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Original Article

Novel Textbook Outcomes following emergency laparotomy: Delphi exercise

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Abstract

Background: Textbook outcomes are composite outcome measures that reflect the ideal overall experience for patients. There are many of these in the elective surgery literature but no textbook outcomes have been proposed for patients following emergency laparotomy. The aim was to achieve international consensus amongst experts and patients for the best Textbook Outcomes for non-trauma and trauma emergency laparotomy.

Methods: A modified Delphi exercise was undertaken with three planned rounds to achieve consensus regarding the best Textbook Outcomes based on the category, number and importance (Likert scale of 1–5) of individual outcome measures. There were separate questions for non-trauma and trauma. A patient engagement exercise was undertaken after round 2 to inform the final round.

Results: A total of 337 participants from 53 countries participated in all three rounds of the exercise. The final Textbook Outcomes were divided into 'early' and 'longer-term'. For non-trauma patients the proposed early Textbook Outcome was 'Discharged from hospital without serious postoperative complications (Clavien–Dindo ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation or death). For trauma patients it was 'Discharged from hospital without unexpected transfusion after haemostasis, and no serious postoperative complications (adapted Clavien–Dindo for trauma ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation on or death)'. The longer-term Textbook Outcome for both non-trauma and trauma was 'Achieved the early Textbook Outcome, and restoration of baseline quality of life at 1 year'.

Conclusion: Early and longer-term Textbook Outcomes have been agreed by an international consensus of experts for non-trauma and trauma emergency laparotomy. These now require clinical validation with patient data.

Introduction

There has been a recent increase in interest in the use of Textbook Outcomes (TOs) for elective surgery, including colorectal[1], oesophagogastric[2], bariatric[3], hepatobiliary[4], gynaecological[5] and cardiac[6] surgery. These TOs are composite outcome measures that seek to better describe the 'ideal' outcome for patients. Rather than using single outcome measures such as 'survival' or 'length of stay', an example of a TO may be 'survival following radical resection with no major complications, no reintervention, no unplanned stoma and no prolonged stay or readmission'[7]. TOs may therefore be more patient-centred, as well as enabling centres to assess performance[2], develop new programmes[8] and investigate risk factors for poorer outcomes[9].

The majority of TOs have been designed for elective surgery, and there has been little attention towards TOs in the trauma and emergency surgery setting. The global burdens of morbidity rate and mortality rate from emergency surgical conditions are highly significant and have been neglected for many years, with millions of disability-adjusted-life years lost from 11 Emergency General Surgery conditions alone[10]. The Global Burden of Disease (GBD) study showed that in 2019, 8% of all deaths worldwide were due to injury[11], and while it is not known what proportion of severely injured patients require emergency laparotomy, when this has been scrutinized at a national level, trauma emergency laparotomy has been found to be both highly morbid and a major drain on resources[12]. Focus on outcomes after trauma emergency laparotomy is particularly important,

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since these can be obscured when larger cohorts of 'injured patients' are evaluated[13].

It is timely for attention to be paid to the design and investigation of TOs following trauma and non-trauma emergency laparotomy, and this should be a focus for the improvement of patient care and for capturing relevant global outcomes that have a high impact on the postoperative functional status and quality of life (QoL)[14].

The aim of the current Delphi exercise was to achieve consensus from an international panel of experts on what might be considered the optimal TO following trauma and non-trauma emergency laparotomy.

Methods

Study design

An international Delphi exercise was undertaken to survey a large and diverse group of surgical experts in both trauma and non-trauma emergency laparotomy. This was undertaken using online survey software distributed in three planned rounds. An interactive session with a patient and public focus group was also used to inform the Delphi exercise and provide patient-centred input.

Participant selection

Participants were selected for the Delphi exercise based on their expertise in the care for patients undergoing trauma and non-trauma emergency laparotomy. A search was made using PubMed for published articles relating to laparotomy using search terms such as 'laparotomy', 'emergency laparotomy' and 'trauma laparotomy'. The corresponding authors for relevant articles were e-mailed a generic invitation to participate in the first round of the Delphi exercise. A link to the survey was also distributed on social media for users who provide surgical care for this patient population. Although there was an expectation that most respondents would be practicing surgeons, the responses of non-surgeons were also welcomed. There was, therefore, a domain in the survey for 'role in healthcare' so that this information could be collected.

Delphi exercise

There were three planned rounds of the Delphi exercise, starting with very broad questions, and then narrowing down the questions in subsequent iterations. Participants were asked whether they agreed with statements using a Likert scale (1–5, corresponding to 'Strongly disagree', 'Disagree', 'Neutral', 'Agree' and 'Strongly agree'). Questions related to which individual outcomes should be included in the TO, how long the follow-up interval should be and how many outcome measures could be included in the TO. The results of the previous rounds were displayed in each iteration (the full surveys are shown in *Results S1–3*) so that participants were able to adjust their answers based on previous results from the whole group. Each survey reiterated the aims and rationale for the exercise and asked the participants to acknowledge their understanding. Participants were masked to each other's identity and responses, and analysis was undertaken masked to the participants. However, names and e-mail address details were recorded centrally to distribute subsequent rounds of the exercise and to inform the collective authorship. Invitations to participate in rounds 2 and 3 of the Delphi exercise were sent to the e-mail addresses of participants who had indicated in previous rounds that they wished to continue to participate. Two subsequent targeted follow-up e-mails were sent for non-responders before moving on to the next round.

Patient and public exercise

After round 2 of the Delphi exercise, a public and patient involvement (PPI) focus group exercise was undertaken to better inform round 3 of the exercise. This was an experienced PPI group that has participated in multiple studies and is based at the Trauma, Accident, Burns and Critical Care Group (TrABC), sponsored by the National Institute of Health Research, UK. This was planned for this stage of the Delphi exercise so that the group could see what answers had already been given, for points of focused discussion. These were discussed in sequence and in detail, and the opinions of the group were sought on these topics.

Data analysis

Data were summarized using median and interquartile range for continuous data and number and percentage for categorical data. A map of worldwide participation was created using Maptive (Maptive™, San Francisco, CA, USA).

Results

Delphi exercise participants

There were 411 participants who completed round 1 of the Delphi exercise, 366 who completed round 2 and 337 participants who completed all 3 rounds. *Figure 1* illustrates the participation at each round. Characteristics of participants are summarized in *Table 1*. Most participants were Attending/Consultant grade surgeons, and 79.5% were male. This was an experienced cohort, with most participants regularly performing both non-trauma and trauma emergency laparotomy, although the former was more commonly performed. There was representation from 53 countries worldwide (*Fig. 2*). The full list of participating countries is in *Table S1*.

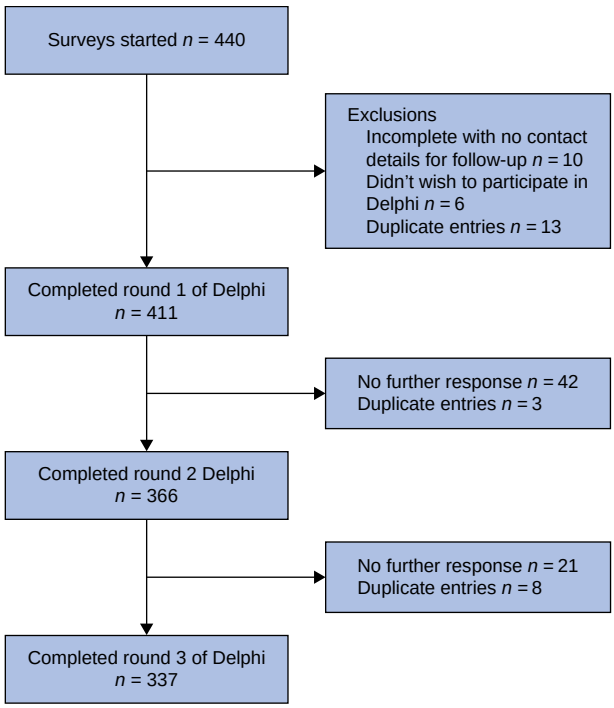

Fig. 1 Flow diagram of participation in the Delphi exercise

Individual outcome measures

When participants were asked about individual outcome measures that should be included in the TOs for trauma and non-trauma emergency laparotomy, the answers with most scores of 5 ('strongly agree') were 'postop complications', 'death/survival', 'intra-abdominal sepsis/fistula/leak/abscess', 'unplanned re-operation on', 'organ failure' and 'QoL' for both types of surgery. In addition, for emergency trauma laparotomy, 'blood products used' also had most scores of 5. These were also the outcome measures most favoured by the PPI group. When asked how many outcome measures should be incorporated into the TOs, the most common answer was '5'. When the PPI group was asked about which QoL measure should be used, they were generally not in favour of long or arduous surveys and would prefer that the QoL measure was more general, such as a patient-reported outcome measure (PROM) 'subjective return to baseline QoL'. This was agreed by the majority of Delphi participants in round 3 of the exercise (284 of 337 (84.3%)).

Table 1 Characteristics of Delphi participants

Characteristic	Summary ($n = 337$)
Role in healthcare	
Medically trained, Attending/Consultant	266 (78.9)
Medically trained, non-Attending/Consultant	54 (16.0)
Researcher	10 (3.0)
Other	7 (2.1)
Sex	
Male	268 (79.5)
Female	63 (18.7)
Other/not declared	6 (1.8)
Year of graduation from medical school, median (i.q.r.)	2005 (1998–2011)
Regularly perform non-trauma laparotomy	298 (88.4)
Regularly perform trauma laparotomy	227 (67.4)
Total number of non-trauma laparotomies performed	
<100	133 (39.5)
100–300	105 (31.2)
>300	96 (28.5)
Not declared	4 (1.2)
Total number of trauma laparotomies performed	
<100	228 (67.7)
100–300	61 (18.1)
>300	41 (12.2)
Not declared	7 (2.1)

Values are *n* (%) unless otherwise stated.

Follow-up requirement

When participants were asked about follow-up interval, the category with the highest number of scores of 5 was '1 year'. When the PPI group was consulted, they stated that it would be a good idea to split the TO into 'short-term' and 'long-term' TOs so that follow-up could be 1 year, but that the shorter-term outcomes should also be recognized. In round 3 of the Delphi exercise this was widely agreed by participants as a good idea (305 of 337 (90.5%)).

Textbook Outcomes

The final agreed TOs for trauma and non-trauma emergency laparotomy after round 3 of the Delphi were divided into Early Textbook Outcome (E-TO) and Longer-Term Textbook Outcome (LT-TO) and are summarized in *Table 2* according to the Delphi exercise. Individual complications were defined

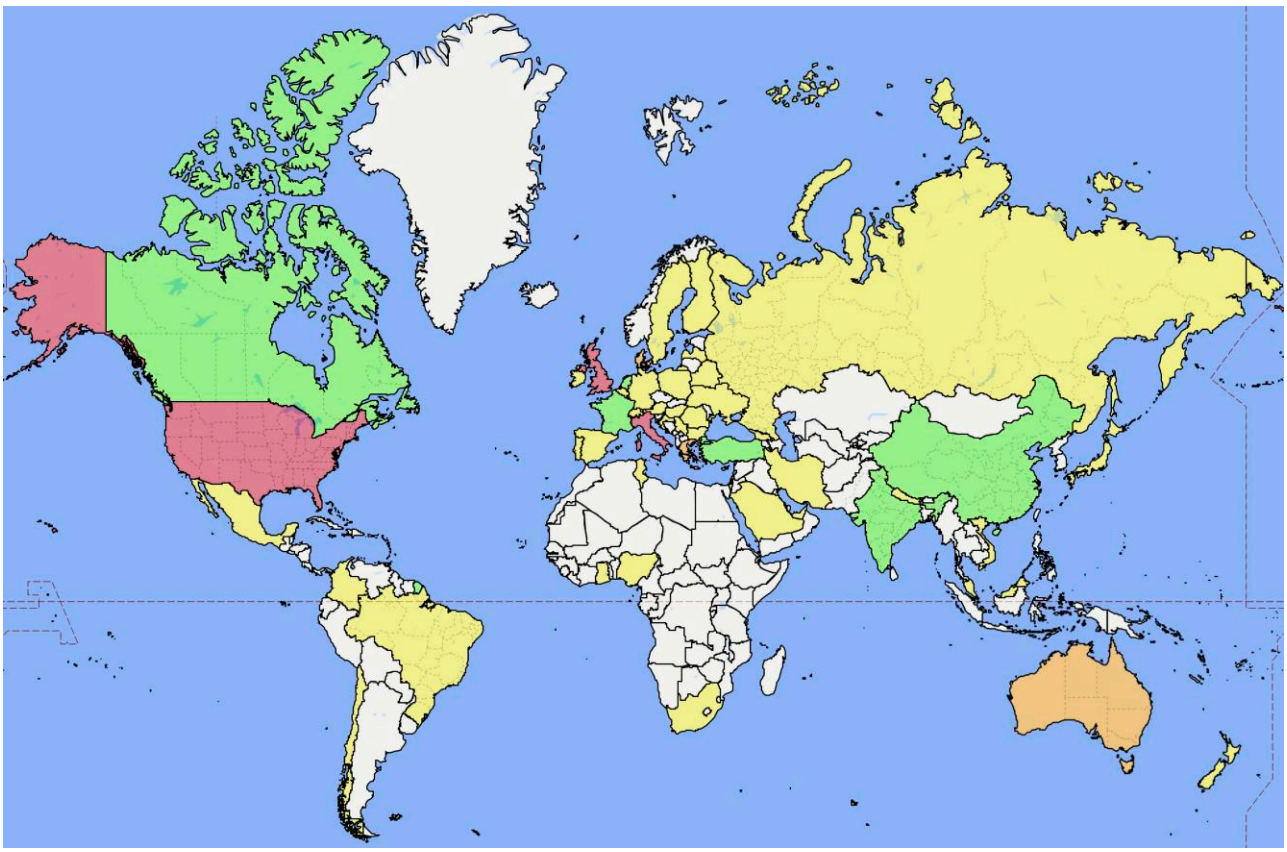

Fig. 2 Representation of countries worldwide (yellow indicates 1–5; green 6–10; orange 11–30; red 31+ participants)

Table 2 Textbook Outcomes for non-trauma and trauma laparotomy after round 3 of the Delphi exercise

Category of surgery	Textbook Outcome definition	Agreed without further comment
Non-trauma laparotomy		
Early	Discharged from hospital without serious postoperative complications (that is Clavien–Dindo ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation on or death)	294 (87.2)
Longer-term	Achieved the E-TO, and restoration of baseline quality of life at 1 year	
Trauma laparotomy		
Early	Discharged from hospital without unexpected transfusion after haemostasis, and no serious postoperative complications (adapted Clavien–Dindo for trauma ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation on or death)	284 (84.3)
Longer-term	Achieved the E-TO, and restoration of baseline quality of life at 1 year	

Values are *n* (%). E-TO, early textbook outcome.

according to well-established Clavien–Dindo definitions[15] that are familiar to surgeons and were therefore not re-defined in this exercise.

Disagreements

As might be expected in a group of diverse contributors including surgeons, there was imperfect consensus amongst the 337 participants. There were six participants that stated that these TOs were too complicated to measure. There were four participants who stated that they thought that 1 year was too long for the LT-TO due to the risk of patients lost to follow-up. There were eight participants who did not think that restoration of baseline QoL was a good measure for the LT-TO. Some of these participants stated that there should be a more specific and objective QoL assessment, and others stated that this was an unrealistic expectation that may result in very few patients achieving the LT-TO. There were three participants who felt that incisional hernia should feature in the TOs.

Discussion

After a Delphi exercise and engagement with a PPI group, consensus has been achieved on both early and longer-term TOs following trauma and non-trauma emergency laparotomy for the purposes of patient-centred research for this important population. For non-trauma emergency laparotomy, the E-TO proposed is: 'Discharged from hospital without serious postoperative complications (that is Clavien–Dindo[15] ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation on or death)'. For trauma laparotomy: 'Discharged from hospital without unexpected transfusion after haemostasis, and no serious postoperative complications (adapted Clavien–Dindo for trauma[16] ≥ grade III; including intra-abdominal sepsis, organ failure, unplanned re-operation on or death).' For both trauma and non-trauma emergency laparotomy, an LT-TO of 'Achieved the E-TO, and also patient-reported restoration to their baseline QoL at 1 year' is proposed.

These represent the first proposals for TOs for patients following trauma and non-trauma emergency laparotomy. Designing TOs for other than elective surgery is complicated due to a higher variability in presentations, co-morbidities, pathologies, interventions, and participation in both short- and long-term follow-up. However, this does not mean that TOs should not be designed or implemented, and in fact argues for the critical necessity of establishing TOs in this patient population. Research in trauma and emergency surgery has historically been relatively neglected even though it has an enormous impact on the global burden of disease[10]. To determine whether these TOs will be of use in future research for patients following trauma and non-trauma emergency laparotomy, it will be important to validate the TOs using patient data[14]. Ideally this should be done on an international scale, as well as for individual institutions and systems. Such an exercise may provide evidence that the data is feasible to obtain, and that there is correlation with other outcomes of interest. If validated, these TOs should be considered for usage as primary outcomes for prospective clinical trials and potentially incorporated into national trauma and emergency general surgery registries focused on quality. Examples may include the Trauma Quality Improvement Program in the USA and the National Emergency Laparotomy Audit in the UK.

It is notable that the LT-TO for both trauma and non-trauma emergency laparotomy includes a subjective measure of restoration of QoL to baseline as a patient-reported measure, without a specific tool or instrument mandated. This represents an opportunity for researchers to have the freedom to choose whichever PROM they wish, as long as it is able to reliably determine and quantify the restoration of baseline QoL. This is an important aspect of this TO since there are already many PROMs that have been proposed[17,18]. A recent trauma trial for patients with haemorrhagic shock used the primary outcome of survival 'with favourable functional outcome at 6 months'[19]. This is a good modern example of such a PROM being used to form a composite outcome and demonstrates the current desire for new trials to use more patient-centred outcomes. It is not the role of a TO to determine the precise tools of measurement, and it is recommended that future studies consult PPI groups to agree which PROM would best-suit the research question at hand and the specific population being studied. There may also be major differences in the ideal QoL metrics or sampling methodology between patient populations based on demographic factors such as nationality, race, ethnicity, gender, income, education level and similar variables. Having the flexibility to adopt the specific PROM methodology to the population being studied may result in greater patient response, diversity of responses and inclusivity.

The proposed LT-TO requires follow-up at 1 year, which may have its own issues regarding patients being lost to follow-up, due to change in contact details or address, loss of details or disengagement. A considerable proportion of patients following trauma and non-trauma emergency laparotomy may have also died within such a follow-up interval[20,21]. Patients lost to follow-up may be demographically different to those with follow-up data[22,23]. However, improvement of follow-up can be achieved by improving systems[24], and identification of risk

factors for loss to follow-up may be useful to implement a targeted approach[25]. The requirement for a 1-year review for research may enable centres and systems to improve their longer-term follow-up data collection and processes, which would be a useful change for patient care. The patient and public focus group were strongly of the opinion that there should be a longer-term review of patients after trauma and non-trauma emergency laparotomy, and this is likely to be reflected in the opinions of other patients. It is recommended that researchers choosing the LT-OT as an outcome measure in the methodology of prospective studies ensure they design robust strategies to better enable 12-month follow-up.

It is acknowledged that for many patients who have an emergency laparotomy, obtaining a TO may never be achievable due to the nature of the physiological insults prior to surgery. This is different to elective surgery, where surgeons might more realistically aim for 100% of their patients to achieve a TO. However, this limitation is shared by most outcome measures used for emergency surgery, where a certain level of poorer outcomes are expected regardless of the quality of care. This makes the design of TOs for emergency surgery different to elective surgery. Nevertheless, such outcome measures are justified because they can be used for purposes such as monitoring quality of care over time, between centres or following novel treatments.

Although more than 84% consensus was achieved for the final TOs, this Delphi process also identified areas of imperfect consensus surrounding perceived complexity of the outcome measures; appropriate length of follow-up; agreement on the definition of what constitutes restoration of QoL, and consideration for inclusion of incisional hernia as a specific (poor) outcome after trauma and non-trauma emergency laparotomy. Achieving perfect consensus on these complex issues is considered unrealistic, and less desirable than having a broad range of opinions and input in the development of robust TOs. Further refinement of these TOs may be desirable in the future. Other limitations include acknowledgement of a relative under-representation of lower-income countries, such as within the African continent. There was also an under-representation of female participants (only 18.7% in this study), which may reflect current overall gender disparities amongst surgeons worldwide. Participants were not asked for their surgical specialty, but instead used the data about numbers of laparotomies that they had performed as a marker of their expertise in the subject. It was not, therefore, possible to summarize the specialties for better characterization of participating surgeons. Since social media was used to amplify the distribution of the invitation to participate, the true denominator of those who had seen the invitation is unknown. It is therefore not possible to report the true proportion of potential participants (invitees) who participated in the Delphi exercise.

There is agreement amongst a large international group of surgeons, other healthcare professionals and patients about which TOs can be proposed for clinical research that includes patients following trauma and non-trauma emergency laparotomy. These are divided into short-term and longer-term TOs and can be used as primary outcome measures to investigate treatments and optimize care for these patients. The proposed TOs now need to be validated to be considered useful for this purpose and promulgated locally and worldwide.

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Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

All data for the present study is either included as supplementary material or obtainable upon reasonable request from the authors.

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