introduced bias to an extent, but on balance it was considered more important to gather as full a data set as possible.

The recommendations derived from this part of the study were not graded by the stakeholders in terms of their perceived importance, which is a process sometimes used in stakeholder-based research. This was not adopted because there was concern that variation between professional and patients' grades would be great. While this would be an interesting and important research finding, it would have perhaps distracted from the study aim. Instead the author took account of the various views recorded in the interviews and judged their relative importance and feasibility as options for change in the proposed intervention.

This exercise found a difference between the comments of the professional and medicine user stakeholders (as reported above). There was a second divergence in responses. The professional stakeholders largely provided a critical appraisal of the pages, e.g. focusing more often on difficulties with the pages; while the CRUK representatives were more complimentary of their own site. This was not highlighted in the findings, because the discussion of this would have eliminated the anonymity of the CRUK representatives when their comments were reported. (Participants' anonymity was guaranteed in 6.3.2). CRUK representatives may have had a different perspective to the other participants about the task, which led to responses biased in emphasising the perceived positive elements of the site and not be critical about it in general.

Recruiting five medicine users from the previous study may have been problematic. Because of their experience of taking part in the usability study, they may have become

more experienced evaluators of e-health web pages than people normally accessing such sites; and therefore their views regarding the pages may not be representative of those people. They may have reinforced this experience by consulting IBMI sites for their own purpose since then. Six months had elapsed since they took part in the previous study, and it was hoped any benefit they had from taking part in it would have lessened. Their comments did not appear to suggest that they had been primed by the previous event to be more critical evaluators, because they were more positive in their praise of the pages than the professionals.

6.4. Stage two: Dissemination of recommendations
6.4.1. Aim and methods

This section reports the recommendations made to *CancerHelp UK*, and the intervention that was carried out. The aim was to convey the perceived strengths and limitations of the *CancerHelp UK* web pages, and the recommended changes to the pages. This was done using two methods:

(i)   A short report detailing the main findings from the stakeholder interviews, and the recommended changes to the intervention set of pages drawn from the following sources:

- Interviews with e-health stakeholders (see 6.2);

- Recommendation for the design of IBMI sites (see 5.8.3);

(ii)   Rewriting of the content and general content formatting of the web pages used in stage three (see 6.5), highlighting the recommended changes to the pages. These changes were made first by the author, then by two PhD supervisors. The changes were based on the sources above, as well as the following:

- Dickinson, Raynor, and Duman (2001) design principles used to develop an information leaflet;

- Supervisors' expertise in User Testing printed patient information leaflets and usability research;

- The author's health information design expertise in evaluating PILs and IBMI sites.

The recommendations made in the report to *CancerHelp UK* were derived by the author using his expertise to synthesise the interview data to derive indicative examples of what the stakeholders said was felt to be useful and difficult about using the current *CancerHelp UK* painkiller web pages. These reflected issues that were frequently reported (in studies of e-health), as well as some that were less common. The author made judgements on the relative importance and feasibility of the problems highlighted and the various options for change. For each problem noted with the pages, one or more recommendations were proposed for the intervention.

A teleconference was then held between the head of the *CancerHelp UK* website and a *CancerHelp UK* web page developer, the author, and one PhD supervisor. This ran for two hours and followed a structured agenda to discuss the feasibility of making the proposed changes to the pages.

6.4.2. Recommendations in the report and changes to the web pages

A report (see Appendix nineteen) was sent to *CRUK* documenting stakeholders' perceptions of the strengths of the *CancerHelp UK* web pages, their difficulties with navigating the pages, reading the content, and confusion surrounding the quality assurance markers. This report also detailed recommended changes for the intervention. Unfortunately following discussions it was agreed that changes would be limited to content, and general content formatting; and no changes could be made to the design features of the pages. Some of the recommendations were implemented by *CRUK*, e.g. the rewriting of text in the attempt to make it easier to understand. But many recommendations were not accepted because they would have required significant changes to the design of the pages, e.g. providing a find bar on the pages. A screenshot of a redesigned page is in Figure 23. A record of tracked changes made to the original version of this page is in Figure 24. Table 26 indicates the intervention made to the web pages; i.e. a record of the generic changes that were made.

Figure 23: Screenshot of a redesigned page
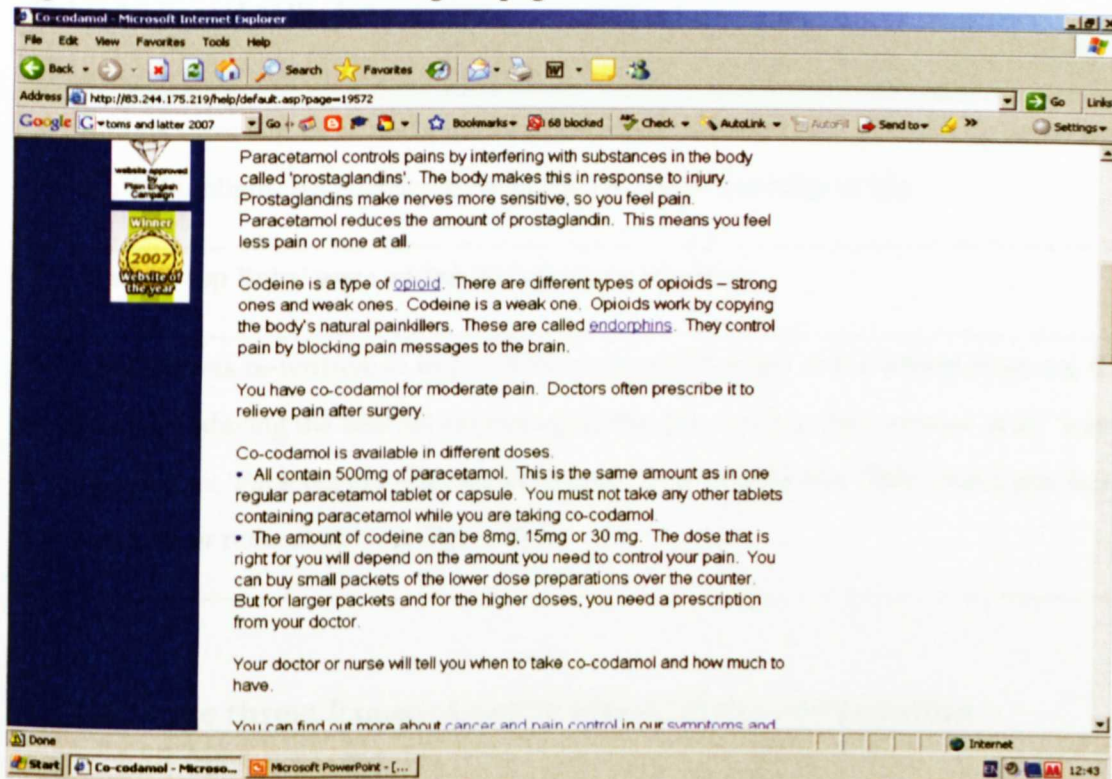
Figure 24: Tracked changes of the redesigned page in Figure 23
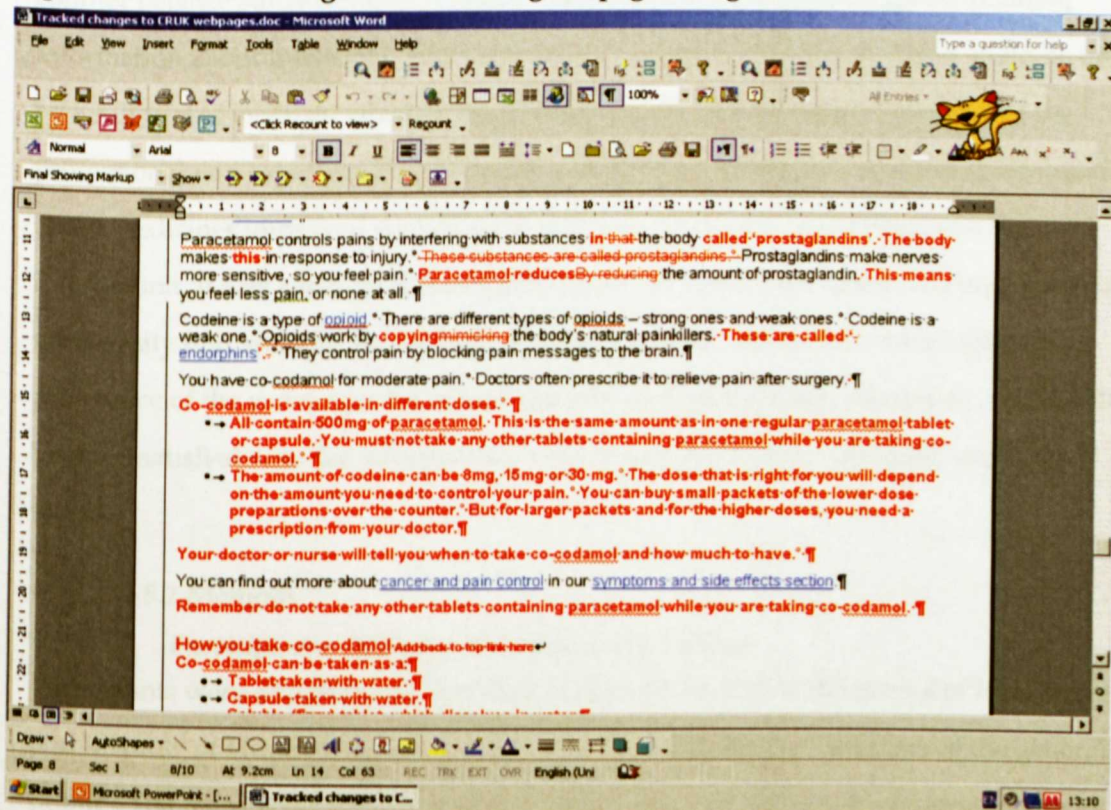
Table 26: Record of the intervention

Three types of changes were made to the web pages
1. **Bullets were added:** to make information stand out better and to break up dense text; e.g. to highlight 'All contain 500 mg of paracetamol' (see Figure 24).
2. **'Back to top links' were added:** to improve navigation.
3. **Content was re-written:** to improve the understandability of the information; e.g. the text 'By reducing the amount of prostaglandin, you feel less pain or none at all' was changed to: 'Paracetamol reduces the amount of prostaglandin. This means you feel less pain or none at all' (see Figure 24).

6.5. Stage three: Examining the effect of the intervention
6.5.1. Aims

The aim of stage three was to pilot the appropriateness of using a repeated measure with counter balance study design, an intervention for redesigning web pages containing information about medicines, and tools for measuring the outcomes. These could be used by a full trial to evaluate whether the redesign based on best design practice and the professional and experiential opinions of stakeholders of websites containing information about medicines improved participants' ability to locate and understand specific information, It was anticipated that participants using the redesigned web pages would more easily find and explain the indicative information, would rate more highly their preference of the web pages for ease of use and understandability of content, and would be more satisfied with the information, when compared to those using the unchanged pages.

6.5.2. Methods

Participant criteria for inclusion and exclusion

Participants were drawn from a convenience sample of staff at the School of Healthcare, and Institute of Health Sciences, at the University of Leeds; i.e. 'members of the general public'. The reasons for this were: (i) the study evaluated pages with information about

painkillers, which the general public are able to relate to, therefore they could be recruited into the study; (ii) this was a pilot study of an exploratory evaluation of a sample of web pages on the *CancerHelp UK* site, therefore it was legitimate not to test this on the 'affected population group'; (iii) and it was hoped that there would be less difficulty recruiting participants from the University than there had been recruiting from a pharmacy in the study reported in Chapter five.

Participants were included if:

- They were administrative and clerical staff, cleaners or porters with any prior experience of using a website.

Participants were excluded if:

- They were 'academics'; i.e. teaching or research staff, or a student.

- Internet naïve participants who would require extensive training before conducting the tests.

Recruitment of study participants

Recruiting was carried out by approaching clerical and administrative staff, and inviting them to take part in the study. They were given full information about the nature of the study, verbally and in writing (see Appendix twenty); and were asked to return a signed consent form (see Appendix eighteen). After completing the study they were given a £10 gift voucher as a token of appreciation.

Study design

A repeated measure design with counterbalancing (crossover trial) was chosen. This design was beneficial because it examines (i) any difference between the two sets of pages; and (ii) any order effects. It may be that the second site performs better regardless of which site it is, due to the practice effect. (See 6.2.1 for a greater explanation of the strengths and weaknesses of this study design).

Intervention

Participants were randomly assigned to the order in which they viewed the original or redesigned set of three pages (see 6.1.1). The rationale for this was to control for any order effects of the pages viewed; because people are known to be sensitive to the order in which they receive information (Bergus *et al.*, 2002). The original pages were those on the *CRUK* website at the time the trial was conducted (in November 2006 to February 2007). A description of the redesigned web pages was provided in 6.4.2.

Participants were randomly assigned to the order in which they received the two sets of User Test questions. Two sets of questions were asked because the same questions could not be asked twice – participants would have an advantage when asked the questions for the second time. This counterbalance sought to control for any order effect from the questions asked. Figure 25 shows the different possible sequences of pages viewed and question set asked. The procedure of randomisation and concealment of allocation was the same as in the usability study (see 5.3.4).

When viewing the separate web pages, the F11 button was used to hide the URL in case participants were able to infer which version they were using. (See Appendix twenty-one for the full protocol instructions for running the study).

Figure 25: Randomisation groups

(i) *Original* pages and User Test version1 ⟶ *Redesigned* pages and User Test version2

(ii) *Original* pages and User Test version2 ⟶ *Redesigned* pages and User Test version1

(iii) *Redesigned* pages and User Test version1 ⟶ *Original* pages and User Test version2

(iv) *Redesigned* pages and User Test version2 ⟶ *Original* pages and User Test version1

At the start of the study all participants were instructed to use only the assigned web pages to answer the questions; and not their general knowledge or by searching on

another website. The study was conducted individually with the author. Participants sat at a PC and performed the study, which had the following parts:

1. They looked at one version of the web pages. Using these pages, they were asked to find information to answer eight questions about the medicines. They then filled in a short questionnaire about what it was like to use the pages and what they thought about the information.

2. After a five minute gap (washout period), this procedure was repeated for the second version of the web pages.

3. At the end they were asked to answer two broad questions: (i) 'please tell me what you think about using the different versions of the web pages' and (ii) 'did you have a preference for one version of the site over the other?'.

The author asked them the User Test questions and noted whether they found the information and what they thought the answer was. The questions differed for each version of the pages so there was not a carry-over effect.

Outcome measures

There were three outcome measures.

- User Test scores: whether participants could find and then explain the indicative information to answer the questions. Participants' explanations of the indicative answer demonstrated their understanding of the information. The questions were devised by the author from reviewing information about analgesics on the *NHSDirect* website, which provides a large range of information about this. The *CancerHelp UK* web pages were checked for the indicative information to answer these questions: there were no questions for which the answer could not be found using the web pages. There were eight questions for each set of versions of pages viewed. This is less than the normal number of questions for a User Test, to take into consideration the time needed for the other outcome measures to be completed, having to navigate the web pages, and having to do this for two sets of pages. The questions were independently assessed for validity before the study by a PhD supervisor who was an experienced User Testing researcher.

- Participants' satisfaction with the medicines information was measured by the *Satisfaction with Information about Medicines Scale (SIMS)* (Horne, 2001) 17-item questionnaire (see Appendix twenty-two). Participants were asked to say whether they felt the amount of information for specific statements was 'too much', 'too little', or 'none received', indicating a lack of satisfaction and scored as zero; or 'about right', indicating their satisfaction and scored as one. Scoring could therefore range from 0-17, with a higher score indicating greater satisfaction with the information.

- Participants' judgement of the ease of use of the pages was measured by the *PSSUQ* (Lewis, 1992). They were asked to rate how much or how little they agreed with four statements on a Likert scale about using the pages. For each statement participants could give a score ranging from 'strong agreement', to 'strong disagreement' with the statement. Therefore a lower score suggested greater agreement with the statements about ease of use. They were asked to answer four follow-up questions. The statements reflected the usability concepts of effectiveness, efficiency, and satisfaction (which determine how easily or not web pages are to use); and were derived from a larger 19-item instrument (Lewis, 1992), for assessing usability (see Appendix twenty-two).

Methods of analysis

For the numerical data, a repeated measures ANOVA was conducted. The primary analysis was the effect of the different type of pages (old versus new) on the outcome measures. The secondary analyses were (i) the effect of order of type of page presentation (old first versus new first), and (ii) the effect of the User Test question set order for the three outcomes. An examination was made of the type of page and also whether there were interactions between:

- Page type and presentation order;
- Presentation order and question order;
- Page type and question order; and
- Page type and presentation order and question order.

It was not possible to conduct a sample size calculation prior to the start of the trial. Based upon (i) the recommendation of Collins *et al.'s* (2007) (see 2.5.1), and (ii) this being a pilot

study; it was decided that a minimum of 20 participants should be recruited, to try to detect a difference in the outcome measures by type of page, if it existed. Had this been a full trial, it would have required a much larger sample.

The four *PSSUQ* follow-up questions generated qualitative data. These were iteratively categorised into four overarching themes which emerged from the data, using the same method as described in 5.3.6. There were two questions at the end of the study, where participants could provide comments about the web pages and the tasks:

1. Please tell me what you think about using the different versions of the web pages.

2. Did you have a preference for one version of the site over the other?

Their responses were categorised into four emergent themes by the author. A PhD supervisor independently marked the responses against the categories. A random sample of 48% was reconciled with the author, and there was agreement in 94% of instances, which was considered sufficient not to warrant further reconciling.

6.5.3. Results

Participant demographics

Thirty seven members of staff provisionally agreed to take part. Two participants withdrew their consent, and one participant was found not to meet the inclusion criteria. Four other participants did not return their questionnaires or consent forms and were not followed up. Of the 30 who participated in the study, their mean age was 40 years (range: 21-61 years), 21 were female, and all spoke English as their first language. A majority were educated to graduate level (19). All participants used the Internet at least weekly, and almost all (28) reported using it daily. Twenty-five had used it for more than five years. Six participants had taken a prescribed medicine for more than 12 months; four for less than 12 months. Nine had taken a short-term course of a medicine (for example, an antibiotic) in the last year. A majority of participants (22) had taken one or more OTC medicines in the last year. Six participants reported having not taken any medicine in the last year. Only two participants said they had previously viewed the *CancerHelp UK* website. No

participants were lost to follow-up. (Note – all numbers in this section are not mutually exclusive.).

Primary outcome measures
- **User Test questionnaire results**

Overall, there was no difference in participants' ability to locate the indicative information when using the original pages or the redesigned pages: mean 6.8 (SD 1.0) for 8 questions when using the original pages, and mean 6.5 (SD 1.1) when using the redesigned pages: (F=2.34; df=1,28; P=0.14).[3] There was no difference in correctly explaining the information: mean 6.4 (SD 1.2) when using the original pages; and mean 6.1 (SD 1.3) when using the redesigned pages: (F=2.24; df=1,28; P=0.13).

Results in relation to the question set

The analysis showed no difference for indicative information found or explained in relation to the question set that was asked, and therefore this variable was not examined in any further analyses (see Table 27).

Table 27: Results in relation to question set

Page	N	Mean total (SD)	F, df, P
Question set re locating			
Question set A	30	6.6 (1.2)	F=0.53; df=1,28; P=0.82.
Question set B	30	6.6 (1.1)	
Question set re explaining			
Question set A	30	6.1 (1.4)	F=1.43; df=1,28; P=0.24.
Question set B	30	6.4 (1.0)	

- **Time taken**

Participants were significantly quicker when viewing the second set of pages (see Table 28). There was no difference in time taken between the original or the redesigned pages (see Table 28).

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[3] Participants received a score for each time that they found, and explained the information, for eight questions. Thus a higher score was 'good' as it indicated that the participants could find/explain the information.

- **Participant satisfaction with the information**

There was no difference in participants' reported total satisfaction with the information on the original or redesigned pages (see Table 29).

Table 28: Time taken (in seconds)

Page	N	Mean total (SD)	F, df, P
		Order of viewing	
First set of pages	30	535 (124)	F=21.50; df=1,28; P<0.001.
Second set of pages	30	444 (117	
		Pages viewed	
Current pages	30	482 (143)	F=1.13; df=1,28; P=0.30.
Redesigned pages	30	497 (113)	

Table 29: *SIMS* scores for the current and revised pages

Page	N	Mean total (SD)	F, df, P
Current pages	30	10.9 (3.1)	F=0.22; df=1,28; P=0.65.
Redesigned pages	30	11.1 (3.7)	

The *SIMS* questionnaire contained four statements that were not applicable to the information contained in the pages. The pages did not contain information on how to get a further supply; whether you can drink alcohol whilst taking the medicines; whether the medicines will affect your sex life; or what you should do if you forget to take a dose. Participants should have answered 'none received' for these statements, but it was noted after the data collection that 17 participants did not do this for one or more of the questions, thereby inflating their total *SIMS* scores. The results were reanalysed without the scores of these four questions, and there remained no difference in satisfaction for the pages viewed (see Table 30).

Table 30: Reanalysed *SIMS* scores for the current and revised pages

Page	N	Mean total (SD)	F, df, P
Current pages	30	9.9 (2.3)	F=0.19; df=1,28; P=0.66
Redesigned pages	30	10.1 (2.8)	

- **Participants' views on the ease of use of the pages**

The results of the *PSSUQ* measuring participants' feelings about using the pages showed no difference (see Table 31).

Table 31: *PSSUQ* scores for the current and revised pages

Page	N	Mean total (SD)	F, df, P
Current pages	30	12.4 (3.5)	F=0.69, df=1,28; P=0.41
Redesigned pages	30	12.6 (4.1)	

Secondary outcome measures
- **User Test questionnaire results by order of page presentation**

There was a significant interaction between the page version and order of viewing, for finding and explaining the information (see Table 32).

- **Participant satisfaction by order of page presentation**

There was no difference in participants' reported satisfaction with the information on the different pages, dependent upon the order of page presentation (see Table 33). As explained above, the *SIMS* questionnaire contained four statements which were not applicable to the information contained in the pages. When the scores of these items were removed, and the results were reanalysed, there remained no difference in satisfaction according to the order of pages viewed (see Table 34).

Table 32: Finding/explaining by order of page presentation

Page	N	Mean total (SD)	F, df, P
Order of presentation of pages for finding			
First set of pages	30	6.4 (0.9)	F=5.68; df=1,28; P=0.02
Second set of pages	30	6.9 (1.2)	
Order of presentation of pages for explaining			
First set of pages	30	5.8 (1.1)	F=12.61; df=1,28; P<0.001
Second set of pages	30	6.7 (1.3)	

Table 33: *SIMS* scores by order of page presentation

Page	N	Mean total (SD)	F, df, P
First set of pages	30	10.9 (3.3)	F=2.17; df=1,28; P=0.65.
Second set of pages	30	11.1 (3.5)	

Table 34: Reanalysed *SIMS* scores by order of page presentation

Page	N	Mean total (SD)	F, df, P
First set of pages	30	9.9 (2.2)	F=1.39; df=1,28; P=0.24.
Second set of pages	30	10.1 (2.8)	

- **Participants' views on the ease of use by order of page presentation**

There was no difference in participants' feelings about ease of use by order of page

presentation (see Table 35).

Table 35: *PSSUQ* total by order of page presentation

Page	N	Mean total (SD)	F, df, P
First set of pages	30	13.7 (4.0)	F=1.92 ; df=1,28; P=0.18.
Second set of pages	30	12.4 (3.6)	

Participants' written feelings about the ease of use of the pages

Each *PSSUQ* statement had a related follow-up question which let participants explain

their rating. Questions of this type provide an insight into their views of the ease of use of

the pages. Four common themes emerged from the data: praise for the current pages;

praise for the redesigned pages; criticism of the old/new pages; criticism of the test design.

For example, comments about 'not having time to read everything', and 'having to jump

between the pages' were categorically similar and condensed as 'criticism of the test

design'.

- **Praise for the current pages**

Participants praised the layout of the current pages. It was felt that the layout of the

information made it easy to find the information:

"For immediate access to the information I found the bullet points were helpful and headers." (Participant is referring to the heading opioids/non-opioids). "The way drugs like morphine were broken down into 'immediate release', 'slow release' enabling the viewer to assess the best way to understand dosage" (P29, old pages viewed 1ˢᵗ).

The layout of the old pages made them satisfying to use because the information could be easily found: *"The pages contained relevant information that was easy to find, and more importantly, understand."* (P4, old pages viewed 1ˢᵗ). The information was felt to be understandable because it outlined *"the uses, strengths, advantages and disadvantages of each medication in a straight forward manner"* (P34, old pages viewed 1ˢᵗ). Participants as a whole felt the information on these pages was clearly organised. For example, it was said of the old pages that they: *"were not too long. Not too much information squeezed in. Not a lot of medical jargon"* (P29, old pages viewed 1ˢᵗ).

- **Praise for the redesigned pages**

Participants had similar praise for the redesigned pages. It was felt that the information was easy to find on the new pages because of its layout: *"an easier format on screen"* (P24, new pages viewed 2ⁿᵈ), and *'Links clearly presented could take you to required information quickly. The information is presented clearly in headers at the top of each page.'* (P4, new pages viewed 2ⁿᵈ). Asked what made the new pages satisfying to use, the additional bullet points were acknowledged: *"Use of bullet points more easy and clearly set out"* (P10, new pages viewed 2ⁿᵈ). The information was felt to be clearly organised, making *"Good use of lists rather than paragraphs of information"* (P10, new pages viewed 2ⁿᵈ). While there was a lot of information to negotiate on the pages, it was felt *"breaking it up into smaller chunks made it more easily navigable"* (P36, new pages viewed 1ˢᵗ). The information was said to be understandable:

"Although a lot of medical terminology was used, it was expressed without resorting to jargon, and therefore someone with little or no medical knowledge would hopefully be able to make sense of the information." (P26, new pages viewed 1ˢᵗ); and *"Good use of language; clear, simple, but not patronising"* (P28, new pages viewed 2ⁿᵈ).

- **Criticism of the current and redesigned pages**

There was an equal amount of criticism about both sets of pages. It was felt that the amount of information on the current pages overwhelmed some participants: for example,

"Seemed to be a lot of information to read through before you got to the part which answered the question" (P18, old pages viewed 1ˢᵗ). To rectify this perceived problem with the current pages, it was suggested there needed to be changes to its layout: for example, *"I had difficulty finding some of the answers. Would prefer better headings and smaller chunks of text"* (P35, old pages viewed 2ⁿᵈ). A similar criticism was made of the redesigned pages, with the amount of text again criticised: *"Links to information did not stand out from the main body of the text. Too many blocks of text; bullet points would be easier to understand"* (P12, new pages 1ˢᵗ); and *"Too much print in large blocks"* (P1, new pages viewed 1ˢᵗ). There was also a criticism that the information was too rudimentary on these pages:

> *"Not easy to understand because there should have been fuller answers. Perhaps one criticism would be the information was too basic. Too much brevity. The pages were too simple"* (P5, new pages viewed 2ⁿᵈ).

- **Limitations of the study**

Participants repeatedly said they did not like having to navigate between pages to answer the questions. For example, it was felt: *"Hard to navigate and jump backwards/forwards for information. Would have preferred to have printed off information"* (P2, old pages 1ˢᵗ); and *"Felt I had to jump around the pages a lot"* (P23, old pages 1ˢᵗ). Most participants said they did not have enough time for looking at the pages before undertaking the User Test. For example, *"I think it would have been easier to find all the answers if there had been more time to read the pages"* (P19, new pages viewed 1ˢᵗ).

The task was felt to have impeded some participants' attempts to find the indicative information, making it *"more difficult than if I'd been looking myself in a relaxed atmosphere"* (P1, new pages 1ˢᵗ). It was also remarked that participants may have found the information with greater ease not because of the page design, but because of increasing familiarity with the pages during the task. For example, a participant said: *"I was familiar with the information at this point with the three different pages, so it was easier to assess the information than at the beginning"* (P29, old pages viewed 1ˢᵗ). It was also felt that the questions were easier the second time around *"I found the second set of questions easier to answer than the first, but this may simply be due to having already viewed the information in the first part of the test"* (P26, new pages viewed 1ˢᵗ). Some participants felt they would have liked longer on the

tasks: *"Maybe more time to look at the pages would alter my opinion?"* (P25, old pages viewed 1ˢᵗ). These factors may have impacted on the participants' performance during the tasks.

Additional questions

Three common themes emerged from the points participants made in the section with additional questions: appraisal of the current pages; appraisal of the redesigned pages; and feeling there was no difference between the websites.

- **Appraisal of the current pages**

Participants gave several reasons for favouring the current pages. Perceived ease of use was a common reason: for example, *"the second did strike me as being slightly easier to navigate"* (P20, old pages viewed 2ⁿᵈ). This participant did not offer a reason to explain why she felt the navigation to be easier. On the other hand, another participant offered a reason; stating:

> *"I thought the second version seemed to be simpler to use. All the necessary information appeared to be there without too much text to read through. The first version seemed to be a lot longer and not as easy to find answers to some questions"* (P19, old pages viewed 2ⁿᵈ).

- **Appraisal of the redesigned pages**

Similar reasons were offered by the participants for favouring the redesigned pages. Viewing the new pages second; a participant offered: *"Lots of information in both but the layout of information is better in the second"* (P19, new pages viewed 2ⁿᵈ). Another participant said: *"Preferred website two. It seemed more logical; slightly easier to use; less links and less jumping around"* (P25, new pages viewed 2ⁿᵈ). A participant viewing the new pages first found them to be *"quite dense with language and more technical too, making it difficult to take in and comprehend. However, finding information on this page was easier to pick out"* (P36, new pages viewed 1ˢᵗ). Another participant said: *"I thought the first one was harder to retrieve information from, although it was all there clearly laid out"* (P13, new pages viewed 1ˢᵗ). Accessing the new pages second, a participant felt:

> *"There was more information in the second one which could be confusing and may put you off if you thought the disadvantages would outweigh the advantages. It may make you more anxious about treatment. But it did give more information if this was something that you were going to go through."* (P34, new pages viewed 2ⁿᵈ).

- **Feeling of no difference in the web pages**

There was no difference in results for the current and redesigned versions of the web pages for the User Test; time taken on the User Test; or the *PSSUQ* and *SIMS* questionnaires. The vast majority of participants reflected this in their feedback: for example, *"I did not notice any significant difference between the two versions of the web pages"* (P26, new pages 1ˢᵗ); *"There was very little difference between the pages"* (P21, new pages viewed 1ˢᵗ); and *"There didn't appear to be a huge difference between the two sites"* (P20, new pages viewed 1ˢᵗ). On a couple of occasions, participants felt there was a difference; but that this was far from explicit: *"It was interesting to see how the two versions differed even though from the start they both looked the same"* (P14, old pages viewed 1ˢᵗ); and *"subtle differences between the sites in how the information is presented"* (P24, new pages viewed 1ˢᵗ).

6.5.4. Discussion: Consideration of the methods piloted in stage three

This pilot study has been a valuable exercise, indicating the methods limitations of this pilot, and there is need to reconsider the methods adopted, if it were run as a full trial of changes to the web pages and their impact on finding and understanding the information. It is important to consider that the results were near 'ceiling level' for the current web pages, which suggests they were already designed adequately enough for the indicative information to be found and explained.

Firstly, the crossover study design may not be appropriate. Despite the effort to reduce a carryover effect, it is likely that this will have impacted on the outcomes. The five minute wash-out period may not have been a sufficient length of time. This was not tested, but could have been by randomising participants to receive different lengths of wash-out period, and comparing the length of wash-out period with their scores on the outcome measures. However, if the period was for a greater length of time, participants could have potentially accessed the web pages outwith the study, thereby invalidating their outcomes on the second half of the RCT.

Running a parallel groups trial would probably be the more appropriate study design in a full trial. The appeal of running a crossover design in the full trial was that it removed

between group differences, and increased statistical power. However to account for an order effect, four randomisation groups were required, presenting a practical challenge for the pilot. Running a parallel groups RCT would have been simpler, and would not have introduced a potential carryover effect. Therefore it would be advisable to run a parallel groups study design in a full trial.

Secondly, the intervention (changes to the content and minor content formatting) of the web pages was not significantly different enough to have had a differential effect on the outcomes. Furthermore some participants felt that there was no difference in the web pages. A full trial should implement greater changes in a mock version of the website, making significant changes to the format and interactivity of the pages which may improve participants' navigation of the pages and understanding of the information.

Thirdly, there were only eight questions per User Test; which was lower than the convention of 12 to 15. Had there been more questions in the User Test, there may have been greater variability in the results, reducing the 'ceiling effect' that was found. The adoption of the *SIMS* and *PSSUQ* tools were valuable because they could be completed by the participants independent of the researcher in a full trial. This could enable several participants to be tested simultaneously if the User Test was completed by the participants (see below). However, by removing the need for the researcher to be present, this would make the study an indirect measure of usability. See 5.2.2 for problems with indirectly measuring usabiity.

Fourthly, participants were University employees, and so they may have been more adept at using a PC and therefore found the task less challenging than the websites target audience. This could be examined by running the study again with participants from the websites target audience, (i.e. people with cancer-related illness, their friends and family). It may be beneficial to run the study with a sub-group of computer naïve participants, to examine ease-of-use of the site for such people. However, it remains to be seen if such people are deterred or not from accessing this or other e-health/IBMI sites it in the real world

Fifthly, a full trial would need to be adequately powered, enrolling larger numbers of people to find a significant effect size. If the task had self-completing outcome measures, many people could be tested simultaneously, making it possible to examine larger numbers of participants in the same period as this pilot, which only examined one person at a time.

6.6. Concluding remarks

Running the pilot to examine the feasibility of the study design, intervention, and outcome measure tools was beneficial as it highlighted changes that would need to be made to these aspects if the study were run as a full trial.

The next and final chapter pulls together the stands of the four empirical studies in this thesis. There is a summary review of the main findings, and then a discussion of the limitations of the work as a whole. It is noted what the work in this thesis adds, and there is an exploration of the implications arising from the findings.

Chapter seven
Discussion

7.1.Introduction

This chapter brings together the work reported in this thesis. Following a summary, it addresses the broad limitations of the research. There is an examination of what this work adds, for the provision of leaflet-based and Internet-based information about medicines, and for the use of mixed methods. The implications arising from the findings are considered for written medicines information, and Internet-based medicines information. Recommendations are made for future research. This chapter concludes by providing final remarks on the usefulness of leaflet-based and Internet-based information about medicines for consumers.

7.2.Summary

The research in this thesis has evaluated the usefulness of leaflet-based and Internet-based medicines information. Grounded in HSR, in particular Medicines Management, it has drawn on theory and methods from Cognitive Psychology and Human Computer Interaction research. Evaluating WMI is important because medicine users need good quality information that will enable them to know how to take a medicine effectively, to understand the benefits and side effects of taking it, and, it is hoped, to make an informed decision about taking the medicine or not.

Chapter one set out the background and aims of this thesis. It found no previous studies that had evaluated Internet-based medicines information (IBMI), and so the main focus of this thesis has been to examine such information. Chapter two critically examined mixed methods research and concluded that this approach would benefit the examination of WMI, because it is driven by a real world problem, and enables a well-rounded overview of WMI both quantitatively and qualitatively. A mixed methods approach was used in three of the empirical studies to enable a comprehensive evaluation of WMI.

Chapter three reported the first empirical study: a systematic review of the effectiveness of WMI, with stakeholder input through two sequential workshops. There was little evidence that leaflet-based WMI is effective for changing attitudes or behaviours. The review found some evidence that WMI can change knowledge. The workshops highlighted that leaflets are not valued by medicine takers. No previous trials evaluating IBMI were found, reinforcing its examination in the remaining empirical studies. Problems were identified with previous research evaluating WMI, and ways to resolve these were raised.

Chapter four reported a content analysis of IBMI sites with information about *simvastatin* and found variation in their design features and quality indicators. From a medicines management perspective, there was concern at the inconsistency in information that was examined across the websites.

In Chapter five a purposive sample of websites derived from this study was examined for usability and readability examined. A User Test examined medicine takers' ability to locate and explain specific information to answer a set of questions using these websites. Three usability methods (observation, think aloud, and online tracking) ran concurrently to examine how the participants navigated the websites. This study found that the way the sites were written and designed impacted on their ease of use, and the readability of their content. A set of evidence-based recommendations for the design of IBMI sites was derived to make them easier to use and read, and this is an important output of this thesis.

The study in chapter six piloted the appropriateness of a repeated measure with counter balance study design, an intervention redesigning an IBMI site, and the proposed outcome measures tools. The crossover study design and limited redesign of the web pages may not be appropriate for a full trial to examine differences in the usability and readability of web-pages with information about medicines.

7.3. Limitations of this thesis

Each study has examined in detail the limitations of the methods used. This section looks at broader limitations of this work as a whole.

7.3.1. The transferability of the findings

In the content analysis, the five most accessed UK and US developed websites were analysed. The findings from these ten sites may not be transferable to other less frequently accessed IBMI sites. Transferability to other less frequently accessed sites may be less important because medicine users in the usability study did not look beyond the first ten links generated from a search engine. The study only examined information about one medicine, *simvastatin*. There is the possibility that the findings may not be generalisable to pages on the same sites about other medicines, although websites tend to have a generic style for presentation and writing. This is an empirical question that invites further work.

A key principle of usability research and User Testing, is that it is the information and website that is tested, and not the participant. This was explicitly stated to the participants in the third and fourth studies. However, variation in performance using websites can also reflect individual differences, and not just the design of the site. Participants in the usability study were mainly older adults, while people who access IBMI will be of a wider age range, have varying levels of Internet familiarity, and different experience of medicines taking. Participants in the pilot study for a trial were university employees, many of whom use the Internet daily, making them more experienced Internet users than many people who access IBMI. Therefore the performance of the participants in these studies and their responses in the interviews may not be generalisable to all medicine takers, or to people who access IBMI. Future research should examine the readability and usability of IBMI sites, enrolling other groups from the general public.

7.3.2. Usability studies and User Testing

The examination of usability reported in Chapters five and six was conducted under controlled conditions. In a more natural setting, different findings may have been made; e.g. some participants said that they would have searched for IBMI differently in their own home, looking at other sources to cross-reference the information. People accessing IBMI may leave a site that they find difficult to navigate, to access another site. In the User Test they had to persevere at using the site they were allocated to.

The aim of these studies was to identify what factors made the sites easy to use and their information readable; not to examine how people use them 'in the real world'. Examining this in a natural setting would have been problematic because extraneous variables may have affected the results. For this reason it was decided to forego some ecological validity in these studies in favour of controlled conditions, in order to increase the findings' reliability. Future research could examine people interacting with IBMI sites in a natural setting.

The focus of examination in this thesis has primarily been the websites, and not the user; driven by the grounding in the ideas of usability (see 1.5.2). But the individual was not ignored. For example, the usability study highlighted where participants' assumptions and previous experiences determined how easily they navigated an IBMI site and understood its content. That said; greater attention could have probably been given to individual differences in participants interacting with the web pages, and the consequences that this has on the outcomes measured.

7.3.3. The option to personalise IBMI

The ability to personalise the information on the sites was found to be a rare option in the sample of sites examined. Only one of the sites examined, *Medicines Guide* offered the option to customise information, limiting this to age and sex. None of the others offered a personalisation option. Therefore this thesis cannot draw any firm conclusions on the usefulness of a personalisation option on an IBMI site. There may be sites (that met the inclusion criteria) that offer personalisation options, but were less frequently accessed than the sample examined, because they were not identified using the search strategy employed. Sites that do not take advantage of the interactive nature of the Internet may miss the chance to customise information to make it more relevant to the individual. The issue of personalisation is clearly important to IBMI For example, Dickinson and Raynor (2003) proposed that personalisation is a key feature of an ideal source of information about medicines. Future research may seek to examine the usefulness of an IBMI site providing this feature or not. From a usability perspective, it can be argued that before an individual can personalise information or customise a site, they first have to be able to

navigate it with ease, and be able to understand the information. For example, Sillence *et al.* (2006) have noted that the personalisation of an e-health site will be important for the person's long-term engagement with it. But in the short term their engagement is based on site design. IBMI sites need to have a basic level of usability and readability for all users. Personalisation of an IBMI site is an important option, but it is argued that this will be of secondary importance to a site being easy-to-use.

7.3.4. The challenges of using a mixed methods approach in this thesis

Using mixed methods in three studies (reported in Chapters three, five and six) was a challenge. Running the sequential workshops before and after the systematic review was difficult because there was a gap of nearly a year between them. Some of the first workshop attendees did not attend the second workshop, and so some participants who expressed their needs from the systematic review at the initial workshop were unable to provide comment on the findings. Their loss to follow-up may have potentially resulted in valuable feedback being lost.

The studies in Chapters five and six used different methods for examining the usability of the web pages. In Chapter five, usability was examined by observing the participants' use of the website in real time, tracking their online activities, and asking them to think aloud. This yielded a rich data set from 15 participants, by which point data saturation had been reached. Running this study demanded great attention to record observations while conducting the User Test. Transcribing the protocols verbatim and noting further observations from viewing back the recordings, was a lengthy process. Analysing the usability data in relation to the User Test results was also time consuming. By comparison, piloting the outcome measures for a proposed full RCT assessing the usability of the original and redesigned sets of web pages (in Chapter six) was relatively straight forward to run and analyse. However, this method did not have as great an insight as the previous study into the ease of use of the site, as it was indirectly measured (see 5.2.2).

7.3.5. Piloting minor content and formatting changes of webpages

Piloting the intervention that made minor content and formatting changes of webpages in chapter six was important. The pilot study data did not suggest any difference in

participants' perceptions of the usability of the original or redesigned pages. This corresponds with some participants' suspicion that they could not distinguish between the pages. These points suggest that the changes to the web pages were probably too limited. Making minor content and formatting changes would not be advisable in a full trial.

7.4. What this work adds

7.4.1. Leaflet-based medicines information

Leaflet-based medicines information can improve knowledge

Study one found evidence from some individual trials that provision of WMI can increase knowledge about medicines. There was clearer evidence that the understanding and perception of the risk of a side effect are determined by the way that the risk is presented (descriptively or numerically), which has implications for EU legislation.

It was argued that knowing and understanding are not the same (see 1.5.2.). People may increase their knowledge about medicines by reading the leaflet, but this does not necessarily mean that they will understand more.

No evidence that leaflet-based medicines information improves attitudes or behaviour

The systematic review found no evidence to suggest that WMI is effective for changing attitudes towards taking a medicine, or that it can improve adherence to taking a medicine. This reflects the systematic review by Haynes *et al* (2008) that found no evidence that individually applied interventions (including written information) were effective for improving adherence to taking a medicine. No conclusive evidence of the effectiveness of WMI was found; and no trials reported an adverse effect from providing WMI.

Leaflet-based medicines information is not valued

An important finding from the workshops reported in Chapter three was that medicine users do not value leaflet-based information. It is unclear whether this results in the information being ignored; but it is known that not everyone reads the information that accompanies a medicine when they receive it for the first time, and fewer people still read the information provided with repeat prescriptions (Raynor *et al.*, 2007b). If WMI is

ignored and not valued by people, its usefulness to aid their understanding about their medicine may be doubted.

7.4.2. Internet-based medicines information

The role of search engines

The findings from Chapter five were based on robust observational methods. This has provided valuable knowledge on how people search for IBMI, adding to findings from focus groups by Peterson *et al.* (2003). The Department of Health (2006) report *'Better information, better choices, better health'* suggested that an NHS-licensed search engine would be popular with Internet users looking for healthcare information. In the search task, only one participant used *NHS Direct* to search for online information about *simvastatin*. This reflects the finding of Eysenbach and Köhler's (2002) that an 'official' healthcare portal may be under-utilised for finding online information about healthcare. In April 2008 around 60 people per million Internet users accessed *NHS Direct*. However, only 6% of those people accessed it to use it as a search tool (Source:*http://www.alexa.com/* accessed April 2008).

The rare use of a healthcare portal for searching may reflect the general dominance of *Google™* as the search engine of choice for all purposes. From a usability perspective, the uncluttered *Google™* homepage can be easily processed; whereas health portals (and other websites) often have an abundance of text that may impair some users' processing of the information, and be off-putting to them.

Adams (2006b) has proposed that information found on the Internet is a product of the search strategy adopted. In the usability study, only one participant specified the search strategy by typing more than the drug name: *'simvastatin – drug for cholesterol'*; and no-one looked beyond the first page of links on the results page. Participants were led directly to a specific page with information about the drug on the site, therefore bypassing the site's homepage. Doing so may make the homepage potentially redundant for some users; therefore site designers should ensure that any information on the homepage that is relevant to the medicine, or about the site, is repeated elsewhere on the site.

Mager (personal communications) has proposed that to become an informed patient, a person using a search engine (such as *Google*™) needs to be aware that this process deconstructs the information from its original context. She argues that this leaves the individual to make sense of the information by trying to reconstruct it, and therefore create their own information. Such an argument is in line with Adams' (2006b) proposal that the user constructs the reliability of information from different sources, including information found from sites accessed via search engines. It is argued that the processes of deconstructing and constructing the information are interwoven because they are two dimensions of the same search and ordering process (Mager, personal communications). The approach of this thesis seems to dovetail with these arguments. Where Adams talks about information being constructed, this can be said to reflect the person's internal representation of IBMI. Where Mager talks about the information having been deconstructed, she is referring to the external representation of the online information.

IBMI can empower some patients

Participants in the usability study spoke about accessing IBMI before consulting their GP, or to expand upon the information that they received from their GP after the consultation. IBMI thereby has the potential to inform and empower medicine users, providing a balance in the doctor-patient relationship. It is a legal requirement for PILs to be given to the medicine taker. There is no legislation for the provision of IBMI, and so it is likely to be sought by the user in a quest for knowledge. This might make a difference to the user's perceptions of the information. Leaflet-based WMI is not valued by medicine users, but IBMI may be more appealing as access to it is independent of receipt of the prescription or the medicine being dispensed. For example, some participants would value IBMI being accessible at the GPs surgery (at the point of prescribing), or at the dispensing pharmacy. It remains to be seen if this is achievable and if it is effective in aiding concordant relations between the health professional and medicine taker. Although IBMI appealed to many participants, there was a strong preference for receiving spoken information from their GP first. Medicine users in the stakeholder workshops similarly placed greater value on spoken information over leaflet-based information.

IBMI has mixed potential as an ideal source of WMI

The evidence reported in this thesis suggests that IBMI sites are currently not easy to use by everybody, and so they are probably not an ideal source of WMI for everyone. Study two found an abundance of online information about *simvastatin*, while Study three found that most participants used limited search strategies. A consequence is that many IBMI sites may be rarely accessed.

Chapter four highlighted the variable quality of the five most frequently accessed US and UK developed IBMI sites. It will be important that people looking for IBMI (or e-health), consider the quality of the information. For example, most of the sites provided some information that corresponded with each of the five EU categories of information; but the precise detail was inconsistent. When the sites were piloted for the User Test, only half were found to provide the necessary indicative information. The implication is that medicine users who rely on sites that do not provide complete information for the correct and safe use of the medicines may not be able to make an informed decision about taking the medicine. In addition they could act on the information, and suffer potentially serious health consequences.

Because of the difficulties that some of the participants had in using the IBMI sites, and because of less than rigorous search strategies, at this time the Internet will probably not be an ideal source of WMI for everyone. This will only be an issue into the near future, as most people will be probably be 'Internet savvy'. A conclusion is that what the person can find and understand is not only determined by her or his knowledge, Internet competence, or motivation. It is affected also by the input of the website designers and information writers.

The importance of well designed IBMI

Participants in Study three were mostly able to find and explain information on the websites. When they failed to do this, analysis highlighted three recurring problems. Firstly, some participants struggled to find information on web pages that had cluttered text and links. Secondly, tables of contents were commonly missed by participants, and when noticed, rarely used. Similarly, hyperlinks designed in an obscure manner were not

noticed. Thirdly, when the site content did not reflect the participant's expectation of the answers, they were unable to locate the information to answer the question. The problem in these examples related to the way that the information was written and presented.

From identifying these problems, this thesis has developed an original and important set of evidence-based guidelines that offer concrete recommendations for the design and content of IBMI sites. These recommendations could make IBMI (and e-health) easier to navigate and read. If IBMI is easy to use and understand, this may be valued by users.

How medicine users assess the trustworthiness of IBMI

Participants in the interviews (in Study three) said that they did not trust IBMI developed by pharmaceutical companies. Study two highlighted that some (US developed) websites promoted a pharmaceutical product, while other websites (UK and US developed) had connections with the pharmaceutical industry. None of the IBMI sites in the sample were developed by a pharmaceutical company. Company sites' ranking by search engines probably reflects their lower number of hits by Internet users. This may be a consequence of medicine users' distrust for the pharmaceutical industry.

Participants in Study three also said that they did not trust websites with commercial interests, such as industry related websites, or sites with advertising. For example, they spoke of having reservations about promotional websites, which would make them consider looking to discussion sites for a more balanced perspective, where they could read about the experiences of people taking the medicine, particularly regarding side effects. Participants also reported a lack of trust for US developed IBMI sites, but said that they trusted sites that were developed by healthcare organisations.

Participants were in principle aware of the need to assess the trust of websites, and described 'lay-techniques' for doing so: e.g. cross-referencing the information with that found on other sites, or trusting a site that was recommended by a GP. These techniques reflect the use of heuristics by people when accessing a new healthcare website for the first time (Sillence and Briggs, 2007); and Adams' (2006b) assertion that the general public construct reliability of e-health from cross-referencing sources of information.

Participants in the usability study did not adopt rigorous means for assessing the trustworthiness of IBMI, and made their judgement based on the assumed 'professional appearance' of the site. Peterson-Clarke reported that pharmacists adopt a similar method, using the 'professionalism' of a website as an indicator of its quality (Savage, 2008).

7.4.3. Methods and methodology

Usability and User Testing can be successfully applied to evaluate IBMI

Chapters five and six reported the first known studies to have applied a User Test to evaluate web pages. This was a novel way to examine the readability of online information for the participants, and provided a real-life scenario in which to study their use of IBMI.

The use of mixed methods is beneficial for the examination of WMI

A mixed methods approach was adopted to provide a well-rounded overview of WMI both quantitatively and qualitatively. This was a challenge (see 7.3.4), but on the whole benefited the examination of WMI. The sequential stakeholder workshops ran before and after the systematic review. This enabled the medicine information stakeholders to input to the aims at the outset of the review, and to give feedback on the findings at the end. Around half of the stakeholders were medicine users, and so this enabled the review to have patient input.

Concurrent verbal protocols enabled insight into the cognitive processes of the person interfacing with the site during the task. This highlighted not only the difficulties that participants had when using the sites; but also their perceptions of why they were able (or not) to find and explain the indicative information on the site. Conducting an interview with the participants immediately after the User Test was essential, because in usability studies an interview is an indirect means for assessing usability (see 5.2.2). By asking participants to talk about using the site immediately after User Test, this study sought to increase the chance that this was the sole focus of their responses, and so reduce the indirectness of the interview.

No known previous studies have mixed a battery of usability methods for examining IBMI, making this an innovative approach for evaluating IBMI. In a study evaluating a Dutch e-health site, *Senior Gezond (Senior Health)* (*http://www.seniorgezond.nl*); Alpay *et al.*

(2004) used different usability methods (questionnaires, observations, focus group discussions, and individual interviews). They concluded that usability methods were beneficial because they enabled the needs, expectations and abilities of participating patients to be considered when the site was designed. It is similarly argued in this thesis that the evaluation of IBMI using the mix of usability methods and enrolling medicine users was advantageous because it highlighted the problems and needs of medicine users accessing IBMI.

Sequential methods were used in Chapter six to pilot a study design, intervention and outcome measures, for a full RCT. This enabled the recording of stakeholders' recommendations for the redesign of IBMI, implementing some of them, and examining their effects on a User Test. Using questionnaire to examine how easily they felt that they navigated the pages, and their reported satisfaction with the information, were efficient means for examining their performance on the main task.

Utilising a mixed methods approach, while a practical challenge; was immensely beneficial to the research in this thesis. The combining of quantitative and qualitative research has provided great insight into the usefulness of WMI, thereby achieving the aim of using this approach. This is an important finding of this thesis.

7.5. Implications

The findings of the research have practical implications for the design and delivery of WMI in general, and specifically for IBMI, and for further research of WMI and IBMI.

7.5.1. Written medicines information

WMI that is understandable can be useful for medicine users

If WMI is understandable, it may be useful to the medicine user. This will depend upon the purpose for which the person uses WMI (see below). WMI should reflect the knowledge and expectations of the medicine user, because the usability study showed that information on a website about a medicine was less easily found and understood, or even misunderstood, when it did not correspond with the reader's knowledge. This can reflect individual differences in interfacing with IBMI sites. Furthermore, there is probably no reason why this does not also apply to leaflet-based WMI.

The risk of a side effect should be presented numerically because the systematic review showed that medicine takers are better able to understand information presented this way, than if presented using verbal descriptors. The review by Berry (2006) recommends this numerical information should be presented as a natural frequency (for example 1 in 100 people may be at risk of a side effect), because this is more easily understood than information presented as a percentage.

Medicine users want information that is specific and relevant to their needs; and would (probably) value it being personalised. They want condition-based information, and to know about other patients' experiences of taking the medicine. Producers of WMI should recognise that, because people want and need different levels of information depending on the nature and severity of their illness, there is a need for different versions of the same information. Furthermore, the information in a leaflet or on a website can quickly be superceded. Therefore there needs to be a means for alerting users who regularly take a medicine, that the information has been updated.

These points highlight the importance of tailoring WMI (leaflet or website) to the needs of the medicine user. The information needs of patients differ between them, and within the same patient, over time. Because of its interactive nature, IBMI could offer personalised information. However, this was a feature of only one site, to a very limited degree. This represents a failure of the potential of IBMI, and there is a need for IBMI sites (in general) to offer the option of personalising information.

If and how people trust WMI

Two common themes emerged from the examination of participants' trust for WMI:

(i)   Participants did not trust information developed by pharmaceutical companies;

(ii)   Participants employed lay-techniques for assessing trust and were unaware of formal methods for assessing the quality of e-health.

Pharmaceutical companies are the main producer of WMI, and the participants' lack of trust for leaflets (see Chapter five) cannot be ignored. EU legislation requiring the User Testing of leaflets has led many pharmaceutical companies to contract out the user-testing

of their leaflets to other organisations (Knapp, personal communications). A result of the legislation should be the improved readability of the PILs, but it may not necessarily increase public trust in the leaflets.

In early 2008 the Royal Pharmaceutical Society of Great Britain introduced a logo to help Internet users identify websites that belong to pharmacies registered in the UK (Connelly, 2008). The hope is that people accessing the websites would see the logo and be assured that the site belongs to a credible retailer selling genuine medicinal products. This logo was introduced after the completion of the empirical research in this thesis, and it remains to be seen if this is helpful for the general public. As with the *HoN Code* seal, the logo will be useful only if the person notices it on sites that display it, and recognises what it stands for. Furthermore, the logo says nothing about the credibility of the content on the site, and so will not benefit the person searching for information.

WMI should be designed to be easy to use

The importance of good design of leaflet-based and Internet-based WMI cannot be over-stated. The usability study found that the design of the sites impacted on how easily participants navigated them, how easily they understood their information, and their trust of the site. To ensure IBMI (and PILs) are useful, in terms of their information being locatable and understandable, will necessitate best design practice for IBMI (and PILs) with user involvement at the design stage. This is already recommended for PILs by Sless (2001), in his proposed good design principles for communicating medicines information. The importance of good design in PILs is legislated for in the EU, and it is hoped that this will have beneficial effects by improving the readability of the leaflets, making them more understandable for medicine takers. Raynor (2008b) has argued that the legislation will raise the level of quality of the leaflets patients receive now and in the future. However, this does not guarantee that people will read and understand the information and IBMI is not regulated.

Applying the evidence-based recommendations for the design of IBMI (see 5.8.3) could make the sites easier to use. For example, the addition of a find bar would enable users to

search for a keyword on the page. Navigation may also be improved with the addition of a hyperlinked table of contents, when not currently available, or by making this feature more prominent, if not easily noticeable.

The purpose of WMI

The purpose of WMI was not specifically addressed in this thesis, which focused on examining usability and readability. However at various points in the research reported in this thesis, participants spoke about the purpose of WMI for themselves, healthcare professionals, and the pharmaceutical industry, therefore this cannot be entirely ignored. For example, they said that they want WMI to complement and not replace spoken information from the health professional (see 3.3.2 or 5.7.5). This will have consequences for the role healthcare professionals assign to WMI (see below). For example, Raynor (2007) has recommended that pharmacists focus on providing spoken information, and use WMI as a means for reinforcing messages for the patient.

Making a similar point, Narhi (2007) has contended that IBMI does not, cannot, and will not replace PILs and spoken information from health professionals, because PILs and spoken information are still trusted more by the general public. The implication of this is that leaflet-based or Internet-based medicines information will not be the primary source of information about medicines for many people, but it may still be a source of information for them. Therefore WMI is not without purpose. While not everyone will rely on WMI as their primary source of information, some people will. For example, Gray and Blenkinsopp (2007) have acknowledged that IBMI has the potential to empower some people to challenge their health professional's treatment recommendations. Medicine users in the usability study gave this as a reason for accessing IBMI (see 5.7.2.).

It has been noted that medicine users perceive a purpose of WMI is to meet legislation requirements (Raynor et al., 2007a). This can suggest that it is incidental if it enables an informed choice to be made. For example, Janse-de Hoog has suggested that pharmaceutical companies focus solely on ensuring that their leaflets pass User Tests to meet the requirements of legislation, rather than focusing on improvements indicated by

the test results (Savage, 2008). Therefore if the leaflet passes a User Test, then the company has achieved its legal duty of providing information that is deemed to be "readable".

Provision of WMI by health professionals

Following on from above, if WMI is to have a role in the consultation process, this will necessitate its provision by healthcare professionals. This could be achieved by using leaflet-based or internet-based WMI to reinforce the consultation. This information would need to be good quality, i.e. accurate and complete, and readable; informing about the condition as much as the medicine.

Latter and Courtenay (2004) have noted that patients value nurse practitioners in particular because of their accessibility and approachability and their provision of information. It remains to be seen if nurses (and GPs) are able to facilitate the use of WMI during consultations, (see also 7.5.3).

Pharmacists are more likely than GPs to be shown information that medicine users have found from the Internet (McCaw *et al.*, 2007). This will necessitate pharmacists having the skills and competence to assess the quality of IBMI that is shown to them, or before recommending it to medicine users.

7.5.2. Internet-based medicines information

Examining the usefulness of redesigned IBMI

No known previous studies have examined whether the redesign of IBMI improved people's finding and understanding of specific information. Research has examined the effect of redesigning leaflet-based information. Fuchs and Hippius (2007) made evidence-based changes to the design of a PIL, and found that participants significantly improved their location and explanation of the information using the redesigned leaflets. Similarly, Dickinson *et al.* (2001) reported that participants found and explained the information in a redesigned leaflet (based on principles of best practice in design) more easily than when using a leaflet based on the EU recommendations for PILs in force at the time. These findings show that it is possible to redesign (leaflet-based) information to make it easier to locate and understand.

No evidence was found that the redesign of the web pages improved their usability or readability. It is argued that this does not negate the importance of good design practice in IBMI, because the changes were limited to content and content formatting alone. It remains to be seen if implementing the recommendations for the design of IBMI sites could improve their usability and readability.

7.5.3. Recommendations for future research

The last set of implications is for future research evaluating WMI.

Improving research examining WMI

The systematic review highlighted the poor conduct of some trials of WMI, and the generally poor reporting of their methods. It is recommended that future research should be conducted in a more rigorous manner (following the CONSORT guidelines), using theory-based or evidence-based interventions, and that valid outcome measures that reflect the needs of medicine users are consistently used across trials.

People overestimate the risk of a side effect when it is presented in words. Future studies of risk perception should examine participants' concurrent thinking aloud when estimating the risk, to attempt to unpick the processes underlying their incorrect risk estimates.

Examining how medicine users searched for IBMI, and navigated web pages to find and understand information was illuminating. However, the sample of participants was not representative of everyone who uses IBMI. Gray and Blenkinsopp (2007) have noted that the full potential of the Internet has not yet been realised for aiding people with sensory impairments or low health literacy. It is recommended therefore that future research replicates the usability study with a wider sample of the general public – people with disabilities, for example.

Examining provision of WMI at the point of prescribing

Participants in the workshops stated a need for the availability of WMI at the point of prescribing. Nurse prescribers or pharmacists may have better scope than doctors for introducing WMI to the consultation process. Future research should examine the

consequences of making available leaflet-based or Internet-based WMI during patient consultations. It would be important to examine if this is achievable; what barriers there are to implementing this successfully, if it is valued when it is given, and how this impacts on the decisions taken by a healthcare professional and patient.

Examining how people search for IBMI

Observing how people search for WMI on the Internet revealed neglect for healthcare portals. Future research should explore the barriers to the public conducting searches from healthcare portals. It remains to be seen if healthcare portals are considered by the public less appealing to use than a search engine, or if this just reflects the popularity or familiarity of search engines. Medicine users may trust search engines more than healthcare portals for searching for sites with information about medicines. They may be more aware of search engines and less knowledgeable of healthcare portals; or they may find search engines easier to use.

Examining new Internet applications

With the emergence in the near future of Web 3.0 there will be a need for a robust evaluation of the usefulness of this and similar applications for people using the Internet to find information about medicines. The Internet can provide information in different formats: for example, as text alone or as broadband sound and vision (e.g. *'You Tube'* *http://www.youtube.com/t/about*). When information is provided as spoken words, it is processed via auditory channels, leaving visual channels free to process images, and having the potential to decrease cognitive load (Moreno, 2006). It is therefore recommended that future research compares IBMI provided via different formats to see if one way is more effective than another for finding and locating specific information, or more favoured by medicine users. Using a mixed methods design, a trial could be run with participants randomly allocated to receive either identical IBMI content as text only, or in video format, providing the same information verbally and visually. They would be asked to think aloud concurrently while performing a User Test; and a follow-up interview could provide further insight into their thoughts about using the different modalities.

Examining the information-seeking behaviours of medicine users

Khechine *et al.* (2008) have shown that patients access e-health (in part) at the treatment identification stage. This is consistent with the finding in this thesis that medicine users said they would access IBMI after consulting a GP, where they may have had a condition and its treatment identified for the first time. The final recommendation is therefore to examine the information-seeking actions of the person once she or he has been prescribed a medicine for the first time. There are many aspects that can be focused upon. For example, does the patient seek out information about the medicine, and if so, what sources does she or he use for searching?

Barriers would need to be overcome to examining these important questions. Firstly there would be ethical issues to address as the research would necessitate the invasive tracking of the person having been told for the first time about a condition and their reaction to this news. Secondly conducting this research would require the collection of a vast array of ethnographic data. For example, it might include observation of GP consultations, individual interviews, and focus groups of people who have recently been prescribed a medicine for the first time.

7.6. Concluding remarks on leaflet-based and Internet-based WMI

People reading leaflet-based WMI can increase their knowledge about their medicines. However, this does not guarantee that the person will necessarily increase their understanding. There is no evidence that people reading WMI will change their attitudes or behaviours relating to taking their medicines. WMI is generally not valued by medicine takers, who value spoken information about medicines from healthcare professionals more than information available as a leaflet, or on the Internet.

The Internet has mixed potential in its usefulness in enabling patients to understand information about medicines. Because of problems with the design of the sites, current IBMI will not be a useful source of medicines information for some people. Changes to the design of the sites could make them easier to navigate. However, the design of IBMI is not (and probably cannot be) legislated for like WMI, and so improvements to the design of sites may not be universal.

How WMI is written in part determines how easily a person understands it; therefore designers of websites (and leaflets) need to ensure that the information reflects the knowledge and expectations of the medicine user, so that it can be understood. As increasing numbers of people access IBMI, the need for websites that are easy to use and that have content that can be easily understood, becomes greater. This could be achieved by involving end-users in the design stage of the website, and evaluating this by adopting a study design that compares the ease of use of the site and the readability of its content with an earlier version of the same website.

IBMI can benefit those who can access it. Therefore it is important that efforts are made to encourage and improve universal access to IBMI. It is vital that the usability and understandability of the IBMI sites are improved, to make them more useful to the medicine user seeking to make an informed choice from reading this information.

The work reported in this thesis has applied User Testing to evaluate websites with information about medicine, which is probably an original contribution to knowledge. Using a mixed methods approach has been both original and beneficial to the research, and again is probably an original contribution to knowledge. The evidence reported in this thesis has shown that improvements are needed to make leaflet-based and Internet-based WMI easier to use; i.e. to read and understand the information. This could make WMI more useful for medicine users who seek to make an informed choice about taking their medicines, or be better informed about the safety and efficacy of taking the medicine.

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Appendices

Appendix 1: Statement regarding contribution to joint authorship of works contained in this thesis
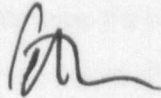
Donald Nicolson was the lead author of the following journal article that is referred to in his thesis.

1. **Nicolson D.J.**, Knapp, P., Raynor, D.K., Grime, J., & Pollock, K. (2006). Do themes in consumer medicines information literature reviews reflect those important to stakeholders? *Pat Educ Couns*, 64, 112-8

Contribution:

- Research idea – DJN had the original research idea
- Methods design – DJN devised the matrix for analysing the results
- Data collection – DJN collated the main themes reported in the published reviews
- Data analysis – DJN led the data analysis
- Writing – DJN wrote all drafts

Signature of another author:
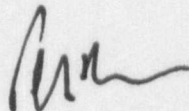
Donald Nicolson was a joint author of the following reports that are referred to in his thesis.

2. Raynor DK, Blenkinsopp A, Knapp P, Grime J, **Nicolson DJ**, Pollock K, Dorer G, Gilbody S, Dickinson D, Maule AJ, Spoor P. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess*. 2007 Feb; 11(5):1-178.

Contribution:

- Data collection – DJN was the primary reviewer and led data extraction for the RCT studies
- Data analysis – DJN led the analysis of the quantitative results
- DJN drafted the quantitative results and the quantitative section of the discussion

Signature of another author:

3. **Nicolson D**, Knapp P, Raynor DK (Theo), Spoor P. Written information about individual medicines for consumers. Cochrane Database of Systematic Reviews, In press.

Contribution:

- Research idea – PK, DKR and DJN conceived the idea for the review
- Data collection – DJN was the primary reviewer and led data extraction
- Data analysis – DJN and PK analysed the data
- Writing – DJN and PK wrote all drafts

Signature of another author:
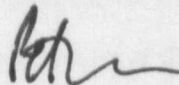
Donald Nicolson has been the lead or joint author of the following conference proceedings which are referred to in his thesis.

4. Using consumer testing to determine the most effective design of web pages containing information about medicines. **Nicolson, D.J.,** Knapp, P., Gardner, P., Raynor, D.K 2008 International Social Pharmacy Workshop Queenstown, New Zealand.

Contribution:

- Research idea – DJN, PK, PG and DKR devised the aims for this study
- Methods design - DJN, PK, PG and DKR devised the methods for this study
- Data collection - DJN conducted the study, observing the participants using the websites
- Data analysis – DJN analysed all study data
- Writing – DJN wrote all drafts of the presentation

Signature of another author:

5. Is the Internet useful for finding and understanding information about medicines?
   Nicolson, D.J., Knapp, P., Gardner, P., Raynor, D.K Health Services Research and
   Pharmacy Practice Conference 2008 Liverpool John Moores University, United
   Kingdom. International Journal of Pharmacy Practice; Supplement 1; A33-A35.

   Contribution:
   - Research idea – DJN, PK, PG and DKR devised the aims for this study
   - Methods design - DJN, PK, PG and DKR devised the methods for this study
   - Data collection - DJN conducted the study, observing the participants using the websites
   - Data analysis – DJN analysed all study data
   - Writing – DJN wrote all drafts of the presentation

Signature of another author:
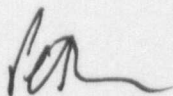
6. How do people find websites with information about medicines? Knapp, P.,
   Nicolson, D.J., Gardner, P., Raynor, D.K Health Services Research and Pharmacy
   Practice Conference 2008 Liverpool John Moores University, United Kingdom.
   International Journal of Pharmacy Practice; Supplement 1; A19-A32.

   Contribution:
   - Research idea – DJN, PK, PG and DKR devised the aims for this study
   - Methods design - DJN, PK, PG and DKR devised the methods for this study
   - Data collection - DJN conducted the study, observing the participants using the websites
   - Data analysis – DJN analysed all study data
   - Writing – DJN wrote all drafts of the presentation

Signature of another author:

7. Comparing the quality, content and design of internet-based medicines information sites. **DJ Nicolson**, N Carrigan, P Knapp, DK Raynor. EACH 2006 Conference. International Conference on Communication in Healthcare. September 2006 Basel, Switzerland.

Contribution:

- Research idea – DJN, PK, and DKR devised the aims for this study
- Methods design - DJN, PK, and DKR compiled the methods for analysing the quality, content and design features of the websites
- Data collection - DJN conducted the search for Internet sites
- Data analysis – DJN analysed the sites quality, content and design features
- Writing – DJN wrote all drafts of the presentation

Signature of another author:

8. Methods issues arising from a systematic review evaluating the effectiveness of written medicines information. **D Nicolson**, DK Raynor & P Knapp. 2006 *IJPP* 14(1) A11 [14th International Social Pharmacy Workshop, St Anne's College Oxford]

Contribution:

- Research idea - DJN, PK, and DKR devised the aims for this study
- Methods design – n/a (discursive paper)
- Data collection - n/a (discursive paper)
- Data analysis - n/a (discursive paper)
- Writing – DJN wrote all drafts of this presentation

Signature of another author:

Appendix 2: Tools used in the assessment of the quality of IBMI content

Health on the Net Code of Conduct (HONCode)

The following summarises the information available at *http://www.hon.ch/HONcode/Conduct.html*. For a site to receive this accreditation, it must meet the following eight terms.

Term	Definition
1. **Authoritative**	Medical/health advice is only offered by trained and qualified professionals, unless otherwise stated.
2. **Complementarity**	The information complements but does not replace the patient-physician relationship.
3. **Privacy**	Respects the privacy and confidentiality of personal information submitted.
4. **Attribution**	Information is supported by clear reference to evidence.
5. **Justifiability**	Provides evidence to back up its claims.
6. **Transparency**	Contact details are clearly presented.
7. **Financial disclosure**	All sources of funding accounted for.
8. **Advertising policy**	Clear distinction of advertising from editorial content.

The DISCERN Instrument

The following is a summary of the questions recommended to be asked in the DISCERN instrument available at *http://www.discern.org.uk/discern.pdf*.

It proposes a good quality publication about treatment choices will:

1. Have explicit aims

2. Achieve its aims

3. Be relevant to consumers

4. Make sources of information explicit

5. Make date of information explicit

6. Be balanced and unbiased

7. List additional sources of information

8. Refer to areas of uncertainty

9. Describe how treatment works

10. Describe the benefits of treatment

11. Describe the risks of treatment

12. Describe what would happen without treatment

13. Describe the effects of treatment choices on overall quality of life

14. Make it clear there may be more than one possible treatment choice

15. Provide support for shared decision-making

Appendix 3: Programmes of the MILK Stakeholder Workshops

Consultation Workshop

Friday October 1st 2004, Leeds

Programme

11.00	**Registration and coffee**
11.30	**Introduction and welcome** Theo Raynor
11.40	**Table Discussion 1: Good and bad examples** • Discuss a previous personal (or friend/family) example of written medicines information. • Was the information useful?
12.05	**Report back to whole group** Alison Blenkinsopp
12.20	**Why is medicines information important?** David Dickinson
12.35.	**What kinds of research have been done?** Alison Blenkinsopp
12.45	**How are we going to do this systematic review?** Peter Knapp • What is a systematic review? • What is your input as a consumer?
13.00	**Lunch**
13.45	**Table Discussion 2 – Introduction** Gill Dorer • What we'd like you to do
13.55	**Table Discussions** • What are the important things about medicine information leaflets? • What is the role (purpose) of medicine information leaflets is? • What makes medicine information leaflets effective? • What makes medicine information leaflets valuable?
14.50	**Coffee Break**
15.05	**Feedback & summing up** Theo Raynor
15.30	**Close**

2nd Stakeholder Consultation Workshop

Monday September 12th 2005, Leeds

Programme

11.00	**Registration and coffee**
11.31	**Introduction and welcome** Theo Raynor
11.41	**What you hope will come out of the review** John Maule introduction, then individual group discussions
12.00	**Role and value review: Summary of main findings** Janet Grime
12.15	**Table discussions of role and value review findings**
12.45	**Lunch**
13.15	**Effectiveness review: Summary of main findings** Donald Nicolson
13.30	**Table discussions of effectiveness findings**
14.00	**Feedback on information design**
14.10	**General feedback of overall findings** Chaired by Peter Knapp
14.50	**Coffee Break**
14.35	**Recommendations** ▪ **For priorities for future research** ▪ **Other general recommendations** Alison Blenkinsopp
15.10	**Feedback on usefulness of stakeholder workshops** John Maule
15.15	**Summing up and what's next** Theo Raynor

Appendix 4: References of trials in the effectiveness review

Trials comparing the absolute effectiveness of WMI

- Arthur, V., & Clifford, C. (1998). Evaluation of information given to rheumatology patients using non-steroid anti-inflammatory drugs. *J Clin Nurs*, 7, 175-181.
- Baker, D., Roberts, D.E., Newcombe, R.G., & Fox, K.A. (1991). Evaluation of drug information for cardiology patients. *Br J Clin Pharmacol*, 31, 525-531.
- Clark, C.M., & Bayley, E.W. (1972). Evaluation of the use of programmed instruction for patients maintained on Warfarin therapy. *Am J Public Health*, 62, 1135-1139.
- Dodds, L.J. (1986). Effects of information leaflets on compliance with antibiotic therapy. *Pharm J*, 236, 48-51.
- Gibbs, S., Waters, W.E., & George, C.F. (1989). The benefits of prescription information leaflets (1). *Br J Clin Pharmacol*, 27, 723-739.
- Johnson, M.W., Mitch, W.E., Sherwood, J., Lopes, L., Schmidt, A., & Hartley, H. (1986). The impact of a drug information sheet on the understanding and attitude of patients about drugs. *JAMA*, 256, 2722-2724.
- Kumana, C.R., Ma, J.T., Kung, A., Kou, M., & Lauder, I. (1988). An assessment of drug information sheets for diabetic patients: only active involvement by patients is helpful. *Diabetes Res Clin Pract*, 5, 225-231
- Little, P., Griffin, S., Kelly, J., Dickson, N., & Sadler, C. (1998). Effect of educational leaflets and questions on knowledge of contraception in women taking the combined contraceptive pill: randomised controlled trial. *Brit Med J*, 316, 1948-1952.
- McBean, B.J., & Blackburn, J.L. (1982). An evaluation of four methods of pharmacist-conducted patient education. *Can Pharm J*, 115, 167-172.
- Morris, L.A., & Kanouse, D.E. (1982). Informing patients about drug side effects. *J Behav Med*, 5, 363-373.
- Peura, S., Klaukka, T., Hannula, A.M., & Eerikainen, S. (1993). Electronically produced information leaflets increase patients' understanding of antibiotics. *Int J Pharm Pract*, 2, 22-25.
- Peveler, R., George, C., Kinmonth, A.L., Campbell, M., & Thompson, C. (1999). Effect of antidepressant drug counselling and information leaflets on adherence to drug treatment in primary care: randomised controlled trial. *Brit Med J*, 319, 612-615.
- Pope, J.E., Stevens, A., & Rooks, M. (1998). A randomized double blind trial of verbal NSAID education compared to verbal and written education. *J Rheumatol*, 25, 771-775.
- Regner, M.J., Hermann, F., & Reid, L.D. (1987). Effectiveness of a printed leaflet for enabling patients to use digoxin side-effect information. *Drug Intell Clin Pharm*, 21, 200-204.
- Robinson GL, Gilbertson AD, Litwack L. The effects of a psychiatric patient education to medication program on post-discharge compliance. The Psychiatric Quarterly. 1986;58:113-8.
- Savas, S., & Evcik, D. (2001). Do undereducated patients read and understand written education materials? A pilot study in Isparta, Turkey. *Scand J Rheumatol*, 30, 99-102.
- Strydom, A., & Hall, I. (2001). Randomized trial of psychotropic medication information leaflets for people with intellectual disability. *J Intellect Disabil Res*, 45, 146-151.
- Vander Stichele, R.H., Thomson, M., Verkoelen, K., & Droussin, A.M. (1992). Measuring patient compliance with electronic monitoring: lisinopril versus atenolol in essential hypertension. *Post Market Surveill*, 6, 79-90.
- Vesco, D., Toumi, M., Faraj, F., Razzouk, H., & Orehek, J. (1990). Manufacturer's information insert and subjective theophylline side-effects. *Eur Respir J*, 3, 1162-1165.

Trials comparing the relative effectiveness of the presentation of WMI

- Clark, C.M., & Bayley, E.W. (1972). Evaluation of the use of programmed instruction for patients maintained on Warfarin therapy. *Am J Public Health*, 62, 1135-1139.
- Desponds G, van MG, Schelling JL. Comparison of patient-oriented package insert for

benzodiazepines [Etude comparative d'une nouvelle notice d'emballage pour benzodiazapines adaptee sux malades]. *Schweiz. Med. Wochenschr.* 1982;112:1376-82.

- Dolinsky, D., Gross, S.M., Deutsch, T., Demestihas, E., & Dolinsky, R. (1983). Application of psychological principles to the design of written patient information. *Am J Hosp Pharm*, 40, 266-271.
- Labor, S.L., Schommer, J.C., & Pathak, D.S. (1995). Information overload with written prescription drug information. *Drug Inf J*, 29, 1317-1328.
- Little, P., Griffin, S., Kelly, J., Dickson, N., & Sadler, C. (1998). Effect of educational leaflets and questions on knowledge of contraception in women taking the combined contraceptive pill: randomised controlled trial. *Brit Med J*, 316, 1948-1952.
- van Haecht, C.H.M., Vander Stichele, R., Debacker, G., & Bogaert, M.G. (1991). Impact of Patient Package Inserts on Patients Satisfaction, Adverse Drug-Reactions and Risk Perception - the Case of Nsaids for Posttraumatic Pain Relief. *Patient Educ Couns*, 17, 205-215.

Trials comparing the relative effectiveness of the presentation risk of side effect information

- Bergus, G.R., Levin, I.P., & Elstein, A.S. (2002). Presenting risks and benefits to patients: the effect of information giving on decision making. *J Gen Intern Med*, 17, 612-617.
- Berry, D., Knapp, P., & Raynor, T. (2002). Is 15 per cent very common? Informing people about the risks of medication side effects. *Int J Pharm Pract*, 10, 145-151.
- Berry, D., Raynor, T., Knapp, P., & Bersellini, E. (2004). Over the counter medicines and the need for immediate action: A further evaluation of European Commission recommended wordings for communicating risk. *Patient Educ Couns*, 53, 129-134.
- Berry, D.C., Michas, I.C., & Bersellini, E. (2002). Communicating information about medication side effects: effects on satisfaction, perceived risk to health, and intention to comply. *Psychol Health*, 17, 247-267.
- Berry, D.C., Michas, I.C., & Bersellini, E. (2003). Communicating information about medication: the benefits of making it personal. *Psychol Health*, 18, 127-139.
- Berry, D.C., Raynor, D.K., & Knapp, P. (2003). Communicating risk of medication side effects: An empirical evaluation of EU recommended terminology. *Psychol Health Med*, 8, 251-263.
- Berry, D.C. (2004). Interpreting information about medication side effects: Differences in risk perception and intention to comply when medicines are prescribed for adults or young children. *Psychol Health Med*, 9, 227-234.
- Knapp, P., Raynor, D.K., & Berry, D.C. (2004). Comparison of two methods of presenting risk information to patients about the side effects of medicines. *QSHC*, 13, 176-180.

Appendix 5: Descriptive information about the trials in the effectiveness review

<u>Medicine information provided by the trials</u>

- **Nineteen trials provided information for medicines for long-term conditions:**
  (Arthur and Clifford, 1998, Gibbs *et al.*, 1989, Pope *et al.*, 1998, Savas and

  Evcik, 2001, van Haecht *et al.*, 1991) .

- **Five trials provided information for non-steroidal anti-inflammatory drugs (NSAIDs):**
  (Baker *et al.*, 1991, Clark and Bayley, 1972, Dolinsky *et al.*, 1983, Gibbs *et*

  al., 1989, Johnson *et al.*, 1986, McBean and Blackburn, 1982, Regner *et al.*,

  1987, Vander Stichele *et al.*, 1992).

- **Nine trials provided information for cardiovascular medicines:**
  (Desponds *et al.*, 1982, Dodds, 1986, Labor *et al.*, 1995, Peura *et al.*, 1993,

  van Haecht *et al.*, 1991).

- **Five trials provided information about a medicine to treat an acute condition:**
  (Dolinsky *et al.*, 1983).

  - One trial provided information about medicines used to treat a chronic
    condition (methyldopa for high blood pressure), and an acute condition
    (ampicillin for bacterial infection):
  (Bergus *et al.*, 2002).

- **Ten trials that examined perception of the risk of a side effect used information about a hypothetical antibiotic:**
  Berry *et al.*, 2002a; Berry *et al.*, 2002b; Berry *et al.*, 2003a; Berry *et al.*, 2003b;

  Berry 2004.

  - **Three trials that examined perception of the risk of side effects provided information about the following respective real medicine**
    aspirin (Berry *et al.*, 2004); *ibuprofen* (Knapp *et al.*, 2004), and *simvastatin* .

<u>Category of outcomes measured by the trials</u>

- **Twenty-nine trials (reported in 24 papers) measured knowledge:**

Arthur and Clifford, 1998, Baker *et al.*, 1991, Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Clark and Bayley, 1972, Dodds, 1986, Dolinsky *et al.*, 1983, Gibbs *et al.*, 1989, Johnson *et al.*, 1986, Knapp *et al.*, 2004, Kumana *et al.*, 1988, Little *et al.*, 1998, McBean and Blackburn, 1982, Morris and Kanouse, 1982, Peura *et al.*, 1993, Pope *et al.*, 1998, Regner *et al.*, 1987, Robinson *et al.*, 1998, Savas and Evcik, 2001, Strydom and Hall, 2001.

- **Seventeen trials (reported in 13 papers) measured an attitude:**
  Baker *et al.*, 1991, Bergus *et al.*, 2002, Berry *et al.*, 2002a, Berry *et al.*, 2002b, Berry *et al.*, 2003a, Berry *et al.*, 2003b, Berry *et al.*, 2004, Berry, 2004, Desponds *et al.*, 1982, Gibbs *et al.*, 1989, Knapp *et al.*, 2004, Labor *et al.*, 1995, McBean and Blackburn, 1982.

- **Nine trials (reported in nine papers) measured behaviour:**
  Dodds, 1986, Dolinsky *et al.*, 1983, McBean and Blackburn, 1982, Morris and Kanouse, 1982, Peveler *et al.*, 1999, Robinson *et al.*, 1986, van Haecht *et al.*, 1991, Vander Stichele *et al.*, 1992.

Appendix 6: Source of identified websites

Sites from Doupi & van der Lei (1999), and Hatfield, May and Markoff (1999)

1. Cheshire Medical Centre: http://www.cheshire-med.com/

2. Druginfonet http://www.druginfonet.com/

3. HealthPhillyNews http://www.philly.com/mld/philly/living/health/

4. Healthtouch Online http://www.healthtouch.com/

5. Infomed Drug Guide http://infomed.org/100drugs/

6. Intelihealth http://www.intelihealth.com/IH/ihtIH/WSIHW000/408/408.html

7. Mayo Clinic http://www.mayoclinic.com/

8. MedicineNet http://www.medicinenet.com/script/main/hp.asp

9. Mediconsult http://mediconsult.8media.org/

10. Medscape http://www.medscape.com/home

11. On-Health http://on-health.com/

12. PharmInfoNet http://pharminfo.8media.org/

13. Rx–Advisor http://e-pharmacy.com/HTML/health_infor/rx_advisor.html

14. Rxlist. http://www.rxlist.com/

15. Thriveonline http://www.thriveonline.com.au/

Sites found from search engines search

16. Australian Prescription Products Guide Online
http://www.appco.com.au/appguide/default.asp

17. Best Treatments http://www.besttreatments.co.uk/btuk/home.html

18. Educate before You Medicate (National Council on Patient Information and Education) http://www.talkaboutrx.org/index.jsp

19. Medicine Guides http://medguides.medicines.org.uk/

20. MedlinePlus http://www.nlm.nih.gov/medlineplus/druginformation.html

21. Net Doctor http://www.netdoctor.co.uk/

22. Patient Health International http://www.patienthealthinternational.com/

23. Patient Information on Medicines http://www.nmhct.nhs.uk/pharmacy/cclg-pat.htm

24. Patient UK http://www.patient.co.uk/

25. PharmWeb http://www.pharmweb.net/pwmirror/pwz/pharmwebz.html

26. SafeMedication.com http://www.safemedication.com/resultsList.cfm via

http://www.intelihealth.com/IH/ihtIH/WSIHW000/408/408.html

27. US Food and Drug Agency http://www.fda.gov/

28. Patient Health UK http://www.patienthealthuk.net/node/home.aspx

29. Zocor http://www.zocor.com/simvastatin/zocor/consumer/index.jsp

30. Simvastatin Disease Database Information
http://www.diseasesdatabase.com/ddb12128.htm

31. Drugs.com http://www.drugs.com/cons/Simvastatin.html

32. eMedicine Health http://www.emedicinehealth.com/articles/53048-7.asp

33. Answers.com http://about.com/health/

34. dmoz open directory project
http://dmoz.org/Health/Pharmacy/Drugs_and_Medications/S/Simvastatin/

35. Vytorin ezetimibe/simvastatin tablets patient information
http://www.vytorin.com/ezetimibe_simvastatin/vytorin/consumer/index.jsp

36. About health and fitness http://aids.about.com/od/miscellaneousmeds/p/zocor.htm

37. myDNA
http://www.mydna.com/resources/resources/meds/leaflets/d05348A1.html

38. worstpills.org http://www.worstpills.org/results.cfm?drug_id=584

39. The Cleveland Clinic Health Information Centre
http://www.clevelandclinic.org/health/health-info/docs/0700/0729.asp?index=4927

40. Health Square http://www.healthsquare.com/newrx/cx1500.htm

41. Medic8 Family Health Guide
http://www.medic8.com/healthguide/articles/simvastatin.html

42. Why Generic http://www.why-generic.com/drugs/generic/zocor.html

43. Online Pharmacy http://www.alldruginfo.com/s/simvastatin/

44. Talk medical http://www.talkmedical.com/medications/5600/Simvastatin

45. GP notebook http://www.gpnotebook.co.uk/simplepage.cfm?ID=-227868642

46. Canadian Pharmacy North
http://www.canadarxgroup.com/drugs/zocor_simvastatin.html

47. Yahoo Health http://health.yahoo.com/drug/_d00746a1

48. Health Digest http://www.healthdigest.org/prescription-drug-
reference/simvastatin-oral-tablet-9572.htm

49. Healthopedia.com http://www.healthopedia.com/drugs/quick/simvastatin/

50. Electronic medicines compendium http://emc.medicines.org.uk/

51. Medic Direct

http://www.medicdirect.co.uk/med_cabinet/medicine.ihtml?pid=333&step=4

52. Wikipedia http://en.wikipedia.org/wiki/Statin

53. Zetia.com http://www.zetia.com/ezetimibe/zetia/consumer/index.jsp

Additional sites found from Patient.Co.UK

54. BNF http://bnf.org/bnf/

55. CancerHelp UK http://www.cancerhelp.org.uk/

56. Medicine Chest Online http://www.medicine-chest.co.uk/

57. Health Supplements Information Service http://www.hsis.org/

58. NWMHP Pharmacy Medicine Information http://www.nmhct.nhs.uk/pharmacy/

Appendix 7: Protocol for data analysis of e-health websites design, quality and content

Design	
1. Search bar function	• Search bar function available
2. Instructions or help page	• Instructions or help page for navigating site
3. Links to external sites	• for example to sites with condition information
4. Printer friendly option	• Print option contains the relevant information and omits (for example) onscreen design features
5. Contains pictures	• Can be drawings, cartoons or photos
6. Contact site link §	• Directly contact link to website producer
7. Text size changeable	• Increase size of font
8. Interactive facilities	• e-mail lists, chat rooms, or option to personalise information
9. Table of contents	• A short summary providing the main section headings (can be hyperlinked or not)
Quality	
1. Date site developed ¥	• Date site was first developed (to year)
2. Specific date last update ¥	• Specific date of last update reported (to month)
3. Reference to evidence §	• Reference to scientific evidence to justify claims – source provided
4. Funding source §	• Funding source of site stated
5. Disclaimer §	• Provides a disclaimer
6. Authorship §	• Specific author(s) stated
7. Advertising policy §	• Provides statement on advertising

	policy
8. Confidentiality/privacy statement §	• Provides confidentiality statement

Medicines information content	
1998 European Commission Directive categories	
1. What the medicine is*	• What the medicine is and what it is used for
2. Before you take*	• Before you take or use the medicine
3. How to take*	• How to take or use the medicine
4. Side effects*	• Possible side effects
5. Storage*	• Storage of the medicine
Recommendations on medicines package leaflets by QRD group	
6. Action to take if overdose occurs ‡	• Provides information about action to take if overdose is taken
7. Interaction with other drugs ‡	• Specifically warns of possibility of statin having an interactive effect with specific other drugs, and not just to notify GP if taking other drugs
8. Notify GP if side effects occur ‡	• In particular, notify re serious side effects
9. Consequences if not taken ¥	• Reports the consequences to health if treatment not taken for a period of time
10. Action if miss a dose ‡	• What to do if miss a dose
11. Complementary or alternative treatment ¢	• Provides information about complementary or alternative treatment(s) (for example diet or exercise)
12. Condition information (about hypercholesterolemia) ¢	• Provides information about hypercholesterolaemia
13. Information about impact on quality of life ¥	• Reports the impact on quality of life

14. Experiential comments ¢	• Provides patients experiential comments

General site content	
1. Promotional pharmaceutical	• Site promotes a pharmaceutical product for sale
2. Neutral pharmaceutical	• Pharmaceutical company site but does not promote a product for sale
3. Purpose/rationale ¥	• Provides the purpose/rationale of the site
4. Shared decision making ¢	• Provides content that explicitly seeks to enable shared decision making, above merely informing.
5. Provides FAQ's	• Provides FAQ's (Frequently Asked Questions) about simvastatin or high cholesterol
6. Plain English information ¢	• Information about medicines appears understandable
7. Plain English site	• Other information on site appears understandable
8. Other languages	• Offers translations in other languages

Items in ¥ are from the *Discern* Handbook .

Items with § are from the *Health on the Net Code of Conduct*.

Items with * are from 1998 EU directive .

Items with ‡ are from the European Medicines Agency recommendations on medicines package leaflets .

Items with ¢ are derived from remarks made from stakeholders at the MILK workshops.

- Charnock, D. (1998). *The DISCERN Handbook Quality criteria for consumer health information on treatment choices* Oxon: Radcliffe Medical Press
- Health On the Net Foundation (2005). HON Code of Conduct (HONcode) for medical and health Web sites.
- European Commission Directorate-General III (1998). A Guideline on the readability of the label and package leaflet of medicinal products for human use. Brussels: European Commission.
- Quality Review of Documents Group (2005). Product Information Templates: Human Medicinal Products: European_Medicines_Agency.

Appendix 8: Data extraction form for IBMI analysis

	Mayo Clinic	MedicineNet	RXlist	Best Treatments	Medicine Guides	Net Doctor	Patient UK	US Food and Drug Agency	Electronic medicines compendium	Drug.com	Number of sites providing the feature	Percent of sites providing the feature
Design												
Search bar											0	0%
Instructions/ help page											0	0%
Links to external sites											0	0%
Printer friendly option											0	0%
Contains pictures											0	0%
Contact site link											0	0%
Text size changeable											0	0%
Interactive facilities											0	0%
Total no design features present	0	0	0	0	0	0	0	0	0	0	0	

	Mayo Clinic	MedicineNet	RXlist	Best Treatments	Medicine Guides	Net Doctor	Patient UK	US Food and Drug Agency	Electronic medicines compendium	Drug.com	Number of sites providing the feature	Percent of sites providing the feature
Quality												
Date site developed											0	0%
Specific date last update											0	0%
Reference to evidence											0	0%

	Mayo Clinic	MedicineNet	RXlist	Best Treatments	Medicine Guides	Net Doctor	Patient UK	US Food and Drug Agency	Electronic medicines compendium	Drug.com	Number of sites providing the feature	Percent of sites providing the feature
Funding source											0	0%
Disclaimer											0	0%
Authorship											0	0%
Advertising policy											0	0%
Confidentiality/ privacy statement											0	0%
Total no quality features present	0	0	0	0	0	0	0	0	0	0	0	
Content												
Promotional pharmaceutical											0	0%
Neutral pharmaceutical											0	0%
Purpose/rationale of site											0	0%
What the medicine is											0	0%
Before you take											0	0%
How to take											0	0%
Side effects											0	0%
Storage											0	0%
Action if overdose											0	0%
Interaction with other drugs											0	0%
Notify GP if side effects occur											0	0%
Effects if not taken											0	0%
Action if miss a dose											0	0%

Complementary or alternative treatment											0	0%
Condition information											0	0%
Shared decision making											0	0%
Quality of life impact											0	0%
Experiential comments											0	0%
Provides FAQ's											0	0%
Plain English information											0	0%
Plain English site											0	0%
Other languages											0	0%
Total no content features present	0	0	0	0	0	0	0	0	0	0	0	

Appendix 9: Sites considered for inclusion in Study two

Identified sites	Reconciled decision
Medscape http://www.medscape.com/home	Exclude – information not primarily for patients
HealthPhillyNews http://www.philly.com/mld/philly/living/health/	Exclude –no statin information
Patient Information on Medicines http://www.nmhct.nhs.uk/pharmacy/cclg-pat.htm	Exclude – policy document
Simvastatin Disease Database Information http://www.diseasesdatabase.com/ddb12128.htm	Exclude – portal to other sites
Intelihealth http://www.intelihealth.com/IH/ihtIH/WSIHW000/408/408.html	Exclude – portal to other sites and no information of its own
On-Health http://on-health.com/	Exclude – portal to other sites and no information of its own
Educate before You Medicate (National Council on Patient Information and Education) http://www.talkaboutrx.org/index.jsp	Exclude – portal to other sites and no information of its own
PharmWeb http://www.pharmweb.net/pwmirror/pwz/pharmwebz.html	Exclude – portal to other sites and no information of its own
dmoz open directory project http://dmoz.org/Health/Pharmacy/Drugs_and_Medications/S/Simvastatin/	Exclude – portal to other sites and no information of its own
worstpills http://www.worstpills.org/results.cfm?drug_id=584	Exclude – registration

	required
Infomed Drug Guide http://infomed.org/100drugs/	Exclude – site explicitly aimed at medical students and professionals
Rx–Advisor http://e-pharmacy.com/HTML/health_infor/rx_advisor.html	Exclude - this site could not be found
Cheshire Medical Centre http://www.cheshire-med.com/	Exclude –no statin information
Mediconsult http://mediconsult.8media.org/	Exclude - access except homepage down on 3 separate occasions in Dec 05 & Jan 06
PharmInfoNet http://pharminfo.8media.org/	Exclude - access except homepage down on 3 separate occasions in Dec 05 & Jan 06
Thrive online http://www.thriveonline.com.au/	Exclude - not medicines information
Answers http://www.answers.com/topic/simvastatin	Exclude – portal to other sites and no information of its own
GP notebook http://www.gpnotebook.co.uk/simplepage.cfm?ID=-227868642	Exclude - not aimed at medicine users

|	
Patient Health International http://www.patienthealthinternational.com/	Met inclusion criteria, but excluded because information is duplicated on Patient Health UK site, and site directs UK visitors to PHUK site
Wikipedia http://en.wikipedia.org/wiki/Statin	Exclude - not aimed at medicine users
BNF http://bnf.org/bnf/	Exclude - not aimed at medicine users
Cancer Help UK http://www.cancerhelp.org.uk/	Exclude –no statin information
Medicine Chest Online http://www.medicine-chest.co.uk/	Exclude –no statin information
Health Supplements Information Service http://www.hsis.org/	Exclude –no statin information
NWMHP Pharmacy Medicine Information http://www.nmhct.nhs.uk/pharmacy/	Exclude –no statin information
Druginfonet http://www.druginfonet.com/	Include
Healthtouch Online http://www.healthtouch.com/	Include
Mayo Clinic http://www.mayoclinic.com/	Include
MedicineNet http://www.medicinenet.com/script/main/hp.asp	Include
Rxlist http://www.rxlist.com/	Include
Australian Prescription Products Guide Online http://www.appco.com.au/appguide/default.asp	Include
Best Treatments http://www.besttreatments.co.uk/btuk/home.html	Include
Medicine Guides http://medguides.medicines.org.uk/	Include

MedlinePlus http://www.nlm.nih.gov/medlineplus/druginformation.html	Include
Net Doctor http://www.netdoctor.co.uk/	Include
Patient UK http://www.patient.co.uk/	Include
SafeMedication http://www.safemedication.com/resultsList.cfm via http://www.intelihealth.com/IH/ihtIH/WSIHW000/408/408.html	Include
US Food and Drug Agency http://www.fda.gov/	Include
Patient Health UK http://www.patienthealthuk.net/	Include
Drugs.com http://www.drugs.com/cons/Simvastatin.html	Include
eMedicine Health http://www.emedicinehealth.com/articles/53048-7.asp	Include
Vytorin ezetimibe/simvastatin tablets patient information http://www.vytorin.com/ezetimibe_simvastatin/vytorin/consumer/index.jsp	Include
About health and fitness http://cholesterol.about.com/	Include
myDNA http://www.mydna.com/resources/resources/meds/leaflets/d05348A1.html	Include
The Cleveland Clinic Health Information Centre http://www.clevelandclinic.org/health/health-info/docs/0700/0729.asp?index=4927	Include
Health Square http://www.healthsquare.com/newrx/cx1500.htm	Include
Medic8 Family Health Guide http://www.medic8.com/healthguide/index.htm	Include
Why Generic http://www.why-generic.com/drugs/generic/zocor.html	Include
Online pharmacy http://www.alldruginfo.com/s/simvastatin/	Include
Talk medical http://www.talkmedical.com/medications/5600/Simvastatin	Include
Canadian Pharmacy North http://www.canadarxgroup.com/drugs/zocor_simvastatin.html	Include
Yahoo Health http://health.yahoo.com/drug/_d00746a1	Include
Health Digest http://www.healthdigest.org/prescription-drug-reference/simvastatin-oral-tablet-9572.htm	Include
Healthopedia http://www.healthopedia.com/drugs/quick/simvastatin/	Include

Electronic medicines compendium http://emc.medicines.org.uk/	Include
Medic Direct http://www.medicdirect.co.uk/med_cabinet/medicine.ihtml?pid=333&step=4	Include
Zetia http://www.zetia.com/ezetimibe/zetia/consumer/index.jsp	Include
Merck Zocor http://www.zocor.com/simvastatin/zocor/consumer/index.jsp	Include

Appendix 10: Screenshots of homepages of ten IBMI sites in January 2006 analysed in study two

Medicine Net.com
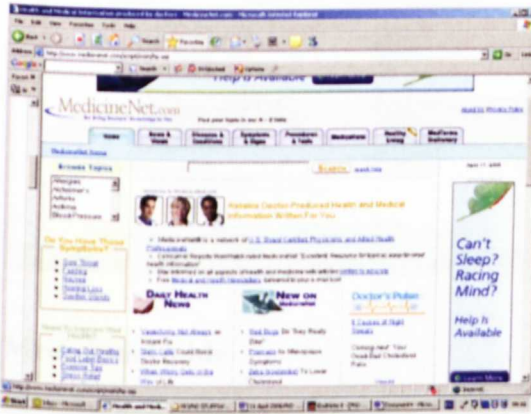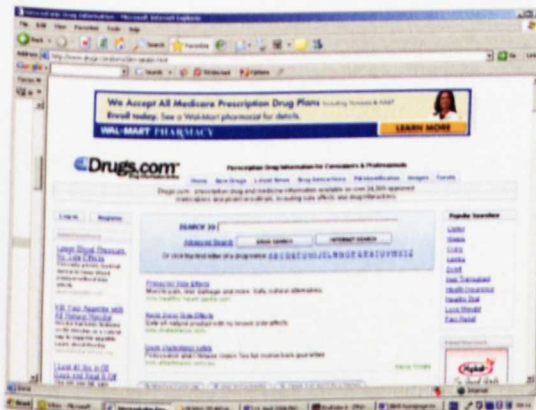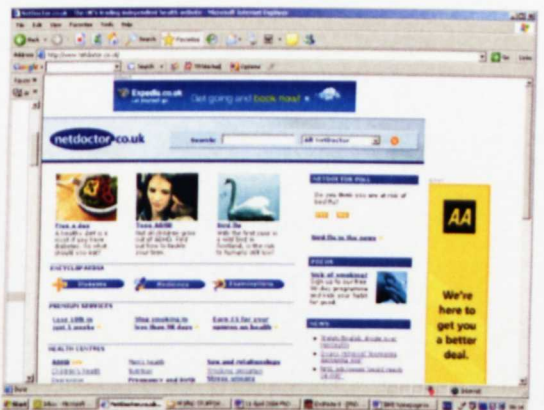

US Food and Drug Administration

MayoClinic.com

RxList

Drugs.com

Netdoctor.co.uk

Patient UK

Best Treatments

Medicines Guide

Electronic Medicines Companion

Appendix 11: Descriptive data about ten IBMI sites analysed in Study two

Descriptive information about sample of 10 included e-health websites
MedicineNet http://www.medicinenet.com/script/main/hp.asp **US developed site Accessed January-February 2006** Online Since: 18-Oct-1995   Home page was cluttered with information that had to be scrolled down. There were three columns with a mass of information options, including conditions, medications, symptoms and 'daily health news', many of which were links. Advertising of pharmaceutical products and healthcare treatment, using flash graphics was prominent on the home page and throughout the site. There were six possible second pages to click on, including *'medications'* and *'diseases and conditions'*. There was a scroll down menu of medical conditions. No icons were available, and there was limited use of pictures. *HonCode* accredited site. Search bar was prominent, top centred. Typing the name *simvastatin* in search bar returned a large number of different links relating to this drug, some relating to *'disease and control'*, *'medication'*, *'doctors views'*, etc. Medicines information was for *Zocor* brand. Provided verbal side effect risk descriptor information: "rare/minor side effects". Information about conditions in relation to medicines information was available. The medicines information page contained dense text in *Arial* font. Headings and important information was in bold print. Medicines information was minimal. Disclaimer information was very discrete. Provided 'suggested reading by our doctors', links to further information, and evidence about the drug. Information last updated less than 3 months before date site was accessed.
US Food and Drug Agency http://www.fda.gov/ **US developed site Accessed January-February 2006** Online Since: 13-Apr-93   Home page was cluttered with information that had to be scrolled down. There were three columns of different text links. There was a limited use of pictures. It was difficult to immediately find the correct WMI. Information was for the *Crestor* brand. Provided

verbal side effect risk descriptor information: "rare side effects". No icons were available. Site had links for subscribing to FDA Consumer magazine. Search bar was in the top, left hand corner. Typing *crestor* produced a vast array of different links, similar in content; thus it was not at all clear what link to click on. Medicines information was available as HTML page, or one page PDF, and found by going to CDER page on FDA site, clicking on *'Index to Drug-Specific Information'*, then *rosuvastatin*, and finally on *'Patient Information Sheet'*. Information was written in *Times New Roman* font and used two columns. Section headings were written as questions. Used bullet point text. Other information was also available, for example *'Prescribing Information'*, which was 20 page PDF, but not primarily aimed at patients. Information last updated between 6 and 12 months before date site was accessed.

Mayo Clinic http://www.mayoclinic.com/

US developed site Accessed January-February 2006 Online Since: 22-Jul-1997

Home page was cluttered with information that had to be scrolled down. There were links to *'managing condition'*, *'healthy living centres'*, *'diet advice'*, and *'health tools'*. Advertising of pharmaceutical products and healthcare treatment was prominent on the home page and throughout the site. Pictures were used throughout the site. Use of icons was limited to font enlargement and print options. There were two separate drop-down menus for *'disease and condition centres'* and *'healthy living centres'*. HonCode accredited site. Search bar was in the top, right hand corner. Medicines information link for *Vytorin* brand was found by typing name in search bar. Provided verbal side effect risk descriptor information: "less common side effects". Provided information about 19 conditions separate to medicines information. The medicines information had *Arial* font, and used bold headings and bullet point text. Disclaimer information was very discrete. There was further information (*'Statin: Is this cholesterol-lowering drug right for you?'*). This was not easily found or sign-posted. This page was extremely informative, providing information about advisable complementary lifestyle changes, the benefits of taking *statin* and further information about side effects. Refers to evidence, (*'a study to reduce the*

risk of colon cancer with statin consumption'), but did not provide a reference. Information last updated between 6 and 12 months before date site was accessed.

Drugs.com http://www.drugs.com/cons/Simvastatin.html

US developed site Accessed January-February 2006 Online Since: 18-Dec-1998

Home page was cluttered with information that had to be scrolled down. There were three separate rows with a mass of links to information about drugs and conditions. No icons were available. Had a box with links to the 12 most popular Internet drug searches, but no evidence to show why these were the twelve most popular searches. Advertising of pharmaceutical products and healthcare treatment, using flash graphics was prominent on the home page and throughout the site. Bar the adverts, there was no other use of pictures by the site. *HonCode* accredited site. Search bar was prominent, top centred. Medicines information link for the *Zocor* brand was found after typing name in search bar, but it was unclear which of the different options for information should be selected. Provided verbal side effect risk descriptor information: "rare side effects". Medicines information was written in *Verdana* and *Arial* font. Section headings were phrased as questions. Used bullet point style for main text. Running mouse over highlighted words opened links to sponsored sites, for example the term *liver disease* referred to a site which detects early liver disease. Provided an additional link to a page that uses a question and answer format. Information last updated less than 3 months before date site was accessed.

Rxlist http://www.rxlist.com/

US developed site Accessed January-February 2006 Online Since: 14-Nov-1995

Home page was cluttered with information that had to be scrolled down. There were three columns with a mass of information. The middle column contained links in faint blue font for 150 medicines. Pictures were used throughout the site. Provided external link to condition information. No icons were available. Advertising of pharmaceutical products and healthcare treatment, using flash graphics was prominent on the home

page and throughout the site. Home page contained a list of *'Top 150 Drug Name Searches on RxList'* – a mass of drug names that were not clearly distinguishable at first. One search bar *'search for a drug name'* was prominent, top centred; and there were three further search bars: *'medical abbreviation finder'*, *'can't find what you need'* and *'drug search'*. Medicines information link for the *Zocor* brand was returned amongst a mass of different links relating to this drug, after typing name in search bar. Provided verbal side effect risk descriptor information: "less severe/severe side effects". The information was well laid out into clearly defined sections and makes use of short paragraphs. Text was written in *Arial* font. Different sections of information were accessed by clicking on the hyper-link, or scrolling down the screen. Information last updated between 3 and 6 months before date site was accessed.

Net Doctor http://www.netdoctor.co.uk/

UK developed site Accessed January-February 2006 Online Since: 25-Aug-1998

Home page was cluttered with information that had to be scrolled down. A number of rows contained a vast amount of information options, including conditions, medications, and examinations. Advertising of healthcare treatments (for smoking) and non-healthcare related products, using flash graphics was prominent on the home page and throughout the site. There were many photos as well. Made some use of icons, for example a pill for *medicines* and a question mark for *investigation*. *HonCode* accredited site. Search bar was prominent, centred. Medicines information link for the *Zocor* brand, along with a choice of many other links, was available after typing name in search bar. Provided verbal side effect risk descriptor information: "occasional side effects". Medicines information page had *Verdana* font. Information was available in printer friendly format. Links to other site information was on the right hand column, making the information pages very busy. Had a large section on the dangers of *statin* interacting with other drugs. Used clear headings for different sections, and often put information across in bullet points. Information last between 13 and 24 months before date site was accessed.

Patient UK http://www.patient.co.uk/

UK developed site Accessed January-February 2006 Online Since: 22-Apr-1997

A relatively uncluttered and well organised home page makes for easy navigation. No scroll was necessary on the home page. There were two separate columns; one with links for information about conditions, medications, and lifestyle issues, examinations, etc. Other column allowed users to book an online appointment with their GP using the *EMIS* service. Contact links provided a standardised feedback form. Provided links to external UK sites for a range of medical conditions. Used icons to relate to different types of information (for example *patient experience* or *information leaflet*). Advertising of non-healthcare related products, using flash graphics was contained throughout the site, but not on the home page. Site provided a translation of information for certain conditions in one or more of 11 different languages, but not for medicines information. Search bar was prominent, centred. Search bar returned three different medicine information leaflet links: *'patient experience'* (provided twice), *'medicines'*, and *'information leaflet'*. Did not specify a brand of *statin*. Did not provide side effect risk descriptor information. Medicines information page had *Helvetica* font. Printer friendly option was available. Names were in italics, and crucial information was in bold. Interaction information was vague, only requesting medicines users to inform their GP if they currently take any of the medicines named. No explanation was given for why to do this. Section headings were clear, and information was often presented in bullet point style. Information last updated between 6 and 12 months before date site was accessed.

Best Treatments http://www.besttreatments.co.uk/btuk/home.jsp

UK developed site Accessed January-February 2006 Online Since: 10-Jan-2003

Home page was cluttered with information that had to be scrolled down. One column had a vast array of links. The other had further links, and two prominent drop-down menus: one for patients and the other for doctors. Minimal use of photos. Had a print icon, but no other icons. Site provided a range of different information options,

including conditions, lifestyle treatments and symptoms. It received the Internet Crystal Mark accreditation from the *Plain English Campaign*, to show its commitment to using plain English language. A search bar was at the top of the screen, and prominently placed were two drop-down menus: clearly specified for patients or doctors. Information about treatments (including *statin* therapy) was available after typing *simvastatin information* in search bar. WMI was not sole focus of this site. By clicking on a statin hyperlink, more information about the drug was available. Did not specify a brand of *statin*. Did not provide side effect risk descriptor information. Provided good, explicit links to other sites. Medicines information text was written in *Arial* font. Different sections of information were accessed by clicking on the hyper-link, or scrolling down the screen. Explicitly stated all information was based on best available evidence, and that the information should be used to enable shared decision making. Provided medicines information in the context of the condition, thus the site discussed *statin* therapy and other treatments for hypercholesterolemia. Information last updated less than 3 months before date site was accessed.

Medicine Guides http://medguides.medicines.org.uk/

UK developed site Accessed January-February 2006 Online Since: 03-Jun-1999

Home page was relatively uncluttered, although it requires to be scrolled down. Site was in development, so therefore a lot of information was either missing or scant; for example condition-based information was for 8 conditions only (when accessed). Pictures were used throughout the site. No icons present. It received the W3C accreditation to show it conformed to technical specification standards. There was no search bar. When the site was accessed in early 2006, it only had comprehensive coverage for medicines for three conditions: cholesterol, epilepsy, and influenza. Provided specific information for both *Zocor* and *Vytorin* brands. Did not provide side effect risk descriptor information. Provided a great amount of information about the medicine. Medicines information text was written in *Verdana* font. Different sections of information were accessed by clicking on the hyper-link, or scrolling down the screen. Different sections were colour coded –

the same colours apply to the same sections, for example purple for side effect information. Running the mouse over certain words generated a pop-up box which provided a definition or explanation of the word(s). These were also listed at the end of the information as a glossary. Bullet point text was used in places. Information last updated between 13 and 24 months before date site was accessed.

Electronic medicines compendium http://emc.medicines.org.uk/
UK developed site Accessed January-February 2006 Online Since: 03-Jun-1999

Home page was cluttered with information that had to be scrolled down (as well as across if the *'favourites'* function was turned on. Had a table that lists all products whose information had been updated in the last 14 days, but was not immediately clear. No pictures were used on the site. There was an information icon showing what details have changed, but no others. Site did not contain explicit advertisements, but as information was provided by pharmaceutical companies, there logos and company name were displayed throughout the site. There was no text size change option, but there was a zoom function, although this was not clearly labelled. There was a search bar at the top right, permitting search by product or company. Medicines information for the *Simvador* brand was found after typing the search term. Provided verbal side effect risk descriptor information: "rare side effects". Medicines information was available as a two page PDF, written in *Frutiger-Roman* font. Section headings were written in bold as questions. Other than this, it was very difficult to distinguish between the different sections. Also provided copies of summaries of product characteristics, which could perhaps be confused by the patients for information intended for them. Interaction information was implicit, only requesting medicines users to inform their GP if they currently take any of the medicines named. No explanation was given for why to do this. Information last updated more than 24 months before date site was accessed.

Appendix 12: Pilot of e-health websites to assess for indicative information

	MedicineNet	US Food and Drug Agency	Mayo Clinic	Drug.com	RXlist	Net Doctor	Patient UK	Best Treatments	Medicine Guides	Electronic medicines
Why should you take simvastatin?	X	X	X	X	X	X	X	X	X	X
Please name 3 unwanted outcomes from taking simvastatin?	X	X	X	X	X	X	X	X	X	X
Is it okay to drink alcohol when taking simvastatin?	X	X	X	X	X	X	X		X	X
What should you do if you forget to take simvastatin?			X	X	X		X		X	X
Is there specific food or drink you should avoid when taking simvastatin?			X	X	X	X	X		X	X

Suppose you are taking Erythromycin, an antibiotic, and the doctor starts you on simvastatin. Is it okay to take it?	X		X	X	X	X			X	X
What effect could having too much cholesterol in your blood have on your body	X		X	X	X	X	X	X	X	X
Suppose you take Simvastatin and you find that your joints start to ache. What should you do?		X	X	X	X		X		X	X
Can you name me at least two lifestyle changes you should make whilst taking simvastatin?	X	X	X	X	X	X	X	X	X	X
If you are pregnant or considering becoming pregnant, should you take simvastatin?	X	X	X	X	X	X	X		X	X

(Sites with information for all ten questions are highlighted. Blank cells are where sites did not have information to answer the question)

Appendix 13: Copy of participant information leaflet

Are health information websites useful?

- I am studying how websites help people to understand their medicines. This research is part of my PhD studies at Leeds University. If you are able to use the internet, and have ever taken a medicine; I would like to recruit you to this project.

- The study will take part at Leeds University, and will take around 60 minutes. You can withdraw at any point, and/or refuse to answer any questions for any reason. You will be compensated for taking part in this study and your travel costs will be repaid.

- Before the study, I will ask you to complete a questionnaire about medicines you have taken, and your experience of using the internet. You will then perform some tasks using a health website. I will ask you to think out loud whilst using it. Afterwards I will ask what you thought of it. A software program will record the Internet on screen, and your voice as you talk about using the site.

- Extracts of what you say about the website will be reported in my PhD report, as well as journal articles. No-one will be able to identify you from the extracts, or any other information; and your name will not appear anywhere, or be revealed to anyone. All information about you and your task performance will only be available to me, my supervisors, and one co-researcher who will check I analyse the data correctly. The study will not pose any risk of physical harm to you.

- If you are still interested in taking part in this study, please contact me for further details. Thank you for showing an interest in this study.

My contact details are:
Donald Nicolson
School of Healthcare
Baines Wing
University of Leeds
Leeds LS2 9UT

Office telephone number:
0113 343 7952
9am-2pm only
Email address:
d.j.nicolson@leeds.ac.uk

Appendix 14: Copy of consent form for Study three

Consent to take part in research study and analysis

Title of Project: An evaluation of the usability and usefulness of internet-based medicines information (IBMI) to support peoples' understanding of medicines

Name of Researcher: Donald Nicolson, School of Healthcare, University of Leeds

Please tick the box to say yes for each question

I have read the information sheet for this study.   ☐

I understand the reason for this study, and how I will be involved.   ☐

Any questions I have about the study have been answered.   ☐

I have had enough time to think about whether I want to take part   ☐

I understand by taking part in the study I will not get any direct personal   ☐
benefit from it, and that my medical care will not be affected.

I understand all data collected will be held in confidence.   ☐

I understand in any reports from the study, my personal details will be   ☐
removed.

I agree to my voice being recorded.   ☐

I understand I do not have to answer all questions, and can withdraw from   ☐
the study at any point for any reason.

I agree to take part in this study.   ☐

Participant's Name: Signed   Date

Researcher: Donald Nicolson   Signed   Date

Appendix 15: Questionnaire

UNIVERSITY OF LEEDS

Questionnaire about using the Internet to find information about medicines

<u>Confidential</u>

Please will you complete this questionnaire, and then return to me (Donald Nicolson) in the pre-paid envelope.

Part one: Information about you

Participant id number: _____ [Will be completed by researcher]

Your name: _____

Sex:

Male   Female

Ethnic group you belong to:

White   Asian or Asian British

Mixed (White and Black   Black or Black British

Caribbean/Black   Chinese or other ethnic groups

African/Asian/other mixed

background)

Do you speak more than one language?

Yes (If yes, what language do you most often speak?) _____

No

Your data of birth:

d	d	m	m	y	y

Your level of education:

Graduate

A level or equivalent

Completed education between 14-16 years of age

Your current job status

Full-time employed (State job) _____

Part-time employed (State job) _____

Unemployed

Retired (State main job when employed) _____

Other (State) _____

Part two: Use of medicines and medicines information

1. How long have you been taking medicines for? (Please name them)

I have been taking medicine for 12 months or longer _____

_____

I have begun taking medicines in the last 12 months _____

_____

I have taken a short-term course of medicines at some point in the last 12 months (for example antibiotics) _____

—

I have not taken any medicine in the last 12 months

Don't know/Can't remember

2. Are you aware of the patient information leaflet accompanying your medicines?

Yes

No

3. Do you read the patient information leaflet accompanying your medicines?

>   Always
>
>   Often
>
>   Sometimes
>
>   Rarely
>
>   Never

(Please explain your answer) _____

_____

4. Which sections of the leaflet would you read?

>   What this medicine is for
>
>   Before taking this medicine
>
>   How to take
>
>   Possible side effects
>
>   How to store

How strongly do you agree or disagree with the following statements?

	Strongly agree	Tend to agree	Neither agree nor disagree	Tend to disagree	Strongly disagree	No opinion
5. I get enough information about medicines						
6. It is valuable to have different types of						

information about medicines from different sources					
7. It would be better to have only one source of information about medicines					

Part three: Experience of using the internet

8. Do you use the Internet at home?

Yes

No

9. Where do you most often use the internet?

_____

–

10. For how long have you used the internet?

More than 5 years

Between 3 years and 5 years

Between 1 year and 3 years

Less than 1 year

11. How often do you currently use the internet?

Every other month

Monthly

Weekly

Daily

12. Why do you use the internet? _____

_____

Part four: Experience of health information sites

13. Have you ever used the Internet to find information about health?

      Yes (Please state which site/s) _____

      No

14. Have you ever used the Internet to find information about medicines?

      Yes (Please state which site/s) _____

      No (Go to question 22)

15. Did you use the Internet to find information about health/medicines because of someone's recommendation?

      Yes (Please state whom) _____

      No

16. Why did you look for information about medicines on the Internet (rather than elsewhere)?

_____

17. How did you find the information?

_____

18. Thinking back to the information, how was the website to use?

[Please state which website you are talking about] _____

_____

Very difficult

Difficult

Neither easy or difficult

Easy

Very easy

19. How useful or not was the information (on the website) for you?

Not at all useful

Not useful

Neither useful or not useful

Useful

Very useful

20. Did you wonder if the information (on the website) was accurate?

Yes

No

21. How did you tell if the information (on the website) was accurate? _____

_____

22. Will you look for information about medicines on the Internet in the future?

Yes (Please explain why you will do so) _____

No (Please explain why you will not) _____

_____

Thank you for completing the questionnaire

Appendix 16: Copy of usability study form

UNIVERSITY OF LEEDS

Usability/user test study of IBMIs

Confidential

Read out the following set of instructions before the interview begins.

Thank you for agreeing to take part in this study to examine how useful and usable internet-based medicines information sites are. There are two parts to the study.

4. An exercise using a medicines information site on the Internet to find specific information, and to see if it is understandable.

5. A short interview where I will ask you some questions about using the medicines information site.

Before we start, do you have any questions you would like to ask?

Participant information

Participant id number: _____ Date:

Name of observer present

Time session started _____   Time session ended_____

IBMI usability and usefulness study

The first part of the study has two tasks and requires you to imagine you have been prescribed *simvastatin*. The first task requires you to find a site that has information about *simvastatin*. The second task requires you to find ten items of information about *simvastatin* using a specific website. The aim of these tasks is to examine how usable and useful the website is. It is not how skilful you are at using the Internet that is being examined, but how easy to use the website is. I am interested in what you say to yourself as you find the information. To do this I will ask you to talk aloud as you perform the tasks. So I want you to say out loud everything you would say to yourself silently. Just try to act as if you are alone in the room speaking to yourself. If you are silent for a length of time, I will remind you to keep talking aloud. Do you understand what you have to do?

Let me now show you an example of talking aloud.

I open BBC news www to find the weather for Leeds

Ensure macromedia captivate is turned on favourites is turned OFF

> I would like you to imagine the following situation. You
> have been prescribed *simvastatin* by your GP for the first
> time and you decide to look for information about the
> medicine on the internet.

I would like you to use the cursor to highlight the information when you find it please.

Task one:

Please use Internet explorer to find any site with information about *simvastatin*.

Show card with name *simvastatin*.

- Note name of site & url

- Ask: why did you search for the information this way?

Task two:

Now I would like you to find information about *simvastatin* using a specific website.

For each question below ask:

- Can you show me where you found the answer to this question?

- In your own words, tell me what it says in answer to this question.

I would like you to use the cursor to highlight the information when you find it please.

	EU section	Question	Information found?	Information explained?
1.	What it is and what it is used for	**Why should you use simvastatin?** *Indicative answer: it lowers the amount of cholesterol and fats in your blood (to protect against heart disease or stroke)*	0 = no 1 = yes	0 = no 1 = yes
2.	Side effects	**Please name three unwanted effects from taking simvastatin** *Indicative answers:*	0 = no 1 = yes	0 = no 1 = yes

		ANY 3 FROM *muscle wastage/pain, constipation, wind, flu-like symptoms, headache, etc*		
3.	Before you take	**Is it okay to drink alcohol when taking simvastatin?** *Indicative answer: yes but take care if you drink large amounts of alcohol*	0 = no 1 = yes	0 = no 1 = yes
4.	How to take	**What should you do if you forget to take simvastatin?** *Indicative answers: take as soon as possible (but not two hours before the next dose); and do not take two doses at once*	0 = no 1 = yes	0 = no 1 = yes
5.	How to take	**Is there specific food or drink you should not have when taking simvastatin?** *Indicative answer: 'grapefruit juice'*	0 = no 1 = yes	0 = no 1 = yes
6.	Before you take	**Suppose you are taking Erythromycin, an antibiotic, and the doctor starts you on simvastatin. Is it okay to take it?** **(Show name 'erythromycin' on card)** *Indicative answer: 'You should check*	0 = no 1 = yes	0 = no 1 = yes

		with the doctor'		
7.	What it is and what it is used for	**What effect could having too much cholesterol in your blood have on your body?** *Indicative answers: Any of: 'It could lead to (coronary) heart disease, clog the arteries and cause atherosclerosis, cause chest pain', lead to a stroke*	0 = no 1 = yes	0 = no 1 = yes
8.	Side effects	**Suppose you take simvastatin and you find that your joints start to ache. What should you do?** *Indicative answer: 'Stop taking it and see a doctor or go to the hospital straight away' (prompt for urgency)*	0 = no 1 = yes	0 = no 1 = yes
9.	What it is and what it is used for	**Name me two things you can do to improve your health while taking simvastatin** *Indicative answer: ANY 2 OF: take exercise/ stop smoking/ lose weight/ eat lower fat diet/ reduce alcohol intake*	0 = no 1 = yes	0 = no 1 = yes
10.	Before you take	**If you are pregnant or considering becoming pregnant, should you take**	0 = no 1 = yes	0 = no 1 = yes

	simvastatin? *Indicative answer: do not take simvastatin*		
11.	Do you think the information is trustworthy? **Follow up q:** Please explain your answer	0 = no 1 = yes	

Post-study interview about the usefulness and ease of use of using an internet-based medicines information site

Now I will ask you some questions about using the site and the tasks you performed. Please explain the reasons for your answers as fully as you can. Before we start, do you have any questions?

1. How did you feel the site was to use?

(Follow-up questions)

    a. Did you feel it was easy to use the site?

    b. Did you feel the site was pleasant to use?

    c. Did you feel the site was helpful for finding the information?

2. Did you feel the information on the site was useful?

(Follow-up question)

    a. Did you understand the information?

3. Will you use the Internet again to find information about medicines?

(Please give reasons)

4. <u>Did thinking aloud affect your task performance?</u>

Only if they ask for clarification of this q:

      a. (For example was it more easy or difficult to perform the task?)

5. <u>Is there anything about the site I haven't asked you about which you'd like to mention?</u>

Appendix 17: Copy of further information leaflet Study four part one

UNIVERSITY OF LEEDS

Information sheet for a study of a medicines information website

As part of my PhD research, I am looking to see if your opinions and recommendations on the design and content of a website with medicines information will make it easier for the general public to use and understand. If you agree to take part, we will discuss your opinions about the web pages. This will be done by telephone. I will record the interview to then make notes about what you said. No-one apart from me will have access to the recording and it will be deleted after I make my notes. The results of this study will be reported in my PhD, as well as articles in research journals. Your name will not appear anywhere, and will not be revealed to anyone. All information from the interview will only be available to me and my supervisors, who will check I have analysed the information correctly – they will not know your name, or hear the recording.

There are three web pages about pain control I will ask you to look at, on the *CancerHelp UK* website (http://www.cancerhelp.org.uk/help/default.asp?page=5899). The three pages are called: what painkillers are; types of painkillers; and side effects of painkillers. You can get to these pages by typing in the link above in the address box. I will ask you to comment on the web pages regarding:

- How easily you believe people could find information using these pages.
- How satisfied you believe people would feel using these pages.
- How easily you believe people would understand the information on these pages.
- How well organised you believe people would feel the information is on these pages.

The outcome of your interview will help me to make recommendations about the redesign of the CancerHelp UK web pages with information about analgesics. The study should not pose any risk of harm to you, and a contact number will be available if you have any questions you wish to follow-up after the study. If you have any further questions before the study, you are welcome to contact me:

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Appendix 18: Copy of consent form for Study four

Consent to take part in research study and analysis

A study of a medicines information website

Name of Researcher: Donald Nicolson, School of Healthcare, University of Leeds

Please tick the box to say yes for each question

- I have read the information sheet for this study. ☐

- I understand the reason for this study, and how I will be involved. ☐

- Any questions I have about the study have been answered. ☐

- I have had enough time to think about whether I want to take part ☐

- I understand by taking part in the study I will not get any direct personal benefit from it, and that my medical care will not be affected. ☐

- I understand all data collected will be held in confidence. ☐

- I understand in any reports from the study, my personal details will be removed. ☐

- I agree to my voice being recorded. ☐

- I understand I do not have to answer all questions, and can withdraw from the study at any point for any reason. ☐

- I agree to take part in this study. ☐

Participant's Name: Signed   Date

Researcher: Donald Nicolson   Signed   Date

Appendix 19: Copy of recommended changes sent to CRUK

The following usability issues were identified with the web pages (in bold, grey shade), and the recommendations for changing the content and formatting to alleviate those difficulties are in indented bullets.

Strengths of the CancerHelp UK web pages

- Stakeholders praised the web pages for being written in an empathic style, and felt people living with cancer would value the information.

- It was felt the pages provided important information clearly, for example the need to take painkillers regularly, not to expect painkillers to provide continuous pain relief immediately, dispelling the myth that there is a threshold where taking more painkillers will not be beneficial, and the concept of the *'analgesic ladder'*.

- Medicine users said they felt the information was understandable.

- Medicine users valued how medical words (for example about treatments) had links to further information to explain them.

- Medicine users valued the way that the site spelled out very long medical words phonetically, because if they had trouble with it, they might skip it.

- The print option is important because it can provide a copy of the information without the distracting links or navigation columns of an *HTML* page.

Navigating the pages

(i) **Participants had difficulty navigating the pages at times; for example the headings were felt to be unclear about the information underneath it, and specific information (for example for particular medicines) was felt to be quite deep within the site, making it more difficult to locate.**

- **Recommendation:** add more bullets and headings to make the information stand out better and to break up dense text. Number titles to differentiate between them (for example on the*"Types of painkillers page"*, one for opiates, two for non-opiates, etc).

- **Recommendation:** make it clearer how the content is structured on each page; for example have a hierarchy of headings and subheadings

- **Recommendation:** provide a clearly referenced table of contents with hyperlinks to different sections on the pages. The inclusion of left-hand navigation, sub-headings and/or a flow chart could also improve navigation.

- **Recommendation:** colour code different areas of the site to help make the sign-posting (saying where the person is on the site) clearer. (This change may also be suggested by the study evaluating the usability of the *CancerHelp UK* site, and so it may be more appropriate to make such a change in light of that study's recommendations).

- **Recommendation:** add symbols, figures or pictures to break up the dense text, and make the pages more appealing to readers (for example pictures corresponding to the different medicines).

- **Recommendation:** add a 'find bar' for locating keywords or phrases easily.

(ii) The layout does not account for people who only occasionally visit the pages, and therefore viewers may miss crucial information if only looking at specific pages.

- **Recommendation:** clearly indicate on the pages what sections have been recently updated, and recommendations on sections that are considered essential for the viewer to read, even if only browsing.

(iii) Some pages were felt to be too long.

- **Recommendation:** pages with large amounts of information should have the content split over separate linked pages to make them manageable, for example the *"Types of painkillers page"*.

(iv) The wording of URLs are not conducive for finding the information.

- **Recommendation:** have the names of the pages included in the *URLs*.

(v) The banner and crumb links are not clear and may not be useful to people unfamiliar with them.

- **Recommendation:** the 'crumbs' colons could be replaced with arrows and the banner links could be colour coordinated to help them stand out.

(vi)   Links for tabbing down (for example at the top of the "side effects of painkillers" page) were unclear; so although something happened, the user was still on the same page which caused confusion.

- **Recommendation:** add a 'back-to-top' link to show when a user had tabbed down the page, and spare their need to scroll back up the page.

(vii)   The link to NHS Direct, whilst helpful, may lead to the site losing visitors.

- **Recommendation:** the consequences of clicking on links should be indicated so the user notices the effect, that she or he is leaving the website.

Difficulties with content

(viii)   The pages are felt to not provide specific information about painkillers.

- **Recommendation:** add a new section on the different ways of treating cancer pain, and anecdotes from users to personalise the information.
- **Recommendation:** add links to the *BNF/Medicines Guides* from the site, which will provide further information about the medicines.

(ix)   The site explained the NSAID acronym, but stakeholders failed to notice this.

- **Recommendation:** make the explanation of the *NSAID* acronym more explicit.

(x)   The pages do not mention pharmacists as a source for information about medicines.

- **Recommendation:** the pages could recommend pharmacists along with GPs and nurses as a source of information about medicines in the community.

(xi)   Information about side effects was provided verbally, which research has shown to be not easily understood by most people.

- **Recommendation:** where the data are available, present the information about the risk of a side effect as a number, or have a numerical accompaniment to the verbal term.

(xii)   Some professional stakeholders felt the information is currently based on compliance, not concordance framework with the focus on type of drug rather than experience, and/or specific methods of pain control.

- **Recommendation:** content could be structured to focus on experience rather than medicine, because of users' different experiences and needs on finding out about ways of treating pain, reflected in the titles of the pages.

- **Recommendation:** content could be structured by choices the patient has to make, or specific methods for pain control, rather than how to comply with your doctor's instructions. This change in approach, if considered appropriate, could be introduced over time.

Difficulties with quality assurance markers

(xiii)   The Plain English Campaign 'Crystal Mark', Most Popular Health Site and Best Health Site logos were not links, and did not explain why they were on the pages.

- **Recommendation:** make the accreditation logos 'clickable' to let the user access information about what they mean.

- **Recommendation:** a hypertext explanation may work as well as a link to an external site.

Appendix 20: Copy of further information leaflet Study four part two

UNIVERSITY OF LEEDS

Information sheet for a study of a medicines information website

I am examining whether websites help people to understand information about medicines. This research is part of my PhD studies at the University of Leeds.

If you agree to take part, the study will take up to one hour, at the University of Leeds, and you will receive a £10 gift voucher as a token of appreciation. The study will require you to look at two versions of pages on a website which provides information about medicines which can be bought 'over-the-counter' (without prescription) at pharmacies. You will be asked to find information using the web pages, to answer questions and then to give your opinions about using the web pages.

You can withdraw from the study at any point, or refuse to answer any questions for any reason.

The results of this study will be reported in my PhD, as well as articles in research journals. Your name will not appear anywhere, and will not be revealed to anyone. All information about your performance in the study will be stored securely, and will only be available to me and my supervisors, who will check I have analysed the information correctly – they will not know your name.

The study should not pose any risk of harm to you, and a contact number will be available if you have any questions you wish to follow-up after the study. If you have any further questions before the study, you are welcome to contact me:

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Appendix 21: Instructions for CRUK Study

Thank you for agreeing to take part in this study. I am looking to see if there is a difference in the usefulness of two versions of the same three web pages on the CancerHelp UK website which have information about painkillers.

- **Have you ever looked at this website before?**

There are three parts to the study, which will take up to one hour to complete.

1. You will look at the first version of the web pages. Using these pages, you have to find the answers to 8 questions about the medicines. You will then fill in a short questionnaire about what it was like to use the pages and how satisfied you were with the information.
2. After a short break, you will look at the second version of the web pages and perform the same tasks.
3. At the end you will have a chance to tell me what you thought about the web pages.

Please note; the aim of this study is to examine how easy-to-use the web pages are and how understandable the information is. I am not testing your intelligence or Internet skills. I am going to record the study, solely to act as an aide memoir for me. This computer program will record your online actions, and I would like you to wear this headset so I can have a record of your answers. *No-one* will be privy to this recording apart from me. Before we start, do you have any questions you would like to ask?

- **Open the envelope to see the order of pages to view and questions to ask**
- **Press F11 to hide URL**

- **Task one: user test questionnaire**

I would like you to spend a few minutes looking at the following three pages only: Types of painkillers, Ibuprofen, and Co-codamol.

Five minutes reading time (but don't state the amount of time!)

Using the three web pages you have been looking at, I want you to find information to answer the following 8 questions that I will ask you. It is important that you only use the three pages to answer the questions. Please do not attempt to answer from general knowledge or use any other websites. For each question, I will ask you to show me where you found the answer on the screen. Rather than read the answer out, where possible I would like you to try to explain it in your own words. Do you understand what you have to do?

TURN ON MACROMEDIA CAPTIVATE NOW

1. Ask participants the User Test questions and note answers and any important observations

2. Hand the workbook over to the participants and let them fill in the *PSSUQ* and *SIMS* questionnaires.

3 minute washout period
Change to the other version of the website

- **Task two: user test questionnaire**

I would like you to spend a few minutes looking at the following three pages only: Types of painkillers, Ibuprofen, and Co-codamol. I will show you where the three pages are on the site.

Five minutes reading time (but don't state the amount of time!)

Using the three web pages you have been looking at, I want you to find information to answer the following 8 questions that I will ask you. It is important that you only use the three pages to answer the questions. Please do not attempt to answer from general knowledge or use any other websites. For each question, I will ask you to show me where you found the answer on the screen. Rather than read the answer out, where possible I would like you to try to explain it in your own words. Do you understand what you have to do?

1. Ask participants the User Test questions and note answers and any important observations
2. Hand the workbook over to the participants and let them fill in the *PSSUQ* and *SIMS* questionnaires.

- **Task three**

3. Using the final page in the workbook, I would like you to tell me if there is anything about the versions of the pages that I haven't asked you about which you'd like to mention?

- **Closing request**

Please listen carefully to the following request which is essential to the successful running of this study.

Please ***do not*** discuss in any specific detail the study with your colleagues. Please ***do not*** tell them the name of the website you looked at, nor the specific pages. If you were to do so, they could then look at the website in advance and have a better advantage of performing the tasks, which will not help me to understand about the usefulness of the pages being examined. If they ask you about the study, I would recommend you say something like: 'you had to look at web pages with information about medicines and comment on them; but you have been asked not to say which website by Donald'. Thank you for your understanding and cooperation on this point, as well as your time for taking part in the study.

- **Give participants the £10 gift voucher and *get them to sign for it***

Appendix 22: Copy of battery of tests for CRUK Study

UNIVERSITY OF LEEDS

Comparing the usability of different versions of the same website with information about medicines

<u>Confidential</u>

Pages order version

| New » Old |
| or |
| Old » New |

Questions order version

| A→B |

Participant ID #:

Date of study:

d	d	m	m	v	v

Have you ever looked at this website before?

| Yes/No |

User Test number one

Prompts to use:

a. Don't forget it's a test of the web page and not you
b. Would you like me to repeat the question?
c. Would you like to keep looking or shall we go on to the next question?
d. So you are saying…
e. Can you expand on your answer?
f. Can you show me where on the page you saw the answer
g. I think you may be getting confused. This question is about …. and you are talking about …

	Question	Type of question	EU categories	Info found?	Info explained?
			Types of painkillers page		
1.	When should you not take *non-opiods*? *Indicative answer: if you have a history of stomach ulcers, bleeding, taking warfarin (need only one answer)*	Factual	What medicine is for	0 = no 1 = yes	0 = no 1 = yes
2.	Why are *opiods* the best way of treating cancer pain? *Indicative answer: they (are based on morphine which is) the most effective (or strongest) painkiller*	Explanation	What medicine is for	0 = no 1 = yes	0 = no 1 = yes
			Ibuprofen page		
3.	How likely is the risk of suffering damage to the kidneys when taking *ibuprofen*? *Indicative answer: its not; its rare*	Factual	Side effect	0 = no 1 = yes	0 = no 1 = yes
4.	If you have black stools or are vomiting blood when taking *ibuprofen*, what should you do? *Indicative answer: stop taking and tell your GP*	Action	Side effect	0 = no 1 = yes	0 = no 1 = yes

	immediately. Mark as 'No' for explain if immediately is not mentioned.				
5.	**Why should you tell your GP if you are taking vitamins when taking *ibuprofen*?** *Indicative answer: because they can react with ibuprofen*	Explanation	Before you take	0 = no 1 = yes	0 = no 1 = yes
	Co-codamol page				
6.	**What should you do if you continue to be sick (or feel sick) a few days after first taking *co-codamol*?** *Indicative answer: tell your doctor*	Action	Side effect	0 = no 1 = yes	0 = no 1 = yes
7.	***Co-codamol* is a mixture of what two drugs?** *Indicative answer: paracetamol and codeine*	Factual	What medicine is for	0 = no 1 = yes	0 = no 1 = yes
8.	**Why should you not take *paracetamol* if you take *co-codamol*** *Indicative answer: because there is already paracetamol in co-codamol*	Explanation	How to take	0 = no 1 = yes	0 = no 1 = yes

User Test number two

	Question	Type of question	EU categories	Info found?	Info explained?
	Types of painkillers page				
1.	What are the strongest painkillers? *Indicative answer: opiods*	Factual	What medicine is for	0 = no 1 = yes	0 = no 1 = yes
2.	Why would you be given immediate release morphine? *Indicative answer: in case you have breakthrough pain*	Explanation	How to take	0 = no 1 = yes	0 = no 1 = yes
	Ibuprofen page				
3.	Why would you be given immediate release morphine? *Indicative answer: in case you have breakthrough pain*	Explanation	Side effect	0 = no 1 = yes	0 = no 1 = yes
4.	If you suffer from asthma and you take *ibuprofen*, what should you do? *Indicative answer: Check with the GP*	Action	Before you take	0 = no 1 = yes	0 = no 1 = yes
5.	If you take 200mg of *ibuprofen*, what is the maximum number of tablets you can take in 24 hours? *Indicative answer: 12*	Factual	How to take	0 = no 1 = yes	0 = no 1 = yes

Co-codamol page					
6.	What should you do if your bowels don't move for more than two days when taking *co-codamol*? *Indicative answers: tell your doctor*	Action	How to take	0 = no 1 = yes	0 = no 1 = yes
7.	How common is the risk of suffering a skin rash when taking *co-codamol*? *Indicative answer: it will only occur rarely*	Factual	Side effect	0 = no 1 = yes	0 = no 1 = yes
8.	How does *co-codamol* work? Indicative *answer: it controls pain by blocking prostaglandins (pain messages) to the brain.*	Explanation	What medicine is for	0 = no 1 = yes	0 = no 1 = yes

PSSUQ: Questions about the ease of use of the pages

I want you to tell me whether you agree with the following statements; and then answer the follow-up questions. Please explain the reasons for your answers as fully as you can. [Note: Participants completed this twice – after completing both User Tests using the both sets of pages]

1.   It was easy to find the information on these pages to answer the questions.

STRONGLY AGREE					STRONGLY DISAGREE	
1	2	3	4	5	6	7

Follow-up question: What made it easy (or difficult) to find the information?

2.   I am satisfied with how easily I found the information on these pages to answer the questions.

STRONGLY AGREE					STRONGLY DISAGREE	
1	2	3	4	5	6	7

Follow-up question: What was it about the pages that made them satisfying (or not) to use?

3.   The information on the pages was easy to understand.

STRONGLY AGREE					STRONGLY DISAGREE	
1	2	3	4	5	6	7

Follow-up question: Please explain why the information was easy to understand (or not easy to understand)

4.   The information on the pages was organised clearly.

STRONGLY AGREE					STRONGLY DISAGREE	
1	2	3	4	5	6	7

Follow-up question: Please explain why the information was organised clearly (or not)

Satisfaction with Information about Medicines Scale (SIMS)

I would like you to rate the information you read as a whole for the following aspects. I would like you to say whether you thought the information was: too much, about right, too little, or if none was received. Please tick one box only.

[Note: Participants completed this twice – after completing both User Tests using the both sets of pages]

1. **What the medicines are called.**

   Too much
   About right
   Too little
   None received

2. **What the medicines are for.**

   Too much
   About right
   Too little
   None received

3. **What the medicines do.**

   Too much
   About right
   Too little
   None received

4. **How the medicines work.**

   Too much
   About right
   Too little
   None received

5. **How long it will take for the medicines to act.**

   Too much
   About right
   Too little
   None received

6. **How you can tell if the medicines are working.**

   Too much
   About right
   Too little
   None received

7. **How long you will need to be on the medicines.**

   Too much
   About right
   Too little
   None received

8. **How to use the medicines.**

   Too much
   About right
   Too little
   None received

9. **How to get a further supply.**

Too much

About right

Too little

None received

10. **Whether the medicines have any unwanted effects (side effects).**

Too much

About right

Too little

None received

11. **What are the risks of you getting side effects?**

Too much

About right

Too little

None received

12. **What you should do if you experience unwanted side effects.**

Too much

About right

Too little

None received

13. **Whether you can drink alcohol whilst taking the medicines.**

Too much

About right

Too little

None received

14. **Whether the medicines interfere with other medicines.**

Too much

About right

Too little

None received

15. **Whether the medicines will make you feel drowsy.**

Too much

About right

Too little

None received

16. **Whether the medicines will affect your sex life.**

Too much

About right

Too little

None received

17. **What you should do if you forget to take a dose.**

Too much

About right

Too little

None receive