Application of Lean Principles to Neurosurgical Procedures: The Case of Lumbar Spinal Fusion Surgery, a Literature Review and Pilot Series

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Abstract

BACKGROUND: Delivery of higher value healthcare is an ultimate government and public goal. Improving efficiency by standardization of surgical steps can improve patient outcomes, reduce costs, and lead to higher value healthcare. Lean principles and methodology have improved timeliness in perioperative medicine; however, process mapping of surgery itself has not been performed.

OBJECTIVE: Utilizing lean principles we applied plan, do, study, act (PDSA) cycles methodology to lumbar posterior instrumented fusion (PIF) to create a standard work flow, identify waste, remove intraoperative variability, and examine feasibility among pilot cases.

METHODS: Process maps for 5 PIF procedures were created by a PDSA cycle from one faculty neurosurgeon at one institution. Plan = modularize PIF into basic components, Do = map and time components, Study = analyze results, and Act = identify waste. Waste inventories, spaghetti diagrams, and chartings of time spent per step were created. Procedural steps were broadly defined in order to compare steps despite the variability in PIF and were analyzed with box and whisker plots to evaluate variability.

RESULTS: Temporal variabilities in duration of decompression vs. closure and hardware vs. closure were significantly different (p=0.003). Variability in procedural step duration was smallest for closure and largest for exposure. Wastes including waiting and instrument defects accounted for 15% and 66% of all waste, respectively.

CONCLUSION: This pilot series demonstrates that lean principles can standardize surgical workflows and identify waste. Though time and labor intensive, lean principles and PDSA methodology can be applied to operative steps, not just the perioperative period.

KEY WORDS: plan, do, study, act cycles; lumbar posterior instrumented fusion; healthcare; value

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INTRODUCTION

"Better is possible. It does not take genius. It takes diligence. It takes moral clarity. It takes ingenuity. And above all, it takes a willingness to try."- Atul Gawande, *Better: A Surgeon's Notes on Performance*.[1]

Healthcare spending growth outpaces gross domestic product growth in many countries including the United States (US).[2] In 2008, the Institute for Healthcare Improvement (IHI) developed the "Triple Aim" quality initiative intended to improve patient experience of care, improve population health, and reduce per capita cost of health care in the US.[3, 4] As the landscape of healthcare and cost containment measures have evolved, so has the paradigm with which we train and evaluate residents. Neurosurgical resident education requires surgical experience. That experience comes from time spent in the operating room and sometimes learning from mistakes. Increased time and waste decreases efficiency and increases costs of medical care, thus competing with the IHI Triple Aim.

In response to the IHI and other national directives, quality improvement departments within hospital systems have shifted focus to improving safety, maximizing outcomes, and decreasing cost. Our institution developed a Performance Excellence System (PEx) in partnership with Graduate Medical Education (GME) as a set of tools and principles for multidisciplinary teams to engage in quality initiatives. The PEx has a dual mission to improve the value of patient care and formally train providers (attendings and residents) in quality improvement. The latter is concordant with similar didactic national education platforms in quality improvement for neurosurgeons.[5]

Quality Improvement Principles

Lean Principles

Lean principles are adapted from the manufacturing industry, from the Toyota Production System, to improve overall customer value by identifying and eliminating waste – any step in a procedure or item that does not add value to the end-product.[6] These principles have been increasingly applied to medicine (Table 1). The fundamental premise of lean principles (lean) is elimination of wastes. Wastes are categorized into one of seven categories; transport, inventory, motion, waiting, overprocessing, overproduction, and defects (Table 2). By categorizing and understanding waste, one can eliminate or reduce that step or item from the process, therefore make it leaner.

The value of a step is defined by the customer and in the case of medicine, the patient. Any step that adds value to the patient's experience, such as safety and satisfaction, should be kept, given that it is economically feasible. Unique to healthcare, though they may not add direct value to the patient, the needs of other parties must be taken into account when assigning value to steps: staff, physician, resident, and student, safety and satisfaction.[7]

A process map is a visual representation of the steps required to achieve a result and is defined by convention.[8] Recent studies have used value stream maps, or sophisticated process maps which identify value and waste, to reduce length of stay in the Emergency Department (ED) and increase patient satisfaction without increased inflation adjusted cost per patient as well as decrease turnover time between same surgeon operative cases.[9, 10] The creation of a process map facilitates the identification of waste and promulgates *standard work*, or the modular steps comprising a process. Standard work allows for reproducibility and becomes the rubric against which changes may be proposed.

The PDSA Cycle

The Plan/Do/Study/Act (PDSA) cycle is one of the core tools of lean (Figure 1). In the *Plan* phase, a problem statement is identified and the current state defined. In the *Do* phase, measurements are obtained to identify value and waste components. At this stage, a process map is constructed defining the component parts of the process and their respective values in creating a product or providing a service. The *Study* phase analyzes the results and categorizes the types of waste (Table 2). Once waste is identified, the *Act* phase allows process improvement by enacting problem solving methodologies to minimize wasteful and non-value-adding steps, which prevent a smooth, continuous flow of work toward the product or service.[11]

Lean Principles in Healthcare and Neurosurgery

Healthcare has repeatedly applied lean principles to improve patient care, reduce costs and reduce medical errors.[12-14] The operating room (OR) is a poignant example where complex combinations of patient needs, medical personnel, and variable inventory interact; consequently, this is also where cost savings can be maximized. Peri-procedural processes, including first start times, turnover times, level loading of cases, and procedure-end to out-of-room times are studied with ever-increasing resolution to identify areas of waste.[8, 15-18] Perhaps because of the heterogeneity of surgical procedures and the politics of measuring surgical procedure times, no studies have looked specifically at defining standard work for neurosurgical procedures, targeting wastes, and improving surgical value. Procedural efficiency itself has thus far avoided scrutiny.

Neurosurgery as a discipline has previously used some of these principles towards faster bed turnover, decreasing length of stay, and reducing unnecessary imaging acquisition.[10, 19] McLaughlin and colleagues at University of California Los Angeles (UCLA) pioneered a multidisciplinary team termed Neurosurgery Enhanced Recovery after surgery, Value, and Safety (NERVS). NERVS involves the entire care team involved with neurosurgical patients and works by creating process maps.[20] The unique clinical quality improvement program at UCLA has also targeted some perioperative initiatives including cost containment in the OR by targeting inventory, overproduction, and defect wastes.[21]

The Problem: Posterior Instrumented Fusion

A lumbar posterior instrumented fusion (PIF) is a heterogeneous set of surgeries aimed at treating a myriad of etiologies for back and/or radicular pain. A 2005 analysis of US administrative data demonstrated a 220% increase in the number of lumbar fusion procedures from 1990 to 2001.[22] In addition, a 2012 analysis of US spinal fusion data between 1998 and 2008 demonstrated a 2.1-fold increase in the utilization rate and a 3.3-fold increase in average total hospital charges.[23] Among all spinal fusion procedures, lumbar fusion experienced the highest increase and the rate of increase in spinal fusion procedures exceeded that of other procedures including laminectomy, hip replacement, knee arthroplasty, percutaneous transluminal coronary angioplasty, and coronary artery bypass grafting.[23]

In this study, we applied lean principles to lumbar PIF, and produced a process map and waste inventory for a small, heterogeneous number of pilot cases. The goal of this study was to determine the feasibility of applying lean to procedural efficiency in neurosurgery. We identified difficulties in using lean tools and suggest some alternative methodologies, which may be more effective at targeting surgical waste in the OR.

Methods

Performance Excellence System (PEx)

PEx is a methodological approach sponsored by institutional leadership to improve performance as rated by the University Health Consortium (UHC). Members of the surgical team (n = 3; AMR, JSR, JJL) participated in a three-part PEx pilot curriculum from October 2014 to January 2015 aimed at training future quality improvement (QI) leaders across surgical and non-surgical disciplines. These sessions paired didactics with experiential group work to train attendees on the core principles of lean, to expose trainees to problem solving methodologies, and to demonstrate the tools used in change management. The PEx System is a way in which the intuition strives to deliver excellence for patients, to empower people to identify and solve problems, improve processes, and do their best work for the people they serve; as such PEx compares effectiveness of performance techniques and methods and is not subject to institutional review board/ethics committee review or approval.

Plan/Do/Study/Act Cycle

Plan

We began by writing a problem statement, which defined the goal of our process map: *"Lumbar spinal fusion surgery is heterogeneous, using varied approaches and multiple vendors. The non-standardization of surgery causes inventory, motion, waiting and over-processing wastes. By standardizing the procedural steps of the operation, we will reduce operative time and reduce cost."*

The process-mapping team included the authors and oversight from key QI administrators to ensure our goal coincided with departmental and hospital goals. We then modularized a PIF surgery into basic component steps.

1. *Exposure* - the duration of time including skin incision, paraspinal muscle dissection and any subsequent dissection for insufficient exposure.
2. *Discectomy/decompression* - the duration of time for disk space preparation and neural element decompression.
3. *Hardware placement* - the duration of time for placement of pedicle screws, rods, caps, or interbody grafts including transpedicular cannulation.

4. *Closure* - the duration of time for hemostasis and multilayer closure until sterile drapes were removed.

A process map was created using Microsoft PowerPoint using conventional notation (Figure 2). It was anticipated that variability in patient anatomy, variable surgeon comfort, and intraoperative changes would lead to spontaneous reordering of these modules during surgery.

Do

Five heterogeneous lumbar instrumented fusions including two anterior lumbar interbody fusion/posterior instrumented fusion (ALIF/PIF), two PIF and one transforaminal lumbar interbody fusion (TLIF) were performed by a single surgeon. Each case was manually mapped, by creating spaghetti diagrams for resident and attending surgeons, beginning at surgical level localization and ending after removal of sterile drapes (Figure 3). Duration of component steps were measured for each case. In two cases, using a head mounted camera, the hand motion of the primary surgeon was videotaped and later examined for hand motion and instrument handling.

Study

We analyzed the results by tabulating the duration for each defined component parts and created waste inventories (Table 3). Average durations for each surgery were calculated and the standard deviations derived. The most common waste categories were graphed (Figure 4). The nature of surgical procedures is not strictly linear, and at times it is necessary to return to a previous step. For example, in several of the cases there was inadequate exposure for hardware placement or decompression and so component step durations were aggregated. Component steps including exposure, decompression/discectomy, hardware placement, and closure were analyzed with box and whisker plots to evaluate the variability in duration. Unpaired, two-tailed Student's t-test was used to identify significant differences among the component steps (Figure 5).

Act

Wastes were identified and categorized by plotting module durations. By tailoring our efforts towards the problem areas, we could anticipate and circumvent wasted time before it occurred. Improvement implementation strategies identified are:

1. pre-measure screw sizes,
2. oral case rehearsal between resident and attending,
3. call for anticipated instrumentation/tools before being needed, and
4. use of a risk matrix[24] to identify when attending oversight is necessary. This risk matrix would assess a resident's comfort with a particular surgical step in relation to his or her perceived risk of that step. When a resident is uncomfortable and perceives the step as risky, the attending should be present.

RESULTS

Five elective spinal fusions were performed by a resident and a single attending surgeon (senior author). The surgeries were randomly selected from a pre-determined elective case schedule to include a heterogeneous mix of lumbar fusion with or without neural decompression and/or interbody placement. Each of the surgeries was observed and duration of component steps and waste times were tabulated.

The most common sources of waste in this series of PIF were defects in OR materials (66%), over processing (18.8 %), and waiting (14.8%), Figure 5. The average total time of each surgery from start to removal of the drape was 256.8 minutes (range 137 – 331 minutes, ± 71.4 minutes). Across all procedures, the exposure and hardware placement had the longest median duration at 88 minutes each with widest variability. Closure was the shortest step with a median duration of 21 minutes, and the least variability. This was a fairly labor intensive process, requiring another researcher to be in the room throughout the entire procedure, timing each step, creating spaghetti diagrams and recording reasons for waste in the case.

Using the methods discussed herein, we created a process map, bundled heterogeneous procedures into common modules, and timed these modules for comparison. Statistics were performed and the types of wastes documented and quantified. Some lessons were learned regarding study attempts, which did not work.

A- Spaghetti diagrams (Figure 3): spaghetti diagrams reflect the physical motion of surgeons in the OR, but the majority of time in the OR is standing at the patient's side, operating. This does not obviate motion as a significant contributor to waste in the OR; motion waste could actually be the most complex of all waste types because it occurs at multiple levels, including hand, instrument, staff, equipment, and patient motion (through table repositioning). Spaghetti diagrams are not sufficient to capture such complexity.

B- Video-taping analysis: some operative systems exist to capture the surgery motion (hand and instruments) and this was attempted on a subset of cases. Human analysis of the video was limited by a small field of view as well as an absence of content out of view, thus limiting perspective. Moreover, review of this data was time restrictive and tedious. We suggest an automated analysis of motion be pursued in the future; there is potential waste saving by efficient use of instruments, hand motions and reduction of exchange of instruments.

Discussion

As value-based healthcare continues to maximize outcomes while reducing costs, OR efficiency will continue to be a major target. Operating rooms are a major revenue generator within hospitals, but also require significant resources.[25] Neurosurgery includes a wide range of procedures, which clearly have different resource costs and durations, making average operating cost per minute difficult and precludes generalizability. Amidst such varied case complexity, individual procedures can be targeted for standardization and subsequent improvement. The Donabedian model, a widely accepted model for evaluating the quality of healthcare, recommends quality improvement starts with recognizing weak areas in the structure of patient care, the processes performed, and outcomes. This accepted model is akin to lean, which purports that eliminating waste will lead to more efficient processes and better patient outcomes.[26]

Our pilot data revealed exposure of the spinal column as the step with the most variability in duration and longest median duration overall. There are multiple factors affecting this phenomenon: residents with variable efficiency and familiarity perform the majority of exposure, revision spine surgery is performed on difficult anatomy, and incomplete exposure requiring later return to this step. Data from different subspecialties demonstrate that operating time is inversely proportional to a surgeon's level of experience.[27] Intuitively, residents who are less trained than attending surgeons will take longer to perform a similar procedure; one study showed an average increased length of surgery of 12 minutes among cardiothoracic residents compared to attendings.[28] Therefore identifying steps least comfortable to residents where attending oversight is needed would help reduce variability. The identification of these steps is enhanced with a resident-specific risk matrix. Difficult anatomy contributes to prolonged exposure times; one patient undergoing a revision ALIF had complicated anatomy due to multiple previous abdominal surgeries. Soft tissue anatomical differences like scar tissue are not readily identified by imaging and are difficult to anticipate, thereby prolonging a case. Instrument defects also lengthen exposure time; defects like malfunctioning drill parts or navigation systems contribute to waiting waste.

Surgeons commonly wait in the OR for biologics or instruments to be transported or for necessary personnel to arrive (e.g., X-ray technician). In many cases, a lack of anticipation contributes to the delay; this may be minimized by anticipating the next need. Seasoned surgeons and staff are obviously better at anticipating the next instruments. In cases like PIF, which commonly use biologic material (e.g. demineralized bone matrix) from a core facility, process improvement here incudes discussion of biologic use during the team pause or written in a common place before the case.

Finally, systems errors such as sterilization failures (poorly processed trays outside of the operating room leading to equipment access delays) and inaccurate case scheduling contribute to significant waste. These systems errors lead to overprocessing and duplication of work. Ensuring the room is scheduled and prepared correctly leads to fewer trays opened, higher specificity of opened trays, less clutter of scrub technician tables, and fewer sterilization failures. Sterilization failures due to room set-up, can be addressed by a standardized procedure-specific room diagram. In spine surgery, this decreases the chance of contaminating the C-arm drape and more efficient surgeon movement around the room.

Inventory resources and OR time represent opportunities for cost control. The commonest wastes identified in our study were waiting (14.8%), over processing (18.8%) and defects in OR materials (66%). Examples of defects in materials included defective drills, broken screws, placing and removing improperly sized rods, errors with the X-ray and navigation system, and trays with missing equipment. A 2010 editorial reported an average OR charge of $62/min (range $22 to $133/min).[29] In two of our cases, waiting for an X-ray tech to arrive in the OR took up to 10 minutes. In two cases, the navigation instruments were noted to be unsterile when opened, and a new tray had to be retrieved from sterile processing. This process also took up to 10 minutes. These wastes would potentially cost around $600 per case. Although direct cost savings were not calculated in this study, due to the small number of cases, this information emphasized where quality improvement energy should be placed and formulated solutions mentioned above.

The creation of a process map defines modules within a complex procedure and allows these modules to be evaluated individually, in variable order, and among different operators (residents). A process map underlies the creation of standard work; based upon standard work, modular component steps can be assessed individually for improved safety and efficiency of the system.[30] Subsequent modifications to the process map can be tracked and further wastes identified for continuous QI. Post-implementation time tracking would be beneficial to determine the extent of waste reduction within the procedure. Decreasing OR times makes procedures less expensive and minimizes patient risk under anesthesia.

Finally, the very action of monitoring and measuring the surgical progress will prompt neurosurgeons to be aware of new opportunities for improvement. These Hawthorne effects can confound objective data measurements, but they can also be opportunities for process improvements.[31, 32] With our method if in-operating-room observers, there can be no blinding to the process of data collection. However, tracking surgical progress allows longitudinal data acquisition, to be archived and compared retrospectively. Ultimately, tracking is labor intensive and time consuming requiring dedicated resources. An improved system may involve routine data collection for similar cases by standard in-room staff such as circulating nurses or equipment vendors. This manuscript provides the initial description of utilizing lean principles and methodology to create standard work for a procedure from standardized modules as well as tracking and analyzing data for each module. This methodology can be implemented for a variety of other neurosurgical procedures.

Limitations

The most important limitation is the small and heterogeneous sample size due to labor intensity. Broad generalizations cannot be made to all PIFs. Though, the steps were defined broadly in the process map, these procedures include differences in primary vs redo and neural vs no neural decompression therefore leading to variability. Future studies would examine a larger, more homogenous set of data. The process map in this study was created by QI officials and surgeons familiar with the procedure, although involvement of other staff, such as nursing, anesthesia and scrub technicians, would be valuable in identifying waste. Some steps that are deemed “wastes” because they do not directly add value to the patient, but are necessary, such as transportation of patients cannot be eliminated entirely. Interpersonal interactions during data collecting could introduce Hawthorne effects.[31, 32] Finally, these data were collected in an academic center and thus the standard work flow in a non-academic hospital would differ. For example, in academic centers, there are residents and medical students who can perform observational data collection whereas at a non-academic hospital, there likely are not such resources. Training and utilizing a team member to observe and collect data could be a significant barrier to more widespread implementation.

One of the criticisms with the initiation of this project were concerns from other surgeons regarding comparisons among surgeons. There was concern that there might be a push to the fastest time for a procedure which potentially puts patient safety at risk. This tool was not intended to be for inter-surgeon comparisons but to aid an individual surgeon's workflow. We suspect that appropriate summary data could be obtained from observing 5-10 index cases, and a surgeon could then begin to evaluate his or her workflow for improvement opportunities. The potential cost of an in-operating-room observer for these 5-10 cases, assuming utilization of a $20/hr clinical research assistant could be a few hundred to a few thousand dollars, depending on the length of time of these cases.

Conclusion

This pilot study is the first to demonstrate application of lean principles in the form of a procedural process map in neurosurgery. Process improvement and systems science can be adapted and applied to surgical procedures. However, the implementation of observational studies is not only time consuming and labor intensive, but there is significant variability in the types of wastes that reduce operative efficiency. This creates a significant barrier to implementation. In addition, in academic practice there is a potential conflict between surgical procedural optimization and trainee education. Surgeon-lead initiatives to improve value and decrease cost are important to teach in a pedagogical way. With formal training, residents become increasingly comfortable with lean principles. After this pilot project, the surgeon (AMR) applied these principles to percutaneous lumbar instrumentation. In addition, residents used the same methodology to evaluate and improve other procedures including ventriculoperitoneal shunt placement and deep brain stimulator electrode placement. Residents become faculty and together, we make medicine 'Better'.

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Figure Legends

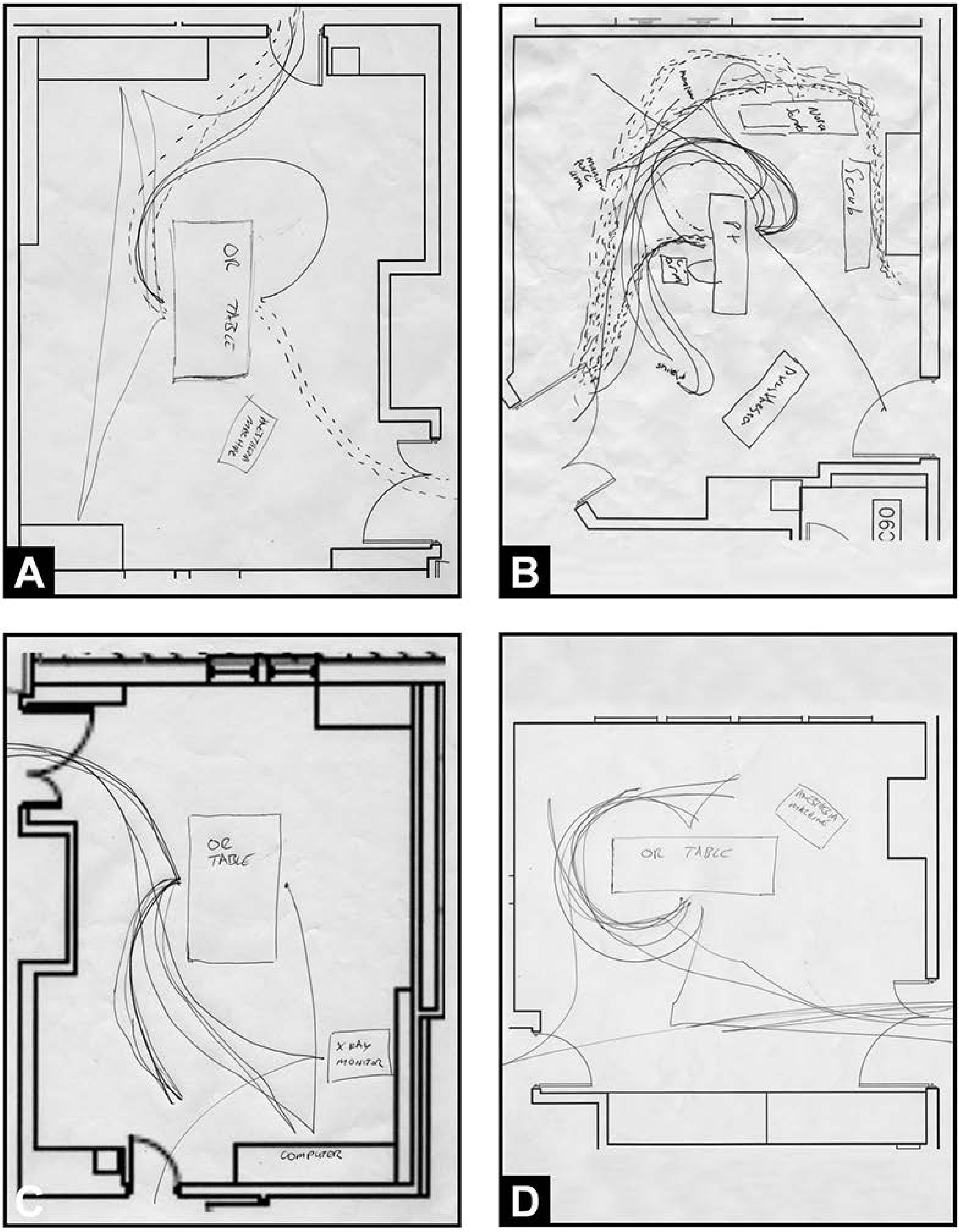
Figure 1: Plan-Do-Study-Act cycle. Adapted from Langley GL, Nolan KM, Nolan TW, et al. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd edition). San Francisco: Jossey-Bass Publishers, 2009, with permission.

Figure 2: Flow chart defines standard work for a PIF. Each box is a coarse representation of multiple smaller surgical steps. The modularization creates standard work, which can be studied in variable sequences.

Figure 3: Intraoperative spaghetti diagrams depict surgeon motion, but not necessarily surgical motion, during cases.

Figure 4: Waste inventory in these 5 PIF cases are predominantly from waiting (14.8%), over processing (18.8%) and defects in OR materials (66%).

Figure 5: Box and whisker plot comparing quartiles across similar surgical steps. Median times differ significantly between decompression/discectomy and closure ($p = 0.0033$) as well as between hardware placement and closure ($p = 0.0032$) using unpaired two-tailed student-t tests.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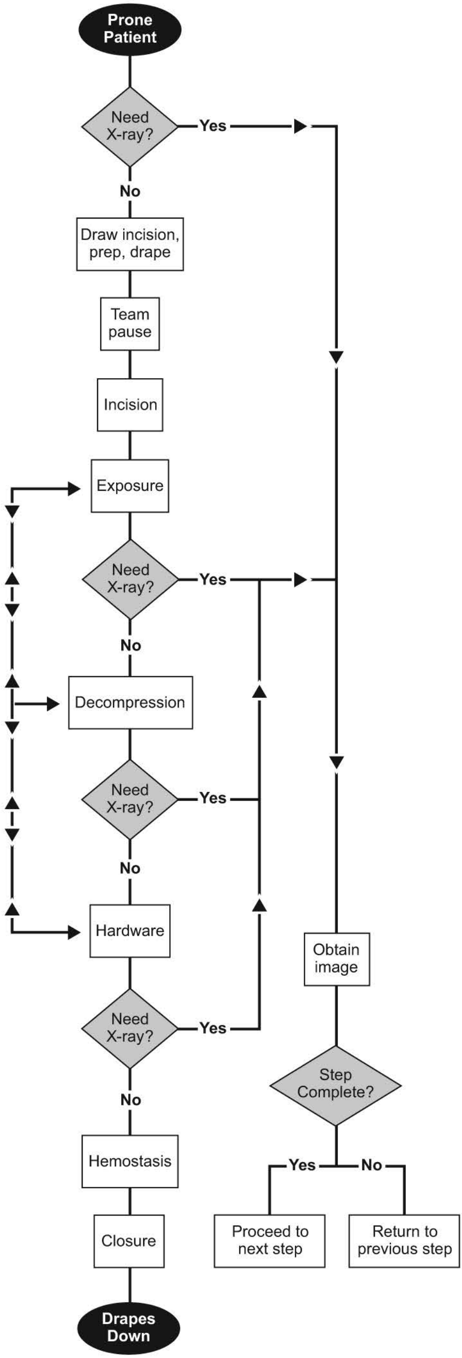
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Hemostasis
Closure
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Step Complete?
Yes
No
Proceed to next step
Return to previous step