

Title: Person Centered Clinical Practice Guidelines | An Editorial

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Roles and Educational Degrees

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Person Centered Clinical Practice

Guidelines | An Editorial

Good Clinical Practice Guidelines can make space for clinicians to focus on the patient in front of them and be prepared with an estimate of guidance on 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 in clinical practice guidelines it is minimally reported. These guidelines are used by clinicians everywhere to identify optimal process, save time, and multiply knowledge. Co-designing person centered clinical practice guidelines with patients contributes to health literacy, policy values, end user integration, and clinical relevance.

Background

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, *“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 Greeks¹ who practiced 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 pooling². The tensions appear constant over centuries: Elwyn et al 2000³ 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 clinical practice guidelines to appear in PubMed was written in 1966. The standard definition for clinical practice guidelines was adopted by Institutes of Medicine

(IOM) [1990]⁴ and was contributed from Field and Lohr as "*systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances*". Patients were not to make significant appearances on the policy making scene or as research partners other than as objects, narratives or experience stories until 2001. At this time, a paper by Elwyn et al³ found no specifically designed instruments to measure the concept of 'involving patients' in medical decision-making. In a systematic review by Elwyn et al, the lack of consensus for what to name patient involvement, shared decision making or clinical practice guidance containing patient collaboration was cited as a barrier. In 2017 this barrier remains on other research domains as well according to an overview of public involvement in research design by Price et al 2017⁵, and The PIRICOM Study⁶ 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 policy⁷.

What We Fail to Name Remains Unreported

The questions asked then and now is “how can we report what we fail to name” and “how can we measure the 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= 256055), clinical practice guidelines (n =125626), 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.

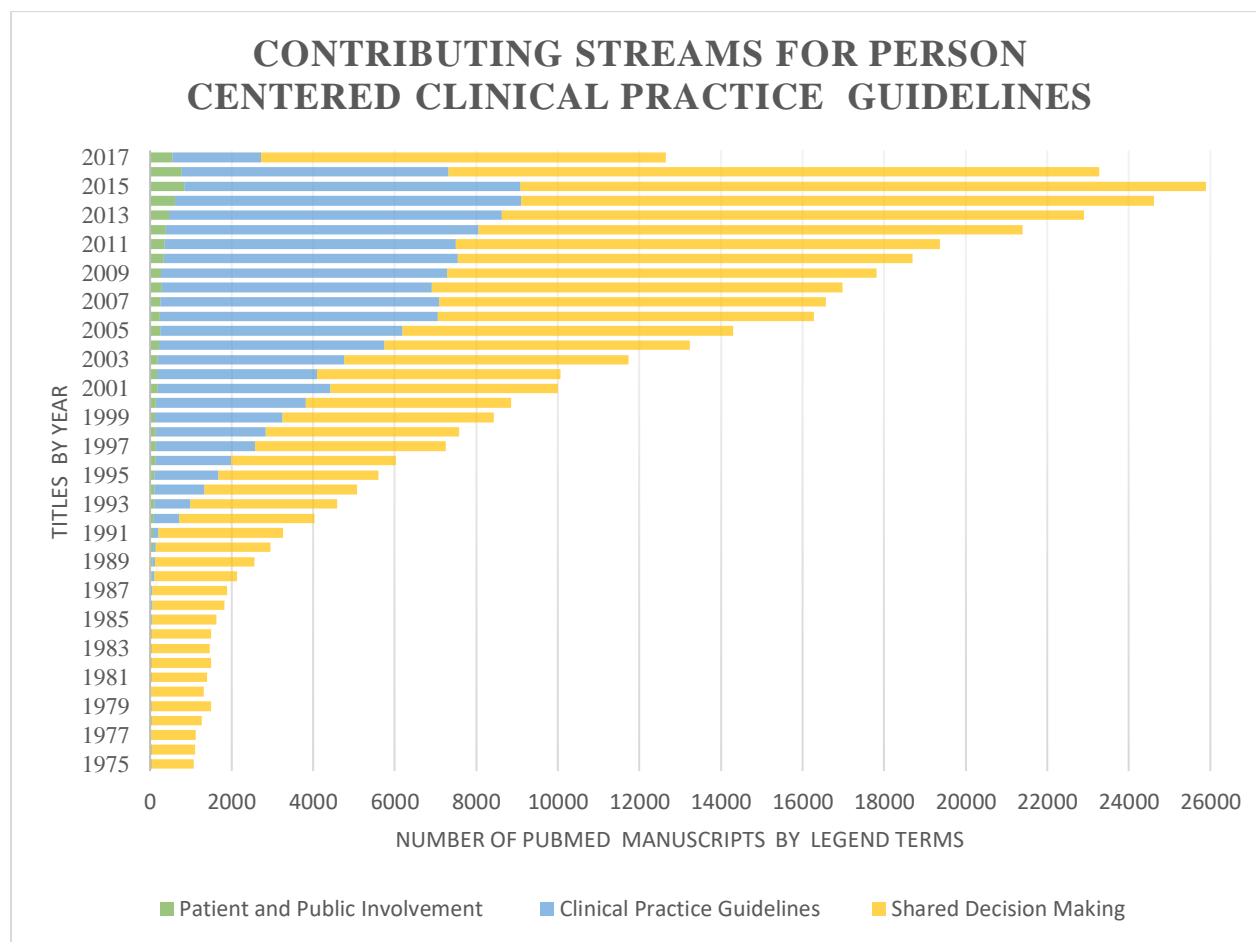


Figure 1 PubMed number of citations by year and Patient and Public Involvement, Clinical Practice Guidelines, and Shared Decision Making

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 practice¹⁰. Involvement and consultation have been regarded as two ends of a spectrum according to Vahdat et al¹¹ who posit that decisions associated with health services affect patients’ lives, thus, patients’ participation in health affairs is their medical right as a healthcare citizen. This group observes co-design in health can symbolize equity and responsiveness across a healthcare system¹¹. This is where the public and patients can help, as 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 the workload and they can learn competencies for engagement in the complex informed shared decision-making development required for health science research and in particular clinical practice guidelines. If we are serious about

integrating evidence into practice, it would seem reasonable to work within these self-limiting time-frames.

Barriers to Implementation

A systematic review by Mickan et al¹² concerning patterns of 'leakage' in the utilization of clinical guidelines mentions patient values and needs as an influence for guideline compliance. The failure to do so is seen in the review as a barrier, however, the recommendations to overcome these barriers involve pushing information to the patient rather than involving them in the design and decision-making process¹². For example, the guidance suggests providing patients with information about the condition, treatment, side effects, contraindications, risks and suggests managing clinical environments through the development of special purpose clinics. They recommend displaying patient education materials and investing in reminder systems to increase adherence¹². 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 the *“AGREE II assessments of recent acne treatment guidelines: how well do they reveal trustworthiness as defined by the Institute of Medicine (IOM) criteria?”* by Eady et al¹³ where authors stated, *“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 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 will be fit for purpose within the humanity and complexity of a clinical encounter. Elwyn et al¹⁴ 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 imbalances¹⁵ and the inability for non-researchers to express their contributions in ways so as to promote implementation¹⁶ are significant barriers to influence within other areas of healthcare, however, in the case of clinical practice guidelines non-researchers have received few invitations to sit at the table and may not yet be involved in negotiating terms.

Person Centered Clinical Practice Guidelines | a Meaningful Contribution

“The job of the human being [in the digital age] is to become skilled at locating relevant valid data for their needs. In the sphere of medicine, the required skill is to be able to relate the knowledge generated by the study of groups of patients or populations to that lonely and anxious individual who has come to seek help” (Sir Muir Gray) ¹⁷.

Miles et al calls us to reflect on the power of person-centered medicine where the patient is a person first and not a statistic to be managed¹⁸. The bridge between individual and population approaches in clinical practice guidelines could be strengthened effectively 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 al²¹ demonstrate medical students report learning beyond clinical practice guidelines from the patients themselves. In Purkayastha et al ²², learning from patients is described within low resource settings and within an online framework of user driven healthcare. Patient and public involvement is reported to add value for policy setting^{23,24}, clinical practice²⁵, research design ²⁶, medical education²⁷, health literacy^{28,29} and in bridging cultural chasms³⁰. Public involvement could add similar values to person centered clinical practice guidelines.

Other groups such as DynaMed Plus with EBSCO Health Option Grid³¹ and WikiRecs with BMJ Rapid Recs³², 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)³³ and The Guidelines International Network (G-I-N)³⁴ have recommended public and patient involvement in clinical practice guidelines and they have included guidance materials for accomplishing this task, however, 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. Clinical practice guidelines 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 ¹³ *“It is inherently different when patients (or their representatives) are fully part of guideline development, because then it’s not only about the patient, it’s with the patient”*. The time is ripe to integrate patient co-design and expertise in clinical practice guideline development.

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 2012-2015³⁴. The 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 SPOR³⁶ (Canada), PCORI³⁷ (USA) and

NIHR³⁸(UK). It may be useful to consider briefing notes for researchers³⁹, the COMET⁴⁰ initiative and the overview published by Price et al⁵ 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 11⁴¹ 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-2⁴² or through the same questions asked of every BMJ author (see Figure-2 box-1). These options will take a small number of extra words and yet can add value and replicability to the guideline.

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.

Figure 2 Box-1 The BMJ Patient Involvement Statement used by permission

Conclusions

Building a health system that people want to use and are able to engage in requires 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 makes use of the evidence and resources at hand. Implementation of patient centered clinical practice guidelines 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, it would therefore be prudent to include patients as co-designers with guideline developers, effective immediately to realize person centered clinical practice guidelines in the next 10 years.

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Ethics: The research used public information and no ethical oversight was needed or sought.

Data sharing: Results for analyses are published within the study. Any further information is available from the corresponding author.

Transparency: The lead author and the manuscript's guarantor (AP) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

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