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Consensus on Training and Assessment of Competence in Performing Chorionic Villus Sampling and Amniocentesis: An International Delphi Survey

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Keywords
Chorionic villus sampling · Amniocentesis · Curriculum · Assessment · Delphi survey · Expert consensus

Abstract
Introduction: The aim of this study was to obtain expert consensus on the content of a curriculum for learning chorionic villus sampling (CVS) and amniocentesis (AC) and the items of an assessment tool to evaluate CVS and AC competence. ***Methods:*** We used a 3-round iterative Delphi process. A steering committee supervised all processes. Seven international collaborators were identified to expand the breadth of the study internationally. The collaborators invited fetal medicine experts to participate as panelists. In the first round, the panelists suggested content for a CVS/AC curriculum and an assessment tool. The steering committee organized and condensed the suggested items and presented them to the panelists in round 2. In the second round, the panelists rated and commented on the suggested items. The results were processed by the steering committee and presented to the panelists in the third round, where final consensus was obtained. Consensus was defined as support by more than 80% of the panelists for an item. ***Results:*** Eighty-six experts agreed to participate in the study. The panelists represented 16 countries across 4 continents. The final list of curricular content included 12 theoretical and practical items. The final assessment tool included 11 items, systematically divided into 5 categories: pre-procedure, procedure, post-procedure, nontechnical skills, and overall performance. These items were provided with behavioral scale anchors to rate performance, and an entrustment scale was

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used for the final overall assessment. ***Conclusion:*** We established consensus among international fetal medicine experts on content to be included in a CVS/AC curriculum and on an assessment tool to evaluate CVS/AC skills. These results are important to help transition current training and assessment methods from a time- and volume-based approach to a competency-based approach which is a key step in improving patient safety and outcomes for the 2 most common invasive procedures in fetal medicine.

Introduction

Chorionic villus sampling (CVS) and amniocentesis (AC) are the most performed invasive procedures within fetal medicine and are used to test for chromosomal or genetic disorders in the fetus [1]. The background risk of all clinically relevant chromosomal anomalies is higher than previously anticipated [2]; this presents broader indications for genetic testing. The latest guideline on screening for chromosomal abnormalities produced by the American College of Obstetricians and Gynecologists (ACOG) suggests that "all pregnant women should be offered both screening and diagnostic tests," irrespective of risk factors [3]. Increasing access to invasive genetic testing requires safe procedures performed by skilled operators [1].

CVS and AC are usually performed by ultrasound-guided transabdominal or transvaginal insertion of a needle into the placenta (CVS) or the amniotic cavity (AC) to collect a sample. The performance of these procedures is generally safe for the woman; however, the procedure-related risk of fetal loss is up to 1% [2, 4–6]. The magnitude of the procedure-related risk has been debated for decades. Previous studies demonstrated an inverse association between the procedure-related risk of fetal loss and operator experience [4, 7]. Yet, there is no international consensus on what should be required of a trainee to perform the procedures independently.

Simulation-based training has been suggested as a supplement to clinical training since it allows trainees to practice in a safe environment without patient risk [8–10]. However, it is not clear what aspects of training would benefit CVS and AC performance on real patients [11] or how much training is needed before progressing from simulated to clinical practice and subsequently from supervised to independent practice. Using an international panel of fetal medicine experts, we aimed to establish consensus on: (1) the content to be included in a curriculum for learning and training of CVS and AC and (2) the content to be included in an assessment tool to evaluate trainees' CVS and AC skills.

Methods

We conducted an international 3-round Delphi process. The Delphi process is a well-established method to obtain consensus among a group of experts using iterative rounds of survey questionnaires followed by individual and/or group feedback until consensus is achieved [12].

The study was conducted by the Department of Fetal Medicine, Rigshospitalet, and Copenhagen Academy of Medical Education and Simulation (CAMES), Denmark, from December 2019 to June 2020. The responses of the panelists were collected through the SurveyMonkey® platform [13]. The Danish legislation exempts survey studies from ethical approval.

Consensus Definition

The definition of consensus was established before data analyses. Based on previous Delphi studies [14], the definition of consensus was set to more than 80% agreement on each individual item. For example, on a 5-point rating scale to measure importance of a given item, we defined consensus as a minimum of 80% of the panelists rating an item as important (4) or very important (5).

Steering Committee

A steering committee of 6 members consisting of fetal medicine experts (K.M.S., L.N.N., and O.B.P.) and medical education scientists (M.G.T., V.J., and L.N.) supervised all processes including identification of panelists, development of questionnaires, data collection, and data analysis.

The Collaborators and the Panelists

The steering committee identified 7 international collaborators prior to the study to expand the breadth internationally and to facilitate the process of data collection. The collaborators were selected based on their geographical location and on their role as recognized experts within invasive fetal medicine and involvement in local, regional, and national planning and implementation of education and training within the field.

The collaborators were asked to invite fetal medicine experts to act as panelists and provide the core data for the study. The panelists were selected based on the collaborators' geographical position and network (A.K. – UK, D.P. – Italy, E.T. – Sweden, F.S. – The Netherlands/Belgium/France, J.H. – Australia/New Zealand, R.W. – Canada/USA, and U.G. – Germany). The inclusion criteria to participate in the study was previous experience in teaching or supervising CVS and/or AC. Written consent was obtained from all the panelists who agreed to participate. All correspondence was sent to the panelists individually through e-mail, and their completed questionnaires were returned directly to the steering committee. All the collected data were anonymized.

The Delphi Rounds

Round 1: Content Description for the Curriculum and the Assessment Tool

The panelists were asked 2 questions: (1) to list in free text all the aspects of learning and training of the CVS/AC procedure to

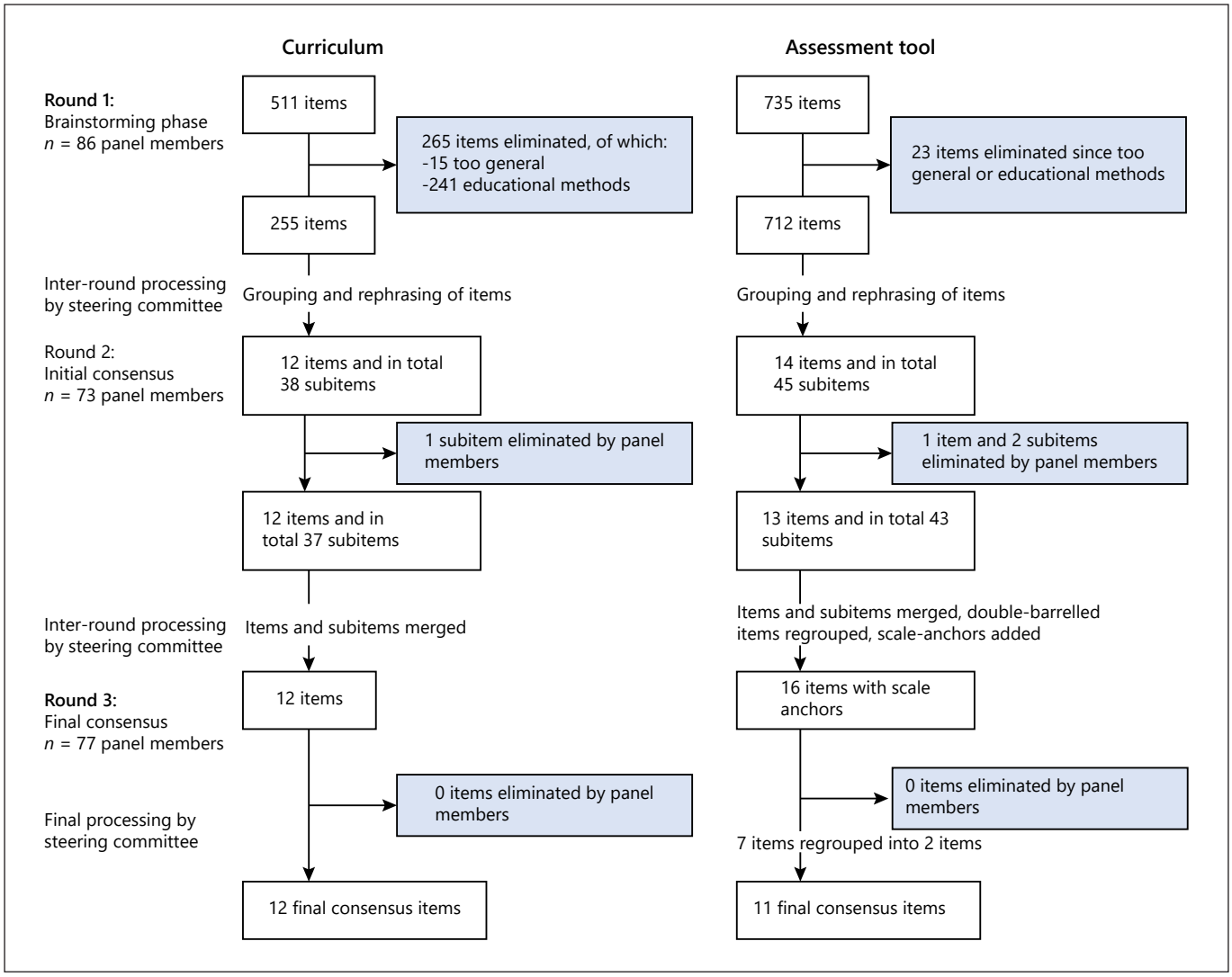

Fig. 1. Flowchart.

be included in a curriculum and (2) to list in free text all relevant items that they would consider when assessing the overall skill level in CVS or AC. Furthermore, they were asked to answer questions about their local practices, personal preferences, and experience in performing CVS and AC.

Data gathered were reviewed and organized by the steering committee. The suggested content for the curriculum was organized into theoretical and practical content items, each with descriptive subitems. The suggested content for the assessment tool was also organized into items, each with descriptive subitems. These organized curriculum and assessment tool items were sent to the panelists to evaluate in the next Delphi round.

Round 2: Initial Consensus

The panelists were presented with the organized lists of items and subitems suggested for (1) the curriculum and (2) the assessment tool. Using a scale of 1–5 (with lower scores indicating less relevance), the panelists were asked to rate the curricular items according to relevance for learning and training of the CVS/AC procedure and assessment tool items according to relevance for the assessment of CVS/AC performance. The panelists also had the opportunity to mark any subitem as irrelevant and to be eliminated. Comment boxes were provided to the panelists to expand on their opinions. The panelists were encouraged to comment on the phrasing of each item and descriptive subitem.

Items and subitems that did not fulfill the consensus criterion of 80% agreement were eliminated. Based on the comments, rephrasing and restructuring of the items were made; however, the main content remained the same. The assessment tool items were expanded with a rating scale ranging from 1 to 5, including behavioral anchors on scales "1," "3," and "5" to guide the raters during assessment. The final lists of curricular and assessment tool items were presented to the panelists in Delphi round 3.

Table 1. Geographical distribution of panel members

Country	Participants, *N* (%)
Germany	15 (17.0)
UK	13 (15.1)
Australia	10 (11.6)
Denmark	9 (10.5)
Sweden	9 (10.5)
Canada	7 (8.1)
Italy	6 (7.0)
The Netherlands	3 (3.5)
Norway	3 (3.5)
Belgium	2 (2.3)
Finland	2 (2.3)
France	2 (2.3)
USA	2 (2.3)
Iceland	1 (1.2)
Lithuania	1 (1.2)
New Zealand	1 (1.2)
Total	86 (100.00)

Table 2. Procedural technique

	N (%)
General	
Use a guide for the CVS/AC procedure	82 (100.0)
Yes, always	22 (26.8)
Yes, sometimes	7 (8.5)
Never	53 (64.6)
Specific for the CVS procedure	
Access path	80 (100.0)*
Always using transabdominal	65 (81.3)
Either transabdominal or transvaginal/cervical	13 (16.3)
Always transvaginal/cervical	2 (2.5)
Local anesthetic	82 (100.0)
Yes	39 (47.6)
No	43 (52.4)
Specific for the AC procedure	
Local anesthetic	82 (100.0)
Yes	1 (1.2)
No	81 (98.8)

CVS, chorionic villus sampling; AC, amniocentesis. *Two panelists reported not performing the CVS procedure.

Round 3: Final Consensus

The panelists were presented with the revised lists of (1) curricular items and (2) assessment tool items with scale anchors for final consensus. They were asked to agree or disagree on each of the items. Eliminated items from round 2 were also presented to the panelists, and they were asked to agree or disagree with the elimination of these items. Comment boxes were provided to the panelists to expand on their opinion.

Results were again reviewed by the steering committee, and items that did not fulfill the consensus criterion were eliminated. The comments were also reviewed, and relevant items were revised accordingly. A flowchart of the Delphi-process is shown in Figure 1.

Data Analysis (Including Statistical Analysis)

Frequency and descriptive analysis were used to calculate the scores. Statistical analyses were performed using SPSS® ver. 26.0., IBM Corporation.

Results

Response Rates

In total, 127 experts were invited to participate in the study. Of these, 86 (68.5%) experts agreed to participate and act as panelists. All the panelists included in round 1 were invited to participate in rounds 2 and 3. In round 2, 83.9% (73/86) responded, while 90.7% (78/86) responded in round 3.

Characteristics of the Panelists

The panel included experts from 16 countries (Table 1) who had a mean experience within fetal medicine of 19.4 (min. 4; max. 36) years. Most of the panelists reported using transabdominal access when performing CVS and AC; however, the use of a guide and use of local anesthetics varied (Table 2).

One-third (31.4%) of the panelists reported having access to a CVS and/or AC mannequin for training of procedural skills. On the question "Is there a specific number of procedures required before a trainee can perform a CVS or AC independently?" 40.7% of the panelists answered in the affirmative. Those who responded yes were asked to specify how many procedures were required. The answers ranged between 0 and 30 procedures (CVS: mean 13 SD 12; AC: mean 11 SD 11.3) on a simulator and 5–100 procedures (CVS: mean 29 SD 19.6; AC: mean 30 SD 24.7) on a real patient.

Curricular Content

In round 1, the panelists suggested a total of 511 items to be included in a CVS/AC curriculum. Items not targeted toward the CVS/AC procedure or items that were too general (e.g., "operation") were eliminated (n = 15). Many items suggested by the panelists included educational methods (n = 241), for example, multiple-choice tests, number of procedures, lectures, apprenticeship learning, and simulation-based training; however, these

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Table 3. Curricular content rounds 2 and 3

item and subitem	Round 2			Round 3		
	participants, *N*	disagree, % (*N*)	mean score (SD)	participants, *N*	agree, % (*N*)	disagree, % (*N*)
1. Screening	71	–	4.66 (0.53)	78	100.0 (78)	0.0 (0)
Principles of screening		2.8 (2)				
Noninvasive screening tests: combined test, NIPT		2.8 (2)				
2. Anatomy and physiology	71	–	4.13 (0.81)	78	98.7 (77)	1.3 (1)
Relevant anatomy and physiology		5.6 (4)				
3. Genetics	71	–	4.22 (0.52)	78	100.00 (78)	0.00 (0)
Basic genetics and the condition tested for		2.8 (2)				
Genetical examination methods and their characteristics (karyotype, array, whole genome, etc.)		2.8 (2)				
Interpretation of test results		2.8 (2)				
Alternatives to invasive testing		5.6 (4)				
4. Ultrasound	71	–	4.65 (0.66)	78	96.15 (75)	3.85 (3)
Prenatal ultrasound (including function and use of ultrasound equipment)		2.8 (2)				
5. CVS and AC procedures	71	–	4.83 (0.41)	78	100.00 (78)	0.00 (0)
Indications and contraindications for AC and CVS		2.8 (2)				
Procedure-related risks and complications and how to avoid them		2.8 (2)				
Maternal risk factors		2.8 (2)				
Choice of method: CVS versus AC		5.6 (4)				
Instruments needed for each procedure		2.8 (2)				
Technical aspects on how to perform CVS and AC		2.8 (2)				
Preparation of material after CVS		8.5 (6)				
Sterile technique: hygiene and disinfection		2.8 (2)				
6. Special cases	71	–	4.51 (0.67)	78	97.4 (76)	2.6 (2)
Handling difficult cases		4.2 (3)				
Considerations specific for multiple pregnancies		2.8 (2)				
7. Documentation	71	–	4.30 (0.80)	78	98.7 (77)	1.3 (1)
Aspects of documentation before, during, and after the procedure		7.0 (5)				
Audit		7.0 (5)				
8. Legal, ethical, and psychological concerns	70	–	4.17 (0.92)	78	96.2 (75)	3.9 (3)
Legal conditions		7.1 (5)				
Ethical concerns		7.1 (5)				
Psychological aspects of CVS and AC		15.7 (11)				
9. Guidelines	70	–	4.33 (0.81)	78	98.7 (77)	1.3 (1)
Knowledge of local guidelines		4.29 (3)				
10. Technical skills: ultrasound	70	–	4.93 (0.26)	78	100.0 (78)	0.0 (0)
Performance of prenatal ultrasound (including hand-eye coordination and image optimization)		2.9 (2)				
Planning and selection of needle insertion site		2.9 (2)				
Ability to visualize needle throughout procedure		2.9 (2)				
11. Technical skills: sampling	69	–	4.75 (0.47)	78	100.0 (78)	0.0 (0)
Handling of equipment		2.9 (2)				
Needle insertion		2.9 (2)				
Aspiration technique		2.9 (2)				
Free-hand technique		15.9 (11)				

Table 3 (continued)

item and subitem	Round 2			Round 3		
	participants, *N*	disagree, % (*N*)	mean score (SD)	participants, *N*	agree, % (*N*)	disagree, % (*N*)
Single- versus double-handed procedures		17.4 (12)				
Strategies for technically challenging patients (poor views, anterior placenta, multiples, obese patients, etc.)		4.4 (3)				
Effective infiltration of local anesthetic*		34.8 (24)		XXX	XXX	XXX
Assess quantity of villi		5.8 (4)				
Preparation of material after CVS		8.7 (6)				
Sterile technique		4.4 (3)				
12. Nontechnical skills	69	–	4.30 (0.75)	78	97.4 (76)	2.6 (2)
Communication skills		5.8 (4)				
Professional behavior		4.4 (3)				
Documentation		2.9 (2)				

CVS, chorionic villus sampling; AC, amniocentesis. *Item eliminated in round 2.

suggestions did not address the specific questions asked in the first round. The steering committee decided to omit these items in order to focus the next rounds on the theoretical and practical content of the curriculum. The remaining items (n = 255) were grouped and rephrased into 12 theoretical and practical content items, each with 1–10 descriptive subitems.

In round 2, almost all curricular content items met the consensus criterion. Only the subitem "effective infiltration of local anesthetics" did not fulfill the consensus criterion and was eliminated (Table 3). Comments were assessed by the steering committee, which led to minor changes in the wording of items.

In round 3, the consensus criterion was reached for all the curricular content items. Complete agreement (100%) was observed for the items Screening, Genetics, The CVS/AC procedure, Technical skills: Ultrasound, and Technical skills: Sampling (Table 3). Comments were assessed, and no major changes were made based on the comments. The final version of the curricular content is shown in Figure 2.

Assessment Tool

In round 1, the panelists suggested 735 items for a CVS/AC assessment tool. Again, items concerning educational methods and items that were too general (e.g., "ultrasound experience") were eliminated (n = 23). The remaining items were grouped and rephrased into 14 items, each with 1–10 descriptive subitems. For example, "Be able to visualize needle throughout its length," "Hand-eye coordination," and "Appropriate insertion technique," were regrouped into needle insertion and tracking.

In round 2, the item "local anesthetics" and the 2 subitems "ask for allergies" and "procedural time" did not fulfill the consensus criterion (Table 4). Comments were assessed, and no major changes were made based on the comments. Two items included double-barreled questions ("Needle insertion and tracking" and "Overall performance") and therefore were regrouped into "Selection of insertion site" and "Needle tracking", and "Systematic approach," "Flow of the procedure," and "Professionalism," resulting in 16 assessment tool items for the final round. Finally, a rating scale from 1 to 5 with behavioral scale anchors were added to each of the items.

In round 3, the consensus criterion was reached for all the included assessment tool items and for eliminating the item "local anesthetics." Comments were assessed, and rephrasing and structural changes were made accordingly without any changes to the main content.

1. Screening
Principles of screening
Non-invasive screening tests: combined test, NIPT
2. Anatomy and physiology
Relevant anatomy and physiology
3. Genetics
Basic genetics and the condition tested for
Genetical examination methods and their characteristics (karyotype, array, whole genome etc.)
Interpretation of test results
Alternatives to invasive testing
4. Ultrasound
Prenatal ultrasound (incl. function and use of ultrasound equipment)
5. The CVS and AC procedure
Indications and contraindications for AC and CVS
Procedure related risks and complications and how to avoid them
Maternal risk factors
Choice of method: CVS versus AC
Instruments needed for each procedure
Technical aspects on how to perform CVS and AC
Preparation of material after CVS
Sterile technique: hygiene and disinfection
6. Special cases
Handling difficult cases
Considerations specific for multiple pregnancies
7. Documentation
Aspects of documentation before, during and after the procedure
Audit
8. Legal, ethical and psychological concerns
Legal conditions
Ethical concerns
Psychological aspects of CVS and AC
9. Guidelines
Knowledge of local guidelines
10. Technical skills: ultrasound
Performance of prenatal ultrasound (incl. hand-eye coordination and image optimization)
Planning and selection of needle insertion site
Ability to visualize needle throughout procedure
11. Technical skills: sampling
Handling of equipment
Needle insertion
Aspiration technique
Free hands technique
Single versus double handed procedures
Strategies for technically challenging patients (poor views, anterior placenta, multiples, obese patients etc.)

Fig. 2. Curricular content. CVS, chorionic villus sampling; AC, amniocentesis.

Table 4. Assessment tool round 2

Item and subitem	Participants, *N*	Disagree, % (*N*)	Mean score (SD)
1. Identification and consent	72	–	4.89 (0.40)
Patient identification		11.1 (8)	
Confirmation of informed consent		11.1 (8)	
2. General preparations	71	–	4.70 (0.62)
Assessment of contraindications for the procedure		4.2 (3)	
Select procedure (CVS or AC)		5.6 (4)	
Check for HIV/HBV/HCV		11.3 (8)	
Check for Rh(D) status		8.5 (6)	
Check if other specimens are required (e.g., maternal sample)		7.0 (5)	
Ask for allergies		39.4 (28)	
Ask for anticoagulation treatment		15.7 (11)	
Strategies for technically challenging patients (multiple pregnancies, obesity, poor vies, anterior placenta, etc.)		11.3 (8)	
3. Preparation of site and instruments	71	–	4.70 (0.64)
Appropriate positioning of patient		11.3 (8)	
Appropriate needle type and size		4.2 (3)	
Preparation of instruments: check needle, needle guide, and angle (if relevant)		7.0 (5)	
4. Pre-procedure ultrasound assessment	71	–	4.79 (0.44)
Check for fetal, maternal, and placental factors. Measure fetal biometrics (if unknown)		7.0 (5)	
Planning and selection of needle insertion site		4.2 (3)	
Image optimization		4.2 (3)	
5. Local anesthetics	71	–	2.38 (1.37)
Use of local anesthetics		49.3 (35)	
6. Needle insertion and tracking	71	–	4.87 (0.34)
Accurate needle insertion to targeted site		2.8 (2)	
Hand-eye coordination		2.8 (2)	
Visualization of needle during the procedure		2.8 (2)	
Visualization of fetus, adjusting trajectory, or waiting for fetal movement (AC)		5.6 (4)	
Instrument handling		11.3 (8)	
7. Sampling technique	71	–	4.41 (0.73)
Aspiration technique for adequate sample		4.2 (3)	
Procedural time		26.8 (19)	
8. Post-procedure care and ultrasound assessment	71	–	4.11 (0.85)
Check fetal heart rate		8.5 (6)	
Search for procedure related complication		18.3 (13)	
Appropriate post-procedure care (cleaning of site and applying patch if needed)		14.1 (10)	
9. Sample preparation and handling	71	–	4.70 (0.49)
Correct sample labeling		4.2 (3)	
Check the color of the amniotic fluid (AC)		12.7 (9)	
Transfer of sample into medium for transport/post-procedure handling (CVS)		5.6 (4)	
10. Documentation and follow-up	71	–	4.51 (0.63)
Appropriate documentation of procedure with images and clinical notes		8.5 (6)	
Appropriate planning for follow-up		5.6 (4)	
11. Sterile technique	71	–	4.68 (0.47)
Preparation and disinfection of needle insertion site, probe, etc.		2.8 (2)	
Safe handling and appropriate disposal of sharps		4.2 (3)	
12. Professional/team work	71	–	4.52 (0.71)
Communication and instructions with other staff present in the room		2.8 (2)	
Awareness of limitations		2.8 (2)	
Recognition of difficult cases		4.2 (3)	
Providing and receiving feedback		5.6 (4)	
13. Communication with the patient	71	–	4.78 (0.42)
Explanation of the procedure to the patient		2.8 (2)	
Communication during the procedure		4.2 (3)	
Debriefing after the procedure		12.7 (9)	

Table 4 (continued)

Item and subitem	Participants, *N*	Disagree, % (*N*)	Mean score (SD)
Information regarding aftercare		2.8 (2)	
14. Overall performance	71	–	4.38 (0.70)
Systematic approach: following of safety checklist before, during, and after the procedure (if relevant)		11.3 (8)	
Ability to deal with complexities which may arise during procedure		2.8 (2)	
Flow of the procedure		8.5 (6)	

CVS, chorionic villus sampling; AC, amniocentesis.

Structural changes included alteration in order of items, regrouping of items, and the adding of an entrustment scale for the last item. "Needle insertion and tracking" and "Sterile technique" were incorporated in the item "Sampling technique." "Systematic approach," "Flow of the procedure," "Professionalism," and "Overall assessment" were regrouped into "Assessment of overall performance," and the scale anchors were changed to an entrustment scale. The results from round 3 including a revised list of the panelists' comments (similar comments and comments including praise have been eliminated) can be viewed in Table 5. The final version of the assessment tool is shown in Figure 3.

Discussion

Summary of Study Findings

Using a 3-round Delphi approach, a panel of international fetal medicine experts reached consensus on (1) items to be included in a CVS/AC curriculum and (2) items to be included in an assessment tool to evaluate trainees' CVS/AC performances.

The final list of curricular content contains 12 items. While 3 of the items (Technical skills: Ultrasound, Technical skills: Sampling, and Nontechnical skills) involve practical training, the remaining items emphasize theoretical content, suitable for lectures or e-learning. The final assessment tool contains 11 items systematically divided into 5 categories: pre-procedure, procedure, post-procedure, nontechnical skills, and overall performance.

Interpretations of Study Findings

Some of the panelists suggested the use of a checklist instead of a rating scale for the pre-procedural item identification and consent and general preparations. This suggests a different use of the assessment tool as a pre-procedural checklist to confirm that the trainee follows all the procedural steps. The use of a checklist in other surgical settings has been shown to improve patient safety [15]. However, rating scales completed by experts are more suitable when assessing and providing feedback during educational activities [16].

One panelist suggested the use of an entrustment scale to make a final entrustment decision. An entrustment decision determines the trainee's level of required supervision (requires complete supervision, requires minimal supervision, etc.) and refers to an entrustable professional activity (EPA) [17]. EPAs describe professional practices that trainees are permitted to perform unsupervised once they have demonstrated competence. Since entrustment decisions align with the movement toward competency-based education, we applied an entrustment scale for the last item "Assessment of overall performance" [17]. Furthermore, we suggest the curricular content items can guide the development of EPAs involving invasive fetal medicine procedures.

There was consensus to eliminate the item "Local anesthetics" from the assessment tool. It could be argued that the item should be included as "if applicable" since only 48% of the panelists reported using local anesthetics. However, it was the decision of the steering committee to respect the consensus of the panelists.

Clinical and Research Implications

The number of performed invasive procedures has decreased in many countries after the introduction of cell-free DNA screening [10]. A consequence of this is fewer opportunities to learn and sustain competencies in performing CVS and AC. The latest ACOG guideline might reverse this trend [3]; however, the critical point of providing safe procedures by skilled operators remains.

The main implication of this study is to enable transition from current training and assessment methods,

Table 5. Assessment tool round 3

Participants: 77	Comments	Agree, % (*N*)	Disagree, % (*N*)
1. Identification and consent Description: patient identification, confirmation of informed consent/written consent 1. Not performed, 3. performed however incomplete, 5. correctly performed	• This is so fundamental, so it should be a complete pass or a fail • The person performing the procedure should be the same person counseling the patient • I miss; information concerning pros/con, e.g., miscarriage risk contraindication • Frequently, they would do the consent, so reword to "obtaining/confirmation of ..."	98.7 (77)	1.3 (1)
2. General preparations Description: select procedure (TC/TV/TACVS or AC) and indication, check for contraindications, check if other specimens are required (e.g., parental blood sample), check for Rh(D) status, check for anticoagulation treatment, and check for HIV/HBV/HCV (if relevant) 1. No pre-procedure general preparations 3. Incomplete pre-procedure general preparations 5. Complete pre-procedure general preparations	• What do TC and TV mean? • I would remove if relevant for HIV/HBV/HCV status. I am not sure in what setting one would consider it "not relevant" • Should anticoagulation, HIV, etc., be subcategories of contraindications? • In practice, it is not always possible to check HIV/HBV and HCV • I would remove "check if other specimens are required," unless directly related with the procedure (type of medium, sample size, etc.) • Maybe anticoagulation treatment is not really critical for an amnio, and it remains arguable about risks to mother or fetus with HIV etc. • I miss the item to check for allergies against disinfectants, local anesthesia, and plasters • May be performed during counseling (which is preferably done by the same person)	98.7 (77)	1.3 (1)
3. Preparation of site and sampling tool Description: positioning patient, preparation, selection, and checking of sampling tool, i.e., needle size and, guide, and angle 1. Inappropriate preparation of the site and sampling tool 3. Acceptable, but not optimal, preparations of site and/or sampling tool 5. Appropriate preparation of site and sampling tool	• This could have the scale as proposed, though suboptimal is difficult to assess as this should be prospective because it is too late if the procedure failed due to these technical issues • Many people don't use guide – therefore (if relevant) could be added. What about antiseptic, preparation of equipment: syringe, culture media (if relevant for CVS), etc.? Also, this should be further down questionnaire – question 5 asks same questions • Checking equipment – needle size – can be moved to point 3 and angle/technique to point 5 • I don't understand positioning of patient; in 99%, they will by lying flat on their back • Position patient not required item	97.4 (76)	2.6 (2)
4. Pre-puncture ultrasound assessment Description: image optimization; check for fetal, maternal, and placental factors; measure fetal biometrics if unknown 1. Poor pre-puncture ultrasound assessment 3. Acceptable pre-puncture ultrasound assessment 5. Excellent pre-puncture ultrasound assessment	• This section should come before 3; the general aspects of the scan should be completed before more specific focus on the procedure • Seems more logic that 4 comes before 3 • I position the patient according to my US findings. Also, I usually decide on transvaginal or transabdominal CVS after the US assessment • We always perform a complete ultrasound before every procedure • 3 and 5 could be better specified such as stating placental position, fetal position, amount of amniotic fluid, etc.	100.0 (78)	0.0 (0)

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Table 5 (continued)

Participants: 77	Comments	Agree, % (*N*)	Disagree, % (*N*)
5. Selection of insertion site Description: selection of insertion site, strategies for technically challenging patients, i.e., multiple pregnancies, obesity, poor views, and anterior placenta 1. Inappropriate selection of insertion site 3. Acceptable, but not optimal, selection of insertion site 5. Appropriate selection of insertion site	• This should be assessed, but there is overlap with section 3, e.g., the needle angle can only be determined once the entry site has been selected • Define what is poor, acceptable, and excellent • I don't understand why the anterior placenta is mentioned specifically – retroflexed uterus with a posterior placenta seems to be much more challenging; may be ability to postpone the procedure because a too difficult approach could be mentioned • Operators performing invasive procedures on multiplets should also be able to perform embryo-reduction	100.0 (78)	0.0 (0)
6. Sampling technique Description: accurate insertion to targeted site, handling of sampling tool and sampling technique, and adapting aspiration to fetal position (AC) 1. Poor sampling technique 3. Acceptable, but insecure, sampling technique 5. Excellent sampling technique	• I am not sure if necessary; intuitively, it will be corrected in the process of tutoring in my opinion	100.0 (78)	0.0 (0)
7. Sampling tool tracking Description: hand-eye coordination and visualization of the sampling tool during the procedure 1. Poor performance: the sampling tool was not visualized during most of the procedure 3. Acceptable performance: was able to visualize the sampling tool during some parts of the procedure 5. Excellent performance: was able to visualize the sampling tool during the entire procedure	• Significant overlap with 6 • I believe that you are not able to do numbers 5 and 6 without having a good hand-eye coordination. I would not allow a trainee to do an invasive procedure before showing excellent hand-eye coordination skills • Adjusting needle route before entry	98.7 (77)	1.3 (1)
8. Sterile technique Description: preparation and disinfection of insertion site, probe, etc. Safe handling and disposal of sharps and cleaning of site 1. Incorrect sterile technique 3. Correct sterile technique in some parts of the procedure 5. Correct sterile technique throughout the entire procedure	• "Aseptic technique" instead of "sterile technique" • Specified what is a minimum • There may be local asepsis guidelines that have to be adhered to (with or without much evidence) • Include this before the sampling technique and needle tracking since preparing the site and ongoing sterile technique starts before insertion of the needle	100.0 (78)	0.0 (0)
9. Post-procedure ultrasound assessment Description: search for procedure-related complication, i.e., check for hemorrhage and fetal heart rate 1. Poor post-procedure ultrasound assessment 3. Acceptable post-procedure ultrasound assessment 5. Excellent post-procedure ultrasound assessment	• I don't feel so strongly about this because this can be seen as the procedure ends, and once it is done it is done, and there is not much that can be done to retrieve a complication except, e.g., to offer a follow-up for amniotic fluid leakage	98.7 (77)	1.3 (1)

Table 5 (continued)

Participants: 77	Comments	Agree, % (*N*)	Disagree, % (*N*)
10. Sample preparation and handling Description: correct sample labeling, check blood contamination of the amniotic fluid (AC), and prepare sample for transport (CVS) 1. Inappropriate sample preparation and handling 3. Acceptable, but not optimal, sample preparation and handling 5. Appropriate sample preparation and handling	• Preparing sample for transport might not be applicable everywhere since other staff members might be in charge for this • Rarely the responsibility of the trainee • These are critical, especially the labeling. Some units delegate this to a nurse assistant, but the operator should check • We always check for the absence of contamination with maternal caduca • Should there be a comment about confirming adequate villous material has been obtained?	96.2 (75)	3.9 (3)
11. Documentation Description: documentation of the procedure and plan for follow-up 1. Not performed 3. Performed, however incomplete 5. Correctly performed	• Follow-up may be covered in pre-procedural counseling • Documentation (in this era of medico-legal environment) has to be a must • For multiples: documented and care fetal mapping	96.2 (75)	3.9 (3)
12. Communication with the patient Description: explanation of the procedure to the patient (before and during) and information regarding aftercare 1. Demonstrate poor communication skills 3. Demonstrate good communication skills during some of the procedure 5. Demonstrate excellent communication skills during the entire procedure	• You should add here a stem on communication with patient/couple	100.0 (78)	0.0 (0)
13. Teamwork Description: interaction with the team, receiving, and providing feedback 1. Poor teamwork 3. Acceptable teamwork 5. Excellent teamwork	• Closed loop communication especially with regard to additional samples for serology or sent to different labs	98.7 (77)	1.3 (1)
14. Systematic approach Description: using a systematic approach before, during, and after the procedure 1. No systematic approach 3. Acceptable, but not optimal, systematic approach 5. Correct systematic approach	• There is scarce information on that item • Isn't this already assessed above? • If you use the assessment tool, this is systematic in itself	91.0 (71)	9.0 (7)
15. Flow of the procedure Description: use of time during the procedure 1. Disrupted flow of the procedure 3. Acceptable, but not optimal, flow of the procedure 5. Efficient flow of the procedure	• There is scarce information on that item • Sorry, this is over the top • Let's not make it too complicated – maybe flow and systematic approach can be together • I don't find this item very important as lack of flow may be due to low performance in other items. Moreover, the flow may depend both on the doctor's skills and the patient. Disrupted flow may often be due to the patient's problem with cooperating to the procedure. If the item is kept, maybe it could be stated in the text that only disrupted flow because of the performer should be evaluated •Comes with practice, even dangerous to try to force a flow in inexperienced hands •Numbers 14 and 15 while perhaps not critical are important	83.3 (65)	16.7 (13)

Table 5 (continued)

Participants: 77	Comments	Agree, % (*N*)	Disagree, % (*N*)
16. Professionalism Description: ability to deal with complexities during the procedure and aware of one's limitations 1. Failed to demonstrate a professional approach during the procedure 3. Demonstrated a professional approach during some of the procedure 5. Demonstrated a professional approach during the entire procedure	•Not necessary when using the protocol, in total will thus be included •I suggest: aware of own personal limitations •Better to have a single field for nontechnical skills. It has become a rather long document	94.9 (74)	5.1 (4)
17. Eliminated: local anesthetics (Agree = item should not be included)	• This is usually only a part of transabdominal CVS. Agree to exclude for all others • Most people use local anesthetic for CVS? • It seems still relevant for transabdominal CVS • I would include this but am aware that some practitioners do not use this. This could be assessed as part of the earlier questions in units that use LA • I think that if LA is used, the checking of the drug should be assessed • For TA CVS, would include effective and appropriate use of local anesthetics • Agree to eliminate as a stand-alone and suggest to be included to prompt discussion/consideration on general preparations	80.8 (63)	19.2 (15)

CVS, chorionic villus sampling; AC, amniocentesis.

based on a time- and volume-based approach to a competency-based approach, which is a key step in improving patient safety and outcomes [11]. An arbitrary number of supervised procedures have traditionally been used as a learning goal for CVS/AC [18, 19]. Yet, there is limited evidence to support the requirement of any specific number of procedures before a trainee is deemed ready for independent practice [8, 9, 20–22].

Trainees learn at different paces and therefore will differ in terms of time to achieve the learning goal. Assuming that competency is met after a specific number of procedures is very unlikely to capture those who need additional training before commencing independent practice. Competency-based learning, on the other hand, relies on the notion that trainees must demonstrate well-defined educational goals before progressing to the next step of their training [23, 24]. The advantage of competency-based learning is that all trainees will meet the same educational goals, and the only variable that differs between trainees is the time to achieve these goals. To apply a competency-based approach, clear educational goals and trustworthy assessment tools are needed to determine what trainees need to learn at each step of their training and when they are ready to move on to the next level of training [11]. The international consensus of the competency-based CVS/AC curriculum and assessment tool presented in this study supports its validity and serves as content evidence [25]. The list of curricular content items should act as a guide in the development of learning goals and objectives for the trainees and in the planning of educational activities. However, this identified curriculum must be adapted to local conditions [26]. The trainees' previous training experiences need to be considered, and some of the content items (e.g., Ultrasound and Nontechnical skills) might be cross-curricular.

The CVS/AC assessment tool is intended to guide feedback during training (formative evaluation) and to guide certifications (summative evaluation). The assessment tool is in alignment with the Royal College of Obstetricians and Gynecologists (RCOG) assessment process [27]. However, further validity studies should be performed to ensure that the assessment scores actually measure what they are purported to measure, to support its use for the evaluation of procedures in a simulated and in a clinical context, and to provide guidance for standard-setting (e.g., pass-fail decisions) [28]. Moreover, the list of theoretical content items suggested for a CVS/AC curriculum indicates a need for theoretical knowledge tests such as multiple-choice tests, which is a subject for further curricular development.

Pre-procedure					
1. Identification and consent *Description:* - Patient identification - Confirmation of informed consent/written consent	1 Not performed	2	3 Performed, however incomplete	4	5 Correctly performed
2. General preparations *Description:* - Select procedure and indication - Check for contraindications - Check if other specimens are required i.e. parental blood sample - Check for Rh(D) status - Check for anticoagulation treatment - Check for HIV/HBV/HCV	1 No pre-procedure general preparations	2	3 Incomplete pre-procedure general preparations	4	5 Complete pre-procedure general preparations
3. Pre-puncture ultrasound assessment *Description:* - Image optimization - Check for fetal, maternal and placental factors - Measure fetal biometrics if unknown	1 Poor pre-puncture ultrasound assessment	2	3 Acceptable pre-puncture ultrasound assessment	4	5 Excellent pre-puncture ultrasound assessment
4. Preparation of site and instruments *Description:*	1 Inappropriate preparation of	2	3 Acceptable, but not	4	5 Appropriate
- Preparation, selection and checking of sampling tool i.e. needle size and, guide and angle (if relevant)	site and sampling tool		optimal, preparations of site and/or sampling tool		preparation of site and sampling tool
Procedure					
5. Selection of insertion site *Description:* - Strategies for technically challenging patients i.e. multiple pregnancies, obesity,poor views, placental position	1 Inappropriate selection of insertion site	2	3 Acceptable, but not optimal, selection of insertion site	4	5 Appropriate selection of insertion site
6. Sampling technique *Description:* - Accurate insertion to targeted site. - Instrument handling and sampling technique - Adapting aspiration to fetal position (AC) - Hand-eye coordination - Visualization of instrument during the procedure - Check for adequate sample - Correct aseptic technique	1 Poor sampling technique	2	3 Acceptable, but insecure, sampling technique	4	5 Excellent sampling technique

Fig. 3. Final assessment tool. CVS, chorionic villus sampling; AC, amniocentesis.

(Figure continued on next page.)

Post-procedure					
7. Post-procedure ultrasound assessment *Description:*	1 Poor post-procedure	2	3 Acceptable post-procedure	4	5 Excellent post-procedure
- Search for procedure related complication i.e. check for haemorrhage and fetal heart rate	ultrasound assessment		ultrasound assessment		ultrasound assessment
8. Sample preparation and handling *Description:* - Correct sample labelling - Check blood contamination of the amniotic fluid (AC) - Prepare sample for transport (CVS)	1 Inappropriate sample preparation and handling	2	3 Acceptable, but not optimal, sample preparation and handling	4	5 Appropriate sample preparation and handling
9. Documentation *Description:* - Documentation of the procedure, including fetal mapping (if relevant) - Plan for follow up	1 Not performed	2	3 Performed, however incomplete	4	5 Correctly performed
Non-technical skills					
10. Communication with the patient *Description:* - Explanation of the procedure to the patient (before and during) and information regarding aftercare.	1 Demonstrate poor communication skills	2	3 Demonstrate good communication skills during **some** of the procedure	4	5 Demonstrate excellent communication skills during the **entire** procedure
Assessment of overall performance					
An overall assessment of the performance with focus on:	1 **Intervention** Requires complete	2 **Direction** Requires partial supervision	3 **Support** Requires minimal	4 **Autonomy** Requires no supervision	5 **Independence** Demonstrates excellence, is a
- **Systematic approach:** using a systematic approach before, during and after the procedure - **Flow of the procedure:** use of time during the procedure - **Professionalism:** ability to deal with complexities during the procedure, aware of own personal limitations and teamwork	supervision for completion	for completion	supervision for completion	for completion	good role model

3

Strengths and Limitations

The Delphi process is a well-established method to obtain consensus, and one of its strengths is the anonymity of the respondents to avoid dominant panelists from getting excessive influences. However, a limitation of the Delphi method is the significant role of the steering committee in processing the data which may bias the results [29]. Therefore, to reduce bias introduced by the steering committee, the panelists were asked to answer open-ended questions as opposed to a predefined list of items in the

first Delphi round and to not narrow their own suggestions. This resulted in several hundred suggested items which needed to be reduced significantly to not exhaust the panelists. In order to organize and condense the suggested items and still maintain the essential content, the steering committee used subitems to inform the curricular content and assessment tool items.

The panelists were included as content matter experts in CVS/AC and not as experts in medical education methods. Consequently, our results inform what to include in future CVS/AC training and assessment programs but not how to deliver the curricular interventions or perform assessments of new trainees. These efforts are context-dependent and should be planned to fit with local requirements and available resources to best match educational goals with the mode of delivery (e.g., gaining theoretical knowledge through textbooks or e-learning and learning practical skills through hands-on exercises).

Conclusion

International fetal medicine experts have agreed on the content to be included in a CVS/AC curriculum and an assessment tool to evaluate CVS/AC performances. The results are important for the transition of current training and assessment programs from a time- and volume-based approach to competency-based learning.

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Statement of Ethics

Written consent was obtained from all the panelists who agreed to participate. The Danish legislation exempts survey studies from ethical approval.

Conflict of Interest Statement

Femke Slaghekke, Karin M. Sundberg, Martin Tolsgaard, Rory Windrim, Leizl Nayahangan, Lone N. Nørgaard, and Dario Paladini declare that they have no conflicts of interest. Vilma Johnsson has received grants from AMEE and the Danish Ministry of Higher Education and Science, and her Ph.D. fellowship is supported by the Novo Nordisk Foundation grant NNFSA170030576.

Jon Hyett is an associate editor of *Fetal Diagnosis and Therapy*. He has within the last 3 years given a promotional talk for Canon Imaging, been involved in an expert panel, given talks for and been involved in the SMART research trial for Natera, and been involved in an expert panel and given talks for Roche (NIPT and preeclampsia screening). Jon Hyett has an ongoing research collaboration looking at biomarkers for prediction of adverse pregnancy outcome with PerkinElmer. Ulrich Gembruch is an editorial board member of *Fetal Diagnosis and Therapy*. Eleonor Tiblad is a member of Janssen Pharmaceutical's advisory board on FNAIT and HDFN. Olav B. Petersen's professorship is supported by the Novo Nordisk Foundation grant NNFSA170030576.

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Author Contributions

Vilma Johnsson has substantially contributed to the conceptualization and design of the work. She has been responsible for the acquisition, analysis, and interpretation of data for the work. She has drafted the work and given final approval of the version to be published. Finally, she agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Martin G. Tolsgaard has substantially contributed to the conceptualization and the design of the work and the interpretation of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Jon Hyett has substantially contributed to the acquisition of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ulrich Gembruch has substantially contributed to the acquisition of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Rory Windrim has substantially contributed to the acquisition of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Asma Khalil has substantially contributed to the acquisition of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Eleonor Tiblad has substantially contributed to the acquisition of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, she has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Femke Slaghekke has substantially contributed to the acquisition of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, she has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Dario Paladini has substantially contributed to the acquisition of data for the work. He has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Leizl Nayahangan has substantially contributed to the conceptualization and the design of the work and the interpretation of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Karin M. Sundberg has substantially contributed to the conceptualization and the design of the work and the interpretation of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Lone N. Nørgaard has substantially contributed to the conceptualization and the design of the work and the interpretation of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Olav B. Petersen has substantially contributed to the conceptualization and the design of the work and the interpretation of data for the work. She has revised the work critically for important intellectual content and given final approval of the version to be published. Finally, he has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data Availability Statement

All data generated or analyzed during this study are included in this article or its online supplementary material files. Further inquiries can be directed to the corresponding author.

References

1 Ghi T, Sotiriadis A, Calda P, Da Silva Costa F, Raine-Fenning N, Alfirevic Z, et al. ISUOG practice guidelines: invasive procedures for prenatal diagnosis. Ultrasound Obstet Gynecol. 2016;48(2):256–68.

2 Salomon LJ, Alfirevic Z, Audibert F, Kagan KO, Paladini D, Yeo G, et al. ISUOG updated consensus statement on the impact of cfDNA aneuploidy testing on screening policies and prenatal ultrasound practice. Ultrasound Obstet Gynecol. 2017;49(6):815–6.

3 Rose NC, Kaimal AJ, Dugoff L, Norton ME. Screening for fetal chromosomal abnormalities: ACOG practice bulletin, number 226. Obstet Gynecol. 2020;136(4):e48–69.

4 Tabor A, Vestergaard CH, Lidegaard Ø. Fetal loss rate after chorionic villus sampling and amniocentesis: an 11-year national registry study. Ultrasound Obstet Gynecol. 2009;34(1):19–24.

5 Gil MM, Molina FS, Rodríguez-Fernández M, Delgado JL, Carrillo MP, Jani J, et al. New approach for estimating risk of miscarriage after chorionic villus sampling. Ultrasound Obstet Gynecol. 2020;56(5):656–63.

6 Wulff CB, Gerds TA, Rode L, Ekelund CK, Petersen OB, Tabor A, et al. Risk of fetal loss associated with invasive testing following combined first-trimester screening for Down syndrome: a national cohort of 147,987 singleton pregnancies. Ultrasound Obstet Gynecol. 2016;47(1):38–44.

7 Kilby MD. Amniocentesis and chorionic villus sampling in Scotland: an audit of techniques and outcomes of all procedures over one year in Scotlandin 1 May 2008 – 30 April 2009. NHS Scotland; 2010. [cited 14 October 2020]. Avaliable from: http://www.healthcareimprovementscotland.org/our_work/reproductive,_maternal_child/programme_resources/amniocentesis_chorionic_villus.aspx.

8 Wijnberger LD, Van Der Schouw YT, Christiaens GC. Learning in medicine: chorionic villus sampling. Prenat Diagn. 2000;20(3):241–6.

9 Pittini R, Oepkes D, Macrury K, Reznick R, Beyene J, Windrim R. Teaching invasive perinatal procedures: assessment of a high fidelity simulator-based curriculum. Ultrasound Obstet Gynecol. 2002;19(5):478–83.

10 Hui L, Tabor A, Walker SP, Kilby MD. How to safeguard competency and training in invasive prenatal diagnosis: "the elephant in the room". Ultrasound Obstet Gynecol. 2016;47(1):8–13.

11 Cook DA, Brydges R, Zendejas B, Hamstra SJ, Hatala R. Mastery learning for health professionals using technology-enhanced simulation: a systematic review and meta-analysis. Acad Med. 2013;88(8):1178–86.

12 Dalkey N, Helmer O. An experimental application of the DELPHI method to the use of experts. Manage Sci. 1963;9(3):351–515.

13 SurveyMonkey Inc. San Mateo, California, USA. [cited 30 September 2020]. Avaliable from: www.surveymonkey.com.

14 Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67(4):401–9.

15 Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360(5):491–9.
16 Swanson DB, van der Vleuten CP. Assessment of clinical skills with standardized patients: state of the art revisited. Teach Learn Med. 2013;25:S17–25.
17 Ten Cate O, Hart D, Ankel F, Busari J, Englander R, Glasgow N, et al. Entrustment decision making in clinical training. Acad Med. 2016;91(2):191–8.
18 Alfirevic Z, Kilby MD. Amniocentesis and chorionic villus sampling. London: Royal College of Obstetricians and Gynaecologists (RCOG). [cited 14 October 2020]. Avaliable from: https: //www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg8/.
19 The Fetal Medicine Foundation. Certificate of competence: invasive procedures. [cited 14 October 2020]. Avaliable from: https://fetalmedicine.org/fmf-certification/certificates-of-competence/invasive-procedures.
20 Saura R, Gauthier B, Taine L, Wen ZQ, Horovitz J, Roux D, et al. Operator experience and fetal loss rate in transabdominal CVS. Prenat Diagn. 1994;14(1):70–1.
21 Tolsgaard MG, Ringsted C, Dreisler E, Nørgaard LN, Petersen JH, Madsen ME, et al. Sustained effect of simulation-based ultrasound training on clinical performance: a randomized trial. Ultrasound Obstet Gynecol. 2015;46(3):312–8.
22 Tolsgaard M, Veluppillai C, Gueneuc A, Taksøe-Vester C, Hajal N, Levaillant JM, et al. When are trainees ready to perform transvaginal ultrasound? An Observational Study. Ultraschall Med. 2019;40(3):366–73.
23 Dagnone D, Stockley D, Flynn L, Egan R, van Wylick R, McEwan L, et al. Delivering on the promise of competency based medical education – an institutional approach. Can Med Educ J. 2019;10(1):e28–38.
24 Holmboe ES, Ward DS, Reznick RK, Katsufrakis PJ, Leslie KM, Patel VL, et al. Faculty development in assessment: the missing link in competency-based medical education. Acad Med. 2011;86(4):460–7.
25 Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. Oxford University Press; 2008.
26 Thomas PA, Kern DE, Hughes MT, Chen BY. Curriculum development for medical education: a six-step approach. Johns Hopkins University Press; 2015.
27 OSATS, maternal and fetal medicine. [cited 4 December 2020]. Avaliable from: https://www.rcog.org.uk/en/careers-training/specialty-training-curriculum/subspecialty-training/maternal-and-fetal-medicine-subspecialty-training/osats-maternal-and-fetal-medicine/#amniocentesis.
28 Cook DA. When I say… validity. Med Educ. 2014;48(10):948–9.
29 Hsu CC, Sandford BA. The Delphi technique: making sense of consensus. Pract Assessment, Res Eval. 2007;12:1–8.