1. Background information

Guideline issue date: 2007
3 year review: 2010
National Collaborating Centre: National Clinical Guidelines Centre (formerly NCC Acute Care)

2. Consideration of the evidence

Literature search

From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 49 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:

- Initial management of faecal incontinence
- Specialised management for faecal incontinence
- Surgical management of faecal incontinence

Five clinical questions were developed based on the clinical areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group, for more focused literature searches.
The results of the focused searches are summarised in the table below. All references identified through the initial intelligence gathering, high-level RCT search and the focused searches can be viewed in Appendix I.
**Clinical area 1: Initial management of faecal incontinence**

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: What are the most effective products (absorbent products, containment and plugs) to manage faecal incontinence?</td>
<td>Through the focused search 6 studies relevant to the clinical question were identified. Literature was identified evaluating the use of anal plugs and absorbent products for management of faecal incontinence. However, all new evidence reported results that were in line with current guideline recommendations.</td>
<td>No new evidence was identified which would change the direction of current guideline recommendations.</td>
</tr>
<tr>
<td>Q2: What is the effectiveness of modifying drug administration in managing faecal incontinence?</td>
<td>Through the focused search 10 studies relevant to the clinical question were identified. Literature was identified evaluating the efficacy of drugs for management of faecal incontinence. However, all new evidence reported results that were in line with current guideline recommendations.</td>
<td>No new evidence was identified which would change the direction of current guideline recommendations.</td>
</tr>
</tbody>
</table>
Clinical area 2: Specialised management of faecal incontinence

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: What is the effectiveness of biofeedback versus all other conservative therapies?</td>
<td>Fifteen studies were identified through the focused search relating to this clinical question.</td>
<td>No conclusive evidence was identified that would invalidate current guideline recommendations.</td>
</tr>
<tr>
<td></td>
<td>In terms of specialised management of faecal incontinence, new literature was identified related to biofeedback therapy and electrical stimulation for management of faecal incontinence. In general, studies included small sample sizes and did not focus on long-term effects of the therapy. As such, no sufficient conclusive new evidence was identified which would warrant an update of the guideline recommendations at this time.</td>
<td>No new evidence was identified which would change the direction of current guideline recommendations.</td>
</tr>
<tr>
<td>Q2: What is the effectiveness of pelvic floor muscle/anal sphincter exercises versus all other</td>
<td>One systematic review and an RCT were identified related to pelvic floor muscle exercises for management of faecal incontinence. The studies do not contradict current guideline recommendations.</td>
<td>No new evidence was identified which would change the direction of current guideline recommendations.</td>
</tr>
<tr>
<td>Clinical area 3: Surgical management of faecal incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical question</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are any surgical interventions more effective than others?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through the focused search 62 studies relevant to the clinical question were identified.</td>
</tr>
</tbody>
</table>

- Studies relating to surgical management of faecal incontinence were generally of poor quality whilst the long-term effect of surgical procedures was rarely evaluated. As such, the evidence does not change the direction of current guideline recommendations.

- There is emerging new evidence on posterior tibial nerve stimulation as a new therapy for faecal incontinence. The studies relating to posterior tibial nerve stimulation report that this procedure is in the pilot stages but it is anticipated that further research (in particular robust RCT studies) will generate an evidence base for this procedure in the future.

<table>
<thead>
<tr>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is currently no new published evidence that would invalidate current guideline recommendations.</td>
</tr>
</tbody>
</table>
Several ongoing clinical trials (publication dates unknown) were identified focusing on the effectiveness of posterior percutaneous tibial nerve stimulation for faecal incontinence in addition to pharmacological treatments for faecal incontinence. The results of these trials have not been published at this time but may contribute towards the evidence base relating to management of faecal incontinence in the next update review. Similarly, the scoping process is underway for a new NICE interventional procedure on percutaneous tibial nerve stimulation for faecal incontinence.

No evidence was identified that was relevant to research recommendations in the original guideline.

In conclusion, no identified new evidence contradicts current guideline recommendations.

**Guideline Development Group and National Collaborating Centre perspective**

A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Five responses were received with respondents highlighting that since publication of the guideline more literature has become available on sacral nerve stimulation, rectal irrigation and radio frequency ablation with emerging data on posterior tibial nerve stimulation as a new intervention. In addition, one GDG member stated there is a planned updated Cochrane systematic review focusing on biofeedback therapy for faecal incontinence. This feedback contributed towards the development of the clinical questions for the focused searches.

There was agreement among respondents that there is insufficient variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.
Implementation and post publication feedback

No new evidence relating to guideline recommendations was identified through post publication feedback. All enquiries were routine and did not reflect a need to update the guideline.

An analysis by the NICE implementation team indicated that adherence to NICE guidance for faecal incontinence is variable. In addition, the Royal College of Physicians (2010) National Audit of Continence Care report highlighted that a great majority of continence services are poorly integrated across acute, medical, surgical, primary, care home and community settings resulting in disjointed care for patients and carers.

No new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

Relationship to other NICE guidance

The following NICE guidance is related to CG49:

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Review date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CG32: Nutrition support in adults, 2006</td>
<td>To be reviewed February 2011.</td>
</tr>
<tr>
<td>CG40: Urinary incontinence: the management of urinary incontinence in women, 2006</td>
<td>Expected review date: TBC.</td>
</tr>
<tr>
<td>IPG159: Stimulated graciloplasty for faecal incontinence,</td>
<td>No review date specified.</td>
</tr>
</tbody>
</table>

CG49: Faecal Incontinence, review proposal consultation document
<table>
<thead>
<tr>
<th>2006</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IPG66: Artificial anal</td>
<td>Reviewed for update in 2007 but no additional evidence found.</td>
</tr>
<tr>
<td>sphincter implantation,</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td></td>
</tr>
<tr>
<td>IPG99: Sacral nerve</td>
<td>No review date specified.</td>
</tr>
<tr>
<td>stimulation for</td>
<td></td>
</tr>
<tr>
<td>faecal incontinence,</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td></td>
</tr>
<tr>
<td>IPG34: Circular stapled</td>
<td>No review date specified.</td>
</tr>
<tr>
<td>haemorrhoidectomy,</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td></td>
</tr>
<tr>
<td>Related NICE guidance not included in CG49</td>
<td></td>
</tr>
<tr>
<td>IPG276: Transabdominal</td>
<td>No review date specified.</td>
</tr>
<tr>
<td>artificial bowel</td>
<td></td>
</tr>
<tr>
<td>sphincter implantation</td>
<td></td>
</tr>
<tr>
<td>for faecal incontinence,</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td></td>
</tr>
<tr>
<td>IPG210: Injectable</td>
<td>No review date specified.</td>
</tr>
<tr>
<td>bulking agents for</td>
<td></td>
</tr>
<tr>
<td>faecal incontinence,</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td></td>
</tr>
<tr>
<td>IPG161: Percutaneous</td>
<td>No review date specified.</td>
</tr>
<tr>
<td>endoscopic colostomy,</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td></td>
</tr>
<tr>
<td>Related NICE guidance in progress</td>
<td></td>
</tr>
<tr>
<td>Interventional procedure -</td>
<td>In progress.</td>
</tr>
<tr>
<td>Provisional publication date: Spring 2011.</td>
<td></td>
</tr>
</tbody>
</table>
Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence (SECCA)

Interventional procedure – Percutaneous tibial nerve stimulation for faecal incontinence

In progress.
Provisional publication date: TBC.

**Anti-discrimination and equalities considerations**

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of all adults (age 18 and older) presenting with faecal incontinence with the guideline relevant in home, care homes and hospitals.

**Conclusion**

Through the process no additional areas were identified which were not covered in the original guideline scope or would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations. The Faecal Incontinence guideline should not be updated at this time.

**3. Review recommendation**

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

Centre for Clinical Practice
27.10.10

CG49: Faecal Incontinence, review proposal consultation document
Appendix I


CG49: Faecal Incontinence, review proposal consultation document


