

# Microbiota Transplantation

**CURRENT STATUS AND  
EMERGING TRENDS**  
Catherine Duff

# Early History of Microbiota Transplantation

Pliny the Elder, Roman naturalist, 23 A.D.

Ge Hong, Chinese healer, 4<sup>th</sup> Century

Le Shizhen, Chinese healer, 16<sup>th</sup> Century

Acquapendente, Italian surgeon, 16<sup>th</sup> Century

# Modern History of Microbiota Transplantation

- Early 1900's, veterinarians use FMT in large animals
- WWII, Nurse packs gut shot with fecal matter
- 1958 Eiseman, et al, Journal of Surgery
- 1983 Schwann, et al, Lancet
- 1994 Bakken, et al, Clinical Infectious Disease
- 2000 Perskey & Brandt, American Journal of Gastroenterology

# FDA Definition of FMT



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

[www.fda.gov](http://www.fda.gov)

## Fecal Microbiota

- When used to cure, treat, mitigate or prevent a disease fecal microbiota for transplantation meets the legal definition of a drug and biological product

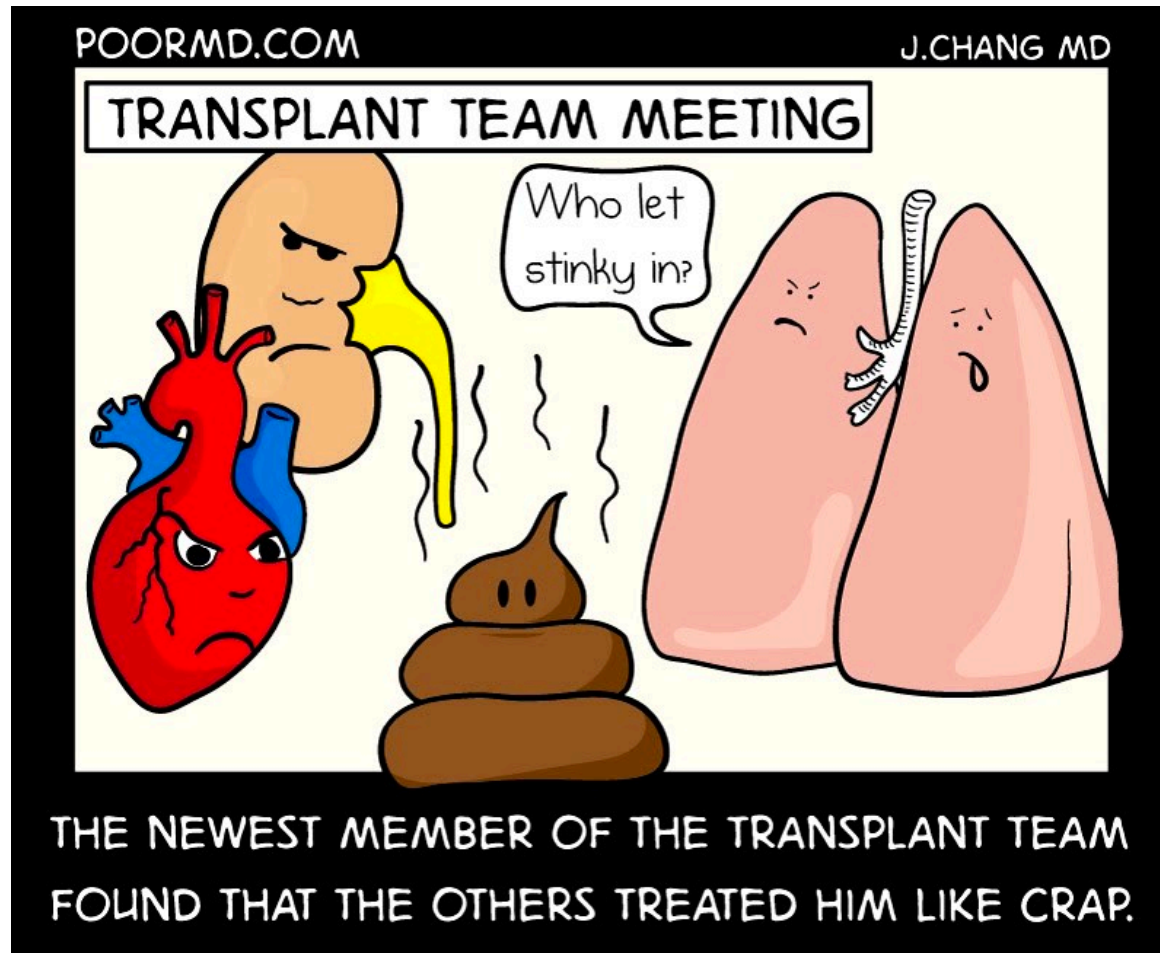
# Current Regulatory Status

- 2013 FDA announces use of FMT requires IND
- 2013 FDA issues “enforcement discretion”
- 2014 FDA announces DG re donors
- 2016 FDA announces DG re stool banks
- 2016 NIH funds MT Working Group
- 2017 NIH/AGA funds FMT Registry
- 2018 MT Working Group issues recs

# Indications for FMT

- C. difficile
- Digestive disorders (IBS, UC, Crohn's, Constipation)
- Metabolic disorders (Diabetes, Obesity)
- Psychiatric disorders (Bipolar, Depression)
- Autoimmune disorders (HIV, AIDS, Arthritis)
- Autism Spectrum disorders (Autism, Asperger's)
- Neurological disorders (Mult. Sclerosis, Parkinson's)
- Dermatological disorders (Eczema, Psoriasis)
- Adjunct therapies (Cancer, Graft vs Host disease)
- Currently 210 clinical trials

# The Transplant Team Greet's New Member



Catherine Duff  
Founder, President  
The Fecal Transplant Foundation

- 2005 diverticulitis > partial colectomy > perforated abscess > partial colectomy > colostomy + MRSA infection > antibiotics > C. difficile
- 2006 colostomy reversal > antibiotics > C. difficile
- 2007 infected poison ivy > antibiotic cream > C. difficile



- 2009 conjunctivitis > antibiotic eye drops > C. difficile
- 2010 steroid injection in hip > C. difficile
- 2011 TKR > antibiotics > C. difficile
- 2012 prophylactic antibiotics for teeth cleaning > C. difficile
- 2012 spinal fusion > antibiotics > C. difficile
- 2013 The Fecal Transplant Foundation

December 2012  
8 weeks after last FMT



# The Biomes of the Human Body

- Gut
- Vaginal
- Nasal
- Skin
- Ears
- Eyes
- Mouth
- Scalp
- Toe Webs
- Heel
- Eyelashes
- Eyebrows

# Indications for MT

- Oral (dental caries, periodontal disease)
- Vaginal (bacterial vaginosis, yeast infections)
- Nasal (sinusitis, allergic rhinitis)
- Skin (eczema, psoriasis, rosacea)
- Eyes (conjunctivitis, blepharitis)
- Ears (tinnitus, otitis, vertigo)
- We don't know what we don't know

# Recommendations of MT Working Group

- Three track system for MT:
- 1) When sample comes from “known donor”, would be considered “practice of medicine” and only under state regulations;
- 2) When sample is from “stool/donor bank”, would require regulation same as tissue/blood banks, register w/ FDA, complying w/ rules for donor screening/testing;
- 3) “modified” products would be treated as biologics/drugs by FDA.

# Latest Developments

- PACCARB 2017
- September 2018 FDA Workshop on Microbiome Based Therapeutics
- September 2018 CDC Begins AMR Challenge at U.N. General Assembly
- MT recognized at all as a novel, non-antibiotic therapy

# FAMILY 2018



# TAKEAWAY

**ALWAYS TRUST YOUR GUT.  
YOUR BRAIN CAN BE FOOLED  
AND YOUR HEART IS AN  
IDIOT BUT YOUR GUT  
DOESN'T KNOW HOW TO LIE.**

*@REBEL CIRCUS*