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Experiences with Lean Six Sigma as improvement strategy to reduce parenteral medication administration errors and associated potential risk of harm

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ABSTRACT

In this controlled before-after study the effect of improvements, derived from Lean Six Sigma strategy, on parenteral medication administration errors and the potential risk of harm was determined.

During baseline measurement, on control versus intervention ward, at least one administration error occurred in 14 (74%) and 6 (46%) administrations with potential risk of harm in 6 (32%) and 1 (8%) administrations. Most administration errors with high potential risk of harm occurred in bolus injections: 8 (57%) versus 2 (67%) bolus injections were injected too fast with a potential risk of harm in 6 (43%) and 1 (33%) bolus injections on control and intervention ward. Implemented improvement strategies, based on major causes of too fast administration of bolus injections, were: Substitution of bolus injections by infusions, education, availability of administration information and drug round tabards.

Post intervention, on the control ward in 76 (76%) administrations at least one error was made (RR 1.03; CI95:0.77-1.38), with a potential risk of harm in 14 (14%) administrations (RR 0.45; CI95:0.20-1.02). In 40 (68%) administrations on the intervention ward at least one error occurred (RR 1.47; CI95:0.80-2.71) but no administrations were associated with a potential risk of harm. A shift in wrong duration administration errors from bolus injections to infusions, with a reduction of potential risk of harm, seems to have occurred on the intervention ward.

Although data are insufficient to prove an effect, Lean Six Sigma was experienced as a suitable strategy to select tailored improvements. Further studies are required to prove the effect of the strategy on parenteral medication administration errors.

PROBLEM

Parenteral medication administration is associated with a high risk of adverse drug events (ADE). A study in 2003 showed that in 36% of parenteral medication administrations an administration error occurs.¹ 34% of

medication errors that lead to an adverse drug event are administration errors.² Moreover, adverse drug events are associated with increased length of hospital stay (6 days per ADE) and costs (€2500 per ADE).³

In the Maastricht UMC+, in order to reduce administration errors, barcode verification and double check by a second nurse were implemented. Also drug round tabards were available to limit interruptions during drug rounds but on a majority of wards nurses resisted to wear the tabards. Despite these measures, 35% of all voluntarily reported medication errors and 58% of voluntarily reported medication errors that resulted in injury to or death of patients concern administration and monitoring errors.⁴

The objective of the project was a 50% reduction in medication administration errors, associated with parenteral medication administration in Maastricht UMC+, in one year by improvements derived from the Lean Six Sigma strategy. The additional goal was to reduce the consequential potential risk of harm.

BACKGROUND

Different strategies to reduce parenteral administration errors have been studied. Examples are education and training of nursing staff, parenteral medication administration instructions, drug round tabards, implementation of computerized physician order entry (CPOE) and barcode verification.⁷⁻¹² Parenteral administration errors may also be reduced by protocol implementation, like the one provided by the Dutch Patient Safety Program.¹³ This protocol for



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preparation and administration of parenteral medication was provided to all Dutch hospitals in 2009 with the purpose to reduce adverse drug events associated with errors in administering parenteral medication. One of the requirements in the protocol was the double check of medication order, patient, medication, dose, administration time, administration route and administration rate. A study in nineteen Dutch hospitals in 2011-2012 showed that complete protocol compliance was only 19%. Double check by a second nurse was least performed. The authors concluded that for complete protocol implementation investment of more time and money would be needed.¹⁴ In accordance with this study, in Maastricht UMC+ double check of all items was not yet completely applied in all parenteral administrations. Therefore, improvements were deemed necessary in Maastricht UMC+.

Lean Six Sigma was chosen as improvement strategy. The reasons for this choice were that it was adopted by Maastricht UMC+ as part of the hospital improvement program called “Operational Excellence” and because the current problems needed a tailored and efficient intervention. Lean Six Sigma is a combination of two complementary improvement strategies that focus on the one side on maintaining valuable process steps and waste elimination, and on the other side on reduction of process variation. In Lean Six Sigma a 5-step-cycle, the DMAIC-cycle (Define, Measure, Analyse, Improve, Control) is used. Evidence for significant effect of Lean Six Sigma in health care is scarce because of methodological limitations of the studies.^{5 6}

BASELINE MEASUREMENT

Prior to the implementation of the improvements based on Lean Six Sigma, parenteral medication administrations were observed by disguised observation on two wards of internal medicine of Maastricht UMC+. The trained disguised observer, a pharmacy technician, was not involved in the improvement project. Parenteral medication administrations by nurses were observed during regular drug rounds in the morning on week days. All relevant details of parenteral medication administration were recorded on a specially designed form. To detect administration errors, the observed administration details were compared with the patients medication administration record chart and medication administration instructions. The deviations were classified into seven categories: Wrong patient, wrong drug, wrong dose, wrong dose form, wrong route of administration, wrong time (deviation ≥ 90 minutes earlier or later than prescribed) and wrong duration (deviation $\geq 15\%$ from the hospital medication administration instruction). Additionally, administration errors were classified into nine classes of seriousness by a medical specialist of internal medicine and clinical pharmacologist, a hospital pharmacist and a nurse independently. The classification was derived from the Taxonomy of Medication Errors of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)¹⁵ (table 1 supplementary file). For errors that were classified into different classes, consensus was reached. When an error was observed that was about to reach the patient, the disguised observer was allowed to

Table 1 Seriousness classification of medication errors by Taxonomy of Medication Errors of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

Category	Explanation
A	Circumstances or events that have the capacity to cause error
B	An error occurred but the error did not reach the patient (An “error of omission” does reach the patient)
C	An error occurred that reached the patient but did not cause patient harm
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
G	An error occurred that may have contributed to or resulted in permanent patient harm
H	An error occurred that required intervention necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient’s death
Definitions	Explanation
Harm	Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom
Monitoring	To observe or record relevant physiological or psychological signs
Intervention	May include change in therapy or active medical/surgical treatment
Intervention necessary to sustain life	Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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intervene. These errors were still included as an error. The primary study outcome is the percentage of administrations with one or more error and the type of medication error and the potential risk of harm were defined as secondary study outcomes.

During baseline measurement a total of 32 parenteral medication administrations were observed (19 and 13 on control and intervention ward respectively). On the control ward in 14 (74%) administrations at least one error was made with a potential risk of harm in 6 (32%) administrations. In 6 (46%) administrations on the intervention ward at least one error occurred and 1 (8%) administration was associated with potential risk of harm. On both control and intervention ward, no errors were observed in the categories wrong patient, wrong drug, wrong dose, wrong dose form and wrong route of administration. In the category wrong time an error (without potential risk of harm) occurred in 9 (47%) and 1 (8%) administrations on control and intervention ward respectively. On the control ward, in 8 (42%) administrations a wrong duration error was made, with an associated potential risk of harm in 6 (32%) administrations. On the intervention ward wrong duration errors occurred in 5 (38%) administrations with potential risk of harm in 1 (8%) administration. The highest percentage of administration errors, that also resulted in the highest percentage of potential risk of harm were present during administration of bolus injections: In 8 (57%) respectively 2 (67%) bolus injections on the intervention respectively control ward an error occurred, of which 6 (43%) respectively 1 (33%) with a potential risk of harm. Examples of too fast bolus injections, with potential risk of harm, were the administration of bumetanide as a bolus in four seconds instead of one minute with the potential risk of ototoxicity (tinnitus and deafness) or metoclopramide in three seconds instead of one minute with possibility of akathisia and cardiovascular side effects.

DESIGN

In this controlled before-after study, during baseline measurement between August and October 2015, administration errors and potential risk of harm were measured on an intervention and control ward. Based on the results of the baseline measurement and in accordance with stakeholders a Lean Six Sigma improvement project was implemented on the intervention ward. The effect of improvements on administration errors and potential risk of harm was measured from March to April 2016 by disguised observation in the same way and on the same intervention and control wards as during baseline measurement.

A team of nurses (two head nurses and two regular nurses), a hospital pharmacist and Lean Six Sigma expert participated in the DMAIC-cycle on the intervention ward. The team that was involved in the study, but did not take part in the DMAIC-cycle, consisted of

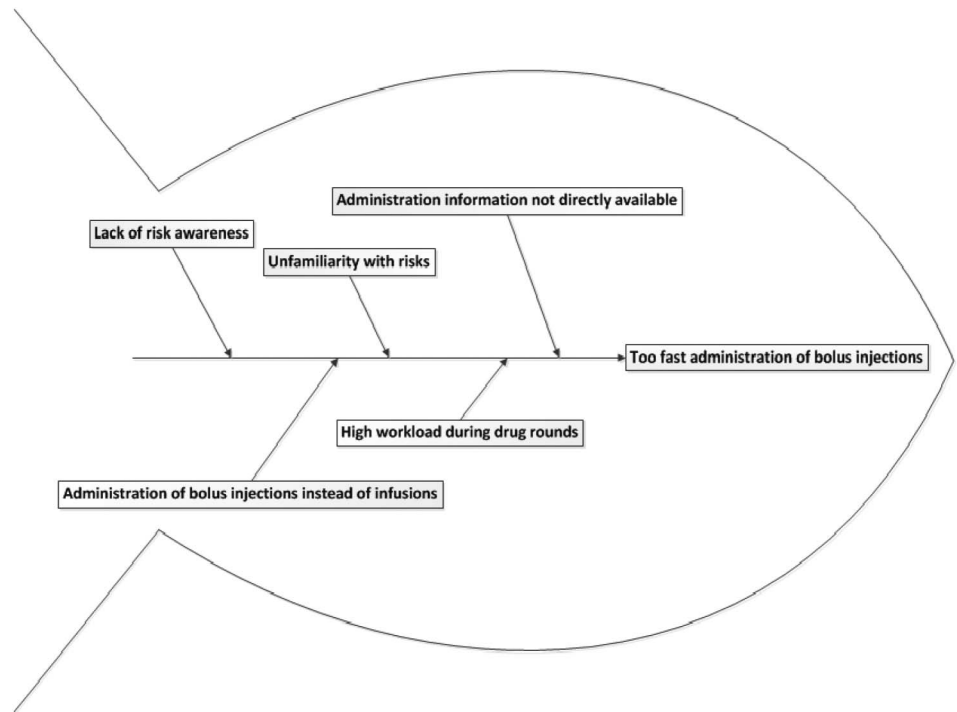
involved stakeholders, a Lean Six Sigma Master Black Belt, a pharmacy technician, a medical specialist of internal medicine and clinical pharmacologist and a hospital pharmacist.

STRATEGY

DMAIC-cycle:

- Define phase: The problem and goal were defined. The goal of the project was a 50% reduction of parenteral drug administration errors.
- Measure phase: The process of parenteral drug administration was mapped in a Value Stream Map (VSM) and administration errors were measured (see baseline measurement).
- Analyse phase: Major causes, that were identified by “fish bone matrix” and “5 times why” and were based on major causes of too fast administration of bolus injections, were: Lack of awareness and unfamiliarity with risks of too fast administration of bolus injections, administration information was not directly available at the moment of administration, administration of bolus injections instead of infusions and experience of high workload during drug rounds by the nurses (See Figure 1. in supplementary file).
- Improve phase: During a brainstorm session, with nurses and hospital pharmacist and Lean Six Sigma expert, improvement strategies were selected by using “5 times why” with the major causes, as defined in the analyse phase, as starting-point. After selection, proposed improvement strategies were tuned with involved stakeholders and consequential risks on the medication administration process were analysed. Then, implementation was planned.
- Improvement strategies were:
 - The most harmful and most frequently prescribed bolus injections were substituted by infusions because administration of bolus injections was considered as a major risk. The hospital pharmacy prepared and dispensed all parenteral medications.
 - Education of nursing staff by the hospital pharmacist to increase awareness and familiarity with risks of too fast administration of bolus injections. During a single half an hour meeting case histories of too fast administration of bolus injections, with high potential risk of harm, were discussed and instructions and guidelines were presented. Afterwards, flyers with highlights were spread and the presentation was sent to all nurses by e-mail.
 - Directly availability of instruction leaflets with administration instructions and adverse event information as a result of too fast administration of bolus injections during drug rounds on each drug trolley.
 - Re-implementation of drug round tabards to reduce interruptions and thereby high workload during drug rounds.
- Control phase: The effect of the intervention was measured (see results section). The substitution of

Figure 1 Fish bone matrix:
Causes of too fast administration
of bolus injections



bolus injections by infusions as well as the drug round tabards were judged as effective measures and were maintained. Administration instructions and adverse event information as a result of too fast administration were integrated in hospital wide instruction software.

RESULTS

In the post intervention measurement 159 parenteral medication administrations were observed (100 and 59 on control and intervention ward respectively). On the control ward in 76 (76%) administrations at least one error was made with a relative risk of 1.03 (CI95%: 0.77-1.38) and a potential risk of harm in 14 (14%) administrations with a relative risk of 0.45 (CI95%: 0.20-1.02). In 40 (68%) administrations on the intervention ward at least one error occurred with a relative risk of 1.47 (CI95%: 0.80-2.71), but no administrations (0%) were associated with potential risk of harm. Just as in the baseline measurement, on both control and intervention ward, no errors were observed in the categories wrong patient, wrong drug, wrong dose, wrong dose form and wrong route of administration. Because of the low quantity of baseline measurements no significant differences between baseline and post intervention measurement could be detected. Yet it seems that on the intervention ward, a shift in wrong duration administration errors from bolus injections to infusions with reduction of potential risk of harm, has occurred.

LESSONS AND LIMITATIONS

Lean Six Sigma was experienced as a suitable quality improvement strategy for selection of tailored actions to

reduce errors and potential risk of harm in parenteral medication administration, particularly too fast administration of bolus injections. It is the first study that describes the implementation of Lean Six Sigma strategy to improve safety of parenteral medication administration.

By using Lean Six Sigma strategy, multi-faceted interventions are matched to identified causes of parenteral medication administration errors. Earlier studies merely measured the effect of single-component interventions like education and training, instructions, drug round tabards, computerized physician order entry (CPOE) or barcode verification⁷⁻¹².

Our results indicate that too fast administration of bolus injections is a common error with a significant potential risk of harm. The routine violation of administration duration seems to be an accepted practice in administration of bolus injections and is in agreement with the study of Taxis and Barber in 2003.¹ Possible reasons for the persistence of too fast administration and acceptance of the violation of the protocol are the low frequency and poor noticeability of adverse events resulting from too fast administration, and the unfamiliarity of nurses with such adverse events. The incidence of serious adverse drug events as a result of too fast administration of bolus injections still remains uncertain. However, nurses, in hospitals where bolus injections are a routine route of administration, should be aware of the potential risks of too fast administration of bolus injections.

The study has several limitations. Because of the low quantity of baseline measurements our study has insufficient power to show a 50% reduction in errors as was the project goal. A source of bias is the inclusion of a

Table 2 Baseline measurements and results: Administrations with an administration error and potential risk of harm

Medication errors	Control ward				Intervention ward							
	Baseline, n=19		Post intervention, n=100		Baseline, n=13		Post intervention, n=59					
	Administration error (%)	Potential risk of harm* (%)	Administration error (%)	Potential risk of harm* (%)	Administration error (%)	Potential risk of harm* (%)	Administration error (%)	Potential risk of harm* (%)				
Administrations with 1 or more errors (all)	14 (74%)	6 (32%)	76 (76%)	14 (14%)	1,03 (0,77-1,38)	0,45 (0,20-1,02)	6 (46%)	1 (8%)	40 (68%)	0 (0%)	1,47 (0,80-2,71)	N/A
Wrong patient / drug / dose / dose form / administration route (all)	0 (0%)	0 (0%)	0 (0%)	0% (0%)	N/A	N/A	0 (0%)	0 (0%)	0 (0%)	0 (0%)	N/A	N/A
Wrong time (all)	9 (47%)	0 (0%)	25 (25%)	0 (0%)	N/A	N/A	1 (8%)	0 (0%)	9 (15%)	0 (0%)	N/A	N/A
Wrong duration (all)	8 (42%)	6 (32%)	65 (65%)	14 (14%)	1,54 (0,89-2,67)	0,44 (0,20-1,01)	5 (38%)	1 (8%)	34 (58%)	0 (0%)	1,50 (0,72-3,08)	N/A
-Bolus injection (% of total bolus injections)	8/14 (57%)	6/14 (43%)	35/46 (76%)	13/46 (28%)	1,33 (0,82-2,16)	0,66 (0,31-1,41)	2/3 (67%)	1/3 (33%)	6/13 (46%)	0/13 (0%)	0,69 (0,26-1,87)	N/A
-Infusion (% of total infusions)	0/4 (0%)	N/A	30/53 (57%)	1/53 (2%)	N/A	N/A	3/10 (30%)	0/10 (0%)	28/46 (61%)	0/46 (0%)	2,03 (0,77-5,38)	N/A
-Continuous infusion (% of total continuous infusions)	0/1 (0%)	N/A	0/1 (0%)	0/1 (0%)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*NCC MERP category ≥ D
N/A; not applicable (a.o. due to value zero in cell)

single control and intervention ward, making it difficult to attribute observed differences to the intervention rather than to other site-specific variables. Generalisability is limited because of the inclusion of a single ward in a single hospital. Additionally, sustainability has not been measured. Nevertheless, sustainability is assumed to be substantial because the majority of parenteral medications is now dispensed as infusions instead of bolus injections.

Despite these limitations, Lean Six Sigma was experienced as a suitable, elegant and efficient quality improvement strategy. Multi-faceted improvements, tailored to barriers, are selected, prioritised and bottom-up implemented. The improvements focus on the actual and most important problem, in our case too fast administration of bolus injections. Using “fish-bone matrix” and “5 times why” is experienced by all members of the project team as a structured, effective and efficient method to select and prioritise causes. Improvements were easily selected with the identified causes as starting point. Natural support for implementation was created because of the direct involvement of nursing personnel. For example, the wearing of drug round tabards was proposed by the involved nurses themselves, while previous attempts to implement the tabards failed. Because in Lean Six Sigma improvements, which are tailored to the true and most important causes, are selected, the strategy is expected to have an effect in comparable settings, but also in other settings in healthcare.

CONCLUSION

In this project, in which improvements focussed on wrong duration errors of bolus injections, Lean Six Sigma was experienced as a suitable quality improvement strategy to select tailored actions. Further studies are required to prove the effect of the strategy on parenteral medication administration errors and the associated risk of harm. Besides having sufficient power, these studies should include at least two DMAIC improvement cycles, measurements to determine sustainability and at least two intervention and control sites, ideally in different centres.

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Declaration of interests Nothing to declare.

Ethical approval For this quality improvement study ethical approval was not required.

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