

THE SOCIETY FOR VASCULAR TECHNOLOGY OF GREAT BRITAIN AND IRELAND

Uncertainty of Measurement in Vascular Technology

Abbreviations

| UKAS | United Kingdom Accreditation Service |
|------|--------------------------------------|
| UoM | Uncertainty of measurement |
| QA | Quality Assurance |
| SOPs | Standard Operating Procedures |
| DVT | Deep vein Thrombosis |
| ABPI | Ankle Brachial Pressure Index |

Introduction

Vascular technology involves assessment and diagnosis of various blood flow disorders. It is essential for services carrying out these assessments to have an appreciation and understanding of how Uncertainty of Measurement affects the test, interpretation of results and the impact on patient management decisions. An example of the importance of recognising UoM is where the degree of variation may deliver results which place diagnostic interpretation into different significance categories. For example, grading carotid stenosis using absolute velocities: If variability is within +/- 5%, a velocity may fall above or below a significance threshold for intervention.

Uncertainty of Measurement describes the level of confidence that is applicable to measurements and is required as part of a quality system. All measurements are prone to some uncertainty and are only considered to be complete if accompanied by an acknowledgement of this level of uncertainty. Measurement uncertainties can come from various sources including equipment, the item being assessed, the environment and the operator. UoM is the quantification of doubt or variability that exists in any measurement, and to understand what an acceptable range is. For example, if we measure an ABPI or blood pressure several times throughout the day, we might expect the measurement values to be similar, but not identical.

The National Physical Laboratory have published guidance on UoM which explains these principles in a format which is aimed at beginners and a good place to start¹. UKAS have

also produced a guidance document which explains how to express levels of uncertainty and confidence in measurement ².

Two things to consider when assessing the level of doubt/uncertainty, are the <u>interval</u> which is the width of the margin in our measurements, and the <u>confidence level</u> which informs on how sure we are that the 'true value' is within that margin ¹.

It can also be wise to repeat measurements as making only one measurement can leave mistakes undetected. If you make several measurements and they all agree, apart from one this may lead you to be suspicious of the outlier.

To understand the principles, it is helpful to consider an everyday example. You could check the temperature inside a domestic oven using an independent thermometer. But how do you know that this thermometer is accurate? Has it been calibrated? Does your measurement depend how long the sensor has been in the oven or where it is placed within the oven? All of these factors need to be considered and may contribute to uncertainty in your measurement of the oven temperature. In this example, we would be able to use the independent thermometer to find out the uncertainty of our measurement. Assuming a good technique, where the independent thermometer has been calibrated and we have the technical data sheet, we may know the size of any error, for example +/- 5%. If the oven temperature is measured using this thermometer as 200° C, we now know the UoM and that the temperature could actually be anywhere between 190° C and 210° C.

Contributing Factors

When related to Physiological diagnostics there are 5 main contributing factors to variability which need to be considered (Figure 1).



Figure 1 Contributing factors

Ensuring Quality

To meet accepted quality standards ^{3 4} services are required to identify and address UoM for the scope of their work. This will be dependent on each individual service, but consideration of the following contributing factors may be a helpful place to start (Table 1). When considering what is important it is helpful to ask, "Does it have an effect on the final outcome?". If it might affect the final reported result, you need to consider it.

Table 1

| Staff | Staff should be appropriately trained, competent and aware of UoM for the measurements that they are undertaking. They should have access to relevant and current evidence-based policies/standard operating procedures. |
|-------------|---|
| Patient | Can the service be provided to the full range of patients considering such things as body habitus, age, ability? Do any of these factors need considering in terms of UoM in diagnosis? Are any limitations taken into consideration when reaching a diagnosis? |
| Equipment | Is equipment appropriate, maintained, replaced when necessary? Services should be aware of the technical specification and how this relates to accuracy of measurements. All equipment should be considered, including ultrasound machines, sphygmomanometers, plethysmography equipment etc. There should be appropriate QA and calibration processes to inform UoM. |
| Methodology | Services should have access to up-to-date evidence-based SOPs and professional body guidance which staff follow. |
| Environment | The environment should be conducive to high quality measurements. Consideration should be given to the effect of temperature, ventilation and noise. |

When considering UoM of results it is also helpful to think about qualitative and quantitative aspects.

<u>Qualitative</u> relates to those tests which that do not involve numerical measurements or produce a number as the result, and depend on empirical observations. A good example for Vascular would be a ?DVT scan in which the result is either positive or negative. We also need to consider qualitative aspects which can affect the performance of a test and therefore the result, such as body habitus, patient fasting and hydration levels. If any of these result in limitations, possible ways of minimising them should be used and limitations acknowledged, for example in reporting.

<u>Quantitative</u> relates to numerical measurements. All measurements have a level of uncertainty and this is what we need to establish before using any measurements for diagnostic purposes. We also need to consider physiological factors which can affect the <u>quantitative</u> performance of a test, such as cardiac arrhythmia or output changes. UoM is particularly important where a measurement is critical, for example where one number informs a decision to recommend surgery for a patient. In assessing

UoM we can employ methods to assess and give confidence in measurements, for example:

- Statistical methods (Coefficients of variability, probabilities
- Control samples to verify techniques/equipment (e.g. ultrasound and flow phantoms)
- Reference ranges (e.g. equipment technical specifications)

How does UoM relate to Vascular Technology?

It is up to individual services to decide how UoM relates to their individual service and ensure that processes are put in place to assess and quantify and work within the UoM. All measurements will have a degree of variability or a margin of doubt, and we need to appreciate the uncertainties in the measurements we are making and how this may affect our diagnoses.

An appreciation of ultrasound QA is a good place to start. Do you have a QA programme to assure various aspects of your service including ultrasound machine operation? The SVT has a useful document for anyone setting up an ultrasound QA programme ⁵.Do you know the resolutions (axial/lateral) for your probes and do you use this to decide how many digits/decimal places you use when reporting measurements? Do you check the resolutions and calliper placement accuracy with a phantom? Is this a regular part of your QA programme? Do you rely on absolute velocity measurements or ratios? If absolute velocities are used, how do you ensure accurate Doppler calibration or QA? Will this affect your confidence in the results? Are you able to check the equipment accuracy range from technical specifications? For example, a sphygmomanometer may be accurate to +/ –3 mmHg or 2% of the reading above 200 mmHg. How will this knowledge affect your interpretation and reporting of results?

Once you have assessed your equipment you may find that, for example, the aortic diameter measurements made in your service with your equipment are +/- a certain percentage, does this range need to be included in your reports? Knowing some of the things listed above will allow you to understand the quantitative limitations or uncertainties.

The SVT has issued some guidance on particular aspects of measurement technique which is included in their Professional Performance guidance documents⁴:

"Measurement technique should ensure accuracy is optimised. As appropriate to the clinical scenario, this may require:

- Optimal adjustment to scale, gain and cursor placement for velocity measurements
- Selection of an appropriate probe including knowledge of probe resolution (axial/lateral) for linear measurements.
- Ensuring reported linear measurements are consistent with the level of accuracy/resolution possible, including the use of rounding where appropriate.

• Optimised technique for volume flow measurements, applying knowledge of all sources of error and ensuring reported measurements do not imply a level of accuracy which is not possible."

In the introduction of this document, we discussed the value of repeating measurements. This method can also be used to minimise uncertainties. It could be used for aortic diameter measurements where the results may inform surgeons on their decision to operate. The operator may decide that additional measurements are needed to enable the mean to be calculated in cases where the aortic diameter is borderline for surgery. This method can be used to decrease the level of uncertainty of this quantitative measurement. We can also apply this principle to qualitative aspects, for example DVT scans. We don't tend to rely solely on B-mode appearance; we include compression, colour and spectral Doppler to confirm our diagnosis. Different ways of assessing the same thing increase confidence in the overall result.

It may also be helpful to decide for each type of scan whether there are quantitative and/or qualitative aspects. The summary in Table 2 may be a helpful starting point.

| Test | Quantitative aspects? | Qualitative aspects? |
|------------------------|---|---|
| ?DVT | If you are measuring lengths of thrombus you will need to know the accuracy of your ultrasound measurements, the level of resolution to which they can be quoted, and whether this is probe dependent. | Are there any limiting factors such as adverse body habitus which impact on your level of certainty in the diagnosis? How do you take account of this? Is the B-Mode dynamic range sufficient to define the thrombus echogenicity and burden to enable measurements? |
| Carotid | Are velocity measurements accurate, reliable and reproducible? Do you check the performance of your ultrasound machines so that you know whether there are systematic errors? Are there operator errors and how can these be minimised? Do you need to assess the coefficient of variation for your measurements so that you know? How do you reach a diagnosis if different velocity criteria give different results? | ✓ Do you comment on plaque morphology, what criteria do you use? How do poor images/calcified walls impact on your diagnoses? |
| Peripheral arterial | Similar to those for carotid scanning | Similar to those for carotid scanning and DVT scanning. Are there any limiting factors such as vessel calcification which impact on your level of certainty in the diagnosis? How do you take account of this? How do you decide between use of inner or outer calliper placement for AAA measurements? |

| Table 2 (| = this | may | appl | y) |) |
|-----------|--------|-----|------|----|---|
| | | | | | |

| ABPI | Are your sphygmomanometers checked and calibrated? Does technique affect measurements? How accurately can you assess systolic pressure and are you quoted results consistent with this? | How do you categorise waveform shapes? Are there any limiting factors such as vessel calcification which impact on your level of certainty in the diagnosis? How do you take account of this? |
|---|---|---|
| AAA assessment and EVAR surveillance | Do you know the limitations of your diameter measurements versus frequency, and any velocity measurements you are using? | Similar to those for carotid and DVT scanning |
| Venous Reflux | ✓ Do you know the limitations of assessing the length of what you think may be reflux? | Body habitus, patient's ability to attain the ideal position may impact on the confidence in the result. |

<u>References</u>

¹ Bell, S. "A beginner's guide to uncertainty of measurement". Measurement Good Practice guide 11 (2). National Physical Laboratory. <u>https://www.dit.ie/media/physics/documents/GPG11.pdf</u>

² M3003 "The expression of uncertainty and confidence in measurement" 2019 United Kingdom accreditation service. <u>M3003-Expression-of-Uncertainty-and-Confidence-in-Measurement-Edition-4-October-2019.pdf</u>

³ Standard for Improving Quality in Physiological Services <u>https://www.ukas.com/accreditation/standards/iqips/</u>

⁴ The Society for Vascular Technology or Great Britain and Ireland <u>https://www.svtgbi.org.uk/professional-issues/</u>

⁵ SVT Ultrasound Equipment Quality Assurance document <u>https://www.svtgbi.org.uk/media/resources/SVTQA_Document_nZT1fSV.pdf</u>

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