Ongoing patient engagement research efforts at the Centre for Pharmaceutical Medicine Research, King's College London

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doi: 10.56012/jcbd5834

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Abstract

Research efforts within the Centre for Pharmaceutical Medicine Research, King's College London, are advancing patient engagement in medicine development and communications through evidence generation. This article presents the ongoing work of two doctoral researchers within the department, whose joint efforts aim to contribute to the evidence base on the integration of meaningful and sustainable patient engagement and involvement across the medicine development lifecycle and within peer-reviewed publications. These works have so far included a systematic literature review as well as qualitative interview-based analyses of both the perceived value of patient engagement across stakeholders and the landscape of patient involvement practices within peer-reviewed publications. Together, these research themes share foundational values, activities, and aspirations that this article explores within a framework of patients communicating to industry, industry communicating to patients, and patients and industry communicating with each other.

Plain language summary

Researchers at the Centre for Pharmaceutical Medicine Research at King's College London are working to improve the ways that patients are involved in medical and pharmaceutical research. Their research aims to make sure that patients' opinions and experiences are incorporated into the development of new medicines and the public sharing of research results. They have reviewed previous studies and interviewed patients and other researchers, including those working in the pharmaceutical industry, to better understand their perspectives and experiences. In this article, the researchers consider where their projects overlap and discuss the flow of communication between patients and the pharmaceutical industry.

Background

Patient engagement in clinical research and medicine development has grown significantly since it first began in the 1980s.[1] As the concept of involving patients in research has gained broader acceptance, both the practice and related academic literature have expanded considerably.[2] At the Centre for Pharmaceutical Medicine Research (CPMR), King's College London, patient engagement in medicine development is one of three primary research themes, with the goals of generating a research base and embedding patient engagement in the practice of future generations of researchers and other stakeholders in this field.[3] Here, we outline the ongoing research efforts of two of our doctoral researchers (FA and AR) working in the patient engagement space, explore the intersections between the themes of engagement and communication, and share relevant learnings for the medical writing community.

> We conducted a systematic literature review of patient engagement models in medicine development to assess the current landscape.

Patient engagement across the medicine development lifecycle

Although several initiatives[4-7] have been established to support patient engagement, there is limited evidence that these are consistently implemented in a meaningful and sustainable manner throughout the medicine development process. To better understand why, FA's research focuses on the generation of evidence for patient engagement in the development and use of medicines. To begin, we conducted a systematic literature review of patient engagement models in medicine development to assess the current landscape.[8]

Key findings from this review are as follows:

- Patient engagement in research is widely recognised as a process that positions patients as valued partners who should be actively involved and respected throughout the development and lifecycle management of medicines. Despite the shared emphasis on the value of patient inputs, the lack of unified definition and understanding of patient engagement hinders its consistent application. This lack of standardisation is further compounded by the absence of consensus on which aspects of patient engagement are most critical or should be prioritised.
- Current patient engagement guidelines are nonbinding and nonprescriptive, serving only as general frameworks for stake-holders seeking to incorporate patient engagement into their practices. Despite numerous initiatives intended to promote patient engagement, evidence of its consistent,

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meaningful, and sustainable application in drug development remains sparse.

- Some of the challenges identified that hinder the systematic implementation of patient engagement include insufficient training and expertise among stakeholders; lack of practical tools and industry-specific metrics to evaluate the impact of patient contributions; behavioural resistance to valuing patient engagement; lack of skills, awareness, and competencies for undertaking effective patient engagement; and unclear definitions of the scope, expectations, and responsibilities associated with patient engagement.
- Addressing these barriers is essential for advancing patient engagement and translating theoretical frameworks into actionable practice. In addition, existing frameworks for assessing the impact of patient engagement must undergo rigorous validation to establish robust evidence supporting its routine integration into drug development processes.

The research gaps identified in this review led to our current study, which explores the perceived value of patient engagement in medicine development from the perspectives of key stakeholders: pharmaceutical industry professionals, patients and patient support groups, and regulators. Our goal is for these insights to guide the future integration of meaningful and sustainable patient engagement in medicine development.

Patient involvement in peer-reviewed publications

The research communications community, including scholarly publishing, has recognised patients as important stakeholders with potential for involvement throughout the publication lifecycle,[9] and in recent years, several reviews and analyses have characterised different aspects of this rapidly evolving practice.[10-12] Meanwhile, pharmaceutical companies are beginning to adopt and formalise broader frameworks for patient engagement in medicine development, including internal policies for publication processes.[13-15] However, owing to the novel and innovative nature of the practice as well as challenges associated with identifying such involvement, consistency across the industry is still being established and best practices are evolving.[10] To better support such frameworks and contribute towards building an evidence base for best practices, AR's ongoing research is a qualitative mapping of the current landscape of patient involvement in publications within the pharmaceutical industry. Current efforts so far include a thematic analysis of scoping interviews with multistakeholder experts in the field – such as patients and other publication professionals – to translate experiential knowledge into theory and evidence.[16]

> Our ongoing research is a qualitative mapping of the current landscape of patient involvement in publications within the pharmaceutical industry.

Where do these research themes intersect?

Although these two bodies of research focus on distinct aspects of patient engagement and involvement within the pharmaceutical industry, they share foundational values, with overlapping and heterogenous concepts and best practices across three broad and not readily delineated domains (see Figure 1).

This overview is intended to reflect the top-line themes and elements common to our combined research efforts, spanning research and development, regulatory,

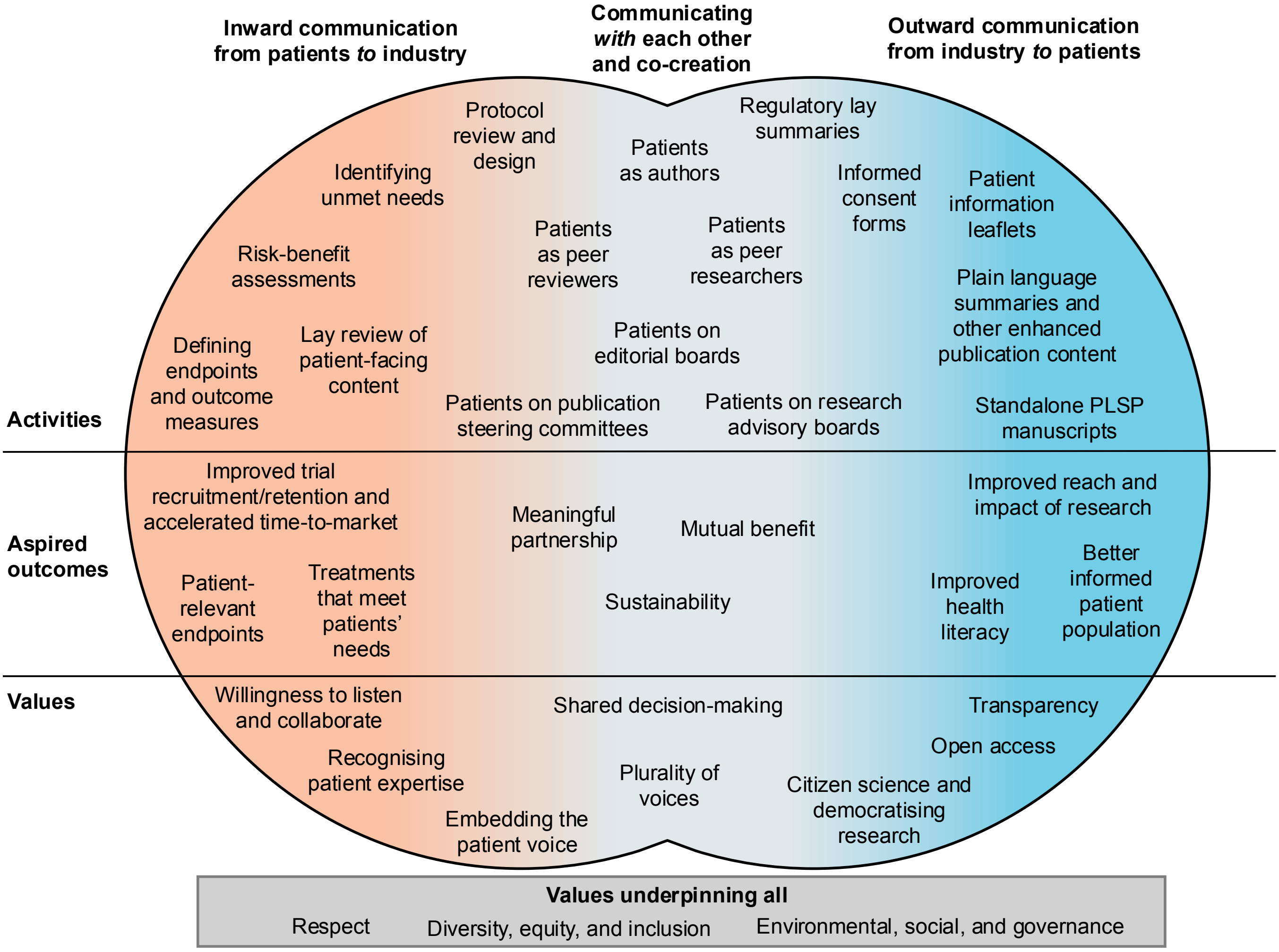

Figure 1. Intersecting research themes.
The activities, aspired outcomes, and values that are shared across our combined research efforts. PLSP, Plain Language Summary Publications

market access, and publications contexts. We recognise that there is a wealth of further activities, aspired outcomes, and values within the broader patient engagement space that we have not included within the scope of this non-exhaustive summary.

1. Inward communication from patients **to** industry

Patients are actively contributing to pharmaceutical industry processes by communicating their priorities and perspectives. Many of these interactions and engagements may be solicited by industry and happening on industry's terms – i.e., industry seeking input from patients – but patients are also leading the charge in ensuring their voices are heard. These activities and their associated values, for example identifying unmet needs and trial protocol reviews, are largely intended to embed the patient voice across industry processes and practice patient-centric medicine development. This domain drives a shift towards patient-relevant outcomes and sustainable models of patient engagement that foster better alignment between research objectives and patient priorities.[8,17]

2. Outward communication from industry **to** patients

Through both fulfilment of regulatory requirements as well as a broader move towards open science principles, pharmaceutical companies are communicating research information to patient communities through multiple channels and formats. These methods of communication, for example plain language summaries of publications and regulatory lay summaries, are an important opportunity for industry to demonstrate transparency and trustworthiness. Through this domain, industry aims to bridge the gap between scientific research and patient understanding, promoting an accessible approach and an ethical commitment towards enhancing health literacy and information equity.[18]

3. Communicating **with** each other and co-creation

At the intersection of these themes is the domain of bidirectional communication and collaborative exchange between stakeholders. Here, patients and industry are communicating together, with, and alongside each other. In cases of best practice and genuine co-creation, they are doing so from a position of equals. The increasing prevalence of patients within pharmaceutical and scientific processes – in such roles as peer researchers and advisory board members to co-authors and journal editorial board members[9,19] – is a result of the increasing recognition of patients as lived experience experts and experiential knowledge as an equally robust form of knowledge or epistemology as other forms of scientific knowledge.[20,21] This domain of (intended) co-creation, built on values of inclusivity and plurality, acknowledges that there is rarely such a clear-cut distinction between stakeholders on a personal level, with individuals capable of bringing multiple perspectives, identities, and experiences to the table.[16]

At the foundation of these three domains are core values that guide meaningful patient engagement and interactions – respect; diversity, equity, and inclusion; and environmental, social, and governance (ESG) goals.[9,18,22-24] These principles help industry work within ethical and responsible frameworks to maximise the impact of patient engagement across all processes and stages of medicine development.

Photo: Wikimedia

Recommendations arising from our research efforts so far

Through continued multistakeholder communication and concerted efforts between patient and industry communities, future work on patient engagement and involvement in medicines development and research communications should focus on the following:

- Establishing a universal, global framework of shared values and principles which can inform the choices involved in good practice. For example, this can include unified terminology as well as an adaptable code of practice that aligns with global regulatory standards.
- Fostering a pre-competitive space to avoid duplication of efforts and resource waste by stakeholders. For example, there may be a role for global industry/regulatory organisations to facilitate collaboration and conversation, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the World Health Organization, or the Council for International Organizations of Medical Sciences, as well as professional organisations such as EMWA.
- Harmonising guidance and training, tailored for specific stakeholder groups and ideally accessible on a digital platform, to provide a common standard whilst saving duplication of effort. For example, standards can be established through publishing case studies of best practices.
- Testing and validating tools, frameworks, and impact measures over time to form a robust evidence base that supports good practice. For example, communications professionals are implementing more meaningful publication metrics.[25]
- Assessing the equity of digital platforms and accessibility of content for all patient populations and particularly under-served communities, to build inclusive and reputable practices, as well as to support the ESG targets for companies. For example, accreditation of health content creators via the Patient Information Forum's PIF TICK scheme helps communities identify trustworthy health content.[26]

These recommendations will help medical writers and industry professionals create a comprehensive, sustainable, and more systematic patient engagement practice that can be effectively integrated into routine medicine development and communications processes. By doing so, we believe that the effectiveness of research will improve, leading to medicines that are more likely to meet the real needs of patients, and thereby benefitting all stakeholders.

Take-home message

The intersection of research themes presented here represents the potential starting point for a coherent approach for the evolution of patient engagement in medicine development and research communications. Additionally, based on our collective research efforts so far, we have found that researchers and sponsors have generally maintained a positive attitude toward patient engagement. However, the regulatory "push" from governments and the "pull" from patients and their representatives have yet to achieve consistent and sustainable patient engagement practices across medicine development and communications processes. We encourage medical writers and industry professionals to focus on identifying and developing a unified patient engagement approach whereby all stakeholders drive progress and harmonisation and ensure long-term momentum in the interests of patients.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Disclosures and conflicts of interest

Adeline Rosenberg is an employee of Oxford PharmaGenesis, Oxford, UK, but this work is independent of her employment. There are no disclosures to provide for the other authors.

Data availability statement

For enquiries about data and other supplemental information, please contact the corresponding author.

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