



Clinical application of FMT

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Follow the faeces





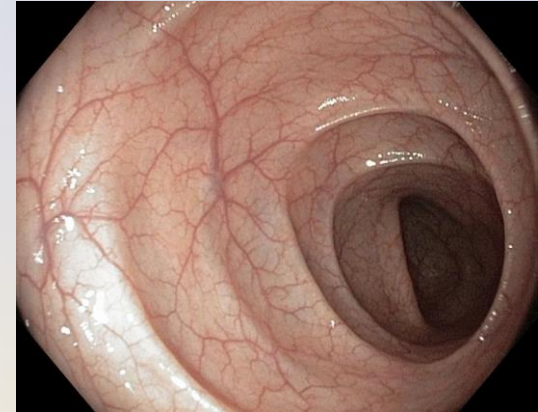
Clinical indications: *C. difficile*

EDQM recommendation, routine use:

1. Recurrent *C. difficile* (second recurrence)
2. Refractory *C. difficile*
3. Fulminant *C. difficile*

Additional routine use (AUH):

1. First or second *C. difficile* infection
2. Multidrug resistance (ESBL)





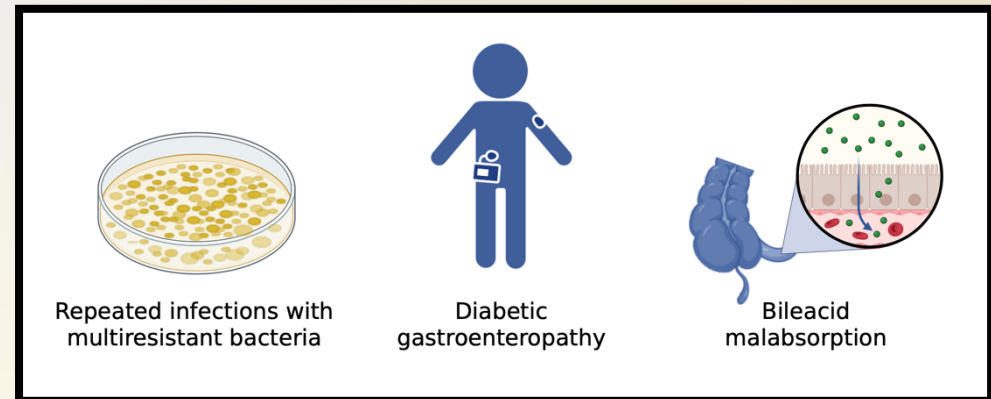
Clinical indications: Expanded access

An individualised healing attempt in other conditions beyond *C. difficile*

General principles for expanded access:

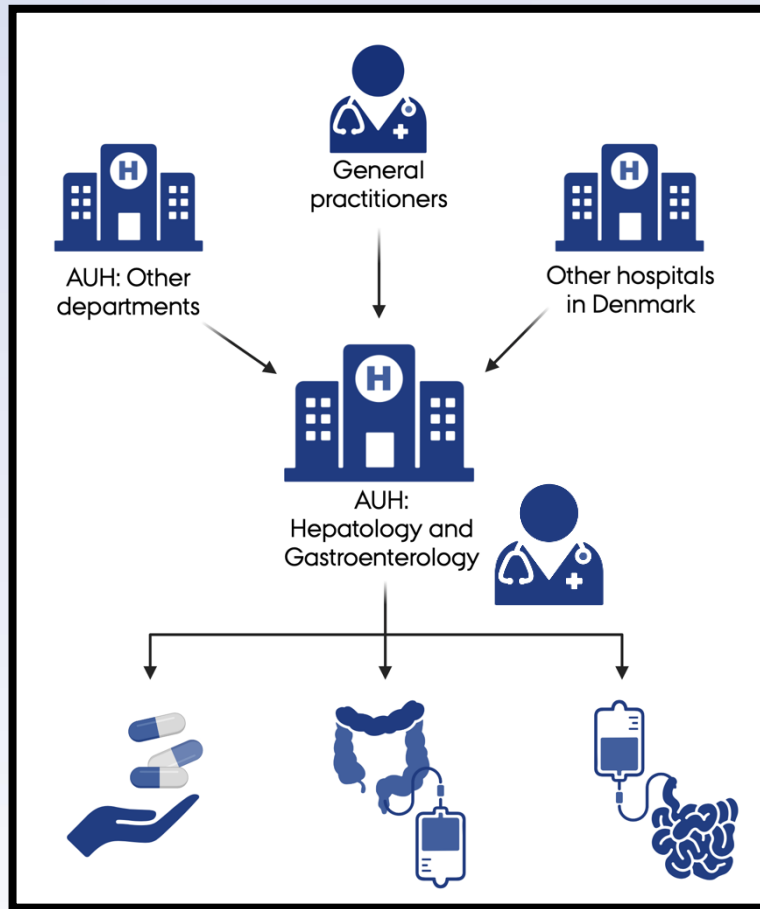
1. The patient's condition should be related to a disrupted intestinal microbiota
2. The use should be supported by clinical or experimental evidence
3. An expert panel should evaluate and document the indication

EDQM: Recommendation





Patient referral – and FMT prescription



Prescribing an FMT (physician)

1. Application method
2. Treatment setting (outpatient clinic/hospitalisation)
3. Single or serial treatment
4. Patient factors (Discontinuation of PPI and non-CDI antibiotics)

EDQM: Good Practice Guidelines



Choosing the application method

1. No capsule FMT for a patient with swallowing difficulties
2. No upper GI administration for a patient with severe small bowel dysmotility

EDQM: Good Practice Guidelines



Capsules



Nasojejunal tube



Colonoscopy



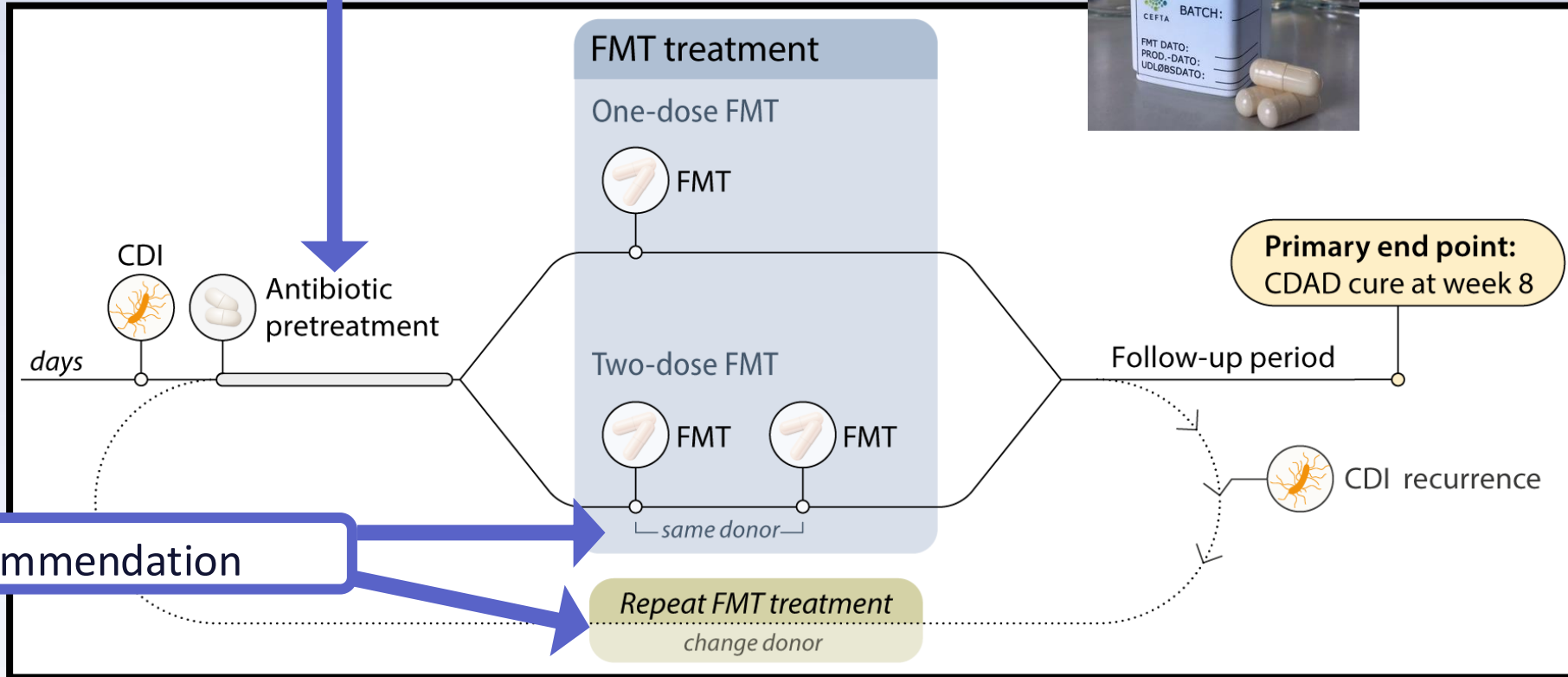
Clinical application: capsules





Treatment strategy

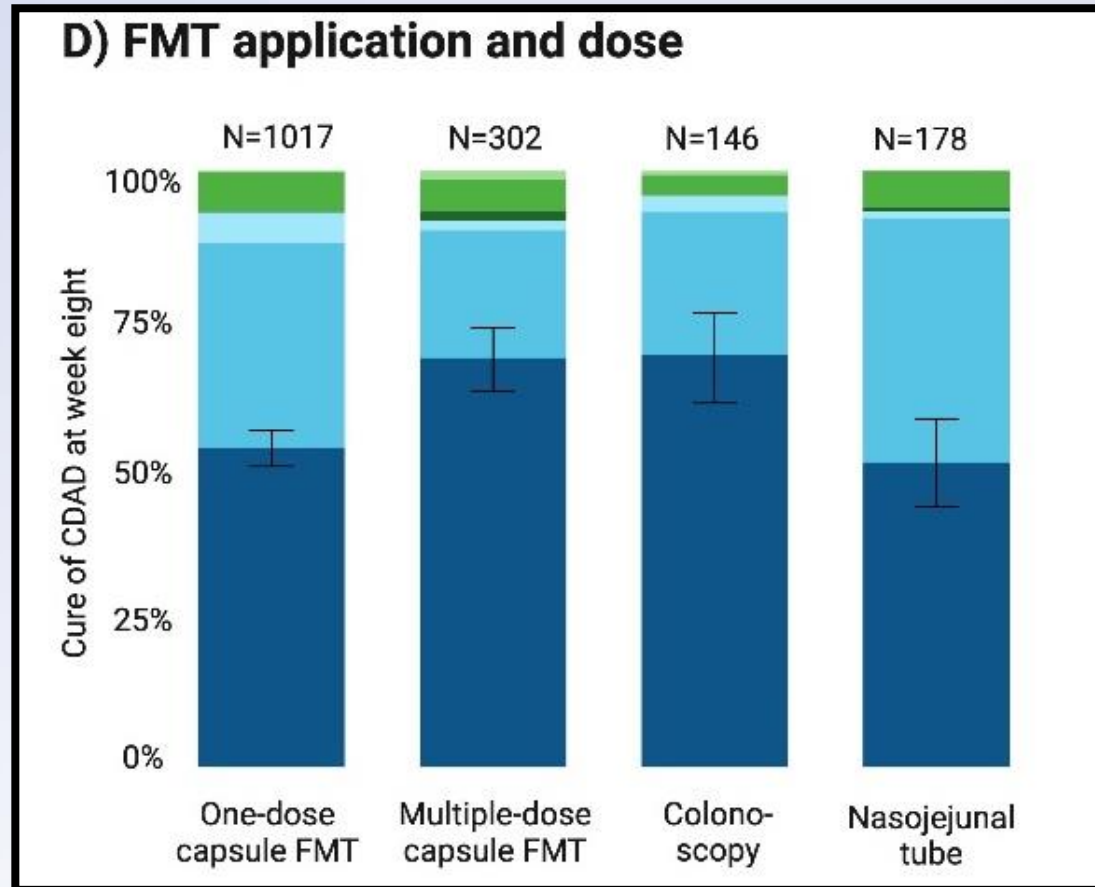
EDQM: Good Practice Guidelines



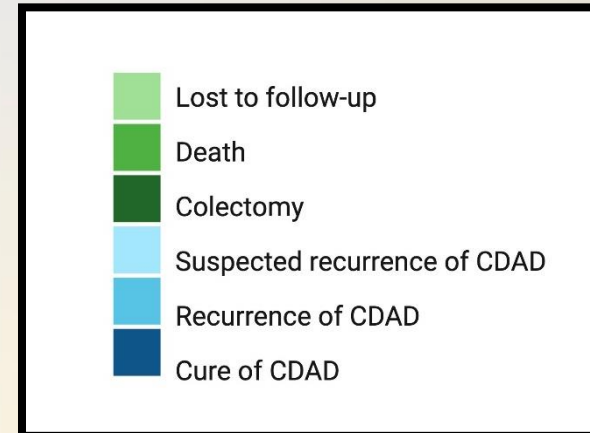
EDQM: Recommendation

Paaske et al., Clin Gastroenterol Hepatol 2025; 23: 602-11.e8.

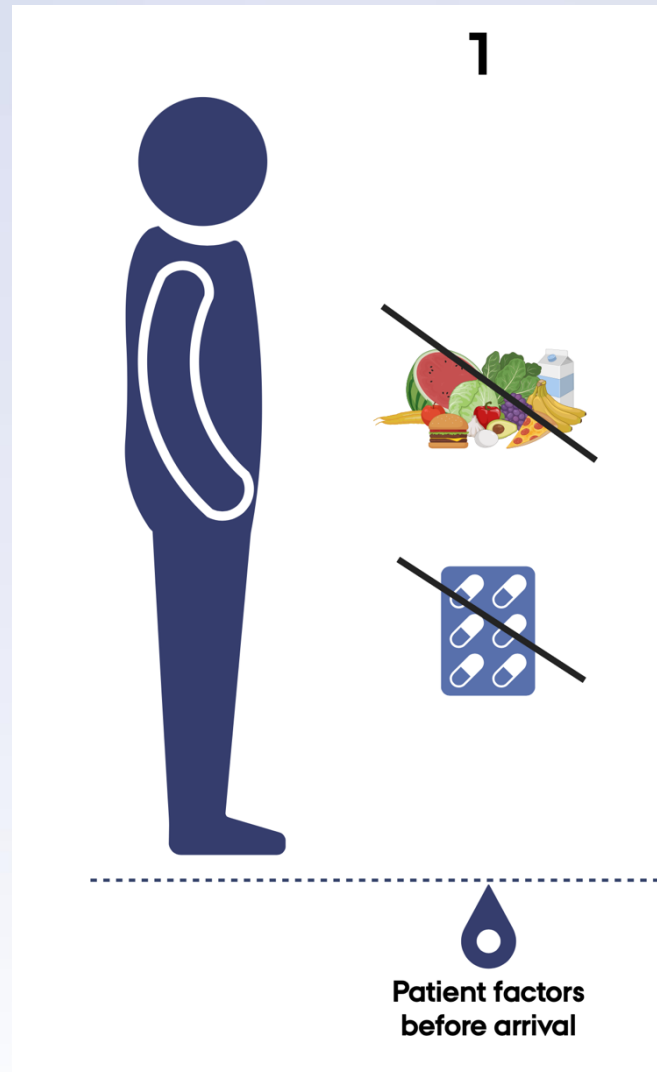
Treatment strategy...continued



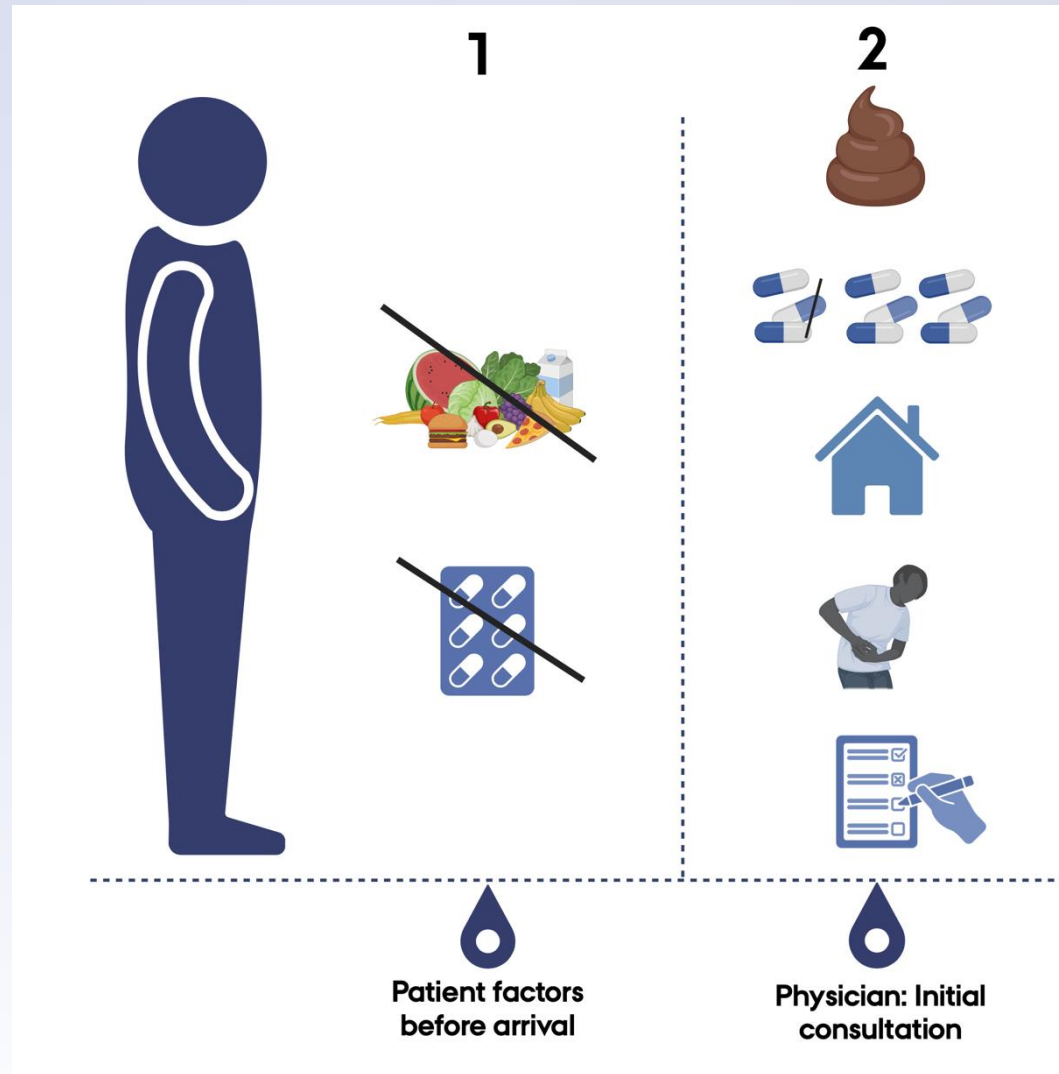
Paaske SE, EClinicalMedicine. 2025 Jun 19;85:103302.



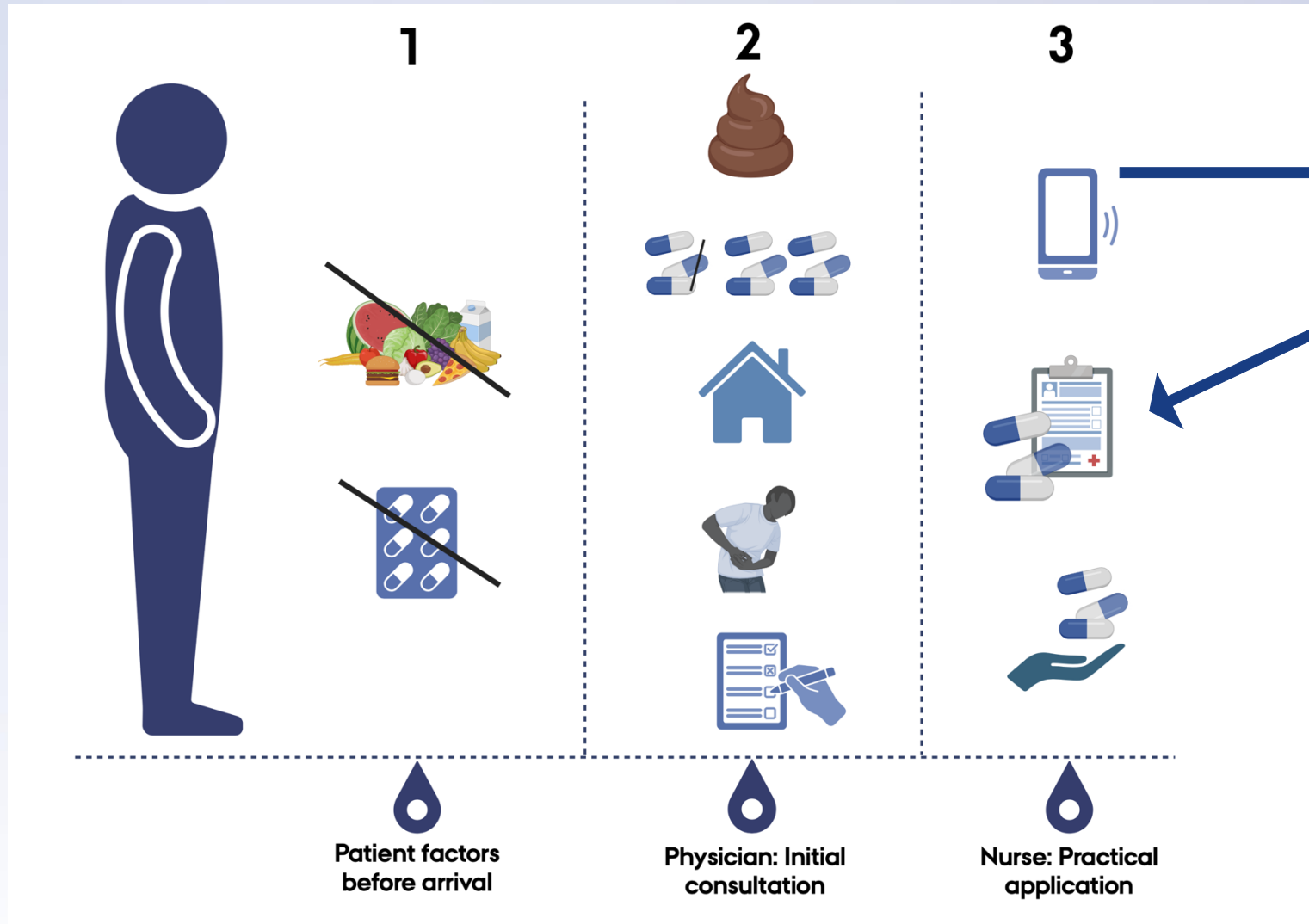
Patient preparation



Patient preparation

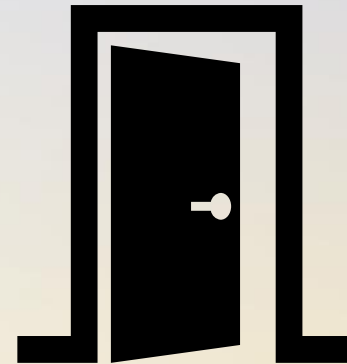
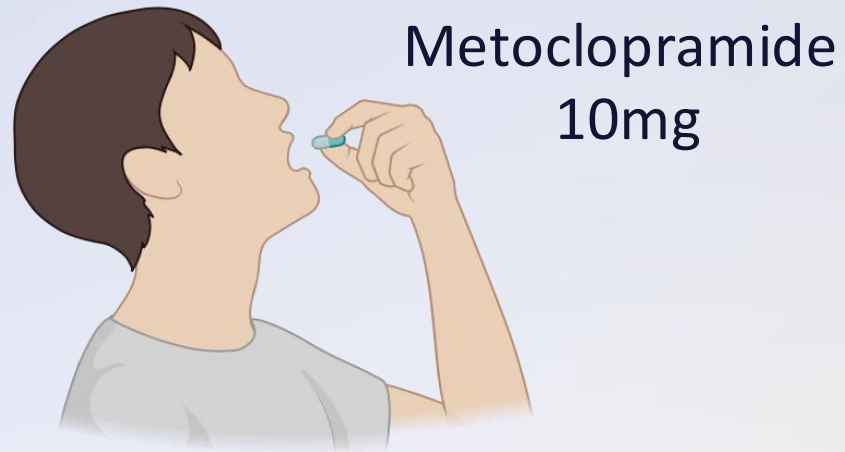


Patient preparation





Practical application



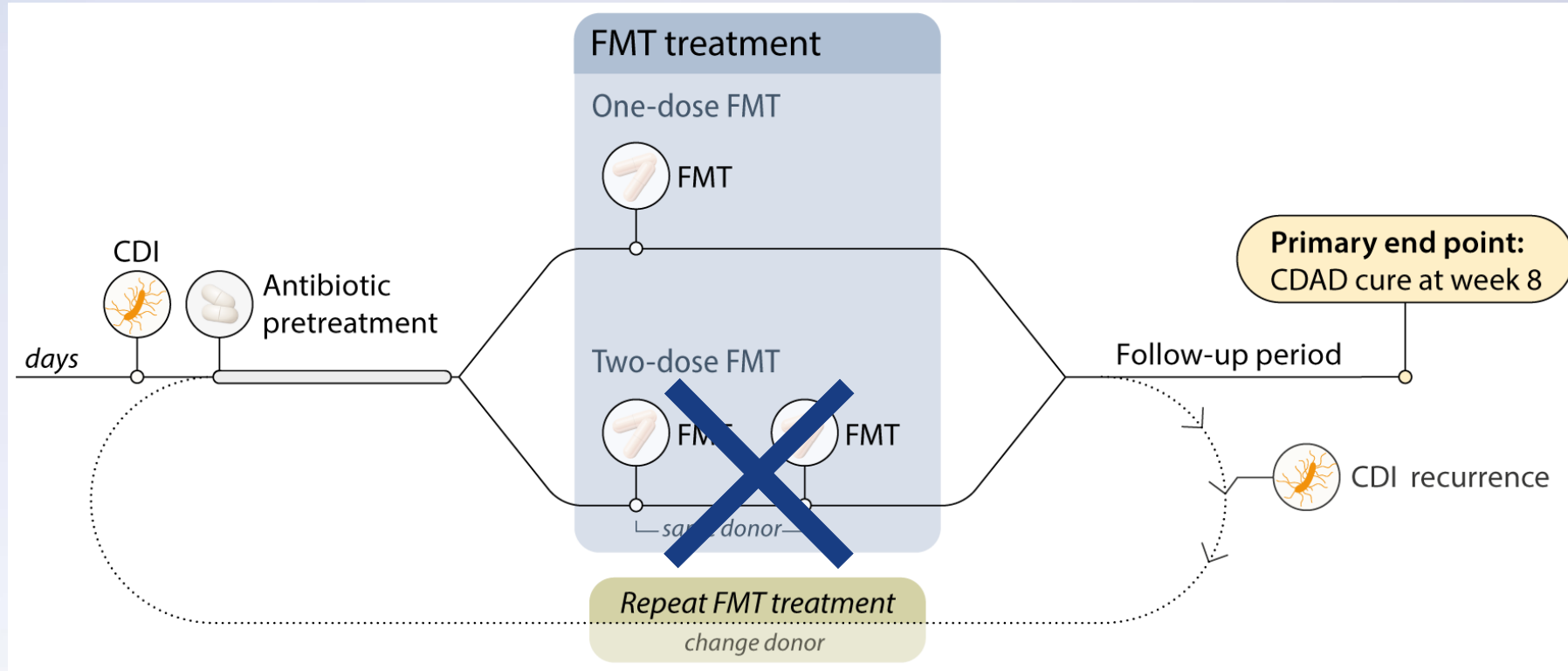


Clinical application: Cryobags





Cryobag application – one dose only



Paaske et al., *Clin Gastroenterol Hepatol* 2025; 23: 602-11.e8.



Upper application – nasojejunal tube

Patient preparation – as for the capsule administration!

Nasojejunal tube (Bengmark):

1. Placement 1-3 days before treatment
2. X-ray to ensure correct placement



EDQM: Good Practice Guidelines

FMT administration:

1. Metoclopramide 10mg
2. Positioned upright (at least 45°)
3. FMT infusion (10 min)
4. Observation: 30 minutes (2 hours in upright position for diminishing the risk of aspiration)





Lower application - colonoscopy

Patient preparation – as for the capsule administration!



Colonoscopy preparation:

1. Bowel cleansing

EDQM: Good Practice Guidelines

FMT administration:

1. NO Metoclopramide
2. FMT infusion: Right colon if possible
3. Observation: 60min (the first 30min on the right side).



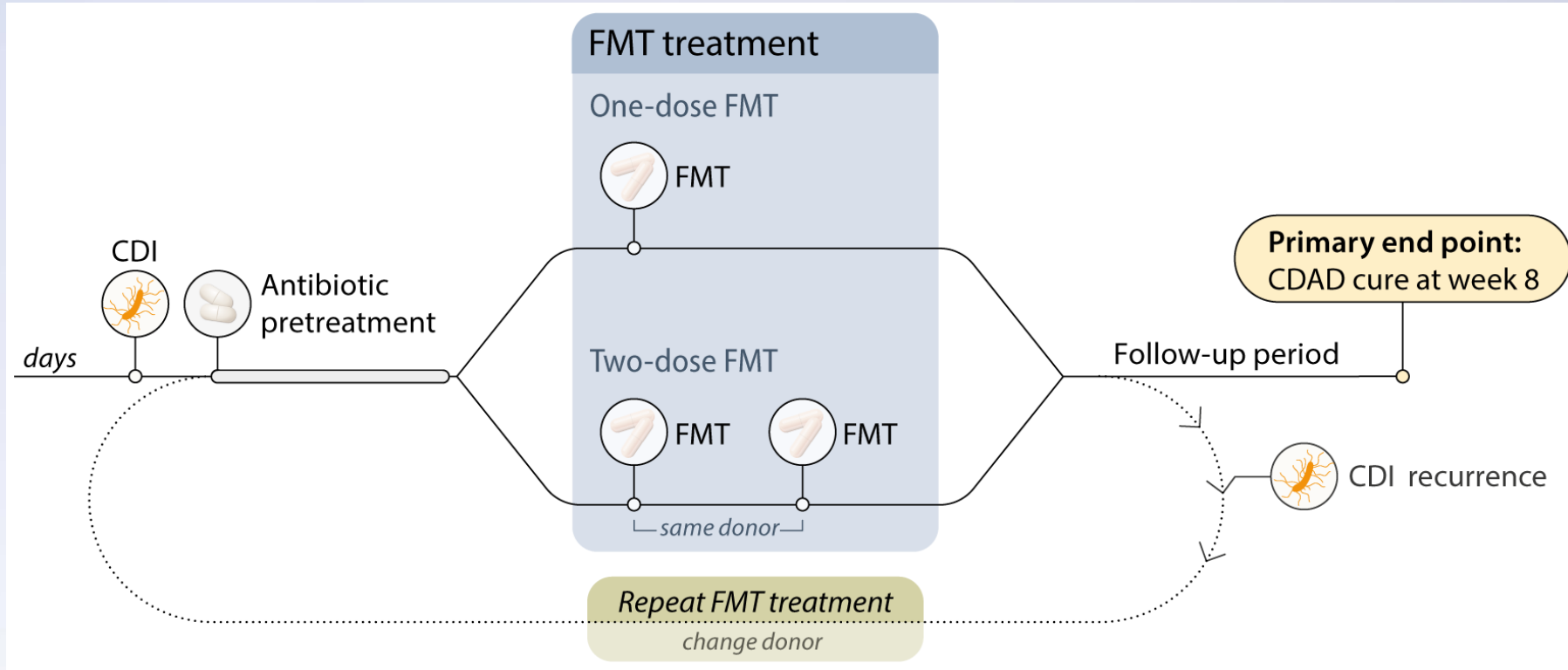


Follow-up



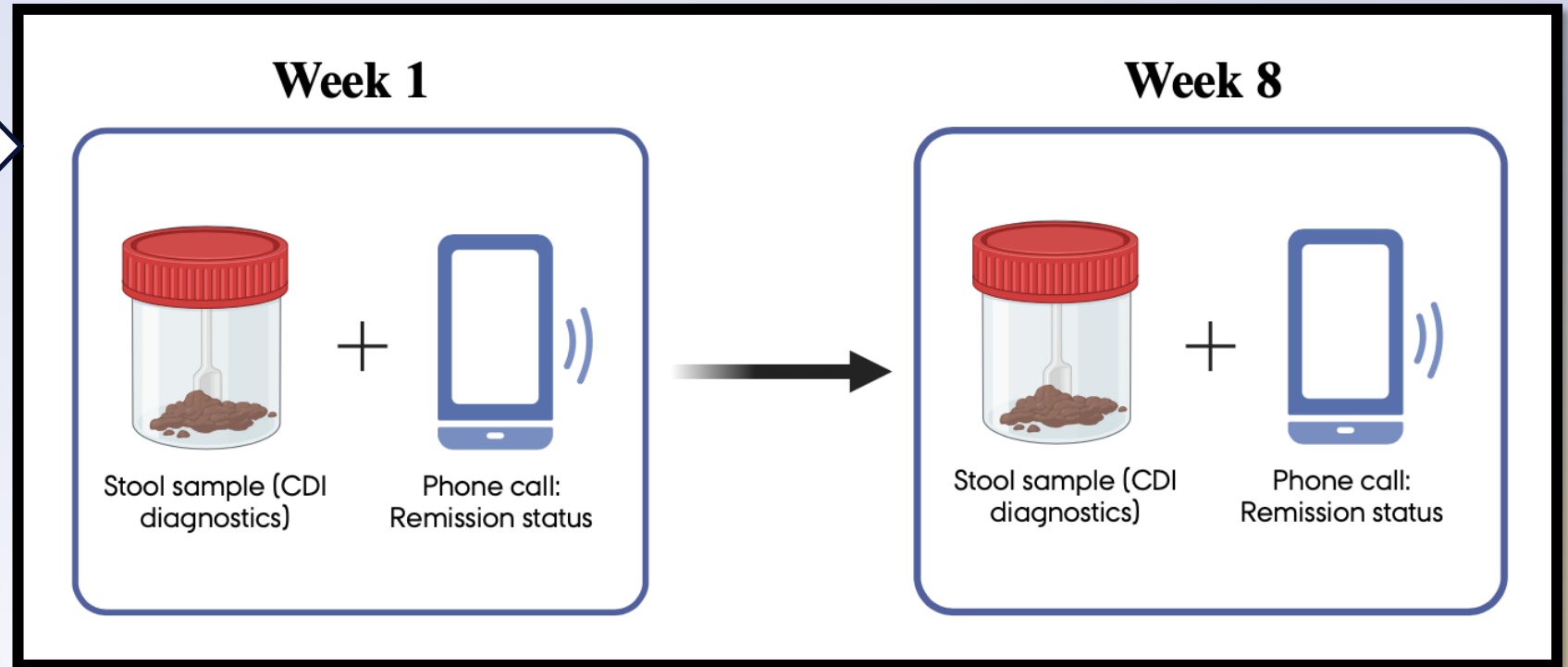
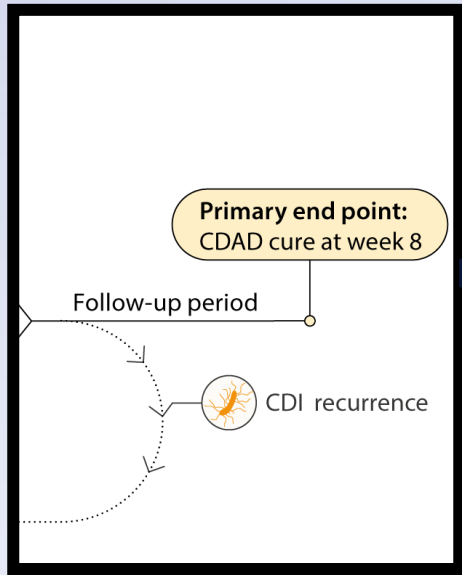


Follow-up strategy





Follow-up strategy



Administrative follow-up after 2 years

General clinical application principles in the SoHO regulation



1. The departments providing clinical application of FMT are considered SoHO entities and must register their activity with their national competent authority (**SoHO Art. 35.1**)
2. A responsible physician must be appointed (**SoHO Art. 50.1-50.4**)
3. Recipient consent must be received in accordance with national legislation (**SoHO Art. 58.15**)
4. Clinical outcome data must be collected and reported to the health authorities (**SoHO Art 41.1**)
5. Monitoring, registration and communication of adverse events must be performed (**SoHO Art. 44.1, Art. 44.2, and Art. 44.4**)
6. There should be a system in place for ensuring full traceability between donor and recipient for a minimum of 30 years (**SoHO Art. 42.2, Art. 42.6**)

What are the main challenges concerning clinical application at your FMT centre?

