



# Gastrointestinal Infection Society of India (GISI)

Department of Gastroenterology (Microbiology Division)

Postgraduate Institute of Medical Education and Research, Chandigarh – 160012, INDIA

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## GISI NEWSLETTER APRIL 2016

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### **GISI team welcomes the following new Life Members:**

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## NEWSLETTER

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Assistant Professor

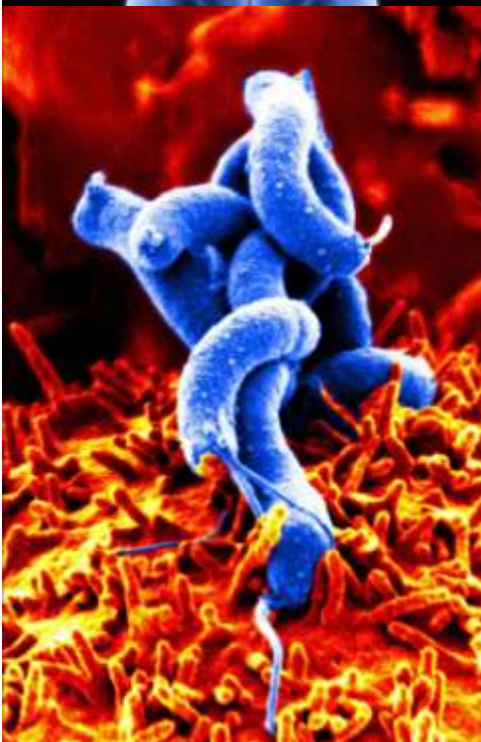
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## US FDA Proposes tighter rules for Fecal Transplants

With an aim to ensure that fecal transplants are safe as well as available to patients, FDA is intending to regulate stool banks offering fecal transplants. These transplants, which can be administered via enemas, colonoscopy, capsules, or gastric intubation, have yet to receive FDA approval. Accordingly, they're deemed investigational new drugs (INDs), and clinicians must apply for FDA authorization to use them. In draft guidance issued earlier this month, the FDA said that it would continue to exercise enforcement discretion for FMT regarding *C. difficile*, but the agency added more conditions. Either the patient receiving the transplant or the treating clinician must know the donor. And the treating clinician must oversee the screening and testing of both the stool donor and the stool.

Furthermore, the FDA will no longer apply enforcement discretion regarding IND requirements to fecal transplants obtained from stool banks, because their clinician customers don't know the donors, nor do they oversee transplant testing and production. Centralized manufacturing in stool banks raises safety concerns "related to the use of FMT from a limited number of donors administered to multiple patients," the agency said in its proposed guidance. "These safety concerns include transmission of infectious agents and other unidentified risks related to changes in the microbiome."

Accordingly, stool banks must secure IND designation for their FMT, which entails identifying someone as the investigator. Physicians would be able to continue using fecal transplants from stool banks to cure *C. difficile* infections as long as they are designated sub investigators. Assuming that role might not be as onerous as expected, because an IND sponsor — such as a stool bank — may waive certain IND requirements for investigators and sub investigators alike, the FDA noted.

Courtesy: Medscape Infectious Diseases

## ACHIEVEMENTS OF GISI MEMBERS

1. Dr. Omesh Goel, Consultant Gastroenterologist and Hepatologist, D.M.C. and Hospital, Ludhiana was conferred the prestigious 'D P Basu Award' for the 'Best Research Paper' at the Annual conference of the Association of Physicians of India at Hyderabad in Jan 2016. The paper was on 'Bovine colostrum and corticosteroids in the management of severe alcoholic hepatitis: a proof of concept trial'
2. Prof. Chetana Vaishnavi, PGIMER, gave a talk on "Prevalence and molecular types of *Clostridium difficile* isolates from fecal specimens of patients in a tertiary care center" in the Prokaryotic Genetics Forum of the Annual conference of Microbiology Society held from 21-24 March, 2016, at Liverpool, UK. She was the only participant from India selected for the oral presentation. She also presented two papers titled, "Occlusion of stents of patients with biliary and pancreatic diseases by various bacterial community" and "Toxigenic *Clostridium difficile* isolates from clinically significant diarrheal patients in a tertiary care center" during the conference. She was also one of 14 prize winners for a scientific quiz session held amongst two thousand delegates during the conference.
3. Congratulations to Dr. Ekta Gupta, Additional Professor, Dept of Clinical Virology, Institute of Liver & Biliary Sciences and her department for starting PDCC in Hepatovirology (after MD, Microbiology). Interested members are requested to visit institute website for more details.

## ANNOUNCEMENTS

1. Bidding for GISICON 2019 and 2021 are invited from all the GISI members and shall be accepted on first-come first-served basis.
2. Life Membership fees of GISI are INR 3000.00 payable by bank draft or cheque at par in favour of "Gastrointestinal Infection Society of India" payable at Chandigarh, INDIA.
3. Manuscripts for Journal of Gastrointestinal Infections should be typed in MS-Word and Figures/Photographs in JPEG format and submitted by e-mail to the Editor-in-Chief only at [jgi.gisi@gmail.com](mailto:jgi.gisi@gmail.com) or [gisi2007@rediffmail.com](mailto:gisi2007@rediffmail.com) so that the papers are not lost. Authors are also encouraged to submit the manuscript online at the website [www.gisi.in](http://www.gisi.in) for rapid processing. Instructions to authors are also available under GISI Journal action link in the website.
4. All GISI members are requested to pass on any news that they desire to be published in the newsletter. This will include information of awards received, fellowships obtained or travel abroad for academic purposes and any other information that may be of interest to the members.
5. Indian Life Members desirous of receiving Certificate of Membership may send a Demand Draft of INR 250.00 in advance. Foreign Members may send USD 25.00 in favour of 'Gastrointestinal Infection Society of India', payable at Chandigarh, addressed to Prof. C. Vaishnavi, Dept. of Gastroenterology, Postgraduate Institute of Medical Education and Research, Chandigarh-160012, India. Kindly quote your Life Membership No. along with the request.

## CONTACT US

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# Gastrointestinal Infection Society of India

Department of Gastroenterology (Microbiology Division)  
Postgraduate Institute of Medical Education and Research (PGIMER)  
Chandigarh – 160012, INDIA

## MEMBERSHIP FORM

Note: GISI Life Membership is open to Clinical Microbiologists/Gastroenterologists/Clinicians and Health Care Workers involved in the speciality of gastrointestinal infections.

PERSONAL INFORMATION <i>(Please type or print clearly in capital letters)</i>			
1	Full Name (Prof/Dr/Mr/Ms/Mrs)	First:	Middle: Last:
2	Date of Birth (DD/MM/YYYY)		
3	Qualification	University:	
	Designation		
4	Official Address		
		State:	PIN: Country:
5	Residential Address	House No:	
		Area/Locality:	
		City/Town:	
		State:	PIN: Country:
6	Telephone (with STD code)	Office:	Residence:
7	Fax (with STD code)		
8	Mobile		
9	E-mail		

REGISTRATION FEE DETAILS		
1	Life Membership Fee	1. Individuals (India): INR 3000.00 2. Individuals (Foreign): USD 200.00 3. Institutions: INR 3000.00 4. Patrons: INR 20,000.00 and above
2	Payment Details	Cheque/Demand draft (select one) Cheque/Draft No. Bank details: Dated: Amount: Cheques/Demand draft should be drawn in favour of "Gastrointestinal Infection Society of India" payable at Chandigarh.
3	Declaration	I declare that the information given by me is true and correct and that I will abide by the association rules and regulations if my membership application is approved.
4	Date	Signature:
5	Place	

OFFICE USE ONLY		
1	Date received	
2	Membership No.	
3	Demand draft No.	Date:
4	Receipt No.	Date:
5	Verified by	Name: Signature:

Membership form and the cheque/draft should be mailed to Dr. Chetana Vaishnavi, Professor, Division of Microbiology, Department of Gastroenterology, PGIMER, Chandigarh. Mobile No. 09417002682, E-mail: c.vaishnavi@rediffmail.com