BJR

■ BONE FRACTURE

Development of a core outcome set for open lower limb fracture

WHAT CORE OUTCOMES SHOULD BE MEASURED?

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Aims

Open lower limb fracture is life-changing, resulting in substantial morbidity and resource demand, while inconsistent outcome-reporting hampers systematic review and meta-analysis. A core outcome set establishes consensus among key stakeholders for the recommendation of a minimum set of outcomes. This study aims to define a core outcome set for adult open lower limb fracture.

Methods

Candidate outcomes were identified from a previously published systematic review and a secondary thematic analysis of 25 patient interviews exploring the lived experience of recovery from open lower limb fracture. Outcomes were categorized and sequentially refined using healthcare professional and patient structured discussion groups. Consensus methods included a multi-stakeholder two-round online Delphi survey and a consensus meeting attended by a purposive sample of stakeholders, facilitated discussion, and voting using a nominal group technique.

Results

Thematic analysis and systematic review identified 121 unique outcomes, reduced to 68 outcomes following structured discussion groups. Outcomes were presented to 136 participants who completed a two-round online Delphi survey. The Delphi survey resulted in 11 outcomes identified as consensus 'in' only. All outcomes were discussed at a consensus meeting attended by 15 patients, 14 healthcare professionals, 11 researchers, and one patient-carer. Consensus was achieved for a four-core outcome set: 'Walking, gait and mobility', 'Being able to return to life roles', 'Pain or discomfort', and 'Quality of life'.

Conclusion

This study used robust consensus methods to establish a core outcome set that should be measured in all future research studies and audits of clinical practice without precluding the measurement of additional outcomes.

Article focus

■ What outcomes are important to patients recovering from open lower limb fracture?

■ What constitutes the UK multi-stakeholder consensus for a core outcome set for adults recovering from open lower limb fractures?

Key messages

■ The core outcome set for open lower limb fractures is 'Walking, gait and mobility', 'Being able to return to life roles', 'Pain or discomfort', and 'Quality of life'.

■ This constitutes the UK patient, healthcare professional, and researcher consensus on the minimum outcomes that should

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be measured on all skeletally mature patients recovering from open lower limb fracture in future clinical research and audits of clinical practice.

■ Further research is needed to establish how these outcomes should be measured, e.g. what standardized outcome definitions or measurement instruments should be used.

Strengths and limitations

■ This study involved the opinions and views of patients at each stage, used robust consensus methods to ensure that all stakeholder voices were heard, and was conducted in line with guidance from the Core Outcome Measures in Effectiveness Trials initiative.

■ Patients were sampled from the South and Midlands areas of England, and their views may not be representative of other global regions. It was unknown how many patients attending the consensus meeting had suffered a severe complication following open fracture, e.g. deep infection or nonunion.

Introduction

Open fracture is a life-altering injury affecting 30.7 per 100,000 adults each year.[1] Open lower limb fracture causes substantial morbidity for patients and a large resource demand on trauma infrastructures.[2,3] Treatment is complex, multifaceted, and subject to regional variation, and often results in considerable functional impairment,[3,4] such that an optimal treatment pathway for these devastating injuries remains unclear. Inconsistency in outcome-reporting and poor-quality studies hamper attempts to evaluate new interventions to improve function, recovery experience, and investigation into the effects of regional variation of treatment on recovery.[5]

A core outcome set is an agreed, standardized set of outcomes to be measured and reported, as a minimum, in all trials for a specific population and health condition, and does not preclude the measurement of other outcomes in addition to the core outcome set.[6] Core outcome set projects have been endorsed as a method to reduce outcome heterogeneity, outcome-reporting bias, and to promote better-quality research that is patient-centred through the involvement of key stakeholders.[6–10] The development of a core outcome set for open lower limb fracture establishes a consensus among healthcare professionals, researchers, and patients over what outcomes are the most important to measure, with an overall aim of improving research and clinical practice in open lower limb fracture care. The core outcome set is anticipated for use in all trials of surgical, medical, and rehabilitation interventions in the setting of clinical research and routine clinical practice, e.g. local and national audit.

This study reports the consensus process undertaken involving key stakeholders to achieve a core outcome set, which defines what should be measured on skeletally mature patients recovering from open lower limb fracture.

Methods

Ethics and registration. The South-Central Research Ethics Committee (REC) granted ethical approval for this study on 1 March 2018 (REC reference: 18/SC/0051, IRAS project ID: 235150). The Core Outcomes for Open Lower Limb Fracture (CO-OLLF) study was prospectively registered on the Core Outcome Measures in Effectiveness Trials (COMET) database,[11] and was adopted by the National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN) (Protocol number: 13257).

Design. Candidate outcomes were identified from a systematic literature review[12] and a secondary qualitative thematic analysis of in-depth patient interviews that explored the lived experience of recovery from open lower limb fracture. Candidate outcomes were fed back to stakeholders in structured discussion groups and a two-round Delphi survey before a final review at a consensus meeting. This study was designed and reported in accordance with the COMET Initiative guidance[7,9] and the Core Outcome Set-STAndards for Reporting statement,[10] respectively.

Population. The population and health condition used for the CO-OLLF study was defined as all skeletally mature patients (age greater than 18 years) following open lower limb fracture of any grade distal to the acetabulum.[12] Health economic outcomes were considered out of scope.[13]
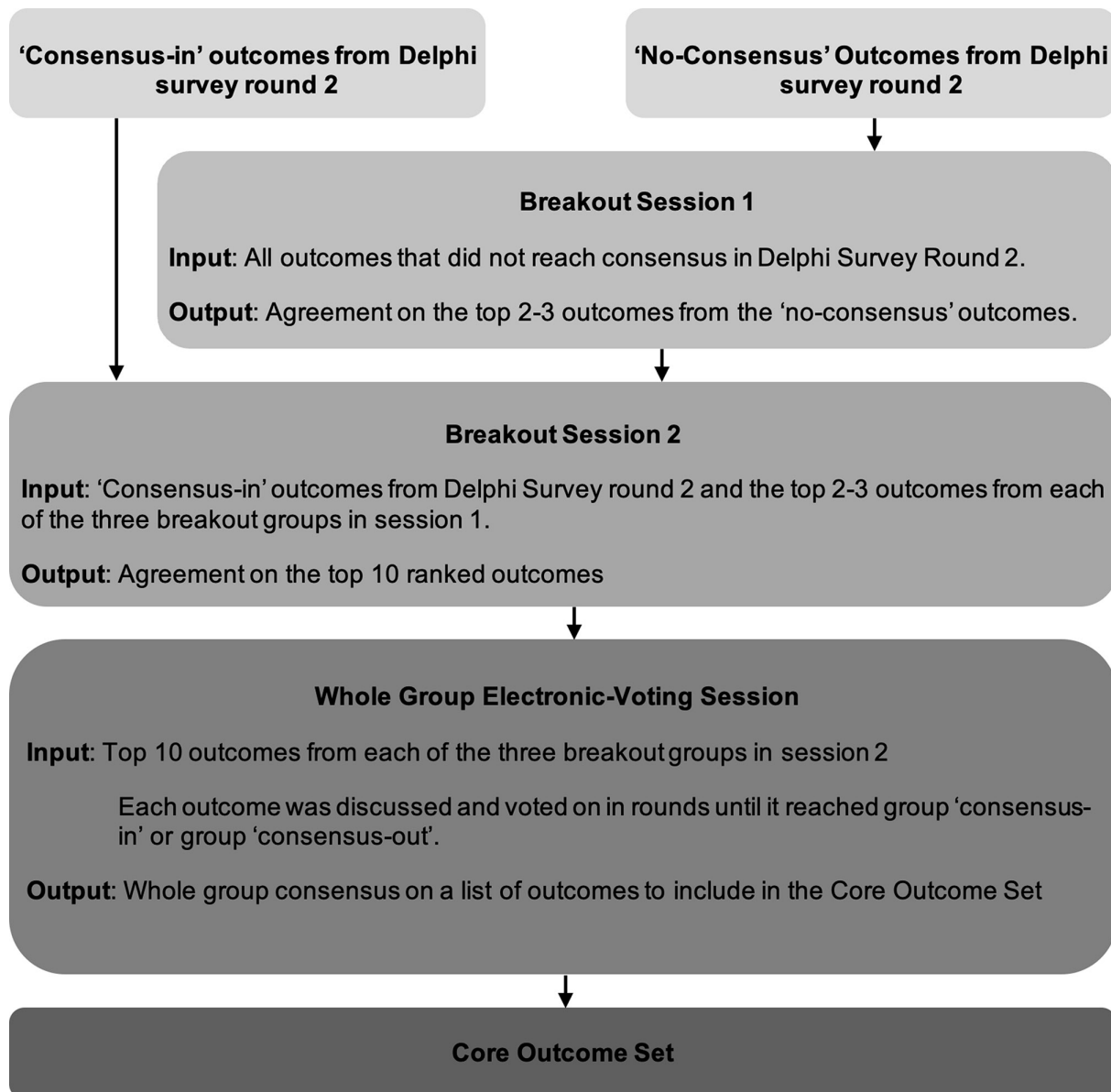
Information sources. Outcomes important to healthcare professionals and researchers were identified using a systematic literature review to collect, summarize, and categorize contemporary outcomes reported in clinical studies on skeletally mature patients following open lower limb fracture over ten years from 2009.[5]

Outcomes important to patients were identified through a secondary thematic analysis of 25 in-depth interview transcripts that explored the lived experience of recovery following open lower limb fracture. Interview participants were recruited as part of the WOLLF HTA-10/57/20 trial.[4] A purposive sampling strategy was used to ensure a range of sex, age, mechanism of injury, the severity of open lower limb fracture, and time since injury. Interviews were conducted between two and four years post-injury to provide an overview of the recovery experience. The primary data collection, qualitative analysis, results, and further methodological detail regarding the research team, reflexivity, study design, participant demographics, and interview structure are published elsewhere.[3,4]

A secondary thematic analysis of interview transcripts was undertaken. Open coding was used to identify and organize text extracts representing outcome codes. Outcome codes were interpreted to create outcome themes. Outcome themes were then grouped and organized under appropriate outcome domains using the COMET taxonomy of outcomes as a framework.[14] Data were organized using NVivo V.12 (QSR International, UK). To facilitate reflection on the process of interpretation,

Table I. Core Outcomes for Open Lower Limb Fracture study consensus criteria.

Criteria	Description
'Consensus-in'	Over 70% of participants in each stakeholder group score the outcome 'critical' (7 to 9) or 'in', AND less than 15% of participants score outcome 'not important' (1 to 3) or 'out'.
'Consensus-out'	Over 70% of participants in each stakeholder group score the outcome 'not important' (1 to 3) or 'out', AND less than 15% of participants score outcome 'critical' (7 to 9) or 'in'.
'No-consensus'	Anything else.

'Consensus-in' outcomes from Delphi survey round 2

'No-Consensus' Outcomes from Delphi survey round 2

Breakout Session 1

Input: All outcomes that did not reach consensus in Delphi Survey Round 2.

Output: Agreement on the top 2-3 outcomes from the 'no-consensus' outcomes.

Breakout Session 2

Input: 'Consensus-in' outcomes from Delphi Survey round 2 and the top 2-3 outcomes from each of the three breakout groups in session 1.

Output: Agreement on the top 10 ranked outcomes

Whole Group Electronic-Voting Session

Input: Top 10 outcomes from each of the three breakout groups in session 2

Each outcome was discussed and voted on in rounds until it reached group 'consensus-in' or group 'consensus-out'.

Output: Whole group consensus on a list of outcomes to include in the Core Outcome Set

Core Outcome Set

Fig. 1

Core Outcomes for Open Lower Limb Fracture study consensus meeting schematic flow diagram.

a sample of five interview transcripts were coded in duplicate by ALA and ET before meeting to discuss and compare identified codes, themes, and interpretations. Rigour was demonstrated through trustworthiness.[15]

Outcome themes grouped under outcome in the COMET taxonomy outcome domains were presented to patients and healthcare professionals at structured discussion groups, a Delphi survey, and at a consensus meeting in
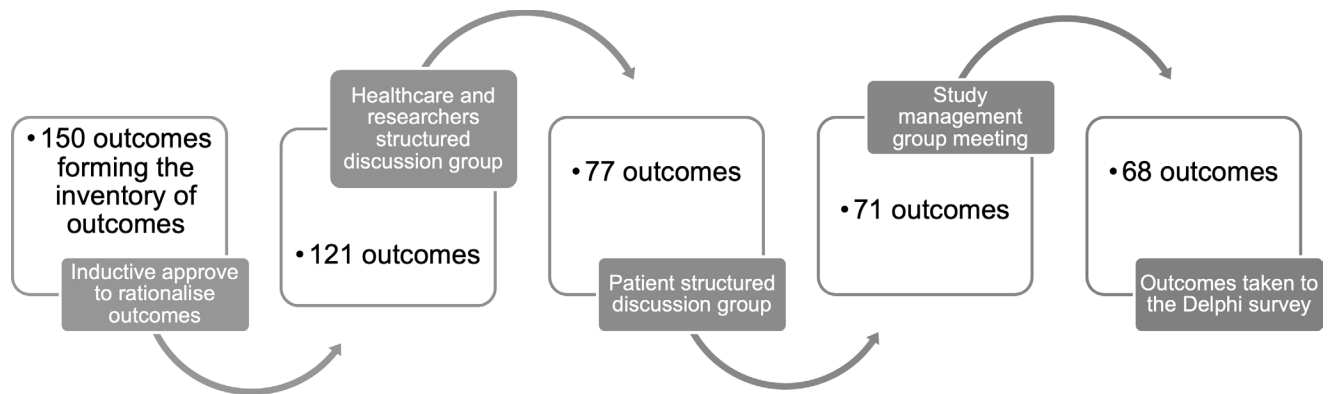
Fig. 2

Refinement of the inventory of outcomes for open lower limb fractures.

an iterative process to enhance clarity. See Supplementary Methods for justification and a detailed summary of the thematic analysis methodology.

Outcomes identified from the systematic literature review and the qualitative analysis were combined and rationalized before being categorized and organized using the COMET taxonomy of outcomes to create an inventory of outcomes for open lower limb fracture. Outcomes were assigned a number to aid later discussion and tracking through the consensus process. The COMET taxonomy of outcomes is a categorization system that provides sufficient granularity and scope for classifying all medical outcomes in core outcome set development.[14] The inventory of outcomes was presented to a purposive sample of healthcare professionals and researchers, followed by patients in two structured discussion groups. Structured discussion groups were used to refine and review outcomes for duplication, use of language, and understandability before the consensus process. The resulting list of outcomes was reviewed and refined by the study management group (consisting: ALA, ET, RF, MLC, and XLG) before being taken forward to the Delphi survey.

Delphi survey. A two-round Delphi survey was conducted using COMET DelphiManager (University of Liverpool, UK)[16] between 9 February 2019 and 19 March 2019. Participants were recruited from three key stakeholder groups: patients, healthcare professionals, and researchers (clinical academics and people working in clinical musculoskeletal research, e.g. members of clinical trial teams). Study adoption by the NIHR CRN facilitated multisite recruitment. Patients were recruited from five UK major trauma centres (MTCs). Patients were eligible if they were over the age of 18 years and had sustained an open lower limb fracture (as defined above) at any point before participation. Healthcare professionals and researchers were recruited through cascade emails sent through the Major Trauma Network, the Orthopaedic Trauma Society, and the British Association of Plastic and Reconstructive Surgeons. Healthcare professionals and researchers were eligible for recruitment if their professional role involved

the regular clinical care of patients following open lower limb fracture or if they actively participated in orthopaedic trauma research, respectively.

In each survey round, participants were presented with the inventory of outcomes for open lower limb fracture and asked to score the outcomes for importance using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) 1 to 9 Likert scale.[17,18] The scale was displayed as 1 to 3 labelled 'not important', 4 to 6 labelled 'important but not critical', and 7 to 9 labelled 'critical'. Participants could suggest additional outcomes at the end of round 1. The study management group reviewed proposed outcomes, and outcomes identified as novel were added to round 2. In round 2, participants were shown a bar chart of round 1 scores for each outcome by stakeholder group, overall score, and their first-round score. They were then asked to reflect on their scoring, considering the additional information before re-scoring each outcome. The consensus criteria used to identify outcomes as consensus-in, no-consensus, and consensus-out were those recommended by COMET and defined a priori (Table I).[9] No outcomes were dropped between rounds.

Consensus meeting. The results of the Delphi survey were presented at a one-day face-to-face consensus meeting hosted at a purpose-built events centre on 26 March 2019. Patients, healthcare professionals, and researchers who had completed both rounds of the Delphi survey were invited to attend. Participants were sampled purposively using a sampling matrix to ensure a balanced representation of patients in terms of age, sex, injury severity, and time since injury, also including healthcare professionals and researchers to achieve a mixed sample of professional backgrounds. All participants were sent a detailed pre-meeting reading pack summarizing the project, results of the Delphi survey, and meeting agenda. The meeting structure and methods were guided by the COMET Handbook[9] and adapted from the James Lind Alliance Priority Setting Partnerships methods for a final priority setting meeting.[18]
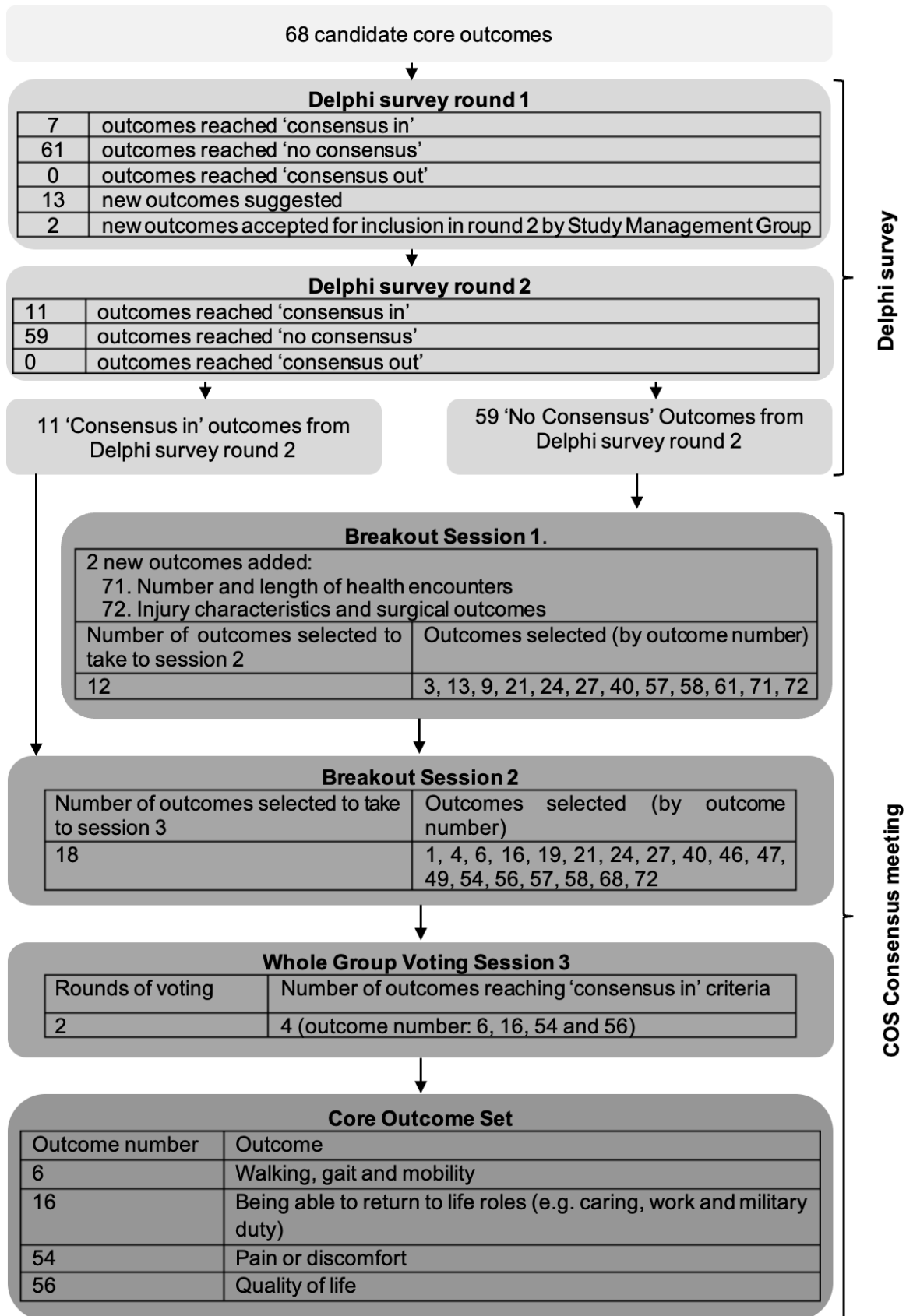
68 candidate core outcomes

Delphi survey round 1

7	outcomes reached 'consensus in'
61	outcomes reached 'no consensus'
0	outcomes reached 'consensus out'
13	new outcomes suggested
2	new outcomes accepted for inclusion in round 2 by Study Management Group

Delphi survey round 2

11	outcomes reached 'consensus in'
59	outcomes reached 'no consensus'
0	outcomes reached 'consensus out'

Delphi survey

11 'Consensus in' outcomes from Delphi survey round 2

59 'No Consensus' Outcomes from Delphi survey round 2

Breakout Session 1.

2 new outcomes added:
   71. Number and length of health encounters
   72. Injury characteristics and surgical outcomes

Number of outcomes selected to take to session 2	Outcomes selected (by outcome number)
12	3, 13, 9, 21, 24, 27, 40, 57, 58, 61, 71, 72

Breakout Session 2

Number of outcomes selected to take to session 3	Outcomes selected (by outcome number)
18	1, 4, 6, 16, 19, 21, 24, 27, 40, 46, 47, 49, 54, 56, 57, 58, 68, 72

Whole Group Voting Session 3

Rounds of voting	Number of outcomes reaching 'consensus in' criteria
2	4 (outcome number: 6, 16, 54 and 56)

Core Outcome Set

Outcome number	Outcome
6	Walking, gait and mobility
16	Being able to return to life roles (e.g. caring, work and military duty)
54	Pain or discomfort
56	Quality of life

COS Consensus meeting

Fig. 3

Schematic flow diagram of the Delphi survey and consensus meeting consensus results. COS, core outcome set.

Table II. Delphi survey and consensus meeting participant characteristics table.

Demographic	Delphi survey		COS consensus meeting
	Round 1 n = 187	Round 2 n = 136	n = 41
Stakeholder group, n (%)			
Patients	74 (40)	55 (40)	15 (37)
Anatomical area of open fracture*			
Open fracture of the thigh (femur)	1 (1)	1 (1)	N/A
Open fracture of the leg including ankle (tibia/fibula)	61 (85)	43 (81)	14 (93)
Open fracture of the foot (all bones of the foot including phalanges)	5 (7)	5 (9)	1 (7)
Open fracture of the thigh and leg	1 (1)	1 (1)	N/A
Open fracture of the leg and foot	3 (5)	2 (4)	N/A
Open fracture of the thigh, leg, and foot	1 (1)	1 (1)	N/A
Indication of severity of open fracture†			
Open fracture closed primarily	16 (22)	11 (20)	6 (40)
Open fracture required a skin graft or muscle flap	52 (72)	40 (74)	9 (60)
Open fracture resulting in an amputation	4 (6)	3 (6)	N/A
Patient carers	N/A	N/A	1 (2)
Healthcare professionals‡	102 (55)	73 (54)	14 (34)
Anaesthetist or intensive care physician	1 (1)	1 (2)	N/A
General practitioner	3 (3)	3 (4)	N/A
Nurse (including advanced nurse practitioners)	9 (8)	7 (10)	3 (21)
Physician (e.g. orthogeriatrician)	3 (3)	3 (4)	1 (7)
Physiotherapist	11 (10)	8 (11)	1 (7)
Plastic and reconstructive surgeon	23 (21)	14 (20)	3 (21)
Psychologist (e.g. trauma psychologist)	1 (1)	1 (2)	1 (7)
Trauma and orthopaedic surgeon	55 (50)	35 (45)	3 (21)
Other	3 (3)	0	2 (16)
Researchers§	11 (5)	8 (6)	11 (27)
Post-doctoral researcher	3 (11)	1 (14)	2 (18)
Professor or associate professor	4 (14)	0	5 (46)
Research nurse/associate	6 (21)	3 (43)	2 (18)
Student (MSc or PhD)	8 (29)	0	1 (9)
Trial manager	2 (7)	2 (29)	1 (9)
Other	5 (18)	1 (14)	N/A
Sex, n (%)			
Male	123 (66)	85 (62)	23 (57)
Female	64 (34)	51 (38)	17 (43)
Patients: Male	43 (58)	31 (56)	9 (60)
Female	31 (42)	24 (44)	6 (40)
Age (years), n (%)			
Patients: 20 to 29	13 (17)	9 (16)	1 (6)
30 to 39	10 (14)	8 (15)	3 (20)
40 to 49	11 (15)	7 (13)	1 (6)
50 to 59	22 (30)	17 (31)	6 (40)
60 to 69	6 (8)	3 (5)	1 (6)
over 70	12 (16)	11 (20)	3 (20)
Mean, yrs	49 (20 to 82)	51 (20 to 81)	53 (26 to 76)
Mean male, yrs	44 (21 to 76)	44 (21 to 76)	48 (26 to 72)
Mean female, yrs	58 (20 to 82)	59 (20 to 82)	60 (31 to 76)
Professionals: 20 to 29 (healthcare professionals and researchers)¶	8 (7)	8 (10)	N/A
30 to 39	51 (46)	36 (45)	N/A
40 to 49	36 (32)	23 (29)	N/A
50 to 59	13 (11)	10 (13)	N/A
60 to 69	3 (3)	2 (2)	N/A
over 70	1 (1)	1 (1)	N/A

Table II. Continued

Demographic	Delphi survey		COS consensus meeting
	Round 1 n = 187	Round 2 n = 136	n = 41
Mean, yrs	41	41	N/A
Patients sustained open lower limb fracture on military duty, n (%)	3 (4)	2 (4)	N/A
Professionals employed by the military, n (%)	9 (9)	6 (8)	N/A
Plastic and reconstructive surgeon	6 (66.7)	5 (83.3)	N/A
Trauma and orthopaedic surgeon	3 (33.3)	1 (16.7)	N/A

*Two patients did not state the anatomical area of open fracture.
†Two patients did not indicate the severity of their open fracture.
‡Seven healthcare professionals self-identified as researchers when selecting stakeholder group.
§A total of 17 researchers self-identified as healthcare professionals when selecting stakeholder group.
¶One healthcare professional entered an incorrect date of birth.
COS, core outcome set; N/A, not applicable.

The meeting consisted of three separate sessions, and participants were split into three groups for sessions one and two, which were independently facilitated by members of the study management group (see Figure 1 for a schematic representation of the meeting structure). Initially, each group selected their top two or three outcomes from the 'no-consensus' outcomes identified in the Delphi survey for inclusion in the second session. Then, each group ranked a top ten list of outcomes from all 'consensus-in' outcomes identified in the Delphi survey second round plus outcomes selected for inclusion earlier. Finally, groups came together, and anonymous electronic voting was undertaken using TurningPoint software and handsets (Turning Technologies, USA). After removing duplicates, all outcomes from the groups' top 10's were added to a Microsoft PowerPoint (Microsoft Corporation, USA) presentation template to facilitate electronic voting for inclusion in the final core outcome set. Electronic voting enabled the presentation of voting results on each outcome immediately to aid discussion. Participants were given the scoring options of 1 to 3: 'not important', 'important but not critical', and 'critical'. Outcomes were voted on in two rounds with the facilitation of discussion on each outcome before repeated voting. Outcomes reaching 'consensus-in' were included in the core outcome set; all others were excluded. The core outcome set was then presented to the participants and ratified.

The meeting was chaired by a facilitator with experience in running consensus meetings (MLC). Group facilitators ensured that contrasting views were actively sought, and all participants had equal opportunity to contribute to the discussion throughout the day. Each participant was encouraged to share their opinions on an outcome before any voting or ranking exercise was undertaken. A modified nominal group technique (NGT) was used to facilitate consensus. NGT is a well-established consensus method used to make decisions efficiently while taking everyone's views into account.[9,19] NGT eliminates duplicate ideas and allows all individual opinions to be considered, which influences the group intending to converge opinions to achieve a consensus.[9,19]

Other analyses and statistical considerations. We analyzed participant attrition rate and outcome scoring changes between Delphi survey rounds. Medians and standard deviations were calculated for the score (1 to 3) of each outcome scored in the consensus meeting electronic-voting session using TurningPoint software.

There is currently no recommended minimum number of participants to include in a Delphi survey and no requirement to demonstrate a statistically representative sample. In previous studies, between ten and 15 participants per stakeholder group have yielded satisfactory results.[9,19] NGT does not depend on statistical power, and there is no robust or commonly used method for calculating the required number of participants.[9]

Results

Information gathering. A systematic review describing outcomes reported in the literature has been previously published;[5] 1,803 outcomes were identified from 786 studies and consolidated to 82 standardized outcome headings (Supplementary Figure a).

Thematic analysis of 25 interview transcripts identified 1,121 codes in the data representing an explicit or underlying outcome that may be important to measure in patients recovering from open lower limb fracture (see Supplementary Methods for examples of patient quotations representative of underlying outcome codes). Interpreting the outcome codes resulted in the development of 88 outcome themes and sub-themes (see the coding tree detailed in Supplementary Figure b). Duplicate data coding by ALA and ET demonstrated consistency over the identification of outcome codes in the data.

Outcome headings and themes from the systematic review and qualitative analysis, respectively, were brought together to create the inventory of outcomes for open lower limb fracture. The resulting inventory of outcomes consisted of a long list of 150 outcomes categorized using the COMET taxonomy of outcomes to

Table III. List of all outcomes discussed at the consensus meeting grouped by the COMET taxonomy of outcome domains and listed by study outcome number.

COMET Taxonomy of Outcome Domains	Outcome
Physical functioning	1. Ability to do activities of daily living
	2. Ability to kneel
	3. Ability to balance
	4. Ability to be independent
	5. Ability to drive
	6. Walking, gait and mobility
	7. Ability to be able to dress and do self and personal care
	8. Ability to have intimate relationships
	9. Ability to exercise
	10. Ability to comfortably wear shoes and clothes of your choice
	11. Lower limb function
	12. Range of motion
Social functioning	13. Ability to participate in social events
	14. Ability to start, maintain and develop relationships
	15. Being able to care for other people and/or animals
Role functioning	16. Being able to return to life roles (e.g. caring, work, military duty)
Emotional functioning and wellbeing	17. Appearance of lower limb e.g. scars, flaps and swelling
	18. Change in body shape or weight
	19. Feelings of self-identity and body wholeness
	20. Feelings of disablement, being damaged or broken
	21. Feelings of giving up and hopelessness
	22. Feeling of loss
	23. Feelings of frustration and anger
	24. Feelings of hopefulness, positivity and determination
	25. Isolation, loneliness and lack of emotional support
	26. Low mood
	27. Ability to move on and feeling of getting life back
	28. Having clear expectations and views on the future with lack of uncertainty
	29. Tolerance of uncertainty and living in fear e.g. fear of falling or going outside and fear for the future
	30. Being anxious or stressed
	31. Loss of confidence or control and feeling of limitation
	32. Experience of flashbacks to the traumatic event
	33. Emotional vulnerability, volatility and fragility.
	34. Ability to accept the event and life change
	35. Feelings of struggle or fighting against the body
	36. Maintaining a feeling of dignity
Cognitive functioning	37. Lack of concentration and focus
Blood and lymphatic system outcomes	38. Venous thromboembolism (blood clot in legs or lungs)
General outcomes	39. Sleep and fatigue
	40. Number of unplanned hospital re-admissions
	41. Length of hospital stay
	42. Number of outpatient appointments
	43. Number of Primary Care visits

Continued

Table III.   Continued

COMET Taxonomy of Outcome Domains	Outcome
	44. Metalwork failure
	45. Complications resulting from soft tissue (muscle flaps or grafts)
	46. Amputation
	47. Bone healing
	48. Malunion, alignment and rotational deformity
	49. Deep infection
	50. Surface infection
	51. Leg or bone shortening
	52. Change in sensation
	53. Muscle weakness
Musculoskeletal and connective tissue outcomes	54. Pain or discomfort
	55. Unplanned return to the operating theatre
Global quality of life	56. Quality of life
Perceived health status	57. Degree of perceived loss of general health and wellbeing
	58. Quality of communication of healthcare professionals to patients
	59. Satisfaction with care
Delivery of care	60. Tolerability and acceptability of surgical intervention e.g. external fixator
	61. Change in lifestyle
	62. Being compensated financially for injury
	63. Personal cost of treatment and care following injury
Personal circumstances	64. Effect of injury on personal finances
	65. Number of adverse events
Adverse events and effects	66. Side effects of medication
	67. Poor experience during anaesthesia
Mortality	68. Survival
Musculoskeletal and connective tissue outcomes	69. Chronic pain (Added following Delphi survey round 1)
	70. Length of stay (Super Spell) (Added following Delphi survey round 1)
General outcomes	71. Number and length of health encounters (Added at consensus meeting session 1: outcomes - 42, 43 and 70 rationalized to create outcome 71)
Musculoskeletal and connective tissue outcomes	72. Injury characteristics and surgical outcomes (Added at consensus meeting session 1: outcomes - 44, 45, 48 and 55 to create outcome: 72)

COMET, Core Outcome Measures in Effectiveness Trials.

18 outcome domains within five core areas. Following rationalization of outcomes byALA, structured discussion groups, and a study management group meeting, 68 outcomes were shortlisted for the Delphi survey (see Figure 2 for a schematic diagram of outcome rationalization, with further detail provided in Supplementary Table i).

Delphi survey. A total of 136 participants completed both rounds of the Delphi survey, of whom 55 (40%), 73 (54%), and eight (6%) were patients, healthcare professionals, and researchers, respectively (see Table II for participant characteristics). Six and 11 outcomes achieved 'consensus-in' in the first and second rounds, respectively. No outcomes met the 'consensus-out' criteria. The remaining 59 outcomes were 'no-consensus' after the second round (see Supplementary Table ii for a complete list of outcomes and their scoring for 'consensus-in').

Participants in the first round suggested 13 additional outcomes. The study management group rejected 11, and two were accepted for inclusion in the subsequent Delphi survey (see Supplementary Table iii for accepting or rejecting justification). Figure 3 shows a schematic flow diagram of the Delphi survey and consensus meeting results. The between round attrition rate was 27%, with attrition spread relatively evenly across the three stakeholder groups (26% patients, 28% healthcare professionals, and 27% for researchers).

Consensus meeting. A total of 15 patients, 14 healthcare professionals, 11 researchers, and one patient carer attended the consensus meeting (see Table II for participant characteristics). The majority of patients were male (nine (60%)), having sustained an open lower limb fracture of the tibia/fibula (14 (93%)) that required a skin graft or muscle flap (nine (60%)), and the mean age of patients

Table IV. Consensus meeting session three whole-group electronic voting results.

Outcome	Number of electronic votes counted in session 3, round 1, n = 41 (%)					Number of electronic votes counted in session 3, round 2, n = 41 (%)				
	1. Not important	2. Important but not critical	3. Critical	Median	SD	1. Not important	2. Important but not critical	3. Critical	Median	SD
1. Ability to do activities of daily living	6 (15)	11 (28)	22 (56)	3	0.74	10 (26)	3 (8)	26 (67)	3	0.87
4. Ability to be independent	6 (15)	8 (21)	25 (64)	3	0.75	19 (51)	2 (5)	16 (43)	1	0.97
6. Walking, gait, and mobility*	0 (0)	8 (21)	30 (79)	3	0.41	N/A	N/A	N/A	N/A	N/A
16. Being able to return to life roles (e.g. caring, work, and military duty)*	3 (8)	3 (8)	33 (85)	3	0.58	N/A	N/A	N/A	N/A	N/A
19. Feelings of self-identity and body wholeness	23 (57)	16 (40)	1 (2)	1	0.55	34 (92)	3 (8)	0 (0)	1	0.27
21. Feelings of giving up and hopelessness	14 (35)	14 (35)	12 (30)	2	0.8	23 (61)	1 (3)	14 (37)	1	0.96
24. Feelings of hopefulness, positivity, and determination	23 (59)	10 (26)	6 (15)	1	0.74	25 (68)	3 (8)	9 (24)	1	0.86
27. Ability to move on and feeling of getting life back	15 (38)	7 (18)	17 (44)	2	0.9	22 (61)	0 (0)	14 (39)	1	0.97
40. Number of unplanned hospital readmissions	20 (53)	10 (26)	8 (21)	1	0.8	25 (64)	4 (10)	10 (26)	1	0.87
46. Amputation	15 (38)	9 (22)	16 (40)	2	0.88	20 (54)	3 (8)	14 (38)	1	0.94
47. Bone healing	11 (28)	13 (32)	16 (40)	2	0.81	24 (60)	1 (2)	15 (38)	1	0.96
49. Deep infection	10 (26)	11 (28)	18 (46)	2	0.82	16 (40)	1 (2)	23 (57)	3	0.97
54. Pain or discomfort†	5 (12)	12 (30)	23 (57)	3	0.71	6 (15)	3 (8)	30 (77)	3	0.74
56. Quality of life*	1 (2)	7 (18)	32 (80)	3	0.47	N/A	N/A	N/A	N/A	N/A
57. Degree of perceived loss of general health and wellbeing	23 (59)	13 (33)	3 (8)	1	0.64	27 (71)	1 (3)	10 (26)	1	0.88
58. Quality of communication of healthcare professionals to patients	16 (40)	14 (35)	10 (25)	2	0.79	21 (58)	1 (3)	14 (39)	1	0.97
68. Survival	21 (54)	6 (15)	12 (31)	1	0.89	21 (54)	6 (15)	12 (31)	1	0.89
72. Injury characteristics and surgical outcome	15 (38)	6 (15)	18 (46)	2	0.92	10 (27)	1 (3)	26 (70)	3	0.89

*Outcomes reaching 'consensus-in' at round 1.
†Outcomes reaching 'consensus-in' at round 2.
N/A, not applicable; SD, standard deviation.

was 53 years (26 to 76). See Table III for a complete list of outcomes by outcome number discussed at the consensus meeting, and Figure 3 for a schematic of results. The first session led to creating two new outcomes and the selection of ten outcomes out of the 59 'no-consensus' outcomes for later consideration (Figure 3). The groups' top ten outcomes included 18 outcomes after removing duplicates. In the workshop's final session, walking, gait, and mobility, being able to return to life roles (e.g. caring, work, and military duty), quality of life, and pain or discomfort outcomes were agreed upon (see Table IV for electronic voting results in full).

Electronic voting in this session stimulated debate over whether the 'bone healing' and 'deep infection'

outcomes should be included in the core outcome set. The patients felt that fundamentally, being able to walk, return to work, and maintain a good quality of life are the most important outcomes to achieve in recovery and that bone healing and infection were secondary. The inclusion of 'deep infection' was a sticking point for several consultant surgeons, arguing that minimizing the risk of infection is a guiding principle of modern practice and is fundamentally an essential component of achieving a positive treatment outcome. A healthcare professional raised a counterargument, pointing out that the core outcome set is intended for use in all research and clinical practice on patients following open lower limb fracture. Studies on rehabilitation or psychosocial support interventions would not consider infection a key outcome to measure. An additional point supported this argument that in any surgical intervention study, infection would be regarded as an adverse event; as such, its measurement would be mandatory. The group agreed that objective surgical outcomes, including 'deep infection' and 'bone healing', are important and need to be measured in surgical intervention trials but not across all open lower limb fracture studies. Therefore, they should not be included in the core outcome set.

The four 'consensus-in' outcomes were presented to the group and ratified as the core outcome set for open lower limb fracture (see Figure 3).

Discussion

This study provides the first combined patient, healthcare professional, and researcher consensus on what outcomes to measure as part of routine clinical practice and research on patients following open lower limb fracture. Our systematic review identifies that the existing literature on open lower limb fracture is hampered by outcome heterogeneity and a lack of evidence to determine which outcomes are important to patients when recovering from open lower limb fracture.[5] This study addresses these shortcomings by using consensus methods that ensure equal representation of stakeholder views,[9] to identify outcomes that have been scored as critically important by more than 70% of patients, healthcare professionals, and researchers.

This study meets the COMET Core Outcome Set-STAndards for Development (COS-STAD),[7] an internationally agreed set of standards recommended to ensure methodologically robust core outcome set development projects.

The Delphi survey round attrition rate was 27%, higher than the average attrition rate of 12%, calculated from 19 core outcome set studies registered on the COMET database in 2018 reporting a Delphi survey.[19] The degree of non-response after the first Delphi round has been demonstrated to be highly variable between studies and can depend on the timing of the Delphi rounds, survey length, the time elapsed between the first and second rounds, and the recruitment method of participants. Several strategies were used to reduce attrition between rounds, including multiple reminder emails and patient follow-up by telephone. It may have been possible to minimize between-round attrition by decreasing the length of the survey. However, this needed to be balanced with presenting a comprehensive long list of potential core outcomes.

The patient sample recruited for the Delphi survey and consensus meeting was representative of age and sex for patients presenting to English MTCs.[20] Patients were recruited from MTCs in Oxford, Bristol, and Coventry; thus, the patient sample is likely to have been mixed in terms of social deprivation due to sociodemographic variation within and between these regions. However, the patient sample was predominantly from the South and Midlands areas of England and may not be representative of worldwide patient views and opinions. We cannot comment on how representative the Delphi survey results are of the race and ethnic diversity of the UK population as these data were not collected. While interview transcripts and patients included in the Delphi survey were representative of experiences of severe complications during their treatment, such as a deep infection or nonunion requiring a return to theatre, it was unknown how many patients attending the consensus meeting had undergone such an experience. Poor representation of patients who underwent treatment complications may explain the exclusion of deep infection and bone union in the core outcome set. Without direct experience of these complications, it is unlikely that patients will have insight into the seriousness of such adverse events and, therefore, not advocate for the inclusion of related outcomes. However, this issue was discussed during the final voting session of the consensus meeting, where surgeons explained the impact of suffering such a complication. Patients felt that the negative life impact of such an event would be sufficiently captured by the 'walking, gait, and mobility' and 'quality of life' outcomes. It was also unexpected that no outcomes directly representative of the emotional functioning and wellbeing outcome domain were included in the core outcome set. This may have resulted from excluding an overarching candidate core outcome for this domain, e.g. 'stress and anxiety'. However, three emotional functioning and wellbeing outcomes (outcomes 19, 21, and 24; Table III) did reach the final voting session, but all received a majority vote of 'not important' in both voting rounds. Participants felt that emotional functioning and wellbeing would be sufficiently measured by 'quality of life' during the discussion.

In conclusion, this study identified a four-outcome core outcome set (Figure 3) representing the recommended outcomes to measure as a minimum in future trials, systematic review, clinical research, and audit on adult open lower limb fracture. Further work is required to identify how these outcomes should be measured.

It is hoped that consistent outcome reporting guided by the CO-OLLF core outcome set will guarantee that future research addresses outcomes agreed upon as important by all stakeholders, facilitates evidence synthesis across

studies, and ultimately leads to enhanced patient care and improvement of treatment results following open lower limb fracture.

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Supplementary material
Text describing a detailed secondary thematic analysis methodology. Figures showing coding trees presenting standardized outcome headings identified from the literature, and outcome themes interpreted from the thematic analysis categorized using the Core Outcomes Measures in Effectiveness Trials Initiative, Taxonomy of Outcomes. Tables illustrating the progression of outcomes from the inventory of outcomes to the Delphi survey, and additional outcomes suggested at the Delphi survey and justification for inclusion or exclusion.

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