



Extend of Implementation of Patient centricity in the Real World through an Analysed Live Survey

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Abstract

Background: The importance of pharmacovigilance (PV) as a critical science for both effective patient care and public health is growing. Patient-centeredness and patient safety have become core elements in today's interactive and responsive healthcare systems. As patients take more interest in their health and healthcare, they support the maxim of "Nothing about me, without me" and expect caregivers to engage in shared decision-making, so that the patient's voice is always included.

Objective: The objective of this study is to gather information on the level of Patient Centricity among healthcare professionals (HCPs) and non-HCPs.

Methods: An independent survey was conducted to understand the current health literacy levels of HCPs and patients. A total of 65 HCPs and 52 non-HCPs participated in this survey.

Results: The findings indicate that 83% of the HCPs reported that they know about Patient Centricity, while only 30% of the patients reported awareness. 41% of HCPs reported taking initiatives to connect with subjects to improve treatment outcomes, while 79%-90% of the patients reported that Patient Centricity is very important to them. Furthermore, 56% of the HCPs reported that they are not utilizing technology to enhance patient centricity and 65% of the patients reported that their doctors do not make an attempt to connect with them outside the four walls. Lastly, 94% of HCPs reported asking about the patient's Family History, while 63% of patients reported that HCPs do not consider their understanding levels of the health information.

Conclusion: Although the majority of HCPs are aware of Patient Centricity, there is still a significant need for education and training within the healthcare community. Furthermore, there is an emerging need for building robust systems and applications to support patient centricity. This study highlights the need for healthcare professionals to take a more patient-centered approach to healthcare and to utilize technology to enhance patient-centricity.

Keywords: pharmacovigilance, HCPs, healthcare community, health information, robust systems.

Introduction

An adverse drug reaction (ADR) is a harmful and unintended response to a medication or medical treatment. It can range in severity from mild symptoms like a headache or nausea, to more serious reactions like anaphylaxis or organ damage.^{1,2} ADRs can occur with any medication, including prescription drugs, over-the-counter medications, and herbal supplements. It is important to report any ADRs to your healthcare provider so that they

can be properly managed and documented in your medical record.²

Patients typically report adverse drug reactions (ADRs) to their doctors, but the traditional mechanisms for reporting may not be effective due to the low participation of physicians in Pharmacovigilance (PV).¹ Literature studies suggest that direct recording of patient concerns may identify new drug safety signals earlier than professional reporting systems alone, highlighting the importance of patients in actively reporting ADRs to improve PV. Public

health programs and responsible media coverage have led patients in many countries to take responsibility for their own health, reflected in the creation of patient charters, bills of rights, and patient advocacy groups. Patient-centric innovation will be crucial in transforming PV over the next few decades, but it remains to be seen whether we are prepared to implement patient-centric approaches in PV.²

In Europe, the EU Directive 2010/84/EU and EU Regulation No. 1235/2010 provide recommendations for patient-centered implementation of pharmacovigilance, developed by the European Patients Forum. These recommendations aim to create a strong, open, and transparent pharmacovigilance system that ensures the confidence of patients, healthcare professionals (HCPs), and regulators alike.^{2,3} The Directive amends the definition of adverse drug reactions to include medication errors and misuse as part of adverse drug reaction reporting to collect more information on the real-life working of medicines when used in different circumstances by different people. Products with new active substances and biologics are identified by a black symbol with a standard explanatory sentence on the packaging, indicating that the medicine is under additional monitoring, without creating unwarranted alarm.^{2,4,5,6}

To implement an effective patient-centric PV model, four main steps are necessary: educate, encourage, engage, and enable patients as shown in figure 1. A recent survey conducted by ClinoSol Research Private in Hyderabad, India, aimed to understand the current practices and future needs and challenges of a patient-centric approach, placing the patient at the center from drug discovery to product usage. The survey involved both healthcare and non-healthcare (patient) communities and highlighted the importance of patient and HCPs relations. Policymakers can use the survey's results to develop a more structured regulatory framework and technology ecosystem for a better and healthier society, and the HCP community can provide treatment and education aligned with patient-centric approaches.

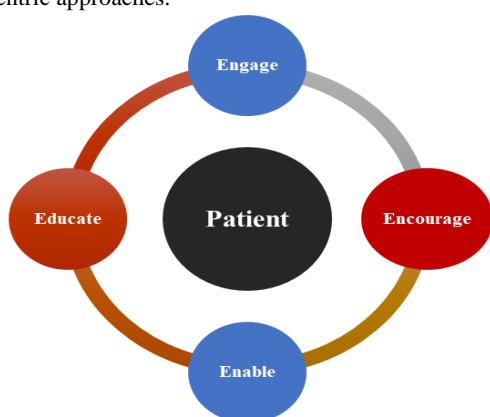


Figure-1 Implementation model for patient-centric pharmacovigilance.

Methods

A survey was created with questions focused on the significance of Patient Centricity, and distributed to both healthcare professionals (HCPs) and non-healthcare professionals in India. Table-1 presents the results of the survey from the HCPs, which consisted of ten questionnaires administered through Google Forms, aimed at understanding the current practices, and identifying future needs and challenges, with a focus on placing the "Patient" at the core of the drug discovery process and usage of the product (e.g. drugs, devices, vaccines). The insights gathered from this survey were valuable to sponsor organizations in their efforts to develop, treat, and achieve better scientific results for their medicinal products.

For the non-HCPs, the patients were first informed about Patient Centricity and the survey's purpose. They were then asked to answer ten questions presented in a multiple-choice format. While the primary objective of this survey was to gather information on Patient Centricity for both HCPs and non-HCPs, other issues of concern regarding the relationship between HCPs and non-HCPs also emerged during the survey.

Table:1 Questionnaire used for analysis

Questionnaire for Health care professionals (HCPs)	Questionnaire for non-HCPs/ Patients
1. Do you know about patient centricity?	1. Do you have an understanding of Patient Centricity?
2. Have you undertaken any initiatives to strengthen the connection between patients and the healthcare system?	2. How important is Patient Centricity to you?
3. Have you utilized technology as an aid to enhance patient centricity?	3. Do you think doctors make an attempt to connect with the patients outside the 4 walls of the clinic?
4. Do You Ask For Your Patients' Family History?	4. Do you feel HCPs (doctors, pharmacists, hospital staff) consider patients' level of literacy on health, and their understanding level and provide information suitably?
5. Have you adopted any practices to increase	5. Are caregivers/patients made aware

health literacy in patients?	of various treatment options before choosing a course of treatment?
6. Have you worked/ collaborated with any Patient Advocacy Groups to discuss and develop strategies that spotlight Patient Centricity?	6. Do you inform HCPs in case a particular choice of treatment isn't working well, and you are experiencing Side effects?
7. Have you tried new advancements in technology, to handle patient centricity?	7. Have you connected with HCPs digitally?
8. Is there a system that takes into account patients' feedback and has that feedback been constructively utilized?	8. If you were to learn about Health literacy, what your first choice would be?
9. On a scale of 1-10 how much according to you has the topic of Patient Centricity been applied in the healthcare system?	9. Do you feel the voice of caregivers and patients is unheard when it comes to the choice of treatment?
10. What are the various hindrances you have faced when it comes to patient centricity?	10. Do you feel that a more digital and tech savvy approach should be considered when it comes to patient centricity?

Results

Outcome analysis for HCPs

The survey involved 65 HCPs from various cities in India. Results show that 83% of the participants are familiar with Patient Centricity, while 17% reported that they have no knowledge about it. It appears that HCPs working in corporate hospitals have a better understanding of Patient Centricity than those in Government Organized PHCs and Own Clinics. Further training is required for the latter group (17%) to improve their understanding of the concept.

41% of the HCPs reported that they are making efforts to engage with their patients and improve treatment outcomes, while 59% are not undertaking such practices. The survey suggests that training is necessary for HCPs to initiate effective communication channels that can help them understand and treat patients more effectively.

Regarding the use of technology, 56% of the HCPs reported that they are not utilizing technology to enhance patient centricity, while 44% are using some of the

currently available technologies. The responses indicate the need for the establishment of well-built IT systems in the facility and training on their effective use to enhance the patient-centric approach of HCPs.

A significant majority of the HCPs (94%) reported that they ask about the patient's Family History, while 6% do not collect this information. Although many HCPs consider family history while making treatment decisions, it is essential to educate others on the importance of collecting this information to identify the root cause of the disease and improve treatment selection. Figure-2 presents a detailed breakdown of the responses.

Improving patient health literacy practices was reported by 58% of HCPs, while 42% indicated they do not educate their patients. From the responses, it is apparent that HCPs require more education and training on health literacy to avoid misconceptions about diseases/symptoms, care plans, and treatment methods. Patient advocacy groups were worked with by 14% of HCPs while 86% did not work with any patient advocacy groups. The results demonstrate the pressing need for healthcare organizations and HCPs to work together with patient advocacy groups to emphasize patient-centric approaches. 52% of HCPs did not implement any new technologies to adopt patient-centric approaches, while 48% used advanced technology. The responses indicate that there is a significant need for education and training, including best practices, in using advanced technology to improve patient centricity. 94% of HCPs reported that there was no structured feedback collection system in place at their facility, while only 6% reported utilizing such a system. The responses suggest a high demand for systems that gather feedback from patients at healthcare facilities and for HCP training/education tools to help them use these systems to improve patient care, as shown in Figure-2.

Result analysis for the HCP data

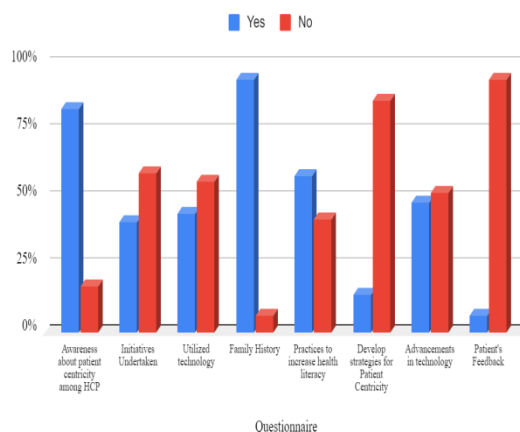


Figure-2 Result analysis for Health-care professionals

The application of patient-centricity in the healthcare system has received mixed ratings from the HCPs. Among them, 8% rated it between 1-3, 33% rated it between 4-6,

and 18% rated it between 7-10. The major hindrances in achieving patient centricity, as reported by 30% of HCPs, are lack of time. Another 25% of HCPs reported a lack of available resources, while 22% of them counted the patient's perception as a hindrance in understanding patient centricity.

Outcome analysis for non-HCPs/ Patients

A survey was conducted among non-HCPs to collect their feedback on patient-centric approaches. The survey included 52 patients of both genders (male and female) aged between 50-80 years. The main objective of the survey was to evaluate the patients' current level of health literacy and their use of technology to aid policymakers in developing a more structured regulatory framework and technology ecosystem for a healthier society. Additionally, the survey aimed to provide insights for the HCP community to align their treatment and education with patient-centric approaches.

70% of the patients reported that they were not aware of patient centricity, while 30% reported being aware of it. However, 79%-90% of the patients reported that patient centricity is very important to them, with only 4%-6% reporting it to be of less importance. The survey results also showed that 65% of patients felt that their doctors do not make an effort to connect with them outside the four walls, while 35% reported otherwise. Additionally, 63% of patients felt that HCPs do not consider their understanding levels of health information, while only 37% reported receiving suitable information based on their level of health literacy.

Further, 70% of patients felt that HCPs do not educate them while choosing a treatment course, while 30% reported that their voice is heard in this regard. The survey also showed that 61% of patients do not report side effects to HCPs as they are not aware of them, while 39% reported that they do report adverse events to their doctors.

Regarding digital connectivity, only 36% of patients reported being connected with their physicians digitally, while 64% reported not being connected. Additionally, 43% of patients reported Google as their first choice for health information, while 23% reported using various online sources such as YouTube. Only 18% reported consulting their physician first for health-related queries. The survey results also showed that 50% of patients reported their voice being heard when they specifically made a point about the choice of treatment, while 50% reported their thoughts and opinions were never heard by HCPs.

Finally, 89% of patients felt that the digital approach should be considered, while only 11% reported otherwise. (Refer to Figure-3 for details.)

Result analysis for Non-HCPs

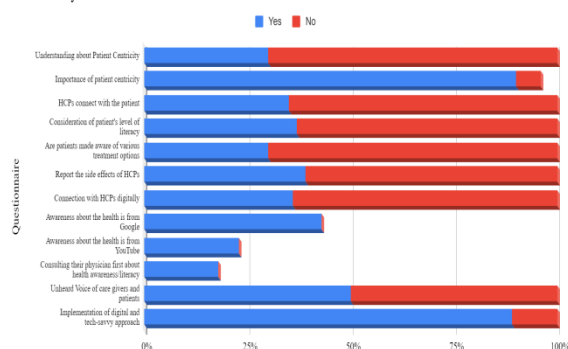


Figure-3 Result analysis for Non- Healthcare Professionals

Discussion

Patient-centric pharmacovigilance involves raising patient awareness about the importance of reporting adverse drug reactions and highlighting the crucial role they can play in pharmacovigilance. Educational initiatives may include training programs to directly train patients regarding the adverse event reporting systems, as well as training investigator site teams, patient organizations, and HCPs. Disseminating product safety summaries, benefit-risk data, and risk management plan summaries for public consumption on a real-time basis is also essential, and social media can serve as an effective tool for risk management and communication.^{1,2}

The results of a recent study demonstrate the need for education and training about patient centricity and the need for developing robust systems and applications in collaboration with healthcare giants, patient advocacy groups, NGOs, Government Initiatives, and regulatory bodies to improve patient health and overall well-being. This requires a focus on the confidentiality of systems and personal data, as well as support from social workers.

While most HCPs are aware of patient centricity, there is still a significant need for education and training in the healthcare community, facilitated by the clinical research industry in collaboration with patient advocacy groups. The development of technological infrastructure and patient education programs that support patient feedback systems is also essential. Pharma-IT organizations must come up with solutions specific to the needs of the healthcare system to analyze root causes at a deeper level through surveys and address any possible roadblocks that hinder providing safe and effective healthcare to patients. By doing so, the patient's voice can be heard by physicians and healthcare professionals can deliver their responsibilities at their best.

Develop targeted educational initiatives, develop targeted educational initiatives aimed at increasing patient awareness about the importance of reporting adverse drug reactions. This could involve training programs to directly

train patients, investigator site teams, patient organizations, and HCPs. Such initiatives could help to build robust systems and applications that support patient feedback systems and the implementation of various patient education programs with the help of technology.

Disseminate product safety summaries, and disseminate product safety summaries, benefit-risk data, and risk management plan summaries for public consumption on a real-time basis. This could be done through various platforms, including company websites, national web portals, and patient information. Social media may also serve as an effective digital tool for the management of risk and communication for PV teams within companies to directly connect and engage with patients, consumers, and HCPs to improve awareness about product safety, leading to improved health literacy amongst consumers and patients.

Coordinate with healthcare giants, patient advocacy groups, NGOs, and Government Initiatives to take patient-centric pharmacovigilance to the next level of care and confidentiality of systems and personal data. This coordination could help in gaining proper education and conscious decision-making in the healthcare system, which aids in making their voice heard by the physicians, and physicians can deliver their responsibilities as a healthcare professionals at their best.

Analyzing the root causes of hindrances to patient-centric pharmacovigilance at a deeper level through surveys and clearing all the possible roadblocks that hinder reaching the safety and overall healthcare benefits to the patients. Pharma-IT organizations could come up with solutions specific to the needs of the healthcare system to facilitate this process.

Overall, these future steps could help improve patient-centric pharmacovigilance and lead to better patient outcomes in the future.

Conclusion

In conclusion, patient-centric pharmacovigilance is crucial for ensuring patient safety and improving health literacy among consumers and patients. While there is still a need for education and training in the healthcare community, initiatives by the clinical research industry, in association with patient advocacy groups, can help build robust systems and applications to support patient feedback and education programs. This will require the collaboration of healthcare giants, patient advocacy groups, NGOs, and regulators to take the next level of care and confidentiality of systems and personal data. With the help of social workers and technological infrastructure, patients can gain proper education and make conscious decisions about their health and well-being, ensuring their voice is heard by physicians and healthcare professionals. By taking these steps, we can move towards a more patient-centric

approach to healthcare, improving patient outcomes and overall public health.

Competing interests

The authors declare that they have no competing interests.

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This survey was unfunded.

Authors' contributions

CS Mujeebuddin designed the study, Noorush Shifa Nizami, Maryam Sadiq, Khuba Raniya, and Pallagolla Harika, and V. Randeep Raj collected the responses from HCPs and Non-HCPs, Uma Priya analyzed the data and Noorush Shifa Nizami drafted the manuscript. All authors have read and approved the final manuscript.

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