

4.16 RESEARCH

Introduction

Research is a rapidly growing aspect of inpatient medicine. The practice of evidence-based medicine and the acute need for more evidence on inpatient conditions require that pediatric hospitalists understand and participate in research related activities. Pediatric hospitalists' role in research will vary depending on their setting and job description. This role may include many facets, from reviewing relevant patient-based articles, to participating in multi-institutional studies requiring enrollment of patients, to leading local or national studies. Pediatric hospitalists should have a basic understanding of research methods and processes in order to participate in and benefit from research. Pediatric hospitalists are well positioned to promote research to patients, the family/caregivers, colleagues, and other healthcare providers and through this, to contribute to the effective care of hospitalized patients.

Knowledge

Pediatric hospitalists should be able to:

- Compare and contrast the advantages and disadvantages of experimental (such as randomized control trials) and observational (such as descriptive, cohort, or case control) study designs, including meta-analyses and systematic reviews.
- Define common sources of bias, including information bias, selection bias, and uncontrolled confounding, and describe how each may impact a study.
- Define basic statistical terms such as sample, discrete and continuous data variables, measures of central tendency (mean, median, and mode), and variability (variance, standard deviation, range).
- List resources available to access current or proposed studies including The Pediatric Health Information System (PHIS), the Healthcare Cost and Utilization Project (HCUP), the Kids' Inpatient Database (KID), clinicaltrials.gov, and others.
- Name potential research funding sources, such as the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), the Patient-Centered Outcomes Research Institute (PCORI), the Robert Wood Johnson Foundation, local and state funding sources, and others.
- Summarize the goals of pediatric hospital medicine-specific research networks, including the Pediatric Research in the Inpatient Setting (PRIS) network and the Value in Pediatrics (VIP) network.
- Discuss the basic resources commonly required to support research components, including data collection, data analysis, abstract and manuscript preparation, grant funding, and others.
- Review the aspects of the research process that relate to protection of participants, including informed consent and/or assent, the institutional review boards (IRB) review, and HIPAA (Health Insurance Portability and Accountability Act) forms.
- Discuss special protections needed when conducting research with vulnerable populations.
- Define "minimal risk" for a healthy child and for a child with an illness.
- Discuss why common training that addresses ethics, vulnerable populations, consenting, data safety, and other items is required prior to participating as a research team member for a research study.
- Compare and contrast the goals, intent, study focus, and IRB requirements for quality improvement studies from those of traditional clinical research.
- Cite the steps needed to obtain approval for a QI study within the local context.
- Compare and contrast the goals, intent, study focus, and IRB requirements for education studies to those of traditional clinical research.
- Cite the steps needed to obtain approval for a study focused on educational outcomes.
- List common barriers to implementation of clinical studies and describe the pediatric hospitalist's role in overcoming these barriers.

Skills

Pediatric hospitalists should be able to:

- Utilize a format such as PICO (Population, Intervention, Comparison, Outcome) to generate an answerable patient-centered clinical question that is relevant to improving patient care.
- Demonstrate proficiency in systematic searching of the primary medical literature using online search engines.
- Perform critical appraisal of the literature, including identifying threats to study validity, determining if study subjects were similar to local patients, and determining if all clinically important outcomes were considered.
- Apply and integrate the results of studies to clinical practice.
- Determine if the likely benefits noted in a treatment study are worth the potential harm and cost.
- Determine whether a test noted in a diagnostic study is available, affordable, accurate, and precise in the present clinical setting and determine whether the results of the test will change the management of patients being treated.
- Determine if the magnitude of risk warrants an attempt to stop the exposure for a given study on harm.
- Identify if the results of a given study on disease prognosis will lead directly to selecting therapy and/or are useful for counseling patients.
- Participate in educating learners and junior faculty about research and research methodologies, within the local context.
- Determine the relevance of potential research studies with regards to impact on patient care.
- Perform effective informed consent or assent for patients participating in research studies, as appropriate.
- Identify and resolve conflict of interest or potential conflict of interest when participating in research studies.
- Demonstrate basic skills in acquiring, managing, and sharing data collected for research purposes in a responsible and professional manner.

- Adhere to standards for protecting confidentiality, avoiding unjustified exclusions, sharing data, and adhering to copyright law.
- Perform peer-review of a manuscript, abstract, or other research-based work, in collaboration with colleagues as appropriate.
- Demonstrate basic skills in communicating about research opportunities with patients and the family/caregivers within the local context.

Attitudes

Pediatric hospitalists should be able to:

- Recognize the value of seeking the research that supports clinical care decisions and how research fills knowledge gaps and challenges the field to advance.
- Realize the importance of informed consent for patient participation in clinical research.
- Reflect on the importance of patient assent, even in the presence of legal guardian informed consent, when involving children in clinical research.
- Exemplify highly ethical behaviors when promoting or participating in research studies.
- Realize the value of and exemplify a willingness to perform journal-requested peer review of manuscripts, conference abstracts, or other research-based work.
- Reflect on and provide support and education for patients

and the family/caregivers on the benefits of research for hospitalized children.

Systems Organization and Improvement

In order to improve efficiency and quality within their organizations, pediatric hospitalists should:

- Lead, coordinate, or participate in interdisciplinary initiatives to develop and sustain participation of interdisciplinary teams in performance of research.
- Collaborate with colleagues, hospital administration, and community leaders for thoughtful application of research findings to improve systems of healthcare delivery.
- Lead, coordinate, or participate in national multi-center research efforts that improve the evidence base in inpatient pediatrics, within local context.
- Collaborate with leaders in the university department of pediatrics and school of medicine, hospital administration, and medical staff to encourage local hospital participation in national multi-center research efforts.
- Collaborate with research team members to educate colleagues, hospital staff, and others on the importance of research in improving child health outcomes.

References

1. Hulley SB, Cummins SR, Browner WS, Grady DG, Newman TB. *Designing Clinical Research*, 4th ed. Philadelphia, PA: Wolters Kluwer; 2013.