

The Rome Foundation Global Epidemiology study: Conception, implementation, results, and future potential

Ami D. Sperber 

Faculty of the Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel

Correspondence

Ami D. Sperber, Faculty of the Health Sciences, Ben Guion University of the Negev, Beer-Sheva, Israel.

Email: amiroie@me.com

Background: Methodological problems have impeded successful epidemiological research into disorders of gut-brain interactions (DGBI), as previous studies were limited in terms of study population, diagnostic criteria, number of disorders assessed, data collection methods, and geographic area. Most prevalence estimates were based on pooling data from heterogeneous studies using inappropriate pooling methods, seriously limiting the relevance of the results. The Rome Foundation Global Epidemiology Study (RFGES) aimed to rectify these limitations using rigorous methodology to survey the prevalence of 22 DGBI in large population samples in 33 countries. Its aims were to conduct a comprehensive, multinational epidemiological study using rigorous research methodology, gain a better understanding of the burden of the DGBI, gain reliable regional estimates of DGBI prevalence, and advance our understanding of the pathophysiology of IBS. The study questionnaire consisted of the 89-item Rome IV Adult Diagnostic Questionnaire enabling the diagnosis of 22 DGBI, and an 80-item supplemental questionnaire that enabled analyses of the association of multiple factors with DGBI diagnoses.

Purpose for review article: This review paper introduces a special issue on the Rome Foundation Global Epidemiology study (RFGES) with a narrative description of its conception, development, and implementation, its outcomes to date, and its potential contribution to neurogastroenterology. It includes 15 papers that reflect the range of RFGES studies from single country papers to intra-regional studies, to inter-regional studies, and one global study.

KEYWORDS

diagnostic criteria, disorders of gut-brain interaction, epidemiology, research, Rome Foundation

1 | INTRODUCTION

This paper introduces a special issue of Neurogastroenterology and Motility dedicated to the Rome Foundation Global Epidemiology study (RFGES). It provides an overview in which we present some

of the important findings of this large project, which has spanned more than a decade from conception to implementation and that is now providing our field with invaluable data on multiple aspects of the disorders of gut-brain interaction (DGBI), previously known as functional gastrointestinal disorders (FGID).

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In this paper I will describe how the study was conceived and developed, how it was implemented, what its outcomes are to date, the potential impact of the results on the field of neurogastroenterology, and how its large database can be mined in future studies.

2 | THE ROME FOUNDATION'S GLOBAL VISION AND INITIATIVE

Around 2005 the Rome Foundation (RF) began to develop active plans to extend its reach from a primarily US/Western European organization to a globally representative one. An aspect of this strategy was to assess our knowledge of the epidemiology of these disorders and, in doing so, it became clear that there were many critical gaps in our knowledge due to a primarily Western orientation, the almost exclusive focus on irritable bowel syndrome (IBS) and to a lesser degree functional dyspepsia (FD), and lack of uniform methodology that thwarted attempts to compare the results of different studies in a scientifically verifiable manner.

The first paper relating to these issues was published in *Neurogastroenterology and Motility* in 2009.¹ It was a personal position paper by the author (ADS) on the potential contribution of multinational, cross-cultural research for DGBI, with a discussion of the methodological problems that impede successful epidemiological research in the field. [Figure 1](#) (adapted from the original paper) presents the increasing level of sophistication of types of epidemiological studies from the pooling of heterogeneous studies (level 1),^{2,3} to the pooling of heterogeneous studies that use a common diagnostic criterion, for example, the Rome III criteria (level 2), to a single country study that uses the same methodology to compare different ethnic groups in that country (level 3),⁴ and concluding with a potential solution in the form of a global study including multiple countries, conducted at the same time, and using the same methodology (level 4), which was realized in the RFGES.

This was followed by the convening of a well-attended meeting in 2011 in Milwaukee co-sponsored by the RF and the World Gastroenterology Organization called "The Global Perspective on Irritable Bowel Syndrome." In a paper summarizing the meeting and its conclusions⁵ the following appeared on future research:

- Guidelines should be developed to improve the quality of multinational research in IBS and to develop cross-cultural research competence.
- The establishment and funding of international research networks for the conduct of cross-cultural, multinational research should be encouraged.
- Future epidemiological research should provide questions and methods to adequately assess the worldwide prevalence of IBS and identify similarities and differences in factors affecting IBS from a multinational perspective.
- Research should focus on "local biotics" and solutions to problems related to language and symptom reporting to elicit the

Key points

- Methodological problems have impeded successful epidemiological research into disorders of gut-brain interactions (DGBI), as previous studies were limited in terms of study population, diagnostic criteria, number of disorders assessed, data collection methods, and geographic area.
- Most prevalence estimates were based on pooling data from heterogeneous studies using inappropriate pooling methods, seriously limiting the relevance of the results.
- The RFGES aimed to rectify these limitations using rigorous methodology to survey the prevalence of 22 DGBI in large population samples in 33 countries.
- The RFGES accomplished most of its goals, in particular achieving a more clear picture of the global distribution and burden of the DGBI.

presence, frequency, and severity of symptoms. Local biotics refers to factors such as sanitation, hygiene, nutrition, climate, genetics, et al. that may be different among different cultures and geographic regions. One should recognize also that health systems vary greatly between countries and that symptoms, diagnoses and the recognition of syndromes is likely to be influenced by the way these systems operate, and by national and cultural understandings. Even within a single culture there may be differing understandings and rationalization of symptoms depending on the sort of health care or practitioner accessed.

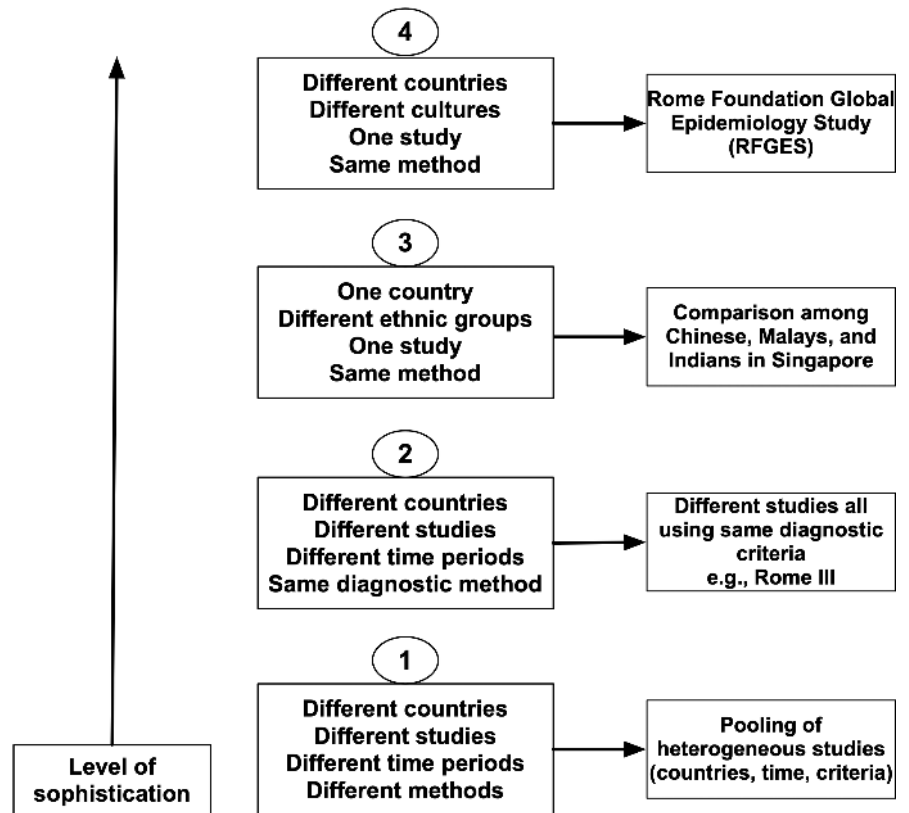
- Research should address whether phenotypic IBS is a model that can be applied worldwide or needs to be modified on the basis of cultural standards.

3 | RF WORKING TEAM ON CROSS-CULTURAL, MULTINATIONAL RESEARCH

To further these goals the next step was the establishment of the RF Working Team on Cross-Cultural, Multinational Research, which conducted its work between 2011 and 2013, concluding with three publications,^{2,6,7} two of which were directly related to the initiation of the RFGES.^{2,7} The working team's recommendations for research were summarized in a paper⁷ and reported in full in a Rome Foundation working team report.⁸

Based on these recommendations, preparations began for the RFGES, starting with its presentation for approval to the RF Board of Directors and the convening of the Global Study Executive Committee in 2013 comprised of leaders in the field of neurogastroenterology with a global distribution ([Figure 2](#)). Dr. Douglas Drossman, the President of RF at the time, was instrumental in gaining approval for the study and attaining funding for it.

FIGURE 1 Levels of sophistication of epidemiology studies in DGBI. Level 4, the most sophisticated level, reflects the methodology used in the RFGES (modified from Sperber AD. The challenge of cross-cultural, multi-national research: potential benefits in the functional gastrointestinal disorders. *Neurogastroenterology and Motility*. 2009;21:351–60).



4 | GLOBAL STUDY EXECUTIVE COMMITTEE AND INITIAL PREPARATIONS

The RFGES executive committee held its first meeting in person, conducted regular business by email and, when critical, phone calls (no Zoom or Teams then), and annual meetings at DDW each May.

The strategy that guided the executive committee's work was that there were 3 years (2013–2016) before publication of the Rome IV diagnostic criteria and the English language version of the Rome IV diagnostic questionnaire in May 2016. In that time the committee would set the parameters and methodology of the study, recruit the country PIs, obtain IRB approval or waiver in all countries, prepare the study supplemental questionnaire, attain funding, and get price proposals from translation companies for translation of the questionnaire into the country languages, and from Internet surveying companies for conduct of the Internet survey. In addition, the methodology of surveying by household interview in countries, where an Internet survey was not feasible, would be planned in detail. During this process the "game changing" decision was reached to expand the study to include all the DGBI and not just IBS, as originally planned. The country PIs were recruited between 2013 and 2015, so that as soon as the Rome IV questionnaire was published in May 2016 the entire plan was in place beginning with translation of the questionnaires (Rome IV criteria for all DGBI and the supplemental questionnaire) into the participating country's languages. The timeline for the RFGES from its inception and through the publication of the first paper is shown in [Figure 3](#). The translation process took about a year from mid-2016 to mid-2017 and the surveys were conducted over

the course of 2017. Each Internet survey took about 1 month and the progress was staggered in parallel with the ongoing availability of validated translations. Once data collection was completed the next year was devoted to data cleanup, validation, and quality control, following which data analyses were initiated.

4.1 | Global study database management and statistical analyses

Dr. Olafur Palsson, a member of the executive committee, who is an expert in database handling, questionnaire development, and computer programming in addition to his roles as GI psychologist and DGBI researcher, was responsible for all of these critical functions in the RFGES. He also worked directly with the professional company that carried out the Internet surveys and with the PIs who conducted the household interviews.

One of the earlier steps taken by the executive committee was to plan for the eventuality that we would need multiple first-tier statisticians to conduct the analyses for the papers based on the anticipated dataset. To this end a Research Analysis Core (RAC) was established under the leadership of Dr. Shrikant Bangdiwala, a world-renowned biostatistician and research methodologist, who has worked on previous projects with members of the RF. He developed guidelines for the statistical analyses and Dr. Palsson developed a codebook of all the dataset variables for the statisticians. In October 2019, a one-and-a-half day meeting was held with potential RFGES statisticians in Barcelona following the UEG Week meeting. This was attended

Members of global study executive committee



FIGURE 2 The global composition of the RFGES Executive Committee, first convened in 2013 to lay the groundwork for the study.

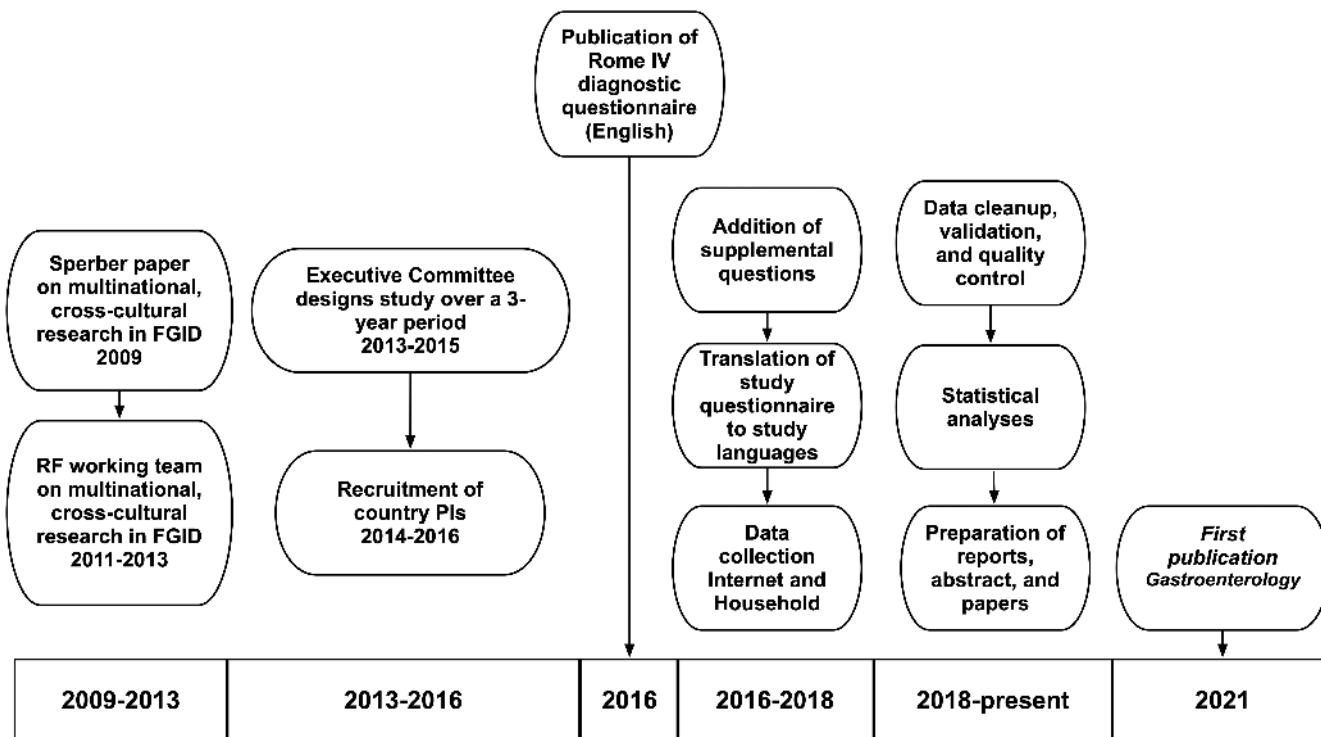


FIGURE 3 The timeline of the RFGES from 2009 (conception of the study) to 2021 (first RFGES paper published).

by close to 50 participants, including some of the country PIs in the study and many statisticians who were recruited by the country PIs or by the RAC. This meeting set the groundwork for a network that today numbers close to 20 statisticians who are active in the RFGES and ranked as tier 1 for global and inter-regional papers or tier 2 for

intra-regional and country papers (see the discussion below on types of RFGES studies and publications). The participating statisticians, who come from around the world, have volunteered their work on this project, so their only remuneration is co-authorship on papers to which they have made a significant contribution.

4.2 | Global study operational committee

When the surveys were completed and data analyses began there was a need for a smaller committee that could be convened more easily. This "Operational Committee" was comprised of seven members, Drs. Shrikant Bangdiwala, Douglas Drossman, Olafur Palsson, Magnus Simren, Jan Tack, William Whitehead, and the author (ADS), who served as committee chair. Beginning in 2018 the operational committee has held annual day long research meetings in Chapel Hill, NC in the framework of the Rome Foundation Research Institute's two-day annual meeting.

4.3 | Study questionnaire

The study questionnaire consisted of the 89-item Rome IV Adult Diagnostic Questionnaire enabling the diagnosis of 22 DGBI, and an 80-item supplemental questionnaire (Table 1) on sociodemographic characteristics, medical and health history, co-morbid symptoms and conditions, GI infection history, healthcare utilization and access, medications, childhood and current living conditions, psychosocial variables, diet, quality of life, and religious affiliation. It incorporated validated questionnaires such as the PROMIS Global-10 questionnaire,⁹ the Patient Health Questionnaire-15 (PHQ-15),¹⁰ the Personal Health Questionnaire-4 (PHQ-4)¹¹ on anxiety and depression, and the IBS Symptom Severity Scale (IBS-SSS).¹² We also included the Rome III IBS diagnostic questions¹³ to facilitate comparisons between these two iterations of the Rome diagnostic criteria.

4.4 | Translation and conduct of the Internet survey

Prior to finalization of the Rome IV Diagnostic Questionnaire and its publication, it underwent a translatability assessment by a professional company (TransPerfect, Inc. USA),¹⁴ in which potential difficulties in translating the questionnaire into nine specific languages were assessed. After the English version was finalized and published it was translated by the same company into 21 languages through a process of two forward translations, reconciliation, one backward translation, comparison of the original and back translated versions (both English), validation of the translation, and linguistic validation (cognitive debriefing). The principles of cross-cultural translation are discussed in a paper on the methodology of this process.¹⁵ A local clinician monitor (usually the country PI) followed the translation process to ensure that the translated versions were not only linguistically valid but also culturally adapted for their country.

The Internet survey was conducted from the University of North Carolina, with recruitment of survey participants carried out world-wide according to pre-defined demographic parameters by Qualtrics, Inc. (Provo, Utah), a US-based company that specializes

TABLE 1 Comparison of the geographic distribution of the RFGES US sample (N = 2014) and the national distribution of the US population (2017 US Census) across the 50 states and the District of Columbia.

State	RFGES sample (%)	US population ^a (%)
Alabama	0.9	1.5
Alaska	0.1	0.2
Arizona	2.2	2.1
Arkansas	0.6	0.9
California	9.2	12.2
Colorado	1.6	1.7
Connecticut	1.6	1.1
Delaware	0.4	0.3
District of Columbia	0.1	0.2
Florida	7.2	6.4
Georgia	2.8	3.2
Hawaii	0.2	0.4
Idaho	0.5	0.5
Illinois	4.9	4.0
Indiana	2.1	2.1
Iowa	0.9	1.0
Kansas	1.1	0.9
Kentucky	1.6	1.4
Louisiana	0.5	1.5
Maine	0.5	0.4
Maryland	1.5	1.9
Massachusetts	2.1	2.1
Michigan	3.7	3.1
Minnesota	1.9	1.7
Mississippi	0.8	0.9
Missouri	2.0	1.9
Montana	0.2	0.3
Nebraska	0.5	0.6
Nevada	1.1	0.9
New Hampshire	0.7	0.4
New Jersey	3.7	2.8
New Mexico	0.4	0.6
New York	8.7	6.1
North Carolina	3.3	3.1
North Dakota	0.5	0.2
Ohio	4.4	3.6
Oklahoma	1.1	1.2
Oregon	1.7	1.3
Pennsylvania	5.0	4.0
Rhode Island	0.3	0.3
South Carolina	1.3	1.5
South Dakota	0.3	0.3

(Continues)

TABLE 1 (Continued)

State	RFGES sample (%)	US population ^a (%)
Tennessee	1.8	2.1
Texas	6.2	8.6
Utah	0.5	0.9
Vermont	0.3	0.2
Virginia	2.1	2.6
Washington	1.9	2.3
West Virginia	0.3	0.6
Wisconsin	2.2	1.8
Wyoming	0.1	0.2

^aBased on the 2017 population estimates of the US Census Bureau.

in global surveying through the Internet. The household interviews were conducted by trained teams in each country, led by the country PI. The methodology of Internet and household interview surveying is analyzed and discussed in detail in the methodology paper in this special issue.

5 | AIMS OF THE RFGES

The aims of the RFGES were: (a) to conduct a comprehensive, multinational epidemiological study using the research methodology recommended by the Rome Foundation working Team on Cross-Cultural, Multinational Research and adapted for the RFGES under the leadership of Dr. Bangdiwala, (b) gain a better understanding of the burden of the IBS (later changed to all DGBI), (c) gain reliable regional estimates of DGBI prevalence, (d) evaluate the reasons for differences among regions, and (e) advance our understanding of the pathophysiology of IBS.

6 | METHODOLOGICAL CONSIDERATIONS

6.1 | Study parameters

The Executive Committee determined the following guidelines at an early planning stage:

- A global representation of participating countries.
- A minimum of 2000 participants in each country. This number provided sufficient statistical power without making the study economically unfeasible.
- A sex distribution of 50% females and 50% males.
- An age distribution of 40% for 18–39 years, 40% for 40–64 years, and 20% for 65+ years.
- A close approximation to the national geographic distribution.
- A representative urban–rural distribution.

6.2 | Data collection method

The preferred method of data collection was by Internet survey (see the methodology paper in this special issue for a detailed explanation). However, it became clear that to attain a more complete global picture and to collect epidemiological data with a global representation we would have to include areas of the world (Africa and Asia) where Internet surveying was not feasible in all countries. Thus, truly global data collection would require two different data collection methods in this project; Internet survey and in-person household interviews.

The RFGES data were collected by Internet surveys in 26 countries (Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, Egypt, France, Germany, Holland, Israel, Italy, Japan, Mexico, Poland, Romania, Russia, Singapore, South Africa, South Korea, Spain, Sweden, Turkey, the United Kingdom, and the United States) and by in-person household survey in seven countries (Ghana, Nigeria, India, Bangladesh, Malaysia, Indonesia, and Iran). In two countries, China and Turkey, both methods were implemented for purposes of comparison and validation.

7 | WERE THE STUDY PARAMETERS REACHED?

In all, 33 countries participated in the study. Every one of the Internet countries had at least 2000 participants. All of the household interview countries recruited 2000 participants, but the final number of valid records was lower in some countries than 2000 due to data entry irregularities that could not occur in the Internet survey method but could occur with manual data entry as in the household interviews.

7.1 | National geographic representation

By definition, national geographic representation could not be achieved in the household interview countries where interviews were conducted in pre-determined catchment areas. In contrast, an excellent approximation of the national geographic distribution was achieved in the Internet surveys. As an example, [Table 2](#) shows the latest US census data available prior to the RFGES (% of population in each state) and the corresponding percentage in our survey.

7.2 | Sex and age representation

The pre-determined parameters of equal sex distribution and an age distribution of 40% for 18–39 years, 40% for 40–64 years, and 20% for 65+ years were met, with the exception of the 65+ age group who turned out to be more difficult to recruit into the study.¹⁶ In six Internet countries, the age group distribution was not fully met due to the inability to enroll sufficient numbers in the 65+ age group. In

TABLE 2 Item content of the supplemental questionnaire.

Question content	Number of items
Demographic questions:	
Age	1
Sex	1
Years of education	1
Relationship status	1
Size of local community where respondent lives	1
Region (state, province, etc.) of residence	1
Race/Ethnicity (not administered in all survey countries)	1
Religious/spiritual self-identification	1
Personal Health Questionnaire-15 (PHQ-15)	15
IBS Severity Scale Score (IBS-SSS)	7
Current living conditions: Whether respondent lives on a farm, has running water and electricity, daily access to telephone and internet, number of people in the household, number of bedrooms and toilets-	4
Childhood living conditions up to age 7: Whether respondent lived on a farm, had running water and electricity, number of people in the household, number of bedrooms and toilets-	4
Childhood country of residence	1
Childhood size of local community	1
Access to medical care if needed	1
Type of medical care that would be sought if needed (Western style medicine and/or traditional or folk healer	1
Frequency of doctor visits	1
Who pays for medical expenses	1
History of medical diagnoses (checklist of 12 GI diagnoses and conditions that may affect FGIDs)	1
History of GI and abdominal surgeries- Checklist of five surgery types	1
Medications taken regularly (at least once a week)-Yes/no list of 10 types of medications	1
Bowel infection history: Whether current bothersome symptoms first started immediately after bowel infection	1
Symptoms, conditions and treatment of bowel infection preceding first onset of current bothersome bowel symptoms	2
History of visiting doctor because of a bowel problem (yes/no)	1
Type of doctor seen for bowel problems	1
Concern about own bowel functioning (yes/no)	1
Embarrassment about bowel functioning (yes/no)	1
Impact of stress, pressure or tension on bowel functioning (yes/no)	1
Diet: Days per week of consumption of 10 food types	1
PROMIS Global-10 quality of life questionnaire	10

(Continues)

TABLE 2 (Continued)

Question content	Number of items
Personal Health Questionnaire - 4 (PHQ-4): Anxiety and depression screening measure	4
Height and weight	2
Rome III diagnostic questions for IBS (not administered in all countries)	8

these countries, there is limited Internet access or lower usage in this age group.

8 | PUBLICATIONS

Due to its size and diversity the RFGES dataset is a rich source of data for research projects and the publication of papers. It can serve as reference material to generate hypotheses for future research including pathophysiological studies using the data derived from the supplemental questionnaire that forms an integral part of the dataset and to inform processes such as the development of the Rome V criteria to be published in 2026.

As of December 2022, nine RFGES papers have been published¹⁶⁻²³ or accepted for publication,²⁴ one editorial has been devoted to it,²⁵ and over 40 other papers are in various stages of review or preparation, including the 15 papers appearing in this special issue.

These papers reflect the diverse levels of analysis that can be accomplished using the RFGES database:

Global level studies – studies that utilize the entire dataset, or the Internet and household datasets separately:

- Descriptive statistics as in the first and main global study paper.¹⁶
- Methodology papers.
- Papers relating to a specific disorder, for example, IBS.
- Papers relating to a specific topic, for example, sex differences.
- Validation papers, for example, factor analyses, symptom networks, patient clustering.

Inter-regional level studies – studies that compare more than one of the geographic regions in the RFGES dataset: North America, Latin America, Western Europe, Eastern Europe, Asia, Africa.

Intra-regional papers – papers that compare countries in the same geographic region.

Individual country papers – presentation of descriptive statistics, specific disorders, and specific topics at the country level.

9 | INFORMING THE ROME V DEVELOPMENT PROCESS

The RFGES dataset provides copious reference material for the chapter committees responsible for updating the Rome diagnostic

criteria and for non-diagnostic committees such as "Age, Gender, Women's Health, and the Patient," "Sociocultural Aspects of DGBI," and "Psychosocial aspects of DGBI." To facilitate this process the Rome V editorial board established an Epidemiology Support Committee, comprised of Drs. Ami Sperber, Olafur Palssson, and Shrikant Bangdiwala. This committee is mining the RFGES database for any information and analyses requested by the Rome V chapter committees. In addition it has begun providing supporting analyses for the development of clinical criteria, and is assessing the question as to whether the RF diagnostic criteria are applicable, without modification, in all geographic regions and cultural groups.

10 | OPPORTUNITIES FOR FUTURE RESEARCH

The RFGES dataset is a rich source of data that can be mined for future research in multiple research directions. It has established guidelines that must be followed to submit proposals for future publications. There is an official submission website, and all proposals undergo a review process before they are either approved, revisions are requested, or the proposal is not accepted because of concerns about, feasibility, duplication, lack of interest, or other possible grounds for rejection. There are strict guidelines for who can serve as a RFGES statistician and rules for authorship on RFGES papers.

11 | CONCLUSION

The RFGES was designed to address the methodological issues that impeded our understanding of the prevalence and burden of the DGBI and associated factors. It is an ambitious project that was in the planning stage for over 5 years, adopted very strict methodological guidelines and constraints, followed and implemented the recommendations of the RF Working Team on Cross-cultural, Multinational Research, made every effort to assure the quality of the data collected, and now serves as a source for multiple papers that are providing invaluable information on the DGBI for our field. It can serve as a source for data mining for years to come and will inform the process of development of the Rome V process. This is of particular importance since there has been a gradual progression from Rome I to Rome IV in the relative weight of evidence-based and eminence-based criteria and Rome V will now be informed by a repository of evidence-based information that was not available for any of the earlier iterations of the diagnostic criteria. This special issue of Neurogastroenterology and Motility showcases the achievements, many key interesting findings at global, inter-regional, regional and national levels of analysis in this vast dataset, and potential future contributions of the RFGES.

AUTHOR CONTRIBUTION

ADS wrote this paper and approved it.

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CONFLICT OF INTEREST STATEMENT

No competing interests declared.

ORCID

Ami D. Sperber  <https://orcid.org/0000-0002-7634-3689>

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