Quality improvement report

Effect of a scoring system and protocol for sedation on duration of patients' need for ventilator support in a surgical intensive care unit

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Abstract

Problem Need for improved sedation strategy for adults receiving ventilator support.
Design Observational study of effect of introduction of guidelines to improve the doctors' and nurses' performance. The project was a prospective improvement and was part of a national quality improvement collaborative.
Background and setting A general mixed surgical intensive care unit in a university hospital; all doctors and nurses in the unit; all adult patients (>18 years) treated by intermittent positive pressure ventilation for more than 24 hours.
Key measures for improvement Reduction in patients' mean time on a ventilator and length of stay in intensive care over a period of 11 months; anonymous reporting of critical incidents; staff perceptions of ease and of consequences of changes.
Strategies for change Multiple measures (protocol development, educational presentations, written guidelines, posters, flyers, emails, personal discussions, and continuous feedback) were tested, rapidly assessed, and adopted if beneficial.
Effects of change Mean ventilator time decreased by 2.1 days (95% confidence interval 0.7 to 3.6 days) from 7.4 days before intervention to 5.3 days after. Mean stay decreased by 1.0 day (−0.9 to 2.9 days) from 9.3 days to 8.3 days. No accidental extubations or other incidents were identified.
Lessons learnt Relatively simple changes in sedation practice had significant effects on length of ventilator support. The change process was well received by the staff and increased their interest in identifying other areas for improvement.

Context

One of the main reasons for treating patients in an intensive care unit is that they need ventilatory support, usually by sedation and endotracheal intubation. Continuous infusion of sedatives and analgesics prolongs ventilator time, increase in which can in itself be harmful.[1] Optimal management of sedation can therefore both improve the quality of care and reduce the duration of need for intensive care.[2]

The "breakthrough method" is a tool for obtaining rapid improvements in medical care using multiple short cycle improvements.[3 4] It entails setting goals, choosing appropriate small changes, and measuring whether the changes do lead to improvements; if so, the changes are incorporated in the departmental routines.[5] We wanted to reduce adult patients' ventilator time by use of a validated sedation scoring system and sedation guidelines. Before this project, the management of sedation in our unit was at the doctors' discretion.

Outline of the problem

Patients with respiratory failure who need to be ventilated are normally given both analgesics and sedatives, commonly by continuous infusion. However, studies have shown that this practice prolongs ventilator time because patients tend to become too heavily sedated.[1 2 6] Use of a sedation scoring system to ensure that sedation is sufficient but not excessive has therefore been recommended, and low rates of continuous infusion, with supplemental bolus doses, have been shown to reduce ventilator time.[7]

Setting

The surgical intensive care unit at Haukeland Hospital, a university hospital with 1100 beds, has 10 beds and a staff of seven consultant anaesthetists, five residents, and approximately 60 registered nurses. During 1999 a total of 396 patients were treated in our unit, with a total length of stay of 2517 patient days, of which 1780 involved invasive or non-invasive ventilation. A postoperative recovery unit with 24 beds is attached to the main unit. Patients may be admitted to the intensive care unit directly or after 24 hours in the recovery unit. The project was part of a national quality improvement collaborative study in adult intensive care medicine, initiated by the Norwegian Medical Association. Our hospital was the largest hospital that specifically studied sedation and ventilator time, and which made a substantial advance. Since the interventions were primarily aimed at doctors and nurses there was no need for patient consent.

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Assessment of problems and strategy for change

Details of approach

The project aimed to achieve a 20% reduction in the mean duration of patients' need for ventilator support by improving the management of sedation. Another goal was to provide the nurses with simple guidelines for adjusting the dosage of sedative drugs.[8] We further wanted to raise the staff's general interest in the small scale rapid cycle improvement strategy.[3 4] This meant using the "plan do study act" cycle (see fig A on bmj.com) and linking a number of such small scale qualitative experiments to obtain improvement over a relatively short time (see fig B on bmj.com).[9] This approach is the so called "breakthrough" methodology developed and described by the Institute for Healthcare Improvement in Boston.[5]

The project was carried out over a period of 11 months from December 1999. Cost containment was not a primary object.

Development of guidelines

A group of two doctors and two nurses developed simple guidelines for the sedative agents used in our department, midazolam and morphine, for their dosages, and for monitoring of sedation level. Before this project, we did not systematically assess or monitor level of sedation. For this purpose we chose the motor activity assessment scale (MAAS), which was translated into Norwegian and found easy to use.[10]

Intervention

The sedation scoring system and a one page protocol for sedation were developed and initially tested on a small sample of patients in the intensive care unit. The protocol was based on recently published scientific papers and adjusted to meet the local needs and traditions.[1 2 8 10] They were then revised after the small scale experiments and questionnaires (table 1). After the modifications, the guidelines were copied on coloured paper and posted at each bed in the intensive care unit.

All adult patients (>18 years) who were treated on a ventilator for more than 24 hours were to be sedated in accordance with the new guidelines. The doctors defined the level of sedation desired twice a day, and the nurse in charge of a patient was then responsible for monitoring the sedation level using the scoring system and was allowed to adjust sedation according to the guidelines. This was new, and increased the nurses' responsibility for control of sedation.

The new guidelines were introduced in several ways. The reasons for the changes in practice were thoroughly explained to all staff. The doctors were invited to discuss modifications after the guidelines had been presented to them at several meetings, to attain a local consensus. The project group also presented the guidelines to the nurses at several meetings. To reach all nursing shifts, three identical presentations were made to the nurses. During the meetings, the rationale behind monitoring level of sedation and the pharmacology of the drugs used were discussed. The guidelines were also distributed by post and by personal emails to the staff, and displayed on a wall poster centrally located in the unit, which was regularly updated with results from the project. We also introduced an "FAQ" section (frequently asked questions—a familiar internet feature) on the poster, where important questions raised in discussions with the staff were answered. The project group also worked in the unit, making it possible for the staff to discuss at any time issues that might arise.

Table 1 Cycles performed to develop and implement sedation protocol (November 1999-February 2001)

Cycle	Action	No of patients
1	Collection of baseline data	147
2	First version of protocol discussed	
3	Protocol trial	4
4	Modification of protocol	
5	Questionnaire survey 1 among staff	
6	Data analysis	
7	Expanded trial	52
8	Questionnaire survey 2 among staff	
9	Data analysis	
10	Change of opiate	82
11	Questionnaire survey 3 among staff	
12	Data analysis	
13	Modification of protocol and implementation	

Measurement of problem

Baseline data were taken from the intensive care unit's clinical database (Regina), which has been in use for several years.[11] Severity of illness was measured by the SAPS II scoring system.[12] Ventilator time (measured in 24 hour days—for example, 6 hours=0.25 days), length of stay in the intensive care unit (in days), and mortality were also recorded. Our department has also operated a confidential reporting system for adverse events, making it possible to identify adverse effects that may be related to sedation practices.[13] Data for each patient were collected and displayed graphically in the unit, allowing the staff to follow progress. Feedback was also provided regularly at staff meetings.

Statistical analysis

Data were analysed using statistical process control time series. Results were plotted in relation to time, to make direct visual evaluation possible.[14] We calculated control limits for mean length of ventilation time before and after intervention and for length of stay in intensive care, and also mean differences and 95% confidence intervals.

Effects of change

During the first 11 months of 1999 a total of 147 adult patients received ventilator support for more than 24 hours. The data from these patients served as baseline. In the following 11 months a total of 138 patients were treated according to the new protocol (table 2). No other important changes took place in our unit or surgical services at the hospital in this period.

Mean ventilator time decreased by 7.4 to 5.3 days (28%), and the mean length of stay was reduced from 9.3 to 8.3 days (11%) (table 2). As the XmR chart (fig 1 of the post-intervention period shows, not only was average ventilator time reduced, but also its variation, indicated by the lowering of the upper control limit. The process is still not statistically stable and its future average and variation limits cannot safely be predicted, as a clinical process like this is inherently unstable and

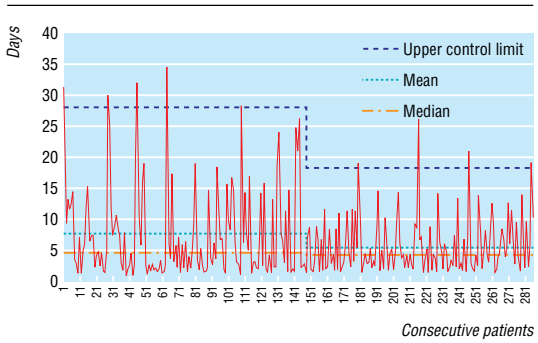

Fig 1 XmR chart for 285 consecutive adult patients (147 before and 138 after adoption of a sedation protocol and guidelines), showing reduction in daily average ventilator time and also in its variation (indicated by lowering of the upper control limit)

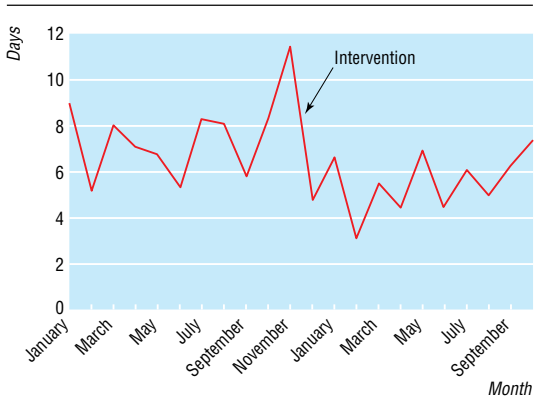

Fig 2 Mean monthly patient ventilator times before and after adoption of a sedation protocol and guidelines

some patients will need longer ventilator support. Our aim was not to standardise ventilator time: we only wished to reduce that part of the variation that might be ascribed to unwanted differences in management style among staff members. The reduced variation in mean ventilator time each month is also shown in figure 2. The mortality in the unit declined (27% in first 11 months, 22% in second 11 months). Data from the department's confidential reporting system did not indicate any adverse effects on the patients Analysis of three short questionnaires answered by the staff did not reveal any major problems regarding the introduction and use of the new protocol.

Lessons learnt and further steps

By introducing a few relatively simple guidelines for the management of sedation in adult patients being mechanically ventilated, we were able to reduce mean ventilator time by nearly 30%.

The main reasons for the success of this project were its specific and concise aims and an interprofessional approach. A dedicated project group and continuous follow up were also important. The medical and nursing directors' open support for the project and short weekly meetings to allocate tasks also contributed. Few data were needed, and these were easily obtainable. The wall poster with graphically displayed results served as an important information source and encouraged staff ownership of the process, and this in turn increased their commitment and willingness to change. The major challenge for the project group was to reach all staff members with information and answer their questions.

One factor that simplified our task was the availability of baseline data from the department's clinical database. The fact that the initiative came from the Norwegian Medical Association and was not a cost cutting exercise by some agency with a financial interest was important for getting the staff involved. This gave the project credibility, especially among the doctors. Interprofessional collaboration has resulted in substantial quality improvements under such conditions.[15]

Key learning points

- Introduction of a few relatively simple guidelines for management of sedation reduced the duration of adult patients' need for mechanical ventilation by nearly 30%
- The need for extensive information during the change process should not be underestimated
- Documented achievement in quality projects encourage staff to identify other areas for improvement

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Competing interests: PEP is also a senior fellow at the Institute for Healthcare Improvement (Boston, USA).

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Table 2 Results before and after introducing simple guidelines for sedating patients receiving ventilator support. Values are mean (SD) unless indicated otherwise

Characteristics	First 11 months	Last 11 months	Difference (95% CI)
No of patients	147	138	
Age (years)	55.8 (17.6)	52.3 (16.6)	3.5 (–0.48 to 7.48)
% died in intensive care unit	27 (39/147)	22 (30/138)	5.0 (–0.5 to 14.9)
Simplified acute physiology score (SAPS II)	48.7 (16.4)	46.5 (14.9)	2.2 (–1.45 to 5.85)
Ventilator time (24 h days)	7.4 (7.5)	5.3 (4.5)	2.1 (0.65 to 3.55)
Length of stay in intensive care unit	9.3 (8.7)	8.3 (7.5)	1.0 (–0.89 to 2.89)

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Clinical endpoints in trials of drugs for cancer: time for a rethink?

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There is a continual debate between health authorities, doctors, researchers, the pharmaceutical industry, and regulatory authorities over the question of when a new drug should be admitted to the market and when it should be prescribed or reimbursed.[1] Divergent interests often obscure the scientific debate, but it is in the interest of all parties that valuable and effective drugs should be licensed without undue delay.[2 3] Yet it may take many years (mostly 10-15) from the time when a clinical development plan for a drug (mapping out how to investigate it) is established to its being prescribed for patients. This is frustrating for all drugs but is particularly so for drugs for fatal diseases such as cancer. I argue here that the process can be improved and focus particularly on three issues: the endpoints, side effects, and more collaboration between the parties, and especially the participation of patients.

Summary points

- The introduction to market of drugs for lethal diseases such as cancer can be improved
- More attention should be given to clinical symptoms and quality of life and less to survival
- Surrogate endpoints and biomarkers should be used as support for proof of effectiveness
- Clinical endpoints such as survival can be investigated after the drug's introduction
- Licensing authorities, pharmaceutical companies, and patients should agree in advance the relevant endpoints and desired effect sizes

Endpoints

The major points at issue in drugs for cancer are the desired endpoint and the degree of change required over existing treatment.[4] Licensing authorities require that drugs have a clinically meaningful effect. In the case of cancer drugs this is often translated as meaning an increase in survival compared with standard treatment. In potentially lethal diseases, however, waiting to assess these clinical endpoints (for example, the effect on five year survival) poses a dilemma as the introduction of a potential valuable drug may be significantly delayed. Kessler and Feiden have argued for a more rapid drug approval process for lethal diseases,[2] but in many conditions, including drugs for cancer, the authorities insist on clinical endpoints. On the other hand, the need for endpoints that can be evaluated in a shorter time is widely acknowledged.

Double standards

Such endpoints are likely to be surrogate endpoints such as biomarkers of a disease.[5] Most licensing authorities accept surrogate endpoints only if the clinical relevance of the surrogate has been well validated. In cancer this is regrettably often not the case.

On the other hand, changes in biomarkers have been accepted as proof of effectiveness before effects on clinical endpoints were shown. Examples are drugs for hypertension, obesity (orlistat), and hypercholesterolaemia. Highly active retroviral treatment for HIV infection and interferon alfa for viral hepatitis or chronic myeloid leukemia were also introduced to market predominantly because of their effects on biomarkers (viral load, CD4 counts, Philadelphia chromosome, etc) and certainly without survival data. The same holds for the enzyme based therapies for rare storage conditions like Gauchez and Fabry's disease, which were accepted mainly on the basis of pharmacodynamic effects.

In these cases the assumption was that the biomarkers (blood pressure, cholesterol, body weight, or viral load of HIV, hepatitis C or B virus) indicated disease activity and that influencing them would be beneficial. Examples of diseases for which the assumption turned out to be true are hypertension, HIV infection, and cholesterolaemia, though for others it remains unclear (such as viral hepatitis, obesity).

Thus a double standard seems to be operating in that well validated surrogates are insisted on for cancer drugs but not for others. Why not make the same assumption for cancer and abandon the demand to show a survival benefit before licensing? Instead the