Clinical and laboratory evaluation of a closed enteral feeding system under cyclic feeding conditions: a microbial and cost evaluation
Moffitt S K, Gohman S M, Sass K M, Faucher K J

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 cyclic feeding schedules with closed enteral feeding system in enterally fed nursing home residents. Laboratory and clinical evaluation was used to investigate the formula contamination via retrograde movement of bacteria under "no-flow" conditions or contamination of the piercing spike.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Enterally fed nursing home residents.

Setting
Nursing home and hospital. The economic study was carried out in Minnesota, USA.

Dates to which data relate
No dates were reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was not carried out on the same patient sample as that used in the effectiveness analysis and was performed retrospectively.

Study sample
Power calculations were not used to determine the sample size. In the simulation of retrograde movement of bacteria, four 1000ml closed system containers with Piercing Spike Sets were used to conduct tests under the conditions of no-flow and flow with corresponding controls. In the "no-flow" arm, one receptacle was inoculated (luer adapter in inoculated formula) and another was not inoculated (control, luer adapter in noninoculated formula); in the "flow" arm, one container was inoculated (luer adapter in inoculated formula) and another was not inoculated (control, luer adapter in noninoculated formula). Four samples were taken from each of the four feeding sets (6 inches above the drip chamber, immediately above the drip chamber, 6 inches below the drip chamber, and 6 inches above the luer adapter).
In the simulation of Piercing Spike Set contaminating closed system container, six deliberately contaminated Piercing Spike Sets were used to spike the containers, which then were subjected to two intervals of "no-flow" conditions over a 48 hour time frame. In the clinical evaluation, the study sample consisted of 57 closed system feeding containers with their feeding sets obtained from nursing home residents receiving pump-delivered cyclic feedings over a 12 to 22 hour period. Within 48 hours of spiking, a total of 5 different samples (testing luer adapter and container at 14 to 24 hours after spiking; and taking samples from above drip chamber, below drip chamber, and container at 36 to 48 hours after spiking) were taken from each container and feeding set.

**Study design**
This was a single centred, non-randomised trial with concurrent controls for the laboratory part of the study and a cohort study for the clinical part of the study. The duration of follow-up was up to 48 hours after spiking. There was no loss to follow-up.

**Analysis of effectiveness**
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. Contamination (measured as levels of microbes greater than 10 colony forming units per millilitre (CFU/ml)) and evidence of retrograde movement of bacteria were among the health outcomes assessed in the study. Retrograde movement of bacteria was operationally defined as the finding of the same organism type in both the luer adapter and above the drip chamber, or in the container in the event of contamination detection.

**Effectiveness results**
In the simulation of retrograde movement of bacteria, no contamination was detected in the continuous flow conditions, while there was one case of feeding-set contamination (at the most distal end of the feeding set, 6 inches above the luer adapter) under no-flow conditions. This, alongside of no bacterial growth in other sites, demonstrated the slowness of retrograde movement of bacteria even under the conditions of "no-flow". In the simulation of Piercing Spike Set contaminating closed system container, a 50% contamination rate of containers (unacceptable levels of microbes) was observed by 48 hours. In the clinical evaluation, at 24 hours, 55 cases of contamination of the luer adapters, and no cases of contamination of the feeding containers were identified. One case of contamination was found below the drip chamber at the 36 to 48 hour time point. The level of growth found in the containers at 36 to 48 hours was insignificant (0.5 CFU/mL). It was judged that no retrograde movement of bacteria could happen since a rod was isolated in the luer adapter, while cocci were isolated from the container.

**Clinical conclusions**
"Retrograde movement of bacteria during cyclic feeding does not appear to be a source of feeding container contamination in closed enteral feeding systems, that utilize a drip chamber."

**Measure of benefits used in the economic analysis**
No explicit summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**
Costs were not required to be discounted due to the short time frame of the study. Amounts of formula waste and the number of Piercing Spike Sets required per month were estimated for the 24 hour versus 36 hour hang time based on three different common scenarios (15, 17 and 21 hours fed) and the 1500mL container. The cost analysis covered the costs of formula waste per month (using the average list price for Novartis Nutrition standard 1500mL closed system formulas) and the number of Piercing Spike Sets required per month (using the list price of a COMPAT Piercing Spike Set). The perspective adopted in the cost analysis was not explicitly specified. The price dates were not given. The parameters which affect the choice of the container size to minimise formula waste were investigated.
Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The incremental cost of formula waste with 24 hours hang-time (compared to 36 hours hang-time) was between $16,200 and $32,400 for 20 patients per year. The total extra cost for 20 patients due to the 24 hours hang time was estimated to be as high as $40,000 per year.

Synthesis of costs and benefits
Not combined.

Authors' conclusions
Retrograde movement of bacteria does not appear to be a source of closed system feeding container contamination in systems that incorporate a drip chamber. Using the appropriate size feeding container and systems with at least a 36 hour hang time will result in significant cost savings.

CRD COMMENTARY - Selection of comparators
No specific health technology was explicitly regarded as the comparator. You, as a database user, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
It is not clear whether the sample size was sufficient to detect differences in the contamination level of the two cyclic feeding systems.

Validity of estimate of costs
Amounts of formula waste and the number of Piercing Spike Sets required per month were estimated for the 24 hour versus 36 hour hang time based on three different common scenarios (15, 17 and 21 hours fed) and the 1500mL container. Adequate details of the methods of cost estimation were given.

Other issues
In view of the small sample size, lack of sensitivity analysis, and statistical analysis of the costs, the results may need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

Implications of the study
The authors suggested that "clinical studies should be conducted in systems without drip chambers to determine whether
they are safe beyond 12 h”.

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