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Educational Article

Reduction and standardization of surgical instruments in pediatric inguinal hernia repair

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Summary

Aim
To standardize and reduce surgical instrumentation by >25% within a 9-month period for pediatric inguinal hernia repair (PIHR), using "improvement science" methodology.

Methods
We prospectively evaluated instruments used for PIHR in 56 consecutive cases by individual surgeons across two separate subspecialties, pediatric surgery (S) and pediatric urology (U), to measure actual number of instruments used compared with existing practice based on preference cards. Based on this evaluation, a single preference card was developed using only instruments that had been used in >50% of all cases. A subsequent series of 52 cases was analyzed to assess whether the new tray contained the ideal instrumentation. Cycle time (CT), to sterilize and package the instruments, and weights of the trays were measured before and after the intervention. A survey of operating room (OR) nurses and U and S surgeons was conducted before and after the introduction of the standardized tray to assess the impact and perception of standardization.

Results
Prior to creating the standardized tray, a U PIHR tray contained 96 instruments with a weight of 13.5 lbs, while the S set contained 51, weighing 11.2 lbs. The final standardized set comprised 28 instruments and weighed 7.8 lbs. Of 52 PIHRs performed after standardization, in three (6%) instances additional instruments were requested. CT was reduced from 11 to 8 min (U and S respectively) to <5 min for the single tray. Nurses and surgeons reported that quality, safety, and efficiency were improved, and that efforts should continue to standardize instrumentation for other common surgeries.

Conclusions
Standardization of surgical equipment can be employed across disciplines with the potential to reduce costs and positively impact quality, safety, and efficiencies.

Introduction

Curtailing escalating healthcare costs continues to be a challenge globally. Efforts to maintain and improve quality while hopefully reducing costs, in an environment of ever-increasing scientific and technological advances, are laudable, but also challenging.

Lean methodologies and other techniques of improvement science have been used successfully in industry to reduce waste, and have been adopted in health care to reduce waste, and thus reduce costs while enhancing safety and quality. The operating room (OR) and central supply (CS) are areas associated with high costs within a hospital. Despite such costs, improvement science has not been broadly implemented in these environments [1,2]. Specifically for the OR, Kenney has adapted the Lean principle of 5S, sort, simplify, sweep, standardize, and self-discipline, to safely reduce and standardize sterile instruments to the minimum number necessary to perform a given surgery [3]. Farrokhi further demonstrated, that by applying such methodology the number of instruments used in minimally invasive spine surgery can be reduced by 70%, with set-up time reduced by 37%, yielding significant cost benefit [4]. In an audit of 38 spine cases performed by two surgical specialty groups, neurosurgeons and orthopedic surgeons, only 58% of instruments were used at least once. By removing the unused instruments, the tray weight was decreased by 17.5 lbs and costs were reduced [5].

Avansino et al. addressed standardization in a common pediatric surgical procedure, laparoscopic appendectomy. They concluded that

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standardization of equipment increases value by reducing costs without negatively impacting quality [6]. Pediatric inguinal hernia repair (PIHR) is one of the most commonly performed operations in childhood and may be performed by both pediatric surgeons (S) and pediatric urologists (U). We hypothesized that a significant number of instruments for PIHR were never used by surgeons in either specialty, yet would be counted by the nursing staff in the OR, and require routine processing and packaging in CS. Our aim therefore, was to develop a single tray for all surgeons performing PIHR and assess the impact on the surgeons, nursing staff, and in CS.

Methods

This was a prospective, single-center, observation and implementation study that was carried out between October 2014 and June 2015 at the Hospital for Sick Children in Toronto after approval by the institutional Quality Improvement Committee. The aim of the study was to reduce instrumentation by at least 25% and develop a single, standardized instrument tray for PIHR that was satisfactory for both S and U over that period of time. Relevant tray set-up included trays for any male patient >3 months corrected gestational age undergoing open elective inguinal hernia repair, thus excluding emergency and newborn hernia repairs, and cases in which laparoscopic herniotomies were performed.

The design of the study employed the primary tool of Lean, observation [7]. A comparison of two clinical phases, pre and post-standardization each with several components was then carried out.

Phase I

A PowerPoint presentation was given to all major stakeholders, all surgeons and OR nurses, to appraise them of the project design and to address potential concerns. A non-validated survey then was administered to U and S surgeons to assess their attitudes toward standardized surgery and its impact on efficiency, quality, and safety. In addition, other questions related to potential costs and standard practice were included in the surgical arm. Four independent observers were trained to observe all PIHRs performed using the routine U and S instrument preferences, with a minimum of two cases/surgeon and >50 cases total being evaluated. The purpose of observation was to count the actual number of instruments used in each operation from induction through closure. Instrument use was defined as those instruments that were held by the surgeon at least once, even if not actually used on the patient. The study team met weekly to discuss collected data, and to assure that ongoing, frequent informal interaction with all stakeholders took place to update them of findings and invite their input. After compiling representative data for this phase, formal PowerPoint presentations were given to the U and S surgeons, CS and nursing service leaders, to engage them in any decisions made before a standardized tray was developed. After these discussions, a standardized tray was constructed with only instruments used in >50% of the cases during Phase I observation.

Phase II

After the new tray was unveiled, plans were to have the "old" routine tray available in all cases as back-up, but to open only the new, standardized tray for each PIHR. Using the same criteria as Phase I, the observers then compiled data on the instruments used in each operation. As with Phase I, ongoing weekly team meetings occurred. Surgeons and OR nurses were invited to submit requests to the project lead and/or the director of CS, to request additional peel pack instruments for their cases, if they felt the standardized set did not meet their needs. A survey similar to the pre-standardization survey with additional questions added related to perception of the standardized tray was administered to nurses and surgeons 6 weeks after implementation of the new tray.

Cycle time (CT) is a key measure used in Lean initiatives that helps to develop standard work and promote consistency [7]. In the CS area, the CT to rinse, sterilize and repack each tray was measured using a calibrated stopwatch on 10 pre-standardization routine U preference hernia sets, 10 pre-standardization routine S hernia sets, and 10 standardized new hernia sets. The same CS worker was used for all 30 cycles to minimize variability. In addition, the weights of each of the three trays were measured.

Results

All fourteen staff surgeons, eight S and six U participated in the study. In Phase I, the pre-standardization period, 56 consecutive open PIHRs over a 6-week period were observed: 44 performed by S and 12 performed by U. The routine preference cards for PIHR performed by U contained 96 instruments, and for S, 51 instruments. Between nine and 23 instruments were used by all surgeons. For U, only 16 instruments were used in >50% of cases, 11 used in <50% of cases, with 69 (68%) never used. For S cases, again 16 different instruments were used in >50% of cases, with 18 used <50% of the time, and 17 (33%) never used (Fig. 1A and B). The new, standardized tray comprised instruments used only >50% of the time in Phase I, 28 instruments with a reduction of 3.4-fold for U and almost a 2-fold reduction for S (Fig. 2).

In Phase II, four old, routine preference (non-standardized) instrument trays were opened in 52 cases observed (8%) over 5 weeks. One of these sets was opened in error so that only three (6%) represented a balancing measure of importance, where an instrument deemed necessary for that surgeon or that operation, would not have been available on the new tray. As the old routine set was available in these cases, although not to be opened unless an instrument was requested that was not on the standardized tray, no circulating nurses had to leave the OR to search for surgical equipment. Five of 14 total U and S (34%) sent emails requesting that three different instruments that were essential to them but were not included in the new standardized tray, be available in peel packs for their cases in addition to the new tray.

In the CS area, processing of a single, standardized tray, measured by CT calculation, was reduced to 5 min from 11 min for the old U hernia set and 8 for the S tray. In addition, the weight of the standardized tray was 8 lbs

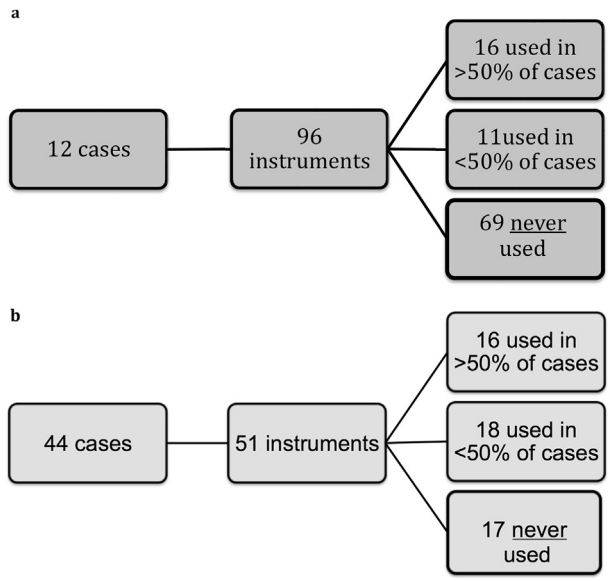

Figure 1 (A) The pre-standardization instrument set used by pediatric urology (U) was observed in 12 instances and it was identified that only 16 of 96 instruments were used in >50% of cases while 69 were never used. (B) The pre-standardization instrument set used by pediatric surgery (S) was observed in 44 instances and it was identified that only 16 of 51 instruments were used in >50% of cases while 17 were never used.

compared with 13.5 and 11.2 lbs for the old U and S sets, respectively.

The survey prior to Phase I suggested that almost all OR nurses and most surgeons agreed that standardization in the OR was cost-effective, efficient, and should be expanded. A majority of the 41 nurses surveyed (87%), but only 8/14 (58%) of surgeons felt that patient care could be affected by use of standardized trays. Six weeks after completing the Phase II observation, the vast majority of both nurses and surgeons surveyed agreed that efficiency, costs, safety, and patient care were improved and standardization should be encouraged. Of the nurses, 91% preferred the new trays, whereas 6% preferred the old, and 3% found no difference. On the other hand, 60% of surgeons found the new set better, 30% observed no change, and 7% (one) felt the old tray was better. The surgeons suggested further efforts be directed to: orchidopexy, laparoscopic

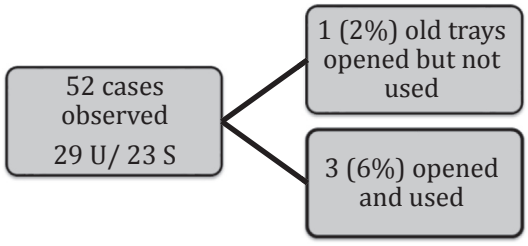

Figure 2 Post-standardization, an instrument tray was constructed containing 28 instruments. In observing 52 cases, 29 U and 23 S, although in four cases the old set was opened, only three of the four actually required additional instrumentation not in the new, standardized set.

appendectomy, and circumcision procedures, as well as some orthopedic, ophthalmologic, and gynecologic procedures (Tables 1 and 2). From a practice perspective, only 35% of all surgeons sent a hernia sac routinely for histopathology, and 58% scheduled a routine postoperative clinic appointment. Surgeons preferred using two sutures in two-thirds of cases, with a quarter using three different sutures and occasional surgeons using only a single suture (12%).

Discussion

Aside from patient factors, the success of an operation depends on the knowledge and skill of the surgeon and the operating team, proper surgical equipment, including operative instruments, and the manner in which this equipment is provided. It has been the inherent culture of our institution to provide each surgeon with his or her individual preferences for instrumentation for each given surgical procedure. We chose to study PIHR as it is common procedure of short duration performed both by S and U. The primary aim of this study was satisfied, which was to reduce the number of instruments and to create a single, standardized surgical tray for open PIHR. Avansino promoted the concept that standard work reduces variation by practitioners, yielding improved efficiency and predictability [6]. PIHR is one of the most common pediatric surgeries performed, is associated with an extremely high success rate, and randomized, prospective trials have supported that accurate postoperative instructions and open access are as effective in follow-up as a standard office visit [8]. Thus the likelihood of adversely impacting safety and appropriate delivery of care as quality measures, would have been unlikely by this intervention. On the other hand, a tray with reduced instruments allows efficiency by providing a more rapid set-up in the OR with less time spent counting those instruments. This may allow the scrub nurse or technician to concentrate more on the issues related to the operation itself, although this was not measured as part of this project [9].

The operating room is a unique environment, in which surgeons often practice "experience based medicine", which may reflect their past training and experience [6]. When there are uncertain personal or professional benefits to the surgeon, nurses, or to patient outcome, a stance of maintaining the status quo is often maintained. As a result, standardization or adopting any change can be difficult within the culture of the OR. Rogers described five characteristic stages related to diffusion of innovation that create an "S" curve based on drivers and barriers to change [10]. In this model, individuals on the left of the curve, innovators and early adopters, will be most likely to adopt new ideas or practices, while those on the right hand side, the late adopters and the laggards, will be the most hesitant to embrace these changes. The early majority is key as they must be won over to support interest from the late majority and laggards. In this project, knowing that each surgeon had his/her own routine and preference card, it was imperative to engage them as groups and as individuals, and encourage their participation frequently throughout the process to achieve, sustain, and even propagate the outcome. Moreover, as has been suggested elsewhere, we presented all data in a de-identified manner

Table 1 Pre and post-standardization surveys of perception of surgeons and OR nurses on standardization of instrument sets for PIHR.

	PRE-standardization		POST-standardization	
	Surgeons, $n = 14$	Nurses, $n = 41$	Surgeons, $n = 12$	Nurses, $n = 32$
Single standardized preference card for inguinal hernia surgery improves patient care	59%	87%	89%	93%
Single standardized preference card for inguinal hernia surgery compromises patient safety	6%	10%	5%	0
Single standardized preference card for inguinal hernia surgery improves efficiency in the OR	95%	93%	100%	98%
Single standardized preference card for inguinal hernia surgery reduces OR costs	82%	96%	97%	98%
We should standardize preference cards for other procedures when possible	80%	100%	100%	98%

Table 2 Post-standardization survey as to perception of post-standardization tray on actual practice and to ascertain need for additional instruments.

Compared with unstandardized (old) tray, how would you rate the standardized (new) tray?	No difference	Better	Worse (prefer old tray)
Nurses (32)	3%	91%	6%
Surgeons (12)	33%	60%	7%

	Yes	No
Do you routinely require additional instruments that are not available on new tray?	9%	91%
If you answered yes, are they readily available?	100%	0

to nurses and surgeons to promote individual motivation and reduce the potential for peer pressure [6]. Based on the survey and the outcomes observed in Phase II, the vast majority of surgeons and nurses agreed that the change had a positive impact or felt that there was no impact on efficiency with the standardized tray.

Although CS is a vital component of any medical center, little literature has focused on opportunities to improve quality and safety in surgical instrumentation and sterile processing. Proper sterile instruments must be provided for a given operation and these instruments must then be returned and re-processed in CS for future use. Processing errors have been reported to occur in >3% of surgical cases, which potentially impact safety and quality by prolonging operative times and anesthesia exposure, distracting OR team members, and delaying other patients awaiting surgery. Lean methodology has successfully been used to reduce errors related to instrument processing [11]. Our study used one of the main tools of Lean, observation, and although instrumentation for PIHR is not as complex as that for spine surgery addressed in Lunardini's study, tray weights were reduced by 3–5 lbs [5]. Previous research in a single site, observational study found that the higher the number of instruments on a tray, the lower percentage of instruments used and the higher the error rate, regardless of operating service [12]. Reducing the number of instruments also reduces costs [4]. Our study did not specifically assess costs, which is a limitation of this study. However, CTs in CS were greatly reduced, in particular for processing the old U tray compared with the new, standardized tray. Stockert and Langerman calculated the cost of for labor and cleaning and re-packaging an instrument to be $0.10. When adding in additional CS operating expenses and considering depreciation, the cost for processing an instrument increased to $0.51 [12]. Applying those cost estimates to our institution, the savings in reducing the tray from 96 instruments for U and 51 in S to 28 would yield, potential cost savings/tray range $2.30(S)-6.80(U) when addressing labor, sterilizing, and re-packaging. If one then adds CS operating expenses and depreciation, these costs/tray escalate by a factor of 5 to $11.73 for S and $34.68 for U. Roughly six to 10 elective PIHRs are performed weekly at our institution, and the mix varies between S and U. Still these indirect calculations support that CT is reduced by standardization, as is overall institutional cost.

There are limitations to this study other than those addressed previously. The follow up is of short duration and thus long-term sustainability was not measured. Given that we based changes for the tray on a finite, randomly selected patient group without studying their demographics, older and especially heavier patients, might require instruments other than those on the standardized tray. The survey questions were developed for this study and not validated. The survey data were collected without identifiers and the number of responses for both surgeons and nurses varied between pre-intervention and post-intervention, potentially introducing a response bias. Because of the small numbers, U and S were not considered separately. We did not audit the counting of instruments in the OR, nor measure the impact that might have on nursing attention to the case. However, the survey did suggest that both surgeons and nursing supported

standardization in promoting efficiency and quality and safety. In addition, after the standardized tray was rolled out, the old tray was made available in the room, and hence the impact on the circulating nurse and the OR itself, by having to leave the room was not measured. However, our data indicated that the old tray was only opened in 6% of cases.

There are additional opportunities to further reduce waste and costs related to this specific operation. For instance, might surgeons agree on using only one suture rather than two or three? Is a routine clinic visit necessary postoperatively given the high success rate, and the costs and time invested by the institution and providers and by the patient and family? Lastly, there are costs associated with routinely, rather than selectively, sending hernia sacs to pathology [13]. As has been suggested by the post-survey, there is interest in expanding standardizing beyond PIHR in our hospital to other common operations. This set could also be tested further for use in other similar inguinal-scrotal surgeries such as orchidopexy, and adjusted as needed, as part of this quality improvement initiative.

Conclusions

Berwick stated that: "Health care is rich in evidence-based innovations, yet even when such innovations are implemented successfully in one location, they often disseminate slowly-if at all" [14]. In health care, the OR represents a unique environment with a culture that often resists change. In the current fiscally constrained healthcare environment improvement, efforts must address costs as well as quality and safety. Surgeons have unique opportunities to address many inefficiencies related to health care and to strive for continuous process improvement augmenting the value of health care.

Conflict of interest

None.

Funding

This was an unfunded study that was approved by the institution's Quality Committee.

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