NICE advice

The Insides System for managing intestinal failure

Medtech innovation briefing
Published: 17 February 2022

www.nice.org.uk/guidance/mib286

Summary

- The **technology** described in this briefing is The Insides System. It is used for managing acute severe intestinal failure (type 2) after bowel surgery.
- The **innovative aspects** are that it is a chyme reinfusion system, which is designed to help people with high-output fistulas or stomas by returning their intestinal fluid lost from the fistula or stoma back into the distal gut.
- The intended **place in therapy** would be used in addition to parenteral nutrition, or as an alternative to distal enteral tube feeding.
- The **main points from the evidence** summarised in this briefing are from 3 studies (2 feasibility studies and 1 case study) including a total of 30 adults in hospitals. They show that The Insides System could be used as an alternative or an addition to parenteral nutrition in managing some patients with acute severe (type 2) intestinal failure. People had reduced stoma losses and reduced the use of anti-diarrhoeal medications.

- **Key uncertainties** around the evidence or technology are that all 3 studies had very small sample sizes, and there was no comparative evidence to show that the system would result in fewer complications, improve quality of life or reduce costs compared with standard care (such as parenteral nutrition).
- There are no **safety** alerts for this technology. One study found that of 10 people, 1 person had a serious adverse event (severe cholecystitis) during the study.
- **Experts advised** that The Insides System should be used in a specialised centre for treating acute severe (type 2) intestinal failure because safe treatment needs a specialist to monitor effectiveness.
- The **cost** of using The Insides System is between £1,900 and £2,400 per month per person with type 2 intestinal failure with an enterostomy, or per person with type 2 intestinal failure with an enteroatmospheric fistula. All costs exclude VAT. One expert estimated that the current cost of home parenteral nutrition is about £75,000 per year (on average £6,250 per month).

The technology

The Insides System (The Insides Company) is a chyme reinfusion system designed to help people with high-output fistulas or stomas after bowel surgery. The system aims to infuse the effluent of the fistula or stoma into the distal gut.

The system works by chyme and intestinal fluid being pumped back into the distal intestines using an Insides Driver. The driver is a handheld battery-powered device that connects magnetically to the Insides Pump found in the stoma bag. The driver powers the pump to refeed the content of the stoma bag back into the distal intestine. An Insides Tube is inserted into the distal intestine and connected to the Insides Pump as a tube to transport chyme. Five driver speed options are available to allow the person to control the rate of infusion manually, depending on tolerability and viscosity.

Innovations

The company is not aware that there are other devices commercially available for reinfusing a fistula or stoma with chyme losses back into the distal gut. In clinical practice, chyme can be reinfused manually using a collection container, syringe, filter and tube. This is time-consuming and labour intensive for staff because they have to manually collect the

bowel contents and interfere with the stoma appliance (Kittscha 2016). The company claims that the device will allow an earlier return to oral feeding and could potentially reduce the need for parenteral nutrition and the length of stay in hospitals because of reduced risks of complications such as dehydration, malnutrition and loss of the gut microbiome. One expert noted that there is no evidence of any effect of changes to the microbiome. The company also claims that it could reduce the risk of liver and kidney damage. One expert added that the system is also likely to reduce the use of intravenous supplementation. At present, there is very limited published evidence to support the company's claims.

Current care pathway

Some conditions, including bowel cancer, diverticular disease and inflammatory bowel disease may need surgery that involves creating a stoma or fistula. The stoma or fistula will be created after intestinal resection when restoring bowel continuity is not possible. The stoma or fistula could be placed temporarily or permanently. People would be observed for signs of high output after stoma formation. If output persists, parenteral nutrition or enteroclysis would be needed to compensate for a persons' nutritional and fluid losses for a period of time. Often these people are in a high dependency unit in hospital. Some people may be discharged with home parenteral nutrition or distal enteral tube feeding depending on their nutrition status and ability to continue treatment at home.

The European Society for Clinical Nutrition and Metabolism (ESPEN) guideline on clinical nutrition in the intensive care unit (2019) states that in specific situations with high-output stoma or fistula, chyme reinfusion should be evaluated and performed if adequate.

Population, setting and intended user

The Insides System is intended for people with acute severe intestinal failure (type 2) after bowel surgery and people with persistent high-output double enterostomy and enteroatmospheric fistula whose small bowel is separated into 2 segments through a stoma or open wound. The technology is likely to be used by healthcare professionals such as nurses in specialist centres for treating intestinal failure.

Costs

Technology costs

The Insides System is a treatment consisting of loaned equipment and consumables, which need monthly refills. For people with type 2 intestinal failure with an enterostomy or people with type 2 intestinal failure with an enteroatmospheric fistula, the first month costs £2,400 (excluding VAT) and the subsequent months cost £1,900 (excluding VAT).

There are no maintenance costs and the patient is sent all the necessary equipment monthly to do chyme reinfusion. All maintenance costs are covered in this including any replacements. Clinicians may withdraw patients from using The Insides System at any time during treatment.

Costs of standard care

The intravenous delivery of nutrients and water (parenteral nutrition) is standard care for intestinal failure. When a person's condition has stabilised, home parenteral nutrition and ongoing maintenance care could be done at home with support from community healthcare teams.

One expert noted that people with intestinal failure can also self-administer distal enteral tube feeding or fistuloclysis (Teubner et al. 2004).

The company claimed that the average cost of home parenteral nutrition is between £4,447 and £5,212 per month per person. This includes additional medicines, nursing, products for home parenteral nutrition fluid bags, deliveries and ancillaries. One expert estimated that the current cost of home parenteral nutrition is about £75,000 per year (on average £6,250 per month). There will be costs associated if parenteral nutrition is delivered in hospital.

Resource consequences

The device has been used in 11 NHS trusts. Clinical experts said that The Insides System would be an additional option to standard care for intestinal failure management such as parenteral nutrition or would potentially replace distal enteral tube feeding.

The technology could be resource releasing if it leads to shorter hospital stays and improved outcomes for patients through improved nutrition management. However, its effect on treatment decisions and length of hospital stay has not been explored. The technology may free up nurses' time in hospital because patients can control the infusion themselves.

One expert said that training would be the same as for distal enteral feeding. The company said that training is needed to ensure patients are able to operate reinfusion themselves, including how to control the frequency and the speed of reinfusion.

Regulatory information

The Inside System is a CE-marked class IIb medical device. The company stated that it is working towards UK Conformity Assessed marking.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Disability, age and sex are protected characteristics under the Equality Act. Intestinal failure can be an extremely debilitating condition, significantly affecting the quality of life of those affected, with a wide range of potential causes such as malignant disease. The malabsorption and malnutrition state can vary in severity and duration.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies including 1 abstract are summarised in this briefing. Two feasibility studies included a total of 29 people with a defunctioning ileostomy or with high-output proximal enterostomies and fistulas. One case study reported using The Insides System in a person with high-output enterocutaneous fistulas.

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence base is limited and mainly comes from single-centre observational studies that involve a relatively small number of people (30 people in all included studies). Two studies assessed the feasibility of using The Insides System for reinfusing chyme in people who had an intestinal failure. All 3 studies had no comparators. None of the studies were done in the UK.

Overall, the evidence base suggests that The Insides System has potential benefits in remediating high-output losses, improving fluid and electrolyte balance, weaning off parenteral nutrition and improving surgical recovery. The device was reported to be easy to use and well tolerated.

The evidence suggested that the system could be used as an alternative intervention to manage intestinal failure. The evidence base would benefit from further evidence including a larger cohort of patients, ideally in the UK. Also, future comparative studies evaluating the impact of using the technology on patient outcomes and changes in clinical management would be useful.

Solis et al. (2021)

Study size, design and location

A case study of a person with high-output enterocutaneous fistulas in an independent centre in Australia.

Intervention and comparator

The Insides System. No comparator.

Key outcomes

Chyme reinfusion (CR) provided adequate nutritional support, with successful stopping of parenteral nutrition. The device was easy to use with minimal need for nursing assistance. Side effects of CR including diarrhoea and abdominal cramping improved because the patient learned to manually adjust the reinfusion rate. No complications were encountered with CR and the use of this novel device.

Strengths and limitations

This is a single case study. The device was supplied free for the study. One author is a member of The Insides Company.

Liu et al. (2021)

Study size, design and location

A feasibility study including 19 people with a defunctioning ileostomy in New Zealand.

Intervention and comparator

The Insides System. No comparator.

Key outcomes

A total of 549 patient days of device use were recorded. Clinical benefits included a reduction in net stoma losses per day, testing of bowel function and reduction or stopping of anti-diarrhoeal medications. There were 14 people who had stoma reversal, with 3 experiencing postoperative ileus. There were 7 minor and 2 serious device-related adverse events recorded including:

- one patient with a possible pressure ulcer in the distal ileostomy limb, needing a small increase of the resected terminal ileum length at time of ileostomy reversal

- one patient who was unable to exchange the custom feeding tube because of bowel mucosa ingrowth around the flanges of the Malecot tube tip that needed removing under general anaesthetic.

Strengths and limitations

Six of the 7 study authors were members of the company. It was designed as a feasibility study. The study authors noted the possibility of incomplete data because patients may not keep their data recorded daily.

Sharma et al. (2020)

Study size, design and location

A feasibility study of people with high-output proximal enterostomies and fistulas (n=8) or people with a routine defunctioning ileostomy (n=2) in New Zealand.

Intervention and comparator

The Insides System. No comparator.

Key outcomes

The study covered over 740 patient days of device installation and testing (median 39.5, range 1 to 234 days). There were 6 out of 10 people who transitioned to outpatient device use once trained. One person withdrew from the study because of bowel obstruction. Another person with multiple enteroatmospheric fistulas had 2 pumps installed.

Reinfusion was well tolerated with the use of regular boluses of about 200 ml. The common patient concerns were pump inlet blockages and reduced CR efficiency because of pump congestion. Clinical benefits included resumption of oral diet, stopping parenteral nutrition (4 of 5 people), correction of electrolytes and liver enzymes, and hospital discharge (6 of 10 people). Of 7 people with restored intestinal continuity, 1 had postoperative ileus. The most common side effects were abdominal discomfort (7 of 10 people), bloating (4 people) and nausea (4 people). One person had a serious adverse event (severe cholecystitis) that needed invasive intervention during the study.

Strengths and limitations

This is the first study of humans using the device. It is a single-centre study with a small number of people included. Some people did not always use the pump every day it was installed, depending on their medical needs. Six of the 10 study authors were employees of the company.

Sustainability

No environmental sustainability benefits are associated with The Insides System.

Recent and ongoing studies

The company noted that a randomised controlled study is currently recruiting in 6 sites in New Zealand. This trial aims to evaluate using the device in people with regular diverting ileostomies with outputs more than 800 ml. Recruitment is expected to be finished in mid-2022. There is also a trial planned that will recruit people with type 2 intestinal failure from 5 sites in the UK and the US, respectively. Recruitment is expected to start in the first quarter of 2022.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four of all 5 experts were familiar with or had used this technology before.

Level of innovation

All 5 experts agreed that The Insides System is an innovative approach to deliver chyme mixed with feeding. One expert said that the concept of distal feeding or fistuloclysis is not new, but reinfusion of chyme and intestinal fluid is novel.

Potential patient impact

The main benefits identified by the experts are the potential to improve the management of intestinal failure and reduce the need for parenteral nutrition. Three experts explained that the device would be likely to get some people off intravenous feeding or distal enteral tube feeding and accelerate recovery to allow surgical reconstruction sooner. One expert suggested that people found the device easy to use, and there was anecdotal evidence that patient experience was positive.

The experts thought that people with intestinal failure or patients with high-output stoma or fistula would be most likely to benefit from the device. One expert said that it would also be beneficial to some people with high-output enterocutaneous fistulae. But the lumen of the fistula may be too small (not mature enough) to place the device. Another expert added that older people may benefit from the device when distal enteral tube feeding or parenteral nutrition is less suitable. Also, people who may be able to manage at home while waiting for reconstruction surgery would benefit from using the device.

Potential system impact

The experts said that the device is currently not widely used in the NHS, and it has been used in a few specialist intestinal failure centres. Three experts thought that there may be potential for cost savings over parenteral nutrition because the device was less expensive, less labour intensive and had a shorter hospital stay. Two experts were uncertain about the potential saving when compared with distal enteral tube feeding because distal enteral tube feeding is less expensive. There is no evidence on the cost impact of using The Insides System.

A reduction in hospital visits and hospital stays were also identified as potential benefits to the healthcare system.

General comments

All experts agreed that parenteral nutrition, with or without distal enteral feeding or fistuloclysis, was the current standard care for intestinal failure. They thought that The Insides System was likely to be used with parenteral nutrition and it could potentially replace distal enteral tube feeding or fistuloclysis in the care pathway.

Three experts agreed that there would be potential risks of using the device outside recognised specialist intestinal failure centres. For example, people would have inadequate treatment for their intestinal failure and have an increased risk of death or delayed provision of adequate treatment. Other potential risks identified by the experts included pain, intolerability of infusion rate, tube or pump blockage, reflux, misplacement of the device, and gut injury, perforation or bleeding from the tube. Two experts said that the device should only be used when distal gut integrity was established. Distal contrast studies are essential before using the device. All experts agreed that training for both nurses and patients would be needed to ensure that the device was used correctly and safely. Evidence on the number of people who have avoided long-term or home parenteral nutrition is needed to show its efficacy.

Expert commentators

The following clinicians contributed to this briefing:

- Gordon Carlson CBE, consultant surgeon and honorary professor of surgery, National Reference Centre, Salford Care Organisation, Northern Care Alliance NHS Foundation Trust. The technology has been provided free of charge to the specialised centre where Professor Carlson has worked in the last 12 months.
- Kirstine Farrer, consultant dietitian intestinal failure, Salford Care Organisation, part of Northern Care Alliance. The technology has been provided free of charge to the specialised centre where Kirstine Farrer has worked in the last 12 months.
- Simon Lal, professor of gastroenterology, Northern Care Alliance, Salford Royal Hospital. Professor Lal's department is receiving research funding from Baxter and Takeda, which may be considered as competitor technologies. Professor Lal has received honoraria for lectures, advisory boards from pharmaceutical companies, including companies manufacturing parenteral nutrition and GLP-2 analogues. These may be considered as competitor technologies. The technology has been provided free of charge to the specialised centre where Professor Lal has worked in the last 12 months.
- Antje Teubner, associate specialist intestinal failure, Northern care Alliance, Salford Royal Hospital. Did not declare any interests.
- Andrew Williams, consultant colorectal surgeon, Guy's and St Thomas' Hospital. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-4433-0