Foreword

Professor Jean White, Chief Nursing Officer for Wales

Faecal incontinence is an embarrassing and undignified condition for the patient, which significantly reduces a person’s quality of life. It can affect all ages, with certain groups of individuals at greater risk than others. If poorly managed, it can lead to other health problems, particularly damage to the skin’s integrity, infection and an increased likelihood of pressure ulcer formation. Faecal incontinence is a difficult condition to manage and the introduction of Faecal Management Systems is a significant advance in caring for individuals.

I welcome these All Wales Guidelines for Faecal Management Systems, which are the culmination of a joint project undertaken by nurses from three nursing specialties: continence, infection prevention and tissue viability. The nurse leads for the project all work in NHS and higher education organisations in Wales and have shown real inspiration and dedication in the development of these guidelines. They are:

Julie Evans Tissue Viability Nurse, Abertawe Bro Morgannwg University Local Health Board
Joanna Price Infection Control Nurse, Cwm Taf Local Health Board
Ann Yates Director of Continence, Cardiff and Vale University Local Health Board
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The purpose of the All Wales Guidelines is to support clinical staff in deciding whether the Faecal Management System is appropriate and suitable for an individual patient. The guidance can also be used as part of local policies and protocols for tissue viability, management of continence and infection prevention. I commend these guidelines to you.

Introduction

There are, at present, no national guidelines available for the management of faecal incontinence with regard to Faecal Management Systems (FMS).

The National Institute for Health and Clinical Excellence (NICE) (2007) recommends that health professionals should consider a faecal collection device on the basis that severe uncontrolled diarrhoea is a threat to skin integrity. In addition, uncontrolled diarrhoea has an impact on psychological health, and increases the risk of cross-contamination and infection from pathogens such as Clostridium difficile.

Padmanabhan et al (2007) published a clinical evaluation of a FMS. Even if the study lacked a control group, they demonstrated an improvement in skin condition using FMS.

In 2007, the Rapid Review Panel (Health Protection Agency) recommended FMS (level 1), indicating that it should be available to NHS bodies as part of their cleaning, hygiene and infection control protocols. The HCAI Technology Innovation Programme (2009) commissioned a Showcase Report which showed that FMS was favourably received by staff and patients, with use being decided locally by healthcare organisations.

The purpose of these guidelines is to ensure the appropriate use of the FMS within the seven Health Boards, one Health Trust and independent sectors in Wales, and to provide guidance to staff during the decision-making process for its suitability to patients. It is suggested that this guidance should form part of continence, infection prevention and tissue viability protocols.

The guidance provided by this document is based on expert consensus, which along with audit has been suggested as a positive method of directing care (Ousey et al, 2010).

Definition of Faecal Incontinence

Faecal incontinence has a variety of definitions. The Royal College of Physicians (1995) state ‘the involuntary or inappropriate passage of faeces’, while Kenefick (2004) defines it as the ‘uncontrolled passage of solid or liquid faeces at socially inappropriate times and place’. The most recognised and used definition is for anal incontinence which includes not only liquid or solid faeces, but also the inappropriate passage of flatus developed by the World Health Organization Consultation on Incontinence (Norton et al, 2002): ‘Anal incontinence is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem’.

Definition of Diarrhoea

Diarrhoea derives from the Greek ‘to flow through’. Diarrhoea is usually the passage of frequent (more than three times daily) loose, watery or unformed stools. It usually presents as either acute or chronic diarrhoea. Chronic diarrhoea is identified if the symptoms persist for 1 month or more (Talley and Martin, 1996).
Guidelines for Faecal Management Systems

The Extent of the Problem

Epidemiological information highlights that between 1% and 10% of adults are affected by faecal incontinence, depending on definition and frequency (NICE, 2007). However, most of the studies relate to chronic problems rather than acute. The management of faecal incontinence has traditionally taken the form of meeting patients’ hygiene needs, changing bed linen and using incontinence pads, etc. While appropriate for some patients after a full assessment has been undertaken, it may be less effective for others. Before any device or treatment is instigated, a full assessment by a health professional trained, skilled and competent in bowel defunction should be undertaken (NICE, 2007). One of the main reasons is the importance of excluding RED FLAG risk groups, which could include: passing of blood, excessive mucous/wind not associated with lifestyle changes; unintentional weight loss; anaemia, and altered bowel habits over the past 6 weeks. Patients identified with any of these symptoms should be immediately referred to a medical practitioner.

The risks of cross-infection, skin excoriation, incontinence-associated dermatitis (IAD), wound contamination, and dehydrosis should also be considered (Ousey and Gillibrand, 2010).

The exact extent of the prevalence of faecal incontinence is unknown. It has been postulated that this may be complicated by the different definitions of faecal incontinence (Ousey et al., 2010). However, faecal incontinence is a common denominator among hospitalised patients (Wishin et al., 2008). In the UK, a small prospective study reported a high prevalence of faecal incontinence within intensive care settings (Ousey and Gillibrand, 2010). A similar study gathered data on 1180 patients, of whom 51.6% (n=350) were incontinent of urine, faeces or doubly, and 1.54% (n=17) had incontinence lesions. Of those at a very high risk of pressure damage according to the Waterlow scoring system (2005), 78% (n=125) were incontinent (Evans, 2010).

C. difficile infection is the most important cause of hospital acquired diarrhoea and is responsible for considerable morbidity and mortality. When certain antibiotics disturb the balance of bacteria in the gut, C. difficile can multiply rapidly and produce toxins that cause diarrhoea. C. difficile is usually spread via the hands of healthcare staff and other people who come into contact with infected patients, or with environmental surfaces contaminated with the bacteria or its spores. Spores are produced when C. difficile bacteria encounter uncomfortable conditions such as being outside the body. They are very hardy and can survive on clothes and environmental surfaces for up to 5 years (Health Protection Agency (HPA), 2009).

Mandatory surveillance of C. difficile in inpatients aged over 65 years in Welsh hospitals was introduced by the Welsh Assembly Government in 2005. The total number of C. difficile cases in Wales reported in 2008–2009 was 27,44, representing rates of 15.46 per 1000 hospital admissions (Welsh Healthcare Associated Infections Programme (WHIAP), 2009). Organisations throughout Wales are mandated to reduce the level of healthcare-associated C. difficile infections by at least 20% year-on-year.

Patients with C. difficile associated diarrhoea may experience faecal incontinence, which has direct implications regarding environmental contamination and cross-infection (Statt, 2005). The FMS is a fully closed system that collects and contains liquid or semi-solid stools, and is therefore effective in containing faeces and helpful in preventing faecal contamination of the environment (Johnston, 2005).

Wishin et al. (2008) identified that hospitalised patients are predisposed to skin damage. In addition, certain patient groups are at risk of skin/pressure damage, specifically those undergoing surgery with or without epidural anaesthesia and those individuals suffering with a degree of sensory impairment (e.g. multiple sclerosis, cerebral vascular accident, epidural anaesthetic) (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Panel (EPUAP and NPUAP), 2009). This risk is due, in part, to reduced mobility and exposure of the skin to uncontrolled moisture from incontinence and/or wound exudate, and prolonged contact with faecal material (Kingsley, 2007). Individuals with established wounds as a result of trauma/burns may also have their skin further compromised by incontinence. In addition, areas of broken skin can restrict the use of adhesive dressings which, being unable to use these products, may have a detrimental effect on skin protection and wound healing (Beldon, 2008).

Effects of Faecal Incontinence

Faecal incontinence has a detrimental impact on psychological, social and physical functioning. The stigma of incontinence is not socially acceptable and results in significant psychological trauma for the individual (Wishin et al., 2008). It is viewed as undignified and the subsequent care is an invasion of personal space. The odour associated with incontinence is a further source of embarrassment (Wishin et al., 2008). It causes distress, embarrassment, anxiety, inconvenience, threat to self-esteem and self-confidence, loss of personal control, loss of dignity and degradation. Cavet (1998) undertook an extensive study of teenagers living with faecal incontinence and stated that they faced exclusion, humiliation, ignorance and ridicule. Therefore, people with faecal incontinence feel they no longer fit societal ‘norms’ and can feel stigmatised. They feel that if they can continue to manage and conceal symptoms they will not be excluded from society (Leigh and Turnberg, 1982). This is just one of the many reasons they do not discuss with health professionals and it remains a hidden topic.

Maintenance of patient’s privacy and dignity should be paramount when caring for these individuals.

Physical symptoms of faecal incontinence can include feelings of abdominal discomfort, pain or blurring, bowel urgency and frequency leading to potential dehydration, urea and electrolyte imbalance, and skin problems if not treated or managed effectively.

Local Effects of Faecal Incontinence

The exact mechanism of skin damage due to incontinence is debatable; however, the following mechanisms of action are recognised as common denominators in skin breakdown.

Infection

Faecal contamination can increase the risk of post-surgical wound breakdown in the susceptible areas such as groins and perineal region (Estrada et al, 2009).

Skin has a mean pH of 5.5, which is slightly acidic. Feces can be alkaline in nature; it’s presence on the skin can immediately change the pH, resulting in skin irritation (Beldon, 2008).

The increase in moisture resulting from episodes of incontinence, combined with bacterial and enzymatic activity, can result in the breakdown of vulnerable skin. If the skin is exposed to fluid for sustained periods of time, it becomes waterlogged, causing it to become soft and wrinkled, and increases its friction coefficient (White and Cutting, 2003). As a result, the protective barrier of the skin is breached, which allows enzymatic onslaughts (Wishin et al, 2008). Damage caused by pressure and shear force is exacerbated by the presence of surface moisture through incontinence (Collier, 1996).

Systemic Effects of Faecal Incontinence

Dehydration owing to faecal/urinary incontinence may result in skin changes such as dryness and loss of turgor (Beldon, 2008). It is also acknowledged that skin damage produces pain, which is exacerbated with the addition of incontinence (Beldon, 2008).

Maintenance of Bowel Continence

Faecal incontinence is a sign or symptom of an underlying condition which is usually multifactorial. Understanding this requires health professionals to have a basic knowledge of the mechanics of bowel continence and what can go wrong. Normal defection relies on movement of faeces into the rectum causing distension and the desire to defecate, known as the ‘call to stool’ (Norton, 2001). A person then adopts a sitting or squatting position which allows for an increase in abdominal pressure and contraction of the abdominal muscles. This is followed by relaxation of the puborectalis muscle and anal sphincters, which allow the stool to then be evacuated.

To achieve all of this and prevent leakage, a compliant, distensible and evacuable rectum is required with intact anal/rectal sensation, intact mucosal columns, bulky and formed faeces, and intact internal/anterior anal sphincters. The internal sphincter is not under voluntary control and if weak, can lead to passive soiling and incontinence of flatus. The external anal sphincter is under voluntary control and weakness in this muscle will lead to urge faecal incontinence and an inability to hold on (Emmanuel, 2004).

Individuals at Risk

Skin Damage

People over the age of 65 years are more susceptible to contracting infections. 80% of C. difficile cases reported are in this age group (HPA, 2010). The risk for C. difficile acquisition significantly increases in patients with recent exposure to antibiotics and in particular, with the use of broad-spectrum antibiotics. Other factors that increase the risks of acquiring C. difficile infection include patients who have undergone recent gastrointestinal surgery, patients who have serious underlying illnesses, immunosuppressed patients, and patients who have been hospitalised frequently or for long periods of time. The risk of patient-to-patient transmission is increased when caring for patients who are faecally incontinent (WHIAP, 2009).

High-risk groups for faecal incontinence include (NICE, 2007): frail older people; women after child birth (especially third/fourth degree tear, instrumental delivery, midline episiotomy, first baby, birth weight over 4kg); people with loose stools or diarrhoea from any cause; neurological or spinal disease; people with severe cognitive impairment; pelvic organ prolapse and or rectal prolapse; colonic resection or anal surgery; undergone pelvic radiotherapy; perianal soreness; itching or pain; and people with learning disabilities.
Patients presenting with acute diarrhoeal symptoms should undergo a thorough assessment performed by a competent health professional, and include recent travel history, recent contacts with people who have experienced similar symptoms, and antibiotic history for the previous 3 months. In addition to persistent diarrhoea (type 6–7 on the Bristol stool chart) developed by Lewis and Heaton (1997); appendix 1), patients who have a C. difficile infection may experience fever, raised white cell count, signs of dehydration, hypotension, mental status changes, abdominal tenderness, abdominal distension and in severe cases, absent bowel sounds.

C. difficile infection should be suspected on clinical judgement and confirmed by laboratory testing. Where C. difficile is suspected or confirmed, the patient should be isolated and standard infection control precautions adhered to. A comprehensive bowel assessment will have been undertaken by a competent practitioner in the assessment of bowel dysfunction before the procedure is undertaken (NICE, 2007). The bowel assessment will have identified high-risk patients and RED FLAG such as those patients with indications of bowel cancers, and will exclude faecal impaction as a cause of overflow (NICE, 2007).

The bowel assessment should be carried out by an appropriate qualified and competent health professional trained in the skill of undertaking a bowel assessment and relevant investigations (i.e. digital rectal examination (DRE)) to determine faeces in the rectum and rectal anal tone if appropriate (NICE, 2007). A structured approach should be applied during the assessment of the patients with bowel dysfunction according to evidence-based guidance and All Wales/ local directives (Skills for Health, 2008). Patient suitability for the FMS should also be assessed and documented in the patient’s records in accordance with organisation policy.

The sites at risk of skin damage due to incontinence are predominately: the perineum, groins, buttocks, and sacrum (Johnston, 2005). In addition, the lower abdomen may also be classed as a vulnerable site (Beldon, 2008).

It has already been stated that defining incontinence is problematic. However, this also relates to the diagnosis of skin damage resulting from incontinence; for example, the confusion between category/ grade 2 pressure damage and IAD (DeBoor et al, 2005).

The correct differentiation between pressure damage and IAD is essential (DeBoor et al, 2005), and in the absence of validated tools will largely depend on clinical assessment based on the patient’s recent history. Skin damage as a result of exposure to excessive moisture is defined as ‘a skin lesion associated with incontinence and not caused by pressure or shearing’ (DeBoor et al, 2005), with moisture contributing to the formation of pressure ulcers (EPUAP and NPUAP 2009).

Padmanabhan et al (2007) devised a skin condition rating scale as part of a larger study into the management of faecal incontinence. However, to date this tool has not been subjected to further validation, so its use in clinical practice remains limited.

Guidance on Skin Care and Appropriate use of FMS

Current Skin Care Regimens

The aim of any skin care regimen is to protect skin integrity (Padmanabhan et al, 2007). The different actions of barrier products should be carefully considered (Beldon, 2008).

Liquid barrier films:

These products consist of polymers combined with adhesives; they are applied as a preventive method to intact skin. If applied to broken skin, some of them can cause dermal irritation (Donovan et al, 2002; Kingsley, 2007).

Emollients:

These are grease-based substances and when applied to the skin either trap water in or allow water to be pulled from the dermis to the epidermis (Loden, 2003). Emollients can also be used as wash products. Once the washing is complete, emollients can be applied to the skin in the form of lotions, creams or ointments to seal water into the skin (Burt and Penner, 2005).

Ointments:

These are highly oil-based and offer water protection to the skin, acting as an occlusive barrier to faecal contamination (Nix, 2006).

Creams:

Many creams are water-based preparations and therefore have a lower oil content than ointments. They act by allowing the oil to sink into the skin, thus providing a barrier. Being less occlusive than ointment, they should be applied more frequently.

Examples of emollients, ointments and creams can be found in the Wounds UK product directory: http://tinyurl.com/wound-directory

Alternative recommendations to contain faecal matter

Anal bags; FMS; Pad containment products.

Other considerations

Beldon (2008) suggests that, when clinically indicated, catheterisation for urinary incontinence can protect the skin from damage. The same principle suggested that FMS could be of use for the same purposes with regard to skin damage caused by faecal incontinence.

Contraindications

FMS should not be used on patients with the following conditions:

1. Lower bowel surgery or rectal surgery within the last year
2. Sensitivity or allergies to any of the materials used in the FMS (i.e. silicone)

Possible adverse events while using FMS:

1. Loss of anal sphincter muscle tone
2. Pressure necrosis of rectal or anal mucosa
3. Infection
4. Bowel obstruction
5. Perforation of the bowel
6. Persistent rectal pain
7. Rectal bleeding
8. Abdominal distension
9. Unable to open bowels for more than 48 hours.

If any of the above adverse events occur, remove device, inform consultant and report as a clinical incident.
Directions for Use

It is imperative that the registered nurse and qualified medical staff follow the manufacturer’s instructions relating to the system, removal of the system, and maintenance of the system. More information can be found at:

http://www.bard.com
http://www.convatec.com
http://www.hollister.com

Currently the only system available through Welsh Health Supplies is Flexi-Seal from ConvaTec and directions for its use can be found in appendix 2, or via the clinical support helpline, freephone: 0800 289 738.

Conflict of Interest

The guideline development group received an unrestricted educational grant from ConvaTec for the development, production and dissemination of this document.

Resources and Training

The majority of staff within the NHS and independent sectors in Wales will not have received any formal training in this procedure. Professionals have to prove competency in assessment and procedure. Nursing staff should be deemed competent under the NMC Code of Professional Conduct (NMC, 2008). This document provides an example of a competency checklist for Flexi-Seal, along with a maintenance checklist and using the FMS Patient Information Leaflet. It is also necessary that staff demonstrate that they have kept their knowledge and skills up-to-date, acknowledging their limitations, and seek expert supervision if required.

Organisational Issues

Each Local Health Board/organisation should identify a ‘Champion’ who will be responsible for allocating the resources and implementation of FMS within the clinical setting.

This document is also available in Welsh via www.welshwoundnetwork.org
References


Ward..........................................................................................

Appendix 1: Bristol Stool Chart

BRISTOL STOOL CHART

Type 1 Separate hard lumps, like nuts.
Type 2 Sausage-like but lumpy.
Type 3 Like a sausage but with cracks in the surface.
Type 4 Like a sausage or snake, smooth and soft.
Type 5 Soft blobs with clear-cut edges.
Type 6 Fluffy pieces with ragged edges, a mushy stool.
Type 7 Watery, no solid pieces.

Date Time Type of Stool as per Bristol Stool Chart Comments including Amount (Small/Moderate/Large) Specimen sent Yes / No State Investigation

Addressograph Label

Ward..........................................................................................

Workbook

Guidelines for Faecal Management Systems
Appendix 2
ConvaTec's instructions for use

Procedure: as an example.
Please refer to other company instructions for guidance of individual products.

1. Create privacy
2. Explain the procedure to the patient and gain consent
3. Assemble equipment including gloves, water-soluble lubricant and 45 ml of tap water in a clean container
4. Open kit, fill syringe with water at room temperature and attach the syringe to the inflation port
5. Securely snap the collection bag to the connector at the end of the catheter and label it with the date and time
6. Unfold the length of the catheter to lay flat on the bed, extending the collection bag towards the foot of the bed
7. Insert a gloved index finger into the retention balloon cuff finger pocket
8. Coat the balloon end of the catheter in lubricating jelly
9. Assist the patient and position left lateral side with knees flexed
10. Undertake effective digital rectal examination and check for adequate rectal sphincter tone
11. If type 6–7 stools are present, or if rectum is empty, proceed with insertion of the Flexi-Seal
12. Gently insert the balloon end through the anal sphincter until the black line is inside the rectum
13. Inflate the balloon with 5 ml water by slowly depressing the inflation port. If the silicone device becomes blocked with solid particles, it can be irrigated by filling the syringe with 30 mls of tap water as many times as required, attaching the syringe to the irrigation port, and depressing the plunger. Repeat this procedure as often as necessary to maintain function of the device. If this fails to rectify the problem then the use of the device should be discontinued.

Removal of FMS
1. Wash hands with soap and water prior to commencing procedure
2. Ensure personal protective equipment is worn prior to any risk of exposure to bodily fluids
3. Deflate retention balloon by attaching the syringe to the inflation port and withdraw all the water
4. Disconnect the syringe and dispose safely
5. Grasp the catheter as close to the patient as possible and slowly slide it out of the anus
6. Dispose of the device, gloves and apron in accordance with Healthcare Waste Strategy for Wales/Health Board policy
7. Wash hands following removal of personal protective equipment with soap and water.

Maintenance of the FMS
1. Wash hands with soap and water prior to commencing procedure
2. Ensure personal protective equipment is worn prior to any risk of exposure to bodily fluids
3. Change the collection bag as required
4. Snap the cap onto each used bag and dispose as per Healthcare Waste Strategy for Wales/Health Board policy
5. Do not reuse bags once detached
6. Observe the device for obstructions, e.g. kinks, faecal particles or external pressure
7. Ensure regular hygiene is maintained around anal region
8. Document skin integrity as per patient care plan
9. Record facial output at least every 8 hours on fluid balance chart
10. When stool samples are required they should be taken from the tubing of the system rather than the bag to ensure a recent sample is taken
11. Dispose of the gloves and apron in accordance with Healthcare Waste Strategy for Wales/Health Board policy
12. Wash hands with soap and water following removal of personal protective equipment.

Troubleshooting
If leakage occurs the device should be inspected to ascertain that there is no external obstruction. If no obstruction can be found, attempt deflating the balloon by withdrawing up to 10 ml from the inflation port. If the silicone device becomes blocked with...
Maintenance Check List

Patient Name: Inserted by: 
Unit Number: Date of Insertion: 

Recommended to check device every two hours

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>12am-2am</td>
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<td>2am-4am</td>
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<td>6am-8am</td>
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<td>8am-10am</td>
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<tr>
<td>10am-12pm</td>
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Consistency of Stool
- Solid
- Semi Solid
- Semi Liquid
- Liquid

Skin Integrity
- Intact
- Reddened

Tube Position
- Correct (y/n)

Check Bag
- Check (v)

Drainage
- Check (v)

Irrigation
- Yes/No - volume used?

Signature

Quick Reference Guide

You need to be able to answer True to ALL the questions below in order to use Flexi-Seal® Faecal Management System.

- The patient is incontinent with liquid or semi-liquid stool
- The Patient is over 18
- The patient is not sensitive or known to have had allergic reactions to any component within the kit
- The patient has not had lower large bowel or rectal surgery within the last year
- The patient does not have suspected or confirmed rectal mucosal impairment
- The patient does not have any rectal or anal injury
- The patient does not have a confirmed rectal/anal tumour or stenosis or stricture
- The patient does not have hemorrhoids of significant size and/or symptoms
- The patient does not have a faecal impaction
- The patient does not have any in-dwelling or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories or enemas in place)

If you have answered ‘True’ to all the above, please refer to Pre-Insertion Checklist and Product Guidelines as patient is suitable for Flexi-Seal® FMS use.

Please discuss the above with a healthcare professional if you have any doubts about the answer to the above questions.