A prospective, randomised clinical evaluation of a new safety-orientated injectable drug administration system in comparison with conventional methods
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of a safety-orientated injectable drug system (Mark II) was examined. The system comprised:

- specialised trays, which supported aseptic technique and promoted a well-organised anaesthetic workspace;
- colour- and bar-coded labelling of syringes, which facilitated the selection and tracking of drugs;
- prefilled syringes for the most commonly used anaesthetic drugs, in order to remove a key error-prone step in the anaesthetic and to save time; and
- automatic visual and auditory verification of syringes using a computer and bar-codes just before each drug administration.

Type of intervention
Other: Anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who required anaesthesia for cardiothoracic surgery. Specific inclusion and exclusion criteria were not reported.

Setting
The setting was secondary care. The economic study was carried out in New Zealand.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not provided. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.
Study sample
Power calculations were based on a published study. These suggested that a group size of 15 was needed to provide 90% power to detect a difference at the required level of significance (p=0.05). One patient refused to participate and two who gave consent were not studied because their procedures were postponed. After randomisation, 4 patients were not included in the analysis due to an unexpected change of anaesthetist between the first and the second anaesthetic. This precluded matching pairs of observations and no group comparison could be performed. Therefore, 15 anaesthetists (performing 15 pairs of anaesthetics) were included in the study. Details of the patients were not provided.

Study design
This was a prospective, randomised clinical trial that was carried out at the cardiothoracic surgical unit at Green Lane Hospital, Auckland, New Zealand. The method of randomisation was not reported. Volunteer anaesthetists providing anaesthesia for coronary artery or heart valve surgery took part in the study. Each anaesthetist performed two anaesthetics in a pair of adults, the first using the conventional method and the second using the new approach. To control for order effects, each anaesthetist was asked to use the new system in the morning and the conventional method in the afternoon, or vice versa, decided at random. No loss to follow-up was reported. No blinding was performed during the outcome assessment.

Analysis of effectiveness
The analysis of effectiveness included all patients who received the anaesthetics. The primary outcomes used were:

setting up the drugs;

the time to prepare supplementary syringes of the drugs;

the preparation of drug infusions;

usability and safety scores, as obtained from visual analogue scales ranging from 0 (worst) to 10 (best), rated by the anaesthetists performing the interventions.

Each anaesthetist received a form to report comments about good or bad aspects of the system used. The improvements associated with the use of the new system were also reported. The study groups were comparable in terms of the type of surgery and details of the anaesthetics.

Effectiveness results
Setting up drugs at the beginning of an anaesthetic was significantly faster with the new approach (median 180 seconds; range: 32 - 480) than with the conventional method (median 360 seconds; range: 120 - 600), (p=0.013). Similarly, the median time to prepare supplementary syringes of drugs during an anaesthetic was shorter with the new approach (10 seconds; range: 2 - 38) than with the conventional method (12 seconds; range: 10 - 60), (p=0.009).

The preparation of drug infusions took a median of 120 seconds in both groups.

The median safety score was 8.1 (range: 6.8 - 9.7) with the new approach versus 7.1 (range: 2.6 - 9.3) with the conventional approach, (p=0.001).

The median usability score was 8.5 (range: 5.9 - 9.4) with the new approach versus 7.5 (range: 3.2 - 9.8) with the conventional approach, (p=0.027).

Improvements were also observed in terms of organisation and layout. The new system resulted in the prevention of a potential error on four occasions.

Six anaesthetists made positive comments, while two stated they preferred to draw up drugs only as and when needed as a safety strategy.
Overall, the new system did not create any new problems or difficulties. However, some problems, such as overcrowding of the anaesthetic workspace, case-scheduling problems, communication breakdown and equipment malfunction, remained.

Clinical conclusions
The effectiveness analysis showed that the new Mark II system was superior to the conventional approach in terms of usability, safety and preparation times before and during anaesthesia.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

Direct costs
Discounting was irrelevant because the costs were incurred during a short time. The unit costs and the quantities of resources used were not reported separately. The health services included in the economic evaluation were drugs, syringes and drawing-up needles used during anaesthesia. The cost/resource boundary of the study was not reported. Resource use was estimated using actual data from the sample of patients included in the effectiveness study. The source of the cost data was not reported, but it was likely to have been the hospital where the study was carried out. The price year was not reported.

Statistical analysis of costs
The costs were presented as median values and ranges. Statistical analyses were performed to test the statistical significance of differences in the costs.

Indirect Costs
The indirect costs were not included in the economic evaluation.

Currency
Euros.

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The median cost was Euro 178 (range: 102 - 428) with the new system and Euro 155 (range: 111 - 390) with the conventional approach, (p=0.041). This led to a median increase of Euro 23.

Synthesis of costs and benefits
The costs and benefits were not combined because a cost-consequences analysis was performed.

Authors' conclusions
The new system was safer and more usable than the conventional approach. It also saved time but resulted in a slight increase in costs (8% of conventional anaesthetic expenses).

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The conventional approach was selected to represent the standard procedure used to administer drugs. However, this comparator was not described. You should decide whether it is a valid approach in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis of effectiveness was a prospective randomised study, which was appropriate for the study question. The method used to select the sample was described, but no information on the sample of patients involved in the study was provided. Details of the randomisation approach were also not given. With the exception of one patient who refused to participate, the study sample was generally representative of the study population. However, the main threat to the internal validity of the analysis was the small sample size. The power calculations were based on a prior study. The authors noted that the lack of blinding might have introduced some observer bias. It should be noted that performance bias could have occurred as one anaesthetist violated the randomisation protocol on one occasion. However, the authors stated that these issues should not have biased their results.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because, in effect, a cost-consequences analysis was conducted.

Validity of estimate of costs
The cost analysis represented a secondary aim of the study. The costs included were restricted to those items strictly related to the administration of anaesthetics. The perspective of the study was not reported, neither were the unit costs and quantities of resources used. The price year was not given, which makes reflation exercises in other settings difficult. Statistical tests were performed when the costs were compared. The cost estimates were specific to the study setting and sensitivity analyses were not carried out.

Other issues
The authors stated that this was the first randomised trial to assess the feasibility and advantages of a system aimed to reduce errors in anaesthetic administration in a clinical setting. Therefore, few comparisons with other non-randomised studies were made. The issue of the generalisability of the study results to other settings was not addressed and the external validity of the analysis was low, owing to the lack of sensitivity analyses. The authors noted some limitations of the study, which have already been reported in other sections of this commentary.

Implications of the study
The study results suggested that the new system was effective and well accepted by the anaesthetists. Savings made as a result of fewer errors leading to iatrogenic harm could easily offset the small increase in costs. The authors highlighted the fact that the introduction of the new system could also reduce the burden of the task of administering intravenous drugs, as the patient receives the same anaesthetic with the new system. Future studies should confirm the results of the present study.

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Other publications of related interest

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