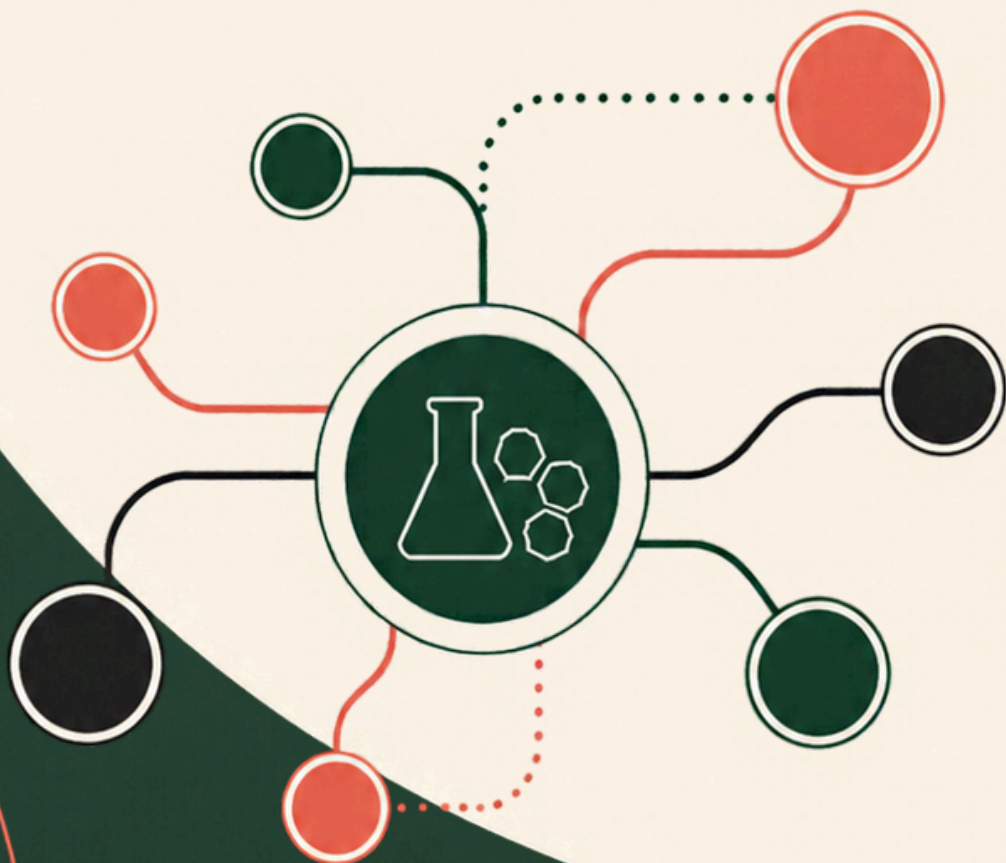


Patient and patient organisation involvement in clinical trials



Engagement in research and clinical trials: What is happening and what people want to happen

Background

The Centre for Community-Driven Response (CCDR) is a non-profit organisation bringing much needed change to the way we think about community engagement in health and research. Our vision is to facilitate meaningful connection between service providers, research organisations, the non-profit sector, practitioners, industry, government, and the communities for which they provide a service or aim to benefit. CCDR listens to the issues that people (patients), researchers, and healthcare and industry partners face and develop solutions - through community engagement - to solve those issues. We do this so that research, healthcare programs, policies and products being developed can reach the patients at the bedside sooner, and better address the needs patients and their families.

Patient organisations are the heart and soul of the health system. They provide linkage between the patients and families that they support, and government, researchers, clinicians, service providers, policy-makers and industry. CCDR provides a space for patient organisations that work at the grass-roots level, to come together – free from distraction – to develop solutions that work best for their patient populations. The program is about developing practical solutions to health system challenges and actively designing systems and policies that work better for patients and their families.

To really move forward and accept patient organisations as part of the health system and their important role informing decision about health, we have to consider the infrastructure needed to support sustainability and independence in community engagement. When we talk about infrastructure we often think of the physical structures and systems needed to deliver health services, basic research, clinical trials and so on. What we do not often talk about is the infrastructure needed to create an environment that supports systematic and independent community engagement. It is this kind of infrastructure that the CCDR helps to achieve.

Section 1: The role of patients and patient organisations in research and clinical trials

The role of patients and patient organisations in research and clinical trials

Patient-centred medicine involves individuals participating in their own healthcare decisions, enabling patients to participate in the research that informs treatments best meets their needs. Engaging patients in research development recognises that the patient perspective is pivotal, that early involvement is best, and that engaging patients at all stages is necessary [1].

In a literature review of patient and patient organisation participation in medicine research and development, Vat et al (2020) [2] identified some of the benefits of patient engagement, including improving relevancy to patients, improving costs to society by appropriate resource allocation based on the needs of the patient, and improving the outcomes of regulatory and health technology by demonstrating the needs and preferences of patients [2]. For research participants, improvements have been demonstrated in the timing of interventions and follow up, patient friendly documentation, and relevant endpoints. In addition, researchers have benefited by improvements in gaining funding by increasing credibility of the research, faster recruitment, improved participant retention, improved protocol adherence, and greater participant diversity [2].

The WHO-ESCEO Working Group published practical guidance for patient engagement in 2019 [1]. The nine best practice principles for engaging patients in health research, treatment guidelines, and regulatory processes, are displayed in the box below [1].

Best practice principles for engaging patients in health research, treatment guidelines, and regulatory processes

- The perspective of patients is pivotal in health research, treatment guidelines, and the authorisation of medicines
- Capturing patient perspectives requires multiple forms of engagement that are complementary; the strategy should be tailored to suit different chronic diseases and contexts
- Transparency for all stakeholders about the role of patients in the process facilitates participation and manages expectations from all perspectives
- Broad representativeness of patient perspectives in terms of demography, geography, disease severity, and sample size must be ensured
- Involvement of at least two patient experts throughout the research, assessment, and deliberation processes ensures that the patient perspective is preserved and increases the validity of the outcomes
- Providing adequate information, support, and feedback to patient representatives is key to effective engagement
- Teaching researchers the knowledge and skills required to support public engagement should always be considered
- Productive participation always requires resources to be allocated to the process, with extra effort in terms of time, money, and energy
- Continuous monitoring and measuring of interactions will be vital for refining procedures according to feedback.

Note. Adapted from de Wit M, Cooper C, Reginster JY; WHO-ESCEO Working Group. Practical guidance for patient-centred health research. Lancet. 2019 Mar 16;393(10176):1095-1096. © 2019 Elsevier Ltd.

Here we present three case studies of patient engagement, one that is community-led, one in a cooperative clinical trials group, and one industry clinical trial.

Case study 1: Community-led Research

Research question development

The UK Polycystic Kidney Disease charity wanted to assess high water intake as a means to slow polycystic kidney disease progression. Despite the importance of this question to people with polycystic kidney disease, the charity was unable to collaborate with an academic partner to conduct a study [3].

Collaborations

The UK Polycystic Kidney Disease charity approached a clinical trials unit in Cambridge UK, which led to the establishment of the Patient Led Research Hub [3].

The Patient Led Research Hub supports patient led research programs, patient organisations and charities can submit research ideas, however, patients and carers can only submit ideas with the support of a patient organisation or charity(<https://plrh.org/>)

Research and results

An online survey was conducted in collaboration with the trials unit and the patient organisation, it reported on current water intake, willingness to take part in clinical research, willingness to change water intake habits, and willingness to self-monitor urine as part of the clinical research [4].

Following this, a pilot study was developed to determine feasibility of a full scale clinical trial, and has since been completed [5]. **Results on the PLRH website report that the study was feasible (<https://plrh.org/completed-research/>).**

A second study was submitted to the Patient Led Research Hub, that was focused on chronic pain interventions. A workshop with the Patient Led Research Hub, the UK Polycystic Kidney Disease charity, patients and nephrologists was conducted to consider feasible trial designs [3]. Since then, funding has been awarded for an observational study and to develop a pain assessment tool. (<https://plrh.org/active-research/>)

Case study 2: Cooperative clinical trials groups

Development of patient involvement in clinical trial design and implementation

Patient involvement in clinical research have improved the patient focus of many cancer research studies, and is encouraged by the National Cancer Institute, a major funding of cancer research in America. The SWOG Cancer Research Network designed a framework for patient engagement in clinical trials, which was tested in four research committees [6].

The role of the patient advocate in the cooperative clinical trial group

The primary role of the patient advocate is to bring perspectives of those affected by cancer to the clinical trial group. Patient advocates must have leadership experience in a lay cancer or survivors organisation, and have had personal experience of cancer as a survivor or primary caregiver to a family member or friend with cancer, or extensive experience as a cancer patient advocate [7].

Input from the patient advocate is across all stages of clinical trial from definition, review, design to implementation of trial to dissemination of results. Advocates work with SWOG public relations manager to share clinical trial information to regional and local advocacy groups. Advocates help the clinical trials group work with the advocacy community, and provide feedback from national, local and regional advocacy community [7].

The framework for patient engagement

The patient advocate collaborates with investigators, research committees, and SWOG leadership from when the trial concept is submitted through to the approval process [6]. At certain points during the process, the patient advocate completes a standard patient advocate executive form that includes concerns, impact of endpoints and patient reported outcomes, and the burden of taking part in the trial [6].

To facilitate the framework, SWOG has developed a training program for both patient advocates and researchers. As of mid-2017, 19 patient advocates participate in SWOG committees [6].

Case study 3: Industry

Background and clinical trial information

Scleroderma is a rare autoimmune disease, that affects more women than men, and usually occurs between the age of 30 and 50. It causes thickening and scarring of the skin and connective tissue of multiple organs in the body.

The SENCIS clinical trial ([NCT02597933](#)), was a randomised clinical trial that investigated the efficacy and safety of nintedanib in patients with lung involvement. It included 580 participants from 195 sites worldwide [8].

Development of a community advisory board.

A community advisory board was set up, initially consisting of 10 members, and rising to 15 over the course of the trial. The community advisory board members represented patient organisations from 10 countries, their role was to collaborate with the clinical research sponsor and the scleroderma patient community [8].

A memorandum of understanding was developed by the community advisory board and the sponsor of the study. It set out the scope and terms of the collaboration [8].

Community advisory board input into the clinical trial.

The community advisory board first met after the finalisation of the clinical trial protocol and before investigator training and before any patients were recruited into the study [8].

The scleroderma community advisory board reviewed and provided advice on trial conduct and reporting to improve participant experience and trial retention. The input of the community advisory board led to improvements in patient safety, patient comfort, and accuracy of trial data. For example, a revision to exclusion criteria to improve participant safety, changes to spirometry equipment for improved data accuracy and patient comfort, changes to needles for blood draw to improve patient comfort, and improvements to investigator training to improve data accuracy and patient comfort [8].

Clinical trial participant engagement

The members of the community advisory board co-developed patient newsletters, thank you letters, and birthday cards that were provided to trial participants via trial sites. The patient newsletters included information about the trial status, managing side effects of treatments and symptoms of Scleroderma [8].

Clinical trial reporting and regulatory submission

The community advisory board gave advice on the benefit and risk after the results of the clinical trial became available, this was included in the regulatory submission dossier of the trial sponsor [8].

The community advisory board gave input into the lay summaries developed by the sponsor, in particular, to ensure that language and figures were understandable. In addition, following advice from the community advisory board, a video format of the lay summary was developed [8].

Non-trial related activities

The community advisory board and the trial sponsor collaborated to develop tools to help open medication blister packs and bottles, as scleroderma affects patients' hands. Additional educational materials were created to raise disease awareness among doctors, patients and caregivers [8].

Section 2: Overview of patient representation in clinical trial cooperative groups

Overview of patient representation in clinical trial cooperative groups in Australia

Purpose

The purpose of this report is to provide insights about what a patient looking to find opportunities to engage in research or clinical trials may experience. To do this, we reviewed the websites of clinical trial cooperative groups.

Methods

A search of the members of the members of the Clinical Trial Alliance (<https://clinicaltrialsalliance.org.au/about-acta/acta-members/>) and Cancer Cooperative Trials Groups of Australia (<https://patientlearning.canceraustralia.gov.au/who>) was conducted 30 September to 1 October 2021.

A search for engagement activities on the website for each of the organisation listed was conducted.

Results

Engagement opportunities

There were 51 organisations identified on the clinical trials alliance websites and the Cancer Australia websites, of these, 48 organisations had operational websites available to search for patient engagement details. Over half of the organisations had details about patient engagement on their website (n=26, 54.17%). There were 17 organisations (35.42%) with patient advisory groups, seven organisations (14.58%) that included patient representatives on their steering or executive committees, and two organisations (4.17%) that described engagement from partner organisations.

Details about how to participate in engagement was given by eight organisations (16.66%), this was either by giving only an email address to get more information (n=4, 8.33%), or a detailed form or instructions (n=4, 8.33%). Four organisations (8.33%) had details about tenure, and the same number published terms of reference on their website.

Patient engagement		N=48	%
Number with details about patient engagement		26	54.17
Type of patient engagement	Patient advisory group	17	35.42
	No patient advisory group, patient(s) on steering/executive committee	7	14.58
	No institutional representation, but partner organisations have representation	2	4.17
Details about how to participate in patient engagement	Details given/application form	4	8.33
	Email only	4	8.33
	No information	18	37.50
Tenure stated	Yes	4	8.33
Terms of reference available	yes	4	8.33

Research activities of clinical trial groups

The majority of groups listed details about clinical trials (n=39, 81.25%), and a third listed details about disease registries (n=16, 33.33%).

Research activities	N=48	%
Clinical trials	39	81.25
Registries	16	33.33
Translational	6	12.50
Population	5	10.42
Observational	4	8.33
Biobank	4	8.33
Community programs	3	6.25
Audit	2	4.17
Basic science	2	4.17
Health economics	1	2.08

Activities of engagement

The most common activities described for patient engagement were raising awareness and advocating about clinical trials to the community (n=11, 22.92%), and reviewing research concepts and strategic planning (n=11, 22.92%). Other activities were facilitating links with members of the community and community groups (n=9, 18.75%), reviewing information sheets, consent forms and other patient/participant focused documentation (n=8, 16.67%), dissemination of clinical trial results (n=4, 8.33%), and fundraising activities, including grant applications (n=4, 8.33%).

Activities of patient engagement	N=48	%
Community projects	3	6.25
Facilitating links with members of the community and community groups	9	18.75
Raising awareness and advocating about community priorities	3	6.25
Advocate for clinical trial participants	1	2.08
Raising awareness and advocating about clinical trials and clinical research to the community	11	22.92
Dissemination of clinical trial results	4	8.33
Training and education to healthcare professionals	1	2.08
Fundraising activities, including grant applications	4	8.33
Strategic planning: identify priorities and gaps	3	6.25
Participation in Scientific working groups	3	6.25
Reviewing research concepts /strategic planning	11	22.92
Study design input including: quality of life, symptoms and treatments important to community,	1	2.08
Reviewing information sheets, consent forms and other patient/participant focused documentation	8	16.67
Participate in clinical trial oversight and management	1	2.08

Qualification for participation in patient engagement

There were six organisations that posted details about qualifications needed to take part in patient engagement. There were five organisations (10.42%) that required patients to be a patient or carer, one organisation required experience in advocacy, and two organisations would consider any interested person (n=2, 4.17%). It is important to

note that in the view of CCDR, the only qualifications that are relevant are having lived experience with the relevant condition. Those conducting the engagement activities should then adapt their approaches to accommodate a demographically balanced range of people.

Qualification for participation in patient engagement	N=48	%
Patient or carer	5	10.42
Experience in advocacy	1	2.08
Any interested person	2	4.17

Section 3: How patients and citizens would like to engage in clinical trials and research

Demographics

Age

Participants were aged over 18, most commonly between 18 and 54 (n=89, 83.18%)

Gender

There were 52 male participants (48.60%), 53 females (49.53%), and two other genders (1.87%) that completed the questionnaire.

Ethnicity

Over 75% of the participants were Caucasian/white (n=81, 75.70%), the next most common ethnicity was Asian (n=10, 9.35%).

Education

There 49 participants that completed some university (45.79%), 11 participants (10.28%) that had a trade, 36 participants (32.71%) had high school qualifications or had some college but no degree, and 12 participants (11.21%) had less than a high school qualification.

Socioeconomic status

The socioeconomic status was determined from postcodes using the Socio-economic Indexes for Areas (SEIFA) (www.abs.gov.au), SEIFA scores range from 1 to 10, a higher score denotes a higher level of advantage. There were 49 participants (45.79%) with a mid to low SEIFA score of 1-6, and there were 56 participants (52.34%) higher SEIFA score of 7-10.

Location

The location of participants was evaluated by postcode using the Australian Statistical Geography Maps (ASGS) Remoteness areas accessed from the Australian Bureau of Statistics. There were 88 participants

(82.24%) that lived in major cities of Australia, 14 participants (13.08%) that lived in inner regional Australia, and three participants (2.80%) that lived in outer regional Australia. There were no participants from remote or very remote Australia.

State

Participants were most commonly from New South Wales (n=37, 34.58%), Victoria (n=26, 24.30%), and Queensland (n=17, 15.89%). There were 12 participants (11.21%) from South Australia, ten participants (9.35%) from Western Australia, two participants (1.87%) from Tasmania, and one participant (0.93%) from the Australian Capital Territory. There were no participants from the Northern Territory.

Employment

There were 38 participants (35.51%) that were employed full time, and 21 participants (19.63%) that were employed part time. There were 15 participants (14.02%) that were not employed and looking for work, 12 participants (11.21%) that were currently receiving Centrelink support, eight participants (7.48%) that were disabled and unable to work, and 11 participants (10.28%) that were retired. Six participants (5.61%) were in full or part time study, and there were three participants (2.80%) that were full or part time carers.

Carer status

There were 45 participants (42.06%) that were carers to spouses or family members. Participants were most commonly carers to children (n=28, 26.17%), followed by carers to spouses (n=9, 8.41%), and to parents (n=8, 7.48%).

Table 2.1: Demographics

Demographics		Number	Percent (n=107)
Age	18 – 24	20	18.69
	25 – 34	29	27.10
	35 – 44	25	23.36
	45 – 54	15	14.02
	55 – 64	7	6.54
	65 – 74	7	6.54
	75+	4	3.74
Gender	Male	52	48.60
	Female	53	49.53
	Transgender	0	0.00
	Other	2	1.87
Ethnicity	African	3	2.80
	Arab	2	1.87
	Asian	10	9.35
	Hispanic/Latino	2	1.87
	Indigenous	1	0.93
	Pacific Islander	1	0.93
	Torres Strait Islander	0	0.00
	Caucasian/White	81	75.70
	Other (Please Specify)	7	6.54
Education	Less than high school degree	12	11.21
	High school degree or equivalent	26	24.30
	Some college but no degree	9	8.41
	Trade	11	10.28
	Associate degree	4	3.74
	Bachelor degree	29	27.10
	Graduate degree	16	14.95
Socioeconomic status	Higher advantage	56	52.34
	Mid to low advantage	49	45.79
	No response	2	1.87
Location	Major Cities of Australia	88	82.24
	Inner Regional Australia	14	13.08
	Outer Regional Australia	3	2.80
	No response	2	1.87
State	ACT	1	0.93
	NSW	37	34.58
	QLD	17	15.89
	SA	12	11.21
	TAS	2	1.87
	VIC	26	24.30
	WA	10	9.35
	No response	2	1.87
Employment	Employed, working full time	38	35.51
	Employed, working part time	21	19.63
	Not employed, looking for work	15	14.02
	Currently receiving Centrelink support	12	11.21
	Disabled, not able to work	8	7.48
	Retired	11	10.28
	Full/part time study	6	5.61
	Full/part time carer	3	2.80
	Other	2	1.87
Carer status	I am not a carer	62	57.94
	Children	28	26.17
	Grandchildren	2	1.87
	Parents	8	7.48
	Grandparents	2	1.87
	Siblings	2	1.87
	Spouse	9	8.41
	Other	2	1.87

Health status and healthcare use

Health conditions

In order to get an idea of the participants' interactions or reliance on the healthcare system, a series of questions about health conditions, healthcare insurance, and use of hospital facilities were asked.

The first question was about any health conditions, there were 81 participants (75.70%) that had at least one condition, the median number of conditions was 2.00 (IQR = 3.00), and the range of other conditions was 1 to 19. The most common conditions were anxiety (n=56, 52.34%), depression (n=44, 41.12%), and sleep problems (n=42, 39.25%).

Table 2.2: Health conditions

Health conditions	n=107	Percent (n=107)
Sleep problems or insomnia	42	39.25
COPD (Chronic obstructive pulmonary disease)	10	9.35
Have you had a stroke?	7	6.60
Hypertension	13	12.26
Anxiety (self for doctor diagnosed)	56	52.34
Anxiety (that you diagnosed) yourself	42	39.62
Anxiety (that a doctor diagnosed)	40	37.74
Depression (self for doctor diagnosed)	44	41.12
Depression (that you diagnosed yourself)?	25	23.36
Depression (that a doctor diagnosed)	37	34.91
Diabetes type I	6	5.61
Diabetes type II	11	10.28
Osteoporosis	13	12.15
Kidney disease	5	4.67
Dermatological conditions	12	11.21
Atrial fibrillation or arrhythmias	8	7.48
Chronic pain	27	25.23
Chronic heart failure	6	5.61
Angina	6	5.61
High cholesterol	24	22.43
Arthritis	19	17.92
Asthma	19	17.92
Cancer	5	4.76

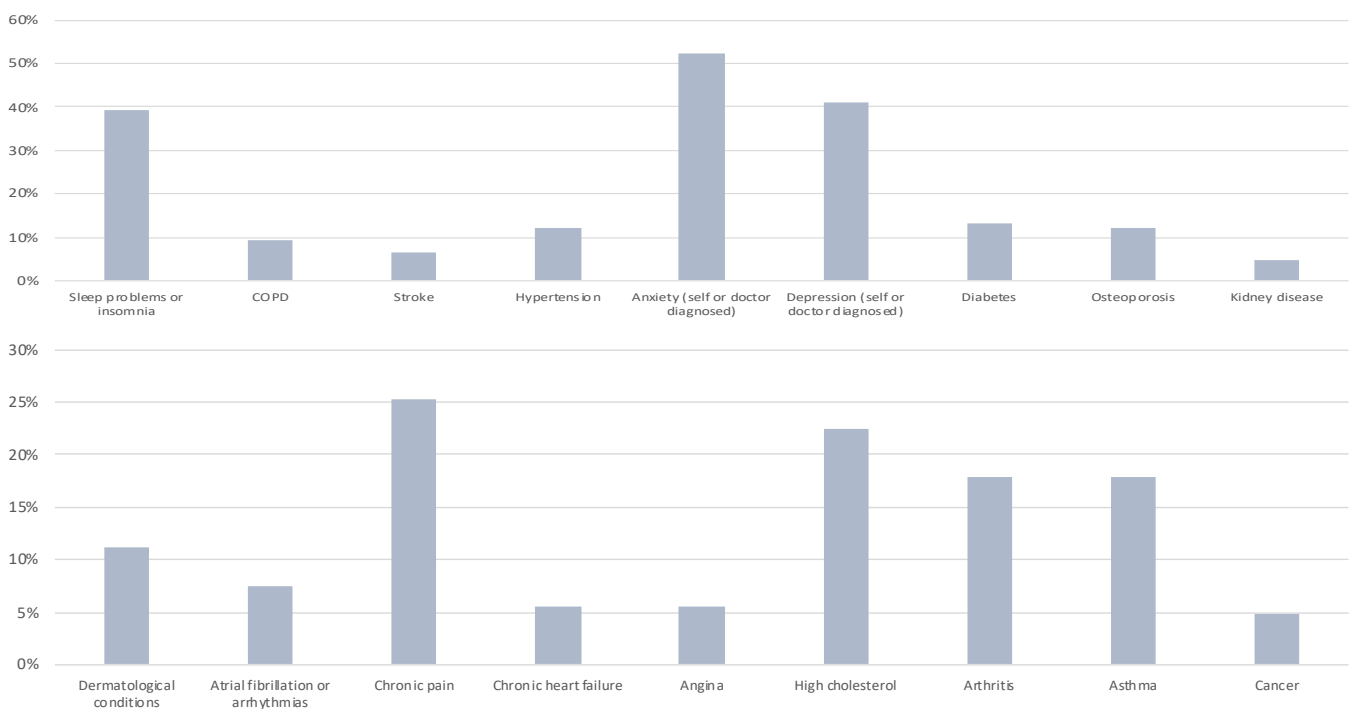


Figure 2.1: Health conditions

Health insurance and hospital use

There were 50 participants (47.17%) with private health insurance. There were 76 participants (71.03%) that had used the public or private hospital system as either an in-patient or an outpatient. There were 71 participants (66.36%) that had used the public hospital

system as either an in-patient or an outpatient, 37 participants (34.58%) that had used the private hospital system as either an in-patient or an outpatient, and 32 participants (29.91%) that had used both the public and private hospital system as either an in patient or an outpatient.

Table 2.3: Health insurance and hospital use

Health insurance and hospital use	n=107	Percent (n=107)
Do you have private health insurance	50	47.17
Have you been treated in a public hospital as an inpatient	65	60.75
Have you been treated in a public hospital as an outpatient	49	45.79
Have you been treated in a private hospital as an inpatient	33	31.13
Have you been treated in a private hospital as an outpatient	24	22.64

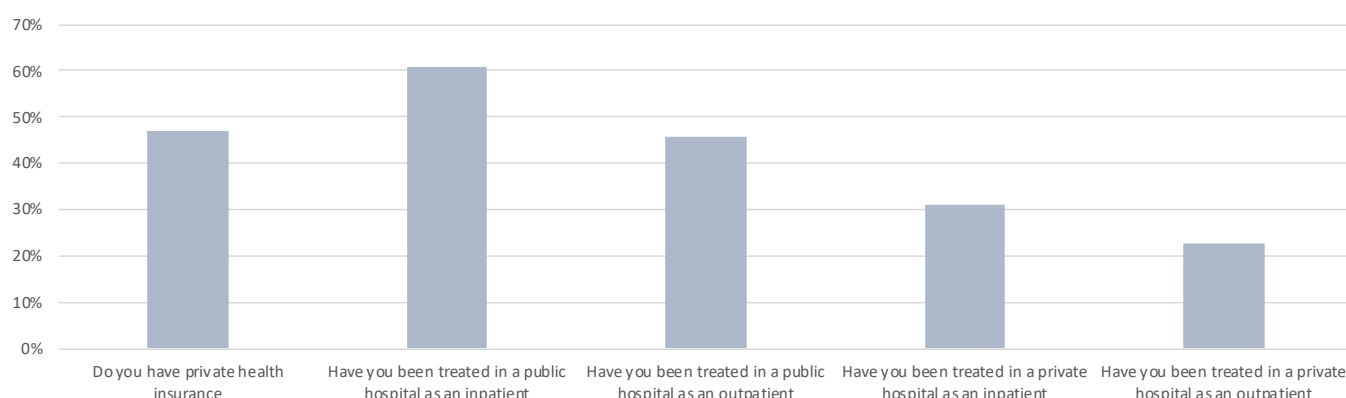


Figure 2.2: Health insurance and hospital use

Healthcare and disability services

There were 70 participants (65.42%) that had used at least one of the health or disability services listed in the table below. The most common service used was an emergency department admission (n=53, 49.53%), followed by pregnancy and childbirth (n=35, 33.02%).

There were 19 participants (17.76%) that had used rehabilitation services for injury or other medical conditions, 13 participants (12.15%) that had used fertility and IVF services, 11 participants (10.38%) that had used the National Disability Insurance Scheme (NDIS), and 10 participants (9.43%) that had used rehabilitation services for drugs and alcohol.

Table 2.4: Healthcare and disability services

Healthcare and disability services	n=107	Percent (n=107)
Pregnancy and childbirth	35	33.02
Emergency department admission	53	49.53
Fertility and IVF services	13	12.15
Rehabilitation (Drug and alcohol)	10	9.43
Rehabilitation (From injury or other medical condition)	19	17.76
NDIS	11	10.38

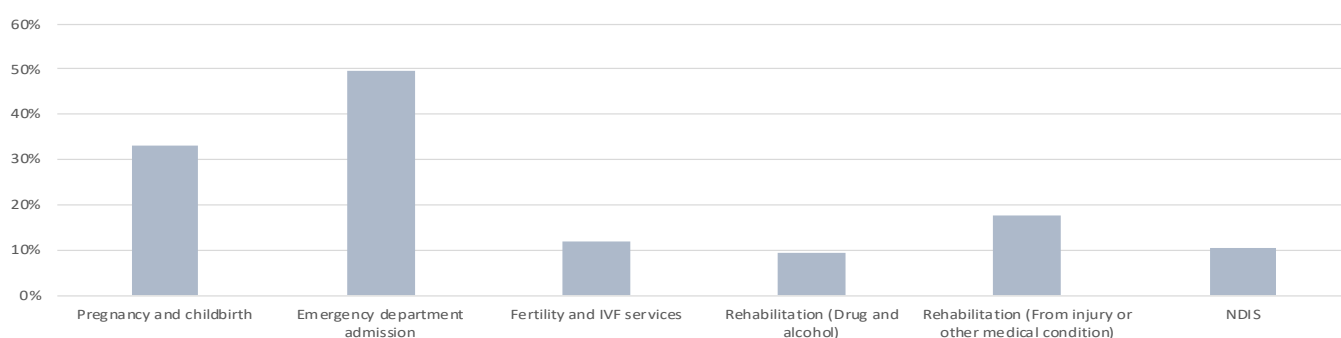


Figure 2.3: Healthcare and disability services

My Health Record

My Health Record is an online summary of key health information, an initiative of the Australian Government. There were 43 participants (40.19%) had accessed My Health Record, 43 participants (40.19%)

had not, 14 participants (13.08%) were not sure if they had accessed it, and seven participants (6.54%) did not know what it was. Of those that had accessed My Health Record, the most common responses were that participants rated its usefulness as good (n=15, 34.88%), or very good (n=18, 41.86%).

Table 2.5: My Health Record

My Health Record	n=107	Percent (n=107)
Yes	43	40.19
No	43	40.19
I am not sure	14	13.08
I don't know what 'My Health Record' is	7	6.54

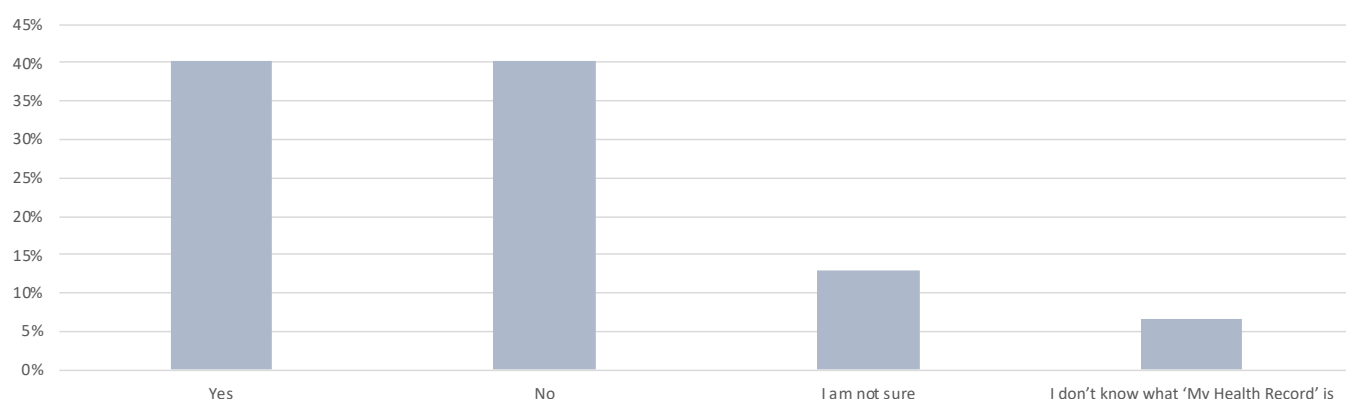


Figure 2.4: My Health Record

Table 2.6: Effectiveness of My Health Record

How useful was My Health Record	n=43	Percent (n=107)
Very good	18	41.86
Good	15	34.88
Acceptable	6	13.95
Poor	2	4.65
Very poor	2	4.65

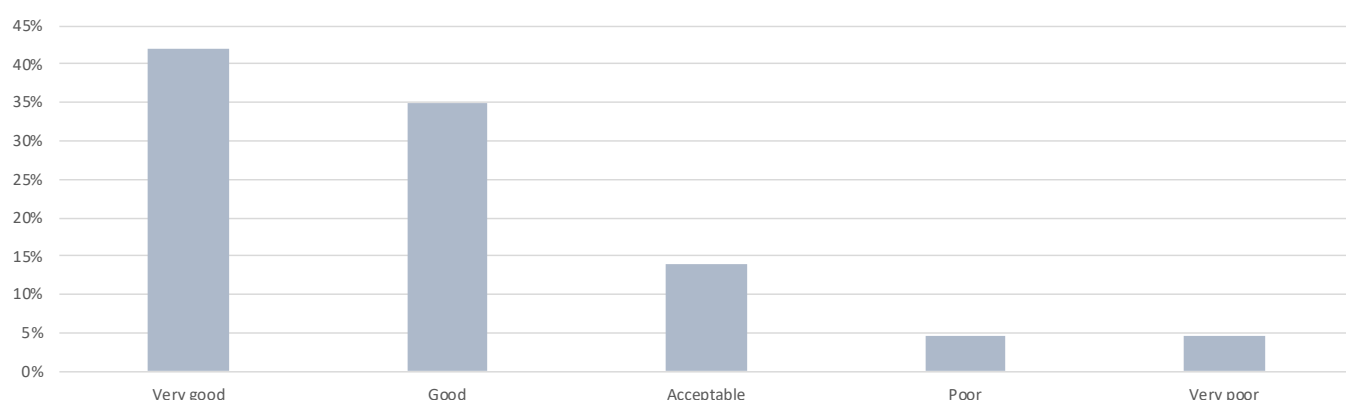


Figure 2.5: Effectiveness of My Health Record

Patient representation at different stages of research

Participants answered a series of questions about when they thought it was important to have patient representation in research. For each question, participants rated importance on a Likert scale from one to five, where one is “Not important” and five is “Very important”.

Setting research priorities

Participants were asked how important patient representation was when research priorities are set. Research priorities may include, allocation of funding, target populations, deciding which research proposals are most important to researchers and the community.

On average, participants thought that patient representation for setting research priorities was very important (median = 5.00, IQR =1.00).

Study development

Participants were asked how important patient representation was when researchers and doctors are developing a study. Study development may include planning how and where treatments are given, ethics and government approvals, producing study documents for researchers, and producing patient information and consent documents.

Patient representation for study development study was important to very important (median = 4.50, IQR = 1.00)

Study launch

Participants were asked how important patient representation was when a study is launched. Study launch involves getting ethics approvals, having paperwork in place, and educating the doctors/medical professionals about all the study procedures.

On average, patient representation at study launch, was important (median =4.00, IQR = 1.00).

While patients are taking part in the study

Participants were asked how important patient representation was when patients are being treated or are taking part in the study. When patients are being treated as part of a study, data is collected and monitored for safety (usually only seen by a safety committee), and newsletters or presentation about the study progress may be sent to all those participating.

On average, patient representation when patients are taking part in a study was important to very important (median = 4.50, IQR = 1.00).

Study finished and reported

Participants were asked how important patient representation was when the study has finished, and the results are being reported. Studies can be presented at conferences, in medical journals, reports, and results may be reported to patients that took part in the study.

On average, patient representation when the study is being reported was important (median =4.00, IQR = 1.00).

Is patient representation more important at some stages compared to others?

A Kruskal-Wallis test was used to determine if there was any significant difference the importance of patient representation at different stages of research.

No significant differences were observed in the importance of patient representation at different stages of research design, $\chi^2(4) = 0.65$, $p = 0.9570$.

Table 2.7: Patient representation at different stages of research

Patient representation at different stages of research	Median (n=104)	IQR (n=104)
Setting research priorities	5.00	1.00
Study development	4.50	1.00
Study launch	4.00	1.00
When patients are being treated or taking part in a study	4.50	1.00
Study being reported	4.00	1.00

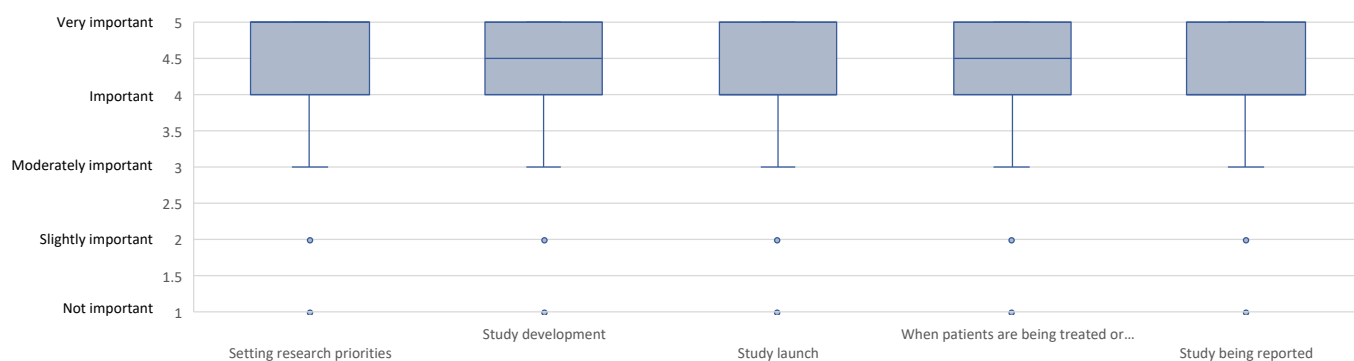


Figure 2.6: Patient representation at different stages of research

Patient representation in different types of research

Participants answered a series of questions about the type of research they thought it was important to have patient representation. For each question, participants rated importance on a Likert scale from one to five, where one is “Not important” and five is “Very important”.

Research about new treatments or new ways of using treatments

Participants were asked how important patient representation was in the research process for new treatments or new ways of using treatments. For example clinical trials, medicines, surgery, radiotherapy, and psychotherapy.

On average, participants thought that it was very important to have patient representation for research into new treatments or new ways of using treatments (median =5.00, IQR =1.00)

Research about new medical devices or new ways of using medical devices

Participants were asked how important patient representation was in the research process for new medical devices or new ways of using medical devices. Medical devices are machines, and equipment used for medical purposes. Examples include wheelchairs, CT scanners, and pace-makers.

On average, participants thought that it was very important to have patient representation for research into new medical devices or new ways of using medical devices (median =5.00, IQR =1.00).

Laboratory-based scientific investigations

Participants were asked how important patient representation was in the research process for laboratory-based scientific investigations. Scientific investigations can involve the study of animals, cells, molecules, proteins, and genes to help understand a disease.

On average, participants thought that it was very important to have patient representation for laboratory based research (median =5.00, IQR =2.00).

Patient registries

Participants were asked how important patient representation was in the research process for patient registries. Patient registries are a central database where information about treatments, side effects, symptoms, and recurrences or progression are kept.

On average, participants thought that it was important to have patient representation for patient registries (median = 4.00, IQR = 1.00).

Biobanks or tissue banks

Participants were asked how important patient representation was in the research process for biobanks or tissue banks. Biobanks or tissue banks are a collection of biological tissues (e.g. blood, tumour samples) along with medical data.

On average, participants thought that it was important to have patient representation for biobanks or tissue banks (median = 4.00, IQR = 2.00).

Diagnosing and screening conditions

Participants were asked how important patient representation was in the research process for studies about diagnosing and screening diseases or conditions. These types of studies look at better ways to diagnose an individual or detect diseases or conditions in the community.

On average, participants thought that it was important to have patient representation for diagnostic and screening studies (median = 4.00, IQR = 1.00).

Quality of life studies

Participants were asked how important patient representation was in the research process for quality of life studies. Quality of life studies are concerned with the physical, emotional, and social health of people with health conditions.

On average, participants thought that it was very important to have patient representation for Quality of life research (median = 5.00, IQR = 1.00).

Community based programs

Participants were asked how important patient representation was in the research process for community based programs. Examples of community based programs are education campaigns, social support, early childhood clinics, and needle exchange programs.

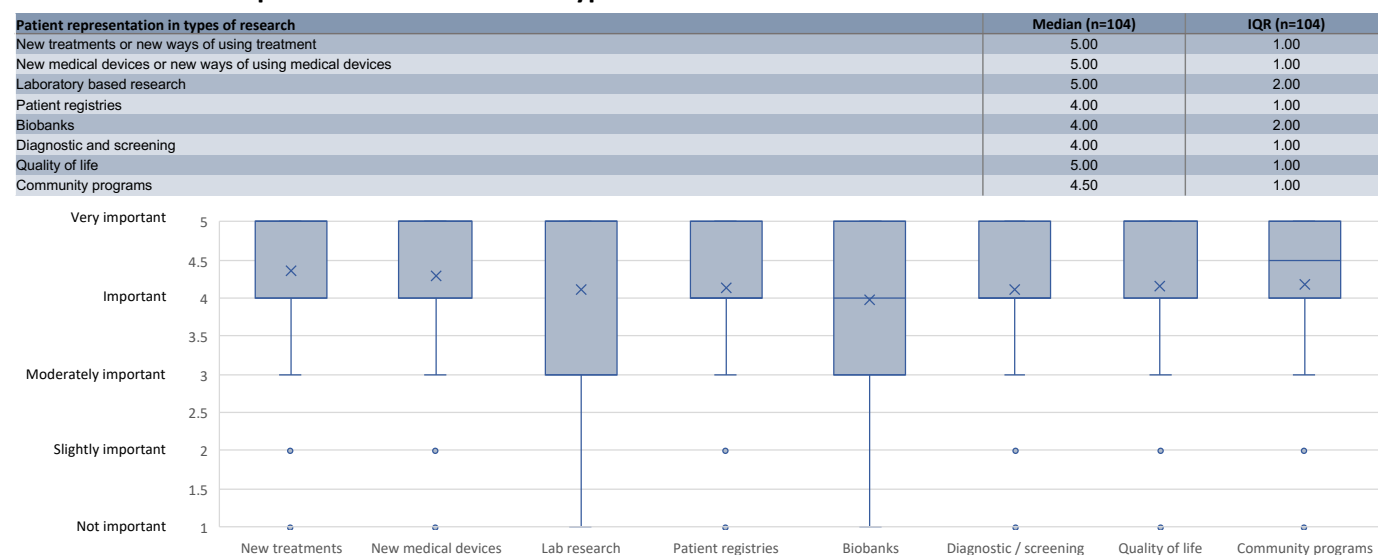
On average, participants thought that it was important to very important to have patient representation for community programs (median = 4.50, IQR = 1.00).

Is patient representation more important for some types of research compared to others?

A Kruskal-Wallis test was used to determine if there was any significant difference the importance of patient representation for different types of research.

No significant differences were observed in the the importance of patient representation for different types of research, $\chi^2(7) = 7.69$, $p = 0.3608$.

Table 2.8: Patient representation in different types of research



Effectiveness of patient engagement

Participants answered a series of questions about the how effective they thought different types of patient engagement were. For each question, participants rated effectiveness on a scale of 0 to 10, where 0 is ineffective and 10 is very effective.

On average, participants rated (from most effective to least effective) the following types of representation; a panel of equal numbers of patient representatives and doctor/researchers (median = 8.00, IQR = 3.00), a patient representative gives a report to researchers at their conference about what it is like to have condition (median = 8.00, IQR = 3.00), a group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that people with the condition have now (median = 8.00, IQR = 3.00), a panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers without administrative assistance (median = 7.00, IQR = 3.00), a panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers, with administrative assistance (median = 7.00, IQR = 3.00), a one-off focus group of patients and researchers (median = 7.00, IQR = 3.00), two patient representatives on a panel with five to ten doctors and researchers (median = 6.00, IQR = 3.00), one patient representative on a panel with five to ten doctors and researchers (median = 6.00, IQR = 4.00), and community members can just post or email in ideas or concerns– no other interactions with researchers (median = 6.00, IQR = 4.00).

A Kruskal-Wallis test was used to determine if there was any significant difference in the participant rated effectiveness of different ways that patients could be represented

A Kruskal-Wallis test indicated a statistically significant difference in the effectiveness of different ways that patients are represented, $\chi^2(8) = 40.13$, $p < 0.0001$.

Post-hoc wilcoxon rank sum tests between groups indicated that a panel of equal numbers of patient representatives and doctor/researchers (median =

8.00, IQR = 3.00), was more effective at patient representation than:

- One patient representative on a panel with five to ten doctors and researchers (median = 6.00, IQR = 4.00, $p = 0.0025$)
- Two patient representatives on a panel with five to ten doctors and researchers (median = 6.00, IQR = 3.00, $p = 0.0178$).
- A one-off focus group of patients and researchers (median = 7.00, IQR = 3.00, $p = 0.0397$).
- Community members can just post or email in ideas or concerns– no other interactions with researchers (median = 6.00, IQR = 4.00, $p = 0.012$)

Post-hoc wilcoxon rank sum tests between groups indicated that a panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers, with administrative assistance (median = 7.00, IQR = 3.00), was more effective at patient representation than:

- One patient representative on a panel with five to ten doctors and researchers (median = 6.00, IQR = 4.00, $p = 0.0397$)
- Community members can just post or email in ideas or concerns– no other interactions with researchers (median = 6.00, IQR = 4.00, $p = 0.0249$)

Post-hoc wilcoxon rank sum tests between groups indicated that a patient representative that gives a report to researchers at their conference about what it is like to have condition (median = 8.00, IQR = 3.00), was more effective at patient representation than:

- One patient representative on a panel with five to ten doctors and researchers (median = 6.00, IQR = 4.00, $p = 0.0025$)
- Two patient representatives on a panel with five to ten doctors and researchers (median = 6.00, IQR = 3.00, $p = 0.0162$)
- A one-off focus group of patients and researchers (median = 7.00, IQR = 3.00, $p = 0.0397$).
- Community members can just post or email in ideas or concerns– no other interactions with researchers (median = 6.00, IQR = 4.00, $p = 0.0012$).

Post-hoc wilcoxon rank sum tests between groups indicated that a group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that

people with the condition have now (median = 8.00, IQR = 3.00), was more effective at patient representation than:

- One patient representative on a panel with five to ten doctors and researchers (median = 6.00, IQR = 4.00, p=0.0026)
- Two patient representatives on a panel with five to ten doctors and researchers (median = 6.00, IQR = 3.00, p=0.00162)

- A one-off focus group of patients and researchers (median = 7.00, IQR = 3.00, p=0.00397).
- Community members can just post or email in ideas or concerns– no other interactions with researchers (median = 6.00, IQR = 4.00, p=0.0012).

Table 2.9: Summary- Effectiveness of patient engagement

Participants rated patient representation more effective	Participants rated patient representation less effective
<ul style="list-style-type: none"> • A panel of equal numbers of patient representatives and doctor/researchers • A patient representative gives a report to researchers at their conference about what it is like to have condition • A group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that people with the condition have now • A panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers, with administrative assistance 	<ul style="list-style-type: none"> • One patient representative on a panel with five to ten doctors and researchers • Two patient representatives on a panel with five to ten doctors and researchers • A one-off focus group of patients and researchers • Community members can just post or email in ideas or concerns– no other interactions with researchers • One patient representative on a panel with five to ten doctors and researchers • Community members can just post or email in ideas or concerns– no other interactions with researchers

Table 2.10: Effectiveness of patient engagement

Effectiveness of patient engagement	Median (n=101)	IQR (n=101)
One patient representative on a panel with five to ten doctors and researchers	6.00	4.00
Two patient representatives on a panel with five to ten doctors and researchers	6.00	3.00
A panel of equal numbers of patient representatives and doctor/researchers	8.00	3.00
A panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers without administrative assistance	7.00	3.00
A panel of five to ten patient representatives that reviews proposals and reports ideas and comments back to the doctors/researchers, with administrative assistance	7.00	3.00
A patient representative gives a report to researchers at their conference about what it is like to have condition	8.00	3.00
A group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that people with the condition have now	8.00	3.00
A one-off focus group of patients and researchers	7.00	3.00
Community members can just post or email in ideas or concerns– no other interactions with researchers	6.00	4.00

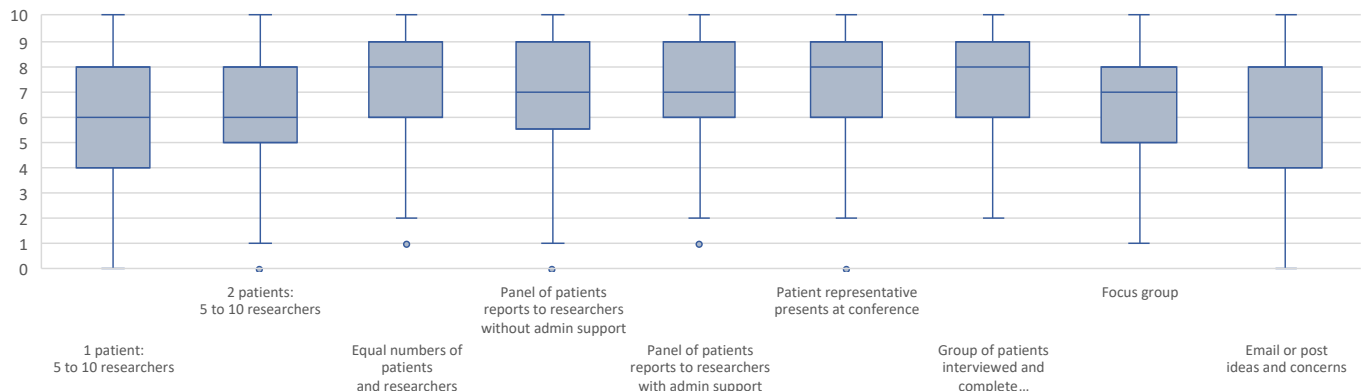


Figure 2.8: Effectiveness of patient engagement

Table 2.11: Post-hoc wilcoxon rank sum tests

Patient representation	1 patient: 5 to 10 researchers	2 patients: 5 to 10 researchers	Equal numbers of patients and researchers	Panel of patients reports to researchers without admin support	Panel of patients reports to researchers with admin support	Patient representative presents at conference	Group of patients interviewed and complete questionnaires	Focus group
2 patients: 5 to 10 researchers	0.4237	-	-	-	-	-	-	-
Equal numbers of patients and researchers	0.0025*	0.0178*	-	-	-	-	-	-
Panel of patients reports to researchers without admin support	0.1420	0.4176	0.0862	-	-	-	-	-
Panel of patients reports to researchers with admin support	0.0397*	0.1598	0.3220	0.4974	-	-	-	-
Patient representative presents at conference	0.0025*	0.0162*	0.8505	0.0693	0.2511	-	-	-
Group of patients interviewed and complete questionnaires	0.0026*	0.0162*	0.8247	0.0739	0.2511	0.9495	-	-
Focus group	0.2168	0.5998	0.0397*	0.7692	0.3220	0.0397*	0.0397*	-
Email or post ideas and concerns	0.9312	0.3338	0.0012*	0.0916	0.0249*	0.0012*	0.0012*	0.1663

Time spent on patient engagement

Time to travel for patient engagement

Participants were asked about how far they would be willing to travel to part in patient engagement. The most common response was that they would travel for up to an hour (n=43, 42.57%), this was followed by

being happy to travel anywhere with overnight stays (n=25, 24.75%), a preference for using telephone or video conference from home (n=24, 23.76%), and travelling for a couple of hours but would not like to stay overnight (n=9, 8.91%).

Table 2.12: Time to travel for patient engagement

Time to travel for patient engagement	n=107	Percent (n=107)
I prefer not to travel at all and use teleconference or video conferencing from home.	24	23.76
I would travel up to an hour	43	42.57
I would travel for a couple of hours, but would not like to stay away from home over night.	9	8.91
I am happy to travel anywhere, with overnight stays	25	24.75

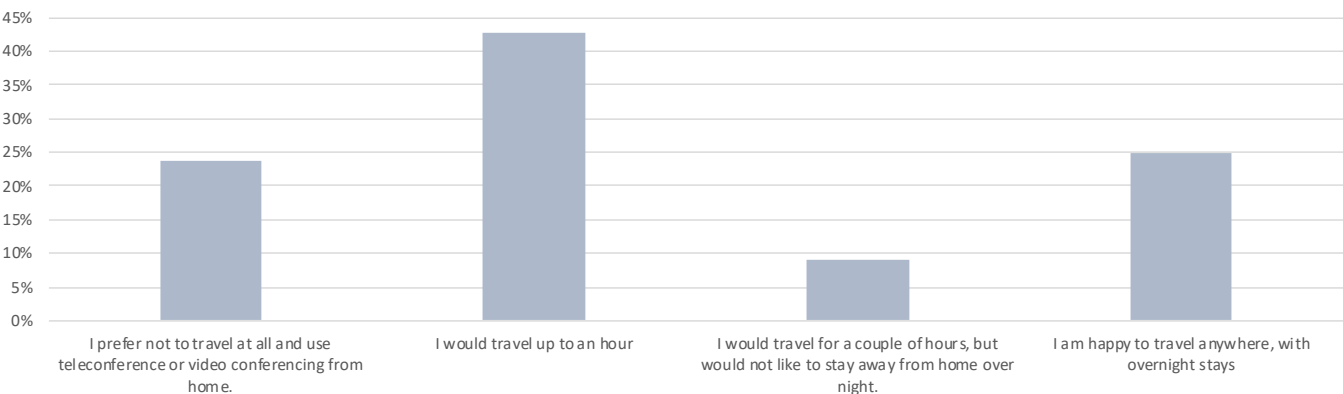


Figure 2.9: Time to travel for patient engagement

Time commitment for patient representation

The time commitment for patient representation, how much time would they be willing to commit to patient representation. Most commonly, participants would prefer an on-going commitment, with a total of 54 participants (53.47%). There were 21 participants (20.79%) that would be willing to have an ongoing commitment of a day once or twice a year, 19 participants (18.81%) that would be willing to have

a commitment of a day per week, and 14 participants (13.86%), a day a month.

A total of 47 participants (46.53%) would be willing to commit to a one-off event, there were 25 participants (24.75%) that would commit to a one-off event that lasted a day or less, and 22 participants (21.78%) would commit to a one-off event that lasted a couple of days.

Table 2.13: Time commitment for patient representation

	n=107	Percent (n=101)
A one-off event that lasted for a day or less	25	24.75
A one-off event that lasted for a couple of days	22	21.78
An ongoing commitment of a day a week	19	18.81
An ongoing commitment of a day a month	14	13.86
An ongoing commitment of a day, once or twice a year	21	20.79

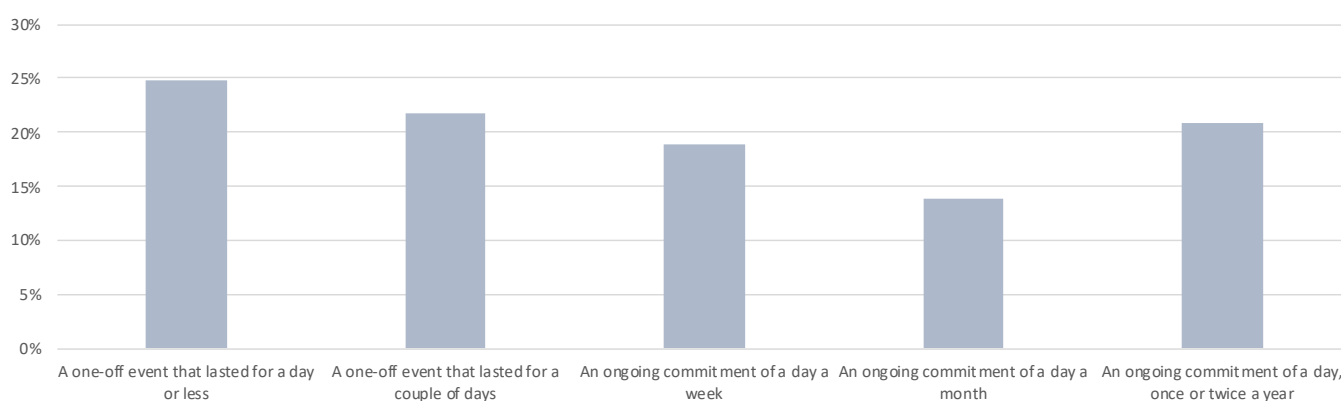


Figure 2.10: Time commitment for patient representation

Patient representative contribution to research development

Participants were asked if they were a patient representative on a research project, how could they contribute to various research development tasks.

general, most commonly participants would contribute by taking part in discussions, generating ideas, and reviewing study documentation and materials.

An overview of the ways that participants would contribute to research tasks is given in Figure 2.11. In

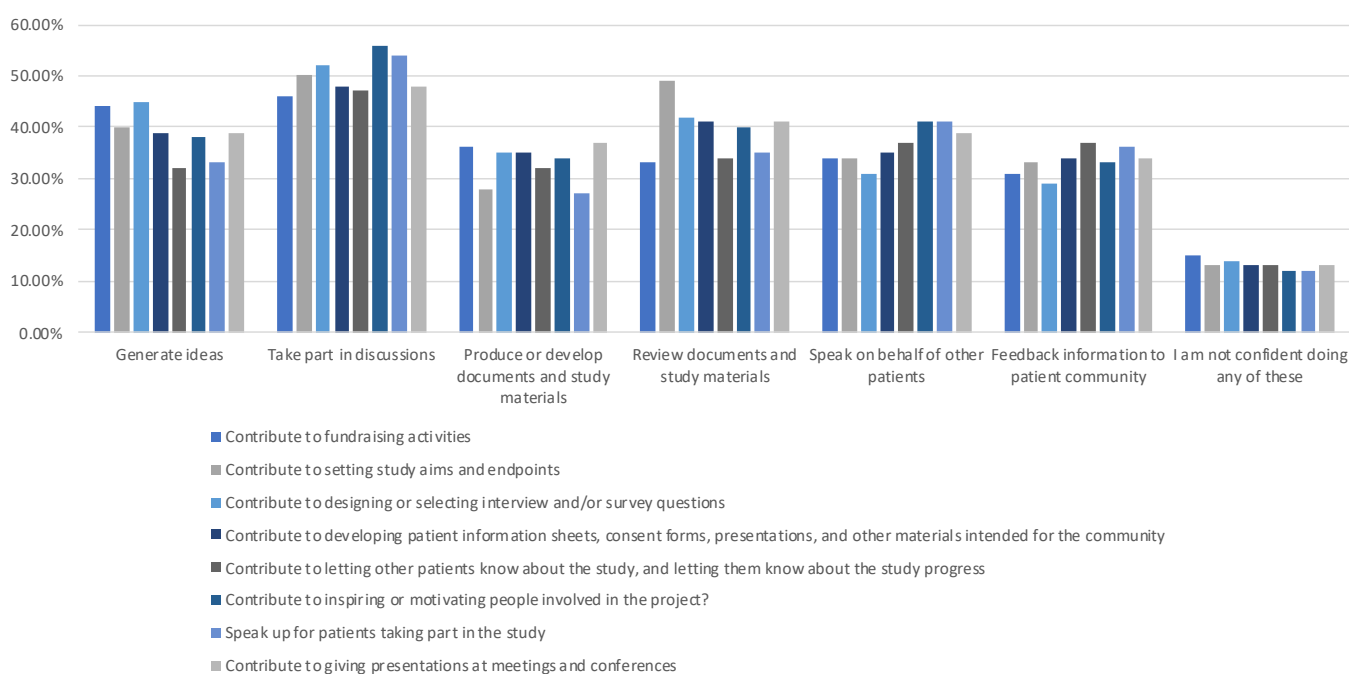


Figure 2.11: Overview of patient representative contribution to research development

Patient representative contribution to setting research priorities

Participants were asked if they were a patient representative on a research project, how could they contribute to setting research priorities. Research priorities may include, allocation of funding, target populations, deciding which research proposals are most important to researchers and the community.

For setting research priorities, the majority of participants would contribute in taking part in

discussion (n=60, 60.00%), and generating ideas (n=52, 52.00%). There were 42 participants (42.00%) that would contribute by reviewing documents and study materials, 41 participants (41.00%) would feel confident to speak on behalf of other patients, 35 participants would contribute by giving feedback to the patient community, and 24 participants (24.00%) would contribute by producing or developing documents and study materials. There were 13 participants (13.00%) that did not feel confident doing any of these tasks related to setting research priorities.

Table 2.14: Patient representative contribution to research development

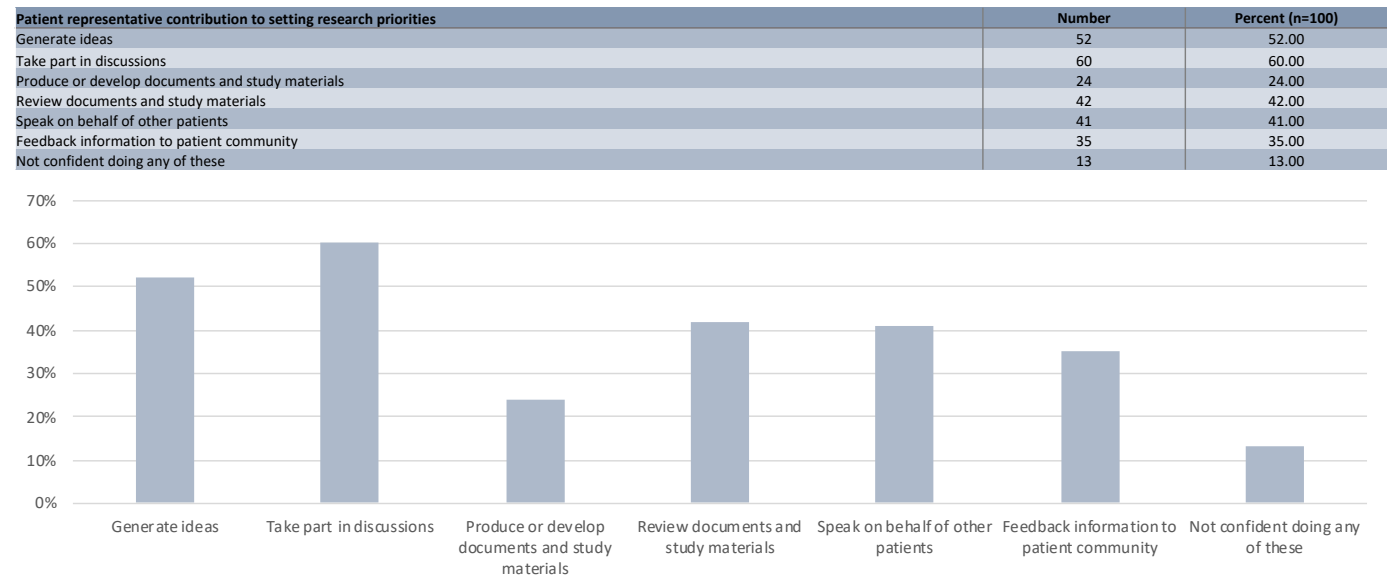


Figure 2.12: Patient representative contribution to research development

Patient representative contribution to background research

Participants were asked if they were a patient representative on a research project, how could they contribute to background research. The majority of participants would contribute by taking part in discussions (n=54, 54.00%). There were 49 participants (49.00%) that would contribute by reviewing documents and study materials, 38 participants (38.00%) would contribute

by generating ideas, 34 participants (34.00%), would contribute by giving feedback to the patient community, 32 participants (32.00%) would contribute by to speaking on behalf of other patients, and 32 participants (32.00%) would contribute by producing or developing documents and study materials. There were 11 participants (11.00%) that did not feel confident doing any of these tasks related to background research.

Table 2.15: Patient representative contribution to background research

Patient representative contribution to background research	Number	Percent (n=100)
Generate ideas	38	38.00
Take part in discussions	54	54.00
Produce or develop documents and study materials	32	32.00
Review documents and study materials	49	49.00
Speak on behalf of other patients	32	32.00
Feedback information to patient community	34	34.00
Not confident doing any of these	11	11.00

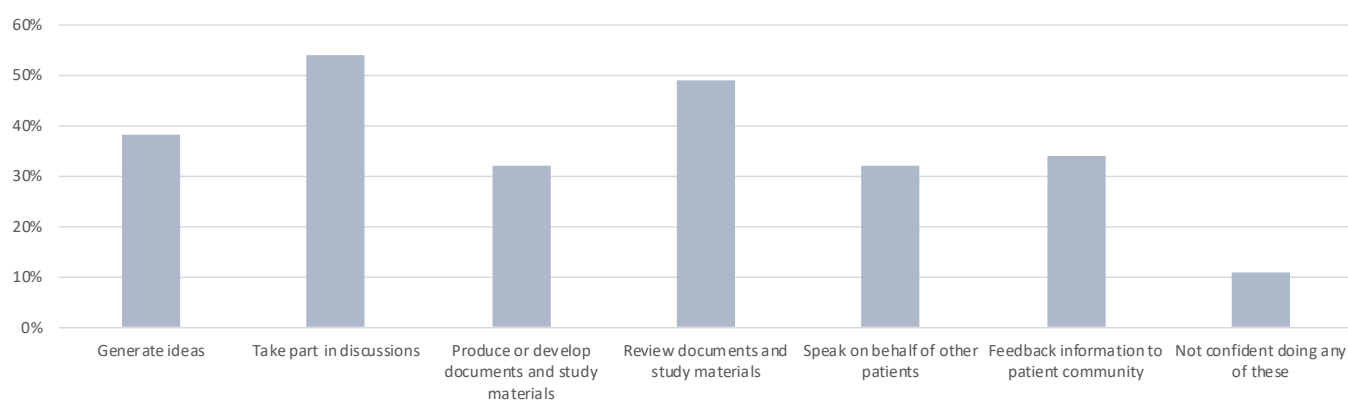


Figure 2.13: Patient representative contribution to background research

Patient representative contribution to fundraising activities

Participants were asked if they were a patient representative on a research project, how could they contribute to fundraising activities. Participants most commonly would contribute by taking part in discussions (n=46, 46.00%), followed by generating ideas (n=44, 44.00%). Approximately a third of

participants would contribute by producing or developing documents and study materials (n=36, 36.00%), speaking on behalf of other patients (n=34, 34.00%), reviewing study documents and study materials (n=33, 33.00%), and to feedback information to the patient community (n=31, 31.00%). There were 15 participants (15.00%) that did not feel confident doing any of these tasks related to fundraising activities.

Table 2.16: Patient representative contribution to fundraising activities

Patient representative contribution to fundraising activities	Number	Percent (n=100)
Generate ideas	44	44.00
Take part in discussions	46	46.00
Produce or develop documents and study materials	36	36.00
Review documents and study materials	33	33.00
Speak on behalf of other patients	34	34.00
Feedback information to patient community	31	31.00
I am not confident doing any of these	15	15.00

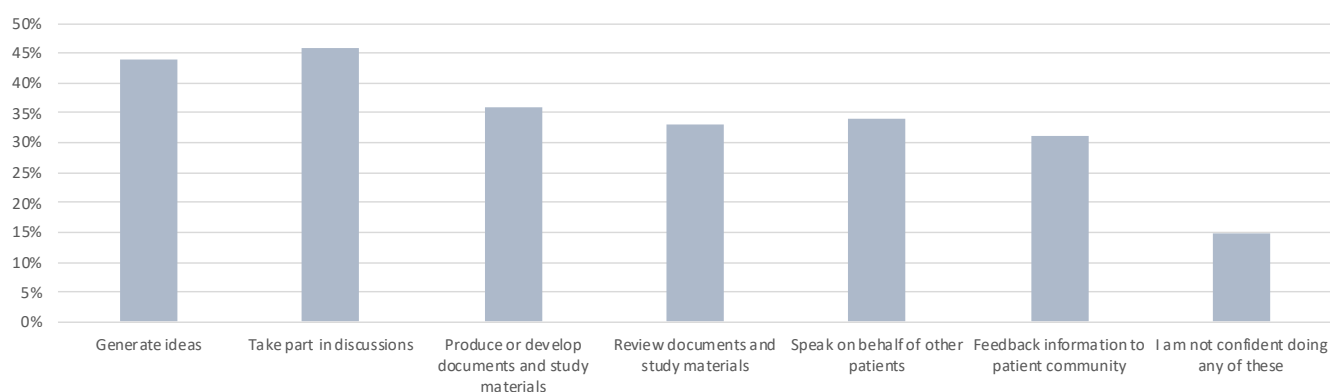


Figure 2.14: Patient representative contribution to fundraising activities

Patient representative contribution to setting study aims and endpoints.

Participants were asked if they were a patient representative on a research project, how could they contribute to setting study aims and endpoints. The study aim is the question being asked by the study, and the endpoints are how the question is measured. For example, endpoints can be related to disease progression, quality of life, or symptoms.

Half of the participants (n=50, 50.00%) would contribute by taking part in discussions, almost half

would contribute by reviewing study documents and study materials (n=49, 49.00%), and there were 40 participants (40.00%) that would contribute by generating ideas. Approximately a third of participants would contribute by speaking on behalf of other patients (n=34, 34.00%), giving feedback information to the patient community (n=33, 33.00%), and producing or developing documents and study materials (n=28, 28.00%). There were 13 participants (13.00%) that did not feel confident doing any of these tasks related to setting study aims and endpoints.

Table 2.17: Patient representative contribution to setting study aims and endpoints.

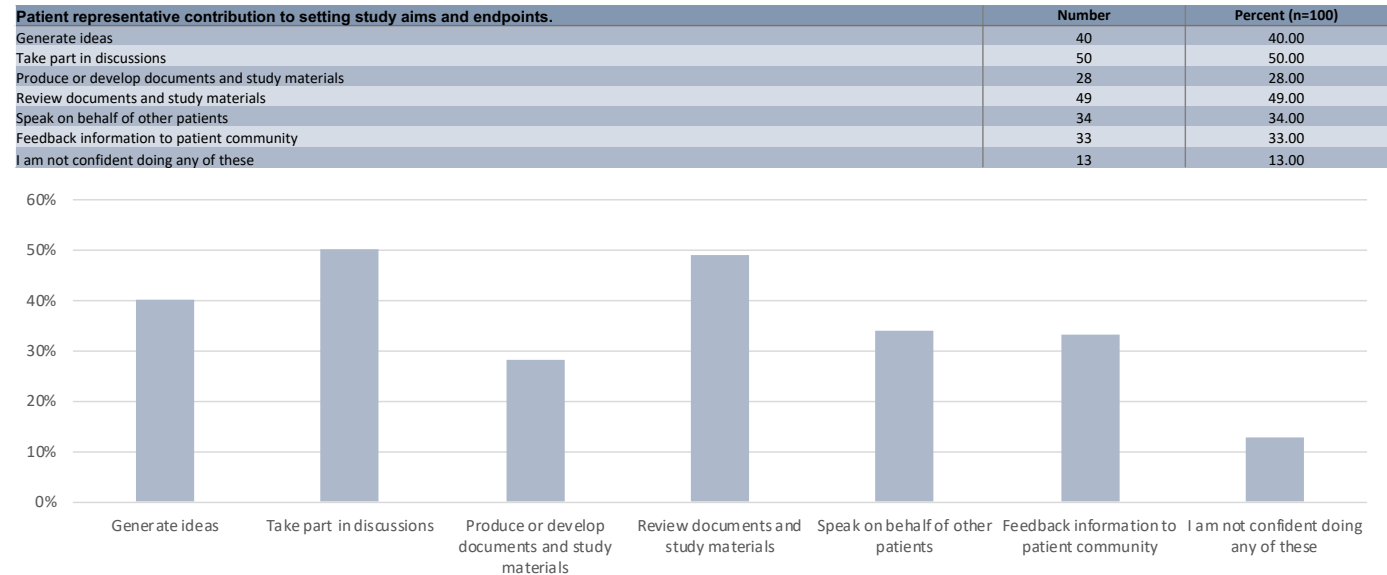


Figure 2.15: Patient representative contribution to setting study aims and endpoints.

Patient representative contribution to designing or selecting interview and/or survey questions

Participants were asked if they were a patient representative on a research project, how could they contribute to designing or selecting interview and/or survey questions. For example, patient representatives may contribute to choosing a survey about quality of life, or may contribute to collecting data about symptoms or side effects important to people the health condition.

Over half of the participants (n=52, 52.00%) would contribute by taking part in discussions, almost half would contribute by generating ideas (n=45, 45.00%), and there were 42 participants (42.00%) that would contribute by reviewing study documents and study materials. Approximately a third of participants would contribute by producing or developing documents and study materials (n=35, 35.00%), speaking on behalf of other patients (n=31, 31.00%), and giving feedback information to the patient community (n=29, 29.00%). There were 14 participants (14.00%) that did not feel

confident doing any of these tasks related to designing or selecting interview or survey questions.

Table 2.18: Patient representative contribution to designing or selecting interview and/or survey questions

Patient representative contribution to designing or selecting interview and/or survey questions	Number	Percent (n=100)
Generate ideas	45	45.00
Take part in discussions	52	52.00
Produce or develop documents and study materials	35	35.00
Review documents and study materials	42	42.00
Speak on behalf of other patients	31	31.00
Feedback information to patient community	29	29.00
I am not confident doing any of these	14	14.00

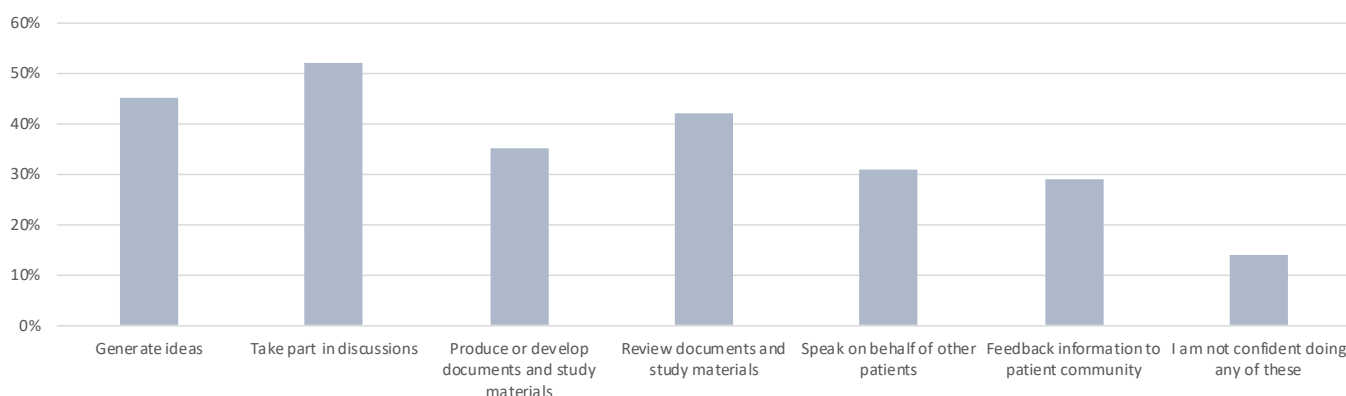


Figure 2.16: Patient representative contribution to designing or selecting interview and/or survey questions

Patient representative contribution to developing patient information sheets, consent forms, presentations, and other materials intended for the community

Participants were asked if they were a patient representative on a research project, how could they contribute to developing patient information sheets, consent forms, presentations, and other materials intended for the community.

Almost half of the participants (n=48, 48.00%) would contribute by taking part in discussions, there were 41

participants (41.00%) that contribute by reviewing study documents and study materials, and there were 39 participants (39.00%) that contribute by generating ideas. Approximately a third of participants contribute by producing or developing documents and study materials (n=35, 35.00%), speaking on behalf of other patients (n=35, 35.00%), giving feedback information to the patient community (n=34, 34.00%). There were 13 participants (13.00%) that did not feel confident doing any of these tasks related to developing materials intended for the patient community.

Table 2.19: Patient representative contribution to developing patient information sheets, consent forms, presentations, and other materials intended for the community

Patient representative contribution to developing patient information sheets, consent forms, presentations, and other materials intended for the community	Number	Percent (n=100)
Generate ideas	39	39.00
Take part in discussions	48	48.00
Produce or develop documents and study materials	35	35.00
Review documents and study materials	41	41.00
Speak on behalf of other patients	35	35.00
Feedback information to patient community	34	34.00
I am not confident doing any of these	13	13.00

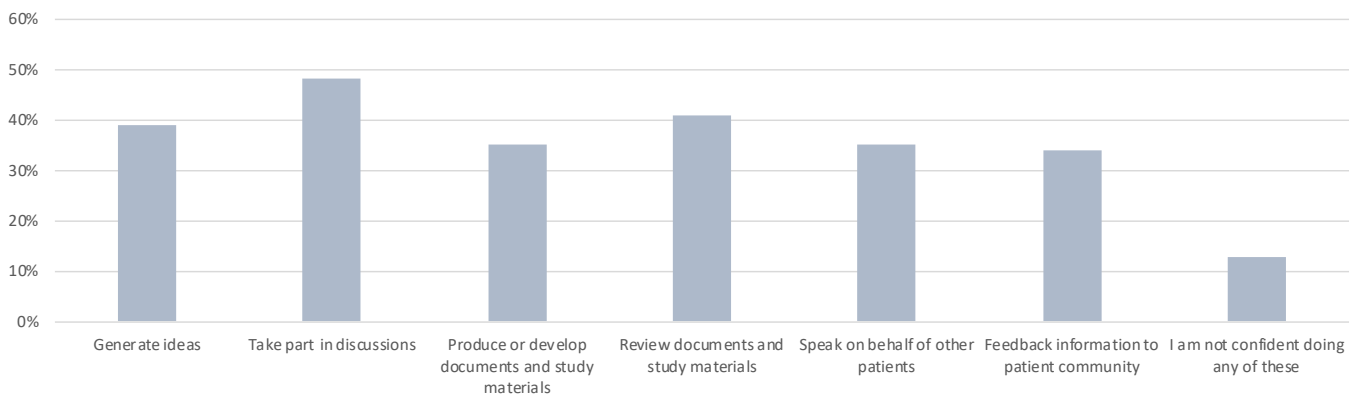


Figure 2.17: Patient representative contribution to developing patient information sheets, consent forms, presentations, and other materials intended for the community

Patient representative contribution to letting other patients know about the study, and letting them know about the study progress.

Participants were asked if they were a patient representative on a research project, how could they contribute to letting other patients know about the study, and letting them know about the study progress.

Almost half of the participants (n=47, 47.00%) would contribute by taking part in discussions, there were 37 participants (37.00%) that would contribute by

speaking on behalf of other patients, and the same number would contribute by giving feedback information to the patient community (n=37, 37.00%). Approximately a third of participants would contribute by reviewing study documents and study materials (n=34, 34.00%), generating ideas (n=32, 32.00%), and producing or developing documents and study materials (n=32, 32.00%). There were 13 participants (13.00%) that did not feel confident doing any of these tasks related to letting other patients know about the study, and letting them know about the study progress.

Table 2.20: Patient representative contribution to letting other patients know about the study, and letting them know about the study progress.

Patient representative contribution to letting other patients know about the study, and letting them know about the study progress.	Number	Percent (n=100)
Generate ideas	32	32.00
Take part in discussions	47	47.00
Produce or develop documents and study materials	32	32.00
Review documents and study materials	34	34.00
Speak on behalf of other patients	37	37.00
Feedback information to patient community	37	37.00
I am not confident doing any of these	13	13.00

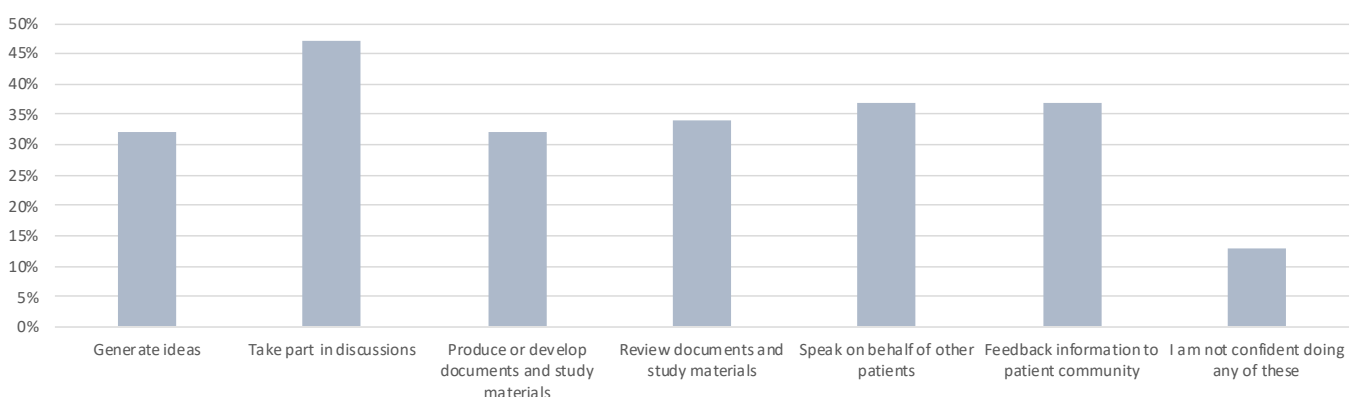


Figure 2.18: Patient representative contribution to letting other patients know about the study, and letting them know about the study progress.

Patient representative contribution to inspiring or motivating people involved in the project.

Participants were asked if they were a patient representative on a research project, how could they contribute to inspiring or motivating people involved in the project.

Over half of the participants (n=56, 56.00%) would contribute by taking part in discussions, and there were 41 participants (41.00%) that would contribute by speaking on behalf of other patients, 40 participants

(41.00%) would contribute by reviewing study documents and study materials, and 38 participants (38.00%) would contribute by generating ideas. Approximately a third of participants would contribute by producing or developing documents and study materials (n=34, 34.00%), and giving feedback to the patient community (n=33, 33.00%). There were 12 participants (12.00%) that did not feel confident doing any of these tasks related to inspiring or motivating people involved in the project

Table 2.21: Patient representative contribution to inspiring or motivating people involved in the project.

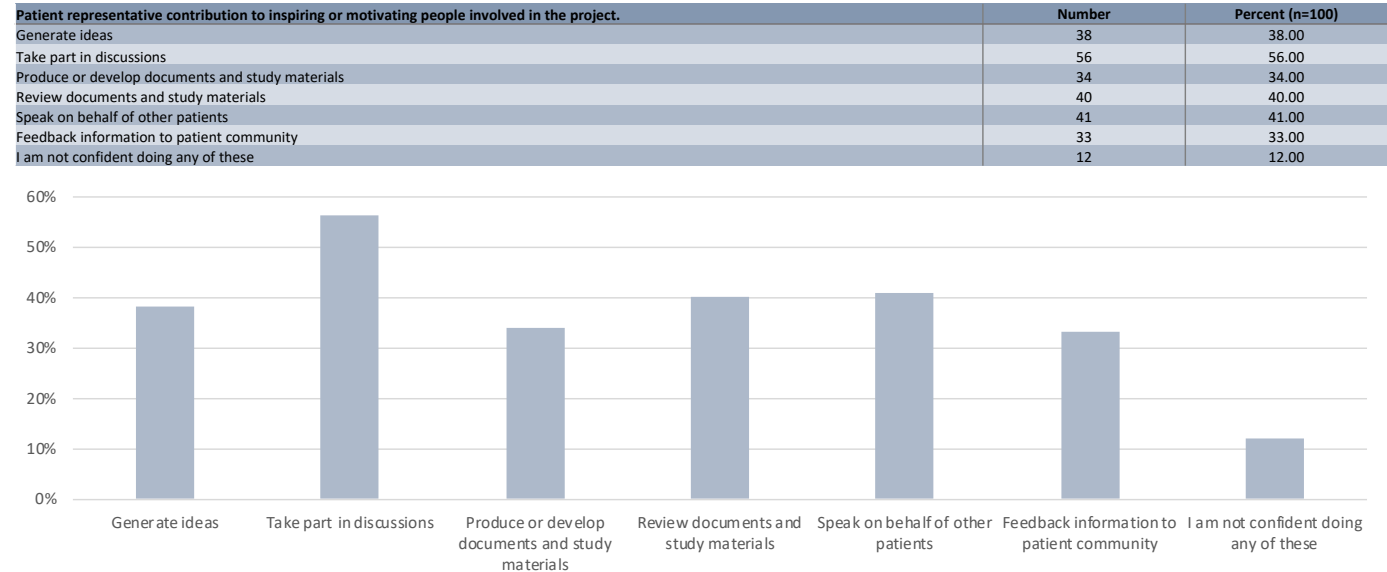


Figure 2.19: Patient representative contribution to inspiring or motivating people involved in the project.

Patient representative speaking up for patients taking part in the study.

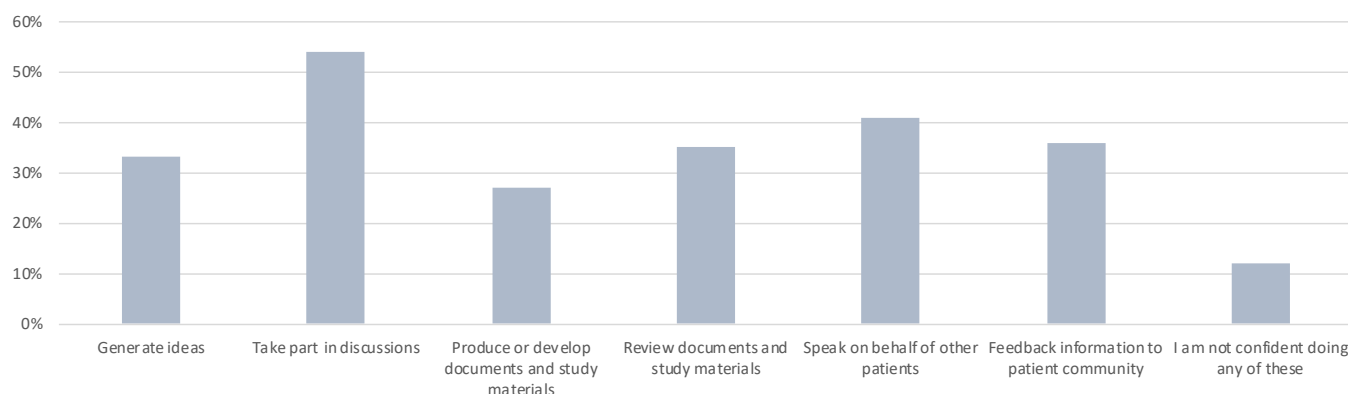
Participants were asked if they were a patient representative on a research project, how could they speak up for patients taking part in the study.

Over half of the participants (n=54, 54.00%) would speak up for patients by taking part in discussions, and there were 41 participants (41.00%) that would speak up on behalf of patients taking part in the study, and 36

participants (36.00%) speak up for patients by giving feedback information to the patient community. Approximately a third of participants speak up for patients by reviewing study documents and study materials (n=35, 35.00%), generating ideas (n=33, 33.00%), and producing or developing documents and study materials (n=27, 27.00%). There were 12 participants (12.00%) that did not feel confident doing any of these tasks related to speaking up for patients taking part in the study.

Table 2.22: Patient representative speaking up for patients taking part in the study.

Patient representative speaking up for patients taking part in the study.	Number	Percent (n=100)
Generate ideas	33	33.00
Take part in discussions	54	54.00
Produce or develop documents and study materials	27	27.00
Review documents and study materials	35	35.00
Speak on behalf of other patients	41	41.00
Feedback information to patient community	36	36.00
I am not confident doing any of these	12	12.00

**Figure 2.20: Patient representative speaking up for patients taking part in the study.**

Patient representative contribution to giving presentations at meetings and conferences

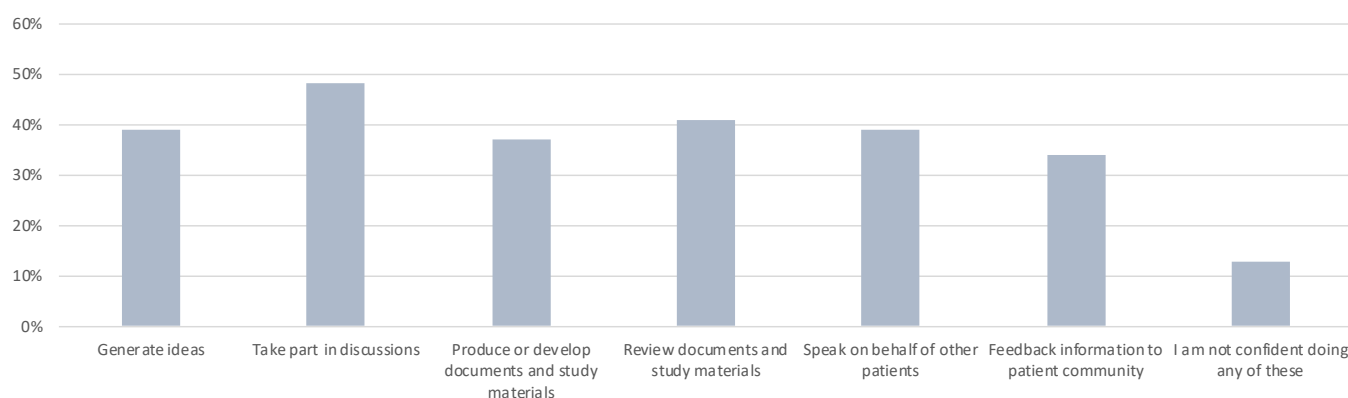
Participants were asked if they were a patient representative on a research project, how could they contribute to giving presentations at meetings and conferences.

Almost half of the participants (n=48, 48.00%) would contribute by taking part in discussions, and there were 41 participants (41.00%) that would contribute by

reviewing study documents and study materials, 39 participants (39.00%), that would contribute by generating ideas, and the same number would contribute by speaking on behalf of other patients (n=39, 39.00%), and there were 37 participants (37.00%) would contribute by producing or developing documents and study materials. Approximately a third of participants would contribute by giving feedback information to the patient community (n=33, 33.00%). There were 13 participants (13.00%) that did not feel confident doing any of these tasks related to giving presentations at meetings and conferences.

Table 2.23: Patient representative contribution to giving presentations at meetings and conferences

Patient representative contribution to giving presentations at meetings and conferences	Number	Percent (n=100)
Generate ideas	39	39.00
Take part in discussions	48	48.00
Produce or develop documents and study materials	37	37.00
Review documents and study materials	41	41.00
Speak on behalf of other patients	39	39.00
Feedback information to patient community	34	34.00
I am not confident doing any of these	13	13.00

**Figure 2.21: Patient representative contribution to giving presentations at meetings and conferences**

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Section 4: Summary and key points

Summary and key points

The role of patients and patient organisations in research and clinical trials was explored in three case studies, a community-led research project, a cooperative clinical trials groups, and an industry clinical trial.

The community-led research project was a research project that was important to the community that was unable to find academic interest. A clinical trials unit developed a community research hub where patient organisations can submit research ideas. The research hub resulted in a feasibility study followed by a pilot study. The benefits of this approach includes allowing questions important to patient community to be answered that may not be of interest to academia or industry, and support to patient organisations to conduct feasibility survey, conducting pilot study, and to secure funding for research

The cooperative clinical trials group case study described a framework for patient engagement, where patient representatives participate in research committees. The framework defined the qualifications of patient representatives, at what stage of the clinical trial process that the representative took part, and the role and responsibilities of the patient representative.

The industry case study described how a community advisory board worked in a clinical trial for a rare disease. The community advisory board had 10 to 15 members their contributions led to improvements in patient safety, patient comfort, and accuracy of trial data. The community advisory board reviewed and provided advice on trial conduct and reporting, co-developed patient documents, advised on the regulatory submission dossier, advised on lay summaries of clinical trial results, and collaborated on non-trial related activities to develop tools and educational materials.

Case studies: Key benefits of patient engagement

- The benefits community-led research includes allowing questions important to patient community to be answered that may not be of interest to academia or industry
- Community-led research establishes experience and can lead to other studies
- Attractive to major funding organisations

- Improvements in patient safety, patient comfort, and accuracy of trial data
- Advisors on regulatory submission dossiers

A review of Australian clinical trial cooperative groups was conducted to provide insights about what a patient looking to find opportunities to engage in research or clinical trials may experience. There were 51 organisations identified and over half had details about patient representation on their website. The most common types of representation was by patient advisory group, followed by patient representatives on steering or executive committees, and engagement from partner organisations.

Details about how to participate were given by very few organisations, where information was given it was either an email address for more information, or a detailed form with instructions. Very few organisations published the terms of reference of patient representation, and very few published details about tenure.

The most common activities described for patient engagement were raising awareness and advocating about clinical trials to the community, and reviewing research concepts and strategic planning. Other activities were facilitating links with members of the community and community groups, reviewing patient/participant focused documentation, dissemination of clinical trial results, and fundraising activities, including grant applications.

Very few organisations posted details about qualifications needed to take part in patient engagement. The most common requirement was to be a patient or carer. Other requirements were experience in advocacy, and some organisations would consider any interested person.

It is important to note that in the view of CCDR, the only qualifications that are relevant are having lived experience with the relevant condition. Those conducting the engagement activities should then adapt their approaches to accommodate a demographically balanced range of people.

Australian clinical trial cooperative groups: Key points

- Patient engagement details on about half of the websites
- Little information given about how to participate
- Terms of engagement were rarely posted on websites
- Most common engagement activities were raising awareness of clinical trials/research, and strategic planning

We conducted a survey of over 100 participants to gain insights into when and how the community would like to participate in patient engagement. The participants were mostly aged between 18 and 54, almost equal numbers of male and females took part, and they were mostly Caucasian. Almost half had some university qualifications, and about half lived in areas of high socioeconomic status. Most were in either full or part time employment, and over a third were carers to family members or spouses.

Three quarters of the participants had at least one health condition, most commonly anxiety or depression. The majority of participants had used the public or private hospital system as either an inpatient or outpatients, most commonly the public health system. About half of the participants had private health insurance.

Participants thought that it was most important for patients to be represented at all stages during the research process, in particular when setting research priorities, study development, and when patients are taking part in the study.

Participants thought it was important to for patient engagement in all types of research, they found it most important to be involved in research about new treatments or new ways of using treatments, research about new medical devices or new ways of using medical devices, laboratory-based scientific investigations, and in quality of life studies.

Participants rated how effective they thought different types of patient representation were, the most effective types of representation were; a panel of equal numbers of patient representatives and doctor/researchers, a patient representative gives a report to researchers at their conference about what it is like to have condition, and a group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that people with the condition have now. The least effective ways of representing patients were; one or two patient representative on a panel with five to ten doctors and researchers, and community members can just post or email in ideas or concerns— no other interactions with researchers

Participants would be willing to travel up to an hour to take part in community engagement, and would prefer to have an ongoing commitment usually for a day once or twice a year.

The most common ways that participants thought that they could contribute as a patient representative was to take part in discussions, followed by generating ideas and reviewing documents and study materials.

Patient engagement questionnaire: Key points

- Important for patient representation at all stages of research
- Important for patient representation for all types of health research
- Most effective ways for patients to be represented were:
 - a panel of equal patient representatives and doctor/researchers
 - patient representative gives a report to researchers at their conference about what it is like to have condition
 - and a group of patients and carers are interviewed and/or complete questionnaires that lets researchers know what the issues and difficulties that people with the condition have now