



Big data: why ignorance is no longer acceptable

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Received: 16 April 2018 / Accepted: 9 May 2018 / Published online: 25 May 2018
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“Half of what you are taught in medical school will be wrong in 10 years’ time” is the famed quote from the then Dean of Harvard Medical School, Sydney Burwell.¹

What is big data?

Big data describes data volume, variety, and velocity; it refers to what we can find at our fingertips and may be used to create greater value. It includes structured data (such as databases), unstructured data (such as emails), and rich content such as video. The amount of data around organizations has become so large that it is sometimes difficult to extract meaningful insight. The development and integration of automatic data capture has become essential, therefore, to the effective operation of many of our services. The true power of this is the ability to separate data from its original source into a unified bespoke source of information, which can be interrogated and

mined according to needs, in this case, understanding health outcomes. It provides the opportunity to set up systems that transcend traditional borders and answer questions that the gold standard of a randomized controlled trial (RCT) simply cannot answer. An example in our field would include the effect of age on outcome for retropubic tapes [1], which requires a sample size of 7500.

Within health care there is increasing recognition of the need to have accurate and relevant information. This was explored by Porter and Teisberg in their book on value-based health care (VBHC) [2]. As a result of their initiative, the International Consortium for Health Outcomes Measurement (ICHOM) (<http://www.ichom.org/>) was founded. ICHOM has subsequently developed minimum data sets for >20 disease areas, including in partnership with the International Urogynecology Association (IUGA) for overactive bladder (OAB) [3]. The early adoption of these value-based health care (VBHC) principles in Sweden has already seen the establishment of >100 government-funded registries with the aim of moving toward the systematic collection of outcomes, which can be used to guide patient choice and support learning and quality improvement (<http://vbhcglobassessment.eiu.com/wp-content/uploads/sites/27/2016/09/Sweden.pdf>).

Current limitations to health care include an over-reliance on cost effectiveness and process measurements as being the most significant markers of quality. As such, where data does not reach the defined standard, it is viewed as if it simply does not exist; e.g., the current National Institute for Health and Clinical Excellence (NICE) guidance on stress urinary incontinence (SUI), where the low-cost strategy of using pessaries is not recommended due to lack of evidence rather than any suggestion of harm or lack of efficacy (<https://www.nice.org.uk/guidance/cg171>).

Likewise, preoperative urodynamics and surgery for SUI is not recommended, as cost effectiveness has not demonstrated any advantage. This illustrates the McNamara

¹ Quote from Sydney Burwell, former dean, Harvard Medical School

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fallacy [4], which says the measurable has become important and the richer and extended value is not understood. Larger data sets, in a non-randomized-controlled-trial (RCT) format, can provide valuable information and help inform decision making (https://en.wikipedia.org/wiki/McNamara_fallacy). However, enriching scientific knowledge using the principle of registry trials already exists [5] and allows return to the crucial point of defining the appropriate data set to make the important issues measurable rather than the other way around. Once established, these standard data sets (capturing outcomes that matter) can be used in routine clinical care, supporting day-to-day decision making and assessment of innovations. Finally, those same data sets can be used in trials, whether the traditional RCT or future registry trials.

We have begun to see the benefits of large data sets in other areas of medicine, such as nuchal thickness screening, where the initial interest around diagnosing trisomy 21 has been added to by the range of other conditions associated with the finding (https://en.wikipedia.org/wiki/Nuchal_scan). Such observations of rare conditions could have only been achieved with large amounts of data collected systematically into a unique data source: big data.

Within Urogynaecology, historically, the lack of data in conjunction with commercial pressure has been persuasive. The relative rate of mesh use was higher among lower-volume surgeons [6], resulting in the subsequent declaration that rare events perhaps were not so rare after all [7], yet individual surgeons could not identify initially with the issue, as it was simply sporadic in their experience. Several databases have now been established due to the work of Karl Tamussino and the Austrian transvaginal tape (TVT) registry (<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm142636.htm>), being perhaps the first to reach prominence. Reviewing these data now reveals complication rates that seem high. However, let us not forget that, at the time, these complication rates were hugely persuasive regarding how good this procedure was compared with the then gold standard of colposuspension. Since then, we have seen the emergence of the British Society of Urogynaecology (BSUG) database, the Danish Urogynaecological Database (DUGAbase), and moves toward an embryonic American database. Most recently was the launch of the IUGA database.

A major limitation of those databases are that they are designed to evaluate procedures and their outcomes rather than for decision making prior to the index surgery, which can only be achieved with a disease data set (<http://www.ichom.org/medical-conditions/overactive-bladder/>). As such, they cannot reliably be used to compare treatments due to the preselection treatment bias. Such data sets can, however, be used for some aspects of Phase 4 research [1].

Due to the introduction of commercial companies with engineering arms, pressure remains in fields where surgical innovation and technology moved faster than our ability to understand, assess, and assimilate implications and outcomes of these treatments. Therefore, the IUGA has proposed standardized outcome measures [8] to aid this process.

In the eyes of the law, ignorance is not a defense. Our challenge is how to harness the opportunity of big data in a meaningful way in whole populations rather than to focus on the processes used to treat them. As such, we need appropriate dialog as to what to measure and how to measure it reliably and consistently. With the advent of electronic patient records, we need to harness data capture early. These conversations should now become mandates, hospitals should have an outcomes unit, and managers and clinicians should work together to improve outcomes and assess them relative to the cost it takes to achieve them, with the aim of achieving the highest value: i.e., the best outcomes at the lowest cost. The challenge, it appears—according to Dean Burwell's theorem—is to know which half of the equation to believe. Achieving this aim on a large or mandatory scale will require technical (IT systems, etc.), cultural (within clinical teams and patient engagement), and financial (how to do this in a time of limited resources) changes. VBHC is a framework that enables us to work toward improving outcomes that matter to patients at the lowest possible cost; it will help ensure our health systems remain sustainable, progressive, and innovative and will continually improve.

The principle remains as stated by Hippocrates: *Primum non nocere*.

The IUGA database challenge: Enter all your data for the week of Monday, 1st October into the IUGA database. In 1 week, we will see the world of pelvic floor surgery through the eyes of the IUGA database.

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