



CMR

INNOVATIONS IN ANAESTHESIA TECHNOLOGY

A CMR INSIGHT INTO THE VIEWS AND NEEDS OF EUROPEAN ANAESTHETISTS

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FOREWORD

Creative Medical Research is a market research company specialising exclusively in medical devices. Anaesthesia is a sector where the company is very well versed and regularly conducts surveys across the whole of the EU, North America, Japan and the Emerging Markets.

In a true Spirit of Enquiry CMR took a stand at ESA last year in Paris and explored future trends in anaesthesia amongst the visiting attendees at the Conference. The results of this research are available free of charge from:

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However, the world of medical devices is constantly changing and in order to keep manufacturers up to date CMR has recently conducted a survey with 100+ European anaesthesiologists to gain their views on the future landscape of technology within anaesthesiology.

Some of our key findings from this new research are summarised below:

- **Cardiac output monitoring** is one of the fastest growing trends. Use of **less invasive, ultrasound based methods** is being driven forward by evidence of **better patient outcomes** and **reduced infection risk**. Further development should focus on delivering more **accurate** and **truly non-invasive** (non-doppler) devices. **Device usability** should also be improved to encourage further take-up among current non/occasional users
- Use of **ultrasound** for **nerve localisation** in **regional anaesthesia** is also a strong trend. In peripheral nerve block, usage is frequently linked to greater accuracy and efficacy. However, risk of nerve damage due to intraneural injection is still a concern. Development is required to provide **modern, user-friendly, high resolution ultrasound devices** and **high visibility needles**

- **Airway technologies**, particularly **videolaryngoscopy**, also emerged as a key focus. Anaesthetists are extremely keen to reduce failed intubations and are seeing more cases with **difficult airways**. Existing videolaryngoscopes are not always deemed sufficiently **robust**, and in some cases **access is poor**
- A further significant trend is for improved **depth of anaesthesia monitoring**. Anaesthetists want to avoid the opposing risks of patient awareness vs. giving high doses. There is clear demand for devices which are **less prone to interference** and highly accurate in 'real-time', with **less delay in recognising shifts**
- A general trend towards **non-invasive monitoring** was observed, this being highly desirable as **risk of infection is reduced**, while **patient comfort is perceived to increase**. However, non-invasive methods are still seen as **less reliable, less accurate** and **less responsive to sudden shifts**. A key frustration with current devices is the **high number of artefacts/ false positives**
- Lastly, results suggest the greatest demand for wireless devices is in **SpO2 monitoring**, followed by **ECG** and **NIBP**. Primary drivers of this demand include the desire to **simplify patient transfers**, and to **decrease clutter** around the patients' bedside



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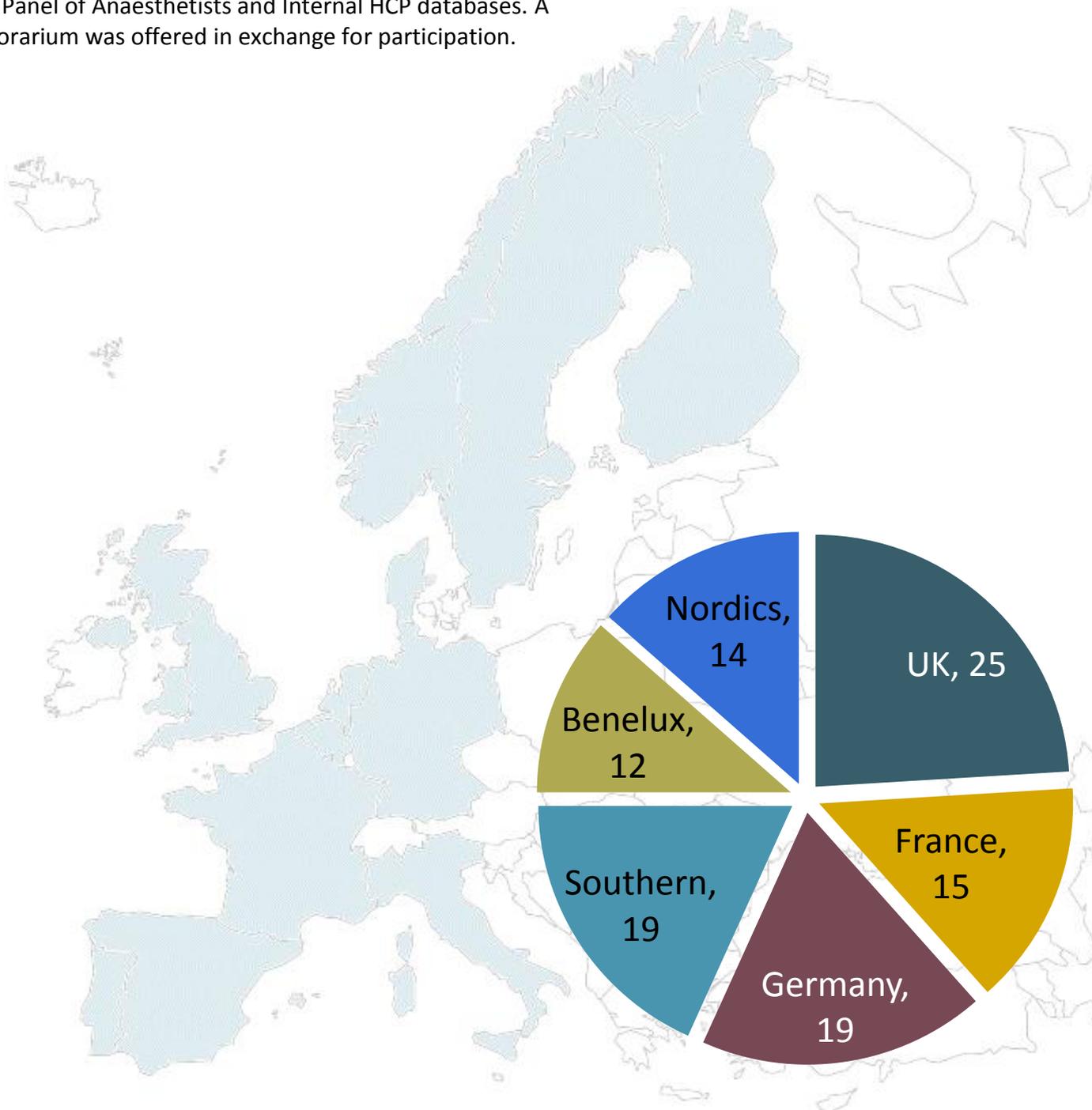
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METHODOLOGY

Creative Medical Research carried out a 15 minute online self-completion survey with N=104 Anaesthetists across key Western European markets during March 2013.

All survey respondents were recruited from CMR's International European Panel of Anaesthetists and Internal HCP databases. A small honorarium was offered in exchange for participation.



KEY TECHNOLOGY TRENDS TODAY

Our survey asked 104 European Anaesthetists:

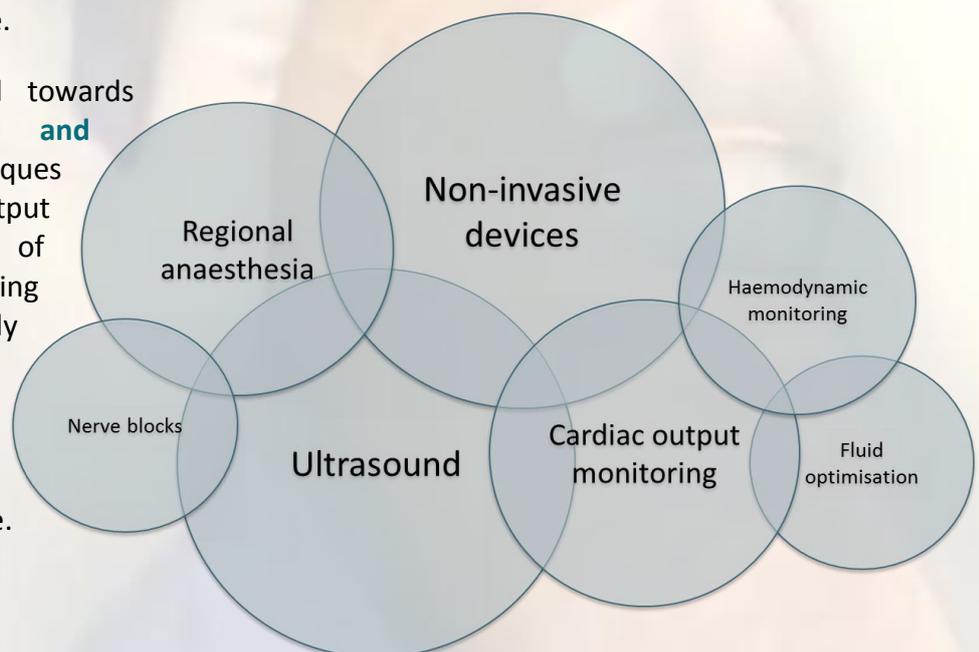
“In your view, what technologies in Anaesthesia are currently seeing the fastest growth, and why?”

Among the technologies frequently nominated by our respondents, **ultrasound devices** were a key focus, being seen to have a wide set of potential applications ranging from diagnostic to localisation and monitoring. In particular, use of ultrasound for localisation in **regional anaesthesia** and for monitoring **cardiac output** were perceived to be fast-growing trends.

Growth in the application of these ultrasound technologies was primarily attributed to a desire to enhance accuracy and efficacy during procedures, to improve patient outcomes and to increase safety. More specifically, use of **ultrasound in regional anaesthesia** was commonly linked to better identification of anatomical structures, enabling more accurate and efficacious **nerve blocks**. Meanwhile, its use in **cardiac output monitoring** was linked to better patient outcomes, through enhanced **fluid optimisation**.

The **non-invasive** nature of ultrasound was also seen as a key benefit of the technique, particularly with regard to its application in cardiac output monitoring, due to the reduced risk of infection versus invasive monitoring via an arterial line.

Results further suggest the trend towards increased use of **non-invasive and minimally invasive monitoring** techniques persists beyond cardiac output measurement to other forms of **haemodynamic monitoring**, including **blood pressure**. With increasingly accurate and user-friendly technologies being developed for continuous non-invasive measurement, this trend only looks set to continue in future.



“Ultrasound in regional anaesthesia: patient comfort, high level of safety”

“Cardiac output monitors. They are becoming more accurate and dependable and anaesthetists are realising their worth in outcomes”

“Non-invasive monitoring. Reduction in complications, enhanced recovery protocols”

KEY TECHNOLOGY TRENDS TODAY

“Airway management – videolaryngoscopes, single-use bronchoscopes”

“Airway: videolaryngoscopes will be the normal way of intubation in the future”

“Depth of anaesthesia monitoring - patients' greatest concern and proper depth of anaesthesia may save money and avoid post-op cognitive dysfunction”

Another key area of focus for our anaesthetists was **airway management**. In particular, new developments in **videolaryngoscopy**, allowing for enhanced visualisation of the glottic opening during intubation, have been met with excitement.

Again, expectations surrounding increased efficacy, accuracy and patient safety are the forces driving adoption forward. In future, our results suggest there is potential for increased use of videolaryngoscopes outside of difficult intubations, with the technology expected to be used increasingly more often for straightforward cases as it becomes established.

A further significant trend observed was for **depth of anaesthesia monitoring**. Unintended awareness during surgery was seen as *the* key concern among patients, and anaesthetists are keen to avoid accidental under-dosing in order to prevent this occurring. However, they are also mindful of giving higher doses than absolutely necessary due to the potential for post-op complications. The advent of **EEG based depth of anaesthesia monitoring systems**, designed to more reliably indicate a patient's stage of anaesthesia, has been a welcome development, though there are still calls for more accurate and reliable systems.

Lastly, a number of smaller trends also received mention. CMR wonders if perhaps these technologies will begin to feature more as their development continues and a solid base of evidence emerges to support their use. In particular we believe it will be interesting to see how things develop over the next year for:

- **Closed-loop monitoring/delivery systems for anaesthesia/analgesia**
- **Low-flow anaesthesia systems**
- **Cerebral oximetry monitoring**
- **Point-of-care coagulation testing**
- **Total intravenous anaesthesia (TIVA)**

MOST WANTED: SAFER DEVICES



In the world of medical devices, safety innovations often drive the adoption of new products and technologies. Thus, in our survey, we sought to establish where within the realm of anaesthesia the greatest need for safety innovations is currently seen to lie (see above).

Anaesthetists were asked to choose up to three areas from a pre-defined list that they saw as being particularly in need of safety innovation. They were then asked an open ended follow up question, which aimed to bring to light the reasons behind their choices, and exactly what developments they considered to be necessary.

MOST WANTED: SAFER DEVICES

“Please explain why you feel device safety needs to be improved in these areas, and what is needed to achieve this?”

1) Patient monitoring:

The area anaesthetists consider most in demand of safety innovation is patient monitoring. A major bugbear with currently available systems is the **high frequency of artefacts/ false positives** caused by extraneous factors. **False alarms** are perceived as a distracting safety hazard and more **reliable non-invasive measurements** that are less prone to interference are highly desirable.

In particular, **depth of anaesthesia monitoring** was identified as being in need of further development to increase reliability of measurement, and **SpO2 monitors** were frequently mentioned as being prone to interference. The need for better measures to assess **cerebral perfusion** was also cited by several respondents.



Our anaesthetists also spoke about the need for **wireless monitoring** technologies, to increase safety for personnel by limiting potential trip hazards and reduce interference/ artefacts caused by wires being moved. Furthermore, there was a clear demand for **simplification and integration** of patient monitoring systems, both in terms of the display screen and the number of connections from the patient.

2) Airway management:

Anaesthetists are highly attuned to the risks of failed airway management, and as such, there is strong demand for device development. This appears to be influenced by the growing number of **bariatric patients** and **patients with respiratory issues**, resulting in more cases with **difficult airways**. Anaesthetists are keen to reduce **failed intubations** and avoid the ‘cannot intubate, cannot ventilate’ scenario.



“Specialist airway devices are still very expensive and not robust. Out of the budget range of many departments...”

Recent advances in **videolaryngoscopy** have been met with excitement; however, further development is clearly still required. Results suggest the **robustness** of existing devices is not always sufficient. Furthermore, access is reported to be poor in some hospitals and there is some evidence this may be budget driven, with several suggesting a need to **reduce costs**.

“Better monitoring of anaesthesia depth, development of existing (BIS/Entropy) is needed”

“Artefacts resulting from various external influences (e.g. electrical power, shivering, movements). Stable signal monitoring”

MOST WANTED: SAFER DEVICES

3) General anaesthesia:



Anaesthetists see safety as a particularly high priority in this area, where risks to patients are often severe when mistakes occur. They are keen to have better tools to enable them to

optimise the depth and evolution of anaesthesia.

Avoidance of unintended awareness is key, as is the desire to avoid giving unnecessarily high doses which may hinder recovery. In line with this, **depth of anaesthesia monitoring** received considerable attention, with a need for **greater accuracy** noted by several respondents.

The need to reliably measure **neuromuscular blockade** and **analgesic administration** in order to inform **accurate dosing** was also noted, as was the potential for developments in **closed-loop anaesthesia** systems.

“Possible improvements for optimising the administration of anaesthesia products....optimisation of the depth of the anaesthesia and relaxation, of the neuromuscular blockade and medical data capture incidents, etc.”

“Please explain why you feel device safety needs to be improved in these areas, and what is needed to achieve this?”

4) Peripheral nerve block:

Anaesthetists favour the use of ultrasound when conducting peripheral blocks, but still perceive a need for better technologies in this area. The risk of nerve damage due to **accidental intraneural injection** is still a key concern.

Specifically, there are calls for more **modern ultrasound devices** to be developed, that are **intuitive to use** and have **high resolution screens**, enabling more accurate localisation of the nerves and other anatomical structures.

“More and more blocks are performed and thus complications will rise. Ever better sonographic visibility and recognition of patterns are important and better visualization of needles”

Results suggest developments to further enhance **needle visibility** on the ultrasound image would also be welcome.

5) Infusion Pumps:

The main need identified in this area was for **more modern pumps** with **intuitive, simple to use interfaces**, which **make programming easier** and less prone to error. Anaesthetists feel it is too easy to make programming errors at present, meaning patients may not always receive the most appropriate dose.

The need for **more precise modelling** to enable **better individualisation of the dosage** for each patient was also noted by several. In particular, results suggest further development of **closed loop** techniques linking depth of anaesthesia monitoring to drug administration would be very welcome.

Finally, the reliability and accuracy of existing devices was once again scrutinised. Inadequate dosing accuracy and unreliable pumps which stop delivering part way through were both mentioned, though by a minority.

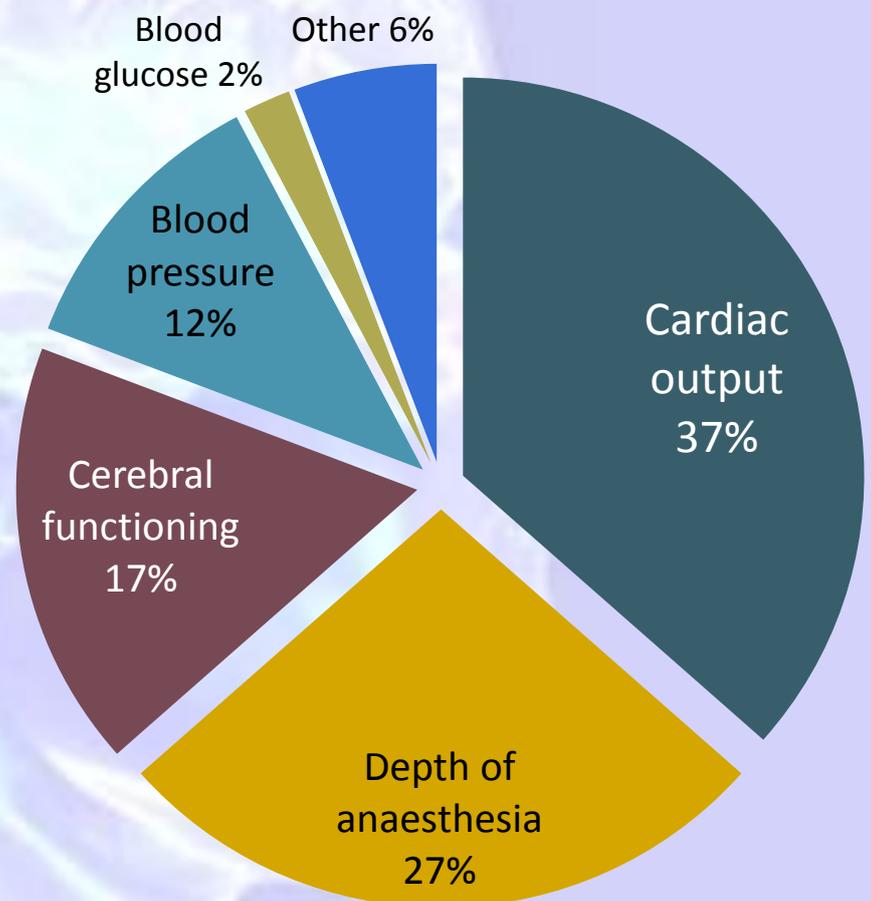
MOST WANTED: NON-INVASIVE

Our findings suggest that **non-invasive monitoring technologies** are generally highly desirable to anaesthetists as risk of patient infection is reduced versus invasive methods, while patient comfort is perceived to be increased. However, non-invasive methods are also commonly considered to be **less reliable, accurate** and **responsive to sudden physiological shifts** than their invasive counterparts, i.e. the measurements they provide are not always 100% 'real-time' continuous. Furthermore, criticisms surrounding the issue of reliability have also been levelled at traditionally non-invasive monitoring devices, such as those for **neurophysiological monitoring** via EEG.

We asked anaesthetists to tell us where they perceive the greatest need for technological developments in non-invasive monitoring devices to be at present. Despite the recent advances in less invasive **cardiac output monitoring devices**, this measure was still elected as the one most important parameter on which future monitoring device development should focus.

However, technologies to measure **depth of anaesthesia** and various aspects of **cerebral functioning** were also seen by many as demanding improvement. If we consider these two areas under the one umbrella of **EEG monitoring technologies**, then this becomes the most prominent need going forward. Indeed, there is some feeling that in the past, cerebral monitoring has been neglected, while the primary focus has been on device developments in cardiac and respiratory monitoring.

“In your view, where in patient monitoring would you most like to see further developments in non-invasive technologies?”



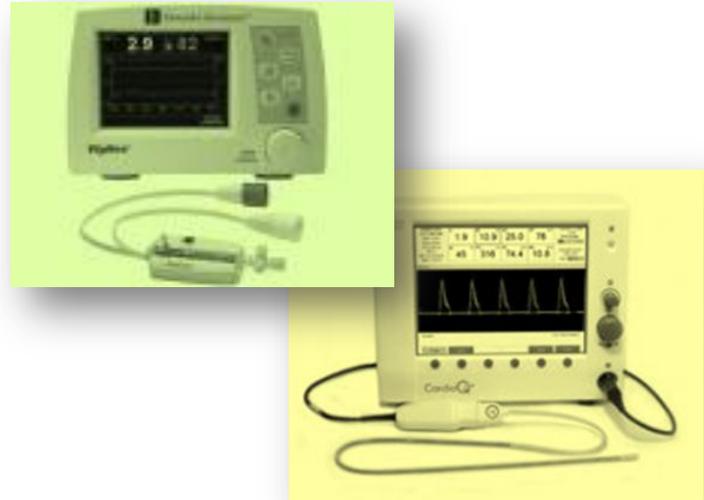
“The data currently available is not sufficient to be sure of an appropriate level of anaesthesia, neither too deep nor too shallow, with the posterior consequences for the medium and long term (disorientation in older patients, night terrors in young children, medical data capture during surgery)”

MOST WANTED: NON-INVASIVE

To gain a deeper understanding of anaesthetists' currently unmet needs in non-invasive monitoring, a further open ended follow up question was posed:

“Please explain why you feel further developments in non-invasive technologies are needed for these devices?”

Respondents answered this question with regard to the area of non-invasive monitoring they had nominated as being most in need of further technological development.



1) Cardiac output:

Several factors seem to underlie the demand for further development in this area. Firstly, anaesthetists note the growing number of **high cardiac risk and elderly surgical patients** in need of tighter levels of **haemodynamic control**. **Invasive arterial monitoring** is deemed particularly risky for this group, given the increased likelihood of post-op complications. However, minimally invasive **oesophageal doppler devices** are not always seen as sufficiently accurate to enable optimal treatment and are also still seen as being quite invasive. The development of **more accurate doppler devices**, or **truly non-invasive options**, could potentially encourage more routine use of cardiac output monitoring.

Furthermore, cardiac output monitoring is still perceived as a technique requiring considerable knowledge and expertise to deliver. Current devices are seen as complex and **aimed at the expert user**. In particular, some feel that the currently available doppler devices are not user-friendly. There is a demand for new devices that are **intuitive to use** and **easy to set up**, even in critical situations.

At present, results suggest traditional invasive monitoring is still often favoured for patients with co-morbidities, those with cardiac disease and/or unstable haemodynamic responses, those who are critically ill and those undergoing major surgery, particularly vascular and abdomino-thoracic surgeries.

“CO monitoring now is invasive and requires a lot of knowledge and expertise. Such it is restricted to very sensitive areas. However, if could be done as easily as saturation monitoring it will be helpful and increase safety of every anaesthetic given”

“Current invasive devices are not used routinely due to their invasive nature, oesophageal doppler is difficult to use and not that reliable”

“Most devices are still relatively “expert user” only. Development to encourage generalists to feel comfortable in their use would be helpful”

MOST WANTED: NON-INVASIVE

“Please explain why you feel further developments in non-invasive technologies are needed for these devices?”

2) Depth of anaesthesia:

Here there is clear demand for devices which enable anaesthetists to give **more accurate doses** and are **less prone to interference**. Anaesthetists feel they are currently in a catch 22 situation; highly motivated to avoid patient awareness, but also the unnecessary drug costs and patient complications associated with higher dosages of general anaesthesia drugs.

Our results suggest anaesthetists are uncertain of the **reliability** of current technologies, with clinical data to support the use of current systems viewed as being limited. Also, while Bispectral Index (BIS) is currently seen as the ‘gold standard’, it is noted that at present there is only data to support its use with particular drugs.

In addition, respondents noted a **delay in recognising shifts in depth of anaesthesia** with current devices. This is seen to present a particular problem when using **TIVA**, itself a technique which is recognised to be gaining ground in current practice. There is therefore some suggestion that wider take-up of TIVA may be limited until more reliable ‘real time’ depth of anaesthesia becomes available.

“We are more and more using total intravenous techniques. These are fine but each patient has his/her own ability to eliminate the drugs and thus there are the problems of awareness and the opposite, accumulation. We must work towards a closed loop system, and for this to be possible we must have dependable monitoring of depth of anaesthesia”

3) Cerebral functioning:

As noted, there seems to be a feeling among anaesthetists that cerebral monitoring has been neglected in the past. However, there now appears to be a desire to make this type of monitoring more routine. Once again, a key factor expressed as driving the need for development is the growing number of **elderly patients** undergoing surgery, particularly because these patients are more likely to present with **pre-existing cognitive issues** such as dementia.

“So far, no trouble-free valid parameters for measuring brain function have been available”

Second to this, there looks to be a more general growing concern that the way in which general anaesthetic drugs affect **neurological function** is not fully understood.

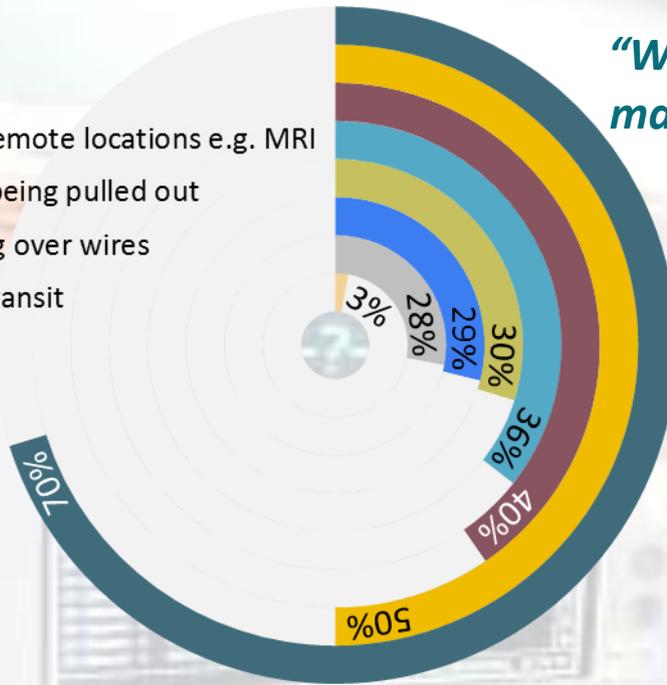
One specific area touched upon in more detail was the need for developments in measuring **cerebral perfusion and oxygenation**. Anaesthetists are mindful of the fact that some surgical positions are associated with poorer cerebral circulation, and keen to avoid any associated complications.

4) Blood pressure:

Better **continuous non-invasive monitoring devices** are desirable for anaesthetists, as those currently on the market are perceived as being **vulnerable to artefacts**, and the measurements they offer not **truly ‘real time’ continuous**. Anaesthetists still perceive a place for invasive blood pressure monitoring, particularly in major surgery, and if heavy blood loss has occurred or is expected. Invasive monitoring is also likely to be used for critically ill patients, those presenting with cardiac disease or poor blood flow and those undergoing cardiac or vascular surgery.

MOST WANTED: WIRELESS

- Simplifying the transfer process
- Reducing clutter around the pt
- Enabling data capture while pt is in remote locations e.g. MRI
- Reducing risk of monitoring devices being pulled out
- Reducing risk of injuries from tripping over wires
- Enabling data capture while pt is in transit
- Enabling remote access of data
- Other



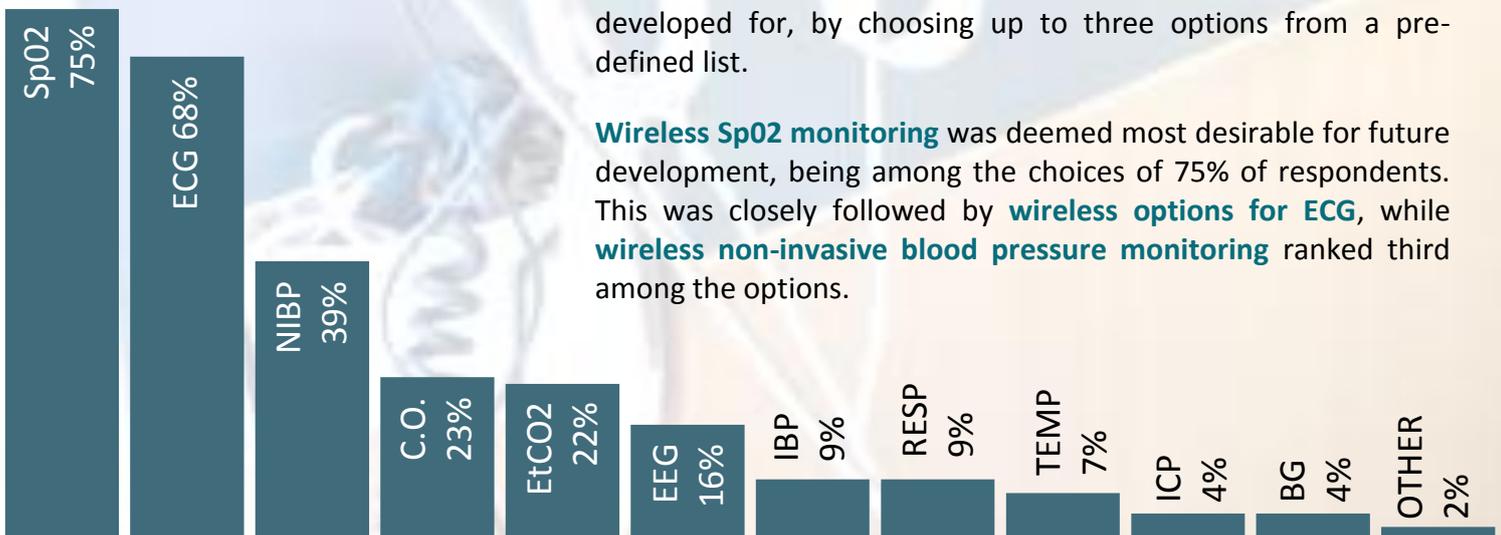
“What would be the main drivers for you to use wireless monitoring technologies?”

“In your view, for which monitoring parameters would you most like to see developments in wireless technologies?”

Our results reveal anaesthetists are keen to have more wireless monitoring technologies. Key drivers to use such technologies include the desire to **simplify patient transfers, to avoid gaps in monitoring** while patients are in transit or remote hospital locations, and to **decrease clutter** around the patients’ bedside, thus **reducing trip hazards, false alarms** due to wires being pulled out and **lowering infection risks**.

To establish where the greatest demand lies for wireless monitoring, we asked our respondents to tell us which parameters they would most like to see wireless options developed for, by choosing up to three options from a pre-defined list.

Wireless SpO2 monitoring was deemed most desirable for future development, being among the choices of 75% of respondents. This was closely followed by **wireless options for ECG**, while **wireless non-invasive blood pressure monitoring** ranked third among the options.



MOST WANTED: WIRELESS

So what are anaesthetists looking for in a wireless monitoring system? To understand this issue in more depth we asked anaesthetists to tell us openly what their ideal system for the future would look like.

Our results suggest the ideal system would be comprised of **wireless, non-invasive probes** on the patient, reliably **linked via wi-fi or bluetooth** to the display device.

It was widely agreed that **portable display devices** should be available, and many anaesthetists suggested a touchscreen design like the iPad would be very desirable. However, it was also felt that a display should also be present **at the patient's bedside**. A design that can be easily affixed to and removed from the bed may have an advantage. Overall, it was agreed the device should be **durable, simple and intuitive to use**.

In addition, several suggested that monitoring data gathered from the wireless probes should also upload to a **central database or 'online cloud'**. This data should then be **accessible in remote locations** such as in the office or at home, **via a PC, iPad** or even **via a mobile app**. Ideally, remote access to the data would be **customisable** for each patient, ensuring that only relevant members of a patients care team are afforded access.

“In your ideal world, what would wireless patient monitoring look like in future?”

“Hand-held and every patient connected so I can observe and also alarm function if I am looking at one so I don't miss any of the other patients”

“Bedside and portable. Easy, not too much information. For me it is important to see the patient, not just a monitor”

“A portable, removable device, with network access for an authorised medical team, data that can be extracted at an IT terminal or similar, would be ideal”



