■ CHILDREN'S ORTHOPAEDICS

Attaining a British consensus on managing idiopathic congenital talipes equinovarus up to walking age

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Aims

The aim of this study was to gain an agreement on the management of idiopathic congenital talipes equinovarus (CTEV) up to walking age in order to provide a benchmark for practitioners and guide consistent, high-quality care for children with CTEV.

Methods

The consensus process followed an established Delphi approach with a predetermined degree of agreement. The process included the following steps: establishing a steering group; steering group meetings, generating statements, and checking them against the literature; a two-round Delphi survey; and final consensus meeting. The steering group members and Delphi survey participants were all British Society of Children's Orthopaedic Surgery (BSCOS) members. Descriptive statistics were used for analysis of the Delphi survey results. The Appraisal of Guidelines for Research & Evaluation checklist was followed for reporting of the results.

Results

The BSCOS-selected steering group, the steering group meetings, the Delphi survey, and the final consensus meeting all followed the pre-agreed protocol. A total of 153/243 members voted in round 1 Delphi (63%) and 132 voted in round 2 (86%). Out of 61 statements presented to round 1 Delphi, 43 reached 'consensus in', no statements reached 'consensus out', and 18 reached 'no consensus'. Four statements were deleted and one new statement added following suggestions from round 1. Out of 15 statements presented to round 2, 12 reached 'consensus in', no statements reached 'consensus out', and three reached 'no consensus' and were discussed and included following the final consensus meeting. Two statements were combined for simplicity. The final consensus document includes 57 statements allocated into six successive stages.

Conclusion

We have produced a consensus document for the treatment of idiopathic CTEV up to walking age. This will provide a benchmark for standard of care in the UK and will help to reduce geographical variability in treatment and outcomes. Appropriate dissemination and implementation will be key to its success.

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Introduction

The Ponseti method is the 'gold standard' for treating congenital talipes equinovarus (CTEV) and is applied worldwide.[1–5] Variations in treatment protocols, including age at the beginning of casting, the health professional involved in casting, casting technique, foot abduction brace regime, and follow-up time have led to operation rates of up to 53.3%.[6,7] On the other hand, the mean reported rate for surgery in Europe is 10.5%, where the Ponseti method is followed without deviation.[7] It has also been shown that patients with CTEV treated with soft-tissue release have poor long-term outcomes, with a correlation between the extent of soft-tissue release and functional impairment.[8–11]

The James Lind Alliance priority setting on lower limb surgery in children highlighted

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Table I. Consensus criteria.

Consensus in	75% or more participants scored it as 'critical for inclusion' and less than 25% of participants scored it as 'not important for inclusion'.
Consensus out	75% or more participants scored it as 'not important for inclusion' and less than 25% of participants scored it as 'critical for inclusion'.
No consensus	Anything else not included in the other two categories.

Table II. Steering group members and Delphi survey respondent background.

Clinical role	n (%)
Steering group (n = 14)	
Consultant orthopaedic surgeon	8
Extended scope practitioner	3
Advanced nurse practitioner	1
Physiotherapist	1
Non-participating consultant*	1
Delphi round 1 (n = 153)	
Consultant orthopaedic surgeon	116 (76)
Advanced practitioner	11 (7)
Advanced nurse practitioner	1 (1)
Physiotherapist	1 (1)
Orthopaedic registrar	1 (1)
Not specified	23 (15)
Delphi round 2 (n = 132)	
Consultant orthopaedic surgeon	113 (86)
Extended scope practitioner	10 (8)
Advanced nurse practitioner	3 (2)
Physiotherapist	2 (2)
Clinical fellow	3 (2)
Orthopaedic registrar	1 (1)

*This refers to someone who was not involved in voting or decision-making; their responsibility was to supervise the proceedings as a Delphi expert only.

Table III. The statements that were deleted, added, or combined during each stage of the Delphi process.

Delphi round 2, four deleted statements
1) A positional clubfoot scores 0 on the Pirani score, and is fully flexible.
2) Other scoring systems may be used in addition to the Pirani score, at the discretion of the treating clinician.
3) The pre-tenotomy cast should only be removed immediately prior to tenotomy.
4) There should be at least eight weeks in-between a primary and a revision tenotomy.
Delphi round 2, one added statement
1) All Ponseti clinics should have a named consultant paediatric orthopaedic surgeon overseeing the clinic.
Final consensus meeting, two combined statements into statement number 10
1) Active movement of the leg and foot (e.g. eversion of the foot, dorsiflexion of the big toe) should be assessed and recorded.
2) A full neurological examination of the leg should be done.

variations in practice as one of their top 20 priorities,[12] which, along with geographical variation and lack of good evidence, motivated the British Society of Children's Orthopaedic Surgery (BSCOS) to develop consensus groups, of which primary CTEV management was one.

Previous attempts at developing consensus at a European level included a relatively small number of experts and healthcare professionals.[13,14] This paper, however, is the first reported consensus of the management of CTEV by all paediatric orthopaedic healthcare practitioners working in the UK.

Consensus methods provide a way of synthesizing information and harnessing the insights of appropriate experts to enable decision-making.[15] The Delphi technique is a structured process that uses a series or 'rounds' of questionnaires to gather information and reach consensus. Since a large number of individuals across diverse locations and areas of expertise can be included anonymously, this method is able to avoid domination of the consensus process by one or a few experts.[16]

The health question covered by the consensus statement is whether the variability of care provision and outcomes in primary CTEV can be reduced by following the same agreed management steps. Setting these standards allows for effective data collection and identification of outliers. Furthermore, it will enable those treating CTEV to share the published consensus document with both carers and patient groups.

The objective of this paper is to provide a statement that could be followed, audited, and benchmarked against the agreed standard of care and presents the final consensus document along with an overview of the process.

Methods

The study protocol, including methods and timeline, was previously published at the start of the study to ensure that the predefined protocol would be followed.[17] A summary of these stages is reported below. The Appraisal of Guidelines for Research & Evaluation checklist was used as the principle for result reporting.[18]

A four-stage process was followed: establishing a steering group; steering group meetings, generating statements, and checking these statements against the published literature; a two-round Delphi survey; and the final consensus meeting. Participants were asked to score each outcome in the survey using a Grading of Recommendations, Assessment, Development and Evaluations (GRADE) scale, which ranges from 1 to 9 (1 to 3, not important; 4 to 6, important but not critical; and 7 to 9, critical for inclusion).[19] The definition of consensus is presented in Table I.

Population. The consensus document applied to all patients with primary idiopathic CTEV of any severity under walking age. It does not apply to patients with neuromuscular CTEV, spina bifida, arthrogryposis, or any other cause of secondary CTEV. The statements do not cover the management of children with non-idiopathic clubfoot or any children after walking age.

Stakeholder involvement. Members of the steering group were all either full or associate members of the BSCOS. Applicants for the steering group included all CTEV practitioners: paediatric orthopaedic surgeons, physiotherapists,

Table IV. Summary of consensus statements at every stage.

Steering group	n
Number of statements	61
Delphi round 1	
Number of statements	61
Number of statements reached 'consensus in'	43
Number of statements reached 'consensus out'	0
Number of statements reached 'no consensus'	18
(Four statements deleted and one new statement added)	
Delphi round 2	
Number of statements	15
Number of statements reached 'consensus in'	12
Number of statements reached 'consensus out'	0
Number of statements reached 'no consensus'	3
Final consensus meeting*	
Number of statements	3
Number of statements 'voted in'	3
Number of statements 'voted out'	0
Final number of statements in the consensus document	57

*Two statements simplified by combining into one.

nurse practitioners, or plaster practitioners who were regularly involved with CTEV management.

All BSCOS members who submitted an expression of interest were subsequently selected by the BSCOS board for participation in the steering group (n = 14). None of the steering committee members had any competing interests that could influence the consensus process or the development of recommendations. The steering group members' clinical roles are presented in Table II. The list of the internal and external members and their affiliations is published in the protocol paper and has not changed.[17]

The Delphi survey was open to all BSCOS members. The number and clinical roles of the BSCOS members and associates who participated in the Delphi survey are presented in Table II. In total, 153 participated in the first round (63% of those invited) and 132 of those in the second round (86%). An introduction question was included to ensure that only clinicians reporting significant experience in treating CTEV would continue to complete the survey. The Delphi process questions submitted to the BSCOS membership were close-ended, with the option to comment on each statement offered.

Target users' preferences and views. The target users are all CTEV practitioners involved in the management of children with CTEV as well as general practitioners (GPs), patient and family groups, and hospital managers involved in planning and budgeting Ponseti clinics. The consensus statements will be shared with carers and parents to improve their knowledge and manage their expectations.

Preference of treatment and views were sought by evidence from the literature, expert opinions from practitioners who formed the steering group, and from all BSCOS members in the form of the Delphi survey. The first steering meeting focused on the process and divided the consensus statement into six successive stages: referral pathways and initial assessment, clinic set-up, the casting process, tenotomy, foot abduction brace (FAB), and relapse. The subsequent meetings continued the brainstorming sessions and discussed each section in detail and prepared statements for the Delphi survey. Between Delphi round 1 and 2, the steering group reassessed and modified the statements that did not reach consensus. The final consensus meeting followed the Delphi survey. In the final meeting, the statements that reached consensus were approved, and the statements that did not reach consensus were discussed in depth and voted upon in order to decide whether there was merit in including them.

Rigour of development. The consensus statement is based on the practice and expertise of the participating BSCOS members. The topics were discussed and scrutinized against the up-to-date literature during the steering group meetings.

Results

Formulation of recommendation: steering group meetings. Six steering group meetings were held throughout the process. Due to the COVID-19 pandemic, these meetings were all undertaken via remote video connection. Four meetings, each lasting three hours, were held prior to the Delphi survey. A fifth meeting took place between Delphi round 1 and 2 and the final consensus meeting took place following Delphi round 2.

In the first meeting, a chair was elected and the six successive stages of the document were decided upon. Detailed statements under each section were suggested by all members over three meetings. Each suggested topic generated a process including a current literature review, as well as the group members' expert opinion, and the statements to be included in each section were selected. A fourth meeting summarized all agreed statements to be presented to BSCOS members in the round 1 Delphi survey. The fifth meeting took place following Delphi round 1. In this meeting, the items that reached 'consensus in' were read and approved, the items that reached 'no consensus' were discussed, reassessed, and modified, and the final list of statements to be presented in round 2 was agreed upon. The final consensus meeting took place following Delphi round 2. Items that reached 'no consensus' following round 2 were discussed in depth and voted upon to decide whether there was merit in including them. The items to be included in the consensus document were finalized. The meetings timeline followed the consensus protocol.[17]

Round 1 Delphi survey. In total, 61 statements were included in Delphi round 1. Overall, 43 statements reached 'consensus in' and were included in the final statement after approval by the steering group. No statements reached 'consensus out'. 18 statements reached 'no consensus' and were discussed in the steering group meeting. Following this discussion, four statements with scoring close to the low cut-off point were removed. A total of 14 statements were added to round 2, and 11 were rephrased based on the comments received from round 1, while three were added as they were. One new statement was added to round 2 based on the comments received from round 1 and following discussion. The total number of statements presented to round 2 was 15. The statements that were deleted and added following round 1 are presented in Table III.

The descriptive analysis of all statements in the Delphi survey round 1, including the median and interquartile ranges, is presented in Supplementary Table i.

Round 2 Delphi survey. A total of 15 statements were included in Delphi round 2. The voting members were able to see the

Table V. The final consensus statement.

Referral pathways
1) Regarding the treatment of idiopathic clubfoot deformity in infants and children up to walking age, the Ponseti technique should be the first line treatment.
2) If antenatal counselling is offered, it should be performed by the Ponseti practitioners.
3) Postnatal referral pathways should allow easy access and early referral.
4) Ponseti casting should begin between two and six weeks of age.
5) Premature infants can have treatment delayed until they reach birth age, bearing in mind foot size and smallest boot size available.
Regarding initial assessment
6) A full history and examination should be performed before treatment commences.
7) All infants with a clubfoot deformity should receive a screening US hip scan.
8) The Pirani scoring system should be used at initial assessment, and at each visit/stage of treatment.
9) Practitioners performing the Ponseti technique should be able to recognize an atypical foot, and a neuromuscular/syndromic foot and refer it onwards if more appropriate.
10) A full neurological examination of the leg should be done to exclude an underlying neurological cause e.g. dorsiflexion of the big toe at initial assessment and evertor activity after full correction.
11) Radiographs of the foot are not routinely performed.
Regarding Ponseti clinic set-up
12) All Ponseti clinics should have a named consultant overseeing the clinic (either on site or visiting).
13) Two trained staff should be present for each casting; the clinic must have enough staff to be able to run a weekly clinic service and support annual leave.
14) The lead clinician should have undergone specific practical Ponseti training on an official Ponseti training course, and have a broad experience of paediatric orthopaedics in addition.
15) To ensure competency, all clubfoot clinics should be run by properly trained personnel, regularly audited, exist in networks providing regional support, and with clear pathways for onward referral to more experienced practitioners in case of difficulty.
16) In line with the CQC inspection framework, ideally, infants and children should be treated in a child-appropriate environment, separately from adults.
17) Results, including the number of casts required and tenotomy and revision tenotomy rates, should be audited at least annually to ensure maintenance of skills and acceptable results.
18) Parent information regarding treatment, cast removal, tenotomy, and boots and bar wear should be made available verbally, with leaflets, and online.
19) Parents should have clear out of hours contact information for emergency advice, with robust pathways for out of hours clinical care, to address e.g. concerns post-tenotomy, plaster slips, including cast removal if necessary.
Regarding the casting process
20) The Ponseti method of casting should be strictly adhered to.
21) A single thin layer of padding without stockinette should be used under the cast.
22) Plaster of Paris should be used in all patients, quick setting if possible.
23) Ponseti casts are above-knee casts, toe to groin.
24) A footplate should be left below the toes and cut out above the toes.
25) Casts should be changed every four to seven days, dependent on the practicalities of clinic set-up.
26) Casts should be removed immediately prior to a casting session, ideally in the clinic and not at home, to allow inspection of quality of the previous cast and to check for slips and pressure areas.
27) If a cast slips, it must be removed immediately.
28) Parents should be taught how to tell if a cast has slipped, how to contact the team out of hours, and told how to remove the cast or where to take the child for it to be removed.
29) When necessary, it is possible and practical to apply Ponseti casts to a child in a Pavlik harness.
30) The skin condition/presence of pressure sores should be assessed/recorded at every cast change.
31) The occurrence of the following in an individual infant should prompt a practitioner to seek help or onward referral: pressure sores, repeated slips, more than seven casts, Pirani score stalling, or presentation of atypical and non-idiopathic feet if they do not have the experience to treat these feet.
Regarding tenotomy
32) The foot is ready for tenotomy when the talar head is covered, the heel is in neutral or valgus, and the anterior process of the os calcis has come out from under the talus.
33) The primary tenotomy should be performed under local anaesthesia, however GA may be considered for children over the age of six months or at the discretion of the surgeon.
34) The tenotomy should be performed by a trained paediatric orthopaedic surgeon or under the direct supervision of such a surgeon.
35) There must be adequate access to a paediatric orthopaedic surgeon so that the tenotomy can be performed in a timely fashion, with no long waits in cast for surgeon availability.
36) An environment with facilities allowing for paediatric resuscitation should be available; this would normally be in a clinic environment within a hospital or health centre.
37) The tenotomy should be a complete tenotomy of the Achilles tendon, performed percutaneously, using as small a blade as possible, and under a sterile environment.
38) The post-tenotomy cast should stay on for two to three weeks, with a cast change option within this timeframe.

Continued

Table V. Continued

39) Boots and bars must be available for fitting as soon as the cast is removed – they may need to be measured prior to the tenotomy.
40) It should be expected that a tenotomy will be required- in 85% to 95% of patients.
Regarding the FAB
41) The maintenance of a well corrected clubfoot relies on compliance with the FAB, which requires:
a) Education of parents on the importance of bracing starting at the first assessment (or antenatal counselling stage) and reinforced at each consultation;
b) Regular contact and support for families from the Ponseti practitioners;
c) Reliable social media sources can be recommended for information/support e.g. Steps Worldwide.
42) The boots used should be attached to a fixed bar, shoulder-width apart, with an ability to set the angles to 60° to 70° on the affected side, and 30° to 40° on the unaffected side.
43) The FAB should be worn for 23 hours a day for the first three months, then at night-time and naps until five years of age (at least 10 to 12 hours per day in this second phase).
44) There is not yet evidence to support the use of unilateral or articulated braces.
45) The FAB should be fitted, and regular follow-up should be performed, by a trained and experienced Ponseti practitioner.
46) At the first fitting, the Ponseti practitioner should fit, teach, and watch parents fitting the boots.
47) The infant should settle before sending home and parents advised that initial unsettled nights are normal.
48) There should be regular follow-up with a recommended plan being: one week after the FAB first fitted, and then three-monthly until two years, and six-monthly until FAB discarded at age 5.
49) If skin issues are encountered some or all of the following are recommended: using long close-fitting socks, trying another make of boot, trying a short rest out of boots, or a period of recasting.
50) At each review appointment foot correction, skin condition and Pirani score should be checked.
51) There should be easy access to a variety of boot sizes, with a good selection of stock or pre-ordered sizes, to ensure that no infant is ever left out of FAB.
52) After discontinuing FAB wear, follow-up should continue up to skeletal maturity.
Regarding relapse
53) Relapse implies a reappearance of any of the clubfoot deformity elements in a foot that has previously fitted easily into the FAB.
54) A foot that has never settled in the FAB merits an assessment of adequate deformity correction.
55) Early relapse should be treated with recasting in an above-knee cast, following careful assessment of which components have relapsed.
56) If revision tenotomy is required, strong consideration should be given to performing it under GA.
57) FAB should be reintroduced when the foot is corrected (sometimes an alternative boots and bar system may help regain trust and compliance and enable reintroduction of the standard brace as soon as possible).

CQC, Care Quality Commission; FAB, foot abduction brace; GA, general anaesthesia; US, ultrasound.

percentage agreement that each statement had reached in round 1. Overall, 12 statements reached 'consensus in', no statements reached 'consensus out'. Three statements reached 'no consensus' and were moved to the final consensus meeting. The descriptive analysis of all statements in the Delphi survey round 2, including the median and interquartile ranges, is presented in Supplementary Table ii.

The final consensus meeting. In the final consensus meeting, all the statements that reached consensus during the Delphi survey were approved. Three statements from Delphi round 2 reached 'no consensus' and were discussed in the final meeting. The scores for these three statements on both rounds were very close to the threshold. These statements were discussed and unanimously 'voted in' by the steering group (threshold of more than 75%). Three statements were incorporated into existing statements for continuity. The number of statements and their status at each stage is shown in Table IV. The statements that were combined following round 2 during the consensus meeting are presented in Table V.

The final consensus document is divided into six successive stages and includes 57 statements (Table V).

Discussion

The gold standard for the management of idiopathic CTEV is the Ponseti method, which includes correction of the deformity through serial manipulation and casting, a percutaneous tenotomy in the majority of patients, followed by a maintenance period in a FAB. In this paper, the Ponseti method of treatment of a child with a CTEV is not in question, but the details of how this treatment is applied are. These details include the timing of procedures, as well as the local set-up for treating the child with a CTEV. This is because although often referred to as 'The Ponseti Method', it may differ widely throughout the country, resulting in varying effects on both the patient's experience and indeed their final outcomes. It is our premise that by creating a consensus in the details of the assessment, correction, and maintenance of the corrected foot will improve the overall level of care and outcomes of CTEV treatment. We present the results of a complete consensus statement following the Delphi process. The consensus includes the holistic approach to managing infants with CTEV and their families through the referral process, and incorporates the assessment of the infant as a whole, the deformity correction and maintenance, as well as the management of early relapse. This process has highlighted several issues that are considered important by BSCOS members, emphasizing the need for attention to detail and optimization of every stage.

The external review for this consensus document is the BSCOS body. The members and associated members who participated in the Delphi survey aimed to improve the quality of the proposed statements, generate feedback, and assess the applicability and feasibility of the suggested statements.

One of the strengths of the study is its vigorous design, meticulous implementation, and interpretation of results. The study protocol was executed as published without changes, and the timeline maintained. The limitation of the methodology includes the participants in the consensus process who were all BSCOS members. This selection is appropriate for a UK consensus statement, but can reflect a bias when attempting to implement the consensus document in other countries. However, we believe that the majority of the consensus document is applicable to most areas worldwide.

It is also acknowledged that there is a larger representation of paediatric orthopaedic consultants than other practitioners in the BSCOS. The steering committee included participants from a wide geographical area, including representatives from numerous units in the UK. The combination of the diversity of steering group members, the high participation rate, and very low dropout of 14% in the Delphi survey contributed to an extensive representation of CTEV practitioners from the UK. The percentage of members who voted (63%, n = 153) possibly reflects the fact that not all members of BSCOS treat clubfeet.

The information regarding barriers to implementing recommendations were sought through feedback from stakeholders during the Delphi process, as well as during the discussions in the steering group meetings. The barriers were identified in two aspects: one access to formal Ponseti training, and the other availability of resources for the clinic set-up that includes two trained practitioners available for every casting, a child-appropriate environment, sufficient level of staff to support communication with parents, regular audits, and training. These barriers did not influence the guideline development process or formation of the recommendations. The barriers were discussed and considered in depth.

The purpose of this consensus process was not necessarily to reflect current management practice, but to explicitly set the benchmark for the best quality of care. It was also felt that by providing the most appropriate standard of care recommendations, it will assist practitioners and managers in understanding the clinic's needs and business planning.

The outcome of this study, and the magnitude of benefit versus harm, was also considered. The benefits of publishing a consensus in treatment include improved quality of care and outcomes of treatment based on the best evidence, improved training and clinic set-ups according to the established standard, and improvement in the information that is offered to families, allowing them to plan and prepare for the process. The consensus in treatment aims to overcome geographical variability in treatment and outcomes.

The potential harm or side effects of this exercise are the risks of anxiety and frustration developing in families in areas that cannot offer this standard of care. As this consensus statement is due to be disseminated between practitioners, GPs, and parents' groups, it will hopefully become common knowledge and will be accepted at every hospital or clinic. However, if and when the standard practice is not provided, it could result in patient and family dissatisfaction. This side effect, however, is expected in any practice when the standard of care is defined and presumed to be followed. However, in our view, the benefits obtained by this consensus far outweigh the possible side effects, and we believe that this standard of care is achievable both in terms of financial planning and training.

The steering group used evidence from the literature to support the discussion and form statements to be used in the Delphi process. The final consensus statement and recommendations are based on both consensus opinion and the available literature. However, not all individual statements have high-quality evidence to support them. There is evidence in the literature of a large variability in practice, as well as variability in outcomes of treatment. To improve practice and outcomes, we have used evidence-based statements and, where no such evidence presently exists, we have applied best practice of a group of experienced clinicians with an established clubfoot practice.

We suggest that the consensus should be reviewed at five years and a decision made regarding whether an update is needed. The methodology for the update includes a new literature search into the key aspects of the consensus document, along with a steering group to review the consensus statement, analyzing any new research, and deciding whether the Delphi process should be repeated or whether any addendum needs to be added.

It is also recommended that the consensus document should be available in every Ponseti clinic, preferably laminated and visible for all to see. BSCOS aims to produce printed versions of the document in English for both parents and carers.

Furthermore, we recommend that adherence to the consensus should be audited regularly at least once a year. Assessing the impact of implementation of the consensus will be done, once the consensus is well established, by prospective data collection of the outcomes of treatment in every region.

This consensus document does not include a cost analysis. In general, the Ponseti method is low-cost and globally accepted in both low-middle-income countries (LMICs) and high-income countries (HICs),[1,6,7] and an economic evaluation is beyond the scope of this project.

This consensus statement has a high applicability to practice context. It provides specific detailed information divided into six successive stages including referral pathways, CTEV clinic set-up, technical casting, tenotomy and bracing details, and the definition and management of early relapse.

In conclusion, this consensus statement was achieved following the Delphi process. It is now the recommended way to manage primary idiopathic CTEV until walking age, and aims to reduce regional variability in treatment and improve outcomes.

Take home message

- This study aim was to reach an agreement on the management of idiopathic congenital talipes equinovarus (CTEV) up to walking age in order to provide a benchmark for practitioners and guide consistent, high-quality care for children with CTEV.
- The consensus process followed an established Delphi approach and resulted in 57 statements allocated into six successive stages. This will help reduce geographical variability of care.
- Appropriate dissemination and implementation will be key to its success.

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Supplementary material

Descriptive analysis of statements included in the Delphi survey rounds 1 and 2.

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