#### HEALTHCARE SYSTEMS: SUPPORTING AND ADVANCING CHILD HEALTH

#### 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 need to have a basic understanding of research methods and process in order to participate in and benefit from research. This understanding contributes to the effective care of hospitalized patients.

# **KNOWLEDGE**

Pediatric hospitalists should be able to:

- Compare and contrast different types of study design such as case-control, cohort, observational, and randomized control trials. Understand the advantages and disadvantages of each study design.
- Name resources available to access current or proposed studies and funding sources such as the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), Robert Wood Johnson Foundation, clinicaltrials.gov, and others.
- Discuss what resources are required to support research components of data collection, data analysis, abstract and manuscript preparation, grant funding and others.
- Explain how results from articles published in the following formats apply to clinical practice:
  - O Case reports and case series
  - O Retrospective chart reviews
  - O Secondary data analyses of large data sets
  - o Randomized controlled trials
  - o Meta analyses and systematic reviews
  - o Practice Guidelines
- Identify and efficiently locate the best available information resources to address questions in clinical practice, and conduct computerized scientific literature searches in a planned and systematic fashion.
- 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).
- Cite the various aspects of the research process including informed consent or assent, the role of institutional review boards (IRB), and HIPAA (Health Insurance Portability and Accountability Act).
- Discuss special protections needed when conducting research with vulnerable populations. Define "minimal risk" for a healthy child and for a child with an illness.
- List common barriers to implementation of clinical studies and describe pediatric hospitalists' role in overcoming these barriers.

## **SKILLS**

Pediatric hospitalists should be able to:

- Demonstrate proficiency in searching the medical literature for existing relevant clinical research for their inpatients.
- Generate an answerable patient-centered clinical question that is relevant to improving patient care.
- Apply the results of studies to clinical practice by determining whether the study subjects were similar to patients being treated, whether all clinically important outcomes were considered, identify threats to validity, and
  - o For treatment studies, describe whether the likely benefits are worth the potential harm and cost.
  - o For studies of diagnostic tests, describe whether the test is available, affordable, accurate and precise in the present clinical setting, and whether the results of the test will change the management of patients being treated.
  - o For studies of harm, describe whether the magnitude of risk warrants an attempt to stop the exposure.
  - o For studies of prognosis, describe whether the results of the study will lead directly to selecting therapy and/or are useful for counseling patients.
- Provide effective informed consent or assent for patients participating in research studies as appropriate.

## **ATTITUDES**

Pediatric hospitalists should be able to:

- Appreciate the importance of full informed consent for purposes of patient participation in clinical research.
- Appreciate the importance of patient assent, even in the presence of legal guardian informed consent, when involving children in clinical research.
- Demonstrate highly ethical principles in participating in research studies.
- Avoid conflict of interest or potential conflict of interest in participation in research studies.
- Acquire, manage, and share data collected for research purposes in a responsible and professional manner, maintaining high standards for protecting confidentiality, avoiding unjustified exclusions, sharing data, and adhering to copyright law.

# SYSTEMS ORGANIZATION AND IMPROVEMENT

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

- Encourage participation of interdisciplinary teams including nursing, social work, nutrition, pharmacy, and others in performance of research.
- Advocate for thoughtful application of research findings to improve systems of healthcare delivery.
- Support national multi-center research efforts that improve the evidence base in inpatient pediatrics. Where appropriate, encourage participation local hospital involvement in these efforts.
- Recognize, support and promote efforts of research team members (analyst, data collector, statistician, nursing, and others).