

Engaging patients as partners in a multicentre trial of spinal versus general anaesthesia for older adults

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Summary

Engaging patients—defined broadly as individuals with lived experience of a given condition, family members, caregivers, and the organisations that represent them—as partners in research is a priority for policymakers, funders, and the public. Nonetheless, formal efforts to engage patients are absent from most studies, and models to support meaningful patient engagement in clinical anaesthesia research have not been previously described. Here, we review our experience in developing and implementing a multifaceted patient engagement strategy within the Regional Versus General Anesthesia for Promoting Independence After Hip Fracture (REGAIN) surgery trial, an ongoing randomised trial comparing spinal vs general anaesthesia for hip fracture surgery in 1600 older adults across 45 hospitals in the USA and Canada. This strategy engaged patients and their representatives at both the level of overall trial oversight and at the level of individual recruiting sites. Activities spanned a continuum ranging from events designed to elicit patients' input on key decisions to longitudinal collaborations that empowered patients to actively participate in decision-making related to trial design and management. Engagement activities were highly acceptable to participants and led to concrete changes in the design and conduct of the REGAIN trial. The REGAIN experience offers a model for future efforts to engage patients as partners in clinical anaesthesia research, and highlights potential opportunities for investigators to increase the relevance of anaesthesia studies by incorporating patient voices and perspectives into the research process.

Keywords: anaesthesia; geriatrics; hip fracture; patient advocacy; patient engagement; research methods; shared decision-making

Editor's key points

- Shared decision-making in healthcare is a paradigm in which patients and clinicians jointly provide input into

key medical decisions, based on best evidence, their respective values, and their preferences.

- Both in clinical practice and in research, the model of decision-making in medicine has historically been

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paternalistic, and the importance of patient agency and the capability of patients to participate in decision-making have often been questioned or even ignored.

- Patients' input into determinations regarding anaesthesia-related care and research is remarkably limited, with surgeons often driving key decisions in relation to anaesthetic techniques and choices.
- In this study, the investigators demonstrate the feasibility of developing and implementing a multifaceted patient engagement strategy for incorporating the perspectives of patients, family members, and organisations that advocate on their behalf into research on perioperative anaesthesia care.

Engaging patients—defined broadly as those with lived experience of a given condition, family members, caregivers, and the organisations that represent them^{1,2}—as partners in clinical research is an important priority for policymakers, funders, and the public.^{2–5} Patient engagement has been called an integral part of a learning health system⁶ and holds promise to support the production of research that is relevant to patients' needs and priorities.^{4,7} Despite this, formal efforts to engage patients as partners are absent from most current clinical research.^{8–10} In the context of anaesthesia research specifically, involvement of patients and other stakeholders has been described at the level of agenda setting.^{11–13} However, few available reports describe efforts to engage patients as partners in actual studies of perioperative anaesthesia care.^{8,9,14}

Identified general barriers to engaging patients in research include logistical concerns, time constraints of patients and researchers, funding limitations, and concerns regarding tokenistic approaches that could devalue patient input.^{8,15,16} In the context of perioperative anaesthesia research specifically, additional barriers may relate to the specialised and technical nature of anaesthesia practice, the delivery of anaesthesia interventions in hospital-based or equivalent settings vs community locations, variability amongst anaesthesia researchers in their familiarity or experience with patient engagement, and variability across patients in their familiarity with aspects of anaesthesia research.

In this paper, we report our experience of developing and implementing a patient engagement approach for an ongoing multicentre randomised trial comparing two standard-care approaches to anaesthesia for major orthopaedic surgery in older adults. Working with a lead patient partner organisation, we identified distinct challenges to engaging patients as partners at the level of overall trial planning and management, and at the level of the individual recruiting site and designed strategies that supported meaningful patient involvement in both of these contexts. We demonstrate how these efforts increased the patient centredness of our work by informing and impacting the design of our project, its conduct in the field, and our plans for dissemination of its results.

Research context: the Regional Versus General Anesthesia for Promoting Independence After Hip Fracture randomised trial

Regional Versus General Anesthesia for Promoting Independence After Hip Fracture (REGAIN) surgery ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02507505) identifier NCT02507505) is a pragmatic randomised trial

comparing two standard-care approaches to anaesthesia for lower-extremity orthopaedic surgery (spinal vs general anaesthesia) amongst adults aged 50 yr and older hospitalised with hip fracture.¹⁷ Patients are recruited into REGAIN at the time of hospital presentation; randomised following written informed consent to receive either spinal or general anaesthesia; and followed by telephone up to 1 yr for collection of key outcomes, including major complications, survival, and functional recovery. Now, ongoing at 45 sites in the USA and Canada with funding from the US Patient-Centered Outcomes Research Institute (PCORI; Washington, DC, USA), REGAIN is projected to enrol 1600 volunteer participants between February 2016 and February 2021. The present summary of the patient engagement efforts of REGAIN was determined to be exempt from institutional review board (IRB) review by the University of Pennsylvania IRB.

As is common for large multicentre studies, the REGAIN trial operates through an organisational structure that incorporates both central study management components and a network of recruiting sites. Central components include the study Executive Committee, which makes decisions regarding overall study governance and policy; the Clinical Coordinating Center (CCC), which provides operational support to participating sites, monitors site activities, and performs certain centralised data collection functions; and the Data Coordinating Center (DCC), which oversees data management and analysis. In addition to these central components, the REGAIN network has included 45 participating hospitals in the USA and Canada that recruit and enrol patients, deliver study treatments, and provide primary data collection functions. Each of these sites maintains a sub-award agreement with the lead study site (University of Pennsylvania, Philadelphia, PA, USA) and is overseen by a site lead investigator. Site reimbursement includes an initial site start-up payment followed by a set amount per randomised participant. Sites do not receive additional reimbursement for investigator effort, and there is no set minimum or maximum number of patients that sites are required or permitted to enrol.

Developing a patient engagement strategy for REGAIN

The conceptual framework of Carman and colleagues¹⁸ highlights key features of patient engagement that informed our approach to designing a patient engagement strategy for REGAIN. Carman and colleagues¹⁸ describe patient engagement activities as occurring along a continuum, ranging from input to collaboration and shared leadership (Table 1), with the degree of power and decision-making authority shared with patients increasing along the continuum. In models focusing on input or consultation, patients provide information to guide researchers' decisions, but have limited power or decision-making authority themselves. In contrast, collaboration and shared leadership models engage patients as active partners in defining agendas and making decisions. Carman and colleagues¹⁸ also describe patient engagement as occurring at different levels in organisations and systems; for example, patient engagement may occur both at the level of organisational governance and in the direct care setting.

In designing the engagement strategy of REGAIN (Table 2), we sought to include patients as partners across a continuum of activities ranging from input to collaboration. We also aimed to incorporate patient engagement at multiple levels within the

Table 1 Continuum of engagement practices in research (adapted from Forsythe and colleagues³).

	Input	Consultation	Collaboration/shared leadership
Defining characteristics	<ul style="list-style-type: none"> • Patient partners provide information that researchers use in defining agendas and making decisions. • Information typically flows in one direction. • Patient partners have no decision-making ability. 	<ul style="list-style-type: none"> • Patient partners provide support or advice on specific study attributes on an ongoing basis or as needed. • Information flows both uni- and bidirectionally. • Decision-making authority is limited to activities defined by research team. 	<ul style="list-style-type: none"> • Patient and stakeholder partners actively define agendas and make decisions. • Information flows bidirectionally. • Decision-making responsibility is shared.
Examples	<ul style="list-style-type: none"> • Focus groups • In-depth interviews • Surveys • User-experience testing • Crowdsourcing • Conferences/forums 	<ul style="list-style-type: none"> • Advisory panels • Working groups • External advisers 	<ul style="list-style-type: none"> • Patient co-investigators or co-principal investigators • Research team members • Embedded advisers • Steering committees • Patient-led tasks

Table 2 Patient engagement and related activities in the Regional Versus General Anesthesia for Promoting Independence After Hip Fracture trial.

Activities related to overall study planning and management			Activities focused on study implementation at individual recruiting sites		
Activity	Engagement level	Outcomes (selected)	Activity	Engagement level	Outcomes (selected)
Engagement of lead patient partner as co-investigator	Collaboration/shared leadership	Participated in developing and refining protocol and manual of procedures; organised patient partner panel; supported central and site-level engagement activities <i>Examples: co-developed engagement strategy; participated in selection of topics for pre-specified secondary analyses</i>	Site investigator 'town hall' and working group to assess opportunities and challenges for local engagement activities	Consultation/input	Identification of key site-level barriers to patient and family engagement; development of site-level engagement model <i>Example: co-developed site engagement model</i>
Creation and engagement of eight-member patient partner panel	Consultation	Reviewed and commented on patient-facing documents; provided input to manual of procedures; provided feedback to refine site engagement materials <i>Examples: identified psychological resilience as a core construct to assess amongst enrolled patients; prioritised cognitive endpoints (delirium and long-term cognitive impairment) for inclusion</i>	Centrally facilitated, site-based engagement events targeted at local communities	Input	Modified/improved site recruitment and enrolment experiences; dissemination of early trial experiences to local communities <i>Example: input led to introduction of prospective outreach to family members by site staff as a component of study enrolment procedures</i>
Focus groups and individual outreach involving 42 older adults and caregivers in Greater Philadelphia area	Input	Selected and validated key outcome measures; specified additional data elements to be collected; informed planning for recruitment processes <i>Example: validated selection of recovery of ambulation as primary study outcome</i>			

organisational structure of REGAIN through activities targeted both at informing the overall design and governance of the study and at guiding operations at the level of the individual recruiting site. The patient engagement strategy for REGAIN was developed collaboratively by the principal investigator (MDN) and staff at the Center for Advocacy for the Rights and Interests of the Elderly (CARIE; Philadelphia, PA, USA), a locally based and nationally active elder advocacy and service organisation that serves as the lead patient partner organisation for REGAIN. This collaboration built on long-standing interactions between the lead investigator (MDN) and CARIE leadership (DM), first initiated in 2008 through a community-based participatory research curriculum organised through the Robert Wood Johnson Foundation Clinical Scholars programme.^{19,20}

Engaging patients at the level of overall study design and governance

Efforts to engage patients and stakeholders at the level of central study leadership included outreach at the proposal development stage to 42 older adults and caregivers in the greater Philadelphia area via two focus groups and additional one-on-one telephone and in-person interviews conducted by the principal investigator and CARIE staff (DM). Participants were identified via an established CARIE volunteer network and through advertisements at local community centres hosting engagement events. We additionally included the Executive Director (DM) of CARIE as a co-investigator for the project and established an eight-member lay patient partner panel, identified via CARIE networks and personal and professional connections of the principal investigator. This panel met one to two times annually to provide ongoing input to trial planning, conduct, and design. Funds were included in the study budget for professional effort of CARIE staff to organise engagement work and for hourly reimbursement of patient partner panel members for work on the project. The rate of reimbursement to panel members was agreed upon before proposal submission and stated explicitly in letters of support received from each of the initial panel members. The members were reimbursed at a rate of \$100 h⁻¹, which approximated the maximum hourly rate permitted under the PCORI salary cap for investigator professional effort assuming a 40 h work week.

Patient partners meaningfully impacted the overall design and oversight of REGAIN via input, consultation, and collaboration. Participants in focus groups and patient interviews provided input on the selection of a measure of functional recovery (inability to walk 10 ft or death at 60 days) as the primary study outcome. Patient partner panel members provided consultative input that led to multiple changes to project design. For example, the initial proposal submitted to the eventual study funder did not specify delirium or cognitive impairment as study outcome; based in part on the input of the patient partner panel, validated measures capturing these endpoints were included in the final funded proposal.^{21,22} During development of the study protocol document, the patient partner panel members reviewed and commented on the draft document; panel input led to addition of a measure of psychological resilience²³ as a data item to be collected before randomisation for all patients. During development of the study manual of procedures, the patient partner panel members decided on aspects of data collection procedures in determining the order of priority for selected outcomes to be assessed at post-discharge follow-up.

Two CARIE staff members (DM and JH) additionally contributed to the project via consultative and collaborative activities. In collaboration with the principal investigator, the CARIE staff participated in co-investigator meetings to develop the study protocol and manual of procedures, provided training for site team members and CCC staff on communicating effectively with older adults and family members during recruitment and data collection, determined expectations for site participation in patient engagement activities in accordance with terms outlined in the site sub-award document, and designed and led site-level patient engagement efforts (detailed as follows). The lead patient co-investigator (DM) served on the REGAIN Publications and Ancillary Studies Committee through which she participated in the review, selection, and approval of proposed analytical plans and draft manuscripts for study publications. Finally, the CARIE staff led and contributed to development of required reports to funders, conference abstract submissions, and manuscripts describing patient engagement efforts in REGAIN.

Engaging patients at the level of the individual recruiting site

Additional efforts involved development of strategies to support engagement at the level of recruiting sites. Leading up to and immediately after the overall study launch in February 2016, the CARIE and CCC staff held meetings with site investigators in person and via teleconference to discuss planning for site-level engagement in REGAIN. Across these meetings, site investigators indicated a willingness to participate in and potentially organise patient engagement activities, but also identified multiple barriers to carrying out engagement efforts at the level of the individual site. These barriers included limitations in site lead investigators' own expertise in patient engagement practices; issues with access to relevant networks and resources; competing clinical demands for site investigators; and competing research-related obligations, including functions essential for successful study start-up and patient recruitment (Table 3).

We next convened a site engagement working group that included selected site investigators, the principal investigator, and the CCC and CARIE staff members. This group designed a strategy for site-level engagement that involved a high degree of central facilitation as a means of accommodating or addressing identified barriers. For example, as we identified competing demands for site investigator and staff time as a key barrier to site-initiated engagement events, we made the CCC and CARIE staff available to individual sites to remotely plan and coordinate patient engagement events in their surrounding communities. To address challenges in identifying appropriate patients and stakeholders to participate in local events, the CARIE staff worked with site personnel to identify and select suitable local partner organisations and coordinate outreach to potential participants.

As site staff varied in their familiarity and comfort with patient engagement activities, we designed a standard meeting format that could be adapted and used across multiple sites. This format involved a half-day session, including live and videotaped presentations on the overall study goals from the perspective of the principal investigator and a member of the patient partner panel. The CARIE, CCC, and site team staff facilitated breakout sessions with participants using a structured discussion guide (see Supplementary content)

Table 3 Identified barriers to carrying out site-level patient engagement activities in the Regional Versus General Anesthesia for Promoting Independence After Hip Fracture trial.

Challenges in identifying appropriate patients and stakeholders for engagement activities
Effort required to identify and arrange local venues to host engagement activities
Managing meeting logistics (event scheduling and transportation)
Securing funding to reimburse local patients and stakeholders for participation in engagement activities
Availability of staff at local site to coordinate and organise engagement activities
Competing clinical demands for site lead investigators
Competing demands on site research staff to carry out other essential study functions
Lack of familiarity of local study teams with principles of patient engagement in research
Lack of familiarity of local patients with principles of patient engagement in research

intended to elicit patient input regarding equipoise and the acceptability of randomisation in studies of established treatments, and strategies to manage challenges in the informed consent process commonly encountered by REGAIN sites. To permit co-learning during sessions, we budgeted time for additional educational programming to be provided by the host site. Where possible, we held engagement sessions in locations within driving distance of multiple REGAIN sites to permit participation by a maximum number of study personnel. Meals and participant honoraria were paid for via contract funds designated for patient engagement activities in the main study award.

We piloted this site-level engagement model via three local patient engagement events held in community locations or hospital-owned conference facilities in Philadelphia, PA, USA; Falls Church, VA, USA; and Winston-Salem, NC, USA, between January 2017 and June 2019. Each meeting convened between 19 and 34 lay community members, with a total of 72 participants across all three events. Sessions were targeted at individuals aged 65 yr and older with personal experiences with orthopaedic surgery or who had served as a caregiver for a patient recovering from an orthopaedic procedure. The median age of participants was 73 (inter-quartile range: 65–79) yr, and 79% of participants were females. Participating REGAIN team members included CCC and DCC staff; CARIE staff; and clinical team members, research staff, and other co-investigators from nine REGAIN sites and academic partner organisations. The PCORI staff attended two of three events. The principal investigator (MDN) and one CARIE staff member (JH) facilitated all sessions; each session included standardised components as described previously, and educational sessions conducted by local site staff focusing on bone health and fall prevention.

We assessed the acceptability of these events to participants via a brief six-item questionnaire (see Supplementary content). Patient and caregiver participant evaluations of session content indicated a high degree of acceptability of the outreach model to local patients and caregivers (Table 4). More than 90% of participants indicated that they ‘agreed somewhat’ or ‘strongly agreed’ that they had learned something new about research from the session, that they would attend a similar session in the future, that researchers should be encouraged to organise similar meetings, and that such meetings could help to build trust between researchers and their communities. In addition, 79.3% agreed with the statement that ‘today’s session gave me an opportunity to contribute to a study based on my own experiences’, with approximately half of the participants (49.3%) indicating strong agreement. All participants were invited to provide written feedback on ways the session could be improved;

responses were obtained from 13 of 72 participants. Identified opportunities for improvement included: ensuring audibility of sessions to participants (five participants), allowing more time or adhering to a more structured agenda (two participants), provision of additional information on the scope of the study or research in general (two participants), and improving communication to participants of the purpose of the meeting (one participant). Subsequent informal debriefing with site staff confirmed that input obtained at engagement sessions impacted local study operations; for example, based on feedback from patient participants, staff at one site implemented a change in recruitment processes to incorporate routine outreach to prospective participants’ family members to

Table 4 Participant survey results from site-based engagement events ($n=72$). Item denominators vary because of missing responses on selected items.

Item	Number indicating ‘agree somewhat’ (%)	Number indicating ‘strongly agree’ (%)
I learned something new about research from today’s session.	18/72 (25)	47/72 (65.3)
The session today gave me an opportunity to contribute to a study based on my own experiences.	20/69 (29.0)	34/69 (49.3)
I would attend a session, such as this one, again if my schedule allowed.	13/71 (18.3)	55/71 (77.5)
Researchers should be encouraged to organise more meetings, such as the session today.	12/71 (16.9)	57/71 (80.3)
Meetings, such as the session today, can help to build trust between researchers and their communities.	8/71 (11.3)	62/71 (87.3)
Item	Number indicating ‘moderately satisfied’ (%)	Number indicating ‘very satisfied’ (%)
Please indicate your overall level of satisfaction with the session today.	12/70 (17.1)	56/70 (80.0)

provide information on the study and answer questions before randomisation.

Discussion

Our experience in developing and implementing a multifaceted patient engagement strategy for the REGAIN randomised trial illustrates the feasibility of meaningfully incorporating the perspectives of patients, family members, and organisations that advocate on their behalf into research on perioperative anaesthesia care. Through an approach that was co-developed by academic researchers and a lead patient partner organisation, we were able to engage patients across a continuum of approaches. These ranged from input-gathering activities by which patients provided information that guided specific decisions about study design and implementation, to collaborative approaches by which patient partners actively participated in decisions that impacted aspects of how REGAIN was organised and conducted. Following guidance that effective patient engagement can take place at multiple organisational levels,¹⁸ our engagement strategy mirrored the overall organisational structure of REGAIN by creating opportunities for patient voices to inform and, at times, guide decision-making at both the level of overall study design and management and at the front line of study work at individual participating study sites. Looking ahead to the eventual dissemination of the study results, we plan for the CARIE staff, members of the patient partner panel, and the lead national stakeholder partner of REGAIN (Gerontological Society of America, Washington, DC, USA) to aid in dissemination and communication of results to patients, families, and stakeholders via plain-language summaries of findings and live or online programming.

Whilst the value of soliciting patient and stakeholder input for agenda setting in perioperative research has been previously explored,^{11,12} few examples currently exist of successful efforts to engaging patients as partners in actual studies of anaesthesia care.^{8,9} In this context, our experience provides a model for how principles of patient engagement can be incorporated into anaesthesia research, and highlights opportunities to increase the patient centredness and potential value of such research through patient engagement. In the context of multicentre clinical studies more generally, multiple examples exist by which patients have been engaged as partners to give input or participate in decision-making at the level of overall study design.^{24–27} However, few examples exist of successful efforts to engage patients at the local site level in multicentre studies outside of research networks focusing on community-based primary care interventions.²⁸ As such, our multilevel approach to engagement, which functioned both at the level of central study design and oversight and at the level of individual recruiting sites, may inform planning of engagement efforts for other prospective multicentre studies within and beyond the context of perioperative anaesthesia care.

Challenges we encountered in developing aspects of the REGAIN patient engagement strategy offer additional insights for efforts to increase the patient centredness of research within and outside of anaesthesia. Most notably, our efforts at fostering patient engagement at the level of the individual recruiting site primarily involved one-time input-seeking activities by which patient partners were invited to provide information that site teams could use to refine and improve local processes. These activities were designed to address

numerous practical and logistical barriers to conducting local engagement efforts identified by site investigators. Moreover, feedback from patient participants in local engagement events indicates that participants overwhelmingly viewed these events as valuable opportunities to contribute to the research process and build trust between researchers and their communities. Nonetheless, it is possible that additional efforts to support longitudinal and sustained partnerships between patients and recruiting site teams may have further enhanced the patient centredness of REGAIN. Such efforts may potentially have included provision of supplemental funding to sites to support engagement activities, additional training of site staff in patient engagement principles, and consideration of site-level capacity to carry out patient engagement in initial site selection processes.

Additional unrealised opportunities may have also existed to enhance the patient centredness of the overall design and oversight of REGAIN by enabling greater degrees of shared leadership between patients and researchers. Notably, understanding how and when to effectively involve patients as research collaborators or co-leaders of research remains an important area for development in patient-centred outcomes research overall. Out of 126 PCORI-funded projects that each involved some degree of patient engagement, the most frequent role of patient partners was in a consultative capacity, with only 37% of studies involving patients as collaborators or co-leaders. Within the context of anaesthesia research, further work to explore the factors that support or complicate the achievement of these deeper levels of patient engagement may aid the design and conduct of future studies, and identify opportunities to increase patient centredness in anaesthesia research more generally.

It is important to acknowledge the specific contextual factors that enabled the development and implementation of a multifaceted engagement strategy for this study. Ensuring patient engagement in research is a fundamental component of the mission of PCORI, the principal funder of REGAIN,^{1,2} and funds were provided in the REGAIN study contract to support engagement activities. Notably, patient engagement activities may be cost-saving for research studies if they improve recruitment rates or allow investigators to avoid protocol modifications.^{16,29} At the same time, directly funding costs related to patient engagement, including provision of support for project staff and reimbursement to patient partners themselves, is vital for ensuring that such work can be carried out in a sustainable fashion and in a manner that appropriately values patients' contributions to the research process. The engagement strategy for REGAIN also grew out of a long-standing collaboration between study investigators and the lead patient partner organisation that relied on a high degree of trust, mutual respect, and commitment to co-learning. These experiences highlight the importance of efforts to facilitate dialogue and longitudinal collaborations between researchers and patient partners, and the potential value of training investigators in anaesthesia in principles of patient engagement and community-based research.²⁰

In summary, the development and implementation of a multifaceted patient engagement strategy in the REGAIN randomised trial demonstrate the feasibility and potential impact of efforts to engage patients as partners in clinical anaesthesia studies across multiple stages and levels of the research process. Moreover, we highlight the potential value for anaesthesia research of models that go beyond patient input alone to incorporate consultative and collaborative roles

for patients that enable ongoing dialogue between researchers and patients, and allow patients to participate in consequential decisions related to study design, conduct, and reporting. Ensuring that the results of clinical research speak directly and meaningfully to the priorities of individuals and communities represents a priority for policymakers, health systems, and the public.^{4,6,7,18} As a result, increasing the available knowledge and resources to conduct meaningful patient engagement represents an important consideration to ensure the successful growth and progression of research in anaesthesia and perioperative care over time. In this context, the REGAIN engagement approach offers both a model for involving patients as partners in multicentre anaesthesia research and a starting point for efforts to identify new strategies to increase the impact and relevance to patients of such work moving forward.

Authors' contributions

Project conception/design: JH, DAM, LJG, MDN

Data acquisition/analysis/interpretation: all authors

Writing of first draft of the article: JH, MDN

Revising of article critically for important intellectual content: DAM, LJG, RAH, LR, CL, JDJ, MDN

All authors gave approval to the final version of the article, and agree to be accountable for all aspects of the work.

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Appendix A. Supplementary data

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