Gloucestershire Hospitals
NHS Foundation Trust

CLOSTRIDIOIDES DIFFICILE INFECTION (CDI) ACTION CARD	
FAECAL MICROBIOTA TRANSPLANT	**CDI7**
FOR USE BY: Infection Prevention & Control Team, Gastroenterologist and Microbiologist	**LIAISES WITH:** Medical and Nursing staff, Pharmacist, Director of Infection Prevention and Control and Deputy Director of Infection Prevention and Control

1. Introduction

1.1 Scope and purpose

The purpose of this action card is to ensure patient safety and enable Health Care Professionals to follow a procedure to administer a Faecal Microbiota Transplant (FMT) for the treatment of *Clostridioides difficile* infection (CDI).

This action card should be used in conjunction with A0297 consent policy http://glnt313/sites/ghnhsft_policy_library/WPP/A0297.aspx and the procedures and guidelines related to insertion of nasogastric tubes or PEG/PEJ use http://glnt313/sites/ghnhsft_policy_library/WPP/A0096.aspx

FMT is a 50 ml filtered suspension of faeces, which has been prepared in the laboratory from a healthy human donor stool. It is used for the treatment of CDI and is usually administered to the patient via an upper GI route. Direct delivery to the colon (lower GI route via colonoscopy, sigmoidoscopy or enema) is also a valid alternative, however, this will require a larger volume of FMT and should be discussed in advance with the University of Birmingham Microbiome Treatment Centre (UoBMTC) Clinical team.

Under NICE approval, FMT treatment can be offered to the following patient with:

Multiple recurrence of CDI

- Patients who have suffered from ≥3 episodes of CDI and failed to respond to standard antibiotic treatment

FMT cannot be given as first line treatment for CDI

2. Methodology

2.1 Patient inclusion and exclusion

The following inclusion and exclusion criteria must be met for patient treatment:

Inclusion

- Patient meets indication criteria
- Patient suitable for nasogastric tube (NGT) insertion
- Patient is refractory to antibiotic treatment or has had 3 episodes of *C. difficile* infection
- Informed consent
- FMT treatment has been ALL agreed by **the Infection Prevention and Control Team, a Consultant Gastroenterologist and a Consultant Microbiologist**

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Exclusion

- Ulceration/bleeding of the upper gastrointestinal tract
- Life threatening food allergy e.g. peanuts
- Patients under the age of 16 years old

Patients who meet the required inclusion criteria and are not contraindicated by the exclusion criteria will be identified by the Infection Prevention Control Nurses on *C. difficile* ward rounds. Identified patient details and recommendation for FMT will be emailed to the Duty Microbiologist on call and Gastroenterology Consultant who will need to agree to progress with FMT for CDI treatment.

2.2 Patient consent

Explain the procedure and its risks using the FMT patient information leaflet (form FMT-DON-011), following local consent policy. The standard consent forms should be signed by the patient and the clinician and retained in the patient's notes. Risks of FMT can include:

- Low risk of perforation from NGT insertion
- Risk of aspiration while NGT in place
- Risk of transmission of an unknown infectious agent(s)
- Risk associated with colonoscopy (perforation/haemorrhage). This is generally considered a very low risk occurring once every 1000 procedures or less.

Whilst FMT can be a lifesaving treatment in immunocompromised patients with CDI it should be remembered that we use donors who could be CMV positive. If you are considering treating an immunocompromised patient who is at risk for infectious agent that we have not screened **for** please discuss the case with one of our medical advisors. For those patients considered to be immunosuppressed ensure the patient is informed of the theoretical increased risk of adverse events and record discussion of risk on the consent form.

2.3 Logistics of FMT treatment

FMT is supplied in 50 ml aliquots, one aliquot should be used for Nasogastric administration

If colonoscopic administration is planned then three aliquots of FMT (150ml) should be requested (request sent in advance to UoBMTC).

All FMT aliquots are sent with an accompanying validation certificate which should be retained in the patient's clinical notes.

2.4 FMT delivery

Subject to reasonable logistics, all FMT treatments will be delivered by the Blood Bikes. In the event the Blood Bikes are unable to deliver FMT a courier will need to be arranged by the requesting clinician.

2.5 FMT administration

In the case of *C. difficile* treatment ensure the patient has received at least 4 days antibiotics for treatment of *C. difficile* prior to FMT. Stopping all antibiotics the evening before FMT treatment must be discussed with the Duty Consultant Microbiologist.

The protocol for nasogastric administration of FMT is:

- Administration will either be carried out or supervised by the Infection Prevention and Control Nursing Team.
- In order not to waste FMT treatments (which are limited in stock), the NG tube should be in place, positioning confirmed and the patient is happy with the NG tube, preferably within day time hours (the inserter must be competent insert an NG tube).
- The patient should be nil by mouth 6 hours prior to FMT
- Give a STAT dose of oral omeprazole 20 mg (adult dose) or appropriate PPI 2 hours prior to FMT administration.
- Give a STAT dose of oral Metoclopramide 10mg 2 hours prior to FMT administration Domperidone 10 mg can be given if Metoclopramide is contra-indicated.
- In the rare situation where patients may be “nil by mouth” but have a naso-gastric tube insitu, PPI and prokinetic agent (in this case metoclopramide) may be administered parenterally.
- Transfer the FMT to an enteral syringe
- Connect FMT enteral syringe to the NG tube and administer 50 ml of FMT into the stomach, slowly over 2-3 minutes.
- Flush the NG tube with 30 ml of saline.
- Remove NG tube one hour after the procedure.
- The patient can eat 1 hour following the procedure, providing the patient’s clinical team is happy with the patient’s condition.

2.6 Disposal in the event FMT is not used

- In the event that an FMT aliquot is not used, dispose of the capped syringe or primary container directly into the clinical waste stream. The reason for disposal must be documented in the patient’s notes/ record (paper or electronic)
- The FMT validation certificate can be discarded into the confidential waste.

2.7 Serious adverse events (SAE) and serious adverse reactions (SAR)

A serious adverse event (SAE) or serious adverse reaction (SAR) is defined as any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient

hospitalization or causes prolongation of existing hospitalization. In the case of FMT we are, in particular, interested in adverse events relating to infectious disease An unexpected adverse reaction (UAR) is an adverse reaction that is not consistent with the product information in the SPC. A suspected unexpected serious adverse reaction (SUSAR) is any UAR that at any dose

In the event of a Serious Adverse Event (SAE), Serious Adverse Reaction (SAR) or a Sudden Unexplained Serious Adverse Reaction (SUSAR) immediately contact, by phone, a member of the Microbiome Treatment Centre's Clinical team listed below.

Please follow up all calls with an e-mail to bhs-tr.FMT@nhs.net within 24 hours

Following notification of the SAE/SAR, the Root Cause Analysis (RCA) must be performed, by the FMT incident group within 5 days.

The FMT incident group must include:

- Patient's Consultant
- Lead Nurse for Infection Prevention and Control
- Risk Manager
- Microbiology Consultant
- Director Infection Prevention and Control (DIPC) or Deputy DIPC
- UoBMTC required personnel as per UoBMTC FMT clinical protocol.

Following investigation if the FMT is thought to be linked to the SAE/SAR the MHRA will be notified within 15 calendar days.

3.0 Appendix documents

University of Birmingham MTC FMT clinical protocol which includes RCA form for adverse events

https://www.gloshospitals.nhs.uk/media/documents/UHB_-FMT_Clinical_Protocol_V2_-_April_2019.pdf

FMT request form

https://www.gloshospitals.nhs.uk/media/documents/FMT_Request_Form.pdf

FMT order form

https://www.gloshospitals.nhs.uk/media/documents/FMT_Order_Form.pdf

Information leaflet

https://www.gloshospitals.nhs.uk/media/documents/UHB_-FMT_Clinical_PIL_v2_-_April_2019.pdf