


BMJ Open Codesign and implementation of an equity-promoting national health literacy programme for people living with inflammatory bowel disease (IBD): a protocol for the application of the Optimising Health Literacy and Access (Ophelia) process

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ABSTRACT

Introduction Non-government organisations (NGOs) often represent people who are underserved or experiencing vulnerability. Crohn's & Colitis Australia (CCA) is aware that many Australians with inflammatory bowel disease (IBD) are not reached by current communication and engagement activities. The aim of the CCA IBD project is to implement the Optimising Health Literacy and Access (Ophelia) process over 3 years to collaboratively codesign ways to improve delivery of information, services and resources for people with IBD and their carers.

Methods and analysis Health literacy and other data for phase 1 will be collected using the Health Literacy Questionnaire, eHealth Literacy Questionnaire, IBD-related questions and qualitative interviews with people with IBD and their carers to ascertain their lived experience. Quantitative data will be analysed using descriptive statistics and cluster analysis. Identified clusters will be combined with qualitative data to develop vignettes (narratives of people's experiences of living with IBD) for stakeholder workshops to generate ideas for useful, accessible and sustainable solutions for identified health literacy needs. Selection and testing of health literacy actions happens in phase 2 and implementation and evaluation in phase 3 (2021–2023). Outcomes of this project include giving voice to people living with IBD, their carers and frontline healthcare practitioners. Genuine codesign informs the development and implementation of what is needed and wanted to improve access to and availability and quality of information and resources that support people to manage their health. There is potential for other NGOs to use the CCA Ophelia model in other health contexts to improve engagement with and understanding of the needs of the people they serve and to reduce health inequalities and improve health outcomes.

Ethics and dissemination Ethics approval for Ophelia phase 1 has been obtained from the Human Research Ethics Committee of Swinburne University of Technology

Strengths and limitations of this study

- The project, through Crohn's & Colitis Australia, will engage a large number of diverse stakeholders (people with lived experience through to healthcare practitioners in metropolitan and rural settings) in codesign of better information and services that work well for both people with inflammatory bowel disease (IBD), their carers and service providers.
- This project uses the Optimising Health Literacy and Access process, which is a well-tested needs assessment and intervention design method that uses bottom-up through to top-down engagement of stakeholders and genuine codesign to ensure all voices are heard and are part of creating useful and wanted solutions.
- A potential limitation of the study is if the phase 1 recruitment procedures do not reach community members who are most in need of support to manage their IBD.
- A limitation of the study is that data collection will be in English only, which means the IBD management needs of non-English-speaking community members may not be captured.

(Ref: 20202968–4652) and by the South West Sydney Local Health District Research and Ethics Office for the purposes of questionnaire recruitment at Liverpool Hospital (Ref: 20202968–4652). Dissemination of the study findings will be the national codesign process and ownership development across the CCA community and through the genuine engagement of clinicians and relevant managers across Australia. The model and process will be directly distributed to international IBD associations and to other NGOs. It will also be disseminated through publication in a peer-reviewed journal, conference presentations

and public reports on the CCA and Swinburne University of Technology website.

INTRODUCTION

Non-government organisations (NGOs) represent the interests of the communities they serve, whether this be locally, nationally or internationally.¹ The role of a community sector NGO is to give voice to its community through citizen engagement, community development, advocacy and provision of information and services.² The people represented by NGOs are often underserved or experiencing vulnerability, including people living with chronic health conditions, and research efforts are often met with the difficulty of reaching those most in need.^{3,4} A recent quality of care initiative has been undertaken by Crohn's & Colitis Australia (CCA)⁵ to apply health literacy principles to better understand the experiences of people living with inflammatory bowel disease (IBD) and address the priority action to improve patient knowledge, as identified in the Australian Government's IBD National Action Plan 2019.⁶⁻⁹ CCA is a national Australian NGO that represents and provides services to people with IBD. However, access to IBD information and care is inequitable, and CCA is aware that there are many Australians with IBD who are not reached by current communication and engagement activities.^{8,10}

IBD in Australia

More than 85 000 Australians live with IBD, a group of chronic relapsing gastrointestinal disorders,^{11,12} the two main forms of which are Crohn's disease and ulcerative colitis. IBD can be diagnosed at any age but most frequently between the ages of 15 and 29 years.¹³⁻¹⁵ Symptoms can be severe and debilitating, and can cause life-long effects on individuals' physical, emotional and social well-being, especially for young people and other vulnerable populations. Due to the nature of IBD, life-long management is required, and medical and lifestyle interventions can be complex and intrusive on people's ability to live their life in the way they wish.¹⁶⁻¹⁹ Optimal self-management of health related to IBD often relies on the capacities of individuals, their engagement with health-care professionals and the expertise of the not-for-profit organisations (such as CCA) that people depend on for multidisciplinary support, information and resources.

People living with IBD seek information relating to their disease and its management.^{20,21} It is known that people with IBD report a need for more information from their health professionals about medications and side effects, diet, disease complications and how to access IBD nurses.^{22,23} Studies also show that information to support self-management is needed for accessing advice and support from allied health professionals (eg, psychologists and dietitians) and IBD communities, including those that are based online.²²⁻²⁴ It is also important to recognise that information needs depend on several factors, including the stage (eg, prediagnosis and postdiagnosis) and status of disease (eg, active and remission).²²

Despite the importance of these information needs, people living with IBD report that access to information is lacking, especially for people experiencing vulnerability (eg, young people).^{23,25}

Self-management efforts are likely to be hindered by patient-related issues including health literacy or system-related issues such as services being perceived as not accessible or not responding to people's needs. In addition, self-management may also be affected by the COVID-19 pandemic. This includes concerns relating to accessing medical care and medications and fears about being susceptible to getting COVID-19 while taking immunosuppressive medications. CCA is well placed to support people with IBD to manage their condition throughout their lives through improving IBD health information materials, services and resources and by being responsive to the health literacy needs and strengths of the IBD community.

Crohn's & Colitis Australia

CCA is an Australian not-for-profit organisation that seeks to empower people to live life to its full potential as the search for causes and cures continues. As a community organisation that undertakes a comprehensive range of activities for and on behalf of people living with IBD, CCA provides information, education, support services and advocacy for people with IBD and their families or carers. It is an NGO that engages with the IBD community across the lifespan and operates in partnership with clinicians, government and industry to generate system change for improved quality of care, raise awareness of the IBD lived experience, and build research capacity in the search for a cause and cure.

The Optimising Health Literacy and Access (Ophelia) process

The Ophelia process^{26,27} is a codesign approach that uses multidimensional health literacy or digital health literacy questionnaires, the Health Literacy Questionnaire (HLQ)²⁸ and the eHealth Literacy Questionnaire (eHLQ)²⁹ to investigate the health literacy strengths, limitations and preferences of individuals and groups of people. The Ophelia process explores ways in which materials, resources and interventions could be designed and disseminated to be accessible, sustainable and useful solutions for the people who need them. It is also a model of collaboration that builds on local knowledge and wisdom to develop health literacy-informed interventions directly based on the needs identified within a community.³⁰⁻³⁴ A capacity building approach is used to support and enable organisations and health services to identify health literacy strengths and needs, codesign and develop interventions, and then implement and evaluate those interventions.³⁵⁻³⁷

Ophelia has three phases (figure 1).^{26,27} All phases involve close collaboration with key stakeholders including community members and frontline practitioners.^{26,27} Each Ophelia project seeks to improve health and equity by increasing the availability and accessibility of health

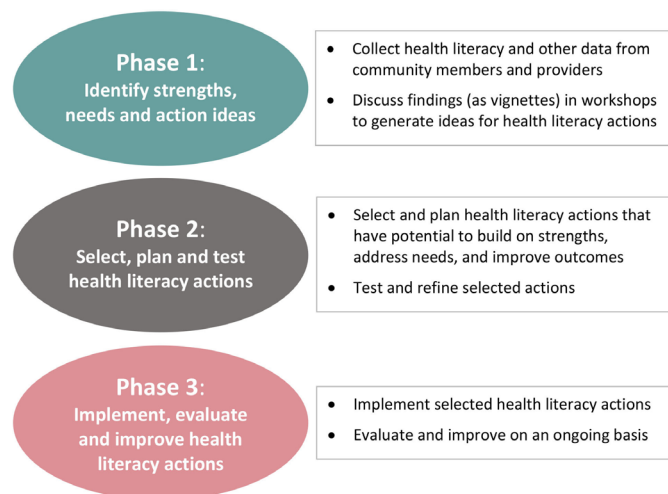


Figure 1 The three phases of the Optimising Health Literacy and Access process.

information and services in ways that are appropriate to people's diverse circumstances, strengths, limitations and preferences. The Ophelia process has previously been used in Australia^{31 32 37 38} and internationally,^{30 35 39 40} as well as being the foundation of the WHO National Health Literacy Demonstration Projects, conducted under the auspices of the WHO Global Coordination Mechanism on the prevention and control of non-communicable diseases (<https://www.who.int/groups/gcm>).³⁴

Rationale

Despite having provided information, services and resources for more than 35 years, CCA continues to seek to understand the experiences of people with IBD and to improve how it supports people to manage their health. A health literacy approach that has a focus on the diversity of health literacy strengths, limitations and preferences in the community can reveal the types and formats of health information and services that are needed, as well as barriers to health information and services for members of diverse communities.^{30 31 34 41–47} Typically, educational resources produced by governments and NGOs are text-based written materials such as newsletters and websites. Such materials are most easily found and used by well-educated and/or technologically capable individuals and may therefore generate health inequities.⁴⁸ Health literacy is a person's (or a family's, workplace's or community's) ability to find, understand, appraise, remember and use health information and services. Health literacy responsiveness describes the way in which policies, services, environments and products make health information and services available and accessible to people with different health literacy strengths and limitations. Health literacy is a useful framework for CCA to listen to the voice of the people they serve, explore the reach and impact of educational materials and to understand the needs of communities and how products and services can be redesigned or built to optimise their utility and reach, and therefore reduce health inequities.

The aim of the CCA Consumer Education and Awareness of IBD (CEA-IBD) project is to implement the Ophelia process over 3 years to collaboratively codesign ways to improve CCA's delivery of information, services and resources for people with IBD and their carers. The study has two overarching research questions:

1. What are the health literacy strengths and needs of people with IBD and their carers, including underserved and vulnerable populations, that may affect their ability and willingness to access and use CCA services and resources (Ophelia phase 1)?
2. What are the key actions that CCA can do in response to the identified health literacy needs to improve access to and use of CCA services and resources and progress equitable health outcomes (Ophelia phases 2 and 3)?

METHOD

Collaborative development of the protocol

For this project, CCA commissioned researchers at Swinburne University of Technology who developed and refined the Ophelia process. Protocol development involved extensive consultation with CCA and its board, advisory committees, community members and other partners. In particular, these consultations aimed to: (A) identify population groups that have been challenging to engage effectively, (B) identify means of obtaining the participation of these groups and (C) identify knowledge limitations that are well known and/or potentially high impact. Groups identified through the consultations to be specifically included in recruitment strategies included young people 15–18 years who are learning to independently manage their health; rural and regional people; migrants and refugees who struggle to navigate the healthcare system; and parents and carers of people with IBD.

Study design

Phase 1 of the Ophelia process²⁶ uses a mixed method design to identify health literacy strengths and needs and to generate action ideas. Data collected using the HLQ and eHLQ and analysed using cluster analysis will establish health literacy profiles of community members. These data are combined with insights from interviews to develop vignettes, which are evidence-based but fictional case studies. The vignettes portray health literacy profiles and lived experiences of people with IBD when trying to understand, access and use health information and services across a range of demographic and medical circumstances. The vignettes are discussed at workshops to generate ideas to improve people's health literacy and to improve the health literacy responsiveness of services. It is expected that ideas will fall broadly into four categories: ideas for health literacy actions for individuals, clinical settings, community settings and policy settings.²⁷

In phase 2 of the Ophelia process,²⁶ ideas generated in phase 1 will be selected to develop into health literacy actions that are meaningful and appropriate for the identified CCA and consumer needs and desired outcomes. A programme logic^{49 50} for each selected action will be developed to identify the mechanisms by which the health literacy actions may produce the beneficial outcomes. Based on the programme logic, a rapid literature review and examination of related theory will be conducted to assess the evidence base for the selected health literacy actions, as well as existing resources and relevant training.²⁶ All information will be revised by the CCA project team and advisory committee to make a final selection of health literacy actions (or a suite of actions) for implementation and evaluation in phase 3. The selected actions will then be designed, planned and refined (using plan–do–study–act or PDSA cycles), and the necessary training, guidelines, documentation and resource allocation will be developed.

In phase 3, the planned health literacy actions will be implemented and evaluated according to the Ophelia protocol.²⁶ Quantitative data will be collected using the HLQ and eHLQ scales used in phase 1, as well as other measurement scales that are relevant to expected outcomes.²⁷ Qualitative data will be collected through focus groups or interviews with key stakeholders (people with IBD and their carers) to understand how the health literacy actions may affect access to and engagement with IBD health information and services. Depending on the number and complexity of actions selected, time will be needed to allow for full implementation, evaluation at all stages of implementation, and data collection, analysis and reporting.

The expected timeline for the three phases is as follows:

- ▶ Phase 1: March 2020–April 2021.
- ▶ Phase 2: May 2021–December 2021.
- ▶ Phase 3: January 2022–September 2023.

Participants

People (15 years and older) who are living with IBD and carers of people with IBD will be included in phase 1 data collection. People unwilling or unable to provide informed consent will be excluded. Recruitment will be through advertisement on the CCA website and the membership network (including paper versions of the questionnaire), as well as via social media, community services and health services to target people with IBD and carers who have not connected to the CCA network. At the end of the questionnaire, participants will be able to indicate their interest in taking part in a follow-up telephone interview and/or a workshop. In order to be contacted to take part in interviews or workshops, participants will need to provide their name, telephone number and email address for a researcher to contact them. The purpose of this recruitment strategy is to enable data collection to identify the supports that a diverse range of people need to manage their IBD.

Identify strengths, needs and action ideas

The data collection period for phase 1 will be from 10 August to 31 October 2020. There are two versions of the questionnaire: one is for people living with IBD and one is for carers of people with IBD. The questionnaire for people living with IBD will consist of the full HLQ, one scale of the eHLQ, IBD-related questions including experience and knowledge, the Manitoba Inflammatory Bowel Disease Index (MIBDI) (a single item patient-defined disease activity measure),⁵¹ two open-ended questions (developed by the researchers for this project) about information needs and looking after health during the COVID-19 pandemic and demographic questions. The version for carers is the same except the HLQ carer and IBD experience questions for carers are used and the MIBDI is not included. The questionnaire will be administered through a secure online platform, and a link to the survey will be on the CCA website or participants can receive and return a paper version by mail. It will take participants up to 20 min to complete the questionnaire.

A range of strategies will be used to maximise the phase 1 recruitment of people most in need of support to manage their IBD. These strategies will include accessing relevant organisations through the professional networks of CCA and the project advisory committee, as well as other recommended recruitment channels. Agreement has been reached with the Royal Flying Doctor Service of Australia to promote the study, which will improve recruitment of people from rural areas. Ethics approval (phase 1) has been obtained to promote the study in two institutions that serve populations of interest: a hospital that serves a culturally and demographically diverse population and a large health service that includes a children's hospital from which people 15+ years and their carers can be recruited. A range of advertising activities will be undertaken (eg, online and direct mailout, social media, newsletters and websites).

The HLQ has been developed, and validity has been tested in multiple studies.^{28 52–59} It has 44 items in nine scales (four to six items per scale). Scales 1–5 use four-point response options (score range 1–4; *strongly disagree* to *strongly agree*). Scales 6–9 use five-point response options (score range 1–5; *cannot do or always difficult* to *always easy*). Results are the nine scale scores. Scores for each scale are summed and divided by the number of items in each scale with all items having equal weighting. Lower scale scores indicate potential need and higher scale scores indicate potential strengths. The low and high levels of each HLQ scale score are displayed in [table 1](#). In addition to the HLQ, the eHLQ scale 5 (motivated to engage with digital services) will be added to capture a sense of how comfortable, confident or motivated respondents are when attempting to use digital resources and services. The eHLQ is based on the seven dimensions of the eHealth Literacy Framework and was developed simultaneously in Danish and English with ongoing psychometric testing.^{29 60} Scale 5 (five items) uses four-point response options (*strongly disagree* to *strongly agree*).

Table 1 Health Literacy Questionnaire (HLQ) scale descriptions

HLQ scale	Low scale score	High scale score
1. Feeling understood and supported by healthcare providers	Unable to engage with doctors and other healthcare providers. Does not have a regular healthcare provider and/or has difficulty trusting healthcare providers as a source of information and/or advice.	Has an established relationship with at least one healthcare provider who knows them well and who they trust to provide useful advice and information and to assist them to understand information and make decisions about their health.
2. Having sufficient information to manage my health	Feels that there are many gaps in their knowledge and that they do not have the information they need to live with and manage their health concerns.	Feels confident that they have all the information that they need to live with and manage their condition and to make decisions.
3. Actively managing my health	Does not see their health as their responsibility, they are not engaged in their healthcare and regard healthcare as something that is done to them.	Recognises the importance and are able to take responsibility for their own health. They proactively engage in their own care and make their own decisions about their health. They make health a priority.
4. Social support for health	Completely alone and unsupported for health.	A person's social system provides them with all the support they want or need for health.
5. Appraisal of health information	No matter how hard they try, they cannot understand most health information and get confused when there is conflicting information.	Able to identify good information and reliable sources of information. They can resolve conflicting information by themselves or with help from others.
6. Ability to actively engage with healthcare providers	Are passive in their approach to healthcare, inactive, that is, they do not proactively seek or clarify information and advice and/or service options. They accept information without question. Unable to ask questions to get information or to clarify what they do not understand. They accept what is offered without seeking to ensure that it meets their needs. Feel unable to share concerns. Does not have a sense of agency in interactions with providers.	Is proactive about their health and feels in control in relationships with healthcare providers. Is able to seek advice from additional healthcare providers when necessary. They keep going until they get what they want. Empowered.
7. Navigating the healthcare system	Unable to advocate on their own behalf and unable to find someone who can help them use the healthcare system to address their health needs. Does not look beyond obvious resources and has a limited understanding of what is available and what they are entitled to.	Able to find out about services and supports so they get all their needs met. Able to advocate on their own behalf at the system and service level.
8. Ability to find good health information	Cannot access health information when required. Is dependent on others to offer information.	Is an 'information explorer'. Actively uses a diverse range of sources to find information and is up to date.
9. Understanding health information well enough to know what to do	Has problems understanding any written health information or instructions about treatments or medications. Unable to read or write well enough to complete medical forms.	Is able to understand all written information (including numerical information) in relation to their health and able to write appropriately on forms where required.

The score is calculated by summing the item scores and dividing by 5, with a score range of 1–4. A lower score on this scale indicates less motivation to engage with digital services and a higher score indicates higher motivation to engage with and use digital services to manage health.

The IBD experience and knowledge questions will be selected or developed in consultation with IBD health professionals to inform the development of vignettes for the ideas generation workshops. The MIBDI measure has shown a high degree of sensitivity for classifying individuals with IBD and strong convergent validity with

expected proxy measures of disease, and these relationships remained consistent over time.⁵¹ An open-ended question will enable respondents to state their main information needs: *for someone in your situation, what information is, or would be, the most useful to you?* A second open-ended question, designed by the researchers, will be included to gauge how the COVID-19 pandemic may have affected the way people manage IBD: *has the COVID-19 pandemic changed the way you look after your health? (Yes – please describe/No)*. Demographic questions will be included.

Telephone interviews

Telephone interviews will be conducted to provide contextual data about people's experiences of living with or caring for someone with IBD to assist with writing the vignettes. Up to 20 people with IBD or carers who volunteer their contact details will be invited to take part in the interviews. Interviews and workshops will be audio recorded with permission from participants. Interviews will take about 30 min to complete.

Ideas generation workshops

The vignettes developed from phase 1 quantitative data and interview narratives will be presented to stakeholders (community members, carers and health professionals) in workshops to generate ideas for ways to improve information and services for people with IBD.

The workshops will be about 2.5 hours and, to comply with Australian Government public health measures in response to the COVID-19 pandemic, will be conducted via a web conferencing facility. The goal will be to have up to four workshops with about 30 people with IBD or their carers and four workshops with about 30 health professionals.

There are four questions that guide the discussion: 'Do you recognise people like this in your community?' or 'Do you see people like this in your clinic?'; 'What sorts of issues is this person facing?'; 'What strategies could you use for an individual like this?'; and 'What could your organisation or community organisations do if you had many clients like this in your organisation or community?'

To get further insights into the information needs of people with IBD and how these needs can be met by CCA across clinical and health communities, up to 50 more health professionals will be sent a survey of the vignettes and four workshop questions. Dissemination of the survey will be through professional networks.

Data analysis

Descriptive statistics of the characteristics of participants and the HLQ and eHLQ scores will be analysed using SPSS V.27.⁶¹ To identify the different health literacy profiles for the development of vignettes, a cluster analysis will be undertaken using Ward's method for linkage, according to the Ophelia protocol.^{26 27} Cluster analysis is an analytical method used to examine multivariate data and identify groups of homogeneous observations.^{62 63} This method is used to ensure equity planning so that different health literacy needs are addressed. The analysis will be based on the 10 scales of the HLQ and eHLQ data. For treatment of missing values, the expectation maximisation algorithm will be used to impute missing item scores if there are fewer than 50% of missing values in a scale.⁶⁴ As the cluster analysis is based on the 10 scales, any participant with one or more scale scores missing will be excluded from the analysis.

There is no consensus on the adequate sample size for a stable solution.⁶⁵ However, our experience from many Ophelia studies indicates that sample sizes of over 100

will generate rich information about potential subpopulations of people.^{37 41 44} We expect over 200 complete surveys will be collected, which will enable exploration of subgroup differences across the community. A total of 3–20 cluster solutions will be explored. The selection of the optimal solution will be based on examination of the pattern of the different cluster solutions, the SD of the scores and the demographic data linked to each cluster. Linking of the demographic data is essential because people with similar health literacy profiles but different demographics can require different intervention strategies.^{26 27} Consequently, the optimal number of clusters is based both on quantitative, clinical and qualitative judgements. The cluster selection process will be undertaken by CC and reviewed by at least two other members of the research team. Basic epidemiological descriptive analyses such as means, SD and statistical differences between groups (eg, metropolitan/rural) will be conducted. Vignettes for ideas generation workshops are developed from the health literacy profiles of the selected clusters and qualitative data from interviews of people within each cluster.

The ideas generated from discussion about the vignettes in the workshops will be categorised into actions for individuals, clinical settings (eg, improving access and use opportunities and clinician interactions with patients), community settings (eg, improving community information and services and supporting individuals to care for their health) and policy settings.^{26 66} The analysis will be undertaken by MH and reviewed by at least two other members of the research team. The health literacy actions to be implemented and evaluated in phase 3 will be determined by the outcome of phase 2 activities.

Patient and public involvement

Community members, including people with IBD and their carers, will be involved in the entire process of this codesign study. They were part of the consultation group in the development of the initial proposal and this protocol. Community members and healthcare professionals will be involved in the generation of ideas for health literacy interventions and throughout the process of selection and implementation of the interventions.

DISCUSSION

As consumer advocacy organisations, NGOs must understand and meet the needs of their communities and partner with stakeholders to deliver system change. The reality for CCA is that it best serves the needs of people who are already engaged with its communications and programmes. The needs of the CCA community are identifiable. To support the needs of people with IBD who are not yet engaged requires a new and evidence-based approach.⁹ The Ophelia process is a systematic way in which to generate an evidence-based strategy because it has an emphasis on investigating local issues in context and tailoring health literacy responses to specific needs.

In particular, it has a focus on bottom-up codesign with the people who live every day with targeted health conditions, such as IBD, and those who have extensive experience working with or caring for these people. The Ophelia process aims to derive organisational reform and communications and engagement approaches to better respond to the health equity divide between people with different health literacy strengths, limitations and preferences. This protocol describes the Ophelia process for the CCA CEA-IBD project, but the Ophelia process is relevant to other NGOs (in Australia and in other countries) that are looking to meet the needs of the communities they serve and to support their members to manage their health on a daily basis.

BreastScreen Victoria has previously applied the Ophelia process to stimulate organisational reform. Among other activities, this included seeking the voice of women in diverse cultural groups who experience barriers to breast cancer screening⁴¹ and then codesigning solutions to these barriers, which generated 10-fold increases in screening among Arabic and Italian speaking women.³¹ The Irish Heart Foundation,⁶⁷ the Portuguese Diabetes Association⁶⁸ and Santé Diabète in Mali⁶⁹ are NGOs currently implementing the Ophelia process and including wide ranges of community stakeholders to better understand the needs of and codesign solutions with the people they serve. The Ophelia process brings together stakeholders from across communities and political landscapes so that all perspectives can feed into local solutions that are appropriate for local problems.^{27 30 32–35 37}

The results from phase 1 inform and set the scene for Ophelia phases 2 and 3. Discussions about phase 1 data, presented in the form of vignettes to stakeholders in the workshops, often generates hundreds of intervention ideas. These ideas come from the experience, knowledge and wisdom of local people who are managing their health on a daily basis and the health professionals who work closely with individuals living with their health conditions. In phase 2, the solutions ideas are sorted, prioritised and codesigned by stakeholders into interventions for implementation and evaluation in phase 3. Accumulation, sharing and scaling up of useful ideas occurs through communities of practice that can develop across health services and communities.

A potential limitation of this study is if the phase 1 recruitment procedures do not reach a diverse range of community members and people experiencing vulnerability (eg, young people, rural) who are among those most in need of support to manage their IBD. Also, data collection for this study will be in English only, which means that the IBD management needs of non-English-speaking community members will not be represented. The study will aim to mitigate this bias by inviting members of cultural groups connected to CCA to the ideas generation workshops. Future research in the IBD community using data collection instruments in other languages and translators or bilingual workshop facilitators is warranted.

Potential implications of the CCA Ophelia project include, importantly, that people who are living with and managing their IBD have their voice heard and that practice and policy can be improved to better reach and engage people who have not previously engaged with CCA. Also, this process will inform CCA (and other Australian and international NGOs working with people with IBD) about the types of resources and information that people need to manage their health while living with IBD. More broadly, the CCA Ophelia model could be used by other NGOs in other health contexts to improve engagement with and better understand of the needs of the people they serve. Understanding the health literacy of communities, especially people who are underserved and experiencing vulnerability, has the potential to reduce health inequalities and improve health outcomes.

ETHICS AND DISSEMINATION

Ethics approval for Ophelia phase 1 has been obtained from the Human Research Ethics Committee of Swinburne University of Technology (Ref: 20202968–4652) and also from the South West Sydney Local Health District Research and Ethics Office for the purposes of questionnaire recruitment at Liverpool Hospital (Ref: 20202968–4652). Written informed consent will be obtained from all participants. Ethics approval for phases 2 and 3 will be sought after phase 1 when actions for implementation and evaluation have been selected. This study is designed to comply with Australian Government public health measures in response to the COVID-19 pandemic and will be reviewed as required. No individual will be identified in reports or papers presenting results of the project. Dissemination of study findings will be through the national codesign process and ownership development across the CCA community and through the genuine engagement of clinicians and relevant managers across Australia. The model and process will be directly distributed to international IBD associations and to other NGOs. It will also be disseminated through publication in peer-reviewed journals, conference presentations and public reports on the CCA and Swinburne University of Technology websites.

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Contributors Conceptualisation: LR, WM, RHO, RB, MH, RGN, GTM and SK; study design: RB, RHO, MH, CC, WM and LR; analytical plan: CC, RB, MH and RHO; project administration: MH, RGN and WM; inflammatory bowel disease strategy and policy: WM and LR; clinical advice and guidance: GTM and SK; funding acquisition: LR, WM, GTM, SK, RHO and RGN; writing (original draft preparation and iterations): MH, CC, RB, RHO and WM; writing (review and editing): all authors critically reviewed manuscript iterations. All authors have read and approved the final manuscript.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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