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# Co-design and implementation of an equity-promoting national health literacy program 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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Title: Co-design and implementation of an equity-promoting national health literacy program 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 underserved or vulnerable populations. Crohn’s & Colitis Australia (CCA) is aware that many Australians with inflammatory bowel disease (IBD) are not reached by current communication and engagement activities. This protocol describes Phase 1 of the Optimising Health Literacy and Access (Ophelia) process to co-design IBD information, services and resources to support people to manage their IBD.

Methods and analysis

Health literacy needs assessment data will be collected using the Health Literacy Questionnaire (HLQ), eHealth Literacy Questionnaire (eHLQ), 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. Intervention co-design and implementation happens in Ophelia Phases 2 and 3 (2021 – 2023). Outcomes of this project include giving voice to people living with IBD, their carers, and frontline practitioners. Genuine co-design 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652) and by the South West Sydney Local Health District (SWSLHD) 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 co-design 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.

Article summary

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 practitioners in metropolitan and rural settings) in co-design 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 (Ophelia) 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 co-design to ensure all voices are heard and are part of creating useful and wanted solutions.

- A potential limitation of the study is if the needs assessment recruitment procedures do not reach vulnerable and diverse community members who are among those 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.

Keywords:

Health literacy; non-government organisation; co-design; inflammatory bowel disease; IBD; Crohn’s disease; ulcerative colitis; chronic disease; Ophelia
Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Optimising Health Literacy and Access (Ophelia) process

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 vulnerable populations, including people living with chronic health conditions, and research efforts are often met with the difficulty of reaching those most in need.³⁴ 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 National IBD 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.⁸¹⁰

Inflammatory Bowel Disease in Australia

More than 85,000 Australians live with IBD, a group of chronic relapsing gastrointestinal disorders,¹¹ 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 30 years, with no known cause or cure.¹³¹⁴ Symptoms can be severe and debilitating, and can cause lifelong effects on individuals’ physical, emotional and social wellbeing, especially for young people and other vulnerable populations.

Patients regularly seek additional information to that provided by their treating clinicians. Self-management of IBD often relies on the capacities of individuals, their engagement with healthcare professionals, and the multidisciplinary expertise of the not-for-profit organisations (such as CCA) that people depend on for support, information and resources.

IBD is a disease that must commonly be managed for life, and both medical and lifestyle management can be complex and intrusive on people’s ability to live their life in the way they wish.¹⁵⁻¹⁸ 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. 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)**

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.

**Health literacy**

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 focuses on the diversity of health literacy strengths, limitations and preferences in the community can reveal the types and formats of health information that are needed, as well as barriers to health information and services for members of diverse communities. 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 inequalities. Health literacy is a person’s (or a family’s, workplace’s or community’s) ability to understand, find, 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 NGOs to 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 inequalities.

**The Optimising Health Literacy and Access (Ophelia) process**

The Optimising Health Literacy and Access (Ophelia) process is a co-design approach that uses multi-dimensional health literacy or digital health literacy questionnaires, the Health Literacy Questionnaire (HLQ) and the eHealth Literacy Questionnaire (eHLQ), to investigate the health literacy strengths, limitations and preferences of individuals and groups of people (see Table 1). 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. A capacity building approach is used to support and enable organisations and health services to identify health literacy strengths and needs, co-design and develop interventions, and then implement and evaluate those interventions.

Table 1. The scales of the Health Literacy Questionnaire (HLQ) and the eHealth Literacy Questionnaire (eHLQ)

| Health Literacy Questionnaire (HLQ) |  |
|-------------------------------------|---|
| 1. Feeling understood and supported by healthcare providers |  |
| 2. Having sufficient information to manage my health |  |
| 3. Actively managing my health |  |
| 4. Social support for health |  |
| 5. Appraisal of health information |  |
| 6. Ability to actively engage with healthcare providers |  |
| 7. Navigating the healthcare system |  |
| 8. Ability to find good health information |  |
| 9. Understand health information well enough to know what to do |  |

| eHealth Literacy Questionnaire (eHLQ) |  |
|--------------------------------------|---|
| 1. Using technology to process health information |  |
| 2. Understanding of health concepts and language |  |
| 3. Ability to actively engage with digital services |  |
| 4. Feel safe and in control |  |
| 5. Motivated to engage with digital services |  |
| 6. Access to digital services that work |  |
| 7. Digital services that suit individual needs |  |

Ophelia has three main phases: needs assessment and generation of intervention ideas (Phase 1), co-design of health literacy interventions and implementation planning (Phase 2), and intervention implementation and evaluation (Phase 3) (see Figure 1). All phases involve close collaboration with key stakeholders including community members and frontline practitioners. Each Ophelia project seeks to improve health and equity by increasing the availability and accessibility of health 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 and internationally, as well as being the foundation of the World Health Organization National Health Literacy Demonstration Projects (NHLDP).
Figure 1. The three phases of the Optimising Health Literacy and Access (Ophelia) process

Rationale

Health literacy has become a focus of community groups, health and community services, researchers, and governments around the world as a way to reduce health inequalities and reform health care.\textsuperscript{40-46} NGOs such as CCA have the opportunity to improve their responsiveness to the health literacy of their communities to improve access and better support the health management needs of the people who are in most need of help. Recent work with the concept of health literacy in public health and health service settings has emphasised integration of health knowledge and care into the activities and settings of usual daily life.\textsuperscript{30,47} This approach is ideally suited to organisations such as CCA that seek to partner with their communities in exactly this way. It is therefore critical that health literacy approaches in NGO settings bring the voices of the people they serve to organisational strategies to strengthen and improve service provision and health promotion activities.\textsuperscript{3,48}

The CCA project will implement the Ophelia process over 3 years to improve CCA’s delivery of information, services and resources for people with IBD and their families and carers. This paper outlines two overarching research questions and related procedures for Phase 1:

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?
2. What can CCA do in response to the Phase 1 data to improve access to and use of CCA services and resources and progress equitable health outcomes?

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 to 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 process uses a mixed method design. This study starts with a needs
assessment using the HLQ and eHLQ to establish the health literacy profiles of community members.
The data are combined with insights from interviews to develop vignettes, which are case study
narratives of people’s experiences of living with IBD across a continuum of diverse health literacy
strengths and weaknesses, as defined by the cluster analysis. The vignettes portray the lived
experiences of people with IBD when trying to understand, access and use health information and
services across a wide range of demographic and medical circumstances. The vignettes are then
discussed at workshops to generate ideas to improve people’s health literacy and to improve the
responsiveness of services.

Participants

People (15 years and older) who are living with IBD and carers of people with IBD will be included in
the needs assessment. 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.

Needs assessment

The data collection period for the needs assessment will be from the beginning of August to the end
of September 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), 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 minutes to complete the questionnaire.

The HLQ has been developed and validity tested in multiple studies. It has 44 items in 9 scales (4 – 6 items per scale). Scales 1 to 5 use four-point response options (score range 1 – 4): strongly disagree, disagree, agree and strongly agree. Scales 6 to 9 use five-point response options (score range 1 – 5): cannot do or always difficult, usually difficult, sometimes difficult, usually easy, always easy. Results are the 9 scale scores. Scores for each scale are summed and divided by the number of items in each scale with all items having equal weighting. In addition to the HLQ, Scale 5 (Motivated to engage with digital services) from the eHLQ 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 7 dimensions of the eHealth Literacy Framework and was developed simultaneously in Danish and English with ongoing psychometric testing. Scale 5 (5 items) uses four-point response options: strongly disagree, disagree, agree and strongly agree. The score is calculated by summing the item scores and dividing by 5, with a score range of 1 – 4.

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 (described in the Ideas generation workshops section). 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. 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 include year born, gender, number of household members, country born, language, postcode, Aboriginal or Torres Strait Islander status, education, employment, long-standing illness status, and having a private health insurance or healthcare card.

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 minutes to complete.

Idea generation workshops

The vignettes developed from the needs assessment and interview data 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 4 workshops with about 30 people with IBD or their carers and 4 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 version 27. To identify the different health literacy profiles for the development of vignettes, a cluster analysis will be undertaken according to the Ophelia process. This is to ensure equity planning so that different health literacy needs are addressed. Cluster analysis is an analytical method used to examine multivariate data and identify groups of homogeneous observations. The analysis will be based on the ten scales of the HLQ and eHLQ data. The Ophelia process recommends hierarchical cluster analysis using Ward’s method for linkage. For treatment of missing values, the expectation maximisation (EM) algorithm will be used to impute missing item scores if there are fewer than 50% of missing values in a scale. As the cluster analysis is based on the ten 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.\textsuperscript{61} However, our experience from many Ophelia studies indicates that sample sizes of over 100 will generate rich information about potential sub-populations of people.\textsuperscript{20, 23, 38} We expect over 200 complete surveys will be collected which will enable exploration of subgroup differences across the community. A total of 3 to 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 standard deviation 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.\textsuperscript{30, 31} Consequently, the optimal number of clusters is based both on quantitative, clinical and qualitative judgments. The cluster selection process will be undertaken by CC and reviewed by at least 2 other members of the research team. Basic epidemiological descriptive analyses such as means, standard deviations (SD) and statistical differences between groups (e.g., 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 sorted into activities or strategies that focus on individual, family, practitioner, organisation or community change.\textsuperscript{30} Where possible, and in preparation for Phase 2 intervention co-design workshops, the ideas will be grouped into sets of activities and/or strategies that could potentially be implemented as packages of related actions. The analysis will be undertaken by MH and reviewed by at least 2 other members of the research team.

\textit{Patient and public involvement}

Community members, including people with IBD and their carers, will be involved in the entire process of this co-design 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.

\textbf{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 programs. 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.\textsuperscript{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 co-design 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 health literacy needs
assessment (Ophelia Phase 1) of CCA but the Ophelia process is relevant to other NGOs 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 screening and then co-designing solutions to these barriers,
which generated 10-fold increases in screening among Arabic and Italian speaking women. The
Irish Heart Foundation, the Portuguese Diabetes Association, and Santé Diabète in Mali are
NGOs currently implementing the Ophelia process and including wide ranges of community
stakeholders to better understand the needs of and co-design 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.

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 co-designed 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, communities.

A potential limitation of this study is if the needs assessment recruitment procedures do not reach
vulnerable and diverse community members (e.g., 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 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 vulnerable and underserved, 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652), and also from the South West Sydney Local Health District (SWSLHD) 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. 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 co-design 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.
References

1. Delisle H, Roberts JH, Munro M, et al. The role of NGOs in global health research for development. *Health Research Policy and Systems* 2005;3(1):1-21.

2. ACT Council of Social Service Inc. Sustaining Community Sector Value in a Vital Community Services Industry. Weston, Australian Capital Territory: ACTCOSS, 2016.

3. Elmer S, Jones R. Health literacy in the community sector project - Evaluation report: Tasmanian Council of Social Service 2016.

4. Teegen H, Doh JP, Vachani S. The importance of nongovernmental organizations (NGOs) in global governance and value creation: An international business research agenda. *Journal of International Business Studies* 2004;35(6):463-83.

5. Crohn’s & Colitis Australia. Australian IBD Standards: Crohn’s & Colitis Australia; 2020 [Available from: https://www.crohnsandcolitis.com.au/ibdqoc/australian-ibd-standards/ accessed 15 September 2020.]

6. Mikocka-Walus A, Massuger W, Knowles SR, et al. Quality of care in inflammatory bowel disease: actual health service experiences fall short of the standards. *Intern Med J* 2019

7. Crohn’s & Colitis Australia. My IBD story: Co-creating IBD care. Melbourne, Australia: Crohn’s & Colitis Australia, 2017.

8. Crohn’s & Colitis Australia. Improving inflammatory bowel disease care across Australia. Melbourne, Australia: Crohn’s & Colitis Australia, 2013.

9. Australian Government Department of Health. Inflammatory Bowel Disease National Action Plan 2019. Canberra, Australia, 2019.

10. Massuger W, Moore GT, Andrews JM, et al. Crohn’s & Colitis Australia inflammatory bowel disease audit: measuring the quality of care in Australia. *Intern Med J* 2018;49(7):859-66.

11. Wilson J, Hair C, Knight R, et al. High incidence of inflammatory bowel disease in Australia: a prospective population-based Australian incidence study. *Inflamm Bowel Dis* 2010;16(9):1550-56.

12. Studd C, Cameron G, Beswick L, et al. Never underestimate inflammatory bowel disease: high prevalence rates and confirmation of high incidence rates in Australia. *J Gastroenterol Hepatol* 2016;31(1):81-86.

13. Mak WY, Hart AL, Ng SC. Crohn’s disease. *Medicine* 2019;47(6):377-87.

14. Steed H. Ulcerative colitis. *Medicine* 2019;47(6):371-76.

15. Knowles SR, Graff LA, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part I. *Inflamm Bowel Dis* 2018;24(4):742-51.

16. Knowles SR, Keefer L, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part II. *Inflamm Bowel Dis* 2018;24(5):966-76.

17. Tormey LK, Reich J, Chen YS, et al. Limited health literacy is associated with worse patient-reported outcomes in inflammatory bowel disease. *Inflamm Bowel Dis* 2019;25(1):204-12.

18. Plevinsky JM, Greenley RN, Fishman LN. Self-management in patients with inflammatory bowel disease: strategies, outcomes, and integration into clinical care. *Clin Exp Gastroenterol* 2016;9:259.

19. Beauchamp A, Mohebbi M, Cooper A, et al. The impact of translated reminder letters and phone calls on mammography screening booking rates: Two randomised controlled trials. *PloS One* 2020;15(1):e0226610.

20. O’Hara J, McPhee C, Dodson S, et al. Barriers to Breast Cancer Screening among Diverse Cultural Groups in Melbourne, Australia. *Int J Environ Res Public Health* 2018;15(8) doi: 10.3390/ijerph15081677

21. Lim S, Beauchamp A, Dodson S, et al. Health literacy and fruit and vegetable intake in rural Australia. *Public Health Nutr* 2017;20(15):2680-84. doi: 10.1017/S1368946517001483

22. Aaby A, Friis K, Christensen B, et al. Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease.
23. Aaby A, Friis K, Christensen B, et al. Health Literacy among People in Cardiac Rehabilitation: Associations with Participation and Health-Related Quality of Life in the Heart Skills Study in Denmark. *Int J Environ Res Public Health* 2020;17(2):443.

24. Klinker CD, Aaby A, Ringgaard LW, et al. Health literacy is associated with health behaviors in students from vocational education and training schools: a Danish population-based survey. *Int J Environ Res Public Health* 2020;17(2):671.

25. Anwar WA, Mostafa NS, Hakim SA, et al. Health literacy strengths and limitations among rural fishing communities in Egypt using the Health Literacy Questionnaire (HLQ). *PLoS One* 2020;15(7):e0235550.

26. Bakker MM, Putrik P, Aaby ASE, et al. Acting together–WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Health Panorama* 2019;5(2-3):233-43.

27. Dodson S, Osicka T, Huang L, et al. Multifaceted Assessment of Health Literacy in People Receiving Dialysis: Associations With Psychological Stress and Quality of Life. *J Health Commun* 2016;21:91-98. doi: 10.1080/10810730.2016.1179370

28. Jessup RL, Osborne RH, Beauchamp A, et al. Health literacy of recently hospitalised patients: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). *BMC Health Serv Res* 2017;17(1):52.

29. Beauchamp A, Backholer K, Magliano D, et al. The effect of obesity prevention interventions according to socioeconomic position: a systematic review. *Obes Rev* 2014;15(7):541-54. doi: 10.1111/obr.12161

30. Batterham RW, Buchbinder R, Beauchamp A, et al. The OPtimising HEalth LiterAcy (Ophelia) process: study protocol for using health literacy profiling and community engagement to create and implement health reform. *BMC Public Health* 2014;14(1):694-703. doi: 10.1186/1471-2458-14-694

31. Beauchamp A, Batterham RW, Dodson S, et al. Systematic development and implementation of interventions to Optimise Health Literacy and Access (Ophelia). *BMC Public Health* 2017;17(1):230.

32. Osborne RH, Batterham RW, Elsworth GR, et al. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;13:658. doi: 10.1186/1471-2458-13-658

33. Kayser L, Karnoe A, Furstrand D, et al. A multidimensional tool based on the eHealth literacy framework: development and initial validity testing of the eHealth Literacy Questionnaire (eHLQ). *J Med Internet Res* 2018;20(2):e36.

34. Jessup RL, Osborne RH, Buchbinder R, et al. Using co-design to develop interventions to address health literacy needs in a hospitalised population. *BMC Health Serv Res* 2018;18(1):989. doi: 10.1186/s12913-018-3801-7

35. Kolarčik P, Belak A, Osborne RH. The Ophelia (OPtimise HEalth Literacy and Access) Process. Using health literacy alongside grounded and participatory approaches to develop interventions in partnership with marginalised populations. *European Health Psychologist* 2015;17(6):297-304.

36. Aaby A, Simonsen CB, Ryom K, et al. Improving Organizational Health Literacy Responsiveness in Cardiac Rehabilitation Using a Co-Design Methodology: Results from The Heart Skills Study. *Int J Environ Res Public Health* 2020;17(3):1015.

37. Jessup RL, Osborne RH, Beauchamp A, et al. Differences in health literacy profiles of patients admitted to a public and a private hospital in Melbourne, Australia. *BMC Health Serv Res* 2018;18:1-11. doi: 10.1186/s12913-018-2921-4
38. Goeman D, Conway S, Norman R, et al. Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *Journal of Diabetes Research* 2016;2016:2483263-63.

39. Bakker M, Putrik P, Rademakers J, et al. OP0257-PARE Using patient health literacy profiles to identify solutions to challenges faced in rheumatology care. *Ann Rheum Dis* 2020;79(Suppl 1).

40. World Health Organization. WHO Independent high-level commission on noncommunicable diseases: final report: it’s time to walk the talk. 2019

41. World Health Organization. Shanghai declaration on promoting health in the 2030 Agenda for Sustainable Development. *Health promotion international* 2017;32(1):7.

42. Bo A, Friis K, Osborne RH, et al. National indicators of health literacy: ability to understand health information and to engage actively with healthcare providers - a population-based survey among Danish adults. *BMC Public Health* 2014;14(1):1095.

43. Boateng MA, Angel S, Agyei-Baffour P, et al. Cultural Adaptation and Validation of the Ghanaian Language (Akan; Asante Twi) Version of the Health Literacy Questionnaire. *BMC Health Serv Res* 2020;(preprint).

44. Dodson S, Good S, Osborne RH. Health literacy toolkit for low- and middle-income countries: a series of information sheets to empower communities and strengthen health systems New Delhi: WHO Regional Office for South-East Asia; 2015 [Available from: http://www.searo.who.int/entity/healthpromotion/documents/hl_toolkit/en/ accessed 12 February 2015.]

45. Kurtz-Rossi S, Schwartz F, Alemayehu G, et al. Building Health Literacy Coalitions and NGOs. *Stud Health Technol Inform* 2020;269:258-63.

46. LaScala K, Erikson M, Sparks S, et al. Health Literacy Initiatives and Lessons Learned with NGOs: Wisconsin Health Literacy. *Stud Health Technol Inform* 2020;269:248-57.

47. Batterham R, Hawkins M, Collins P, et al. Health literacy: applying current concepts to improve health services and reduce health inequalities. *Public Health* 2016;132:3-12.

48. Thielking M, Lee S, Elmer S, et al. A house for good measure: How health researchers can play a role in improving the outcomes of people experiencing homelessness. *Parity* 2019;32(7):40.

49. Clara I, Lix LM, Walker JR, et al. The Manitoba IBD Index: evidence for a new and simple indicator of IBD activity. *Am J Gastroenterol* 2009;104(7):1754-63.

50. Debussche X, Lenclume V, Balcou-Debussche M, et al. Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk: Validity testing of the Health Literacy Questionnaire. *SAGE Open Medicine* 2018;6:2050312118801250-50. doi: 10.1177/2050312118801250

51. Kolarčik P, Cepova E, Geckova AM, et al. Structural properties and psychometric improvements of the health literacy questionnaire in a Slovak population. *International journal of public health* 2017;62(5):591-604.

52. Maindal HT, Kayser L, Norgaard O, et al. Cultural adaptation and validation of the Health Literacy Questionnaire (HLQ): robust nine-dimension Danish language confirmatory factor model. *SpringerPlus* 2016;5(1):1232 DOI 10.186/s40064-016-2887-9.

53. Nolte S, Osborne RH, Dwinger S, et al. German translation, cultural adaptation, and validation of the Health Literacy Questionnaire (HLQ). *PloS One* 2017;12(2): doi.org/10.1371/journal.pone.0172340. doi: doi: 10.1371/journal.pone.0172340

54. Wahl AK, Hermansen Å, Osborne RH, et al. A validation study of the Norwegian version of the Health Literacy Questionnaire: A robust nine-dimension factor model. *Scandinavian Journal of Public Health* 2020;1403494820926428.

55. Leslie CJ, Hawkins M, Smith DL. Using the Health Literacy Questionnaire (HLQ) with Providers in the Early Intervention Setting: A Qualitative Validity Testing Study. *Int J Environ Res Public Health* 2020;17(7):2603.
56. Norgaard O, Furstrand D, Klokker L, et al. The e-health literacy framework: a conceptual framework for characterizing e-health users and their interaction with e-health systems. Knowledge Management & E-Learning: An International Journal 2015;7(4):522-40.
57. IBM SPSS Statistics for Windows [program]. 27.0 version. Armonk, NY: IBM Corp., 2020.
58. Everitt BS, Landau S, Leese M, et al. Cluster analysis. 5th ed: John Wiley 2011.
59. Hair J, Black W, Babin B, et al. Multivariate Data Analysis 2014.
60. Beauchamp A, Buchbinder R, Dodson S, et al. Distribution of health literacy strengths and weaknesses across socio-demographic groups: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). BMC Public Health 2015;15:678.
61. Windgassen S, Moss-Morris R, Goldsmith K, et al. The importance of cluster analysis for enhancing clinical practice: an example from irritable bowel syndrome. Journal of Mental Health 2018;27(2):94-6.
62. Irish Heart Foundation. [Available from: https://irishheart.ie/ accessed 16 September 2020.
63. Associação Protectora dos Diabéticos de Portugal (APDP). [Available from: https://apdp.pt/ accessed 16 September 2020.
64. Santé Diabète. [Available from: https://santediabete.org/ accessed 16 September 2020.
Phase 1: Identify health literacy strengths and needs
- Collect health literacy and other data from community members
- Discuss results (as vignettes) in workshops to generate intervention ideas

Phase 2: Co-create health literacy interventions
- Identify and plan the interventions that have potential to address local health literacy need or improve outcomes

Phase 3: Implement interventions and evaluation cycles
- Health literacy interventions are implemented
- Interventions are evaluated on an ongoing basis
Figure 1. The three phases of the Optimising Health Literacy and Access (Ophelia) process
Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) process

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**Title:** Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) 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 Ophelia (Optimising Health Literacy and Access) process over 3 years to collaboratively co-design 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 (HLQ), eHealth Literacy Questionnaire (eHLQ), 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 co-design 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652) and by the South West Sydney Local Health District (SWSLHD) 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 co-design 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.

Article summary

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 co-design 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 (Ophelia) 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 co-design 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.

Keywords:

Health literacy; non-government organisation; co-design; inflammatory bowel disease; IBD; Crohn’s disease; ulcerative colitis; chronic disease; Ophelia
Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) process

Introduction

Non-government organisations (NGOs) represent the interests of the communities they serve, whether this be locally, nationally or internationally. 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. 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. A recent quality of care initiative has been undertaken by Crohn’s & Colitis Australia (CCA) 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. 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.

Inflammatory Bowel Disease in Australia

More than 85,000 Australians live with IBD, a group of chronic relapsing gastrointestinal disorders, 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. Symptoms can be severe and debilitating, and can cause lifelong effects on individuals’ physical, emotional and social wellbeing, especially for young people and other vulnerable populations. Patients regularly seek additional information to that provided by their treating clinicians. Self-management of IBD often relies on the capacities of individuals, their engagement with healthcare professionals, and the multidisciplinary expertise of the not-for-profit organisations (such as CCA) that people depend on for support, information and resources.

IBD is a disease that commonly requires life-long management, and both medical and lifestyle interventions can be complex and intrusive on people’s ability to live their life in the way they wish. 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.
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)**

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 Ophelia (Optimising Health Literacy and Access) process**

The Ophelia process\citep{20,21} is a co-design approach that uses multi-dimensional health literacy or digital health literacy questionnaires, the Health Literacy Questionnaire (HLQ)\citep{22} and the eHealth Literacy Questionnaire (eHLQ),\citep{23} 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.\citep{24-28} A capacity building approach is used to support and enable organisations and health services to identify health literacy strengths and needs, co-design and develop interventions, and then implement and evaluate those interventions.\citep{29-31}

Ophelia has three phases (Figure 1).\citep{20,21} All phases involve close collaboration with key stakeholders including community members and frontline practitioners.\citep{20,21} Each Ophelia project seeks to improve health and equity by increasing the availability and accessibility of health 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\citep{25,26,31,32} and internationally\citep{24,29,33,34}, as well
as being the foundation of the World Health Organization (WHO) National Health Literacy Demonstration Projects (NHLDP), conducted under the auspices of the WHO Global Coordination Mechanism (GCM) on the prevention and control of noncommunicable diseases (NCDs) (https://www.who.int/groups/gcm).

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

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. 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. Health literacy is a person’s (or a family’s, workplace’s or community’s) ability to understand, find, 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 Crohn’s & Colitis (CCA) Consumer Education and Awareness of IBD (CEA-IBD) project is to implement the Ophelia (Optimising Health Literacy and Access) process over 3 years to collaboratively co-design 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 to 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 process\(^2^0\) 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 then 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.\(^2^1\)

In Phase 2 of the Ophelia process\(^2^0\), 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 program logic\(^4^3\)\(^4^4\) 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 program 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. 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. 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. 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 to April 2021
- Phase 2: May 2021 to December 2021
- Phase 3: January 2022 to 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), 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 minutes 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 (e.g., online and direct mailout, social media, newsletters and websites).

The HLQ has been developed and validity tested in multiple studies. It has 44 items in 9 scales (4 – 6 items per scale). Scales 1 to 5 use four-point response options (score range 1 – 4; strongly disagree to strongly agree). Scales 6 to 9 use five-point response options (score range 1 – 5; cannot do or always difficult to always easy). Results are the 9 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 7 dimensions of the eHealth Literacy Framework and was developed simultaneously in Danish and English with ongoing psychometric testing. Scale 5 (5 items) uses four-point response options (strongly disagree to strongly agree). 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.

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. Doesn’t 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 don’t 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          | Doesn’t 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 i.e., they do not proactively seek or clarify information and advice and/or service options. They accept information without question. Unable to ask questions to | Is proactive about their health and feels in control in relationships with healthcare providers. Is able to seek advice from additional healthcare providers when |
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.

| 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. |

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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. 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 minutes 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 4 workshops with about 30 people with IBD or their carers and 4 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 version 27. 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. Cluster analysis is an analytical method used to examine multivariate data and identify groups of homogeneous observations. This method is used to ensure equity planning so that different health literacy needs are addressed. The analysis will be based on the ten scales of the HLQ and eHLQ data. For treatment of missing values, the expectation maximisation (EM) algorithm will be used to impute missing item scores if there are fewer than 50%
of missing values in a scale. As the cluster analysis is based on the ten 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. However, our experience from many Ophelia studies indicates that sample sizes of over 100 will generate rich information about potential sub-populations of people. We expect over 200 complete surveys will be collected which will enable exploration of subgroup differences across the community. A total of 3 to 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 standard deviation 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. Consequently, the optimal number of clusters is based both on quantitative, clinical and qualitative judgments. The cluster selection process will be undertaken by CC and reviewed by at least 2 other members of the research team. Basic epidemiological descriptive analyses such as means, standard deviations (SD) and statistical differences between groups (e.g., 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 (e.g., improving access and use opportunities and clinician interactions with patients), community settings (e.g., improving community information and services and supporting individuals to care for their health), and policy settings. The analysis will be undertaken by MH and reviewed by at least 2 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 co-design 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 programs. 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. 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 co-design 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 screening and then co-designing solutions to these barriers, which generated 10-fold increases in screening among Arabic and Italian speaking women. The Irish Heart Foundation, the Portuguese Diabetes Association, and Santé Diabète in Mali are NGOs currently implementing the Ophelia process and including wide ranges of community stakeholders to better understand the needs of and co-design 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.

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 co-designed 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, 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 (e.g., 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652), and also from the South West Sydney Local Health District (SWLHD) 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 co-design 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.
References

1. Delisle H, Roberts JH, Munro M, et al. The role of NGOs in global health research for development. *Health Research Policy and Systems* 2005;3(1):1-21.

2. ACT Council of Social Service Inc. Sustaining Community Sector Value in a Vital Community Services industry. Weston, Australian Capital Territory: ACTCOSS, 2016.

3. Elmer S, Jones R. Health literacy in the community sector project - Evaluation report: Tasmanian Council of Social Service 2016.

4. Teegen H, Doh JP, Vachani S. The importance of nongovernmental organizations (NGOs) in global governance and value creation: An international business research agenda. *Journal of International Business Studies* 2004;35(6):463-83.

5. Crohn’s & Colitis Australia. Australian IBD Standards: Crohn’s & Colitis Australia; 2020 [Available from: https://www.crohnsandcolitis.com.au/ibdqoc/australian-ibd-standards/ accessed 15 September 2020.]

6. Mikocka-Walus A, Massuger W, Knowles SR, et al. Quality of care in inflammatory bowel disease: actual health service experiences fall short of the standards. *Intern Med J* 2019

7. Crohn’s & Colitis Australia. My IBD story: Co-creating IBD care. Melbourne, Australia: Crohn’s & Colitis Australia, 2017.

8. Crohn’s & Colitis Australia. Improving inflammatory bowel disease care across Australia. Melbourne, Australia: Crohn’s & Colitis Australia, 2013.

9. Australian Government Department of Health. Inflammatory Bowel Disease National Action Plan 2019. Canberra, Australia, 2019.

10. Massuger W, Moore GT, Andrews JM, et al. Crohn’s & Colitis Australia inflammatory bowel disease audit: measuring the quality of care in Australia. *Intern Med J* 2018;49(7):859-66.

11. Wilson J, Hair C, Knight R, et al. High incidence of inflammatory bowel disease in Australia: a prospective population-based Australian incidence study. *Inflamm Bowel Dis* 2010;16(9):1550-56.

12. Studd C, Cameron G, Beswick L, et al. Never underestimate inflammatory bowel disease: high prevalence rates and confirmation of high incidence rates in Australia. *J Gastroenterol Hepatol* 2016;31(1):81-86.

13. Mak WY, Hart AL, Ng SC. Crohn’s disease. *Medicine* 2019;47(6):377-87.

14. Steed H. Ulcerative colitis. *Medicine* 2019;47(6):371-76.

15. Johnston RD, Logan RF. What is the peak age for onset of IBD? *Inflamm Bowel Dis* 2008;14(suppl_2):S4-S5.

16. Knowles SR, Graff LA, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part I. *Inflamm Bowel Dis* 2018;24(4):742-51.

17. Knowles SR, Keefer L, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part II. *Inflamm Bowel Dis* 2018;24(5):966-76.

18. Tormey LK, Reich J, Chen YS, et al. Limited health literacy is associated with worse patient-reported outcomes in inflammatory bowel disease. *Inflamm Bowel Dis* 2019;25(1):204-12.

19. Plevinsky JM, Greenley RN, Fishman LN. Self-management in patients with inflammatory bowel disease: strategies, outcomes, and integration into clinical care. *Clin Exp Gastroenterol* 2016;9:259.

20. Batterham RW, Buchbinder R, Beauchamp A, et al. The OPermitising HEst Health LiterAcY (Ophelia) process: study protocol for using health literacy profiling and community engagement to create and implement health reform. *BMC Public Health* 2014;14(1):694-703. doi: 10.1186/1471-2458-14-694

21. Beauchamp A, Batterham RW, Dodson S, et al. Systematic development and implementation of interventions to Optimise Health Literacy and Access (Ophelia). *BMC Public Health* 2017;17(1):230.
22. Osborne RH, Batterham RW, Elsworth GR, et al. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;13:658. doi: 10.1186/1471-2458-13-658

23. Kayser L, Karnoe A, Furstrand D, et al. A multidimensional tool based on the eHealth literacy framework: development and initial validity testing of the eHealth Literacy Questionnaire (eHLQ). *J Med Internet Res* 2018;20(2):e36.

24. Anwar WA, Mostafa NS, Hakim SA, et al. Health literacy strengths and limitations among rural fishing communities in Egypt using the Health Literacy Questionnaire (HLQ). *PLoS One* 2020;15(7):e0235550.

25. Beauchamp A, Mohebbi M, Cooper A, et al. The impact of translated reminder letters and phone calls on mammography screening booking rates: Two randomised controlled trials. *PLoS One* 2020;15(1):e0226610.

26. Jessup RL, Osborne RH, Buchbinder R, et al. Using co-design to develop interventions to address health literacy needs in a hospitalised population. *BMC Health Serv Res* 2018;18(1):989. doi: 10.1186/s12913-018-3801-7

27. Kolarčik P, Belak A, Osborne RH. The Ophelia (OPtimise HEalth Literacy and Access) Process. Using health literacy alongside grounded and participatory approaches to develop interventions in partnership with marginalised populations. *European Health Psychologist* 2015;17(6):297-304.

28. Bakker MM, Putrik P, Aaby ASE, et al. Acting together–WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Health Panorama* 2019;5(2-3):233-43.

29. Aaby A, Simonsen CB, Ryom K, et al. Improving Organizational Health Literacy Responsiveness in Cardiac Rehabilitation Using a Co-Design Methodology: Results from The Heart Skills Study. *Int J Environ Res Public Health* 2020;17(3):1015.

30. Jessup RL, Osborne RH, Beauchamp A, et al. Differences in health literacy profiles of patients admitted to a public and a private hospital in Melbourne, Australia. *BMC Health Serv Res* 2018;18(1):1-11. doi: 10.1186/s12913-018-2921-4

31. Goeman D, Conway S, Norman R, et al. Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *Journal of Diabetes Research* 2016;2016:2483263-63.

32. Kinsman L, Radford J, Elmer S, et al. Engaging “hard-to-reach” men in health promotion using the OPHELIA principles: Participants’ perspectives. *Health Promot J Austr* 2020:1-8. doi: 10.1002/hpja.403

33. Bakker M, Putrik P, Rademakers J, et al. OP0257-PARE Using patient health literacy profiles to identify solutions to challenges faced in rheumatology care. *Ann Rheum Dis* 2020;79(Suppl 1)

34. Boateng MA, Agyei-Baffour P, Angel S, et al. Co-Creation and Prototyping of An Intervention Focusing On Health Literacy In Management of Malaria At Community-Level In Ghana. *Research Involvement and Engagement* pre-print under review

35. O’Hara J, McPhee C, Dodson S, et al. Barriers to Breast Cancer Screening among Diverse Cultural Groups in Melbourne, Australia. *Int J Environ Res Public Health* 2018;15(8) doi: 10.3390/ijerph15081677

36. Lim S, Beauchamp A, Dodson S, et al. Health literacy and fruit and vegetable intake in rural Australia. *Public Health Nutr* 2017;20(15):2680-84. doi: 10.1017/S1368946917001483

37. Aaby A, Friis K, Christensen B, et al. Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease. *European Journal Of Preventive Cardiology* 2017;24(17):1880-88. doi: 10.1177/2047487317729538

38. Aaby A, Friis K, Christensen B, et al. Health Literacy among People in Cardiac Rehabilitation: Associations with Participation and Health-Related Quality of Life in the Heart Skills Study in Denmark. *Int J Environ Res Public Health* 2020;17(2):443.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
39. Klinker CD, Aaby A, Ringgaard LW, et al. Health literacy is associated with health behaviors in students from vocational education and training schools: a Danish population-based survey. *Int J Environ Res Public Health* 2020;17(2):671.

40. Dodson S, Osicka T, Huang L, et al. Multifaceted Assessment of Health Literacy in People Receiving Dialysis: Associations With Psychological Stress and Quality of Life. *J Health Commun* 2016;21:91-98. doi: 10.1080/10810730.2016.1179370

41. Jessup RL, Osborne RH, Beauchamp A, et al. Health literacy of recently hospitalised patients: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). *BMC Health Serv Res* 2017;17(1):52.

42. Beauchamp A, Backholer K, Magliano D, et al. The effect of obesity prevention interventions according to socioeconomic position: a systematic review. *Obes Rev* 2014;15(7):541-54. doi: 10.1111/obr.12161

43. McClintock C. Evaluators as applied theorists. *Evaluation Practice* 1990;11(1):1-12.

44. McClintock C, Colosi LA. Evaluation of welfare reform: A framework for addressing the urgent and the important. *Evaluation Review* 1998;22(5):668-94.

45. Clara I, Lix LM, Walker JR, et al. The Manitoba IBD Index: evidence for a new and simple indicator of IBD activity. *Am J Gastroenterol* 2009;104(7):1754-63.

46. Bo A, Friis K, Osborne RH, et al. National indicators of health literacy: ability to understand health information and to engage actively with healthcare providers - a population-based survey among Danish adults. *BMC Public Health* 2014;14(1):1095.

47. Boateng MA, Angel S, Agyei-Baffour P, et al. Cultural Adaptation and Validation of the Ghanaian Language (Akan; Asante Twi) Version of the Health Literacy Questionnaire. *BMC Health Serv Res* 2020;(preprint)

48. Debussche X, Lenclume V, Balcou-Debussche M, et al. Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk: Validity testing of the Health Literacy Questionnaire. *SAGE Open Medicine* 2018;6:2050312118801250-50. doi: 10.1177/2050312118801250

49. Kolarčík P, Cepova E, Geckova AM, et al. Structural properties and psychometric improvements of the health literacy questionnaire in a Slovak population. *International journal of public health* 2017;62(5):591-604.

50. Maindal HT, Kayser L, Norgaard O, et al. Cultural adaptation and validation of the Health Literacy Questionnaire (HLQ): robust nine-dimension Danish language confirmatory factor model. *SpringerPlus* 2016;5(1):1232 DOI 10.186/s40064-016-2887-9.

51. Nolte S, Osborne RH, Dwinger S, et al. German translation, cultural adaptation, and validation of the Health Literacy Questionnaire (HLQ). *PLoS One* 2017;12(2): doi.org/10.1371/journal.pone.0172340. doi: 10.1371/journal.pone.0172340

52. Wahl AK, Hermansen Å, Osborne RH, et al. A validation study of the Norwegian version of the Health Literacy Questionnaire: A robust nine-dimension factor model. *Scandinavian Journal of Public Health* 2020:1403494820926428.

53. Leslie CJ, Hawkins M, Smith DL. Using the Health Literacy Questionnaire (HLQ) with Providers in the Early Intervention Setting: A Qualitative Validity Testing Study. *Int J Environ Res Public Health* 2020;17(7):2603.

54. Norgaard O, Furstrand D, Klokker L, et al. The e-health literacy framework: a conceptual framework for characterizing e-health users and their interaction with e-health systems. *Knowledge Management & E-Learning: An International Journal* 2015;7(4):522-40.

55. IBM SPSS Statistics for Windows [program]. 27.0 version. Armonk, NY: IBM Corp., 2020.

56. Everitt BS, Landau S, Leese M, et al. Cluster analysis. 5th ed: John Wiley 2011.

57. Hair J, Black W, Babin B, et al. *Multivariate Data Analysis* 2014.

58. Beauchamp A, Buchbinder R, Dodson S, et al. Distribution of health literacy strengths and weaknesses across socio-demographic groups: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2015;15:678.
59. Windgassen S, Moss-Morris R, Goldsmith K, et al. The importance of cluster analysis for enhancing clinical practice: an example from irritable bowel syndrome. *Journal of Mental Health* 2018;27(2):94-6.

60. Batterham R, Hawkins M, Collins P, et al. Health literacy: applying current concepts to improve health services and reduce health inequalities. *Public Health* 2016;132:3-12.

61. Irish Heart Foundation. [Available from: https://irishheart.ie/ accessed 16 September 2020.

62. Associação Protectora dos Diabéticos de Portugal (APDP). [Available from: https://apdp.pt/ accessed 16 September 2020.

63. Santé Diabète. [Available from: https://santediabete.org/ accessed 16 September 2020.
Phase 1: Identify strengths, needs and action ideas

- Collect health literacy and other data from community members and providers
- Discuss findings (as vignettes) in workshops to generate ideas for health literacy actions

Phase 2: Select, plan and test health literacy actions

- Select and plan health literacy actions that have potential to build on strengths, address needs, and improve outcomes
- Test and refine selected actions

Phase 3: Implement, evaluate and improve health literacy actions

- Implement selected health literacy actions
- Evaluate and improve on an ongoing basis
Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) process

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Title: Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) 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 Ophelia (Optimising Health Literacy and Access) process over 3 years to collaboratively co-design 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 (HLQ), eHealth Literacy Questionnaire (eHLQ), 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 co-design 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652) and by the South West Sydney Local Health District (SWSLHD) 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 co-design 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.

**Article summary**

**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 co-design 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 Ophelia (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 co-design 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.

**Keywords:**

Health literacy; non-government organisation; co-design; inflammatory bowel disease; IBD; Crohn’s disease; ulcerative colitis; chronic disease; Ophelia
Co-design and implementation of an equity-promoting national health literacy program for people living with inflammatory bowel disease (IBD): a protocol for the application of the Ophelia (Optimising Health Literacy and Access) process

Introduction

Non-government organisations (NGOs) represent the interests of the communities they serve, whether this be locally, nationally or internationally. 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. 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. A recent quality of care initiative has been undertaken by Crohn’s & Colitis Australia (CCA) 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. 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.

Inflammatory Bowel Disease in Australia

More than 85,000 Australians live with IBD, a group of chronic relapsing gastrointestinal disorders, 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. Symptoms can be severe and debilitating, and can cause lifelong effects on individuals’ physical, emotional and social wellbeing, 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. Optimal self-management of health related to IBD often relies on the capacities of individuals, their engagement with healthcare 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. 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. Studies also show that information to support self-management is needed for accessing advice and support
from allied health professionals (e.g., psychologists, dietitians) and IBD communities, including those that are based online.\textsuperscript{22-24} It is also important to recognise that information needs depend on several factors, including the stage (e.g., pre- and post-diagnosis) and status of disease (e.g., active, remission).\textsuperscript{22} Despite the importance of these information needs, people living with IBD report that access to information is lacking, especially for people experiencing vulnerability (e.g., young people).\textsuperscript{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.

\textit{Crohn’s & Colitis Australia (CCA)}

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.

\textit{The Ophelia (Optimising Health Literacy and Access) process}

The Ophelia process\textsuperscript{26 27} is a co-design approach that uses multi-dimensional health literacy or digital health literacy questionnaires, the Health Literacy Questionnaire (HLQ)\textsuperscript{28} and the eHealth Literacy Questionnaire (eHLQ),\textsuperscript{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.\textsuperscript{10-34} A capacity building approach is used to support and enable organisations and health services to identify health literacy strengths and needs, co-design and develop interventions, and then implement and evaluate those interventions.\textsuperscript{35-37}

Ophelia has three phases (Figure 1).\textsuperscript{26,27} All phases involve close collaboration with key stakeholders including community members and frontline practitioners.\textsuperscript{26,27} Each Ophelia project seeks to improve health and equity by increasing the availability and accessibility of health 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\textsuperscript{31,32,37,38} and internationally\textsuperscript{30,35,39,40}, as well as being the foundation of the World Health Organization (WHO) National Health Literacy Demonstration Projects (NHLDP), conducted under the auspices of the WHO Global Coordination Mechanism (GCM) on the prevention and control of noncommunicable diseases (NCDs) (https://www.who.int/groups/gcm).\textsuperscript{34}

\textit{Figure 1. The three phases of the Ophelia (Optimising Health Literacy and Access) process}

\textbf{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.\textsuperscript{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.\textsuperscript{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 Crohn’s & Colitis (CCA) Consumer Education and Awareness of IBD (CEA-IBD) project is to implement the Ophelia (Optimising Health Literacy and Access) process over 3 years to collaboratively co-design 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 to 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 process 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 process26, 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 program logic49 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 program 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 outcomes27. 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 to April 2021
- Phase 2: May 2021 to December 2021
- Phase 3: January 2022 to 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), 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 minutes 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 (e.g., online and direct mailout, social media, newsletters and websites).

The HLQ has been developed and validity tested in multiple studies. It has 44 items in 9 scales (4 – 6 items per scale). Scales 1 to 5 use four-point response options (score range 1 – 4; strongly disagree to strongly agree). Scales 6 to 9 use five-point response options (score range 1 – 5; cannot do or always difficult to always easy). Results are the 9 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 7 dimensions of the eHealth Literacy Framework and was developed simultaneously in Danish and English with ongoing psychometric testing. Scale 5 (5 items) uses four-point response options (strongly disagree to strongly agree). 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.

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. Doesn’t 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 don’t 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                  | Doesn’t 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 i.e., 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 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. 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 minutes 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 4 workshops with about 30 people with IBD or their carers and 4
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 version 27. 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. Cluster analysis is an analytical method used to examine multivariate data and identify groups of homogeneous observations. This method is used to ensure equity planning so that different health literacy needs are addressed. The analysis will be based on the ten scales of the HLQ and eHLQ data. For treatment of missing values, the expectation maximisation (EM) algorithm will be used to impute missing item scores if there are fewer than 50% of missing values in a scale. As the cluster analysis is based on the ten 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. However, our experience from many Ophelia studies indicates that sample sizes of over 100 will generate rich information about potential sub-populations of people. We expect over 200 complete surveys will be collected which will enable exploration of subgroup differences across the community. A total of 3 to 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 standard deviation 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. Consequently, the optimal number of clusters is based both on quantitative, clinical and qualitative judgments. The cluster selection process will be undertaken by CC and reviewed by at least 2 other members of the research team. Basic epidemiological descriptive analyses such as means, standard deviations (SD) and statistical differences between groups (e.g., 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 (e.g., improving access and use opportunities and clinician interactions with patients), community settings (e.g., improving community information and services and supporting individuals to care for their health), and policy settings. The analysis will be undertaken by MH and reviewed by at least 2 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 co-design 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 programs. 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. 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 co-design 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 screening and then co-designing solutions to these barriers, which generated 10-fold increases in screening among Arabic and Italian speaking women. The Irish Heart Foundation, the Portuguese Diabetes Association, and Santé Diabète in Mali are NGOs currently implementing the Ophelia process and including wide ranges of community stakeholders to better understand the needs of and co-design 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

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 co-designed 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, 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 (e.g., 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 (HREC) of Swinburne University of Technology (Ref: 20202968-4652), and also from the South West Sydney Local Health District (SWSLHD) 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 co-design 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.

References

1. Delisle H, Roberts JH, Munro M, et al. The role of NGOs in global health research for development. *Health Research Policy and Systems* 2005;3(1):1-21.
2. ACT Council of Social Service Inc. Sustaining Community Sector Value in a Vital Community Services Industry. Weston, Australian Capital Territory: ACTCOSS, 2016.
3. Elmer S, Jones R. Health literacy in the community sector project - Evaluation report: Tasmanian Council of Social Service 2016.
4. Teegen H, Doh JP, Vachani S. The importance of nongovernmental organizations (NGOs) in global governance and value creation: An international business research agenda. *Journal of International Business Studies* 2004;35(6):463-83.
5. Crohn's & Colitis Australia. Australian IBD Standards: Crohn's & Colitis Australia; 2020 [Available from: https://www.crohnsandcolitis.com.au/ibdqoc/australian-ibd-standards/ accessed 15 September 2020].
6. Mikocka-Walus A, Massuger W, Knowles SR, et al. Quality of care in inflammatory bowel disease: actual health service experiences fall short of the standards. *Intern Med J* 2019.
7. Crohn’s & Colitis Australia. My IBD story: Co-creating IBD care. Melbourne, Australia: Crohn’s & Colitis Australia, 2017.
8. Crohn’s & Colitis Australia. Improving inflammatory bowel disease care across Australia. Melbourne, Australia: Crohn’s & Colitis Australia, 2013.
9. Australian Government Department of Health. Inflammatory Bowel Disease National Action Plan 2019. Canberra, Australia, 2019.
10. Massuger W, Moore GT, Andrews JM, et al. Crohn’s & Colitis Australia inflammatory bowel disease audit: measuring the quality of care in Australia. *Intern Med J* 2018;49(7):859-66.
11. Wilson J, Hair C, Knight R, et al. High incidence of inflammatory bowel disease in Australia: a prospective population-based Australian incidence study. *Inflamm Bowel Dis* 2010;16(9):1550-56.
12. Studd C, Cameron G, Beswick L, et al. Never underestimate inflammatory bowel disease: high prevalence rates and confirmation of high incidence rates in Australia. *J Gastroenterol Hepatol* 2016;31(1):81-86.
13. Mak WY, Hart AL, Ng SC. Crohn’s disease. *Medicine* 2019;47(6):377-87.
14. Steed H. Ulcerative colitis. *Medicine* 2019;47(6):371-76.
15. Johnston RD, Logan RF. What is the peak age for onset of IBD? *Inflamm Bowel Dis* 2008;14(suppl_2):S4-S5.
16. Knowles SR, Graff LA, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part I. *Inflamm Bowel Dis* 2018;24(4):742-51.

17. Knowles SR, Keefer L, Wilding H, et al. Quality of life in inflammatory bowel disease: a systematic review and meta-analyses—part II. *Inflamm Bowel Dis* 2018;24(5):966-76.

18. Tormey LK, Reich J, Chen YS, et al. Limited health literacy is associated with worse patient-reported outcomes in inflammatory bowel disease. *Inflamm Bowel Dis* 2019;25(1):204-12.

19. Plevinsky JM, Greenley RN, Fishman LN. Self-management in patients with inflammatory bowel disease: strategies, outcomes, and integration into clinical care. *Clin Exp Gastroenterol* 2016;9:259.

20. Pittet V, Rogler G, Mottet C, et al. Patients’ information-seeking activity is associated with treatment compliance in inflammatory bowel disease patients. *Scand J Gastroenterol* 2014;49(6):662-73.

21. Restall GJ, Simms AM, Walker JR, et al. Coping with inflammatory bowel disease: engaging with information to inform health-related decision making in daily life. *Inflamm Bowel Dis* 2017;23(8):1247-56.

22. Daher S, Khoury T, Benson A, et al. Inflammatory bowel disease patient profiles are related to specific information needs: A nationwide survey. *World J Gastroenterol* 2019;25(30):4246.

23. Karadag P, Morris B, Woolfall K. The information and support needs of patients living with inflammatory bowel disease: A qualitative study. *Chronic Illness* 2020:1742395320968617.

24. Reich J, Guo L, Groshek J, et al. Social media use and preferences in patients with inflammatory bowel disease. *Inflamm Bowel Dis* 2019;25(3):587-91.

25. Harris RJ, Downey L, Smith TR, et al. Life in lockdown: experiences of patients with IBD during COVID-19. *BMJ Open Gastroenterology* 2020;7(1):e000541.

26. Batterham RW, Buchbinder R, Beauchamp A, et al. The OPtimising HEalth LiterAcy (Ophelia) process: study protocol for using health literacy profiling and community engagement to create and implement health reform. *BMC Public Health* 2014;14(1):694-703. doi: 10.1186/1471-2458-14-694

27. Beauchamp A, Batterham RW, Dodson S, et al. Systematic development and implementation of interventions to Optimise Health Literacy and Access (Ophelia). *BMC Public Health* 2017;17(1):230.

28. Osborne RH, Batterham RW, Elsworth GR, et al. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;13:658. doi: 10.1186/1471-2458-13-658

29. Kayser L, Karnoe A, Furstrand D, et al. A multidimensional tool based on the eHealth literacy framework: development and initial validity testing of the eHealth Literacy Questionnaire (eHLQ). *J Med Internet Res* 2018;20(2):e36.

30. Anwar WA, Mostafa NS, Hakim SA, et al. Health literacy strengths and limitations among rural fishing communities in Egypt using the Health Literacy Questionnaire (HLQ). *PLoS One* 2020;15(7):e0235550.

31. Beauchamp A, Mohebbi M, Cooper A, et al. The impact of translated reminder letters and phone calls on mammography screening booking rates: Two randomised controlled trials. *PLoS One* 2020;15(1):e0226610.

32. Jessup RL, Osborne RH, Buchbinder R, et al. Using co-design to develop interventions to address health literacy needs in a hospitalised population. *BMJ Health Serv Res* 2018;18(1):989. doi: 10.1186/s12913-018-3801-7

33. Kolarčik P, Belak A, Osborne RH. The Ophelia (OPtimise HEalth Literacy and Access) Process. Using health literacy alongside grounded and participatory approaches to develop interventions in partnership with marginalised populations. *European Health Psychologist* 2015;17(6):297-304.
34. Bakker MM, Putrik P, Aaby ASE, et al. Acting together—WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Health Panorama* 2019;5(2-3):233-43.

35. Aaby A, Simonsen CB, Ryom K, et al. Improving Organizational Health Literacy Responsiveness in Cardiac Rehabilitation Using a Co-Design Methodology: Results from The Heart Skills Study. *Int J Environ Res Public Health* 2020;17(3):1015.

36. Jessup RL, Osborne RH, Beauchamp A, et al. Differences in health literacy profiles of patients admitted to a public and a private hospital in Melbourne, Australia. *BMC Health Serv Res* 2018;18:1-11. doi: 10.1186/s12913-018-2921-4

37. Goeman D, Conway S, Norman R, et al. Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *Journal of Diabetes Research* 2016;2016:2483263-63.

38. Kinsman L, Radford J, Elmer S, et al. Engaging “hard-to-reach” men in health promotion using the OPHELIA principles: Participants’ perspectives. *Health Promot J Austr* 2020:1-8. doi: 10.1002/ hpja.403

39. Bakker M, Putrik P, Rademakers J, et al. OP0257-PARE Using patient health literacy profiles to identify solutions to challenges faced in rheumatology care. *Ann Rheum Dis* 2020;79(Suppl 1)

40. Boateng MA, Agyei-Baffour P, Angel S, et al. Co-Creation and Prototyping of An Intervention Focusing On Health Literacy In Management of Malaria At Community-Level In Ghana. Research Involvement and Engagement pre-print under review doi: 10.21203/rs.3.rs-123009/v1

41. O’Hara J, McPhee C, Dodson S, et al. Barriers to Breast Cancer Screening among Diverse Cultural Groups in Melbourne, Australia. *Int J Environ Res Public Health* 2018;15(8) doi: 10.3390/ijerph15081677

42. Lim S, Beauchamp A, Dodson S, et al. Health literacy and fruit and vegetable intake in rural Australia. *Public Health Nutr* 2017;20(15):2680-84. doi: 10.1017/S1368946217001483

43. Aaby A, Friis K, Christensen B, et al. Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease. *European Journal Of Preventive Cardiology* 2017;24(17):1880-88. doi: 10.1177/2047487317729538

44. Aaby A, Friis K, Christensen B, et al. Health Literacy among People in Cardiac Rehabilitation: Associations with Participation and Health-Related Quality of Life in the Heart Skills Study in Denmark. *Int J Environ Res Public Health* 2020;17(2):443.

45. Klinker CD, Aaby A, Ringgaard LW, et al. Health literacy is associated with health behaviors in students from vocational education and training schools: a Danish population-based survey. *Int J Environ Res Public Health* 2020;17(2):671.

46. Dodson S, Osicka T, Huang L, et al. Multifaceted Assessment of Health Literacy in People Receiving Dialysis: Associations With Psychological Stress and Quality of Life. *J Health Commun* 2016;21:91-98. doi: 10.1080/10810730.2016.1179370

47. Jessup RL, Osborne RH, Beauchamp A, et al. Health literacy of recently hospitalised patients: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). *BMC Health Serv Res* 2017;17(1):52.

48. Beauchamp A, Backholer K, Magliano D, et al. The effect of obesity prevention interventions according to socioeconomic position: a systematic review. *Obes Rev* 2014;15(7):541-54. doi: 10.1111/obr.12161

49. McClintock C. Evaluators as applied theorists. *Evaluation Practice* 1990;11(1):1-12.

50. McClintock C, Colosi LA. Evaluation of welfare reform: A framework for addressing the urgent and the important. *Evaluation Review* 1998;22(5):668-94.

51. Clara I, Lix LM, Walker JR, et al. The Manitoba IBD Index: evidence for a new and simple indicator of IBD activity. *Am J Gastroenterol* 2009;104(7):1754-63.
52. Bo A, Friis K, Osborne RH, et al. National indicators of health literacy: ability to understand health information and to engage actively with healthcare providers - a population-based survey among Danish adults. *BMC Public Health* 2014;14(1):1095.

53. Boateng MA, Angel S, Agyei-Baffour P, et al. Cultural Adaptation and Validation of the Ghanaian Language (Akan; Asante Twi) Version of the Health Literacy Questionnaire. *BMC Health Serv Res* 2020;(preprint)

54. Debussche X, Lenclume V, Balcou-Debussche M, et al. Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk: Validity testing of the Health Literacy Questionnaire. *SAGE Open Medicine* 2018;6:2050312118801250-50. doi: 10.1177/2050312118801250

55. Kolarčik P, Cepová E, Geckova AM, et al. Structural properties and psychometric improvements of the health literacy questionnaire in a Slovak population. *International journal of public health* 2017;62(5):591-604.

56. Maindal HT, Kayser L, Norgaard O, et al. Cultural adaptation and validation of the Health Literacy Questionnaire (HLQ): robust nine-dimension Danish language confirmatory factor model. *SpringerPlus* 2016;5(1):1232 DOI 10.186/s40064-016-2887-9.

57. Nolte S, Osborne RH, Dwinger S, et al. German translation, cultural adaptation, and validation of the Health Literacy Questionnaire (HLQ). *PLoS One* 2017;12(2):doi.org/10.1371/journal.pone.0172340. doi: doi: 10.1371/journal.pone.0172340

58. Wahl AK, Hermansen Å, Osborne RH, et al. A validation study of the Norwegian version of the Health Literacy Questionnaire: A robust nine-dimension factor model. *Scandinavian Journal of Public Health* 2020:1403494820926428.

59. Leslie CJ, Hawkins M, Smith DL. Using the Health Literacy Questionnaire (HLQ) with Providers in the Early Intervention Setting: A Qualitative Validity Testing Study. *Int J Environ Res Public Health* 2020;17(7):2603.

60. Norgaard O, Furstrand D, Klokker L, et al. The e-health literacy framework: a conceptual framework for characterizing e-health users and their interaction with e-health systems. *Knowledge Management & E-Learning: An International Journal* 2015;7(4):522-40.

61. IBM SPSS Statistics for Windows [program]. 27.0 version. Armonk, NY: IBM Corp., 2020.

62. Everitt BS, Landau S, Leese M, et al. Cluster analysis. 5th ed: John Wiley 2011.

63. Hair J, Black W, Babin B, et al. Multivariate Data Analysis2014.

64. Beauchamp A, Buchbinder R, Dodson S, et al. Distribution of health literacy strengths and weaknesses across socio-demographic groups: a cross-sectional survey using the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2015;15:678.

65. Windgassen S, Moss-Morris R, Goldsmith K, et al. The importance of cluster analysis for enhancing clinical practice: an example from irritable bowel syndrome. *Journal of Mental Health* 2018;27(2):94-6.

66. Batterham R, Hawkins M, Collins P, et al. Health literacy: applying current concepts to improve health services and reduce health inequalities. *Public Health* 2016;132:3-12.

67. Irish Heart Foundation. [Available from: https://irishheart.ie/ accessed 16 September 2020.

68. Associação Protectora dos Diabéticos de Portugal (APDP). [Available from: https://apdp.pt/ accessed 16 September 2020.

69. Santé Diabète. [Available from: https://santediabete.org/ accessed 16 September 2020.
Phase 1: Identify strengths, needs and action ideas

- Collect health literacy and other data from community members and providers
- Discuss findings (as vignettes) in workshops to generate ideas for health literacy actions

Phase 2: Select, plan and test health literacy actions

- Select and plan health literacy actions that have potential to build on strengths, address needs, and improve outcomes
- Test and refine selected actions

Phase 3: Implement, evaluate and improve health literacy actions

- Implement selected health literacy actions
- Evaluate and improve on an ongoing basis