**Faecal Microbiota Transplant (FMT) Patient Information Leaflet**

**What is Clostridium difficile?**

Clostridium difficile (C.diff) are bacteria that live in the bowel (also known as the gut). In a healthy person, C.diff bacteria can live amongst normal bacteria in the gut and don’t cause disease. However, if the normal bacteria are reduced, e.g. by the use of antibiotics to treat other infections, then the numbers of C.diff can increase causing disease.

**What are the symptoms of Clostridium difficile infection?**

C.diff causes diarrhoea, fever, loss of appetite, nausea and abdominal pain. It can also cause life-threatening inflammation of the bowel; however this is a rarer complication.

**Treatment of Clostridium difficile disease using antibiotics**

Treatment with the antibiotics metronidazole or vancomycin kills the C.diff bacteria. However, in some people diarrhoea returns a few days after stopping the antibiotics, this is called a recurrence. Recurrence can occur when the normal gut bacteria do not return to healthy levels, allowing any remaining C.diff bacteria to increase in numbers and cause symptoms again. Patients who have one recurrence are at increased risk of suffering from further recurrence of infection.

**Treatment of Clostridium difficile disease using a Faecal Microbiota Transplant**

A Faecal Microbiota Transplant (FMT) is a filtered suspension of donated faeces prepared in the laboratory at the University of Birmingham. The normal bacteria in the donated faeces replace the bacteria which are missing in the gut of the patient, competing with C.diff and preventing it from growing. As C.diff is unable to grow it cannot cause the symptoms of infection and the diarrhoea stops. This is a novel treatment for CDI.

The symptoms of C.diff infection are stopped in around 91% of patients who receive FMT treatment, compared to only 30–40% of patients who receive antibiotic treatment. Patients usually see improvement in their diarrhoea within 24–72 hours after the FMT. Flatulence, belching and/or constipation may be experienced in the days following FMT.

**What’s involved in FMT treatment?**

Faeces donors are anonymous, healthy adults, between the ages of 18 and 50, who have not taken antibiotics in the last 3 months and have had no recent change in bowel habit. They are screened for gut infections and for infections that can be transmitted by bodily fluids (usually blood), including Hepatitis A, B, C, E, HIV and syphilis. Only those negative for these infections will be allowed to be donors.

The patient will be given vancomycin antibiotic tablets for four days before FMT, which will stop the night before treatment. FMT can be given to a patient either by a tube inserted through the nose, down the throat and into the stomach (called a nasogastric tube) or via an endoscope camera which is inserted into the bowel via the rectum (called colonoscopy). When given by nasogastric tube the patient will receive a tablet of omeprazole on the morning of treatment to reduce the amount of stomach acid which could kill the bacteria being given in the FMT. A tablet of Domperidone will also be given to promote stomach emptying into the small intestine. The nasogastric tube is placed into the stomach the morning of the procedure and a syringe containing the FMT is connected to the nasogastric tube. The FMT is administered down the tube. The patient should not smell or taste the FMT. The nasogastric tube is then flushed with saline and removed.

When a FMT is administered by colonoscopy the patient is given a bowel preparation liquid to drink before the colonoscopy, this clears the bowel of faeces. During the procedure the endoscope camera is inserted into the large bowel via the rectum. The FMT treatment is then be sprayed into the bowel via the endoscope.

**What are the risks of treatment?**

There is a theoretical risk of transmission of a pathogen from the donor to the recipient. Donors are screened for common infections spread by blood and faeces and restricted from donating if any are detected. Donors undergo clinical, social and travel risk assessment and are only allowed to donate if there are no additional risks for infection found. However, there may be unrecognised pathogens in the FMT, which could cause infection in the recipient.

To date FMT has been used for the treatment of C.diff infection in many research studies and clinical trials. Although FMT is sometimes associated with mild self-limiting gastro-intestinal symptoms no significant safety concerns have come to light.

If FMT is delivered by a nasogastric route there is a very small risk of perforation from placement of the nasogastric route. If FMT is delivered by colonoscopy this carries risks associated with the colonoscopic procedure. These would include the risks of sedation and the small risk of bowel perforation. The risks of causing serious harm associated with colonoscopy are very low and will be discussed with you by your medical team.

**What will happen after FMT treatment?**

FMT is a new treatment and it is therefore important to understand if the treatment works. In addition to any routine clinical follow up you may have, your doctor will complete a FMT specific questionnaire about your progress 90 days after your FMT treatment. To complete this questionnaire your doctor will ask you questions about your health after FMT, any side effects of the treatment and how satisfied you were with the treatment. This data will be collected by your doctor and used in audit. Your treatment outcome data will be anonymised in this questionnaire.