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in **HEALTHCARE**  
**HONG KONG**



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香港中文大學醫學院  
**Faculty of Medicine**  
The Chinese University of Hong Kong

# Implementation of a New Intestinal Microbiota Transplantation Service in Hong Kong

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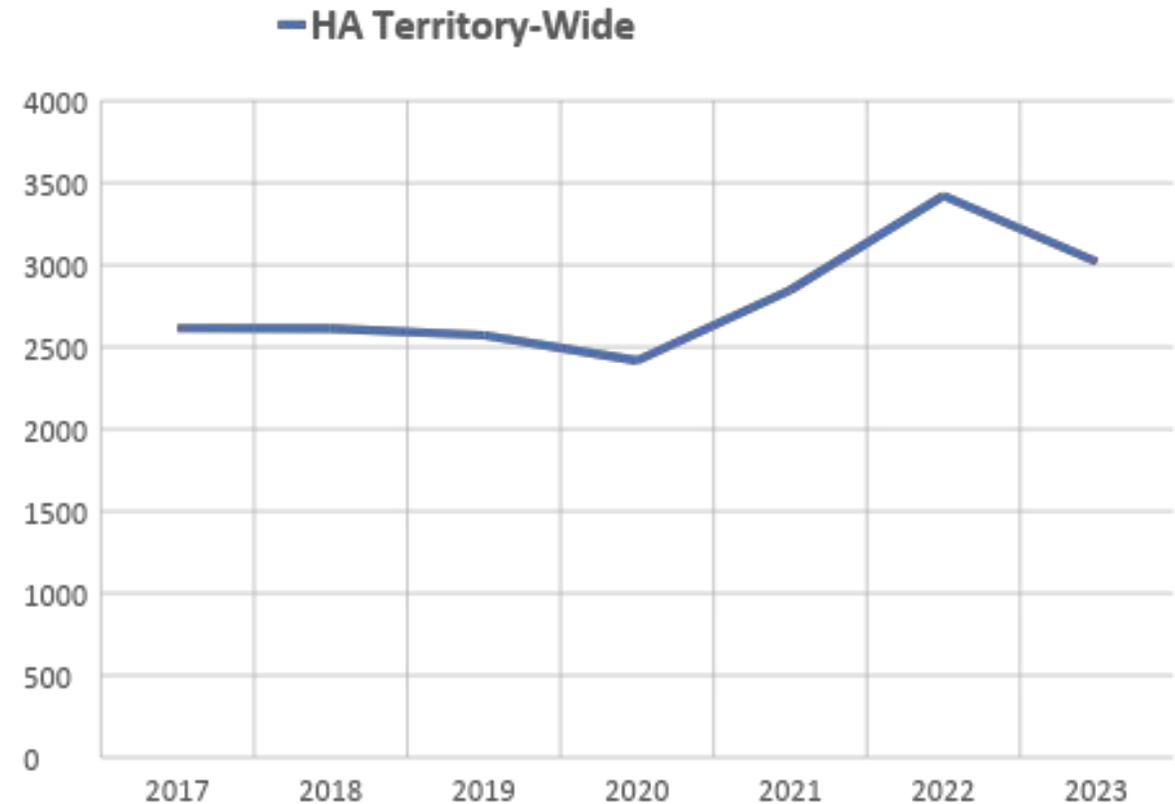
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Clinical Assistant Professor (Honorary), Department of Medicine and Therapeutics, Prince of Wales Hospital

Coordinator, Hospital Authority Faecal Microbiota Transplantation Service

@RashidLui

# Latest *C. difficile* infection (CDI) caseloads in Hong Kong (HK)

- Public sector data in 2023:  
~12% positivity rate of CDI for acute hospitals
- Territory-wide > 3,000 cases
- Healthcare related in ~ 90%<sup>1</sup>
- Recurrence rate ~ 10%<sup>1</sup>



Data from the Centre for Health Protection. Accessed Aug 2024  
1 Guo CLT et al. Emerg Infect Dis. 2021 Dec;27(12):3036–44

# The NEW ENGLAND JOURNAL of MEDICINE

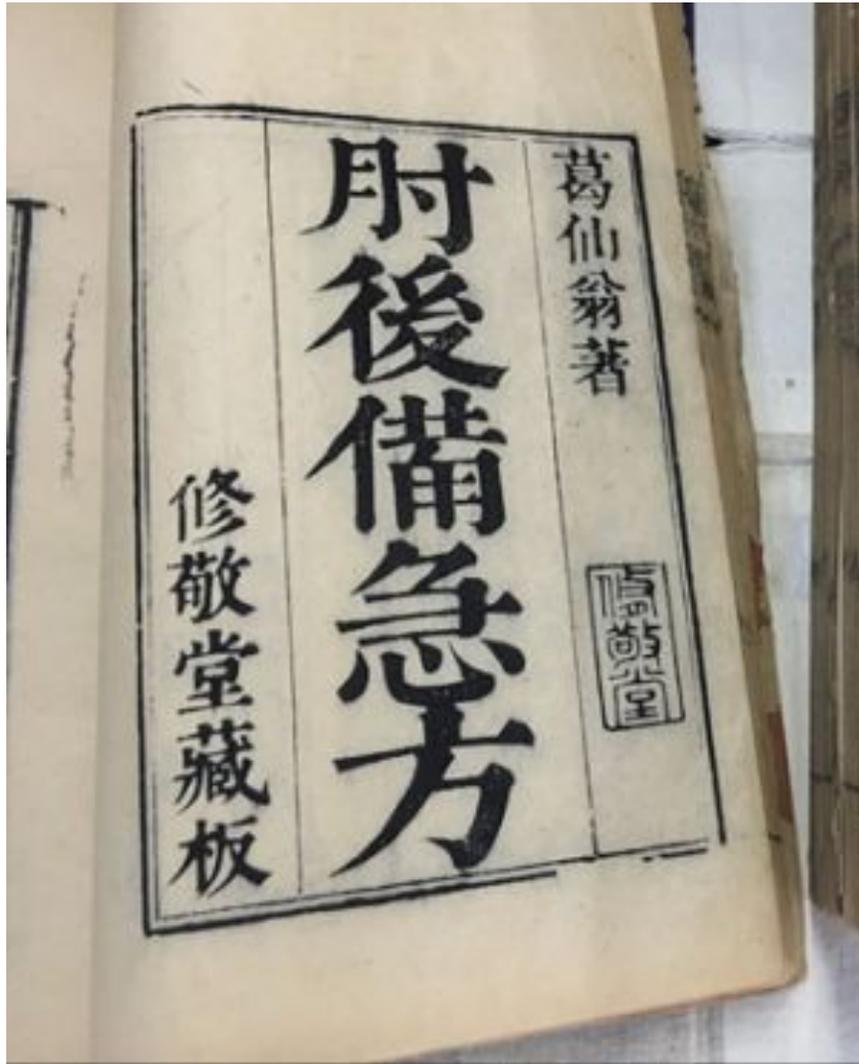
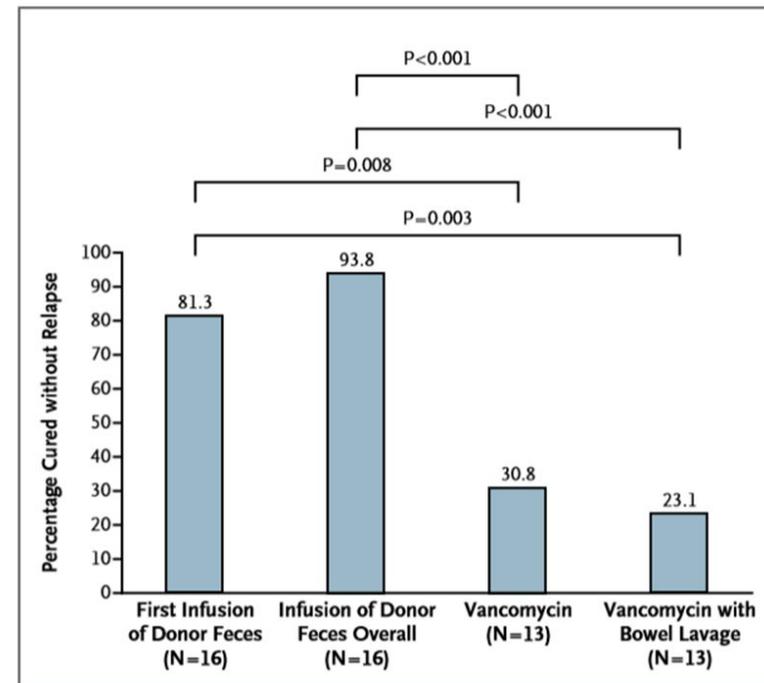
ESTABLISHED IN 1812

JANUARY 31, 2013

VOL. 368 NO. 5

## Duodenal Infusion of Donor Feces for Recurrent *Clostridium difficile*

Els van Nood, M.D., Anne Vrieze, M.D., Max Nieuwdorp, M.D., Ph.D., Susana Fuentes, Ph.D.,  
Erwin G. Zoetendal, Ph.D., Willem M. de Vos, Ph.D., Caroline E. Visser, M.D., Ph.D., Ed J. Kuijper, M.D., Ph.D.,  
Joep F.W.M. Bartelsman, M.D., Jan G.P. Tijssen, Ph.D., Peter Speelman, M.D., Ph.D.,  
Marcel G.W. Dijkgraaf, Ph.D., and Josbert J. Keller, M.D., Ph.D.

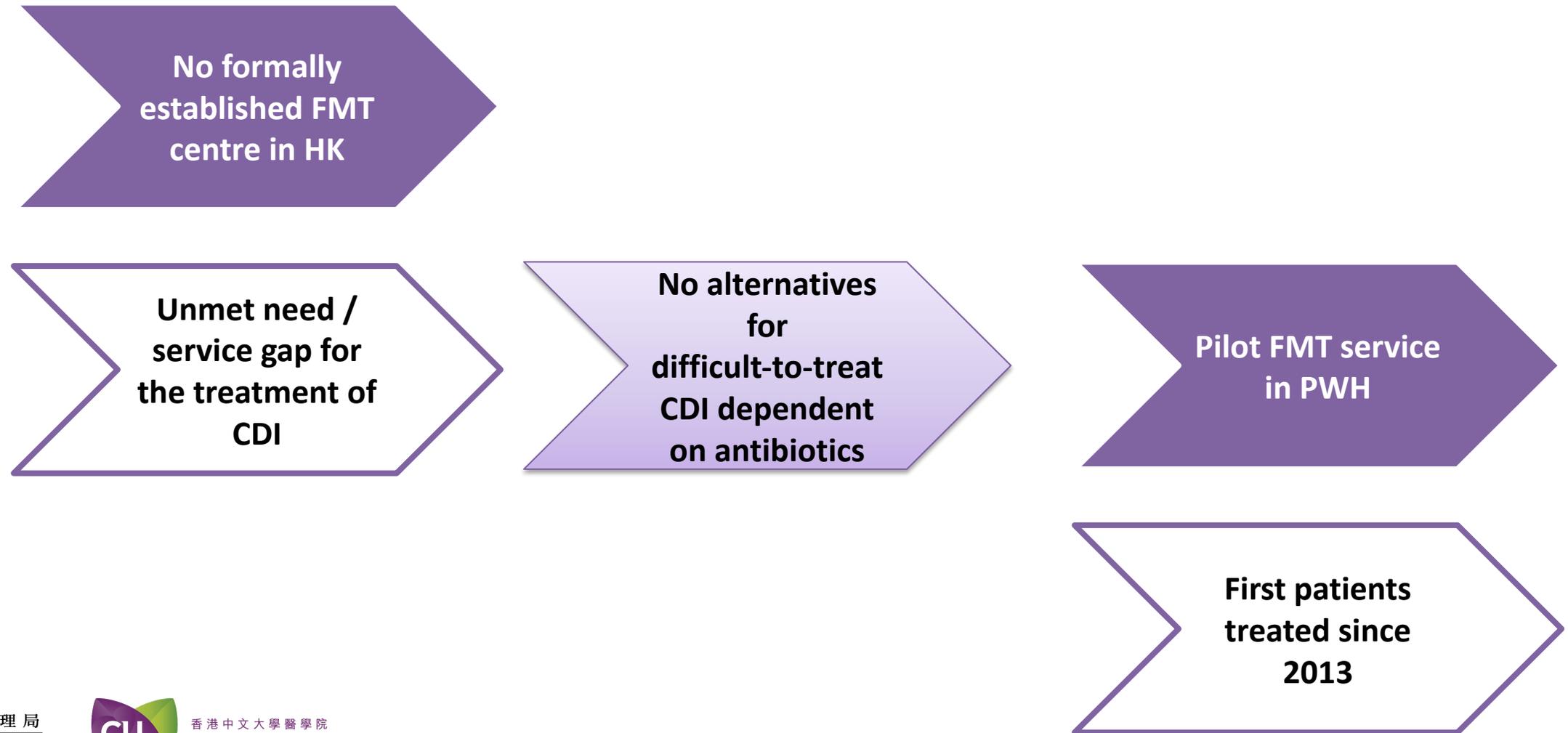


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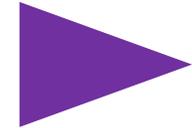




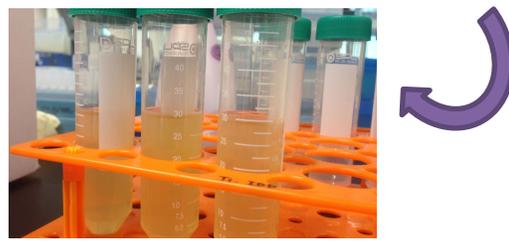
# Inception of a pilot Intestinal Microbiota Transplantation (IMT) / Faecal Microbiota Transplantation (FMT) service in PWH since 2013



# Initially used fresh stools from related donors

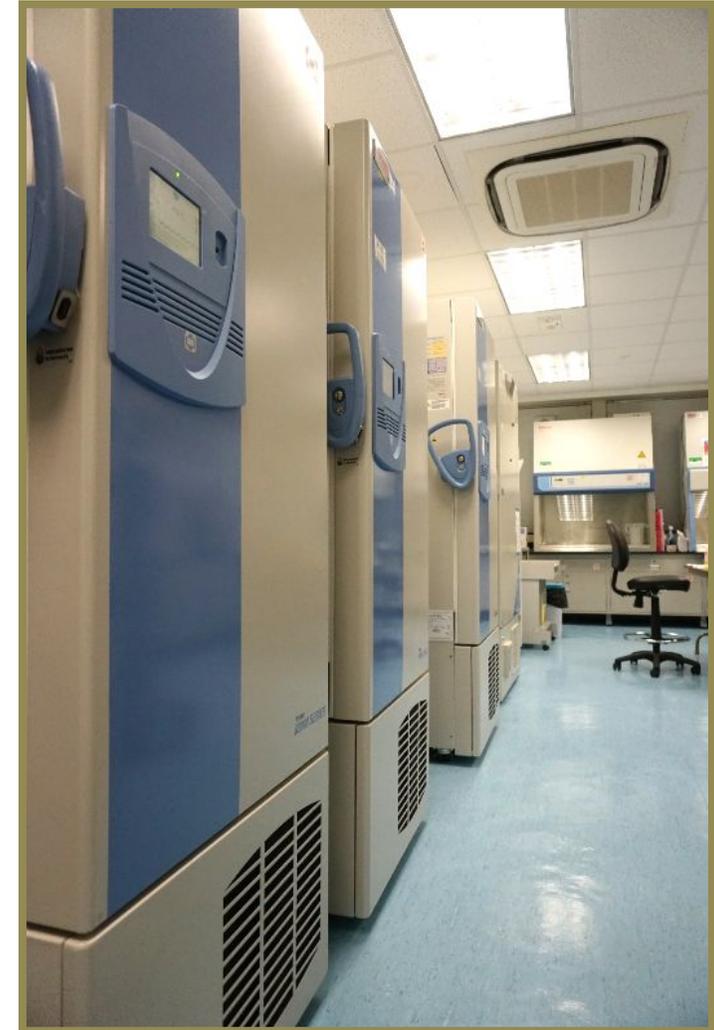


Frozen Stools



# Establishment of Stool Bank in CUHK

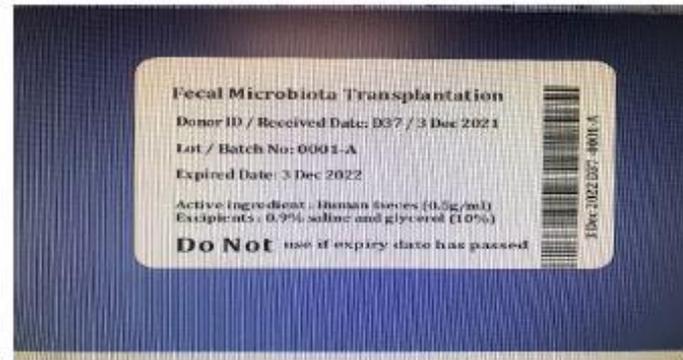
- Access by qualified personnel only
- Biosafety level 2
- Clean environment
- SOPs following international standards
- Strict donor selection
- Accredited testing
- Quality control procedures
- Traceability, archive & retro-testing systems



# Donor screening

- **General screening procedures**
  - Donor history questionnaire similar to blood donations
  - Screen for chronic diseases
    - CBC, LRFT, CRP, ESR, fasting bloods
  - Screen for risk of infection
- **Serology assays**
  - Viral hepatitis
  - HIV
  - HTLV
- **Stool assays**
  - Viral
  - C. difficile
  - Pathogenic bacteria
  - Parasites

# Final IMT product



## Name and Description of the Product:

Stool filtrate for fecal microbiota transplantation (FMT) 0.5g/mL in 50ml yellow-cap container

## Pack Size:

Each yellow cap container contains approximately 25g stool in a total volume of 50ml filtrate. The filtrate is prepared at a concentration of 0.5g of stool in 1.0ml of saline with the active ingredient of human feces (0.5g/ml) and excipients (90% saline and 10% glycerol).

# Results of our pilot IMT service

CME

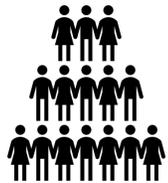
ORIGINAL ARTICLE

## Faecal microbiota transplantation for treatment of recurrent or refractory *Clostridioides difficile* infection in Hong Kong

Rashid N Lui, Sunny H Wong, Louis HS Lau, TT Chan, Kitty CY Cheung, Amy YL Li, ML Chin, Whitney WY Tang, Jessica YL Ching, Kelvin LY Lam, Paul KS Chan, Justin CY Wu, Joseph JY Sung, Francis KL Chan, Siew C Ng \*



Best Oral Presentation Award  
at HA Convention 2018



24 patients with recurrent or refractory CDI



Median age 70 years (IQR = 45.0-78.3 years)



> 80% recently hospitalised or long-term care facility residents



87.5% patients had resolution of diarrhea



Safe and well tolerated (no deaths within 30 days; 17% GI upset)

# Real-world data over 8 years from the Hong Kong FMT Registry

**Table 2.** Adverse Events Reported in the Short Term (Within 1 Month) and Medium Term (1–12 Months) After FMT

Adverse Event	Within 1 mo	1–6 mo	6–12 mo
Primary indication: recurrent <i>Clostridioides difficile</i> infection (n = 27)			
GI symptom	10 (40.0)	12 (60.0)	5 (27.8)
Diarrhea	6 (24.0)	9 (45.0)	2 (11.1)
Constipation	0	0	1 (5.6)
Abdominal pain	6 (24.0)	5 (25.0)	3 (16.7)
Abdominal bloating	1 (4)	2 (10.0)	0
Nausea and vomiting	1 (4)	2 (10.0)	1 (5.6)
IBD flare	0	4 (20.0)	2 (11.1)
Septicemia	0	1 (5.0) <sup>a</sup>	1 (5.6)
Death	0	2 (10.0) <sup>b</sup>	1 (5.6) <sup>c</sup>
Related to FMT	0	0	0
Not related to FMT	0	2	1
Primary indication: obesity and type 2 diabetes mellitus (n = 48)			
GI symptom	3 (6.4)	1 (2.2)	1 (2.2)
Diarrhea	2 (4.3)	0	1 (2.2)
Constipation	2 (4.3)	0	0
Abdominal pain	0	0	1 (2.2)
Nausea and vomiting	0	1 (2.2)	0
Primary indication: irritable bowel syndrome (n = 36)			
GI symptom	3 (8.6)	0	0
Diarrhea	3 (8.6)	0	0
Abdominal bloating	1 (2.9)	0	0
Primary indication: others (n = 12) <sup>d</sup>			
GI symptom	2 (25.0)	1 (14.3)	2 (33.3)
Diarrhea	2 (25.0)	1 (14.3)	2 (33.3)
Abdominal pain	2 (25.0)	0	2 (33.3)
Abdominal bloating	1 (12.5)	0	0
IBD flare	2 (25.0)	0	1 (16.7)

## Low medical conditions beyond 12 months

New onset condition	Event	Rate (95% CI, per 1000 person-years)	Follow-up duration (month, median)
Primary indication: Recurrent <i>Clostridioides difficile</i> infection (n=27)			
Eczema	1	19.3 ( 0.5 - 107.3 )	23.13
Fatty liver	1	19.3 ( 0.5 - 107.3 )	43.85
Thyroid	1	19.3 ( 0.5 - 107.3 )	43.85
Epilepsy	1	19.3 ( 0.5 - 107.3 )	43.85
Colonic IBD	1	19.3 ( 0.5 - 107.3 )	43.85
Obstructive chronic disease	1	19.3 ( 0.5 - 107.3 )	43.85
Bullous skin disease	1	19.3 ( 0.5 - 107.3 )	43.85
Fatty liver	1	19.3 ( 0.5 - 107.3 )	43.85
Knee and joint disease	1	19.3 ( 0.5 - 107.3 )	43.85
Hypertension	1	19.3 ( 0.5 - 107.3 )	43.85
Gastroesophageal reflux disease	1	19.3 ( 0.5 - 107.3 )	43.85
Perianal abscess	1	19.3 ( 0.5 - 107.3 )	43.85
Myeloma	1	19.3 ( 0.5 - 107.3 )	43.85
Cervical radiculopathy	1	20.9 ( 0.5 - 116.6 )	41.91
Fasciitis	1	20.9 ( 0.5 - 116.6 )	46.41
Acute nephritis	1	20.9 ( 0.5 - 116.6 )	31.38
Primary indication: Others (n=12)			
Fatty liver	1	39.1 ( 1 - 218 )	27.93
Intraductal papillary mucinous neoplasm	1	39.1 ( 1 - 218 )	21.61
Osteonecrosis	1	39.1 ( 1 - 218 )	26.68

Values are n (%).

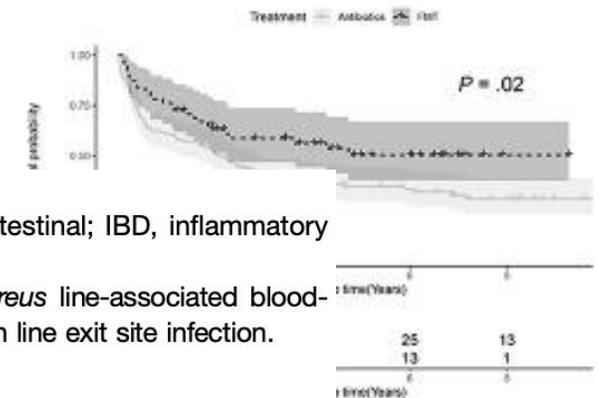
FMT, fecal microbiota transplantation; GI, gastrointestinal; IBD, inflammatory bowel disease.

<sup>a</sup>Septicemia: methicillin-resistant *Staphylococcus aureus* line-associated bloodstream infection (about 4 months after FMT) Hickman line exit site infection.

<sup>b</sup>Cause of death (1–6 months): 2 pneumonia.

<sup>c</sup>Cause of death (6–12 months): 1 pneumonia.

<sup>d</sup>Inflammatory bowel disease; vancomycin-resistant *Enterococcus*/carbapenem-resistant Enterobacteriaceae infections; graft-vs-host disease; autism.



It was associated with a significantly higher cumulative survival probability compared with matched controls.

Clinical Gastroenterology and Hepatology

# HA implementation of FMT in phases

6/2023

9/2023

1/2024 and beyond



## Tender Phase

## Pilot phase

## Implementation phase

Drafting of corporate protocols and other documents

Commissioned training & practicum

Roll out of service to other acute hospitals and clusters

Kickstart of HA service 10/2023 (PWH)

Regular monitoring and review of FMT service

Dry run of logistics in PWH

Adapt existing protocol for corporate use

# Current HA service indications for IMT

$\geq 2$

## Recurrent CDI

- Defined as at least 2 episodes of *C. difficile* infection

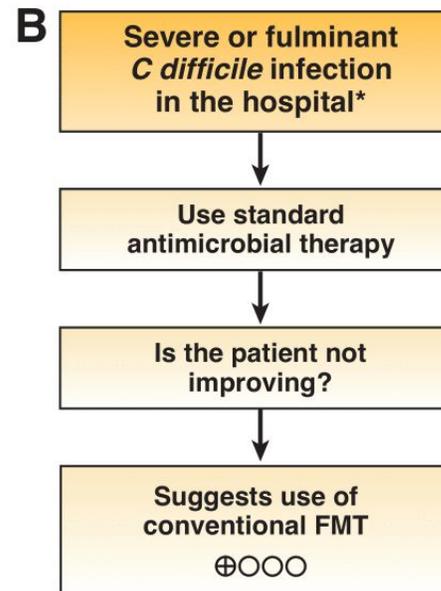
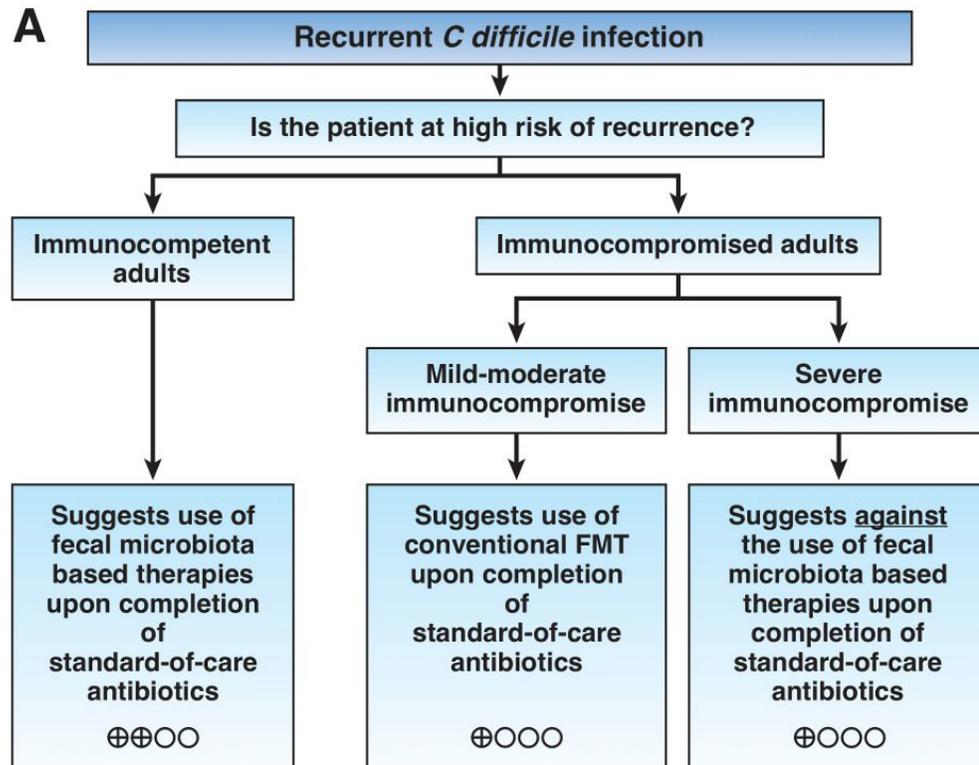


## Refractory CDI

- Not responding to conventional therapy, or
- Severe and fulminant disease

# Latest AGA guideline

## Clinical Decision Support Tool Consideration for Use of Fecal Microbiota Based Therapies in Adults With GI Disorders

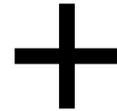


\*Severe CDI is defined as patients with a leukocyte count  $\geq 15 \times 10^9$  cells/L and/or creatinine  $\geq 1.5$  mg/dL. Fulminant CDI presents as severe disease with shock, ileus, or megacolon.

The panel intentionally refrains from limiting fecal microbiota–based therapies to after the second recurrence. Some patients are at increased risk of recurrence and/or morbid recurrence and may benefit from fecal microbiota–based therapy after the initial CDI episode or first recurrence. Select patients who may benefit from earlier therapy for prevention include those recovered from severe, fulminant, or CDI more refractory to standard treatment. Patients with significant comorbidities recovered from CDI may also benefit from earlier fecal microbiota–based therapies. However, those with recurrences driven by subsequent antibiotic administration may benefit from an alternative strategy to prevent CDI recurrence.

# Education, training and accreditation

Practicum



Course



## INTRODUCTION OF FAECAL MICROBIOTA TRANSPLANTATION SERVICE IN HA

7 OCTOBER 2023 / 9:15 AM – 12:15 PM  
Seminar Room 1, 2/F Lui Che Woo Clinical Sciences Building, PWH  
(Webinar is available)

*Faecal Microbiota Transplantation (FMT) is the instillation of processed stool from healthy donors to the intestinal tract of patients via endoscopy to treat patients with recurrent and refractory Clostridium Difficile Infection. HA is going to implement the service in 2023/24.*

All HA staff are welcome  
(Especially gastroenterologists, infectious disease specialists, microbiologists, ward and endoscopy nurses, pharmacists, lab staff, and etc.)

### Program Highlights:

- Latest Advances in FMT
- Treatment of C. difficile Infection
- Local Experience of FMT and Corporate Service Model

### Co-Directors & Invited Speakers



Prof Francis CHAN, SNS, JP  
CUHK



Dr Rashid LUI  
PWH



Dr Wyman HUI  
MED. AHNH



Mr Siu-fung LAM  
Endoscopy Centre, PWH



Dr Louis LAU  
GI, CUHK



Dr Joyce MAK  
GI, PWH



Dr Rita NG  
MIC, CUHK

For enquiry, please contact Ms Jaclyn Wu at 2300 6805 or Mr Chris Lau at 2300 6190

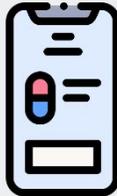
REGISTER NOW



Deadline: 3 October 2023

Approval for CME and CPD applications pending

### Patient Selection



Local GI Team to assess & select suitable patients (recurrent/refractory CDI)

Seek prior approval from FMT Service Coordinator

Local GI Team to make request to HKFMT Stool Bank (CUHK), prescribe via Local Pharmacy, book endoscopy

Accredited GI team personnel as hospital/cluster coordinator for FMT service

### Implementation and Aftercare



FMT administered by Local GI Team via endoscopy and completed in IPMOE

Monitor and care of patient's condition Repeat FMT if needed

Discharge patient and FU both by Local GI Team and at PWH GI IMT(FMT) clinics

### Payment Covered by Public Health Authority



### Local Pharmacy



- (2) IPMOE
- (3) Non-formulary drug form

### (4) Validation certificate

Issue Purchasing Order to Stool Bank (CUHK)

### Request for FMT



- (1) FMT request form

FMT and validation certificate received & signed by EC nurse

Consult PWH GI for opinion if complicated cases +/- takeover (quaternary referral centre)

### Courier Service (CUHK)

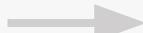


Stool Bank (CUHK) to liaise with GI team, ward and Endoscopy Centre to deliver FMT materials for the right patient, location, time

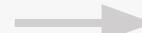
### HKFMT Stool Bank (CUHK) (designated site within HA premises)



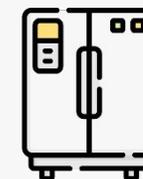
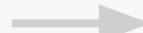
Assess donor



Collect stool



Test and prepare stool



Store processed stool at stool bank

Invoice



醫院管理局  
HOSPITAL  
AUTHORITY



香港中文大學醫學院  
Faculty of Medicine  
The Chinese University of Hong Kong

Stool collection, preparation & storage to follow international standards and benchmark with well-known organizations

# Standardized checklist on request form

## B. Indications for FMT (must choose ONE)

- Recurrent *C. difficile* infection (at least 2 episodes of moderate to severe infection)
- Refractory *C. difficile* infection
- Others (please specify: \_\_\_\_\_)

## C. Contraindications for FMT (ALL items must be NO)

Item	No	Yes	Contraindications for FMT
1.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Presence of ANY of the follow contraindications for endoscopy:</b> - Luminal perforation - Intestinal obstruction or severe ileus - Hemodynamic instability or compromised airway without support
2.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Life threatening food allergies or anaphylaxis</b>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Allergy to glycerin/glycerol</b>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Moribund condition with the patient not expected to survive for &gt; 4 weeks</b>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Significantly immunocompromised patients*</b>
6.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Younger than 18 years of age</b>
7.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Unable to provide informed consent (patient, next of kin, or legal representative)</b>
8.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Pregnant mothers</b>
9.	<input type="checkbox"/>	<input type="checkbox"/>	<b>Any condition where FMT may pose a significant health risk to the patient</b>

\*including but not limited to severe neutropenia  $< 0.5 \times 10^9/L$ , and human immunodeficiency virus infection with a CD4 count of  $< 200$ , clinical discretion is advised for other potentially immunocompromised states



# Clinical documentation

PR: no mass

CO2 insufflation. Poor bowel prep.

Scope to TI: NAD.

Throughout the cecum, ascending colon, transverse colon and descending colon, severe pseudomembranous colitis is noted. Right sided colon spacious but not overtly dilated. No obvious stricturing mass or large polyps seen.

100ml FMT solution infused via scope channel into the TI and cecum (Donor ID D26, FMT lot number 7; batch number B&C). No immediate complication.



# Endoscopic procedure coding

Category Keyword Help Feedback

Keyword: OGD Code: Find

ICD9CM	Description
	Therapeutic OGD
45.13	Esophagogastroduodenoscopy
45.16	OGD with biopsy
29.11	Panendoscopy, resp + upper GI
29.12	Panendoscopy + Bx, resp + upper GI
42.23	EUS, esophagus
42.24	EUS + biopsy, esophagus
44.13	EUS, stomach
44.14	EUS + biopsy, stomach
45.33	Endoscopic clipping - small bowel
45.33	Endo thermocoagulati - small bowel

Other OGD Procedures		Biopsy
<input type="checkbox"/>	Dilatation -- balloon dilator	<input type="radio"/> Yes
<input type="checkbox"/>	-- bougie	<input checked="" type="radio"/> No
<input type="checkbox"/>	-- others	
<input type="checkbox"/>	Insertion of stent	
<input type="checkbox"/>	Mucosectomy	
<input type="checkbox"/>	Submucosal dissection	
<input type="checkbox"/>	Polypectomy	
<input type="checkbox"/>	Radiofrequency ablation	
<input type="checkbox"/>	Removal of foreign body	
<input type="checkbox"/>	EHL for bezoar	
<input type="checkbox"/>	Intragastric balloon -- placement	
<input type="checkbox"/>	-- removal	
<input type="checkbox"/>	Percutaneous endoscopic gastrostomy	
<input type="checkbox"/>	Insertion of feeding tube	
<input type="checkbox"/>	Fibrin glue injection for fistula	
<input type="checkbox"/>	FNA	
<input checked="" type="checkbox"/>	Faecal microbiota transplantation	



# Prescription as a drug item

Start	Review	Drug	IP Prescribing History
05/Oct	-	<b>Fecal Microbiota Transplantation Materials</b> <Special Drug> as directed: at 11 a.m. for 1 DOSE(S) 50 grams via OGD	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
04/Oct	-	<b>Sodium Chloride 0.9%</b> continuous IV infusion: 500 mL Q12H while fasting	<input checked="" type="checkbox"/>
04/Oct	-	<b>Mesalazine (PENTASA)</b> prolonged release granules 2 g/sachet oral: 1 sachet(s) BD	<input checked="" type="checkbox"/>
04/Oct	-	<b>Frusemide (LASIX) tablet</b> oral: 20 mg daily PRN	<input checked="" type="checkbox"/>



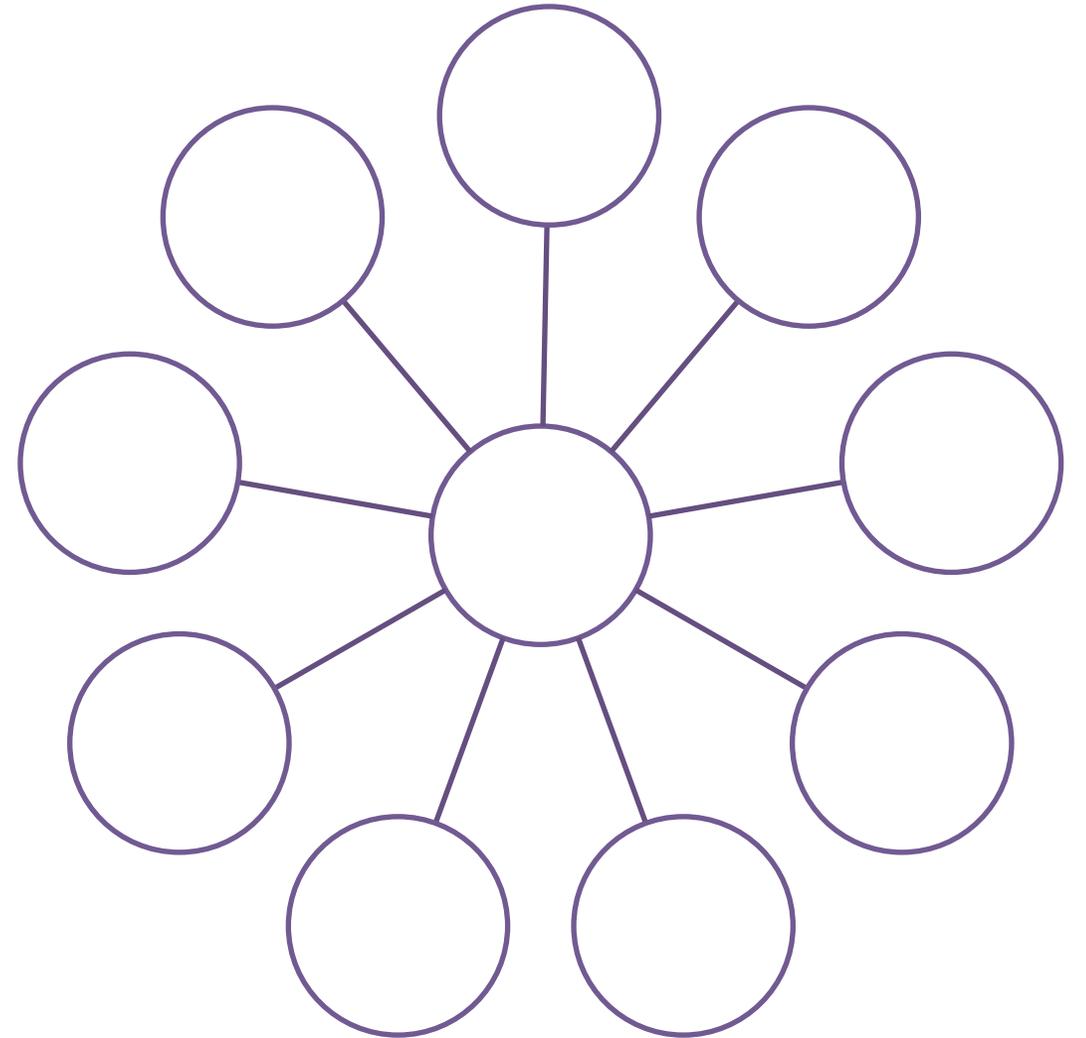
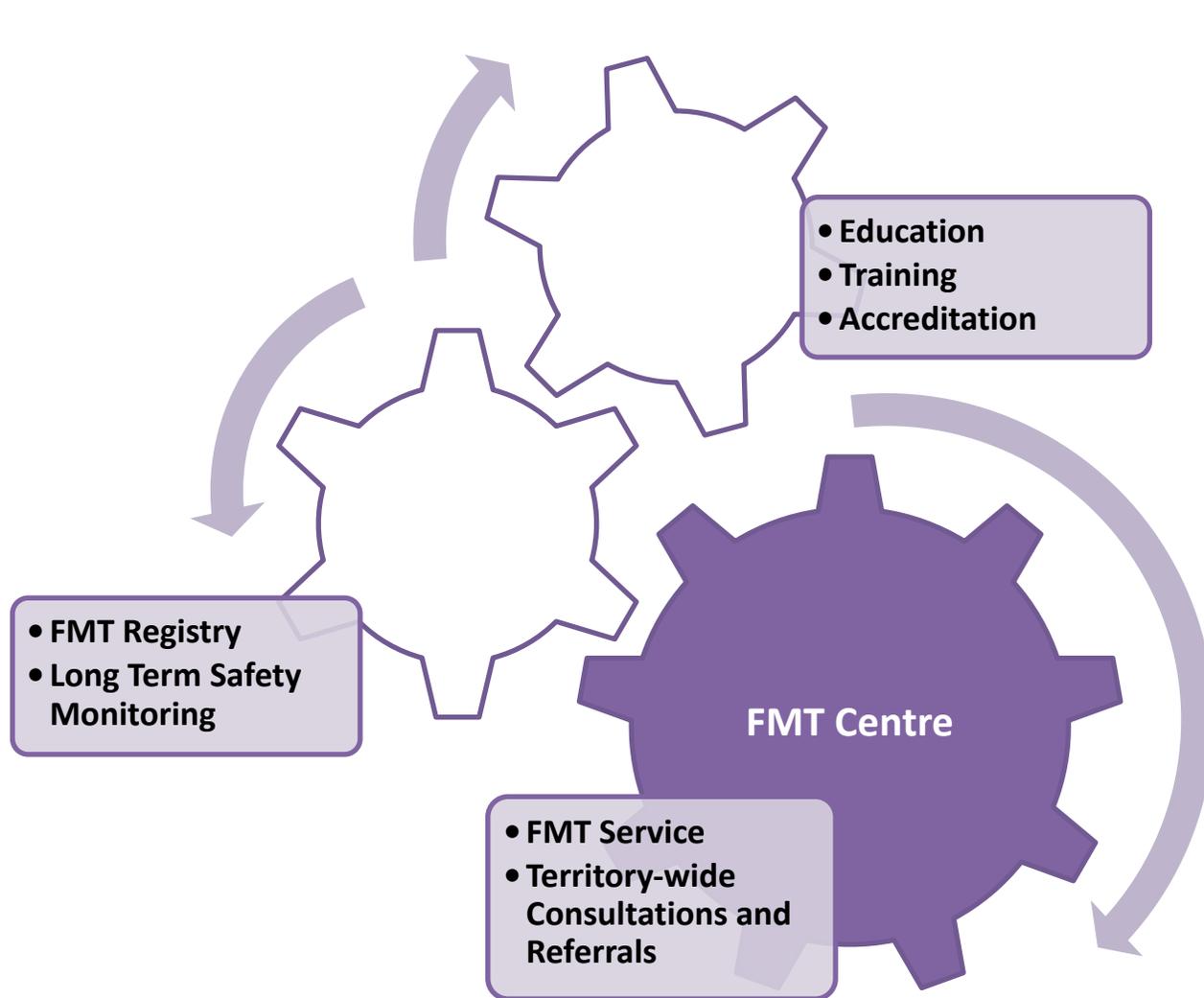
# Outcome assessment

- Resolution of diarrhea symptoms: typically within **48-72** hours
- Recheck stool for *C. difficile*: **NOT** routinely required
- For CDI with suboptimal response, a clinical decision may be made to repeat FMT (either same or different route) which is required in ~ 15-20% of patients

# Long-term safety monitoring

- **Pre-** and **Post-** FMT stool collection
- Arrange long term follow-up if possible
- Keep record of patients who have received FMT
- Audit clinical outcomes
- Recruit subjects into FMT registry in collaboration with CUHK (CREC: 2017.260)

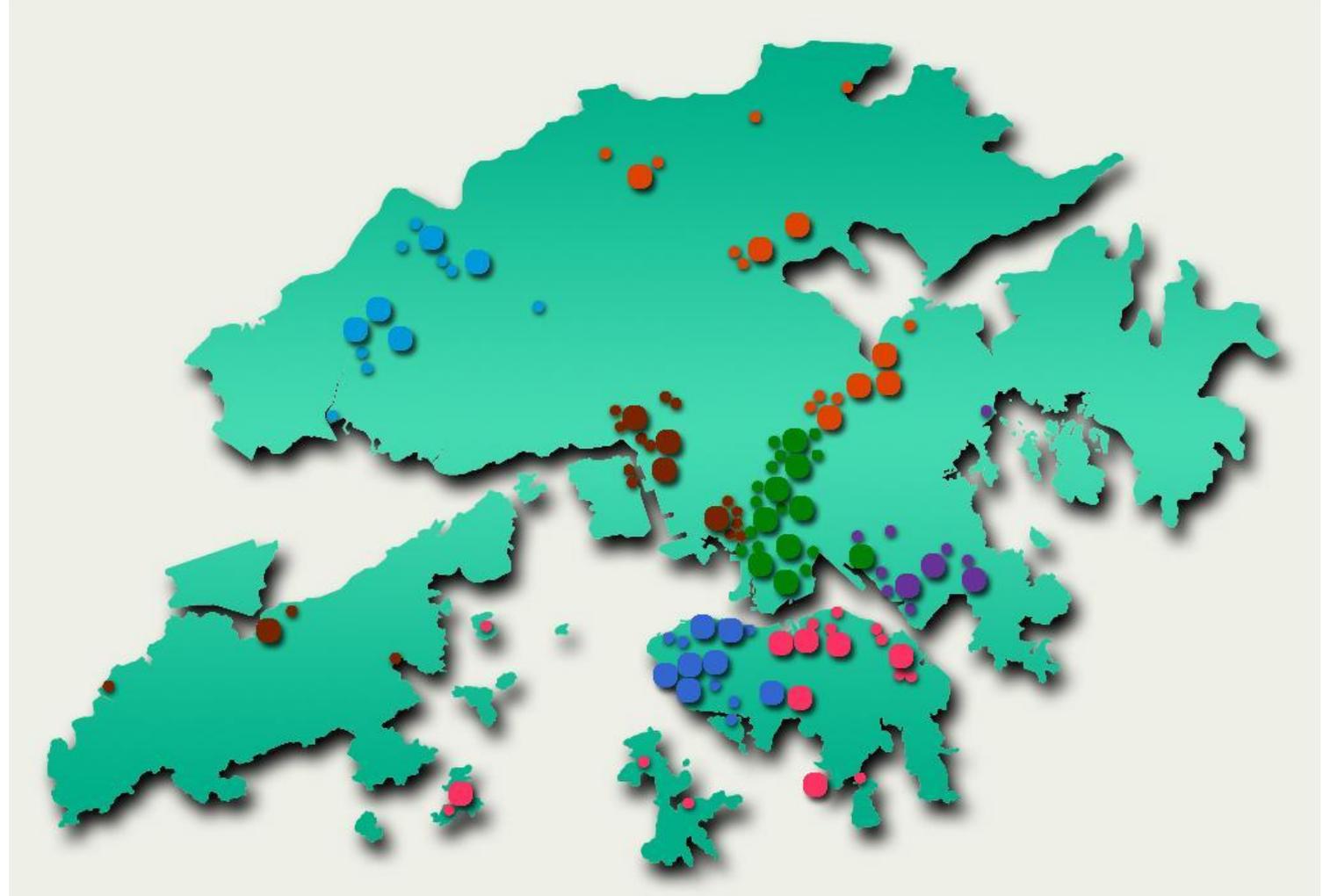
# Key components of IMT service



# Our Mission: to provide IMT to all citizens of HK

## Accredited FMT Centres:

- PWH
- PMH
- TMH
- QEH
- QMH



# Take home messages

- IMT for recurrent and/or refractory CDI is safe, cost-effective and feasible in Hong Kong
- Demand will further increase due to an aging population, and updates in guidelines
- Excellent track record since inception of pilot service in 2013
- Training, education and accreditation essential for the safe delivery of FMT
- Territory-wide IMT service to benefit more patients
- Need continued monitoring for medium- to long-term safety outcomes

# Questions are most welcome!

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X @RashidLui



醫院管理局  
HOSPITAL  
AUTHORITY



香港中文大學醫學院  
Faculty of Medicine  
The Chinese University of Hong Kong

