The election of the President Obama in 2008 brought the issue of health care reform to the forefront as part of the administration’s agenda. Underlying much of the discussion about improvement in access to health care is the concept that significant change could be implemented with the broader use of electronic medical or health care records (EMR/EHRs). What has been less clear, however, is how EHRs can directly facilitate actual improvement in patient outcomes. To address this issue, the concept of meaningful use was also introduced to providers interested in receiving incentive payments from the federal government to establish EHRs, although the phrase was
initially not well defined. The Department of Health and Human Services Web site in June 2009 stated the following:

To receive the incentive payments, providers must demonstrate “meaningful use” of a certified EHR. Building upon the work done by the HIT Policy Committee, the Centers for Medicare & Medicaid Services (CMS), along with the Office of the National Coordinator for Health Information Technology (ONC), will be developing a proposed rule that provides greater detail on the incentive program and proposes a definition of meaningful use.1

Subsequently, the Health Information Technology (HIT) Policy Committee developed a phased implementation of meaningful use for the years 2011 to 2015 in the following categories:

- Improve quality, safety, and efficiency, and reduce health care disparities
- Engage patients and families
- Improve care coordination
- Improve population and public health
- Ensure adequate privacy and security protection of personal health information.2

In 1996, Pediatrix Medical Group anticipated this issue and began to develop several modalities for care delivery in the neonatal intensive care unit (NICU) that would permit true meaningful use of electronic data collection. A proprietary EHR was initiated to provide a daily medical record note for practicing physicians within the organization. The EHR, initially known as RDS, was a modification of an already existing electronic record, and was subsequently replaced by a proprietary system that was developed in-house, called BabySteps.

This EHR also served as a tool for data gathering on a rapidly expanding patient population (Pediatrix Medical Group currently cares for approximately 20% of all NICU patients in the United States), while creating a system that would accurately code for the delivery of care according to guidelines developed by the American Academy of Pediatrics Perinatal Section Coding Committee. More importantly, however, serious consideration was given to extracting data from the database that was being developed, ultimately giving rise to the Pediatrix BabySteps Clinical Data Warehouse (CDW). Currently, the CDW is believed to be one of the largest repositories of data on neonates, containing detailed information on more than 600,000 infants and approximately 11,000,000 patient days. Because of the extent and depth of the data collected, it has been queried not only within the organization for novel research observations, but also by the US Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the National Institute of Child Health and Human Development (NICHD), and several academic neonatology programs.3–6 Many of these queries have resulted in publication in peer-reviewed literature.

Most recently, these tools were complemented by a new electronic module dedicated specifically to clinical quality improvement (CQI) initiatives, known as the QualitySteps System, or Quality Improvement Project System. The QualitySteps System is designed to allow the user to define an area for quality improvement, support a project with dedicated evidence-based literature, measure outcomes to be evaluated, enter and track data with annotated run charts, and then reassess outcome improvement (the Plan, Do, Study, Act cycle for quality improvement). This article describes these tools in detail to provide an understanding of their structure and how they have fulfilled the concept of “meaningful use” for true outcome improvement in the NICU.
BABY STEPS DEVELOPMENT AND DATA EXTRACTION

In 1996, Pediatrix Medical Group initiated development of a proprietary EHR throughout its practices. Several goals were associated with this project. First, the EHR was intended to create a clear, easily-readable admission, discharge, and daily medical record note that was consistent throughout the expanding number of neonatal practices within the organization (now numbering approximately 200 in 33 states plus Puerto Rico). Beginning in 2004, a series of concepts was defined as being critical for optimal EHR documentation, known as the four “Cs,” and are listed in Box 1.

| Box 1 |
The four “Cs” of electric health record documentation |
|---|
**Conciseness of notes** |
- Reduce the daily note to the specific needs of the patient
- Notes should not be so voluminous that they lose readability
- The daily note should, in general, only contain that day's information
- Avoid carryover of excessive amounts of information from previous days
- Excessive verbiage should be excluded, since it tends to breed inconsistency in charting and increases liability

**Convey information to other caregivers** |
- Notes must be easily readable
- Daily changes in the patient’s condition or the management plan should be immediately apparent to the reader
- The medical record should accurately chart the progress of care
- Problems should be diagnosed, assessed, treated, resolved, and removed from daily notes as appropriate
- Simple recitation of numbers or laboratory reports does not constitute patient assessment, and further evidence of physician thought processes must be provided in the record
- Spelling and grammatical errors should be eliminated through careful rereading of notes and use of spell-checking

**Confirm clinical decisions** |
- Note should not be simply recount numbers or events, but must assess the patient’s clinical condition and provide a cogent and coherent approach to care
- Notes should be read carefully before being placed into the chart
- Confirmation of the clinical plan and the reasons for that plan are essential in assigning proper codes for the care being delivered

**Consistent internally** |
- Notes should be consistent from the physical examination through the management plan. There should not any discrepancies between the physical examination, laboratory values, radiographic studies, the assessment, or the plan for the patient
- Entry of information into fields, rather than as comments, is essential in refining the daily progress note and limiting inconsistency
- A methodology of checking for internal consistency should be a part of everyone’s charting
- Inconsistencies are the most common problematic issue within the chart that is difficult to defend in malpractice cases
- Consistency and accuracy in the note supports correct daily coding
Without attentiveness to these issues, there is a tendency within the EHR to add excessive detail that makes evaluation of the daily note difficult, especially for consultants and reviewers, while potentially increasing liability risks. Because parts of notes in many EHRs can be readily cloned and carried over from day to day, it is sometimes erroneously believed that voluminous documentation aids in the care of the patient. Unfortunately, nonrepresentative information is often brought forward unnecessarily, while simply enhancing risks for liability, either through patient error or the potential for malpractice. To offset these risks, Pediatrix has had an extensive corporate-wide documentation training project in place for many years that all physicians are required to review on a regular basis.

The initial EHR was a modification of another program and was called RDS. Because of its limitations, it was phased out starting in 2004 and gradually replaced by BabySteps within the Pediatrix practices. Ultimately, the information in both RDS and BabySteps was merged and validated in the CDW, so that the changeover did not result in a loss of information for any of the physicians. Fig. 1 shows a sample of the front page of the BabySteps admission note.

In planning for automated data extraction, several decisions had to be made that were critical toward obtaining accurate outcome results. These processes are often overlooked during the adoption of the EHR and are most important in the concept of meaningful use. Because the daily medical record note contains a combination of drop down/specific field entry menus and areas for text entry, the question of whether to use both parts of the note for data extraction was debated for some time.

For several reasons, the decision was made to extract data only from the drop down/field entry menu. First, selection of specific diagnoses and other defined parts of the note yields a consistency of information that would otherwise not be possible. Secondly, based on an assessment of how a few specific, common diagnoses were designated in the text areas of the note, great potential variability exists in documentation. As an example, the diagnosis of neonatal intraventricular hemorrhage was found to be mentioned in the text areas in more than 1000 different ways. A partial list of these is shown in Box 2, all of which would need to be examined (and any other variations that one might encounter) if the text boxes were to be accurately reviewed. In addition to the increased complexity of the programming that would be needed, this process would slow the data evaluation and extraction to a serious degree, limiting the

Fig. 1. Part of the BabySteps admission note to the neonatal intensive care unit.
The developers therefore believed that limiting extraction to the drop down menu fields, accompanied by a strong documentation education effort, would be the optimal approach.

### GOALS FOR DATA EXTRACTION FROM BABY STEPS, THE BABY STEPS DATA WAREHOUSE

The ultimate goals for the data were also discussed in great detail and several key objectives were identified. Most importantly, outcome data needed to be extracted.
from the electronic record automatically. This approach would have several benefits. Physicians would not be burdened by designing a way to get chart information into a database, which would require additional time commitment on their part or the cost of a data extractor. In addition, automated data extraction would eliminate the possibility for any bias that might creep into the information. For example, many referral centers show a tendency to exclude some patients in databases who are sent for the highest level tertiary care, because they tend to bias outcomes negatively. Babies sent for laser surgery for retinopathy of prematurity (ROP), neonates requiring major cardiac or gastrointestinal surgical procedures, and infants with complex congenital malformations all tend to adversely influence outcomes in these NICUs. The hospital stays lengthen with complex issues from care that is rarely straightforward, even in the hands of the finest medical and nursing staff. With intensifying scrutiny being given to outcomes, shouldering the burden for these patients in a database often leads to outcome results that initially appear less than optimal. Consequently, including these types of patients in data sets is often less than ideal. Automated extraction of information, therefore, leads to a much more precise data set, from which sounder conclusions can be drawn.

When attempting this sort of data extraction, several issues become apparent. Each practice must be intimately aware of evolving outcomes. Often, when viewing this information initially, one is often left with a sense of disbelief. Most physicians believe that they perform optimally, and therefore their outcomes must, of course, be second to none. Unfortunately, this view is rarely supported by the actual data, and when viewing the data for the first time, a complex emotional process frequently must be negotiated. Dan Ellsbury, MD, the Pediatrix Director of Quality Improvement, describes humorously (but accurately), with apologies to Elizabeth Kübler-Ross, the five stages of “data grieving”:

- Denial: These data can’t be right! You must have made a mistake.
- Anger: Why are you picking on me? Don’t I have enough to do already?
- Bargaining: My patients must be sicker than everyone else’s; my NICU is different; I don’t agree with those data definitions.
- Depression: I can’t do anything about it anyway….
- Acceptance: OK…what can I do to improve the outcomes in my NICU?

The goals of Pediatrix Medical Group, therefore, have been to help physicians confront their data and move through these stages as quickly as possible so that they can ultimately focus on their outcomes and work toward improvement, which is the primary reason for providing them with this information.

Furthermore, the decision was made to present these data in the form of a graphic report, rather than a table, to provide a more visually and mentally indelible impression. Therefore, many months of inpatient hospital data sometimes had to be rapidly scanned and processed to create certain reports. In addition, developers believed that looking at outcome data in the abstract would not be meaningful, and the data had to have some basis for comparison. In a company of this size, the obvious comparison would be with the remaining patient population in Pediatrix Medical Group, at least as an initial starting point. Each report, therefore, would have to present outcomes from not only the individual practice but also all other Pediatrix practices to provide summary comparative data. These outcomes had to be provided in an easily viewable format so that the practitioner was not overwhelmed by a report that required a significant investment of time to interpret.

Because outcome data were going to be used in a comparative manner throughout Pediatrix Medical Group, the CDW had to be HIPAA (Health Insurance and Portability
and Accountability Act of 1996) compliant. Moving data from the consolidated data set required eliminating all patient-identifying information. Although a practice could look at its own outcome data in summary form, it could determine the origin of any patient when viewing other practices’ results. Therefore, all identifying information that could be used to trace a patient back to a source had to be methodically eliminated. To accomplish this result, data “cleansing” excludes information such as day, month, and year of birth; date of admission; date of discharge; date of specific therapy initiation; addresses; and free text fields. All events are therefore recorded as days since birth to eliminate any possibility of discovery.

Research use of the de-identified data set is approved annually by the Western Institutional Review Board (IRB). One of the original goals was to use the CDW for novel research observations involving large patient populations, and this IRB certification of HIPAA compliance permits it to be used as a research tool. IRB approval is also required from any institution, company, or university whose investigators wish to query the CDW. During the past decade various groups have published more than 50 peer-reviewed papers using information from the CDW. Some of these papers appear in the reference list.

 Elimination of selection bias was also important because practices tend to avoid taking credit for patients who might have adverse outcomes, especially in transport situations. Through collecting data on all patients and allowing comparisons between inborn and outborn patient populations and NICUs of similar size, controls were built into the CDW to avoid situations in which large referral institutions were somewhat unfairly penalized for accepting the most difficult cases in transport. Although some databases either risk-adjust or assign severity indices to outcomes, the developers believed that presenting the actual real data, with selection of appropriate comparison groups, was a preferable way to examine outcomes. Accumulation of these more complex clinical cases often leads to outcomes in tertiary institutions that initially appear far worse on the surface than those in community hospitals, which rarely care for these infants. Finally, to examine any regional variations in outcomes that might be of interest, the CDW also allows grouping of all hospitals covered by an individual practice to allow comparison with other groups within the state or a region of the country.

BABYSTEPS DATA WAREHOUSE REPORTS

The CDW is constantly evolving to provide practicing physicians with the most current data possible, and as many report types as is practical for managing patients in their NICU. By responding to clinician feedback, the CDW has become an increasingly useful tool for meaningful assessment of outcomes and quality improvement initiatives. Data within the CDW is refreshed on a weekly basis to retain currency.

Box 3 lists currently available CDW reports. Reports are categorized into several types: activity reports, which indicate basic demographic types of information; management reports, which reflect decision-making processes in patient care; morbidity and mortality reports, which document a variety of common outcomes of greatest interest in NICU patients; and summary reports, which provide a selected one-page snapshot of outcomes for a specific NICU, or network trends in various outcomes that are constantly tracked.

Summary Reports were developed as a request from the regional management teams, who are each responsible for approximately 40 to 70 practices in one of six regions of the country. To provide a sense of the quality of care being delivered
### Box 3
**Current Pediatrrix Clinical Data Warehouse reports**

**Activity Reports**
- Types of discharges (eg, home, transfer, in-hospital)
- Admissions by gestational age
- Admissions by birth weight
- Length of stay
- Average daily census
- Type of delivery (vaginal vs cesarean section)

**Morbidity and Mortality Reports**
- Mortality
- Survival
- Oxygen at 28 days of life (bronchopulmonary dysplasia [BPD])
- Oxygen at 36 weeks’ gestational age (BPD)
- Intraventricular hemorrhage (IVH)
- Late-onset sepsis, necrotizing enterocolitis
- Patent ductus arteriosus
- Periventricular leukomalacia
- Respiratory distress syndrome and surfactant use
- ROP
- Severe IVH
- Severe ROP
- Pneumothorax

**Management Reports**
- Maximal ventilator support
- Median ventilator days
- Temperature from delivery room to NICU
- Types of lines inserted and duration of use
- Median daily weight gain during the first 28 days
- Hepatitis B immunization rates
- Percent of infants breastfeeding at discharge
- Bilirubin reports
- Late-onset sepsis rates

**Infection reports**
- Percent of NICU admissions treated with antibiotics
- Median days of antibiotic therapy with negative cultures
- Use of cefotaxime
- Percent of patients treated without cultures
- Nosocomial/line sepsis: infections/1000 catheter days (in testing)
in an individual unit, or all units within the region, the Summary Report was developed to present a snapshot picture of overall outcomes, and is shown in Fig. 2. The Summary Report is flexible, in that it can be altered to follow NICU trends of greatest interest at any time. For example, the use of dexamethasone postnatally is included as a medication-related report, because the use of this drug remains controversial. It would be easy, however, to replace dexamethasone with another medication should that be desired, because the CDW tracks the use of most of the important medications used in the NICU. Overall, Summary Reports provide an instant snapshot of a year’s general outcome measures that can be evaluated within minutes. Observers desiring more data could reference the more detailed reporting levels available.

A typical CDW report is illustrated in Fig. 3. Reports can be viewed for yearly, quarterly, or monthly periods. Many morbidities, even in large NICUs, occur so infrequently that annual reports often work best, but clinicians at least have the option to examine an outcome during various time frames, which is very helpful in quality improvement projects.

![Fig. 2. Annual summary report for an individual NICU from the Clinical Data Warehouse with selected indicators in 14 different areas. The gray bars on each gauge represent the 33rd to 66th outcome percentiles (middle third) for all Pediatrix Medical Group neonatal intensive care units.](image-url)
Clinicians may filter report results using multiple combinations of birth weight and gestational age selections to facilitate detailed “drill down” for various outcomes. Results can also be filtered using admission status - inborn, outborn, or combined. The selected filtering parameters are used to provide the specific network comparison group, and can be further refined by selecting high- (>450 discharges annually), medium- (225–450 discharges annually), or low-volume (<225 discharges annually) NICUs as the comparison group (Fig. 4).

The report illustrated in Fig. 3 examines catheter-related blood stream infections between January 1, 2006 and July 30, 2009. The annual rate of infections, shown as the rate per 1000 catheter line days, is shown for this specific NICU as dots connected by a solid line from year to year. In the background in gray is the 33rd to 66th percentile for all of Pediatrix Medical Group. As can be seen during this period, the infection rate in this NICU was declining, as was the rate for all NICUs in Pediatrix, partly from an increasing CQI focus on reducing catheter-associated bloodstream infections. This type of run-chart methodology is extremely useful in assessing whether interventions in a specific NICU have value over time.

Fig. 5 is a management report examining the highest level of ventilatory assistance given to patients over time. Interesting trends in patient care can be discerned, particularly the increasing use of nasal continuous positive airway pressure (CPAP), reflecting the current tendency to try to avoid mechanical ventilation of extremely low birth weight infants. As Fig. 5 indicates, the use of nasal CPAP rose from 13% of ventilated neonates in 2006 to 33% in 2009, whereas the use of both conventional and high-frequency ventilation declined, which is an encouraging overall trend.

Some reports cannot be provided easily in graphic form in the CDW, but still have great value for patient care and quality improvement. The medication report is an example of a report in tabular format, again allowing clinicians to examine the use of many of the most common neonatal medications in their NICU, while
Fig. 4. The panel on the left shows multiple weight and gestational age options that may be selected to filter reports. Admission status (inborn or outborn) is available as an additional filter. The comparison network group may be selected based on annual neonatal intensive care unit (NICU) volume and/or specific region or state (see panels on right for examples of network variation based on NICU volume).

Fig. 5. Clinical Data Warehouse report from an individual neonatal intensive care unit (NICU) showing the changing patterns of ventilator support between 2005 and 2009. Y axis shows percentage of NICU admissions treated with each modality. O2, oxygen only; CPAP, continuous positive airway pressure; HFNC, high flow nasal cannula; Ventilator, standard mechanical ventilation; HFV, high frequency ventilation.
using the scope of Pediatrix Medical Group as the basis for comparison. A section of this report is illustrated in Fig. 6. The medication classes examined in this report are listed in Box 4.

THE DATA WAREHOUSE IN QUALITY IMPROVEMENT

The Pediatrix CDW is a valuable technology for examining many common neonatal outcomes and some basic population data. Although the provision of outcome data can have a strongly influential effect in improving the quality of care, the effect can be magnified through the use of directed methodology in quality improvement. The application of these evidence-based strategies can further enhance improvement, truly illustrating how an EHR can provide “meaningful use.”

The CDW has been the basis for many quality improvement interventions in Pediatrix Medical Group during the past several years, and several toolkits have been devised that use this resource as the foundation for CQI projects. For instance, in 2004 to 2005, a corporate-wide program was initiated that focused on reducing the rate of ROP. This project, known as COMP-ROP (Comprehensive Management of ROP), provided educational programs, nursing and physician assessment of their understanding of ROP pathophysiology, a slide presentation, parent information, isolette stickers for correct oxygen level management, and several other informational programs for caregivers and parents. More detailed information about this effort can be found in the article by Ellsbury and Ursprung, elsewhere in this issue. The CDW was the tool used to follow ROP rates, which have improved markedly since that time. From 2003 to 2008 a striking decrease in severe ROP (stage 3, 4, or 5, or surgical) was seen in the Pediatrix Network. In infants with birth weights of 400 to 1500 g, severe ROP dropped from 11% in 2003 to 5.8% in 2008 (Fig. 7). Given the fact that Pediatrix Medical Group admits 25,000 to 30,000 extremely and very low birth weight infants annually, the reduction in rates of severe ROP unquestionably represents an important public health initiative. Over this 6-year period, several thousand infants experienced decreased morbidity and preservation of their sight, which is well documented in the CDW.

Similarly, other Pediatrix quality improvement programs have also resulted in significant wide scale outcome improvements in areas such as reducing unnecessary antibiotic therapy, enhancing growth rates, improving temperature from the delivery room to the NICU, and decreasing medication use of drugs with limited evidence of therapeutic value for the neonate (eg, metoclopramide, spironolactone). Fig. 8 shows the rates of use for several of these medications from 2003 to 2008.

In practice, Pediatrix corporate quality improvement projects have started with identifying a pressing outcome concern that must be addressed. The CQI team, with consultation from several medical directors, reviews the literature, defines the appropriate evidence necessary to support the project, and proceeds to build a toolkit. The toolkit contains reprints of key publications from the literature, slide presentations for the medical and nursing staffs, an operations manual that describes the methodology for rolling out the project, and any ancillary materials needed for project management. Toolkits are finally posted on the Pediatrix University Web site (www.pediatrixu.com) for participating practices to review. The toolkits do not represent specific recommendations on how to practice, but rather provide a series of alternate approaches that may be valuable for certain NICUs looking to enhance their outcomes. Each practice has the ability to modify and tailor the toolkit to their particular unit’s needs. Timelines are then established for projects, and enrollment is
Fig. 6. Medication usage report. Table of yearly medication use for certain drugs between 2003 and 2008 in the Clinical Data Warehouse. Table shows individual neonatal intensive care unit use (NICU) and comparison with other NICUs.

<table>
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<tr>
<th>Year</th>
<th>NICU Use (n)</th>
<th>Amphotericin</th>
<th>Fluconazole</th>
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<td></td>
<td>n</td>
<td>%</td>
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<td>789 pats.</td>
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<tr>
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<td>15</td>
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<td>780 pats.</td>
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<td>2008</td>
<td>787 pats.</td>
<td>10</td>
<td>1.3%</td>
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<th>Antibiotic-Aminoglycosides</th>
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<th>Ceftazidime</th>
<th>Ceftriaxone</th>
<th>Nafcillin</th>
<th>Vancomycin</th>
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initiated for units desiring to participate. The CDW then serves as the primary method of following outcome data.

As can be seen from these data extracted from the CDW, having a tool at this level of sophistication allows truly meaningful health care improvement and cost savings. The scope of cost reduction can be gathered from Fig. 9. From 2003 to 2009, when Pediatrix Medical Group intensified its quality improvement efforts, length of stay in the company declined from a mean of 15.9 to 14.2 days. With nearly 90,000 NICU admissions per year and an approximate overall daily cost of care (hospital and physician) during this time period of $2200, this shortened length of stay could potentially result in more than $330,000,000 of health care savings this year in participating NICUs. This saving has not occurred from the more traditional use management approach, in which outliers are identified and an effort is made to discharge them from the hospital. It has instead come about through the application of thoughtful application of evidence-based medicine, leading to reduced hospital use from decreased morbidity and mortality, which also adds immeasurably to parent satisfaction.

THE QUALITY IMPROVEMENT PROJECT SYSTEM (QUALITYSTEPS)

In recognizing the value of data-driven applications in health care, Pediatrix Medical Group has also noted a growing need exists for other applications for measuring patient outcomes. Ideally, these applications should allow simplified data entry, extraction of summarized information, and generation of annotated run charts that would enable users to follow targeted outcomes over time. Furthermore, this system should enable comparisons with other databases, yet be flexible enough to allow modifications for various quality tracking projects. For example, although the CDW
facilitates tracking of many outcome variables, some projects of great value and interest might not normally be captured in the daily progress note that forms the basis of the CDW. Safety projects, evaluation of hand hygiene, and similar measures require an alternative tracking mechanism. To meet this demand, the group developed the Quality Improvement Project System, or QualitySteps.

QualitySteps was initially devised to assist Pediatrix Medical Group physicians in creating annotated run charts for CQI projects. Data can easily be extracted from the BabySteps EHR and inserted into QualitySteps for use in quality assessment. The welcoming screen for QualitySteps is shown in Fig. 10.

Fig. 8. Declining use of several drugs in the neonatal intensive care unit between 2003 and 2008. Y axis represents percentage of patients treated with these medications. X axis shows the individual years. Epo, erythropoietin.

Fig. 9. Length of stay (LOS) report from the Clinical Data Warehouse between 2003 and 2009. Arrow indicates decline in LOS from 15.9 to 14.2 days for all Pediatrix neonatal intensive care units on average.
Projects can be designated and worksheets readily created that allow data entry on a selected patient population. Each facility or practice using QualitySteps has one or more administrators who are responsible for designing the project and devising the appropriate questions to be answered by participants in the module. The administrator’s screen is shown in Fig. 11. Ultimately, a panel of questions about a specific issue can be designed. Answering the questions allows a run chart to be generated. This process is shown in Figs. 12 and 13. On the run chart, annotations can be placed as indicated, along with comments that outline the types of interventions that were initiated on the specific dates. Communication among CQI participants can also occur in the form of text messages left on the Web site, so that all members of the project are always up-to-date with the project status. In addition, administrators can include supporting documentation (eg, published papers, manuscripts) to ensure that the background evidence necessary to support the initiative is available to everyone.

Fig. 10. QualitySteps system welcoming screen.

Fig. 11. QualitySteps administrator screen.
Although Fig. 12 indicates a series of questions related to the presence of the ductus arteriosus, the flexibility of the system permits administrators to devise a module and questions on any topic desired, not only those related to neonatal medicine. As a result, QualitySteps is a very flexible, easy-to-use tool that can be applied in any field of medicine to track a quality improvement initiative.

Fig. 12. QualitySteps module screen related to ductus arteriosus management. Other accessible modules are noted in the left-hand column.

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Fig. 13. Run chart tracking outcome of hand hygiene intervention program. Goal line is set at 85% compliance. Three boxes resting on x-axis indicate points of intervention. Annotations for these interventions are noted elsewhere in the program.
The BabySteps Research Data Warehouse

The clinical value of the CDW is immediately apparent in terms of neonatal outcomes and quality improvement, especially in the areas noted. Furthermore, Pediatrix has attempted to be responsive to the requests of its practicing physicians, and many of the clinical reports that have been developed were designed to meet their needs in providing optimal patient care. Given the fact, however, that the BabySteps record is scoured daily for 563 data fields, when combined with the extraordinary volume of patients in this database (now >600,000), the potential for novel research observations cannot be overlooked. In fact, the CDW has been queried by the NIH and the NICHD Neonatal Network, the FDA, several major universities, and private corporations, all of whom have sought data that are not available elsewhere.

As an example of the usefulness of the CDW, the FDA contacted Pediatrix in 2005 because it was interested in knowing the 30 most commonly used medications in the NICU. These data were furnished to the FDA and published in Pediatrics. On further examination of these data, the FDA noted that three of the five most commonly used medications were antibiotics: ampicillin, gentamicin, and cefotaxime. Because the most common neonatal admission to the NICU is suspected septicemia, these drugs clearly represented the two most common antibiotic regimens used for suspected sepsis, namely ampicillin and gentamicin, and ampicillin and cefotaxime. These two approaches were believed to be equivalent, with equal outcomes and equal risks. Cefotaxime had the advantage of greater central nervous system penetration than gentamicin, and blood levels of cefotaxime did not need to be measured during treatment.

When Pediatrix examined the outcomes in the CDW in more detail, however, they discovered that the use of cefotaxime had nearly a twofold (100%) greater association with mortality at certain gestational ages than gentamicin in this patient population of more than 128,000 infants diagnosed with suspected sepsis. (Fig. 14) Extensive attempts to eliminate confounding variables through the use of logistic regression analysis strongly suggested that this finding was correct. Because of this risk, the use of cefotaxime for early-onset suspected septicemia can no longer be supported. Use of this medication has fallen to an extremely low rate in participating NICUs across the country.

This type of observation, which otherwise might have gone unnoticed, became apparent only when sufficient numbers of patients could be evaluated. Many of the

![Fig. 14. Adjusted odds ratios for mortality rate of ampicillin and cefotaxime compared with ampicillin and gentamicin; 95% confidence intervals are indicated. (From Clark RH, Bloom BT, Spitzer AR, et al. Empiric use of ampicillin and cefotaxime, compared with ampicillin and gentamicin, for neonates at risk for sepsis is associated with an increased risk of neonatal death. Pediatrics 2006;117:67–74; with permission.)](image)
data warehouse observational studies now consist of similar large populations of patients. A more recent publication examining rates of meconium aspiration syndrome and persistent pulmonary hypertension in neonates during the past decade among 162,075 term neonates showed a continuing level of these problems had not changed during this interval, despite what many people believed.9

Pediatrrix continues to expand the data warehouse capabilities for research, and constantly invites inquiries for its use. This type of database not only provides answers to many outcome questions but also can provide a model for prospective trials and studies in which targeted data collection is required. Much more information can continue to be extracted and evaluated that will have additional significant benefits for the practice of newborn medicine.

SUMMARY

The Pediatrix BabySteps CDW is a rich and novel tool allowing unbiased extraction of information from an entire neonatal population care by physicians and advanced practice nurses in Pediatrix Medical Group. Because it represents the practice of newborn medicine ranging from small community intensive care units to some of the largest NICUs in the United States, it is highly representative of scope of practice in this country. Its value in defining outcome measures, quality improvement projects, and research continues to grow annually. Now coupled with the BabySteps QualitySteps program for defined CQI projects, it represents a robust methodology for meaningful use of an EHR, as designated during this era of health care reform. Continued growth of the CDW should result in continued important observations and improvements in neonatal care.

REFERENCES


FURTHER READINGS


