

Medical Technologies Evaluation Programme

MT 315- Peristeen anal irrigation system to manage bowel dysfunction

Expert Adviser Questionnaire Responses

| Name of Expert Advisers | Job Title | Professional Organisation/ Specialist Society | Nominated by | Ratified |
|--------------------------|-------------------------------|--|--------------------|----------|
| Dr Ian Beales | Consultant gastroenterologist | British Society of Gastroenterology | NICE | Yes |
| Ms Brigitte Collins | Lead Nurse | Royal College of Nursing | Specialist Society | - |
| Ms Karen Nugent | Consultant Colorectal Surgeon | Association of Coloproctology of Great Britain & Ireland | Specialist Society | - |
| Mr Oliver Jones | Consultant Colorectal Surgeon | Association of Coloproctology of Great Britain & Ireland | Specialist Society | - |
| Dr Simon Dunlop | Consultant gastroenterologist | British Society of Gastroenterology | NICE | Yes |
| Professor Paul Skaife | General Surgeon | Association of Coloproctology of Great Britain & Ireland | Sponsor | Yes |
| Professor Anton Emmanuel | Consultant gastroenterologist | British Society of Gastroenterology | Sponsor | Yes |

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

| Expert Advisers | I have had direct involvement with this | I have referred patients for its use | I manage patients on whom it is used in another part of their care pathway | I would like to use this technology but it is not currently available to me |
|---|--|--------------------------------------|--|---|
| Dr Ian Beales Consultant gastroenterologist | Blank | Blank | Blank | Yes |
| Ms Brigitte Collins Lead Nurse | Yes | Yes | Yes | No |
| Ms Karen Nugent Consultant Colorectal Surgeon | No | Yes | No | No |
| Mr Oliver Jones Consultant Colorectal Surgeon | Blank | Yes | Yes | Blank |
| Dr Simon Dunlop Consultant gastroenterologist | No | No | No | No |
| Professor Paul Skaife General Surgeon | Blank | Blank | Blank | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Yes | Blank | Blank | Blank |
| <i>Any Comments?</i> | | | | |
| Dr Ian Beales Consultant gastroenterologist | I have had limited direct involvement in this technology. Although in the recent past, I have supervised the management of 2 patients using this technology, with some recent changes to funding and care pathways, at present this technology is not available to me. | | | |
| Ms Brigitte Collins Lead Nurse | Blank | | | |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank | | | |

| | |
|---|---|
| Mr Oliver Jones Consultant Colorectal Surgeon | This is rarely directly used by surgeons but I am a very frequent referrer of patients for this treatment. It is given by our colorectal nurse specialists. |
| Dr Simon Dunlop Consultant gastroenterologist | Very infrequently used by few centres |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | I have used the technology for 8 years as a clinician and undertaken clinical research over that period. |

Question 3: Have you been involved in any kind of research on this technology? If Yes, please describe?

| Expert Advisers | Yes/No | Comment |
|---|--------|---|
| Dr Ian Beales Consultant gastroenterologist | No | Blank |
| Ms Brigitte Collins Lead Nurse | Yes | Just about to use in the Capacity 2 trial with Charlie Knowles |
| Ms Karen Nugent Consultant Colorectal Surgeon | No | about to embark as part of capacity study which may allocate patients who have constipation to irrigation |
| Mr Oliver Jones Consultant Colorectal Surgeon | No | Blank |
| Dr Simon Dunlop Consultant gastroenterologist | No | Blank |
| Professor Paul Skaife General Surgeon | Blank | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Yes | Clinical audit of outcome, and studies in particular patient groups. |

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: How would you best describe this technology?

| Expert Advisers | It is a minor variation on existing technologies with little potential for different outcomes and impact | It is a significant modification of an existing technology with real potential for different outcomes and impact | It is thoroughly novel - different in concept and/ or design to any existing |
|---|---|---|---|
| Dr Ian Beales Consultant gastroenterologist | Blank | Yes | Blank |
| Ms Brigitte Collins Lead Nurse | No | Yes | No |
| Ms Karen Nugent Consultant Colorectal Surgeon | No | Yes | No |
| Mr Oliver Jones Consultant Colorectal Surgeon | No | Yes | No |
| Dr Simon Dunlop Consultant gastroenterologist | Yes | No | No |
| Professor Paul Skaife General Surgeon | Blank | Blank | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Blank | Blank | Yes |

| <i>Any Comments?</i> | |
|--|--|
| Dr Ian Beales Consultant gastroenterologist | The concept of planned and stimulated bowel evacutaions to manage severe constipation or faecal incontinence is not new. The technology considered here is a signifcant development in that the system is self-contained and much easier to use and appears to be safer than any other systems that have gone before |
| Ms Brigitte Collins Lead Nurse | Other products available with similarities |
| Ms Karen Nugent Consultant Colorectal Surgeon | There was a brain irrimatic pump available but the peristeen is port able and does not need an electronic pump. Others irrigation systems are available |
| Mr Oliver Jones Consultant Colorectal Surgeon | Blank |
| Dr Simon Dunlop Consultant gastroenterologist | Several colonic irrigation systems are currently in use within the UK. |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | There have been other derivative products since Peristeen appeared on the market. |

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | <ol style="list-style-type: none"> 1. Severe intractable symptomatic constipation that has proved refractory to available therapies (diet, lifestyle, drugs and biofeedback) and much more aggresive and higher risk interventions would otherwise be considered (colectomy or more controversial sacral nerve stimulation. 2. Faecal incontinence that is impairing quality of life, that has failed to respond to conservative methods and before the use of surgical interventions such as colectomy and sacral nerve stimulation. |
| Ms Brigitte Collins Lead Nurse | For patients with chronic constipation and/or faecal incontinence for patients in general and for those with a neurological disability |

| | |
|--|---|
| <p>Ms Karen Nugent Consultant Colorectal Surgeon</p> | <p>This can be used to empty the rectum. This may help with constipation patients and those who have incontinence to faeces due to incomplete emptying</p> |
| <p>Mr Oliver Jones Consultant Colorectal Surgeon</p> | <p>It is likely to be used in patients with evacuatory problems or faecal incontinence.</p> |
| <p>Dr Simon Dunlop Consultant gastroenterologist</p> | <p>In those who have failed other medical treatments for constipation or faecal incontinence for a number of reasons. It is important that it is used appropriately by careful assessment. I have never felt the need to refer to a centre for a patient to use one. In those I have come across whom have used them (eg expert witness reports) I have not been convinced that this was the best treatment option in those particular cases.</p> |
| <p>Professor Paul Skaife General Surgeon</p> | <p>Blank</p> |
| <p>Professor Anton Emmanuel Consultant gastroenterologist</p> | <ol style="list-style-type: none"> 1. Patients with neurological disease who have bowel dysfunction. 2. Patients with functional colorectal disorders 3. Patients with post-surgical colorectal dysfunction 4. Paediatric use in functional gut disorders. |

COMPARATORS (including both products in current routine use and also “competing products”)

Question 6: *Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate “comparators” for this technology which are in routine current use in the NHS?*

| Expert Advisers | Comment |
|--|---|
| <p>Dr Ian Beales Consultant gastroenterologist</p> | <p>There are no clear comparitors in current use in the NHS. This technology would clearly be used after drugs and other conservatie methods, such as biofeedback have failed. It would be desirable to use this before much more aggressive and irreversible surgical procedures such as colectomy and implantation of either an artifical neo-anal sphincter, colectomy or sacral nerve stimulator. Perhaps the nearest competing management is the surgical formation of an antegrade irrigating colostomy to allow bowel irrgriation and stimulated bowel emptying. However that involves a surgical procedure and a stoma formation.</p> |
| <p>Ms Brigitte Collins Lead Nurse</p> | <p>All of the above</p> |
| <p>Ms Karen Nugent Consultant Colorectal Surgeon</p> | <p>phosphate and other enemas or glycerine / other suppositories</p> |
| <p>Mr Oliver Jones Consultant Colorectal Surgeon</p> | <p>Pelvic Floor retraining and/ or biofeedback.</p> |
| <p>Dr Simon Dunlop Consultant gastroenterologist</p> | <p>A comprehensive, detailed clinical assessment with careful evaluation of psychological and physical symptoms. Medications, lifestyle and bio-feedback would be appropriate comparators. A surgical procedure termed ACE is a related comparator, but involves a surgical operation to place a catheter in the caecum, and then to flush with a solution in antegrade (rather than as a retrograde or enema like action) to provoke a bowel action.</p> |
| <p>Professor Paul Skaife General Surgeon</p> | <p>Blank</p> |
| <p>Professor Anton Emmanuel Consultant gastroenterologist</p> | <p>Laxatives, suppositories. Possibly prokinetics, although off-licence.</p> |

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | No. A variety of methods of bowel lavage have been described but these are not standardised and vary between units. There are no other self-contained, easy to use system |
| Ms Brigitte Collins Lead Nurse | Yes |
| Ms Karen Nugent Consultant Colorectal Surgeon | qufora system |
| Mr Oliver Jones Consultant Colorectal Surgeon | No |
| Dr Simon Dunlop Consultant gastroenterologist | There are some alternatives although I have never personally been involved in them. |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Yes - Qufora (MacDonald) and Navina (Wellspect) |

POSSIBLE BENEFITS FOR PATIENTS

Question 8: What are the likely additional benefits for patients of using this technology, compared with current practice/comparators?

| Expert Advisers | Comment |
|--|---|
| Dr Ian Beales Consultant gastroenterologist | Improved quality of life. Regular bowel emptying. Safer and easier to use than the variety of other methods of colonic lavage developed. Avoidance of surgical procedures and lack of need to form a stoma. |
| Ms Brigitte Collins Lead Nurse | It has been in practice for longer but I tend not to look at comparing until I know the type of patient that is going to try irrigation as each person is individually assessed |

| | |
|--|---|
| Ms Karen Nugent Consultant Colorectal Surgeon | This system allows a wash out where the anus is incompetent and would be unable to hold either a suppository or enema. It also proves a more proximal wash out than a suppository. It uses water which patients find acceptable. The obstacles include a need for some dexterity in order to be able to insert the system into the anus. There have been reports of balloons bursting and occasionally perforation of the rectum. |
| Mr Oliver Jones Consultant Colorectal Surgeon | it is a non-operative approach with few, if any, side effects. |
| Dr Simon Dunlop Consultant gastroenterologist | When all else fails for whatever reason |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Better efficacy than standard bowel care. Data suggesting reduced health care costs also. The other change has been that the advent of an alternative technology has helped establish a pathway for patients with neurogenic bowel dysfunction (NBD) who often previously languished without a clear care algorithm if they did not respond to standard care. |

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | It seems very likely that all benefits will be realised in practice. The main obstacle would seem to be availability of training to use the technology, which may be concentrated in units that have a special interest in constipation or incontinence. However, ultimately there is no real reason why the technology (which is not complicated to use) cannot be adopted much more widely. |
| Ms Brigitte Collins Lead Nurse | Anyone using irrigation should have full knowledge of the benefits and to whom this product may be helpful |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | Yes |

| | |
|--|--|
| Dr Simon Dunlop Consultant gastroenterologist | Some patients seem to cope with it but not all centres have access to Peristeen systems. |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | <p>Benefits need formal pathways (which exist) to be adopted in order to allow patients to respond. This needs a measure of outcome to be accepted which indicates whether there has been a satisfactory response or whether treatment needs escalating.</p> <p>Also it is important that staff and patient training continues to be of high quality to optimise safe and effective use of the technology.</p> <p>Similarly, professional training to ensure prescribers know which patients need investigation pre-treatment and which can be started directly.</p> |

Question 8.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?

| Expert Advisers | Comment |
|---|--|
| Dr Ian Beales Consultant gastroenterologist | The main measureable benefit will be quality of life for patients with these intractable conditions. For incontinence, the most easily assessed (if superficial) measure would be episodes of incontinence. For constipation, there are several widely used measurements as applied in recent trials of novel constipation-drugs. These again measure quality of life and symptoms referable to constipation. A secondary measure would be reduction in expensive and potentially problematical surgical procedures. |
| Ms Brigitte Collins Lead Nurse | Questionnaires to individual may indicate whether staff understand the product. Ensuring competency based assessment, ensuring follow up and having a database |
| Ms Karen Nugent Consultant Colorectal Surgeon | A bowel care diary would show whether the patient had emptied and whether they had suffered from incontinence whilst using this system. |
| Mr Oliver Jones Consultant Colorectal Surgeon | Quality of life scores and functional GI scores. |
| Dr Simon Dunlop Consultant gastroenterologist | Control or evaluation of constipation or incontinence symptoms |

| | |
|---|--|
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | 1. Symptom scores like the NBD score (validated) and quality of life scores. 2. Health care data being collected prospectively. |

Question 8.3: How good is this evidence for each of these additional benefits?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | The benefits and risks have been systematically reviewed and overall the results seem to show that the technology is safe and effective and a superior alternative to irreversible surgery. |
| Ms Brigitte Collins Lead Nurse | Not sure |
| Ms Karen Nugent Consultant Colorectal Surgeon | this is subjective and relies on patient reported outcomes |
| Mr Oliver Jones Consultant Colorectal Surgeon | Reasonable but no trials. |
| Dr Simon Dunlop Consultant gastroenterologist | Limited |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | There is a definitive clinical trial and over 80 publications on efficacy in different patient groups. |

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | Blank |
| Ms Brigitte Collins Lead Nurse | Great to have an additional treatment in addition to conservative management thus having more chance to help the individual patient |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | Nil else |
| Dr Simon Dunlop Consultant gastroenterologist | Blank |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Potential to reduce urinary tract infections in neurological patients is consistently shown and important. |

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/ comparators?

| Expert Advisers | Comment |
|---|--|
| Dr Ian Beales Consultant gastroenterologist | Reduced use of irreversible surgery. Less utilisation of expensive treatments such as neo-sphincters, sacral and tibial nerve stimulators, all of which require long-term continued follow-up management. Less repeated referrals for ineffective treatments and investigations in this refractory group of patients. |
| Ms Brigitte Collins Lead Nurse | Better patient outcomes |
| Ms Karen Nugent Consultant Colorectal Surgeon | It gives us an alternative avenue when others are failing. |
| Mr Oliver Jones Consultant Colorectal Surgeon | It is non-operative. After initial instruction, the patient requires little or no professional input. |
| Dr Simon Dunlop Consultant gastroenterologist | Last resort |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | 1. Health cost savings (as alluded to above). 2. Adoption of pathways of NBD management |

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

| Expert Advisers | Comment |
|--|---|
| Dr Ian Beales Consultant gastroenterologist | Yes, there seems no reason why these would not be realised. |
| Ms Brigitte Collins Lead Nurse | Obstacles such as lack of follow up, lack of knowledge and teaching events |

| | |
|--|---|
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | Yes, I can see no reason why this should not occur. |
| Dr Simon Dunlop Consultant gastroenterologist | See 8.1 |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Realisable if expert societies and local care providers adopt the audit and pathways - this requires education and would be facilitated by NICE approval. |

Question 9.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?

| Expert Advisers | Comment |
|---|--|
| Dr Ian Beales Consultant gastroenterologist | Objective measurements of surgical rates, repeat referrals or tertiary or more onward referrals. |
| Ms Brigitte Collins Lead Nurse | ensure competency based assessment with staff and having attended formal teaching |
| Ms Karen Nugent Consultant Colorectal Surgeon | Patient reported diaries with symptoms pre and post treatment |
| Mr Oliver Jones Consultant Colorectal Surgeon | Quality of life scores |
| Dr Simon Dunlop Consultant gastroenterologist | See 8.2 Patient satisfaction |
| Professor Paul Skaife General Surgeon | Blank |

| | |
|--|---|
| Professor Anton Emmanuel Consultant gastroenterologist | Reduction uti treatment and hospitalisation. Reduction in drug spend on laxatives. Reduced admissions for bowel care (we know spinal injured individuals with bowel dysfunction are twice as likely to be hospitalised than non-bowel dysfunction individuals). |
|--|---|

Question 9.3: How good is this evidence for each of these additional benefits?

| Expert Advisers | Comment |
|--|--|
| Dr Ian Beales Consultant gastroenterologist | There seems to be little published data, to support this logical conclusions |
| Ms Brigitte Collins Lead Nurse | Not sure |
| Ms Karen Nugent Consultant Colorectal Surgeon | Poor at the moment |
| Mr Oliver Jones Consultant Colorectal Surgeon | No trial evidence to my knowledge |
| Dr Simon Dunlop Consultant gastroenterologist | Limited |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Less studied than clinical efficacy |

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

| Expert Advisers | Comment |
|---|-----------------------------|
| Dr Ian Beales Consultant gastroenterologist | Blank |
| Ms Brigitte Collins Lead Nurse | Blank |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | Nil else |
| Dr Simon Dunlop Consultant gastroenterologist | Very limited data available |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | Blank |

FACILITIES, TRAINING AND FUNCTIONING

Question 10: Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | There is little specific needed in terms of facilities or technologies, because of the rare but potential complications, the main limitations would be that this technology would need to be supervised by clinicians experienced with the management of chronic constipation, incontinence and neuropathic bowel disorders. |
| Ms Brigitte Collins Lead Nurse | Training courses, assessment and competency based assessment every year |
| Ms Karen Nugent Consultant Colorectal Surgeon | patients need instructions and demonstrations as to how to work the system |
| Mr Oliver Jones Consultant Colorectal Surgeon | No |
| Dr Simon Dunlop Consultant gastroenterologist | Stoma / colorectal nurse training- usually manage these irrigation systems |
| Professor Paul Skaife General Surgeon | Training for (?) in a tertiary setting involving pelvic floor teams |
| Professor Anton Emmanuel Consultant gastroenterologist | The company have a training system to educate practitioners and patients directly. This needs to be dovetailed with NHS provision to ensure geographic availability and consistent quality of training. |

Question 11: Is special training required to use this technology safely and effectively?

| Expert Advisers | Comment |
|--|---|
| Dr Ian Beales Consultant gastroenterologist | yes, training is required but the technology is not difficult to master. |
| Ms Brigitte Collins Lead Nurse | Yes |

| Expert Advisers | Comment |
|---|--|
| Ms Karen Nugent Consultant Colorectal Surgeon | Simple training |
| Mr Oliver Jones Consultant Colorectal Surgeon | Specialist nurses need simple training supported by industry. Nurses in turn train patients to perform this independently. |
| Dr Simon Dunlop Consultant gastroenterologist | Yes |
| Professor Paul Skaife General Surgeon | Yes |
| Professor Anton Emmanuel Consultant gastroenterologist | Yes – as above |

Question 12: Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced

| Expert Advisers | Comment |
|--|---|
| Dr Ian Beales Consultant gastroenterologist | It seems reliable, safe and effective. |
| Ms Brigitte Collins Lead Nurse | Must consider the type of patient and whether suitable, and any contraindications to using irrigation as in safety |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | It is simple to use and not complicated |
| Dr Simon Dunlop Consultant gastroenterologist | A robust service needs to be in place by a hospital provider. Patients will need a helpline, delivery service and ability to change irrigators if problems arise. |
| Professor Paul Skaife General Surgeon | Blank |

| | |
|---|---|
| Professor Anton Emmanuel Consultant gastroenterologist | In untrained hands there is a danger of damage to the bowel. Published evidence puts this risk at 1 in 500,000, Careful training and patient supervision / access to health care advice is key to reduce risk and optimise outcome. |
|---|---|

COSTS

Question 13: Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above

| Expert Advisers | Comment |
|---|--|
| Dr Ian Beales Consultant gastroenterologist | Overall costs should decline if this technology is before irreversible surgical procedures, especially those with indefinite follow-up and complex technological review (such as sacral and tibial nerve stimulation). |
| Ms Brigitte Collins Lead Nurse | Should this replace comparators then there will be less patient choice and the chance of a decrease in patient outcomes |
| Ms Karen Nugent Consultant Colorectal Surgeon | some parts of the kit are reusable but the system is relatively expensive |
| Mr Oliver Jones Consultant Colorectal Surgeon | It has low start up costs. The equipment is not expensive in terms of initial outlay but the annual cost is significant as there is a disposable element to the equipment. There is little administration or staffing costs. |
| Dr Simon Dunlop Consultant gastroenterologist | In units without this set up, there will be an associated cost. I do not think that the use of it is particularly complex, but key is ensuring that a thorough assessment has been made by a specialty service. |
| Professor Paul Skaife General Surgeon | I think it would be cost- neutral in the majority of circumstances |
| Professor Anton Emmanuel Consultant gastroenterologist | Emerging data of cost savings through reduced stoma surgery, reduced urinary tract infection and reduced hospitalisation |

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

| Expert Advisers | Comment |
|---|---|
| Dr Ian Beales Consultant gastroenterologist | There seems little controversy about the technology being generally safe and effective in the limited studies reported. Any controversy would seem to rest mainly in how cost-effective it is. |
| Ms Brigitte Collins Lead Nurse | No |
| Ms Karen Nugent Consultant Colorectal Surgeon | Not aware of any |
| Mr Oliver Jones Consultant Colorectal Surgeon | No |
| Dr Simon Dunlop Consultant gastroenterologist | I believe that there are enthusiasts who encourage its use. Others manage well without it. |
| Professor Paul Skaife General Surgeon | No |
| Professor Anton Emmanuel Consultant gastroenterologist | Some CCGs are not funding the technology so when patients are seen in specialist centres (as typical for NBD) they may not be able to receive the therapy. It is not clear on what basis this lack of funding is validated. |

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

| Expert Advisers | Comment |
|--|--|
| Dr Ian Beales Consultant gastroenterologist | It would be extremely useful. This would directly guide the practicing clinician in utilising the technology and also in working with commissioners in developing and funding the appropriate pathways for the use of this technology. |
| Ms Brigitte Collins Lead Nurse | Very useful as community based treatment in some areas are not offering such treatments when patients have failed to adequately improve their symptoms with conservative treatment |
| Ms Karen Nugent Consultant Colorectal Surgeon | It would be useful to give guidelines, ways of measuring improvement to assess whether it has worked and pathways for treatment including algorithms for constipation and faecal incontinence |

| | |
|---|---|
| Mr Oliver Jones Consultant Colorectal Surgeon | Very useful, I believe |
| Dr Simon Dunlop Consultant gastroenterologist | It would be useful to have a robust assessment of the evidence available for its' use. |
| Professor Paul Skaife General Surgeon | Some use |
| Professor Anton Emmanuel Consultant gastroenterologist | As professionals it would help with ensuring all patients have equal access to the treatment. Also, it would give the chance to audit outcomes and hopefully reduce specialist referral if the treatment can be started in appropriate patients and only treatment refractory individuals referred. |

Question 16: Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why

| Expert Advisers | Comment |
|---|--|
| Dr Ian Beales Consultant gastroenterologist | No specific groups of patients seem to require special consideration |
| Ms Brigitte Collins Lead Nurse | Neurological patients, those that come under the contraindications and those that should not use completely as per the information |
| Ms Karen Nugent Consultant Colorectal Surgeon | anyone with diseases of the rectum, such as colitis should not use this technology |
| Mr Oliver Jones Consultant Colorectal Surgeon | No |
| Dr Simon Dunlop Consultant gastroenterologist | Yes those that have neurological or myopathic disorders eg paraplegia. In specialist areas, when other medical treatments have failed. |
| Professor Paul Skaife General Surgeon | No |
| Professor Anton Emmanuel Consultant gastroenterologist | There are established patient groups in whom the technology is relatively or absolutely contraindicated. These are published on. |

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal financial interest? The main examples are as follows:

| Expert Advisers | Consultancies or directorships | Clinicians receiving payment for a procedure | Fee-paid work | Shareholdings | Financial interest in a company's product | Expenses and hospitality | Funds | Personal non-pecuniary interest |
|---|--------------------------------|--|---------------|---------------|---|--------------------------|-------|---------------------------------|
| Dr Ian Beales Consultant gastroenterologist | Yes | No | Yes | No | No | No | No | No |
| Ms Brigitte Collins Lead Nurse | No | No | No | No | No | Yes | No | No |
| Ms Karen Nugent Consultant Colorectal Surgeon | No | No | No | No | No | No | No | No |
| Mr Oliver Jones Consultant Colorectal Surgeon | No | No | No | No | No | No | No | No |
| Dr Simon Dunlop Consultant gastroenterologist | No | No | No | No | No | No | No | No |
| Professor Paul Skaife General Surgeon | No | No | No | No | No | Yes | No | No |
| Professor Anton Emmanuel Consultant gastroenterologist | No | No | Yes | No | No | No | No | No |

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

| | |
|--|---|
| Dr Ian Beales Consultant gastroenterologist | I have received payment for consultancy and advisory activities from Shire and Allergan (manufacturers of prucalopride and linaclotide respectively). These drugs are used in the treatment of chronic constipation. However the peristeen technology under consideration is clearly recognised as not competing with the pharmacological management of constipation. These payments are declared in the spirit of transparency. I have no other interests that could be regarded as conflicting. |
| Ms Brigitte Collins Lead Nurse | Provided finances by company for teaching on 2 occasions |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | Blank |
| Dr Simon Dunlop Consultant gastroenterologist | Blank |
| Professor Paul Skaife General Surgeon | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | I have acted on advisory boards for the company producing this technology (Coloplast) as well as on boards for "rival" companies (as cited above) |

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

| Expert Advisers | Grant for the running of a unit | Grant or fellowship for a post or member of staff | Commissioning of research | Contracts with or grants from NICE |
|---|---------------------------------|---|---------------------------|------------------------------------|
| Dr Ian Beales Consultant gastroenterologist | No | No | No | No |
| Ms Brigitte Collins Lead Nurse | No | No | No | No |

| | | | | |
|---|-------|----|----|----|
| Ms Karen Nugent Consultant Colorectal Surgeon | No | No | No | No |
| Mr Oliver Jones Consultant Colorectal Surgeon | No | No | No | No |
| Dr Simon Dunlop Consultant gastroenterologist | No | No | No | No |
| Professor Paul Skaife General Surgeon | No | No | No | No |
| Professor Anton Emmanuel Consultant gastroenterologist | No | No | No | No |
| <i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i> | | | | |
| Dr Ian Beales Consultant gastroenterologist | Blank | | | |
| Ms Brigitte Collins Lead Nurse | Blank | | | |
| Ms Karen Nugent Consultant Colorectal Surgeon | Blank | | | |
| Mr Oliver Jones Consultant Colorectal Surgeon | Blank | | | |
| Dr Simon Dunlop Consultant gastroenterologist | Blank | | | |
| Professor Paul Skaife General Surgeon | Blank | | | |

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|--|-------|
| Professor Anton Emmanuel Consultant gastroenterologist | Blank |
|--|-------|

Question 18.3: Do you or your organisation or department have any links with, or funding from the tobacco industry?

| Expert Advisers | Yes or No? | <i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i> |
|--|-------------------|--|
| Dr Ian Beales Consultant gastroenterologist | No | Blank |
| Ms Brigitte Collins Lead Nurse | No | Blank |
| Ms Karen Nugent Consultant Colorectal Surgeon | No | Blank |
| Mr Oliver Jones Consultant Colorectal Surgeon | No | Blank |
| Dr Simon Dunlop Consultant gastroenterologist | No | Blank |
| Professor Paul Skaife General Surgeon | No | Blank |
| Professor Anton Emmanuel Consultant gastroenterologist | No | Blank |