What are the important outcomes in traumatic dental injuries? An international approach to the development of a core outcome set

Kate P. Kenny[1]| Peter F. Day[1] | Mohammad O. Sharif[2] | Peter Parashos[3] | Eva Lauridsen[4] | Carlos Alberto Feldens[5]| Nestor Cohenca[6]| Tony Skapetis[7] | Liran Levin[8] | David J. Kenny[9]| Serpil Djemal[10] | Olle Malmgren[11] | Yong-Jin Chen[12] | Misuhiro Tsukisboshi[13] | Lars Andersson[14]

[1]Department of Paediatric Dentistry, School of Dentistry, University of Leeds, Leeds, UK

[2]Departments of Orthodontics, Eastman Dental Hospital and Croydon University Hospital, London, UK

[3]Department of Restorative Dentistry, Melbourne Dental School, University of Melbourne, Melbourne, Vic., Australia

[4]Resource Center for Rare Oral Disease, University Hospital Copenhagen, Rigshospitalet, Copenhagen, Denmark

[5]Department of Paediatric Dentistry, School of Dentistry, Universidade Luterna do Brasil, Porto Alegre, Brazil

[6]Lakeside Endodontics, University of Washington and Seattle Children's, Seattle, WA, USA

[7]Faculty of Dentistry, Oral Health, Western Sydney LHD, University of Sydney, Sydney, NSW, Australia

[8]Division of Periodontology, Faculty of Medicine and Dentistry, School of Dentistry, University of Alberta, Edmonton, AB, Canada

[9]Department of Dentistry, The Hospital for Sick Children and School of Graduate Studies, University of Toronto, Toronto, ON, Canada

[10]Department of Restorative Dentistry, King's College Dental Hospital, Denmark Hill, London, UK

[11]Orthodontic Clinic, Tandregleringen, Huddinge, Stockholm, Sweden

[12]State Key Laboratory of Military Stomatology, Department of General Dentistry and Emergency, School of Stomatology, The Fourth Military Medical University, Xian, China

[13]Tsukiboshi Dental Clinic, Aichi, Japan

[14]Department of Surgical Sciences, Faculty of Dentistry, Health Sciences Center, Kuwait University, Kuwait, Kuwait

Correspondence:

Kate P. Kenny, Department of Paediatric Dentistry, School of Dentistry, University of Leeds, Leeds, UK. Email: K.Counihan@leeds.ac.uk

ABSTRACT

Background/Aims: There are numerous treatment options following traumatic dental injury (TDI). Systematic reviews of different treatments are challenging owing to the diversity of outcomes reported between clinical studies. This issue could be addressed through the development and implementation of a agreed and standardized collection of outcomes known as a core outcome set (COS). The aim of this study was to develop a COS for TDI in children and adults. The secondary aim was to establish what, how, when and by whom these outcomes should be measured.

Materials and Method: The project was registered with Core Outcomes Measures in Effectiveness Trials (COMET). A web-based survey was developed to capture the opinions of dentists globally as to which outcomes should be recorded. A list of outcomes was entered into a Delphi Survey and scored by an Expert Working Group (EWG). The scoring was repeated, followed by conference calls to discuss, refine and finalize the COS. The EWG split into small groups of subject-specific experts to determine how, when and by whom each outcome would be measured.

Results: The questionnaire was completed by 1476 dentists. The EWG identified 13
core outcomes to be recorded for all TDI's. An additional 10 injury-specific outcomes were identified. A table has been produced for each outcome detailing what, when,
and how each outcome should be recorded.

Conclusions: A robust consensus process was used to develop an international COS for TDI in children and adults. This includes both generic and injury-specific outcomes across all identified domains.

KEYWORDS

dento-alveolar trauma, diagnosis, prognosis, record, treatment

1 | INTRODUCTION

Dental trauma is common and can occur throughout the life course with prevalence reported at 20%–30%.[1] Numerous treatment options and interventions are possible, depending on the specific traumatic injury sustained. Dental trauma has been shown to have significant financial and social costs for the child, their family and to funders of health services.[2,3] Evidence-based comparisons of treatments and interventions can be challenging due to the diversity of outcomes reported in clinical studies. A recent systematic review identified significant heterogeneity in outcomes reported for TDI in the literature.[4] Such heterogeneity can result in substantial outcome-reporting bias.[5] It also precludes meaningful meta-analysis between studies. Indeed, a call for the standardization of outcomes is a regular conclusion of systematic reviews.[6]

An outcome is a clinical measure used to make judgements about the efficacy of treatment. However, outcome measures also represent the suffering or loss of health experienced by an individual as a result of the process of disease.[7] Therefore, outcomes need to be relevant to patients, clinicians and policy makers if the findings of research are to influence practice and future research. Sharif and colleagues[4] identified that patient-related outcomes were particularly poorly represented in dental trauma literature, with no outcomes reported for quality of life or family outcomes. These issues can be addressed through the development and use of an agreed standardized collection of outcomes, known as a core outcome set (COS). Core outcome sets increase the likelihood that important outcomes are measured, improve evidence synthesis by reducing heterogeneity between studies and reduce outcome-reporting bias.[8] Adoption of a COS does not imply that a particular study or review should be restricted only to these outcomes but rather act as a foundational framework of measured outcomes. The expectation is that, as a minimum, the core outcomes will always be collected and reported,[9] but researchers will continue to explore additional outcomes. Successful implementation of a COS for rheumatoid arthritis, for example, has resulted in improved harmonization of research by establishing outcomes that are now more frequently measured by researchers.[10]

The primary aim of this study, therefore, was to use a robust consensus process to develop an international COS for TDI in children and adults. The secondary aim was to identify when, how and by whom these outcomes should be measured.

2 | MATERIALS AND METHOD

A protocol with explicitly defined objectives, consensus development methods and criteria for participant selection was developed and published on the International Association of Dental Traumatology (IADT) website (http://www.iadt-dentaltrauma.org/CoreOutcomeSet.html). The study design is summarized in Figure 1. The study was prospectively registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative [registration number 601 available online at http://www.comet-initiative.org/studies/details/601].

An Expert Working Group (EWG) was established, who supported the Research Team in delivering the project. A foundational systematic literature review of TDI outcome measures was undertaken.[4] Further outcomes were identified via a web-based questionnaire to dentists from around the world using Survey Monkey. For each injury, dentists were asked which outcomes should be included via free text and discrete yes/no questions. By contacting multiple dental professional organizations, dentists were asked to complete the online survey. The Research Team then reviewed all the outcomes and identified those that were duplicated as a result of varied terminologies, and those not meeting the criteria of an outcome were removed.[7] Outcomes were then organized into six domains (injury activity, physical consequences of injury, functional status, social outcomes and quality of life, side effects of therapy and health resources utilization).

A two-round electronic Delphi survey design was undertaken by the EWG. The EWG were asked to rate the importance of each outcome on a 9-point Likert scale score between 1 “limited importance” and 9 “critical importance.” Such a scale was recommended by the Grading of Recommendations Assess, Development and Evaluation (GRADE) working group.[11] The mean score results from the first round were included in the questionnaire for the second round so that the EWG members could consider these values while completing the survey. The EWG were then asked to score all the individual outcomes again, using the same 9-point Likert scale.

Consensus was considered a priori. Core outcomes 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.”[12] Outcomes excluded in the core outcome set required at least 70% to score the outcome as “limited importance” and less than 15% to score the outcome as “critical.” If outcomes did not meet either criteria they were classified as outcomes with no consensus. The scores were collated and results sent to the EWG. Two web-based conference calls were arranged where the outcomes with “no consensus” were discussed with the group and consensus reached as to whether these outcomes were to be included in the COS. Following agreement of the COS by the EWG, dentists who had completed the initial web-based survey were given a final opportunity via email, to make further comment on the COS.

To undertake the secondary aim, “how, when and by whom to record,” the EWG was asked to identify which outcomes aligned best to their individual areas of expertise. In addition, external experts were consulted for their opinions on several outcomes. Where possible, dental traumatology gold-standard outcome measurements were used, but if not available, best evidence-based outcome measurement tools were chosen. For some outcomes, no suitable outcome measurement yet exists. This was an iterative process with the research team developing each outcome table. The small teams taken from the EWG then provided comments and suggestions and a second draft of the table was drafted and commented on by the team. This iterative process continued until the small team reached consensus with the final outcome table. Once all outcome tables were finalized these were sent to the entire EWG. The EWG then had a final opportunity to comment on the entire COS by email and through further web-based conference calls.

3 | RESULTS

3.1 | Expert working group

A panel of nine invited experts was initially chosen. The nine invited EWG experts were from the field of dental traumatology. This ensured that each specialty area of dentistry involved in management of dental trauma, from a variety of geographical locations, was represented.

Three additional experts were then selected following an expression of interest among IADT members. Applications were then sought from the members of the IADT to join the EWG. Applicants were asked to write a short summary of their expertise and their reasons for wanting to participate. Twenty-one applications were received and the nine invited experts elected three further members. The final EWG members are listed in Table 1.

3.2 | Outcomes

Ten clinical studies met the inclusion criteria for the systematic review.[4] This review identified 14 primary outcomes. The web-based questionnaire was completed by 1476 dentists between September and October 2014 (Figure 2). A total of 1158 outcomes were suggested, and these were combined with the 14 primary outcomes from the systematic review. One hundred and ninety-three outcomes went through to the Delphi process, following the removal of duplicates and non-outcomes (Figure 3). The outcomes were grouped into the six outcome domains.

3.3 | Delphi

In rounds 1 and 2 of the survey, 100% of the EWG completed the scoring. Following collation of the scores in round 1, 68 outcomes were identified as "consensus in" and 4 outcomes were identified as "consensus out." All outcomes were entered into Round 2 and following this a further 3 outcomes were identified as "consensus in," and a further 7 outcomes were identified as "consensus out." The Research Team sent the final list of outcomes to the EWG prior to web-based conference calls to decide on "consensus in or out" outcomes.

3.4| Core outcome set

A number of outcomes were identified as recurring throughout the different injury types. These outcomes were then included as "generic" that is relevant to all TDI as reported in Table 2. The remaining or "injury-specific" outcomes were included in a separate table (Table 3)—that is those outcomes related only to one or more particular TDI.

3.5 | Outcome measurement—when, how and by whom

The EWG decided unanimously to measure the COS at the routine recall intervals as recommended by the IADT guidelines for different TDI.[13–15] These timelines are shown in Table 4. An outcome table was produced for each outcome and is included in supporting materials with an example shown in Table 5.

4 | DISCUSSION

Delphi methodology is a well-established method to achieve consensus, based on an iterative process with anonymous consultation and controlled feedback.[16] More widely used in medicine, it has also been applied in Dentistry relating to competencies and education.[17] Using this formal consensus method, the EWG has agreed on a core outcome set of 23 outcomes. The outcomes are relevant for children and adults and are appropriate for all TDI. It is anticipated that the outcomes will be used in future clinical and research studies, reviews and for helping to develop future guidelines for TDI.

This project is world leading, with just one other published COS in dentistry.[18] There are several strengths, notably compliance with guidelines for COS development as outlined by the COMET initiative.[6] Secondly, the COS was underpinned by a systematic review which is considered best practice. In addition however, further outcomes were identified following a questionnaire to dentists which was completed by 1476 dentists in over 30 different countries. This yielded many more outcomes than had been identified through the systematic review alone. Moreover, the involvement of these dentists was maintained by providing them a final opportunity to comment on the COS before the "how," "when" and "by whom" research objective was started. Thirdly, a Delphi exercise was used—this is a well-established method that has the advantage of capturing opinions of geographically distant participants compared with face-to- face discussions. This allows participants to reconsider their opinion without the pressure to agree with senior or domineering individuals.[16] Fourthly, the use of an international EWG is innovative, and allowed a broad range of experience from experts in a variety of dental specialties from across the world. The majority of the participants are prominent in their field and many have been involved in international guideline development. The group was highly motivated, which contributed to the 100% response rate to each phase of the Delphi process.

Although patients were not involved directly in the development of this COS, many outcomes relevant to patients have been included. In particular, these include the strong emphasis on oral health-related quality of life, which has been deemed of such importance that it is to be recorded for each patient, regardless of the severity of their dental injury. Other outcomes related particularly to patients include measurement of pain, discolouration, patient perception of the quality of any restoration present and the levels of dental anxiety following the injury. This will be the first time that data such as this has been collected in the routine clinical setting, and as such is likely to increase clinicians understanding of how TDI impacts patients and their families both immediately after the injury and over the often long, follow-up period. Finally, many COS established across medicine have simply identified what core outcomes should be recorded. This COS is one of the very few outcome sets where the authors have continued the development process and identified the "how," "when" and "by whom" for each outcome. Although this study was completed prior to the publication of written guidelines about how to select outcome measurement instruments,[19] and how to report studies developing COS,[20] it is pleasing to note that that this study has complied with many of established across medicine have simply identified what core outcomes should be recorded. This COS is one of the very few outcome sets where the authors have continued the development process and identified the "how," "when" and "by whom" for each outcome. Although this study was completed prior to the publication of written guidelines about how to select outcome measurement instruments,[19] and how to report studies developing COS,[20] it is pleasing to note that that this study has complied with many of their recommendations in methodology design and in the selection of outcome measures.

The first limitation of the study is the lack of patient and parent (when applicable) involvement. This is an important limitation because patients can identify outcomes not considered by other stakeholders or within the literature.[21,22] Sharif and colleagues[4] also identified a paucity of patient-reported outcomes in their systematic review, which again highlights the lack of engagement with patients and their parents in designing appropriate research methodology.

All participants acknowledge that patient input is extremely important but how to manage this in a group like the EWG was unclear. As discussed above, many outcomes related to patients have been included in the COS. There is a feeling that patient outcomes may differ from region to region and may be related to how health services are delivered in individual countries. Work is underway in the UK with patients and their parents (where indicated) to identify other potential outcomes of importance but, importantly, also to explore what patients think about using some of the outcome measurements that have been chosen—for example the OHIP short form for assessing oral health-related quality of life.[23]

A second limitation surrounds the use of the questionnaire instrument sent to dentists across the world. The questionnaire was not validated, and it is possible that some outcomes may have been missed. It also must be acknowledged that only 1144 responses from a global pool of dentists may not be accurate or representative, which may have biased the results. A further limitation is the lack of other stakeholder involvement such as government bodies, policy makers and other professionals such as emergency doctors and nurses who may regularly treat TDI. Their outcomes of importance may be very different to those of dental specialists. However, much like the patient-reported outcomes, there is a feeling that the other stakeholders may have very different views on TDI from country to country. Further work is needed to explore these potential differences between countries prior to inclusion of other outcomes in an international COS.

It is important to emphasize that a COS is dynamic and will require review and adjustment in the future. One obvious area is where no validated outcome measures were identified. This included pulp repair and necrosis with infection, pain in young children and how to measure the frequency of pain, quality of restoration and root maturation (supporting materials). For each of these outcome tables, a pragmatic measurement tool to evaluate the outcome was chosen while clearly identifying to readers, clinicians and researchers the need for further research in these areas.

Consistency of measurements and reporting of COS in clinical studies and trials is only the first step in the attempt to improve the quality of research and to reduce waste and duplication of effort.[24] Journal editors, funders and review boards also have an important role encouraging and or mandating the use of COS in research while at the same time advertising that this is a core dataset and encouraging researchers to collect other data as well. Before mandating that the COS is used in research and clinical case series submitted to dental journals, implementation research is needed to ensure the COS is "fit for purpose."

5 | CONCLUSIONS

A Core Outcome Set has been developed for Traumatic Dental Injuries for both children and adults using the Delphi research methodology. How, when and by whom to measure these outcomes have also been reported. Implementation will ensure that data from clinical studies and trials may be better compared, contrasted and/or combined leading to improved research outcomes. This may facilitate future treatment guidelines relating to TDI.

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CONFLICT OF INTEREST

The authors confirm that they have no conflict of interest.

ORCID

Kate P. Kenny http://orcid.org/0000-0001-9076-5856
Carlos Alberto Feldens http://orcid.org/0000-0002-9783-9309
Nestor Cohenca http://orcid.org/0000-0002-0603-5437
Liran Levin http://orcid.org/0000-0002-8123-7936

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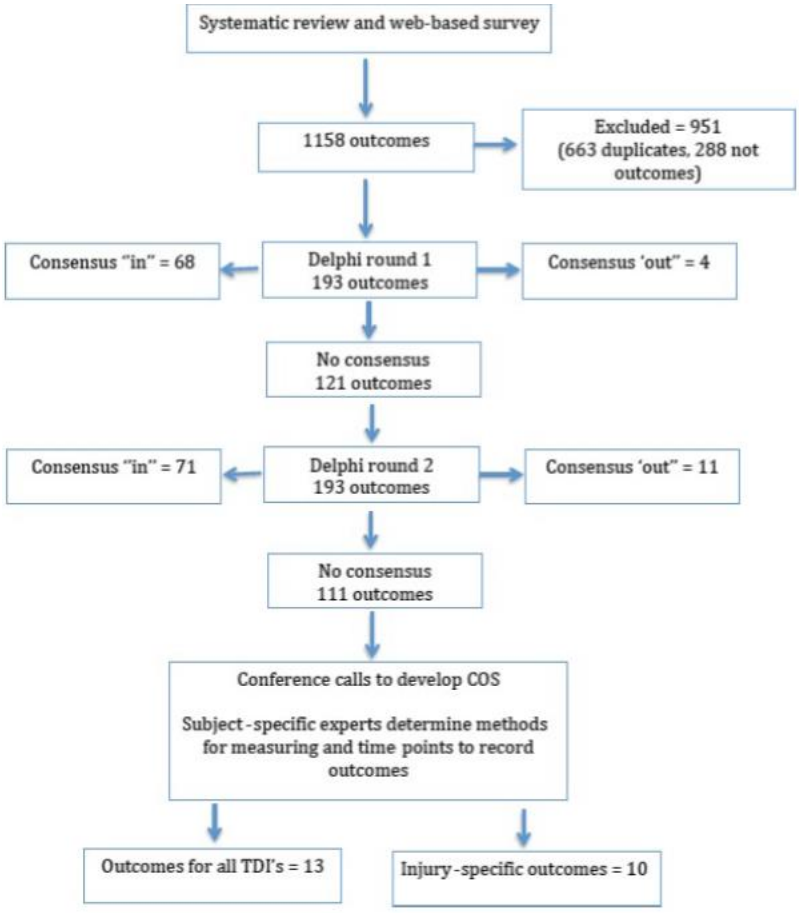

FIGURE 1 Study design summary

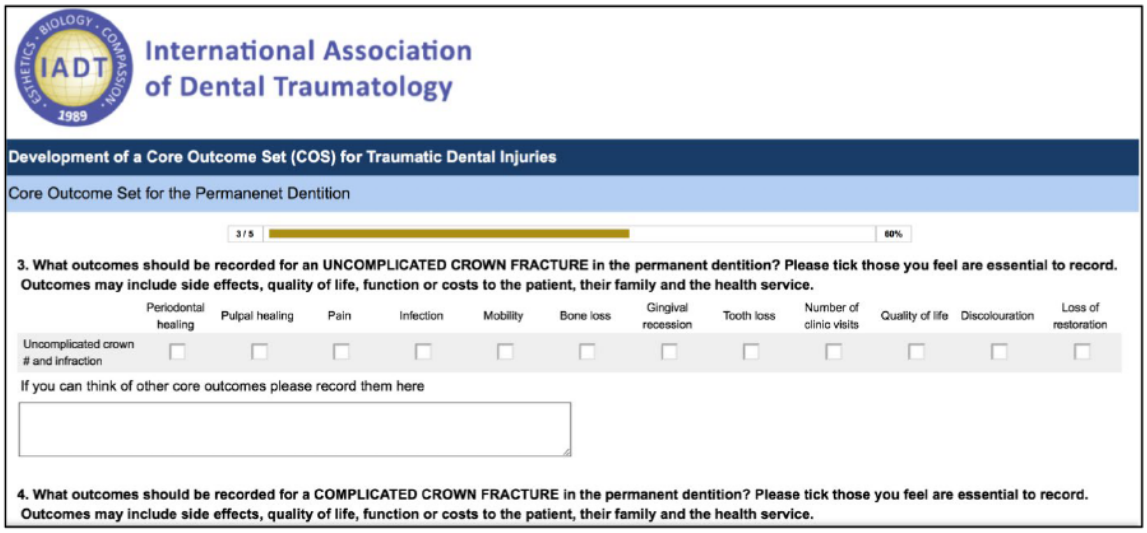

FIGURE 2 Screenshot from web-based survey to capture opinions of dentists from around the world

FIGURE 3 It is best practice when developing a core outcome set to ensure outcomes from each of six domains are included

TABLE 1 Expert working group

Name	Location	Specialty
Lars Andersson	Kuwait	Oral and Maxillofacial Surgery
Yongjin Chen	China	General & Emergency Dentistry
Nestor Cohenca	USA	Endodontics
Serpil Djemal	UK	Restorative
Carlos Feldens	Brazil	Paediatrics/Epidemiology
Dave Kenny	Canada	Paediatrics
Eva Lauridsen	Denmark	Paediatrics
Liran Levin	Israel	Periodontology
Olle Malmgren	Sweden	Orthodontics
Peter Parashos	Australia	Endodontics
Tony Skapetis	Australia	Emergency Dentistry
Mitsuhiro Tsukiboshi	Japan	General Dental Practice

TABLE 2 Core outcome set—generic outcomes

Domains	Generic outcomes
Injury activity	Periodontal healing [to include bone loss, gingival recession, mobility, ankylosis and resorption]
	Pulpal healing [to include infection]
Physical consequences of disease	Pain
	Discolouration
Functional status	Tooth loss [to include premature loss for primary teeth]
Social outcomes and quality of life	Quality of Life [to include days off work, school or sport]
	Aesthetics [patient perception]
Side effects of therapy	Trauma-related dental anxiety
Health resource utilization	Number of clinic visits

TABLE 3 Core outcome set – injury specific outcomes

	Injury							
Domains	**Uncomplicated crown fracture**	**Complicated crown fracture**	**Crown root fracture**	**Root fracture**	**Extrusion, lateral luxation, alveolar fracture**	**Intrusion, avulsion**	**Immature non-vital permanent teeth**	**Primary teeth**
Injury activity				Root fracture site repair			Late stage crown fracture	
Physical consequences of disease			Mobility	Mobility	Infraocclusion	Re-alignment[1]	Root length	Re-alignment[1]
							Root width	Impact on permanent successor
Functional status	Quality of restoration	Quality of restoration	Quality of restoration					
Side effects of treatment	Loss of restoration	Loss of restoration	Loss of restoration					

TABLE 4 When to measure outcomes

	Review									
Injury	1 wk	2 wk	4 wk	6-8 wk	3mo	4mo	6mo	1 yr	Yearly for 5 yrs	5 yrs
Uncomplicated crown fracture				√				√		
Complicated crown fracture				√				√		
Crown root fracture				√				√		
Root fracture			√	√		√		√		√
Concussion			√	√				√		
Subluxation		√	√	√			√	√		
Extrusion, lateral luxation,		√	√	√			√	√	√	
Alveolar fracture			√	√		√	√	√		√
Intrusion		√	√	√			√	√	√	
Avulsion	√		√		√		√	√	√	

TABLE 5 How to measure outcomes—example of Trauma-related dental anxiety

Domain	Generic Outcome	Measurement and rationale	Time points for assessment of outcomes
Side effects of therapy	Trauma-related dental anxiety	What to record: Levels of dental anxiety immediately after the accident and at various time points throughout the treatment. A traumatic dental injury in childhood has been shown to lead to increased levels of dental anxiety in some patients[a]. Definition: Anxiety is a feeling of apprehension characterised by fear, tension, nervousness or restlessness. A traumatic dental injury in childhood has been shown to lead to increased levels of dental anxiety in some patients[a]. How: Children aged 5-8 year: Facial Image Scale[b] Children aged 8-12 years: Faces version of the Modified Child Dental Anxiety Scale [$MCDAS_f$][c] Age 12 and over: Kleinknecht's DFS Dental Fear Survey and/or Corah's DAS Dental Anxiety Scale [d,e,f,g] By Whom: by a dentist *[or a member of the wider clinical team with appropriate training]*	When: At the time of the injury 3 months 1 year

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