Received: 10 May 2023 | Revised: 24 August 2023 | Accepted: 5 November 2023

DOI: 10.1002/hsr2.1735

ORIGINAL RESEARCH

Health Science Reports Open Access WILEY

Patient involvement in research within the Gynecological Cancer InterGroup: A call to action for a systematic approach: Results from a survey

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Abstract

Background and Aims: Involving patients in research, not only as trial subjects, is not a newly established practice. Over the last two decades, patient roles have gradually expanded to become active research contributors, creating a more patient-centered research landscape. Our survey has explored the scope of patient involvement within the Gynecologic Cancer InterGroup (GCIG), an International Gynecologic Cancer Research Consortium, and identified challenges in developing a systematic, meaningful and sustainable level of patient involvement.

Methods: In late 2019, the GCIG Harmonisation Operations Committee conducted an online survey across 26 national and/or international research cooperative groups, aiming to identify current patient involvement practices implemented by each group. Twelve questions were asked. The results have been generated to support a systematic strategic planning process to increase patient involvement into clinical research projects.

Results: More than half of the 26 participating groups have either already involved (15, [58%]) or are planning (6, [23%]) to involve patients in their research activities. Gaining patient support in raising public awareness around clinical trials appears to be one of the most desired benefits (21, [81%]). Ten respondents managed to integrate patient involvement into their standard practice. When involving patients in research the groups mostly consider that patients bring added value to the study (19, [73%]), although only eight groups (40%) have a well-organized process in doing so.

Raw data of the survey were generated at EORTC GCG. All authors have read and approved the final version of the manuscript [CORRESPONDING AUTHOR or MANUSCRIPT GUARANTOR] had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis. Derived data supporting the findings of this study are available from the corresponding author [IN] on request.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Conclusion: Even though patient involvement is considered a significant added value to clinical research, its application within GCIG groups is not considered on a regular basis and is predominantly limited to operational aspects of research activities. The lack of resources and expertize, as well as the missing well-organized and structured process of some groups, combined with their ability to ensure process sustainability, are among the main factors affecting implementation and adoption of patient involvement within GCIG research activities.

KEYWORDS
cancer clinical research, cooperative research groups, GCIG, gynecology, oncology, patient involvement

1 | INTRODUCTION

The strategy of involving patients in clinical research development to better reflect their concerns, needs and interests has been evolving for almost two decades. Various systematic reviews evaluated the patient-centered research landscape to explore the value brought by patients into research and to find a solution on how to best involve patients so they may benefit from their experience whilst being treated for a disease.[1–7]

Despite a broad consensus for patient involvement within clinical trials, the quantity and quality of patient-relevant priorities has not increased significantly over time. Research activities that ideally could utilize patients, but have been identified as challenging in doing so, include enrollment, funding, trial design, and the implementation and dissemination of results.[8–14]

Previous research stressed the lack of clarity and guidance regarding the role and impact of patient involvement in trial oversight and conduct.[11] Further problems are identified in the mutual interaction between researchers and patients in poor quality of reporting.[13,15]

Sacristan et al.,[16] suggest changing the emphases to the ethical principles guiding the physician–patient relationship. Therapeutic misconception, the absence of patients in Institutional Review Boards, poor quality of information provided to patients and low levels of patient involvement in establishing research priorities and study design are all elements indicating that the benevolence principle predominates in the research field.[16]

Cultural barriers have also been identified as restricting the change process. This is of special interest in the conduct of international trials. In this context patient involvement should also include members of migrant populations.[17]

The lack of guidance on how to undertake public and patient involvement in trial oversight remains an issue.[11,18] Patients' negative perceptions of research and researchers' lack of training have been identified as main barriers.[19] Effective communication further underlies an improved clarity in research planning and associated outcomes.[20] A study conducted by Buck et al.,[15] described how plans for public and patient involvement were implemented within clinical trials, and identified the challenges and lessons learned by research teams.[15] Early patient involvement and ensuring clarity about patients' activities, roles and responsibilities, is crucial for success. Furthermore, funders, reviewers and regulators should recognize the value of patient involvement in research and allocate further resources to it.[15]

Recent studies focus on the evaluation tools supporting patient and public engagement in research to ensure the integrity of engagement principles and practices and to demonstrate accountability for public investments.[21]

Manafo et al., identify methods for, and outcomes of, patient engagement in health research.[22] They opine that stronger evidence of specific patient and healthcare system outcomes is required. However, certain questions remain as to which values to emphasize, and how patients can be better engaged as valued partners in health research.[23–25]

This need led the Gynecologic Cancer InterGroup (GCIG) Harmonisation Operations Committee to conduct a survey focusing on the extent of patient involvement across the clinical research activities of each research group involved in GCIG. The survey also aimed to identify challenges to increased levels of patient involvement in the research being developed, predominantly facilitated through the consortium's strategic planning activities.

2 | METHODS

To identify the extent of patient involvement in the overall development of clinical trials amongst the GCIG consortium, an exploratory qualitative online survey was distributed to all 32 GCIG member groups between 2019 and 2020. The survey was conducted and distributed to the relevant groups by members of the GCIG Harmonisation Operations Committee utilizing the SurveyMonkey™ data collection platform. The survey consisted of twelve (12) questions (Appendix 1) regarding each national group's experience with patient involvement in the development of clinical trial concepts, the subsequent benefits and challenges identified in doing so, and the overall implementation of relevant processes and procedures to

encourage sustainable patient involvement. Most questions included multiple response items, and the groups were allowed to select any response options items available.

The sample size for each question was the number of groups with at least one response to the items in the question. For example, 26 groups responded to Q1 (Do you involve patients/carers/patient advocates in clinical research?). Q2 (If not/not yet: do you think patient involvement can improve clinical research?) was limited to groups with a negative response to Q1. As such, the sample size for Q2 was 14 groups. Item-level response rates were estimated as binomial proportions of groups choosing a given item in the question, among all the groups choosing at least one item in the question. The two-sided 95% confidence interval for each response rate estimate was estimated using Jeffreys method,[26–28] without adjustment for multiple comparisons or finite sample sizes. The confidence interval may be interpreted as the plausible range for the true (unknown) response rates as supported by the available data.

3 | RESULTS

Twenty-six of the 32 (81%) participating member groups of GCIG representing the European, Canadian, United Kingdom, and Asia-Pacific regions submitted responses to the online survey. Upon review of the responses received, 15 of the 26 national groups involved patients to some extent within the group's clinical research (response rate [95% confidence interval]: 0.58 [0.39, 0.75]) and six groups (0.23 [0.10, 0.42]) intended to involve patients in the near future. Five groups (0.19 [0.08, 0.37]) indicated no intention of involving patients at the time of submitting a response (Q1). Of the 14 groups that were not already involving patients, 12 groups (0.86 [0.62, 0.97]) felt that involving patients at some point could improve their clinical research activities.

For all 26 responding groups, Table 1 shows the multifaceted reasons that groups identified for involving patients in clinical research. From a prepopulated list of items, 21 groups indicated that involving patients would increase public awareness of clinical trial activity, 19 groups felt that patient involvement would identify unmet needs, and 16 groups suggested that patient involvement would improve the quality of lay language in patient-facing documentation.

Further insight was provided by respondents, whereby 19 groups (0.73 [0.54, 0.87]) considered that involving patients and/or their carers, or patient advocates, would add value to the quality of study development, and 14 groups (0.54 [0.35, 0.72]) considered their inclusion a necessary requirement in the current clinical research landscape (Q4). Nineteen respondents (0.73 [0.54, 0.87]) felt staff members overseeing these activities should have specific expertize, namely in their ability to communicate in lay language and for understanding the specific needs of, and intricacies surrounding, patient advocates (Q5). Thirteen groups already utilized patients in this space, 11 used patient advocates, and 9 used insights from patient carers (Q6).

In Table 2, 18 responding groups provided feedback on methods for achieving patient involvement in the clinical trial development. Nine groups involved patients, carers or advocates in all of their clinical research projects (Q7), and eight groups (0.44 [0.24, 0.67]) identified a structured approach for doing so (Q8). As shown in Table 2, seven of the respondents achieved this through the establishment of a relationship with a patient organization, and six groups established a working group or committee that was formally linked with their organization. Similar numbers relied on selected individuals, or on contacts with existing patient groups to help involve patients in research (Q9).

Table 3 shows the stage of study development when the 19 respondents involved patients, carers and/or advocates. Eleven groups involved these stakeholders during the informed consent review process and also in raising awareness amongst patient groups about their clinical research. Ten groups used these patients to help design their informed consent documentation and also consulted them regarding a study's feasibility and acceptability. Generally, patients were not likely to be involved in the full protocol design, or in the dissemination of results.

TABLE 1 A table representing 26 respondent answers to the survey question "If you think patient involvement can improve clinical research, please tell how." (**Q3**).

Response	Responses/*N*	Response rate (95% CI)
To increase public awareness of clinical trials	21/26	0.81 (0.63, 0.92)
To bring out unmet needs relevant for patients	19/26	0.73 (0.54, 0.87)
To develop outcomes in accordance with patients' needs	18/26	0.69 (0.5, 0.84)
For a better application in real life	17/26	0.65 (0.46, 0.81)
To improve the quality of lay language documents	16/26	0.62 (0.42, 0.78)
To increase enrollment rate	12/26	0.46 (0.28, 0.65)
To improve clinical trial design	11/26	0.42 (0.25, 0.61)
To promote clinical trial access to a wide variety of patients	10/26	0.38 (0.22, 0.58)
Other (please specify)	0/26	0 (0, 0.09)

TABLE 2 Responders were asked select provides methods for how best to achieve patient involvement in the clinical trial development process. Responses are the number of groups indicating each stratify as a viable approach (**Q9**).

Response	Responses/*N*	Response rate (95% CI)
Through establishment of a privileged relationship with patient organization(s)	7/18	0.39 (0.19, 0.62)
By setting up a working group or committee within or linked to your organization	6/18	0.33 (0.15, 0.56)
Through relying on selected individuals	6/18	0.33 (0.15, 0.56)
By linking to an existing group/panel set up by another organization	6/18	0.33 (0.15, 0.56)
By setting up ad hoc group or panel	5/18	0.28 (0.11, 0.51)
Other (please specify)	2/18	0.11 (0.02, 0.31)

TABLE 3 From specified list, respondents were asked at what stage of clinical research they involved patients/carers/patient advocates. (**Q10**).

Response	Responses/*N*	Response rate (95% CI)
Patient information/consent review	11/19	0.58 (0.36, 0.78)
Raising awareness among other patients about importance of clinical research	11/19	0.58 (0.36, 0.78)
Patient information/consent design	10/19	0.53 (0.31, 0.73)
Consultation on the study feasibility/acceptability (whether as a part of the study review or not)	10/19	0.53 (0.31, 0.73)
Participation in conferences and symposiums	9/19	0.47 (0.27, 0.69)
Full protocol review	8/19	0.42 (0.22, 0.64)
Part of advisory body (not study specific)	8/19	0.42 (0.22, 0.64)
Research concept review	7/19	0.37 (0.18, 0.59)
Lay summary of results review	7/19	0.37 (0.18, 0.59)
Contribution to general group meetings	7/19	0.37 (0.18, 0.59)
Participation in the study governance (trial management group, steering committee, IDMC, etc.)	6/19	0.32 (0.14, 0.54)
Collaboration on the purpose of grant submission for some projects	6/19	0.32 (0.14, 0.54)
Research concept design	5/19	0.26 (0.11, 0.48)
Lay summary of results design	3/19	0.16 (0.05, 0.36)
Dissemination of results	3/19	0.16 (0.05, 0.36)
Full protocol design	2/19	0.11 (0.02, 0.3)
Contribution to the discussions on methodology (not study specific)	1/19	0.05 (0.01, 0.22)
Other (please specify)	5/19	0.26 (0.11, 0.48)

Responding groups identified a variety of methods used to communicate with their patients, carers and/or advocacy stakeholders, with 14 of 17 (0.82 [0.6, 0.95]) reporting face-to-face meetings at least once per year, with 6 of these conducting annual meetings (likely at annual scientific or organizational meetings). E-mails (11 of 16) and social media posts (12 of 18) at least once per year were also popular amongst groups. However, these were conducted at more regular intervals, predominantly monthly (Q11).

All 26 respondents provided feedback on an ordinal ranking scale (0 = not challenging, to 5 = most challenging) that addressed the challenges faced when engaging patients, carers and advocates in clinical research. The topics deemed to be the most challenging (as measured by the proportion of responding groups indicating 4 or 5) included ensuring process sustainability and funding to engage stakeholders (each with 11 of 21 groups responding). Assessing the representativeness and value of patient experts were also considered

main challenges (10 of 21 groups). Other challenges included finding patient experts (7 of 21), and the training those experts (9 of 21). Conversely, of least concern for respondents was management support to engage these specialist groups (3 of 19) and training of staff and clinicians in understanding the relevance, value and potential benefit of patient involvement (4 of 21) (Q12).

4 | DISCUSSION

4.1 | Variability of patient involvement

Although patient involvement in research is a means to increase the quality of research, no previous exploration of patient involvement in clinical research activities across the GCIG groups has been undertaken.

From the results of our survey, only half of the groups (58%) have involved patients in their clinical research activities, although most groups (86%) found patient involvement as beneficial to improving clinical research. The benefit can especially be seen in the increase of public awareness of clinical trials (81%) and in identifying unmet needs relevant for patients (73%).

Contrary to this belief, one fifth of the groups (23%) do not include patients in their research activity yet, and almost the same number of groups (19%) do not plan to do so. This finding demonstrates the inexperience, uncertainty and lack of specific structure of some GCIG groups in how to start effective collaboration with their patients, regardless of the fact that many recommendations to do so can be found in literature.[10,24,29–35] Understanding the reasons of limited patient involvement may help overcome barriers. The difficulties in finding patient volunteers and the need to train their representatives are among the major barriers identified (Table 4, Q12). This requires resources, group experience and time. Smaller groups have less opportunities to involve patients. The value and return on expenditure have also been questioned.

Despite the growing literature on the value of patient engagement, the published literature contains little evidence demonstrating the impact of this investment.[21,24,36] Richards et al., (2017) see evidence that co-producing research with patients and the public provides an appreciable return on investment.[37] For confirmation of the financial value that patient engagement activities provide, Levitan et al., (2018) developed an approach to estimate the financial value of patient engagement, accounting for the business drivers of cost, risk, revenue, and time.[38]

A further presumption of success is a well-organized, structured process to support patient involvement. Based on the experience of several GCIG groups, a well-organized process can take several years to achieve. In these groups, patient activities are reflected in several different ways, including the creation of an effective communication strategy with patient partners, utilization of volunteers interested in furthering research and its activities, patient reviews of patient-facing documentation, patient participation in trial group meetings, establishing an advisory patient panel, tracking patient feedback, and keeping records for process review. Furthermore, patient training opportunities are provided to raise awareness of cancer and cancer clinical research, and to enhance the experience of the patient's involvement.

Conversely, barriers can be observed not only from the perspective of the group but also on the part of patients. The GCIG groups focus on the treatment of individuals diagnosed with gynecological cancer. Their involvement in clinical trial research can be limited due to patient frailty caused by the severity of their illness, as well as their age.

Unique regional requirements should also be considered. Different regions, and their governments can implement various requirements for patient involvement in clinical trials. For example, in Australia, some government grant applications require patient input, and there is the expectation that at least one associate investigator on a competitive government funded grant is a patient, as evidenced through the Statement on Consumer and Community Involvement in

TABLE 4 Main challenges relevant to the success of patient involvement, sorted from most to least challenging. Response defined a groups selecting a challenge score of 4 or 5 (**Q12**).

Response	Responses/*N*	Response rate (95% CI)
Ensuring process sustainability	11/21	0.52 (0.32, 0.72)
Resources/funding	11/21	0.52 (0.32, 0.72)
Measuring value of contribution of patient experts	10/21	0.48 (0.28, 0.68)
Representativeness of patient experts	10/21	0.48 (0.28, 0.68)
Expertize/training of patients experts	9/21	0.43 (0.24, 0.64)
Finding patient experts	7/21	0.33 (0.16, 0.55)
Remuneration/compensation of patient experts	5/20	0.25 (0.1, 0.46)
Training of your staff and clinicians in understanding the relevance, value and potential of patient involvement	4/21	0.19 (0.07, 0.39)
Management support	3/19	0.16 (0.05, 0.36)

Health and Medical Research (2016[39]). Due to the increasing requirement to involve patients as a precondition for funding, patient involvement is becoming an inevitable part of the cancer research process.[40–43] Consistent with these developments, 11 of the responding GCIG groups reported that their endeavors to meet the requirements of research grant funders, of legislation and Ethics committees (Table 5) (9), and the possibility to obtain funding from patient organizations (8) influenced their position in doing so.

Furthermore, the systematic involvement of patients in clinical trials development should start at study conception. Patients involved at the development phase will be better equipped for input to finalizing the protocol, statistical analysis, interpretation of the results, the outcomes, discussion of other scientific projects, and disseminating study results into the patient community.

So far, research and literature have introduced several strategies to enable effective patient involvement in research.[12,41,44–46] These strategies serve as models, and can be further developed within the activities of individual GCIG groups, the consortium as a whole, and other collaborative research groups.

4.2 | Limited application

In general, patient engagement is feasible in most settings and most commonly undertaken at the beginning of research (agenda setting and protocol development) and less commonly during the execution and translation of research.[13] Patient influence on the development and implementation of clinical trials may significantly improve the quality of lay language documents, and find a balance between academic knowledge and its understanding by patients.

This survey describes the utilization of patient involvement in reviewing clinical trial documents, such as patient information sheets and protocol reviews. Interestingly, the majority of the responding research groups (10/19) consult with patients, carers or patient advocates for study feasibility and acceptability. However, most are not involved in further stages of trial design. Patient review and input are common when drafting patient information sheets and patient informed consent forms (53%), however, rates of patient involvement in research concept design (26%), protocol design (11%), and lay summary of results design (15.79%) remain low. Our survey confirms that active patient involvement in the decision making-process of designing trials is less common than consultation on what has already been decided.[8]

Patients mostly help in raising awareness amongst patient groups about the importance of clinical research in more than half of the responding groups (11/19). It is worth mentioning that "raising public awareness around cancer research" has been recognized by respondents as a commonly expected benefit of patient involvement (Q3, 21 of 26), in addition to its actual application in the clinical trial process (Q1 15 of 26). This finding may indicate an assumption of poor public perception of clinical trials, seeing the "raising public awareness" as one of the desired outcomes indicates that there is a lack thereof. Another key finding of the survey pertains to later activities in a trial and patient involvement in the dissemination of study results. This is revealed as one of the most neglected parts of the research process involving patients with only 3 of 19 responding groups doing so.

The significant issue remains around how best to involve patients in discussions on methodology. Only one GCIG group out of the 19 respondents has already found an effective way to do so. Irrespective of how effective a process or strategy can be, what plays a more significant role is the magnitude of patient involvement. Patient partners may only be involved in reviewing patient-facing documentation or participating throughout the whole clinical trial process from identifying research priorities to the dissemination of trial results. Researchers, before initiating involvement, should decide what impact they expect from patient feedback.[47] This can include setting clear expectations and communicating these to patients, as well as keeping records of each of their contributions. Only then it can be evaluated whether, and how, their involvement makes a difference for the research activity and whether researcher expectations are met. Such a practice can gradually help optimize the experience of involving patients for GCIG groups that aren't already doing so and could also be of interest to other collaborative research

TABLE 5 A table representing 26 respondent answers to the question "What aspects did/will you take into account when involving patients/carers/patient advocates?" (**Q4**).

Response	Responses/*N*	Response Rate (95% CI)
Considered as bringing the added value for the study	19/26	0.73 (0.54, 0.87)
Considered as must have in the current clinical research landscape	14/26	0.54 (0.35, 0.72)
Requirement(s) of research grant(s)/funders	11/26	0.42 (0.25, 0.61)
Previous positive experience	11/26	0.42 (0.25, 0.61)
Required by legislation/legislator/Ethical Committee	9/26	0.35 (0.19, 0.54)
Possibility to get funding from a patients' organization(s)	8/26	0.31 (0.16, 0.5)
Requirement(s) of journals/publishers	2/26	0.08 (0.02, 0.22)
Other (please specify)	1/26	0.04 (0, 0.17)

groups looking to do the same. Clearly establishing the roles, goals and the timing of when to involve patients in clinical trials is crucial for success.[15] Researchers also note that late and/or minimal patient involvement engagement can diminish the value of their research.

4.3 | Identified challenges

Respondents indicated the following key challenges in optimizing their patient involvement practices in the context of the clinical research process. A strong majority of the responding groups (21/26) highlighted their ability to ensure sustainability of the patient involvement process. The results of Manafo et al., demonstrate existing efforts to involve patient partners, however, these efforts are often limited to preliminary activities and are not sustained across the whole research process.[22] Theoretical frameworks, which can better inform and sustain patient engagement across the lifecycle of health research, are lacking.[22] Ensuring adequate resources and funding for patient involvement is a key area influencing the rates of patient engagement in 21 out of the 26 surveyed research groups.

Further challenges to be considered surrounded the identification of patient experts and their expertize and training were reported by 21 out of 26 groups. The survey, unfortunately, did not allow respondents to elaborate on what exactly defines this challenge and has been identified as a limitation warranting further discussion amongst GCIG member groups. Presumably, the difficulty might lie in the recruitment stage where researchers need to decide on the skills and experience patient contributors should have. This will depend on the research question and objectives, as well as on the level of expected involvement of patients. No less important is the ability to utilize the unique skills of patient contributors in a way that benefits a particular study.

However, not all patients have knowledge of or experience in being involved in the design and conduct of clinical trials, and the dissemination of their results. Therefore, researchers should provide training opportunities to all lay contributors giving them at least a basic understanding regarding the research environment, medical terminology, and methodology. We believe that besides providing training for patient partners, researchers also need certain guidance and support in how to effectively engage and empower patient partners.[47,48]

Further, we observe the challenges in sharing experience among the respective GCIG member groups on how best to achieve patient involvement. The survey shows that various approaches are evident. There are small differences in patient involvement through the establishment of a privileged relationship with patient organizations (7 of 18), and by setting up a working group or committee within –or linked to –a group (6 of 18), or by linking to an already existing group (6 of 18) (Q9). Establishing relationships with patient organizations seems to prevail. So far, multiple recruitment strategies have been identified for patients as research partners.[49] A conceptual framework may be used to guide teams of GCIG member groups in developing strategies for engaging patients in their research activities, which could also be replicated and adapted by other collaborative research groups hoping to do the same.[10,36]

5 | LIMITATIONS

One of the limitations we have identified is the lack of clarity on the concept of a "well-organized process for patient involvement". The respondents were not provided with the ability to clarify their response, so their understanding of the question may vary. Further, as is the challenge with surveys, we cannot exclude that respondents give socially desirable answers with respect to the formal demand and trends for patient involvement. Another limitation identified is answering the survey questions by only one group representative. The level of experience of individual respondents with patient involvement is also questionable and may vary amongst member groups. However, as a matter of practice and policy within GCIG, representatives completing any questionnaire on behalf of a member group discuss each question with a relevant subject matter expert.

Surprisingly, two groups reported that they were not convinced of the benefits of patient involvement in their research. With that in mind, all respondents answered an item surrounding how patient involvement could improve clinical research and identified some benefits. This contradictory finding might be explained by the inability of these two respondents to perceive benefit from patient involvement in the research they develop, for example, due to certain feasibility issues, one of which may be related to cultural practices. Also, having a list of potential benefits may be associated with the ability to implement them, whereas a general yes/no question limits the ability to see the applicability of those benefits. Therefore, educational programs should be implemented to increase the awareness and highlight the benefit of patient involvement in study teams.

6 | CONCLUSION

While the scope of implementation of patient-centric approaches and involvement of patients as partners in research vary across the GCIG member groups, the lack of established frameworks is evident. Given the wide range of previously developed frameworks, many groups still tend to involve patient partners in a limited fashion, or in a small subset of research activities. The concept of a "well-organized process" is not developed to the extent necessary to surpass the traditional narrowness of patient involvement in group research activities, and the best and most effective approach is needed to be clarified for future guidance. Identifying and establishing resources and ensuring sustainability play a significant role in this process. Expertize on the part of patients, as well as intra-group experts from each GCIG member group is another prerequisite for success. Sharing individual group experience and creating tools for facilitating patient involvement seem to be beneficial for the achievement of effective patient involvement within and across the GCIG member groups.

Owing to the survey being used as a baseline assessment, a follow-up survey is needed to evaluate whether uptake by individual groups is gaining momentum and to determine if and why the process of patient involvement is improving. It is necessary to identify how the challenges of implementation can be addressed. Research is mostly focused on researcher needs regarding patient involvement and the challenges they face. However, our next aim should be to evaluate patient perspectives on their involvement within clinical trial development. If we can bring together the needs of both researchers and patients, we would have a clearer picture of whether those needs align with one another and how best to facilitate the involvement of both in future, and ongoing, research activities. Future directions in the field of patient involvement in research should focus on improved sharing of the experience of effective patient engagement methods and the impact of patient engagement on research outcomes.[50] Furthermore, standardized reporting of engagement processes is needed to allow for reproducibility by others.[51]

AUTHOR CONTRIBUTIONS

Ivana Nohová: Conceptualization; Project administration; Supervision; Writing—original draft. **John Andrews**: Writing—review and editing. **Bénédicte Votan**: Writing—review and editing. **Austin Miller**: Writing—review and editing; statistical data processing. **Jalid Sehouli**: Writing—review and editing. **Regina Berger**: Writing—review and editing.

ACKNOWLEDGMENTS

We would like to acknowledge the patient advocates for their manuscript review and valuable feedback, namely Janette Rawlinson (EORTC) and Wanda Lawson (ANZGOG). We thank our colleagues from the respective GCIG groups [AGO-Austria (Arbeitsgemeinschaft Gynaekologische Onkologie Austria), AGOG (Asian Gynecologic Oncology Group), AGO Study Group (Arbeitsgemeinschaft Gynaekologische Onkologie Studiengruppe), ANZGOG (Australia New Zealand Gynaecological Oncology Group), BGOG (Belgium and Luxembourg Gynaecological Oncology Group), CCTG (Canadian Cancer Trials Group, CTI (Cancer Trials Ireland), CEEGOG (Central and Eastern European Gynecologic Oncology Group), COGI (Cooperative Gynecologic Oncology Investigators), DGOG (Dutch Gynecologic Oncology Group), EORTC GCG (European Organization for Research and Treatment of Cancer-Gyne Cancer Group), GCGS (Gynecologic Cancer Group Singapore), GEICO (Grupo Espanol de Investigacion en Cancer de Ovario), GINECO (Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens), GOTIC (Gynecologic Oncology Trial and Investigation Consortium), GICOM (Grupo de Investigación en Cáncer de Ovario y Tumores Ginecológicos de México), KGOG (Korean Gynecologic Oncology Group), KolGoTrg (Kolkata Gynecological Oncology Trials & Translational Research Group), MaNGO (Mario Negri Gynecologic Oncology Group), MITO (Multicenter Italian Trials in Ovarian Cancer), NCRI (National Cancer Research Institute), NOGGO (Nord-Ostdeutsche Gesellschaft für Gynäkologische Onkologie), NSGO-CTU (Nordic Society of Gynaecological Oncology-Clinical Trial Unit), PMHC (Princess Margaret Hospital Consortium), SGOG (Shanghai Gynecologic Oncology Group), SGCTG (Scottish Gynaecological Cancer Trials Group)] who provided an insight surrounding their groups'collaboration with patients by responding to the survey questions.

We would like to thank the GCIG Operations Manager Katherine Bennett for her exceptional support.

We are also grateful to EORTC GCG (the European Organization for Research and Treatment of Cancer-Gyne Cancer Group), who initiated the conduct of the survey within GCIG, and was also involved in the first result analysis and its description.

Finally, we would like to acknowledge the respective patients, carers, and patient advocates for each of the GCIG group.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest. The authors declare that they did not use any supporting source and have no financial relationship that may have influenced the work presented in this article.

DATA AVAILABILITY STATEMENT

Raw data of the survey were generated at EORTC GCG. All authors have read and approved the final version of the manuscript [CORRESPONDING AUTHOR or MANUSCRIPT GUARANTOR] had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis. Derived data supporting the findings of this study are available from the corresponding author [IN] on request.

TRANSPARENCY STATEMENT

The lead author Ivana Nohová affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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REFERENCES

1. McCarron TL, Clement F, Rasiah J, et al. Patients as partners in health research: a scoping review. *Health Expect*. 2021;24(4):1378-1390.
2. Al-Janabi H, Coles J, Copping J, et al. Patient and public involvement (PPI) in health economics methodology research: reflections and recommendations. *Patient*. 2021;14(4):421-427.
3. Crocker JC, Pratt-Boyden K, Hislop J, et al. Patient and public involvement (PPI) in UK surgical trials: a survey and focus groups with stakeholders to identify practices, views, and experiences. *Trials*. 2019;20(1):119.
4. Gamble C, Dudley L, Allam A. An evidence base to optimise methods for involving patient and public contributors in clinical trials: a mixed-methods study. *Health Serv Deliv Res*. 2015.
5. Gradinger F, Britten N, Wyatt K, et al. Values associated with public involvement in health and social care research: a narrative review. *Health Expect*. 2015;18(5):661-675.
6. Easley J, Wassersug R, Matthias S, et al. Patient engagement in health research: perspectives from patient participants. *Curr Oncol*. 2023;30(3):2770-2780.

7. Estrup S, Barot E, Mortensen CB, et al. Patient and public involvement in contemporary large intensive care trials: a meta-epidemiological study. *Acta Anaesthesiol Scand*. 2023;67(3):256-263.
8. Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical trials: an overview of systematic reviews. *J Eval Clin Pract*. 2018;24(1):240-253.
9. Lamberti MJ, Awatin J. Mapping the landscape of patient-centric activities within clinical research. *Clin Ther*. 2017;39(11):2196-2202.
10. Hamilton CB, Hoens AM, Backman CL, et al. An empirically based conceptual framework for fostering meaningful patient engagement in research. *Health Expect*. 2018;21(1):396-406.
11. Coulman KD, Nicholson A, Shaw A, et al. Understanding and optimising patient and public involvement in trial oversight: an ethnographic study of eight clinical trials. *Trials*. 2020;21(1):543.
12. Schilling I, Herbon C, Jilani H, Rathjen KI, Gerhardus A. Aktive beteiligung von patient*innen an klinischer forschung – eine einführung. *Z Evid Fortbild Qual Gesundhwes*. 2020;155:56-63.
13. Domecq JP, Prutsky G, Elraiyah T, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89.
14. Forsythe LP, Ellis LE, Edmundson L, et al. Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med*. 2016;31(1):13-21.
15. Buck D, Gamble C, Dudley L, et al. EPIC Patient Advisory Group. From plans to actions in patient and public involvement: qualitative study of documented plans and the accounts of researchers and patients sampled from a cohort of clinical trials. *BMJ Open*. 2014;4(12):e006400.
16. Sacristán JA, Aguarón A, Avendaño-Solá C, et al. Patient involvement in clinical research: why, when, and how. *Patient Prefer Adher*. 2016;10:631-640.
17. Dimitrova D, Naghavi B, Richter R, et al. Influence of migrant background on patient preference and expectations in breast and gynecological malignancies (NOGGO-expression V study): results of a prospective multicentre study in 606 patients in Germany. *BMC Cancer*. 2021;21(1):1018.
18. Katirai A, Kogetsu A, Kato K, Yamamoto B. Patient involvement in priority-setting for medical research: a mini review of initiatives in the rare disease field. *Front Public Health*. 2022;10:915438.
19. Harrison JD, Anderson WG, Fagan M, et al. Patient and family advisory councils (PFACs): identifying challenges and solutions to support engagement in research. *Patient*. 2018;11(4):413-423.
20. Doria N, Condran B, Boulos L, Curtis Maillet DG, Dowling L, Levy A. Sharpening the focus: differentiating between focus groups for patient engagement vs. qualitative research. *Res Involv Engagem*. 2018;4:19.
21. Boivin A, L'Espérance A, Gauvin FP, et al. Patient and public engagement in research and health system decision making: a systematic review of evaluation tools. *Health Expect*. 2018;21(6):1075-1084.
22. Manafo E, Petermann L, Mason-Lai P, Vandall-Walker V. Patient engagement in Canada: a scoping review of the 'how' and 'what' of patient engagement in health research. *Health Res Policy Syst*. 2018;16(1):5.
23. Fruytier SE, Vat LE, Camp R, et al. Monitoring and evaluation of patient engagement in health product research and development: co-creating a framework for community advisory boards. *J Patient Cent Res Rev*. 2022;9(1):46-57.
24. Street C, Twells LK, Leamon T, Taylor L, Etchegary H. Changing health-related behaviors 1: patient-oriented research and patient engagement in health research. *Methods Mol Biol*. 2021;2249:537-552.
25. Schuster ALR, Hampel H, Paskett ED, Bridges JFP. Rethinking patient engagement in cancer research. *Patient*. 2023;16(2):89-93.
26. Agresti A, Coull BA. Approximate is better than "exact" for interval estimation of binomial proportions. *Am Stat*. 1998;52(2):119-126.
27. Newcombe RG. Two-sided confidence intervals for the single proportion: comparison of seven methods. *Stat Med*. 1998;17(8):857-872.
28. Brown LD, Cai TT, DasGupta A. Interval estimation for a binomial proportion. *Stat Sci*. 2001;16(2):101-117.
29. Kirwan JR, de Wit M, Frank L, et al. Emerging guidelines for patient engagement in research. *Value Health*. 2017;20(3):481-486.
30. Supple D, Roberts A, Hudson V, et al. U-BIOPRED PIP group. From tokenism to meaningful engagement: best practices in patient involvement in an EU project. *Res Involv Engagem*. 2015;1:12.
31. Selman LE, Clement C, Douglas M, et al. Patient and public involvement in randomised clinical trials: a mixed-methods study of a clinical trials unit to identify good practice, barriers and facilitators. *Trials*. 2021;22(1):735.
32. Abma TA, Broerse JEW. Patient participation as dialogue: setting research agendas. *Health Expect*. 2010;13(2):160-173.
33. Price A, Clarke M, Staniszewska S, et al. Patient and public involvement in research: a journey to co-production. *Patient Educ Couns*. 2022;105(4):1041-1047.
34. Marcu A, McGregor F, Egan B, Hill K, Cook T, Arber A. Developing sustainable patient and public involvement in mesothelioma research: multi-method exploration with researchers, patients, carers, and patient organisations. *Res Involv Engagem*. 2023;9(1):15.
35. Partridge A, Hitchman J, Savic L, Shelton CL. How to plan, do and report patient and public involvement in research. *Anaesthesia*. 2023;78(6):779-783.
36. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. *J Comp Eff Res*. 2015;4(2):133-145.
37. Richards T. Patient and public involvement in research goes global. *BMJ Patient Perspectives*. 2017. Accessed March 12, 2019. https://blogs.bmj.com/bmj/2017/11/30/tessa-richards-patient-and-public-involvement-in-research-goes-global/
38. Levitan B, Getz K, Eisenstein EL, et al. Assessing the financial value of patient engagement: a quantitative approach from CTTI's patient groups and clinical trials project. *Ther Innov Regul Sci*. 2018;52(2):220-229.
39. Statement on Consumer and Community involvement in Health and Medical Research, National, Health and Medical Research Council. *Consumers Health Forum of Australia*. 2016. https://www.nhmrc.gov.au/sites/default/files/documents/reports/consumer-community-involvement.pdf
40. Maccarthy J, Guerin S, Wilson AG, Dorris ER. Facilitating public and patient involvement in basic and preclinical health research. *PLoS One*. 2019;14(5):e0216600.
41. https://www.thebraintumourcharity.org/funding-for-brain-tumour-researchers/patient-public-involvement/
42. Costa Alencar AB, Selig WKD, Geissler J, et al. Adopting recommendations for implementing patient involvement in cancer research: a funder's approach. *Res Involv Engagem*. 2023;9(1):6.
43. De Simoni A, Jackson T, Inglis Humphrey W, et al. Patient and public involvement in research: the need for budgeting PPI staff costs in funding applications. *Res Involv Engagem*. 2023;9(1):16.
44. Armbrust R, Alavi S, Pirmorady A, et al. Results of the inter-professional and interdisciplinary Berlin round table on patient-reported outcomes, quality of life, and treatment expectations of patients with gynecological cancer under maintenance treatment. *Int J Gynecol Cancer*. 2020;30(10):1603-1607.
45. Rohr I, Alavi S, Richter R, et al. Expectations and preferences of patients with primary and relapsed ovarian cancer to maintenance therapy: a NOGGO/ENGOT-ov22 and GCIG survey (Expression IV). *Int J Gynecol Cancer*. 2020;30(4):509-514.
46. Oskay-Özcelik G, Alavi S, Richter R, et al. Expression III: patients' expectations and preferences regarding physician-patient relationship and clinical management-results of the international NOGGO/ENGOT-ov4-GCIG study in 1830 ovarian cancer patients from European countries. *Ann Oncol*. 2018;29(4):910-916.
47. Tscherning SC, Bekker HL, Vedelø TW, Finderup J, Rodkjær LØ. How to engage patient partners in health service research: a scoping review protocol. *Res Involv Engagem*. 2021;7:20.

48. Weiler-Wichtl LJ, Leiss U, Gojo J, et al. Good to know - this is PPIE! Development of a training tool for public and patient involvement and engagement in pediatric oncological research. *Cancer Rep (Hoboken)*. 2023;6(6):e1835.
49. Vat LE, Ryan D, Etchegary H. Recruiting patients as partners in health research: a qualitative descriptive study. *Res Involv Engagem*. 2017;3:15.
50. Stergiopoulos S, Michaels DL, Kunz BL, Getz KA. Measuring the impact of patient engagement and patient centricity in clinical research and development. *Therap Innov Regul Sci*. 2020;54(1):103-116.
51. Duffett L. Patient engagement: what partnering with patient in research is all about. *Thromb Res*. 2017;150:113-120.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Nohová I, Andrews J, Votan B, Miller A, Sehouli J, Berger R. Patient involvement in research within the Gynecological Cancer InterGroup: a call to action for a systematic approach: results from a survey. *Health Sci Rep*. 2023;6:e1735. doi:10.1002/hsr2.1735