QUALITY IMPROVEMENT REPORT

Effect of a "Lean" intervention to improve safety processes and outcomes on a surgical emergency unit

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Abstract

Problem Emergency surgical patients are at high risk for harm because of errors in care. Quality improvement methods that involve process redesign, such as "Lean," appear to improve service reliability and efficiency in healthcare.

Design Interrupted time series.

Setting The emergency general surgery ward of a university hospital in the United Kingdom.

Key measures for improvement Seven safety relevant care processes.

Strategy for change A Lean intervention targeting five of the seven care processes relevant to patient safety.

Effects of change 969 patients were admitted during the four month study period before the introduction of the Lean intervention (May to August 2007), and 1114 were admitted during the four month period after completion of the intervention (May to August 2008). Compliance with the five process measures targeted for Lean intervention (but not the two that were not) improved significantly (relative improvement 28% to 149%; P<0.007). Excellent compliance continued at least 10 months after active intervention ceased. The proportion of patients requiring transfer to other wards fell from 27% to 20% (P<0.000025). Rates of adverse events and potential adverse events were unchanged, except for a significant reduction in new safety events after transfer to other wards (P<0.028). Most adverse events and potential adverse events were owing to delays in investigation and treatment caused by factors outside the ward being evaluated.

Lessons learnt Lean can substantially and simultaneously improve compliance with a bundle of safety related processes. Given the interconnected nature of hospital care, this strategy might not translate into improvements in safety outcomes unless a system-wide approach is adopted to remove barriers to change.

Background

Surgical wards are an area of vulnerability in healthcare systems because patients are much less closely monitored, and patients usually stay on surgical wards during the time when the risk of operative complications is highest. It is now widely accepted that high technology surgical care causes unintentional harm to around 10% of inpatients.[1-4]

Substantial improvement to reduce unintentional harm is likely only if the system of care is redesigned to eliminate small contributory errors across a wide range of care processes, which is relatively common in other industries but rare in healthcare.

The five principles of "Lean"

- **"The five S's"** (sort; set in order; shine; standardise; and sustain): the re-ordering of the working environment to clarify and simplify process and to reduce time wasted in finding supplies and equipment[14]
- **Process mapping:** identification of problems to facilitate directed measurement and improvement[15]
- **Error visibility:** development of audit methods to make problems instantly obvious[16 17]
- **Elimination of waste:** minimising waste and wasted effort to make work easier[18]
- **"Plan, do, check, act" (PDCA):** introducing cycles that allow rapid refinement of interventions,[19] and defining problems and solutions by measurement rather than assumption

The most successful example of system redesign in industrial settings has been the Toyota Production System, or "Lean."[5-8] Defining Lean is difficult: it is in essence the elimination of waste through continuous improvement (box). Identifying waste leads inevitably to the need to define customer value, and reducing waste requires elimination of error. In medical settings, there is extensive evidence of the benefits of Lean in improving efficiency, reducing costs, and improving patient satisfaction.[9-12] Few studies have directly measured the impact of Lean on patient safety.[13]

The problem

The surgical emergency unit at the John Radcliffe Hospital is a 38 bed acute surgical ward. It receives all general surgical emergency admissions to the hospital, as well as a small number of elective surgical patients. The unit is typically fully occupied, with an average turnover of 10 patients a day and a staffing ratio of one trained member of staff to six patients. The mean length of stay is 3.2 days.

The unit is served by 10 consultant teams involved in the general surgery on-call service. Patients are reviewed by a consultant team the morning after admission and a care plan confirmed.

We developed the hypothesis that process redesign using Lean with a focus on improving safety relevant care processes might significantly reduce the risk of care related harm to patients on surgical wards.

Table 1 | Study measure and intervention used for each safety relevant process studied

Safety relevant care process	Study measure	Intervention
Direct verbal communication between medical and nursing teams on daily rounds	All ward rounds for general surgical inpatients on the unit were observed at different times of the day. To avoid qualitative problems, the quality of the verbal communication between doctor and nurse on the ward round was recorded in a binary fashion: "Yes" if a nurse was present during the ward round review of a patient; "No" if he or she wasn't.	We conducted a protracted root-cause analysis and a problem identification exercise with representatives of all users. Improvements were made in visual communications on the ward to facilitate staff identification, and a simple protocol was used to allocate roles and responsibilities.
Correct administration of prophylaxis for deep vein thrombosis	Use of compression stockings (thrombo-embolus deterrent stockings) and low molecular weight heparin on all general surgical inpatients on the unit was audited against the local protocol.	Fishbone problem analysis was used, followed by solution design. Stickers were put in drug charts to ensure compression stockings and dalteparin sodium (fragmin) were prescribed, and nurses checked that patients were complying. Information was distributed to patients. Four "plan, do, check, act" cycles were used, with refinement and improvement at each stage. Intervention culminated in pre-printed drug chart and self audit.
Reduction of drug prescribing errors	An experienced ward pharmacist used a bespoke form to record all prescribing errors identified during routine daily drug chart review in all general surgical inpatients on the unit.	Data driven analysis of prescribing errors identified that a few medications were being incorrectly prescribed frequently. Prompt cards kept on the staff ID card fob were distributed. Other areas were tackled with education alone—with no improvement.
Use of alcohol gel for hand hygiene on entering ward	An observer recorded use of alcohol gel by visitors and staff entering the ward.	Simple attempt to improve compliance was made using better visual cues and availability of alcohol gel. No formal "plan, do, check, act" process was done.
Correct use of venous site infection protocol	Compliance with local venflon usage and infection monitoring guidelines was audited by ward staff against hospital guidelines for all general surgical inpatients on the unit with a venflon.	A pre-printed check box on drug charts was used to improve reliability, and a checklist handover regimen was introduced to promote compliance.
Adequate monitoring of patients' vital signs and recording of their risk scores	Observation charts were evaluated for the preceding 24 hour period and audited against the local protocol. The quality of completion of the "track and trigger" component of the observation chart was scored on a four point Likert scale for all general surgical inpatients on the unit.	A nurse led exercise to improve inter-shift handover was introduced. The bedside handover process was implemented in association with a basic care checklist, which included a track and trigger chart.
Adequate completion of fluid balance chart	The quality of the written documentation in the fluid balance chart over the most recent 24 hour period was scored on a five point Likert scale (excellent to poor) for all general surgical patients receiving intravenous fluids or with a documented request for fluid balance monitoring.	Given the high level of pre-intervention compliance, the staff did not consider this process a high enough priority to address.

Key measures for improvement

Our study collected the following two main types of data: data on the performance of specific safety relevant care processes; and outcome data on patient safety incidents.

Evaluation of safety relevant care processes

Seven routine care processes were selected to represent aspects of care important to the safety of surgical patients (table 1). Processes were selected if: (*a*) they had a clear relation to patient safety; (*b*) they were reliant on ward staff to ensure implementation or compliance; and (*c*) they were not directly related to another selected process.

Evaluation of patient safety incidents

Data on patient safety outcomes were collected from cohorts of consecutive general surgical admissions in the four months before introduction of the Lean intervention and the four months after completion of the intervention. We evaluated harm and potential harm by prospective daily direct observation.[20] Patients were tracked daily by a surgical research fellow from admission until discharge, transfer, or death. Each day, clinical staff were interviewed, case notes examined, and ward rounds attended to establish expectations for the patient's course over the next 24 hours. Actual events were reviewed the following day, and discrepancies with predicted events were analysed.

The definition of a patient safety incident used was: "Any unintended or unexpected incident that could or did lead to harm for one or more patients receiving NHS funded healthcare."[21] If actual harm occurred, the incident was recorded as an adverse event; if not, then a potential adverse event was recorded.

Table 2 | Demographic and clinical details of the pre-intervention and post-intervention cohorts

	Pre-intervention (n=607)	Post-intervention (n=602)
Age (mean)	51.1	52.8
Gender (proportion female)	58.2%	52.0%
American Society of Anesthesiologists grade (mean (±95% CI))	1.7 (±0.1)	1.7 (±0.1)
Required surgery	32.0%	32.9%
Diagnosis		
Abscess	9.4%	6.3%
Appendicitis	10.4%	11.8%
Elective	3.3%	3.3%
Hernia	3.5%	3.8%
Lower gastrointestinal pathology	17.5%	25.4%
Malignancies	6.8%	4.2%
Non-specific abdominal pain	15.5%	10.6%
Other	13.2%	15.8%
Right upper quadrant pain	12.9%	9.3%
Upper gastrointestinal pathology	7.7%	9.5%

American Society of Anesthesiologists grade is a five point semi-objective measure of fitness for surgery, and thus reflects the degree of physiological abnormality or illness.

Process of gathering information

We studied safety relevant care processes and patient safety incidents before and after introduction of the Lean quality improvement intervention. The observation, intervention, and re-observation phases lasted four months (May to August 2007), eight months (September 2007 to April 2008), and four months (May to August 2008), respectively.

Collection of data on safety relevant care processes

Compliance with the protocol for each process was monitored by repeated audits of all eligible patients present on the ward on a single day. Additional observations on deep vein thrombosis prophylaxis were made 10 months after completion of the project to measure the sustainability of improvement.

Collection of data on patient safety incidents

We followed a large convenience sample of patients in both cohorts (63% of patients before the introduction of the intervention and 54% after it). To control for observer bias

and ensure consistency, vignettes of all cases were analysed independently by a consultant surgeon, and classification disagreements were resolved by discussion.

Observation was limited to patients on the surgical emergency unit; patients transferred to other wards (23%) were only followed for a portion of their stay in hospital. This category included many of the most seriously ill patients. We traced all patients who were not discharged directly home and used retrospective case note review to identify safety events that occurred after the patient left the surgical emergency unit.

Strategy for change

Lean quality improvement intervention

Our key approach to improving each safety relevant care process was the elimination of waste while trying to redesign a more robust and reliable system. Examples of the ways in which we implemented the five principles of Lean were:

- **The five S's:** reorganising drug cupboards and storage areas
- **Process mapping:** mapping the whole patient pathway and identifying main points of weakness
- **Error visibility:** displaying daily audit results for correct use of thrombo-embolus deterrent stockings and heparin administration in prophylaxis against deep vein thrombosis
- **Elimination of waste:** reorganisation and labelling of intravenous fluids to ensure they were easily found
- **PDCA:** used for all interventions.

The Lean intervention was delivered by a team that comprised an academic expert in Lean, two members of a consultancy specialising in Lean improvement techniques, senior and junior surgeons, and a human factors expert. All ward staff involved with patient care were invited to educational half day workshops, followed by a five day training event.

Staff were encouraged to address the problems they felt to be most important. Their priorities were not necessarily focused purely on safety. Front line staff were made responsible for the development and implementation of systems redesign.

Staff developed about a dozen mini projects in which they applied Lean to ward processes. Five of the seven safety relevant care processes measured were addressed by specific Lean projects (table 1).

The ward manager was given licence to introduce changes to nursing routines. Management and senior clinical staff provided no active support. Problems generated by interactions with other parts of the hospital—for example, delays in obtaining radiology examinations or access to operating theatres—were beyond the scope of the study.

Effects of change

We observed process compliance before the introduction of the intervention during which time 969 general surgical emergency patients were admitted, and after completion of the intervention, during which time 1114 surgical emergency patients were admitted. A total of 607 patients in the first cohort and 602 patients in the second were prospectively observed for adverse events and potential adverse events. The diagnostic and demographic profiles of these populations were very similar (table 2).

The improvement strategies developed for the five processes that underwent Lean intervention used between one and four PDCA cycles. The degree of compliance before and after intervention is shown in table 3.

A significant improvement in compliance was observed in all five processes subjected to Lean intervention, but not in the two processes that were not. Improvement generally increased with successive PDCA cycles, but not every cycle led to improvement. A delayed audit for sustainability in the deep vein thrombosis prophylaxis project 10 months after the end of the main observation period (January 2009) showed 78% compliance (median compliance during the improvement process 80%; fig 1).

A total of 156 (26%) of the 607 patients studied in the pre-intervention period experienced a patient safety incident on the surgical emergency unit, compared with 152 (25%) of the 602 patients followed in the post-intervention period. Despite demonstrable improvements in processes and workplace organisation, there was no evidence of any change in the rate of all events after the Lean intervention, and no significant difference in the ratio of adverse events

Table 3 | Compliance with the safety relevant processes studied before and after introduction of the "Lean" intervention

Safety relevant care process	Number of "plan, do, check, act" cycles	Pre-intervention compliance (n (%))	Post-intervention compliance (n (%))	χ^2	P
Underwent Lean intervention					
Correct administration of prophylaxis for deep vein thrombosis	4	161 (35%)	157 (87%)	87.41	<0.0001
Correct use of venous site infection protocol	3	89 (46%)	75 (79%)	18.17	<0.0001
Direct verbal communication between medical and nursing teams on daily rounds	2	171 (57%)	170 (94%)	61.70	<0.0001
Adequate monitoring of patients' vital signs and recording of their risk scores	1	322 (68%)	321 (99%)	111.0	<0.0001
Patients without a drug prescribing error	1	249 (47%)	240 (60%)	7.302	0.007
Did not undergo Lean intervention					
Use of alcohol gel for hand hygiene on entering ward	0	98 (23%)	161 (31%)	1.287	0.257
Adequate completion of fluid balance chart	0	101 (89%)	91 (90%)	—	—

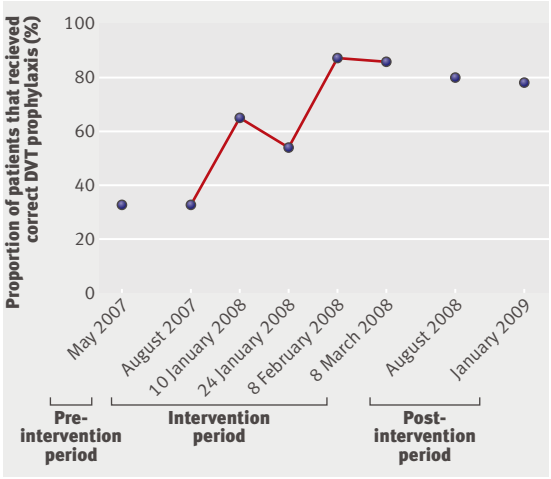

Fig 1 | Proportion of patients that received correct deep vein thrombosis (DVT) prophylaxis according to risk level

Table 4 | Association of adverse events and potential adverse events with potential modifying factors before and after introduction of the "Lean" intervention

	Pre-intervention period		Post-intervention period	
	χ^2 (degrees of freedom)	P	χ^2 (degrees of freedom)	P
All events (adverse events and potential adverse events)				
Day of week	8.329 (6)	0.215	4.912 (6)	0.555
Sex	0.988 (1)	0.320	0.137 (1)	0.711
Diagnosis	10.783 (9)	0.291	14.037 (9)	0.121
Admitting team	1.344 (4)	0.856	2.961 (3)	0.398
American Society of Anesthesiologists grade >2	5.638 (1)	0.018*	0.799 (1)	0.371
Surgery required	6.852 (1)	0.009*	3.993 (1)	0.046*
Length of stay in hospital (Mann-Whitney test)	U=19273z=8.562	0.009*	U=18998z=8.318	<0.001*
Age (*t* test)	t=0.656 (605)	0.512	t=1.115 (600)	0.265
Adverse events only				
American Society of Anesthesiologists grade >2	3.279 (1)	0.053	2.045 (1)	0.153
Operation	12.225 (1)	<0.001*	22.458(1)	0.0001*
Length of stay in hospital	U=12884z=4.628	<0.001*	U=12316z=5.748	<0.0001*
Age	t=0.656 (605)	0.512	t=1.115 (600)	0.265
Potential adverse events only				
American Society of Anesthesiologists grade >2	3.279 (1)	0.53	0.078 (1)	0.48
Operation	0.01 (1)	0.969	4.854 (1)	0.028*
Length of stay in hospital	U=12400z=6.501	<0.001*	U=12454z=5.127	0.0001*
Age	t=2.053 (605)	0.040*	t=1.17 (600)	0.242

Separate testing for potential adverse events and adverse events performed only for variables showing significance in overall analysis.

*P<0.05.

to potential adverse events before and after intervention (χ^2=1.502, P=0.22). Length of stay in hospital and whether surgery was required remained the most important risk factors for patient safety incidents (table 4).

The most common causes of both adverse events and potential adverse events were delays in management and investigation, followed by inappropriate management and readmission for the same problem (fig 2). Delays in management and investigation that were beyond the control of the project team were responsible for the largest numbers of events. We therefore analysed the residual adverse event and potential adverse event rates before and after intervention excluding these irremediable events, but found no difference between the cohorts (χ^2=0.814; P=0.367).

Discussion

Lean intervention can achieve major improvements in the reliability of safety relevant care processes. Previous reports using quality improvement to address patient safety have concentrated on single processes, but we were able to show that a multimodal Lean approach is feasible. We also found evidence that improvements could be sustained over considerable periods of time.

The proportion of patients transferred out of the surgical emergency ward fell from 27% to 20% after the intervention, suggesting that the Lean intervention significantly improved the efficiency of care. However, we did not detect any significant difference in the rates of adverse events or potential adverse events after the intervention compared with before the intervention. This apparently paradoxical finding requires careful analysis and has implications for the way Lean is implemented within healthcare organisations.

The patient outcome measures we used were not directly linked to any of the safety relevant care processes studied but were intended to identify all adverse safety events from whatever source. More targeted outcome measures would have shown the effects of our improvement exercises more precisely, but would arguably have given us less information about overall patient safety.

Limitations of our study include the uncontrolled design and the study's vulnerability to observer bias and the Hawthorne effect. Data collectors were aware of the study hypothesis, but most process data were strictly objective, limiting the scope for bias, and any bias from observer expectation would have been in the direction of improvement after intervention. The Hawthorne effect is unavoidable in this type of intervention study. An additional limitation was our failure to involve patients directly in discussions around priorities.

Inadequate application of Lean seems an unlikely explanation for its lack of effect on adverse events and potential adverse events. The major causes of adverse events and potential adverse events were delays in investigation and surgical management, which would have required changes in the operations of other hospital departments. A particularly powerful component of Lean is that quality improvements

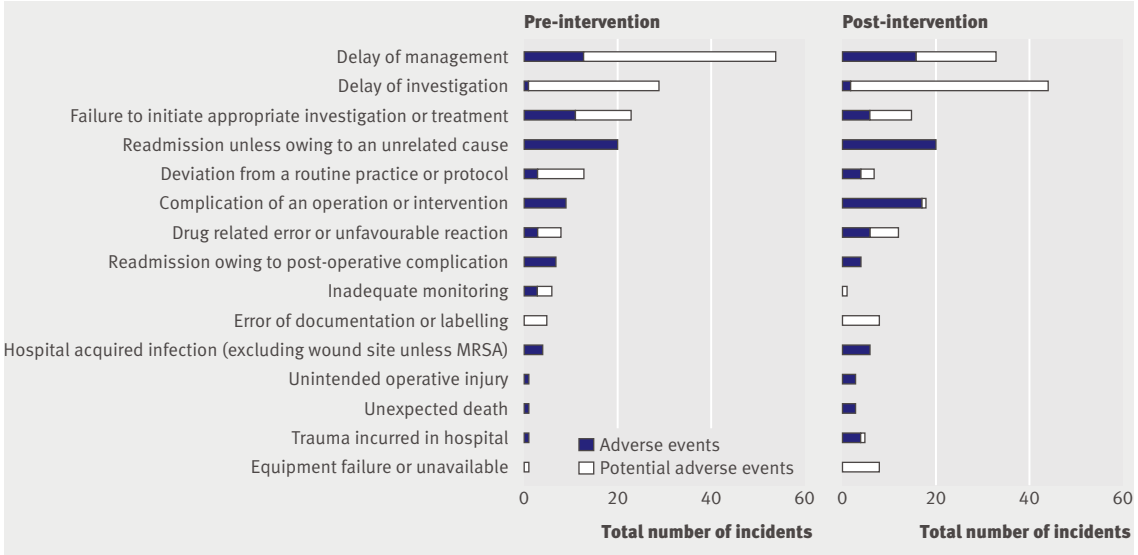

Fig 2 | Types of safety incident before and after Lean intervention

are driven by front line staff according to their perceptions of what needs to change, but in this study this approach could have led to some important safety issues being neglected in favour of mini projects that improved ward function overall. Finally, our study may not have been powerful enough to detect a significant improvement in the rates of adverse events and potential adverse events.

Our experience illustrates that Lean is unlikely to be successful without the senior management support necessary to facilitate change across multiple departments, and without a long term, system-wide commitment.

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Contributors: PMcC had the idea for the study. The study design was developed by PMcC, KC, and SN, with contributions from SK and AH. The observations were conducted by SK, with assistance from YS. The study interventions were conducted by SK with assistance from KC and guidance from SN. Data analysis was led by KC and largely conducted by SK, with guidance by PMcC and other authors. PMcC wrote the first and final drafts of the paper. All authors contributed to redrafting and editing processes. PMcC is the guarantor of the paper.

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1 Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170:1678-86.
2 Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370-6.
3 Kohn LT, Corrigan JM, Donaldson MS. *To Err is Human: Building a Safer Health System*. National Academy Press, 2000.
4 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517-9.
5 Sugimori Y, Kusunoki K, Cho F, Uchikawa S. Toyota production system and kanban system: materialization of just-in-time and respect-for-human system. *International Journal of Production Research* 1977;15:553-64.
6 Womak JP, Jones DT, Roos D. *The Machine that Changed the World*. Rawson Associates, 1990.
7 Liker J. *The Toyota Way*. McGraw-Hill, 2004.
8 Plenert G. *Reinventing Lean*. Butterworth-Heinemann, 2007.
9 Newman K. Re-engineering for service quality: the case of Leicester Royal Infirmary. *Total Quality Management* 1997;8:255-64.
10 King DL, Ben-Tovim DI, Bassham J. Redesigning emergency department patient flows: application of Lean Thinking to health care. *Emerg Med Australas* 2006;18:391-7.
11 Dickson EW, Anguelov Z, Vetterick D, Eller A, Singh S. Use of lean in the emergency department: a case series of 4 hospitals. *Ann Emerg Med* 2009;54:504-10.
12 Dickson EW, Singh S, Cheung DS, Wyatt CC, Nugent AS. Application of lean manufacturing techniques in the emergency department. *J Emerg Med* 2009;37:177-82.
13 Raab SS, Grzybicki DM, Sudilovsky D, Balassanian R, Janosky JE, Vrbin CM. Effectiveness of Toyota process redesign in reducing thyroid gland fine-needle aspiration error. *Am J Clin Pathol* 2006;126:585-92.
14 Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;324:377-84.
15 Sarkar D. *5S for Service Organisations and Offices: A Lean Look at Improvements*. ASQ Quality Press, 2006.
16 Rother M, Shook K. *Learning to See: Value-Stream Mapping to Create Value and Eliminate Muda*. Lean Enterprise Institute, 1999.
17 Zhao B, Olivera F. Error reporting in organizations. *Acad Manage Rev* 2006;31:1012-30.
18 Bicheno J, Holweg M. *The Lean Toolbox: The Essential Guide to Lean Transformation*. PICSIE Books, 2008.
19 Womack JP, Jones D. *Lean Thinking: Banish Waste and Create Wealth in Your Corporation*. Free Press, 2003.
20 Kaul A, McCulloch P. Patient harm in general surgery—a prospective study. *J Patient Saf* 2007;3:22-6.
21 National Patient Safety Agency. *Seven steps to patient safety: the full reference guide*. NPSA, August 2004. http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787.

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SAFETY ALERTS

Safer treatment doses for low molecular weight heparins: summary of a safety report from the National Patient Safety Agency

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Following a Department of Health review in July 2010, the National Patient Safety Agency will be abolished and some of its functions transferred to a Patient Safety subcommittee of the new NHS Commissioning Board. Reports of incidents are, however, still encouraged at www.npsa.nhs.uk.

Why read this summary?

Low molecular weight heparins such as enoxaparin are used to prevent and treat venous thromboembolism and to treat acute coronary syndromes. These medicines are given parenterally by intravenous or subcutaneous injection. They offer advantages over regular unfractionated heparin: they are seen as effective,[1] with a low risk of heparin induced thrombocytopenia; patients are likely to spend less time in hospital because of the long duration of action and, where appropriate, subcutaneous administration. In the UK, low molecular weight heparins are considered the treatment of choice and are increasingly being used including outside hospital. Indicative figures for prescribing in England in 2008/09[2] suggest that over a third (1.1 million) of all enoxaparin doses of 60 ml or greater were prescribed in the community.

However, different clinical indications require different doses and frequency. For instance doses for treatment depend on the patient's weight, unlike the standard doses given for prophylactic use. Underdosing can increase the risk of a further thromboembolic event, while overdosing can increase the risk of bleeding. Accurate dosing and careful monitoring is needed, particularly for those with renal impairment, because low molecular weight heparins are excreted through the kidneys.

Concerns about inconsistent use of prophlyaxis for venous thromboembolism has led to high-profile guidelines by the UK's National Institute for Health and Clinical Excellence.[3] But clinicians may be less aware of the potential for harm from errors in treatment doses. A recent audit of 16 hospitals in Wales showed that weight was not recorded in almost half of patients receiving low molecular

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Recent NPSA safety alerts

- Reducing the risk of retained swabs after vaginal birth (*BMJ* 2010;341:c3679)
- Checking for pregnancy before surgery (*BMJ* 2010;341:c3402)
- Early detection of complications after gastrostomy (*BMJ* 2010;341:c2160)
- Reducing risks of tourniquets left on after finger and toe surgery (*BMJ* 2010;340:c1981)
- Improving the safety of oxygen therapy in hospitals (*BMJ* 2010;340:c187)

weight heparins and, most worryingly, doses were not adjusted in 93% (38/41) of those with renal impairment.[4] A larger observational study in the United States of more than 10 000 patients over five years showed that almost half of patients treated with enoxaparin did not receive the recommended dose; these dosing errors were associated with greater risks of major bleeding and death.[5]

Between January 2005 and September 2009, the NPSA received 2716 patient safety incident reports relating to low molecular weight heparins dosing errors. These included one incident reported to have led to death and three reports of severe harm. A further death was reported in litigation data in England.

A typical incident report read: "Patient was prescribed 15 000 units of Fragmin, but when weighed on admission . . . was only 46 kg. Treatment dose for this weight is only 10 000 units, so a 50% overdose was prescribed and administered. Patient subsequently transferred to ICU for respiratory support. [Reported as severe harm]."

Problems identified by the National Patient Safety Agency

A review of all incident data suggested a number of underlying factors:

- Failure to identify clinical need when prescribing
- Patients being weighed inaccurately or not at all—some due to weighing equipment broken, not available, or difficult to use
- Failure to record renal function or take this into account when prescribing
- Gaps in patient information (weight, renal function) when transferring patients across sectors
- Doses not calculated accurately or not checked by pharmacist
- Lack of familiarity of staff with characteristics and risks of these medicines (and confusion with many products used in single organisations).

Weighing patients is important—not just for safe dosing of these and other medicines, but also for correct fluid balance and nutrition. Observational data from Australia suggest that only a quarter of hospital patients taking renally excreted medicines had been weighed.[6] Another observational study from Canada showed inaccurate patient weights used for enoxaparin dosing.[7] Health professionals' visual estimates of patient weight have been shown to be unreliable[8] and less accurate than weight information given by patients or carers, or calculation by tools using approximations such as knee height or mid-arm circumference.[9] National guidance in England now requires all NHS organisations to have accurate weighing equipment.[10]

This summary is based on a safety report (known as a rapid response report or RRR) on reducing treatment dose errors with low molecular weight heparins, issued by the National Patient Safety Agency (NPSA) in June 2010 (NPSA/2010/RRR013, www.nrls.npsa.nhs.uk/heparin).

What can we do?

The RRR recommended system changes to reduce errors. These include ensuring staff have access to appropriate weighing equipment; making dose calculation tools available to prescribers; reviewing local clinical records, medicine charts, shared care protocols, and discharge letters to ensure they prompt staff to provide essential information such as weight and renal function; and considering rationalising products used in each organisation.

For individual clinicians:

- Always weigh patients and record weight (in kg only) on admission or before starting therapy and during treatment
- Use appropriate weighing equipment,[10] including hoists and under-bed weighing systems for those who are bedbound or who cannot stand
- Patients who are morbidly obese (body mass index >40) will need special equipment and may need monitoring of anti-Xa level because they are at increased risk of bleeding
- Prescribe according to clinical indication, using practical dose calculation tools (see examples at www.nrls.npsa.nhs.uk/heparininfo)
- Know and record your patient's renal function, as low molecular weight heparins pose particular risks to patients with renal impairment—ideally before prescribing, but don't delay first dose until you get renal function tests
- Always record the patient's weight, renal function, clinical indication (treatment for deep vein thrombosis, pulmonary embolism, myocardial infarction, or unstable coronary artery disease), and duration of treatment when prescribing. This information should be used to check doses again by those dispensing and administering in the hospital and community
- Indicate at start what kind of monitoring is needed (frequency, full blood count/platelets, etc). Consider anti-Xa activity monitoring for those at increased risk of bleeding (such as the elderly, those with renal impairment, or those at extremes of weight) or those who are actively bleeding
- For patients with renal impairment (creatinine clearance less than 30 ml/min), monitor carefully for signs of bleeding.[1] Dose adjustments and monitoring of anti-Xa levels, or use of an alternative product such as unfractionated heparin, may be necessary. More detailed guidance on dosing regimens is given in the *BNF*[11]
- Particular care is needed after surgery owing to patients' risk of catastrophic bleeding early in the postoperative period. Senior staff should determine doses for these patients
- Reduce the number of different low molecular weight heparin products used in your organisation to minimise risks of error.

What else do we need to know?

Although detailed information is available for individual products,[11] it is sometimes difficult for busy clinicians to access, and national standard dosing regimens are needed based on weight, renal function,[12] and clinical indications.

How will we know when practice has become safer?

All NHS organisations were given until January 2011 to comply with actions in the RRR. Staff should continue

to report incidents relating to treatment dosing errors so that any continuing problems can be identified. Local organisations could undertake simple audits by checking number of prescriptions, drug charts, or discharge letters without patient weight or doing spot checks of availability of weighing equipment on wards.

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1 Baglin T, Barrowcliffe TW, Cohen A, Greaves M, for the British Committee for Standards in Haematology. Guidelines on the use and monitoring of heparin. *Br J Haematol* 2006;133:19-34.
2 NHS Prescribing Services. Prescribing data for England 2008/09. www.nhsbsa.nhs.uk/PrescriptionServices/960.aspx.
3 National Institute for Health and Clinical Excellence. Venous thromboembolism: reducing the risk. 2010. www.nice.org.uk/guidance/index.jsp?action=byID&o=12695.
4 McArtney R, Ashelby S, Chouhan U, Gilbertson J, Goddard J, Williams R, et al. All Wales audit of prescribing of therapeutic doses of low molecular weight heparins. *IJPP* 2009;17(suppl 17):B38-9.
5 LaPointe NM, Chen AY, Alexander KP, Roe MT, Pollack CV Jr, Lytle BL, et al. Enoxaparin dosing and associated risk of in-hospital bleeding and death in patients with non-ST segment elevation acute coronary syndromes. *Arch Intern Med* 2007;167:1539-44.
6 Hilmer SN, Rangiah C, Bajorek BV, Shenfield GM. Failure to weigh patients in hospital: a medication safety risk. *Int Med J* 2007;37:647-50.
7 Marcil A, Semchuk W, Poulin S, Kuntz D. Accuracy of weights used to determine doses of enoxaparin, eptifibatide, tirofiban, and tenecteplase in the regina Qu'Apelle health Region: impact on therapy in patients with acute coronary syndromes. *Can J Hosp Pharm* 2004;220-9.
8 Hendershot KM, Robinson L, Roland J, et al. Estimated height, weight, and body mass index: implications for research and patient safety. *J Am Coll Surg* 2006;203:887-93.
9 Lin BW, Yoshida D, Quinn J, Strehlow M. A better way to estimate adult patients' weights. *Am J Emerg Med* 2009;27:1060-4.
10 Department of Health Estates and Facilities. Alert DH (2010) EFA/2010/001—medical patient weighing scales. www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Estatesalerts/DH_114046.
11 British National Formulary 59th ed, March 2010. BMJ Group, Pharmaceutical Press: 2010.
12 Edith AN, et al. Low-molecular-weight heparins in renal impairment and obesity: available evidence and clinical practice recommendations across medical and surgical settings. *Ann Pharmacotherapy* 2009;43:1064-83.

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CORRECTIONS AND CLARIFICATIONS

Italy's drug regulator is cleared of any wrongdoing

In giving the background to this latest news about Nello Martini, former head of the Italian drug regulatory agency, the Agenzia Italiana del Farmaco (*BMJ* 2010;341:c3747, print publication 17 July, p 120), we said that a few days after the sacking of Martini in July 2008, it was announced that the agency's responsibilities would be curtailed and that several functions, including drug pricing, would be reassigned to the health and welfare ministry. That announcement was indeed made, but we should have added that despite the announcement, drug pricing since then has in fact remained among the responsibilities of the agency.

How Ukraine is tackling Europe's worst HIV epidemic

This article by Richard Hurley contained a slight inaccuracy in the fourth paragraph (*BMJ* 2010;341:c3538, print publication 17 July, pp 124-6). The Global Fund to Fight AIDS, Tuberculosis, and Malaria did not award a grant to the Ukrainian government in 2004 but rather in 2002 ("round 1" of funding). However, the government's slow progress in responding to HIV/AIDS in Ukraine led to an investigation by the fund and the cancellation of the grant in late January 2004. In March 2004 the fund awarded a grant to the International HIV/AIDS Alliance for completion of round 1.

This Week in Numbers

An error in correcting the final proofs meant that a decimal point was inadvertantly removed from The Week in Numbers in the print issue of 25 September 2010. In fact, 21.3 [not 213] was the drop in deaths per million daily dispensed doses resulting from overdose where methadone was the only drug mentioned, between 1993 and 2008 in England.

Obstetric anal sphincter injury

The authors of this clinical review, Danielle Abbott and colleagues (*BMJ* 2010:3401:c3414, print publication 17 July, pp 140-5), would like to clarify a point in the second sentence of the second paragraph. They confirm that the external anal sphincter and the internal anal sphincter are both circular in nature and that the sentence should therefore have said that a third degree perineal tear "can affect the external anal sphincter (circular fibres) or the internal anal sphincter (including the longitudinal fibres of the longitudinal smooth muscle layer between internal and external sphincters)."

UK ranks eighth out of 13 countries on drug prescribing

The fourth paragraph of this news article by Caroline White (*BMJ* 2010;341:c4128, print publication, 7 August pp 270-1) mistakenly referred to 13 developed countries. In fact, the analysis covered 14 countries (during editing we omitted Canada). The title reflected this error.

Do GPs have the stomach for the battle ahead?

In the final paragraph of this Observations article by Nigel Hawkes (*BMJ* 2010;341:c4035, print publication 31 July, p 232), we wrongly referred to Laurence Buckman as being the chairman of the BMA's General Commissioners Committee; he is in fact chairman of the BMA's General Practitioners Committee (the BMA does not have a General Commissioners Committee).

Too few people in UK at high risk of stroke are getting carotid endarterectomies

In this news article by Zosia Kmietowicz (*BMJ* 2010;341:c3879, print publication 24 July, p 169) the first sentence should have said that a carotid endarterectomy can improve blood flow "in the artery" (not "in the veins of the neck").