

GUEST EDITORIAL

Person-centered clinical practice guidelines

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Introduction

Good clinical practice guidelines (CPGs) can make space for clinicians to focus on the individual patient in front of them and to be prepared with an estimate of guidance with which to weigh their patient's individual care. They ought to be person-centered, patient co-designed and include pathways for shared decision-making. Collaborative development and research design with patients as partners in healthcare is endorsed and advised by funders, reported as beneficial and yet it is minimally reported for CPGs. These guidelines are used by clinicians everywhere to identify optimal process, save time and increase knowledge. Co-designing person-centered CPGs with patients contributes to health literacy, policy values, end user integration and clinical relevance.

The concept of physician information sharing precedes Hippocrates and yet this culture did not include information pooling with patients, informed shared decision-making, or self-managing health. Indeed, "Hippocratic physicians declared that they were not primarily the agents of their patients, performing services at their request. Instead, they were practitioners of a scientific art of careful diagnosis and indicated treatments, with knowledge of medicine but not without technical limitations." Person-informed decision-making was adopted by educated Greeks [1] who practised collaborative decision-making where the course of disease was explained to the person by the doctor, followed by the doctor and patient deciding on the best intervention. It was built on relationship and a foundation of trust rather than joint information pooling [2]. The tensions appear constant over centuries: Elwyn *et al.* [3] reported "Experienced GPs with educational roles have positive attitudes to the involvement of patients in decisions, [provided] the process matches the role individuals [wish to play]."

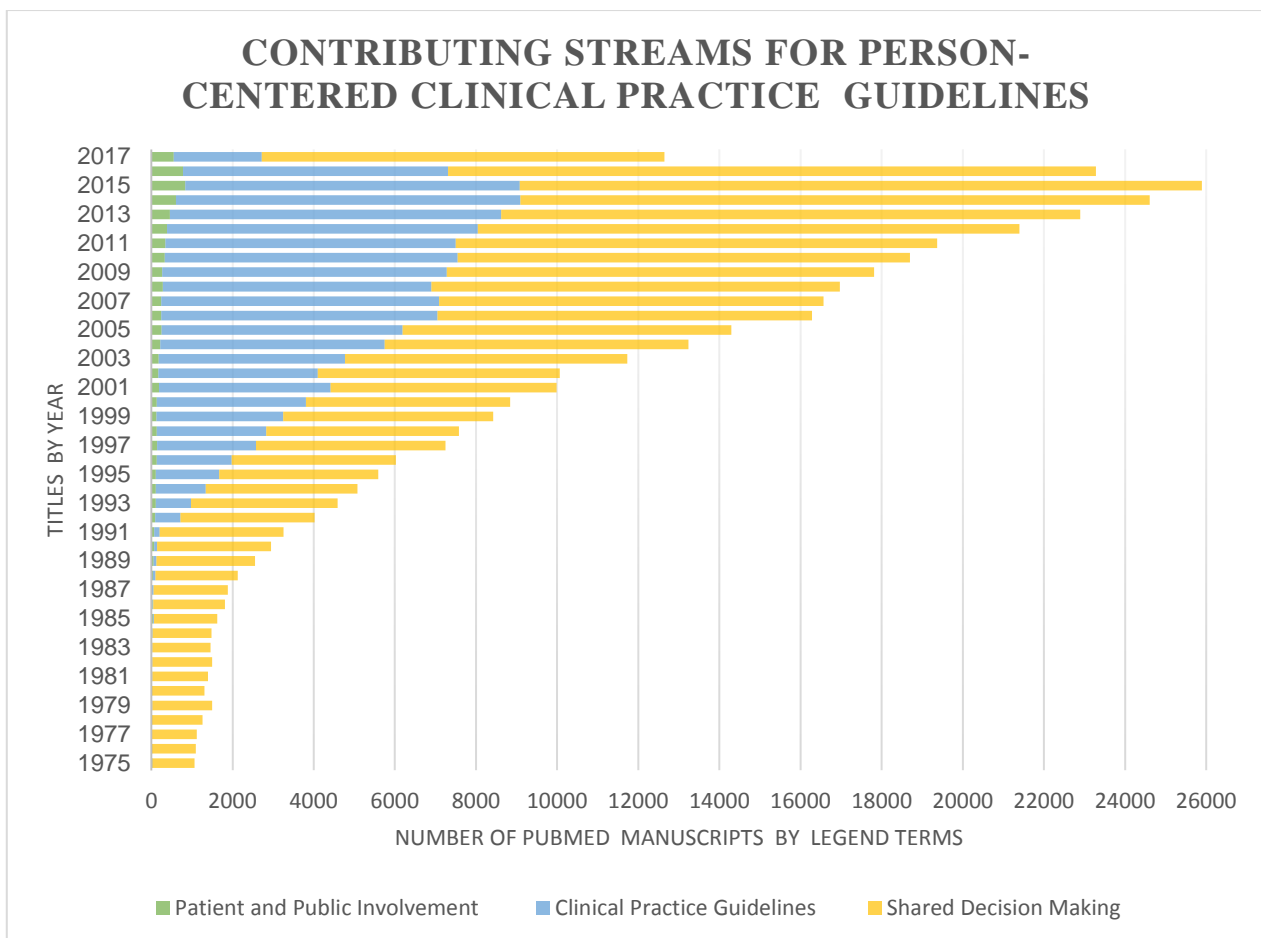
Progress to date

The first paper on CPGs to appear in PubMed was written in 1966. In 1990, the standard definition for clinical practice guidelines adopted by the Institute of Medicine (IOM), contributed by Field and Lohr, described CPGs as "systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances" [4]. Patients were not to make significant appearances on the policymaking scene or as research partners in roles other than as objects, narratives or experience stories until 2001. At this time, a paper by Elwyn *et al.* [3] found no specifically designed instruments to measure the concept of 'involving patients' in medical decision-making. In a systematic review by the same authors, the lack of consensus for what to name patient involvement, shared decision-making or clinical practice guidance containing patient collaboration, was cited as a specific barrier. In 2017, this barrier remains in other research domains as well according to an overview of public involvement in research design by Price *et al.* [5] and The PIRICOM Study [6] which was a systematic review of the concepts, measurement, impact and outcomes of patients and public involvement in health and social care research. A Cochrane systematic review by Nilsen *et al.* includes research involvement and lack of reporting quality as it pertains to implications for policy [7].

What we fail to name remains unreported

The questions asked then, as now, are "How can we report what we fail to name?" and "How can we measure the

Figure 1 PubMed number of citations by year for Patient and Public Involvement, Clinical Practice Guidelines and Shared Decision-Making



value of what is not included or remains unidentified?” To make the discussion more visible a search of titles was completed in PubMed from inception to the present according to entries catalogued as shared decision-making (n=256,055), clinical practice guidelines (n=125,626) and public and patient involvement (n=7980), total (n=389,661). The spread of publications can be seen in Figure 1. It appears that out of 389,661 papers and a considerable outlay of public monies, no contenders were found to provide consensus for naming or agreed reporting terms and yet all purport to at least name these terms in their titles and abstracts. What we fail to name we do not address, evaluate or replicate.

More research needed.

Jurisprudence or another road to obscurity

Some will argue the present fields are emergent and it takes “time” and “more research is needed”. A reasonable question to ask would be how many more research papers than (n = 389,661) will it take before the investment expended is classified as research waste [8,9]? At the

current rate health research outstrips medical school learning and becomes outdated during the lifetime of clinical practice [10]. Involvement and consultation have been regarded as two ends of a spectrum according to Vahdat *et al.* [11] who posit that decisions associated with health services affect patients’ lives and thus patient participation in health affairs is their medical right as a healthcare citizen. These researchers observe that co-design in health can symbolize equity and responsiveness across a healthcare system [11]. This is where the public and patients can help, given that they are potential experts on their own conditions which is a narrow, but important, window where contributing to the chain to keep best research knowledge current is vital. Citizens can contribute to reducing workload and they can learn competencies for engagement in the complex informed shared decision-making development required for health science research and in particular CPG development. If we are serious about integrating evidence into practice, it would seem reasonable to work within these self-limiting timeframes.

Barriers to Implementation

A systematic review by Mickan *et al.* [12] concerning patterns of ‘leakage’ in the utilization of clinical guidelines mentions patient values and needs as an influence for guideline adherence. The failure to do so is seen in the review as a barrier; however, the recommendations to overcome these barriers involve providing information to the patient rather than involving them in the design and decision-making process [12]. For example, the guidance suggests providing patients with information about the given condition, treatment, side-effects, contraindications and risks and suggests managing clinical environments through the development of special purpose clinics. The authors recommend displaying patient education materials and investing in reminder systems to increase adherence [12]. This gap in active patient involvement may be the result of long-term guideline development over many years that was entered into without space being protected for the input of patients.

This concern was reinforced in “AGREE II assessments of recent acne treatment guidelines: how well do they reveal trustworthiness as defined by the Institute of Medicine (IOM) criteria?” and in which the authors stated that a recent paper by Eady *et al.* [13] “Acne treatment guidelines published since 2013 were deficient in several key areas, even those developed using the AGREE II Instrument and that they universally lacked adequate stakeholder involvement, transparency and methodological rigor.” They go on to state that the guideline development group (GDG) for the US guideline had a single patient representative. This was even more astonishing given that one qualification requirement to serve as a GDG member was a dermatology practice of 5000+ active patients. From this potential pool of thousands of patients, only one was selected as a stakeholder, the remaining GDGs reported no patients as stakeholders.

To be person-centered, a clinical guideline must be ‘fit for purpose’ within the humanity and complexity of a clinical encounter. Elwyn *et al.* [14] suggest the knowledge needs to be fast and frugal to be usable and they suggest outcomes of importance to the encounter. These include flexible format and accessible content, direct relevance to the visit, a place for clinicians to share uncertainties that patients would want to know about and the opportunity to present and discuss alternatives. To be usable the guideline becomes a servant to the clinician and the patient, it builds a bridge without distracting from the relationship.

Power imbalances [15] and the inability for non-researchers to express their contributions in ways so as to promote implementation [16] are significant barriers to influence within other areas of healthcare. However, in the case of CPGs non-researchers have received few invitations to sit at the table and may not yet be involved in negotiating terms.

Person-centered CPGs - a meaningful contribution

Miles [17,18] calls us to reflect on the power of person-centered healthcare, where the patient is a person first and not a statistic to be managed. The bridge between individual and population approaches in clinical practice guidelines could be strengthened and made effective immediately by inviting patients as co-designers and collaborators whether in guideline updates or for the initial design. From the perspective of empathy and ethics, the public is the end recipient of clinical practice guidelines and it is important that research evidence guiding their use is relevant and useful to them [19,20]. Arora *et al.* [21] observe that medical students report learning beyond clinical practice guidelines from the patients themselves and Purkayastha *et al.* [22], describe a process of learning from patients within low resource settings and within an online framework of user-driven healthcare. Patient and public involvement is reported to add value to policy settings [23,24], clinical practice [25], research design [26], medical education [27], health literacy [28,29] and in bridging cultural chasms [30]. Public involvement could add similar values to person-centered clinical practice guideline development.

Other groups such as DynaMed Plus with EBSCO Health Option Grid [31] and WikiRecs with BMJ Rapid Recs [32], invite patients as collaborators, co-designers and, in The BMJ Rapid Recs, as co-authors. These instruments can be used to integrate shared decision-making within existing clinical practice guidelines. They can be accessed by a clinician and patient working through choices during an appointment, or by either party before an appointment to arrive prepared, or after an appointment to refresh the information. The tools can be used on the Internet or printed out for use offline.

The World Health Organization (WHO) [cf.33] and The Guidelines International Network (G-I-N) [34] have recommended public and patient involvement in clinical practice guidelines and have included guidance materials for accomplishing this task although reporting research involvement is not yet mandatory. It may be useful to develop core outcome sets for patient and public involvement and for shared decision-making within guideline development, as the core outcome sets could enable evaluation of these initiatives. Guideline developers may want to consider embedding method studies within guideline development to improve guideline quality, uptake and usability. The accepted standard of renewing content every 4-5 years allows opportunity for methods research at a low resource cost within the existing work.

Clinical practice guidelines might serve as a trusted conduit between evidence-based medicine and evidence-based practice where both groups incorporate patient values and preferences in their mission statements and could be used to grow the enablement of informed shared decision-making between a clinician and patient. They could exemplify the ethical practice of “nothing about me without me” or, as stated by Eady *et al.*, that “It is inherently different when patients (or their representatives)

Box 1 The *BMJ* Patient Involvement Statement, reproduced with permission

As part of [its Patient Partnership Strategy](#), *The BMJ* is encouraging active patient involvement in setting the research agenda.

We appreciate that not all authors of research papers will have done this, and we will still consider your paper if you did not involve patients at an early stage. We do, however, request that all authors provide a statement in the methods section under the subheading **Patient involvement**.

This should provide a brief response to the following questions:

- How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?
- How did you involve patients in the design of this study?
- Were patients involved in the recruitment to and conduct of the study?
- How will the results be disseminated to study participants?
- For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

Patient advisers should also be thanked in the contributorship statement/acknowledgements.

If patients were not involved please state this.

If this information is not in the submitted manuscript we will ask you to provide it during the peer review process.

are fully part of guideline development, because then it's not only about the patient, it's with the patient" [13]. For sure, the time is ripe to integrate patient co-design and expertise in clinical practice guideline development.

questions asked of every *British Medical Journal* author (see Box 1). These options will take a small number of extra words and yet can add clear value and replicability to the guideline.

Design to dissemination

Practical guidance for how to include the patients in GDGs is available in the G-I-N PUBLIC Toolkit: Patient and Public Involvement in Guidelines, with many of the guidance segments written from 2012-2015 [34]. The UK National Institute for Health and Care Excellence (NICE) [35] also offers substantial guidance and transparency about public involvement in multiple aspects of their clinical practice guidelines including involvement with children and young people. This guidance could be usefully adapted in other clinical guideline development settings. Other national resources for including patients in research design, although not guideline specific, can be accessed from SPOR [36] (Canada), PCORI [37] (USA) and NIHR [38] (UK). Additionally, it may be useful to consider briefing notes for researchers [39], the COMET [40] initiative and the overview published by Price *et al.* [5] as they provide materials and practical examples of what others have done or offer suggestions for how to get started with Research Involvement.

Reporting patient and public involvement in clinical practice guidelines

The AGREE II [41] instrument asks developers only to state if "The views and preferences of the target population (patients, public, *etc.*) have been sought". More detailed reporting could be introduced by using the research reporting guideline GRIPP-2 [42] or through the same

Conclusion

Building a health system that people want to use and are able to engage in requires that we "focus health financing on health" and "measure what matters most" [43]. Let us move forward from adapting theories and frameworks that fragment the information and fail to name the outcomes or capture the focus. We can document the research that matters to the clinical decision, the patient's values and preferences and make use of the evidence and resources at hand. Implementation of person-centered CPGs to include patient important outcomes and shared decision-making tools is desired by patients and is needed by clinicians. The accepted shelf life of a clinical practice guideline spans 4-5 years and it would therefore be prudent to include patients as co-designers with guideline developers, effective immediately, to realize person-centered CPGs within the next 10 years.

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statement shown in Box 1. This Guest Editorial did not require ethical approval. There are no conflicts of interest to report.

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