REVIEW
Quality and Safety in Pediatric Hematology/Oncology

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INTRODUCTION

While the field of pediatric hematology goes back to the time of the discovery of the microscope, pediatric oncology has only a relatively short history of about 60 years [1]. However, incredible progress has been made, most of it due to extensive collaborations, agreement on general treatment approaches, such as protocols and guidelines, and rigorous attention to treatment results, and unwanted side effects. Pediatric hematology/oncology should thus be a leader in patient safety and evidence-based care. This article reviews some of the obstacles and problems that continue to persist.

Patient safety and quality of care are the cornerstones of modern medicine. Quality transformation is the conversion of a health care delivery system from its baseline service performance to one of high quality care. The Institute of Medicine (IOM) defines health care quality as “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” and high quality care [2] as care that is safe, effective, patient-centered, timely, efficient, and equitable. This can be achieved through the use of several measures (Table 1).

USING EVIDENCE TO GUIDE BEST PRACTICE AND MINIMIZE VARIATION, STANDARDIZATION AND ADHERENCE TO RULES AND GUIDELINES

Pediatric oncology is one of the prime examples of what can be achieved by using evidence and standardization for the development of treatment approaches. We have created numerous protocols for different diseases, each based on the results of the previous ones. Examples are the rhabdomyosarcoma studies (IRS I–V and now the ARST protocols) [3] or the different leukemia studies conducted by the Children’s Cancer Group (CCG), Pediatric Oncology Group (POG), both now incorporated into the Children’s Oncology Group (COG), the European Berlin-Frankfurt-Muenster (BFM) and other groups [4–7].

However, we still do not have standardization in other areas, especially supportive care. For example, there is wide variation regarding the absolute neutrophil count at which a patient can be safely discharged from the hospital [8–10], whether patients with acute myelogenous leukemia should remain hospitalized during count recovery [11], or what initial treatment to use in a patient with newly diagnosed immune thrombocytopenia [12]. Even more problematic is the consistent adherence to rules and guidelines. Although we do have a multitude of guidelines, few institutions monitor adherence, especially if the treatment is not part of a research protocol [13]. Some of our patients with sickle cell disease may not be followed according to published guidelines, for example, may not get the recommended frequency of transcranial Doppler exams [14].

TRACKING PATIENT QUALITY OUTCOMES

The Institute for Healthcare Improvement (IHI) has published the “triple aim” of improving the patient experience of care, including quality and satisfaction; improving the health of populations; and reducing the per capita cost of health care. When patients are enrolled on protocols, we obtain various outcomes measures, such as efficacy of treatment, documented as cure rates and survival data, tolerance and toxicities, and for many protocols also quality of life information [15]. Except for SEER data, we have limited information regarding the outcomes of patients that were not enrolled on protocols, such as the majority of our patients with hematologic or oncologic problems, for whom no protocol was available. We often do not even know the length of stay for certain diseases that require hospitalization or the readmission rate.

Most treatment centers regularly obtain data on patient and family satisfaction. However, we rarely know what impact lost days of work or school have on our patients and families [16]. Although we gather the data, most centers have not yet successfully addressed one of the most common complaints, that is, excessive waiting, in our hematology/oncology clinics [17].

Population health can be defined as taking care of our patient population outside of the immediate treatment encounter or taking care of a larger population in regards to preventive interventions. We have made some progress in regards to the first approach, for example by the creation of the Passport for Care, an Internet-based tool that allows long-term survivors of cancer to be followed into adulthood, and gives both them as well as their physicians guidelines on what late effects to consider and test for [18,19]. Population health is also beginning to be addressed, for example by studying the impact of parental smoking, immunizations, or sun retribution when mentioning a problem. This review explores why specialists in pediatric hematology/oncology should be leaders in the field of quality and safety in healthcare. Pediatr Blood Cancer 2014;61:966–969. © 2014 Wiley Periodicals, Inc.

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Many principles of quality of care and patient safety are at the foundation of pediatric hematology/oncology. However, we still see too many errors, continue to have problems with communication, and the culture in many of our areas is still one of worrying about errors; high reliability; quality; safety

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exposure on cancer incidence [20–22]. However, we are probably not yet proactive enough in keeping our patients with sickle cell disease healthy so they do not need to be hospitalized, or in addressing the increased health risks of smoking, depression, and obesity in our childhood cancer survivors, to name just a few examples. We also have opportunities for improvement in optimizing the follow up of patients who are discharged after an inpatient stay, to make sure that they were able to fill their prescriptions, understand their instructions and thus are able to prevent readmissions.

Medical errors, the use of superfluous tests and a lack of standardization impact medical costs, length of stay and readmission rates [23]. Readmissions are often taken as an unavoidable part of treating children with cancer or blood diseases [9,24–26]. In pediatric hematology/oncology we are still in the early stages of assessing the economic impact of different treatment modalities [27]. Reports have mainly focused on the economic feasibility of treating childhood cancer in low or middle-income countries [28,29], but we are only starting to consider economic variables when deciding on treatments or other interventions in industrialized countries [27,30–32]. With the upcoming changes in the reimbursement models, all of us will have to become much more cognizant of the economic impact of out therapies and will have to justify any outlier costs [33].

SUPPORTING A TRANSPARENT PROCESS, CREATING A CULTURE OF SAFETY AND QUALITY

In 1999, IOM published its report To Err Is Human: Building a Safer Health Care System. The authors estimated that 44,000–98,000 deaths are caused by medical errors every year [34]. In adults, at least 2 out of every 100 hospital admissions result in a preventable adverse drug event, leading to estimated national costs of $17–$29 billion due to lost income, prolonged hospitalizations, disability, excess health care costs [35–37]. One study found 55 medication errors per 100 inpatient admissions at a single, leading pediatric teaching hospital [38], and others estimated that approximately 70,000 hospitalized children experience an adverse event each year in the United States and that up to 60% of these events may be preventable [39].

A search of a national, voluntary, internet-accessible error reporting system (United States Pharmacopeia MEDMARX database) for all error reports from 1999 through 2004 that involved chemotherapy medications and patients aged <18 years revealed that 85% (264) of the 310 reported pediatric chemotherapy errors reached the patient, and 49 (15.6%) required additional patient monitoring or therapeutic intervention. The chemotherapeutic agents that were most commonly involved included methotrexate (15.3%), cytarabine (12.1%), and etoposide (8.3%) [40]. In a review of oral chemotherapy for children with acute lymphoblastic leukemia, one or more errors were found with 17 of 172 (9.9%) of medications prescribed [41]. Although groups such as COG have made an effort to standardize the ways protocols are written, current protocols and roadmaps often include various specific dosing rules or modifications for each different disease status (e.g., CNS positivity or not), response rate or treatment cycle, thus making the correct writing of an order a challenging endeavor. There might be regulatory requirements to report errors or variances if an investigational drug or experimental protocol design are involved, but it is still very difficult to obtain safety data at a hospital or patient level. Furthermore, relatively few studies have looked at medication errors that occur outside of the hospital, when parents or patients administer the drugs [42]. One study found 36 errors with potential for injuries and 3.6 actual injuries due to errors per 100 patients [43].

Educational components to improve safety in the chemotherapy process include a requirement for defined competencies for chemotherapy for all three disciplines involved (physicians/nurse practitioners, nurses, and pharmacists), an ongoing education process for all new protocols, and development and dissemination of multidisciplinary policies for both oncology and nononcology chemotherapy. Patient or parent participation can also help prevent adverse drug events. However, possibly even more important is the creation of a blame-free environment that is actively and visibly supported and nurtured by leadership. It has been emphasized that a major shift in culture from a punitive to a nonpunitive environment is necessary to create and maintain positive changes, especially when they emphasize teamwork instead of placing the blame on the – provider [44]. Although we in pediatrics and especially pediatric hematology/oncology think of ourselves as collegial and nonjudgmental, safety culture surveys still show either fear of retribution from either a colleague or supervisor when reporting an error or an impression that nothing was done in response to the reporting [45,46]. This results for example in nurses not stopping a consultant from going into the patient’s room without observing the isolation signs on the door, because of concerns regarding the response [45]. Many healthcare professionals feel that the electronic medical record system has added to their workload, that their input is not being sought or heard and they thus stop mentioning problems and instead develop potentially unsafe workarounds [47–49].

TABLE I. Approaches to Achieve the Institute of Medicine Goals to Provide Care That Is Safe, Effective, Patient-Centered, Timely, Efficient and Equitable

| Using evidence to guide best practice and minimize variation | Standardization and adherence to rules and guidelines |
| Tracking patient quality outcomes | Includes process, as well as clinical, humanistic and economic outcomes measures |
| Supporting a transparent process | Creating a culture of safety and quality |
| Employing a team approach within and external to its infrastructure | Offering educational opportunities |
| Continually seeking to improve the processes to improve outcomes | Participation in local, national, and international expert groups |

Quality/safety in pediatric hematology/oncology

Employing a team approach within and external to its infrastructure

Care for the pediatric hematology/oncology patient is based on a multi-disciplinary team approach, including social workers, nurses, physical therapists, physicians and other providers, as well as child...
life specialists, nutritionists, and others. However, to make progress in quality and safety, the team concept needs to be taken to the next level. Not only does each team member lend their expertise, there also needs to be cross-functionality that allows everyone to check and comment on all actions, like it has become routine for example in the airline industry [50]. Hand-offs between different care providers are becoming ever more numerous and without a standardized approach that is regularly monitored for its quality will result in confusion, wasted time and resources and in the end to more errors that threaten our patients' safety [51].

Several tools are available to improve teamwork. The Department of Defense and the Agency for Healthcare Research and Quality (AHRQ) have developed Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPSTM) as a systematic approach to integrate teamwork into practice (http://www.ahrq.gov/qual/teamstepps/) [52,53]. Others are modeled on the aviation industry’s Crew Resource Management [54] model, the Microsystems approach (http://www.clinicalmicrosystem.org/), or the Comprehensive Unit-based Safety Program (CUSP), developed initially to decrease catheter-associated blood stream infections (CLABSIs) in intensive care units (http://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html).

CONTINUALLY SEEKING TO IMPROVE THE PROCESSES TO IMPROVE OUTCOMES

There are numerous opportunities for improvement. Pediatric hematologists/oncologists are already participating in national and international expert groups when it comes to the design of new treatment strategies. Similar groups that focus on quality of care and patient safety as it pertains to our specialty are emerging. The American Academy of Pediatrics has a subgroup (Council on Quality Improvement and Patient Safety, COQIPS) that focuses on quality and safety and the American Society for Pediatric Hematology/Oncology (ASPHO) has conducted several workshops during the annual meetings where best practices could be shared. Several healthcare institutions offer formal training in quality and safety, and more and more journals, including this one, are accepting articles describing improvement efforts [55,56].

One of the goals is to become a high-reliability organization (HRO) [57–59]. Although ensuring that patients receive the standard of care is important, there needs to be a mechanism to reduce the opportunities for humans to make mistakes, also referred to as error-proofing or reducing the need for work-arounds [60]. Reliability principles are used successfully in industries such as air travel and manufacturing to help evaluate and improve the overall reliability of complex systems. Reliability is measured as the inverse of the system’s failure rate. It is estimated that the US health system has a defect rate of 1 in 10 (i.e., we do it right only about 90% of the time), thus performs at a level of $10^{-5}$. High reliability industries, such as the nuclear power industry or the airline industry function as or above the $10^{-6}$ level [60]. A performance level of $10^{-1}$ relies on basic standardization, such as guidelines, standardized order templates, on memory aids, including checklists, and on feedback mechanisms regarding compliance with standards and awareness-raising as well as training of new staff. To get to the next level ($10^{-2}$, or 95% reliability) we need to implement real time identification of failures, introduce redundancy, such as double verification of chemotherapy orders, and create an environment that makes the right way the easy way to do it [59]. Level 3 ($10^{-3}$ failures or fewer than 5 failures per 1,000) gets to the core principles of HROs:

Preoccupation with failure: Real time awareness of failures, daily monitoring of process, reporting of near misses, and an enhanced sensitivity to processes that could potentially fail before they actually do, is the hallmark of this trait.

Reluctance to simplify: The first, obvious explanation for a failure may not be the right one. Just like in research, we need to challenge simple assumptions, expect data to back up any statements. It is rarely true that a single person is responsible for a failure; it is usually the system that allowed an error to be made. Jim Conway, who was the Executive Vice President and Chief Operating Officer at The Dana Farber Cancer Institute, when an error, a cyclophosphamide overdose, lead to the death of a patient, said: “Our systems are too complex to expect merely extraordinary people to perform perfectly 100% of the time. We as leaders must put in place systems that support great practice by people who suffer from being human and thus will make mistakes.”

Sensitivity to operations: Leaders and staff are constantly aware of how processes and systems affect the organization. Any process that does not work is highlighted and modified in real time. Transparency is a great tool to increase sensitivity to operations.

Commitment to resilience: Failures and especially near-miss situations are learning opportunities. High reliability organizations are constantly learning, improving, and testing new ways of operating. This takes skilled people that have the appropriate tools, as well as adequate time to evaluate, measure and implement. A common tool is the Plan-Do-Study-Act (PDSA) cycle [61].

Deference to expertise: This includes taking advantage of the different levels and areas of expertise that team members contribute, and the recognition that the most senior person is often not the most knowledgeable. Just like we use multi-disciplinary teams to discuss patient care, we may use the same approach to discuss any real or potential failures.

Examples already exist that such high performance levels are possible to achieve: the safety of blood transfusions or general anesthesia approach a low failure rate of $10^{-5}$, similar to the airline industry [62]. Clearly, an investment will be necessary, not just in dollars, but also in people and time. In the new reimbursement system hospitals that experience safety events will be at even greater risk, not just because of potential litigation, but also because insurance companies will no longer reimburse us for events they consider preventable, such as ventilator-associated pneumonias, catheter-associated blood stream infections, pressure ulcers. A study from Cincinnati Children’s was able to demonstrate measurable savings for the hospital. Over a 2-year period estimated harm-related hospital costs decreased by 22% due to a decrease in serious safety events (from 1.15 to 0.19 events per 10,000 adjusted hospital-days), and a decrease in preventable harm events by 53% [63]. However, in order to be successful, such an initiative, although executed at the microsystem or individual unit level, must be supported by the mesosystem, such as the division chiefs or service line leaders, as well as the macrosystem, which includes the hospital, or the pediatric department, or even the health system [59,64,65].

Pediatric hematologists and oncologists are in a great position to take the lead in quality and safety. We are well acquainted with protocols, guidelines, and comparative effectiveness and are very aware of the potential hazards of our care. We can collaborate to standardize our care of hematology patients, just as we are doing in...
oncology [66]. We should assess cost effectiveness of both hematology and oncology [27,30,67], and insist on following proven quality and safety procedures in our daily practice [68–70].

REFERENCES