

The Role of Patient Reported Outcomes (PROs) in Healthcare Policy Making

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ABSTRACT

Patients are the most valuable and authoritative source of information on outcomes like health-related quality of life, functional status, symptom and symptom burden and health behaviors. However, even traditionally, the only information collected from patients was feedback on satisfaction or experience with care. Patients have always remained an untapped resource in assessing the quality of healthcare and of long-term support services. The scenario has however changed with the increasing realization of Patient-Reported Outcome Measures (PROMs) as an efficient quality improvement tool. Routine collection of patient-reported outcomes (PROs) to inform, compare and manage healthcare professionals and facilities are implemented in a number of countries, including England, Australia, United States of America, Sweden, and the Netherlands. This review article discusses examples of PROMs in routine practice in some countries to illustrate the importance of building capacity and infrastructure to capture PRO routinely and utilize that data for developing performance measures for assessing provider's quality and efficiency. Also, discussed are the barriers to implementation of PROMs and factors responsible for its minimal influence on patient outcomes and ineffectiveness in comparing hospital performance. Finally lesson for health care policy makers especially Indian health care policy makers for successful implementation of PROMs are summarized.

Key words: Patient Reported Outcomes, PROs, Patient Reported Outcome Measures, PROMs, Healthcare Policy.

SUMMARY

- PROMs can assist clinicians to provide better patient centered care, that will have positive implications on healthcare policy making.
- PROMs can improve patient-clinician communication.
- The concept should be encouraged in India, which is a hub of clinical trials.

Abbreviations used: PROMs: Patient Reported Outcomes Measures, EHR: Electronic Health Record, PRO: Patient Reported Outcome.

AUTHOR PROFILE



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INTRODUCTION

In the disease-centered model of conventional medicine much of clinical care is directed at making patients “feel better”. In contrast the bio-psycho-social approach focuses on improving the biological aspects with psychological and social considerations. The disease-centered model has therefore been subject to wide criticisms since the sixties and emphasis has been on wider uptake of the bio-psycho-social approach to improve quality of care.^{1,2}

The “patient-centered” approach was developed by the American psychiatrist G. Engel who claimed that patients should be active participants in their care or simply put become experts of their experience of disease (illness). In the eighties, the patient-centered model was introduced for the first time but relegated as a “soft” model for a small group of fans.¹

Accordingly its use was restricted to research that culminated in some regulatory bodies mandating their use.³ Subsequently clinicians began to perceive the added value of using reports on patient's functioning and

well being in conjunction with other clinical information (e.g., lab tests, imaging studies and clinic notes) in patient management. Patient reported outcome measures (PROMs) thus became quite popular with some clinicians as a useful tool to enhance clinical management of individual patients. Role of PROMs later expanded from facilitating patient-clinician communication to evaluating the quality of healthcare services.³

The scenario today is different with PROMs receiving support of leading clinicians and encouragement of politicians as a tool to assess and compare the outcomes achieved by healthcare providers.³ Although some doctors still question their use, it is widely accepted that PROMs can drive changes in the organization and delivery of healthcare. Success of this endeavour lies in linking doctor's use of PROMs in the treatment of their patients with collection and aggregation of data for assessing and comparing the performance of providers. This step is essential to stimulate improvements in services and thereby realize the full potential of PROMs.³

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THE POLICY LANDSCAPE

Health policy in the United Kingdom (UK) and other countries have long ago prioritized patient empowerment and patient evaluation of health care.⁴

The Coalition Government in the UK took several initiatives to empower patients. These strategies aimed at:⁴

- Giving patients more choice and control over their healthcare.
- Making hospital funding contingent upon performance against a range of quality measures including PROMs.

In the United States (US) implementation of the electronic health record (EHR) was supported by the 2010 Patient Protection and Affordable Care Act. This act also mandated clinical care and clinical research to incorporate patient's perspective following the 2009 guidance issued by the Food and Drug Administration (FDA) on necessary criteria for using patient reported outcomes (PROs) to support claims for medical product labelling.⁵

Further the Congress in 2009 prioritized, comparative effectiveness research (CER) and requested for sharing of funds by the Agency for Healthcare Research and Quality, National Institutes of Health, and U.S. Department of Health and Human Services to support the same. This step was taken on realizing the limited empirical information medical providers and patients had for comparison of benefits of different treatments so as to inform clinical decisions. The sacrosanct process of informed decision was further hampered by scant data on treatment efficacy, side effects and adverse events for different subgroups of patients (e.g., sex, race, age, medical co-morbidities). Moreover, from a national economic perspective it was realized that in comparison to other industrialized countries the nation's medical care expenditures were astronomically high. These facts provided the necessary impetus to re-examine the effectiveness of health policy approaches in the US. The developments converged to create a strong interest in patient-monitoring tools in clinical care.⁵

Countries where PROMs has been implemented in routine practice

Although the concept of PROMs has been well accepted, surprisingly its widespread use is still uncommon. Till date the use of PROMs is restricted to England, Sweden and parts of the US. The medical profession in Sweden and the US encouraged the use of PROMs to enhance clinical care of individual patients. In England, the government has been the driving force in their attempt to make accessible to the public, comparisons of provider's performance.³

PROMs was implemented in Sweden since 1975 on a nationwide basis with the support of the disease specific clinical databases (quality registers) established by the medical profession. In the US however use of PROM was more restricted for e.g., in northern New England for spinal conditions only, in Pittsburgh for primary care and in Minnesota for depression. The only area where PROMs was adopted on a nationwide basis was in the comparison of health plan that purchased care for those over 65 years of age (Medicare). In 2015 the Federal government expanded the role of PROMs to include reimbursement mechanisms for accountable care organisations (health maintenance organisations with a focus on outcome measurement) so as to enable level of reimbursement to reflect the value that patient's ascribe to the outcome of their treatment.³

The first nationwide application of PROMs in England was in the year 2008, as a voluntary audit of mastectomy and breast reconstruction. This was followed in 2009 by a mandatory audit of all providers of hip and knee replacement, groin hernia repair and varicose vein surgery. Although the principal use of PROM in England so far has been for elective surgery in future procedures for e.g. coronary revascularisation would

be added and the feasibility of extending to long term conditions, cancer survivors and people with dementia are being explored. There are currently 50 established national clinical audits in England thus paving the path for opportunities for wider use of PROMs.³

The implementation of PROMs in routine primary and secondary care in Sweden, US and England was developed by experienced, practising physicians. Although the system differed in design, the objective was the same. In all the three countries it was demonstrated that PROMs had the potential to narrow the gap between the clinician's and patient's view of clinical reality thereby permitting treatment plans to be tailored so as to meet patient's preference and needs.⁴

Examples of PROMs in routine practice in Sweden, US and England as described below argue for it wider uptake to improve quality of care.⁶

Swedish rheumatology quality registry

Established in 1995, the Swedish rheumatology quality registry contains data on over 66000 patients, about 85% of people in Sweden with rheumatoid arthritis. Each patient is provided with a personal identifier to access the registry and input information into a user friendly "dashboard" on both disease specific and general measures of function and health. The patient reported outcome measures enables clinicians to provide more appropriate and patient centred care. The system displays trends and is also useful in guiding treatment, sharing decision making and self-management. Patient benefit the most by this engagement as they feel empowered and confident in managing and controlling their condition.⁶

The improved confidence translates into better clinical response. Comparison of clinical outcome measures between patients in a region (Gävle County) implementing routine use of PROMs to those where structured communication with doctors was not necessarily part of routine care revealed better response on implementing PROMs. It was clearly evident that the disease activity as measured by C reactive protein decreased after patients started measuring, reporting and sharing responsibility for the management of their condition with their physician.⁶

Although not done so far, the registry data can be aggregated to examine population health, improve quality of care and provide transparent public reports on patient outcomes at the county level.⁶

US primary care model: HowsYourHealth.org

The Hows Your Health system was developed in 1994 and disseminated on the internet since 1999 at no cost to primary care practices. Patient entered data from home or within the doctor's office by ticking in boxes in response to questions on their function, diagnosis, symptoms, health habits, preventive needs, capacity to self-manage chronic conditions, and their experiences of care. The system also provided a summary of all patient data (with national benchmarks) and a secure registry to target interventions at groups of patients with similar needs (such as those with diabetes, emotional problems, or low confidence to self-manage health problems). The system has been endorsed by several medical specialty organisations and used by hundreds of practices in the US and Canada. Plans are now underway to increase its usage in Iowa, Massachusetts and British Columbia.⁶

In two controlled trials involving primary care physician it was found that Hows YourHealth tool brought to light important concerns that the physicians were unaware about. In the first trial involving 45 primary care physicians and 1651 patients aged ≥ 70 years it was observed that the tool significantly improved patient ratings of overall care quality, their understanding of important risks (such as falls and advance planning of care) and also supported them with their daily activities, emotional issues and social support. The second trial on 47 primary care physicians and 644 adults with pain and emotional problems noted sustained improvement on combined use of the tool with a problem solving intervention sup-

ported by a nurse educator.⁶

Yet another successful example in the US is that of the Improve Care Now network that uses patient reported outcome and clinical data to improve results in children with inflammatory bowel disease. This system was established in 2007 and is currently used by over 60 practices in the US. Results reported with this network are encouraging i.e. remission rates have improved from 55% to 77% for 17000 patients, in 30 states.⁶

National PROMs programme in England for elective surgery

In England, from April 2009, all providers NHS hospitals, independent sector treatment centres, private hospitals treating NHS patients for any of four elective procedures i.e. hip or knee replacement, groin hernia repair, or varicose vein surgery had to compulsorily participate in the national PROMs programme that required all these patients to complete a pre and post-operative questionnaire. The preoperative questionnaire collected data on the patient's socio demographic characteristics, duration of condition, general health, comorbidities, history of a repeat/ revision procedure and the disease specific and generic PROMs. The postoperative questionnaire included all questions of the preoperative questionnaire and additionally the overall view of results of surgery, extent of improvement if any and reports on adverse outcomes (complications, readmission, and further surgery). With the help of this report providers were identified and compared to show whether or not any provider's outcome was significantly different from what would be expected.³ Results were publicly reported online at the NHS Trust level.⁸

Potential of PROs for Improving Clinical Care

PROs can play several roles in clinical care of the patient, viz.:⁵

- Provide clinical information for medical decision-making,
- Identify patient's areas of concern that may be unrecognized by the provider,
- Contribute information for pre-planning of visits by the patient care team,
- Assist clinicians in monitoring patient status longitudinally and
- Provide an important source of information about treatment response.

As PROs results in greater engagement of patients in health care, shared decision-making and patient-centered care they are highly relevant in the care of chronic diseases. Success of care in chronic diseases is highly dependent on sustained and active patient involvement in daily disease management.

New Roles for PROs

The scope of clinical outcomes evaluated in trials gets expanded by increasing focus on CER and patients dialogue. In a typical scenario during clinical studies the health providers focuses primarily on biological outcomes such as laboratory tests and imaging results. The patients however give more importance to additional outcomes such as fatigue, sleep quality, ability to engage in valued activities and depression. These health experiences provide opportunities for understanding treatment effects that extend beyond conventional clinical research activity. This can only be achieved if they are measured accurately through patient self-reports and used in conjunction with biological clinical data. Additionally if PRO measures can be calibrated to a common metric the data may be aggregated across practitioners and clinical sites to enable repurposing of the EHR and PROs data for CER.⁵

Barriers in implementation of PROM

Research has revealed many technical, social, cultural, legal and logistic barriers to successful use of PROMs. Clinicians are often reluctant to use PROMs routinely due to several practical issues such as complicated

PRO collection method, rushed assessments in the waiting room or lack of time during the medical visit. They fear that this system would simply add to their work load rather than making it more effective and efficient. There also exist a category of clinicians who spend time talking to patients and claim to understand patient's problems with no need for additional information from them. Although patients generally welcome systems that routinely use PROMs at times they do feel burdened. It is thus essential to use the system well, focus on factors of value to the clinician and prevent misdirecting the focus of the clinical encounter. The system must also ensure that the privacy of the patient is maintained.³

Challenges in successful implementation

Systematic reviews examining the impact of feeding back PROMs data to clinicians surprisingly demonstrate that although PROMs can improve patient-clinician communication and the processes of care for individual patients it has minimal influence on patient outcomes and are ineffective in comparing hospital performance. In 2013, the evaluation of the English PROMs Programme that compared NHS Trust performance for four common surgical procedures, revealed the Programme to have little impact on patient outcomes. Five reasons or themes have been identified for these findings.⁸

Under the practical theme it was identified resources allocated to implement PROMs are inadequate. Collecting PROMs data takes people away from other activities and therefore additional staff time needs to be resourced to render this process feasible. Careful planning is essential so as to prioritize collection of PROMs data over existing activities. Additionally, high level of collaboration among colleagues and proactive managerial input is essential. Education and training for professionals and access to appropriate technology to process the information in the most efficient manner is also needed for successful implementation of PROMs in practice.⁸

The attitudinal theme captures suspicion among healthcare professionals about the motives in adopting PROMs. In this case healthcare professionals also includes nurses, allied health professionals and medical staff. In the absence of transparency of the purpose of PROMs collection professionals question the motives for the data collection and fear adverse effects on their practice and patient care. Some clinicians are apprehensive of PROMs being utilized as an audit tool by the management to monitor performance, or even worse to "name and shame" professionals. Finally there exists a group of clinician who are unwilling to receive any feedback from patients.⁸

The methodological theme is an extension of the attitudinal theme into specific scientific concerns frequently asked by the professionals on the measurement properties of PROMs, the extent to which data collection is carried out to a high degree of quality, and the extent to which clinicians or facilities are fairly compared.⁸

The impact theme captures a frustration with the value of PROMs in identifying and implementing opportunities for quality improvement. It is believed that the attention given to modelling the causal mechanisms leading some healthcare professionals to perform better than others on comparing PROMs data is inadequate.⁸

A fifth theme i.e. the conceptual issues reveals difficulties among professionals in comprehending the nature of subjective measurement, confusing PROMs with patient satisfaction measures and incorrectly associating PROMs with clinical data.⁸

Improvement in PROMs as quality improvement tools - lessons for policy makers

Most of the policy makers assume that healthcare providers can find staff and materials to collect PROMs data. The presumption that healthcare providers can "just get on with it" using their own resources is wrong.⁸

Professionals must be provided with necessary training and greater practical and methodological support to ensure better collection and interpretation of PROMs data.⁸ During design of quality improvement programmes using PROMs data it must be ensured that healthcare professionals, such as nurses, physicians, pharmacists and allied health professionals are engaged at a much deeper level.⁸ Reason or concerns cited by the professionals for not implementing or using PROMs must not be simply dismissed as being “old-fashioned” or “disrespectful of patients.”⁸ More focus is needed on inter-provider comparisons so as to achieve improvements in the care of whole patient groups (e.g., all patients undergoing hip replacement surgery within a hospital system).⁸ A study of hospital level variation in PROMs for patients undergoing hip replacement, knee replacement, groin hernia repair or varicose vein surgery found “little inter-provider variation” which “did not change significantly over time”. In such cases it might be useful to change the focus on other aspects of care. Explanation for variation in outcomes can be explained by paying attention to patient characteristics, type of treatment, or type of provider.⁹

Lastly it is essential to have PROMs that are fit for purpose. PROMs that are employed as diagnostic tools for poor clinical performance require evidence on their sensitivity and specificity in this context. These tools need to be validated against “gold standard” measures of performance. Unfortunately this evidence is unavailable for most of the PROMs currently being used.¹⁰

Policy makers therefore need to ensure development of PROMs possessing strong track record of detecting providers known to have quality failings. Until such PROMs are made available, one must circumspect about league tables or other output that purport to discriminate among providers.⁸

Indian Scenario

The physicians in India depend on disease-related outcome measures to support their clinical decisions with minimal importance to PROMs. This practice is being followed despite the average Indian patient becoming more knowledgeable with regards to his/her health, disease and

treatment options. A similar attitude is observed even in clinical studies wherein PROs, if used, are only secondary to disease-related outcomes.¹¹ The concept of patient-centered outcome researches (PCORs) has yet to catch up in India. The role of PROs in clinical studies for determination of patient eligibility and compliance, as a study endpoint, determination of health-related quality of life (HRQoL), and assessing economic burden and indirect impact of disease and treatment is significant.¹¹ Including PROs assessment in clinical trials can enable determination of side effects of therapy, comparison of two standard therapies with similar survival outcomes and identifying whether a therapeutic regimen is better than supportive care when the survival time is short. Data obtained from PROs in clinical trials can be useful in making health-related decisions at all levels in India.¹¹

CONCLUSION

It is widely accepted that PROs expands the focus of clinical encounters to include additional health experiences of importance to the patient. PROMs can therefore assist clinicians to provide better and more patient centred care by monitoring patient status and treatment outcomes longitudinally. It has also been purported that PROMs can enable assessment and comparison of the quality of providers and provide data for evaluating practices and policies. However systemic review of studies have revealed that while PROMS can improve patient-clinician communication it has minimal influence on patient outcomes and are ineffective in comparing hospital performance. Policy makers must take cognizance of these findings and work toward development of PROMs possessing strong track record of detecting providers known to have quality failings. More studies are also needed to investigate the best methods for using PROs in clinical care and to evaluate their impact on patient outcomes. In India, a country with a strong and widespread generic market it is highly recommended to make PRO implementation in clinical trials mandatory for pharmaceutical companies to prove their label claims. Besides data obtained from PROs in clinical trials should serve as the source document for all health-related decisions in India.

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