I. Background and Objectives for the Technical Brief

Clinicians, informaticians, policy makers, and professional organizations such as the American Academy of Pediatrics (AAP) have described a need for electronic health record (EHR) systems and information technology tools specific to pediatric health care.[1-3] EHRs in pediatric care may increase patient safety through standardization of care and reducing error and variability in the entry and communication of patient data.[4-9] While EHRs may improve safety, implementation of general EHR systems that do not meet pediatric functionality and workflow demands could be potentially dangerous.[10] Some studies have described improvements in immunization rates,[8,11,12] attention-deficit/hyperactivity disorder care,[13] preventive care counseling for children and adolescents,[14,15] and hepatitis C follow-up in infants.[16] However, few studies of EHRs overall have been conducted in the pediatric setting and available research about outcomes has yielded inconsistent results, potentially due to the variability of systems reviewed.[17-39]

While the Health Information Technology for Economic and Clinical Health (HITECH) Act has promoted adoption of EHRs by providers and hospitals, development and implementation of functionality to promote quality of pediatric care specifically has been inconsistent.[40] Organizations including the Agency for Healthcare Research and Quality (AHRQ),[41] Health Level 7 (HL7) International,[42] and the AAP[3] have described data formats and desired functionalities for pediatric EHRs. The Children's Electronic Health Record Format developed by AHRQ and the Centers for Medicare and Medicaid Services (CMS) provides a set of critical functionality, data elements, and other requirements for EHR systems that can address children's health care needs, especially for those enrolled in Medicaid or the Children's Health Insurance Program (CHIP).[41]

A 2007 AAP report noted immunization management, growth tracking, medication dosing, patient identification, data norms, terminology, and privacy as important concerns/requirements for EHR in pediatric populations.[43] Recent recommendations from the Society for Adolescent Health and Medicine also urge that EHR design take into account "the special needs of adolescents for access to health information and the vigorous protection of confidentiality" and note that EHR developers should ensure that systems meet regulatory requirements and privacy needs.[44] The degree to which currently available systems follow these recommendations and the individual recommendations' relative importance and effectiveness in improving outcomes with EHRs that have specific functionalities is unknown but constitutes data possibly available in the published and grey literature, and these could form the basis for future research.

"Meaningful Use" incentives associated with the HITECH Act have resulted in increased implementation and use of EHRs by pediatricians,[45] but the degree to which pediatricians are actually using EHRs appropriate for or specific to pediatric practice appears to be minimal. For example, suggested minimum requirements for a "pediatric-supportive" EHR include well-child visit tracking, support for anthropometric analysis such as growth charts, immunization tracking and forecasting, and support for weight-based drug dosing.[43,46] Only 31 percent of pediatricians use an EHR with basic functionality, and

only 14 percent use a fully functional[1] EHR.[4848] Only 8 percent of pediatricians are using a fully functional EHR with pediatric functionality.[49]

The Children's Electronic Health Record Format includes over 700 requirements pertaining to pediatric functionality. While the Format is expansive, the large number of requirements as well as the lack of prioritization may have had a paralyzing effect on vendors, who, confronted with Meaningful Use requirements, have not leveraged the Format to improve their products. Similarly, the HL7 requirements include over 100 unique pediatric items. Importantly, this Technical Brief will map consistencies across the published recommendations and analyze the degree to which an evidence base exists for individual or groups of functionalities. This will form the framework for creating the map of existing evidence and gaps.

Scope

This project will summarize the state of the literature on pediatric EHR functionality, including whether a set of functionalities arise in the literature as more important than others, and the degree to which these functionalities have been evaluated. Secondarily, the report will assess the availability and penetration of specific pediatric EHR functionalities in systems and identify challenges to implementation. Information about desired functionalities will be reported in descriptive reports and in reports and documents in the grey literature. We do not anticipate a significant body of comparative literature assessing the potential benefits of pediatric EHR use. Thus, the technical brief format is ideal.

Issues and Challenges in the Evidence Base

A significant challenge in this brief is likely to be the breadth of pediatric practice, including subgroups and special populations requiring specific elements of care that may merit specific EHR functionalities, all of which may diffuse agreement on key pediatric EHR features. We anticipate categorizing findings by subgroups or populations as appropriate.

Another challenge is that requirements and EHRs for inpatient and outpatient settings may differ and be represented differently in the literature. For the most part, inpatient pediatric functionalities are subsets of outpatient pediatric functionalities and inpatient adult functionalities. Our focus will be on functionalities for pediatrics primarily in the outpatient environment, and we will exclude functionalities also required by adults. As such, we will include functionalities that are useful in both the outpatient and inpatient environments, but will exclude functionalities that are exclusive to the inpatient environment. Similarly, individual reports may address specific elements of EHRs such as order entry or electronic prescribing. Again, we will clearly articulate the setting and populations associated with existing recommendations and will identify crosscutting elements where possible. Stakeholder groups such as the AAP have published numerous position papers and recommendations, which will provide important themes and crosscutting approaches.

In providing a complete view of the state of pediatric EHR use, it may also be difficult to compare and document the components of commercial EHR systems. Many vendors have contractual "gag clauses" that prevent users and purchasers of their software from discussing problems or even sharing screens. As

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[1] During 2007-2009, NAMCS defined a fully functional EHR system as having all 14 functionalities in basic systems plus the following additional features: 1) medical history and follow-up notes; 2) drug interaction or contraindication warnings; 3) prescriptions sent to pharmacy electronically; 4) computerized orders for lab tests; 5) test orders sent electronically; 6) providing reminders for guideline-based interventions; 7) highlighting out-of-range lab values; 8) computerized orders for radiology tests. American Hospital Association administered survey on EHR adoption defines comprehensive EHR to include the basic EHR core functionalities plus 14 additional functionalities implemented across all units (see Nakamura et al., 2013[45] and Jha et al., 2009[47]).

a result, deficiencies may be underreported, which we will try to address through use of the AAP EHR review site, which provides a collection of individual EHR reviews by pediatricians.

As expected given the relatively recent increase in adoption of pediatric EHRs, few RCTs of their effects likely exist, and the field is developing rapidly. A preliminary review of the literature suggests that some studies assessing the effects of pediatric health information technology on procedures such as immunizations and medication administration have been published and will provide emerging data on outcomes. Questions of applicability will therefore be important to address if EHRs are evaluated in very specific settings.

We will focus on the functionalities, needs, and desiderata uniquely relevant to pediatric care and beyond those functionalities available for adult care. Some functionality required for pediatric care is also critical for aspects of adult care, and we will include those functionalities, but focus on their use in pediatrics (e.g., immunization tracking, which is a key aspect of children's care as well as that of pregnant women and the elderly).

II. Guiding Questions

We propose Guiding Questions (GQs) that focus specifically on EHR tools and functionalities to support safe healthcare delivery for children. The need for and the benefits of core functionality is well accepted; therefore, the GQs will examine functionalities that have been or are being evaluated and can be disseminated and replicated by our end users. Sub-questions may evolve slightly over the course of the research as the researchers gain a deeper understanding of the topic. Other considerations include the degree of complexity for vendors and for users.

GQ1. Description of EHRs

A. Are there functionalities that have been identified in the literature and feature more prominently than others as potentially important to achieve for improving children's health?

GQ2. Description of the context in which EHRs are implemented

A. What is the potential value of pediatric-specific functionalities in the context of care transition, specifically from newborn care to pediatric primary care, from pediatric primary care to pediatric specialist care, and from pediatric primary care to adolescent care?

B. Are certain pediatric-specific functionalities beneficial for a pediatrician to conduct her work including sick and well-child visits? If so, does this vary by health care setting (e.g. primary care office, specialty care office, school health, and alternative care settings) or by type of visit (e.g., preventive vs. acute care)?

C. What are the challenges to implementing specific functionalities? Are some harder than others to implement by

    i.   vendors?

    ii.   Pediatric providers?

GQ3. Description of the existing evidence

A. Is there any evidence that using an EHR adapted for the specific needs of pediatric providers compared with using a "regular" EHR or not using an EHR at all produces:

    i.   better quality, including safety and cost outcomes for patients?

<div align="right">ii. improved workflow or job satisfaction for providers?</div>

B. Which pediatric-specific functionalities influence:

    i. Patient outcomes including:

        a. safety?

        b. quality?

        c. cost?

        d. equity?

        e. standardization of care?

        f. efficiency?

    ii. the ability of a pediatric provider to conduct work within the EHR?

    iii. improvement of workflow and provider satisfaction?

    iv. involvement of patients and families (including their education and shared decision making)?

GQ4. Dissemination and future developments

A. How does testability and usability of core functionalities promote or impede dissemination and future development of pediatric EHRs?

III. Methods

Data Collection

A. Discussions with Key Informants

The range of settings in which the pediatric EHR is intended for use complicates this project. We will engage stakeholders with multiple perspectives to help elucidate the decisional dilemmas that led to the project. Key Informants will help to identify key issues related to definitions, clinical areas, population, implementation, resources, and future research.

Following approval by AHRQ of the completed Disclosure of Interest forms from Key Informants, we will schedule one-hour conference calls with six to eight Key Informants to review the preliminary Guiding Questions and discuss the project parameters. Because the literature may not be optimally indexed on this subject, the Key Informants will also help to ensure that the search results capture the research landscape. We will record and transcribe the call discussion and distribute a call summary to call participants. Discussions with Key Informants may be used to refine the Guiding Questions and will inform the responses to all of the Guiding Questions

B. Grey Literature Search

Technical briefs combine contextual information from Key Informants with a search of the grey literature and the published literature. We anticipate that the grey literature is likely to yield model programs and example approaches. Examples of sources of grey literature include government websites, clinical trial databases, trade publications, and meeting abstracts. We will search for information from health and hospital systems that may have developed criteria for pediatric health information applications. We will work with the Scientific Resource Center to contact organizations, individuals, and vendors directly to request unpublished data or reports. We will be careful in our presentation of the grey literature to identify it as such, given that it is more likely that positive studies will be provided than negative or neutral ones.

The grey literature is likely to yield example approaches, policy statements, and proposed models. For the grey literature search, we will use Google and as a starting point, several known resources including the AAP's Child Health Informatics Center and HL7 sites.

The results of the grey literature searches will inform responses to all Guiding Questions, particularly Guiding Questions 2 and 4.

C. Published Literature Search

We will search the published literature for any studies that evaluate systems or models. We will use indexing terms and keywords to search the published literature for reports of EHR tools and functionalities as well as child health needs and related data elements. (See Appendix A for preliminary search strategies). An experienced library scientist who is familiar with all aspects of the technical brief protocol will examine the selection of databases and all search strategies.

We will review the reference lists of retrieved publications for other potentially relevant publications missed by the search strategies. We will hand search recent issues of core journals including the *Journal of the American Medical Informatics Association*, *BMC Medical Informatics and Decision Making*, *Journal of Biomedical Informatics*, *Pediatrics*, *Applied Clinical Informatics,* and *Methods of Information in Medicine*.

The search will be updated while the draft brief is being reviewed to identify newly published relevant information. We will incorporate the results from the literature update into the technical brief prior to submission of the final report. The results of the published literature searches will inform responses to all Guiding Questions.

D. Inclusion and Exclusion

We will use pre-specified criteria to screen the full text of the search results for inclusion. We will develop a simple categorization scheme for coding the reasons for exclusion from the report. We will use EndNote® to record and track the disposition of references (from the grey literature and published literature searches). We will focus on mapping existing evidence for health improvements, prioritizing functionalities, and identifying gaps.

Population: We will limit to the pediatric outpatient population, excluding data for adult functionality unless critical to the pediatric context and not considered core functionality of an EHR.

Intervention/Technology: We will not limit specific functionalities but expect to find more information to support certain functionalities (e.g., immunization, growth and developmental screening, weight-based and surface area dosing).

Outcomes: We will seek pediatric health outcomes but will include evidence for functionalities that improve workflow and process outcomes (e.g., reduced wait times). Indirect and process outcomes will provide meaningful information.

Timeframe: To capture key publications, we will include literature published in or after 1999 to include the period of accelerated EHR implementation.

Setting: There is significant overlap between needs of inpatient and outpatient, but some inpatient needs (e.g., tracking radiation exposure) that are also relevant to adult care are less relevant to outpatient. Certified EHR technology (CEHRT) was not intentionally designed for outpatient settings.

We will evaluate core concepts and functionalities that can support specialty and primary care and promote interoperability with other HIT applications in pediatric outpatient settings and will exclude functionalities also required in adult care.

Designs: We will allow randomized controlled trials, cohort, and pre-post study designs because these are likely the majority of studies and, at this point in the field, may provide clues about where further study should be pursued. The inclusion/exclusion criteria for the evaluation studies are summarized in Table 1.

Other: It is not necessary to assess availability of specific pediatric EHR systems but more important to map consistencies across the published recommendations on pediatric EHR functionalities and analyze the degree to which an evidence base exists for individual or groups of functionalities. We will include information addressing issues of testability, integration, and usability. We will include reports on all types of EHR systems including but not limited to commercial, homegrown, and hybrid systems.

Table 1. Inclusion and Exclusion Criteria for Evaluation Studies

Category	Criteria
Study population	Pediatric, outpatient
Publication languages	English only
Admissible evidence	Study design Randomized controlled trials, including wait-list control, cohorts with comparison, pre-post cohort without comparison, stepped wedge designs, and case-control. Outcomes • Healthcare quality including safety and cost • Improved workflow • Job satisfaction for providers • Patient outcomes including safety, quality, cost, equity, standardization, efficiency • Patient and family involvement including education and shared decision making Other criteria Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results.

Data Organization and Presentation

A. Information Management

We will develop data collection forms to record and summarize study design, methods, and results. We will summarize data from the data abstraction forms in tables. The dimensions (i.e., areas of special focus, or the columns) of each table will vary by guiding question but will include the following when reported: a) general information such as study design, year, setting, geographic location, and duration; b) population information including patient indication or inclusion criteria and details about the clinical environments such as the number and types of participating practices or providers; c) characteristics of the EHR and/or the specific functionalities, and if included, information and characteristics of the comparator (e.g., administrative database, paper records, health information exchange); and d) key contextual information (e.g., implementation, documentation, duration of followup) pertinent to the identification of facilitators and barriers to EHR functionality. Among other data, we will include any available information on prevalence and variation in practice.

B. Data Presentation

We will compile all of the information from the published and grey literature, with the ultimate goal of identifying functionalities that have been evaluated and example programs in those categories, as well as approaches that warrant further evaluation. We will characterize the information to include functionalities linked to outcome and workflow and aspects of testability and usability. The horizon scan of current practice and research will also be presented in summary tables and in the written report. If information from individual health care systems or hospital system is available, we will capture and catalogue the data that are meaningful to pediatric-specific features and functionalities for an EHR.

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V. Definition of Terms

Not applicable.

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient or policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or individuals with other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available

literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants, and those who present with potential conflicts may be retained. The Task Order Officer and the Evidence-based Practice Center work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the Evidence-based Practice Center in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

Appendix A

Preliminary Search Strategies (updated: 7/18/2014)

Table B1. Medline via PubMed

	Search terms	Search results
#1	("pediatrics"[mh] OR "infant"[mh] OR "Child"[mh] OR "adolescent"[mh] OR "child health services"[mh] OR "intensive care units, pediatric"[mh] OR "hospitals, pediatric"[mh])	2843532
#2	(child*[tiab] OR paediatr*[tiab] OR pediatr*[tiab] OR adolescent*[tiab] OR neonat*[tiab] OR infant*[tiab])	1529072
#3	("Medical records systems, computerized"[mh] OR "decision support systems, clinical"[mh])	28448
#4	(("cpoe"[tiab] OR "computerized physician order entry"[tiab] OR "computerized order entry"[tiab] OR "computer order entry"[tiab] OR "cdss"[tiab] OR "clinical decision support systems"[tiab]) OR (electronic[tiab] AND (health record*[tiab] OR medical record*[tiab])))	13323
#5	Search (#1) OR #2	3233572
#6	Search (#3) OR #4	34922
#7	Search (#5) AND #6	3270

Abbreviations: mh=Medical Subject Heading; tiab=title/abstract word;
Note: Using "medical order entry system" subject heading instead of "medical records systems, computerized" retrieves 2165 records. Using the broader term, "medical records systems, computerized" which encompasses "medical order entry system" and "electronic health records" retrieves an additional 1105 records- many of which may not be relevant to this topic. Cataloguers use the most specific heading available, however in this case, the broader term "medical records systems, computerized" was introduced in 1991, more than a decade before the more specific headings "medical order entry system" and "electronic health records".

Table B2. EMBASE Search Query

	Search terms	Search results
#1	(pediatric* or child* or infant* or paediatric* or neonat* or adolescen*).mp	3024185
#2	("computerized provider order entry" or "cpoe" or "electronic health" or "EHR" or "clinical decision support" or "CDS" or "CDSS").mp	18384
#3	#1 AND #2	1475
#4	Limits: NOT Medline, Publication Date: 2000-Current	83

Table B3. United States Patent and Trademark Office (USPTO)

Query	Results
(APT/1 and spec/((pediatric or child or neonate) and (health or medical) and (electronic or computerized) and (function or standard or functionality or functionalities)) and APD/1/1/2000->6/1/2014)	5511

Abbreviations: APT=Application Type; ADP=Application Date; Spec=Description/Specification

Notes: Limited to the utility patents (APT 1). The USPTO issues three types of patents: utility, design, and plant patents. Office of the National Coordinator for Health Information Technology (ONC) notes that "only utility patents, which include "process" or "method" patents that outline a way for performing a function or achieving an outcome, are significantly relevant" to the area of HIT. (From "ONC's Thoughts on Patents, Health IT, and Meaningful Use")