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INTRODUCTION

The pace of medical technological innovation (e.g., new diagnostic tests and medical treatments) brings benefits such as longevity, improved quality of life, and less absence from work (Cutler and McClellan 2001). A major side effect, however, is rising health care costs (Newhouse 1992). Crucial is how physicians make use of all of the available technological possibilities. Some professionals prescribe barely useful tests and treatments that are potentially harmful for patients, causing unnecessary costs at the same time (Chassin and Galvin 1998). For patients tests can be painful or stressful, and harm can be done as well by false-positive results (Brandspigel and City 1994; Johnson and Mortimer 2002; Owens 1998). Defensive use of diagnostic tests has been argued to reduce the overall quality of patient care (DeKay and Asch 1998). An additional reason for higher costs is the fact that providers have an almost complete lack of understanding of the costs of patient care delivery (Kaplan and Porter 2011).

With the "fitness for use" definition of quality, we understand that more is not necessarily better (Juran 1989). Fitness for use implies that the paramount focus should be the patient's needs and expectations (Reeves and Bednar 1994) and may offer clinicians a conceptual framework for thinking through how to provide better quality while reducing costs. Health care professionals should focus attention on what is "fit" for the particular patient and should prevent overuse, underuse, or misuse of diagnostic tests (Does et al. 2010) to improve resource utilization, reduce delays, and eliminate processes that do not have added value (Kaplan and Porter 2011).

Since 2005 the funding of Dutch health care is based on the diagnosis–treatment combination (DTC) system with fixed reimbursement per case for providers and medical specialists. For hospitals with budget problems, the waste related to diagnostic tests is an opportunity to decrease costs, based on what the trauma unit of the University Medical Center Groningen (UMCG) experienced. The UMCG (1,339 beds and more than 10,000 employees on the payroll, medical staff included) is the only level 1 trauma center in the northern part of The Netherlands and the final referral for many patients. The unit is responsible for emergency, inpatient, one-day surgery, and outpatient treatments after traumatic injury. Critically ill trauma patients are admitted on a distinct intensive care unit (ICU) service, led by an intensivist. The trauma unit serves approximately 10,000 outpatients and 2,000

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inpatients/one-day surgery each year. In 2006 and 2007 the diagnostic costs at the clinic were 45% of the total patient's specific costs (€853,969). The challenge is to reduce these costs while maintaining—or even improving—the quality of care.

A project in 2008 had two goals: to avoid redundant diagnostic tests and increase cost awareness among medical doctors. The number of diagnostic tests per patient and the cost per diagnostic test were introduced as additional performance indicators. An important side effect is that quality of care improved as well, because patients experience less exposure to potential adverse effects from the tests itself.

METHODS

Over the last decade, the method of Lean Six Sigma (LSS) was introduced in health care to improve efficiency and to provide better care. LSS is a combination of the innovative approaches lean thinking and Six Sigma and is developed in industry with the aim of achieving high levels of operational efficiency and reliability (De Koning et al. 2006; De Mast et al. 2012). The health care industry is beginning to recognize the value of Lean methods to achieve process optimization (Smith et al. 2011). Six Sigma, a combination of industrial safety and reliability and quality management tools, represents an effective approach to quality improvement in, for example, surgery (Sedlack 2010). The key role for improvement in medical care belongs to medical doctors, who directly influence the quality of care and the variable costs.

In February 2008, the head of the trauma unit initiated a project aimed at optimal and appropriate use of diagnostic tests with an expected cost reduction of 10%. The project leader was a physician assistant, who was trained as an LSS improvement specialist (a so-called Black Belt). Physician leadership has proven to be an essential condition for a quality improvement project on changing physicians' practice by reducing unnecessary variation in care (Forthman et al. 2002; Xirasagar et al. 2006). The project followed the LSS framework of the Define–Measure–Analyze–Improve–Control (DMAIC) road map (De Mast et al. 2012). An essential part of the DMAIC road map is to define suitable measurements for the problem, derived from the voice of the customer (VOC) and the voice of the business (VOB), thus indicating what is critical to quality (CTQ). The CTQ determination makes explicit the rationale underlying the project by showing hierarchically how CTQs relate to higher-level concepts, such as an organization's performance indicators and strategic focal points (Niemeijer et al. 2011). The VOC was established as patients receive optimal care based on as few as possible informative diagnostics tests. The VOB was established as diagnostic tests are used efficiently to improve the quality of care. The CTQ determination resulted in a measurement plan to determine the current performance of (redundant) volume and (extra) costs of diagnostic tests.

During the Measure phase, we collected the numbers of all diagnostic tests and patients from January 2007 through July 2008. All diagnostic tests were categorized into three different main groups: laboratory tests (blood and microbiological tests), radiology (including computed tomography [CT], magnetic resonance imaging [MRI], and ultrasound examination), and isotope scans. The Black Belt analyzed the data to select the vital few diagnostic tests, based on volume and costs, according to the Pareto principle. In addition, a value stream map with a focus on diagnostic tests was made of some treatments. A value stream map is a flowchart with information about workflow, waste (redundancies and inefficiencies), and process performance of diagnostic testing (e.g., number, frequency, prescription order) from a customer's point of view. The analysis identified root causes for possible overuse or misuse of diagnostic tests:

- Lack of standards for laboratory tests.
- Insufficient experience of the resident physician.
- Lack of supervision of the resident physician during daily bedside rounds.
- Early postoperative diagnostic imaging.
- Lack of knowledge and ownership regarding volume and costs of diagnostics.

These causes affect the CTQ behavior and are the cause of problematic or substandard performance.

A few years earlier (before 2007), the clinic standardized the guidelines for diagnostic imaging for common and uncomplicated injuries to secure the quality of care by the resident physicians at the emergency room and clinic. For example, the guidelines required a one-day postoperative radiograph for the clinical treatment to verify the treatment result. Often, however, the quality of this measurement was insufficient because of the poor physical condition of the patient. Another radiograph was needed for proper verification. The guidelines were especially directed toward conventional radiology; CT, MRI, and PET scans were not part of the guidelines and were ordered as deemed needed by the physicians. For the laboratory diagnostics (contributing to 75% of the total number of diagnostic tests), no guidelines existed at all. The resident physician requested laboratory diagnostics at will, often without considering clinical consequences.

At the end of the Analyze phase the results were presented to the medical staff. We learned that the majority lacked the knowledge of the volume and costs of diagnostic tests. Most physicians were surprised to learn that a CT scan was 5.7 times as expensive as a conventional radiograph, and a positron emission tomography (PET) scan was 29.6 times as expensive as a bone scintigraphy. The root causes of waste and inefficiencies were the basis for improvement actions of the Improve phase of the DMAIC road map. Designing improvement actions was a team effort of the trauma surgeons. Two types of actions were roughly distinguished: the creation of a "lean mindset" and evidence-based medicine.

Creating a lean mindset is a continuous process. The main characteristics are standardization of work processes and reduction of waste. Five improvements show this in more detail:

1. Postpone the postoperative radiograph to check the reposition and fixation of the fracture(s) after 1 or 2 days to avoid unnecessary repetition.
2. Daily diagnostics were not ordered unless a superior approved. Because all patients are different, directives for daily laboratory diagnostics were prohibited.
3. Diagnostic tests were only ordered when the official information would be useful for patient care. If the treatment would be the same, irrespective of the outcome of the test, then the test would not benefit the patient. At the patient's review with the doctors, this is now a daily explicit consideration.
4. The medical need for diagnostics is now on the agenda of the daily patient's review, a meeting of trauma surgeons and resident physicians, to improve communication between surgeons and resident physicians. The resident physician presents all new patients and patients for surgery in the past and next 24 hours. If necessary, they review results in a second bedside round.
5. The resident physician in the clinic and outpatient clinic may contact a supervisor (a staff member) to discuss treatment and diagnostics. At the end of the day, the supervisor takes time to meet the resident physician in the clinic, coach about treatment in nonstandard situations, and prevent overuse of diagnostic tests. Supervision by senior staff and leadership is of paramount importance for rationalizing laboratory utilization (Miyakis et al. 2006).

Evidence-based medicine leads to a number of improvements, of which the two most important are mentioned here. The dual-energy x-ray absorption (DEXA) scan and PET scan scored high in the top 10 diagnostic costs. The DEXA scan of the distal radius was part of the screening protocol for osteoporosis, even though it is no longer considered evidence based (Dutch Institute for Healthcare Improvement 2002). We therefore skipped the test and adjusted the protocol jointly with the other departments involved, internal medicine and radiology. We also investigated the PET scans that were performed and learned that only one of six scans had added value. These expensive scans are now only requested after permission from the clinic head.

We emphasized the principle that additional diagnostics should be considered only based on the patient's medical history and physical examination. Following the literature (Blery et al. 1986; Brandspigel and City 1994; Johnson and Mortimer 2002), the same principle was applied for preoperative tests. The actions were implemented in the nursing department and outpatient clinic. For acute (poly) trauma patients, there are specific guidelines for the use of diagnostic radiology tests and treatments for almost every type of injury.

The Control phase of the DMAIC road map serves the purpose of maintaining the improvements. New protocols are to become new standards adhered to by everyone. An essential element of quality improvement is that employees experience a sense of control; that is, ownership to influence the process and its outcomes. For this project, it meant the following:

- Agreement between the staff and resident physicians about responsibilities and expectations regarding ordering diagnostics.
- The duty for everyone to account for requested diagnostics, with clinical consequences in mind.
- Visual management (e.g., control charts) with regular feedback on the volume and costs of diagnostics.
- Active supervision of the staff on diagnostic requests from resident physicians.

This phase is also the start of continuous improvement. With visual management and involvement of everybody, this is now actively practiced. The results of the project were concluded from a comparison of monthly data of diagnostic tests from 19 months before and 33 months after the intervention with improvement measures in July 2008. Either the two-sample *t*-test or the two-sample Poisson rate test was used to judge a significant difference between the two periods (before and after).

RESULTS

The average number of tests per treatment decreased significantly (16%; see Table 1). This is a combined result of 7% fewer diagnostic tests and 10% more treatments in the period after the intervention. The largest relative decrease was in the category of laboratory tests, where no guidelines existed. This clearly shows the need for standardization.

Table 1 shows that the volume of tests decreased in all groups except radiology. The 18% reduction after the intervention in the clinical setting is especially interesting. This reduction was obtained by fewer laboratory tests at the clinic and for one-day surgery patients. The data showed an average reduction of the most commonly used tests per treatment: hemoglobin (−78%), platelets (−57%), white cell counts (−31%), chloride (−23%), potassium (−17%), calcium (−28%), sodium (−17%), urea (−12%), and creatinine (−12%). Some of these tests were standard for preoperative laboratory testing.

A control chart is shown in Figure 1. The chart suggests a decrease in diagnostic tests in March 2008, immediately after the start of the project in February. A Hawthorne effect—improvements based on attention only—may be responsible. However, lasting improvements do require a formal intervention with new protocols and guidelines. In July 2008, the improvements were formally implemented.

In Figure 1, we see a clear (and lasting) drop and less variation in the average number of tests per treatment after the intervention. Diagnostic tests per treatment of inpatient and one-day surgery patients

TABLE 1 **Average number of treatments and diagnostic tests before (19 months) and after (33 months) intervention**

	Patients/setting	Pre (average per month)	Post (average per month)	% Difference	*P*-value
Treatments	All	1,008.68	1,110.27	10	0.001
	Inpatient and one-day surgery	161	192.33	19	
	injury severity score > 16	19.26	17.03	−12	0.139
Laboratory tests	All	5,458.58	4,830.42	−12	0.004
	Inpatient and one-day surgery	2,688.11	2,158.94	−20	0.003
Radiology	All	1,776.42	1,895.06	7	0.012
	Inpatient and one-day surgery	267.68	257	−4	0.309
Isotope tests	All	94.68	69.06	−27	0.000
	Inpatient and one-day surgery	2.16	0.76	−65	0.000*
Pathology tests	All	8.74	6.85	−22	0.074
	Inpatient and one-day surgery	1.63	2.30	41	0.089*
PET scans	All	0.32	0.06	−81	0.060*
Total of diagnostic tests	All	7,338.74	6,801.45	−7	0.016
	Inpatient and one-day surgery	2,959.84	2,419.67	−18	0.003
Average number of diagnostic tests per treatment	All	7.35	6.14	−16	0.000
	Inpatient and one-day surgery	18.68	12.68	−32	0.000

*Two-sample Poisson rate test.

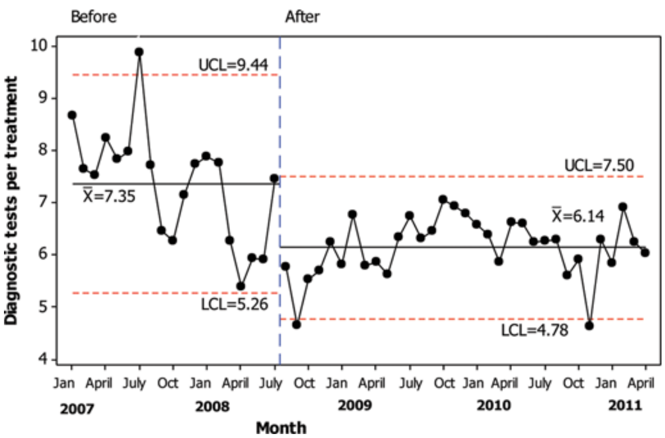

FIGURE 1 **Average number of diagnostic tests per treatment before and after intervention. (Color figure available online.)**

(Figure 2) also decreased substantially after the intervention.

We also introduced control charts to monitor current performance, because the charts are valuable to physicians and managers in controlling variation (Berwick 1991; Blumenthal 1993; Forthman et al. 2002). A monthly update of the data enables management of the clinic to measure and analyze the diagnostic request process at a glance (visual management).

As a result of the interventions, the average cost of diagnostics per treatment decreased from €32.44 to €28.51. Additional benefits for the traumatology clinic were obtained by reducing and standardizing diagnostics for osteoporosis screening, saving 0.5 full-time equivalent (€27,000) from a specialized nurse.

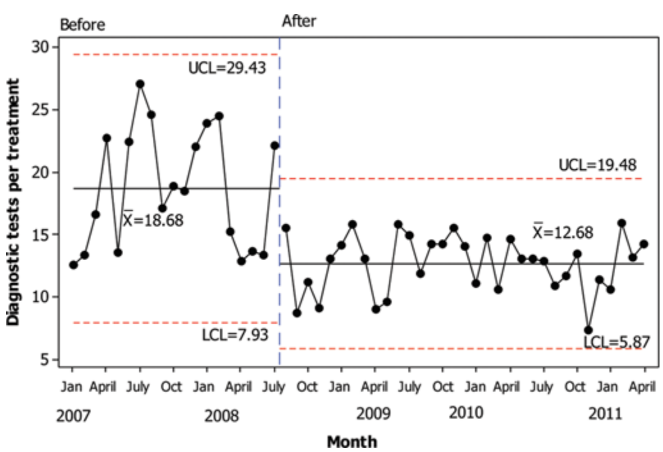

FIGURE 2 **Control chart of diagnostic tests per treatment of inpatients and one-day surgery patients before and after intervention. (Color figure available online.)**

DISCUSSION

This study proves that the LSS method is successful in health care to improve care processes, eliminate waste, reduce costs, and limit patients' exposure to the effects of overuse or inappropriate use of diagnostic tests. The systematic approach of Six Sigma (the DMAIC road map), combined with easily applicable tools from lean thinking, allows quick results. These results can be made permanent when physicians accept ownership of the improvements and utilize management information, preferably in the form of a dashboard or a similar type of visual aid.

The project in the trauma unit was part of the introduction of LSS in the UMCG, which started in 2007. The reason for introducing LSS was an increasing focus on costs and quality of care for the whole organization. This might explain the decreasing number of diagnostic tests (for inpatient and one-day surgery patients) immediately after the start of the traumatology project in February 2008. Generally, a Hawthorne effect is only temporary, and the previous situation will return. The aim of LSS is, however, to find and implement lasting improvements. Active supervision of the trauma surgeons regarding diagnostic requests from a limited number of resident physicians at the trauma ward is an important success factor. In the emergency room, with a wider supervisory span of control for the same trauma surgeons, improvements were observed only after formal interventions.

A smaller number of polytrauma patients (i.e. patients with a high injury severity score) after the intervention might also be the reason for fewer diagnostic tests. But the decrease from 19.3 to 17 is not significant (and less than the 16% overall decrease in tests per treatment). The observed increase in radiology diagnostics might be attributed to a combination of an increasing number of patients and preexisting partial standardization of diagnostic imaging.

The results of the project are lasting. In 2010 the overall cost was 1.2% lower than in 2007, despite 10% more treatments. Selective and timely approach of diagnostic tests resulted in average cost savings of 12.1% or €3.93 per patient. For the clinic, this represents €52,360 annual cost savings.

A limitation of the study is that nothing pertinent can be said about patient outcomes and patient satisfaction. This research was not specifically designed to evaluate factors related to clinical outcome. The study design and the size and diversity of the study population of 55,804 treatments make it difficult to determine a specific relation between outcome (e.g., morbidity) and selective ordering of diagnostic tests. We may expect a positive effect on patient outcome, however, because treatment guidelines have not been changed, and the selection of diagnostic tests is better aligned to what is fit for the patient. Continued daily use of diagnostic laboratory tests (e.g., hemoglobin, C-reactive protein) has no added value when the results conform to the reference laboratory values. There is now a collective awareness that the need of clinical consequence (i.e. is the test really necessary for further treatment?) is the norm for additional diagnostics. Trauma surgeons, for instance, deliberate about the need for preoperative CT scans in cases of possible preexisting sufficient imaging of the fracture.

Development of (new) protocols was beyond the scope of this study. During the 4 years of the study, there were no major changes in diagnostic tests and treatment protocols of the different injuries or in the number of outpatient visits. Reference ranges of the laboratory tests did not change and we did not compromise our postoperative tests. Before and after the improvements, laboratory tests were ordered as single tests and not in panels. Contextual factors, like the Dutch health care system, may have influenced the results, and the external validity of the study can be improved by replicating this approach to reduce the overuse of diagnostic tests in other contexts. The results of this project stimulated the sense of ownership among physicians in using medical means and shared responsibility to improve processes and reduce costs while improving the quality of care.

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