

Patient advocacy and its importance to laboratory medicine practice: A response from patient advocacy groups

Dear Editor,

It is increasingly popular to talk about the importance of involving patients in medical decision-making, also known as shared decision-making.¹ Patient-centeredness has been described as a valuable moral concept.² Several identified ethical theories focus on positive outcomes of providing patient-centered care (PCC), how PCC reflects the ethical norms inherent in medicine, and the importance of developing patient-centered attitudes and traits, which in turn influence practitioners' behaviors toward patients.²

The concept of PCC has evolved through the years from providers simply trying to interpret the patient experience to organizations and institutions engaging patients and their representatives to gain a deeper perspective of their experience navigating the healthcare world and *together* propose ways to improve it. In 2012, the Food and Drug Administration (FDA) committed to a new initiative known as "*Patient-Focused Drug Development*" to create a more systematic way to gather the patient's perspective on several chronic conditions and their currently available therapies.³ By 2016, the FDA exceeded their original commitment by holding 24 "consultative meetings" with patient stakeholders including patients and patient advisory groups.⁴

To further extend the reach into the patient experience and increase engagement, the 21st Century Cures Act directed the FDA to issue new guidance's to capture and measure the patient's perspective.⁵ These experiences and perspectives are meant to be directly reflective of patients, caregivers, and patient advocacy organizations and not filtered by providers, researchers, or others' interpretations. While these guidance's are related to drug development, they demonstrate the FDA's commitment to incorporate the patient's voice.

The pharmaceutical industry and others assumed a leadership role by establishing patient and caregiver advisory committees to consult with them from the earliest stages of product development. Likewise, the American Society for Clinical Pathology (ASCP) developed a program called "*Patient Champions*" that "raises awareness of the vital role the medical laboratory plays in patient care through real-life stories of patients."⁶ This excellent program highlights the patient's experience through their medical journey as they interact with the laboratory. The benefit to the patient is the opportunity to share their story and, in turn, empower and educate others in their healthcare journey. Patient champions also receive training to build their communication skills, present to the media, provide interviews, and engage in public speaking opportunities.

While demonstrating patient engagement, this program could be improved by integrating a deeper involvement of patients in its advisory and development stages, like the FDA's Patient-Focused Drug Development Program. Only initiatives that actively involve patients in all stages of development can truly reflect their values, goals, and preferences. Conversely, those that do not may instead characterize (not always correctly) what professionals "assume" may be the patients' priorities. The ideal program requires both the professional's expertise and the patient's experience and perspectives that can only come directly from them. Of course, cultural issues and health literacy and numeracy are important issues to consider and are areas where patient engagement in development of laboratory navigation programs would excel.¹

It all comes down to how the patient and practitioner align on issues such as shared decision-making (SDM) which ultimately promotes patient engagement and PCC. A 2016 JAMA article suggested that those who were more actively engaged in their healthcare decisions had a better understanding of their choices and were more likely to receive care consistent with their values, goals, and preferences.¹ The National Quality Forum (NQF) has published six SDM fundamentals that can help focus healthcare organizations, departments, and practitioners as they work toward developing patient engagement programs that truly involve patients at core development stages.¹

This early consultation and input from those who have an intimate and real-life understanding of a disease or condition has proven invaluable to the strategies of research programs and clinical studies, as well as in preclinical study design. Probably nowhere is patient and caregiver perspective as crucial to a positive outcome than in the clinical setting where the patient's personal experiences and symptoms are gathered and interpreted to formulate an accurate diagnosis. Ideally, then, the triad of patient, caregivers, and healthcare providers engage in a meaningful conversation where together they can make optimal healthcare decisions that align with that which is most important to the patient.

Patients want to be treated as partners when it comes to decisions about the services/treatments relevant to their health care. It assuredly is gratifying to them when the "system" requests and respects their input and makes them an integral part of decision-making. SDM and thus PCC benefit healthcare providers, caregivers, and the healthcare systems by reducing misunderstandings, errors and increasing the chances of successful outcomes. Patients also want and need access to practitioners who have the capacity to explain

the healthcare journey, including the myriad of laboratory and imaging tests required to determine a diagnosis and evaluate their treatment. Patients want to talk candidly about risks and probabilities, have their practitioner be accessible for follow-up questions, concerns, and emergencies, and also have access to advocacy groups for information, education, and financial assistance.

Despite incredible advances in medical innovation, there remain barriers to incorporating SDM and PCC in every day practice, including the lack of institutional adoption and development of tools to improve communication. Patients want active partnerships with healthcare providers, healthcare organizations, and advocacy groups and shy away from the paternalistic approaches of the past. The benefit to the patient is improved quality of life, control, and dignity. For the healthcare system, a more engaged patient leads to better healthcare experiences, healthier behaviors, and less episodes of emergency care—all of which drive down healthcare costs.⁷

As patient advocacy organizations, we commend the 2020 Thrombosis Hemostasis Societies of North American (THSNA), the International Society for Laboratory Hematology, and all the other associate organizations in their efforts to promote patient advocacy, SDM, and PCC. Some of the THSNA associate patient advocacy organizations have already partnered with the FDA to present programs to other organizations on how to put together a meeting that focuses on the burden of disease and unmet needs of patients. It would be a pleasure to extend that offer to any laboratory organization who would value the input. As individual organizations and as a unified group, we encourage all patients and practitioners to both define and co-create patient empowering solutions.

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