NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Faecal incontinence

Date of Quality Standards Advisory Committee post-consultation meeting:
01 November 2013.

2 Introduction

The draft quality standard for faecal incontinence was made available on the NICE website for a 4-week public consultation period between 23 August and 20 September 2013. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 9 organisations, which included Royal Colleges, other national organisations, medical technology companies and patient groups.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the

process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include overarching outcomes, thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which is provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Stakeholders were also invited to respond to the following statement specific question:

3. For draft quality statement 3: How should the 'period of assessment and initial management' be defined?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- General support for the draft quality statements on faecal incontinence.
- Concern that urogynaecological aspects not covered throughout.
- Suggestion to emphasise pathway between identification and diagnosis of underlying cause, including setting.

- Request to highlight that a number of definitions for faecal incontinence are available (QS defines faecal incontinence as 'any involuntary loss of faeces that is a social or hygiene problem').

Consultation comments on data collection

- Data collection is possible.
- Some data could be accessed through the IBD Registry or UK IBD Audit.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People at risk of faecal incontinence are asked in a sensitive way whether they experience bowel control problems.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders note that people with spinal injuries or other neurological conditions are at particularly high risk of bowel control problems.
- Concerns about identifying the denominator population.
- At-risk groups should specifically mention Crohn’s Disease and Ulcerative Colitis.

5.2 Draft statement 2

People with faecal incontinence are offered a full baseline assessment, which is carried out by healthcare professionals who do not assume that symptoms are caused by any existing conditions or disabilities.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Support for diagnostic overshadowing aspect of statement, but also suggestion that this intent needs to be clearer.

- Stakeholders highlight the importance of appropriate expertise of healthcare professionals conducting the baseline assessment.
- Suggestion to clarify that assessment means history taking, examination and special investigations.
- Suggestion that psychological impact should be explored as part of a baseline assessment.
- Concern that the definition of a baseline assessment does not address obstetrical or gynaecological aspects of history taking, examination or points to decide plan of management.

5.3 Draft statement 3

People with faecal incontinence and their carers are offered support and advice about how to cope with persisting symptoms during the period of assessment and initial management, including a choice of appropriate continence products.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Support for emphasis on choice of products.
- Suggestions to include more detail on the full range of available products.
- Suggestion for coping strategies to include personalised toileting plans.

Consultation question 3

Stakeholders made the following comments in relation to consultation question 3 (How should the 'period of assessment and initial management' be defined?):

- Duration of initial management will depend on individual circumstances, including the underlying cause(s).
- Stakeholders note the need to distinguish between people needing early or immediate specialist referral (such as people whose underlying cause is a neurological condition or spinal injury) and people for whom initial management in the community is appropriate.

- Suggestion that initial assessment and conservative treatment (including pelvic floor rehabilitation and ideally psychosocial support) should take place fortnightly over a three to six month period.
- Stakeholders highlight methods of quantifying the severity of symptoms experienced by people with faecal incontinence before and after treatment such as ePAQ, Wexner and QoL score.

5.4 Draft statement 4

People with faecal incontinence have an initial management plan based on the findings of the baseline assessment and tailored to their individual needs and preferences.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Suggestion that specialist dietary assessment and management should be included in the initial management plan (rather than in specialised management).

5.5 Draft statement 5

People who continue to experience episodes of faecal incontinence after initial management are offered referral for specialised continence management.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Stakeholders note the need to distinguish between people needing early or immediate specialist referral (such as people whose underlying cause is a neurological condition or spinal injury) and people for whom initial management in the community is appropriate.
- Stakeholders highlight patient reported outcome measures to assess the effectiveness of initial management.
- Stakeholders consider it essential that patients are offered care and assessment from clinicians who specialise in bowel management.

- Suggestion to emphasise pathway between identification and diagnosis of underlying cause, including setting.
- Concern that medical management of faecal incontinence is not specifically mentioned.
- Issues specific to people with IBD are raised.
- Suggestion to expand the definitions to list surgical options, including SNS and stoma.
- Stakeholders note that people with persistent faecal incontinence would ideally be discussed at a specialist MDT meeting.
- Suggestion that review by specialists in a multidisciplinary pelvic floor clinic is ideal, where the initial management of medication, diet and fluid intake is assessed.
- Suggestion that specialist dietary assessment and management should be included in the initial management plan (rather than in specialist management).
- Stakeholders suggest use of a pelvic floor/biofeedback plan, with examples of interventions given (some of which are currently captured under 'initial management').

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Awareness raising including health education, health promotion and events like National Continence Awareness Week.
- Long-term assessment and care, with regular review for people with long term bowel dysfunction.
- Chronic constipation (which may cause overflow incontinence, or treatment for which may cause incontinence).
- Diabetic neuropathy.
- Inflammatory bowel disease.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Comment on	Comments
1	Crohn's and Colitis UK	General	Largely reflects key areas for quality improvement. The recognition that faecal incontinence is a 'symptom, rather than a diagnosis' is welcome, but the pathway between identification of faecal incontinence and the diagnosis of its underlying cause (usually in secondary care) needs much greater emphasis. For example, there is no mention of how a person presenting with faecal incontinence is then transferred to secondary care specialists for further investigation. Swift diagnosis of continence related conditions such as IBD is a vital aspect of good quality care.
2	Crohn's and Colitis UK	General	Healthcare professionals and social care practitioners involved in identifying, assessing, caring for and treating adults with faecal incontinence" – There is no mention here of the importance of specialist care, for example gastroenterologists in addressing the underlying causes of faecal incontinence – such as IBD.
3	MacGregor Healthcare Limited	General	MacGregor Healthcare Limited welcomes these quality standards in this area of healthcare which affects so many yet is discussed by few in the public arena. So any effort to ensure a higher percentage of patients seeking and getting help is worthwhile.
4	RCOG	General	The title anal incontinence might be more appropriate, as incontinence can be to flatus as well as to faeces (loose and solid).
5	RCOG	General	The fact that a number of definitions for faecal incontinence are available should be highlighted before giving the definition to be used by NICE.
6	RCOG	General	Key areas for quality improvement are depended on areas where improvement is needed on the basis of audit and/or research. Including these in the introduction will make the value and relevance of the recommendations more obvious.
7	RCOG	General	This document is suitable for general practitioners, community nurses, social workers, carers and colorectal surgeons as well as all those who may come across patients who may suffer from faecal incontinence. However, at no point these specialists are ever specified. The same applies to commissioners and providers mentioned repeatedly through the document.
8	RCOG	General	The document does not address urogynaecological side at all.

ID	Stakeholder	Comment on	Comments
9	RCOG	General	A number of statements are made without backing references.
10	RCOG	General	Questions are posed without question marks.
11	RCOG	General	Carers can balance their caring roles and "maintain the desired quality of life of people with faecal incontinene" rather than "maintain their desired quality of life" , as this seems to refer to the quality of life of the carers themselves.
12	Royal College of Paediatrics and Child Health	General	We thought that whilst the document in general was good and covers those aged 18 and over, it is relevant to young people reaching transition age and also has relevance for managing this issue in younger adolescents and children.
13	SCA Hygiene Products UK LTD	General	SCA would like to thank NICE for the opportunity to comment on the draft clinical guideline. SCA welcomes the focus of the Quality Standard and believes it reflects the key areas for quality improvement.
14	SCA Hygiene Products UK LTD	General	SCA would recommend the addition of the APPG Continence Care survey report on 'Continence Care Services England 2013' to the policy context section. This survey provides the latest data on continence care services in the UK. The article is accessible: http://www.appgcontinence.org.uk/pdfs/Continence%20Care%20Services%20England%20Report%202013.pdf
15	Urology User Group Coalition	General	We welcome the five quality standard statements which are likely to improve provision of service and patient care and outcomes. This quality standard does accurately reflect the key areas for quality improvement.
16	Crohn's and Colitis UK	Data collection	Some of the QS could be examined through the IBD Registry or future rounds of the UK IBD Audit (also managed by the RCP).
17	RCOG	Data collection	Collecting data for the proposed quality improvement recommendations should be integral to recognition visits and annual reports, as in colposcopy. The need to have clinics, specialist staff, trained staff, protocols, guidelines, data return sheets etc should be planned with this in mind.
18	Urology User Group Coalition	Data collection	We believe that if the systems and structures were available, it would be possible to collect the data for the proposed quality measures.
19	NHS England	New statement	This reflects the key areas but should also include; patients with chronic constipation who may have overflow incontinence and also whose treatment may cause them to have incontinence; diabetic neuropathy;

ID	Stakeholder	Comment on	Comments
		suggestion	inflammatory bowel disease;
20	RCOG	New statement suggestion	The inclusion of health education, health promotion and events like National Continence Awareness Week would be a good idea.
21	Urology User Group Coalition	New statement suggestion	We would like to see an additional statement: It is vital that those with long term bowel dysfunction for example due to neurological conditions are offered lifelong on going assessment and care, with regular review. Care may require changes in management as the patient needs alter.
22	Coloplast Limited	Statement 1	We welcome the inclusion of quality statement 1, which states that people at risk of faecal incontinence are asked in a sensitive way whether they are experiencing bowel problems. We would note that, while anyone can be at risk of bowel problems, those with spinal injuries or other neurological conditions are at a higher risk – and we are pleased to see this reflected in the definition of at-risk patients. For such at-risk patients, it is vital that GPs actively raise bowel management with them, and encourage them to be open about any problems they are facing.
23	Coloplast Limited	Statement 1	We welcome the fact that data on this quality statement will be collected through the National Audit of Continence Care. However, we would assume that those questioned as part of the audit will be those who have been referred to some kind of continence service – we would welcome clarification on how at risk patients who are not being asked about their bowel habits, and hence may not have been able to access continence services, will be identified and measured. We would also welcome clarification on future plans for the National Audit of Continence Care.
24	Crohn's and Colitis UK	Statement 1	We agree that it is important to treat people with sensitivity and dignity when discussing continence issues.
25	Crohn's and Colitis UK	Statement 1	"People with loose stools or diarrhoea from any cause" should specifically include mentions of Crohn's Disease and Ulcerative Colitis as in the briefing document - http://www.nice.org.uk/nicemedia/live/14099/65013/65013.pdf p3.
26	RCOG	Statement 1	Point starting with health and social practitioners..... whether "they" experience.
27	RCOG	Statement 1	Obstetric anal sphincter injuries is a better term than third and fourth degree "perineal tear" rather than third

ID	Stakeholder	Comment on	Comments
			and fourth degree "obstetric injury".
28	RCOG	Statement 1	Patients with pelvic organ prolapse and mothers having obstetric anal sphincter injuries, as well as patients with urinary incontinence, are at risk of faecal (anal) incontinence.
29	Coloplast Limited	Statement 2	We welcome the statement that people with faecal incontinence should be offered a full baseline assessment.
30	Crohn's and Colitis UK	Statement 2	No exploration of the psychological impact of incontinence in the 'baseline assessment' despite acknowledgement that faecal incontinence can be 'depressing, demoralising and detrimental to everyday life' in the subsequent Statement.
31	NHS England	Statement 2	Patients should be offered a full baseline assessment but by healthcare professionals with an expertise in managing patients sensitively, who do not assume symptoms are caused by pre-existing conditions, but who do have the knowledge to understand the associated complications and are able to tailor their advice and interventions to the needs of the patient.
32	RCOG	Statement 2	The point about ensuring comprehensive assessment without premature linking of faecal incontinence to any risk factor that is known in advance or becomes apparent in the early part of the assessment, so as to void overlooking factors that can still contribute or might be the real contributory ones, in order to get the correct aetiological diagnosis, need to be made clearer. This statement is repeated several times in the document and may not be clearly understood even to medical staff.
33	RCOG	Statement 2	Making clear that assessment means history taking, examination and special investigations would avoid ambiguity.
34	RCOG	Statement 2	Denominator .... newly presenting with or found to have faceal incontinence, rather than diagnosed. Diagnosis means full history, examination and investigation(s), which may not be required or may not have been carried out till the next stage.
35	RCOG	Statement 2	It does not mention vaginal examination to check for pelvic organ prolapse and pelvic floor muscle tone nor does it deal with any obstetrical or gynaecological aspects of history taking or points to decide plan of management.
36	Royal College of Paediatrics and Child Health	Statement 2	It is excellent to see it being stressed that assumptions should not be made about the cause of faecal incontinence and, in particular, this problem should not initially be attributed to an individual having a cognitive impairment.

ID	Stakeholder	Comment on	Comments
37	SCA Hygiene Products UK LTD	Statement 2	SCA welcomes the focus on ensuring that healthcare professional recognise the many forms and causes of incontinence and the aim of NICE Quality Standard to increase the number of full baseline assessments conducted on people with faecal incontinence.
38	SCA Hygiene Products UK LTD	Statement 2	SCA recommend that Commissioners be advised to commission services with key identified people responsible for continence promotion to increase baseline assessments. SCA welcomes as set out in the APPG's continence care report, the ideal continence care service would be led by an expert clinical leader who is responsible for strategy, service improvement, education, research and audit activities and at least one full time specialist practitioner per 100,000 population. Prioritising this key role among healthcare professionals will support greater number of baseline assessments and ensure that healthcare professionals recognise their responsibility to conduct them. Cost-effective Commissioning for Continence Care, All Party Parliamentary Group for Continence Care Report, 2012 http://www.appgcontinence.org.uk/pdfs/CommissioningGuideWEB.pdf NICE can support the increased number of baseline assessments by ensuring that Commissioners identify key individuals within their service who are responsible for ensuring continence care is undertaken and service provision is improved.
39	Crohn's and Colitis UK	Statement 3	Although the inclusion of a 'toilet access card' within the coping strategies is welcome, it would be beneficial to restore the footnote from the briefing document that identifies Crohn's and Colitis UK as one of the sources of these cards (http://www.nice.org.uk/nicemedia/live/14099/65013/65013.pdf) p15
40	Crohn's and Colitis UK	Statement 3	It should be noted that the 'Service Standards for the Healthcare of People with Inflammatory Bowel Disease' (http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf) recommend access to psychological support for people with IBD as part of the multidisciplinary team that manages their care, this should be recognised in the 'What the quality statement means for service providers, health and social care practitioners, and commissioners' section
41	MacGregor Healthcare Limited	Statement 3	A small rectal irrigation product (Qufora Mini) may be useful in this early phase if specialist referral is not deemed appropriate for some patients. This may negate the use of pads in this challenging area of care. Could this be considered for addition to the initial list?
42	RCOG	Statement 3	Point starting with people with faecal incontinence.... bowel "control" problems.

ID	Stakeholder	Comment on	Comments
43	SCA Hygiene Products UK LTD	Statement 3	SCA supports Quality Statement 3's emphasis on the provision of a choice of appropriate continence products.
44	SCA Hygiene Products UK LTD	Statement 3	SCA recommends that Quality Statement 3 should include reference to personalised toileting plans that can, in some cases, promote a return to continence. SCA supports patient-centered care that utilises intelligent care programmes to respond to individuals' case histories and personal needs. SCA welcomes the rationale for Quality Statement 3 as it recognises the immediate and long-term benefits that can be gained from implementing non-medical intervention strategies. In addition to those listed, SCA propose the inclusion of toileting plans, to be implemented during the period of initial management and then based on the findings of the baseline assessment. Individual toileting plans can lead to greater independence and restore confidence in the individuals' ability to self-manage their condition with appropriate products. This addition would therefore support individuals coping with the symptoms of incontinence during the initial management stage.
45	SCA Hygiene Products UK LTD	Statement 3	SCA recommends that Quality Statement 3 should define options for disposable and non-disposable body-worn pads. SCA notes that as well as traditional pad provision, comprehensive information on product provision would need to specify a range of alternative, modern forms of products available on the market, including both disposable and non-disposable products. A 2008 community found considerable individual variance between the effectiveness of care pads and notes that "cost-effective management may best be achieved by allowing users to choose combinations of designs for different circumstances within a budget." (Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product designs (2008), M Fader, A Cottenden, K Getliffe, H Gage, S Clarke-O'Neill, K Jamieson, N Green,) The existing text states that information on disposable body-worn pads should be given 'across a choice of styles and designs'. SCA believe that greater clarity for healthcare professionals over the types of product available within the Quality standard, including disposable/ reusable and pads / pull-ups / belt-up products, would support them to ensure that they were offering and advising on the full range of available product styles.

ID	Stakeholder	Comment on	Comments
			The impact of supporting the full breadth of has been evidenced in a recent SCA study in Kettering, which found that improved access to a range of incontinence management products reduced the numbers of moisture lesions on medical wards by 80%.
46	Urology User Group Coalition	Statement 3	It is essential that patients are offered choice of appropriate continence products.
47	Crohn's and Colitis UK	Question 3	No view
48	MacGregor Healthcare Limited	Question 3	The period of initial assessment and where appropriate early referral to specialist help should be defined to be the shortest feasible time. So that patients can see the route to improvements in their quality of life.
49	NHS England	Question 3	It is difficult to define a period but a patient-centred approach is important. A standardised method of quantifying the severity of symptoms experienced by the patient will gain their confidence in how they to be are managed ie ePAQ, Wexner, QoL score before and after any therapy. ePAQ is a global questionnaire which asks the patient about associated problems which they may have never discussed before plus it allow quantifiable outcome measures before and after the treatment.
50	RCOG	Question 3	The period for assessment and initial management is best defined from the time the patient presents with the complaint of faecal incontinence or is found out to have this problem on probing other problems. An algorithm that can filter those who need immediate referral to a specialist and those who can be managed in the community, as in women with urinary incontinence, will be helpful in this respect. A duration of conservative management in the community can then be specified for those who do not need immediate referral to hospital and a target duration for hospital assessment can be set.
51	Urology User Group Coalition	Question 3	For draft quality statement 3, the initial assessment and conservative treatment, including pelvic floor rehabilitation and ideally psychosocial support, should take place fortnightly over a three to six month period, depending on individual need and the underlying causes. If no progress after this time then then onward referral should be made. Pelvic floor rehabilitation is not suitable for all people with faecal incontinence, and some whose main underlying cause is a neurological condition or spinal injury may benefit from early specialist input to find the most appropriate management option.
52	Coloplast Limited	Statement 4	We would argue that specialist dietary assessment and management should be included in the initial management plan, rather than in specialist management, as this dietary advice should be offered before more

ID	Stakeholder	Comment on	Comments
			radical interventions are considered.
53	Crohn's and Colitis UK	Statement 5	Although the recommendation for 'specialised continence management' is welcome, this should specifically include medical or surgical management of the condition from secondary care specialists if the cause is found to be IBD, in addition to the day-to-day management of incontinence. There is no mention of medical management of faecal incontinence.
54	Coloplast Limited	Statement 5	We welcome the statement that people who continue to experience episodes of faecal incontinence after initial management should be offered referral for specialist continence management.
55	Coloplast Limited	Statement 5	We are pleased to see rectal irrigation included in the definition of specialist management techniques, but would argue that this should be offered before sacral nerve stimulation as it is far more cost effective and has a higher success rate.
56	Coloplast Limited	Statement 5	We would argue that specialist dietary assessment and management should be included in the initial management plan, rather than in specialist management, as this dietary advice should be offered before more radical interventions are considered.
57	MacGregor Healthcare Limited	Statement 5	Early referral to specialised assessment is critical as limited management options are available at the initial assessment phase.
58	MacGregor Healthcare Limited	Statement 5	Page 20 – is the list of specialist management looks to be in order of less invasive to more invasive, therefore should rectal irrigation be listed before electrical stimulation?
59	Medtronic Limited	Statement 5	Sacral Nerve Stimulation (SNS) is specifically included in the Clinical Guideline for Faecal Incontinence under 'Surgery', and is included in the NICE Patient Pathway. Although the Quality Standard does include 'surgery' as an option for specialised treatment, it does not provide clarity on what 'surgery' involves i.e. sphincter repair and SNS. We believe that it would be helpful for all audiences if this section was expanded to specifically state the surgical options. Further, SNS has been prioritised by NHS England as a commissioned specialised service, with a routine commissioning policy on SNS for faecal incontinence. It is therefore important to explicitly include SNS as a treatment option within the specialised treatment section of the Quality Standard.
60	NHS England	Statement 5	Specialised management of patients with faecal incontinence; Ideally patients would be reviewed by specialists in a multidisciplinary pelvic floor clinic where the initial

ID	Stakeholder	Comment on	Comments
			management of medication, diet and fluid intake is assessed. The patient who has failed this conservative management should be assessed by anorectal physiology, endoanal ultrasound or other imaging as described. Other tests may include proctography for patients with associated dyskinesia. The results of these investigations can then form the basis of the pelvic floor/biofeedback plan and the patient will gain an understanding of how and why the plan has been made for them. This plan could include; reviewing fluid intake and type manipulation and moderation of dietary fibre to achieve an ideal stool consistency explanation of titration of loperamide to achieve optimum stool consistency training in pelvic floor exercise and pelvic floor relaxation techniques advice on toileting position encouraging weight loss in the overweight patient use of glycerine suppositories to encourage a regular bowel habit Neuromodulation - percutaneous tibial nerve stimulation (PTNS)
61	NHS England	Statement 5	Evaluation of the patient reported outcome measures can be made by simple scoring systems eg Wexner score or global ePAQ questionnaires.
62	NHS England	Statement 5	Patients with persistent FI would ideally be discussed at a specialist MDT meeting where the specialists can give input into the next stage of the patients care; If appropriate making a case to the commissioners for a trial of sacral nerve stimulation (SNS) to evaluate the response prior to a permanent SNS system Surgery, including stoma
63	RCOG	Statement 5	The first part of the first 2 lines seems to be missing.
64	Urology User Group Coalition	Statement 5	It is essential that patients are offered care and assessment from clinicians who specialise in bowel management.