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Patient Reported Outcome Measures in Routine Clinical Care: The PROMise of a Better Future?

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Most healthcare providers treat patients with the goal of improving patients' health based on biochemical, histological, radiological and clinical assessments. From the patient's perspective, treatment should be based on symptomatology and focus on the experience of the patient in order to better refine interventions. Such data are best gathered from patients rather than from the laboratory or the imaging suite [1]. In contrast, the usual endpoints measured in clinical trials are the relatively uncommon outcomes of death, infection, or readmission [1]. Moreover, some symptoms reported by patients may be undetected or underestimated by clinicians [2] and some conditions may fail to manifest with clinical or biochemical abnormalities, complicating clinical assessment.

Patient-reported outcome measures (PROMs) are patient-completed tools that assess the patients' perception of their disease severity, quality-of-life or wellbeing or a combination of these. Since PROMs were initially developed for research use, many regulatory authorities advocate their use[3 4]. As more proactive clinicians recognised their benefit to clinical management, PROMs have gained additional use in routine clinical practice[5]. The medical profession is now increasingly recognising that as well as measuring clinical outcomes, it is also important to measure PROMs as part of patient assessment. Consequentially, an increase in the development, validation, and use of PROMs has occurred. The King's Fund report reflects on this as "a growing recognition throughout the world that the patient's perspective is highly relevant to efforts to improve the quality and effectiveness of health care" and that PROMs are likely to become "a key part of how all health care is funded, provided and managed"[1]. In 2009, the U.K. Government implemented the routine collection of PROMs in England for four routine elective surgical procedures- hip and knee replacement, groin hernia repair and varicose vein surgery (http://content.digital.nhs.uk/proms) in order to compare performance. It is likely that this will be extended to more conditions in the future.

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In order to provide meaningful information, PROMs need to be appropriately developed and validated according to robust criteria [6]. PROMs are normally used to examine the impact a disease state has on a patient's emotional, physical, social, functional, and family wellbeing. As the population ages, there are increasing numbers of patients living with the consequences of diseases and their treatment. It is therefore becoming more important to assess the impact of the disease from the patient perspective and to evaluate how a disease affects the patient at any juncture, enabling better-targeted treatment and care.

Although the benefit of using PROMs as part of routine clinical care is apparent, there are practical challenges that may limit its widespread integration into clinical practice. The first of these relates to the most appropriate tool to apply to the patient population. Although a plethora of PROMs exist for many conditions, many PROMs: are not robustly validated; may have limited generalisability; may not be sensitive enough to detect changes in a patient's condition; are long and require excessive time to complete; use terms that are difficult to understand for patients; or have detailed scoring systems complicating application to short clinical consultation. Furthermore, collecting this information also presupposes that the patients can complete the tools. This may not always be possible because the patient may be elderly and frail, have limited mental capacity or intellectual understanding, may not speak the language in which the tool was developed, or may simply be too sick to be able to complete the tool.

The King's Fund report that there are also challenges in relation to the assessment of chronic conditions in clinical practice [1]. When PROMS are used following elective procedures, it is likely that a change of condition (i.e. an improvement or deterioration) will be detected rather easily following the intervention. Contrariwise, for long-term conditions, PROMS assessment may be complicated by the

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lack of specific intervention and symptom heterogeneity and unpredictability in terms of a waxing and waning. The authors state that "measurement of PROMs therefore becomes, in a sense, a continuous process of recording trends in patients' assessments of their health-related quality of life and one where, even with the best management and intervention, 'no change' might be the best that can be expected"[1].

In this issue of *Digestive Diseases and Sciences*, Koloski and co-authors [7] report on the development and validation of a new PROM - the Gastrointestinal Symptoms Scale (SAGIS) which they hope can be used routinely to support the standardised clinical assessment of patient symptoms with a wide range of gastrointestinal conditions. The authors justify the need for this tool particularly with gastrointestinal patients due to the range of patient symptoms, the potential for bias in the clinical assessment and the time required to collect this information during the clinical consultation. By gathering more focused patient-related information using the SAGIS, the authors believe that care can be better targeted.

The authors have undertaken a large and robust validation in 1120 patients with various gastrointestinal conditions that included reliability, construct and discriminant validity, and utility in a routine clinical setting. Exploratory and confirmatory factor analysis identified five components, comprising 22 questions. The tool could differentiate between different disease groups, was reliable over time, and had good utility in clinical practice, reducing clinical assessment time by 38%.

Although the SAGIS was developed and rigorously evaluated as far as was feasible in this study, the authors recognise that further work is required to validate the tool such as validation in other centres and environments such as primary care, in different treatment facilities, and in other populations such as the pediatric population. They also recognise the need for clinical training in its use before applying it

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in practice. The authors have therefore gone some way to address some of the common issues with applying PROMs in practice: they have produced a short questionnaire that is sensitive enough to be applied across a broad range of gastrointestinal conditions, they have demonstrated a robust validation, and they have demonstrated the clinical utility of the tool which reduced consultation times. It is hoped that their proposed further work, including clinical training, will result in a practical tool that can be applied to and calculated in the clinical setting. Further work is still needed to evaluate the applicability of the tool in the long-term management of patients in clinical practice, what constitutes a clinically important difference for different gastrointestinal conditions and whether the tool can be routinely implemented within a busy clinical environment.

In summary, the use of PROMs now seems to be extending from the research to routine clinical application. The shift in the balance of patient assessment from purely clinical to a more integrated approach is laudable. Although many challenges remain that limit the applicability of PROMS assessment to clinical practice, alternative approaches to overcome some of these challenges are being tested. For example, the implementation of online or Web-based platforms to collect routine PROM data to feed into and supplement the clinical assessments may be one way forward. In a recently published trial in patients receiving cancer treatment, patients who submitted PROM data through a Web-based platform had better survival outcomes when compared with patients who did not submit PROM data. The authors inferred that the routine integration of PROMs data into routine clinical care for these patients was therefore beneficial to patient survival [8]. Other research has focused on the development of proxy PROM scores, which would overcome some of the difficulties associated with the patient's ability to complete the tool[6 9].

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It is clear that as most treatment is based on symptomatology, more input is needed from the patient in order to better manage and target treatment and to monitor outcomes. Certainly, the will and determination are there for those who see the benefit to patients. Bojic et al [10] have commented that "to find a place in routine clinical practice, PROMs should be easy to use, acceptable to patients and healthcare teams, and be able to demonstrate added value to normal practice, supporting decision making at the level of individual patients"[10]. They also recommend that ideally the same PROM should be used in clinical practice and trials to avoid the current disconnect when interpreting the results of clinical trials and translating them into routine clinical practice [10]. Koloski et al [7] have gone some way towards achieving this goal and their SAGIS tool shows initial promise. Nevertheless, it remains to be seen whether the challenges associated with routine PROM collection can be overcome in order to allow the successful integration of the SAGIS into clinical practice so as to better manage patients with gastrointestinal disorders.

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