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ORIGINAL ARTICLE

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 Methods: 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, five children and six parents. Two key themes emerged from the analysis—communication and aesthetics. In Stage 2, 34 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, 15 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.

KEYWORDS
classification, dental trauma, record

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 judgements, 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.[6–8] 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.[9]

A Core Outcome Set (COS) for TDI was published in 2018,[10] 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.[11] Minimum datasets have been developed in various medical specialities.[12–14] 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.[15]

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[9] 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,[16] 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.

2 | MATERIALS AND METHODS

This is a three-stage sequential, mixed-methods study, using evidence-based best practice for dataset development[17] (Figure 1). Normalisation process theory (NPT) was used in the development of the study protocols (Table S1). This theory identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice.[18] 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—that is it becomes normalised.[19]

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 2 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 (Data S1). 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.[20] Outcomes from the previously published Core Outcome Set for TDI[10] were used to develop a two-stage Delphi survey. Outcomes were listed by injury type (see Table 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 were 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.

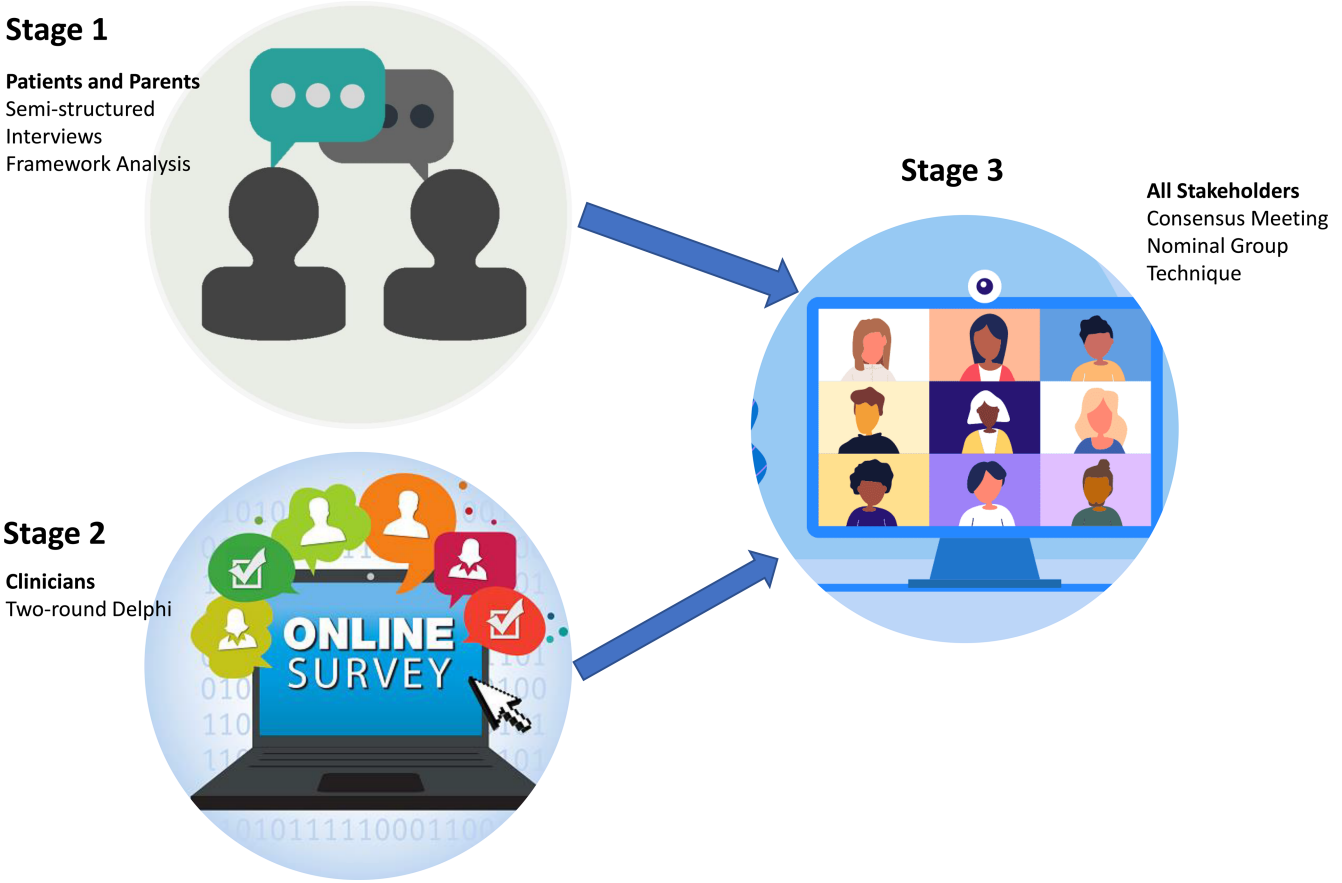

FIGURE 1 Study methodology—Results from Stage 1 and Stage 2 were brought forward to Stage 3.

TABLE 1 Outcomes included in Delphi survey.

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	

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'.

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 1 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[10] 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 (Table S2). 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.[21] 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).[22] 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.[22,23] 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 | RESULTS

Stage 1: Eleven participants were recruited, five children and six 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 2) were recruited, and 32 completed both rounds of the survey (97% retention). Just over half

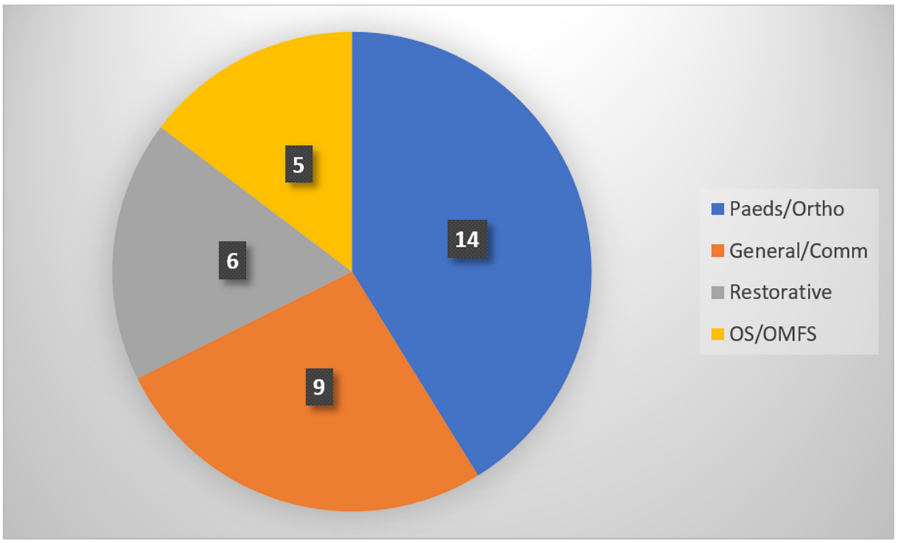

FIGURE 2 Clinicians recruited to Delphi study.

TABLE 2 Median and IQR for Intrusion injuries—Round 1.

	Combined		GDP		Paed		Rest		OS	
Outcome	M	IQR	M	IQR	M	IQR	M	IQR	M	IQR
Periodontal—bone loss	7	3	7	3	8	2.75	7	2.25	5	4
Periodontal—gingival recession	7	3	7	4	8	2.75	6.5	2.5	6	2
Periodontal—mobility	9	2	9	2	9	0.75	8	2.75	7	1
Periodontal—ankylosis	9	2	9	2	9	0	9	1.5	7	2
Periodontal—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

Note: Green indicates the outcome is of critical importance, amber/orange indicates the outcome is deemed important.

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.

In the first round, participants were asked to grade each outcome by injury type. Table 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 shows an example of the bar charts included in the Round 2 survey.

Table 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.

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, that is 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 4).

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 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

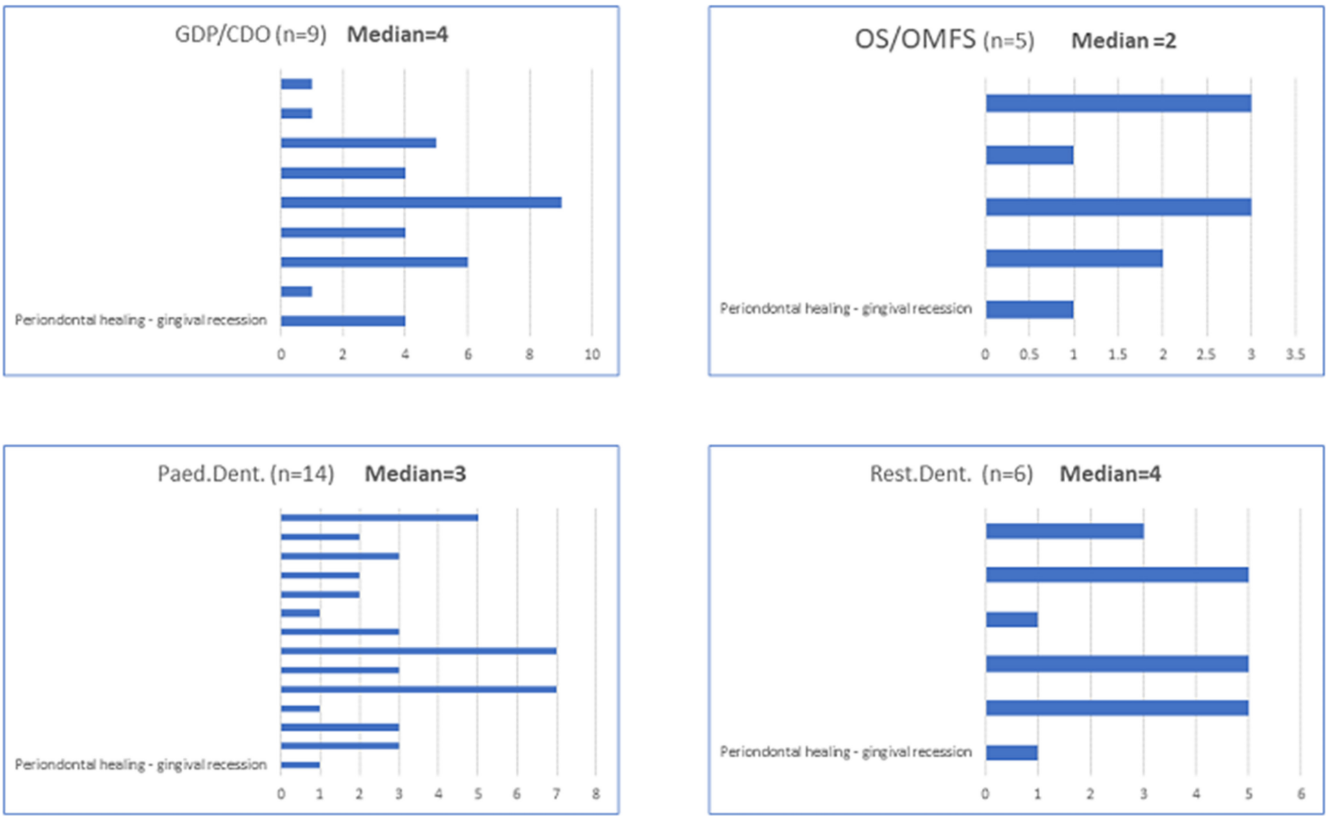

FIGURE 3 Example of bar chart of median scores included in Delphi survey Round 2.

TABLE 3 Median and IQR for intrusion injuries—round 2.

	Combined		GDP		Paed		Rest		OS	
Outcome	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

Note: Green indicates the outcome is of critical importance, amber/orange indicates the outcome is deemed important.

TABLE 4 Outcomes for discussion (with explanation in lay language) at the consensus meeting.

Outcome	Description
Aesthetics	How it looks
Communication[a]	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

[a]Communication was one of the key areas of importance when interviewing patients and parents about their experience of treatment for dental trauma. However, 'Communication' is really difficult to 'measure' as an outcome! We have some time during the meeting to chat about this in more detail.

Patient recorded certainly felt like it helped to clarify approaching the minimum data set' (Participant 10, Patient Representative).

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 4). It has been decided to use the same outcome measurement instruments as those set out by the COS-TDI[10] 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 predefined standards which, when coupled with effective performance feedback methods can lead to data-driven improvement of healthcare delivery and hence improved patient outcomes.[24]

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'.[25] The IADT has endorsed the Core Outcome Set for TDI which was published in 2018,[10] and aims to standardise recording of outcomes in clinical trials. In March 2022, a revision of the International Classification of Diseases (ICD) was published.[26] It now includes more detailed codes on dental trauma, allowing for better data collection and surveillance.[27] For the first time, TDI is mentioned in the WHO global oral health report.[28] 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.[29] This has long been identified as an issue in NHS primary dental care.[30]

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. Table S1 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.[31] 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.[32] 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

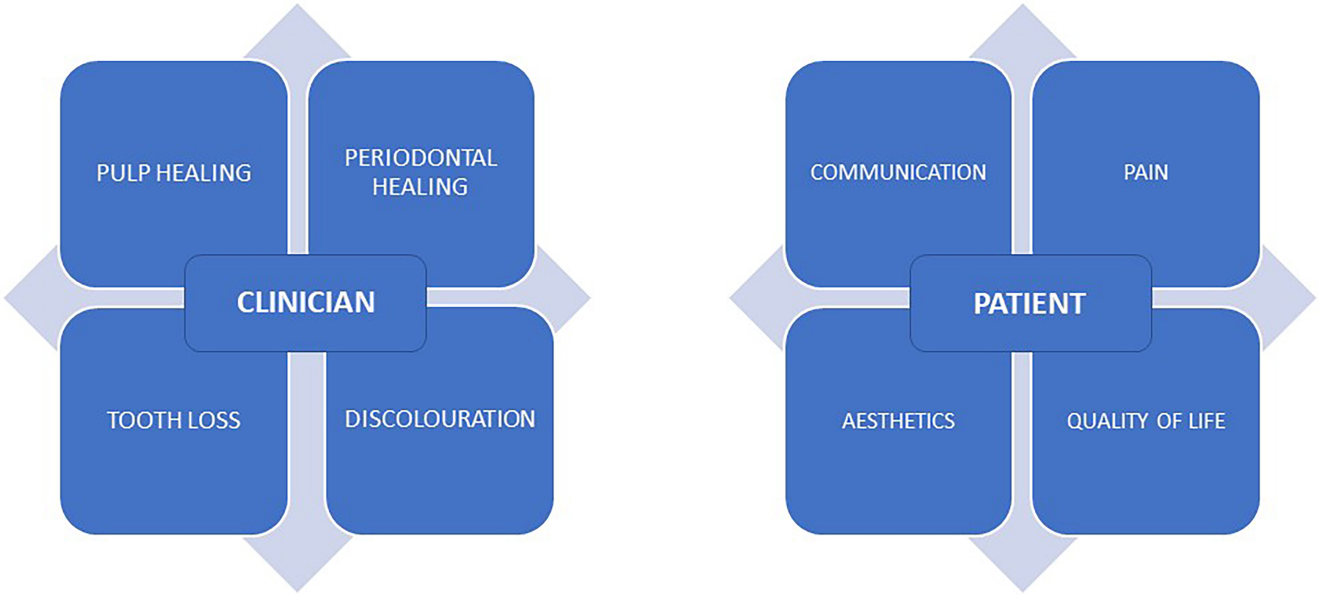

FIGURE 4 MDS-TDI: Clinician-important and Patient-important outcomes.

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'.[17] 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.[17] 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 panelists 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.[17,39] 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.[17,40] 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 judgements of respondents.[43] Delphi studies generally use median scores to summarise the first sort of agreement, that is 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 has 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[20,39]; 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.

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 both clinically and those valued by patients across a range of scenarios.

AUTHOR CONTRIBUTIONS

All authors contributed to concept, design, data analysis, manuscript preparation and final review. KK was responsible for delivery and data collection.

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CONFLICT OF INTEREST STATEMENT

None of the authors declare any conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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