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Patient-centred outcome metrology for healthcare decision-making

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Abstract. Valid and precise quantification of clinical variables is essential for appropriate interpretation to inform healthcare decision making. The outcomes produced from different measurement procedures and instruments, purporting to quantify the same measurand, should be directly comparable. This ensures the appropriate application and widespread adoption of clinical research findings. Metrology provides a framework for the development of a *common language* of reference measurement systems, which have the potential to improve the accuracy and comparability of patients' results. However, the practices, procedures and instruments used in social measurement are currently excluded from any formal metrological framework. In this paper, we build on previous arguments, and propose a new international body to bring together metrology, psychometrics, philosophy, and clinical management to support the global comparability and equivalence of measurement results in patient centred outcome measurement to improve healthcare.

1. Introduction

Previously, we put social measurement 'on trial', and provided two perspectives arguing why measurement in the social and in the physical sciences are incompatible and countered with two perspectives supporting compatibility [1]. We concluded that measurement, whether physical or social, should have the same definition (i.e., the ratio of two magnitudes of the same *thing* in which the denominator is the unit, providing for invariant comparisons) and the same broad goal (i.e., quantification of meaningful variables). The role of social measurement methods in high-stakes decision making for education, psychology, and health more generally, highlights the need for the field to advance. We offered a way forward potentially applicable to both physical and social measurement (see section 3 below). In this paper, we proffer potential next steps, focussing on the area of healthcare. We

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propose establishing a joint international effort aimed at delivering patient-centred outcome measures (PCOMs) in support of healthcare policy decision-making.

2. The quest for better healthcare

Patient experience affects patient safety, clinical effectiveness, allocation of funding [2], and is associated with: health outcomes; adherence to therapeutic regimens; preventative care; healthcare resources; quality of care delivery; and adverse events [3]. It is unsurprising, then, that patients who are more engaged in decision-making have better outcomes [4]. Therefore, decision makers within health systems increasingly rely on timely and relevant information about patient outcomes to improve policy and practice.

PCOMs are instruments (e.g., questionnaires, biometric equipment, wearables) that quantify patients' health, health-related quality of life and other latent health constructs, such as pain, mood, and function. They can also be used to quantify patient experience and satisfaction of healthcare, which play an increasingly central role in evidence-based medicine [5]. PCOMs have the potential to 'speak' to patients, carers and clinicians. Used alone, or in tandem with surrogate data (e.g., analysed in the laboratory), PCOMs offer the opportunity for more meaningful and interpretable measurement of patient outcomes. This helps to improve our understanding of the natural course of disease and guiding treatment decisions.

There is increasing interest in embedding PCOMs within health information systems [6]. It has been suggested that they have the potential to transform healthcare into a more patient-centred model [7]. In 2017, the Organisation for Economic Cooperation and Development (OECD) went so far as to claim that a specific type of PCOM (viz., patient reported outcome measures; PROMS) have a role in benchmarking the performance of whole healthcare systems [8]. The routine collection of PROMs has already been implemented internationally, including United Kingdom, Australia, United States of America, Sweden, Canada, and the Netherlands [8].

Thus, PCOMs have a potentially significant role in modern healthcare policy decision-making and evidence-informed practice. But are we able to deliver high-stakes measurement of this kind? Some suggest not. For example, it has recently been estimated that only 10% of existing PROMs have been developed based on patient-identified priorities [9]. In addition, reflecting upon the current OECD initiative, Angela Coulter suggests that using PCOMs for high stakes decision making may be premature [5]:

“Multi-purpose applications of [PCOMs] - using them in individual clinical care and aggregating the data for performance assessment - remains largely aspirational at present...”

Elizabeth Teisberg provides a potential reason as to why [10]:

“The quest for better health care, driven by measuring safety and quality, is well intentioned and has notable achievements. But like the Biblical story about building a better city, the measurement effort has become a cacophonous muddle that is distracting clinicians, raising the cost-of-care delivery, and not helping consumers make better health care choices...The lack of measurement standards [has resulted]...in contradictory conclusions...The problem isn't requiring measurement; health care needs meaningful measures...But...despite their vast number, the [existing] metrics don't measure the things that define health for patients and success for clinicians.”

The absence of standardization of PCOMs, and lack of recourse to formal metrological frameworks, can be ascribed to historical, ideological, and political differences [11]. But the deleterious sequelae of this situation is profound [12-14]. PCOMs are currently in a position not dissimilar to the measurement of temperature in the 17th Century [15]. As in other areas of clinical sciences [16], recourse to a metrological framework can help to provide a resolution.

3. The promise of the synthesis of metrology, psychometrics and philosophy

To ensure decision makers within health systems have access to the necessary objective evidence, we need the same kind of quality-assurance of PCOMs as is established in physics and engineering [17]. This translates into assurance with objective metrological comparability ('traceability') and declared measurement uncertainty. A possible way forward involves the synthesis of metrology, psychometrics and philosophy [1]. Essentially, evidence-based measurement for evidence-based clinical management would involve:

- extending traditional metrological concepts via an operational model of a specific measurement system, in which the output of the instrument (which could be human) in response to probing the object ('entity') is a *performance* metric, i.e., how well the set-up performs an assessment [17];
- exploiting the unique properties of Rasch Measurement Theory [18], which enables key metrological components (e.g., references for traceability and means of evaluating measurement uncertainty) to be established;
- establishing metrological references founded on objective and clinically meaningful measurement against the backdrop of the specific challenges of social measurement methods.

4. International co-operation, innovation and communication

In laboratory medicine, the standardization of measurements is a high priority, with the goal of comparability of results obtained using routine procedures [16, 19]. Recommendations of the IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes (TF-ICO) include: "Effective collaboration with clinicians, and a determination to accept patient outcome and patient experience as the primary measure of laboratory effectiveness." [14]. The benefits of this are clear. For example, the standardization of cholesterol testing in the evaluation of cardiovascular risk has led to savings in the region of 100 million USD/year in treatment costs with a parallel significant reduction of untreated "false-negative" individuals who are at increased risk [20].

But, international cooperation for developing reference measurement for PCOMs is in its infancy. Its aims could include traceability, comparability, and the inclusion (and possible reduction) of measurement uncertainty. This would require the consideration of five key components: 1) key stakeholder involvement (including patients, clinicians, caregivers, policy makers); 2) a clear definition of the measurand in regards to the intended clinical use [21]; 3) a clear definition of the clinically allowable error of measurements; 4) international cooperation and consensus to navigate the complexities of the development of metrologically sound reference measurement systems; and 5) continued clinical validation of newly calibrated instruments.

International cooperation would require the involvement of international metrology treaty organizations, professional societies and federations devoted to improving measurement quality in health sciences. One of its central functions would be an online database listing: reference materials; reference methods; and reference measurement services meeting appropriate international standards. This database would allow PCOM providers to select references for calibration traceability and provide support for suppliers of these services. In addition, it would be important to consider three key components to navigate the complexity of the scientific and political landscapes.

First, the development and evaluation of new PCOMs is time consuming and resource intensive. As such, we should move towards a non-competitive exercise where expertise and resources are pooled to avoid the development of multiple instruments for the same purpose, thus engendering wider reaching collaboration. Second, as our understanding of the etiology, sequelae, and natural history of many diseases expands, we should be open to innovative ways to capture impact and patient benefit. One size does not fit all, and the most appropriate fit-for-purpose instrumentation should be established early on (e.g., de novo instruments, adaptation of existing instruments, exploitation of information technology resources [e.g., computer adaptive testing], or mobile health technologies). Third, open communication is key to establish wider dissemination of important patient research, further avoiding the duplication of efforts, and involving a wider range of audiences. Ultimately, PCOMs will lead to

patient-based evidence and the realization of patient-centered care. Patients should always be involved as key stakeholders in the process of identifying and interpreting meaningful clinical outcomes that resonate with their experience, preferences, expectations and values.

5. Towards a common language for patient-centred outcome metrology

The comparability of findings among measurement procedures and instruments will result in harmonization; a *common language* to enable interchangeability geographically and temporally. However, as described above, the situation is complex. For example, as Angela Coulter [5] flags, different contexts will require different information needs. It is unlikely, that these needs are amenable to perfect alignment. But with several individual and separate global initiatives currently happening (e.g., ICHOM, COMET [22-25]) this will require more coherent coordination and alignment than is currently the case. There are two components to this situation.

First, universality is not an *a priori* fact of objective existence for some measured constructs. This is typically assumed for physical variables, but not for others, such as psychological and social variables. However, contrary to common assumptions, universality is not an inherent property, even in the domains of physical variables, apart from language and culture. ‘Things’ in themselves do not retain constant and invariant forms over time, space, and levels of information and organizational complexity. Instead, universality is a social construct that emerges as a product of a particular way of organizing experience. It arises via complex processes in which signal-noise ratios are lower than would be expected if physical variables were objectively constituted in and of themselves [26]. The counter-intuitive conundrum is that:

“In order for a statistical logistics to enhance precise decision making, it has to incorporate imprecision; in order to be universal, it has to carefully select its locales.” [26], p. 55

This kind of psychosocial stochastic resonance (interdependency of noise and signal) has been posited in other studies of scientific standards and universals [27], pp. 843-844; [28], pp. 69-71.

Second, the incorporation of standards in information infrastructures must be sensitive to the discontinuous shifts in context that occur across applications:

“With the rise of decentralized technologies used across wide geographical distance, both the need for common standards and the need for situated, tailorable and flexible technologies grow stronger. A lowest common denominator will not solve the demand for customized possibilities; neither will rigid standards resolve the issue.” [29], p.111

In relation to PCOMs, the general assumption is that common standards require common content; the same questions asked of every patient in every health care context and no matter what the individual patient's needs and conditions might be. The unworkable rigidity of this approach has prevented the development of information infrastructure standards in health care that would be of great value in patient care, quality improvement initiatives, and accountability. With the increasing availability of computerized adaptive administrations of PCOM items from calibrated banks [30], this lowest common denominator approach is being supplanted by methods better able to meet the demand for customized information relevant to the needs of individual patients.

But this shift from *fixed forms* to dynamically configured PCOMs is insufficient for the need of a health care information infrastructure integrating local sensitivities with universal standards across applications. In the same way public health has adopted an ecological frame of reference distinguishing micro-, meso-, and macro-levels of complexity in its policy and practice implications [31], so too, must PCOMs be used to similarly attend to the relational properties obtained in applications requiring different forms of information and organization [29]. For example, spanning the gulf of complexity from individual interpretation of PCOMs (micro-), aggregating outcomes for quality improvement purposes (meso-), and producing theories of health status and the impact of care (macro-). Each level demands a learning and subsequent relearning about patients' health status.

In other words, denotative statements of fact at the local, individual level (e.g., “your PCOM

indicates your health is good”) are not automatically commensurable with metalinguistic statements (e.g., “your patients’ PCOM survey results indicate your care is producing satisfactory outcomes relative to the outcomes obtained by your peers”) and neither are automatically commensurable with metacommunicative statements (e.g., “if I adopt that new treatment modality perhaps my patients’ PCOMs will be superior to my colleagues’ PCOMs”). An individual’s array of clinical indicators and responses to a health status survey may correspond well with expectations formed regarding the natural history of a chronic disease or the developmental effects of aging and growth. The information relevant and applicable at that level, however, is not the same as the information needed at the metalinguistic or metacommunicative levels.

The consequences of not attending to the specific demands that must be met to coordinate common standards for expressing the information needed across these levels is well stated by Star and Ruhleder:

“If we, in large-scale information systems implementation, design messaging systems blind to the discontinuous nature of the different levels of context, we end up with organizations which are split and confused, systems which are unused or circumvented, and a set of circumstances of our own creation which more deeply impress disparities on the organizational landscape.” [29], p. 118

Suggestions for coherently coordinating information across these levels are offered elsewhere [32, 33]. But, in the end, a common language for patient-centered outcome metrology would significantly contribute to improvements in patient-centered care by allowing results of clinical studies undertaken in different locations or times to be universally applied. The ‘semantic interoperability’ has to be good i.e. the “the ability to ensure that the precise meaning of exchanged information is unambiguously interpretable by any other system, service or user”, where we borrow the term from the context of digital solutions that enable public administrations, businesses and citizens to benefit from interoperable cross-border and cross-sector public services [34]. It would also support an effective application of evidence-based medicine and use of guidelines (established by scientific or professional bodies) to define specific decision limits for diagnosis and therapeutic interventions.

Thus, a joint international effort aimed at delivering PCOMs in support of modern healthcare policy decision-making could lead to the appropriate embedding of PCOMs in health systems. This would allow us to evaluate the effectiveness and cost-effectiveness of major policy initiatives, to identify conditions or interventions where substantial variation in patient outcome exists across providers, and improve the choice of treatment plans for individual patients.

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