1. Introduction

An enterocutaneous fistula (ECF) is defined as an abnormal connection between the gastrointestinal tract and the skin. Almost 75% of ECF are secondary to laparoscopic or open surgery, with other causes including inflammatory bowel disease, trauma, radiation, diverticular pathology and malignancy. ECF carry a high incidence of morbidity including dehydration, electrolyte disturbances, sepsis and skin excoriation.

High output fistula is defined as an output of >500mls/24 hours, however clinical experience should be exercised in interpreting additional clinical factors such as location of the fistula and fluid and electrolyte balance when initiating a treatment plan.

This guideline is aimed at healthcare professionals caring for inpatients within UHL with enterocutaneous small bowel fistula. The guideline sets out the identification and management of patients with ECF, including reducing and replacing fluid and electrolyte losses, drug management, nutritional support, and ongoing monitoring of an adult patient with an enterocutaneous fistula. The guideline aims to stabilise patients for discharge or for surgical treatment.

2. Scope

2.1 This guideline applies to adult inpatients within UHL with proven or suspected ECF of the small bowel. It does not cover the management of pancreatic/biliary fistulas, colovesical fistulas or fistulas of the large bowel.

2.2 The aim of this document is to reduce the morbidity associated with ECF by promoting evidence-based practice amongst medical, nursing and healthcare professionals working with this patient population.

2.3 Whilst the guideline is aimed at patients on surgical/medical wards, certain aspects (such as the use of medication to reduce intestinal losses) are transferable to other areas, such as critical care, oncology and medical admission areas.

2.4 The following professional groups are authorised to use this guideline:

- Surgical / medical teams and associated ward nursing staff
- Pharmacists
- Dietitians
- Nutrition Nurse Specialists
- Colorectal, Tissue Viability and Stoma Care Nurse Specialists

3. Recommendations, Standards and Procedural Statements

3.1 Assessment:

3.1.1 Type of fistula:

3.1.1.A Pseudostomas (where bowel is exposed, everted and matured) **do not heal spontaneously and require a definitive reconstruction operation** (Bannon *et al*, 2019)**.**

3.1.1.B Enterocutaneous fistulas evolve into non-healing pseudostomas, however **may be managed as drain-controlled fistulas** if local tissue coverage is provided before a pseudostoma develops.

3.1.1.C Open abdominal fistulas/enteroatmospheric fistulas arise within a laparostomy wound. They lack abdominal wall integrity. They are associated more complications and less favourable outcomes (Bannon *et al*, 2019).

3.1.1.D Closed abdomen fistulas arise in the absence of a laparostomy wound.

3.1.2: Sepsis:

3.1.2.A Sepsis remains the leading cause of death in patients with ECF (Gribovskaja, 2016).

3.1.2.B Imaging to assess for intra-abdominal leaks or collections, with appropriate antimicrobial therapy should be carried out.

3.1.4 Fistula Output:

3.1.3.A Fistulas with output below 200mls/24hrs are considered low output. Low output fistulas are associated with a greater incidence of spontaneous closure (Dumas *et al*, 2017). Patients with low output fistulas should be able to tolerate oral and/or enteral diet. Fistula output should be monitored in addition to fluid and electrolyte status and PN considered if oral/enteral nutrition results in a significant increase in output.

3.1.3.B Output of 200-500mls/24hrs is likely to be manageable with a low residue diet in conjunction with optimisation of anti-secretory medications +/- IV fluid and electrolyte therapy, as per recommendations below.

3.1.3.C Output greater than 500mls/24hrs is considered high output, however location of fistula and nutrition and electrolyte status should be taken into consideration. Patients with a high output fistula should be referred to LIFT and Tissue Viability.

3.1.4 Location of the fistula:

3.1.4.A Location of the fistula within the GI tract will affect volume and composition of losses and degree of absorption of fluids and nutrients. Other factors affecting bowel health (e.g. distal obstruction) also have a bearing on dietary consistency and route of nutrition.

3.1.4.B Imaging to confirm exact position of fistula, including length of bowel proximal to the fistula, size of fistula and status of surrounding bowel is therefore required in order to effectively deliver a safe and suitable nutrition solution and manage fluid and electrolyte status.

3.1.5 Nutrition and Hydration assessment:

3.1.5.A All patients should be assessed using the Malnutrition Universal Screening Tool (MUST) on Nerve Centre, using recent weight and height.

3.1.5.B Full TPN1 profile bloods (Na, K, Ur, Cr, eGFR, PO4, Mg, Ca and Glucose) should be checked, including Magnesium. Note that whilst serum albumin is a prognostic outcome indicator, it is an acute-phase protein which is frequently found to be below reference range in acutely unwell patients. It is not a marker of nutritional status and therefore not an indication for parenteral nutrition.

3.2 Managing fluid and electrolyte status (see appendices 1 and 2 for processes and rationale for treatment)

3.2.1 In order to maintain hydration status, nutrition status and electrolyte balance, as well as promoting fistula closure, efforts should be made to reduce fistula output.

3.2.2 Initial management of fistulas should focus on fluid resuscitation and correction of electrolyte disturbances. Common electrolyte disturbances as a result of increased GI losses include hyponatraemia, hypokalaemia and acidosis (Dumas *et al*, 2017). Strict fluid balance monitoring should be maintained and requirement for ongoing IV fluid and electrolyte replacement considered. Refer to UHL guidelines on IV correction of electrolytes.

3.2.3 In patients with fistula output >500ml/24 hours, oral hypotonic fluids should be limited to 500mls/24hrs. St Mark's Solution may be required if the patient is not receiving intravenous fluids or enteral or parenteral nutrition. This will ensure total fluid requirements are met without exacerbating electrolyte impairment.

3.2.4 Medications should be reviewed and unnecessary medications which may exacerbate fistula output (such as prokinetics or laxatives) should be stopped.

3.2.5 Loperamide should be commenced to reduce gastric motility, in conjunction with a proton pump inhibitor to reduce gastric secretions (Nightingale, 2018).

3.2.6 A somatostatin analogue (Ocreotide) in high output fistulas may reduce output and reduce time to healing (Phuong *et al* 2010, Kumpf *et al*, 2017), however this also increases risk of biliary stasis, cholelithiasis, liver dysfunction, GI disturbance, hypoglycaemia and hyperglycaemia. If fistula output remains >500ml/24 hours after two weeks of therapy, then Ocreotide 200micrognammes TDS can be trialled. The effect of Ocreotide should be reviewed after 3-5 days and discontinued if of no beneficial effect.

3.3 Wound care

3.3.1 Involve tissue viability to advise on managing the skin and area surrounding the wound.

3.3.2 Prognostic factors affecting fistula closure (Dumas *et al*, 2017)

Favourable	Unfavourable
Nutritionally replete	Nutritionally deplete
Albumin >30g/L check units	Low albumin, low transferrin
Long fistula tract (>2cm)	Short fistula, multiple, complex fistulas
Diverticular fistula	Large enteral defect (>1cm), visible mucosa
Low output	High output (>500ml/day)
Single fistula	Prior radiation
Intestinal Continuity	Multiple prior operations
Index operation performed at same centre	External referrals to a high-volume centre

3.3.3 Guidelines for application of wound manager bags can be found in Appendix 3

3.4 Nutrition

Due to a low grade of evidence surrounding the nutritional treatment of intestinal fistulas, the following recommendations are based on a clinical guideline produced by an expert panel of healthcare professionals. The policy was developed under the joint guidance of the Boards of Directors of American Society for Parenteral and Enteral Nutrition (ASPEN) and the Federación Latino Americana de Terapia Nutricional, Nutrición Clínica y Metabolismo (FELANPE).

3.4.1 When considering route of nutrition, the current nutritional status, fluid status and position of the fistula should be considered, as well as the volume of output. Oral/enteral intake may be tolerated in patients with low output fistulas, either solely, or with supplemental parenteral nutrition. High output fistulas, or those with poor surrounding skin integrity are more likely to require total parenteral nutrition. Distal fistulas can usually be managed with a low fibre diet.

3.4.2 Earlier enteral nutrition (EN) is associated with higher success rates in surgical closure compared to EN started after 14 days. Early nutritional assessment and intervention is therefore important.

3.4.3 Protein requirement of 1.5-2g protein/kg/day (0.25-0.32g N/kg/day) should be aimed for. In patients with high output enteroatmospheric fistulas, up to 2.5g protein/kg/day (0.4g N/kg/day) may be required.

3.4.4 For patients with a BMI of 30-50kg/m^2, 11–14 kcal/kg/d actual body weight should be aimed for. For patients with a BMI >50kg/m^2, 22–25 kcal/kg/d ideal body should be the target. For protein intake, provision of 2g/kg/d ideal body weight for patients with BMI 30–40 and 2.5 g/kg ideal body weight if BMI >40 kg/m^2 is recommended.

3.4.5 Oral glutamine in combination with PN may improve mortality and fistula closure rates, but quality of evidence is very low.

3.5 Smoking cessation advice should be offered where necessary with support of nicotine replacement

4. Appendices

This guideline is supported by the following appendices

Appendix	Title	Page
1	**Summary: Management of Fistulas**	6
2	**Rationale for Medications and Fluid Treatment**	9
3	**Application of a Wound Manager Bag**	11
4	**St Marks Oral Re-hydration Solution Instructions**	12

5. Education and Training

The professional staff authorised to use this guideline as detailed in section 2 must have received relevant training in this patient population and accept responsibility for updating knowledge and skills on a regular basis to maintain competence. The Nutrition Team offer regular training to teams such as colorectal surgical doctors and can provide training to relevant clinical areas / specialities on request.

6. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
Length of time patients with fistulas remain on PN	Audit	Biannual	Clinical Lead, LIFT
Stage 2 measures implemented prior to LIFT referral	Audit	Biannual	Clinical Lead LIFT

7. Supporting Documents and Key References

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8. Key Words

ECF, Enterocutaneous Fistula, fistula, High Output Fistula, LIFT (Leicester Intestinal Failure Team), Intestinal Failure

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Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
March 23		Sarah Crawford	Format changes Addition of Section A management of fistula <200mls Addition of St Marks Solution Instructions

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Summary: Management of Fistulas

Summary: Initial Assessment

1. Evaluate for treatable foci of sepsis and manage accordingly
2. Strict 24 hour fluid balance chart
   Monitor colour, consistency, volume of output from fistula
3. Full TPN 1 bloods (Na, K, Ur, Cr, eGFR, PO4, Mg, Ca and Glucose)
   Correct fluid/electrolyte imbalance
4. Perform or review imaging to confirm exact location and size of fistula and status of surrounding bowel
5. Perform MUST to assess nutritional status

Fistula output <200mls per 24h refer to Section A	Fistula output 200-500mls per 24h refer to Section B	Fistula output >500mls per 24h refer to Section C

Summary: Section A: Management fistula output <200mls per 24h

1. Oral/enteral intake may be tolerated in patients with low output fistulas, though may require supplementary PN.
2. Commence patient on option 3 low fibre menu (available from catering folder via ward house keeper or catering department). If the patient remains on a modified fibre diet for over 2 weeks, consider referral to Nutrition and Dietetics (a micronutrient supplement may be required).
3. Encourage normal oral fluids and a high salt diet. Do not restrict hypotonic fluids or start oral rehydration initially. Refer to Nutrition and Dietetics if nutritional intake poor
4. Consider tissue viability referral
5. Optimise pain control
6. Continue to monitor strict fluid balance, at least biweekly weights and full bloods including AKI staging, U&E, Magnesium levels. Supplement if required

Review after 48 hours. If output increased or patient unable to maintain fluid and/or electrolyte balance, proceed to Section B or Section C

Summary: Section B: Management fistula output 200-500mls per 24h and/or if unable to maintain fluid and/or electrolyte balance

1. Strict low fibre diet. Use Option 2 low fibre menu (available from catering folder via ward house keeper or catering department). If the patient remains on a low fibre diet for over 2 weeks, consider referral to Nutrition and Dietetics (a micronutrient supplement may be required)

2. Encourage normal oral fluids and a high salt diet. Do not restrict hypotonic fluids or start oral rehydration initially. Refer to Nutrition and Dietetics if nutritional intake poor

3. Complete tissue viability referral

4. Optimise pain control

5. **Commence Loperamide 2mg QDS.** Loperamide dose can be increased by 2mg QDS every 24hours. Review effect on fistula output before increasing to 8 mg QDS

This should be given 30-60minutes before meals and at bedtime (if using capsules open and mix with jam/yogurt. Once gut transit time has been reduced, whole capsules can be swallowed and the effect on stoma output monitored).

6. Initiate **Esomeprazole/Omeprazole** 40mg BD

7. Continue to monitor strict fluid balance, at least biweekly weights and full bloods including AKI staging, U&E, Magnesium levels. Supplement if required

Review after 48 hours. If output increased or patient unable to maintain fluid and/or electrolyte balance, proceed to Section C

Summary: Section C: Management fistula output >500mls per 24h and/or if unable to maintain fluid and/or electrolyte balance

1. Refer to LIFT on ICE

2. Commence/review adherence to measures implemented in section 2

3. **Restrict oral hypotonic fluids** to 500mls. Continually review compliance

4. **Commence St Marks oral rehydration** solution 1000ml daily, in addition to oral fluid restriction (this replaces stoma sodium losses but will still increase output if taken in excessive amounts). Once IV fluids are stopped, check random urine sodium (aim >20mmol/l). Continually review compliance. See appendix 4 for instructions on how to prepare St Marks solution.

5. Once allowed to eat offer a strict low fibre diet option1 low fibre menu (available from catering folder via ward house keeper or catering department). If the patient remains on a strict low fibre diet for over 2 weeks, consider referral to Nutrition and Dietetics (a micronutrient supplement may be required)

6. **Add in codeine phosphate** 15mg – 60mg QDS, 30-60minutes before meals (use cautiously in patients with renal impairment and contraindicated if GFR<15).

7. **Loperamide dose can be increased by 2-4mg**
   (re-assess every 2-3days. Only increase further if a significant improvement in output is seen. Maximum dose is 24mg QDS but >12/16mg QDS rarely required).

This should be given 30-60minutes before meals and at bedtime (if using capsules open and mix with jam/yogurt. Once gut transit time has been reduced, whole capsules can be swallowed and the effect on stoma output monitored).

8. If fistula output remains >500ml daily after 2weeks of therapy can **trial octreotide** 200microgrammes TDS for 3-5 days. If no significant improvement stop. If improvement consider longer-term analogues.

9. Complete tissue viability referral

10. Optimise pain control

11. Continue to monitor strict fluid balance, at least biweekly weights and full bloods including AKI staging, U&E, Magnesium levels. Supplement if required

Section B – Output 200-500mls	**Rationale for treatment**
Commence loperamide 2mg QDS to reduce fistula losses. This should be given 30-60minutes prior to meals and at bedtime (if using capsules open and mix with jam/yogurt). NB This may not be effective in patients with very high/proximal fistula.	Loperamide can reduce intestinal motility and thus decrease ileostomy output by 20-30% (Newton, 1978). Loperamide has benefits over codeine phosphate and should therefore be the first choice of anti-diarrhoea medication (Loperamide is not sedative, addictive and does not cause fat malabsorption).
Increase loperamide dose to 8mg QDS.	Loperamide doses above recommended and licensed doses are often needed in patients with intestinal failure, as absorption is reduced (both due to reduced surface area and altered enterohepatic circulation). Higher plasma levels are needed to control a high output fistula than in the treatment of acute diarrhoea. Higher doses of loperamide can lead to cardiac arrhythmia. An ECG should be performed and the QT interval recorded for all patients before their dose of loperamide is increased above 4mg QDS. Serum loperamide levels should be measured in patients whose daily dose exceeds 80mg. Further information can be found in the BIFA position statement on the use of high-dose loperamide in patients with intestinal failure at bapen.org.uk.
Review medication and aim to stop any medications which can increase fistula output (such as prokinetics).	
Review proton-pump inhibitors. Give Esomeprazole/Omeprazole 40 mg BD	Omeprazole has been shown to reduce jejunostomy output. (Nightingale, 1991b, Jeppesen *et al*, 1998). This can be given orally if >50cm jejunum remains, as it is readily absorbed in the duodenum and upper small bowel (by giving omeprazole, gastric secretion is reduced, decreasing the osmotic pressure on the intestine).
Section C – Output 500mls or greater and/or additional complications	**Rationale for treatment**
Commence St Mark's solution 1000mls/24hrs If compliance to St Marks is a problem – liaise with LIFT (Leicester Intestinal Failure Team) as other options are available NB - St Marks solution should not be given in unrestricted amounts as excess consumption will still increase fistula volume.	There is a coupled absorption of glucose and sodium in the jejunum (Olsen, 1968). Sodium concentrations >90mmol/l result in sodium absorption and improve sodium balance (Newton *et* al, 1985, Nightingale *et al* 1992). St Marks solution does not reduce stoma volume per se when compared to the same quantity of water consumed (Nightingale et al, 1992) It improves sodium balance, which in turn improves thirst, so that overall fluid intake can be reduced (when used in conjunction with a hypotonic fluid restriction). This will then reduce stoma output. In patients with very short proximal lengths of bowel (<50cm) total fluid volume, including St Marks should be restricted if stoma output needs to be controlled.

Add in codeine phosphate 15mg – 60mg QDS, 30-60minutes prior to meals.	Codeine phosphate in combination with loperamide reduces fistula volume. It should be used cautiously in patients with renal impairment and is contraindicated in patients with GFR <15.
Restrict oral hypotonic fluids to 500mls/24hrs	Fluids with a sodium concentration of <90mmol/l will cause a net secretion of sodium from the blood to the gut lumen and this is lost via the stoma (Rodrigues C *et al*, 1988).
Increase loperamide dose by 2-4mg (effect of this should be assess for 2-3 days before increasing the dose further as significant additional benefit may be unlikely above 8mg QDS). Maximum dose 24mg QDS.	Loperamide doses above recommended and licensed doses are often needed in patients with intestinal failure. BSG guidelines recommend a maximum dose of 24 mg QDS (Nightingale and Woodford, 2006). This should only be used in cases where the effect of low doses has been properly considered. Significant further benefit is often unlikely above 32mg daily (Carlson et al, 2010)
If fistula output remains above 500ml daily after 2 weeks of therapy try sub/cut octreotide 200microgrammes TDS. Give for 3-5 days. If no improvement stop.	Subcutaneous octreotide 50micrograms twice daily reduces ileostomy/jejunostomy outputs (Nightingale *et* al, 1989) by reducing salivary, gastric and pancreatico-biliary secretions and slowing bowel transit. Longer acting analogues may also be useful. It may not be more effective than high dose loperamide and a proton pump inhibitor so these options should be considered first.

Equipment required can be obtained from a surgical ward if your clinical area does not stock them.

1. Using the template of the wound manager bag, flip this over and place over the wound/fistula, then draw around the wound edge
2. Cut the template out (using curved scissors if possible)
3. Flip the template back over so that it is the correct way around and place this over the wound manager bag (the writing will now be lined up)
4. Draw onto the wound manager bag and cut out shape required
5. Prepare the peri-wound skin by applying a barrier film (stick or wipe)
6. Apply stoma paste to any skin creases to ensure a flat surface
7. Consider applying a hydrocolloid around the wound margin to enhance the efficiency of the adherence of the bag and further protect the skin
8. Apply wound manager bag and press down for at least 30 seconds, paying attention to the lower end
9. If fistula is high output, then consider attaching the bag to a catheter drainage bag as this will prevent the bag pulling on the skin when its full
10. All output needs to be accurately recorded on fluid balance chart

A video guide, produced by UHL Tissue Viability Team, can be found using the following link:

https://www.eakin.eu/wound-care/

Measure the following ingredients :

20g	Glucose powder with vitamin C	- SIX level 5ml spoonfuls
3.5g	Table Salt	- ONE level 5ml spoonful
2.5g	Sodium bicarbonate powder	- ONE heaped 2.5ml spoonful or half a 5ml spoonful

1Litre Water

Directions

- 5ml spoon is equivalent to a standard tea spoon
- Mix to dissolve all powder ingredients in one litre of water.
- Use within 24 hours and discard any remaining solution after this time.
- This solution may be diluted with a little fruit squash and refrigerated to make it more palatable (make sure the total volume of water and squash is one litre).
- Glucose powder and sodium bicarbonate powder (also known as bicarbonate of soda) is inexpensive and can be bought from any chemist or is available on prescription from GP.
- Standard table salt available from any supermarket is suitable for use.
- In an emergency situation double strength Dioralyte may be used as a substitute.

Drink …… litre(s) of this mixture throughout the day.

If you need to get these prescribed please show your GP/Doctor this leaflet. They will need to be prescribed in the following way.

St. Marks electrolyte mix

Formula	Glucose	20g	
	Sodium chloride	3.5g	
	Sodium bicarbonate	2.5g	Made up to 1L with tap water daily

Supply	Glucose powder with Vitamin C	500g
	Sodium chloride powder (table salt)	500g
	Sodium bicarbonate powder	100g

If the prescription is written in this way, your community pharmacist can claim for these items and will be able to supply them to you.

If you have queries, contact : _____