

National Institute for Health and Clinical Excellence

352 – Injectable bulking agents for faecal incontinence

Comments table

IPAC date: 14th December 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response
Individual respondent – patient organisation	1 - Recommendations	1	No specific mention of the paediatric population. Is the procedure being suggested for post-surgical problems in adults or children who have Hirschsprung's disease? (see my comments on doc for more)	Please respond to all comments The Committee agreed to delete "...including operations for congenital anorectal conditions, such as anorectal atresia or Hirschprung's disease" from the fourth sentence of section 2.1.1.
Individual respondent – patient organisation	2.1 – Indications	2	Children with Hirschsprungs disease and other congenital motility disorders of the gut often have complex, diffuse neuro/myopathic disorders. For those children with well localised Hirschsprungs Disease (fewer than previously thought), post Pull-Through surgery, problems with the anal sphincter are usually resolved by further resection of the area since the difficulty is generally continuing spasticity. Continuing problems require thorough investigation of the whole gut for further neuropathy. Bulking agents are unlikely to help this group.	See response to comment no. 1.

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Individual respondent – clinician	2.1 – Indications	3	Bulking agents are useful for the treatment of faecal incontinence in a select group of patients whose main problem is seepage of liquid faecal material which has not responded to a combination of stool bulking agents and constipating medications. Typically this select group would not be suitable for surgical intervention such as sphincter repairs and sacral nerve stimulation and are resistant to having a permanent colostomy. With this criteria, it is unlikely that a large series of patients can be recruited into a trial.	The Committee agreed to amend section 1.3 to: <i>“The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence and in the context of a clinical trial or formal audit protocol which includes information on well-defined patient groups.”</i>
Individual respondent – patient organisation	2.2 – Outline of the procedure	4	Delicate paediatric tissues could be damaged by injection. Our medical advisor at Gt Ormond St would not consider this in young children. (Mr David Drake, Consultant Paediatric Surgeon)	The Committee agreed to amend the fourth sentence of section 2.2.1 to: <i>“The injections can be done via proctoscope or with simple manual anal dilatation, either directly or via a trans-sphincteric route, with or without ultrasound guidance.”</i>
Individual respondent – clinician	2.2 – Outline of the procedure	5	Alternatives to bulking agents, is House flap anoplasty which has been tried in the treatment of faecal incontinence [results are published in the BJS in 1995/6 from the Swansea group of surgeons]. While this alternative, is cheaper, it may be associated with flap infection as a complication. Therefore, this needs to be evaluated against injectable bulking agents in a randomised controlled trial, with post operative evaluation over a period of at least 2 years.	Noted, thank you.
Individual respondent – patient organisation	2.3 - Safety	6	No studies in children or teenagers	Noted, thank you.