



International e-Delphi survey to define best practice in the reporting of intracranial pressure monitoring recording data

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ABSTRACT

Introduction: Intracranial pressure (ICP) monitoring is a very commonly performed neurosurgical procedure but there is a wide variation in how it is reported, hindering analysis of it. The current study sought to generate consensus on the reporting of ICP monitoring recording data.

Research question: “What should be included in an ICP monitoring report?”

Material and methods: The exercise was completed via a modified eDelphi survey. An expert panel discussion was held from which themes were identified and used to produce a code to annotate the transcript of the discussion. Statements were generated for a further two rounds of electronic questionnaires distributed via the REDcap platform. A Likert scale was used to grade agreement with each statement in the survey. A statement was accepted if more than 70% agreement was achieved between respondents. Data was collated using Microsoft Excel and analysed using R.

Results: 149 relevant statements were identified from the transcript and categorised into recording parameters, waveform characteristics or reporting. A total of 22 statements were generated for the first round of the survey which was answered by 39 respondents. Following the electronic round of surveys consensus was achieved for all but one statement regarding the acceptability of automating ICP reporting. This was put forward to a second round after which 79% agreement was reached.

Discussion and conclusion: The themes and statements from this eDelphi can be used as a framework to allow the standardisation of the reporting of intracranial pressure monitoring data.

1. Introduction

Intracranial pressure (ICP) monitoring has been used for several decades to aid clinicians in the management of patients with neurological disorders. Lundberg is credited with the initial classification of various waveforms found in neurosurgical patients (Lundberg, 1960). These descriptions, first made in the 1960s in the pre-CT era, were used to aid clinicians to identify patients at high risk of imminent poor

neurological outcome and those in need of a surgical procedure. Over the subsequent decades the process of monitoring has remained broadly similar; a pressure monitor is inserted into either the brain parenchyma, subdural space or ventricular system and the resulting ICP and waveform are then available for visual review at the bedside and recording in the medical record. The indications and interpretation have naturally broadened over this time period. The analysis of ICP waveforms has been a topic of great interest in neuroscience over the past few decades.

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In the field of neurocritical care, ICP monitoring and its various derived outputs have been linked to improvements in outcomes for patients with traumatic brain injury. ICP monitoring is included in best practice guidelines from the Brain Trauma Foundation (BTF) and the Seattle International Brain Injury Consensus Conference (SIBICC) (Chesnut et al., 2015; Carney et al., 2017). ICP monitoring is also commonly used in the management of hydrocephalus and associated disorders and other neurological conditions such as subarachnoid haemorrhage and stroke.

ICP monitoring is used extremely widely and there is a wealth of research into the interpretation and management of variations in ICP to improve outcomes in neurological disease. However, despite the frequent use of the procedure, variability exists in how the episodes of monitoring are interpreted and reported; as yet no consensus exists. There has been an exponential rise in the power of computing in recent years and the volume of data collected in medical practice is ever increasing. Therefore, the best ways to archive and report this data is an important area of interest. In addition, the increasing use of artificial intelligence in healthcare mandates a discussion about what should and should not be automated.

Despite the widespread use of ICP monitoring there exists significant heterogeneity in the reporting and interpretation of the data obtained. As yet there is no standardised method across centres for how an ICP tracing should be interpreted or what a report should contain. Therefore, the main aim of the current Delphi study was to generate consensus as to how the data collected during ICP monitoring is best reported. The goal is not to provide a complete checklist that must be adhered to for every case of ICP monitoring as there will be significant heterogeneity depending on the indication. The purpose, rather, was to provide a tool to aid clinicians and researchers as to what might be important to report in the data they collect.

2. Material and methods

Ethical approval was obtained for the study via the local ethics committee. The Delphi method is used to generate consensus amongst experts through the generation of statements that are subjected to rounds of surveys to reach agreement (Keeney et al., 2011). The process for this eDelphi process is illustrated in Fig. 1. The first round of the process was a panel discussion with audience participation held at a session at the ICP 2019 conference between five invited experts in the field of ICP monitoring with more than 20 years experience in their field and who have published widely in the field of ICP monitoring. This consisted of one senior neurosurgeon (author 7), one senior neuro-intensivist (author 8), two senior scientists (authors 4 and 6) and one engineer (author 9). The panel were selected to be sufficiently broad to capture all relevant opinions of those involved in the reporting and interpretation of ICP recording data for clinical, research and industry development. There were a series of planned open-ended prompts from the compere as well as additional comments and questions from the audience. There were two broad topics for the panel discussion as per the study protocol; the generation of clinical reports from ICP readings and the human vs. automated approach to ICP reading interpretation. For each topic the compere gave a brief introduction and the panel were then allowed to discuss the topic. The opening question to discussion of the first topic was “What should an ICP report contain?”. The expert panel then freely discussed what was done at their institution and what they felt was relevant to the question posed. For the second topic the panel were asked how feasible automation of reporting is from a technical point of view and from the clinicians point of view how comfortable they would be receiving an automatic report. Following these two broad areas of discussion the panel and audience were asked to raise other issues they felt were relevant to the reporting of intracranial pressure recording data. The audio recording of the discussion was transcribed by a team of four researchers and analysed using the

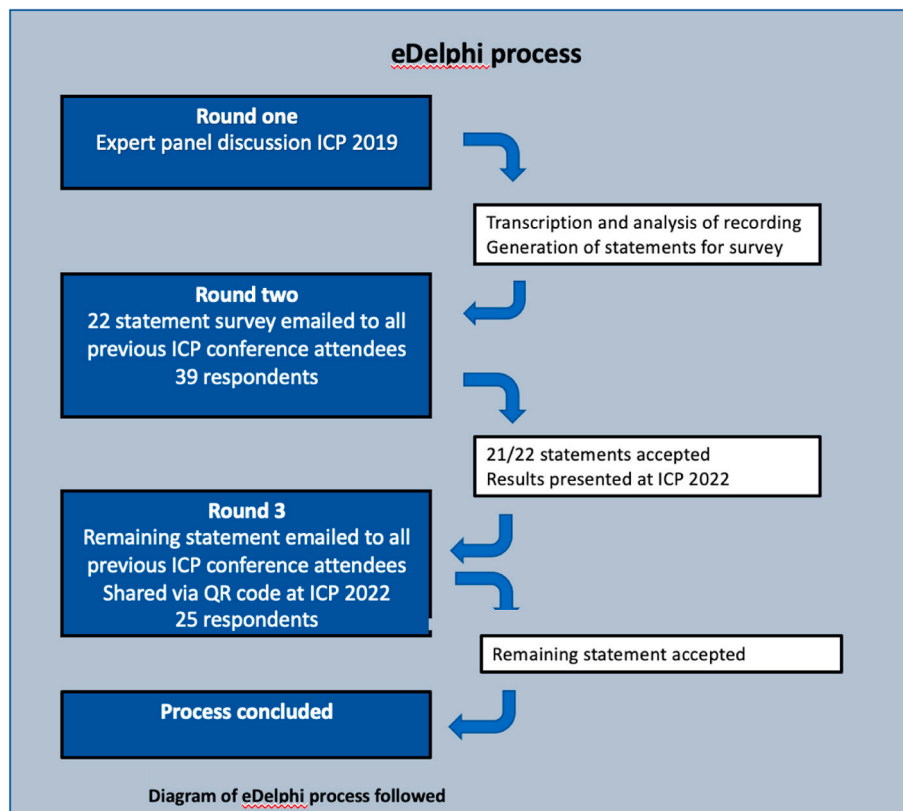


Fig. 1. Diagram of eDelphi process followed.

framework methodology for qualitative research by two researchers (Gale et al., 2013). Relevant comments in the transcript were annotated by two researchers independently and a code developed. Each statement from the transcript was then placed into a common theme with sub-headings. From the coded transcript a number of statements were generated for the subsequent rounds of the eDelphi process. Study data were collected and managed using REDCap electronic data capture tools hosted at the local institution. Respondents consented to the questionnaire and responded to each of the statements using a five point Likert scale as to how much they agreed with the statement. Links to questionnaires were directly emailed to stakeholders in the field of ICP that were identified by previous attendance at an ICP conference. The survey was approved by the European Association of Neurological Surgeons research committee and a link to the survey was published on the societies' website. Respondents to the survey were encouraged to share a link to other interested parties via email and social media.

The questionnaire was organised into 3 sections: recording parameters, waveform characteristics and reporting and analysis. In addition to this, demographic data was recorded and there was space for free text responses.

In line with the accepted standard for Delphi processes a threshold for accepting the statement was set in advance (Diamond et al., 2014; Trevelyan and Robinson, 2015). There is no universally agreed definition of consensus in Delphi processes as this will vary depending on the topic and number of respondents. We chose a threshold of 70% for this survey in line with other published healthcare Delphi processes (Campbell et al., 2018; Creamer et al., 2012). For a statement to be accepted agreement (aggregate of agree and strongly agree) of 70% had to be reached. If 70% consensus was not reached the statement was put to a further round. After the first round of the electronic survey the results were presented orally at the ICP 2022 conference and a further round of the survey was distributed to the same email list of potential respondents as the first electronic round and also via QR code with a link to the survey during the meeting. Data was collected using Microsoft® Excel and analysed using R (Team, 2013).

3. Results

The total length of the panel discussion was 01h31 min. Following transcription and annotation 37 relevant themes were identified and divided into the categories of recording parameters, waveform characteristics and reporting and analysis. From this the transcript was recoded and 22 statements were generated for the second round of the survey; these are shown in Table 1.

The second round of the survey was answered by 39 respondents of whom 79% were clinicians. 54% defined their specialty as neurosurgery, 31% anaesthesia and neurocritical care and 15% in field of basic science. The median length of time in specialty was 10 years (IQR 8–23 years). 28/39 respondents came from Europe and 11/39 from the USA; there were no respondents from lower or middle income countries. All statements except for one reached the a priori agreement threshold of 70%. This statement was “It is appropriate to automate the analysis of ICP recordings”. 59% agreed with the statement, 32% neither agreed nor disagreed and 8.8% disagreed with statement, 5 respondents chose not to answer the question.

The third round of the survey was answered by 25 respondents of whom 85% were clinicians. 65% defined their specialty as neurosurgery, 25% anaesthesia and neurocritical care and 10% were in field of basic science. The median length of time in specialty was 10 years (IQR 6–21 years). 14/25 respondents came from higher income countries, 6/25 from lower or middle income countries, country of origin was not stated for 5 respondents. The remaining statement for consideration was “Is it appropriate to automate the reporting of ICP recordings?”. 79% agreed with the statement, 16% neither agreed nor disagreed, 5.3% disagreed with the statement, 6 respondents chose not to answer the question.

Table 1

This table shows each statement put forward for consideration in the electronic surveys following expert panel discussion.

| Statements for consideration | Agreement Score Round 2 N = 39 % |
|---|---|
| Recording parameters | |
| 1 Two distinct patient populations exist in whom ICP monitoring is undertaken; Neurointensive care patients and patients with CSF hydrodynamic problems | 89 |
| 2 The patients position and state of wakefulness is important and should be recorded | 95 |
| 3 Physiological data such as heart rate, blood pressure and respiratory rate should be recorded along with intracranial pressure | 89 |
| 4 The total length of time of the recording should be monitored | 89 |
| 5 It is important for the sampling to be high frequency and high resolution | 95 |
| Waveform characteristics | |
| 6 The morphological characteristics of the waveform should be described | 97 |
| 7 The presence and frequency of B wave events should be reported | 86 |
| 8 Events should be annotated on the recording | 100 |
| Reporting and analysis | |
| 9 ICP reports should be interpretable by all members of the multidisciplinary team | 85 |
| 10 Two types of report exist; real time visualisation and post hoc static reports | 91 |
| 11 Both types of report should be available for all patients undergoing ICP monitoring | 76 |
| 12 The report should include definition of events and methods used | 85 |
| 13 The date, time, software and person producing the report should be included | 91 |
| 14 The report should have a standardised time and amplitude scale | 91 |
| 15 The report should include summary statistics such as mean, median, max and minimum ICP | 91 |
| 16 The methodology for artefact removal should be included in the report | 82 |
| 17 It is helpful to visualise the data on graphs or charts | 100 |
| 18 It is useful to be able to scroll back through the ICP recording | 100 |
| 19 The report should include derived data such as cerebral perfusion pressure, PRx and ICP burden | 76 |
| 20 It is appropriate to automate the analysis of ICP recordings | 59 |
| 21 It is necessary to have human supervision of automated analysis | 88 |
| 22 I would use ICP reports to aid my clinical decision making | 91 |

4. Discussion

4.1. Recording parameters

There is a wide variety of conditions in which ICP monitoring is undertaken and the nature of a dichotomy between those patients in neurocritical care versus those who are presenting with more chronic conditions such a hydrocephalus was confirmed by the survey. Furthermore, a different approach may be necessary for the reporting of these two distinct populations. This was alluded to in the free text responses generated in round two. As such, the indication for ICP monitoring and underlying clinical diagnosis of the patient should be recorded to aid with interpretation and research.

Much research has been performed into the effect of body position and the state of wakefulness on ICP. In the context of critical care it is known that the degree of head up tilt of the bed affects the intracranial pressure and the most recent BTF guidelines recommend a 30–45° elevation of the head of the bed to assist in optimising cerebral perfusion (Carney et al., 2017). As part of patient position the height of levelling of

the ICP and arterial pressure transducers should also be included. In neurocritical care analgesia and sedation are used to control pain and agitation. These affect the degree of wakefulness of the patient and their use should be recorded. In addition, the use of sedative agents known to lower ICP such as propofol should also be recorded. Andresen et al. have shown that the mean ICP changes with body position in healthy individuals and those with CSF hydrodynamic problems, and that the way in which the ICP changes relates to the underlying disease process and whether the patient has been treated with CSF diversion (Andresen et al., 2015). This work has been further expanded by Mitchell et al. in their study of patients being investigated for idiopathic intracranial hypertension (IIH) (Mitchell et al., 2022). In this study they also found that mean ICP changed with alteration of body posture and in addition that some measures of the waveform such as amplitude also changed with body posture. This group also showed that there is a change in ICP that occurs throughout the night with ICP continuing to rise up until waking. These studies and the consensus statement clearly argue for the importance of noting the patients position and state of wakefulness on the ICP report.

There was consensus that physiological data for example heart rate, blood pressure and respiratory rate should be recorded along with intracranial pressure. Other physiological data that is captured in neurocritical care such as arterial blood gas information could also be included. This is performed as standard for patients in neurocritical care and allows the calculation of important parameters such as cerebral perfusion pressure as well as the response of intracranial pressure to variations in factors such as PaCO₂. This also allows clinicians to assess whether autoregulation is likely to be intact by observing the response of ICP to changes in arterial blood pressure. The recording of routine physiological data also aids interpretation of the ICP waveform by allowing the removal of superimposed waveform due to, for example, the respiratory pattern (Czosnyka and Pickard, 2004). Routine physiological data is less commonly recorded for patients undergoing elective ICP monitoring but it is likely the case that recording the ECG and performing basic pulse oximetry would aid the interpretation of the waveform and more accurately identify artefact in the tracing.

To aid with interpretation it is important to record total length of time of ICP monitoring; this allows an overview of the whole trace as well as the ability to match fluctuations or changes in morphology with clinical events. Respondents agreed that it was necessary for the data recorded to be high frequency and high resolution. The recording of high frequency data is necessary to allow the changing morphology second by second to be visible. An increase in the amplitude of the second peak in the ICP waveform relative to the first is indicative of a loss of intracranial compliance in head injured patients (Fan et al., 2008). High resolution data also allows the use of more complex computational techniques such as Morphological Cluster and Analysis of Intracranial Pressure (MOCAIP) to be used (Hu et al., 2009).

4.2. Waveform characteristics

Consensus was reached that the morphological characteristics of the waveform should be described. When considering the morphology of the ICP waveform both the shape of the individual pulses of the intracranial pressure as well as the characteristics of any periods of elevations should be considered. The shape of the pulse is usually described as having three component peaks; the percussion wave (P1), tidal wave (P2) and dicrotic wave (P3) (Carra et al., 2023). Debate remains as to the precise origin of each of the peaks but it is thought to represent the interplay between the arterial pulse and intracranial contents. It has been well described that increasing amplitude of the P2 wave relative to the P1 wave reflects reduction in intracranial compliance. It is well recognised that the morphological shape of the waveform changes in different physiological and pathological states, the recognition of this has most commonly been done by human analysis but artificial intelligence has also been used in morphological analysis. Nucci et al. trained an

artificial neural network to identify pathological pulse waveform morphologies and compared this to interpretation by a human expert (Nucci et al., 2016).

In Lundberg's original paper three types of spontaneous fluctuations in ventricular fluid pressure are described (Lundberg, 1960).

- A. Plateau-like waves of pressure elevation of 50–100 mmHg lasting 5–20 min
- B. Smaller, sharper rhythmic waves at a frequency of ½-2 per minute with an amplitude of up to 50 mmHg
- C. Small rhythmic oscillations at a frequency of 4–8 per minute up to 20 mmHg

In this paper the waves are thereafter referred to as A, B and C waves. A waves were associated with clinical symptoms such as headache, nausea, vomiting and altered consciousness as well as changes in respiratory and cardiovascular physiology such as rises in systolic blood pressure and tachycardia. It was noted that the amplitude of the pressure rise corresponded with more severe symptoms and signs. It is also observed that A waves often started when the patient was moved or during activities such as coughing or straining and could be modified by interventions such as drainage of CSF.

B waves according to the above definition were noted by Lundberg to be present during both periods of normal sleep and reduced consciousness described as "pathological somnolence". It was noted that these type of waves often coincided with periods of deep sleep and snoring and occurred at both high and low levels of pressure. B waves were often observed in association with altered respiratory patterns such as Cheyne-Stokes respiration and apnoeas. Large amplitude B waves were also noted in association with symptoms such as headache and restlessness. C waves were felt to be of limited clinical interest and thought to reflect the spontaneous variations in blood pressure known as Traube-Hering-Mayer or vasomotor waves.

The research into elevations of ICP first described by Lundberg has been greatly expanded over the last several decades but there remain questions as their source and clinical significance where B waves are concerned. A recent review of B waves identified 19 different definitions in the literature including B waves, slow waves, slow vasogenic waves with differing frequencies and amplitudes from those stated in the original Lundberg paper (Martinez-Tejada et al., 2019). In addition to the manual identification of these events several groups have automated the identification of B wave events (Hu et al., 2009). In this paper Kasprovicz et al. have further classified the B wave shapes as symmetrical, asymmetrical and containing plateau like phases using MOCAIP. Regardless of ongoing debate as to their origin and significance in health and disease the results of this study emphasise the importance of their inclusion in an ICP report; the definition used in the report should nonetheless be stated.

The critical observations made by Lundberg et al. were only possible due to accurate annotation of clinical events on the ICP report. There was clear consensus that events should be annotated on the recording in our study. This can be achieved easily through the use of multimodality monitoring such as that used increasingly in neurocritical care. In patients admitted to standard neurosurgical wards this may be more difficult and relies on patients and nursing staff annotating recordings with events such as sleep, coughing and periods of increased headache. Ideally an integrated computerised system should be used that allows these annotations to be made electronically and exported along with the numerical ICP values. During the ICP reporting process this allows variations in the ICP to be assessed in a clinical context.

4.3. Reporting and analysis

ICP reports should be interpretable by all members of the multidisciplinary team. In the expert panel discussion it was noted that in critical care many different healthcare professionals are involved in patient

care. The effects of different interventions such as physical therapy and administration of medication on ICP should be easy to interpret by all team members. This allows everyone involved in the care of the patient to understand how they are progressing in terms of intracranial pressure management. In addition, in the modern healthcare setting an increasing variety of healthcare professionals and indeed patients have access to all clinical information available. An increasing importance is placed on communication and the avoidance of jargon. Using clear and consistent methods and terminology also allows the comparison of different episodes of monitoring.

A theme that was raised repeatedly during the discussion was the existence of two types of report; real time visualisation and post hoc static reports. In the critical care environment the real time visualisation of data in the form of numbers, graphs and charts allows rapid decision making. Bedside systems are in clinical use that can display parameters such as bar charts of ICP over chosen time periods as well as derived indices such as optimal cerebral perfusion pressure (CPPopt) and pressure reactivity index (PRx). Post hoc static reports are more commonly used in patients undergoing elective monitoring such as for CSF hydrodynamic problems. Nonetheless, the respondents in the survey felt that both types of report would be useful in all patients undergoing monitoring. Post hoc ICP reports in the context of neurocritical care would allow clinicians to review their clinical practice for research and quality improvement; for example to assess adherence to protocols in ICP management. Adherence to protocols can also be done in real time using software to compare physiological data from the patient to process modules generated from large data sets and clinical guidelines (Stell et al., 2021).

Standardisation was another common theme in the expert panel discussion that reached high levels of consensus in the further rounds of the survey. Standardisation allows the comparison between discrete episodes of monitoring for each patient, comparisons between patients and also between different institutions. This is extremely useful for research as the total numbers of patients undergoing monitoring in each center may be very small and as such multicentre datasets such as Collaborative European NeuroTrauma Effectiveness Research in Traumatic Brain Injury (CENTER-TBI) (Maas et al., 2015) and BrainIT (Piper et al., 2003) are required to draw meaningful conclusions for patients with traumatic brain injury and other neurological disorders. The report should include definitions of events, for example b-waves, as well as definitions of methods used for example how amplitude was calculated as this may vary between centres. For audit purposes the date, time, software used to produce the report and the name of the person producing the report must also be included. In order for the data to be interpretable there should be a standardised time and amplitude scale included. Whilst some of these points may seem obvious the wide variation in practice in ICP reporting mandates their inclusion in the survey.

More than 90% of respondents to the survey felt that the report should include summary statistics such as mean, median, maximum and minimum ICP. These measures are a useful method to rapidly assess the overall trace; particularly if grossly abnormal. They are easy to understand and as such can be interpreted by the multidisciplinary team and the patient.

The nature of physiological signals is such that a significant amount of artefact is included in the data. There was consensus that the methodology for removal should be included in the report. Various methods of artefact removal exist for waveform data. Often visual inspection is performed to identify areas of definite artefact such as patient movement or disconnection of the monitor. A degree of interpretation is, however, required if removing for example spikes of extremely high ICP such as greater than 100 mmHg that are felt to be artefactual. As stated previously event annotation is mandatory to allow this to take place. In addition to manual inspection there are methods of automating artefact removal that have been performed on ICP waveform signals. Lee et al. used a convolutional neural network to accurately identify artefact in

the ICP signal of patients in the first 24 h after head injury (Lee et al., 2019).

Visualisation of data has been discussed above within the context of multidisciplinary interpretation of the report however it is necessary to highlight that the respondents felt that it was helpful to visualise data on graphs or charts and also to be able to scroll back through the ICP recording at the bedside. This is possible using a variety of IT systems currently available on the market. This can be very simple in the form of histograms or be more complex to include where patients sit with respect to ICP burden in relation to previously collected prediction models (Güiza et al., 2015). Scrolling back through the recording at the bedside is also key to the clinicians on rounds making decisions at the bedside based on what has happened to the patient's intracranial pressure in the preceding hours.

Consensus was reached that the report should include derived data such as cerebral perfusion pressure, PRx and ICP burden. It is increasingly recognised that individualised assessment of a patient's cerebral reserve is important in management rather than just the ICP value. There is much research currently into the benefits of targeting CPPopt and in order to do this these values must be displayed to allow the clinician to make an assessment of, for example, autoregulatory status and what the next appropriate step in management should be (Depreitere et al., 2021). There is increasing recognition that treatment thresholds might be personalised to each patient and may change during the patients ICU admission and in response to therapeutic intervention. It is recognised that alternative derived indices may be used in other neurocritical units and as such these could be included in the report. If these indices are not available, as is the case in most neurocritical units worldwide, then of course it is not possible to include them in the ICP monitoring report.

In the expert panel discussion much attention was drawn to the automation of the process of ICP analysis and reporting; this is a controversial topic in healthcare and the rejection of the initial statement in the first round of electronic surveys reflects this. On the basis of the rejection there was a change to the wording of the statement; a change of focus from analysis to reporting. Although the two words are often used interchangeably analysis has the subtext of a degree of interpretation rather than just a statement of the components contained within a waveform. Advanced computational techniques are increasingly being used in healthcare to aid analysis and decision making. The use of artificial intelligence has dramatically increased in healthcare over the past few years. The ICP waveform is a complex physiological signal which takes significant time and manpower to analyse as well as being highly subjective. There is increasing interest in the use of advanced computing techniques to analyse waveform data for signals such as EEG, ECG and arterial BP waveforms. It is possible these techniques are able to detect irregularities in a waveform more accurately and quickly than a human and as such may alert the clinician that things like a rise in ICP may be imminent and allow the clinician to act to prevent this. The concept of alerting clinicians in real time to changes in high volume and highly complex physiological data has been realised for patients in critical care (Moss et al., 2022). A recently published study was able to use machine learning to accurately forecast episodes of high ICP burden (Carra et al., 2023). In this study Carra et al. used test data from 264 patients to train an algorithm to predict episodes of high ICP burden, this was then validated on 294 patients from the CENTER-TBI dataset. In the event that aspects of the ICP report are automated it was felt by 88% of the respondents that human supervision of the automated analysis should occur. This reflects that clinical judgement should still be used when managing patients with disorders of raised intracranial pressure. Automation of certain aspects of reporting should act as decision support rather than replacement.

More than 90% of respondents said that they would use ICP reports to aid their clinical decision making. This is helpful as it shows the value of producing ICP reports; this is not routine in all neurosurgical centres. In some centres a single value of ICP is recorded hourly by nursing staff. This may not only be misleading but does not allow ICP monitoring to

reach its full potential in aiding clinicians. In neurocritical care a lack of detail in ICP reporting may result in clinicians missing opportunities to treat rising intracranial pressure in a timely manner. In the elective setting, for example to assess for shunt dysfunction, a report allows the clinician to combine numerical, morphological and clinical observations to make what can often be a difficult decision to revise a shunt; potentially subjecting a patient to an unnecessary procedure with risks of serious complications. A formal report also allows episodes of monitoring to be compared for each patient given that many elective neurosurgical patients have a coexisting headache disorder that can be difficult to separate from a potentially treatable neurosurgical cause.

5. Limitations of the study

The authors acknowledge the broad nature of the population of patients undergoing ICP monitoring. It is therefore accepted that not all consensus statements will be applicable in all situations and those that are relevant should be applied to the clinical or research question. The authors acknowledge the low numbers of respondents but are confident that a wide range of the ICP community has been surveyed and responded. We also acknowledge the difference in respondents between round two and round three of the survey. This was most likely influenced by the presentation of the second round at a conference held in a lower and middle income country (South Africa). The third round was however emailed to the same group of respondents as the first, it was not possible to influence who responded to each round of the survey.

6. Conclusions

The results of this eDelphi process provide a tool to aid researchers in the reporting of ICP monitoring data. The main areas under consideration are the recording parameters, waveform characteristics and the reporting analysis as described above. The consensus statements accepted during this process provide a framework by which clinicians and researchers may report the ICP monitoring data that is collected at their institution. The exact format and content report produced will vary according to the clinical and/or research situation.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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