Multicenter food protein–induced enterocolitis syndrome (FPIES) data collection: Leveraging a REDCap FPIES registry for improved clinical outcomes

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Background: Food protein–induced enterocolitis syndrome (FPIES) is a non–IgE-mediated food allergy typically presenting in infancy but has also been recognized in adults. FPIES is an allergic emergency due to severe vomiting occurring 1 to 4 hours after ingesting the causative food protein. Since the 2017 FPIES guidelines, no prospective data exist on the prevalence, incidence, and clinical characteristics of FPIES.

Objective: We established a multicenter FPIES registry to systematically collect clinical data and biospecimens on FPIES patients.

Methods: The FPIES registry is a US multicenter REDCap database collecting epidemiologic data to support the evolving FPIES landscape in relation to age at diagnosis, triggers and coreactivity, disease resolution, and risk of disease conversion to IgE allergy. Questionnaire and biosampling strategies have been developed using a systems biology approach to identify determinants of FPIES.

Results: The registry includes patients with physician diagnosis of FPIES (ICD-10 code K52.21) from January 2015. Longitudinal REDCap instruments for FPIES data collection include: age at first reaction, age at diagnosis, reaction timing, symptoms, treatment, medical care or hospitalization for reaction, dietary triggers, atopic comorbidities, family history of atopy and FPIES, oral food challenge procedures (eg, intravenous line placement, dosing protocol, observation period, reaction timing, symptoms and treatment), age at food trigger resolution, food-trigger IgE, cases converting from atypical FPIES to IgE-mediated food allergy, and sample collection data.

Conclusions: The registry will provide a multicenter repository of data and biospecimens, enabling identification of clinical determinants and phenotypes of FPIES, better understanding of conversion risks, and identification of biomarkers and mechanisms associated with FPIES. (J Allergy Clin Immunol Global 2025;4:100434.)

Key words: *Database, registry, food protein–induced enterocolitis, FPIES, REDCap, epidemiology, biosamples*

Food protein–induced enterocolitis syndrome (FPIES) is a delayed non–IgE-mediated food allergy and remains a significant diagnostic challenge, given its elusive pathophysiology and lack of clinical biomarkers to confirm diagnosis. Diagnosis of FPIES is based on suggestive clinical history and an FPIES oral food challenge (OFC).[1] In the pediatric population, FPIES presents with delayed repetitive vomiting, along with lethargy, pallor, and possibly diarrhea and/or dehydration.[1] In the adult population, FPIES typically presents with severe abdominal pain, and vomiting may only be present in up to 60% of patients.[2] The condition's delayed symptom onset after allergen exposure further complicates timely and accurate diagnosis, necessitating a nuanced understanding of and a targeted approach to management and care.[3] There is an unmet need for more diverse epidemiologic studies to better characterize the pediatric and adult population-level burden of FPIES and its natural history in the United States. Since the publication of the 2017 FPIES guidelines,[1] comprehensive FPIES studies examining age at diagnosis, symptoms, triggers, and disease resolution or persistence are lacking. Previous findings suggest an evolving dietary practice that is based on early food introduction as well as better disease recognition by practitioners since the publication of the 2017 FPIES guidelines.[4]

Recognizing these challenges, the establishment of this multicenter registry, leveraging the REDCap (Research Electronic Data Capture) platform,[5,6] marks a transformative step toward a systematic and collaborative approach to FPIES research. The registry will

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Abbreviations used
eCRF: Electronic case report form
ED: Emergency department
FPIES: Food protein–induced enterocolitis syndrome
HIPAA: Health Insurance Portability and Accountability Act
OFC: Oral food challenge
REDCap: Research Electronic Data Capture

standardize the approach to data collection and include pertinent information that will help us better understand the natural history of FPIES for different food triggers in FPIES patients. This initiative is uniquely positioned to harness the power of collective insights from multiple health care institutions in diverse geographic locations, enabling multicenter data aggregation that captures the wide variability in FPIES presentations and outcomes.

This registry aims to bridge critical knowledge gaps in FPIES by facilitating the standardization of data collection on a large scale. This registry will provide details on diagnosis, natural history, symptom severity grading, food triggers and coreactivity, rates of disease resolution, conversion risk from FPIES (a non–IgE-mediated allergic disease) to IgE-mediated food allergy, food challenge protocols and outcomes, and a repository for biobanked samples collected longitudinally. The registry will capture epidemiologic information to broaden our understanding of FPIES and provide evidence when updating future guidelines. To fulfill this critical need, an FPIES REDCap database has been designed to improve the collection of end points of interest.

METHODS

Study design and platform setup

This multicenter registry has been designed to collect comprehensive data on patients diagnosed with FPIES. The registry was developed using the REDCap platform, a secure, web-based application designed to capture research data efficiently and systematically, which is widely used in the research community because of its flexibility and compliance with the Health Insurance Portability and Accountability Act (HIPAA).[5,6] The database is hosted at Baylor College of Medicine, and data are collected by 3 additional institutions across the Southwest United States: University of Texas Southwestern, Dell Children's Hospital, and Arkansas Children's Hospital. Each center has been selected because of its expertise in diagnosing and managing FPIES, ensuring a high-quality and comprehensive data set in the Southwest United States.

Inclusion criteria

Details of patients diagnosed with FPIES at all participating centers will be entered in the registry. Inclusion criteria include a confirmed diagnosis of FPIES by an allergist with an ICD-10 diagnosis code of K52.21 based on the criteria established by the International Consensus Guidelines for FPIES.[1] This includes the major criterion of delayed projectile vomiting with an absence of skin or respiratory symptoms, followed by 3 or more minor criteria: presence of extreme lethargy, pallor, dehydration, need for emergency department (ED) visit for suspected reaction, need for intravenous fluid support for suspected reaction, diarrhea within 24 hours, hypotension, and hypothermia. To ensure that potential FPIES patients are not overlooked, when a subject has experienced delayed projectile vomiting to a specific food allergen on more than 2 separate occasions and all other possible causes have been excluded, a diagnosis of FPIES will be considered. For adult patients, the adult FPIES algorithm as outlined by Gonzalez-Delgado et al[2] will be utilized.[1]

Database development

Data collection protocol. A data collection protocol was developed to outline the procedures for data collection, including specific instructions for capturing clinical information, laboratory parameters, and longitudinal data. A REDCap data dictionary codebook is generated from the REDCap database, and all personnel involved in data collection across study sites are trained on all data collection instruments by board-certified allergists and immunologists to maintain data consistency and accuracy.

Standardized data entry and quality control. To ensure data accuracy and consistency across study sites, standardized data entry procedures have been implemented. The validation feature in REDCap will automatically conduct validation checks, enforcing data integrity. Weekly quality control procedures to be conducted by an assigned biostatistician using REDCap's Data Quality feature. This process facilitates the identification and resolution of issues such as missing data, outliers, or inconsistencies.

Data security and confidentiality. Ensuring the utmost security and confidentiality of our data is paramount. REDCap serves as a secure web-based, HIPAA-compliant database granting access solely to designated study members authorized to utilize the data collection instruments. All data collected within the REDCap database are deidentified and will be securely stored on a server maintained by Baylor College of Medicine, further enhancing the protection of sensitive information. Rigorous data security protocols will be implemented to safeguard against unauthorized access or breaches. Our registry is committed to strictly adhering to regulatory requirements and institutional policies governing data privacy and confidentiality, underscoring our dedication to maintaining the highest standards of data security and confidentiality throughout the entirety of our study.

Data backup and documentation. Automatic data backup will be regularly conducted within REDCap. Furthermore, the platform provides a log feature to meticulously record all activities within the database, including time stamps for any modifications made.

Communication among sites. Communication among sites regarding data quality control is crucial. Any issues identified in the data quality will be promptly communicated via email or telephone as soon as they are discovered, facilitating swift resolution and ensuring the integrity and reliability of the data across all sites.

Data collection instruments

Standardized electronic case report forms (eCRFs), also called instruments, were developed in REDCap. These forms are designed to capture comprehensive, high-quality data consistently across all participating centers. The eCRFs include multiple sections tailored to gather detailed information on demographic characteristics, clinical history, diagnostic criteria, treatment regimens, and longitudinal outcomes associated with FPIES (Fig 1). The registry applied REDCap's repeatable

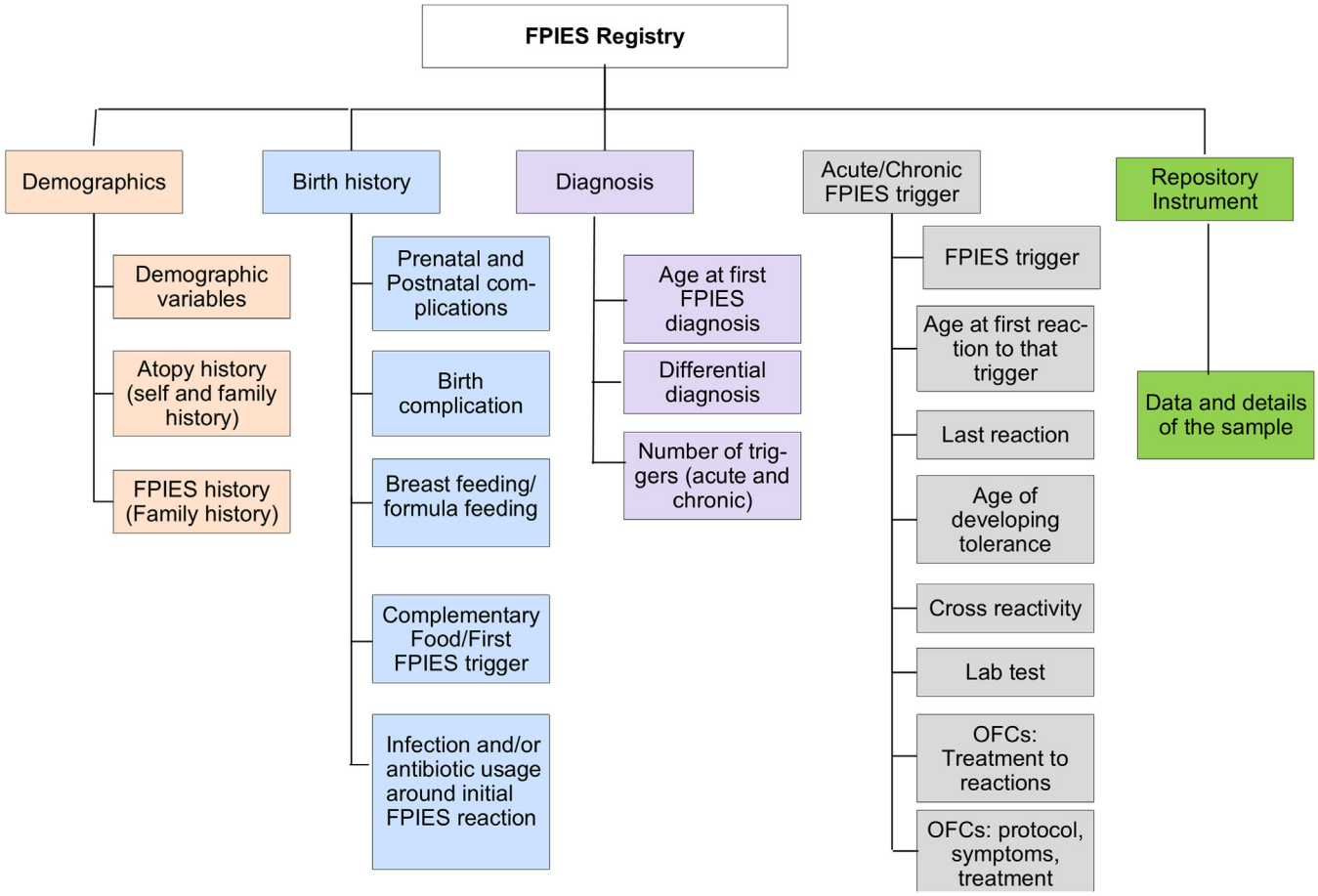

FIG 1. Flowchart showing subheadings of each instrument in FPIES registry.

instruments, which allow for the collection of multiple instances of the same type of data, such as hospital visits or FPIES episodes. In total, 7 instruments were created (Demographics, Atopy/Family History, Birth History, FPIES Diagnosis, Acute Food Triggers, Chronic Food Triggers, and Repository Instrument), which collected the key data elements that follow.

Demographic data

Basic information. Basic information includes biological sex, race, ethnicity, zip code of residence, and insurance status.

Atopy history and medical history. Detailed information about the patient's atopy history, comorbidities such as eczema, allergic rhinitis, asthma, and IgE- and non–IgE-mediated food allergies are included. The allergen or allergens associated with IgE- and non–IgE-mediated food allergy are also collected within the registry. We will also collect details on whether the patient has received diagnoses of colic, gastroesophageal reflux disease, or failure to thrive.

Family history. Detailed records of any family history of atopy or FPIES will be obtained.

Clinical presentation and diagnosis

Trigger foods. Specific foods triggering reactions are cataloged, along with the age at first reaction and age at resolution for each trigger. Details of the OFC protocol and dose given are recorded, as well as whether the OFC was performed in a clinical setting or the food trigger was introduced at home.

Symptomatology. We will perform detailed logging of symptoms associated with each trigger reaction, such as vomiting, abdominal pain, diarrhea, lethargy, and pallor, as outlined in the 2017 FPIES international guidelines[1] and in Gonzalez-Delgado et al.[2] Timing of symptom onset after exposure is meticulously recorded. Treatments received and whether the patient required medical attention (ED, hospitalization) is recorded for each trigger reaction. Differential diagnoses that the patient may have received before being diagnosed with FPIES will also be included.

Diagnostic tests. Data on skin prick tests and food-specific IgE testing, where applicable at the time of diagnosis, follow-up, and each OFC, will be collected. Other laboratory tests, like routine blood tests obtained at time of an FPIES reaction, are recorded.

Treatment and management data

Management of reactions. We will collect information on treatments administered (eg, ondansetron, intravenous fluids, corticosteroids) and route of treatment during acute episodes, and whether a patient required ED evaluation or hospitalization.

Long-term management. We will record information about dietary modifications and avoidances, receipt of amino

acid–based formulas, and any other long-term management strategies.

Outcome tracking

Follow-up assessments. Scheduled follow-up examinations monitoring the development of tolerance to trigger foods, changes in symptom severity, monitoring for IgE sensitization to the food trigger, and risk of conversion from FPIES to IgE-mediated food allergy are assessed at each of the follow-up and OFC visits. Follow-up visits will be considered every 6 months, and OFCs will be scheduled by a shared decision-making process between the medical provider and the family.

Growth and development. Regular tracking of growth parameters will permit monitoring of any impacts of dietary restrictions or chronic symptoms on the child's development.

Training and standardization

Before commencing data collection, all personnel involved in data entry and management underwent standardized training. This training covered the use of REDCap, understanding of the eCRFs, and detailed instructions on ensuring data accuracy and consistency. Periodic refresher training sessions were conducted to uphold high standards of data quality.

Data review and monitoring

The data are reviewed regularly for completeness and accuracy. A data monitoring committee was established to oversee the data collection process, conducting periodic audits to identify and rectify any irregularities or deviations from the protocol. Feedback from these audits is used to continuously refine data collection and entry processes.

Data quality and management

Data integrity is maintained through REDCap's built-in validation rules, which detect data entry errors and inconsistencies in real time. Regular audits are conducted to ensure data accuracy and completeness. Data are encrypted and backed up regularly, with access restricted to authorized personnel. This is a live registry capable of actively capturing longitudinal data on new and established FPIES patients. The goal of the registry is to review and analyze the data every 1 or 2 years to identify changes observed in the FPIES cohorts that will provide new evidence of the disease's natural history and potentially discovery of diagnostic biomarkers or markers of disease resolution and avenues for management and therapeutics.

Statistical analysis plan

Descriptive analysis. The normality of different continuous variables will be evaluated by the Shapiro-Wilk test. Descriptive data will be summarized as medians and interquartile ranges for continuous variables and frequencies and proportions for categorical variables.

Inferential analysis. Differences between groups in patient characteristics and outcomes will be compared by the Kruskal-Wallis test for continuous variables and the chi-square or Fisher exact test for categorical variables, as appropriate. Market basket analysis will be used to identify associations among coallergens. Multivariable logistic regression analysis will be used to identify the potential risk factors associated with FPIES resolution and progression, as well as risk of conversion from FPIES to IgE-mediated food allergy to the FPIES trigger.

Longitudinal analysis. Kaplan-Meier curves and Cox proportional hazards regression will be used to examine time-to-event outcomes (eg, time to resolution of FPIES trigger). Frailty models will be used if the same event is measured repeatedly. Mixed-effects modeling will be used to explore the patterns of the disease persistence or conversion over time. Statistical analyses will be conducted by software packages that support advanced statistical modeling, including, but not limited to, R v4.3.3 (R Core Team, Vienna, Austria; www.r-project.org) and/or STATA v18.5 (StataCorp, College Station, Tex).

Model validation and diagnostic checks

All models will be validated using various diagnostic measures, including goodness-of-fit tests, Akaike information criterion for model selection, and visual inspection of residual plots. Cross-validation techniques or a validation subset of data may be used to assess the predictive accuracy of the final models.

Ethical considerations

The study conforms to the principles outlined in the Declaration of Helsinki and has been approved by the respective ethical review boards of all participating institutions. This registry operates under a multicenter protocol, with data contributions from over 4 centers across the Southwestern United States. Each center obtained local institutional review board approval, ensuring adherence to ethical standards and patient confidentiality (approval BCM IRB H-50482). A centralized training program was provided to all sites to standardize the data entry process and minimize variability. The Data Access Group feature within REDCap will be utilized to allocate precise data access permissions to study staff members across various sites. Collaborative data sharing will strictly adhere to the study protocol and comply with institutional policies governing data privacy and confidentiality. Participating sites have disclosed their annual number of cases that are diagnosed and managed. Communication among sites regarding data quality control is crucial. Any issues identified in the data quality will be promptly communicated via email or telephone as soon as they are discovered, facilitating swift resolution and ensuring the integrity and reliability of the data across all sites.

DISCUSSION

The establishment of this registry represents a pivotal development in understanding FPIES. This multicenter FPIES registry is anticipated to shed light on several critical aspects of FPIES that have hitherto been obscured by the limitations of smaller, less diverse study cohorts.

This database provides a novel and feasible framework for improved understanding of FPIES for 3 reasons. First, this will be the first multicenter FPIES registry since the publication of the 2017 FPIES guidelines[1] and will serve to describe the prevalence of FPIES, risk factors associated with developing FPIES, natural history of the disease, and the relationship between atopy and FPIES. This information will help to identify different FPIES

phenotypes according to demographics and associated risk factors so that clinicians may provide individualized guidance. Furthermore, it will also provide the framework to examine longitudinal cohort studies to better determine outcomes and progression of natural history of FPIES. Second, this will be the first site-specific multicenter FPIES registry encompassing the 2017 FPIES international guidelines[1] and the adult FPIES criteria by Gonzalez-Delgado et al[2] with the goal of discovering new, more accurate, and timely information on FPIES. Recently, we have demonstrated our ability to create a formalized registry to collect up-to-date information on our FPIES cohort.[4]

Our comprehensive registry will collect data on the following clinical outcomes:

- FPIES reaction age, timing, symptoms, amount of food ingested, and treatment.
- Age at diagnosis.
- Dietary trigger.
- Coreactivity risk of dietary trigger.
- Atopic comorbidity.
- OFC intravenous line placement and protocol used for OFC dose administration.
- Symptoms and treatment during OFC.
- Age at resolution of food trigger.
- IgE sensitization to FPIES food trigger.
- Cases of FPIES converting to IgE allergic reactivity.

This registry will lay the groundwork for a global registry that can be adopted across national and international centers to contribute to this registry to further expand our knowledge about FPIES.

Third, the registry will serve as a biorepository database linking clinical data to FPIES blood samples collected at time of diagnosis and at time of OFC. The registry will serve as a central location for prospectively cataloging FPIES samples obtained. The development of the biorepository within this registry will provide a significant level of breadth and depth on our understanding of FPIES by utilizing bioinformatic programs to explore and predict which potential diagnostic biomarkers and clinical end points can predict disease development and resolution. These findings have the potential to offer new insights into the creation of targeted therapeutics to hasten disease resolution.

Our anticipated findings regarding time to disease resolution and development of dietary tolerance to FPIES triggers are expected to offer significant clinical benefits. For instance, if early data suggest that certain foods may have a shorter duration to dietary tolerance development, then dietary management guidelines can be tailored to potentially accelerate the reintroduction of these foods under medical supervision. This could reduce the duration of restrictive diets, which often pose nutritional, psychologic, and economic burdens on patients and their families.[7] Additionally, identifying specific demographic or clinical predictors of disease severity or resolution could lead to more personalized treatment approaches. For example, if the presence of multiple food triggers is correlated with prolonged disease, this could support the development of aggressive management strategies in these cases.

Policy and educational implications

The comprehensive data from this registry could also influence policymaking at both institutional and national health levels. Better understanding of the disease patterns and risk factors may inform the allocation of resources, such as the need for specialized allergy services or support programs in areas with higher prevalence. Furthermore, the registry could serve as an educational platform by providing data-driven insights into FPIES, which can be used to train clinicians, thereby enhancing the overall quality of care.

Challenges and limitations

While the registry's multicenter design enhances the robustness of our data, it also introduces challenges related to data consistency and quality control. FPIES is predominantly observed in Organization for Economic Co-operation and Development countries, which are high-income democracies with market economies and advanced human development; research from lower-income countries is extremely limited, and low-middle–income countries face unique challenges.[8,9] Variations in diagnostic criteria and management practices across centers could lead to heterogeneous data, potentially complicating the analysis and interpretation of results. Efforts to standardize data collection and validation are crucial to mitigate these issues.

The sample set may be affected by selection bias in that all participating centers are allergy clinics located at tertiary-care centers/academic pediatric hospitals. Another limitation concerns the potential underrepresentation of patients with mild FPIES, who might not seek hospital care; patients managed at primary-care or community-based allergy clinics; or those without a formal diagnosis. These factors could lead to a bias toward more severe cases, skewing our understanding of the true spectrum of FPIES severity.

Future research directions

This registry opens several avenues for future research. Longitudinal studies focusing on the immunologic changes in children with FPIES over time could provide insights into the mechanisms driving the disease and its resolution. Such studies might explore the role of the gut microbiota, immune tolerance mechanisms, biomarkers associated with possible disease activity (eg, interleukin, thymus activation regulator chemokine, allergen lymphocyte stimulation) or genetic factors influencing disease progression or resolution.

Moreover, interventional studies based on registry findings, such as randomized controlled trials of early dietary interventions or probiotics, could directly test strategies to prevent or mitigate FPIES. These studies would be instrumental in moving from observational to causal understandings and interventions.

Conclusion

This registry is positioned to make substantial contributions to our understanding of FPIES. By clarifying the natural history, risk factors, and outcomes associated with this challenging condition, the registry not only promises to enhance clinical practice but also sets the stage for transformative research that could improve the lives of children affected by FPIES and their families. By compiling detailed patient histories, treatment responses, and long-term follow-up data, the registry serves as a foundational tool for identifying patterns and trends that are otherwise obscured in smaller, isolated studies. This multicenter approach

not only enhances the statistical power of the research but also enriches the data with a broad spectrum of demographic and environmental variables, offering a more representative and robust analysis of the condition. This is the largest regional multi-institutional FPIES registry with aims to expand nationally and internationally to streamline the collection of information relevant to FPIES. Furthermore, the goal of the data obtained through this registry will provide evidence for guideline updates in FPIES as well as improve our understanding about the various facets of this disease to aid in diagnosis of and therapeutics for FPIES.

DISCLOSURE STATEMENT

Disclosure of potential conflict of interest: S. Anvari receives research grant funding from National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID), AstraZeneca, Regeneron, and DBV Technologies; and serves on the medical advisory board for the International FPIES Association (iFPIES). J. A. Bird reports consultancy for Allergenis, DBV Technologies, Food Allergy Research and Education (FARE), Genentech, Hanimmune Therapeutics, HAL Allergy, Infinant Health, Novartis, Nutricia, and Parexel; and research support from Aimmune, DBV Technologies, FARE, Genentech, NIH/NIAID, Novartis, Regeneron, and Siolta. M. Gupta serves on the board of directors for iFPIES and on the medical advisory board of Alerje. A. M. Scurlock reports grants for clinical trial support and consulting fees from DBV Technologies; payment or honoraria as speaker fees for Aimmune Therapeutics, manuscript writing for DBV Technologies, meeting attendance support from Aimmune Therapeutics, DBV Technologies, and FARE; served on the advisory board for DBV Technologies; has leadership or fiduciary duty for the AAP Section on Allergy and Immunology Executive Committee (2023-26); is member of AAAAI Adverse Reactions to Foods Committee and the CoFAR steering committee; and reports other financial or nonfinancial interests including clinical trial support/grants to institution from NIH/NIAID, Aimmune Therapeutics, DBV Technologies, Astellas, Siolta Therapeutics, Novartis, Genentech, Aravax PTY, and FARE; and receipt of fees from Vindico CME. P. Varshney reports research grant funding from DBV Technologies, Aimmune, and Siolta; and served on the advisory board for DBV Technologies. The rest of the authors declare that they have no relevant conflicts of interest.

Key messages

- **A multicenter FPIES registry will improve our understanding about the epidemiology, management protocols, and natural history of FPIES.**
- **Development of our standardized multicenter FPIES registry and biosample repository will lay the groundwork needed to accelerate FPIES clinical and scientific research.**
- **The FPIES registry will allow for streamlined collection of clinical data on patients across the age spectrum and will provide evidence to support the diagnosis and management of FPIES.**

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