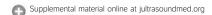
# Knowledge of Safety, Training, and Practice of Neonatal Cranial Ultrasound

# A Survey of Operators

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### Abbreviations

ALARA, as low as reasonably achievable; ODS, output display standard; TI, thermal index

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Objectives—Ultrasound can lead to thermal and mechanical effects in interrogated tissues. This possibility suggests a potential risk during neonatal cranial ultrasound examinations. The aim of this study was to explore safety knowledge and training of neonatal cranial ultrasound among Australian operators who routinely perform these scans.

Methods—An online survey was administered on biosafety and training in neonatal cranial ultrasound, targeting all relevant professionals who can perform neonatal cranial ultrasound examinations in Australia: namely, radiologists, neonatologists, sonographers, and pediatricians. The survey was conducted between November 2013 and May 2014.

Results—A total of 282 responses were received. Twenty of 208 (10%) answered all ultrasound biosafety questions correctly, and 49 of 169 (29%) correctly defined the thermal index. Two-thirds (134 of 214 [63%]) of respondents failed to recognize that reducing the overall scanning time is the most effective method of reducing the total power exposure. Only 13% (31 of 237) indicated that a predetermined fixed period of training or that a specified minimum number of supervised scans was used during training. The reported number of supervised scans during training was highly variable. Almost half of the participants (82 of 181 [45%]) stated that they had received supervision for 10 to 50 scans (median, 20 scans).

**Conclusions**—There is a need to educate operators on biosafety issues and approaches to minimize power outputs and reduce the overall duration of cranial ultrasound scans. Development of standardized training requirements may be warranted.

Key Words—bioeffects; cranial ultrasound; neonatal brain; neurosonology (pediatric); output display standards; thermal index; ultrasound safety

he developing brain of premature neonates is vulnerable to injury<sup>1–4</sup> because of the fragility of the germinal matrix. Thus, cranial ultrasound screening is used in neonatal intensive care units and special care units to enable early detection of perinatal brain injury. Sequential cranial ultrasound examinations are used routinely to assess the evolution and complications of hemorrhagic and ischemic brain injury in preterm neonates, as well as in term neonates born after antenatal or perinatal stress such as traumatic delivery or episodes of hypoxia. With its real-time nature, portability, cost-effectiveness, and lack of ionizing radiation, cranial ultrasound has become the primary imaging modality worldwide for visualization of the preterm brain and is generally understood to be safe.

Ultrasound can lead to thermal and mechanical effects in interrogated tissues. We have recently reviewed the literature in this field, and the results of animal studies have suggested that ultrasound exposure of the fetal or neonatal brain may lead to a substantial temperature elevation at the bone-brain interface. Mean temperature increases between 4.3 °C and 5.6 °C have been observed in utero with guinea pigs and mature mice as animal models.<sup>6–8</sup> This temperature change presents a potential, hitherto undetermined, risk during neonatal ultrasound imaging. The interface between the neonatal brain and the transducer has thin overlying tissues that attenuate the sound energy. The interfaces within the brain tissue may be analogous to a fat-muscle or soft tissue-water interface, whereby only about 1% of the transmitted sound is reflected back to the transducer as echoes. The remaining 99% of the sound energy is attenuated through scattering and absorption. Scattering is thought to contribute a negligible amount of attenuation. Therefore, neural tissues lying immediately adjacent to the sound beam will be exposed to potentially high temperatures as a result of absorption and conversion of the energy to heat. Animal studies suggest that brain tissue exposed to ultrasound may increase in temperature by as much as 5.6 °C when measured immediately adjacent to the transducer.<sup>6-8</sup> Such temperature rises could potentially damage neonatal neural tissue. 10

Output display standards (ODSs) were introduced in 1992 as recognition of the need to inform operators on the potential for bioeffects of ultrasound. 11 The ODSs consists of 2 biophysical indices: the thermal index (TI) and the mechanical index. The TI provides an indication of the likely tissue temperature rise under "reasonable worst-case conditions," and the mechanical index indicates the probability of nonthermal effects occurring within the tissue.<sup>11,12</sup> These bioeffect indices do not include any factors associated with the time taken to perform the scan. Efficient scanning with minimal time exposure to ultrasound remains an important component in limiting potential bioeffects, especially in this era of technological revolution and the associated increasing acoustic output levels. 11,13-15 Average intensities for B-mode imaging increased almost 7-fold from 1991 to 1995. This value almost tripled from 1995 to 2010, which represented a 20-fold increase from the originally published measurements in 1991.<sup>16</sup> It is well established that the highest exposure intensities during a scan are associated with the pulsed Doppler mode.

Therefore, safety guidelines have placed a greater emphasis on limiting pulsed Doppler use for neonatal cranial scans, with minimal consideration of B-mode imaging. 10,15 Most often, regulatory bodies recommend to scan with as low as reasonably achievable (ALARA) acoustic outputs to attain a diagnostic study. 15,17 However, ultrasound intensity levels (spatial-peak temporalaverage intensity) for B-mode ultrasound have increased at a substantially greater rate relative to those of the Doppler mode. In 2010, the mean ultrasound intensity value (spatial-peak temporal-average intensity) during pulsed Doppler imaging was approximately 2.5 times higher than the B-mode value, whereas between 1991 and 1998, this ratio varied between 9.2 and 81.11,16 In practice, this change means that with modern clinical equipment, B-mode ultrasound alone could potentially be capable of producing high intensities. 11,13,16 The safety aspects of neonatal cranial ultrasound have recently been reviewed by our group.<sup>5</sup>

Given that neonatal cranial ultrasound involves interrogating neural tissue with a relatively stationary transducer in direct contact with the dura mater, it is imperative that operators who perform these scans are well informed of ultrasound safety aspects during the course of their training. There is evidence to show that at some hospitals, neonatal cranial scans are performed by junior staff with no or minimal supervision and with varied levels of training. 18,19 Where formal training is stipulated, safety issues appear to be largely overlooked.<sup>20</sup> Previous studies have demonstrated that operators in Europe and the United States had poor knowledge of ultrasound safety aspects. 12,21,22 These studies, however, only referred to safety aspects during obstetric and general ultrasound use. We speculate that similar findings will be shown among Australian ultrasound operators, but this idea has not been explored to date. In particular, there are no studies to date exploring the safety knowledge of operators performing neonatal cranial scans.

The objectives of this study were to explore knowledge and practice of biosafety among ultrasound operators who routinely perform neonatal cranial scans and identify training protocols in neonatal cranial ultrasound among Australian end users. We hypothesized that (1) most operators do not know how to interpret information on the biosafety indices; (2) a greater fraction of operators are unaware of the appropriate measures to control the energy output during a neonatal cranial scan;

(3) the initiatives of professional bodies to provide the ODS and their commitment to the ALARA principle for the use of diagnostic ultrasound in neonatal cranial applications remain without practical impact; and (4) current training in neonatal cranial ultrasound is highly variable and inconsistent.

# Materials and Methods

# Survey Tool

This study was approved by the Monash University Human Research Ethics Committee, and completion of the survey implied consent. Respondents retained complete anonymity. A structured anonymous survey was developed to explore operator knowledge of ultrasound safety concepts as well as training and current practice in neonatal cranial ultrasound (online supplemental Appendix). The survey was developed with the input of academic and clinical staff, including a neonatologist, a pediatric radiologist, and a senior sonographer who is involved in training sonographers to perform neonatal cranial ultrasound examinations.

The survey comprised a total of 39 items, including multiple-choice and open-ended questions, and consisted of 3 sub-sections: Section 1 explored general demographic characteristics of the participants such as sex, age, educational and employer profiles, as well as clinical experience in neonatal cranial ultrasound. Section 2 investigated participant training and current practice in neonatal cranial ultrasound. Section 3 examined participants' knowledge of ultrasound equipment, aspects of ultrasound biosafety, and basic principles of ultrasound physics, specifically assessing the clinical application of the TI, acoustic power adjustments, and scan durations. Participants were given the opportunity to define the TI in open-ended questions and describe whether this information is actively considered during a neonatal cranial ultrasound examination. Participants were also asked to identify protocols of the neonatal cranial ultrasound examination, including imaging windows and indications for the use of the spectral Doppler mode. In the closing items, participants were asked about their awareness of the general safety of neonatal cranial ultrasound and their need for more information on the potential bioeffects on developing neural tissue. Participants who did not perform neonatal cranial scans as a routine part of their current employment or who were currently undergoing ultrasound training were

excluded from the study. The survey was pilot tested among 10 academic and clinical staff at the Department of Medical Imaging and Radiation Sciences of Monash University to assess the relevance and clarity of the survey questions before it was made available online.

Surveys were delivered online by Qualtrics (Provo, UT) software, targeting all relevant professionals who may be performing neonatal cranial ultrasound examinations in Australia: namely, radiologists, neonatologists, sonographers, and pediatricians. The survey was active online for a total of 7 months between November 2013 and May 2014. To promote the study and enhance participation, flyers were distributed to all hospitals with a neonatal intensive care unit or a special care unit within Australia. Advertising of the survey was also conducted via social media, including announcements and discussions on online educational forums and notices on professional organizational websites, including Australian Sonographer Accreditation Registry, Australasian Society of Ultrasound in Medicine, Australian Sonography Association, and Royal Australian and New Zealand College of Radiologists.

# Statistical Analyses

A frequency analysis was performed with SPSS version 22.0 software (IBM Corporation, Armonk, NY).

# Results

In total, 306 recorded responses were received. Of those, 24 respondents were trainees or did not perform cranial ultrasound examinations routinely as a standard part of their current jobs and were therefore excluded from the study, forming a final cohort of 282 participants.

# Demographic Characteristics

Table 1 presents the demographic characteristics of the study participants. Of the 282 respondents, 250 were sonographers. The remainder of the respondents (32 of 282 [11%]) were pediatric radiologists, neonatologists, general radiologists, as well as neonatology and radiology fellows.

# Knowledge of Ultrasound Safety

The operators' knowledge of safety issues is presented in Table 2. Almost all participants stated that they understand the ALARA acronym. One third of the respondents consider the TI during a routine cranial scan, whereas even fewer provided the correct definition of

this parameter. Only 20% of the respondents manually adjust the acoustic power settings during a cranial scan. Only 10% of respondents answered all 4 questions on ultrasound safety and power correctly. More than half of the respondents were not able to identify the best approach to reduce power exposure during a cranial scan. These respondents incorrectly believe that avoiding spectral Doppler imaging altogether is the most effective method of reducing overall power exposure to the patient. A total of 67% of respondents correctly identified "gain" as the parameter that does not affect power output during a scan, whereas 45 of 213 (21%) erroneously identified transducer frequency, acoustic power, and beam focus as parameters irrelevant to the total

**Table 1.** Demographic Characteristics of Survey Participants (N = 282)

Characteristic	n (%)
Sex	
Male	88 (31)
Female	194 (69)
Age, y	
≤29	24 (9)
30–50	181 (64)
≥50	77 (27)
Occupation	
Sonographer	250 (89)
Pediatric radiologist	10 (4)
Neonatologist	9 (3)
General radiologist	9 (3)
Fellow (radiology/neonatology)	4 (1)
Qualification	242 (76)
Graduate diploma	213 (76)
Bachelor's/master's degree	48 (17)
Doctoral degree	13 (5)
No response	8 (3)
Years qualified in ultrasound <5	61 (22)
≥5 6–15	100 (35)
>15	120 (43)
No response	1 (0.4)
Years performing cranial ultrasound	1 (0.4)
<5	98 (35)
6–15	101 (36)
>15	81 (29)
No response	2 (0.7)
Organization	(,
Public (tertiary)	187 (66)
Private (nontertiary)	90 (32)
No response	5 (2)
Site of work	
Regional	104 (37)
Metropolitan	177 (63)
No response	1 (0.4)

acoustic power exposure. Only half of the respondents recognize the high acoustic energy absorption properties of bone, correctly identifying bone-soft tissue as the interface where sound absorption is at its maximum. Nearly the entire survey population (205 of 214 [96%]) recognizes the impact of Doppler ultrasound on temperature increase, whereas B-mode imaging is given no consideration in this context. More than two-thirds (142 of 210 [68%]) of operators are "unsure" of the recommended TI during a cranial scan, whereas 66 of 210 (31%) believe this value to be less than or equal to 1.

# Training and Practice

Table 3 summarizes the answers to the key questions regarding training and practice of the participants in neonatal cranial ultrasound. When asked how training for cranial ultrasound was conducted, supervised scanning by a "qualified sonographer" was the most common form of training. Most participants stated that supervision was given "until competency was reached" without defining the minimum number of scans required or any competency standards. Only 13% indicated that a predetermined fixed period of training or specified minimum number of supervised scans was used during training. The reported number of supervised scans during training was highly variable. Almost half of the participants stated that they had received supervision for 10 to 50 scans (median, 20 scans). Most were satisfied with their training. As with most other ultrasound training regimens, training in neonatal cranial ultrasound was reported to be based on a multisource structure with the

**Table 2.** Knowledge of Ultrasound Safety Issues During Neonatal Cranial Ultrasound Scans

Characteristic	n/N (%)
Can correctly define the TI	49/169 (29)
Is familiar with the term TI	91/169 (54)
Considers the TI	65/213 (31)
Always manually adjusts the acoustic power	43/217 (20)
Correct response to all 4 items	20/208 (10)
on power and safety	
Effective method of reducing acoustic exposure	
Efficient scan time	80/214 (37)
Avoid spectral Doppler	119/214 (56)
Identifies parameters that affect acoustic power	143/213 (67)
Identifies interfaces with highest power absorption	109/209 (52)
Identifies modes that produce	121/214 (57)
highest temperature rise	
Identifies cranial ultrasound as be safe	188/213 (88)
Identifies ALARA acronym	204/214 (95)

combination of "self-education/online" and "seminar" attendance as the most popular arrangement for initial and ongoing education (95 of 259 [37%]). Regarding individual preferences in further training in neonatal cranial ultrasound, common cited methods included a "structured online" program (33 of 102) and "practical/workshop" training (46 of 102). Recurring items requested to be addressed within new training regimes included "pathology recognition" (20 of 102), "scanning planes" (8 of 102), and "current tertiary protocols" (6 of 102).

Table 3. Training and Practice in Neonatal Cranial Ultrasound

Characteristic	n (%)
No. of supervised scans during training $(N = 181)$	
<10	29 (16)
10–50	82 (45)
>50	37 (20)
Undefined	33 (18)
Who supervised the practical training	, ,
(N = 258; multiple responses)	
Qualified sonographers	189 (73)
Consultants (neonatologists, pediatric	139 (54)
radiologists, general radiologists)	
Qualified sonographers and consultants	83 (32)
Other trainees (registrars, sonographers)	35 (14)
Quality of training according to the trainee ( $N = 258$ )	33 (±4)
Adequate or better	46 (18)
Inadequate	46 (18)
Training requirements for new staff ( $N = 237$ )	40 (10)
Supervised scans (no fixed period/no	142 (60)
	142 (00)
specified No. of scans)	21 (12)
Supervised scans (fixed period/specified No. of scans)	
Undefined	64 (27)
Further training requested ( $N = 259$ )	100 (44)
Yes	108 (44)
No	109 (39)
Not sure	42 (17)
Further education requested on bioeffects	
between ultrasound and brain tissue (N = 211)	470 (04)
Yes	170 (81)
No	15 (7)
Not sure	26 (12)
Color/spectral Doppler used routinely $(N = 216)$	
Yes	103 (48)
No	59 (27)
Occasionally	54 (25)
Ultrasound windows used $(N = 216)$	
Single fontanel only	90 (42)
>2 fontanels	121 (56)
Anterior and mastoid	36 (30)
Undefined	5 (2)
Average estimated scan duration, min $(N = 213)$	
5–10	192 (90)
>10	21 (10)

Regarding the clinical practice of performing neonatal cranial ultrasound examinations, nearly half of the participants stated that color/pulsed Doppler imaging is used "routinely" during a cranial scan. Most (123 of 156 [79%]) of those who used color/spectral Doppler imaging at any time during a scan reported an average scan duration using this mode of 15 seconds. Nearly half of the operators use only a single fontanel to survey the neonatal brain, whereas the rest of the participants use at least 2 fontanels, with the "anterior and mastoid" fontanels being the most common combination. The total duration of an average neonatal scan was most often reported to be 5 to 8 minutes (123 of 213 [58%]).

# Discussion

To our knowledge, this study has for the first time explored the training and knowledge of safety associated with neonatal cranial ultrasound examinations among Australian operators. It is pleasing to find that 95% of survey participants understand the ALARA principle. This finding demonstrates that operators are in general aware of the underlying potential risks and the need to minimize risk factors during such scans. However, paradoxically, the survey showed a general perception among Australian operators that neonatal cranial ultrasound is "safe" (Table 2). A greater fraction of respondents believe that the most effective method of minimizing power outputs and therefore maintaining this acoustic safety is to avoid the use of spectral Doppler imaging (Table 2). These results concur with previous studies among European and American operators. 12,21,22

The survey highlights 4 key issues: (1) Almost all operators understand the importance of the ALARA principle for neonatal cranial scans; (2) operators have suboptimal knowledge of the safety issues of diagnostic ultrasound and the implications of extended scan durations; (3) opinions on optimal practice are divided, especially with regard to the routine use of the Doppler mode and the use of supplemental scanning windows; and (4) there is a lack of standardization in the training of operators who routinely perform neonatal cranial scans and no assessment of the competency of those who have completed their training.

# Knowledge of Ultrasound Safety

Operators performing neonatal cranial scans routinely in Australia appear to be aware of the safety implications of

the scans. However, many stated that the scan was safe and yet lack the knowledge of how to best apply power minimization strategies. Similar to other reports, our study has confirmed poor use of the ODS by ultrasound operators. 12,21,22 This factor may be partially due to the lack of knowledge and standardization in training, especially with regard to the biosafety aspects of these scans. There is little consensus on optimal ODS thresholds which help operators reduce potential risks. Only the British Medical Ultrasound Society provides concrete advice and recommendations regarding ultrasound scans of the neonatal brain.<sup>23</sup> For neonatal cranial ultrasound, the British Medical Ultrasound Society safety guidelines recommend that the scanning time be restricted for any TI value of greater than 0.7. For a TI between 1.5 and 2.0, it is recommended that the duration of such scans be restricted to 15 minutes; for a TI between 2.0 and 2.5, the duration is restricted to 4 minutes; and for a TI of greater than 3.0, scanning of the neonatal brain is not recommended.<sup>23</sup> There are no publications reporting on actual TIs observed during neonatal scans, which warrants investigation given the poor knowledge of the TI and safety guidelines in general by operators in Australia and other countries. The World Federation for Ultrasound in Medicine and Biology has issued updated recommendations. <sup>10,17,24</sup> In response to the poor uptake of the ODS, the World Federation for Ultrasound in Medicine and Biology has recommended that "safety guidelines should include an appropriate duration factor," acknowledging that the overall duration of exposure remains an important consideration for thermal effects. However, this recommendation has not yet been adopted by 5 of the 6 major bodies that govern the safe practice of diagnostic ultrasound imaging. The recommendations also revert to the use of the ALARA principle, which depends heavily on the knowledge and

clinical application of the ODS by each individual operator. The survey results indicate that although almost every sonographer could correctly define the ALARA acronym, very few demonstrated sound knowledge of ultrasound power and safety aspects, which are the key fundamentals in applying the ALARA principle in clinical practice. Only 10% of respondents answered all 4 questions on ultrasound safety and power correctly. Our findings question the uptake and usefulness of the ODS and the ALARA principle. Efforts to incorporate a scan duration factor into these recommendations should be supported.

Three other studies evaluated ultrasound operators' knowledge of safety issues, although none focused specifically on neonatal cranial scans (outlined in Table 4). Marsal<sup>12</sup> distributed a questionnaire to ultrasound operators who undertake obstetric ultrasound examinations in Europe. In another study, Sheiner et al<sup>21</sup> conducted a similar survey among ultrasound operators performing obstetric scans in America. In the third study, Houston et al<sup>22</sup> assessed the knowledge of ultrasound operators in the United States regarding ultrasound safety and the use of ODSs. There are several differences between these 3 studies and our study, particularly with regard to the study population. In the European study, physicians and midwives formed the primary cohort of participants, with sonographers only accounting for a minority group. In the study by Sheiner et al,<sup>21</sup> 63% of the study participants were physicians, most of them obstetric and gynecologic specialists, and only 31% were sonographers. The study by Houston et al<sup>22</sup> was aimed at postgraduate (year 4) obstetric and gynecologic residents and maternal-fetal medicine fellows, with no sonographers in the cohort. Training in ultrasound, especially with regard to the theoretical components, may vary substantially between these professions, subject to the type and

Table 4. Clinical Application of the TI: Comparison With European and American Operators

Item	European, Marsal (2005) (N = 199) <sup>a</sup>	American, Sheiner et al (2007) (N = 130) <sup>b</sup>	American, Houston et al (2011) (N = 165) <sup>c</sup>	Australian (N = 282) <sup>d</sup>
Correctly defined TI, n (%)	43 (22)	23 (18)	Not reported	49/169 (29)
Familiar with term TI, n (%)	64 (32)	42 (32)	121 (73)	91/169 (54)
Considered TI/knew where to find TI, n (%)	56 (28)	27 (21)	33 (20)	65/213 (31)

<sup>&</sup>lt;sup>a</sup>Physicians (n = 145), midwives (n = 32), and sonographers (n = 22).

<sup>&</sup>lt;sup>b</sup>Physicians (obstetric and gynecologic specialists; n = 82), sonographers (n = 41), and nurse/nurse practitioner (n = 6).

<sup>&</sup>lt;sup>c</sup>Obstetric and gynecologic residents (n = 67), maternal-fetal medicine fellows (n = 92), and not reported (n = 6).

 $<sup>^{</sup>d}$ Sonographers (n = 250), pediatric radiologists (n = 10), neonatologists (n = 9), general radiologists (n = 9), and neonatology and radiology fellows (n = 4).

duration of the academic curriculum. This factor may reflect the observed differences in the level of knowledge displayed in the survey responses concerning ultrasound biosafety issues and account for differences between the 3 studies and our study. Several questions on safety concerns were similar between the European and American studies and our survey. These questions included openended responses to the definition of the TI, familiarity with the term TI, and consideration of the TI during a scan. Operators in all 3 studies were poorly informed regarding the TI. Although Australian operators appear to be more familiar with the TI compared to American and European operators, knowledge of its clinical application remains unsatisfactory across all 3 study populations. 12,21,22 In all studies to date, little consideration has been given to the overall scan duration. This finding raises concern, given that minimizing the exposure time is the single most important factor for ensuring patient safety from thermal effects<sup>25</sup> and can be easily adopted with appropriate training and mentorship. It is more difficult to interpret and monitor the TI during a scan, given the lack of consensus on appropriate threshold levels to use.

It is important to recognize that the TI is dimensionless, and its goal is to provide an indication of the relative potential for increasing the tissue temperature, but it is not synonymous with the actual temperature rise. In our study, of the 120 of 169 (71%) incorrect responses with regard to the definition of the TI, nearly half (56 of 120 [47%]) associate the TI with actual "heat rise in tissue as a result of insonation." Furthermore, two-thirds of operators do not even consider this parameter during a neonatal cranial scan. Although the concept of using an index value appears simple, in practice it is often not or incorrectly used by operators. Operators probably do not refer to the TI during a cranial scan because they do not fully understand the parameter and its clinical implications for developing neural tissue. This custom is in keeping with the general consensus within the scientific ultrasound community that the current TI formulations do not provide enough information to determine the real-time risk to the patient.<sup>26</sup> To practice ALARA, the operator must be informed of any changes in the risk to the patient as the operating conditions of the ultrasound transducer are varied. In a modern ultrasound machine, these changes include both increases in output power and changes in source focusing. However, when the transmit aperture size and focusing locations

are varied, the TI does not always correlate with the temperature rise values predicted by the TI formulation. 27,28 Therefore, there may be instances in which a decrease in the TI due to changes in focusing could correspond to an increased risk to the patient. The duration of exposure is known to be a critical factor in determining the likelihood of inducing a thermal effect. 29,30 Although the risk of thermal effects increases with the exposure time, the current TI formulations do not include any dependence on exposure durations. As a result, a longer exposure at a lower TI value might be more of a risk to the patient than a shorter exposure at a higher TI value. The net effect of the ODS is self-regulation, placing the responsibility on the operator to maximize the benefits of ultrasound examinations while minimizing the potential risks.<sup>17</sup> Since the current TI formulations do not inform the operator of the dependence of risk with regard to the exposure duration, the TI is not providing a valid assessment of risk.

One hundred seventy of 211 respondents highlighted the need for more information on the interaction and possible bioeffects between ultrasound and neural tissue. Although this aspect of practice can be immediately addressed by improving continued education and increasing the awareness of this issue during conferences and workshops, future consideration should be given to incorporating a time-dependence factor to the ODS. Such an indicator is one proposed by Lubbers et al.<sup>31</sup> The time-to-threshold indicator would model the timetemperature curve for a given exposure condition and then calculate the exposure time required to exceed some predefined temperature threshold. Large time-tothreshold values would correspond to longer heating times and safer exposures, whereas smaller time-tothreshold values would represent a greater risk to the patient. Such modifications to the ODS are especially imperative with the use of modern ultrasound equipment, which have technical innovations that require the implementation of new scanning techniques that fall outside the assumptions inherent in the current ODS.<sup>26</sup>

Although it is well established that the highest exposure intensities during a scan are associated with the pulsed Doppler mode, Doppler imaging plays an important role in diagnosis and follow-up of brain damage secondary to ischemia, hemorrhage, infection, developmental disorders, and tumors.<sup>26</sup> Color and spectral Doppler imaging of cranial blood flow is valuable for evaluation of cystic lesions, including vascular lesions and extra-axial collections, and

for diagnosis of venous thrombosis and, as such, has an important role to play in the treatment of neonates. Current safety guidelines recommend limiting pulsed Doppler use in neonatal cranial applications, with minimal consideration for B-mode imaging, which is used exclusively or during most of the scan. It is encouraging that 90% (192 of 213) of survey participants reported overall scan durations of less than 10 minutes. This duration would be considered safe according to British Medical Ultrasound Society guidelines, as long as the TI is maintained at less than 2. Nevertheless, nearly two-thirds (134 of 214 [63%]) of respondents failed to recognize that reducing the overall scanning time is the most effective method of reducing total power exposure to the patient as opposed to completely avoiding spectral Doppler imaging. 11,16,32 It is not well known among ultrasound operators that B-mode imaging alone can also cause heating of neural tissue.

A recent study on ex vivo lamb brains<sup>25,26</sup> demonstrated that B-mode ultrasound can contribute to significant brain surface heating  $(3.82 \,^{\circ}\text{C} \pm 0.43 \,^{\circ}\text{C})$  after just 5 minutes of scanning in the B-mode when the transducer is held in a stationary position. The heating during B-mode imaging was significantly higher than during a 15-second exposure to the Doppler mode (2.13  $^{\circ}$ C  $\pm$ 0.44 °C; P < .001). These outcomes may be higher than those observed during clinical scans because of the lack of vascularization in this model. Although there are no studies that have compares these findings to clinical applications, operators should nevertheless be aware that B-mode imaging alone could potentially be capable of producing high intensities, especially given the stationary position of the transducer over the fontanel, intensifying heat absorption in a small area of the interrogated brain.<sup>33</sup> More consideration needs to be given to the overall scan duration, including the use of B-mode imaging. Furthermore, different settings need to be considered for extremely preterm neonates (<28 weeks' gestation) compared to term neonates. Term neonates have an increased skull thickness, which may further contribute to the resultant temperature deposition in brain tissue immediately adjacent to the skull. 11,13,16 Extremely preterm neonates have wider fontanels, potentially resulting in temperature increases deeper into the more sensitive brain tissues. Although the literature in this field is limited, operators should be aware of the implications of scan parameters on the level of prematurity of the neonate. There is no information on scan parameters according to the degree of prematurity.

More research is needed to evaluate the effects of clinically relevant ultrasound-induced heating on brain tissue according to gestational age, or more specifically, skull thickness and fontanel size.

# Training and Practice

As with many other modules of ultrasound training, supervised scanning is the common approach to training in neonatal cranial ultrasound. However, assessment of the level of competency in our cohort was highly variable and appears to be at the discretion of the trainee or supervisor. There is no standardized training regimen to ensure consistency in the number and "quality" of supervised scans and no assessment of competency. Although some trainees underwent more than 100 supervised scans, others reported only 4 to 5 supervised scans or "however many was needed." However, training is never based on one single scheme. As the survey findings indicate, supervised scanning is often supported by external sources such as workshop and educational seminar attendance as well as self-education and online reading. However, with regard to external sources, it is interesting to note that between 2004 and 2014, there have not been any documented workshops, webinars, or online refresher sessions specifically on neonatal cranial ultrasound for Australian operators. With regard to selfeducation on neonatal cranial ultrasound, only 1 accredited online program exists to guide Australian ultrasound operators. It is unclear whether participants sought out international education forums to source specific neonatal cranial ultrasound education. In an open-ended question regarding preferred methods of further training in neonatal cranial ultrasound, a structured online program and online refresher sessions highlighting "current trends" were most commonly mentioned, followed by practical/workshop training. Fundamental aspects such as subtle pathology recognition, current tertiary protocols, and supplemental scanning windows were emphasized as key areas of weakness in the current educational information available.

There are 2 programs for Australian operators that are formulated to specifically address education in neonatal cranial ultrasound. One is the Certificate of Clinician-Performed Ultrasound, which is the model for training and accreditation for neonatal cranial ultrasound in Australia and New Zealand. However, the curriculum for the Certificate of Clinician-Performed Ultrasound qualification covers all aspects of ultrasound, with

a major emphasis on functional echocardiography and assessment of line position. The training program is aimed at specialist registrars as well as neonatologists and radiologists. This emphasis is reflected in the survey responses, whereby 29% (7 of 24) of the specialists referred to the Certificate of Clinician-Performed Ultrasound as the training program for neonatal cranial scans compared to only 0.9% (2 of 235) of sonographers (P < .0001). Given that most neonatal cranial ultrasound scans in Australia are performed by sonographers, and training is also conducted by qualified sonographers, the curriculum for the Certificate of Clinician-Performed Ultrasound as a training module specifically for neonatal cranial ultrasound is not well suited to this profession. It is better adapted for ultrasound operators in countries such as those of the United Kingdom, where most neonatal cranial scans are performed and interpreted by general pediatricians, neonatologists, and specialist registrars.<sup>35</sup> The second program involves an online learning module provided by an American-based company, SIMTICS (Richmond, VA), which is a corporate member of the Australian Sonographers Association. 18 The neonatal cranial ultrasound module can be accessed online through a single payment. However, the module, which is not directly advocated by Australian Sonographers Association, does not include current Australian protocols, address ultrasound safety issues with respect to cranial ultrasound, or advise on current trends or supplemental windows.

It can be argued that the content required for training in neonatal cranial ultrasound is covered in the postgraduate diploma of medical ultrasound, which is a prerequisite for all accredited medical sonographers. This idea is reflected in the survey results, in which half (29 of 57 [46%]) of the written responses in the sonographer group regarding "theoretical training" specified the completion of the diploma of medical ultrasound as the source. However, the survey also indicated that operators generally train in performing neonatal cranial scans at least 5 years after the completion of the postgraduate qualification. Therefore, a "refresher session" specific to neonatal cranial ultrasound may be warranted in these cases, especially given that these training sessions are site specific and predominantly performed at tertiary hospitals. It is evident that any theoretical knowledge about cranial ultrasound obtained at one of these postgraduate courses will be of limited value in subsequent years of practice unless the operators are continually working in

this field and seek ongoing information on technological advances and associated biosafety risks.

The survey provides an impression of uncertainty among operators in the use of supplemental scanning windows and the routine use of color/pulsed Doppler imaging to survey the neonatal brain. This uncertainty is reflected in the divided response with regard to the routine use of color/pulsed Doppler imaging and the number of fontanels used in clinical practice to scan the neonatal brain. Supporting statements such as "we are supposed to take images from the mastoids but have had no training in this," "we routinely look through the mastoid fontanel but need to set a protocol for this view and how often it is used," and "we were using anterior only, but neonatal intensive care units now require mastoid fontanels" further add to the inconsistency in the routine surveillance of the neonatal brain. It is difficult to conclude from the survey findings whether the routine use of Doppler imaging in neonatal cranial scans is an individual operator practice or part of a department protocol. Such a conclusion would require an in-depth evaluation of each individual hospital's protocol. Nevertheless, it is clear that there is a lack of standardization in the practice of neonatal cranial ultrasound scans in Australia. Evidently, this deficiency is due to the lack of uniformity in training and the lack of competency standards.

# Limitations of This Study

There is no published information on the total number of sonographers and clinicians who routinely perform neonatal cranial ultrasound scans in Australia, and it is therefore not possible to provide an accurate response rate for the survey participants. In 2013, there were 124 hospitals with a neonatal intensive care unit or special care unit across Australia, including metropolitan and regional areas, and approximately 4500 registered sonographers working in Australia overall (Australian Sonographer Accreditation Registry, 2010). However, only a relatively small subgroup of these routinely perform neonatal cranial scans. Most neonatal intensive care units and special care units employ 2 to 10 such sonographers at any given time (Michal Schneider, PhD, written communication, 2014). It is therefore estimated that the total number of sonographers who routinely perform neonatal cranial scans ranges somewhere between 250 and 1250 sonographers. The response rate for this survey would therefore fall between 20% and 100%. Only relatively few clinicians participated in the survey, and it is difficult to calculate a response rate for these specialist clinicians. This factor limits the interpretation of the survey results for this group of operators, and further studies are required to validate the findings for these survey participants. However, given that sonographers constitute the main group of operators performing neonatal cranial scans in Australia, the findings capture an appropriate snapshot of operators.

## **Future Directions**

All safety statements for neonatal cranial ultrasound recommend the use of the ODS and the ALARA principle. To apply these principles in practice during a neonatal cranial scan, a certain level of knowledge on biosafety is necessary. Our findings indicate that this prerequisite requires further education, and we therefore question the uptake and usefulness of these recommendations for neonatal cranial scans. We believe that an alternative method of regulating the output levels during cranial scans should be sought to facilitate the safe use of ultrasound during neonatal cranial scans. As provided by the British Medical Ultrasound Society, an appropriate scan duration factor incorporated into the safety guidelines of Australian (and other) professional guidelines would enhance the awareness of the operators. In addition, training methods such as the proposed accredited online refresher courses specifically targeted to sonographers supplemented with standardized practical training regimens with assessment of competency would enhance training standards and improve the uniformity of knowledge and practice.

Finally, further research is needed to explore the potential of thermal bioeffects on neuronal tissue and the associated risks to the neonatal brain in the short and long terms. <sup>33,36–41</sup>

# Conclusions

Australian operators need to become aware of the biosafety of neonatal cranial ultrasound and implement appropriate practices to reduce the power output during each scan. Until more evidence comes to hand to provide more specific guidelines for the safety of neonatal cranial examinations, all operators must ensure that overall scan durations, including B-mode, are kept to a minimum and the Doppler mode be restricted as much as possible.

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