GUIDANCE FOR THE DETERMINATION OF MEASUREMENT UNCERTAINTY IN URODYNAMICS

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Abbreviations

ICS	International Continence Society
IQIPS	Improving Quality in Physiological Services
UKAS	United Kingdom Accreditation Service
UKCS	United Kingdom Continence Society
UoM	Uncertainty of Measurement
UPP	Urethral Pressure Profile

1. Purpose

This document seeks to give guidance for urodynamic departments seeking to estimate the measurement uncertainty in their urodynamic data. It will be particularly relevant for the department seeking to gain accreditation under the IQIPS standard assessed by UKAS.

2. Introduction

IQIPS v2 2020[1] states protocols must include diagnostic criteria and consider uncertainty of measurement (UoM) as appropriate. Measurement uncertainty shall be determined for each measurement procedure used to report patient results. The service is also required to define performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

The National Physical Laboratory has published guidance on UoM which explains these principles in a format which is aimed at beginners and a good place to start[2]. UKAS have also produced a guidance document which explains how to express levels of uncertainty and confidence in measurement[3].

It is recognized that most measurements are subject to errors which are not perfectly quantifiable and that, therefore, there is uncertainty associated with the results of such measurements. A measurement result is therefore incomplete without a statement of the corresponding measurement uncertainty. The sources of such errors will need identifying and their magnitude estimating in order to assess UoM.

3. Uncertainty of Measurement (UoM) in Urodynamics

The biggest factor in measurement error in urodynamics is the technique employed by the practitioner. The definition of and encouragement of adherence to Good Urodynamic Practices[4,5] are beyond the scope of this document, but due to their influence on accuracy, consideration of UoM needs to take these factors into account.

Such elements of good practice that affect measurement accuracy are:
- Setting zero to atmospheric pressure
- Ensuring transducers set to reference height (water systems)
- Keeping catheter tips at constant position (air and solid state systems)
- Ensuring good pressure transmission throughout test
- Ensuring resting pressures are in the normal ranges
- Reading pressure and flow values away from artefacts
- Using markers to explain features of the trace

There will also be variation from patient to patient in the values measured, simply by virtue of the fact that no two patients' situations are identical. UoM does not deal with the real differences in the values measured, but with the departures from the true value that may occur when reporting and recording. These additional uncertainties arise from the performance of the equipment.

The uncertainty that this document will therefore consider is that arising from the measurement equipment, method and environment. The potential areas of uncertainty each department will need to consider for their own situation include[6]:

- Method used to zero to atmosphere
  - the zero must be set when equipment is set up for use, e.g. with domes in place
- Transducer height for water-filled systems
  - resting pressures will be affected, even though p_{det} will not be
- Catheter tip height for air-filled or solid state systems
  - movement with respect to patient or to the other catheter tip will change readings
- Air bubble in water-filled catheter
  - transmission of pressure, particularly dynamic changes, will be reduced
- Resting pressures out of normal range
  - indicative of poor connection between catheter and patient
- Individual transducer response to applied pressure
  - linearity, temperature, hysteresis will all affect the measurement value
- Calibration accuracy of individual transducers (for both pressure and flow)
  - the precision of the reference pressure used will be reflected in the accuracy
- Accuracy of infusion pump rate and infusion volume
  - this may be affected by different size catheters, and needs regular checking
- If UPP is measured, the puller arm speed, and liquid infusion rate if relevant[7]
  - variations in the infusion rate can change the rate of response to pressure
- Assumptions made about body and fluid density
  - some height between catheter and symphysis pubis is tissue or contrast, not water
- Errors from digitisation of parameters
  - the acquisition of data by a computer is done at fixed intervals, not continuously

The practitioner must also be aware of the intrinsic variability that occurs with the particular measurement technology they use (i.e. water-filled, air-filled or solid state). Each system can introduce variations to the measured value that are not due to variations in the actual patient parameter being reported. Reduction of uncertainty arising from these causes can be achieved by following good practices and interpreting the data with good understanding of the method used.

The above discussion is concerned with pressure measurement. Urodynamics of course includes measurement of flow rate, either by a weight transducer or a spinning disc, and of infused volume, either by bag weight or by counting pump revolutions. For UoM in flow rate, departments will need to consider their calibration accuracy, variation due to noise even when no flow occurs and the uncertainty inherent when estimating the real point of maximum flow, e.g. when a spike artefact occurs. UoM for bladder volume will also be affected by calibration errors and signal noise on the infusion channel, but more significantly by assumptions made regarding natural diuresis volume during the test. Departments will be expected to consider these factors too.

4. Method

The urodynamics department is required under IQIPS to assess these and any other potential causes of uncertainty, in order to estimate the possible range of values of their measurements. The uncertainties arising from each cause are normally combined by calculating the square root of the sum of squares of possible errors. This will give a value for the UoM for each parameter reported. The department should document and regularly review this assessment.

A worked example for use of square root of the sum of the squares for pressures is as follows:

Consider the measurement of pressure by a water-filled transducer. What factors could influence the accuracy of this measurement? Influencing factors could be:

- Position of transducers with respect to patient's symphysis pubis
  - This may be up to 4.5 cmH_2O[6] on each pressure line, though 0 cmH_2O on p_{det}
- Rounding errors and movement by eye of pressure markers off artefacts
  - This might result in uncertainty of 2-3 cmH_2O
- Drift of zero from original set point, due either to noise, temperature or dome movement
  - This can vary by up to 2 cmH_2O[6]
- Accuracy of reference pressure used for calibration
  - A water column was found to give a variation in 0.7 cmH_2O in readings, when the level of the column was judged by eye and the tube height held manually[6]
- Linearity of transducer response to pressure changes
  - Manufacturer specifications normally state a non-linearity of 0.5%, which equates to around 0.2 cmH_2O for the typical range of pressures
- Temperature response of transducer
  - Manufacturer specifications suggest a difference of 10^{o}C could lead to a change in reading of 0.5 cmH_2O at a typical pressure value
- Tissue and fluid density assumptions
  - When contrast medium is used, the error from assuming that the environment has the density of water could be approximately 0.5 cmH_2O[6]

Combining these factors using root sum of squares gives:
Total uncertainty of measurement on $p_{det} = \sqrt{(3^2 + 2^2 + 0.7^2 + 0.2^2 + 0.5^2 + 0.5^2)} = 3.7\ cmH_2O$

The department can thus state that they expect their p_{det} pressure measurements to be made to an accuracy of 4 cmH_2O, even when most elements of good practice are followed. This can be a guide to limit the number of digits or decimal places used to report results. In this case, reporting pressures to the nearest integer is justified, but not to tenths of a cmH_2O, even if the equipment reports this. It can also guide practitioners reviewing varying pressure readings; changes within the range of accuracy reported would not normally be a concern for measurement quality.

Departments are expected to keep a record of the uncertainty of measurement expected for each parameter – pressure, flow and volume in this case – used in diagnostics.

5. Maintenance and calibration

It is incumbent upon the department to maintain equipment and periodically check calibration. Without these, extra errors will accumulate and be unpredictable. UoM arises from the physical limitations of these processes, not from their absence. Calibration checks must be recorded and should follow ICS guidelines of good practice[8].

6. References

[1] IQIPS Standard v2, 2020. UK Accreditation Service. https://www.ukas.com/download/iqips/IQIPS-Standard-v2-2020.pdf

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

[3] M3003 "The expression of uncertainty and confidence in measurement" 2019 United Kingdom accreditation service. M3003-Expression-of-Uncertainty-and-Confidence-in-Measurement-Edition-4-October-2019.pdf.

[4] Schafer W, Abrams P, Liao L, et al. Good urodynamic practices: uroflowmetry, filling cystometry, and pressure-flow studies. Neurourol Urodyn. 2002; 21:261–274.

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[8] Gammie A, Clarkson B, Constantinou C, et al. International Continence Society guidelines on urodynamic equipment performance. Neurourol Urodyn. 2014; 33:370–379.