

8-1-2022

Firearm-Related Pediatric Head Trauma: A Scoping Review.

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Recommended Citation

Citation Information:Gadot, Ron; LoPresti, Melissa A; Smith, David N; Ouellette, Lara; and Lam, Sandi, "Firearm-Related Pediatric Head Trauma: A Scoping Review." (2022). Neurosurgery DigitalCommons@TMC, Texas Medical Center Library, *Library Staff Publications*. Paper 31. https://digitalcommons.library.tmc.edu/library_docs/31

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REVIEW ARTICLE

Quality assessment of optic nerve sheath diameter ultrasonography: Scoping literature review and Delphi protocol

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Funding information

None.

Abstract

Background and Purpose: The optic nerve is surrounded by the extension of meningeal coverings of the brain. When the pressure in the cerebrospinal fluid increases, it causes a distention of the optic nerve sheath diameter (ONSD), which allows the use of this measurement by ultrasonography (US) as a noninvasive surrogate of elevated intracranial pressure. However, ONSD measurements in the literature have exhibited significant heterogeneity, suggesting a need for consensus on ONSD image acquisition and measurement. We aim to establish a consensus for an ONSD US Quality Criteria Checklist (ONSD US QCC).

Methods: A scoping systematic review of published ultrasound ONSD imaging and measurement criteria was performed to guide the development of a preliminary ONSD US QCC that will undergo a modified Delphi study to reach expert consensus on ONSD quality criteria. The protocol of this modified Delphi study is presented in this manuscript.

Results: A total of 357 ultrasound studies were included in the review. Quality criteria were evaluated under five categories: probe selection, safety, positioning, image acquisition, and measurement.



Conclusions: This review and Delphi protocol aim to establish ONSD US QCC. A broad consensus from this process may reduce the variability of ONSD measurements in future studies, which would ultimately translate into improved ONSD clinical applications. This protocol was reviewed and endorsed by the German Society of Ultrasound in Medicine.

KEYWORDS

consensus, Delphi, intracranial pressure, ONSD, optic nerve sheath diameter, quality criteria, ultrasound

INTRODUCTION

The value and limitations of optic nerve sheath diameter measurement

The optic nerve (ON) is a continuation of the central nervous system and is surrounded with cerebrospinal fluid (CSF) and meningeal layers that are directly contiguous with those around the brain. Therefore, when the pressure in the CSF increases, the optic nerve sheath (ONS) can distend, which makes optic nerve sheath diameter (ONSD) a potential surrogate for intracranial pressure (ICP) assessment. Transorbital ultrasonography (US) is an ideal tool for repetitive noninvasive measurements.¹⁻⁶ The retrobulbar segment of ONS appeared to be the most sensitive to increases in CSF volume according to previous cadaveric studies.^{7,8} ONSD had been compared to invasive ICP measurements including spinal taps, external ventricular drains, and intraparenchymal transducers^{5,6,9-12}; ventriculoperitoneal shunt malfunction¹³; and CT or MRI imaging findings consistent with elevated ICP.¹² US of the ONSD has shown to have moderate to high sensitivity for the detection of elevated ICP, ranging from 86% to 97%.^{6,10-12} However, ONSD has still not found widespread acceptance in the clinical practice, as studies uncover several issues including wide heterogeneity in measurements with I^2 ranging from 50.6% to 97.3%,^{10,11,14,15} large variations in ONSD cutoffs used for determination of elevated ICP, ranging from 4.2 to 6.5 mm with wide confidence intervals,^{5,10-12} limited reporting of the effect of age and gender on measurements,¹⁶ variations in transducers and frequencies used,^{10,15} different measurement planes,^{6,10} variable requirements for averaging multiple measurements from the same eye or both eyes,^{10,12} different patient positioning during measurement,¹⁰ using different training requirements or definitions of experts,^{10,12,17} and large inter-observer variations.¹⁸⁻²⁰ In addition, some studies performed ONSD measurements incorrectly measuring the ON instead of ONSD,¹⁴ or not including the entire ONSD in the sample measurement image.²¹ These inconsistencies in ONSD image acquisition and measurement are implicated as a potential cause of large heterogeneity in the results of ONSD studies.^{10,14} This scoping review aims to identify and classify existing ONSD measurement quality criteria (QC) and describe variations in transorbital US technique.

Justification of a modified Delphi methodology and rationale behind systematic review to extract ONSD imaging and measurement criteria

The QC from this review were used to inform the synthesis of a preliminary ONSD Quality US Criteria Checklist (ONSD US QCC), which will undergo a modified Delphi method to obtain expert consensus on ONSD US QCC. The Delphi method is a reliable method of obtaining expert consensus through a series of questionnaire rounds with each round adjusted based on prior expert commentary.^{22,23} Advantages of the Delphi method over other consensus techniques include removing peer pressure or individual dominance due to the anonymity of experts, allowing experts to refine their opinions based on feedback between rounds, increased content validity and real-world applicability by using experts with variable areas of expertise, and removing geographical restrictions by using surveys.²⁴⁻²⁸ The Delphi method is useful when the available evidence does not meet the clinical needs.²⁵ The “classical Delphi method” starts with an unstructured round to gather expert opinion, and any modification to that design is defined as “modified Delphi method.”²⁹ A modified Delphi with a literature-supported “starting point” for experts to comment on allows for prioritizing specific topics in the first round in addition to saving the time and effort of the expert panelists.^{26,29} Therefore, the preliminary ONSD US QCC is a starting point for the modified Delphi method.

METHODS

Registration and support

This review was performed and presented in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews (PRISMA-SCr).^{30,31} The scoping review protocol was registered with the Open Science Framework: <https://osf.io/9p5w3>. All authors have no financial disclosures or funding support for this work. Baylor College of Medicine provided the software used to conduct this study.



TABLE 1 Databases and search strategy

Databases used for this systematic review:

Medline OVID (Primary database for this search)

Embase

Web of Science

PubMed

ONSD ultrasound measurement original search strategy for medline OVID

1. "optic nerve sheath diameter*".ti,ab,kw.
2. ("optic nerve sheath" adj3 diameter*).ti,ab,kw.
3. ONSD.ti,ab,kw.
4. 1 or 2 or 3
5. Ultrasonography/
6. (ultrasound* or "ultra-sound*" or ultrason* or "ultra-son*" or sono*).ti,ab,kw.
7. 5 or 6
8. 4 and 7

*Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to March 17, 2021

Abbreviations: *, truncation; ab, abstract; Epub, electronic publication; kw, keywords; ONSD, optic nerve sheath diameter; ti, title.

Search strategy and information sources

In February 2021, a medical librarian (LO) created a systematic search string to look at literature on ultrasound measurements of ONSD. Using Medline OVID (Medline on OVIDSP) as the primary database, the topic was explored and determined to have two main concepts: ONSD (1) and US (2). Each concept was developed using both controlled and natural languages. Medical Subject Headings terms were identified, and keywords were gathered along with various synonyms. The keywords were searched using the title, abstract, and keyword fields within the Medline OVID database. No limiters were used once the concept was thoroughly developed (Table 1).

The initial search was performed on March 18, 2021. The results were uploaded to the EndNote(R) citation manager for automatic and manual de-duplication. The number of results prior to de-duplication was 2,440, 921 after automatic de-duplication, and then 892 after manual de-duplication.

Screening strategy, inclusion/exclusion criteria, and critical appraisal

Studies were screened using Rayyan (<https://www.rayyan.ai/>). The titles and abstracts were reviewed independently by two authors (MUH and RM). Only studies that included two-dimensional US ONSD measurement in humans were selected for full text review. Disagreements were discussed and resolved by MUH, RM, and MIH. Further quality assessment using the tool for Quality Assessment of Diagnostic Accuracy Studies-2 was not necessary for this scoping review as it primarily evaluated differences in measurement methods rather than evaluating measurement results. Figure 1 summarizes the review process and types of manuscripts reviewed.

QC extraction, synthesis, and analysis

A data extraction sheet was developed and piloted by the oversight committee to collect data on the different QC used in different studies. Seven categories for data collection were identified: probe selection, safety, body position, probe placement, image acquisition, measurement, and reporting findings. These categories were then merged into five final categories: probe selection, safety, body position, image acquisition, and measurement. Each category had different subcategories identified during an initial scoping review in addition to "other" subcategory for any additional subcategories identified during data collection, discussion of findings, or peer review.

RESULTS

Characteristics and summary of sources of evidence

QC were evaluated under five categories: probe selection, safety, positioning, image acquisition, and measurement. Each category had subcategories, as shown in Table 2. The proportion of studies that specified certain quality subcategories was variable, ranging from 10.1% to 95.0%. A list of the results of the individual sources of evidence from each study is provided online.³² Figure 1 summarizes the number and types of studies included.

The probe selection category included two subcategories: probe type and frequency. The most used probe type was the linear probe (88.8%). Probe frequency ranges were difficult to group due to the large variety of frequency ranges available by different manufacturers and were grouped by the lowest frequency in the range instead. The lowest frequencies ranged from 2.4 to 13 MHz; 7 MHz was the most common (37.3%). A total of 30.3% of studies were <7 MHz (range 2.5-6) and 20.4% were >7 MHz (range 8-20).

The safety category included 3 review subcategories: mechanical index (MI), thermal index (TI), and the avoidance of globe pressure. These subcategories were specified in 16.2%, 6.2%, and 27.2% of studies, respectively. While not formally listed as a category, we noticed that at least 15 studies followed the ALARA (as low as reasonably achievable) principle when using ultrasound.

The positioning category included five review subcategories: body position, gaze direction, probe placement axis, the eyelid used for imaging, and barrier use. Body position was heterogeneous across studies. Flat or supine (42.3%) was the most common, followed by elevated head position (22.1%). Gaze direction was not specified in most studies (81.0%), but mid- or neutral gaze (17.9%) was the most common direction, when specified. Regarding the probe placement axis, the combination of axial and lateral axial (37.6%) was more frequently used compared to the sagittal one (0.8%) or to the use of multiple axes (33.9%). The eyelid imaged through was not specified in most studies (58.5%), but, when specified, the upper eyelid (40.9%) was the most common one. The use of barriers applied between the eyelid and the probe was not specified in most studies (69.7%).

**TABLE 2** Summary of different ONSD image acquisition and measurement methods in the literature

Category	Subcategory	Subcategory methodological choices	N	%
Probe selection	Type	Linear	317	88.8%
		Not specified	36	10.1%
		Curved array	3	0.8%
		Endocavity probe	1	0.3%
	Lowest frequency (MHz)	7	133	37.3%
		<7 (range 2.5-6)	108	30.3%
		>7 (range 8-20)	73	20.4%
		Not specified	38	10.6%
Safety	Multiple frequencies	5	1.4%	
	MI specified	No	299	83.8%
	TI specified	No	335	93.8%
Positioning	Avoiding globe pressure	No	260	72.8%
	Body position	Flat (supine)	151	42.3%
		Not specified	104	29.1%
		Head elevated	79	22.1%
		Multiple	17	4.8%
		Upright	4	1.1%
		Prone	2	0.6%
		Gaze direction	Not specified	289
	Mid gaze		64	17.9%
	Up gaze		2	0.6%
	Downgaze		1	0.3%
	Probe placement axis	Lateral gaze	1	0.3%
		Multiple	121	33.9%
		Not specified	99	27.7%
		Axial (transverse)	98	27.5%
		Lateral axial (lateral transverse)	36	10.1%
		Sagittal (longitudinal)	3	0.8%
Eyelid	Not specified	209	58.5%	
	Upper	146	40.9%	
	Both upper and lower	1	0.3%	
	Lower	1	0.3%	
	Probe placed directly on cornea	1	0.3%	
	Barrier	Not specified	249	69.7%
		Did not use	65	18.2%
Transparent film dressing or glove		37	10.4%	
Image acquisition	Lens inclusion	Not specified	340	95.2%
		Included	15	4.2%
		Excluded	2	0.6%
	Thinnest optic nerve head interface selected	No (or not specified)	339	95.0%
	Identification of optic nerve	No/not specified	264	73.9%
	Identification of subarachnoid space	No/not specified	329	92.2%

(Continues)

**TABLE 2** (Continued)

Category	Subcategory	Subcategory methodological choices	N	%			
Measurement	Identification of dura	No/not specified	327	91.6%			
	Example Image published	Yes	228	63.9%			
	Depth reference structure (starting point)	Retrolubar (posterior to the globe/eye)	Papilla	60	16.8%		
			Retina or vitreoretinal interface	46	14%		
			Optic disc	35	9.8%		
			Not specified	22	6.2%		
			Lamina cribrosa	15	4.2%		
			Sclera	12	3.4%		
			Depth reference axis	Not specified	Longitudinal to the optic nerve	64	17.9%
					Perpendicular to the eye	5	1.4%
	Vertical axis of scanning plane	4			1.1%		
	Measurement depth	3 mm			Not specified	24	6.7%
			Multiple depths including 3mm	7	2.0%		
			ONSD reference points (structures included)	Not specified	SAS	31	8.7%
	Dura	13			3.6%		
	ON	5			1.4%		
	SAS space and dura reported separately	1			0.3%		
	Measurement angle relative to depth axis	Not specified			90 degrees	75	21.0%
			Averaging multiple measurement from two axes	Not required or not specified	259	72.5%	
	Reporting right and left independently	No			294	82.4%	
Performing longitudinal testing over time	No	237	66.4%				

Abbreviations: ALARA, as low as reasonably achievable; MI, mechanical index; N, number; ON, optic nerve; ONSD, optic nerve sheath diameter; SAS, subarachnoid space; TI, thermal index.

The image acquisition category included six subcategories: lens inclusion (not specified in 95.2%), selection of the thinnest ON head interface (not specified in 95%), identification of the ON (26.1%), identification of the subarachnoid space (7.8%), visualization of the dura (8.4%), and inclusion of a sample image in the publication (63.9%). There was little agreement on which areas of the image represented different ONS components.

The measurement category included eight subcategories: depth reference structure, depth reference axis, measurement depth, ONSD reference points, ONSD measurement angle relative to the depth reference axis, averaging images from multiple axes, independently

reporting right and left sides, and performance of longitudinal testing. The depth reference structure, the starting point to perform the depth measurement, was most frequently described in generic terms, such as “retrolubar,” “posterior to the globe,” or “behind the eye” in 45.7% of publications, and when specified, the papilla was the most frequent depth reference structure (16.8%). Depth reference axis, along which the depth measurement is performed, was not specified in 79.6% of studies, and when specified, the most frequent axis was longitudinal to the ON (17.9%). The depth measurement was performed at 3 mm from the reference axis in 91.3% of studies. The reference points used to measure ONSD (structures included) were

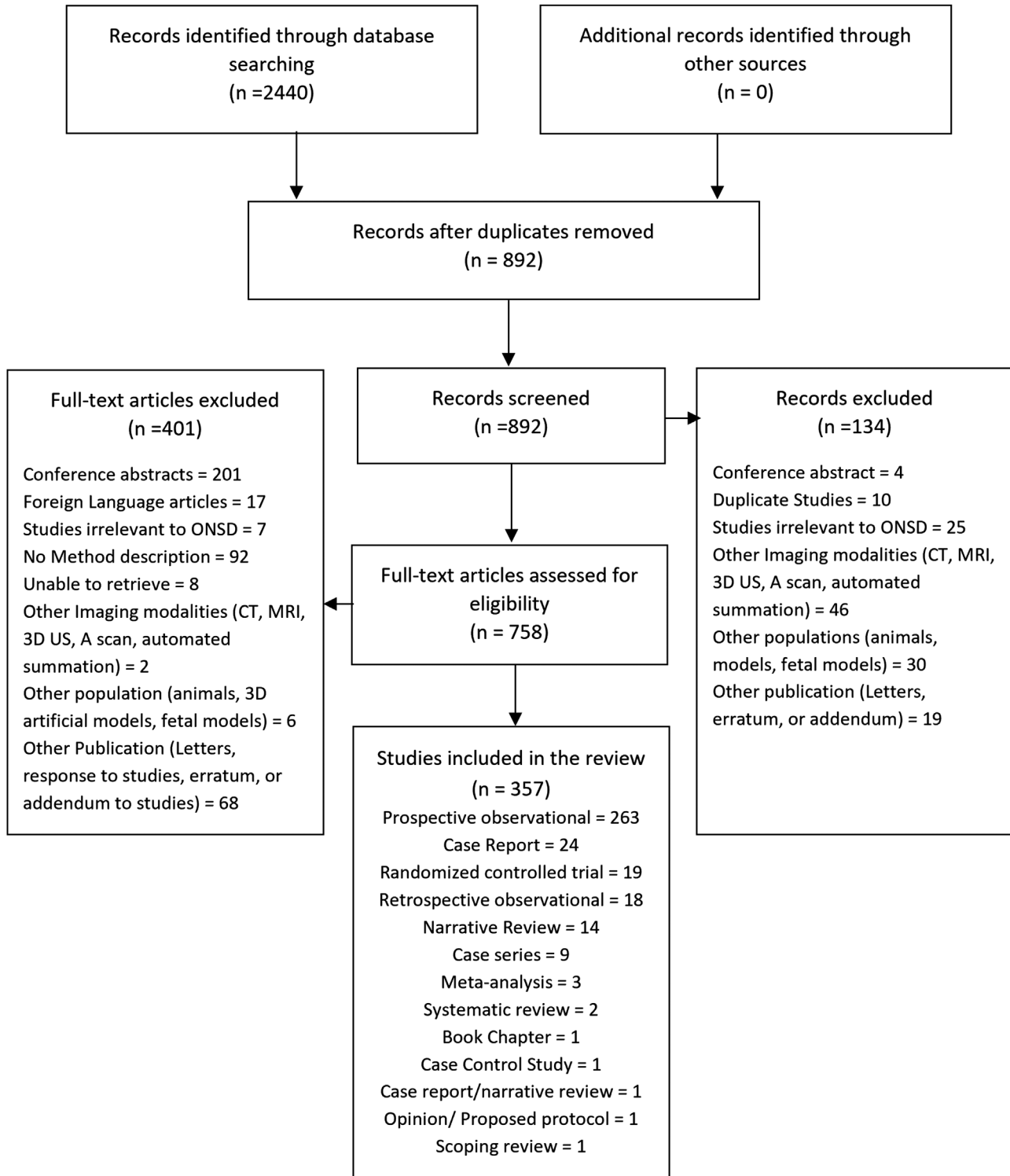


FIGURE 1 Summary of the review process and types of manuscripts reviewed. *n*, number of studies; US, ultrasound

not specified in 86% of studies. When specified, the inner hypoechoic band (IB) behind the eye, which represents the ON, was used in 1.4% cases, the stripped hyperechoic band (SHB) in 8.7%, and the outer hypoechoic band (OB) in 3.6% of the studies. One study (0.3%) compared both SHB and OB (0.3%) for ONSD measurement. Variations in descriptions of anatomy and the definitions of IB, SHB, and OB are

discussed in more detail in the “DISCUSSION” section below and in Figure 2.

ONSD measurement angle, defined as the angle at which the ONSD line is drawn relative to the depth reference axis, was not specified in 79% and was defined at 90 degrees in 21.0% of the studies. Averaging measurements from multiple axes was required from two axes in 27.2%

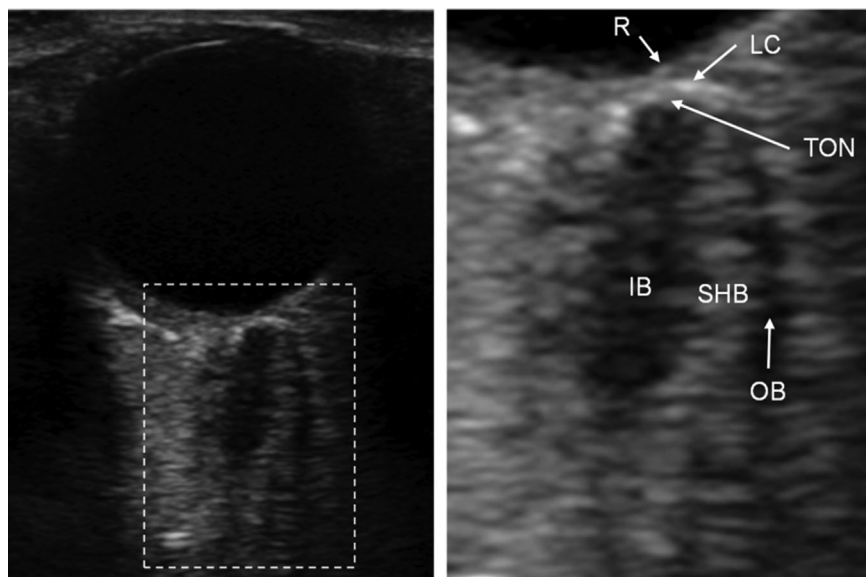


FIGURE 2 Anatomic definitions. Example ONSD image with the definitions of anatomic and descriptive terms used in this manuscript. R, retina; LC, lamina cribrosa; TON, top of the optic nerve; IB, inner band; SHB, stripped hyperechoic band; OB, outer band

of studies but not used or not specified in 72.5% cases. Most studies did not report right- and left-sided ONSD measurements independently (82.4%) and did not perform longitudinal testing where multiple measurements were compared over time (66.4%).

DISCUSSION

Summary of evidence

In this scoping review, we identified 357 studies that utilized B-mode US to measure the ONSD. Our findings show heterogeneity in performing and reporting ONSD measurements. The categories used to evaluate the ONSD measurement and reporting are summarized in Table 2. The preliminary recommendations for the ONSD QCC are summarized in Table 3. The categories are discussed in further details below.

Probe selection

The use of linear probes for ONSD measurement is recommended, as this was the most used probe in the different studies included in this review. It is recommended to use a minimum effective frequency of 7.5 MHz or above given no significant differences in lateral resolution when compared to higher resolution in one study.³³ The majority of studies reviewed had the lowest frequency in the probe range above this recommendation.

Safety

Most studies included in our review did not specify MI, TI, or the avoidance of globe pressure. Some studies mentioned to follow the ALARA

principle when using ultrasound. The U.S. Food and Drug Administration guidance recommends utilizing a $TI \leq 1$ and $MI \leq 0.23$.³⁴ It is worth noting that TI is dependent on the duration of the examination and at $TI \leq 1$, the maximum recommended scan time is 30 minutes, which is much longer than what would be generally needed to obtain an ONSD measurement.³⁵ Following the ALARA principle is a recommended standard of care in US that applies to ONSD examination.³⁶

Positioning

The subjects should be semi-recumbent or in reverse Trendelenburg during ONSD measurement, unless the study aims to specifically assess the effect of body position on ONSD or if the clinical setting does not allow this position, such as in patients in prone positioning in the perioperative period. This is because most hospitalized patients are placed in the head-up position,³⁷ and body position may affect ONSD measurement.³⁸ Therefore, standardizing body position is important for standardizing body position. Gaze direction can also affect ONSD measurement.²⁰ Therefore, neutral gaze (mid gaze) should be utilized during ONSD measurement. Slight adjustments in gaze direction are permissible to enable the imaging plane to be orthogonal to the ON plane. The closed upper eyelid should be used for imaging given its larger area that reduces the likelihood of air bubbles stuck in the eyelashes causing imaging artifacts.³⁹

Image acquisition

The image with the thinnest ON head interface where the nerve penetrates the globe without interposition of a thick echogenic scleral layer should be selected for measurement.³⁹ This ensures that the imaging plane is orthogonal to the nerve axis and improves reproducibility in our experience.

**TABLE 3** Preliminary recommendations to be discussed in the Delphi study

Category	Subcategory	Preliminary recommendation
Probe selection	Type	A linear probe should be used to obtain ONSD images.
	Lowest effective frequency	Lowest effective frequency should be ≥ 7.5 MHz.
Safety	Mechanical index	MI should be ≤ 0.23 per FDA guidelines.
	Thermal index	TI should be ≤ 1 per FDA guidelines, understanding that TI is a function of scanning time.
	Globe pressure	Avoid excessive globe pressure.
	Other: ALARA	Utilize ALARA principles, including the lowest possible MI and scanning time.
Positioning	Body position	Subject should be supine with upper part of the body elevated 20–30° unless the study aims to specifically evaluate the effect of body position or if the setting does not allow this.
	Gaze direction	Neutral gaze (midgaze) should be utilized during measurement. Slight adjustments in gaze direction are allowed to enable the imaging plane to be orthogonal to the optic nerve plane.
	Probe placement axis	Lateral transverse (lateral axial) imaging axis should be utilized.
	Eyelid	Closed upper eyelid should be utilized for measurement.
	Barrier	Usage of barrier devices such as probe covers, gloves, or transparent dressing is optional.
Image acquisition	Lens inclusion	Lens inclusion or exclusion is of unclear value.
	Thinnest optic nerve head interface	The image with the thinnest optic nerve head interface should be used for measurement.
	Identification of the different ONSD components	The image with the clearest anatomic differentiation of ON and ONS components should be selected for measurement.
Measurement	Depth reference structure (starting point)	If the lamina cribrosa (LC) is visible, it should be utilized as the depth reference point. If LC is not visible, the papilla at the level of the retina (Figure 2) should be utilized. All three depth reference structures will be presented to the panelists for discussion.
	Depth reference axis	The measurement axis should be orthogonal (same axis) to the ON axis (Figure 3).
	Measurement depth	The depth measurement should be performed at 3 mm.
	ONSD reference points (structures included)	In clinical use, the SHB-OB interface should be used as the measurement reference point, also known as ONSDint. For research purposes, investigators should consider reporting both ONSDint and ONSDext. ONSDext utilizes the OB as the measurement reference point.
	ONSD measurement angle relative to depth reference axis	ONSD measurement should be performed at a 90-degree angle relative to the depth axis (Figure 3).
	Averaging multiple measurements by probe placement axis	Averaging longitudinal and transverse measurements can be considered but is not mandatory.
	Averaging multiple measurements on same side versus reporting right and left independently	If brain pathology is global, averaging measurements on right and left can be considered, but is not mandatory. If the pathology is unilateral, the measurement can be considered on the ipsilateral eye or most affected eye. This should be determined a priori when used in clinical research.
	Averaging multiple measurements on the same side	Averaging multiple measurements using the same measurement axis on the same side can be considered but not mandatory.

(Continues)

**TABLE 3** (Continued)

Category	Subcategory	Preliminary recommendation
Other: study design and publication	Longitudinal testing (multiple measurements over time)	Reporting baseline ONSD and monitoring change overtime can be considered.
	RA Doppler	Neutral gaze with ON orientation orthogonal to the image frame are more important than using CRA for all ONSD measurements. CRA can be considered when nerve kinking or poor anatomic differentiation limits the examiner's ability to visualize ONSD orientation.
	ONSD-ETD ratio	ONSD-ETD ratio is a promising measurement to normalize ONSD and further research is needed before it is widely recommended in for ONSD evaluation.
	Blinding	If possible, while designing the study, the person performing the measurement should be blinded to the patient's condition, other investigators' measurements, and intracranial pressure to avoid bias.
	Example Image published	An example image with measurements should be included in the publication for quality assessment.
	Training	The investigators should be trained in transorbital sonography before starting with the study.
	Inter-observer variation	The inter-observer variation among investigators could be assessed at the beginning of the study when possible.

Abbreviations: ALARA, as low as reasonably achievable; FDA, food and drug administration; MI, mechanical index; OB, outer hypoechoic band; ON, optic nerve; ONSD, optic nerve sheath diameter; ONSD-ETD ratio, ONSD to eye transverse diameter ratio; ONSDext, external ONSD; ONSDint, internal ONSD; RA, retinal artery; SHB, stripped hyperechoic band; TI, thermal index.

Most studies did not clearly present sufficient anatomic differentiation to identify the different ONS components. Imaging should focus on good anatomic differentiation of the ONS components and the image with the clearest anatomic differentiation should be selected for measurement. The implications of inconsistencies in using anatomic terms to describe ONS components on marker placement for measurement are discussed below.

Measurement

Analysis of published sample images showed that three depth markers were used: at the levels of the retina (R), lamina cribrosa (LC), and top of the optic nerve (TON) (Figure 2).¹⁶ Despite the different markers used, one study suggests no differences in ONSD sensitivity in detecting elevated ICP due to depth marker placement.¹⁶ Therefore, standardization and reproducibility of depth marker placement may be more important than the selection of a specific depth marker. The 3 different depth marker options will be presented to the Delphi panelists to undergo voting and discussion. Our preliminary recommendation is to use the LC as depth marker, and if the LC is not visible, to use the papilla at the level of the retina (also referred to as the vitreoretinal interface). Depth reference axis, along which the depth measurement is performed, was not specified in most studies. The depth measurement axis should be orthogonal to the ON axis (Figure 3), as using this axis yielded reproducible measurement in experimental studies.⁷

The depth measurement should be performed at a depth of 3 mm, as described by the majority of studies reviewed here and according to experimental work on pathology samples and cadavers that show a maximum ONSD distensibility at the depth of 3 mm.^{7,8} However, it is worth noting that the optimal depth for assessing the changes in ICP has not been extensively evaluated.

The reference points used to measure ONSD (or structures included in the measurement) were not specified in most studies. Addressing this category is challenging because of three main issues: poor anatomic differentiation, little agreement on the ONS anatomic structures on ultrasound, and the use of two main measurement methods (Figure 4), referred to here as internal ONSD (ONSDint) and external ONSD (ONSDext). Poor anatomic differentiation, where the ON cannot be differentiated from the ONS,⁴⁰ can be due different factors including incorrect transducer placement, inability to capture the central cross-section of the ONS, or use of low transducer frequency with lower resolution,⁸ which can lead to incorrect measurements.¹⁴ When a good anatomic differentiation was present, three sonographic areas were noted: the inner hypoechoic band corresponding to the ON, surrounded by the stripped hyperechoic band, which in turn, was surrounded by an outer hypoechoic band (Figure 2).¹⁶ ONSD can be measured in two different ways: ONSDint, where ONSD is measured at the border between the SHB and OB, and ONSDext, where ONSD is measured outside the OB. One study showed that ONSDext had mean values higher by 0.67 (range: 0.2-1.2) mm compared to the ONSDint. ONSDint also had a higher effect size between elevated

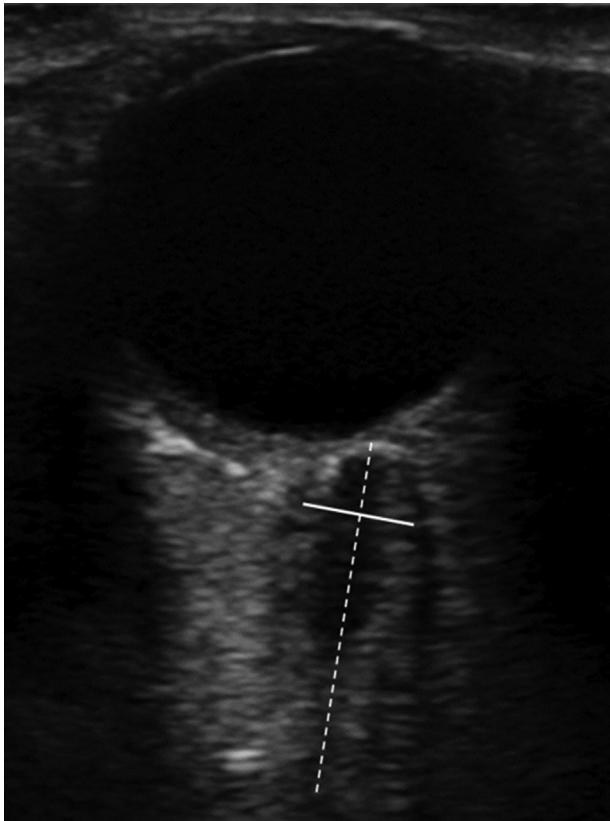
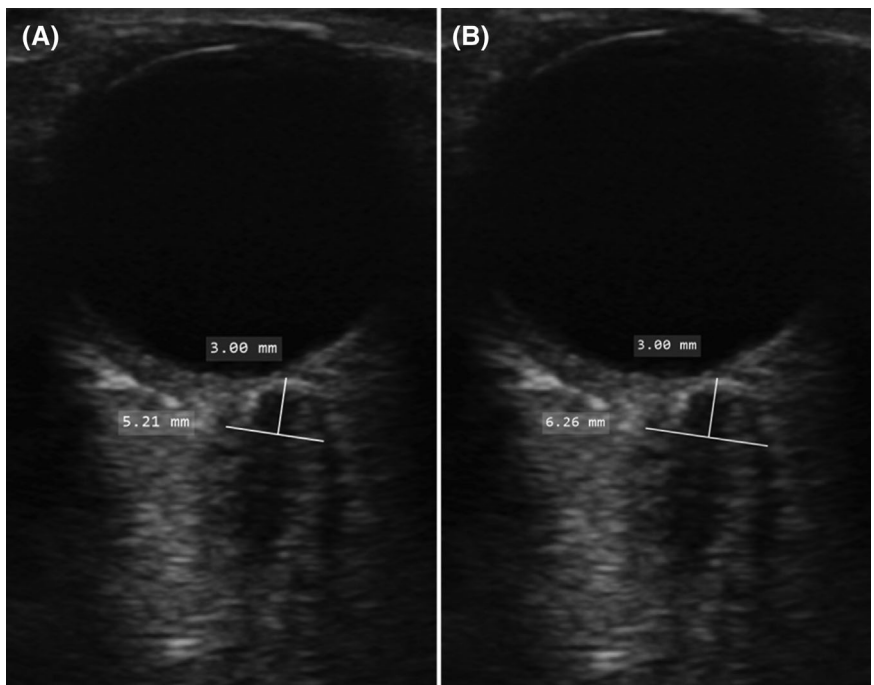


FIGURE 3 Measurement axis. The measurement axis should be orthogonal to the optic nerve, that is, parallel to optic nerve boundaries (dashed line). The ONSD measurement line (solid white line) should be at a 90° angle to the axis reference line.

FIGURE 4 ONSD measurement methods. The two main measurement methods reported in the literature measure the stripped hyperechoic band (SHB) alone by placing the measurement caliper at the boundary between the SHB and the surrounding outer hypoechoic band (OB), referred to here as the “internal ONSD” (A); alternatively, the calipers are placed outside the OB, referred to here as the “external ONSD” (B).



ICP and normal controls (1.5 mm difference) when compared to the ONSDext (0.9 mm difference).¹⁶ To complicate this issue further, two small studies showed a higher diagnostic accuracy, as determined by the area under the curve (AUC) of receiver operating characteristics curves, for the detection of elevated ICP using ONSDext compared to ONSDint.^{41,42} In this review, most studies did not specify the structures included but when specified, ONSDint was used more frequently (8.7%) than ONSDext (3.6%).

Several contradictory descriptions exist in literature for other ONSD contents, and it is difficult to pinpoint which anatomic structures represent the SHB and OB (Table 4; Figures 2 and 4). Two main anatomic groupings have been used in literature for both ONSDint and ONSDext measurement methods. ONSDint group 1^{43–45} suggests that the IB represents the pia mater and ON, SHB the subarachnoid space, and the OB the dura mater and the hyperechoic area surrounding the nerve is the periorbital fat. In contrast, ONSDint group 2^{8,46} suggests that the SHB represents both the pia and subarachnoid space and agrees with group 1 on the other descriptions. Both groups suggest that ONSDint represents ONSD. Other descriptions suggest that ONSDext represents ONSD, but describe the anatomy differently. ONSDext group 1 suggests that the SHB is the pia mater, the OB is the subarachnoid space, and the surrounding dura and peri-orbital fat appear hyperechoic.^{41,47–50} ONSDext group 2 suggests that the SHB represents the pia and subarachnoid space, while the OB represents the dura.⁵¹ A small cadaveric study sheds some light on this issue by performing ONSD measurements after injecting saline into the ON sheath. The authors suggested that the SHB represents the pia and OB the dura mater.⁸ In this study, the subarachnoid space appeared to be hypoechoic and collapsed in before the saline injections, but was distended and merged with SHB after saline injections. However, the published sample images do not show clear boundaries between what



TABLE 4 Summary of the anatomic interpretation of the ONS structures

	IB	SHB	OB	hyperechoic area surrounding the nerve
ONSDint,group 1 ⁴³⁻⁴⁵	ON + Pia	Subarachnoid space	Dura	Periorbital fat
ONSDint,group 2 ^{8,46}	ON	Subarachnoid space + Pia	Dura	Periorbital fat
ONSDext,group 1 ^{41,47-50}	ON	Pia	Subarachnoid space	Dura + Periorbital fat
ONSDext,group 2 ⁵¹	ON	Pia + subarachnoid space	Dura	Periorbital fat

Abbreviations: IB, inner hypoechoic band; ON, optic nerve; SHB, stripped hyperechoic band; OB, outer hypoechoic band; i, internal; e, external.

the authors identified as pia and subarachnoid space. Furthermore, no pathologic confirmation of the different layers was performed to validate the findings.⁸

ONSD measurement angle is the angle at which the ONSD line is drawn relative to the depth reference axis. ONSD measurement should be performed at a 90-degree angle relative to the depth axis (Figure 3), following basic principles of measuring the cross section of a cylinder.

Averaging measurements from multiple axes or the same axis were not required or not specified in most studies and there is no evidence that averaging multiple measurements improves ONSD estimation. Therefore, averaging longitudinal and transverse measurements can be considered but should not be mandatory.

Most studies did not report the measurement of right and left sides, independently. It is unclear whether averaging bilateral measurements, reporting them independently, or reporting the largest of the two measurements would be helpful. A consideration of the underlying pathology can be important in this context, and if the brain pathology is global, averaging measurements on the right and left side can be considered. On the other hand, if the pathology is unilateral, the measurement should be considered on the ipsilateral or the most affected eye. This should be determined a priori when using ONSD in clinical research, and further research is needed to determine the importance of underlying brain injury laterality on ONSD measurements.

Most studies did not perform longitudinal testing. Reporting baseline ONSD and monitoring changes overtime could be considered, and further research is needed to recommend the utility of ONSD change overtime versus spot measurement.

Other identified parameters

The steering committee identified additional criteria during the discussion of the review results and the peer review process. Those include the use of retinal artery Doppler, ONSD to eye transverse diameter (ONSD-ETD) ratio, blinding investigators performing measurements, investigator training, and interobserver assessment.

Using central retinal artery (CRA) Doppler to verify the direction of ONSD has been suggested in literature to identify the direction of the nerve and minimize the effects of acoustic shadow artifacts from the lamina cribrosa when the nerve is tilted due to imaging axis, gaze direction, or ON kinking.⁵² A protocol for ONSD standardiza-

tion that included the use of color Doppler to demonstrate the CRA has been proposed.⁵³ While the sample images published with this protocol demonstrated that CRA correctly delineated the trajectory of ON, the images had a combination of low anatomic differentiation and incorrect marker placement, where the measurements were performed at the edges of ON in some frames and the edges of the ONS on other frames. This puts into question the utility of protocolized CRA use in the presence of good anatomic differentiation and correct marker placement. This protocol was further evaluated in a prospective study that demonstrated excellent inter- and intrarater reliability for ONSDint and ONSDext assessment. The sample images showed excellent anatomic differentiation with correct marker placement according to author definitions.⁵⁴ However, measurements with and without RA Doppler were not performed in this study and it is unclear whether the excellent reliability was due to the protocolized use of RA Doppler or the use of images with good anatomic differentiation and vertical ON orientation. Additionally, lateral gaze can lead to ONSD deformation and smaller ONSD measurements.^{55,56} Therefore, in the instances where lateral gaze leads to tilted ON trajectory, assuring neutral gaze and ON orientation orthogonal to the image frame may be more important than using CRA to get around obtaining images orthogonal to ON trajectory. However, CRA may have some role in cases with kinked ON or vague orientation due to artifacts.

ONSD-ETD ratio was proposed to normalize ONSD measurements and minimize the effects of individual variations on ONSD accuracy. This is based on multiple linear regression analyses that correlated individual variations such as gender, height, weight, body mass index, head circumference, and ETD with ONSD. Only ETD had significant correlation with ONSD across multiple studies.⁵⁷⁻⁶⁰ ONSD-ETD ratio had a larger AUC of receiver operating characteristics curve (AUC-ROC) than ONSD alone for the detection of brain injury.⁵⁷ In addition, while ONSD alone tends to have a sizable overlap between the confidence intervals of "normal" and "elevated" ICP, ONSD-ETD ratio did not, suggesting higher precision.^{59,61-64} ONSD-ETD ratio also had higher sensitivity and specificity for the prediction of poor neurological outcomes in patients with supratentorial injuries.⁶⁵ Two studies compared the accuracy of ONSD-ETD ratio to ONSD alone in the detection of elevated ICP. One study ICP showed insufficient discriminative accuracy in detecting elevated ICP between the two measurements.⁶⁶ The study appears to measure the ON diameter in the "normal ICP" and ONSD in the "elevated ICP" sample MRI images, which puts the study findings into question. Another study evaluated ONSDint,



ONSDext, and ONSD-ETD ratio in patients with brain injury and an ICP monitor. ONSD-ETD ratio showed higher accuracy than both ONSD measurements, but it is worth noting that this study used admission CT scans to obtain ETD and ultrasound to obtain ONSD, which may limit the applicability of this measurements in bedside US.⁴² In summary, ONSD-ETD ratio is a promising measurement to normalize ONSD and further research is needed before it is widely recommended for ONSD evaluation.

Some studies blinded the investigator performing the measurement to the patient or subject condition.^{67,68} When possible, the person performing the measurement should not be aware of the patient's condition and ICP to avoid bias. Furthermore, in order to achieve adequate standardization in the measurement of ONSD, all investigators performing the measurement should be adequately trained prior to the study,¹⁹ and their interobserver variation to be assessed at the beginning of the study, when possible.⁶⁹

Limitations

The terminology used in the literature to describe different criteria was very heterogeneous, and several iterations of each criterion were made to accommodate this variability. This might have led to a loss of granularity to capture broad categories and criteria. Future work can use these categories as a starting point for more focused reviews, if necessary. Other limitations include heterogeneity of study designs, variability of techniques in the literature, publication bias, and variable quality and quantity of published details on US measurement of ONSD.

CONCLUSION

Measurements of ONSD may be a valuable noninvasive surrogate marker for elevated ICP. Transorbital US is widely used for this purpose, being a noninvasive bedside tool with an excellent safety profile. We reviewed the literature on US techniques and measurements of ONSD and provide a preliminary QC checklist (Table 3). Pitfalls related to ONSD included use of probes with beam patterns or frequencies not suitable for ONSD images, inconsistent body position and gaze direction, poor anatomic differentiation, unclear depth marker, unclear ONSD edges, and inconsistencies in the structures measured.

These results will be used to create a modified Delphi study to further refine the ONSD US QCC and achieve consensus among an expert panel. The resulting ONSD US QCC will have the potential to reduce the methodological heterogeneity currently encountered in literature and could improve the precision and accuracy of ONSD measurements by transorbital sonography in future studies. This will be essential for the development of clinical applications of ONSD US, including non-invasive ICP assessment. Table 5 summarizes the key aspects of this work.

TABLE 5 Key points

1. Optic nerve sheath diameter is used as noninvasive estimator of intracranial pressure.
2. We performed a systematic review to extract ultrasound optic nerve sheath diameter imaging and measurement criteria.
3. The methodology of optic nerve sheath diameter measurement is very heterogeneous among authors.
4. Quality criteria obtained from the review were grouped to create preliminary statements/recommendations.
5. The statements/recommendations will undergo voting and discussion within a multidisciplinary expert panel.
6. This work will allow for developing a consensus on ultrasound optic nerve sheath diameter quality criteria.

DELPHI STUDY PROTOCOL

Planning and process

This protocol follows the guidance on Conducting and REporting DELphi Studies recommendations (CREDES).^{70,71} Three rounds of surveys will be administered using a secure web-based survey platform. After each round, items reaching consensus will be dropped from the following survey rounds. The remaining items will be modified based on the panelists' comments and presented to the panelists again along with a summary of their comments. This process is described in more detail below.

Oversight committee

The study authors will serve as the oversight committee. MIH is an assistant professor of neurology and neurocritical care, and an expert in ONSD. PL is an assistant professor of neurology, a neurosonology expert with a PhD in optic neuritis US, and educator with interest in the applications of transorbital sonography in neurological diseases. MUH is a neurocritical care fellow who managed screening, reviewing, and extracting data from the existing literature and ensured its accuracy. AGL is a professor of ophthalmology with research and clinical expertise in neuro-ophthalmology. CK is a professor of neurology with clinical, research, and leadership expertise in neurosonology and its applications in neurological diseases. DD is a lead programmer analyst who served as a methodologist on Delphi studies for medical curriculum development and enrichment. NDH is an associate professor of emergency medicine with experience in leading modified Delphi technique studies to derive expert consensus on clinical and education topics. ME is an assistant professor of neurology with leadership, clinical, and research expertise in neurosonology, including applications in cerebrovascular diseases and ocular sonography. FS is an associate professor in neurology including a subspecialty in intensive care medicine and clinical, research, and leadership expertise in neurosonography. CR is an associate professor in general and neurocritical care with a PhD in brain US and the ONSD.

**TABLE 6** Five-point Likert scale

1	2	3	4	5
<i>Very unimportant</i>	<i>Unimportant</i>	<i>Neutral</i>	<i>Important</i>	<i>Very important</i>

Expert panel eligibility and retention plan

Selecting expert panelists is crucial for the validity of consensus by a Delphi study. The ideal number of panelists in a Delphi study can vary greatly, but 10-18 panelists can help to ensure the development of a productive group dynamic.²⁶ The more heterogenous is the panel, the larger it needs to be. However, the variety of expert categories can be more important than the number of experts itself.²⁵ Our goal is to have a minimum of 30 panelists. Definitions of ONSD experts vary widely in the literature with experience requirements from 2 months to 10 years or 17-30 scans performed.^{5,17,20} The number of supervised scans required to reach proficiency can be as much as 17-25 scans for novice sonologists,^{19,72} and as little as 10 scans for more experienced sonographers.⁷² To accommodate the variable definitions of experts, experts will be required to have performed at least 20 scans over the preceding year. Five types of experts were identified: (1) experts with insights on the importance of ONSD standardization as identified during the scoping review portion of this protocol; (2) ONSD research experts identified by searching the web of science core collection (<http://webofknowledge.com/>) for ultrasonographic ONSD publications and contacting the top 30 experts organized by number of publications; (3) ONSD education experts identified by contacting ultrasound fellowship directors registered in the Society for Clinical Ultrasound Fellowships (<https://eusfellowships.com/program-list-new/>); (4) self-nomination after reviewing this manuscript; and (5) experts recommended through other experts identified through the above categories. The steering committee will review all nominations prior to sending invitations to the expert panelists. Only panelists that can dedicate the time needed to complete three rounds and are experienced in performing ultrasonographic ONSD will be invited to participate in the Delphi rounds. At least 70% retention rate in every round is necessary to maintain rigor.²⁵ Retention will be improved by using streamlined surveys that are consistent in style and easy to fill, short intervals between rounds, clear invitations that emphasize the importance of the work, and a "personal touch" when communicating with expert panelists are all important factors in improving retention.^{25,26} Panelists will also have the option of being acknowledged by name in the final publication.

Prevention of bias

The oversight committee members have no conflicts of interest. The expert panelists will be required to disclose any conflict of interest prior to participating in this study. To prevent seniority bias and peer pressure, the panelists will not be aware of other responses in the same round and the research team will collate all the comments in a neu-

tral anonymous format between rounds before presenting them to the panelists.

Description of the methods: Survey design

A variety of Likert scales have been used in previous Delphi surveys.²⁵ A 5-point Likert scale (Table 6) will be used to evaluate for importance, as scales with less than 5 points performed poorly on indices of reliability, validity, and discriminating power, with no significant increase in performance with higher scales points.⁷³ This checklist will be distributed using a secure online platform. The survey will be organized into categories and subcategories following the organization presented in Table 3. Each preliminary recommendation will represent a survey item and the respondents will indicate the level of importance using the 5-point Likert scale. Each item will be accompanied by a free text box to collect comments, a statistical summary of the prior round, and summaries of the anonymous remarks. This survey will be piloted by the oversight committee prior to the first round.

Informational input and preparatory phase

All expert panelists will be provided with a copy of this manuscript. This will assure equal informational input and a clear understanding of the study rationale and goals. The expert panelists will also receive a clear explanation of the study goal, number of rounds, consensus rules, and survey structure.

Number of rounds

The number of Delphi rounds can vary in literature. In the original Delphi design, four rounds were used²³ and was later shortened to two or three rounds to improve retention.²⁵ Furthermore, panelists usually reach consensus after two rounds.²⁸ As we are using a modified Delphi design with predetermined survey, we do not anticipate to need more than two rounds to achieve consensus and if all items reach consensus before round 3, the study will be concluded early. However, we opted for three rounds to enable panelists contributions through open-ended questions in the first phases of the survey. If an item does not reach consensus after round 3, the oversight committee will have 2 options. If the item is considered essential for performing ONSD measurement, the oversight committee may consider having a focus panel meeting with the expert panelists to resolve the issue or extend additional survey rounds. If the item is considered

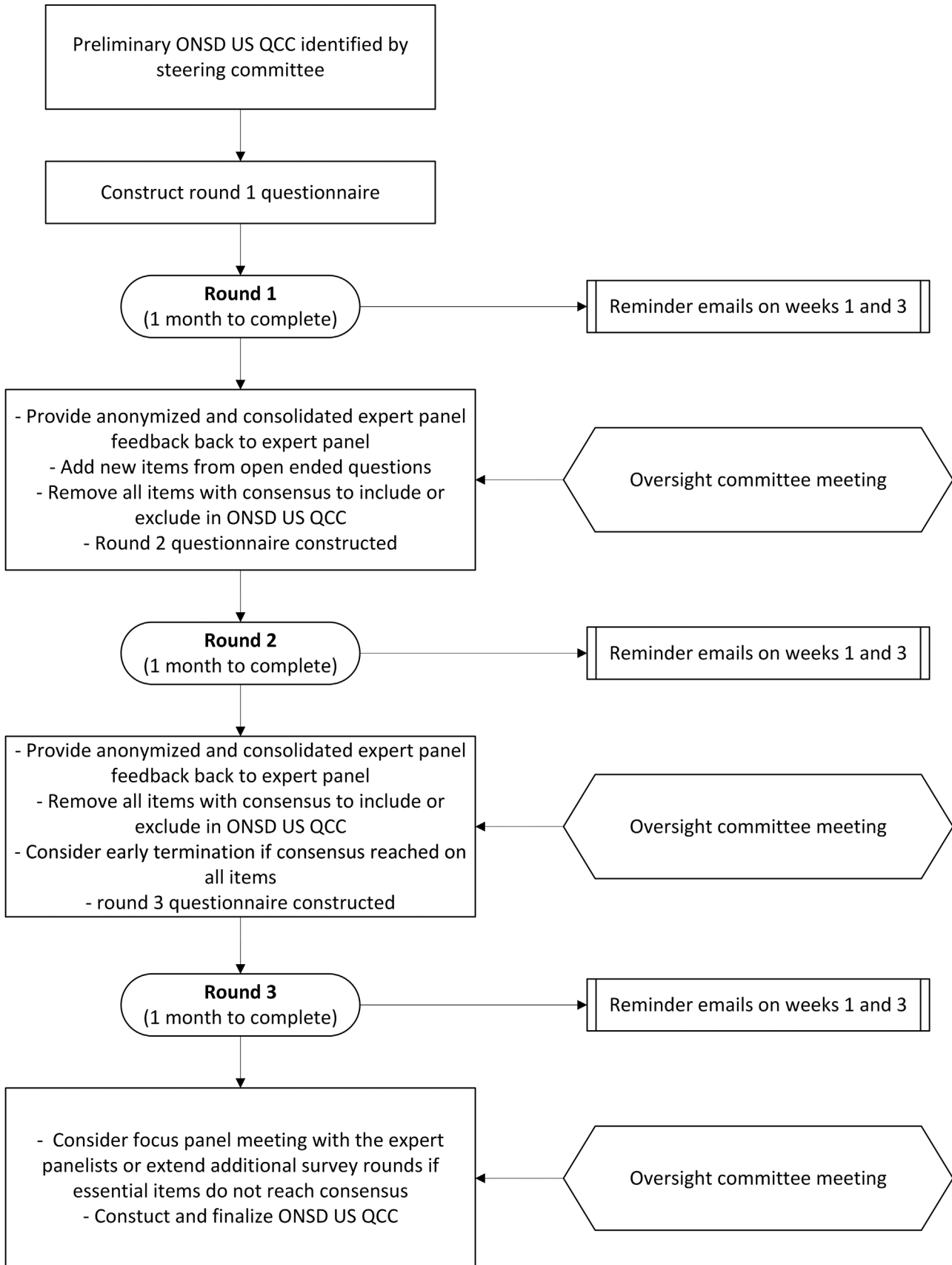


FIGURE 5 Modified Delphi process and timeline. ONSD US QCC, optic nerve sheath diameter ultrasound quality criteria checklist



TABLE 7 Definitions of agreement, importance, and consensus for the Delphi process

	Definition
Agreement	$\geq 70\%$ of panelists agree on importance or unimportance
Importance	Mean Likert scale ≥ 4
Unimportance	Mean Likert scale ≤ 2
Consensus to include in final ONSD US QCC	$\geq 70\%$ agreement + Mean Likert scale ≥ 4 + no concerns based on expert feedback
Consensus to exclude from final ONSD US QCC	$\geq 70\%$ agreement + Mean Likert scale ≤ 2 + no concerns based on expert feedback

Abbreviations: US, Ultrasound; QCC, Quality Criteria Checklist.

“nonessential,” it will be reported as a nonconsensus item that may represent an opportunity to explore knowledge gaps that need further research.

Data collection: Round 1

The round 1 survey will present statements on the preliminary QC and the panelists will be able to indicate the level of importance on a 5-point Likert scale. Additionally, the panelists will have the option to propose new criteria that were not included in the initial survey, suggest alternative grouping or wording for the QC, or add any other comments. The survey will be open for 3 weeks and two email reminders will be sent and the option to withdraw will be offered if the panelists are unable to continue the study (Figure 5).

Data collection: Rounds 2 and 3

Panelists that have completed the previous round will be invited. Round 2 and 3 surveys will be constructed, based on the results of the previous round. Each survey item will be modified based on the panelists' suggestions. Quantitative feedback about importance of each item will be provided. Additionally, qualitative feedback will be summarized for each survey item and provided to the panelists. Criteria that have reached consensus at the previous round will also be reported to the panelists as a completed item but will not be included in the survey. The survey will be open for the same duration and will have the same reminders as the prior round.

Data analysis between rounds

Data analysis will be performed in the 2 weeks following each round. The online survey tool will generate the pooled results per item for each round. This will be provided to the panelists during the following round in the form of descriptive statistics including median,

interquartile range, and percentage of agreement. Qualitative data and suggestions made by the panelists will be summarized by the oversight committee and provided to the panelists in the form of a narrative summary in the following round. We will require two or more suggestions for adjustment of each item. The rationale of each change will be provided to the panelists.

Definition of consensus and processing results between rounds

There are various ways of achieving consensus in Delphi studies. This includes formal measures of agreement (kappa statistic, Cronbach's alpha, and correlation coefficient), Rand criteria, measures of central tendency, proportions, stability, and rank order. The most used measure is proportions with preset agreement. Specifically, a consensus of 70%–80% is frequently used by Delphi studies.^{26,74} Additionally, excluding an item that has reached consensus between rounds can have advantages and disadvantages. Advantages include shortening the survey, which motivates panelists and increases participation. A disadvantage is that an item that reaches consensus in later rounds has a higher chance of having a higher consensus, which may give it a higher rating of importance.²⁵ Since the categories and subcategories in this study are mutually exclusive in many instances, items reaching consensus will be excluded. However, to balance the risk of falsely inflated importance, we will use both agreement (determined by percentage of responses) and importance (mean Likert scores) as summarized in Table 7.²⁵ Consensus to include will be defined as 70% agreement on importance (percentage of panelists choosing 4 or 5) and Mean Likert scale ≥ 4 . Consensus to exclude will be defined as 70% agreement on unimportance (percentage of panelists choosing 1 or 2) and Mean Likert scale ≤ 2 without qualitative comments to improve the recommendation.

Publication and dissemination

The results of the Delphi will produce recommendations that will be disseminated through the scientific community through peer-reviewed manuscripts and conference proceedings.

Limitations of the Delphi process

The limitations of the Delphi process include difficulties accounting for widely differing opinions, facilitator's view biasing the analysis, and the time needed that requires high participant motivation and active iterative participation. It is also important to acknowledge that consensus of opinion does not automatically mean that opinion is true. A limitation of the Delphi method is generating a group “compromise” due to anonymity of feedback, which may lead experts to compromise on important issues, particularly if the surveys are poorly designed and responses are restricted.^{24–28}



ACKNOWLEDGEMENTS AND DISCLOSURES

The authors declare no conflict of interest.

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How to cite this article: Hirzallah MI, Lochner P, Hafeez MU, Lee AG, Krogias C, Dongarwar D, et al. Quality assessment of optic nerve sheath diameter ultrasonography: Scoping literature review and Delphi protocol. *J Neuroimaging* 2022;32:808–824. <https://doi.org/10.1111/jon.13018>