Chyme Reinfusion Therapy Clinical Guideline

Goals of Chyme Reinfusion

- Improve renal and liver function via reintroduction of oral feeding and increased length of small intestine available for fluid and nutrient absorption [1,3,5,6,10]
- Reduce/wean off parenteral nutrition (PN) requirements [1,5–10]
- Restore the gut microbiome [1]
- Rehabilitate atrophied distal gut [1,9]
- Improve postoperative outcomes post closure of ostomy [1,2,4,5,11]
- Improved nutritional outcomes [1,9,10]

Definitions

- Chyme (“kʌɪm”) – A pulpy semi-fluid composition of partly digested food, fluid, stomach acid/gastric juices, and digestive enzymes. Chyme is nutrient rich and readily absorbed in the small intestine to keep the person nourished.
- Chyme Reinfusion (CR) – Reintroduction of a patient’s own chyme down the efferent or distal limb of their small intestine double barrelled, loop enterostomy or enteroatmospheric fistula (EAF). [1,9,10]
- Double Barrel Enterostomy (stoma) – A surgical procedure where the intestine has a diseased portion resected, and the proximal and distal ends are brought to the skin surface together and secured to create a stoma.
- Loop Enterostomy (stoma) – A surgical procedure where a loop of the small intestine is brought to the skin surface, an opening is created and secured to create a stoma.
- Enterocutaneous fistula (ECF) – An abnormal connection or tract between the intestine (entero) and skin (cutaneous), causing efflux of gut contents through the abdominal wall. The majority arise as a complication of surgery with the remainder forming spontaneously.
- Enteroatmospheric fistula (EAF) – A small catastrophic subset of ECF’s, where a segment or multiple segments of intestine (entero) migrate to the skin surface and become visible to the atmosphere (atmospheric).
- Parenteral Nutrition (PN) – Nutrition that is administered via an intravenous route to provide a patient with nutrition to sustain life.
- Enteral Nutrition (EN) – Nutrition that is administered directly into the stomach or intestine to provide a patient with nutrition to sustain life. It is generally administered via a nasogastric tube or percutaneous endoscopic gastrostomy tube (PEG).

Chyme Reinfusion Techniques

- Manual CR – A process of collecting and sieving the patient’s own chyme then manually syringing it into the patient’s downstream (distal) intestine via a feeding tube installed in the intestine. This is an open system, generally performed by nursing staff.
- Automated CR – A closed system which collects the chyme and reinfuses it into the patient’s distal intestine, via a feeding tube attached to a small pump that is magnetically coupled to an external driver. Generally, a patient managed therapy. The Insides™ System is the medical device that performs this therapy. This guideline predominantly focuses on automated CR.

Healthcare Professional Training

- The health care professional must receive formal training and be proficient in installation, set up, and troubleshooting the automated CR process. They must also have experience managing patients undergoing CR.
- Training will be provided by the manufacturer, with full access to the Training Hub for additional training materials. Found here: https://training.insidescompany.com/knowledge

Indications for the use of Chyme Reinfusion

- Intestinal Failure Type 2 and 3
- Management of high output double lumen enterostomies that have an output over 1 litre in 24 hours
- Management of high output EAF's that have an output over 500 ml in 24 hours
- Rehabilitation of distal intestine before reversal of enterostomy
- Testing bowel function before consideration of reversal of enterostomy. This provides patients an understanding of their potential bowel habits, such as urgency or clustering of bowel motions, prior to reversal

Patient Criteria

Inclusion

- Double enterostomy (Double barrel or loop) or EAF with unobstructed afferent and efferent limbs visible on the abdominal wall (Afferent and efferent limbs must share the same ostomy bag)
- Distal limb of double enterostomy or EAF can be intubated by a minimum of 20Fr feeding tube (dilation of orifice strictures is allowable)

Exclusion

- Are under the age of 18
- Insufficient distal access channel for device insertion
- Bowel obstruction proximal and/or distal to the fistula
- Small bowel obstruction, anastomotic leak, or perforation distal to the ostomy (diagnostic procedure such as a gastrografin test, fistulograms, or similar must be performed to ensure that the patient is suitable)
- Current infection with *Clostridium difficile* colitis and SIBO (must be resolved before starting therapy)
- Signs and symptoms of peritonitis or major systemic infection
- Pre-existing gastrointestinal motility disorders including slow transit constipation, outlet obstruction, faecal incontinence, and gastroparesis
- If using The Insides™ System, have a pacemaker
- If using The Insides™ System, does not have sufficient dexterity to handle device and mental capacity

Registry

The Insides Company maintain a clinical registry for all patients that use (any form of) CR therapy. Patient consent is required to enter the patient's de-identified data. The objective of the Registry is to track patients weaning off PN and EN, increasing their oral feeding and CR, and safety and efficacy of the device. Submission of patient data is not mandatory for use of The Insides™ System but is recommended to provide on-going quality assurance.

Initiating Chyme Reinfusion

Guideline for choice of feeding tube and ostomy appliance

EAF patients

Due to the anatomy of the EAF, the choice of feeding tube for use in CR requires careful consideration.

- A feeding tube that is 20Fr or larger is recommended initially as this allows for easier reinfusion and thicker chyme viscosities to pass through. Once the distal intestine has been rehabilitated it may be possible to increase the size of the feeding tube.
- As the EAF matures and adhesions soften, the feeding tube should be reassessed to ensure it continues to be fit for purpose. There is no fascia to anchor the tube and as the EAF matures, there is a risk of the tube being sucked into the distal intestine.
- The feeding tube should be as soft as possible, with no cuff, to reduce the risk of luminal damage due to pressure injury.
- The ostomy appliance needs to be large enough to accommodate the feeding tube, so that it sits straight and is not coiled. Initially a large wound bag may be required to accommodate the fistula wound. As it heals, switching to a conventional ostomy appliance will be easier to manage, provide more options of types of pouches to use, and will provide the patient with a psychological boost.

Enterostomy patients

- For most patients, The 28 Fr Insides™ Tube is fit for purpose. This allows the patient to continue using their ostomy appliance of choice, the tube keeps a low profile for the patient, and has easier coupling with The Insides™ Pump
- Patients with a prolapsed or herniated distal enterostomy have an increased risk of damage to the intestine on tube insertion because there is an increased length of intestine external to the fascia. Careful consideration as to whether CR is a suitable therapy is required. A longer balloon retained feeding tube needs to be considered for these patients. A gastrostomy tube may be necessary.
- Obese patients have a greater distance from the skin surface to the fascial layer so tube consideration is critical. A gastrostomy tube may be necessary.
- If a balloon retained feeding tube is selected, a high output ostomy appliance is needed to accommodate the feeding tube, so it sits straight and is not coiled in the ostomy appliance.

Guideline for Increasing Tolerance to Chyme Reinfusion

For patients who have been defunctioned for >6 months

- Day 1: Reinfuse two boluses of 50 - 80ml, one in the morning and one in the afternoon
- Day 2 - 5: Incrementally increase the frequency within patient tolerance
- Day 6 onwards: Increase the bolus volume within patient tolerance
- Note: It may take one to three weeks to rehabilitate their distal intestine and be reinfusing over 90% of their daily output

For patients who have been defunctioned for <6 months

- Day 1: Reinfuse two boluses of 100 – 200ml, one in the morning and one in the afternoon
- Day 2 - 7: Incrementally increase the frequency of the boluses and then the bolus volume when they are comfortable to do so
- Note: It may take one week to rehabilitate their distal intestine and be reinfusing over 90% of their daily output

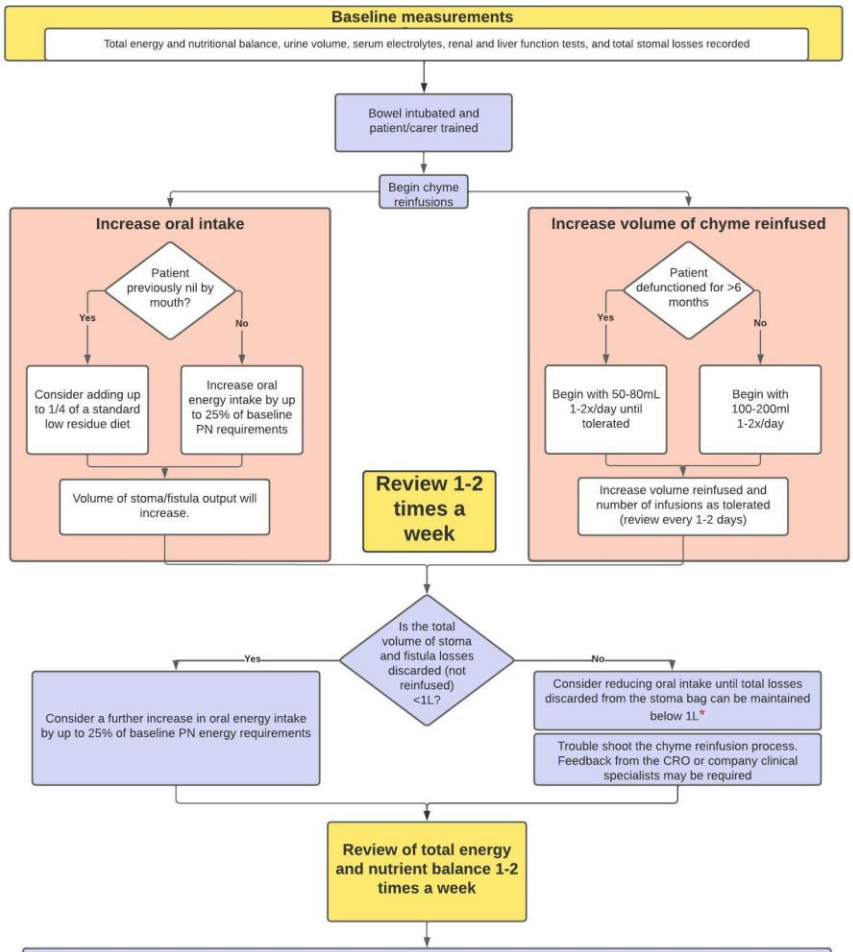
Things to remember,

- The patient should not start reinfusing their entire output on day one due to atrophy of the distal intestine. Initially CR will be cause luminal stretch which may cause bloating, nausea, and abdominal discomfort.
- If the patient has **ischemic** aetiology, **slow** titration of chyme reinfusion is necessary to reduce the risk of non-obstructive mesenteric ischemia (NOMI).
- To improve compliance with CR and ensure safe rehabilitation of the distal intestine it is important to minimise the side effects when increasing bolus volumes and frequency. Reflux is expected when the patient is rehabilitating their distal intestine. It does not cause harm but does increase the time to reinfusing what is in the ostomy appliance.
- If using The Insides™ System, always use the lowest speed on the Driver that moves the chyme up the tube.
- If performing manual CR, always depress the plunger slowly.
- If patient discomfort is unmanageable, pause reinfusions until side effects have completely resolved before restarting. Consider Paracetamol/Acetaminophen.
- "A little and often" is the golden rule.

Suggested Chyme Reinfusion and PN Weaning Guidelines

- The following flow chart is there to guide the clinician in safely weaning the patient off PN, increase oral intake, with a continued reduction in net losses from the ostomy.
- If the patient is not reliant on PN, they should maintain their baseline oral diet and antimotility medication regime until their distal intestine is rehabilitated and reinfusing over 90% of their output. This is to ensure they are independent with The Insides™ System before starting to wean off anti-motility medication.

Suggested Chyme Reinfusion and Parenteral Nutrition Weaning Guidelines



If the patient:
a. is taking in an increased amount of energy orally, and successfully refeeding most energy distally, or
b. has adapted physiologically, and thus may require less parenteral energy
Then consider decreasing the PN regimen, if the following criteria are also met:

1. The following are at or near normal levels - sufficient testing should be conducted to ensure clinical confidence in these levels

Criteria	Normal Range	Testing frequency during weaning	Testing frequency when stable
Glucose	3.5-11 mmol/L 140-180 mg/dL	at least weekly	at least monthly
Sodium	136-145 mmol/L	at least weekly	at least monthly
Potassium	3.5-5.2 mmol/L	at least weekly	at least monthly
Magnesium	0.7-1 mmol/L 1.6-2.2 mg/dL	at least weekly	at least monthly
Calcium	2.1-2.55 mmol/L 8.4-10 mg/dL	at least weekly	at least monthly
Phosphate	0.74-1.4 mmol/L	at least weekly	at least monthly
BUN	2-7 mmol/L 21-43 mg/dL	at least weekly	at least monthly
Creatinine	60-105 mcmol/L	at least weekly	at least monthly

2. The following are showing a trend towards the normal rage - testing should be frequent enough to indicate a trend

Criteria	Normal Range	Testing frequency during weaning	Testing frequency when stable
Albumin	35-50 g/L	at least weekly	weekly
Prealbumin	150-306 mg/L	at least weekly	weekly
CRP	<5 mg/L	at least weekly	weekly
LFT		at least weekly	weekly

3. The following should be monitored and can be supplemented if levels are below the suggested range without effect on weaning

Criteria	Normal Range	Testing frequency during weaning	Testing frequency when stable
Trace Elements (Zn, Se, Cu, Mn)	Zinc: 10-17mcmol/L Selenium: 1.5-1.9 mcmol/L Copper: 11-20 mcmol/L Manganese: 70-220 nmol/L	at least monthly	every 1-3 months
Vitamins (A, D, E, B12)	Vit A: 1-1.4mcmol/L Vit D: 50-75 nmol/L Vit E: 14-30 mcmol/L Vit B12: 118-701 picomol/L	at least monthly	every 1-3 months

4. The following criteria are met

Criteria	Normal Range	Testing frequency during weaning	Testing frequency when stable
Urine volume	>12mL/kg/day	at least weekly	at least weekly
Weight	stable or gaining (unless oedematous)	weekly	weekly

* Some patients may have persistent high overnight losses which are subsequently discarded. For these patients consider moving the evening meal early enough so that most energy can be infused before going to sleep. Overnight fluid losses can be supplemented by IV fluid

Patient Management

- The Insides™ System is a patient managed therapy so encourage independence with the system as early as possible. Encouraging independence with the system and with ostomy care helps the patient to trouble shoot their own care.
- Psychological support and encouraging quality of life practices is paramount to success with CR.
- If the patient has a good understanding of why they are performing CR, the necessary modifications to diet and lifestyle, and the alternatives to their care journey, they are more likely to remain engaged with this therapy.
- Close, supervised support in the first week of use will set the patient up for continued safe use of the device for the duration of their therapy. Once the patient is independent, a minimum monthly review is recommended for patient monitoring, tube changes, and safe use of the device.

Stoma Care

- Ostomy care is much the same with the use of The Insides™ System except the patient needs to thread their ostomy appliance over / off the Tube and Pump complex. Care is required when removing the ostomy appliance to not accidently dislodge the feeding tube. Supervision of the patient changing their ostomy appliance is recommended in the first week so they can practise removing the ostomy appliance without dislodging the Tube.

Safety

- Observe and comply with all manufacturer warnings and patient contraindications when using The Insides™ System.
- If the patient is experiencing pain (not the expected discomfort from rehabilitating their distal intestine) during installation or use of The Insides™ System, this is not normal, and a clinical assessment should be performed to evaluate cause. The Insides™ System may not be suitable, or adjustments need to be made for continued safe use of the device.

Clinical Support

- Please refer to the information manuals contained within The Insides System product box and the Training Hub for Frequently Asked Questions and further guidance around The Insides System. https://training.insidescompany.com/knowledge
- Please contact the Clinical team at The Insides Company for specific clinical support. clinical@insidescompany.com

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