INTRODUCTION

- ‘Patient engagement’ is an umbrella term covering all the interactions that patients have with their healthcare system.
- Patient engagement in research is an upcoming interest.
- Historically, ‘experts create, patients participate’ in research.
- Nowadays, growing interest is involving patients from an earlier stage of research.
- There is growing interest in more fully engaging patients in the research process.1

WHY INVOLVE PATIENTS IN RESEARCH DESIGN?

- Patients have a personal experience of disease that is not available to most researchers, which complements researchers’ analytical skills and scientific perspective.
- Involving patients in research projects improves both the methodology and outcomes of the research.
- Patients often are able to provide invaluable additional insights about selecting, appropriate research parameters and solving practical difficulties.

HISTORY OF PATIENT ENGAGEMENT IN RESEARCH

- The first major government-supported initiative to engage patients and the public in health-related research was the United Kingdom’s National Health Service INVOLVE program, launched in 1996.2
- INVOLVE trains and encourages patients and the public to participate in all levels of research from design to review to dissemination.
- Activities included in INVOLVE project:
  - Working with research funders to prioritise research
  - Offering advice as members of a project steering group
  - Commenting on and developing research materials
  - Undertaking interviews with research participants.

METHODS OF PATIENT ENGAGEMENT IN RESEARCH

 Patient Reported Outcomes (PROs), PCOR, and PCORI

 Patient Focused Drug Development

 Patient-Centric Clinical Trials

 Patient Advocacy

PATIENT-REPORTED OUTCOMES (PROS) AND PATIENT-CENTERED OUTCOMES RESEARCH (PCOR)3

- PROs are any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else (USFDA).
- There has been an increasing call by the authorities that clinicians use PROs in patient care.
- Analysis of ‘patient-centered’ and ‘patient-reported’ data is the core aspect of PCOR.
- Focus is now shifted from ‘clinical effectiveness’ of a treatment modality to ‘quality of life improvement’ it can bring.

PATIENT-FOCUSED DRUG DEVELOPMENT

- Patient-Focused Drug Development (PFDD) is a new initiative from the Food and Drug Administration (FDA) intended to bring patient perspectives into an earlier stage of product development.
- The goal is that patients will be able to provide context for benefit-risk assessments and input to review decisions, and also in the development of new assessment tools, study endpoints, and risk communications.
- USFDA conducts regular PFDD meetings involving patients to determine the acceptability of new drug approval.

PATIENT-CENTRIC CLINICAL TRIALS (PCCT)

- PCCT is an emerging concept in the Western world.
- Patient participation in the RCTs is enhanced.
- Patients are involved from the stage of protocol preparation.
- ACT data is made easily available to the participating patients.

PATIENT ADVOCACY4

- A patient advocate is a healthcare specialist (individual or organization) who, as a liaison between patients and healthcare providers, argues with the best interest of the patient in view, in order to maintain or improve the quality of healthcare delivery to the patients that he/she is representing.
- Role of Patient Advocacy Groups:
  - Promoting patient engagement in health policy decision making.
  - Promoting health literacy.
  - Ensuring the availability of adequate health information.
  - Building a strong patient’s voice.

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BENEFITS OF INCLUDING PATIENT PERSPECTIVES IN RESEARCH5

- Increase in range of research topics.
- Identification of new themes.
- Highlighting issues of importance to patients.
- Improved quality of data on using patients as co-researchers and interviewers.
- Enhanced recruitment rates.
- Improved trial consent procedures.
- Pushing science forward.
- Improved quality of data on using patients as co-researchers and interviewers.
- Enhanced patient and public engagement.
- Education and research opportunities.

IMPACT OF TAKING PATIENTS AS PARTNERS IN RESEARCH

- In 2010, the PCORI (Patient-Centered Outcomes Research Institute) was created in the US.7
- PCOR is a U.S. non-profit non-governmental organization, which focuses on creating and promoting research that includes patients and caregivers.
- PCOR’s aims include funding research that can help patients and those who care for them to make better-informed decisions about the healthcare choices they face every day, guided by those who will use that information.

PATIENT ENGAGEMENT IN RESEARCH: INDIAN PERSPECTIVE

- Patient engagement in research is an upcoming interest.
- Clinical trials in India have started to use PROs as primary outcome measures.
- Indian researchers have started to realize the importance of PROs in improving the validity of their findings.
- At present there are no proper guidelines for conducting proper PRORIs in India.

REFERENCES

5. Dang A, Laghate T, VSN M