

A Strategy for Public Involvement (PI) and Engagement (PE) in Inflammatory Diseases at the NIHR Birmingham Biomedical Research Centre



*Medical knowledge isn't the only
important knowledge. It's important to
know what it's like to actually have a
condition or to use services and how that impacts
on someone's life; medical knowledge doesn't tell
you that.*

Service user

Quotation taken from INVOLVE leaflet (2010)

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1.0 EXECUTIVE SUMMARY

The NIHR Birmingham Biomedical Research Centre (BRC) values patient and public involvement and engagement in all stages of our research. We have been guided by NIHR standards and guidelines in creating a step change in our PI activity following the establishment of the BRC in April 2017. We have developed and agreed a strategy in conjunction with the senior leadership team and our three distinct patient partnership groups and our objectives are summarised below.

- Improve representation, opportunity and organisation in our PI groups
- Increase accessibility to PI opportunities by further use of online tools
- Focus on patient driven research questions
- Incorporate patient reported outcomes into early phase clinical trials
- Develop effective training programmes and resources for researchers, patients, the public and service users to deliver best practice within PI
- Develop and deliver co-produced research
- Deliver public engagement programme to raise the profile of the BRC's work, which informs and stimulates thinking about BRC research
- Collaborate locally, regionally and nationally/practice share
- Evaluate the quality and impact of PI effectively

2.0 INTRODUCTION

2.1 What exactly is Public Involvement and Engagement?

INVOLVE, the partnership organisation established by the National Institute for Health Research, define public involvement (PI) within research as working in partnership ‘**with**’ or ‘**by**’ members of the public rather than ‘**to**’, ‘**about**’ or ‘**for**’ them¹. The ‘public’ members of PI groups are patients, potential patients, carers, health and social care services and their representatives. The involvement of patients and the public means ‘active partnership between the public and researchers in the research process Active involvement may take the form of consultation, collaboration or user control’.

INVOLVE provides clear and distinct definitions of involvement, participation and engagement to assist researchers working in partnership with PI:

Involvement	Participation	Engagement
Where members of the public are actively involved in research projects and in research organisations	Where people take part in a research study	Where information and knowledge about research is provided and disseminated
<p>Examples of public involvement are:</p> <ul style="list-style-type: none"> - as joint grant holders or co-applicants on a research project - identifying research priorities - as members of a project advisory or steering group - commenting and developing patient information leaflets or other research materials 	<p>Examples of patient participation are:</p> <ul style="list-style-type: none"> - people being recruited to a clinical trial or other research study to take part in the research - completing a questionnaire or participating in a focus group as part of a research study 	<p>Examples of engagement are:</p> <ul style="list-style-type: none"> - science festivals open to the public with debates and discussions on research - open day at a research centre where members of the public are invited to find out about research - raising awareness of research through media such as television

¹ INVOLVE, Briefing Note 2: What is Public Involvement

<http://www.invo.org.uk/posttypresource/what-is-public-involvement-in-research/>

2.2 NIHR Birmingham Biomedical Research Centre (BRC)

The NIHR Birmingham BRC brings researchers, scientists, clinicians, patients and other members of the public together in a collaborative partnership to support the efficient translation of scientific discoveries into new treatments for patients with inflammatory and autoimmune joint, muscle, bowel and liver diseases.

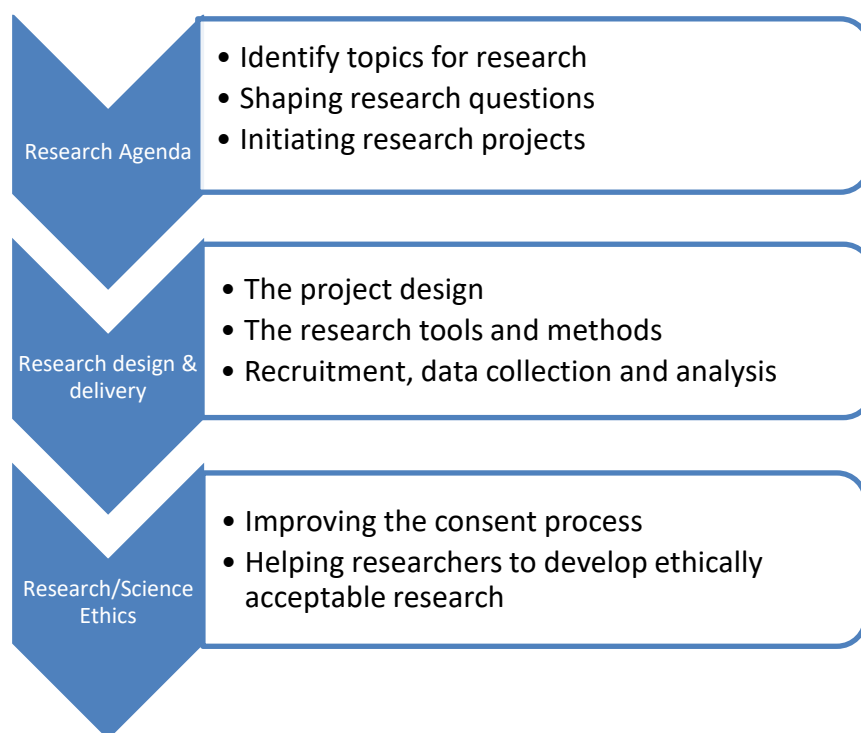
“Chronic inflammatory diseases such as arthritis, colitis and liver diseases are increasingly common and a major cause of suffering and early death. In Birmingham, we have been researching the underlying processes behind these diseases for many years” says Professor David Adams, Director of NIHR Birmingham Biomedical Research Centre, Director of Birmingham Health Partners and Head of the College of Medical and Dental Sciences at the University of Birmingham.

Examples of current PI include;

- working with researchers to prioritise research,
- developing and supporting funding applications,
- offering insights as members of a project steering group or management committee,
- commenting on and developing research materials such as consent forms and surveys, and
- helping with interviews with research participants.

PI within the BRC impacts positively upon research quality and relevance by offering a different perspective. Researchers seek to involve patients and the public who have a unique experience of and insight into a research topic. ‘Exploring Impact: Public involvement in NHS, public health and social care research’ [Staley K (2009) INVOLVE, Eastleigh] presented evidence of the positive effect of PI on the research agenda, design and delivery along with the ethics. It is anticipated that the BRC will demonstrate an impact in these areas.

How PI can influence the research agenda and have impact on all stages of the research cycle, including ethics:



2.3 Impact of PI on patients, public and the researchers

It is important to acknowledge that patient and public involvement can have both positive and negative impacts on those involved in the process.

Patient and the Public	Researchers
<i>The positive benefits can include:</i> <ul style="list-style-type: none"> ❖ acquiring new skills and knowledge ❖ personal development ❖ support and mentorship ❖ enjoyment and satisfaction ❖ can help to speed up research (focus on priorities only) 	<i>The positive benefits can include:</i> <ul style="list-style-type: none"> ❖ better knowledge and understanding of the community ❖ enjoyment and satisfaction ❖ career benefits ❖ challenges to beliefs and attitudes ❖ more effective/ cost-effective research
<i>Negative effects can include:</i> <ul style="list-style-type: none"> ❖ feeling emotionally burdened ❖ being overloaded with work ❖ exposed through the media ❖ frustrated at the limitations of involvement 	<i>Negative effects can include:</i> <ul style="list-style-type: none"> ❖ increased demand on resources ❖ slower pace of research ❖ loss of power ❖ challenges to value and assumptions

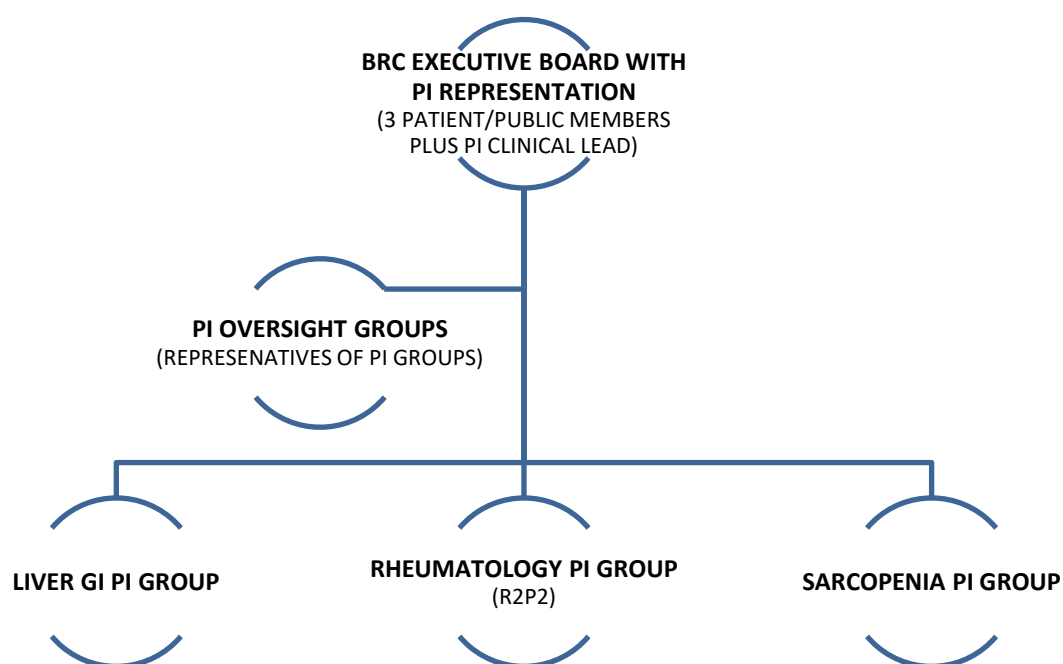
We believe that by identifying these impacts the PI/PE Manager will be able to work with researchers and PI groups to be mindful of potential bias, negative impacts and ensure respectful, informed and effective partnerships are developed to further effective research.

3.0 STRATEGY

3.1 Improve representation, opportunity, collaboration and organisation in existing PI groups

In order to achieve our vision for the BRC, we have developed the following strategy. We appointed a Patient and Public Involvement and Engagement (PI/PE) Manager on a full time basis in January 2018 (Laura Chapman) who will work closely with our well-established PI Clinical Lead (Dr James Ferguson). Our PI Clinical Lead attends BRC Executive Board Meetings, along with a member from each of the three research themes.

Each of the BRC's three PI groups is a partnership between patients, ex-patients, carers, ex-carers, family members and other interested members of the public. The members share an interest in adding the voices of patients, service users and the public to provision for, and research into, the conditions concerned.



- i) The Liver GI Reference Group is formed from people living with diseases of the liver, stomach and gut, their relatives and members of the public, who are interested in both the disease and research. It was originally set up for liver-related conditions in 2013 and has evolved to incorporate gastrointestinal conditions. It is led by a steering group, chaired by one of their members and members are active in involvement and engagement.

- ii) The Rheumatology Research Patient Partnership (also known as R2P2) is a partnership between people living with Rheumatoid Arthritis, Sjögren's Syndrome, family members, members of the public and researchers at the University of Birmingham, Sandwell and West Birmingham Hospitals NHS Trust and University Hospitals Birmingham NHS Foundation Trust.
- iii) The Sarcopenia PI group has a direct link to the '1000 Elders', consisting of about 640 people. It was established over 30 years ago by the University of Birmingham for over 65 year olds to participate in research about all aspects of life as an older adult in the UK including the physical aspects of ageing. In the last 10 years this has expanded to include involvement in medical research including research into heart disease, infections in old age and falls. It remains an active participation and group and the involvement in research aspect is evolving.

The PI Manager will work with these groups to help with;

- organising and facilitating their meetings and appropriate ways/means of communicating,
- establishing their different needs,
- finding ways to ensure they are truly reflecting the diversity of the patients they represent,
- ensuring inclusivity by investigating what barrier may exist and providing suggestions and the means to overcome them,
- recruitment to increase active membership,
- provision of learning and development to enhance the effectiveness of the partnership (for members and researchers alike) to aid the future development of the groups.

They are invited to attend each other's meetings, have access to each other's newsletters and all inform the BRC's strategy.

3.2 Increase accessibility to PI opportunities by further use of online tools

We will develop online tools (Twitter feeds, webchats, video conferencing and our website) to develop a wide-ranging virtual PI network that will provide public and patients with access to information about research, involvement, participation and engagement opportunities.

A virtual clinic environment that has been co-designed with patients aims to reduce unnecessary visits and breaks down geographic barriers for accessing research. The first virtual clinics have taken place and a randomised controlled trial of virtual clinics has been funded by Collaboration for Leadership in Applied Health Research and Care (CLAHRC) and this builds on the award winning MyHealth@QEHB patient

records system. This system has a 'my research' page within it which will allow patients to review a summary of the project in which they are participating in, along with their consent and patient information sheet. It will facilitate two-way communication between trials teams and their participants.

We are working to widen its application to other specialties and as a tool to increase our diversity in PI and significantly increase our commitment to inclusion of all.

3.3 Focus on patient driven research questions

The James Lind Alliance (JLA), a not-for-profit initiative funded by the NIHR 'brings patients, carers and clinician groups together on an equal footing to identify treatment uncertainties which are important to all groups' [<http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/>]. It works with them to consider research priorities for the different conditions and diseases. The BRC has referred to the JLA's findings for inflammatory bowel disease (see Appendix One) and Alcohol-related Liver Disease (Appendix 2).

We await the publication in 2018 of the top ten research priorities in Non Alcohol-related Liver Disease for further guidance. We will be working with the R2P2 group to choose a disease area and aim to work to establish priorities for research in a similar way.

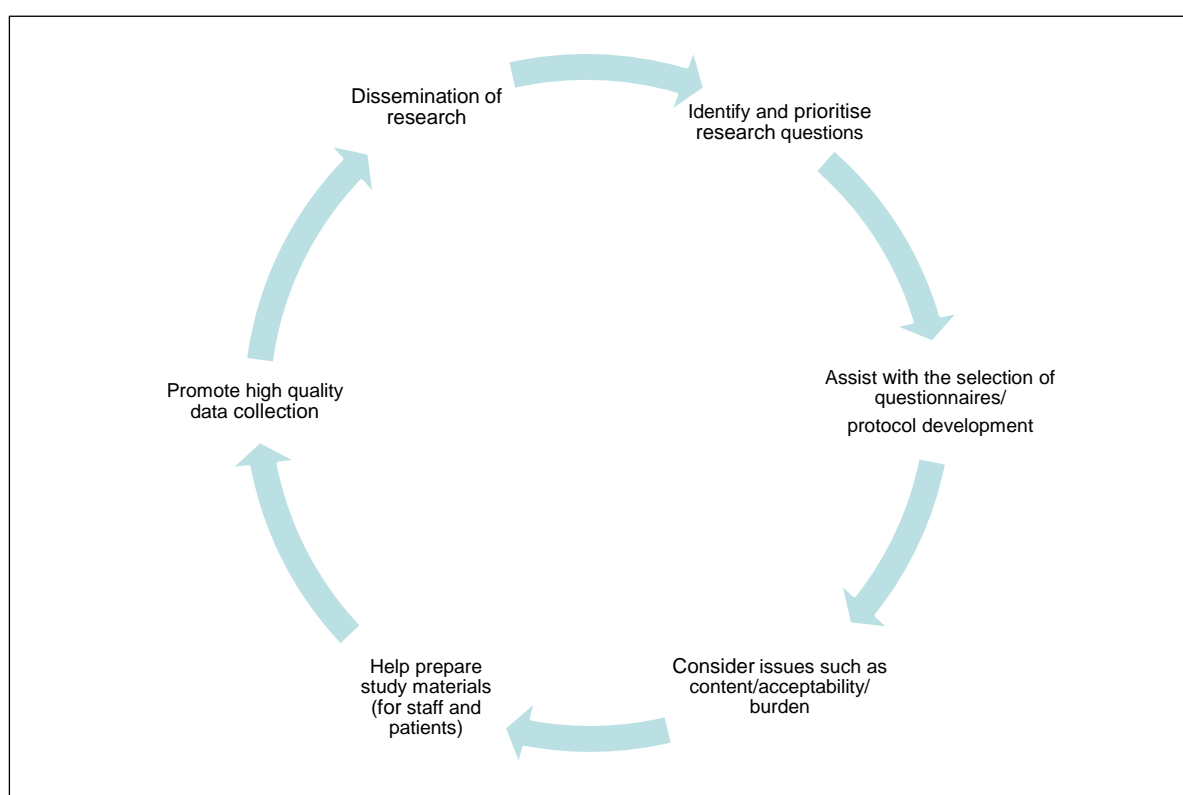
3.4 Incorporate patient reported outcomes into early phase clinical trials

It is increasingly recognised that clinical outcome measures (such as an improvement in liver tests) fail to capture the full impact of disease on a patient's life. Patient-reported outcomes (PROs) help address this important deficit in the clinician's knowledge both in the clinical and research settings. PROs are collected using validated questionnaires which ask patients to self-rate their health status; providing important information regarding the patient's perspective on the physical, functional and psychological consequences of treatment and the degree and impact of disease symptoms.

We are working with Prof Melanie Calvert, Professor of Outcomes Methodology at the University of Birmingham to develop PROs for our patients and then integrate them into an electronic capture system supporting early phase clinical trials. The BRC will recruit a post-doctoral researcher who will work with Prof Calvert to develop PROs and integrate them into an electronic capture system supporting early phase clinical trials.

This information is important as it can help address patient questions regarding 'how might I feel on this treatment?'. Data from early phase trials can be used to inform larger, later phase studies to provide valuable evidence of the impact of treatment on quality of life which can be used to inform treatment choice, clinical guidelines and health policies.

Patients will work in partnership with researchers in the Centre for Patient Reported Outcomes Research on all aspects of the research programme as illustrated:



Some members of our groups have already participated in a research prioritisation workshop (December 2017) and further workshops and training are planned. Patient partners have access to the freely accessible web-based information resource [www.birmingham.ac.uk/prolearn/] which has a dedicated page for patient advocates. Members of the PI groups will be invited to attend CPROR events including annual PROMs Conferences.

3.5 Development of effective training programmes and resources for researchers, patients, the public and service users to deliver best practice within PI

Our PI/PE Manager will work with researchers and PI groups to analyse training needs to aid prioritisation and appropriate development of learning and development opportunities/materials.

Effective learning and development is critical for high quality engagement and involvement. This will be developed and made available online as well as through face-to-face sessions with patients, the public and relevant charities/collaborating organisations/public bodies. Researchers will benefit from general PI training on practice and evaluation, which will be facilitated by monthly 'clinics' held by our PI/PE Manager, along with the development of resources which include collaborating with other BRC PI leads, RDS West Midlands and the PI leads for University Hospitals Birmingham, relevant charities, West Midlands CLAHRC and the SRMRC.

Our lay contributors will be supported with learning and development, empowering them to participate proactively in discussions and research and one of our Key Performance Indicators will be the amount of training delivered and to whom. One example is of this, is that our PI group members will be offered 'Improving Healthcare through Clinical Research'. This is a MOOC (Massive Open Online Course) available to anyone around the world and free to follow. The course has been prepared by the Clinical Research Network (CRN) working in conjunction with Leeds University and is hosted by FutureLearn: [<https://www.futurelearn.com/courses/clinical-research>].

We will work with the University of Birmingham to establish a method to deliver courses on-line, in conjunction with Birmingham Health Partners (BHP), on-line, in addition to face to face training courses. This is through collaborating with CLAHRC, Birmingham Health Partners, PI groups and the SRMRC.

3.6 Develop and deliver co-produced research

Our PI Manager will meet regularly with researchers to ensure that they are given information and support about PI in research, to ensure that all BRC research is developed and co-produced with patients/public.

We will encourage PI groups to lead and develop their own research studies and to apply for funding. As an example of this, the Liver GI PI group provided insight and valuable work into an NIHR Research for Public Benefit² application to evaluate patient developed Patient Information Sheets, which has been submitted.

² Inspired by patients and practice, the RfPB scheme generates research evidence to improve, expand and strengthen the way that healthcare is delivered for patients, the public and the NHS.

3.7 Deliver programme of engagement to raise the profile of the BRC's work

We will run a number of engagement events each year. The BRC will participate in the annual International Clinical Trials Research Showcase Day to ensure our work is promoted and disseminated. We advertise events which we believe are of relevance and interest to our groups, such as 'The Big Data and Consent workshop' in February 2018. This was run in collaboration with the University Hospitals Birmingham NHS Trust (UHB) and 100,000 Genome Project's PI leads. This is in addition to attendance/promotion of our work and recruitment to the groups at events such as the West Midlands CRN's Patient Ambassador in Research Awards day, public lectures and education days.

Our PI/PE Manager will work with the University of Birmingham's Public Engagement with Research Committee (PERC) and the University Hospitals Birmingham NHS Foundation Trust's/Birmingham Health Partners PI lead in addition to our PI groups to deliver innovative and collaborative exhibitions and events. This will include public events showcasing the BRC in the new university facility – the redeveloped Municipal Bank on Broad Street - in the cultural and commercial centre of the city of Birmingham .

3.8 Collaborate locally, regionally and nationally/practice share

We will work with charities such as Arthritis Research UK, Bowel and Cancer Research UK, The British Liver Trust, Crohn's and Colitis UK to provide national access for patients to our BRC's research and PI groups, in addition to creating more effective distribution channels for dissemination of our work.

Our PI/PE Manager will work with INVOLVE, University Hospitals Birmingham NHS Trust's PI lead and other BRCs and is sharing best practice, ideas, learning and development via regularly communication and meetings.

In addition to this, we will actively collaborate with the West Midlands group of the regional network for public involvement and lay accountability in research (PILAR), NIHR Research Design Service (RDS) and The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (CLAHRC) West Midlands.

3.9 Effective evaluation of PI

We will develop Key Performance Indicators based on the major objectives within our programme and set out an ongoing evaluation programme co-ordinated by our PI/PE Manager. We will consider using focus groups to assess the quality and impact of PI on researchers and patients/the public, in addition to using tools such as GRIPP2³, to report on our PI.

³ GRIPP2 is the improved/revised version of the Guidance for Reporting Involvement of Patients and the Public (GRIPP). It is a checklist developed to help researchers, patients,

Each year we will produce an Annual Report to the NIHR. This will be an action plan available on-line based on KPIs including the number of projects developed with patients, the number of patients actively involved as co-researchers, the diversity of our PI groups and metrics around online and physical engagement with our events and dissemination outputs.

4.0 CONCLUSION

This document is intended to demonstrate our commitment to meaningful PI/ PE and provide an outline how we will ensure that we will achieve this important objective.

This strategy will be referred to by the BRC Executive Board, PI/PE Manager and PI groups to ensure adherence and development of ideas/innovation throughout the duration of the BRC funding (April 2017 to March 2022).

carers and the public to improve the quality, consistency and transparency of PPI reporting, to strengthen the quality of the international PPI evidence base (Staniszewska, S, Brett J, Mockford C, Barber R. The GRIPP checklist: strengthening the quality of patient and public involvement report in research)

5.0 APPENDIX 1

JLA; Inflammatory Bowel Disease; Top 10 Priorities (2015)

1. What is the optimal treatment strategy considering efficacy, safety and cost-effectiveness (immunomodulators, biologics, surgery, combinations) in IBD management: selecting the right patient group, right stage of disease, and assessing potential for withdrawal?
2. What are the optimal markers/ combinations of markers (clinical, endoscopic, imaging, genetics, other biomarkers) for stratification of patients with regards to (a) disease course and (b) monitoring disease activity and (c) treatment response?
3. What role does diet have in the management of mildly active or inactive ulcerative colitis or Crohn's Disease to achieve normal daily activities and symptom control?
4. How can pain be most effectively managed in people with IBD?
5. What is an optimal treatment strategy for perianal Crohn's Disease and what individual factors determine this?
6. What is the best treatment for controlling diarrhoea and/or incontinence symptoms in people with IBD, including novel pharmacological and non-pharmacological options? Is high-dose Loperamide safe and effective in the treatment of diarrhoea in IBD?
7. What is the optimal dietary therapy (liquid enteral diet and/or reintroduction diet) and duration to achieve mucosal healing in active IBD and/or remission either as a primary or adjunctive treatment? Is there a difference between adults and children?
8. What is the association between IBD and fatigue and how should it be managed?
9. Does early surgery or later surgery for terminal ileal Crohn's disease result in better outcomes (quality of life, cost-effectiveness)?
10. Does influencing the gut microbiota influence the course of IBD?

6.0 APPENDIX 2

JLA; Alcohol-related Liver Disease; Top 10 Priorities (2016)

1. What are the most effective ways to help people with alcohol-related liver disease stop drinking?
2. What are the most effective ways of delivering healthcare education and information about excessive alcohol consumption, the warning signs and the risks of alcohol-related liver disease to different demographics (including young people)?
3. What is the most effective model of community-based care for patients with alcohol-related liver disease?
4. What is the patient's experience of alcohol-related liver disease?
5. Do attitudes to perceived 'self-induced illness' amongst healthcare professionals affect treatment, care provision and compassion for individuals with alcohol-related liver disease?
6. What are the most effective strategies to reduce the risk of alcohol-related liver disease in heavy drinkers?
7. Does the stigma associated with alcohol misuse affect the willingness of people with alcohol-related liver disease to ask for help?
8. What interventions improve survival in individuals with complications of advanced alcohol-related cirrhosis?
9. How should depression be managed in the context of alcohol-related liver disease?
10. What models of involvement of palliative care services in advanced alcohol-related liver disease are most beneficial?