



PRESIDENT'S REPORT

Douglas A. Drossman, MD
President, Rome Foundation
Senior Editor, Rome III Book

Another year has passed and the Rome Foundation continues to grow. Perhaps our most notable effort is to continue to gear up for Rome IV. Other major events include the initiation of the Rome Foundation – AGA Institute Communication Skills Workshop to be held in June 8-9, 2012, the initiation of “The Rome Update From DDW”, and our successful “Fourth Annual Rome Foundation – AGA Institute Lectureship” at DDW 2011. We also continue to expand our international activities in Latin America, Western Europe and Asia. Our mission: **“To improve the lives of people with functional GI disorders”** and our two goals, **To: “promote clinical recognition and legitimization of the functional GI disorders”** and **“develop a scientific understanding of their pathophysiological mechanisms to achieve optimal treatment”** have been our focus in all activities. Listed below is a review of our Rome IV program development and other activities pursuant to these goals.

ROME IV

- **Why Rome IV?** This is a logical question since we have gone through 3 prior versions over the last 20 years. However, much like the DSM system (now going into version 5) an update occurs when the need exists. Since publication of *Rome III* 6 years ago there is much new information accumulating in all scientific areas relating to these disorders. Rome IV will come out in 2016, fully 10 years after the Rome III version. In addition we are rapidly moving away from consensus to evidence based knowledge but consensus (“Delphi approach”) will be used at times when evidence is not available and the judgment of experts is needed. We also expect to show with Rome IV that we can finally move away from the functional-organic dichotomy that tends to stigmatize these disorders. Functional GI disorders are now understood as having structural abnormalities and the work in biomarkers is likely to be a feature for understanding these disorders in the future. Also scientific investigation and clinical practice is a global phenomenon and we must to expand our knowledge to accommodate a multinational context. Finally there are many residual questions that need clarification as we move forward; for example, “How can we best understand the relationship between IBS-C and functional constipation?” or “what is the latest physiological understanding for subclassifying functional dyspepsia?”

- **What is new for Rome IV?** Perhaps the most important and novel initiative relative to previous Rome criteria versions is that we plan to prospectively acquire knowledge in predefined areas of interest prior to activation of the Rome IV chapter committees in 2013. We have several working teams now charged to provide

the needed content in areas such as gut microflora, symptom assessment in Asia, the role of food and diet, and the nature of severity for FGIDs. In addition there are several support committees who will work with the chapter committees to enhance the Rome IV work. This includes concurrent development of the Rome IV questionnaire and its validation, and a systematic review committee that will provide evidence based information to the chapter committees to help answer important questions to help the chapter committees have up to date information. There is also a primary care committee to 1) clarify how primary care clinicians manage patients with these FGIDs and 2) to “translate” the criteria into ways that are more relevant for primary care. There is also a cross cultural committee that will provide information about how to conduct research in FGIDs that would be acceptable around the world. Finally we have initiated a multi-dimensional clinical profile committee that will help provide the full dimensionality of a patient in order to provide better therapeutic options to manage patients. The work of these committees will be presented in May 2013. This will be before DDW at a separate daylong meeting for committee members and sponsor. This information will then be available to the committees for their use over the subsequent two years.

- **How will Rome IV be available?** By 2016 most all information acquisition will be by computer access. This provides more opportunities for readers since they may purchase unlimited access (which will be available to Rome IV sponsors and members), download individual chapters or even do free text searching for information. In addition we will be incorporating cross-links to other chapters and have considerably more graphic material from our computer based learning programs. We will also publish a supply of printed books including special editions for pediatrics, and primary care as well as the Rome IV questionnaires. Finally are planning to have several translations of the Rome IV book available within one year of the English publication.

- **What is the Multi-Dimensional Clinical Profile?** A diagnostic classification system that provides a categorical diagnosis such as Rome or DSM criteria is helpful particularly for classifying patients for research studies. However, it may not capture the full dimensionality of a patient’s clinical profile. For example an IBS patient seen in primary care may be treated quite differently from a patient with the same diagnosis seen at a major medical center, the latter having with more severe symptoms, psychological comorbidities or more severe physiological disturbances. Therefore the multi-dimensional clinical profile will permit an ability to characterize the patient not only in terms of the diagnosis but also in terms of any clinical modifiers (e.g., IBS-C, D, or M), the impact of the condition (mild, moderate or severe), the presence

continued on page 4



ROME FOUNDATION AND AGA INSTITUTE

Communication Skills Workshop

JUNE 8 & 9, 2012

EXTRAORDINARY VENTURES CONFERENCE CENTER • CHAPEL HILL, NC

Course Director: Douglas A. Drossman, MD, AGAF

President, Rome Foundation

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Center for Functional GI and Motility Disorders, University of North Carolina at Chapel Hill

This activity is supported by educational grants from Takeda Pharmaceuticals North America, Inc.;
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OUR MISSION IS:
“TO IMPROVE THE LIVES OF PEOPLE WITH FUNCTIONAL GI DISORDERS.”

TABLE OF CONTENTS

PROGRAM AND PROJECT UPDATES

PRESIDENT'S REPORT.....	1
ROME TRANSLATION PROJECT.....	4
WORKING TEAM ON CROSS-CULTURAL, MULTINATIONAL RESEARCH.....	4
ROME FOUNDATION RESEARCH PROGRAM.....	6-9
ASSOCIATES OF ROME.....	10
INTERNATIONAL LIAISON COMMITTEE UPDATE.....	11
ROME FOUNDATION – AGA UPDATE.....	12
ROME RUNNERS UPDATE.....	12
INTESTINAL MICROBIOTA IN FUNCTIONAL BOWEL DISORDERS.....	13

MEETING AND EVENTS

ROME FOUNDATION – AGA LECTURESHIP AT DDW 2012.....	14
ROME FOUNDATION BREAKFAST SYMPOSIUM AT NGM 2012.....	15
10TH INTERNATIONAL SYMPOSIUM ON FUNCTIONAL GASTROINTESTINAL DISORDERS.....	15

ANNOUNCEMENTS

NEW BOOK ON IBS BY AMI SPERBER, MD.....	16
IFFGD UPDATE.....	17
ROME CRITERIA REFERENCE LIST.....	19
IFFGD 2013 RESEARCH AWARDS.....	19

of any psychosocial modifiers, or the degree of physiological dysfunction and biomarkers.

OTHER NEW INITIATIVES

• **Rome Foundation – AGA Institute Communication Skills Workshop.** We are pleased to announce a new CME initiative for clinicians that will teach skills related to the process of patient care. The communication skills workshop will be held in Chapel Hill, NC on June 8-9. It will be a 1 ½ day workshop that focuses on effective medical interviewing, communication techniques and management skills relating primarily to patients with FGIDs. The specific objectives are: 1) To understand the pathophysiological, diagnostic and treatment aspects of patients with IBS and other FGIDs, 2) To understand how to conduct a patient-centered biopsychosocial interview that optimizes time and enhances the patient-doctor relationship, and 3) To learn how to manage “difficult” clinical situations (e.g., anger, dependency, clinical uncertainty, emotional distress, reports of abuse, etc.). By using a series of lectures and demonstration, small group sessions and live facilitated interviews, attendees will learn effective clinical techniques from experienced facilitators. The faculty will include **Doug Drossman MD, William Chey MD, Lin Chang MD and Alben Halpert MD.** For further information please contact **Ms. Ceciel Rooker** at crooker@theromefoundation.org.

• **Rome Update from DDW.** In May 2011 we began a new educational initiative to highlight the most important abstracts on Functional GI and Motility Disorders presented at DDW. Several members of the Rome Foundation Board selected, reviewed and prioritized the highest quality posters and oral presentations at the meeting. Using this information the Foundation produced a CME webcast: “**The Rome Update from DDW**”. Drs. Douglas Drossman, William Whitehead, Jan Tack and Lin Chang selected and critiqued the abstracts and Drs. Bill Chey and Lin Chang reported them using a news media format, with Dr. Drossman serving as moderator. The webcast is still available on the Rome Foundation website www.focusmeded.com/special_event/rome2011/index.cfm. We plan to continue this educational program at DDW 2012.

Fifth Annual Rome Foundation-AGA Institute Lectureship. In 2008 we launched a “prime time” lectureship at DDW with the goal to have outstanding speakers present on the broader areas of health care as related to the functional GI and motility disorders. **For 2012** we will have 3 speakers addressing the theme of “*Intestinal Permeability in Gastroenterology and its relevance to Functional GI Disorders*”. **Dr. Alessio Fassano** will speak on “*Regulation of Intestinal Permeability in Health and Disease*”, **Dr. Roy Orlando** will speak on “*Esophageal Permeability: Does it explain the symptoms of NERD?*” and **Dr. Giovanni Barbara** will speak on “*Intestinal Permeability: Does it explain the symptoms of FGIDs?*” **The lectures will be held on Sunday, May 20 from 10:30 AM – 12:00 PM in the San Diego Convention Center, Room 9, San Diego, CA.** We hope you will attend.

INTERNATIONAL INITIATIVES

We continue to expand our global educational efforts:

• **Translations.** The Rome III book was translated into Chinese (2007), Japanese (2008), and Spanish (2009), and a monograph of the Rome III criteria and selected chapters was translated into Portuguese (2009). The translation committee has translated the Rome III diagnostic criteria, and the Rome III Diagnostic Questionnaire into 16 languages and several more

are in progress. The Rome Diagnostic Algorithms for Common GI Symptoms has been translated into Spanish. The translation committee, coordinated by Ami Sperber MD (Israel) has helped expand knowledge of the functional GI disorders internationally. Dr. Sperber is recognized for his research in cross-cultural aspects of FGIDs and for his work in translating and validating research questionnaires into multiple languages.

• **International Symposium at UEGW.** These annual meetings at the United European Gastroenterology Week provide quick updates on clinically challenging topics, all in a one hour symposium. The format is to provide concise clinical knowledge on a variety of challenging clinical topics: “How I manage a patient with difficult....”. In 2011 at UEGW in Stockholm the topics were: “Food Allergy” (Javier Santos MD), IBS in IBD (Magnus Simren), and Postfundoplication Dysphagia (Andre Smout MD). In 2010 at UEGW in Barcelona the topics were: “Psychosocial Stress and Abdominal Pain” (Douglas A. Drossman MD), “Recurrent Vomiting” (Mark Fox MD), and “Atypical Chest Pain” (Albert Bredenoord MD PhD). In 2009 at UEGW in London the topics were: “Vomiting” (Jan Tack MD, PhD), “Regurgitation” (Mark Fox MD, PhD), and “Constipation” (Satish Rao MD, PhD). In 2008, at the Vienna UEGW meeting, the topics included: “Recurrent belching” (André Smout MD), “Bloating” (Peter Whorwell MD), and “Chronic Diarrhea after Acute Gastroenteritis” (Robin Spiller MD).

• **International FGID conferences in Eastern Europe.** Under the directorship of Dan Dumitrascu MD of Cluj, Romania, a member of the Rome International Liaison Committee, there have been three international conferences on Functional GI Disorders which have promoted Rome III knowledge and the use of the criteria. To help assist in the effort to bring this information to Eastern Europe, the Rome Foundation has donated both Rome II and Rome III books to libraries in Romania, Moldavia and the Ukraine.

• **Pan American International Conferences.** Thanks to the facilitation by Max Schmulson MD (Mexico) and Carlos Francisoni MD (Brazil), several symposia have been organized to highlight Rome Foundation activities and to educate gastroenterologists in Latin America about the use of the Rome criteria and more recently the diagnostic algorithms. In November 2008, a symposium on the Rome Foundation was held with presentations that included “Rome III, Rationale for the Criteria and Diagnostic Implications” and “The Rome Foundation and its Activities”. In May 2009, Dr. Francisoni organized a conference in Sao Paulo, Brazil on IBS which was sponsored by Solvay, Brazil. The conference, which was simultaneously telecast to gastroenterologists in Rio de Janeiro, Belo Horizonte and Porto Alegre, not only addressed pathophysiology, diagnosis and treatment of IBS, but it provided an opportunity for the launching of the Portuguese translation of Rome III. The book contains the diagnostic criteria and selected chapters of the Rome III book. Finally the Rome Foundation will be sponsoring a symposium for the Pan American Meetings on November 10, 2012 in Panama.

• **Sponsorship of International Meetings.** The Rome Foundation has provided financial support to organizations with international representation and which foster symposia or lectureships in the FGIDs. This has included the North American Society of Pediatric Gastroenterology and Hepatology (NASPGHAN) in 2007, “Lessons learned from Rome III”; at DDW yearly since 2008; and the Neurogastroenterology and Motility meetings in Lucerne (2008) and Chicago (2009).



ROME TRANSLATION PROJECT - UPDATE

THE THAI PEDIATRIC QUESTIONNAIRE THE PROCESS OF TRANSLATION AND VALIDATION

AMI D. SPERBER, MD, MSPH
CHAIR, TRANSLATION PROJECT

The Rome Foundation published guidelines for the translation of Rome-copyrighted instruments such as the Rome diagnostic questionnaires into languages other than English and for validation of the translation.

Once the process is successfully completed the Rome Foundation extends official approval of the translation and makes it available for use through the Translation Project website (www.theromefoundation.org/translations/) in accordance with its licensing and usage policy, which is also detailed on the website. The individuals who carried out the process are acknowledged.

The following is an example of the process, highlighting the recently completed and approved translation of the Rome pediatric questionnaire (Parents report form and Self-report form) into Thai.

Step 1. Forward translation

The English language original questionnaire was translated independently by two translators from English to Thai. The products were designated as Thai versions 1a and 1b.

Step 2. Reconciliation

Thai versions 1a and 1b were analyzed for differences and reconciled into a unified Thai version designated as Thai version 2.

Step 3. Backward translation

Thai version 2 was translated back into English, producing the back-translated English version.

Step 4. Item-by-item comparison

The two English versions (original and back-translated) were compared on an item-by-item basis on the dimensions of similarity of language and comparability of interpretation. They were also compared using the Item-Objective Congruence (IOC) method. Any discrepancies were analyzed by expert discussion to determine the best Thai formulation to reflect the intention of the original English question in a culturally appropriate way. The product was the final Thai version.

Step 5. Testing of the final Thai version

The final Thai version was tested on 50 Thai school children (23 parent report and 27 self-report). Analyses using the Cronbach's a-coefficient showed that the translation was valid.

Step 6. Rome Foundation approval

Formal documentation of the process was submitted to the Rome Foundation and formal approval of the version was extended.

Acknowledgments:

Initiator: Thitima Ngoenmak, MD

Rome monitor in Thailand: Suporn Treepongkaruna, MD

Translators: Sutatip Pongcharoen, MD; Suwannee Uthaisangsook, MD; Mary Elizabeth (Sautter) Sarawit, PhD (Linguistics); Phisek Yimyaem, MD

Support: Supasit Pannaranonthai, MD and the Research Foundation of Naresuan University

UPDATE ON WORKING TEAM ON CROSS-CULTURAL, MULTINATIONAL RESEARCH,

MARCH 2012 – AMI SPERBER

The working team has been divided into three sub-committees; each comprised of working team members and invited consultants for some of the tasks. The final sub-committee reports and final working team document are expected to be ready in the middle to end of 2013.

The following is an update on the work of the sub-committees

1. Systematic global review of IBS/FGID epidemiology - Chair, Ami Sperber

Study parameters have been set and the collaborators are conducting literature searches and beginning to input data into the database. Dr. Chen Minhu from Guangzhou, China will be helping with the literature search from China including native language papers, as an invited collaborator. One of the strengths of this review, compared to similar reviews in the past, is that the process is being conducted by a multi-lingual team that can survey and review original papers published in many major languages.

2. Methodology issues in cross-cultural, multinational research - Chairs, Pali Hungin and Bill Whitehead

This sub-committee will cover the following topics in depth:

- Study design for cross-cultural studies
- Availability and development of appropriate study instruments
- Translation and validation of study instruments
- Development of culturally appropriate endpoints and outcomes

- Subject recruitment
- Guidelines for documenting confounders such as diet, pathogen exposure, health care delivery models, gender differences in access to care, literacy rates, language diversity, education, living abroad, and cultural differences in illness explanatory modes

3. Fostering cross-cultural, multinational research Chair – Kok Ann Gwee

Update: This sub-committee will cover the following topics in depth:

- Development of research networks
- The challenge of language in symptom-reporting of fullness, bloating, and distension
- Comparison of the health care infrastructure in different countries
- A study of intra-family illness behavior dynamics in different countries
- Avenues for collaboration with other organizations, pharmaceutical companies and regulatory agencies with particular reference to clinical trials



ROME FOUNDATION RESEARCH PROGRAM

WILLIAM E. WHITEHEAD, PHD
CHAIR, RESEARCH COMMITTEE

The Rome Foundation has a 9-year history of sponsoring research. The goals of the research program have been three-fold: (1) to test the validity of the diagnostic criteria so that revisions to the criteria can be empirically based; (2) to increase knowledge of the prevalence and epidemiology

of the FGIDs, especially in non-Western countries, in order to provide new insights into pathophysiology; and (3) to interest young investigators in research and clinical practice in the area of functional gastrointestinal disorders (FGIDs) and motility disorders.

ROME FOUNDATION RESEARCH AWARD

see page 7 for the 2012 recipient

The Rome Foundation provides a \$50,000 research grant each year. Preference is given to applications that (1) test the validity and/or utility of the Rome III diagnostic criteria, (2) assess the epidemiology of functional GI and motility disorders, or (3) advance knowledge of outcome assessment or trial design for FGID treatment trials. The applications receive an NIH-style review by an independent review committee. This year the review committee was chaired by Dr. Brooks Cash, Professor of Medicine at the Uniformed Services University for the Health Sciences and Chief of Medicine at Walter Reed Army Medical Center.

RAY CLOUSE PRIZE FOR THE BEST RESEARCH ARTICLE ON FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS 2011

see page 8 for the 2011 recipient

In 2008, the Rome Foundation created an award in memory of Ray E. Clouse, MD, a gastroenterologist and scholar at Washington University School of Medicine and a devoted member of the Rome Foundation. This award recognizes the author of the best original research paper published in the functional gastrointestinal and motility disorders for the calendar year preceding each DDW. While many papers are nominated by the Board of the Rome Foundation, anyone may submit a nomination by briefly describing how the paper will impact the field of functional gastroenterology and motility along with a pdf of the paper. Rome Foundation board members are ineligible. The best paper is selected by a vote of the Rome Foundation board.



Ray E. Clouse, MD

RAY CLOUSE PRIZE FOR THE MOST CITED ARTICLE IN FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS 2010

see page 9 for the 2010 recipients

Each year the Rome Foundation awards a prize of \$500 for the most frequently cited paper on functional gastrointestinal disorders in the penultimate year before DDW. The methodology is straightforward: we use the Web of Science search engine to rank order the most frequently cited original research paper identified by the search terms "functional gastrointestinal disorder", "functional bowel disorder", "Irritable bowel syndrome", "IBS", or "FGID". We exclude reviews and papers on which a board member of the Rome Foundation is an author. The reason for going back two years to select the prize is to minimize the impact of time since publication on the number of citations; if we were to select the most recent year, a paper published early in the year would have an advantage over a paper published at the end of the year.



ROME FOUNDATION RESEARCH GRANT AWARD 2012 WINNER – NICHOLAS J. TALLEY MD, PHD

Nicholas J Talley, MD, PhD

*Pro Vice Chancellor/Professor
Faculty of Health
University of Newcastle*

Professor Nick Talley is Pro Vice Chancellor of the Faculty of Health at the University of Newcastle, in Australia, and Professor of Medicine. He was formerly Chair of the Department of Internal Medicine at Mayo Clinic in Jacksonville, Florida where he held the rank of Professor of Medicine at the Mayo Clinic College of Medicine; he also held the rank of Professor of Epidemiology. Previously, Nick was the Director of the Motility Interest Group in the Division of Gastroenterology and Hepatology at Mayo Clinic, Rochester, Minnesota, and before that was the Foundation Professor of Medicine at the University of Sydney, Nepean Hospital. He currently holds adjunct research appointments as Professor at Mayo Clinic, University of North Carolina and the Karolinska Institute. He undertook his undergraduate medical degree at the University of New South Wales, and holds doctorates from his alma mater and the University of Sydney as well as a Master's degree from the University of Newcastle.

Nick is currently co-editor-in-chief of *Alimentary Pharmacology & Therapeutics*. Previously, he was co-editor-in-chief of the *American Journal of Gastroenterology*, and serves on a number of prominent editorial boards. He is a founding member and Director of the Rome Foundation, a past President of the Functional Brain-Gut Research Group, was a counselor in the American Gastroenterology Association Motility Section, and served as a member of the Board of the American College of Gastroenterology. He

currently serves as a Director on the Board of the Hunter Medical Research Institute in Newcastle. He is a Fellow of the Royal Australasian College of Physicians, Royal College of Physicians (both London and Edinburgh), and the American College of Physicians. Nick is a Visiting Medical Officer at the John Hunter Hospital in Newcastle.

Nick has a deep interest in medical education and has authored a number of prominent textbooks. His popular student textbook, "Clinical Examination: A Systematic Guide to Physical Diagnosis", is in its 6th edition and is distributed worldwide.

Nick's research is primarily focused on functional gastrointestinal disorders, dyspepsia, *Helicobacter pylori*, gastroesophageal reflux disease, and eosinophilic disorders of the gut. He has recently described with his team a new disease entity in adults, eosinophilic duodenitis, linked to functional dyspepsia. His group has documented a genetic component in upper and lower functional bowel diseases. He has published over 700 original and review articles in the peer-reviewed literature, and he is considered one of the world's leading authorities in clinical research on the stomach. He currently has research support as a Chief Investigator from the National Health and Medical Research Council, and has been funded as a Principal Investigator (RO1) by the National Institutes of Health in the USA.

Title: *Usefulness of Rome III symptoms, psychological characteristics and cytokines in accurately diagnosing FGIDs* **ABSTRACT:**

Background: Despite the high prevalence of FGIDs in the population and associated high costs because of presentations for medical care, the diagnostic validity of current symptom based criteria (Rome III) remains to be firmly established. New evidence including our novel pilot data suggest that certain psychological characteristics and biological markers may together better discriminate functional bowel disorders from organic bowel diseases. To date no studies have evaluated a diagnostic test based on all the available knowledge and technology.

Aim: To determine if a novel diagnostic test (combining symptoms, psychological characteristics and biological data) is superior to symptoms alone for distinguishing lower FGIDs (including IBS) from lower organic GI disease. We will also determine if the testing can distinguish IBS from other lower FGIDs.

Methods: In a sample of 600 outpatients referred by their physician for a colonoscopy for lower colonic symptoms we will collect detailed symptom data (*Rome*

III criteria and alarm features by validated questionnaire), psychological data based on validated instruments (anxiety, depression and extraintestinal symptoms) and clinical biomarkers by standard blood tests and a cytokine panel (TNFalpha, IL-6, IL-8, IL-10). We will determine which diagnostic test characteristics best identify lower functional from organic GI disease versus functional disease and major FGIDs (IBS) from lower FGIDs using logistic regression modeling. Diagnosis of organic versus functional disease will be based on an a priori algorithm after a minimum of 6 months follow up; the diagnostic coding will be undertaken by an independent expert clinician blinded to the test data after interviewing the patient and review of all clinical records including the findings at colonoscopy. We will then prospectively test the best diagnostic model (identified above) in a new sample of consecutive outpatients (n=400) with lower colonic symptoms referred for colonoscopy. This high novel study has the potential to refine the Rome criteria.

RAY CLOUSE PRIZE

FOR THE BEST RESEARCH ARTICLE ON FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS 2011

This year's award goes to:



Nathalie Bertiaux-Vandaële MD

Department of Gastroenterology
Rouen University Hospital
France

Bertiaux-Vandaële N, Youmba SB, Belmonte L, Lecleire S, Antonietti M, Gourcerol G, Leroi AM, Déchelotte P, Ménard JF, Durcotte P, Coëffier M. *The expression and the cellular distribution of the tight junction proteins are altered in irritable bowel syndrome patients with differences according to the disease subtype.* AmJ Gastroenterol 2011;106:2165-73.

ABSTRACT:

Objectives: Recent studies have suggested that an increased intestinal permeability is involved in the pathophysiology of irritable bowel syndrome (IBS). However, the differential expression of tight junctions (TJs) proteins according to IBS subtypes and symptoms remained unknown. The objective of this study was to study zonula occludens-1 (ZO-1), occludin, and claudin-1 in the colonic mucosa of patients with IBS.

Methods: Fifty IBS patients fulfilling the Rome III criteria and 31 controls were included. All types of IBS patients participated with predominant diarrhea (IBS-D, n=19), predominant constipation (IBS-C, n=14), constipation alternating with diarrhea (IBS-A, n=15), or unclassified (IBS-U, n=2). IBS symptom intensity was quantified on 10-cm Visual Analog Scale (VAS). TJ proteins (claudin-1, ZO-1, occludin) were quantified by quantitative reverse transcriptase-polymerase chain reaction (qRT-PCR), western blot, while their localization was determined by immunofluorescence.

Results: ZO-1 and occludin expression was lower in IBS patients compared with controls, whereas only a trend for a decrease of claudin-1 was observed. The mRNA levels remained unaffected. In the subgroup analyses, occludin and claudin-1 expression was decreased in IBS-D patients but not in IBS-C and IBS-A patients. The subcellular distribution of these three proteins was altered in IBS-C and IBS-D patients. Occludin ($r=0.40$, $P<0.01$) and claudin-1 ($r=0.46$, $P<0.01$) expression was correlated with the duration of symptoms. The expression of occludin was lower in patients with an abdominal pain intensity higher than 6 on the VAS ($P<0.05$).

Conclusions: Occludin and claudin-1 appeared markedly affected in IBS-D patients. In addition, our results suggest that alteration of TJ proteins may be involved in the initiation of IBS and contribute to visceral hypersensitivity.

RAY CLOUSE PRIZE

FOR THE MOST CITED ARTICLE IN FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS 2010

This year's prize for the most cited paper goes to co-awardees



Ted J. Kaptchuk, OMD
Beth Israel Deaconess Medical Center
Boston, MA, USA



Anthony J. Lembo, MD
Beth Israel Deaconess Medical Center
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Ted J Kaptchuk, Elizabeth Friedlander, John M Kelley, M Norma Sanchez, Efi Kokkotou, Joyce P Singer, Magda Kowalczykowski, Franklin G Miller, Irving Kirsch, Anthony J Lembo. *Placebos without deception: a randomized controlled trial in irritable bowel syndrome*. PLoS One 2010;5(12):e15591.

ABSTRACT:

Background: Placebo treatment can significantly influence subjective symptoms. However, it is widely believed that response to placebo requires concealment or deception. We tested whether open-label placebo (non-deceptive and non-concealed administration) is superior to a no-treatment control with matched patient-provider interactions in the treatment of irritable bowel syndrome (IBS).

Methods: Two-group, randomized, controlled three week trial (August 2009-April 2010) conducted at a single academic center, involving 80 primarily female (70%) patients, mean age 47±18 with IBS diagnosed by Rome III criteria and with a score ≥150 on the IBS Symptom Severity Scale (IBS-SSS). Patients were randomized to either open-label placebo pills presented as “placebo pills made of an inert substance, like sugar pills, that have been shown in clinical studies to produce significant improvement in IBS symptoms through mind-body self-healing processes” or no-treatment controls with the same quality of interaction with providers. The primary

outcome was IBS Global Improvement Scale (IBS-GIS). Secondary measures were IBS Symptom Severity Scale (IBS-SSS), IBS Adequate Relief (IBS-AR) and IBS Quality of Life (IBS-QoL).

Findings: Open-label placebo produced significantly higher mean (±SD) global improvement scores (IBS-GIS) at both 11-day midpoint (5.2±1.0 vs. 4.0±1.1, $p < .001$) and at 21-day endpoint (5.0±1.5 vs. 3.9±1.3, $p = .002$). Significant results were also observed at both time points for reduced symptom severity (IBS-SSS, $p = .008$ and $p = .03$) and adequate relief (IBS-AR, $p = .02$ and $p = .03$); and a trend favoring open-label placebo was observed for quality of life (IBS-QoL) at the 21-day endpoint ($p = .08$).

Conclusion: Placebos administered without deception may be an effective treatment for IBS. Further research is warranted in IBS, and perhaps other conditions, to elucidate whether physicians can benefit patients using placebos consistent with informed consent.



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INTERNATIONAL LIAISON COMMITTEE UPDATE

WELCOME DR. MEIYUN KE TO THE
INTERNATIONAL LIAISON COMMITTEE

Ke Meiyun, MD

*Professor of Medicine
Department of Gastroenterology
Peking Union Medical College Hospital (PUMCH)
Chinese Academy of Medical Science (CAMS)
China*

Dr. Ke, Professor of Medicine, in the Department of Gastroenterology, Peking Union Medical College Hospital (PUMCH), Chinese Academy of Medical Science (CAMS), China. As a visiting scholar, she studied gastrointestinal motility at Yale University from 1983-1984, then studied colon motility at Helosaky Medical College in Japan (1987). She then went on to study experimental gut motility at UCLA and the Mayo Clinic (1989). She also worked on clinical trials in gastrointestinal motility in Utrecht, The Netherlands (1992). Prof. Ke was Chairman in the

Department of Gastroenterology, PUMCH from 2000-2005. She was also Chair of the Chinese Motility Group, Chinese Society of Gastroenterology, Chinese Society of Medicine between 2000-2007 and currently serves as an advisor. Finally, Dr. Ke served as a Rome III committee member and on the Council of ANMA (Asian Neurogastroenterology and Motility Association) between 2008-2012. Her major research is to focus on the FGIDs including study of the psychological aspects of these disorders.

ASSOCIATES OF ROME - continued from previous page

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ROME FOUNDATION - AGA UPDATE

THE ROME FOUNDATION AND AGA INSTITUTE TEAM UP TO ENHANCE PHYSICIAN COMMUNICATION SKILLS WITH PATIENTS DIAGNOSED WITH FUNCTIONAL GI DISORDERS (FGIDs).

Submitted by Dianne Bach, APR

*Senior Vice President, Corporate Relations
AGA Institute*

Patients with FGIDs can prove particularly challenging. They often make urgent requests for diagnostic tests, exhibit dysfunctional coping styles and convey unrealistic expectations for a cure. This may lead to a strained clinician-patient relationship and negative attitudes exhibited by both clinician and patient.

The AGA Institute and Rome Foundation are addressing these critical issues by hosting a clinical skills workshop on Improving the Medical Interview and the Physician-Patient Relationship with Patients Having Functional GI Disorders, June 8 and 9, 2012 at the Extraordinary Ventures Conference Center in Chapel Hill, NC. This workshop will help physicians develop an effective clinician-patient relationship and enhance satisfaction for both the physician and the patient. Skills acquired at the workshop can be readily applied to all patients with GI and other medical disorders, allowing for improved treatment adherence and clinical outcomes.

By attending this workshop participants will be able to 1) understand the pathophysiological diagnostic and treatment aspects of patients with IBS and other functional GI disorders, 2) conduct a patient-centered bio-psycho-social interview that optimizes time and enhances the patient-clinician relationship. This will include active listening, establishing rapport, setting the agenda, emotional handling, learning verbal and non-verbal communication techniques, and more and 3) learn how

to better manage uncomfortable clinical situations (e.g. anger, dependency, clinical uncertainty, emotional distress, reports of abuse, etc.).

Faculty include Douglas Drossman, MD, Course Director and President of Rome Foundation, Lin Chang, MD, Professor of Medicine, UCLA, William Chey, MD, Professor of Medicine, University of Michigan and Alben Halpert, MD, Assistant Professor of Medicine, Boston University.

Space is limited. **There are only 50 seats available for this workshop.** The AGA Institute designates this live activity for a maximum of 12.00 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is supported by educational grants from Forest Laboratories, Inc.; Ironwood Pharmaceuticals, Inc.; Salix Pharmaceuticals, Ltd.; and Takeda Pharmaceuticals North America, Inc.

For more information on the workshop's program, contact Ceciel Rooker, director of public relations, Rome Foundation at crooker@theromefoundation.org or 843-364-4292.

For assistance with registration, contact Sarah Barrett at sbarret@med.unc.edu.



ROME RUNNERS

The Rome Foundation created a Team to run/walk at the **Walt Disney World® Marathon Weekend** held January 5-8, 2012. We were pleased to have 15 runners participate in this year's race.



The Disney Marathon Weekend hosts a variety of races for all ages including a Marathon, Half Marathon, 5K and kids races. All proceeds from this project benefited the Rome IV project.

We will be creating another team to participate in the 2013 races this January 10-13. Please contact Ceciel Rooker at crooker@theromefoundation.org for information, if you would like to sign up for next year's race or if you would like to support this program.





INTESTINAL MICROBIOTA IN FUNCTIONAL BOWEL DISORDERS: A ROME FOUNDATION WORKING TEAM REPORT

MAGNUS SIMRÉN, MD, PhD
CHAIR

The Rome Foundation in early 2010 decided to initiate a Working Team Committee: The Role of the Intestinal Microbiota in Functional Gastrointestinal Disorders. The purpose was to develop a summary of the research and literature in this content area to date and then offer guidelines or recommendations to help advance future research and clinical care. The goal was to submit a summary as a Working Team Report to one of the major scientific journals in our field, as well as produce a more thorough background document to be published on the Rome Foundation website. The manuscript was recently accepted by *Gut* for publishing. The abstract is below:

ABSTRACT

It is increasingly perceived that gut host-microbial interactions are important elements in the pathogenesis of functional gastrointestinal disorders (FGID). The most convincing evidence to date is the finding that functional dyspepsia and irritable bowel syndrome (IBS) may develop in predisposed individuals following a bout of infectious gastroenteritis. There has been a great deal of interest in the potential clinical and therapeutic implications of small intestinal bacterial overgrowth in IBS. However, this theory has generated much debate because the evidence is largely based on breath tests which have not been validated. The introduction of culture-independent molecular techniques provides a major advancement in our understanding of the microbial community in FGID. Results from 16S rRNA-based microbiota profiling approaches demonstrate both quantitative and qualitative changes of mucosal and faecal gut microbiota, particularly in IBS. Investigators are also starting to measure host-microbial interactions in IBS. The current working hypothesis is that abnormal microbiota activate mucosal innate immune responses which increase epithelial permeability, activate nociceptive sensory pathways, and dysregulate the enteric nervous system. While we await important insights in this field, the microbiota are already a therapeutic target. Existing controlled trials of dietary manipulation, prebiotics, probiotics, synbiotics and non-absorbable antibiotics are promising, although most are limited by suboptimal design and small sample size. In this article we provide a critical review of current hypotheses regarding the pathogenetic involvement of microbiota in FGID and evaluate the results of microbiota-directed interventions. We also provide clinical guidance on modulation of gut microbiota in IBS.

MEMBERS OF THE WORKING TEAM

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Gothenburg, Sweden

CO-CHAIR

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Bologna, Italy

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Peter Whorwell, PhD
Manchester, UK

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Nottingham, UK

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BASIC/MICROBIOLOGY

Erwin Zoetendal, MD
Wageningen, the Netherlands

Harry Flint, PhD
Aberdeen, UK

The Rome Foundation/AGA Institute Lectureship at Digestive Disease Week 2012

*"Intestinal Permeability in Gastroenterology and its Relevance to
Functional GI Disorders"*



*Alessio
Fassano, MD
University of
Maryland*

*Regulation of Intestinal
Permeability in Health and
Disease*



*Roy Orlando, MD
University of
North Carolina at
Chapel Hill*

*Esophageal Permeability:
Does it Explain the
Symptoms of NERD?*



*Giovanni
Barbara, MD
University of
Bologna*

*Intestinal Permeability: Does
it Explain the Symptoms of
Functional GI Disorders?*



Sunday, May 20, 2012 10:30 AM-12:00 PM
Room 9 San Diego Convention Center
San Diego, CA



THE AGA INSTITUTE

2538

The Rome Foundation encourages you to visit our booth in the DDW Exhibit Hall

- FREE copies of the Rome Foundation Diagnostic Algorithms for Common Gastrointestinal Symptoms on CD-ROM and in print
- Information on the Associates of Rome
- Products for sale (at a discount)
 - Rome III book
 - Computer-Based Learning Program
 - Understanding the Irritable Gut
- Dozens of FREE Handouts on Functional GI Disorders

Be sure to visit us at booth 3826!!



The Emerging Role of Dietary Factors in the Functional GI Disorders

Chairs: Jan Tack and Magnus Simren

- Role of food in shaping the microbiome – Robin Spiller, MD
- The role of food allergy and food sensitivities in FGIDs – Javier Santos, MD
- Role of dietary interventions in IBS – William D. Chey, MD



Join the Rome Foundation for a breakfast symposium at NGM

NGM 2012
Joint International Neurogastroenterology
and Motility Meeting
6 – 8 September 2012 // Bologna, Italy



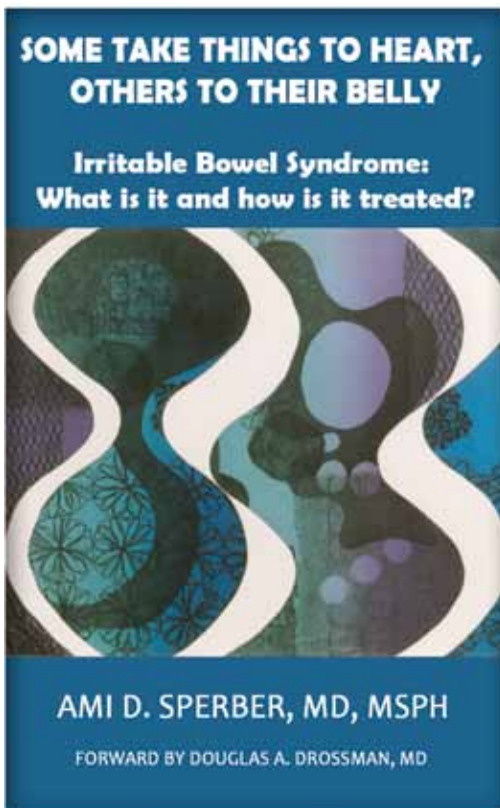
10TH INTERNATIONAL SYMPOSIUM ON FUNCTIONAL GASTROINTESTINAL DISORDERS

April 12 – 14, 2013
Pfister Hotel
Milwaukee, Wisconsin

For further information:
Elisabeth Vink
IFFGD
Phone: 414-964-1799
E-mail: symposium@iffgd.org

Terese Bailey
OCPD in Medicine and Public Health
Phone: 608-240-2141
E-mail: tmbailey@ocpd.wisc.edu

This CME accredited symposium will be held April 12-14, 2013, at the Pfister Hotel, Milwaukee, Wisconsin. It is jointly sponsored by the University of Wisconsin School of Medicine and Public Health, Office of Continuing Professional Development in Medicine and Public Health, and the International Foundation for Functional Gastrointestinal Disorders. A global audience of clinicians and investigators will exchange information on the latest advancements in functional gastrointestinal and motility disorders. The symposium will offer a format of plenary sessions, interactive workshops and mini symposia on both adult and pediatric disorders - from basic science to clinical applications.



NEW BOOK ON IBS NOW AVAILABLE

Some Take Things to Heart, Others to their Belly: Irritable Bowel Syndrome; What is it and How is it Treated?



Internationally recognized physician and researcher, Ami Sperber MD, MSPH, has recently written this book in English as a Kindle e-book, published by the International Foundation for Functional GI Disorders (IFFGD) (November 2011).

In this book, Dr. Sperber provides a fresh and clear guide to help people understand the condition and the diagnostic process. Individuals with IBS will find useful ways to self-manage and gain a greater sense of confidence.

Available at www.amazon.com

Please join the Rome Foundation at the XXXIII Pan American Congress of Gastroenterology in Panama. There will be a Rome Symposium, Rome-Sponsored Lecture and Rome will have a booth in the Exhibit Hall.

Rome Symposium (SAT Nov 10th, 8:00 AM to 10:00 AM)

Chairs Carlos Francisconi, Brazil & Doug Drossman, USA

- The Road to Rome IV with Doug Drossman, USA
- A global perspective of FGIDs in Latin America with Max Schmulson, Mexico
- Diet and IBS with Bill Chey, USA
- Microflora with Magnus Simren, Sweden
- Update on constipation: Issues for Rome IV with Bill Chey, USA

Rome Lecture-Plenary Session

Newer understanding of Neurogenesis for the treatment of severe refractory pain with Doug Drossman, USA



**XXXIII CONGRESO
PANAMERICANO DE
GASTROENTEROLOGIA 2012**

**ATLAPA Convention Center
Panama City, Panama
November 7-10, 2012**



PATIENT PERSPECTIVE: AN UPDATE FROM THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS



By: William F. Norton
Vice President and Co-founder

IFFGD activities continue to include awareness, advocacy, education, and research efforts. Global economic pressures add to the challenges. Now more than ever we need to be active in making our voices heard and the needs of our community known.

Awareness and Advocacy

Many of our current activities are focused on legislative and federal funding issues. On June 19–20, 2012 we will host our 5th annual IFFGD Digestive Health Alliance Advocacy Day on Capitol Hill. Advocates from across the nation will gather in Washington, DC to educate policymakers about the needs of patients, providers, and researchers in the functional GI and motility disorders community and inform them of how they can take meaningful action. To attend, register on our web page at www.dha.org/advocacyday/2012.

Our Advocacy Day 2011 culminated with the introduction in the U.S. House of Representatives of the first federal bill focused on functional GI and motility disorders, the *Functional Gastrointestinal & Motility Disorders Research Enhancement Act* (H.R. 2239). Among the bill's aims are to:

- Grant the National Institutes of Health (NIH) new authority to initiate innovative research projects
- Establish a Centers of Excellence Program in this area
- Coordinate research activities with the Department of Defense and the Veterans Administration

Call on the Food and Drug Administration (FDA) to improve review, approval, and oversight of treatments for functional GI and motility disorders

Through its introduction, the bill is raising critical awareness about functional GI and motility disorders as advocates reach out to their representatives. To become law, it needs to pass with a majority in the House, and also be introduced and passed by a majority in the Senate. The revenue neutral bill is gaining bipartisan support. U.S. citizens can ask their House Member to support the bill by going to our web page at www.iffgd.org/2239action.

As a result of our Advocacy Day 2011 effort, we were invited to appear before the U.S. Senate Defense Appropriations Subcommittee to testify about the high number of veterans who served in Iraq and Afghanistan who are

returning with newly acquired functional GI disorders. We subsequently held a briefing on this issue for Senate and House legislative staff members in Washington, DC. Rome Foundation member Brennan M. R. Spiegel, MD, MSHS along with a young retired veteran now affected by a functional GI disorder spoke at the briefing. Sadly, the impact of functional GI disorders is still under-appreciated by many policy makers and appropriators. Explaining the impact the disorders have on war veterans goes a long way toward raising awareness.

Another issue important to us all is the looming cut in the NIH budget. Under current law, NIH faces an automatic 7.8% or \$2.5 billion cut in their fiscal 2013 budget unless an alternative plan becomes law later this year to meet deficit reduction targets. IFFGD is mobilizing advocates to contact their Congressional Members and ask that they support NIH funding of at least \$32.0 billion in fiscal 2013, an increase over the current \$30.7 billion in funding. Once again, you can take action by going to our web page at www.iffgd.org/action and clicking on "NIH 2013 Budget Action."

Education and Research

We will be hosting the 10th International Symposium on Functional Gastrointestinal Disorders on April 12–14, 2013 at the Pfister Hotel in Milwaukee, WI. The meeting will again be jointly sponsored by the University of Wisconsin School of Medicine and Public Health, Office of Continuing Professional Development, and IFFGD. We look forward to seeing many of you there. Find information at www.iffgd.org/symposium or on page 15 of this issue.

We are also seeking applications for Research Awards. To be eligible, investigators must have completed an M.D. or Ph.D., have demonstrated research activities, and be currently active in investigating basic or clinical aspects of functional GI or motility disorders, or neurogastroenterology. Up to six awards will be given, each in the amount of \$7,500 (pretax U.S.). Details are at www.giresearch.org/awards or on page 19 of this issue.

Thank you all for your continued support of IFFGD, and your work on behalf of patients.

The Rome Foundation Proudly Presents



the latest educational resources for all health care professionals and patients concerned with functional gastrointestinal disorders (FGIDs)



Rome Clinical Algorithms

The Diagnostic Algorithms for Common Gastrointestinal Symptoms are now available on CD-ROM.

Books reduced 50%!

Be sure to get your copy at the Rome booth (#3826) at DDW in San Diego, CA

The Rome Foundation is committed to develop and support research and education to help people with Functional GI Disorders.

Learn more about any of our educational materials at:
www.theromefoundation.org



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WE ARE PLEASED TO PROVIDE SOME OF THE ARTICLES THAT HAVE BEEN PUBLISHED OVER THE LAST YEAR THAT HIGHLIGHT THE ROME CRITERIA.

- 1: Engsbro AL, Simrén M, Bytzer P. The Rome II and Rome III criteria identify the same subtype-populations in irritable bowel syndrome: agreement depends on the method used for symptom report. *Neurogastroenterol Motil.* 2012 Mar 16. doi: 10.1111/j.1365-2982.2012.01908.x. [Epub ahead of print] PubMed PMID: 22420629.
- 2: Tam YH, Li AM, So HK, Shit KY, Pang KK, Wong YS, Tsui SY, Mou JW, Chan KW, Lee KH. Socio-Environmental Factors in Family, School and Lifestyle Associated with Childhood Constipation: The First Territory-Wide Survey in Hong Kong Chinese Children Using Rome III Criteria. *J Pediatr Gastroenterol Nutr.* 2011 Dec 22. [Epub ahead of print] PubMed PMID: 22197949.
- 3: Yao X, Yang YS, Cui LH, Zhao KB, Zhang ZH, Peng LH, Guo X, Sun G, Shang J, Wang WF, Feng J, Huang Q. Subtypes of irritable bowel syndrome on Rome III criteria: A multicenter study. *J Gastroenterol Hepatol.* 2012 Apr;27(4):760-5. doi: 10.1111/j.1440-1746.2011.06930.x. PubMed PMID: 21929652.
- 4: Park JM, Choi MG, Cho YK, Lee IS, Kim JI, Kim SW, Chung IS. Functional Gastrointestinal Disorders Diagnosed by Rome III Questionnaire in Korea. *J Neurogastroenterol Motil.* 2011 Jul;17(3):279-86. Epub 2011 Jul 13. PubMed PMID: 21860820; PubMed Central PMCID: PMC3155064.
- 5: Jung HK. Rome III Criteria for Functional Gastrointestinal Disorders: Is There a Need for a Better Definition? *J Neurogastroenterol Motil.* 2011 Jul;17(3):211-2. Epub 2011 Jul 13. PubMed PMID: 21860813; PubMed Central PMCID: PMC3155057.
- 6: Tam YH, Chan KW, To KF, Cheung ST, Mou JW, Pang KK, Wong YS, Sihoe JD, Lee KH. Impact of pediatric Rome III criteria of functional dyspepsia on the diagnostic yield of upper endoscopy and predictors for a positive endoscopic finding. *J Pediatr Gastroenterol Nutr.* 2011 Apr;52(4):387-91. PubMed PMID: 21415670.
- 7: Anbardan SJ, Daryani NE, Fereshtehnejad SM, Taba Taba Vakili S, Keramati MR, Ajdarkosh H. Gender Role in Irritable Bowel Syndrome: A Comparison of Irritable Bowel Syndrome Module (ROME III) Between Male and Female Patients. *J Neurogastroenterol Motil.* 2012 Jan;18(1):70-7. Epub 2012 Jan 16. PubMed PMID: 22323990; PubMed Central PMCID: PMC3271257.
- 8: Engsbro AL, Simren M, Bytzer P. Short-term stability of subtypes in the irritable bowel syndrome: prospective evaluation using the Rome III classification. *Aliment Pharmacol Ther.* 2012 Feb;35(3):350-9. doi: 10.1111/j.1365-2036.2011.04948.x. Epub 2011 Dec 18. PubMed PMID: 22176384.
- 9: Yao X, Yang YS, Cui LH, Zhao KB, Zhang ZH, Peng LH, Guo X, Sun G, Shang J, Wang WF, Feng J, Huang Q. Subtypes of irritable bowel syndrome on Rome III criteria: A multicenter study. *J Gastroenterol Hepatol.* 2012 Apr;27(4):760-5. doi: 10.1111/j.1440-1746.2011.06930.x. PubMed PMID: 21929652.

IFFGD IS SEEKING APPLICATIONS FOR 2013 RESEARCH AWARDS

The International Foundation for Functional Gastrointestinal Disorders is seeking applications and nominations for research awards. The awards will be offered to active investigators in six categories who have a record of research interest in basic mechanisms or clinical aspects of functional gastrointestinal and motility disorders, and neurogastroenterology. These awards of \$7,500 each are intended to encourage the participation of clinicians and scientists in multidisciplinary efforts aimed at advancing the understanding of these basic mechanisms and clinical aspects in adults and in children.

Individuals selected for awards will be recognized at IFFGD's 10th International Symposium for Functional GI Disorders to be held in Milwaukee, WI on April 12-14, 2013.

THE DEADLINE FOR RECEIPT OF APPLICATIONS IS OCTOBER 1, 2012.

For details visit: www.giresearch.org/awards.

ABOUT THE ROME FOUNDATION

The Rome Foundation is an independent not for profit 501(c) 3 organization that provides support for activities designed to create scientific data and educational information to assist in the diagnosis and treatment of functional gastrointestinal disorders (FGIDs). Our mission is to improve the lives of people with functional GI disorders.

Over the last 20 years, the Rome organization has sought to legitimize and update our knowledge of the FGIDs. This has been accomplished by bringing together scientists and clinicians from around the world to classify and critically appraise the science of gastrointestinal function and dysfunction. This knowledge permits clinical scientists to make recommendations for diagnosis and treatment that can be applied in research and clinical practice.

The Rome Foundation is committed to the continuous development, legitimization and preservation of the field of FGIDs through science-based activities. We are inclusive and collaborative, patient-centered, innovative and open to new ideas.

The goals of the Rome Foundation are to:

- Promote clinical recognition and legitimization of the functional GI disorders
- Develop a scientific understanding of their pathophysiological mechanisms
- Optimize clinical management for patients with FGIDs



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