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Development of the Rome V Diagnostic Questionnaires

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This article describes the development of the Rome V adult and pediatric diagnostic questionnaires. Important updates from the Rome IV versions included improved response scaling, new questions to diagnose 3 additional adult disorders of gut–brain interaction (DGBI) and 14 additional pediatric DGBI (compared with the Rome IV questionnaires), extra questions to clarify the context of DGBI symptoms for research purposes, and the addition of anatomical images to enhance response accuracy. The performance of the Rome V adult questionnaire was tested in internet surveys in 15 countries and the pediatric questionnaires in 4 countries. The results indicate that the new questionnaires generally identify DGBI to a similar degree and with the same demographic patterns as the prior Rome IV versions. The Rome V Questionnaire Committee concluded that these new diagnostic questionnaire versions are well suited for epidemiologic and clinical research of DGBI in the Rome V era for both adult and pediatric populations.

Keywords: DGBI; Epidemiology; Rome V; Diagnostic Questionnaires.

The Rome diagnostic questionnaires must be updated with every new iteration of the Rome criteria to ensure that they accurately diagnose disorders of gut–brain interaction (DGBI) according to new criteria. These questionnaires have become essential tools for reliably identifying cases that meet the formal published Rome criteria, especially in epidemiological and clinical research, but frequently in clinical practice as well. The questionnaires translate the official Rome diagnostic criteria, written by DGBI experts for medical professionals, into a set of self-report questions about symptom patterns that patients and research participants can be expected to answer reliably. The questionnaires include response scales that enable determination of whether the required patterns of symptoms that define each disorder are sufficiently present to warrant diagnosis. The global availability of these self-administered questionnaires has transformed our understanding of DGBI, made large-scale research studies possible, and resulted in multiple landmark publications. The Rome Foundation's Global Epidemiology Study (RFGES)[1,2] illustrates the utility and impact of the Rome diagnostic questionnaires. The study's comprehensive assessment of more than 75,000 adults in 33 countries on 6 continents, all of whom completed the same diagnostic questionnaire regarding 22 DGBI (ie, the Rome IV Adult Diagnostic Questionnaire), provided the first truly global picture of these highly impactful disorders. To date, the RFGES has resulted in more than 50 published scientific papers, many of which have provided novel insights into the epidemiology, characteristics, effects, and associated factors of the various DGBI, and the findings have been cited in more than 1200 papers in the field. The Rome diagnostic questionnaires also have become invaluable tools in both pharmacologic and nonpharmacologic research on DGBI, and grant funding bodies and regulatory agencies have increasingly required their use in clinical studies to help ensure dependable case definitions.[3,4]

Although these questionnaires have proved invaluable for DGBI diagnosis, it must be recognized that they do not offer the same level of utility for identifying all DGBI. For some Rome DGBI entities, such as irritable bowel syndrome (IBS), the questionnaires can identify the disorder with high reliability, although potential alternative causes of the symptoms may have to be ruled out on a case-to-case basis. For others, such as the esophageal DGBI, the diagnostic criteria specify particular objective test findings as part of the criteria and a more extensive need to rule out alternative causes for the symptoms. For those disorders, it is more appropriate to consider the criteria-congruent symptom patterns that the questionnaires identify as being cases "consistent with" or "compatible with" the DGBI diagnosis in question, rather than being diagnostic. Finally, a few DGBI do not lend themselves to questionnaire-based identification as the criteria defining them are primarily based on physiologic test results. Examples of these are sphincter of Oddi disorder, dyssynergic defecation, and the new Rome V diagnoses

Abbreviations used in this paper: **CC, chronic constipation; DGBI, disorders of gut–brain interaction; FD, functional dyspepsia; FICAI, Frequency, Intensity, Chronicity, and Impact; IBS, irritable bowel syndrome; RFGES, The Rome Foundation's Global Epidemiology Study.**

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of rectal hypersensitivity and rectal hyposensitivity. It is not possible to identify those particular disorders effectively with questions in diagnostic questionnaires, so the Rome diagnostic questionnaires cannot assess the entire spectrum of DGBI defined by the Rome criteria.

Updating the diagnostic questionnaires in preparation for a new version of the Rome criteria involves multiple steps by experts in the field. These steps include adjusting question wording and adding or deleting questions to reflect the various changes in diagnostic criteria; reviewing performance problems identified in the current version, such as poorly performing questions or response scales that require revisions; and incorporating new questions to reflect new diagnoses. This work is done by the Rome Questionnaire Committee, which is appointed by the editorial board for the Rome criteria. In addition, testing the performance of new questionnaire versions in formal clinical or population-based studies has become an integral part of the committee's work.

The Rome V Questionnaire Committee

The Rome V Questionnaire Committee was composed of 7 individuals, including 2 gastrointestinal (GI) psychologists (Olafur S. Palsson, Tiffany Taft), 2 pediatric gastroenterologists (Marc A. Benninga, Miguel Saps), and 3 gastroenterologists (Brian E. Lacy, Magnus Simrén, Ami D. Sperber) who focus on DGBI in adults; one of these experts is also an expert on multicultural issues and questionnaire translations. The committee was divided into adult and pediatric subcommittees to streamline work on the respective questionnaires, although the entire committee made overall decisions as a single group during the development process.

The committee began holding meetings via video conference in early 2023 to initiate the questionnaire development process and to review the Rome IV questionnaires for potential revisions and additions. One of the major early decisions in those meetings was a commitment to carrying out multinational epidemiology and validation studies with the new diagnostic questionnaires as soon as possible after they had been drafted to make preliminary results available to the Rome criteria committees for reference before they finalized the Rome V criteria. This decision was made at the direction of the Rome V Editorial Board and was important for multiple reasons: (1) to ensure that the questionnaires could identify the new DGBI entities introduced into Rome V, for which no prior diagnostic questions or data existed; (2) to confirm reasonable comparability in performance to Rome IV data so that the Rome V DGBI could be expected to be diagnosed similarly to the extent that the criteria were comparable; and (3) to ensure that alterations in the Rome criteria introduced in Rome V did not result in unforeseen implausible diagnostic results such as excessively high or low population prevalence rates for specific DGBI. Completing these studies in advance of finalizing the new criteria enabled any necessary adjustments to the criteria and/or to the questionnaire scoring rules to be made before publication.

The committee also decided that true clinical validation studies of the new diagnostic questionnaires (ie, studies using clinical diagnosis by experienced gastroenterologists as a gold standard to measure the performance of the questionnaires) would not be feasible as a part of the Rome V questionnaire development process. The primary reason for this decision was the amount of time required to collect prospective questionnaire data in a sufficiently large clinical population. It was not deemed feasible in the short period between the creation of the diagnostic questionnaires (which could not be created until the criteria had reached near-final form) and the release of the criteria. A study comparing clinical and questionnaire DGBI diagnoses to validate the questionnaires takes years to carry out and involves substantial personnel resources across multiple sites, as the sample size must be large enough to encompass all of the DGBI measured by the questionnaires. A limited study of this nature[5] was accomplished by the Rome IV Questionnaire Committee in advance of the release of the Rome IV Adult Diagnostic Questionnaire, but the results highlight the difficulties of this approach for validating such comprehensive questionnaires. Despite involving 9 large GI clinics in multiple countries and obtaining analyzable data on 843 distinct patients over several years of research, sensitivity and specificity analyses to examine the questionnaire diagnostic performance could be carried out for only a few of the 22 disorders that the questionnaire assessed (ie, IBS, functional dyspepsia [FD], and chronic constipation [CC]). Appropriate analyses could not be performed for many of the less prevalent DGBI because few or no patients with many of the disorders that the questionnaire was designed to detect visited the clinics. Also, it was unclear whether the clinicians had even considered, or asked about, symptoms that might indicate the presence of some of the disorders, as those symptoms might not have been their focus or a presenting problem in the clinical encounters. It was therefore decided by the Rome V Questionnaire Committee that evaluation of the performance of the Rome V questionnaires would be limited to (1) an assessment of general similarity of DGBI prevalence and demographic patterns to comparable prior results, and (2) a review of the distributions of responses to each question by study respondents in the general population to determine whether the response patterns were indicative of a correct understanding of the questions by respondents.

After multiple meetings and the collection of new data to inform decisions about adjustment in the response scales of the new version of the adult questionnaire, the questionnaire committee members met in person in Rome, Italy, with all the DGBI criteria committees (6 adult criteria committees and 2 pediatric committees) in December of 2023 to learn about the new criteria proposed by the individual committees and to discuss any potential issues with questionnaire assessment of those new criteria.

Drafts of both the adult and pediatric questionnaires were created immediately after those meetings in Rome. The questionnaires were finalized in the spring of 2024 after the criteria committees had each reviewed drafts of

the diagnostic questions relevant to their section, had provided feedback, and had approved a final version of their questionnaire sections after adjustments based on their input. The questionnaires were then immediately sent for professional translation into the languages needed for the planned multinational epidemiology and validation studies, and applications for ethics approval were carried out in all countries. Both the adult and pediatric survey studies were launched in December of 2024 and were completed within approximately 4 months. Immediately following completion of these multinational surveys, preliminary analyses were carried out and the results reported to the Rome V criteria committees and the Rome V Editorial Board.

Development of the Rome V Adult Diagnostic Questionnaire

In a review of the Rome IV questionnaire to assess the need for possible modifications, the Rome V Questionnaire Committee identified several problems with the response scaling of that questionnaire that warranted changes for the Rome V iteration. These problems concerned 1 of the 3 main response formats used in the questionnaire—a 9-point absolute frequency scale used to assess the frequency of symptoms in the past 3 months, required for the diagnosis of most DGBI. As shown in Figure 1*A*, the response options on that scale range from "never" to "multiple times per day or all the time." The primary problem was that 2 of the response options combined more than 1 specific symptom frequency into a single response option (ie, "2 to 3 times per month" and "2 to 3 times per week"). This made it difficult to pinpoint the precise frequency of symptoms for diagnostic purposes, which was a significant drawback for ensuring accurate assessment of multiple Rome-defined DGBI. For example, the Rome IV FD criteria required 3 days per week of either uncomfortable fullness or early satiety, but determining whether respondents met that criterion had to rely on approximation because the corresponding threshold on the response scale was 2 to 3 days per week (which incorrectly let some people with less than the required minimum symptom frequency qualify for the diagnosis in the scoring rules). Moreover, the combination of multiple symptom frequency steps artificially caused an unevenness in the natural progression of steadily lower prevalence with each higher frequency step across the scale, with elevated prevalence of endorsement for "2 to 3 times per month" and "2 to 3 times per week" compared with the surrounding frequency steps. This made the symptom variables measured with this scale less suitable for analysis compared with a scale with more even intervals. A potential third issue with the 9-point Rome IV questionnaire response scale was that it switched timeframes, from "days per month" to "once per week," at a frequency point critical to the diagnosis of some of the DGBI. This was thought to be potentially confusing to respondents and could lead to diagnostic inaccuracies.

The committee decided to empirically test 2 alternatives in response scaling as potential improvements for these problems: an alternative 9-step frequency scale that that did not combine 2 and 3 days per month and 2 and 3 days per week, respectively, and that also added "4 days per month" as a descriptor to the once-per-week timepoint for consistency with a lower number of days (Figure 1*B*). The other response scale that was tested was a 31-point scale with a response option for each day from 0 to 30 days.

A nationwide population-based survey of 2000 adults was conducted in the United States via the internet in the fall of 2023 to compare the response characteristics of these 3 response scale variants when used to obtain answers about the same GI-symptom questions. Because of the number of questions needed to test 3 alternative response scales, the survey was limited to Rome IV symptom questions (with some modifications to be more consistent with the emerging Rome V criteria) for diagnosing just 5 DGBI, representative of 4 different regions of the GI tract: functional dysphagia, FD, IBS, proctalgia fugax, and levator ani. Questions about the frequency of key diagnostic symptoms of these disorders were asked in 3 different ways of each survey participant, using each of the response scale variant options to be considered for Rome V. The 3 versions of the questions were presented in random order to the research participants to avoid an order effect.

The results of this survey revealed that the frequency distribution with the modified 9-point frequency scale (Figure 1*B*) successfully corrected the unevenness in the

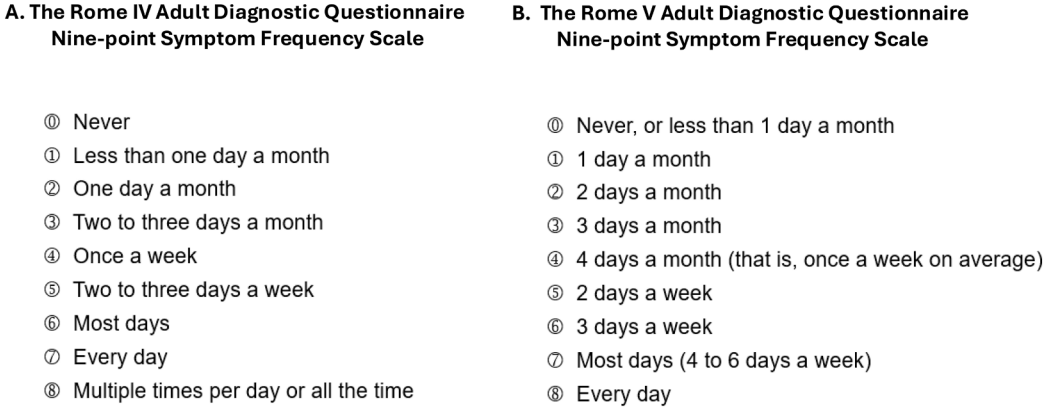

Figure 1. Comparison of the 9-point response scales in the Rome IV (*A*) vs Rome V (*B*) Diagnostic Questionnaire.

prevalence of symptom frequency reporting across the scale, eliminating the "humps" in the descending frequency at the "2 to 3 times a month" and "2 to 3 times a week" frequency points. The results with the new 9-point frequency scale were generally comparable to the original Rome IV version (Figure 1) with regard to the prevalence of identified cases of the DGBI evaluated, although the prevalence was slightly higher when the modified scale was used. In contrast, the prevalence rates of the same DGBI were different and higher for 4 of the 5 DGBI tested when the 0- to 30-day scale was used compared with results for the other 2 scale variants, indicating that it elicited different reporting of symptoms. The results further revealed that the 0- to 30-day scale was used in a biased manner by respondents, as an excess of responses was evident at symptom frequencies of 10, 15, 20, 25, and 30 days compared with the other surrounding response options, suggesting that the precision requested was likely resulting in inaccurate approximation at convenient mental anchor points. Based on these findings, the committee decided unanimously to use the new modified 9-point response scale in the Rome V Adult Diagnostic Questionnaire shown in Figure 1*B* instead of the one used in the Rome IV version.

Characteristics of the Rome V Adult Diagnostic Questionnaire and Differences From the Rome IV Version

The Rome V Adult Diagnostic Questionnaire is composed of 114 questions, compared with 86 questions for the Rome IV predecessor. It is designed to assess the presence of 25 distinct DGBI, 3 more than the number evaluated by the Rome IV questionnaire. The 3 additional DGBI assessed with the new questionnaire include inability to belch syndrome, abdominal migraine, and narcotic bowel syndrome (the first 2 of these are new DGBI in the Rome criteria system). The main differences in the Rome V Adult Diagnostic Questionnaire compared with Rome IV can be summarized as follows:

- *Addition of questions to diagnose 3 more DGBI than the Rome IV version.*
- *Modifications of Rome IV diagnostic questions to accommodate changes in criteria and to enhance diagnostic precision.* An example of the latter is asking separately about the frequency of epigastric pain and epigastric burning sensations for the diagnosis of epigastric pain syndrome.
- *Addition of anatomical images.* Three images were added to the questionnaire at the request of the gastroduodenal and gallbladder/sphincter of Oddi criteria committees to indicate to questionnaire responders the location of epigastric pain, epigastric burning sensation, and biliary pain.
- *Additional questions for research purposes.* Some of the criteria committees requested inclusion of questions related to the symptom patterns of particular DGBI that were not required for diagnosis, but that either might be needed for diagnosis in future versions or that were thought important to include to enhance the utility of the diagnostic questionnaire as a research questionnaire, by eliciting additional self-report data for context on the DGBI it assesses. The questionnaire committee carefully weighed the value of all such extra question requests against the burden of increasing the questionnaire length and agreed to several such additions that were deemed important. Examples of these include questions about how quickly epigastric symptoms occur after meals and about the ability to control the passing of gas.
- *Modification of the 9-point frequency response format*, as described previously.

The Adult Rome V Epidemiology and Validation Survey

The questionnaire committee, jointly with the Rome Foundation Research Institute, carried out a global survey using the newly created Rome V Adult Diagnostic Questionnaire. The goal of this was 2-fold: (1) to test the performance of the new diagnostic questionnaire, with results available early enough to inform the Rome V criteria committees about any critical changes to diagnostic criteria or scoring formulas that might be needed, and to enable needed modifications in the questionnaire or the diagnostic scoring formulas in time for such changes to be made; and (2) to provide an early comprehensive picture of the global epidemiology of DGBI according to the emerging Rome V criteria.

Regarding the testing of the diagnostic questionnaire, the aims were to compare the prevalence and global demographic patterns of DGBI from previous results with the global findings for Rome V DGBI, examine the distributions of responses to identify any unexpected patterns that might indicate problems with respondents' understanding of the meaning of questions, and test scoring formulas generated for the new questionnaire. An additional goal was to examine whether the 3 DGBI entities assessed for the first time with the Rome V version of the questionnaire (ie, abdominal migraine, inability to belch syndrome, and narcotic bowel syndrome) could be effectively identified with the novel questions and scoring formulas that were created for these disorders.

Survey Methodology and Conduct

The study was an internet survey in 15 countries: Argentina, Canada, China, France, Germany, Japan, South Korea, Mexico, Poland, Romania, Spain, Sweden, Turkey, the United Kingdom, and the United States. The survey methodology was identical to the internet part of the RFGES.[1] All data collection was managed from the University of North Carolina at Chapel Hill, which served as the data coordination center for the study. Participants were recruited nationwide in each country according to prespecified demographic quotas by Qualtrics Inc, a global market research

company. The company invited people who were registered members of large survey-taker panels in the different countries to participate via e-mail, with the help of subcontractor survey companies in those countries, until all demographic quotas had been successfully filled. In addition to the entire Rome V Adult Diagnostic Questionnaire, the survey contained an extensive supplementary questionnaire that included questions on demographics, select medical history, health care utilization, medication use, use of special diets and dietary supplements, quality of life, psychological symptoms, and history of COVID infection and illness.

The study survey was translated by a professional translation company, TransPerfect, into the main languages of the surveyed countries. The translation process included cognitive debriefing of patients with GI disorders in the respective countries to ensure understandability and appropriate cultural adaptation of all questions, as well as monitoring and certification of each translation by a native GI disorders expert.

As in prior Rome Foundation epidemiological surveys, the survey used a number of quality-control measures to help ensure accurate and complete responses. All skip patterns were automatically implemented in the survey software, and completion of all questions was enforced, so there were no missing data or uninterpretable answers due to incorrect skips in the dataset. The survey included 2 attention-check questions, a completion speed check, and 2 repeated GI-symptom frequency questions for assessing self-report consistency. All of these were used to eliminate inattentive and excessively inconsistent survey responders during and after data collection. To minimize self-selection bias, prospective survey participants were unaware of the GI-symptom focus of the survey when they decided to enroll; the survey was simply described to them as a "health survey."

The data collection in the study was conducted in a fully deidentified manner. The study participants were anonymous to the investigators. The study was either approved or formally exempted from review and ethical oversight by institutional review boards or ethics committees in all 15 countries surveyed.

The survey data collection was carried out between December 20, 2024, and March 12, 2025. A total of 30,000 valid participants completed the survey (exactly 2000 in each country, as originally planned). The mean age of survey completers was 46.5 years, with a range from 18 to 99 years. The age group distribution was 40.2% for ages 18 to 39 years, 40.2% for ages 40 to 64, and 19.6% for those 65 years and older.

Diagnostic Scoring of Survey Data

The newly generated draft diagnostic scoring formulas for the Rome V questionnaire were applied to the survey responses in the dataset to identify all cases of the 25 DGBI that the questionnaire is designed to measure. As is conventional in Rome Foundation epidemiologic research, individuals with a self-reported history of organic GI diagnoses that might account for DGBI-type GI symptoms were excluded from assignment of the relevant Rome V DGBI diagnoses. People reporting a history of celiac disease, GI cancer, or inflammatory bowel disease were excluded from all Rome V DGBI diagnoses. Those reporting peptic ulcer disease were excluded from esophageal, gastroduodenal, and biliary diagnoses but could be assigned bowel, centrally mediated abdominal pain, and anorectal DGBI diagnoses. People reporting diverticulitis and those with a history of bowel resection were excluded from bowel, centrally mediated abdominal pain, and anorectal diagnoses, but were not excluded from esophageal, gastroduodenal, or biliary diagnoses.

Analyses of the survey results indicated that overall, the global DGBI prevalence using Rome V criteria is comparable to that of Rome IV in the RFGES.[1] The global prevalence of having at least 1 DGBI based on the present study was 42.2% vs 40.3% in Rome IV. The demographic patterns of having DGBI were closely comparable in the present results to what was found in Rome IV. The sex ratio of having any DGBI in the current survey was identical to that found in the RFGES (female/male odds ratio, 1.66 vs 1.67), and most DGBI declined in prevalence with age in a way comparable to that seen in the RFGES, with the most marked prevalence drop again typically seen in the 65 and older age group.

The great majority of DGBI in the current survey showed prevalence levels that were relatively similar to those previously reported in Rome IV. There were, however, a few marked prevalence differences compared with Rome IV in these new Rome V results that are worth noting, almost all of which were logical or even expected due to specific criteria or question changes:

Prevalence of IBS was doubled compared with Rome IV, at 8.9% vs 4.1%. This was expected from the changes in the criteria in Rome V, which include lowering of the minimum pain frequency threshold to 3 days per month and reincorporating the word "discomfort" into the definition.

Prevalence of cannabinoid hyperemesis syndrome was increased compared with Rome IV, although still low (0.6% vs 0.05%). This increase was likely due to wording changes in the questionnaire to reduce reactivity to inquiry about cannabis use, and perhaps also in part because of increased cannabis use in many countries over the past decade.

Opioid-induced constipation prevalence was greatly reduced compared with Rome IV, at 0.2% vs 1.6%. This was likely largely because of a more stringent assessment in the new questionnaire, and requiring self-report of opioid-type medications rather than just establishing prescription pain medication use as in the Rome IV questionnaire.

Fecal incontinence prevalence was substantially higher than in Rome IV, at 4.2% vs 1.6%. This was largely because of lowering of the diagnostic frequency threshold of fecal incontinence episodes in Rome V from 2 per month to 1 per month.

Proctalgia fugax prevalence was increased compared with Rome IV, at 7.4% vs 5.6%. This was despite revision of the anorectal pain description in the Rome V Adult Diagnostic Questionnaire to refer only to pain rather than the overly broad and inaccurate "aching, pain, or pressure"

characterization in the Rome IV questionnaire. That adjustment had been expected to lower the prevalence, which was already thought to be remarkably high in the Rome IV population data, but instead, the opposite prevalence change was observed. The cause of this is unclear.

It must be noted that the Rome V vs Rome IV global prevalence estimates for the different DGBI are based on study samples that included partly different groups of countries (11 countries surveyed in the Rome IV study were not included in the Rome V study) and the sample sizes per country were also not entirely the same. Future analyses likely will be done to provide more precise comparisons between the study findings by limiting analysis to the same countries and using weights to equalize the per-country sample sizes. However, it is likely that the patterns of differences described previously will be similar in more exact comparisons due to the size of the differences observed.

Among the 3 diagnostic entities added to the Rome questionnaire assessment for the first time, abdominal migraine was found to be the most prevalent in the survey sample (5.3%), indicating that it may be a major addition to the Rome DGBI family of disorders. Inability to belch syndrome had a prevalence of 1.5%. Very few people met the criteria for narcotic bowel syndrome (0.08%), potentially underscoring that effective identification of that disorder by questionnaire self-report may be difficult.

Regarding the validation of the Rome V Adult Diagnostic Questionnaire, the questionnaire committee concluded that the Rome V version seems generally as effective at identifying DGBI as its Rome IV predecessor, showing a comparable overall DGBI global rate, largely similar prevalence rates for those individual DGBI where the criteria were not changed much, and very comparable DGBI prevalence patterns for sex and age groups as observed with the Rome IV questionnaire. Examination of frequency distributions of responses to individual questions did not identify any indications of inappropriate use of the response scales that might suggest understandability problems or unexpected response patterns, except for a single question. That question asked whether abdominal pain had been continuous every day in the past 3 months, which was answered affirmatively by approximately 20% of people with abdominal pain who previously reported on another question that their pain occurred less frequently than every day. This discrepancy was likely because of ambiguity of the wording, but this was compensated for by adjusting the diagnostic scoring rules for the questionnaire, using responses for both questions in combination where needed to produce valid scoring for the diagnoses that rely on this question (ie, IBS and centrally mediated abdominal pain syndrome).

Development of the Rome V Pediatric Diagnostic Questionnaire

The Rome V Pediatric Diagnostic Questionnaire was developed using the same methodology as the adult questionnaires to ensure consistency of assessment across the lifespan. For Rome V, the pediatric DGBI have been reclassified based on anatomic regions: upper GI DGBI that include esophageal, feeding, nausea and vomiting, and gastroduodenal problems, and lower GI and gallbladder DGBI that include abdominal pain syndromes, defecation and anorectal disorders, and other lower GI disorders (discomfort disorders including abdominal bloating and infant distress syndrome). The pediatric questionnaire underwent significant changes to align with these reclassifications.

In Rome V, there are 2 parent-report versions of the questionnaire: (1) an "Infant" version for ages 0 to 3 years, and (2) a "Child and Adolescent" version for ages 4 to 17 years. There is considerable overlap in the questions between these versions, and they can be integrated into a single questionnaire with appropriate age-related skip patterns. However, there are also some notable differences. The Infant version contains 18 questions specific to infants and toddlers, such as the amount of time of breast or bottle feeding and extreme fussiness or crying; these items do not appear in the Child and Adolescent version. In addition, questions specific to diagnoses that do not exist in children younger than 4 years (eg, IBS) are not in the Infant version of the questionnaire. In addition to the parent-report questionnaire versions, a self-report version was created for children ages 10 to 17 years. The items in that version mirror those of the Child and Adolescent parent-report questionnaire, with language modified to be suited for child reading and comprehension.

The Rome IV parent-report questionnaires were reviewed by the Rome V Questionnaire Committee, and recommendations for significant changes were made based on prior feedback related to scoring and interpretation. One of the key decisions about changes was that the committee unanimously decided to modify the Rome V pediatric questionnaire frequency response scales wherever possible to make them more consistent with those of the adult questionnaire. The main reason for this change was to mitigate risk of discrepancy in the prevalence rates of DGBI that exist in both pediatric and adult populations due to psychometric differences in the questionnaires. For example, in the Rome IV pediatric questionnaires, a variety of frequency scales were used, which were very different from what was used in the assessment of adult DGBI symptoms: a frequency scale of 0 (never) to 5 (5 days or more) was used for bowel symptoms, whereas 0 (never) to 4 (every day) was used for upper digestive conditions. Based on the empirical data from the population-based study done in adults that found that the 9-point frequency scale corrected unevenness in symptom frequency distribution across the response scale, that same scale was adopted in the Rome V pediatric questionnaires for most diagnoses (Figure 1*B*). Exceptions include frequency reporting for cyclical vomiting syndrome, abdominal migraine, infant distress syndrome, and infant dyschezia, which necessitated frequency reporting unique to these conditions. In addition, response formats were harmonized to be more consistent across questions and diagnoses than in the Rome IV questionnaires.

Table 1. Proposed FICAI Scores for Assessing the Severity of Pediatric Irritable Bowel Syndrome

	Mild	Moderate	Severe
Frequency (*d/wk*)	1–2	3–5	6–7
Intensity (average pain)	1–3	4–6	7–10
Chronicity (*mo*)	2–5	6–12	>12
Impact	<4 times/mo	4 times/mo–4 times/wk	>4 times/wk

FICAI, Frequency, Intensity, Chronicity and Impact classification system.

In addition to the Rome V diagnostic criteria, the pediatric committees also proposed a classification system named "Frequency, Intensity, Chronicity, and Impact" (FICAI) to evaluate the severity of some of the DGBI symptoms. The FICAI scoring system independently assesses 4 severity-related variables for each diagnosis—-frequency, intensity, chronicity, and impact on the child's and caregivers' lives—to recognize each as a distinctive component in the assessment of the disorder. These 4 items are the general structure of the FICAI. However, in a few disorders, one of the items was substituted for another item based on relevance; an example is CC, in which the "I" stands for incontinence instead of intensity. The FICAI is based on a combination of literature review and expert opinion and was developed using a Delphi process. The committee felt that there was a need for a simple instrument to assess the severity and impact of DGBI, and such an instrument was lacking in the current literature. The goal of the FICAI is to help communication among practitioners at the time of referral, guide treatment decisions, monitor progress, and once validated, be used in research. An example FICAI for IBS is presented in Table 1. The FICAI items were included in the pediatric epidemiology and validation survey outlined later in this article for research purposes. Importantly, however, the FICAI items are not a part of the Rome V diagnostic criteria or the diagnostic questionnaire scoring for pediatric DGBI.

Characteristics of the Rome V Pediatric Diagnostic Questionnaire and Differences From the Rome IV Version

The Rome V Pediatric Diagnostic Questionnaire is composed of 127 symptom questions, 7 impact on activities items (eg, school, extracurricular activities, socializing), and 10 background questions, which include information about comorbid medical and neurodevelopmental diagnoses. Of these, 18 questions are specific to children ages 0 to 3 years. The questionnaire is designed to assess the presence of 27 distinct DGBI—14 more than evaluated by the Rome IV questionnaire. The additional DGBI assessed with the new questionnaire are (1) anticipatory restrictive feeding, (2) hypersensitive dysphagia, (3) hunger dysregulation: excess hunger drive, (4) hunger dysregulation: reduced hunger drive, (5) medically triggered feeding disorder, (6) reflux hypersensitivity, (7) reflux negative pain disorder, (8) centrally mediated abdominal pain syndrome, (9) cannabinoid hyperemesis syndrome, (10) infant distress syndrome, (11) supragastric belching syndrome, (12) functional abdominal bloating, (13) biliary pain syndrome, and (14) proctalgia fugax.

The main differences in the Rome V Pediatric Diagnostic Questionnaire compared with Rome IV can be summarized as follows:

- new questions to diagnose 14 more DGBI than the Rome IV version
- modifications of Rome IV diagnostic questions to accommodate changes in criteria
- addition of anatomical images: 4 images were added to the questionnaires to indicate the location of abdominal pain, epigastric pain, epigastric burning sensation, and biliary pain
- addition of questions for the FICAI, as described previously
- modification of response formats, including introduction of a 9-point frequency scale, as described previously

The Pediatric Rome V Epidemiology and Validation Survey

In collaboration with the Rome Foundation Research Institute, the Rome V Questionnaire Committee carried out the first multinational population survey of pediatric DGBI using the newly created Rome V Pediatric Diagnostic Questionnaire. The goals of the study were (1) to evaluate the likely prevalence of pediatric DGBI under the substantially revised Rome V criteria, and (2) to evaluate the ability of the substantially revised pediatric questionnaire to diagnose DGBI effectively, including 14 new disorders. The study was undertaken with sufficient time to inform the Rome V criteria committees about any critical changes to criteria that might be needed and to enable needed modifications in the questionnaire or diagnostic scoring formulas before release of the new criteria.

Because no prior global epidemiological study on pediatric DGBI exists, the diagnostic rates found in this study were compared with prevalence rates in the extant literature for the more common DGBI (eg, IBS, abdominal migraine) for consistency. Furthermore, the response distributions were examined to identify unexpected patterns indicative of respondents misunderstanding the meaning of questions, as was done with the adult questionnaire.

Survey Methodology and Conduct

The study was an internet survey in 4 countries: China, Italy, Mexico, and the United States. These countries were selected to ensure the representation of several different

world regions in the overall sample (ie, Asia, Europe, Latin America, and North America). Similar survey methodology was used as outlined previously for the adult epidemiologic study in that data collection was managed from the University of North Carolina at Chapel Hill and participants were recruited in each country by Qualtrics Inc. However, only biological or adoptive mothers of children ages 0 to 17 years who were registered members of survey panels in the different countries were invited to participate. Prior research methodology often has used mothers in such survey studies as they are more often than fathers in primary caregiving roles and also are more likely to participate in this type of research; however, the risk for bias in this approach needs to be recognized. Participants with more than 1 child were instructed to report on the child whose name came first in alphabetical order when answering the survey. In addition to the Rome V Pediatric Diagnostic Questionnaire, the survey contained an extensive supplementary questionnaire with questions on demographics, select medical history, health care utilization, medication use, use of special diets and dietary supplements, quality of life, psychological symptoms, and history of COVID infection and illness. The same translation process was undertaken as in the adult study, with professional translation completed by TransPerfect, and quality-control measures used in the adult study were replicated in the pediatric study. Data were fully deidentified and anonymous, and the study received either approval or formal exemption from review and ethical oversight by institutional review boards or ethics committees in the 4 countries surveyed.

The survey data collection was carried out between December 12, 2024, and February 1, 2025. We aimed to survey 2000 participants per country, with children of different ages from infancy to age 17 years. After data integrity checks, the final study sample consisted of 7724 participants with complete and valid responses, evenly distributed across the 4 countries. Children were represented across 3 age groups as follows: 16.0% ages 0 to 3 years, 45.6% ages 4 to 10 years, and 38.4% ages 11 to 17 years.

Diagnostic Scoring of Survey Data

The newly generated draft diagnostic scoring rules for the Rome V questionnaire were applied to the survey responses in the dataset to identify all cases of the 27 DGBI that the questionnaire is designed to measure. Of note, because the survey was launched before finalization of the criteria for proctalgia fugax, a new DGBI in pediatrics, data on this condition were not collected in the study.

Analyses of the survey results indicated that the global DGBI prevalence rates using Rome V criteria are broadly comparable to what was found in the extant literature. For example, in this study, the prevalence rate of IBS was 2.1%, which aligns with a 2022 meta-analysis that finds the overall worldwide prevalence of pediatric IBS to be 3%.[6] The 17.1% global CC prevalence found in the present Rome V study is within the 95% confidence interval (CI) of the pooled prevalence estimate of 14.1% (95% CI, 11.2–17.6) reported in a 2023 review of studies of that disorder from around the world.[7] A 2015 meta-analysis found the pooled prevalence of pediatric FD to be 4.5%[8]; in the present study, the rate was 1.7% for epigastric pain syndrome and 5.5% for postprandial distress syndrome. Prior country-level studies have found rates of postprandial distress to be 2 to 3 times higher than epigastric pain.[9] These results suggest that the Rome V Pediatric Diagnostic Questionnaire is correctly evaluating the prevalence of existing DGBI where comparative data exist in the literature.

Conclusions

The Rome V Questionnaire Committee has developed new versions of the Rome diagnostic questionnaires that appear to be well suited for epidemiologic and clinical research of DGBI in the Rome V era for both adult and pediatric populations. Comparison of survey results from a global sample using the Rome V Adult Diagnostic Questionnaire with Rome IV global prevalence data indicates that the new questionnaire generally identifies DGBI to a similar degree and with the same demographic patterns as the Rome IV version. However, the new version is incrementally enhanced in multiple ways compared with the Rome IV questionnaire. These improvements include the addition of several research questions that may facilitate understanding of the DGBI it measures, improved response scaling that supports greater precision in diagnostic scoring, and the addition of anatomical figures that add clarity to questions about epigastric pain and burning and biliary pain. Finally, the new version of the adult questionnaire enables detection of 3 additional Rome DGBI compared with the Rome IV version, further broadening the value and utility of the questionnaire.

The pediatric diagnostic questionnaires underwent substantial revision to reflect major updates to the Rome V pediatric diagnoses. This included approximately doubling the number of DGBI assessed compared with the Rome IV diagnostic questionnaire, with the addition of questions to identify 14 new DGBI. Although no previous global epidemiological data exist for pediatrics, comparisons with the extant literature, including meta-analyses, find that the prevalence rates in the Rome V study are similar to those reported in the past for well-studied conditions such as IBS, CC, and FD. The increased similarity of symptom frequency scales between pediatric and adult questionnaires in the Rome V questionnaires enhances the consistency in assessment of DGBI across the lifespan. This harmonization will facilitate conduct of longitudinal studies that span from childhood into adulthood and make it easier to set inclusion criteria and select endpoints for combined studies between pediatric and adult subjects. It also will enable comparisons of data between age groups for examination of variations in DGBI risk, protective factors, and pathophysiology. Finally, although not part of the diagnostic criteria, the addition of the FICAI system to the pediatric questionnaires will, once validated, provide a simple instrument to assess the severity and impact of pediatric DGBI.

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The authors disclose no conflicts.

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