

Ethical Considerations Within the ESPGHAN Community

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ABSTRACT

There are limited data on ethical issues related to the daily practice of members of the European Society for Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN). The role of the ESPGHAN Ethics Committee (EC) is to provide advice on such matters to its members. The present survey aimed to evaluate the current function, and reasons that ESPGHAN members consulted the ECs. One hundred and five participants from 24 different countries answered the questionnaire. Thirty-five point seven percent of the participants used the ESPGHAN EC to ask about clinical practice problems and patient-related issues whereas 21.4% ask about human research questions. An important additional finding was that 66.3% of respondents consulted their hospital's EC when they had ethical concerns and 17.4% consulted with other colleagues with expertise. This is the first survey in the ESPGHAN and Europe that analyses ethical issues that are important to members of the National Societies for Pediatric Gastroenterology Hepatology and Nutrition.

Key Words: ESPGHAN, ethical issues, survey

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The Ethics Committee (EC) of the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) is one of the “youngest” committees within the Society and was formed in 2008. The role of the Committee is to provide advice on all aspects of: ethics in journalism, for example, when publishing on medical journals; animal ethics, for example, moral consideration of animal use for training or research purposes; and cases of alleged ethical misconduct among others. Plagiarism, fraud, and relationship with industry and commercial companies have been the most frequent issues referred to the EC to date. As a result, ESPGHAN has published “Rules and Regulations regarding declaration of interest,” “Policy on Due Process for Alleged Ethical Misconduct,” and the ESPGHAN “Code of Conduct” (1). With time EC has gradually dealt with the more complex ethical aspects of clinical and research-related work. Bridges were built with other committees within North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) as well as other pediatric societies. After a joint effort, ESPGHAN

What Is Known

- Ethical issues are crucial in clinical practice and patient management.
- Most of the hospitals which have research practice have Ethical Committee that should be consulted for ethical issues.

What Is New

- A considerable number of healthcare professionals consult with colleagues with expertise in ethics when they have doubt about ethical issues and not with official organism.
- Considerable gaps in the healthcare professionals need related with ethical issues in their daily clinical practice.

and NASPGHAN published the “Ethics/Publications Committee Policy for the Journal of Pediatric Gastroenterology and Nutrition (JPGN) editors” in 2018 (1).

Other societies of pediatric subspecialties in Europe, such as Genetics and Metabolic Diseases, have published data on the ethical issues involved in their clinical and research work and concluded that official ethical recommendations for clinicians, researchers, ethics committees companies, and patients have been long anticipated (2,3).

These types of publication are extremely important because clinical problems with significant ethical implications raise an ever-growing dilemma in everyday medical practice in the 21st century and not often have an easy solution. This is particularly the case with ethical issues involving the clinical practice and research in children (4,5). Patient cases where there are ethical issues and concerns are not straightforward and require a variety of health professionals to be involved in decision-making (6). The lack of data

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on ethical issues faced by patients with pediatric gastroenterology, hepatology, and nutrition problems worldwide pinpoint the need to upgrade and solidify the function of the EC among its members and it is also essential to establish an ethically acceptable code of practice which will allow healthcare professionals to provide an objective approach to ethical management both for the child as well as society at large.

Based on this premise, the EC of ESPGHAN considered it important to elucidate how ethical issues are addressed in different European countries and by different healthcare professionals. For that reason, the aim of the present survey was to study and evaluate the existence and function of ECs among National Societies of Pediatric Gastroenterology, Hepatology, and Nutrition from different European countries.

METHODS

Design and Structure of the Survey

A web-based prospective cohort study was designed aiming to find out how ethical issues are addressed among different countries within ESPGHAN. A questionnaire was designed with input from the members of the ESPGHAN EC. The survey was approved by the ESPGHAN Council and included 7 multiple choice and 3 free text questions. Questions 5 and 7 had the option to choose more than 1 answer whereas in the remaining multiple choice questions the participants could only choose 1 answer.

Demographic data, including the country where the participants were working as well as their field of National Society, were collected. Participants were asked whether there is an EC within their National society and their opinion about its importance. Responders were asked if they have ever asked for the committee's advice and if yes, were asked to specify the reason. The matter of efficacy of the respective committee was also addressed as well as the issue of how the ESPGHAN EC could aid with adequate advice to ESPGHAN members when asked. The completed questionnaire is available in the Supplemental Digital Content 1, <http://links.lww.com/MPG/D35>.

Dissemination

An electronic mail message (e-mail) including a letter regarding ESPGHAN EC's initiative and a web link to complete the questionnaire in Google Docs® was disseminated on July 10, 2020. The current study was conducted between July 10 and August 8, 2020. The questionnaire was distributed electronically to all representatives of National Societies of Pediatric Gastroenterology, Hepatology and Nutrition within ESPGHAN (N = 30) who in their turn have sent it to the ESPGHAN members.

The completion of the questionnaire was voluntary and no financial incentive was offered to respondents for their participation on the survey. The letter to the participants is available in Supplemental Digital Content 2, <http://links.lww.com/MPG/D36>.

Study Population

The study population included adult healthcare professionals belonging to a National Society for Pediatric Gastroenterology, Hepatology and Nutrition located in Europe. All of the participants voluntarily answered the questionnaire anonymously and voluntarily.

Data Analysis

Data were extracted directly from the Google Docs® in Microsoft Excel format and descriptive statistics were subsequently used to summarize all variable. Reported percentages of

outcomes were extracted from participants' responses. The results were presented graphically ("pie" and "bar" charts) with the help of the Adobe Illustrator C26 program. Two open-ended questions were included (question 5 and 7). One asking what kind of information or support the participants think that ECs should provide to health professionals. The answers were grouped in 3 general topics for analysis: (1) Research and Ethical Approval, (2) Treatments and Procedures, and (3) Others (not related with any of the other 2 topics). The second open-ended question addressed the matter of why the participants consider important to develop a scientific position of its ethical implications. The results were grouped in 5 general areas, according to the main topic of the answers: (1) Nutrition, (2) Transplantation, (3) Diagnostic, treatment and procedures, (4) Research issues, and (5) Others (not related with any of the other 4 topics).

RESULTS

Information was received by 105 participants from 24 different countries. Figure 1 represents the number of answers by country: 19% of participants were Spanish, 12.4% were from Belgium, and 5% from The Netherlands. The rest of participants were from: Finland, France, Switzerland, Austria, Armenia, Israel, Luxemburg, Ukraine, Denmark, Russia, Hungary, Greece, Czech Republic, Germany, Ireland, Poland, Turkey, Croatia, Lithuania, Latvia, and Bulgaria. Table 1 summarizes the results obtained in the 7 multiple choice questions.

The most significant results from the multiple-choice questions were that more than half of participants (51.4%) had never used the EC of their societies but 62.9% considered the existence of such of committee important. Most of the questions to these committees were related to clinical practice problems and nobody had raised animal research-related questions. The answers to question 6 were very positive since all participants responded that the EC always resolved their doubts.

In question 7, one of the most significant results was that up to 17.4% consulted with colleagues with expertise when they had doubt about ethical issues but the majority (66.3%) consulted with hospitals' own EC. Additionally, some respondents added that they consulted with EC of Universities or Committees of Medical Academies.

Regarding the remaining open questions, we asked, "*what kind of information or support do you think that Ethics Committees such as the ESPGHAN Ethics Committee, should provide to health professionals?*" As we have described in previous section, we grouped all the responses in 3 general areas according to the main topic of the answers. All the answers received are detailed in Supplemental Digital Content 3, <http://links.lww.com/MPG/D37>.

Within the first topic "Research and Ethical Approval," the answers were very different. Some participants requested information about ethical issues related with treatments and new drugs and European rules to participate in multicenter studies. Others requested support and paperwork that can be used to apply to their local ECs for research studies.

Concerning second topic "Treatments and Procedures," the 2 main topics raised were related with medication that is not licensed for pediatric patients, but could be appropriate to use and controversies between healthcare personnel and parents as to whether to continue or stop the treatment. Other participants requested support in challenging situations such as when different treatment options are available in other countries.

Finally, we received other suggestions from very different issues that are described in Supplemental Digital Content 3, <http://links.lww.com/MPG/D37>.

TABLE 1. Results obtained in the 7 multiple choice questions (n = 105)

Question	Answers
2. Which is the specialty of your National Society?	• 21.9% Gastroenterology • 8.6% Nutrition • 0% Hepatology • 69.5% All of the above
3. Have your National Society an ethic committee?	• 24.8% Yes • 75.2% No
4. If yes, have you ever used this committee?	• 48.3% Yes • 51.7% No
5. If yes, for what type of information have you asked to this committee?	• 21.4% Human research questions • 0% Animal research questions • 35.7% Clinical practice problems • 35.7% Patients issues • 7.1% Others
6. Did the ethics committee resolve your question?	• 100% yes
7. Who do you ask when you have an ethical question?	• 66.3% Hospital's Ethics Committee • 17.4% Colleagues with expertise • 6.5% Governmental Institutions • 9.8% Others
8. Do you think that it is important that National Societies have ethics committee?	• 62.9% Yes • 37.1% No

The last question of the survey was “Please, indicate any specific topic you consider crucial to develop a scientific position of its ethical implications”. As in previous question, we grouped all the responses in 5 general areas, according to the main topic of the answers. All the answers received were very diverse and are detailed in Supplemental Digital Content 3, <http://links.lww.com/MPG/D37>.

Within nutrition topic, one of the most demanded was about specific diet in children, and treatment in critical children at the end of life.

DISCUSSION AND CONCLUSIONS

This is the first survey in ESPGHAN and Europe that analyses ethical issues within National Society for Pediatric Gastroenterology, Hepatology and Nutrition. If we consider that, the complexity of biomedical research has increased considerably in the last decade; this an important topic to investigate. In fact, this complexity has generated novel ethical issues for healthcare professionals, clinical investigators, institutional review boards, and other oversight committees. As a result, many institutions and scientific societies have created ethics committees (7,8). In addition, there are other important organization, such as The American Society for Bioethics and Humanities which has developed their own guidance on ethics case consultation (9,10).

Although we obtained a limited number of answers, we have extracted very relevant results. One is there is a considerable number of participants who consults with colleagues with expertise and not a committee, when they had doubts about ethical issues. The ethical matters are especially sensitive in clinical practice with patients, so these data are a bit alarming if we consider that the respondents were healthcare professionals.

Another relevant result was that the main topic discussed with the EC included practice problems and patient-related issues. This suggests that these are areas where the ECs should focus and concentrate their work.

The present research can be used as the basis for the ESPGHAN EC to develop further position papers related to the issues,

which have been raised in this survey. The role of the committee is to increase the awareness about certain topics' determinants among its members. This Committee should not only be an advisory body, but it has to be an active committee as there are many relevant issues on which members raise doubts.

Finally, the last 2 open questions have revealed the real need of healthcare professional among Europe related with ethical problems. The main topics identified with the multiple responses received will be the starting point of the work of ESPGHAN EC. One difficult issue in the clinical practice of pediatric gastroenterologists is the refusal of parents to consent to medical procedures needed as treatment for their children's medical problem. This topic should be considered a priority for this Committee in the following period.

The main limitation of this survey is the small number of responses received, possibly due to lack of attention to ethical questions, but this should be considered by the EC for further surveys. We also consider it a limitation that we do not know how many people receive the questionnaire due to its mode of distribution and this should be further considered for future surveys. Another limitation is that this survey was not previously piloted, and this is the first survey developed as Committee.

Another limitation is that there are no similar studies or surveys which we can compare our results with so this data is very helpful as a starting point. We can conclude that the results are important enough to start work on developing useful information and materials for healthcare professionals in Europe.

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