NHS

The Results

Using technology to help fight infection

HCAI Technology Innovation Programme
Showcase Hospitals report number 5

The Flexi-Seal® Faecal Management System

DH Department of Health

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The Healthcare Associated Infections (HCAI) Technology Innovation Programme

The basic ways of preventing and reducing healthcare associated infections (HCAIs) are largely unchanging. The principal strategies for combating HCAIs are those associated with hand hygiene/aseptic techniques, prudent antibiotic prescribing and good clinical practice. However, new technologies and equipment can support these strategies by helping get things done differently, more swiftly or more reliably.

As part of the strategy set out in *Clean, Safe Care*[1] the Department of Health is funding the HCAI Technology Innovation Programme[2]. The Programme aims to

- Speed up the development and adoption of technologies to further help combat HCAIs
- Identify which new technologies provide the best value and will have the most impact

The Showcase Hospitals Programme

In 2004 the Department of Health set up the Rapid Review Panel (RRP) to "provide a prompt assessment of new and novel equipment, materials and other products that may be of value to the NHS in improving hospital infection control and reducing hospital acquired infection". The RRP does not undertake any product trials itself but makes recommendations based on written evidence provided by industry.[3] The highest recommendation (Recommendation 1) is

Basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

As part of the HCAI Technology Innovation Programme, technologies which have gained a RRP Recommendation 1 are being placed in up to 8 Showcase Hospitals around the country for periods up to six months during which time a detailed evaluation of their in-use and economic features along with adoption characteristics is undertaken. The Showcase Hospitals which took part in this evaluation are The Royal Wolverhampton Hospitals NHS Trust, Imperial College Healthcare NHS Trust, Calderdale and Huddersfield NHS Foundation Trust, Southampton University Hospitals NHS Trust, County Durham and Darlington NHS Foundation Trust, The Lewisham Hospital NHS Trust and Central Manchester University Hospitals NHS Foundation Trust.

These are service evaluations, as defined by the National Patient Safety Agency's National Research Ethics Service, and do not therefore require Research Ethics Committee review.[4]

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[1] Clean, safe care: Reducing infections and saving lives. Department of Health, 9 January 2008.

[2] For further information on the Programme see http://www.clean-safe-care.nhs.uk/index.php?pid=28

[3] For more information on the Rapid Review Panel see http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1158313434380?p=1158313434380

[4] See leaflet on defining research at http://www.nres.npsa.nhs.uk/news-and-publications/publications/nres-research-leaflets/

Acknowledgements

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Showcase Hospitals report number 5

The Flexi-Seal® Faecal Management System

Contents

Executive summary

The Department of Health has set up a Rapid Review Panel (RRP) to assess new and novel technologies and consider their potential for reducing hospital infections. As part of the Department's Healthcare Associated Infections (HCAI) Technology Innovation Programme, technologies that have received an RRP1 recommendation ("basic research and development, validation and in-use evaluations have shown benefits that should be available to NHS bodies") have been placed in selected Showcase Hospitals for review of their acceptability in everyday use and to gather information that may be useful for other hospitals.

The Flexi-Seal® Faecal Management System is used in patients with little or no bowel control and liquid or semi-liquid stool. A soft silicone catheter is inserted into the rectum and retained by a low-pressure balloon. A collection bag is connected at the other end. The device contains and diverts faecal waste to protect the patient's skin and keep the bedding clean. Flexi-Seal® was awarded Rapid Review Panel (RRP) recommendation 1 in 2007.

Flexi-Seal® was available for use in seven Showcase Hospitals for five to six months. Staff and patient opinions were favourable, and use of the product led to a significant reduction in the number of times bedding etc had to be changed and to fewer skin problems compared with standard ways of managing faecal incontinence.

In some circumstances, use of Flexi-Seal® may be cheaper than standard ways of managing faecal incontinence. However, in most circumstances savings would only arise if the product reduced infections and skin problems. A template business case has been produced.

Keywords: Faecal management, HCAI, Flexi-Seal®, Rapid Review Panel

Introduction

This report sets out the findings from an evaluation in NHS Showcase Hospitals of the in-use and economic features and adoption characteristics of the Flexi-Seal® Faecal Management System.

The Rapid Review Panel which assesses new and novel products which may help infection prevention and control has concluded that basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

The objective of this document is to help Directors of Infection Prevention and Control and other stakeholders to decide whether they should consider Flexi-Seal® as part of their trust's strategy to reduce healthcare associated infections.

The problem

Faecal incontinence

Whilst faecal incontinence has a number of causes, one of them is infections with viruses or bacteria such as *Clostridium difficile* (*C. difficile*). A patient who has *C. difficile* diarrhoea excretes large numbers of the spores in their liquid faeces. These can contaminate the general environment around the patient's bed (including surfaces, keypads, equipment), the toilet areas, sluices, commodes, bed pan washers, etc. They can survive for a long time and be a source of hand-to-mouth infection for others. If these others have also been given antibiotics, they are at risk of *C. difficile* disease[1].

Faecal incontinence can cause extensive prolonged damage to the perineal skin due to bacteria and enzymes contained in faeces. It is a risk factor for pressure sores, leading to increased morbidity, mortality and length of stay.
Traditional methods of managing faecal incontinence include the use of disposable pads. This can lead to patient discomfort and distress when the pads become soiled. Several time consuming linen and pad changes may be required during a single nursing shift to reduce the skin's exposure to moisture and bacteria.[2]

The National Institute for Health and Clinical Excellence (NICE) recommends that healthcare professionals should consider a faecal collection device for people in intensive care settings and people receiving palliative care with faecal incontinence and associated loose stools. This recommendation is based on expert advice and a consensus development exercise, and is justified on the basis that severe uncontrolled diarrhoea is a threat to skin integrity and a major nursing care problem.[3]

The product
The Flexi-Seal® Faecal Management System

The Flexi-Seal® Faecal Management System manufactured by ConvaTec Inc. (see Figure 1) is designed for the faecal management of patients with little or no bowel control and liquid or semi-liquid stool. A soft silicone catheter is inserted into the rectum and retained by a low-pressure balloon. A collection bag is connected at the other end. The device contains and diverts faecal waste to protect the patient's skin and keep the bedding clean.

Figure 1 – The Flexi-Seal® Faecal Management System

Flexi-Seal® was awarded Rapid Review Panel (RRP) recommendation 1 in 2007. The panel concluded that Flexi-Seal® had demonstrated effectiveness in containing faeces and preventing faecal contamination of the environment. It added that clinical contraindications should be assessed prior to use.

The knowledge base
What was known before this evaluation

Two studies have reported on the use of the Flexi-Seal® system for the acute management of faecal incontinence. One study[4] assessed the use of Flexi-Seal® as evaluated by three patients admitted to hospital diagnosed with liver infection, *E. coli* infection and one with unexplained diarrhoea. The study reports a cost analysis carried out in intensive care based on nursing time, linen and laundry required three times daily with an estimated cost of £78.96 per day or £550.83 per week. The cost of Flexi-Seal® reported was £250 which lasted up to 29 days. It is unclear whether the episode of use of the Flexi-Seal® system was 29 days or less. This study also assessed the benefits to patients receiving the Flexi-Seal® management system. Three patients were monitored and it was reported that the system was successful in managing faecal incontinence and resolved any skin problem that had developed in patients. Patient benefits were taken into account, although the

method of doing so was not reported. However, patients reported increased psychological benefits due to decreased emotional trauma and embarrassment and increase in physical comfort and dignity.

Another case study report[5] of four patients managed in acute settings reported marked improvement in skin condition, though one patient had rectal bleeding due to gastrointestinal haemorrhage, unrelated to the device. Patients received the system for different reasons such as admission with Crohn's disease or management of *C. difficile* infection. On average it was reported that nurse time spent on the Flexi-Seal® system ranged from 10 minutes to 20 minutes. The total cost of nurse time spent in managing faecal incontinence ranged from £105.64 to £130.56. The study reported an overall marked improvement in skin condition after the use of the system, where all patients had extensive redness at baseline.

A US study[6] reported the use of Flexi-Seal® to manage the risk of perineal dermatitis and transmission of nosocomial infections. A single arm study of 42 patients from seven hospitals was included, with 38 completing the study. The majority of patients enrolled had pulmonary problems, while others included cardiovascular or metabolic and infection problems. 90% of patients had continuous stool every two to four hours. The duration of the treatment ranged from 1 to 14 days with a mean of 5.6 days. 35 patients retained the device. Faecal incontinence was resolved in ten patients within the first day and hence Flexi-Seal® use was discontinued, and another ten patients were transferred or discharged. Adverse events were reported in two patients with one categorised as unrelated to the treatment while another one reported bleeding with ulceration. It was unclear whether the patient was discontinued from the treatment. Of 39 patients who had skin evaluations at baseline 26% had normal skin which improved to 92% at final visit.

A case report[7] reported an adverse event from the use of Flexi-Seal®; significant rectal bleeding in a 65 year old male administered in ICU due to thrombosis. The authors report that the injury could have been due to the mechanism by which the device was inserted or retained. This suggests no direct safety concerns from the device itself, but a need for care in its utilisation.

The evaluation

How the evaluation was done

As part of the Showcase Hospitals programme, Flexi-Seal® was introduced for five to six months in selected NHS hospitals with the aim of evaluating its in-use features and adoption characteristics. The objective was to evaluate

- Reasons for selection
- User acceptability
- Patient acceptability

Following appropriate staff training, Flexi-Seal® was made available for use on all adult inpatient wards at the Showcase Hospitals sites. Posters in staff only

areas of wards were used to remind staff of the availability of the system, and arrangements for supply from a central point.
The users of the product at the Showcase Hospitals were asked a series of questions about the product and its characteristics and 243 surveys relating to individual patients were received.

Why was Flexi-Seal® used?

In almost all cases (95%) the presence of liquid or semi-liquid stools was cited as a reason for the use of Flexi-Seal® but a number of other reasons were given (see figure 2).

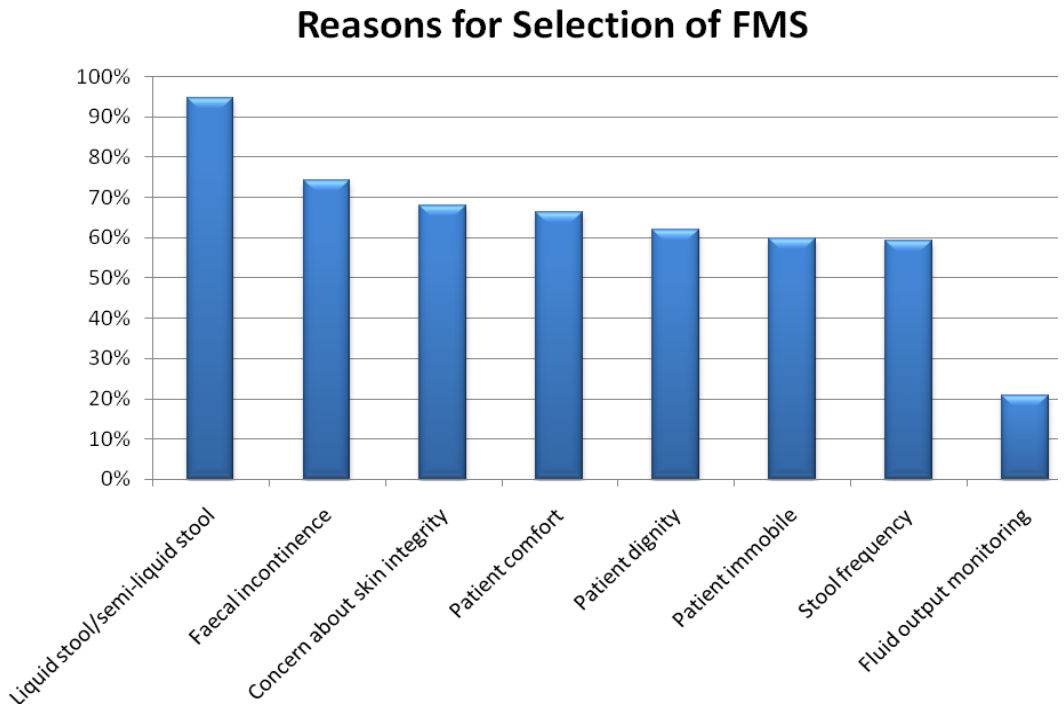

Figure 2 – Reasons for Selection of the Flexi-Seal® Faecal Management System

In the 12 hours prior to insertion of Flexi-Seal® between 1 and 12 episodes of faecal incontinence were recorded. There is no clear pattern or cut off point in these results (see Figure 3).

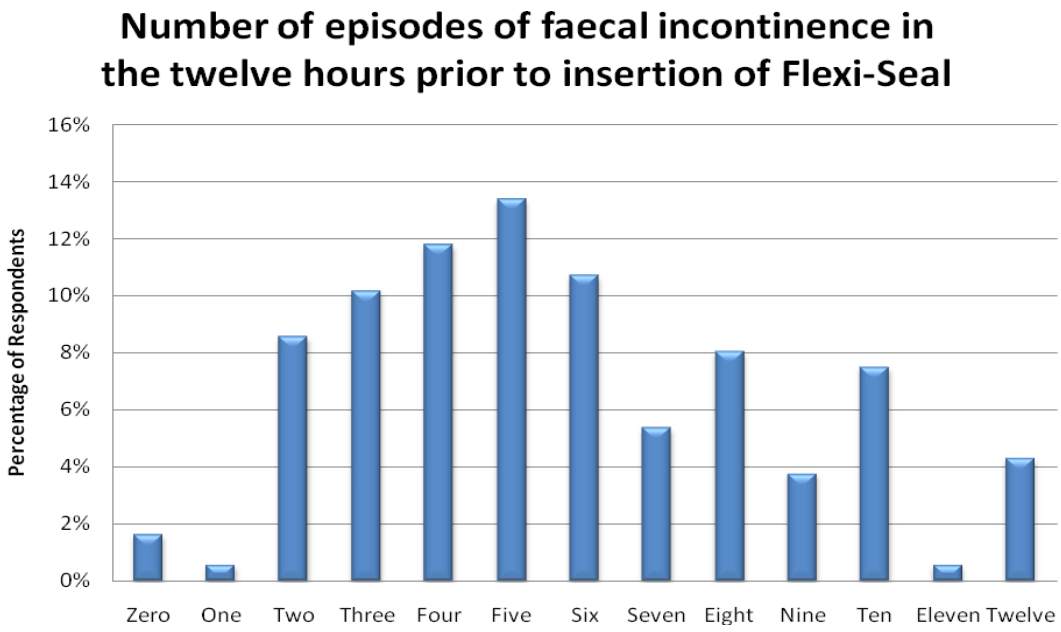

Figure 3 – Episodes of Faecal Incontinence in the 12 Hours Prior to the Insertion of Flexi-Seal®

What was the outcome of using the product?

A large majority of staff agreed or strongly agreed that Flexi-Seal® enhanced the patient's dignity, helped reduce the risk of cross infection and reduced nursing time spent of dealing with episodes of faecal incontinence. Fewer respondents felt that Flexi-Seal® enhanced patient comfort. Although the staff who disagreed were still in the minority it should be noted that 70 out of 243 staff members strongly disagreed with this claim.

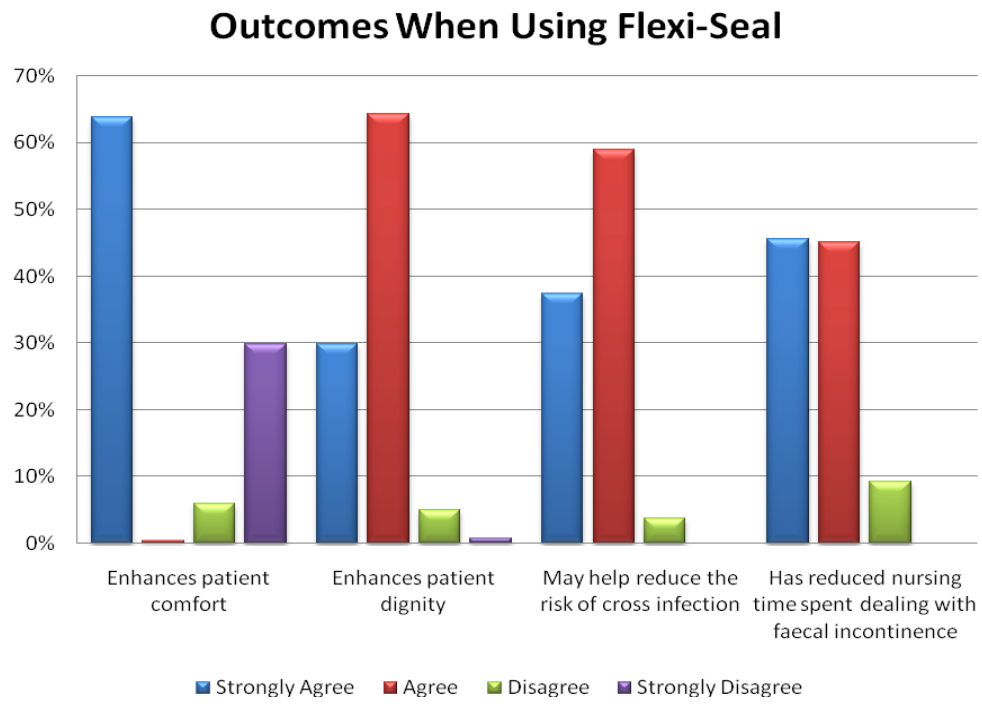

Figure 4 – Outcomes When Using Flexi-Seal®

Patients' skin integrity was evaluated once Flexi-Seal® had been in place usually for between 1 and 10 days and the results indicate that in 69% of cases the patient's skin integrity stayed the same and in 29% it was improved. In only 2% of cases did the patient's skin deteriorate.

After the devices had been in place between 1 and 10 days, 20% of staff saw no leakage at all with the majority of respondents (55%) indicating slight moisture or seepage at the insertion site. A further 22% found significant leakage. In one case leakage occurred when the balloon was inflated to the recommended amount on a petite patient. This was resolved by adding a further 5ml to the balloon. (It should be noted, however, that this practice is not approved by ConvaTec – it has been noticed in clinical practice that deflating the balloon by 5ml can provide a safer alternative as the decreased pressure allows the balloon to better adapt to rectal anatomy.) However, the need for very frequent pad changes decreased markedly. Prior to use pad changes had to be made up to 12 times but whilst the Flexi-Seal® was in-situ the maximum number of changes was 7 (only 1% needed this amount). The number of times no pad changes were required rose from 2% to 20%.

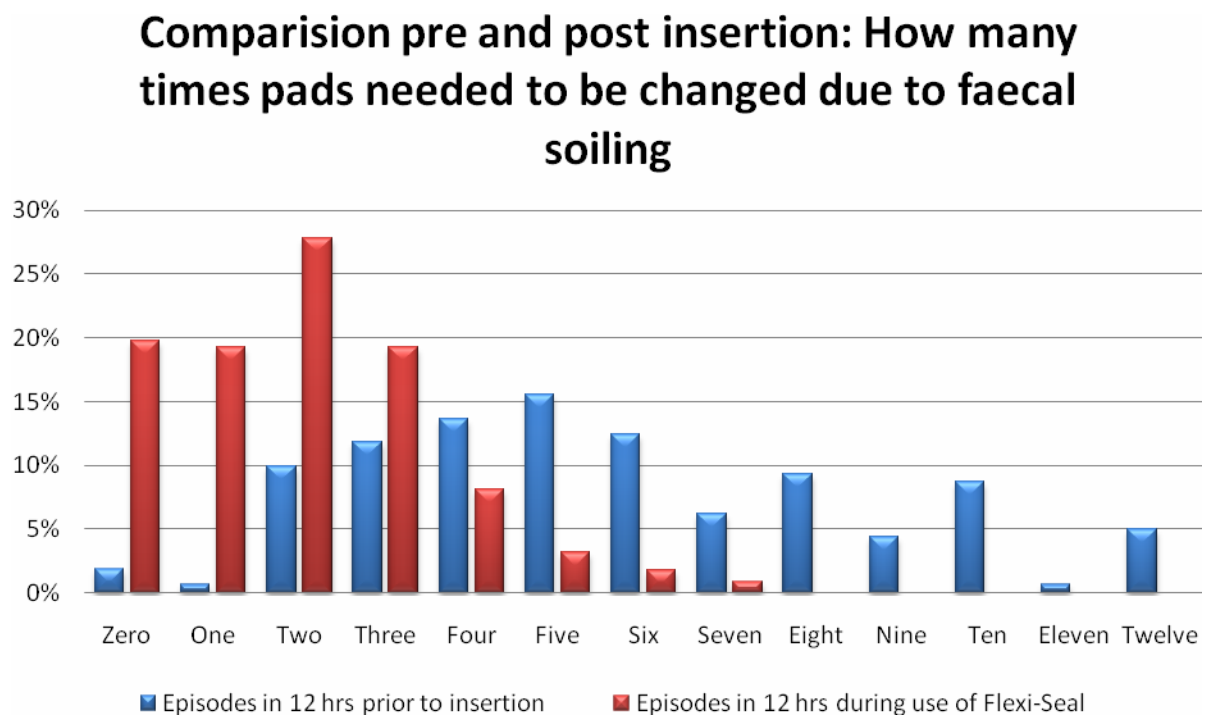

Figure 5 – Comparison between the need for changing pads prior to insertion and post insertion of Flexi-Seal®

How acceptable was the product to staff?

Flexi-Seal® was seen to be easy to use. 91% of responding staff found the system easy to insert; 97% found inflating the balloon easy/very easy; and 99% of staff found attaching the bag easy/very easy. 92% found the instructions provided with Flexi-Seal® to be good to excellent and the packaging was assessed as 99% good to excellent.

Flexi-Seal® scored highly among the 243 staff in all categories from ease of measuring output and ease of bag changes through to patient comfort, odour management, patency without kinking and reduced nursing time spent on faecal incontinence. 89% of staff would recommend Flexi-Seal ® to their colleagues.

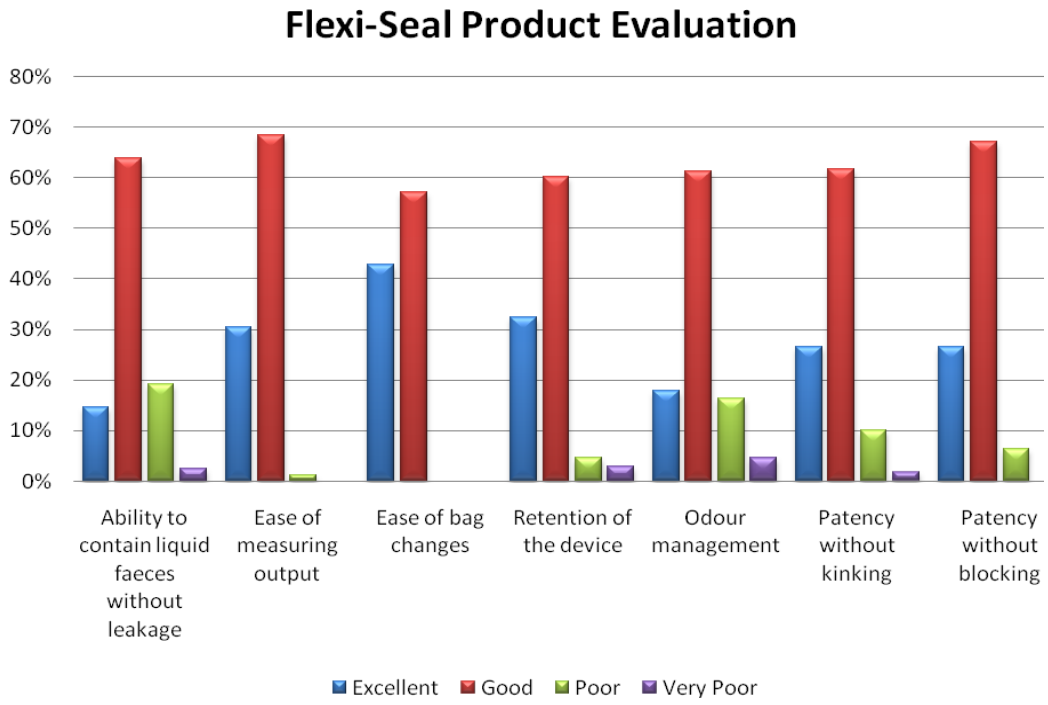

Figure 6 – Staff Evaluation of Flexi-Seal®

How acceptable was the product to patients?

The number of evaluation forms completed by patients was very low (38), because Flexi-Seal® was predominantly used in intensive care, so many patients were not aware that the device had been inserted.

36% of patients said that they felt no pain upon insertion of Flexi-Seal® and 69% felt no pain whilst it was in use. Patients were asked to rate the pain on a scale of between 1 and 10 where 0 is no pain and 10 is worst possible pain. Pain levels appeared to decrease over time. Figure 7 shows the percentage of patients who rated their pain zero through to ten and at which stage they gave that rating.

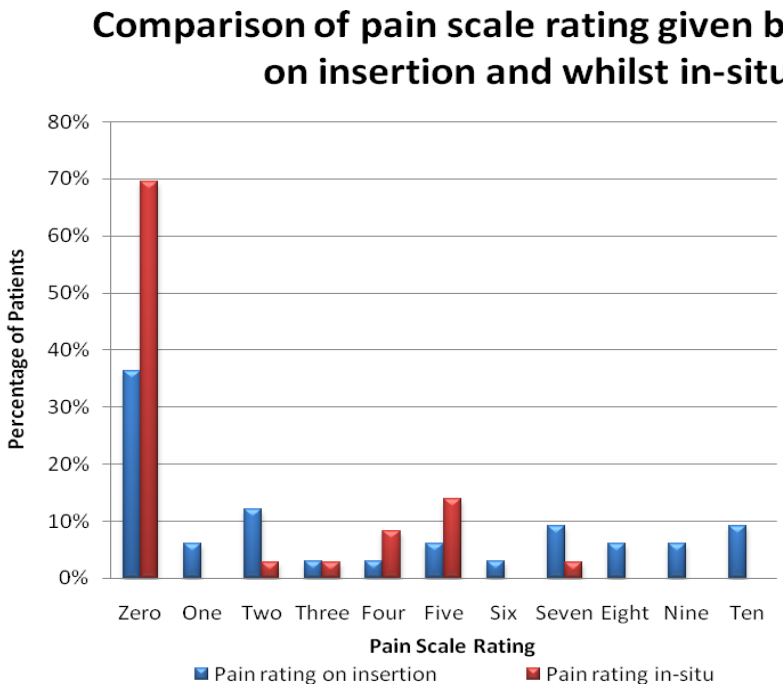

Figure 7 – Patient Pain Comparison

Patients were asked their opinion of Flexi-Seal® and the results indicated that the majority surveyed felt very positive about it (see Figure 8). 97% agreed or strongly agreed that the device made them more comfortable and that they preferred the tube than relying on pads alone. 91% of patients would recommend the product to another patient with the same problems.

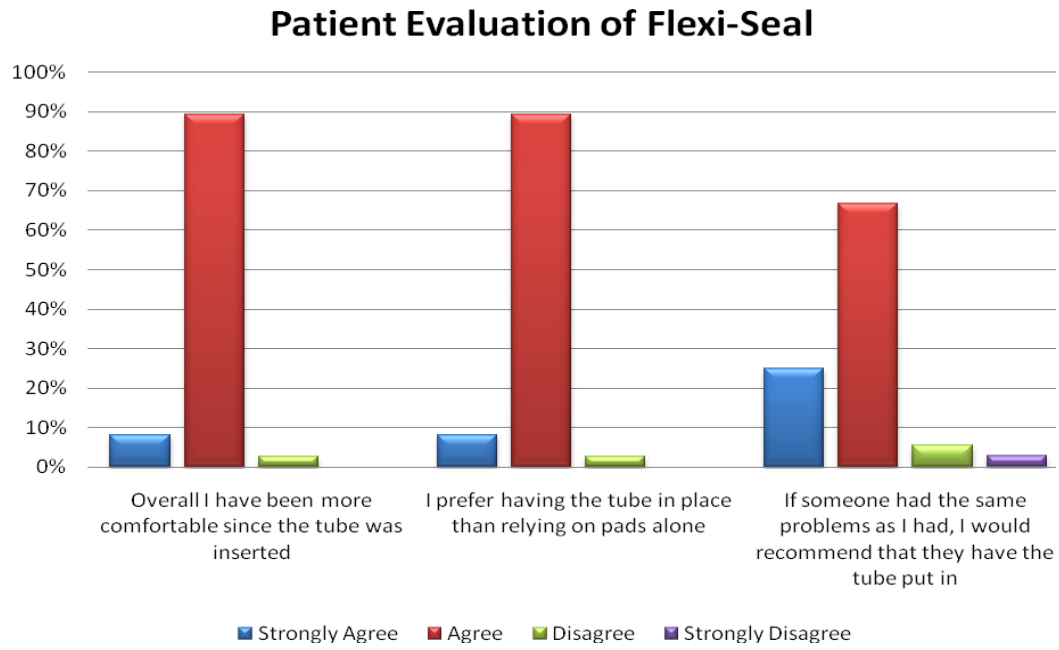

Figure 8 – Patient Evaluation of Flexi-Seal®

What issues arose in relation to implementation and adoption?

The relatively small number of units used across the Showcase Hospitals means that issues which may arise less frequently are unlikely to have been identified. In the Showcase Hospitals issues arose in relation to takeup and training. These were overcome by the Project Leads and a marked increase in trust-wide communication which increased the numbers of systems in use.

As noted above, **takeup** of Flexi-Seal® was fairly low. It was mainly used in intensive care settings and many hospitals utilised two areas for supplies – one in a central place and one on ICU/ITU. In the Showcase Hospitals, staff could choose between Flexi-Seal® and an alternative faecal management system. Where Flexi-Seal® was chosen this was because it looked simpler to use and (in general wards) less uncomfortable for the patient. Where the alternative system was chosen, this was because that product had been introduced earlier than Flexi-Seal® and was preferred because it was seen as a 'known' product.

Where appropriate patients did not benefit from use of Flexi-Seal®, the Project Leads utilised further training in patient selection and increased communication, in particular to ITU staff to ensure uptake was optimal.

Training is of great importance when introducing a new product such as Flexi-Seal®. Staff should not use a product until they are confident in its use. The initial training provided on the wards by ConvaTec Inc. representatives does not seem to have been sufficient in the opinion of the Showcase Hospital staff. Many trusts experienced only a 10 minute training session which was deemed insufficient. This led to the ward managers and the Project Lead in one Showcase Hospital taking the decision not to let staff use the system until further training had been given. The others simply arranged further training. Once these initial issues had been overcome, however, more flexible, tailored options were made available and feedback was much more positive. For example, one hospital had the nurse trainer come in during the night to train staff and another had spontaneous positive feedback about another trainer. ConvaTec's trainers were overall considered very supportive of staff, reliable in their provision of training records and flexible in training times and repeat sessions. Regular, on occasions weekly, training took place and at one site the trainer was able to attend to provide additional training within 24 hours.

One site came to the conclusion that at least 4-6 staff per hospital area were needed in order to allow successful implementation. ConvaTec were able to train between 50 and 100 staff over the course of a month.

Few **in-use issues** arose, though one patient developed a pressure ulcer which was considered to have resulted from the patient sitting on the tube.

Advice and tools for trusts considering introducing Flexi-Seal®

Important points to consider

It is vital to good uptake that the user is fully conversant with the system – measures should be taken, prior to training, to fully communicate expectations to the nurse educator to ensure quantity and quality of training is appropriate. This could, in turn, lead to increased use of the system.

It is unlikely that an implementing trust would use very large quantities of this product and thus costs are not likely to be significant. It may not be necessary to keep large numbers of Flexi-Seal® in stock. It is clear that ITU are the highest users and so they would need to have their own supply but a general stock should also be maintained.

Costs and Benefits

With the help of one of the Showcase Hospitals, we have compared the possible cost of using Flexi-Seal® with the cost of standard management of faecal incontinence in a hospital setting. This is inevitably subjective and the assumptions we have used are set out in the Appendix. Trusts may wish to make their own assessment.

In this evaluation, the average number of times pads needed to be changed each day due to faecal soiling prior to the insertion of Flexi-Seal® was 5. On this basis the average cost of standard care is estimated to be £29.91 per day. Most of the cost is attributed to the cost of nursing time involved.

In this evaluation, the average number of times pads needed to be changed each day due to faecal soiling following the insertion of Flexi-Seal® was 2. In comparison with standard care, use of Flexi-Seal® reduces the cost of managing patients significantly in terms of nursing time, but against this has to be set the high initial cost of the system (£228.85). As can be seen from figure 10, if patients under standard management required 5 changes a day, which reduced to 2 a day with the use of Flexi-Seal®, the device would have to be in place for a minimum of 17 days for Flexi-Seal® to be cost neutral.

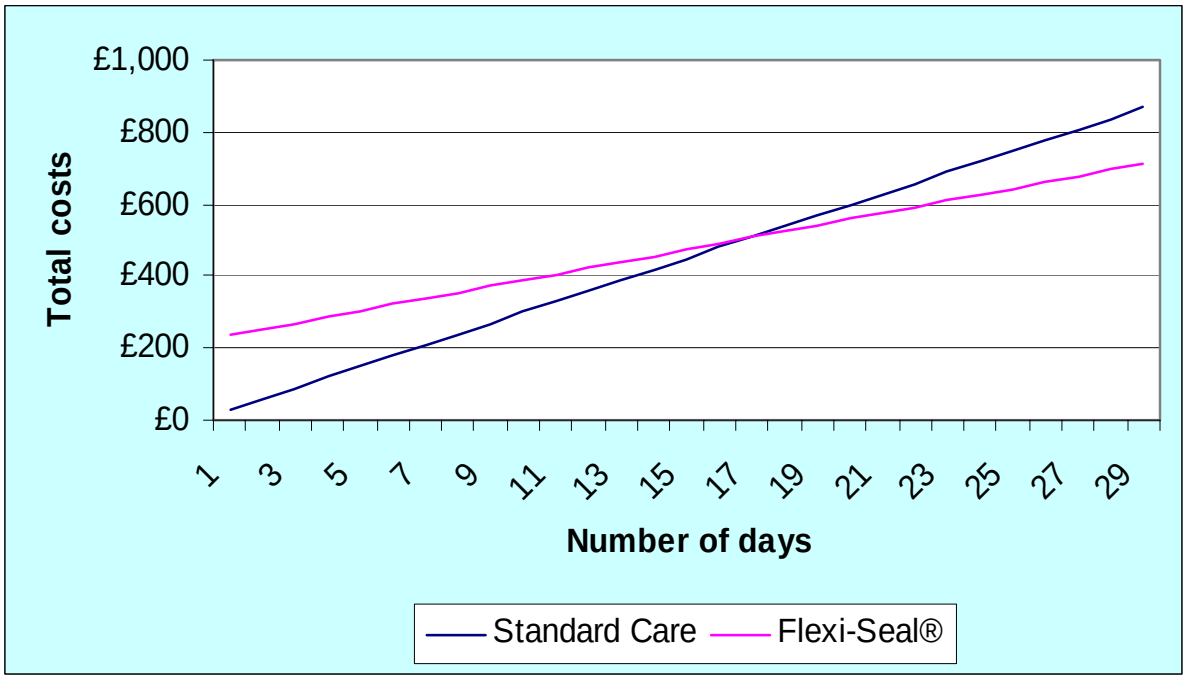

Figure 10: Total cost of management of patients with faecal incontinence by Length of Episode (based on 5 pad changes per day with standard care and 2 changes per day when using Flexi-Seal®)

However, in this evaluation, some patients needed 12 pad changes per day prior to the insertion of Flexi-Seal® and some patients needed no changes following the insertion of Flexi-Seal®. On the assumption that a patient with 12 changes needed no changes at all following the insertion of Flexi-Seal®, as can be seem from figure 11, the device would have to be in place for a minimum of 4 days for Flexi-Seal® to be cost neutral.

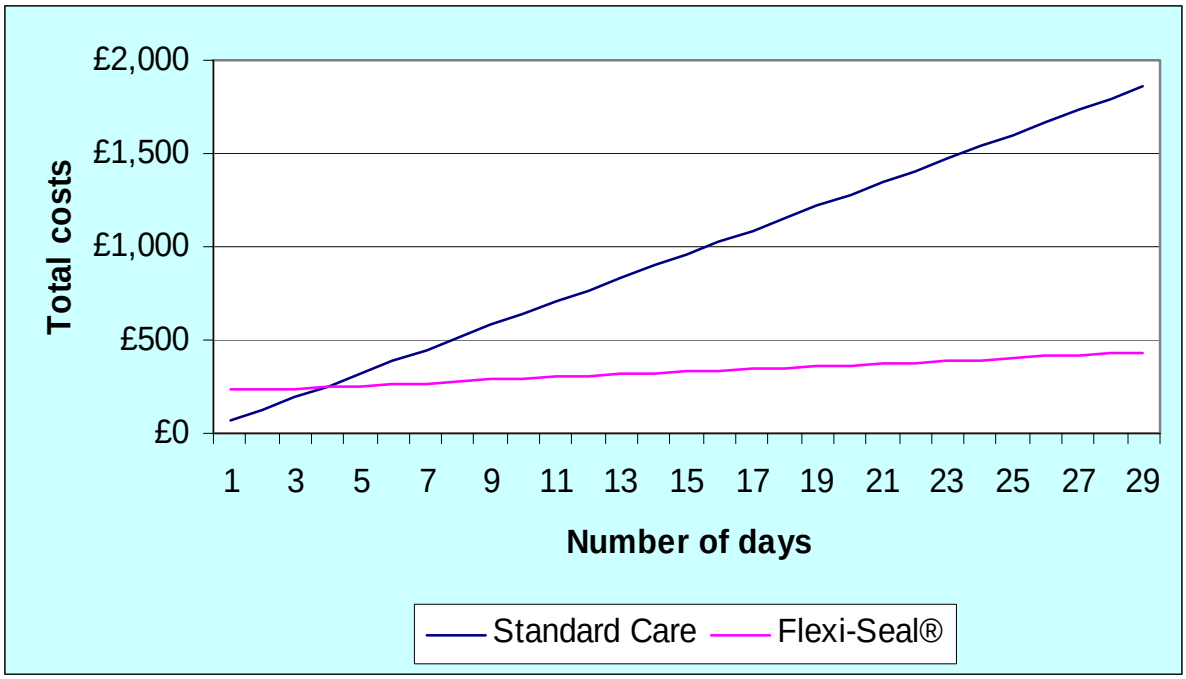

Figure 11: Total cost of management of patients with faecal incontinence by Length of Episode (based on 12 pad changes per day with standard care and 0 changes per day when using Flexi-Seal®)

This analysis, however, looks only at the comparative costs of standard management and the use of Flexi-Seal®. Better management of faecal incontinence can enhance patient comfort and dignity. It can also help reduce mortality and morbidity.

Patients suffering from a *C. difficile* infection spend on average more than 21 extra days in hospital compared with non-infected patients[8]. Taking into account the cost of hospitalisation and the added cost of nursing time with treatment, the total cost of treating a patient with an infection with standard care is substantial. By containing the spores which are found in the diarrhoeal faeces of patients with *C.difficile* infection, use of a faecal management system could help reduce the risk of other patients suffering such an infection, though further studies would be required to demonstrate this. This would translate into significant savings.

Similarly, because faecal incontinence degrades the skin barrier, it is a risk factor for pressure sores especially in patients who are critically ill or bedridden[9]. Previous studies estimated that the median length of stay for patients to develop a pressure ulcer was four days with a range of two to eleven days. While other factors such as norepinephrine infusion, anaemia and length of stay have been associated with development of a pressure sore[9], properly managing faecal incontinence would reduce the chances of a patient developing an ulcer. The cost of managing a patient with a pressure ulcer varied from £42-£196 per day in 2002/2003 prices[10].

Drawing up a Business Case

Trusts may wish to adopt and adapt the following model when drawing up a business case for this product. Text in italics (other than the section headings) gives information about how to complete the business case. Text in ordinary font (and the section headings) is intended to be suitable for cutting and pasting into the business case. The symbol ♥ indicates where numbers need to be inserted.

The Problem

A patient who has *C. difficile* diarrhoea excretes large numbers of the spores in their liquid faeces. These can contaminate the general environment around the patient's bed (including surfaces, keypads, equipment), the toilet areas, sluices, commodes, bed pan washers, etc. They can survive for a long time and be a source of hand-to-mouth infection for others. If these others have also been given antibiotics, they are at risk of *C. difficile* disease(5).

Insert information about cases of C. difficile infection (CDI) in the trust, noting in particular the extent to which cases are considered (for example, as a result of Root Cause Analysis) to arise from cross-infection from patients already suffering from CDI.

Faecal incontinence can cause extensive prolonged damage to the perineal skin due to bacteria and enzymes contained in faeces. Faecal incontinence is a risk factor for pressure sores, leading to increased morbidity, mortality and length of stay.

Insert information about skin problems in the trust associated with faecal incontinence.

Traditional methods of managing faecal incontinence include the use of disposable pads. This can lead to patient discomfort and distress when the pads become soiled. Several time consuming linen and pad changes may be required for a single shift to reduce the skin's exposure to moisture and bacteria. Staff managing patients with faecal incontinence often require supplies such as clean bed linen, incontinence pad, towel, yellow bags, plastic apron, soiled/contaminated linen bag, wet/dry wipes, clear bag and disposable gloves.(6)

NICE recommends that healthcare professionals should consider a faecal collection device for people in intensive care settings and people receiving palliative care with faecal incontinence and associated loose stools. This recommendation is based on expert advice and a consensus development exercise, and is justified on the basis that severe uncontrolled diarrhoea is a threat to skin integrity and a major nursing care problem.(7)

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[5] A simple guide to *Clostridium difficile.* Department of Health.
[6] Bardsley A. Innovations in the management of faecal incontinence. Continence UK. 2008;2
[7] NICE Clinical Guideline. Faecal incontinence: the management of faecal incontinence in adults. June 2007.

Regulations made under the Health and Social Care Act 2008[8] require trusts to ensure as far as possible that patients are protected against identifiable risks of acquiring healthcare associated infections.

The Flexi-Seal® Faecal Management System

The Flexi-Seal® Faecal Management System is designed for the faecal management of patients with little or no bowel control and liquid or semi-liquid stool. A soft silicone catheter is inserted into the rectum and retained by a low-pressure balloon. A collection bag is connected at the other end. The device contains and diverts faecal waste to protect the patient's skin and keep the bedding clean.

Flexi-Seal® is recommended by the Rapid Review Panel (which assesses new and novel equipment, materials and other products that may be of value to the NHS in improving hospital infection control and reducing healthcare associated infections) as being a product where basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

A recent evaluation by Showcase Hospitals as part of the Department of Health's Healthcare Associated Infections Technology Innovation Programme showed that Flexi-Seal® was favourably received by staff and patients.

Current Practice

Describe current practice in your trust for the management of faecal incontinence.

Options

We have looked at 4 options

1. Continue with current practice.

2. Use Flexi-Seal® for patients with liquid or semi-liquid stool and who are diagnosed (or suspected) as having *C. difficile* infection.

3. Use Flexi-Seal® for patients with liquid or semi-liquid stool who are diagnosed (or suspected) as having *C. difficile* infection, are in intensive care or who are receiving palliative care, complying with NICE guidelines.

4. Use Flexi-Seal® for patients with liquid or semi-liquid stool who are diagnosed (or suspected) as having *C. difficile* infection, are in

[8] The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009

intensive care or who are receiving palliative care, complying with NICE guidelines, or who otherwise have diarrhoea.

Costs and Benefits

We have compared each of the options 2-4 with current practice, looking at

(a) The number of patients who might receive the Flexi-Seal® system

(b) The cost per patient of using the Flexi-Seal® system (we have assumed that, on average, the system will remain in place for ♥ days and that there will be an average of ♥ *[Experience with the Showcase Hospitals would suggest an average of 2]* changes of bedding etc per day still required) *This should be based on local experience of the duration of diarrhoea in each of the categories of patient i.e. (options 2-4) patients with* C. difficile*; (Options 3-4)patients in intensive care or receiving palliative care; (Option 4) other patients who have diarrhoea.*

(c) The total cost of using the Flexi-Seal® system *[(a)x(b)]*

(d) The cost per patient of current practice (we have assumed that an average of ♥ changes of bedding etc per day will be required) *Ideally this should be based on local experience. Experience from the Showcase Hospitals would suggest an average of 6.*

(e) The total cost of current practice *[(a)x(d)]*

(f) Costs/savings of using Flexi-Seal® *[(c)-(e)]*

(g) (Options 2-4) Number of cases of *C. difficile* infection prior to introduction of Flexi-Seal® *[use local data]*

(h) (Options 2-4) Cost per case of *C. difficile* infection *[The National Audit Office report on healthcare associated infections[11] uses an estimate of £4,200 per case]*

(i) (Options 2-4) Total cost of cases of *C. difficile* infection prior to introduction of Flexi-Seal® *[(g)x(h)]*

(j) (Options 2-4) Estimated number of cases of *C. difficile* infection following introduction of Flexi-Seal® *[You will need to assess what proportion of C. difficile infections are associated with cross-infection and what proportion of these infections will be prevented. You may wish to consider a range of possible outcomes.]*

(k) (Options 2-4) Estimated cost of *C. difficile* infections following introduction of Flexi-Seal® *[(j)x(h)]*

(l) Savings in cost of *C. difficile* infections following introduction of Flexi-Seal® *[(i)-(k)]*

(m) (Options 2-4) Number of cases of skin problems associated with faecal incontinence prior to introduction of Flexi-Seal® *[use local data]*

(n) (Options 2-4) Cost per case of skin problems associated with faecal incontinence *[Use local costs]*

(o) (Options 2-4) Total cost of cases of skin problems associated with faecal incontinence prior to introduction of Flexi-Seal® *[(m)x(n)]*

(p) (Options 2, 3 and 4) *Different figures for each* Estimated number of cases of skin problems associated with faecal incontinence following introduction of Flexi-Seal® *[You will need to assess what proportion of such problems will be prevented in patients with liquid or semi-liquid stool who are diagnosed (or suspected) as having C. difficile infection (Options 2, 3 and 4), are in intensive care or who are receiving palliative care (Options 3 and 4), or whose diarrhoea does not resolve within x days (Option 4). You may wish to consider a range of possible outcomes.]*

(q) (Options 2, 3 and 4) *Different figures for each* Estimated cost of skin problems associated with faecal incontinence following introduction of Flexi-Seal® *[(p)x(n)]*

(r) (Options 2, 3 and 4) *Different figures for each* Savings in cost of skin problems associated with faecal incontinence following introduction of Flexi-Seal® *[(o)-(r)]*

(s) Transitional costs *[e.g. training]*

Other Benefits

Better management of faecal incontinence can enhance patient comfort and dignity. It can also help reduce mortality and morbidity.

Reducing the number of *C. difficile* infections and skin problems associated with faecal incontinence, both of which are associated with increased length of stay, will reduce blocked beds which may in turn help with delivery of other trust targets, such as waiting times.

Conclusions and Recommendation

Taking action to reduce *C. difficile* infections and skin problems associated with faecal incontinence is desirable in order to reduce harm to patients and increase confidence in the safety of the services provided by the trust. Failure to comply with NICE guidelines will be hard to justify.

However, these risks have to be balanced against the costs of Flexi-Seal® compared with current practice in the management of faecal incontinence, whilst taking account of the potential benefits and hence savings which the use of Flexi-Seal® may bring.

Our recommendation is *to be decided locally*

Appendix – Assumptions underlying the Cost Comparisons

Standard Care

Description	Quantity per Change	Cost per Change	Comments
Foam Cleaner	12.5 mls	£0.05	
Wipes	4	£0.08	
Gloves	4	£0.10	
Aprons	2	£0.16	
Red Linen Disposal	1	£0.08	
Yellow Clinical Waste Bags	1	£0.07	
Bed Pads	1	£0.11	
Laundry	1	£0.30	
Nurse Band 6	2.5 minutes	£0.68	Nursing time is estimated to be 20 minutes per change – split will depend on availability of staff.
Nurse Band 5	7.5 minutes	£1.66	
Clinical Support Worker	10 minutes	£1.58	
	Quantity per Day	**Cost per Day**	
Barrier Cream	1 sachet	£0.43	
Faecal Pouch	1	£5.08	

Flexi-Seal®

Description	Quantity per Change	Cost per Change	Comments
Foam Cleaner	12.5 mls	£0.05	
Wipes	4	£0.08	
Gloves	4	£0.10	
Aprons	2	£0.16	
Red Linen Disposal	1	£0.08	
Yellow Clinical Waste Bags	1	£0.07	
Bed Pads	1	£0.11	For 0 changes, 1 per day has been included
Laundry	1	£0.30	
Nurse Band 6	2.5 minutes	£0.68	Nursing time is estimated to be 20 minutes per change – split will depend on availability of staff.
Nurse Band 5	7.5 minutes	£1.66	
Clinical Support Worker	10 minutes	£1.58	
	Quantity per Day	**Cost per Day**	
Barrier Cream	1 sachet	£0.43	Also included in 0 changes
Flexi-Seal® Bags	2	£6.81	Price taken from NHS Supply Chain Catalogue on 27 November 2009. As the kit includes 3 bags, no additional bag is included for day 1 and only 1 additional bag is included

			for day 2.
	Quantity per Episode	**Cost per Episode**	
Flexi-Seal® Kit	1	£228.85	Price taken from NHS Supply Chain Catalogue on 27 November 2009

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