Development of a minimum dataset for recording traumatic dental injuries in children

Thesis by Alternative Format

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Intellectual property and publications

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others. After early discussion with supervisors in 2020 the decision to undertake thesis by alternative format was made as it would be appropriate for this project given the structure and scope of the aims and objectives of the study. The thesis is constructed of chapters comprising of one or more related publications:

Kenny KP, Chauhan A, Pavitt S, Foy R, Day PF. Qualitative research in dental traumatology—A narrative review. Dental Traumatology. 2024 Jan 24.

I contributed to conception, literature searching and reviewing and drafted the manuscript. Amrit Chauhan, Prof Robbie Foy, Prof Sue Pavitt, and Prof Peter Day contributed to interpretation and critically revised the manuscript.

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I contributed to conception, study design, data collection, data analysis and interpretation and drafted the manuscript. Professor Peter Day, Professor Robbie Foy and Professor Sue Pavitt contributed to conception, study design and data interpretation and critically revised the manuscript.

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Abstract

Background: Traumatic dental injuries (TDI) are common and can occur across the life course. Children with TDI experience negative social judgments, bullying and teasing by their peers about their appearance. Poor epidemiological data and limited recording of diagnosis and treatment in general dental practice hinder quantifying the impact and burden of TDI to children, their families and healthcare services.

Aim: To develop and feasibility test a minimum dataset for TDI (MDS-TDI) for use in routine clinical practice.

Methods: The MDS-TDI was conceptualised and developed as a complex intervention whilst Normalisation Process Theory (NPT) was used as an underpinning implementation framework. Formal consensus techniques guided the inclusion of outcomes in the dataset. User testing was used to integrate the MDS-TDI into an existing electronic patient record. A single-site feasibility study undertaken in a teaching hospital assessed data collection processes and acceptability of outcome measures. A focus group with clinicians was audio-recorded before coding and framework analysis informed by NPT.

Results: Dentists, dental specialists, patient and parent representatives and other stakeholders were recruited to the consensus study. The MDS-TDI comprises clinician-oriented outcomes (pulp healing, periodontal healing, discolouration, tooth loss) and patient-oriented outcomes (communication, aesthetics, pain, quality of life). User testing enabled the integration of the outcomes to the electronic patient record in a clinician-friendly way. The feasibility study assessed data from 95 patient appointments; patient outcome completion rates were high at all study time-points. Clinicians understood and valued the MDS-TDI but identified challenges in integrating the MDS-TDI within daily practice.

Conclusions: An MDS-TDI has been developed and integrated into an existing electronic patient record**.** The MDS-TDI is feasible and acceptable

to use in a specialist paediatric dentist setting. Further work is required to validate the patient-oriented outcome measures and explore MDS-TDI feasibility in other clinical settings.

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List of Abbreviations

A&E	Accident and Emergency
CASP	Critical Appraisal Study Designs
COMET	Core Outcome Measures in Effectiveness Trials
COREQ	Consolidated criteria for Reporting Qualitative research
COS	Core Outcome Set
COS-TDI	Core Outcome Set for Traumatic Dental Injuries
CREDES	Conducting and Reporting Delphi Studies Standards
dPROMs	Dental Patient Reported Outcome Measures
DREC	Dental Research Ethics Committee
EPR	Electronic Patient Record
FIS	Family Impact Scale
GP	General Practitioner
GCP	Good Clinical Practice
GDP	General Dental Practitioner
GDPR	General Data Protection Regulations
IADT	International Association of Dental Traumatology
IPA	Interpretative Phenomenological Analysis
IQR	Interquartile Range
JARS-Qual	Journal Article Reporting Standards for Qualitative Research
JBI	Joanna Briggs Institute
LDI	Leeds Dental Institute
LTHT	Leeds Teaching Hospitals Trust
MCDS	Minimum Clinical Dataset
MDS	Minimum Dataset
MDS-TDI	Minimum Dataset for Traumatic Dental Injuries
MRC	Medical Research Council

NGT	Nominal Group Technique
NHS	National Health Service
NHS BSA	National Health Service Business Service Authority
NIHR	National Institute for Health and Care Research
NPT	Normalisation Process Theory
OHRQoL	Oral Health Related Quality of Life
OIDP	Oral Impacts on Daily Performance
OR	Operating Room
PPIE	Patient and Public Involvement and Engagement
PPQ	Parental Perception Questionnaire
PROMs	Patient Reported Outcome Measures
QoL	Quality of Life
RCT	Randomised Controlled Trial
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
TDI	Traumatic Dental Injury
UCD	User Centred Design
UDA	Unit of Dental Activity
UK	United Kingdom
US	United States

Chapter 1 Introduction

1.1 Dental Trauma

Traumatic Dental Injuries (TDI) are considered a public health problem due to their high prevalence and physical, physiological, social, and economic consequences. In addition, TDI can have a negative impact on the quality of life of children and adolescents.

1.1.1 Classification

TDI are injuries to the hard and soft tissues within and around the vicinity of the oral cavity, including the teeth, gingivae, and alveolar bone. They can be defined as simple (one or two teeth involved, root development is complete, or hard tissue injury only) or complex (multiple teeth involved, immature root, or periodontal ligament involvement).

1.1.2 Aetiology

A systematic review of systematic reviews, published by Magno and colleagues in 2020, identified 22 risk factors that were associated with TDI (1). These were summarised as sociodemographic factors, clinical factors, socio-economic indicators, behavioural habits, factors associated with sports, special needs status, use of lip and/or tongue piercings and previous history of TDI. The complete list of risk factors is included in **Table 1.1**.

Category	**Risk Factor**
Sociodemographic factors	Gender
	Age
Clinical factors	Overjet
	Lip coverage
	Overbite
	Dental caries
	Anterior open bite
	Obesity
Socioeconomic indicators	Household income
	Socio-economic status
	House ownership
	Parental schooling
Behaviour habits	Physical activity
	Alcohol use
	Drug use
Sports habits	Professionalism in sports
	Use of a mouthguard
Special needs status	Autism spectrum condition
	Down syndrome
	Cerebral palsy
	Epilepsy
Other	Lip and/or tongue piercings
	Previous history of TDI

Table 1.1: Risk factors for TDI.

The authors concluded that many of the systematic reviews included were of low quality and may not provide an accurate and comprehensive summary of research on TDI aetiology (1). The role of gender and age risk factors are well known, whereas others such as ethnicity and socio-economic status require further understanding (2). TDI usually affects a single tooth, but certain trauma events, such as sport, violence, and traffic accidents can result in multiple injured teeth (3).

1.1.3 Incidence and prevalence

Traumatic dental injuries have been ranked as the fifth most prevalent disease or injury after caries, tension-type headache, iron deficiency anaemia and hearing loss (4). The oral region comprises approximately 1% of the total body area, however, oral injuries account for 5% of all bodily injuries. This figure is higher in children (5). TDI are common with more than one billion people having experienced TDI (4). The global prevalence has been reported as ranging from 6% to 34.8% in children and adolescents (6). The incidence of TDI is variable across different age groups, being highest among children under 12 years of age with a global incidence rate of 2.75% per year in the permanent dentition (4). In the UK, the 2013 Children's Dental Health Survey (England, Wales, and Northern Ireland) found that 10% of children at age 15 years had clinical evidence of TDI (7).

A significant limitation of many of these epidemiological surveys is that only clinical examinations are undertaken. Radiographs are not taken, nor are they available to the examiners. This may lead to under-reporting of TDI, as teeth treated for TDI (e.g. root canal treatment or composite resin restoration) or teeth with periodontal ligament injuries or root fractures may not be easily identified with a clinical examination alone (8). Therefore, even in high quality epidemiological surveys, with appropriate sampling techniques, the true prevalence of TDI in any population is likely to be underestimated.

Consequently, the exact prevalence of TDI remains unknown, but it is considered that many children, their families, and dental healthcare professionals will experience the impacts of TDI in one way or another.

1.1.4 Treatment

Appropriate diagnosis, timely immediate management and long-term follow-up are essential to achieve favourable outcomes (9,10,11). Management can be complicated by such things as the child's ability to cope with treatment, medical co-morbidities, and orthodontic considerations. Retention of the damaged tooth and repair and/or regeneration of the surrounding tissue is encouraged to preserve function and aesthetics (12). TDI can have long-term sequalae (e.g. pulp necrosis, invasive cervical resorption, ankylosis-related resorption) requiring further clinical intervention to promote favourable outcomes, including root canal treatment, surgical intervention and decoronation (2,10).

Children with TDI can present to their general dental practitioner (GDP) or may present or be referred to a specialist in paediatric dentistry or a consultant-led service in secondary dental care (13). It has been reported that 60% of children across the United Kingdom (UK) initially presented to their GDP following a TDI. However, only half of these had a course of emergency treatment carried out in this setting (14). Some patients with TDI may present to a hospital accident and emergency (A&E) department. Two studies have identified that dental trauma was the most common reason for dental attendances to A&E in children (15,16). Parten *et al* (16) also reported that 28.5% of those attending A&E for dental issues were from areas of the highest deprivation in the UK. Together, these studies demonstrate that the delivery of care for patients with TDI can be disjointed and confounded by access issues.

1.1.5 Impact

1.1.5.1 **Child**

TDI is a significant dental public health problem that impacts children, affecting their masticatory function and quality of life, as well as creating ongoing economic consequences (2,4).

Children with TDI experience negative social judgments, bullying and teasing by their peers about their appearance (17,18). Further studies have shown that TDI has a considerable impact on oral health related quality of life, comparable to impacts reported by children with cleft lip and palate (19). The first paper to report on TDI-related oral health related quality of life (OHRQoL) in children was published in 2002 (20). This was a school-based cross-sectional study involving 304 Brazilian children aged 12-14 years. Following a clinical exam to identify TDI, caries or malocclusion, children completed the oral impacts on daily performance (OIDP) questionnaire. The scores were adjusted for potential cofounders such as malocclusion. The key finding was that children with an untreated TDI were 20 times more likely to report a negative impact on their daily life compared to their peers. Impacts were noted across all domains, particularly affecting smiling, eating, and socialising. Since this significant study was published, there have been several similar investigations across different populations and geographical regions A well-conducted cross-sectional study in Brazil determined that even enamel fractures – which are the least severe form of TDI - have a negative impact on the OHRQoL of adolescents, especially affecting emotional and social well-being (21). Two additional Brazilian studies that assessed trauma involving periodontal ligament damage reported negative outcomes in 8–10-year-old children (22) and in 12-year-olds (23). Tooth avulsion among children under 18 years had an adverse effect on OHRQoL in an Italian population (24). Girls report poorer OHRQoL than boys (23,25). Good family support and mixed coping styles have been identified as predictors of better OHRQoL, and interestingly, the severity/complexity of the TDI has not directly predicted OHRQoL (26).

Societal pressures to conform to beauty ‘norms’ are immense for today's young people. Furthermore, there is a wealth of literature showing that social judgments are commonly made in relation to an individual's facial or dental appearance (27,28). These social judgements, negative or positive, may have profound and lifelong consequences in terms of relationship success, career prospects and even judicial outcomes (29). The clinical relevance of this is clear: children should be provided with high quality and expedient dental treatment for their injuries, which restore aesthetics as well as function. Furthermore, anxieties can be heightened at important life events, such as moving schools (18). The psychosocial impacts of TDI are unique to each patient, influenced by their treatment preferences, resilience, and ultimate recovery (26). Clinicians should therefore be empathetic and alert to each child's social circumstances and endeavour to provide timely treatment to restore incisor appearance and function (26).

Milani and colleagues undertook a systematic review and meta-analysis to assess whether TDI treatment affects OHRQoL of children, adolescents, and their families. Six studies were included, each with low to moderate risk of bias, The meta-analysis determined that in children and adolescents, treatment of TDI reduced the negative impact on OHRQoL (30). The authors concluded that more studies are necessary to detect the TDI treatment influence on OHRQoL of younger children and the family unit (30).

Ultimately, research shows that children with TDI report worse OHRQoL than their peers. This is borne out by the experience of my patient and public involvement and engagement (PPIE) contributors with lived experience of TDI, who have referred to the disfigurement and long-term impact of treatment and the concerns they have about treatment continuing well into adulthood.

1.1.5.2 **Family**

TDI can also impact the OHRQoL of families and carers. Berger and colleagues (19) identified that severe dental injuries have a profound and lasting effect on Parental Perception Questionnaire (PPQ) and Family Impact Scale (FIS) scores, indicating a large effect on parents QoL following dental injury. The authors proposed that the unexpected nature of the trauma immediately throws parents into a situation that involves multiple dental visits, time away from work, a financial burden, and seeing their child in pain. These are the suggested reasons for the impact on family QoL (19). Several additional studies have corroborated these findings (31-34).

A more recent mixed methods study included semi-structured interviews with GDPs, exploring their perceptions of TDI management in primary care (13). The participants identified that parents were concerned about the long-term implications of TDI.

The evidence supports the fact that parents report a reduction in their own health-related quality of life after their child has sustained a TDI. However, it has been reported that this improves over time if they are satisfied with the dental treatment provided and long-term complications are minimised (35).

1.1.5.3 Health service

TDI have a very high-cost burden, estimated to be between 2-5 million US dollars per one million population (4). Direct cost of care for dental injuries includes the costs of emergency management and subsequent treatment needs across the patient's lifetime. Indirect costs include the time missed from school and work, transportation, and potential childcare costs incurred for both the initial trauma management and follow-up visits, which can be lengthy depending on the traumatic injury (35). Injury severity and complexity are associated with increased direct and indirect costs (37-40). Despite the importance of the economic aspect of dental trauma, studies on the costs associated with TDI are scarce (36). One study conducted in Sweden reported an average cost of 2955 Swedish Krona (equivalent to £1950.00) for permanent tooth injuries over a 2-year period (37). A slightly later Canadian study found that the direct cost of replantation of avulsed permanent teeth during the first-year post injury was $1465 Canadian Dollars (£602.00) (41). A prospective study conducted in Ireland reported the 1-year cost of TDI management as €1687.9 (£1445.78) for complex injuries and €1350.80 (£1157.03) for non-complex injuries (40). A recent retrospective analysis of dental records in US children's hospital, calculated the mean cost of $1396 (£1112.00) for two years of treatment and follow-up of avulsed permanent teeth (36).

There have been two published UK studies looking at the costs, both direct and indirect, of treating TDI. The first reported that the average cost of treating a TDI per patient was £856, attributing the majority of this to the indirect costs incurred – travelling to and from the clinic, and time off work and school (38). The second estimated that the average cost for any traumatic injury was £1097 (42). The authors acknowledged that this simple estimate did not consider the future costs for ongoing and potentially more definitive dental care in adulthood. They also identified that following a TDI, the median number of visits to a specialist centre for required treatment was nine, with a range of 1-28. Almost one quarter of the patients were still attending for treatment more than four years after the initial injury (42).

It is possible that these costs may in fact be an underestimation of the true cost, as in most of the studies, the costs were calculated only for one tooth in each patient, and it is known that dental trauma commonly includes injuries to multiple teeth. The costs were estimated for one- or two-years duration which does not represent the real outcome of such complex injuries where patients with TDI are often committed to a lifetime of dental treatment. The number of visits following any TDI is unpredictable. Knowing the cost of managing TDI should be of interest to individuals, health services and the insurance industry so that adequate resources can be planned.

1.2 The research problem

Due to poor epidemiological data and poor recording of diagnostic and treatment codes in general dental practice and secondary dental care, it is currently difficult to estimate the number of children having treatment for TDI in the NHS Thus, it is challenging to quantify the impact and burden of TDI on the child, their family, or the NHS. Appropriate and accurate recording of treatment for TDI would allow the collection of data that has hitherto been challenging. Only then will it be possible to determine the impact of TDI accurately and robustly on patients and the NHS in the UK, and the success or otherwise of treatment interventions.

If all (or at least a majority of) clinicians are recording the same outcome data, in the same way and at the same time points, we can then use this data to monitor and compare services. Routine, robust recording offers a platform for clinical audit against pre-defined standards which, when coupled with effective performance feedback methods can lead to data-driven improvement of healthcare delivery and hence improved patient outcome*s* (43)*.* Results could be used to identify the training needs of practitioners, areas where there are gaps in service provision (e.g. access to specialist level-care for complex TDI), and costs to the NHS for management of these dental injuries. When robust data has been collected and analysed it can also be used in clinical research. The results from this research will be more generalisable because data will be sourced from all settings (primary care and specialist centres).

The Commissioning Standard for Dental Specialties – Paediatric Dentistry document (44), states clearly that commissioners are to ensure sufficient 24/7 provision and clear signposting to trauma care and out of hours dental care services for the timely and effective management of dental trauma in children. Commissioning should be based on a needs assessment. Currently, it is impossible to do this without accurate data on treatment provided, by whom, and their level of training.

Therefore, considering the significant impact TDI has been demonstrated to have on children, their families and health services, in addition to this requirement for appropriate commissioning of services, there is a clear need to improve the recording of treatment outcomes following TDI management.

1.3 Research Approach

1.3.1 Minimum datasets

A minimum dataset has been described as a recommendation for a standardised minimum set of metrics to be collected along with the method of collection, to allow aggregated use of data (45). The term Minimum Dataset or MDS is a commonly used but poorly defined term in the healthcare literature (46). It is used in healthcare to describe an ontology, an existing set of data elements used for a specific purpose and a standardised protocol for collecting data. Conceptualisation of the MDS range from that of an essential or pertinent set of data elements related to a single clinical condition, procedure, specialty, discipline, or healthcare process, to that of a comprehensive and inclusive set of elements related to an entire domain of health (46). The term ‘national minimum dataset’ is frequently used to describe several distinct types of datasets and registries. These datasets have been developed and used for purposes ranging from surveillance (47), epidemiological tracking (48), service planning (49), budgeting (50) and population level clinical research (51). Svensson Ranello and colleagues proposed the term ‘minimum clinical dataset (MCDS)’ as a subset of MDS, developed for collecting data during the routine process of care. The authors defined this as “a coherent, explicitly articulated set of standardised data elements, developed using an explicit, empirically based approach to defining and naming relevant clinical constructs, designed to optimally represent and capture data at the patient-microsystem interface and oriented towards the acquisition of actionable knowledge to be used at the microsystem level”.

To aid comparison of data between groups it is crucial to have a common dataset that clinicians and researchers collect in a standardised way, with items clearly defined (52). When these items are measured over time, they can help capture disease outcomes/treatment response, which can facilitate both patient care and translational research (52). Use of standard consistently reported outcomes can demonstrate and allow differentiation of the effectiveness and value of different treatments (53). This is particularly important in dental traumatology as we have hitherto been unable to report on treatment success or otherwise, cost and impact on the NHS.

Quality of data collection strongly contributes to quality and trustworthiness of the results. Poor-quality data entry often leads to unreliable data output – this is also known as the “garbage in-garbage out” concept (54). Metrics to be recorded within an MDS must be clinically relevant, otherwise clinicians are unlikely to record the data consistently and reliably (45). Equally, an MDS cannot be imposed, and clinicians must decide what information is important to measure oral health of their patients (55).

1.3.2 Minimum datasets in dentistry

To date, there have been two published minimum datasets in dentistry. The first was published in 2001 (55). The authors developed a minimum dataset for primary dental care and proposed that “a standardised clinical minimum dataset will not only facilitate self-audit but, as it is standardised across primary dental care, it will be possible for practitioners to compare the success of their interventions with those of their colleagues. Adopting this approach will support clinical decision making and foster an evidence-based perspective to the delivery of primary dental care. Preventive activity or treatment interventions that are shown to be ineffective could be modified or discontinued” (55). There have been no further publications about the dataset, and it appears not to have been implemented.

A minimum dataset for auto transplantation was published in 2023 (56). Auto-transplantation is a specialist procedure and as such, this dataset will be used by specialist teams in tertiary referral centres. Implementation in primary care will not be required.

1.3.3 Minimum dataset as a complex intervention

Minimum datasets are currently not used in routine dental practice. In fact, dentistry has a poor track record in recording outcomes for any treatment or intervention that is provided. As such, the implementation of a minimum dataset for TDI (MDS-TDI) will need to overcome many hurdles. Although a minimum dataset may not be initially thought of as a complex intervention, if we look to the Medical Research Council (MRC) definition: “*a complex intervention is any deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care or some other formal organisational setting “(*57), it could indeed be described as such.

Careful development of complex interventions is necessary so that new interventions have a better chance of being adopted widely in the real world (58). Key actions for intervention developers were described in the ‘Guidance on how to develop complex interventions to improve health and health care’ that was published in 2019 (58). These actions are summarised in **Table 1.2**.

Action
Plan the development process
Involve stakeholders, including those who will deliver, use, and benefit from the intervention
Bring together a team and establish decision-making processes
Review published research evidence
Draw on existing theories
Articulate programme theory
Undertake primary data collection
Understand context
Pay attention to future implementation of the intervention in the real world
Design and refine the intervention

Table 1.2: Key actions for intervention development

For intervention research to be most useful to decision makers, it should consider the complexity that arises both from the intervention's components and from its interaction with the context in which it is being implemented (59). Implementation of the MDS-TDI will require 'buy-in' from NHS commissioners and managers to mandate that clinicians use the dataset in routine practice. It will require a considerable change in how clinicians record clinical findings in patients that are treated for TDI. Hitherto, they are likely to have used 'free text' boxes when recording clinical outcomes, with little or no guidance on which outcomes to record or how to record them.

The eventual implementation of the MDS-TDI across dental primary care was a key consideration when planning this project. According to the MRC, both intervention development and evaluation require a strong theoretical foundation. It has been proposed that making explicit use of theory to develop an intervention prior to testing may lead to a more effective intervention than a purely empirical or pragmatic approach (60).

1.4 Theoretical framework

There is a wide range of implementation theories that we could have considered as a guiding framework. Normalisation Process Theory was chosen as it provides an understanding of the dynamic social processes involved in implementation.

Normalisation Process Theory began life as a model, constructed based on empirical studies of the implementation of new technologies (61). The model was subsequently expanded upon and developed into a theory as change mechanisms and the relationships between various constructs were explored and described (62). Rather than focusing on predictors of behaviour, NPT focuses on the work that individuals do to integrate interventions into routine practice (63). The theory identifies four determinants of embedding (i.e. normalising) complex interventions in practice – coherence or sense making, cognitive participation or engagement, collective action, and reflexive monitoring (64). It can be used in both the development and the evaluation of an intervention. A systematic review using NPT in primary care in the United Kingdom (UK) concluded that NPT is widely used and seemingly beneficial in the development and evaluation of implementation of interventions across UK primary care (65). For example, NPT was used to inform the redesign and subsequent evaluation of an intervention to promote evidence-based care of patients with back pain in UK primary care (66). The NPT analysis identified that the intervention had low coherence among GPs – it did not make clinical sense to them, and hence there was low cognitive participation – the GPs didn’t understand why it was necessary. The analysis ensured the researchers redesigned the intervention to improve its coherence and fit with existing practices. GPs could then easily understand what was involved and see the potential benefits for patients. It is now generally accepted that NPT provides a consistent framework that can be used to describe, assess, and enhance implementation potential (63). NPT has been used in the development of the MDS-TDI (see **Table 1.3**).

NPT Components	Questions to consider within the NPT framework	Examples as a guide for consideration
A: COHERENCE Meaning and sense of content *'What is it'*	1. Is the intervention easy to describe?	I will need to ensure patients, parents, clinical team, and commissioners understand the term 'minimum dataset'. The terms minimum datasets, or even 'outcomes' are not widely used in dentistry.
	2. Is it clearly distinct from other interventions?	Yes, there is no other data-collection system for TDI in use
	3. Does is have a clear purpose for all relevant participants?	<u>Patients and parents</u> – to ensure they have treatment that provide outcomes that are relevant to them. <u>Clinical team</u> – to enable them to follow evidence-based practice, provide data for audit and clinical research and ultimately to improve treatment outcomes. <u>Commissioners</u> – to enable them to direct appropriate resources with greater confidence and optimising a cost-effective approach.
	4. Do participants have a shared sense of its purpose?	By taking an inclusive 'equal voice' approach with all stakeholders I anticipate we should be able to co-develop a shared vision of what is valued. This is central to the intervention development.
	5. What benefits will the intervention bring and to whom?	<u>Patients and Parent</u> – to ensure they have treatment that provides outcomes that are relevant to them. <u>Clinical Team</u> – to enable them to follow evidence-based best practice, improve treatment outcomes, provide data for audit and research. <u>Commissioners</u> – direct resources to TDI more confidently by enabling an evidence-based cost-effective commissioning approach.
	6. Are these benefits likely to be valued by potential participants?	<u>Patients and Parents</u> – by adopting a patient/carer-centric approach from the outset we aim to incorporate outcomes they have deemed are of importance to them. <u>Clinical Team</u> – stakeholders are from a wide clinical perspective, from generalist to specialist and will likely have differing perception of value – it will depend on their practice, areas of interest and management ethos (i.e. exposure to treating TDI, 'buy-in' to monitoring practice to drive service quality and improvement) <u>Commissioner</u> – confidence in quality and reach of data collected will influence value.

B: COGNITIVE PARTICIPATION Commitment and engagement by participants ‘Who does it’	1. Are target users likely to think the intervention is a good idea?	Specialists – yes General Dentists – potentially, will depend on ethos and belief in evidence-based dentistry
	2. Will they see the point easily	See A6
	3. Will they be prepared to invest time, energy, and work in it?	This is reliant on the user testing generating a tool that is optimised to be easy to complete within the EDR system used in practice, quick and potentially bi-directional. So, for example, provides dashboards that benefit local clinical team delivery of care. By nature of it being a MDS is will streamline data collection. Again, like response to B1, it will depend on value and management ethos in care setting.
C: COLLECTIVE ACTION The work participants do to make the intervention function. “How does it get done?”	1. How will the intervention affect the work of user groups?	It has potential, at least initially, to be more time consuming – particularly if current practice involves very little ‘data collection’ – i.e. poor recording of clinical and radiographic findings during treatment for TDI.
	2. Will it promote or impede their work?	The user-testing aims to allow optimised design considerate of time constraints in different work settings. It should promote their work and allow them to clearly record treatment and outcomes for TDI.
	3. What effect will it have on consultations?	Potential initially to increase time for consultation – particularly if patient/parent data collection is required. If a dashboard approach is favoured/achieved, the bi-directional flow of data in the electronic data system may optimise treatment options and improve decision making.
	4. Will staff require extensive training before they can use it?	Yes – all clinicians will require education and training on both the content of the MDS-TDI and the process of how to incorporate its use in their daily clinical practice.
	5. How compatible is it with existing work practices?	The aim of the design consultation will be to consider incorporating into existing EDRs so to be as widely compatible as possible
	6. What impact will it have on division of labour, resources, power and responsibility between different professional groups	Patient/Parent: potential to feel empowered if they feel their opinions and wishes regarding treatment and outcomes are being taken seriously. Clinical Team: i) Dental nurses – if they can be involved in routine data collection may contribute to sense of team-working and professional development. ii) Dentists – may improve confidence in management of TDI, may allow for shared care with specialists or easy contact with specialists for opinion or advice

		iii) Specialists – may improve opportunities for shared care with colleagues in primary care and will also ensure useful information is available from the referring dentist iv) Commissioners – responsive to adopting a patient-centred evidence based and cost-effective commissioning of service
	7. Will it fit with overall goals and activity of the organisation?	Clinical Team – stakeholders are from wide clinical perspectives from generalist to specialist and will likely have differing perception of value – it will depend on their practice, areas of interest and management ethos (i.e. exposure to treating TDI, 'buy-in' to monitoring practice to drive service quality and improvement) Commissioner – confidence in quality and reach of data collected will influence value.
D: REFLEXIVE MONITORING Participants reflect on or appraise the trial. *"Why did it happen like that"*	1. How are users likely to perceive the intervention once it has been in use for a while?	The goal is that they will find it easy as familiarisation grows and beneficial to their practices and patients
	2. Is it likely to be perceived as beneficial for patients and staff	The pros and cons will be evaluated across stakeholders. Data entered will be fed back to the clinicians and evaluation undertaken to see if they perceive it to be useful
	3. Will it be clear what effects the intervention has had?	Yes, particularly as we move to data collection and analysis. We have never had good data on TDI management in primary or even secondary care so there is real potential for improved and relevant information on treatment outcomes
	4. Can users/staff contribute feedback about the intervention once it is in use?	Yes, we would plan for this and include it in any implementation planning
	5. Can the intervention be adapted/improved based on experience?	Yes, otherwise feedback etc. is pointless. A minimum dataset will require review at pre-defined intervals to ensure the outcomes are being measured and how they are being measured is still relevant (e.g. consider advances in treatment)

Table 1.3 Normalisation Process Theory used in study development.

1.5 Previous, related work

1.5.1 Core Outcome Set

A Core Outcome Set for TDI (COS-TDI) was published in 2018 (66). The COS-TDI was specifically designed for use in clinical trials. It comprises fourteen generic outcomes and eight additional injury specific outcomes. No patient-reported outcomes were included. The outcome measurement instruments for each included outcome were also defined, as was the timepoint for each measurement to take place.

1.5.2 Patient important outcomes

Semi-structured qualitative interviews were undertaken with children and their parents/guardians to determine outcomes of importance to them following treatment for TDI. This work was undertaken prior to the start of this PhD. Communication and aesthetics emerged from the thematic analysis as the two most important outcomes to both groups.

1.6 Outline of the development and implementation of MDS-TDI

As described in section 1.4, this project was underpinned by NPT.

For Chapter 2, I insert a narrative review of qualitative research in dental traumatology. Qualitative methods are used throughout the project to explore patient and professional views of outcomes and acceptability.

In Chapter 3, I present the results of the MDS-TDI development. Formal consensus techniques were used to determine which outcomes should be included in the dataset.

In Chapter 4, I present the findings of the approach used to incorporate the MDS-TDI into an existing electronic patient record (EPR). Multiple EPRs exist in dental practice across the UK. A pragmatic decision was made to use the EPR system in place in the authors place of work, Leeds Dental Institute (LDI).

In Chapter 5, I explore the feasibility of using the MDS-TDI in a ‘real-life’ clinical setting. Again, a pragmatic decision was made to run the test in the LDI, due to time and funding constraints. It was felt that if the MDS-TDI was not feasible or acceptable to dentists with expertise and interest in dental traumatology, then it would be unlikely to work in other clinical settings.

In Chapter 6, I summarise and discuss the findings from each stage of the project.

1.7 Aims and objectives.

The aim of this project is to develop, and feasibility test the minimum dataset for traumatic dental injuries for use in routine clinical practice. **Table 1.4** presents a summary of each stage, including the research question, objective, and study design.

Stage	Research Question	Objective	Study Design	Chapter
1	Which outcomes are important to clinicians?	To identify outcomes of importance to clinicians managing patients with TDI.	Delphi survey	3
2	Which outcomes should be included in the MDS-TDI?	To identify which outcomes should be included in the MDS-TDI.	Consensus meeting, informed by the nominal group technique.	3
3	How can the MDS-TDI be designed to use in an EPR?	To design the MDS-TDI into an existing EPR.	A user-centred design approach involving usability testing, think aloud.	4
4	Is it feasible to use the MDS-TDI?	To undertake an early phase feasibility study in a teaching hospital.	Feasibility test to explore the feasibility of data collection and acceptability of the MDS-TDI to clinicians.	5

Table 1.4: Summary of research stages

1.8 Ethical considerations

The study was adopted by the NIHR Clinical Research Network and conducted in accordance with the ethical principles outlined in the 1964 Declaration of Helsinki (67) and its later amendments or comparable ethical standards. The Good Clinical Practice (GCP) training was completed prior to commencement of the study and a GCP e-learning refresher course was completed during the research period.

1.9 Data management

Data was collected and processed in accordance with the University of Leeds Data Protection Code of Practice (68) and General Data Protection Regulations (GDPR) (69). All research data was stored anonymously and securely in a University of Leeds One Drive account. Consent forms with participant name and signature were stored in a locked filing cabinet in the researcher office in the University of Leeds School of Dentistry with restricted access. Data was only stored for the duration of the research and processed for the purpose of the research for which explicit consent had been obtained.

Transcription of audio-recordings was undertaken by the researcher (KK). Audio-recordings and transcriptions were labelled only with the study identifier, stored in the University of Leeds secure One Drive account, and were only accessible to the researcher.

1.10 Ethical approval

The ethical approvals for each stage of the study are summarised in **Table 1.5**. and presented in **Appendix Figure a.1.** Advice from the Leeds Teaching Hospitals Trust (LTHT) Research Governance team was that the feasibility test was viewed as a quality improvement project and therefore aplicaiton for NHS ethical approvals was not deemed necessary.

Study component	Ethics body	Approval
Consensus study	DREC	301120/KK/312
Usability test	DREC	230822/KK/356
Feasibility test	DREC	010223/KK/365

Table 1.5: Summary of ethical approvals

1.11 Funding

The research was funded through an NIHR Doctoral Research Fellowship (NIHR300206) awarded after a competitive peer-reviewed application process. Funding supported research and training costs, but the research is independent. NIHR were not involved in the design and conduct of the research or the interpretation of research data. The thesis and associated publications represent the view of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

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Chapter 2 Literature review: qualitative research in dental traumatology

Qualitative research in dental traumatology – a narrative review

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Abstract

Qualitative research methods can generate rich and detailed data to provide explanations and insights into people's experiences, beliefs and attitudes and the complexity of human decision-making and behaviour. Qualitative methods are used to generate hypotheses and address questions of 'how' and 'why'. In the past decade there have been a growing number of publications of qualitative studies in dental journals. However qualitative studies remain a small percentage of the published dental traumatology research. This may be because of limited understanding about the background, methods, and rigour of qualitative research. This review highlights the recent contributions of qualitative research in Dental Traumatology, summarises the common approaches and methods used and outlines the key factors that guide the appraisal of qualitative studies.

2.1 Introduction

Dental traumatology researchers have traditionally undertaken quantitative enquiry to develop the evidence base in the field. From the early laboratory-based studies of histology and tooth healing, through to questionnaires, surveys, cross-sectional and cohort studies, research in dental traumatology has generally adopted a biomedical approach, striving to provide a robust evidence base for clinical management (1).

Quantitative research focuses on answering the questions "what?", "how much?" and "when?". Many quantitative researchers work from the assumption that there is an absolute truth, a 'reality', which they are trying to discover. Knowledge is objective and neutral. This belief about knowledge has been called 'objectivism' and the theoretical framework it implies is called 'positivism' (2). Quantitative data can be statistically analysed and interpreted but inevitably can only offer incomplete insights into complex phenomena (1).

Conversely, qualitative research addresses the questions "why?" and "how?" (2). Qualitative research is generally interpretive in nature and through this, seeks to develop an understanding of and explanation for the behaviours, experiences and interactions of individuals and the social context in which these occur (3). Most qualitative researchers today share a different belief about knowledge, called ‘constructivism’, which proposes that the reality we perceive is constructed by our social, historical, and individual contexts – therefore there can be no absolute truth (2).

Qualitative research methods have a long track record in healthcare sciences and are making an increasingly important and distinctive contribution to evidence-based medicine (4,5). However, there has been limited qualitative research in the field of dental traumatology (1,6). This review aims to provide an overview of qualitative research, its key approaches and how to appraise it, and to explore its potential value to dental traumatology research.

2.1.1 Qualitative research in dental traumatology.

Rodd and Noble highlighted that the first published narrative to describe the wider impacts of a traumatic dental injury was in fact published over 60 years ago (1). They describe a case report (7) of a 9-year-old boy who attended a British dental hospital having sustained uncomplicated crown fractures of four permanent incisors. As well as detailing the clinical treatment, the authors described the patient’s psychosocial upset from the injury. The boy was a chorister but after fracturing his incisors he lost his place in his choir due to a lisp. The child’s mother reported that her son had become quiet and moody, experienced disturbed sleep and sibling rivalry.

A 2016 comprehensive review of dental trauma literature to determine the degree of children’s involvement in clinical research did not identify any qualitative or mixed methods studies (6). For the purposes of this current review, the first author (KK) hand searched Dental Traumatology issues from January 2015 until October 2023. Only five qualitative or mixed methods studies were identified. This accounts for less than 1% of all published articles. In part, this may be because health professionals and researchers have little training and experience in conducting and appraising qualitative research methods or are uncertain as to how it can inform or affect practice or policy. **Table 2.1** summarises these five papers, and they are used to illustrate the different approaches throughout the article.

Author **Year**	**Qualitative approach**	**Aim**	**Data collection & analysis**	**Findings**
Ode, 2018 (8)	Sequential mixed methods	(i) To examine the functional, psychological, and social impacts of TDI and associated factors among a sample of adult patients (ii) explore the perceptions and attitudes of patients with experience of TDI and dentists managing such TDI (iii) to compare the attitudes and perceptions between patients and dentists	Oral Health Impact Profile (OHIP)-14 then focus groups. Thematic analysis	Patients wanted dentists to be reassuring, confident, willing to engage in shared decision making and to walk the journey with them. Dentists were also mostly aware of the patients' needs; however, they were less attuned to the psychological impact experienced by patients.
Zencricoglu 2019 (9)	Mixed methods	To evaluate the accessibility of on-time and proper treatment quantitatively after dental trauma in children by means of their parents, and qualitatively by interviewing parents and health professionals in Izmir, Turkey	Questionnaire then semi-structured interview with patients and dentists Thematic analysis	Treatment access was summarised into three main themes: physical accessibility of dental health services, a quality dental health service as an outcome and communication among parties.
Bamashmous, 2020 (10)	Mixed methods	To investigate (i) the different ways that patients undertaking treatment for dental trauma	Semi-structured interviews with patients	The findings from the qualitative analysis allowed development of a patient and parent centred questionnaire that had good face validity.

		and their parents look for relevant information (ii) their information needs (iii) their preferred format of information (iv) the differences between the information seeking behaviour of children and their parents	Content and framework analysis Questionnaire developed from themes	
Taylor 2021 (11)	Mixed methods	To explore and contextualise the knowledge and attitudes of general dental practitioners regarding their management of traumatic dental injuries in the permanent dentition in 7- to 16-year-olds	Questionnaire survey. Findings from this used to develop topic guide for semi-structured interviews. Thematic analysis	Four major themes arose from the interviews – the impact of TDIs on patients' parents and GDPs, barriers to providing treatment, educational opportunities for GDPs and the interactions between primary and secondary care services.
Morgan 2021 (12)	Interpretivist	To assess the opinions and experiences of transitional care pathways for young people with TDI	Semi-structured interviews Thematic analysis	Five themes related to the transitional care experience – patient-clinicians communication, impact of dental trauma, feelings of uncertainty, patient personal development and transitional care planning. Clear communication and involvement of young people in decision making was identified as a vital factor to facilitate a successful transition of care form paediatric to adult services

Table 2.1: Summary of articles with qualitative or mixed methods approach in Dental Traumatology 2015-2023

2.2 Common approaches and methods used in qualitative research.

Theory plays a crucial role in qualitative research, both as a guiding framework to inform the design and methodology of a study or as an outcome where studies can be designed to generate theory from the findings. Theory and methodology in qualitative research have distinct roles although they are interconnected. Many approaches exist - four of the most common approaches in applied health research are grounded theory, ethnography, narrative analysis, and phenomenology. **Table 2.2** summarises these approaches. The overview has been simplified for the scope of this paper. General characteristics of participant selection, data collection and data analysis that can apply to different qualitative approaches are described below

	Grounded Theory	**Ethnography**	**Narrative Analysis**	**Phenomenology**
Aims	To produce a theory that is grounded in the data	To immerse the researcher in the natural environment of the study participants to gain insider experience	To understand and interpret the stories told by individuals and the meanings they ascribe to them.	To describe the lived experiences of individuals about a particular phenomenon.
Sampling & Methods	Uses theoretical sampling. Data collection is mainly through interviews, observation, and review of documentation	Purposive sampling Data is collected through extensive fieldwork: Observational studies supplemented with field notes, and/or follow-up interviews.	Usually, purposive sampling with one or more individuals who have life experiences or stories to share. Data collection is mainly through in-depth interviews and other written narratives (e.g., diaries, letters, documents)	Purposive sampling of individuals with the lived experience of a phenomenon Data collection is mainly in-depth interviews but may also include personal documents and descriptive observations.
Analysis Features	Constant comparison method. Generation of concepts and relationships.	Interpretative, data-driven (inductive) but no fixed commitment to developing new theory. Considers the whole context of the social setting.	Analyses how the stories are structured with a focus on the content (what is said) and how it is said. Often uses chronological organising.	Data-driven (inductive) that can either be interpretative or descriptive. Descriptive phenomenology: The researcher engages in bracketing (epoché).

	Concurrent data collection and analysis.	Detailed accounts (thick descriptions) of field experiences that convey the significance of social action, which is reflective.	Takes into account the cultural and historical context. Collaborative approach with participants. Involves looking for themes within the stories.	Identification of Significant Statements (narrow units), formation of meaning clusters (broader units), then detailed description of the experience and synthesis of meanings and essence. Interpretive Phenomenological Analysis (IPA): Interpretive and iterative process. Researchers engage in a double Hermeneutic. Researchers develop experiential statements and personal experiential themes.
Example	Hoglund 2023 (13)	Lingard 2004 (14)	Kettle 2019 (15)	Hazevah & Hovey 2018 (16)

Table 2.2: Summary of common qualitative approaches in applied healthcare research

Qualitative research adopts a naturalistic approach that explores, interprets, and obtains a deeper understanding of social phenomena. A key feature of qualitative research is the collection and analysis of non-numeric data, such as text, audio, or visual material. The detailed examination of these types of data allows researchers to gain a nuanced understanding of human beliefs, attitudes, and behaviours. This approach is more concerned with explanation than with measurement. As such qualitative research provides an in-depth understanding of phenomena that quantitative research may overlook, prioritising the richness of human experience over numerical generalisation (17,18).

Within the broad context of health, qualitative approaches can help determine the attitudes, beliefs and perspectives of patients, carers and clinicians to a condition, intervention, or policy. They can help understand the interpersonal nature of caregiver and patient relationships and behaviours and enable insights into illness experience (3). Bamashmous and colleagues (10) used semi-structured interviews with both patients and parents to explore how they look for relevant information following a TDI, and Morgan (12) explored how patients managed a transitional care pathway from the paediatrics team to the adult restorative team for the management of TDIs. Qualitative approaches have also been used to explore healthcare structures and policy. Zencricoglu and colleagues (9) used qualitative approaches to explore both how patients accessed emergency dental care following TDI, and the perspectives of clinicians in providing this care.

Qualitative methods have long played an important role in research into quality and safety in health care – to understand how medical errors occur, to consider how to minimise them and to identify ways to improve the quality of care (19). Lingard and co-workers (14) study on identifying communication errors and challenges in teamwork operating theatres that may lead to medical errors is one of the most cited qualitative studies in health care research. This ethnographic study of general and vascular surgery revealed different types of communication errors. This informed the development of a pre-operative communication checklist which has subsequently led to significant reductions in communication errors amongst surgical teams (19). A purely quantitative approach to this significant issue is unlikely to have obtained such rich data about communication errors. A solely quantitative study may have measured the frequency of communication errors, or their correlations with outcomes, but it would likely have failed to grasp the underlying reasons for these errors, or the specific ways in which communication broke down.

As health care and health care systems become increasingly complex, simply knowing ‘what works’ is not enough. Research problems that can be approached particularly well using qualitative methods include assessing complex multi-component interventions or systems of change, addressing questions beyond “what works” towards “what works, for whom, when how and why” (20,21).

It is also necessary to know how significant research findings can be translated into front line health care delivery (19). Rigorous effectiveness evaluations are generally necessary but insufficient by themselves to inform healthcare policy and practice. A qualitative approach alongside the RCT can help in the development, feasibility, piloting and evaluation of the trial and the intervention itself.

One of the most powerful reasons to undertake qualitative research is its ability to explore the patient and the professional’s perspective. Taylor and colleagues (11) used a mixed methods approach to explore and contextualise the knowledge and attitudes of GDPs regarding their management of TDIs in 7–16-year-olds. An interesting finding from the semi-structured interviews was that the TDI and its management had an impact on the GDP – for some the potential for a poor outcome resonated with them and was identified as a significant stressor when providing treatment (11).Health and social care policymakers increasingly expect engagement with the voices and perspectives of patients (22,23) and for policy to include patient values, beliefs and preferences (24). Qualitative research not only allows exploration of patient perspectives, but also offers methods to investigate anything from health policy to doctor-patient interactions (25). Policy is especially amenable to qualitative research given how policy endeavours to be responsive to real world contexts (26).

Author Year	Qualitative approach	Aim	Sampling	Data collection	Analysis	Findings
Hoglund 2023 (13)	Grounded theory	To identify, describe and generate concepts regarding dentists' recognition of dental anxiety	Purposive and theoretical sampling	Semi-structured interviews	Inductive analysis by constant comparison	The core category was identified as 'the clinical eye'. This comprised five categories: sympathetic activation, patient-reported anxiety, controlling behaviours, avoidance, and accomplishment
Lingard 2004 (14)	Ethnography	To describe systematically the content and effects of procedurally relevant communication events and to define and classify common communication failures	One hospital site Purposive sampling of procedures to observe – to represent a range of surgical cases	90 hours of observation during 48 procedures. Ethnographic field notes methods	Field notes were analysed in a constant comparative manner. Rhetorical framework used	Communication failures in the operating room (OR)exhibited a common set of problems. One third of the errors resulted in effects which put patient safety at risk by increasing cognitive load, interrupting routine, and increasing tension in the OR
Kettle 2019 (15)	Narrative analysis	To explore how stories relating to oral health practices	Convenience sample	In-depth interviews	Realist tale approach with thematic analysis	Demonstrated how oral health practices are constituted through family connectedness and at the same time how these practices contribute to the constitution of family

		emphasise connectedness				
Hazevah & Hovey 2018 (16)	Phenomenology	To explore in depth ‘what does it mean to live with chronic orofacial pain?’	Purposive sample from a pain clinic	In-depth interviews	Interpretive phenomenological approach	Three main findings emerged 1) suffering from loss; 2) encountering disbelief by others; 3) feeling dissatisfied with the health care system

Table 2.3: Qualitative approaches in the wider dental literature

Table 2.3 provides examples from the wider dental literature of how the differing approaches have been used to explore a broad range of topics. Subjects as diverse as medical errors, the meaning of living with chronic orofacial pain, dentists’ recognition of dental anxiety and the relationship between oral health and connectedness have all been explored.

2.2.1 Participant selection

Qualitative research is focused on achieving depth rather than breadth in its inquiry into a selected population. The primary objective of qualitative sampling is to capture a diverse range of perspectives and experiences within the research population that are relevant to the study's aims (21). The most common type is purposive sampling, where researchers intentionally select a diverse range of participants who have specific characteristics or experiences that are directly relevant to the research questions and objectives (18). Researchers typically use various purposive sampling techniques such as snowball, maximum variation sampling, critical case sampling or deviant case sampling (21). Snowball sampling is especially useful when accessing ‘hard to reach’ groups, as this involves identifying an initial participant who meets the research criteria and then asking them to refer other individuals who also meet the criteria (2). Other approaches such as convenience sampling may be used to recruit participants who are easily accessible. This approach tends to capture a limited range of perspectives as participants are selected based on their accessibility rather than their relevance to the research questions or the diversity of their experiences (27,28).

Sample size and determination of an appropriate sample size are very different in qualitative research when compared with quantitative research. Rather than having prespecified sample sizes, recruitment in a qualitative study will cease when ‘saturation’ is achieved (2). This is defined as the point when the collection and analysis of new data no longer elicits new insights (28).

However, there is no set rule about what constitutes data saturation, and it is often determined by researcher judgement.

2.2.2 Data collection

Focus groups and semi-structured interviews are the most common data collection methods in qualitative health research (8,9,10,11,12,29). Both methods are useful and effective in exploring individual experiences, preferences, and values, thereby offering invaluable insights that can inform clinical practice (28). Observations and document analysis, while less frequently employed in qualitative health research are particularly suited to understanding how organisations work or how different members of the healthcare team interact with each other (29).

2.2.3 Data analysis

The analysis of qualitative data generally seeks to develop understanding and description of the phenomenon being investigated (28). There are many types of qualitative analysis methods each suited to different kinds of data and research questions. Some of the key types of qualitative analysis include thematic analysis, content analysis, narrative analysis, discourse analysis, grounded theory, phenomenological analysis, and ethnographic analysis. The choice of a method depends on the research question, the nature of the data, and the theoretical framework guiding the research. This steers how the analysis is undertaken such as the coding process or whether there is a development of themes or generation new theories. The main ones have been outlined in **Table 2.2**.

Kuper and colleagues, in their review of qualitative research appraisal, highlight that data analysis should be iterative, involving cycles of data collection, analysis and then resumption of data collection to further explore and challenge emerging themes or theories (2,28).

2.3 Combining qualitative and quantitative research methods

Mixed methods research combines elements from both qualitative and quantitative paradigms to produce converging findings in the context of complex research questions (30). It can be used to view a research question from multiple lenses, providing a more robust and comprehensive analysis. Mixed methods research requires an integrated analysis and the used of rigorous qualitative and quantitative research methods (31). It can be classified into three core mixed methods designs (**Table 2.4**).

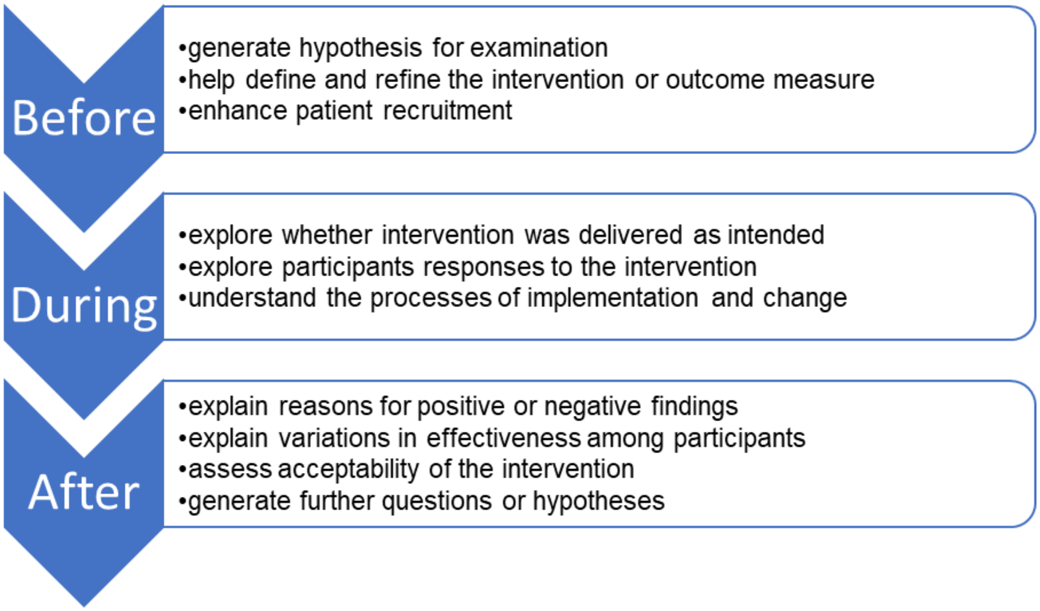
Type	Explanation	Example
Convergent	Qualitative and quantitative data are collected and analysed simultaneously within a single phase	Templeton et al 2015 (32)
Sequential exploratory	Quantitative data is collected first, then qualitative data is collected to explain the quantitative findings	Ode et al 2018 (8) Taylor et el 2021 (11)
Sequential exploratory	Qualitative data is collected, a feature such as a new instrument or intervention is built, and then the feature is tested quantitatively	Bamashmous et al 2020 (10)

Table 2.4: Explanation of mixed methods research

Mixed methods approaches were used in four of the five qualitative articles published in Dental Traumatology (**Table 2.1**). Interviews and/or focus groups were used after a questionnaire or survey instrument to contextualise and explore the findings (8,9,11) or used to develop a survey with increased validity

(10). This is especially useful where there is limited evidence on a topic and a lack of validated tools for exploring the research question.

Mixed methods designs can be incorporated into more complex research designs such as randomised controlled trials – this is a process evaluation (33). (**Figure 2.1**).



Before

- generate hypothesis for examination
- help define and refine the intervention or outcome measure
- enhance patient recruitment

During

- explore whether intervention was delivered as intended
- explore participants responses to the intervention
- understand the processes of implementation and change

After

- explain reasons for positive or negative findings
- explain variations in effectiveness among participants
- assess acceptability of the intervention
- generate further questions or hypotheses

Figure 2.1: Mixed methods design in process evaluations.

2.4 Reporting and appraisal of qualitative research

As with any research we need to be able to distinguish poor research from high quality research to judge its relevance and appropriateness for healthcare services (19). Transparency is essential if qualitative methodologies are to be developed further and to maintain methodological rigour (4). Four criteria are widely used to appraise the trustworthiness of qualitative research: credibility, dependability, confirmability, and transferability (34). Reflexivity is an additional marker of quality (35). **Table 2.5** summarises these key concepts.

Criteria	What it means	How to recognise it
Credibility	The research findings are plausible and trustworthy	There is alignment between theory, research question, data collection, analysis, and results. Sampling strategy, the depth and volume of data and the analytical steps taken, are appropriate within that framework. Techniques that can enhance credibility include triangulation, member checking and reflexive journalling.
Dependability	The extent to which the research could be replicated in similar conditions	There is sufficient information provided such that another researcher could follow the same procedural steps, albeit possibly reaching different conclusions
Confirmability	There is a clear link or relationship between the data and the findings	The researchers show how they made their finds through detailed descriptions and the use of quotes. The findings should be shaped by the participants and not the researcher's bias or motivation.
Transferability	Findings may be transferred to another setting, context, or group	Detailed description of the context in which the research was performed and how this shaped the finds
Reflexivity	A continual process of engaging with and articulating the researcher and the context of the research	Explanation of how reflexivity was embedded and supported in the research process and how the researchers have reflected on their own biases and experiences and how this may have influenced the research and its findings.

Table 2.5: Summary of appraisal in qualitative research (adapted from Stenfors 2020 (35)

There is, however, no consensus on the appropriate approach to appraising the quality of qualitative research (36). More than 100 appraisal tools are now available. Consolidated Criteria for Reporting Qualitative Health Research (COREQ) (37) is one of the most used tools, but others such as Critical Appraisals Skills Programme (CASP) (38), Joanna Briggs Institute Checklist for Qualitative Research (JBI) (39) and American Psychological Association's Journal Article Reporting Standards for Qualitative Research (JARS-Qual) (40) are also widely used. Some concern has been expressed about the use of appraisal frameworks. It has been argued that checklists can lead to an uncritical adoption of a range of technical 'fixes' such as grounded theory or purposive sampling, which do not in themselves improve the quality of the research (4). Checklists can only strengthen research rigour if they are used in the context of a broad understanding of qualitative research design and data analysis (4). It has been suggested that the use of such checklists and appraisal tools my even be counterproductive if used uncritically and without careful consideration of the research context (35).

2.5 Opportunities and challenges in qualitative research.

Qualitative research has the potential to generate a deep understanding of people's experiences, motivations, beliefs, goals, expectations, and needs (28). It also offers a rich range of method to explore anything from health policy to doctor-patient interactions. Good clinical practice, and indeed policy, depends on the sort of knowledge generated through small, in-depth qualitative studies, as well as information generated through large-scale clinical trials (25).

In qualitative research, the researcher is the research instrument. Therefore, a qualitative researcher who is also a clinician must consider how their dual position informs participant consent, data collection and analysis (41). The balance of maintaining a professional duty of care while ensuring methodological integrity can be challenging (42). Additional challenges include a perceived (and often real) power imbalance between the research participant and the clinician interviewer, and the fact that the transfer of skills from clinical practice to qualitative interviewing does not necessarily equate to good qualitative research conduct (41). It is also necessary to remember that the “patient” becomes the participant in qualitative research who is the expert on their lived experience and knowledge and the researchers’ role is to seek to understand this knowledge and experience rather than provide clinical care. Reflexivity ensures the challenges related to being a clinician-researcher are acknowledged and discussed openly (41).

There is a common perception that the scientific rigour of qualitative studies may not match those with a quantitative methodology. This may account for the lower acceptance rates of such papers by many journals. Retrouvey and colleagues (43) undertook a bibliometric and altimetric analysis comparing the academic and social impact of quantitative and qualitative articles and did not find a dominant article type using those metrics. They found no indication that qualitative articles published in the BMJ had less impact than quantitative articles.

Another common perception is that qualitative research is not generalisable. It may be true to say it is not generalisable in the traditional sense, but by providing thick, rich description of the context and the participants the reader is able to judge the transferability of the findings to other settings or groups.

2.6 A future for qualitative research in dental traumatology?

Health research must strive to address issues that patients feel are important rather than just those that clinicians believe are a priority (6). Some would argue that without appropriately conducted qualitative enquiries, opportunities are being missed to gain meaningful insights into the child's perspective of TDI (6).

It is important that researchers reappraise patients views and opinions in relation to TDI. Such inquiry will help identify what is important to young patients and to prioritise where improvements can be made to better meet their needs (6). The recently published narrative review of dental patient reported outcomes following TDI and treatment emphasises the importance of the patient in the development of the appropriate outcome measures (44).

This can best be achieved using qualitative approaches. Further qualitative research is also required, particularly with adolescents, to inform clinicians about young patients' perspectives, experiences, and values and how these may change over the course of treatment and indeed over the life course (1). Incorporating insights from qualitative studies into clinical care, policies and trials can help promote patient-centred care to improve outcomes for patients (28).

2.7 Conclusion

There has been limited qualitative research in the field of dental traumatology. Qualitative research can broaden the evidence base in both policy and practice because it allows researchers to answer research questions that are difficult to address satisfactorily using quantitative methods alone. It can also address evidence gaps regarding patient priorities and clinician perspectives in the management of TDI.

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Chapter 3 Development of the minimum dataset for traumatic dental injuries

Improving data quality from routine clinical appointments - development of a minimum dataset for traumatic dental injuries in children and adolescents.

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Abstract

Background/Aims It is currently difficult to evaluate the success or not of treatment for dental injuries due to poor recording of diagnostic and treatment codes in clinical dentistry. A minimum dataset comprises a standardised minimum set of outcomes along with a specified outcome measurement instrument, to allow aggregated use of data from routine clinical care appointments. This study aimed to determine which outcomes should be included in a minimum dataset for traumatic dental injuries (TDI).

Materials and Method This is a three-stage sequential, mixed-methods study, using evidence-based best practice for dataset development. Normalisation Process Theory informed the development of the study protocols. In Stage 1, semi-structured interviews with patients and their parent or guardian were undertaken to identify outcomes of importance to patients. In Stage 2, an online Delphi survey was undertaken to identify outcomes of importance to clinicians. In Stage 3, a National Consensus Meeting was undertaken involving patient representatives, clinicians, and other stakeholders, to agree which outcomes should be included in the minimum dataset.

Results Stage 1: Eleven participants were recruited, 5 children and 6 parents. Two key themes emerged from the analysis – communication and aesthetics. In Stage 2, thirty-four dentists were recruited, and 32 completed both rounds of the survey (97% retention). Most outcomes were deemed by participants to be of ‘critical importance’, with three outcomes deemed ‘important’ and none to be ‘of limited importance’. In Stage 3, fifteen participants took part in the consensus meeting. Participants agreed that the dataset should comprise a list of clinician-important outcomes (pulp healing, periodontal healing, discolouration, tooth loss) and a list of patient-important outcomes (communication, aesthetics, pain, quality of life)

Conclusion A Minimum Dataset for TDI has been developed using a robust and transparent methodology.

3.1 Introduction

Traumatic dental injury (TDI) has been identified as the fifth most prevalent disease or injury globally after caries, tension-type headache, iron deficiency anaemia and hearing loss (1). TDI affect an estimated one billion people worldwide, with a prevalence of around 20% in children aged up to 12 years (1,2). Children with TDI experience negative social judgments, bullying and teasing by their peers about their appearance (3). TDI can have a life-long and significant impact on oral health-related quality of life (OHRQoL) and children with a TDI experience poorer OHRQoL than their peers (4,5).

Effective management of TDI requires swift emergency treatment and appropriate long-term follow-up care (6). Evidence-based guidelines are freely available for all clinicians involved in treating TDI (7,8,9). However, due to poor recording of diagnostic and treatment codes across dentistry, it is currently difficult to evaluate the success or not of treatment strategies for dental injuries (10).

A Core Outcome Set (COS) for TDI was published in 2018 (11), with the express aim of harmonising reporting of outcomes used in clinical trials. It includes a list of 14 generic outcomes that should be recorded for each injury type, as well as several injury-specific outcomes. The COS also defines when and how to measure each outcome. Due to the extensive number of outcomes to be recorded, it is not practical or feasible to use the COS outside of the clinical trial setting. Consequently, there is a need to establish a “minimum dataset” that comprises a standardised minimum set of metrics along with a specified data collection method to allow aggregated use of data from routine clinical care appointments (12). Minimum datasets have been developed in various medical specialities (13,14,15). The main advantage of using minimum datasets to record clinical outcomes is the ability to undertake robust audit and service evaluation, thereby allowing comparison of treatment options, identification of service and training needs and monitoring the impact of the condition over time. However, the dataset outcomes must be clinically relevant and feasible to record in busy clinical practice (16).

Minimum datasets are currently not used in routine dental practice. In fact, clinical dentistry has a poor track record in recording outcomes for any provided treatment or intervention (10). At face value, a minimum dataset may appear relatively straightforward to adopt but it may be a deceptively complex intervention to implement into routine care. Considering the UK Medical Research Council (MRC) definition: “a complex intervention is any deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care or some other formal organisational setting (17), it could indeed be described as such. Intervention development, implementation and evaluation require a strong theoretical foundation to make explicit mechanisms of action.

This study aimed to determine which outcomes should be included in a minimum dataset for TDI.

3.2 Materials and Methods

This is a three-stage sequential, mixed-methods study, using evidence-based best practice for dataset development (18) (**Figure 3.1**). Normalisation Process Theory (NPT) was used in the development of the study protocols (**Appendix Table b.1**). This theory identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice (19). It also explains how these interventions work, looking not only at early implementation, but beyond this to the point where an intervention becomes entirely embedded into routine practice – i.e., it becomes normalised (20).

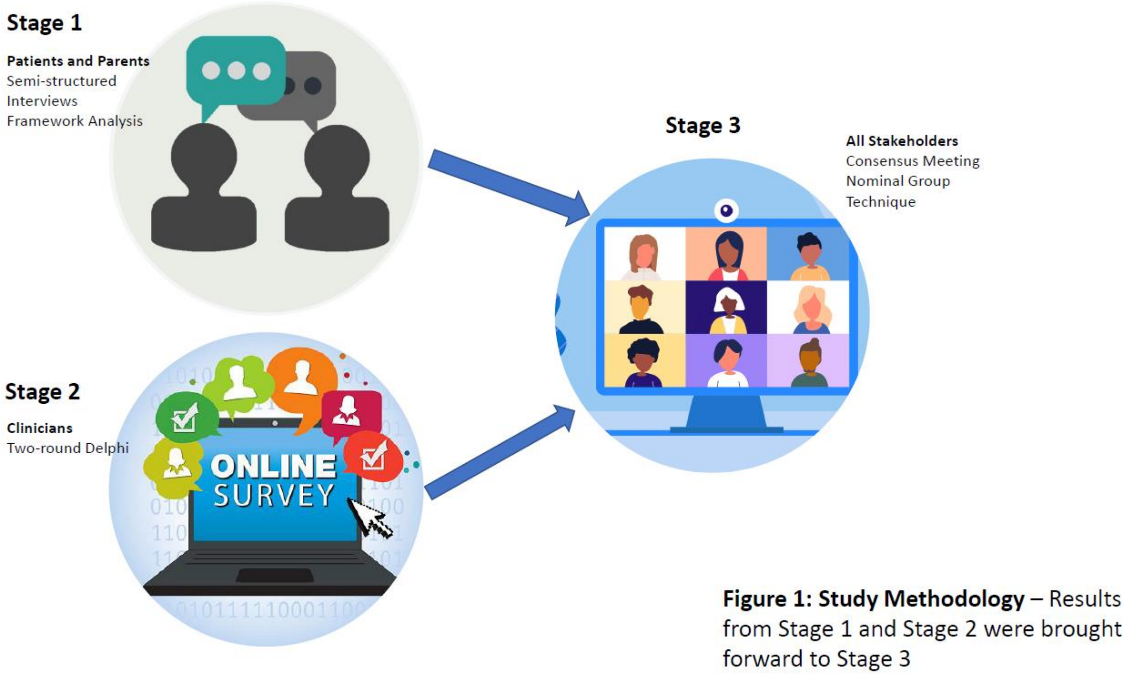

Figure 3.1: Study methodology

In Stage 1, semi-structured interviews with patients and their parents or carers were undertaken to identify outcomes of importance to patients and their parents. Children aged 7-16 years who had completed treatment for a TDI in the previous two years and their parent or guardian were eligible to participate. Potential participants were identified from clinic lists in a Teaching Hospital and Community Dental Services Paediatric Clinics. They were invited to participate in an interview, either in their own home, during a clinic appointment, or via phone. Written consent was obtained. A topic guide was developed following a review of the literature (**Appendix Figure b.1**). Each interview was conducted by one researcher (KK) who had training and experience in qualitative research, and audio-recorded and transcribed verbatim. Transcripts were uploaded to NVivo 1.6.1(QSR) for management. Analysis was undertaken using the framework analysis technique, by first author (KK).

In Stage 2, an online Delphi survey was undertaken to identify outcomes of importance to clinicians. The survey was developed, administered, and reported to the guidance on Conducting and Reporting Delphi Studies (CREDES) standards (21). Outcomes from the previously published Core

Outcome Set for TDI (11) were used to develop a two-stage Delphi survey. Outcomes were listed by injury type (see **Table 3.1**). The outcomes included generic and injury-specific outcomes. Delphi Manager software™ was used to develop and administer the survey. A pilot was undertaken with five dentists. Clinicians with an interest in dental trauma, including general dentists, paediatric dentists, restorative dentists, and oral surgeons, were recruited nationally by email invitation via professional associations and snowball sampling. Participants were sent an information sheet which included an explanation of minimum datasets, Delphi surveys and a reassurance that a minimum dataset does not instruct a clinician what treatment to do nor does it preclude them from recording any other outcomes they see fit to record. Once they had agreed to participate, each participant was sent a link to Round 1 of the survey. Participants were asked to rate the importance of each outcome on a 9-point Likert scale score between 1 “limited importance” and 9 “critical importance”.The scores were exported from the Delphi Manager software to an Excel spreadsheet and the median and interquartile range for each outcome was calculated. Simple bar charts were developed for inclusion in the Round 2 survey, to show participants how each outcome was graded by the rest of the participants.

Two weeks after Round 1, the link for Round 2 was sent to each participant. Medians and interquartile ranges were calculated, and each outcome was given a final score of “critically important”, “important” or “limited importance”*.* Consensus was considered *a priori.* Outcomes to be included in the dataset required at least 70% of participants to score the outcome as “critical” and less than 15% of participants to score the outcome as “limited importance”. Outcomes to be excluded from the dataset required at least 70% to score the outcome as “limited importance” and less than 15% to score the outcome as “critical”.

Injury	**Generic Outcomes (all injuries)**	**Injury Specific Outcomes**
Uncomplicated Crown Fracture	Periodontal healing – bone loss	Quality of restoration Loss of restoration
Complicated Crown Fracture	Periodontal healing – gingival recession	Quality of restoration Loss of restoration
Crown root Fracture	Periodontal healing - mobility	Mobility Quality of Restoration Loss of Restoration
Root Fracture	Periodontal healing - ankylosis	Root fracture site repair Mobility
Alveolar Fracture	Periodontal healing - resorption	
Concussion/Subluxation	Pulp healing	
Extrusive luxation	Pulp infection	Infraocclusion
Lateral Luxation	Pain	Infraocclusion
Intrusion	Discolouration	Re-alignment
Avulsion	Tooth loss	Re-alignment
Immature Non-Vital Permanent teeth	Quality of Life	Late-stage root fracture Root length Root width
	Aesthetics (patient Perception)	
	Trauma-related dental anxiety	
	Number of clinic visits	

Table 3.1: Outcomes included in Delphi survey

In Stage 3, a National Consensus Meeting was undertaken involving patient representatives, clinicians, and other stakeholders to agree which outcomes should be included in the minimum dataset. Feasibility of recording at a routine appointment was considered. A face-to-face consensus meeting was planned, but Covid-19 restrictions meant the meeting was undertaken online via Zoom. A professional facilitator with experience in priority setting was engaged and helped inform the methodology. The first author (KK) undertook facilitation training and attended another, similar consensus meeting to gain experience. Recruitment was by invitation to ensure a mix of stakeholders: patients and/or parent/guardian, clinicians (including those who had participated in the Delphi survey of Stage 2), NHS managerial and commissioning staff and Public Health England representatives. An information pack was sent to each participant one week prior to the meeting. This included background to the study, consent forms, a short biography of each participant and the list and definition of each of the outcomes to be discussed. Clinicians were informed that the outcome measurement instruments chosen for the Core Outcome Set for TDI (11) would be used to measure the outcomes chosen for the MDS – for example the Faces Pain Scale would be used to measure pain in children under the age of 10 years (**Appendix Table b.2**). Participants were asked to prepare a list of their three most important outcomes and their three least important outcomes. The meeting was structured using a modified Nominal Group Technique. The Nominal Group Technique (NGT) is a facilitated and structured face-to-face group interaction which aims to empower participants by providing an opportunity to have their voices heard and opinions considered by other members (22). This enables equal participation among members in generating information and achieving outcomes. It comprises four key stages: silent generation, round robin, clarification, and voting (ranking or rating) (23). NGT has been used in numerous healthcare settings to develop guidelines, explore opinions of different health professionals, lay people and carers, or to compare views of both parties (23,24). The lead author (KK) introduced a session with a short presentation. Participants were divided into two groups, ensuring a mix of participant type in each. Each participant was asked to list their three most and three least important outcomes, outlining the reasons for their choices. The small group then worked to rank the list of outcomes, using a traffic light system – green for ‘critical’, amber for ‘important’, and red for ‘not important.’ After a break, all participants reconvened and compared the rankings from each group. Discussion was undertaken and a final list of outcomes to be included in the minimum dataset was agreed upon. Feedback forms were sent to each participant immediately after the meeting.

The project was approved by the Northwest Greater Manchester East Research Ethics Committee (Stage 1 Ref 18/NW/0628) and the University of Leeds Dental Research Ethics Committee (Stages 2 & 3 Ref 30/120/KK312).

3.3 Results

Stage 1: Eleven participants were recruited, 5 children and 6 parent/ guardians. Covid-19 precluded inclusion of those who had treatment provided in a primary care setting. Full description of the process and analysis is described elsewhere (manuscript in preparation). Framework analysis was undertaken by KK. Two key themes emerged from the analysis – communication and aesthetics.

Stage 2: Thirty-four dentists (**Figure 3.2**) were recruited, and 32 completed both rounds of the survey (97% retention). Just over half of participants (n=18) had more than 10 years clinical experience. The majority (n=18) worked in a teaching hospital or university setting, 10 worked in general dental practice, and the remaining five in community dental services or district hospitals.

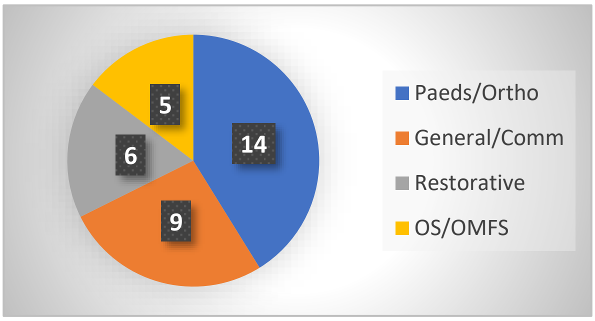

Figure 3.2: Clinicians recruited to Delphi study.

N=34 (total)

In the first round, participants were asked to grade each outcome by injury type. **Table 3.2** shows the median and IQR for intrusion injuries, as an example. As no outcomes were deemed to be of limited importance by at least 70% of participants (as determined by the a priori definition of consensus), no outcomes were removed for the Round 2 survey. **Figure 3.3** shows an example of the bar charts included in the Round 2 survey.

Outcome	Combined		GDP		Paed		Rest		OS	
	M	**IQR**	**M**	**IQR**	**M**	**IQR**	**M**	**IQR**	**M**	**IQR**
Perio – bone loss	7	3	7	3	8	2.75	7	2.25	5	4
Perio – gingival recession	7	3	7	4	8	2.75	6.5	2.5	6	2
Perio - mobility	9	2	9	2	9	0.75	8	2.75	7	1
Perio - ankylosis	9	2	9	2	9	0	9	1.5	7	2
Perio - resorption	9	2	9	2	9	0	8	2	7	2
Pulp healing	9	2	9	0	9	0.75	8	2	7	1
Pulp infection	9	1.75	9	0	9	0	8	2	7	4
pain	9	1	9	1	9	0	9	1.5	7	3
Discolouration	7.5	3	9	3	8	2.75	6.5	1.75	6	1
Tooth loss	9	2	9	1	9	1.75	8.5	1.75	7	0
QoL	6	1	6	1	7	1	6	0.75	6	2
Aesthetics (px perception)	7	2	7	2	7	1.75	6.5	1	7	3
Trauma related dental anxiety	6.5	1.75	7	1	7	1	6	1.5	7	2
Number of clinic visits	6	1.75	6	1	6.5	1	6	0.75	7	4
Re-alignment	9	2	9	2	9	0	7.5	1.75	7	2

Table 3.2: Median and IQR for intrusion injuries – round 1

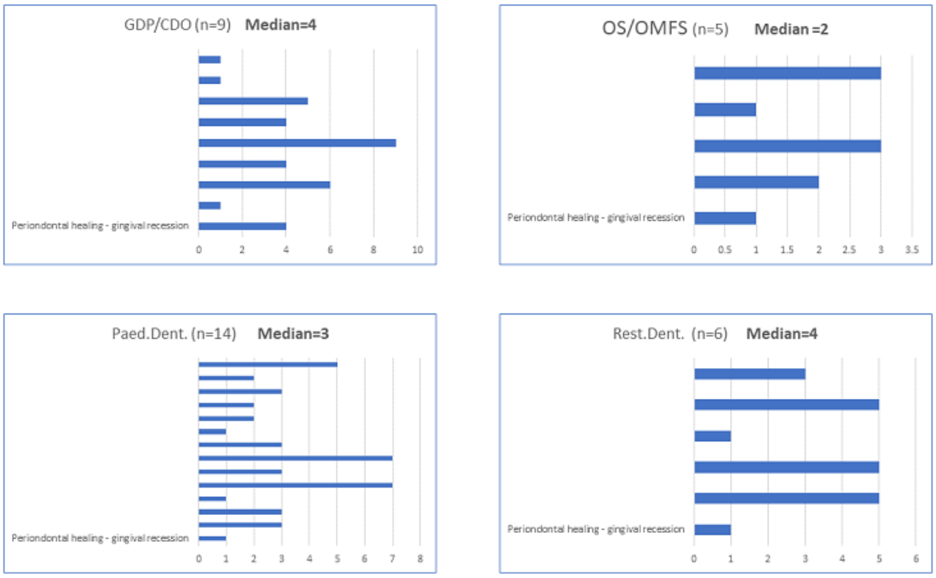

Figure 3.3: Example of bar chart of median scores included in Delphi survey round 2

Table 3.3 shows the median and interquartile ranges for intrusion outcomes as an example of the analysis undertaken. This demonstrates that most outcomes were deemed by participants to be of ‘critical importance’, with three outcomes deemed ‘important’ and none to be ‘of limited importance’. This was a trend across all injury types, particularly for complex injuries that involve both the hard tissues and the periodontal ligament.

Outcome	Combined		GDP		Paed		Rest		OS	
	M	**IQR**	**M**	**IQR**	**M**	**IQR**	**M**	**IQR**	**M**	**IQR**
Perio – bone loss	7	1	7	1	8	2	7	1	7	2
Perio – gingival recession	7	2	6	2	8	2	6	2	6	2
Perio - mobility	9	2	8	1.5	9	0	7	2	8	1
Perio - ankylosis	9	1	8	2	9	0	9	0	8	2
Perio - resorption	9	1.75	8	1.5	9	0	9	1	7	0
Pulp healing	9	1	9	1	9	0	8	1	9	1
Pulp infection	9	1	9	1	9	0	7	2	8	1
pain	9	0.75	9	1	9	0	9	1	8	1
Discolouration	7.5	2.5	8	1	8	2	7	1	7	2
Tooth loss	9	1.75	9	1.5	9	0	9	0	7	1
QoL	6	1	6	0.5	7	1	6	0	7	2
Aesthetics (px perception)	7	1	6	1	7	2	7	1	7	1
Trauma related dental anxiety	6.5	1	7	1	7	1	6	0	7	1
Number of clinic visits	6	1	6	1.5	7	1	6	1	6	9
Re-alignment	9	1	9	1.5	9	0	7	1	9	1

Table 3.3 – Median and IQR for intrusion injuries – round 2

The lead author (KK) and study supervisory group (PD, RF, SP) discussed which outcomes to take to the Consensus Meeting, considering the length of the meeting and the participants (which would include some non-clinicians). The overall aim of the minimum dataset development was emphasised i.e., that it should be feasible to use in routine clinical practice. It was decided that the list of generic outcomes should be included in the discussion, along with the two patient-important outcomes from Stage 1 (**Table 3.4**).

Outcome	**Description**
Aesthetics	How it looks
Communication	This refers to communication between the dentist and the patient
Pulp healing or infection	What happens to the nerve (which is the living part of the tooth)?
Pain	Pain could be after the injury, during treatment or after treatment
Discolouration	Has the tooth changed colour since the accident or after treatment?
Tooth loss	Did the tooth need to be taken out by the dentist because of the trauma or any complications?
Aesthetics – patient perception	What do the patients think about how the tooth looks?
Periodontal healing ankylosis/bone loss/gingival recession	What happens to the ligament of the tooth – the ligament holds the tooth in the bone?
Trauma-related dental anxiety	Is the patient more worried or fearful about going to the dentist and having treatment since the accident?
Quality of life	Has the injured tooth or treatment affected things like smiling, speaking, eating?
Number of clinic visits	How many times has the patient had to attend for treatment and follow-up appointments?

Table 3.4: Outcomes for discussion (with explanation in lay language) at the consensus meeting

Stage 3: Fifteen participants took part in the consensus meeting. All of those invited to participate agreed to take part or recommended a colleague who would be suitable and available to participate. Participants included paediatric dentists, restorative dentists, GDPs, an oral and maxillofacial surgeon, as well as, patient and parent/guardian representatives, and a Public Health England representative. Many of the clinicians involved had dual roles as clinicians and commissioners, Chair of Local Dental Networks, and a representative of Dental Trauma UK (a UK charity that aims to promote best practice in TDI management). The patient representatives included an adult patient who had completed treatment for multiple TDIs, and a young person and his parent, who was still undergoing treatment following a complex TDI in early childhood. Although Covid-19 prevented a face-to-face meeting, one participant commented the *"the online platform worked well and ensured wider participation"* (Participant 6, clinician).

Participants agreed that the dataset should comprise a list of clinician-important outcomes (pulp healing, periodontal healing, discolouration, tooth loss) and a list of patient-important outcomes (communication, aesthetics, pain, quality of life) (**Figure 3.4**). It was acknowledged that the communication outcome is difficult to measure but that due to perceived importance, it should be included, and further work undertaken to identify how best to record it.

Feedback forms were returned by 10 of the 15 participants. All participants who returned the feedback form (n=10) either agreed or strongly agreed that to the statement *"I felt able to talk about my thoughts and opinions, and I felt I was listened to"* and there were a number of positive comments on the final dataset "*I feel the idea of having patient and clinician recorded data sets was a really good one as all of a sudden being able to include more of the outcomes and not discarding some sat much more comfortably".* (Participant 5, clinician) and "*The decision to divide the categories into Clinician recorded, and Patient recorded certainly felt like it helped to clarify approaching the minimum data set"* (Participant 10, patient representative)

3.4 Discussion

A Minimum Dataset for TDI has been developed using a robust and transparent methodology. Four clinician important outcomes – pulp healing, periodontal healing, discolouration, and tooth loss, and four patient important outcomes – communication, pain, aesthetics, and quality of life, have been agreed as the TDI minimum clinical outcomes that clinicians should record at routine appointments (**Figure 3.4**). It has been decided to use the same outcome measurement instruments as those set out by the COS-TDI (11). If implemented successfully, it will facilitate accurate recording of these outcomes of treatment across a variety of clinical settings. This, in turn, will allow high quality service evaluation and 'real-world' clinical research to be undertaken in the field of dental traumatology. This has hitherto proven challenging due to the paucity of good clinical data. Routine, robust recording also offers a platform for clinical audit against pre-defined standards which, when coupled with effective performance feedback methods can lead to data-driven improvement of healthcare delivery and hence improved patient outcomes (25).

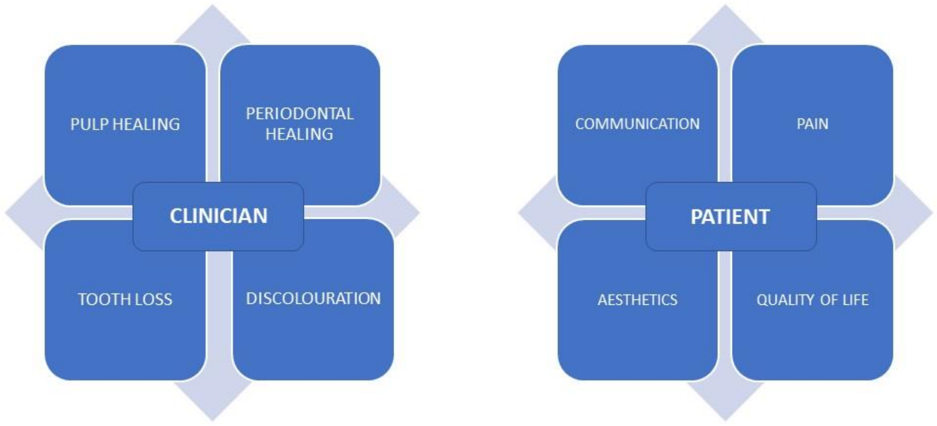

Figure 3.4: The MDS-TDI

The MDS-TDI development is timely, as there is a drive towards standardised recording across dental trauma research, led by the International Association for Dental Traumatology (IADT). The IADT has a

Standardised Records Committee, which has been convened with the express aim of presenting “a standardised way to record Traumatic Dental injuries to be used worldwide” (26). The IADT has endorsed the Core Outcome Set for TDI which was published in 2018 (11) and aims to standardise recording of outcomes in clinical trials. In March 2022, a revision of the International Classification of Diseases (ICD) was published (27). It now includes more detailed codes on dental trauma, allowing for better data collection and surveillance (27,28). For the first time, TDI is mentioned in the WHO global oral health report (29). The foundations are now in place for high quality, dental trauma research to be undertaken in various clinical settings.

However, the widespread use of the MDS-TDI will only occur if clinicians are willing to use it in their routine practice. There are several advantages in using an MDS as a clinician - audit and feedback with ‘real-time’ data, which allows clinicians to benchmark themselves against peers, the possibility of using the clinical data to support a logbook of clinical experience. This can be useful for early-career dentists, or those seeking to enter specialist training programmes. Multi-practice and corporate practice owners could use it to identify those patients with failing anterior teeth and plan for expensive implant and restorative dentistry in the future. Ultimately, it may only truly be successful if recording the MDS-TDI defined outcomes act as a driver for payment. A lack of sufficient financial remuneration associated with the long-term management of dental trauma was the main barrier for dentists to manage TDI in primary care (30). This has long been identified as an issue in NHS primary dental care (31).

The design of the MDS project was specifically undertaken with eventual implementation in mind. Therefore, in line with MRC guidance, an appropriate theoretical framework was chosen.
NPT can be used to inform intervention development, implementation, and evaluation, and was chosen for this reason. Using the theory highlighted the need to involve end-users throughout the development process and this directly informed the methodology throughout the project. Supplementary

Material 1 shows an example of how the framework was used to develop the study at each stage. A previous systematic review has identified NPT as useful for understanding implementation within UK primary care (32). None of the studies included in the review were undertaken in a dental setting. NPT has previously been criticised for its complexity and the potential difficulty researchers may have in translating the theory into a form that can be used to solve problems in everyday settings (33). The theory developers have however worked to mitigate this by developing a web-based toolkit for researchers to use when developing a study (33). The authors certainly found that the theory and the online toolkit helped guide the project and was helpful to reflect on as it progressed through its various stages. There is a wide range of implementation theories that the authors could have considered as an alternative guiding framework (34), but NPT was chosen as it provides an understanding of the dynamic social processes involved in implementation.

Involving patients and their parents/guardians in the development of the dataset was another important consideration in the project planning. Patient-reported outcomes have not previously been reported in the dental literature (35) and were not included in the Core Outcome Set. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative, which publishes guidance on outcome set development, emphasises that a Core Outcome Set needs to “include outcomes that are most relevant to patients and carers, and that the best way to do this is to include them in development” (18). Involving patients in dataset development ensures that the outcomes recorded are of relevance to patients, and that they can trust the development process has genuinely taken account of the patient perspective (18). This is particularly important in the taxpayer-funded UK National Health Service (NHS), where patients and the public are central to the organisation, as set out in the NHS constitution (36). Patients were involved in two key stages – firstly to identify outcomes of importance to them, and secondly in the consensus meeting to determine the final content of the dataset.

Communication was emphasised as a key outcome of importance in both the interviews and the consensus meeting. This is even though it is difficult to quantify or measure communication as an outcome. There is precedence for this in the literature. A project undertaken in Ontario, Canada to ensure audit and feedback initiatives were aligned with patient priorities, found that panellists valued communication skills over the task-oriented items that were readily measurable, and the limitations in measurement capacity for communication indicators were a source of frustration. The authors concluded that patient input will ultimately ensure that primary care providers focus their quality-improvement efforts in ways that are aligned with patient priorities (37). One participant in the consensus group suggested that the NHS Friends and Family Test could be used as a proxy measure for communication as an outcome. The FFT asks people if they would recommend the services they have used and offers a range of responses. This is likely to be acceptable in the UK setting, where use of FFT is widespread (38). However, it is probable that further work is required to determine how to optimally record ‘communication’ as an outcome for both children and their parents.

There is currently no standard method for sample size calculation in Delphi processes (18,39). Sample size estimates are based on a pragmatic approach considering responses from similar studies using a Delphi web-based survey distributed via professional associations. It was deemed important to engage those with expertise and experience in TDI, and to include a representative sample of participants. The sample selection was weighted to ensure those in primary care were well represented as these are key stakeholders for the eventual implementation of the project. A review of consensus development techniques indicated that relatively little is gained in reliability by exceeding 10-12 participants per stakeholder group (39).

The 9-point Likert scoring system was chosen as it is recommended by the Health Technology Assessment in their methodological review of consensus techniques and in the COMET Handbook (18,40). It has been used in the development of many core outcome and minimum datasets (41,42). Typically, 1 to 3 signifies an outcome is of limited importance, 4 to 6 important but not critical, and 7 to 9 critical. The 1-9 range may accommodate for greater sensitivity to change, which is important to detect during consensus development processes, than when using a narrower scale.

The major statistics used in Delphi studies are measures of central tendency (means, median and mode) and level of dispersion (standard deviation, and interquartile range) in order to present information concerning the collective judgments of respondents (43). Delphi studies generally use median scores to summarise the first sort of agreement, i.e. agreement with a statement. A median score represents the value below and above which half the cases fall, the 50th percentile. The second sort of agreement, consensus, is generally calculated by using interquartile range (IQRs) IQR represents the distance between the 25th percentile and the 75th percentile values in opinions, with a smaller IQR indicating larger consensus (44). An IQR < 1 means that more than 50% of all opinions falls within one point on the scale (45).

The consensus meeting was successful in engaging patient representatives, a variety of clinicians and other stakeholders. Fifteen participants have been suggested as the ideal Nominal Group Technique consensus group size and is based on recommendations from the COMET and OMERACT collaborative groups who work extensively in dataset development (45,46). The online format proved inclusive and was accessible for all. Good preparation was key, and engagement of a professional facilitator proved invaluable. This ensured good preparation of the facilitators and the participants, which enabled the meeting to run smoothly and on time.

We highlight three main study limitations. First, the qualitative study in Stage 1 presented some challenges. No patients who received treatment for their TDI by non-specialists in primary care were recruited to interview in Stage 1, determination of patient-important outcomes. Accessing patients from primary care proved challenging due to the impact of Covid-19 restrictions. It is possible that those who receive care for TDI in primary care have a different experience than those receiving care in a specialist centre or a community dental service. Additional work is required to explore this further. Patients were recruited from one geographical area in the UK which may limit the transferability of the outcomes to other regions, and certainly to other countries where healthcare and dental services are structured very differently. Recruitment continued in the specialist centre until no new themes were emerging from the data analysis as recommended (47). Only children 2 years post-treatment were included as it was felt that this period would allow for more accurate recollection of treatment details. However, this may have missed outcomes that become evident more than several years post treatment.

Many of the outcomes included in the Delphi were scored by participants as ‘of critical importance’. Delphi survey methodology assumes experts will allow their decisions to be influenced by understanding the views of others (21,39); however, in this study, opinions did not significantly change from round to round. This may be because there was generally good agreement from the outset on broad item ratings and perhaps more importantly, no limit was given for how many items could be included in the final list. There was good engagement of an appropriate variety of clinicians, and good retention of participants, which can be a challenge in Delphi studies. The issue of multiple outcomes being deemed important or of critical importance has occurred in other similar projects (48). Ultimately the consensus meeting proved more valuable in terms of reaching consensus and understanding of what the MDS should be.

Thirdly, only 10 of the 15 participants responded to the post-meeting feedback survey. The non-responders included two of the patient representatives, two commissioners and one from corporate general practice. Non-response may indicate dissatisfaction with the meeting and/or meeting outcomes, or perhaps the participants simply forgot to respond. If further consensus meetings are planned when the MDS-TDI is under review, the importance of responding to post-meeting questionnaires will be emphasised.

3.4.1 Implications for Research

Further work is needed to integrate the MDS-TDI into an existing electronic patient record system, ideally drawing further upon user-centred design methods. Once this is complete, a feasibility test will be undertaken to determine such outcomes as feasibility (feasibility of data collection processes and outcome measures (i.e. data completeness) and intervention fidelity) and acceptability (dentists' satisfaction, intention to continue use, perceived appropriateness of the intervention). Normalisation Process Theory will be used as a framework for analysis of post-test focus groups and interviews with clinicians.

The MDS-TDI may need modification prior to implementation in other clinical settings – this is acceptable as an MDS should be flexible and undergo regular review to ensure it is working appropriately.

Implementation of this MDS-TDI will enable much needed tracking of differing treatment strategies for TDI enabling continued evaluation across secondary, community and primary care settings. This will inform which treatment options deliver the best outcomes of importance both clinically and those valued by patients across a range of scenarios.

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Chapter 4 Integrating the minimum dataset into an existing electronic patient record

Integrating a minimum dataset into an existing electronic patient record – a novel use of user testing.

Will be submitted to BMC Health Services Research.

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Abstract

Background Traumatic dental injuries (TDI) are common, and can have a significant impact on children, their families, and the health service. Data about treatment of TDI in the NHS is scarce. A minimum dataset for TDI has been developed with the aim of improving the quality of data from routine clinical appointments. If the MDS-TDI is to be used in routine clinical practice it will need to be suitable for use within existing electronic patient records.

Methods A qualitative study was informed by a user-centred design approach. Iterative cycles of user testing using the think aloud method and interviews with end-users (dentists) were undertaken. The conventional content analysis approach was used to code the data. Instructions based on usability-related themes were brought to the software developers so that appropriate revisions could be made. The next cycle of testing began once the revisions were made.

Results Ten dentists participated in this study. In the first cycle, problems with the order of data entry, and the radiograph report boxes were identified by all participants. Further adjustments were made to data entry order and navigation after cycle 2 and by cycle 3, participants were able to complete the tasks with ease. The main identified categories were effectiveness, navigation and structure, and integration into professional role.

Conclusion The MDS-TDI has been integrated into an existing EPR. As minimum datasets become more widely used across dentistry, further work is required to develop robust methodology and evaluation of user testing to integrate them into existing EPRs.

4.1 Introduction

Traumatic dental injuries (TDI) are common and occur across the life course (1,2). Children with TDI experience negative social judgments, bullying and teasing by their peers about their appearance (3). TDI can have a significant impact on oral health-related quality of life (OHRQoL) and children with TDI experience poorer OHRQoL than their peers (4,5). Data about treatment of TDI in the NHS is scarce, due in large part to poor recording of clinical findings and treatment outcomes (6). Until there are robust and consistent data collected, audit and research are negatively impacted, and we cannot identify the true impact of treatment for TDI on the patient, their family, and the NHS, nor guide improved treatment outcomes for this significant cohort of children.

A minimum dataset (MDS) comprises a standardised minimum set of metrics to be collected along with the method of collection (the outcome measurement instruments) (7). The outcomes should be clinically relevant and feasible to record in routine clinical practice (8). Minimum datasets have been developed in various medical specialties (7,9,10). We have developed a minimum dataset for TDI (MDS-TDI), using formal consensus methods. The development was underpinned by normalisation process theory (NPT) (11) to enable anticipation of potential problems with implementation and increase the likelihood of use in routine practice. The dataset aims to facilitate accurate recording of outcomes for treatment of TDI across a variety of clinical settings. It comprises four clinician outcomes (pulp healing, periodontal healing, tooth loss and discolouration) and four patient outcomes (pain, quality of life, aesthetics, communication) (**Figure 4.1**). The outcome measurement instrument for each outcome has also been recommended.

Electronic record keeping is well established in primary dental care in the UK (12). Therefore, if the MDS-TDI is to be used in routine clinical practice it will need to be suitable for use within existing electronic patient records (EPR). There is much in the literature regarding development of MDS, but little on how to use them in ‘real-life’ clinical practice. The NPT approach to this project highlighted the need to involve end-users at all stages, with the aim of making eventual implementation more straightforward.

A user-centred approach to the development and design of interventions in EPR can help ensure subsequent utility and acceptability to end-users (13). Usability has been defined by the International Organisation for Standardisation as *“the extent to which a product can be used by specified users to achieve goals with effectiveness, efficiency and satisfaction in a specified context of use”* (14). Therefore, usability testing can be described as evaluation of the extent to which interaction with a system is effective, efficient, and perceived as satisfactory by users. Good usability is critical to successful information technology (IT) implementation and adoption, and its subsequent ability to improve health care quality (15). Poor EPR usability has been shown to reduce efficiency, decrease clinician satisfaction and even compromise patient safety (16).

The aim of this study was to integrate the MDS-TDI into an existing EPR to ensure ease of use, that it is acceptable to dentists and that it is efficient to complete.

4.2 Methods

This qualitative study was informed by a user-centred design approach. Iterative cycles of usability testing using the think aloud method and interviews with end-users (dentists) were undertaken. Participants in a think aloud study are asked to carry out a task, while verbalising their thoughts. The researchers record all verbalisations, write them down in a verbal report and then analyse them (17).

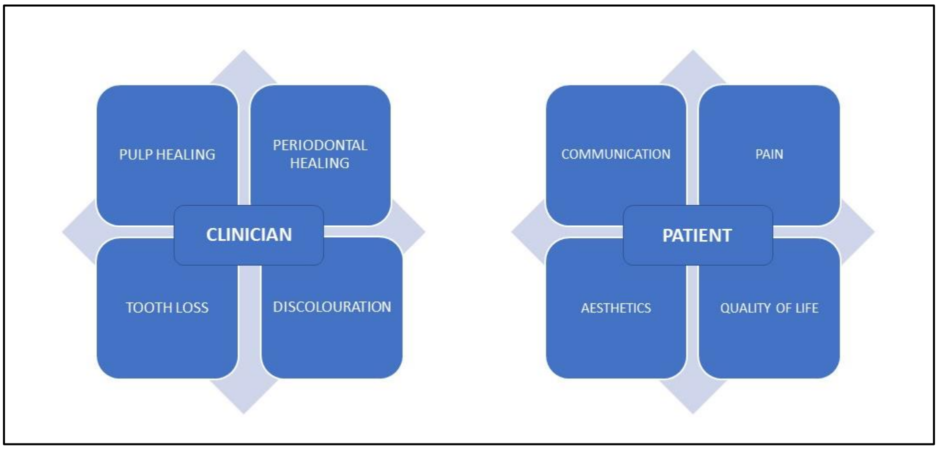

Figure 4.1: The minimum dataset for traumatic dental injuries (MDS-TDI)

It is a direct method to gain deep insight into the problems that users encounter when interacting with a computer system (18). Previous, similar studies have augmented data from think aloud by undertaking short, semi-structured interviews with participants immediately after they have completed the task (19,20). “Consolidated criteria for reporting qualitative research” (COREQ) (21) has been adhered to in the reporting of this study **(Appendix Table c.1**).

4.2.1 Participants

Potential participants were identified from a staff list in a department of paediatric dentistry in a teaching hospital. Dentists, including foundation dentists, postgraduate students, specialty dentists, specialty trainees and consultants were eligible to participate. Staff were informed of the project during the monthly department meeting and via email. A participant information sheet was sent with the email. Staff contacted the principal investigator (KK) directly if they were interested in participating. Once agreed, they were sent the study consent form to complete. Participants were sampled purposively to ensure a mix of clinical and EPR experience. Each participant took part in one session. Each round of testing included new participants so there was no learning effect from round to round.

4.2.2 Sample size.

This study employed an iterative testing approach. Therefore, the final sample size was determined by (i) the number of testing cycles needed to sufficiently refine the dental trauma pages to include the MDS-TDI and (ii) the number of participants per testing cycle needed to reach data saturation. Review of the literature and previously conducted user testing studies indicated that refinement is typically achieved within 2 to 3 cycles of testing (22-24). Additionally, data saturation can usually be reached with samples as small as 4-7 participants per usability cycle (25). We aimed to recruit up to 15 dentists for 2-3 cycles of user testing.

4.2.3 Tested materials.

Simulated cases were prepared in advance of the sessions. The cases developed for the project were diverse in terms of complexity and involving different traumatic dental injuries, to reflect the clinical case mix that is seen on the dental trauma clinic (Appendix XX).

4.2.4 Electronic patient record

The EPR used in the study setting was ‘Salud’. It is described as ‘a tailored academic dental software’ system (26). It is used exclusively in academic and teaching hospital settings.

4.2.5 Procedure

Participants were sent a link to a short training video demonstrating how the think aloud approach works. They were offered the opportunity to watch the video again immediately prior to the test session if they wished. Each participant was reminded that this was a test of the EPR system, not of their knowledge and skills (27).

The think aloud observations and semi-structured interviews were undertaken by KK. KK is a female, paediatric dentist who has undertaken training in qualitative research and has experience in interviewing and focus group facilitation. She is part of the wider clinical team in the department and was known to all participants. Each testing session and interview took place in a quiet room in the School of Dentistry building.

Demographic data, such as professional roles and years of experience was collected for each participant. A brief warm-up “think aloud’ task was described for each participant to complete so they could get used to thinking aloud. Each participant was given two simulated cases and asked to enter the data on the dental trauma pages of the EPR. They were asked to verbalise their thoughts, reactions, and emotions as they performed the task (concurrent think-aloud). Field notes were taken during the usability testing session to record any observed technical difficulties. Each session was digitally audio-recorded to facilitate note-making, transcription, and analysis. Once the participant had completed the tasks, a brief semi-structured interview related to the MDS-TDI was conducted. The interview topic guide was developed and informed by the usability literature (**Appendix Figure c.1**).

Three iterative cycles of user testing were conducted to integrate the MDS-TDI into the existing dental trauma pages in the Salud EPR (**Figure 4.2**).

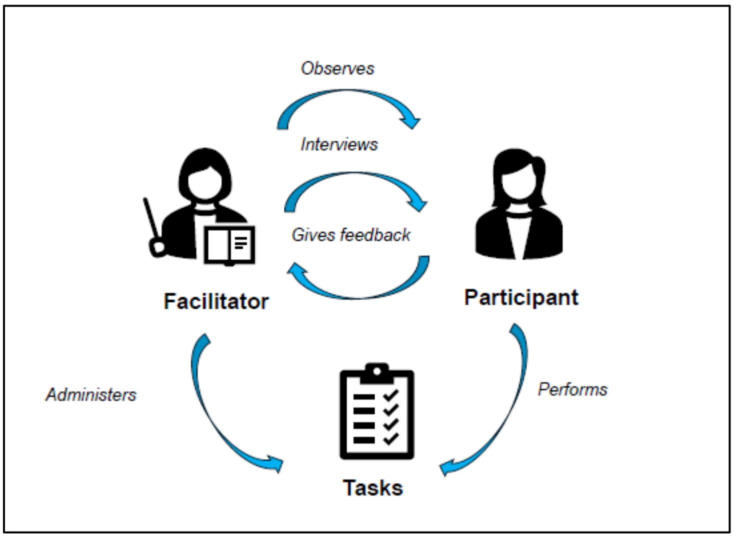

Figure 4.2: User testing procedure.

The audio-recordings were transcribed verbatim. The transcripts were not returned to the participants for review. The testing sessions continued until no data were generated that had not already been categorised. KK brought instructions based on usability-related themes to the software developers so that appropriate revisions could be made. The next cycle of testing began once the revisions were made.

4.2.6 Data Analysis

Demographic data was analysed descriptively using Microsoft Excel. Qualitative data analysis started after the first user testing session. NVivo software (*QSR International, V.14*) was used to facilitate management of the data. The analysis was led by KK with one other member of the research team (AC), who is an experienced qualitative researcher, also with extensive dental knowledge. Audio-recorded data was referred to as necessary. The conventional content analysis approach was used to code the data (28). The objective in content analysis is to systematically transform a large amount of text into a highly organised and concise summary of key results (29).

Analysis started with reading all data repeatedly to achieve immersion and obtain sense of the information. The data was then read word by word to derive codes by first highlighting exact words from the text that appeared to capture key thoughts or concepts which were referred to as meaning units. Next, the lead author (KK) approached the text by making notes of her first impressions, thoughts, and initial analysis. AC also coded the first two transcripts. Coding was compared and discussed, and a codebook developed. KK continued to code the additional transcripts. Codes were then sorted into subcategories and then categories based on how different codes were related and linked. The coding and categories were further discussed and refined with AC.

4.2.7 Research Ethics

Ethical approval was obtained from the University of Leeds Dental Research Ethics Committee (DREC Ref 230822/KK/356).

4.3 Results

Ten dentists participated in this study. The mean duration of the sessions was 52 minutes. Those recruited were of varying levels of seniority and experience with the EPR system (**Table 4.1**).

Participant	Role	Years of experience with EPR
1	Specialty trainee	Less than 1 year
2	Consultant	1-2 years
3	Postgraduate student	1-2 years
4	Specialty trainee	3-4 years
5	Specialty trainee	3-4 years
6	Consultant	3-4 years
7	Consultant	1-2 years
8	Specialty dentist	1-2 years
9	Specialty dentist	5 years or more
10	Foundation dentist	Less than one year

Table 4.1: Participants role and EPR experience.

In the first cycle problems with the order of data entry, and the radiograph report boxes were identified by all participants. These issues were brought to the software expert who made appropriate changes. Further adjustments were made to data entry order and navigation after cycle 2.

Table 4.2 presents an example of how the codes, subcategories and categories were derived from the data.

Meaning unit	Code	Subcategory	Category
“it’s asking about infection related resorption so I’m going to click no in this case but again if I were to click yes again there’s no box for me to write down which teeth or what teeth and then presence of sinus”	Limited response options – need for ability to provide additional information.	Need to add more information.	**EFFECTIVENESS**
“But I like that these are free text so you can kind of record what you want to in them based on what you like to do as long as it’s clear for everyone else”	Free text provides flexibility in information.	Ability to add extra information.	
“Actually you’ve got radiographic report there so you could put loss of PDL space there. And then you can do the rest of your report, quite easily there”.	Radiograph report box means you can add extra details.		

Table 4.2: Example of coding

Figure 4.3 presents the subcategories and categories that emerged from the content analysis. The number of codes associated with each is presented in brackets (n=). The main identified categories were effectiveness, navigation and structure, and integration in professional role. Other categories that emerged from the analysis included perceived usefulness and efficiency. The most frequent codes were related to subcategories such as ability to add information and clarity of what is required. These were included in the ‘effectiveness’ category. Other frequent codes were linked to navigation, order, and sequence – how the clinicians found their way around the page and in what order they wanted to record the required information. These are described in more detail below, alongside supporting statements.

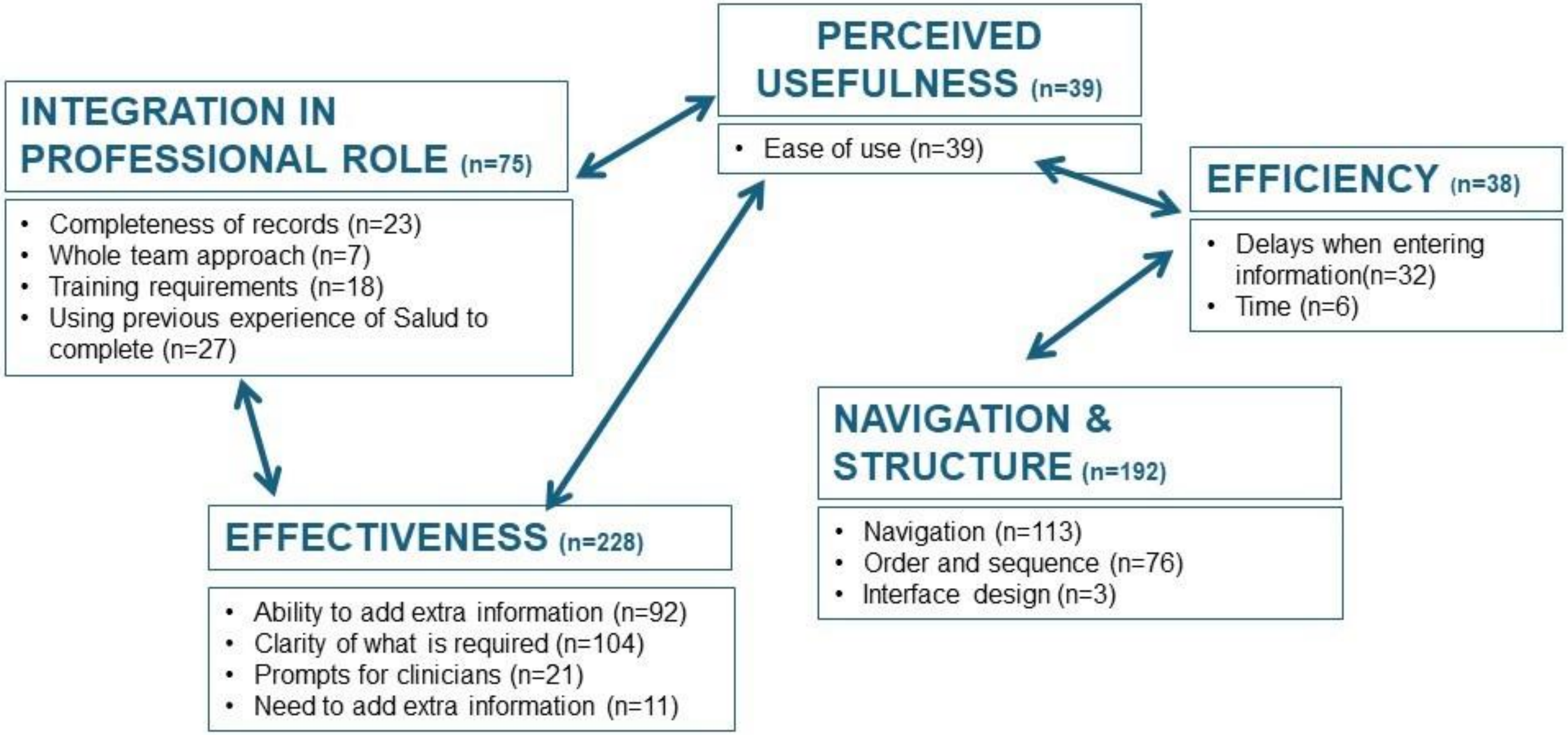

Figure 4.3: Subcategories and categories from content analysis and how they are linked. (n= number of codes)

Navigation and structure

The navigation and structure category included order and sequence, interface design and navigation subcategories.

Navigation

Blue banners (used to define differing sections in the page) were noted to be useful as visual indicators for navigating the page and so these were used to signpost the patient outcomes sections - pain and quality of life.

> *"We're moving on now to the next blue box which is basically telling me that we're moving on from headings, so the previous one was history of injury, and this one now is nature of dental injury". (P1)*

***Order and sequence*.**

In cycle 1 problems with where the patient-reported outcome measures should be situated were identified (order and sequence) as were difficulties with radiograph report (need to add extra information)

> *"If you are going through an actual consultation, you get your history and everything and then if you do your examination and then you go back to so how much is this tooth bothering you, well actually maybe that could have been done at the beginning" (P1)*

This improved in the second and third cycles:

> *"You can actually see how starting with this stuff would be helpful in terms of the appointment cos you're asking all the questions to the patient first" (P5)*

Effectiveness

The effectiveness category is defined as a 'usability' metric within user testing. It included ability to add extra information, need to add extra information, clarity of what is required and prompts for clinician subcategories.

Need and ability to add extra information.

There were many codes in this subcategory: it was important to clinicians to be able to record sufficient clinical information and at various points in the page it was noted that a ‘dropdown’ box or extra box would be useful so that additional information could be recorded.

> *“Again, I wonder if there needs to be, I wonder if it would be helpful to have a dropdown box about that because we don’t know if it’s because they’re uncomfortable or if it’s because they don’t look right.” (P7)*

Clarity of what is required.

Clinicians required further clarification about what information was required in the radiograph report sections and the quality-of-life questions in particular,

> *“Does somebody know what the difference is between root growth and root maturation, should there be a little information box about that, what are you wanting”. (P7)*

Prompts for clinicians.

Several participants noted that the presence of the MDS-TDI outcomes prompted them to record the outcome using the appropriate outcome measurement instrument:

> *“Bone loss again it’s asking me to do it in mm’s” (P5)*

It was identified by some participants that the dataset acts as a prompt and ensures all necessary information is considered and all steps are completed:

> *“And from what I can see there we can’t see any infection related resorption, that’s quite handy. So you’ve got all the sort of things to prompt you about there. “(P9)*

The integration in professional role, efficiency and perceived usefulness categories were less frequently coded, but did identify some important issues as described below.

Integration in professional role

Completeness of records

Using the MDS-TDI engendered confidence that all relevant and pertinent information would be recorded and acted as a prompt for clinicians.

"I like it I like that it's quite thorough because I think, think filling this in I'll feel confident that I've covered everything that I need to, and I've covered everything that's really important." (P1)

However, one participant expressed concern that the MDS-TDI outcomes alone are not sufficient for completeness of clinical records:

"Yeah, I agree and so that will be fine it gives you your audit stuff but at the moment just the audit stuff isn't enough for our records" (P7)

It also encouraged reflection on practice.

"Yeah, because it's a fairly quick question and having that included makes me reflect and feel like I don't necessarily quantify what their pain is enough" (P1)

Whole team approach

There were relatively few codes in this subcategory (n=7), but it was identified by some participants that the dental assistant may require training so that they could input the required outcomes:

"you'd have to probably almost work with like your nurse and your assistants and like train them so you can do it as efficiently as possible" (P10)

Efficiency

Codes relating to delays when clicking or saving were identified across all three cycles.

"So sometimes after you've clicked a box it takes a while for you to be able to type in the box. So, I've just clicked on that, and it's probably taken about 3 seconds to allow me to type in the box." (P6)

These delays were related to the system itself and so it was not possible to make changes to mitigate this. The **efficiency** category was represented in the interview analysis also. Participants spoke of the time required to input the data but that this was due to system delays and not the MDS-TDI itself:

> *“The ermm trauma assessment box can take quite a long time to complete...eh I think that’s probably a Salud issue.” (P6)*

Participants did not feel it added significantly to time taken to enter the data:

> *“I found it overall very easy, and it really compared to the usual trauma appointment Salud set-up, it took very little additional time” (P4)*

In cycle 3, a participant identified that due to the prompts and the order the dataset outcomes are presented in, that it may save time for the clinician.

> *“Yeah, I think actually it doesn’t I don’t think it would add much time or much more time because we’re asking these questions anyway, actually saves time because it’s there, you can quickly, quickly populate something like this, rather than going through a massive, back and forth” (P9)*

Some other issues with the dental trauma page not related to the MDS-TDI were also noted - location of diagnosis box (too ‘early’ in the page) and no box to add in discussions with parents and child. Changes were made to improve overall satisfaction and user workflow.

In cycle 3 both participants, who had limited experience in dental trauma management, felt that the new pages were ready to go live in the system. These findings were discussed with the research team and the software developer, and it was decided that no further testing would be undertaken and that the updated pages were ready to be uploaded to the live version of the EPR.

4.4 Discussion

User testing was employed successfully with dentists to integrate a minimum dataset for TDI into an existing electronic patient record. Ten dentists participated, and categories such as effectiveness, navigation and structure and integration in professional role were identified following analysis of think aloud scripts and semi-structured interviews.

Data from EPR have the potential to be used in research to produce ‘real-world’ evidence. This, in turn, can help accelerate advances in care, improve outcomes for patients, and provide important insights for daily practice (30). This potential is limited by data quality concerns. It is generally accepted that, given differences in priorities between clinical practice and research, clinical data are not recorded with the same care as research data (30). Use of a minimum dataset can mitigate this by defining what key outcomes should be recorded and, importantly what outcome measurement instrument should be used to do this. The need to improve user interface in EPR has been identified as a concern in the literature, as has the need to streamline workflow integration (16, 19,30,32).

There is no guidance in the literature for integrating MDS into existing EPRs. Therefore, we had to adapt user testing methods to facilitate this and employed a pragmatic approach. The EPR system we were working with was already ‘live’. Hence, there were limitations to the changes that could be made. We aimed to ensure that recording of the MDS-TDI outcomes of importance to both patients and clinicians, would be relatively easy, efficient, and acceptable to clinicians.

Think aloud is a method that requires participants to talk aloud while solving a problem or performing a task (33). It offers a unique source of information on cognitive processes through generating direct data on the ongoing thought processes during task performance (33). The sequential interview gave the participants the opportunity to express their opinions about the changes to the EPR and whether they were appropriate and acceptable to them. This was conducted immediately after the user testing, to minimise disruption during the task and to make it easier to recall the reasons for their actions. The questions were devised to examine issues related to usability of the site and the value of the MDS-TDI. We chose this approach as it has been identified in the literature that a multi-method approach is preferable as it provides a comprehensive picture of usability challenges (19,20).

4.4.1 Study Limitations

Only ten dentists participated in this study, although across arrange of experiences. There has been considerable debate about the appropriate sample size for user testing (22,34-36). The decision needs to be based on the careful consideration of several factors, namely (i) iterative nature of user testing, (ii) homogeneity of target end users, (iii) complexity of the system and (iv) type of user testing (36). There is precedence in the literature for undertaking user testing with small groups (37). The identification and selection of a representative sample of end-users has been identified in the literature as crucial for generating valid usability data in a think aloud test (18,25). All participants were representative of the eventual end-users of the dataset. Task cases should be realistic and representative of daily life situations and those that end users are expected to perform while using the system (18), therefore robust simulated cases were used for the data entry tasks.

The main interviewer KK was known to the clinical group and could have introduced reporting bias. However, her familiarity with the system aided a thorough capture of feedback.

The EPR system used in this study is only used in academic settings. This limits the generalisability of changes made. However, the technique used could be replicated to ensure optimal integration of the MDS-TDI in other EPR and in other clinical settings.

Finally, we did not use objective measurements of usability when undertaking testing. There is a lack of consensus in the literature on which methods to use when evaluating usability, and there is little guidance on the measurement of usability metrics as applied to assessment of EPR systems used by clinicians (39). Time to task completion is one easily measured metric and so it may have been useful to formally measure the time taken to complete each task. However, we wanted participants to take the opportunity to describe their thoughts in detail and using a timer may have been inhibiting. Consideration was made to using an appropriate questionnaire, such as the System Usability Scale (39,40), but it was felt that as the system was already live and the changes we could make were limited, it was not likely to add significant value and would increase the burden for participants.

4.5 Conclusions

To the best of our knowledge, this is the first application of user testing methods to integrate an MDS into an existing EPR. As minimum datasets become more widely used across dentistry, further work is required to develop robust methodology and evaluation of user testing to integrate them into existing EPRs.

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Chapter 5 Feasibility test of the minimum dataset for traumatic dental injuries

A theory-guided feasibility study of using a minimum dataset to improve routine recording of traumatic dental injuries.

Will be submitted to the International Journal of Endodontics.

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Abstract

Background Traumatic Dental Injuries (TDI) are common and can have a considerable impact on oral health-related quality of life. Poor epidemiological data and limited recording of diagnostic and treatment codes in general dental practice make it challenging to quantify the impact and burden of TDI to children, their families and healthcare services. This study evaluated the feasibility and acceptability to dentists of a newly developed minimum dataset for traumatic dental injuries (MDS-TDI).

Methods Single site feasibility study undertaken in a teaching hospital in Leeds, UK. All dentist participants used the MDS-TDI during clinical sessions for a period of three months. Following this, dentists were invited to participate in a focus group to explore satisfaction, intention to continue use and perceived appropriateness. Data collection processes and acceptability of outcome measures were assessed by reviewing data completeness. Framework analysis was used to analyse the focus group transcript, with coding informed by Normalisation Process Theory (NPT).

Results Data from 95 patient appointments were used in the analysis. Patient-reported outcome measures had high completion rates at all time points in the study, regardless of staff level. Some of the outcomes had lower completion rates, especially the periodontal healing outcomes of gingival recession, bone loss, and tooth mobility, with overall percentage completion rates of 59%, 55% and 70% respectively. Nine dentists participated in the focus group. Clinicians understood and valued the MDS-TDI but identified some challenges in the integration of the MDS-TDI in their daily practice.

Conclusions Recording many of the clinician and patient outcomes for the MDS-TDI is feasible and acceptable to dentists working in a tertiary referral centre. Further work is required to explore what is feasible to record in primary care.

5.1 Background

Traumatic Dental Injuries (TDI) are common with a global prevalence of 15.2% in the permanent dentition and a global incidence rate (i.e. new cases) of 2.75% per year in the permanent dentition (1). Appropriate diagnosis, timely immediate management and regular follow-up are essential to achieve favourable outcomes (2,3,4).

Children with TDI experience negative social judgments, bullying and teasing by their peers about their appearance (5,6). Further studies have shown that TDI has a considerable impact on oral health related quality of life, comparable to impacts reported by children with cleft lip and palate (7). Evidence based guidance for management of TDI is freely available (2,3,4).

Owing to sparse epidemiological data and limited recording of diagnostic and treatment codes in general dental practice, it is currently difficult to estimate the number of children attending general dental practice in the UK with TDI. Thus, it is challenging to quantify the impact and burden of TDI to NHS dental care. Appropriate and accurate recording of treatment for TDI will allow collection of data that has hitherto been challenging. Only then will it be possible to determine the impact of TDI correctly and robustly on patients and the NHS in the UK, whether clinicians are adhering to the evidence-based guidance, and the success or otherwise of treatment interventions.

A minimum dataset has been described as a recommendation for a standardised minimum set of metrics to be collected, along with the method of collection (8). Minimum datasets are currently not used in routine dental practice. A minimum dataset may not initially be thought of as a complex intervention. However, in considering the Medical Research Council (MRC) definitiona complex intervention is "*any deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care or some other formal organisational settin*g" (9), it could indeed be described as such. It will require a considerable change in how clinicians record clinical findings in patients that are treated for TDI. Hitherto, they are likely to have used 'free text' boxes when recording clinical outcomes, with little or no guidance on which outcomes to record or how to record them. We have developed an MDS-TDI **(Figure 5.1**) (10).

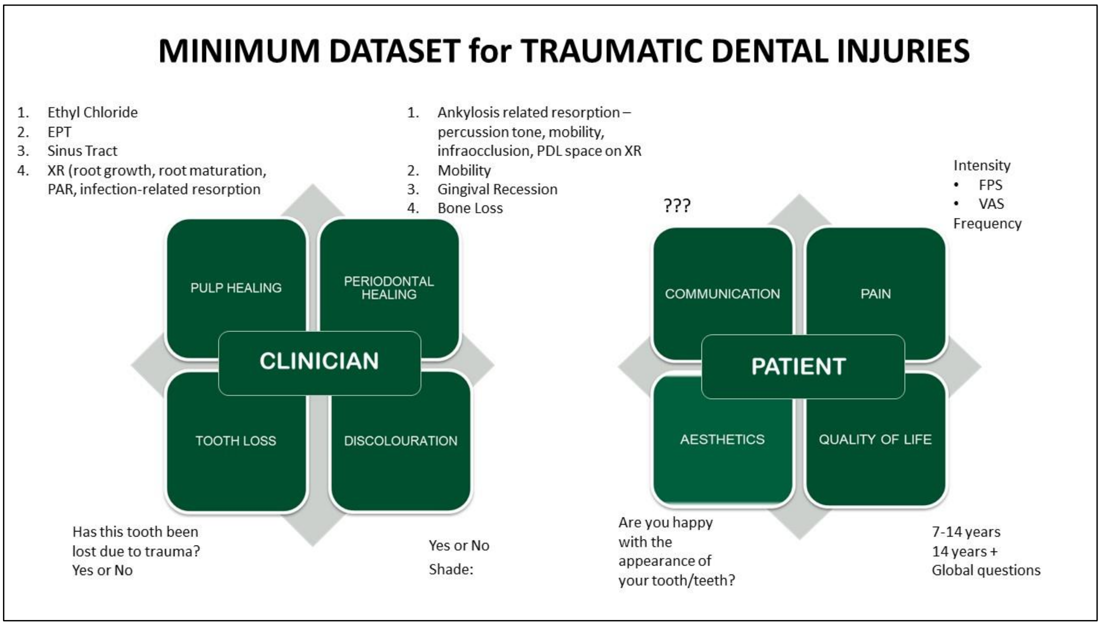

Figure 5.1: Minimum Dataset for Traumatic Dental Injuries – outcomes and outcome measurement instrument. *EPT – electric pulp test; XR – radiograph; PAR – periapical radiolucency; FPS – Facial Pain Scale; VAS- visual analogue scale*

The development of the MDS-TDI was underpinned by Normalisation Process Theory (NPT) in line with MRC guidance for complex intervention development. We chose NPT because it has a strong focus on implementation. It has been described as a sociological behavioural theory that describes how likely it is that new practices will be successfully adopted (11). It aims to theorise how the process of innovations, in this case, the MDS-TDI, become routine in everyday work and are thus normalised. NPT focuses on social actions and interactions. These actions are operationalised through four constructs: coherence, cognitive participation, collective action, and reflexive monitoring (**Table 5.1**). Various authors have described these constructs as ‘making sense of it’, ‘working out participation’, ‘doing it’ and ‘reflecting on it’ (12,13).

An important component of intervention development is feasibility testing. Feasibility can be defined as the extent to which a tool or intervention can be applied to the practice it was designed for (14). Therefore, this study aimed to evaluate the feasibility and acceptability of the MDS-TDI to dentists.

Coherence: How do people individually and collectively make sense of the MDS-TDI?	**Cognitive participation** How do people engage to ensure the MDS-TDI can be used?
• Differentiation • Communal specification • Individual specification • Internalisation	• Initiation • Enrolment • Legitimation • Activation
Collective action How do people integrate the MDS-TDI into their daily working practice?	**Reflexive monitoring** How do people individually and collectively appraise the use of the MDS-TDI?
• Interactional workability • Relational integration • Skill set workability • Contextual integration	• Systematisation • Communal appraisal • Individual appraisal • Reconfiguration

Table 5.1: Description of Normalisation Process Theory mechanisms and subconstructs

5.2 Methods

5.2.1 Study Design

This is a single-site feasibility study to investigate the feasibility and acceptability of an MDS-TDI to improve outcome measurement during treatment for TDI.

5.2.2 Setting

The study site is a teaching hospital in Leeds, UK. The Leeds Dental Institute (LDI) is part of the Leeds Teaching Hospitals Trust (LTHT) and works in close partnership with the University of Leeds. Undergraduate and postgraduate education is provided, including training for speciality trainees in paediatric dentistry. The LDI is a tertiary referral centre, and as such receives referrals from across North and West and Yorkshire with a total population of just under 3.2 million people (15). Children and young people are referred for assessment and specialist management of TDI with a dedicated dental trauma clinic taking place biweekly.

5.2.3 Participants

Any dentist providing treatment at the dental trauma clinic at LDI was eligible. Dental trauma clinic is a consultant-led clinic. Treatment is undertaken by specialty dentists (general dentists with special interest in paediatric dentistry) and specialty trainees (both postgraduate and NHS trainees in paediatric dentistry).

5.2.4 Intervention

The MDS-TDI was developed using evidence-based best practice. End-users, both clinicians and patients, were engaged throughout the dataset development (10). The dataset comprises four patient and four clinician outcomes that should be measured at routine clinical appointments (Figure 1). The appropriate outcome measurement instrument has also been included. User testing with the Think Aloud approach was undertaken to incorporate the dataset into the electronic patient record (EPR) already in use in the LDI. (16). The intervention is described in line with the TIDieR

(Template for Intervention Description and Replication) checklist (**Appendix Table d.1)** (17).

5.2.5 Training

The MDS-TDI was introduced by the lead author (KK) at a monthly Departmental meeting, following permission from the Head of Department and Clinical Lead. Face to face training was undertaken and led by KK and included a presentation, video demonstration and opportunity for questions. A link to the training video was sent to every dentist in the department for them to view and review as often as required.

5.2.6 Data Collection

All dentist participants used the MDS-TDI during clinical sessions for a period of three months. The dentists were reassured that the feasibility test was not a test of them or their clinical or writing skills. The lead author (KK) was present for every dental trauma clinic for the first four weeks. She observed, took notes and was available to answer any questions the dentists had. She used this information to create a short report, called a Lightning Report (18) at the end of each week. Data were collected between June 2022 and September 2022. Patients were given an age-appropriate questionnaire to complete in the waiting room, in advance of their appointment (**Appendix Figure d.1**). The questionnaire included questions about pain, quality of life and aesthetics (the patient outcomes, see **Figure 5.1**). The questionnaire was given to the dentist at the start of the appointment and used as a prompt for the dentist to input the answers directly in the EPR. The clinician outcomes were recorded and inputted during and after the patient examination. A retrospective case note review was undertaken to identify the key feasibility outcome of data completeness. The electronic patient records of each patient who attended the trauma clinic in the study period were accessed and relevant data recorded in an Excel spreadsheet.

Following the three-month period of MDS-TDI use, dentists were invited to participate in a semi-structured interview or a focus group to explore their thoughts on the dataset use: satisfaction, intention to continue use and perceived appropriateness of the intervention. The focus group took place in a quiet room in the School of Dentistry and was led by an independent experienced facilitator (JO). The focus group was audio recorded. A topic guide (**Appendix Figure d.2**), informed by the components of NPT was used to guide the conversation.

5.2.7 Data Analysis

Data collection processes and acceptability of outcome measures were assessed by reviewing data completeness. This was calculated and presented as percentage proportions including:

- How many outcomes have been completed out of possible eligible completions?
    - To indicate overall uptake and implementation
- Variation in time over use
    - To aid identification of learning effects and assess sustainability.
- Variation in use by clinic or clinician
    - To guide the targeting of implementation strategies at lower completing clinics or clinicians.

The focus group recording was transcribed verbatim. The participants were assigned identification numbers to ensure confidentiality. Framework analysis was used to analyse the focus group transcript, with the four NPT mechanisms and their subconstructs forming the framework. The NPT coding manual (19) was used to inform the initial coding. The manual aims to facilitate transparency in data analysis processes and to simplify the theory for users (19). First, the focus group transcript was independently coded by KK, JO, and EM. This initial coding was deductive and based on the coding manual. Interpretations of the coding framework, and of the data were discussed until agreement was reached. NVivo software (*QSR*

International, V.14) was used to facilitate management of the data. Once initial analysis was completed, all authors reviewed and discussed the coding in a team meeting before coming to agreement on the final interpretations (20). Participants were not invited to comment on findings. The themes that emerged from the data were mapped to Normalisation Process Theory.

5.2.8 Ethical Approval

The Leeds Teaching Hospitals Trusts Research Governance team assessed the application as a quality improvement project; therefore NHS ethical approvals were not required. Ethical approval for the study was thus obtained from the Dental Research Ethics Committee at the School of Dentistry, University of Leeds (Ref. No: 010223/KK/365). The MDS-TDI was added to the existing EPR in LDI. The Clinical Director and the Department Clinical Lead gave consent for the MDS-TDI to be used in every dental trauma clinic.

Individual, written informed consent was obtained for participation in the focus group. Participants were informed of their right to withdraw at any stage without consequence.

5.3 Results

5.3.1 Number of patient appointments

There were 27 dental trauma clinics during the study period, with a total of 215 patient appointments. Of these, 41 appointments were for general emergency (non-trauma) patients, 31 were for children under the age of 7 years and therefore were too young for the MDS-TDI data collection. Nine appointments were for follow-up after auto-transplantation procedure. The incorrect form was used (general follow-up and not trauma-specific follow-up) 39 times. Therefore, data from 95 patient appointments were used in the analysis.

5.3.2 Lightning Reports

Four lightning reports were produced. Initial problems with distribution of the patient questionnaires and recording of the pain scales were identified.

5.3.3 Data completeness

Table 5.2 presents the data completeness figures by month and overall. **Table 5.3** presents the data completeness by staff level. Patient-reported outcome measures had high completion rates at all time points in the study, regardless of staff level. Pain and aesthetics were recorded over 90% of the time, with quality of life recorded 88% of the time. The trainees and specialty dentists had particularly high completion rates for recording pain, 97% and 100% respectively. Some of the clinician outcomes had lower completion rates, especially the periodontal healing outcomes of gingival recession, bone loss, and tooth mobility, with overall percentage completion rates of 59%, 55% and 70% respectively. Discolouration was recorded less frequently, at all stages and irrespective of staff level. The scores were low due to recording of discolouration as present or absent (yes/no), rather than the specific shade of the tooth being recorded. The pulp healing and the tooth loss outcomes were well recorded, with over 85% completion at each stage and by different staff throughout the study.

Outcome	Month 1				Month 2				Month 3				Overall			
	Y	N	n/a	%	Y	N	n/a	%	Y	N	n/a	%	Y	N	n/a	%
Patient-important																
Aesthetics	29	3	0	91	31	1	0	97	25	3	0	89	85	7	0	92
Pain	31	1	0	97	29	3	0	91	27	1	0	96	87	8	0	95
Quality of Life	31	1	0	97	28	4	0	86	22	6	0	79	81	11	0	88
Clinician-important																
Pulp healing																
Ethyl chloride	20	2	10	91	20	1	11	95	24	2	2	92	64	5	23	93
Electric pulp test	18	4	10	82	19	2	11	95	21	5	2	81	58	11	23	84
Presence of sinus tract	31	1	0	97	31	1	0	97	27	1	0	96	89	3	0	97
Radiograph findings	25	0	7	100	24	1	7	96	23	1	4	96	72	2	18	97
Periodontal healing																
Gingival recession	16	16	0	50	19	13	0	59	19	9	0	68	54	38	0	59
Bone loss	15	17	0	47	18	14	0	56	18	10	0	64	51	54	0	55
Ankylosis-related replacement resorption	24	2	6	92	23	2	7	92	23	1	4	96	70	5	17	93
Mobility	22	10	0	69	18	14	0	56	24	4	0	86	64	28	0	70
Tooth loss	32	0	0	100	31	1	0	97	28	0	0	100	91	1	0	99
Discolouration	19	13	0	59	17	15	0	53	18	10	0	64	54	38	0	58

Table 5.2 Percentage completeness of outcomes over time.

Outcome	**Specialty dentist (n=15)**				**Specialist trainee (n=63)**				**Consultant (n=7)**			
	Y	N	n/a	%	Y	N	n/a	%	Y	N	n/a	%
Patient-important												
Aesthetics	14	1	0	93	59	4	0	94	5	2	0	71
Pain	15	0	0	100	60	3	0	97	5	2	0	71
Quality of Life	14	1	0	93	55	8	0	87	6	1	0	86
Clinician-important												
Pulp healing												
Ethyl chloride	9	0	6	100	44	4	15	92	6	1	0	86
Electric pulp test	9	0	6	100	38	10	15	79	6	1	0	86
Presence of sinus tract	13	2	0	87	62	1	0	98	7	0	0	100
Radiograph findings	15	0	0	100	49	2	12	96	7	0	0	100
Periodontal healing												
Gingival recession	5	10	0	33	39	34	0	62	5	2	0	71
Bone loss	3	12	0	20	38	35	0	60	5	2	0	71
Ankylosis-related replacement resorption	12	0	3	100	47	4	12	94	6	0	1	100
Mobility	9	6	0	60	43	20	0	68	7	0	0	100
Tooth loss	15	0	0	100	62	1	0	98	7	0	0	100
Discolouration	7	8	0	47	38	25	0	60	5	2	0	71

Table 5.3: Percentage completeness of outcomes by staff level.

5.3.4 Focus group.

Nine dentists participated in the focus group (**Table 5.4**). The focus group took place 16 weeks after the introduction of the MDS-TDI and took 62 minutes.

Participant Number	Staff Level
01	Specialty dentist
02	ST2
03	ST2
04	ST1
05	ST1
06	DCT
07	ST3
08	Specialty dentist
09	ST3

Table 5.4: Focus group participants. *ST: specialty trainee, 1/2/3 indicates year of training. DCT: dental core trainee*

NPT and Subcategories:

Table 5.5 presents the main findings based on the NPT coding manual. Described below are how each of the subcategories of the implementation mechanism construct were applied to the focus group material:

Coherence deals with how people collectively and individually make sense of using the MDS-TDI. For the subconstruct of differentiation – how participants distinguish their use of the MDS-TDI from their previous way of working - several identified that using the MDS-TDI supported a more standardised examination of the patient.

> *"It just means that we're providing a more comprehensive standardised exam" (P2)*

> *"It kind of provides specific aspects of data, so that it's been standardised" (P3)*

It was also noted that the examination now had a more holistic and patient centred approach.

> *"And it's more like patient related outcomes as opposed to measurable clinical outcomes as well and the impact that that has on the patient's quality of life as a whole" (P1)*

Overall, both individual and shared understanding of the aims and objectives of the MDS-TDI (communal and individual specification) were positive.

> *"It might make it easier to compare whether there are changes and quite often we will see patients over a long period of time" (P3)*

> *"So, I'm not influenced by biases depending on, maybe you know specific injuries which we know have certain sequelae" (P2)*

This explicit understanding of the use of the dataset appears to have contributed to the internalisation or 'sense' making' of the MDS-TDI for participants. Again, several participants identified that it provided a framework for examination, allowed objective recording of outcomes, and helped trainees whilst also being patient centred.

> *"I think quite an important role it plays is when you've got different clinicians seeing the same patient each time,. it's just really clear to see what's been done in the last appointment" (P2)*

> *"I suppose it's a bit more objective, isn't it, in terms of looking at the patient as a whole rather than actually the traumatic injury, the diagnosis and your treatment that you provided" (P3).*

Cognitive participation explores how people engage to ensure the MDS-TDI is used. The first sub-construct here is initiation, which deals with roles that leadership or key stakeholders take on. For context, the permission to allow the use of the MDS-TDI in the dental trauma clinics was granted by the Clinical Director of the LDI and by the Department of Paediatric Dentistry clinical lead. This wasn't discussed in the focus group. Availability and support of the research team were considered positive, but there was no discussion about the training that was provided. Despite this there was clear support for the MDS-TDI – most participants believed the MDS-TDI is ‘right’ and should be part of their work. This is part of the legitimation subconstruct.

> *“I think it’s a very good idea actually and encourages lots of good things.” (P7)*
>
> *“Focuses on the holistic care rather than just focusing on the injury which is a really important part of the Leeds way” (P8)*
>
> *“For quality improvement...it helps and that’s sort of one of our big promises in the Trust” (P1)*

Despite this strong belief that the dataset should be part of their work, the participants identified several problems when using the MDS-TDI in their regular practice. These problems could be mapped to the activation subconstruct and as such are potential barriers to their support of the ongoing use of the MDS-TDI.

> *“I suppose it just it doesn't’ allow for the fact that there might be potentially multiple injuries” (P8)*
>
> *“if you’re seeing somebody who’s an absolute fresh trauma, who’s maybe coming with a massive luxation injuries and the teeth are really high up.... I think it would be just best to ask some of those questions next time”. (P7)*

Collective action is concerned with how people integrate the MDS-TDI into their everyday work. Interactional workability addresses how participants use MDS-TDI in their everyday work, including how they interact with the tools and systems required for its use. Participants found that recording of the specific outcomes acted as a prompt:

> *“I think also the prompts that you get, especially in the new patient appointment as trauma is so specific on all the details...and it’s really good at recording all of those details” (P2)*

Some concerns were raised about the quality-of-life questions and the potential for language barriers, or challenges in understanding what are perceived as nuanced questions.

> *"So, there was one about like pain, quality of life or something and then something else, quality of life and parents, patients might be confused with what's the difference between that and that?" (P4)*

Skill-set workability was fulfilled in that the participants felt it was appropriate that they record and input the outcomes. There was some discussion about whose role it was to give the patient outcomes questionnaire to the patients as they arrive: whether it should be the administrative or the nursing staff.

Some problems with the EPR, in which the MDS-TDI is integrated were identified, particularly with the speed of the system. Concerns were also raised about the use of paper forms for recording the patient-important outcomes. These issues can be mapped to the contextual integration subconstruct.

> *"Although we want to do all these things actually when it comes to filling it in, it's really really slow, but I think because it's so slow that can be quite frustrating and potentially could affect the thought going into it and potentially the outcomes of it" (P5)*

> *"With all the sustainability stuff, just whether it would be better with an iPad or I don't know if we've got the resources to offer people iPads to do that while they're in the waiting room" (P8)*

Reflexive monitoring how people individually and collectively appraised using the MDS-TDI is considered in the section on reflexive monitoring. The participants had not yet had any feedback or reports on the data collected during the study period, so it is unsurprising that the systematisation subconstruct was not explored in the focus group, nor was there any discussion about how they had changed their own work in response to their appraisal of using the MDS-TDI. Despite the lack of feedback, both individual and communal appraisal were predominantly positive,

> *“We can compare things, just kind of what works in our hands and doesn't in terms of like if we’ve decided to monitor or decided to do a specific treatment like we’ve repositioned it. It actually makes it a lot easier to reflect on” P4*

Participants could envision the data being useful in terms of fulfilling their medico-legal requirement, helping with decision making, and ensuring patient-focused consultations:

> *“You know so that triggered the discussion that later on when I saw her that oh well yeah she's not happy with that and I fully understand but in the previous notes it was just like, yeah, she completely loves that the tooth looks like that and sort of thinks it’s cool but now she’s really not happy. So, it made sure it was more patient focused.” P7*

NPT Construct	Coding Summary	Supporting Evidence
Coherence		
Differentiation How do participants distinguish their use of MDS-TDI from their previous way of working?	MDS-TDI supports a more standardised examination, with a more holistic and patient centred approach.	*"Well, this particular one, we were not perhaps as good at recording quality of life stuff, so I think yeah, this is much better for that" P8*
Communal specification How do participants collectively achieve a shared understanding of the use of MDS-TDI?	The standardised examination and recording ensure that key information is easily accessible when reviewing clinical notes, even if the patient has been treated by different clinicians. This can help with treatment planning, the development of trainees and students and allows comparison and analysis of outcomes over time.	*"It can mean that the relevant points in terms of treatment planning are very, you know where to go to look for them and they are going to be there so it could help potentially with treatment planning also making it easier for them to help to develop trainees or students because they've got that kind of template to support that learning there." P7*
Individual specification How do participants individually understand the use of MDS-TDI?	Recording specific outcomes that wouldn't usually be recorded, helps avoid bias when treating specific injuries.	*"Some of the clinical outcomes are quite specific, so things like gingival recession, bone loss. Previously I might not have recorded these unless it was really relevant to the traumatic injury" P3*
Internalisation	It supports objective recording of outcomes, helps trainees, is patient centred and gives patients a voice.	*"I think it can help give the patients a bit more of a voice as well, because we give them their leaflets in the waiting areas, and ask how they feel about their teeth and their appearance and they can*

Does the use of MDS-TDI make sense for the people involved?		*then, and I find asking them face to face and what they actually write on the forms sometimes can be a little bit different, and it can help that to open up a conversation" P5*
Cognitive participation		
Legitimation How do participants come to believe that the MDS-TDI is right and should be part of their work?	Using MDS-TDI supports the 'Leeds way' which is about focusing on holistic care and the patient journey. It also supports the Trust's quality improvement programme by enabling audit and evaluation of clinical practice.	*"For quality improvement again, it sort of it helps and that's sort of one of our big promises in the Trust. So I think yeah, it will definitely like help that process become much more streamlined and efficient so that you can audit and ehm evaluate the way we're doing things and introduce changes and upgrades" P1*
Collective action		
Skill-set workability Is the work involved in using the MDS-TDI allocated appropriately to those involved?	Clinicians are happy to record the outcomes. There was some discussion about who should distribute the patient questionnaires – nurses or reception staff.	*"I think there's a bit of lack of clarity about who's supposed to have it, but I don't know where it's kept but my understanding was that they were giving it at reception to fill out whilst waiting" p3*
Contextual integration Are resources made available for implementing the use of the MDS-TDI?	Problems with the existing EPR – slow and therefore time consuming to complete. Concerns re sustainability (important in Trust) about using paper forms.	*But the only barrier I suppose has been time to fill it out, which isn't that I wouldn't want to do it. Just making sure the Salud works well" (P8)*

Reflexive monitoring		
Communal appraisal How do participants evaluate the impact of using the MDS-TDI?	Allows comparison of treatments over time, to see what works and what doesn't. Contributes to patient safety by ensuring that all necessary information is recorded appropriately.	*"I think like the long-term benefit is, it's always the patient in that it improves patient safety. It's eliminating human factors; it's eliminating the risk of missing something so overall the standard of care is better" (P4)*
Individual appraisal What further benefits/uses of the MDS-TDI can participants envision?	Structured examination, medico-legal requirements, patient focused consultations, help with decision making.	*"I just feel like if I follow that structure that I feel I'm going to cover everything that I think that's really relevant even if that's like medicolegally or just kind or predictions of success" P3*

Table 5.5 – **Main findings of framework analysis using NPT**

5.4 Discussion

This study has demonstrated the feasibility of using the MDS-TDI to record outcomes in a teaching hospital setting. There were high levels of data completeness for patient outcomes such as pain, aesthetics, and quality of life, and clinical outcomes such as tooth loss, pulp, and pulp healing over a three-month period. Data completeness appeared stable over time. Clinicians understood and valued the MDS-TDI (coherence) but identified challenges in integrating the MDS-TDI within their daily practice (collective action).

The high completion rates for many of the MDS-TDI outcomes, both clinical and patient-reported, are encouraging. However, even in this tertiary care setting, several outcomes were less well recorded. These included gingival recession, bone loss, mobility, and discolouration. The reasons for this are unclear and were not explored in the focus group. Possible explanations include the nature of the user interface for the EPR used in this centre, clinicians not understanding the reason for recording such outcomes for patients, or a lack of awareness that negative findings are important, even if they are rare. Moreover, these outcomes may present at a later point in follow-up or become more relevant in adulthood. Coherence or ‘sense making’ has been identified as an important facilitator to implementation in other studies (21).

The feasibility of implementing minimum datasets in nursing, neurology, psychotherapy, and dementia care has been explored (22,23,24,25,26). These studies used a variety of implementation interventions to promote adoption of MDS’s (e.g. education, audit, and feedback). However, in this study, by virtue of using the NPT framework to plan the project, the aim was to make the MDS-TDI usable in practice, following relatively brief training, without the need for a resource-intensive implementation strategy. This was undertaken by considering NPT in MDS-TDI development and integrating the MDS-TDI within the EPR guided by clinician engagement and user-centred design principles (10,16). This did not however, mitigate some of the underlying issues with the EPR, notably data entry hindered by slow system speeds during peak periods and an autosave feature delaying clinician completion of records.

This study is novel in evaluating the feasibility of a minimum dataset in dentistry. Guidance on developing complex interventions suggests the value of progressive refinements prior to full scale implementation and evaluation (27). Even in a specialist setting, where clinicians regularly assess and manage TDI, there was relatively low completion rates of some of the outcomes. Further work is needed to determine what is feasible to record in the primary care setting. It may be that, for the purposes of audit, quality improvement and exploration of the costs associated with TDI management, it is sufficient to know whether there are pulp complications (yes/no/uncertain) and/or periodontal complications (yes/no/uncertain). The level of detail that has been prescribed by the MDS-TDI may be unnecessary. Additional work is also required to determine how to manage and use the data once it has been collected by the clinician. In this study, measuring data completeness was a manual process as there was no functionality in the EPR to do this automatically. This is not sustainable. It will also be helpful to identify what information clinicians would value in the reports as this may influence their motivation to continue to record the MDS-TDI outcomes in the longer term.

The overarching aim of the MDS-TDI project was always to improve data collection for TDI management from routine clinical appointments in dental primary care. Implementation of any type of change in primary care is challenging and it may require an implementation strategy tailored to barriers and needs (28). The use of NPT has identified that building coherence is paramount - understanding the meaningfulness and recognising advantages for the individual and the team. Therefore, educational strategies, audit, and feedback and incentivisation are potential strategies that could be used as the MDS-TDI is implemented across dental primary care.

5.4.1 Limitations

A pragmatic decision was made to run the feasibility test in a specialist setting. If the MDS-TDI had poor uptake in such a setting, successful implementation in primary care would be unlikely. Undertaking the feasibility test in this specialist setting has identified several issues which can be addressed prior to implementation in primary care. However, the transferability of the findings to other settings may be limited.

Initiation of the data analysis prior to the end of the feasibility test may have helped to identify the problem with poor recording of gingival recession, bone loss, tooth mobility and discolouration, so that the causes could be explored and addressed as the feasibility test continued. The Lightning Reports, though useful, did not pick up this issue, nor did they identify the problem of clinicians using the incorrect form in the EPR. This meant that data from 39 patients did not include the MDS-TDI outcomes. This may have been a genuine error by the clinicians, or it may have been a ‘workaround’ to avoid completing the MDS-TDI outcomes. However, this was not explored in the focus group.

Acceptability of the MDS-TDI to clinicians was explored in the focus group but acceptability could have been assessed more robustly by using a relevant framework such as the theoretical framework of acceptability (29).

Social desirability bias may have influenced the focus group findings (26). It was facilitated by a researcher not known to the clinicians; however, they were aware that the analysis would be undertaken by the lead researcher (KK) who is a member of the clinical team. It was also emphasised that there were no right or wrong responses we were exploring the feasibility of using the MDS-TDI, not assessing individual clinicians.

5.5 Conclusion

Recording many of the clinician and patient outcomes in the MDS-TDI is feasible and acceptable to dentists working in a tertiary referral centre. Further work is required to explore the transfer of these reports to primary care to initiate opportunity for longitudinal treatment outcome monitoring alongside exploring what is feasible to record in primary care on different EPR systems.

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Chapter 6 Discussion

6.1 Summary

In this chapter, I will first discuss the methods and findings of my studies, before moving on to consider their strengths and limitations. Then I will discuss the clinical implications of the work and describe the incremental steps and future research that is required for the wider implementation of the minimum dataset for traumatic dental injuries.

Traumatic dental injuries are common and can occur across the life course (1,2). It is unknown how many children and young people (CYP) in the UK are receiving treatment for TDI (3). There is a mature evidence base that describes the impact of TDI for the child, their family, and the health service (4,5). Currently, it is difficult to quantify these impacts for CYP in the UK, or on the NHS due to the paucity of consistently collected clinical data.

Routine outcome measurement provides a mechanism to improve service quality and accountability (6). Where high-quality data is available it can provide a wide range of opportunities for evaluation, support and service development at an individual clinician, practice, regional and national level. National audit programmes such as the Sentinel Stroke National Audit Programme and the Cleft Registry and Audit Network have demonstrated that it is possible to monitor performance and drive quality improvement using routinely collected clinical data (7,8).

A Core Outcome Set for Traumatic Injuries (COS-TDI) has been developed for use in clinical trials (9). Use of a COS helps to prevent bias in reporting study results, provides consistent data for systematic reviews, and allows for comparisons of therapies to answer questions about the (cost) effectiveness of interventions (10). The COS-TDI comprises 14 generic outcomes and 8 injury specific outcomes. It is not suitable for use in routine clinical appointments due to the significant extra time required to record all the mandated outcomes appropriately. This led us to question how Icould improve the recording of outcomes in routine appointments, which is where most dental trauma treatment is provided. On review of the outcome measurement literature, we identified that minimum datasets have been developed to enable outcome recording in healthcare. A minimum dataset has been described as a standardised minimum set of outcomes to be recorded at routine clinical appointments (11). Development and implementation of a minimum dataset for traumatic dental injuries (MDS-TDI) could facilitate recording and analysis of outcomes that has hitherto been challenging, therefore addressing the gap in the research base that we have identified.

6.1.1 Development of a complex intervention with theoretical underpinning

Currently clinicians use ‘free text’ boxes when recording clinical outcomes, with little or no guidance on which outcomes to record or how to record them. Using a minimum dataset, where clinicians are encouraged to record outcomes in systematic way using outcomes from a pre-defined list, will require a considerable change in how clinicians’ complete clinical records for patients that are treated for TDI. A critical step in this thesis was to identify that the MDS-TDI is a complex intervention. By defining it as a complex intervention we can access a wide body of literature and methodology that we can use to approach its development and subsequent evaluation. Complex interventions can be defined as having several interacting components, requiring new behaviours by those delivering or receiving the intervention or having a variety of outcomes (12). Robust and incremental development of complex interventions is essential, so they are more likely to be effective and adopted widely in the real world (12). The use of theory when developing complex interventions is encouraged (12-15).

Nilsen described five categories of theoretical approaches used in implementation science – process models (such as the Knowledge to Action framework), determinant frameworks (Theoretical Domains Framework), classic theories (Theory of Diffusion), implementation theories (Normalisation Process Theory) and evaluation frameworks (Reach Effectiveness -Adoption Implementation Maintenance (RE-AIM)) (16). Normalisation Process Theory

(NPT) was chosen as the preferred framework as it has a strong implementation focus. It pays particular attention to the work required of stakeholders to embed and normalise innovations in routine practice. A recent systematic review of the application of NPT in understanding implementation processes in primary care settings in the UK concluded that NPT provides researchers with tools to understand the theoretical and practical challenges of implementation design and evaluation across, and within, complex health systems such as UK primary care (17). There is evidence that clinical best practice recommendations and evidence-based guidelines have poor uptake in primary medical care (18). This intervention was designed to consider outcomes of importance to patients and their parents/guardians, as well as being clinician friendly from the outset (or ‘upstream’) and using the principles of NPT to ensure accelerated uptake of the MDS-TDI into clinical practice.

Guidance on the development of complex interventions also recommends the use of qualitative research methods in both intervention development and evaluation (12). Research in dental traumatology has generally adopted a biomedical approach (19). There has been limited qualitative research in the field (19,20). A hand search of the Dental Traumatology journal for years 2015-2023 identified only five qualitative or mixed methods studies. This accounted for less than 1% of all published articles. This may be because dentists and dental traumatology researchers have little training and experience in conducting and appraising qualitative research methods but the gap highlights huge potential to use these methodologies to provide breadth of understanding and knowledge of mechanisms of action that can improve practise and inform policy in dental traumatology research. Qualitative methods such as semi-structured interviews and focus groups were planned throughout this MDS-TDI project. Chapter 2 presents a narrative review of qualitative research in dental traumatology, which was undertaken to provide an overview of qualitative research, its key approaches and how to appraise it, and to explore its potential value to dental traumatology research.

The aim of this PhD work, therefore, was to develop, and feasibility test the minimum dataset for traumatic dental injuries for use in routine clinical practice. Each study objective is discussed in the following sections.

6.1.2 Study objective 1: to identify outcomes of importance to clinicians managing patients with TDI.

Numerous Core Outcome Sets have been reported in the literature and there is a strong evidence base for the methodological approaches in their development (21). Minimum datasets are less well established. Several methodological approaches have been used (11). Outcomes to be recorded within an MDS must be clinically relevant, otherwise clinicians are unlikely to record the data consistently and reliably (11*).* Research that focuses purely on clinical outcomes and fails to consider the patient's experience of a particular intervention or course of treatment is less relevant to patients and their families. (20).

There are three main consensus methods in use by researchers across multiple fields: consensus development panels, the Delphi technique, and the nominal group technique (22). Consensus development panels are commonly used to develop healthcare policy and strategic plans. The Delphi technique is widely used in dataset development and is described as an excellent method for gaining information about opinions from a wide group of participants (21,23). Therefore, the Delphi method was selected as an appropriate approach to reach consensus on which outcomes should be included in the MDS-TDI. Guidance is available on optimising the approach (23), and this was followed to ensure transparent, reproducible, and robust methodology for selection of the outcomes to be included in the minimum dataset. A Delphi survey is a structured process requiring experts to respond to non-leading, unambiguous statements with the aim of achieving consensus. A key advantage of the Delphi approach is that it creates a level playing field where every individual is equally important and one dominant individual cannot assert undue influence (10).

Chapter 3 presents the methodological approach that we undertook to develop the MDS-TDI. Paediatric dentists, general dental practitioners, restorative dentists, oral and maxillofacial surgeons, and orthodontists were recruited to the Delphi survey, as all can be involved in providing treatment for children with TDI. The outcomes from the COS-TDI and the patient outcomes study (previous work) were used in the survey development. The survey was constructed with a separate section for each injury type. This meant that participants had to grade the importance of 170 outcomes. Each participant received an individualised report after every voting round that compared their vote with those of the other participants. Participants could then reconsider their response based on this information without any one individual imposing their viewpoints on others. Participants were asked to rate the importance of each outcome on a 9-point Likert scale score between 1 “limited importance” and 9 “critical importance”. Consensus was considered *a priori.* Outcomes to be included in the dataset required at least 70% of participants to score the outcome as “critical” and less than 15% of participants to score the outcome as “limited importance”. Outcomes to be excluded from the dataset required at least 70% to score the outcome as “limited importance” and less than 15% to score the outcome as “critical” (24). No outcomes were deemed to be of limited importance by at least 70% of participants. Most outcomes were deemed by participants to be of ‘critical importance’, with only three outcomes deemed ‘important’ and none to be ‘of limited importance’. This was a trend across all injury types, but especially for complex injuries that involve both the hard tissues and the periodontal ligament. There is little guidance in the Delphi literature on how to manage a scenario such as this. We discussed which outcomes to take to the consensus meeting, considering the length of the meeting (no more than three hours) and the participants, some of whom were not clinicians. The overall aim of the minimum dataset development was emphasised i.e., that it should be feasible to use in routine clinical practice. The study team, which included a subject expert in dental traumatology (PD), made a pragmatic decision to take the list of generic outcomes from the COS-TDI and the two patient-important outcomes identified in earlier work, to the consensus meeting.

6.1.3 Study objective 2: to identify which outcomes should be included in the MDS-TDI

A consensus meeting was undertaken involving patient representatives, clinicians, and other stakeholders from across England to agree which outcomes should be included in the minimum dataset. A face-to-face consensus meeting was planned, but Covid-19 restrictions were still in place. The meeting was therefore held online, via Zoom. A professional facilitator with experience in priority setting was engaged. It has been identified in the literature that a trained facilitator can help to ensure that patient input is solicited and considered during large group discussions (10). The meeting was structured using a modified Nominal Group Technique. The Nominal Group Technique (NGT) is a facilitated and structured face-to-face group interaction which aims to empower participants by providing an opportunity to have their voices heard and opinions considered by other members (25). This aimed to enable equal participation among members in generating information and achieving outcomes. This can offer more transparency in decision-making than informal methods. Time was allocated for a group discussion on how many outcomes should be included, with particular emphasis on what would be feasible to record in a busy clinical practice.

Participants agreed that the dataset should comprise a list of clinician outcomes (pulp healing, periodontal healing, discolouration, tooth loss) and a list of patient outcomes (communication, aesthetics, pain, quality of life) (**Figure 3.4,** page 70). It was acknowledged that the communication outcome is difficult to measure but that due to perceived importance, it should be included, and further work undertaken to identify how best to record it.

6.1.4 Study objective 3: to design the MDS-TDI into an existing electronic patient record.

As dental records are increasingly moving towards electronic patient records (EPR), if the MDS-TDI is to be used in routine practice it will need to be suitable for use within existing EPR. This was one of the more difficult aspects of this project. There was no precedence in the literature for integrating MDS into existing EPR. Chapter 4 describes the user testing process that we used to do this.

Early involvement with key stakeholders and target users is crucial to uncover usability and experience, and to inform development and refinement of digital health care interventions (26,27). It has been reported that a high degree of user involvement is associated with successful implementation of digital interventions (28,29). The NPT focus on engaging end-users throughout intervention development ensured that clinicians were identified as the most appropriate participants in this stage of the project.

Each type of usability assessment method has benefits and drawbacks related to ease of conducting the study, predictive power, and generalisability (30). No single approach will answer all questions because each approach can identify only a subset of usability problems. A combination of multiple usability methods has been proven to detect more problems in a dental EPR than any single approach (31). Therefore, user-testing followed by a semi-structured interview was chosen as the most appropriate methodology for integrating the MDS-TDI into an existing EPR. The EPR system we were working with was already ‘live’. Therefore, there were limitations to the changes we could make. The goal was to ensure that recording the MDS-TDI outcomes of importance to both patients and clinicians, would be easy, efficient, and acceptable to clinicians.

Ten clinicians of varying levels of experience, were recruited to this stage of the project. All clinicians engaged with the process and required little guidance or prompting to ‘think aloud’. They provided feedback on various aspects of the dental trauma form in the EPR, not just the MDS-TDI elements. Several key findings emerged from the analysis of the data. It was important to clinicians to be able to record sufficient clinical information and at various points in the page it was noted that a ‘dropdown’ box or extra box would be useful so that additional information could be recorded. This was particularly important around the recording of the pulp outcome, where often it is uncertain whether the pulp is maintaining vitality or not. A simple yes or no forced choice option is therefore not sufficient There is precedence for this in the literature, Davey and colleagues noted that although forced choice was used where possible to allow clean data, free text boxes are essential to provide further opportunity to record additional clinical perspectives (11).

Clinicians required further clarification about what information was required in the radiograph report sections and the quality-of-life questions. Several participants noted that the presence of the MDS-TDI outcomes prompted them to record the outcome using the appropriate outcome measurement instrument, but also that the dataset acts as a prompt and ensures thorough and systematic recording of information, so that nothing important is missed. Using the MDS-TDI engendered confidence that all relevant information would be recorded.

Problems with delays when clicking or saving were identified across all three cycles. These delays were related to the server speeds of the system and so it was not possible to make changes to mitigate this. However, overall participants did not feel that recording the MDS-TDI outcomes added significantly to time taken to enter the data from the simulated cases.

In cycle 3 both participants, who had limited experience in dental trauma management, completed the tasks with ease and no prompting was required. This indicated that the user testing cycle was complete. The updated pages were then integrated into the live system, ready for feasibility testing.

6.1.5 Study objective 4: to undertake an early phase feasibility study in a teaching hospital.

Chapter 5 describes the results of a feasibility test undertaken in the Leeds Dental Institute, a tertiary referral site for TDI. Feasibility testing is a key step in intervention development. The importance of developing data shaping initiatives like minimum datasets is increasingly recognised by research authorities. However, evaluating their clinical feasibility is equally important to enhance implementation. A pragmatic decision was made to undertake this in a specialist setting. If the MDS-TDI was found not to be feasible with specialists who have additional training in assessment and management of TDI, it would be unlikely to work in primary care.

Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given setting (32). For clinical or public health interventions, pilot and feasibility studies may serve to identify potential refinements to the intervention, address uncertainties around the feasibility of intervention trial methods, or test preliminary effects of the intervention (33).

Data collection processes and acceptability of outcome measures were assessed by reviewing data completeness. This was calculated and presented as percentage proportions. Patient-reported outcome measures had high completion rates at all time points in the study, regardless of staff level. Some of the clinician outcomes had lower completion rates, especially the periodontal healing outcomes of gingival recession, bone loss, and tooth mobility, with overall percentage completion rates of 59%, 55% and 70% respectively. Previous work by Day and colleagues to investigate the role of structured history forms for recording clinical findings in dento-alveolar trauma reported that 75.3% of important prognostic factors were recorded when clinicians used a structure history form, compared to 53% recorded when using an unstructured history and 58.6% when using a computer database (34). These results, however, are from a simulated dentoalveolar trauma scenario. There is little in the literature to inform what ‘acceptable/ unacceptable’ levels of data completeness are in real life clinical settings.

The subsequent focus group was undertaken to explore clinicians’ thoughts on the dataset use: satisfaction, intention to continue use and perceived appropriateness of the intervention. Several participants identified that using the MDS-TDI supported a more standardised examination of the patient. It was also noted that the examination now had a more holistic and patient-centred approach. Overall, both individual and shared understanding of the aims and objectives of the MDS-TDI were positive. Despite a strong belief that the dataset should be part of their work, the participants identified several problems when using the MDS-TDI in their regular practice, including how to manage using the dataset at the time of acute trauma presentation, and when managing a patient with multiple traumatised teeth. Some concerns were raised about the quality-of-life questions and the potential for language barriers, or challenges in understanding what are perceived as nuanced questions. The quality-of-life questions used were chosen as they were included in the COS-TDI and had been defined as ‘global’ questions (9). However, they have not been validated in the UK population. It has been reported in the literature that the development of patient reported outcome measures (PROMs) for children and young people (CYP) is complex and challenging due to diversity in cognitive ability and understanding (35).

Using NPT in the analysis of the focus group provided a framework that characterised a range of factors that clinicians perceive to impact their understanding of the purpose of (coherence), engagement with (cognitive participation), anticipated use (collective action) of the MDS-TDI. The participants had not yet had any feedback or reports on the data collected during the study period, therefore it is unsurprising that the appraisal of (reflexive monitoring) its use and engagement with the MDS-TDI was not as well explored in the focus group.

Overall, this study has demonstrated the feasibility of using the MDS-TDI to record outcomes in a teaching hospital setting.

6.2 Strengths and limitations

6.2.1 Strengths

This thesis has several noteworthy strengths. It is the first minimum dataset in dentistry to be developed with an appropriate theoretical underpinning and approached as a complex intervention. Despite the considerable resources devoted to clinical and health services research, a consistent finding is that the transfer of research findings into practice is unpredictable. Several early reviews of implementation research (36,37) demonstrated that most interventions achieved moderate improvements in care with considerable variation in the observed effects within and across interventions (38).

Difficulties in implementing new interventions result from multiple factors, not least the failure to consider implementation strategies early during intervention development, as well as potential barriers including policy context, organisational context and change, professional identity and relationships, individual actions, and the dissemination and uptake of knowledge (17).

Using theory may enhance our understanding of barriers to implementation, but more than that, it may enhance our ability to design interventions and explore how we can shape and improve implementation processes (39). The application of formal theory enables the maximum exploitation of learning and accumulation of knowledge, and promotes the transfer of learning from one project, one context, one challenge, to the next (40). In contrast, poor theoretical underpinning makes it difficult to understand and explain how and why implementation succeeds or fails, thus limiting the identification of factors that predict the likelihood of implementation success (16).

NPT was used throughout the project. It was used in the early planning stages (**Table 1.3**, page 15) and informed the study design. It ensured a strong focus on end-users throughout the MDS-TDI development. NPT was used in the feasibility test to generate questions for the focus group topic guide. It was useful when constructing the topic guide as it provided a framework from which to derive questions and allowed consideration of aspects of end-user engagement that may have otherwise been overlooked. During analysis of the focus group transcript, the recently developed NPT coding manual was used (41). The theory was applied to make sense of the themes emerging from the codes and categories. This approach allowed the constructs of NPT to flexibly guide the research and provided a theoretical basis to data collection.

NPT provided a useful set of conceptual tools to aid understanding of preparing for MDS-TDI use as a dynamic process. Using NPT enabled insights to be gathered on the ‘work’ that is involved in implementation. An additional strength is that NPT was used in a prospective manner, from the very start of the project. This use of implementation theory ‘upstream’ has been recommended in the literature (39,42,43), but is novel in dentistry.

Chapter 2 summarises the contribution of qualitative research to the field of dental traumatology. It was identified that additional qualitative studies are required, particularly to identify patient experiences and views of treatment planning, communication and eventually outcomes of importance to them. This prioritisation of patient views was further demonstrated in Chapter 3, when patient representatives were included in the national consensus meeting. Appropriate facilitation aimed to ensure their opinions were considered by the group. The resulting MDS-TDI has a strong patient focus, with four patient-important outcomes being identified as important outcomes to record at routine appointments. Prior to this, patient involvement in dental traumatology research has been limited (19). A recently published narrative review of patient recorded outcomes in TDI research concluded that it is necessary to develop a set of validated dental patient reported outcomes measures (dPROMS) that are specific to the field of dental traumatology (44). The MDS-TDI offers an important first step towards the realisation of that goal.

The clinicians, who will be the eventual end-users of the MDS-TDI, were involved in every stage of the project as demonstrated in Chapters 3, 4 and 5. Meaningful engagement with appropriate stakeholders at each phase of research has been identified as a key step to maximising the potential of developing an intervention that is likely to have positive impacts and to enhance prospects of achieving change in policy of practices (14). Engaging key stakeholders in the development of interventions such as a MDS is crucial to ensuring the intervention is relevant to the clinical context, meets the needs of the users and can be successfully implemented and utilised (15). PPIE was also utilised at various stages in the project, particularly in the early development stages. The project proposal was brought to the LDI Smile Aiders patient group for review. Group members, despite not having lived experience of TDI, appreciated it was an important problem and were very supportive of the project. Some changes to the plain English summary of the project protocol were made based on the group recommendations. More informally, patients from the Dental Trauma clinic were shown the early iterations of the patient questionnaire and asked for feedback about design and layout. The patients and their parent/carer were enthusiastic with their feedback and ensured the final questionnaire was fit for purpose.

An additional strength of the project is the use of evidence-based, formal consensus techniques as described in Chapter 3. The consensus meeting included patients, clinicians, commissioners, and a Public Health England representative, and use of the nominal group technique ensured all participants had an equal voice.

6.2.2 Limitations

Nonetheless, this thesis has several limitations that may affect validity and interpretation of the findings. Despite the use of best practice guidance for the Delphi survey, it did not help to reduce the list of outcomes to discuss at the consensus meeting. In hindsight, it may have been useful to have reduced the number of outcomes included in the Delphi survey, and it was likely not necessary to have a separate survey section for each injury type. The impact of this was that it made the subsequent analysis very time-consuming. The consensus that was achieved was that all outcomes were critically important and should be included in the MDS-TDI. This may point to a lack of participant understanding of the purpose of ‘minimum’ for the MDS-TDI. In the future, there may be value in consideration of further training for participants prior to survey completion.

Secondly, the user testing and feasibility test in Chapter 4 and 5 were undertaken in a specialist paediatric dentistry environment. This was a pragmatic decision, related to the time and funding available for the project. It was also felt that if the MDS-TDI was not acceptable to specialists with expertise in the management of TDI, it would not be likely to be acceptable to primary care clinicians. Therefore, the results of the feasibility test may not be generalisable to other settings, and further exploratory work is required before planning implementation of the MDS-TDI in dental primary care. Use of an appropriate framework, such and the theory of acceptability framework (45) would allow for more robust analysis of acceptability.

In addition, even in a specialist setting, where clinicians regularly assess and managed TDI, there was relatively low completion rates of some of the outcomes. Further work is needed to determine what is feasible to record in the dental primary care setting. It may be that, for the purposes of audit, quality improvement and exploration of the costs associated with TDI management, it is sufficient to know whether there are pulp complications (yes/no/uncertain) and/or periodontal complications (yes/no/uncertain). The level of detail that has been prescribed by the MDS-TDI may be a point of compromise.

Several of the patient-important outcome measures require validation and further refinement before wider implementation. The quality-of-life questions used in the patient questionnaires were identified by clinicians as potentially being difficult to understand. There is no validated measure for ‘communication’ which was identified by patients and their families as an important outcome to them. It may be plausible to provide guidance on the questionnaire to aid communication with patients to achieve more uniform completions.

We did not use objective measurements of usability when undertaking testing. There is a lack of consensus in the literature on which methods to use when evaluating usability. Time to task completion is one easily measured metric and so it may have been useful to formally measure the time taken to complete each task. However, we wanted participants to take the opportunity to describe their thoughts in detail and using a timer may have been inhibiting. Consideration was made to using an appropriate usability questionnaire. However, as the system was already live and the changes we could make were limited, it was not likely to add significant value and would increase the burden for participants.

Initiation of the data analysis prior to the end of the feasibility test may have helped to identify several issues such as clinicians using the incorrect form in the EPR, and poor recording of the discolouration outcome, so that the causes could be identified and addressed as the feasibility test continued. It would have been useful to explore these issues in the focus group.

Finally, social desirability bias may have influenced the focus group findings. It was facilitated by a researcher not known to the clinicians; however, they were aware that the analysis would be undertaken by the lead researcher (KK) who is a member of the clinical team. It was also emphasised that there were no right or wrong responses we were exploring the feasibility of using the MDS-TDI, not assessing individual clinicians.

6.3 Implications for practice and policy

Data are seen as central to facilitate quality, accessibility, and equity of oral and dental care in the coming decades (46). Maximising the use of health data for research, innovation and improvements in health and care services is a key element of the UK Governments Industrial Strategy (47,48). Accessing data from primary care services is essential for judging such things as population health and care needs, service uptake, patient outcomes, and performance of services (11).

Large volumes of data are submitted by NHS dental practitioners at the end of every course of treatment, including urgent episodes of care. This data is primarily submitted to enable financial payment of the practitioner. A summary record of treatment activity is included but it is extremely limited in clinical information collected such as diagnosis, treatment provided and no data about quality of care is collected (47). It is not possible to quantify how many CYP are undergoing treatment for TDI in NHS primary dental care from the submitted data (49). The alternative option is to review the EPR in individual practices to collect the required information. However, this is not practical in terms of time required and information governance challenges. Measuring outcomes is useful to identify needs, monitor symptoms, examine success or not of treatment interventions. This can enable commissioning of appropriate services as well as developing a greater understanding of the costs (both direct and indirect) involved in management of TDI.

Ultimately, implementation of routine outcome measurement requires significant resource commitment from services. Governance of data collection systems and robust mechanisms of data interpretation, reporting and dissemination are necessary to inform others and enhance the service delivery and user’s experience (6). Structures need to be developed so that the collected data can be analysed in a standardised way and thus made useable for the teams (50). A decision will need to be made regarding risk and the sensitivity of the data being transferred to determine the most suitable electronic solution for data transfer and storage (11). Ethical aspects of using anonymous patient data for public health purposes also needs to be considered. Extensive work has been undertaken for the Connected Bradford Whole System Data Linkage Accelerator, and many of the above-mentioned challenges have been identified and managed (51). This data linkage model combines primary, community and secondary healthcare data with education, social care, environmental and other local government data to drive learning health systems, prevention, and population health management. Data linkage across health care organisations aims to harness linked routine data to drive health service improvement and research and ensuring that the MDS-TDI outcomes are included in such data linkage models will open opportunities for novel research in the future.

Implementation requires addressing several important contextual factors such as leadership, culture, resources, networks, and communication (52). Context is known to affect the process and outcome of interventions to improve the quality of healthcare (53). The combined pressures of increasing demands, the legacy of the pandemic, increasing numbers of dentists going private, and a stagnant budget have all adversely affected access to NHS dental services. The 2023 Nuffield report ‘*Bold action or slow decay? The state of NHS dentistry and future policy actions.’* identified that NHS dentistry in England is at its most perilous point in its 75-year history (54). In a similar vein, a recent Lancet editorial stated that the whole NHS dental system is close to collapse (55). This may be the most significant factor in the success or not of the implementation process. The use of NPT has identified that building coherence is paramount - understanding the meaningfulness and recognising advantages for the individual and the team.

Therefore, educational strategies, audit and feedback and incentivisation are potential approaches that could be used as the MDS-TDI is implemented across dental primary care.

It has been well documented that children with TDI experience negative social judgement, bullying and teasing by their peers about their appearance (56,57). PPIE contributors that we worked on previous projects, who had lived experience of TDI, referred to the disfigurement and long-term impact of treatment and the concerns they have about treatment continuing throughout adulthood. This highlights the importance of improved evidence in TDI management, so patients can be informed of success rates and long-term implications of TDI.

6.4 Future research

Adoption of the MDS-TDI across primary dental care will require the following research:

1. Investigation of the validity of the patient outcomes.
This is the first study in dentistry to integrate patient reported outcome measures (PROMs) in a minimum dataset. Although patients and parents were involved in the choice of outcomes included in the MDS-TDI, they were not involved in the choice of the outcome measurement instrument, nor was a TDI-specific PROM developed. This was beyond the scope of the thesis. An important future step is to refine and validate the chosen PROMs. Carlton and co-workers have recently published an emerging framework, identifying ways in which public involvement can have a meaningful role and contribution to the co-development of PROMs (58). Incorporating public involvement is critical to the development process, and their inclusion contributes to strengthening the relevance, acceptability, and validity of the PROM itself. The authors identified that there is little guidance on how best to incorporate public involvement with CYP (58). We will need to consider how meaningful public involvement can occur. Innovative methods may incorporate discussions through interactive play, learning technologies, communication aids and social media (59)

2. Work with stakeholders to determine feasibility of the MDS-TDI dental primary care.

Primary care has its own distinctive research and implementation culture, described as contributing to the evidence-to-practice gap (60). Engagement with clinicians, commissioners and dental software providers will be required. Implementing change is likely to require a ‘carrot and stick’ approach.

Clinicians: Potential barriers to clinicians engaging with the MDS-TDI include lack of time, perception of work overload, and motivational factors. Potential enablers may include additional payments and access to continuing professional development. Both barriers and enablers require further exploration.

Commissioners: With the current, flexible commissioning, local commissioners can adjust ‘Units of Dental Activity’ (UDA) rates or pay sessional rates for dentist’s time and incentivise quality improvement initiatives (61). An additional UDA for acute trauma treatment or follow up may be helpful, but payment is only secured if the clinician completes the minimum dataset. Data uploaded from their own clinical records may be a short-term solution but is likely to be labour intensive. Changes at a national level, including amendments to the FP17 form that dentists submit to receive payment, will require rigorous and robust feasibility data to justify such a change.

Software developers: to capture data for the MDS it is likely that software used in primary care dentistry will need to be updated to be MDS compliant. We will need to consider what software platforms are used and how dentists in primary care use their electronic records. Some platforms are more detailed and may lend themselves better to having additional pages added or integrated for MDS-TDI. Further exploration of this is needed, and working with GDPs that refer into LDI, to understand which EPR are commonly used in the region, may help guide prioritisation of which software suppliers to work with. Innovative approaches such as patient completion of patient related outcomes before attendance or while waiting for their appointment could be explored.

3. Identify how to manage and use the MDS-TDI outcome data

Additional work is also required to determine how to manage and use the data once it has been collected by clinicians. In this study, measuring data completeness was a manual process as there was no functionality in the EPR to do this automatically. This is not sustainable. It will also be helpful to identify what information clinicians would value in summary reports as this may influence their motivation to continue to record the MDS-TDI outcomes in the longer term. Data providing organisations must invest time and expertise to setup the data extraction process and help interpret the data; therefore, it is important that they see some return on that investment. Engagement with commissioners and practitioners across all sectors is essential in identifying how the data can support their priorities and objectives, ensuring that the analysis feeds into quality improvement and supports the best use of limited resources. One motivation for embedding MDS-TDI into routine care would be as part of a wider quality improvement strategy, with feedback on data completeness, attainment of processes of care and patient outcomes (18).

6.5 Conclusions

A minimum dataset for TDI has been developed and integrated into an existing EPR**.** A feasibility test has demonstrated the feasibility and acceptability of the MDS-TDI for clinicians in specialist paediatric dentist setting**.** Until there are robust data that can be used for audit and research, and assessment of longitudinal outcomes, we cannot identify the true impact of treatment for TDI on the patient, their family, and the NHS, nor improve outcomes for this significant cohort of children.

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Chapter 7 Appendices

Appendix a.

Figure a.1 Ethical approvals.

Figure a.1.1 Ethical approval for consensus study

Dear Kate

DREF ref: 301120/KK/312
Study title: Determination of outcomes to be included in a minimum dataset for traumatic dental injuries (MD-TDI)

Thank you for re-submitting the amended documents for the above study. The documents have been reviewed and I am pleased to inform you that the application has been approved by the Dental Research Ethics Committee (DREC).

Documents reviewed

Document name	Version number/date
Ethics application form	Dated 26/02/2021
Research protocol	Version 2 26/02/2021
Appendix A Information sheet – Delphi	Version 2 26/02/2021
Appendix B Consent form – Delphi	Version 3 26/02/2021
Appendix C Information sheet – Consensus meeting	Version 3 26/02/2021
Appendix D Consent form – Consensus meeting	Version 2 07/01/2021
Appendix E Consent form – Use of video	Version 2 07/01/2021
Appendix F Needs interest form	Version 1 05/11/2020
Appendix G Email invitation	Version 1 05/11/2020
Appendix H Reminder email	Version 1 05/11/2020

With best wishes for the success of your project.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, signed consent forms, participant information sheets and all other documents relating to the study, including risk assessments. This should be kept in your study file, and may be subject to an audit inspection. If your project is to be audited, you will be given at least 2 weeks' notice.
It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

For and on behalf of
Professor David Wood
DREC Chair

Figure a.1.2 Ethical approval for user testing study

Dear Kate

DREC **ref: 230822KK356**
Study title: Usability Testing of the Minimum Dataset for Traumatic Dental Injuries in a Dental Electronic Patient Record

I am pleased to inform you that your research ethics application has been reviewed by the Dental Research Ethics Committee (DREC) and can confirm that the application has been given ethical approval based on the documentation reviewed as per below. Please retain this email as evidence of ethical approval in your study file.

Documents reviewed

Document	Version number/date
Research ethics application form	Updated 8 September 2022
Protocol	Version 1 8 September 2022
Appendix A Letter of invitation	Version 1 8 September 2022
Appendix B Participant information sheet	Version 1 8 September 2022
Appendix C Research participant privacy notice	Version 1 8 September 2022
Appendix D Consent form	Version 1 8 September 2022
Appendix E Think aloud video link	Version 1 8 September 2022
Appendix F Demographic data collection sheet	Version 1 8 September 2022
Appendix G Topic guide	Version 1 22 July 2022

Please notify DREC if you intend to make any amendments to the research as submitted and approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementation. Please see https://ris.leeds.ac.uk/research-ethics-and-integrity/applying-for-an-amendment/ or contact Julie McDermott for further information if required.

Ethical approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, risk assessments and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

With best wishes for the success of your study.

For and on behalf of

Dr Karen Vinall-Collier
DREC Chair

Attendee panel closed

Figure a.1.3 *Correspondence from Leeds Teaching Hospitals Trust regarding ethical approvals for feasibility study*

Hi Kate

Reviewing this information again and the additional details provided (many thanks) NHS ethical approval will not be required for this study.

Best Wishes

Sarah

Sarah Hall (she/her)
Research Governance Manager | Sponsored Research
Leeds Teaching Hospitals NHS Trust

NHS
The Leeds
Teaching Hospitals
NHS Trust

Research & Innovation
Research and Innovation Centre
St. James's University Hospital
Beckett Street
Leeds LS9 7TF

RAAFt | Research Assurances & Approvals Facilitation team

🖂 Research Governance & sponsorship queries leedsth-tr.researchgovernance@nhs.net
🖂 General research queries ltht.researchoffice@nhs.net
🖂 Hosted research CCC advice leedsth-tr.centralcoordinators@nhs.net

Please note: I am hybrid working and can best be contacted by email or teams.
From: Kate Kenny <K.Counihan@leeds.ac.uk>
Sent: 12 December 2022 16:17
To: HALL, Sarah (LEEDS TEACHING HOSPITALS NHS TRUST) <sarah.hall50@nhs.net>
Subject: FW: FAO Anne Gowing or Sarah Hall - query re ethical approvals for Dental Trauma project

Dear Sarah,

I'm sure you are really busy, with lots of queries, but I wondered had you had any further thoughts on this? Getting the SoECAT approved following amendment is proving tricky (and time consuming!). If you are happy with local ethical approval I can get on with submission but if NHS ethical approval is required I'll restart the process of getting the SoECAT approved as part of the submission documents,

Many Thanks,
Kate

From: Kate Kenny
Sent: 07 December 2022 13:21
To: HALL, Sarah (LEEDS TEACHING HOSPITALS NHS TRUST) <sarah.hall50@nhs.net>
Subject: RE: FAO Anne Gowing or Sarah Hall - query re ethical approvals for Dental Trauma project

Hi Sarah,

Jean had initially had the same queries as yourself as to whether or not it was research as no patient participants were being recruited.

The study doesn't involve NHS patients/carer or their data in any way. The dentists are collecting routine clinical data (nothing new) , just undertaking the collection in a more uniform manner and using the same outcome measurements. The data is being recorded in the usual electronic dental record (Salud), which is used across the LDI for every patient appointment.

Jean had advised querying with yourself whether NHS ethics is required. If you feel that on balance, it is not, the study would still be subjected to ethical review by our dental ethics committee (DREC) so it would still be suitable for publication and future work with any findings would not be at risk,

Thanks again for your time with this, it is much appreciated,

BWs
Kate

Figure a.1.4 Ethical approval for feasibility study

Dear Kate

DREC ref: 010223/KK/365
Study title: Feasibility test of minimum dataset in dental trauma.

I am pleased to inform you that your research ethics application has been reviewed by the Dental Research Ethics Committee (DREC) and can confirm that the application has been given ethical approval based on the documentation reviewed as per below. Please retain this email as evidence of ethical approval in your study file.

Documents reviewed

Document	Version number/date
Research ethics application form	Version 1

Protocol	Version 2 24.02.2023
Participant information sheet	Version 2 24.02.2023
Participant consent form	Version 2 24.02.2023
Letter of invitation	Version 1 25.01.2023
Topic guide	Version 1 25.01.2023

Please notify DREC if you intend to make any amendments to the research as submitted and approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementation. Please see https://ris.leeds.ac.uk/research-ethics-and-integrity/applying-for-an-amendment/ or contact Julie McDermott for further information if required.

Ethical approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, risk assessments and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

With best wishes for the success of your study.

For and on behalf of
Dr Karen Vinall-Collier
DREC Chair

Attendee panel closed

Appendix b.

Table b.1 Using Normalisation Process Theory in study design.

NPT Component	Questions to consider within NPT	Examples
COLLECTIVE ACTION	How will the intervention affect the work of user groups?	It has potential, at least initially, to be more time-consuming – particularly if current practice involves very little ‘data collection’
	Will it promote or impeded their work?	The user-testing aimed to allow optimised design considerate of time constraints. It should promote their work and allow them to record clearly treatment and outcomes for TDI
	What effect will it have on consultations?	Potential initially to increase time for consultation
	Will staff require extensive training before they can use it?	Yes, all staff will require education and training on both the content of the MDS-TDI and the process of how to incorporate it’s use in their daily clinical practice
	How compatible is it with existing work practices?	The aim of the design consultation will be to consider incorporating into existing EDRs so to be as widely compatible as possible
	What impact will it have on division of labour, resources, power and responsibility between different professional groups	Dentists – may improve confidence in management of TDI, may allow for shared care with colleague or easy contest with specialists for opinion or advice Commissioners – responsive to adopting a patient-centred evidence base and cost-effective commission of services

	Will it fit with overall goals and activity of organisation?	Yes
REFLEXIVE MONITORING	How are users likely to perceive the intervention once it has been used for a while?	The goal is they will find it easy as familiarisation grows and benefits their practice and patients
	Is it likely to be perceived as beneficial for patients and staff?	The pros and cons will be evaluated across stakeholders. Data entered will be fed back to the clinicians and evaluation undertaken to see if they perceive it to be useful
	Will it be clear what effects the intervention has had?	Yes. We have never had good data on TDI management in primary or secondary care so there is real potential for improved and relevant information on treatment outcomes
	Can staff/users contribute feedback about the intervention once it is in use?	Yes, this has been included in the study design and will be included in wider implementation planning
	Can the intervention be adapted/improved on the basis of experience	Yes, otherwise feedback is pointless. A minimum dataset requires review at pre-defined intervals to ensure the outcomes are being measured and evaluate how they are being measured.

Figure b.1 Interview topic guide.

Topic Guide – Interviews

Introduction:

The purpose of this interview is to talk to parents and children about their experience of having treatment for a traumatic dental injury. In particular, we are interested in what were the most important ‘outcomes’ of their treatment.

Interview:

The interview will last as long as they wish, but on average should take around 30 minutes. The interview will be digitally sound recorded by the researcher. Parents and children should be reminded that this is not a test and that there are no right or wrong answers (the parent/guardian and child are the experts). They do not need to talk about anything that they don’t want to talk about and that participation is entirely voluntary. They can change their mind and stop the interview at any point.

Confidentiality:

Parents/Guardians and children should be reminded that the answers that they give during the interview will be private. They may also choose a pseudonym that they would like to be referred to on the tape.

The interviewer will open to the participants’ narratives and be flexible in switching between the interview topics.

PARENTS

- Can you tell me about any emergency treatment your child received following their dental injury?
  - Time after injury
  - How did you access treatment (e.g. using 111?)
- Once the emergency treatment was completed what was the next step?
- What was the most important thing for you in terms of their treatment? For example…
  - Colour of tooth
  - Shape of tooth
  - Number of appointments
  - Location of appointments/appointment times
- Did you find anything about their treatment particularly difficult?
- Is there anything about their treatment that you would change?

- Do you have any information about what treatment your child might need in the future?

CHILD

- Can you tell me/draw a picture(s) of how you got your teeth sorted out?
- Are you glad that you had your teeth sorted in the way that you had?
- Did you understand why you had your teeth sorted out the way that you did?
- How well do you think the dentist and dental nurse explained things to you?
- Was there anything that you wished that you had been told about your treatment?
- How did you feel after you had had all your teeth sorted out and your treatment was finished?
- What words would you use to tell your friends about having their teeth sorted the way that you had and how it made you feel?
- Is there anything else that you want to tell us about getting your teeth sorted?

Closing:

- I think we have covered everything, is there anything else that you would like to raise (to both parent/guardian and child)

Next steps:

Thank the participants for taking part in the study and remind and reassure them again about confidentiality. Discuss that the findings will be used to develop a …………..

Table b.2 Example of outcome measurement instruments as defined by COS-TDI

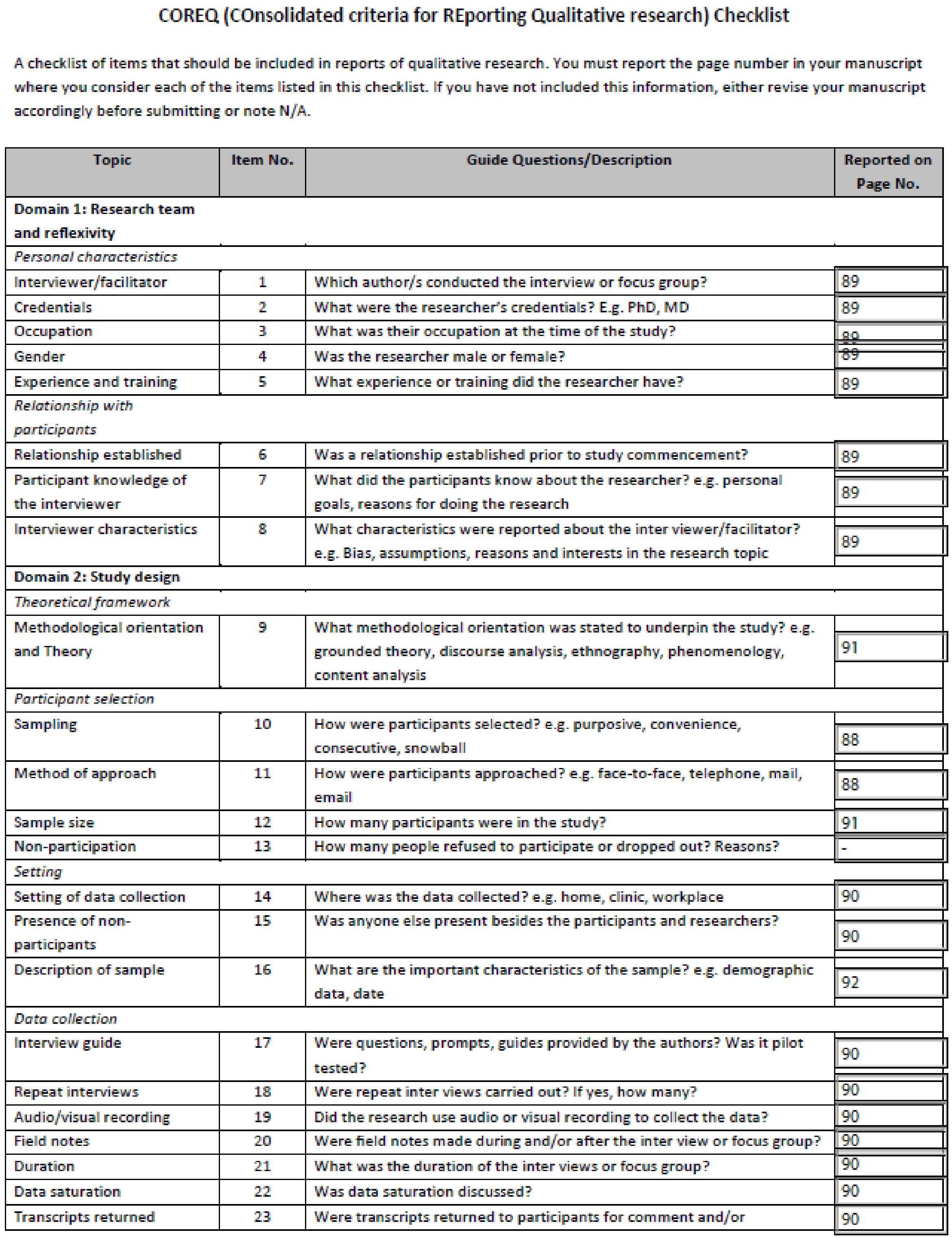
Adapted from: Kenny KP, Day PF, Sharif MO, Parashos P, Lauridsen E, Feldens CA, Cohenca N, Skapetis T, Levin L, Kenny DJ, Djemal S. What are the important outcomes in traumatic dental injuries? An international approach to the development of a core outcome set. Dental traumatology. 2018 Feb;34(1):4-11.

Outcome (Clinician Important)	**Outcome Measurement Instrument**
Pulp Healing	Sensibility tests [thermal and EPT] Radiographs [root growth, maturation, periapical radiolucency, infection related resorption] Sinus tract
Periodontal Healing	Bone loss (recorded in mm) Gingival recession (recorded in mm from gingival margin to CEJ) Mobility – Miller's Classification Ankylosis-related resorption (percussion tone and radiograph)
Discolouration	Record shade
Tooth Loss	Has this tooth been lost due to trauma – Yes/No
Outcome (Patient – Important)	
Quality of Life	<u>Aged 7-14 years</u> CPQ 11-14 ISF + global questions <u>Aged 15 years and over</u> OHIP 14 short form + global questions
Aesthetics	Patient perception – are you happy with how your tooth/teeth look?
Communication	Not in COS-TDI
Pain	<u>Intensity</u>

	Children under 10 :FPS-R Over 10 and adults: VAS Frequency Children under 10: Since the last time you attended the clinic how often have you had pain like the face you have chosen? Not at all/ a bit/ a lot Parents and children over 10: Since you/your child's last dental visit how often have you/they had pain in your/their traumatised teeth, lips, jaw or mouth?

Appendix c

Table c.1 COREQ checklist



COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	89
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	89
Occupation	3	What was their occupation at the time of the study?	89
Gender	4	Was the researcher male or female?	89
Experience and training	5	What experience or training did the researcher have?	89
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	89
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	89
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	89
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	91
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	88
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	88
Sample size	12	How many participants were in the study?	91
Non-participation	13	How many people refused to participate or dropped out? Reasons?	-
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	90
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	90
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	92
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	90
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	90
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	90
Field notes	20	Were field notes made during and/or after the inter view or focus group?	90
Duration	21	What was the duration of the inter views or focus group?	90
Data saturation	22	Was data saturation discussed?	90
Transcripts returned	23	Were transcripts returned to participants for comment and/or	90

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	90
Description of the coding tree	25	Did authors provide a description of the coding tree?	90
Derivation of themes	26	Were themes identified in advance or derived from the data?	90
Software	27	What software, if applicable, was used to manage the data?	91
Participant checking	28	Did participants provide feedback on the findings?	-
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	96
Data and findings consistent	30	Was there consistency between the data presented and the findings?	96
Clarity of major themes	31	Were major themes clearly presented in the findings?	96
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	98

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Figure c.1 Interview topic guide

'Think-aloud' tasks– Semi-structured interviews - Topic Guide

Introduction

- Thank you for agreeing to take part today....
- Today we are going to complete some "Think Aloud" tasks to test the new pages on Salud, which will collect the Minimum Dataset outcomes for TDI. After this I will ask you some questions about your thoughts and experiences
- Are you happy for this to be recorded?
- It will be anonymised

Explain 'Think Aloud' Tasks

- The "Think Aloud" process allows us to test the Minimum Dataset outcomes pages in the Dental Trauma section of Salud – looking at how you find navigating different areas on it, how you find the information and how you manage entering the outcome data
- Remember we are testing the Salud entry pages and how easy/difficult it is to use, not you as an individual
- We'll ask you to enter clinical data from two different simulated patients. We ask that as you do this you will continue to talk out loud
- This verbal talking "out loud" as you use it is really important for us to record and analyse so we can refine and redevelop the pages
- If you get stuck, pleases say out loud what you are having issues with. If you stop speaking out loud, I will ask you to "please keep talking"
- I'll be able to tell you when to start and when to stop
- Once you have completed the tasks we'll have an informal interview where I will ask specific questions about how you found using it

Warm up 'Think-Aloud' task

- OK so let's try a practice task
  - What is 24+24? Talk out loud as you figure it out. For example adding 20 to 20 (40) then add 4+4 (8) then 40+8=48
  - What is the 4th letter before F in the alphabet (B) ….how did you find that?
- Any questions? OK so now please get started with the first task

Participant will then start data entry from two simulated cases – a mix of complexity/dental injury/treatment

Post-‘Think Aloud’ Interview

Experience

Overall, how did you find using the Minimum Dataset on Salud?

Usability

What did you like about it?

What didn’t you like?

Navigation

How did you find getting around the pages?

- Prompt – what are your thoughts on the Dental Trauma page layout?

What support do you think would be needed to use the Minimum Dataset in clinic in the future?

Prompt – frequency of support/type

Content

Is there anything else you would like to see included?

- Prompt: for example links to information or explanation of the various outcomes

Future

Would you be happy to start using this on clinic during/after patient consultations or treatment?

Do you think patients should be involved in recording the Patient Important Outcome Measures?

Appendix d.

Table d.1 TIDIeR checklist for intervention development

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	**Item**	**Where located ****	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Minimum dataset for Traumatic Dental Injuries (MDS-TDI)	Pg110	Kenny et al 2023 (https://doi.org/10.1111/edt876)
	WHY		
2.	To improve quality of data from routine clinical appointments. Normalisation Process Theory (NPT) informed the development of this complex intervention. End-users (dentists) were involved in the development of the MDS-TDI and the choice of outcomes that should be recorded (at a minimum) at routine clinical appointments during treatment and review of TDI. End-users were further involved in	Pg 110	Paper in preparation

	the integration of the MDS-TDI outcomes into an existing electronic dental record (EDR) informed by user-centred design approach of ‘think aloud’ user testing/		
	WHAT		
3.	The training package included an introductory lecture and a short training video (the training video is specific to the electronic dental record (EDR) used in the feasibility test institution. Colour images of the clinician-important and patient-important outcomes of the MDS were printed, laminated and displayed by clinic PCs Patient-important outcome questionnaire (paper-based) for different-age groups (7-10year, 11-14 years and 15-16 years)	Pg 113	
4.	1. Clinician-important outcomes 2. Patient-important outcomes Paper-based questionnaires were given to patients on arrival at reception (by reception staff) and asked to complete them. The patient handed them to the clinician at the start of the appointment and the clinicians used them as prompts to complete the patient-important outcomes on the EDR.	Pg 113	questionnaires are available in Appendix Figure d.1
	WHO PROVIDED		
5.	Reception staff distributed the patient questionnaires. No training provided.	Pg 113	______________

	Dentists recorded the patient-important and clinician-important outcomes in the appropriate section of the EDR. Dental trauma clinic is a consultant-led clinic. Treatment is undertaken by specialty dentists (general dentists with special interest in paediatric dentistry) and specialty trainees (both postgraduate and NHS trainees in paediatric dentistry).		
	HOW		
6.	The Clinical Director and Department Clinical Lead gave permission for the MDS-TDI to be integrated into the 'live' version of the EDR. Therefore, every patient who attended for assessment or management of a TDI had the MDS-TDI outcomes recorded as part of their clinical record.	Pg 113	______________
	WHERE		
7.	The LDI is a tertiary referral centre and as such receives referrals from across North and West and Yorkshire with a total population of just under 3.2 million inhabitants (datacomms, 2019). Children and young people are referred for assessment and specialist management of TDI	Pg 111	______________
	WHEN and HOW MUCH		
8.	The MDS-TDI outcomes were recorded for every patient who attended the bi-weekly dental trauma clinic from June-September 2023. A mean number of 8 patients were seen per clinic, and there were a total of 92 patient appointments in the three months study period.	Pg 113	______________
	TAILORING		

9.	N/A	______	______
	MODIFICATIONS		
10.[ǂ]	N/A	______	______
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Pg 116	______
12.[ǂ]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	See Table 5.2,5.3 pg 117,118	______

** **Authors -** use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

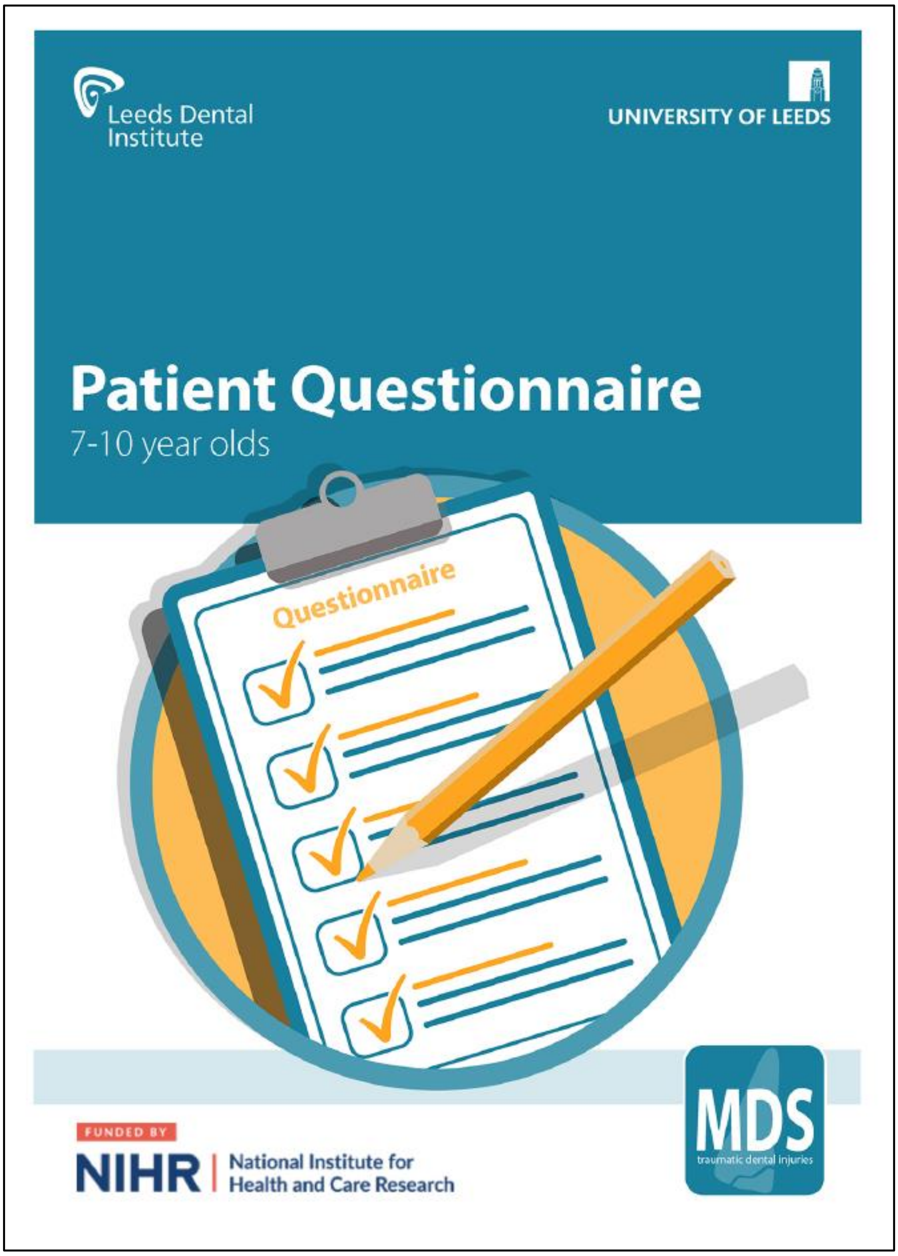
ǂ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see

www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Figure d.1 Example of patient questionnaires



Leeds Dental Institute

UNIVERSITY OF LEEDS

Patient Questionnaire

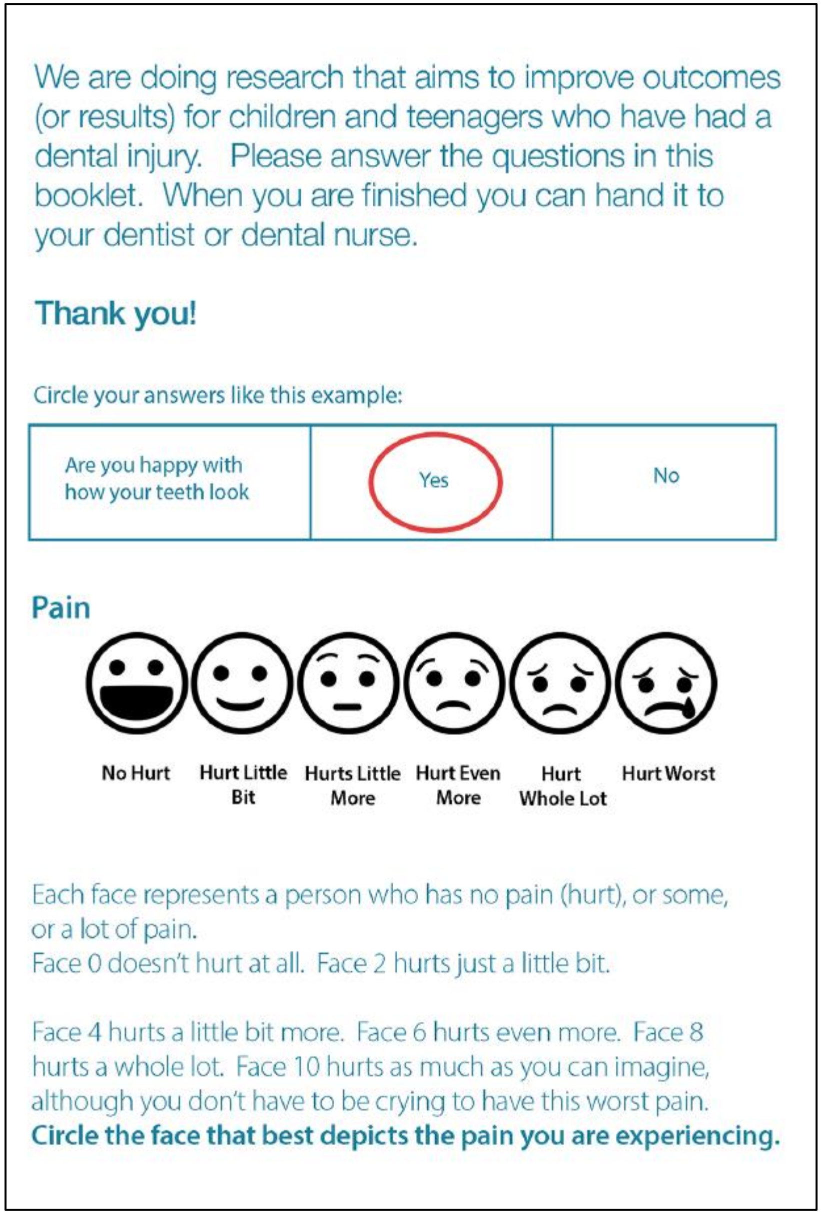
7-10 year olds

FUNDED BY

NIHR | National Institute for Health and Care Research

MDS

traumatic dental injuries



We are doing research that aims to improve outcomes (or results) for children and teenagers who have had a dental injury. Please answer the questions in this booklet. When you are finished you can hand it to your dentist or dental nurse.

Thank you!

Circle your answers like this example:

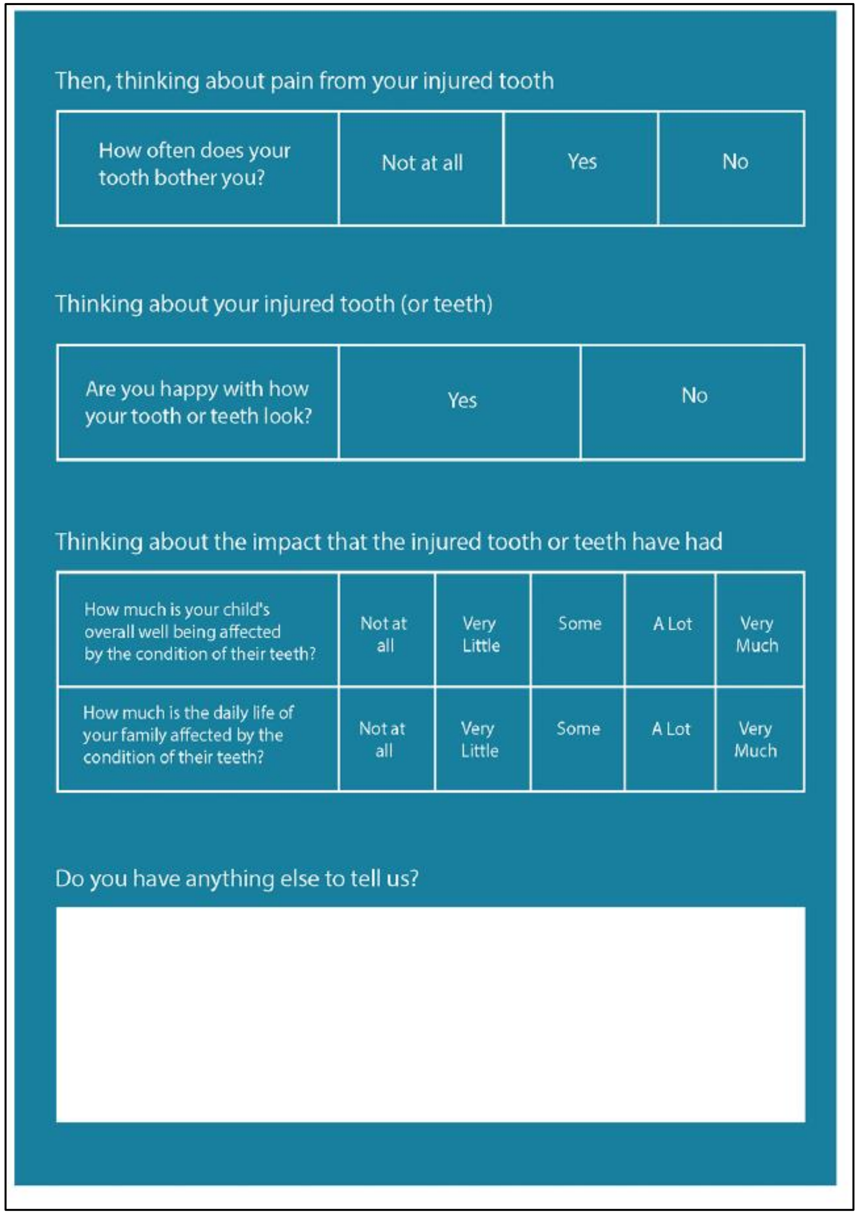
Are you happy with how your teeth look	[✓ Yes]	No

Pain

No Hurt	**Hurt Little Bit**	**Hurts Little More**	**Hurt Even More**	**Hurt Whole Lot**	**Hurt Worst**

Each face represents a person who has no pain (hurt), or some, or a lot of pain.
Face 0 doesn't hurt at all. Face 2 hurts just a little bit.

Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurts a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.
Circle the face that best depicts the pain you are experiencing.



Then, thinking about pain from your injured tooth

How often does your tooth bother you?	Not at all	Yes	No

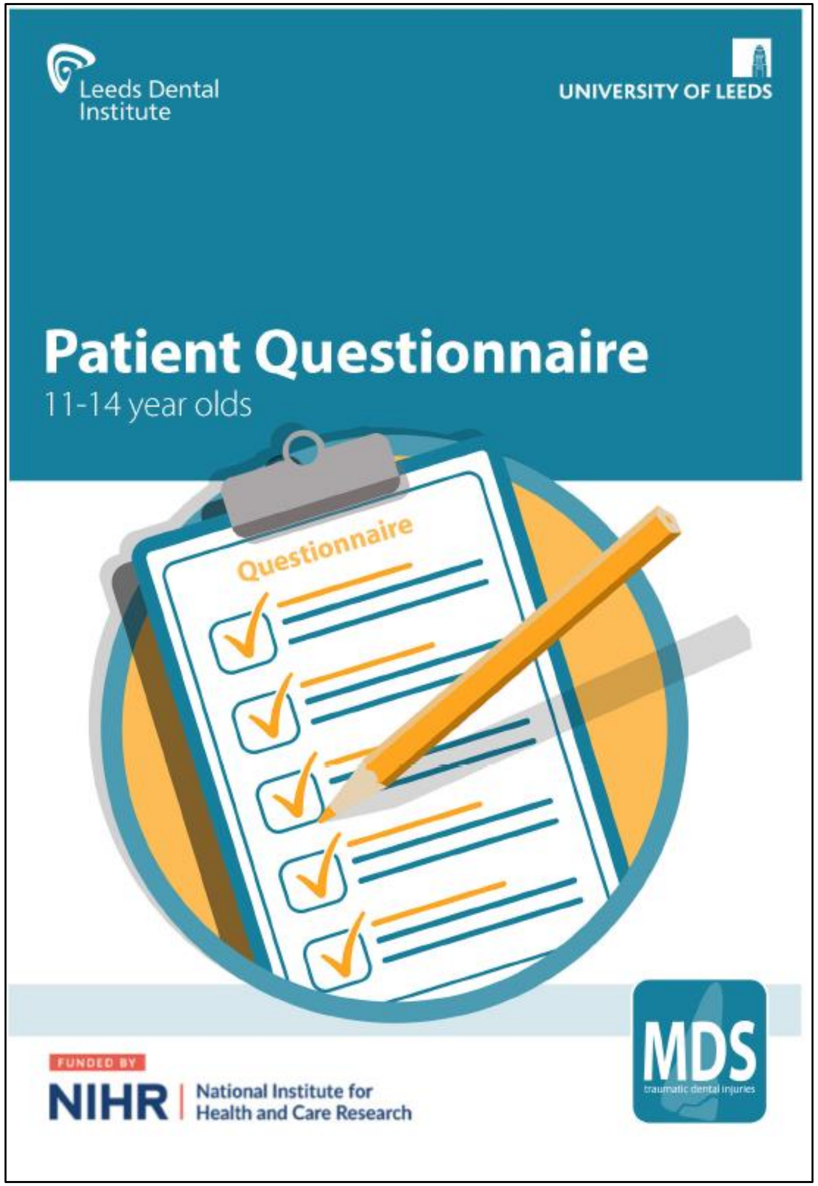
Thinking about your injured tooth (or teeth)

Are you happy with how your tooth or teeth look?	Yes	No

Thinking about the impact that the injured tooth or teeth have had

How much is your child's overall well being affected by the condition of their teeth?	Not at all	Very Little	Some	A Lot	Very Much
How much is the daily life of your family affected by the condition of their teeth?	Not at all	Very Little	Some	A Lot	Very Much

Do you have anything else to tell us?



Leeds Dental Institute

UNIVERSITY OF LEEDS

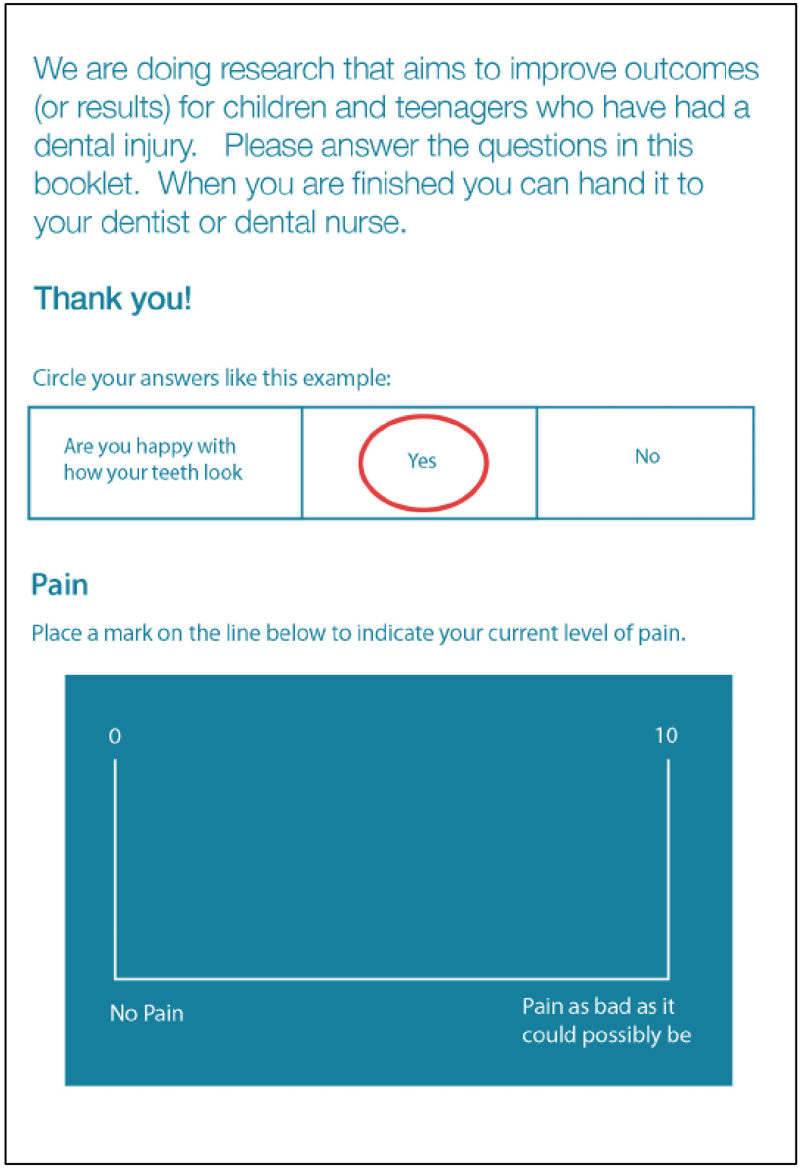
Patient Questionnaire

11-14 year olds

FUNDED BY

NIHR | National Institute for Health and Care Research

MDS
traumatic dental injuries



We are doing research that aims to improve outcomes (or results) for children and teenagers who have had a dental injury. Please answer the questions in this booklet. When you are finished you can hand it to your dentist or dental nurse.

Thank you!

Circle your answers like this example:

Are you happy with how your teeth look	[✓ Yes]	No

Pain

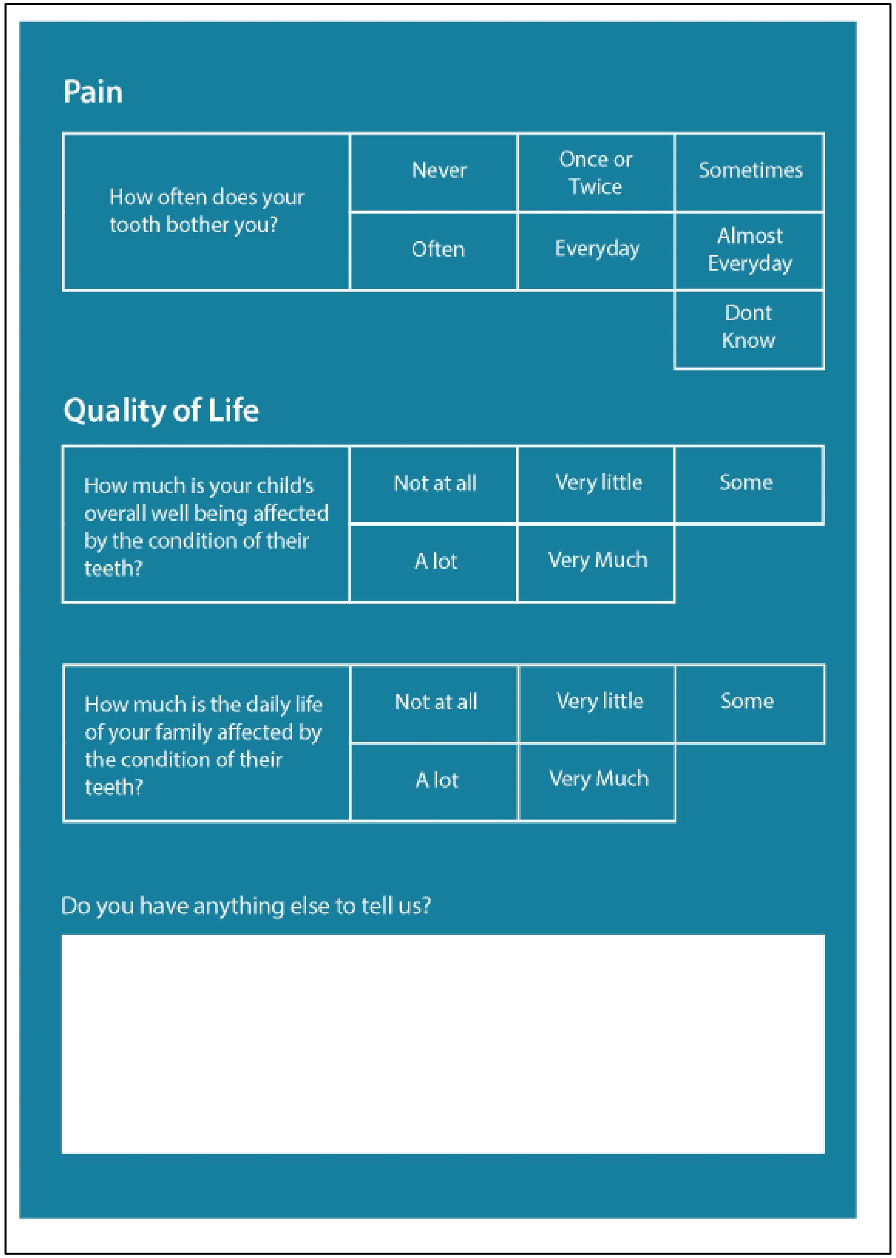
Place a mark on the line below to indicate your current level of pain.

0

10

No Pain

Pain as bad as it could possibly be



Pain

How often does your tooth bother you?	Never	Once or Twice	Sometimes
	Often	Everyday	Almost Everyday
			Dont Know

Quality of Life

How much is your child's overall well being affected by the condition of their teeth?	Not at all	Very little	Some
	A lot	Very Much	

How much is the daily life of your family affected by the condition of their teeth?	Not at all	Very little	Some
	A lot	Very Much	

Do you have anything else to tell us?

Leeds Dental Institute

UNIVERSITY OF LEEDS

Patient Questionnaire

15-16 year olds

FUNDED BY
NIHR | National Institute for Health and Care Research

MDS
traumatic dental injuries

We are doing research that aims to improve outcomes (or results) for children and teenagers who have had a dental injury. Please answer the questions in this booklet. When you are finished you can hand it to your dentist or dental nurse.

Thank you!

Circle your answers like this example:

Are you happy with how your teeth look	[✓ Yes]	No

Pain

Place a mark on the line below to indicate your current level of pain.

0 — 10

No Pain

Pain as bad as it could possibly be

Pain

How often does your tooth bother you?	Never	Once or Twice	Sometimes
	Often	Everyday	Almost Everyday
			Dont Know

Quality of Life

How would you rate the health of your teeth	Very Good	Good
	OK	Poor

How much do your teeth or mouth bother you?	Very Good	Good
	OK	Poor

Aesthetics

Are you happy with how your tooth or teeth look?	Yes	No

Do you have anything else to tell us?

Figure d.2 Focus group topic guide.

Interview Topic Guide

Background Information

- How long have you been working in Paeds Trauma Clinic?
- How many years have you been working at the trust?

Coherence:

- What do you think a Minimum Dataset is and what does it do?
- How do you think the Minimum Dataset differs from your usual clinical records
- What do you think the benefits of the Minimum Dataset will be and for whom?
- What do you think the reasons for introducing it are?
    - Were you made aware of this formally (I.e. by Clinical Lead) and if so how (e.g. at departmental meeting?)
- How do you think the MDS fits in with the overall aims/ambitions of the Trust/Department

Cognitive Participation

- Do you have any concerns about the MDS?
- Do you think the MDS is a good idea?
- Have you had any training or support explaining how to use the MDS or its introduction?
- Are there any staff dedicated to helping you use it?
- Have you been given any dedicated time to get used to the new system or attend on-going training?

Collective Action

- How do you think using the MDS impacted your practice
    - Did it help or impede you?
- How does using the MDS fit with existing work practices?

Reflexive Monitoring

- What do you think will be the long-term benefits of the MDS?
- What barriers do you think there will be to using it?
- What disadvantages do you think there will be to using it?
- Will there be opportunity for users to feedback or adapt/improve the MDS?

End of Interview

→ *Thank participant and ask if they have any other comments*
→ *Explain again about how data will be used and reiterate about anonymity and confidentiality*

→ *Provide opportunity for questions and state that PI is contactable after the interview should questions arise*