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Health literacy and long-term health outcomes following myocardial infarction: protocol for a multicentre, prospective cohort study (ENHEARTEN study)

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ABSTRACT

Introduction Low health literacy is common in people with cardiovascular disease and may be one factor that affects an individual's ability to maintain secondary prevention health behaviours following myocardial infarction (MI). However, little is known about the association between health literacy and longer-term health outcomes in people with MI. The ENhancing HEAlth literacy in secondary pRevenTion of cardiac evENts (ENHEARTEN) study aims to examine the relationship between health literacy and a number of health outcomes (including healthcare costs) in a cohort of patients following their first MI. Findings may provide evidence for the significance of health literacy as a predictor of long-term cardiac outcomes.

Methods and analysis ENHEARTEN is a multicentre, prospective observational study in a convenience sample of adults (aged ≥18 years) with their first MI. A total of 450 patients will be recruited over 2 years across two metropolitan health services and one rural/regional health service in Victoria, Australia. The primary outcome of this study will be all-cause, unplanned hospital admissions within 6 months of index admission. Secondary outcomes include cardiac-related hospital admissions up to 24 months post-MI, emergency department presentations, health-related quality of life, mortality, cardiac rehabilitation attendance and healthcare costs. Health literacy will be observed as a predictor variable and will be determined using the 12-item version of the European Health Literacy Survey (HLS-Q12).

Ethics and dissemination Ethics approval for this study has been received from the relevant human research ethics committee (HREC) at each of the participating health services (lead site Monash Health HREC; approval number: RES-21-0000-242A) and Services Australia HREC (reference number: RMS1672). Informed written consent will be sought from all participants. Study results will be published in peer-reviewed journals and collated in reports for participating health services and participants.

Trial registration number ACTRN12621001224819.

INTRODUCTION

Coronary artery disease (CAD) remains a leading cause of death worldwide,[1–3]

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ By examining the relationship between health literacy and long-term outcomes in a cohort of patients following their first myocardial infarction (MI), this study will provide much-needed evidence for the role of health literacy in cardiovascular disease, which was distinguished as a 'research evidence gap' by the American Heart Association.

⇒ Findings may inform future research directions for understanding mediators of the relationship between health literacy and health outcomes post-MI.

⇒ Inclusion of rural participants and people from culturally and linguistically diverse groups and/or those living with socioeconomic disadvantage will provide evidence for health literacy barriers to secondary prevention in vulnerable populations.

⇒ All study outcomes will be ascertained via validated survey instruments and linkage with government databases.

⇒ A limitation is that we will not be able to capture health service use data (eg, hospitalisations) for participants who access health services outside the state of Victoria, Australia.

accounting for almost 9 million deaths globally in 2019.[4] CAD can present as myocardial infarction (MI) or angina and is a progressive disease which may be slowed through long-term management of cardiac risk factors.[4] Following an MI, clinical guidelines recommend that patients are supported to reduce their risk of further cardiac events through lifestyle changes and medication use.[5–7] However, these secondary prevention behaviours can be difficult for patients to initiate and sustain over time, leading to potential adverse consequences such as hospital readmission or increased risk of mortality.[8–10]

One factor that may influence an individual's ability to maintain positive health behaviours is health literacy; defined as 'the personal characteristics and social resources needed for individuals to access, understand and use information and health services to make decisions about health'.[11] Health literacy is more than just the ability to read and understand health information (known as 'functional' health literacy); it also encompasses the skills and resources that people need to appraise health information, and to access and engage with health services and providers.[12] Health literacy is now considered a determinant of health that contributes to health inequalities, with many policy documents recognising its importance, not just at the individual level, but as a concept that health professionals and health services can measure and respond to.[13 14] Low health literacy also carries a significant economic burden, estimated to cost between 3% and 5% of total healthcare costs worldwide,[15] although this has not been explored in cardiovascular disease.

Groups at greater risk of lower health literacy include culturally and linguistically diverse communities, those living with socioeconomic disadvantage, and rural or regional populations.[16] Low health literacy is also common in people with cardiac disease, with previous studies suggesting that approximately 40% of cardiac patients have a level of health literacy that is inadequate for managing their health.[17 18] Longitudinal studies in patients with CAD have shown that lower health literacy is associated with a 75% increase in 30-day hospital readmissions,[19] a 13% increase in 1-year mortality rate[20] and reduced engagement in healthy lifestyle behaviours post-MI.[21 22] No studies have investigated the association between health literacy and emergency department (ED) use in people with CAD, but a meta-analysis identified that inadequate health literacy was associated with a greater number of ED presentations in patients with heart failure.[23] Of note, the majority of these cardiac-related studies have assessed 'functional' health literacy only, with few studies using measures that capture broader aspects of the concept, such as the ability to appraise the quality of health information or make decisions about health.[17 24 25] It is therefore plausible that the significance of health literacy as a predictor of cardiac outcomes remains underestimated. Further, few studies have explored the means by which low health literacy might lead to adverse health outcomes post-MI.[20] Health literacy is considered to influence outcomes in several ways including through access and use of healthcare, patient–provider interaction and ability to self-care.[20 26–28] Identifying the significance of these factors in cardiac patients will allow for targeted strategies to mitigate the effects of low health literacy and may enhance secondary prevention outcomes, including for more vulnerable populations.

Aims and hypotheses

As noted by the American Heart Association, there are significant gaps in evidence for the role of health literacy in cardiovascular disease.[29] This study aims to address this through:

1. Examining the relationship between health literacy and all-cause unplanned hospital admissions in a cohort of patients at 6 months following their first MI (primary outcome).
2. Examining the relationship between health literacy and a number of other health outcomes in this cohort at 30 days, 6 months and/or 12 months following their first MI (all-cause/cardiac hospital admissions; ED presentations; health-related quality of life (HRQoL); mortality; cardiac rehabilitation attendance and healthcare costs).
3. Identifying factors that may act as potential mediators of the relationship between health literacy and health outcomes.

We hypothesise that patients with MI with lower health literacy at baseline, in comparison to those with higher health literacy, will have a higher rate of hospital admissions (all-cause and cardiac-related); a higher rate of ED presentations for ischaemic or non-ischaemic chest pain; lower HRQoL; higher mortality rates; greater healthcare costs; and lower attendance and completion rates at cardiac rehabilitation.

Conceptual model

Figure 1 presents a simplified conceptual model showing the potential associations between health literacy (predictor variable) and various health outcomes, including healthcare costs. In addition to the direct association between health literacy and health outcomes, the model also identifies potential factors or 'mediators' that may influence this association. In this model, health literacy is conceptualised as the ability to find and understand health information, to judge the quality and relevance of that information, and then to use that information to make decisions about health. The potential mediators by which health literacy might subsequently influence health outcomes are conceptualised as: interaction with the health system (ability to navigate the system and actively engage with clinicians); personal attributes (self-efficacy and activation to manage their cardiac condition); and social support (people within their social support networks who can help manage their health, eg, attend medical appointments with them). In turn, these factors may influence health behaviours including medication adherence and physical activity, shown in multiple studies to impact on health outcomes following MI.[30 31]

While figure 1 presents these associations as unidirectional, in reality they are likely to be much more complex and multidirectional. For example, social support is also likely to influence health literacy (eg, people may consult with family members before making health decisions), as well as influencing people's health behaviours. This model has been developed in order to contribute to the limited evidence for the relationship between health literacy and health outcomes following MI, and to identify potential
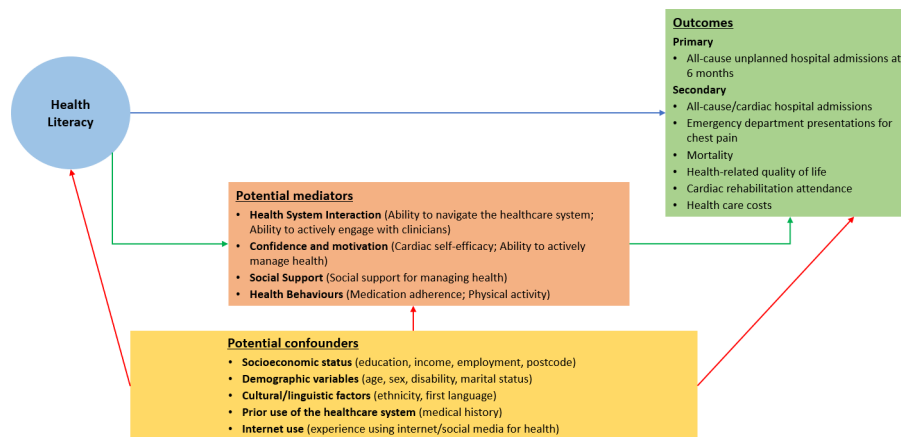
Figure 1 Simplified conceptual model for the association between health literacy and health outcomes.

underlying mechanisms in this relationship that can be explored in future mediation analyses.

METHODS AND ANALYSIS
Study design and setting
This is a multicentre, prospective observational study exploring the relationship between health literacy and health outcomes (including healthcare costs) in a convenience sample of adults with MI. The study is being conducted across two metropolitan health services (Monash Health, Northern Health) and one rural/regional health service (Ballarat Health Services) in Victoria, Australia.

Study population
Patients admitted with their first MI ('incident MI') are currently being recruited from the three health services. This includes patients with ST-segment elevation MI (STEMI) and non-ST-segment elevation MI (NSTEMI). The inclusion criteria are as follows: aged 18 years or above; hospitalised with an incident MI (primary or secondary discharge code of I21 or I22 using the International Statistical Classification of Diseases and Related Health Problems Tenth Revision (ICD-10) codes); able to understand one of the following languages: English, Arabic, Chinese (Simplified), Greek, Italian or Vietnamese; and able to provide informed consent. Exclusion criteria include prior MI; cognitive impairment; discharged with diagnosis of heart failure, or on targeted therapy for heart failure; B-type natriuretic peptide ≥100 ng/L or left ventricular ejection fraction (LVEF) <25% at discharge; discharged to a residential aged care facility; other significant in-hospital complication (eg, stroke); HIV positive status; active cancer with <1-year life expectancy; or renal impairment (creatinine >200 mg/dL or glomerular filtration rate<30 mL/min).

Sample size
The estimated cumulative incidence of hospital re-admission at 6 months post-MI is approximately 40%,[32] and has been found to increase over time.[33] No studies have examined 6-month hospital admission rates by health literacy in patients with MI. Bailey *et al* found that 30-day all-cause readmission rates were higher in patients with lower versus higher health literacy (26% vs 21%, respectively).[34] We therefore expect to find a difference of 15% in the rate of 6-month unplanned all-cause hospital admissions between the lowest and highest groups of health literacy (15% admission rate in highest health literacy group and 30% in lowest health literacy group). At 80% power and two-sided 95% CI, this equates to a sample size of 134 in each health literacy group (n=402). Allowing for an attrition rate of 10%, the required sample size is 442 (rounded to 450 for this study).

Recruitment and consent
Potential participants will be identified by research nurses (RNs) employed within each health service. Each RN will identify patients with MI in the electronic medical records system and screen for inclusion based on the eligibility criteria. The RN will approach all eligible patients and invite them to participate by providing a verbal overview of the study. Interested patients will be provided with the participant explanatory statement and written consent will be sought. Participants will be offered a $20 gift voucher for completing the baseline survey; and an additional $20 gift voucher for each subsequent survey completed. Recruitment materials will also be translated into the five most common languages spoken (other than English) across the three health services for patients with a cardiac diagnosis: Arabic, Chinese (Simplified), Greek, Italian and Vietnamese. In-house interpreters will be engaged to support RNs with the invitation and consent process if required. For patients who are eligible but refuse to participate, the RN will collect data from their hospital medical records on their age, sex and whether they had a STEMI or NSTEMI infarction. These participants will be excluded from further analysis.

Study variables
The data collection variables and schedule are discussed below and summarised in table 1.

Table 1 Study outcomes, source and data collection schedule

Outcomes	Questionnaire/Source	Mode	Data collection schedule			
			Baseline*	6 months	12 months	24 months
Predictor variable						
Health literacy	HLS-Q12	Self-report questionnaire	X	X	X	
Primary outcome						
All-cause hospital admissions (unplanned) at 6 months	VAED (episode dates, admission and separation status, elective/emergency)	Linkage with VAED			X	
Secondary outcomes						
Cardiac-related hospital admissions at 30 days, 6, 12 and 24 months	VAED (episode dates, admission and separation status, elective/emergency)	Linkage with VAED			X	X
All-cause hospital admissions at 30 days, 12 and 24 months	VAED (episode dates, admission and separation status, elective/emergency)	Linkage with VAED			X	X
ED presentations for chest pain at 30 days and 6 months	VEMD (episode dates, length of stay, admission and separation status)	Linkage with VEMD			X	
Mortality at 30 days, 12 and 24 months	NDI (date of death, cause of death)	Linkage with NDI			X	X
HRQoL	EQ-5D-5L	Self-report questionnaire	X	X	X	
Cardiac rehabilitation attendance	% of sessions attended	Self-report questionnaire/ CR staff		X		
Healthcare costs	Date, provider charge, benefit paid, net benefit, patient contribution, concession, absence from work	Linkage with MBS and PBS			X	
Potential mediation variables						
Confidence and motivation	Health literacy questionnaire (scale 3)	Self-report questionnaire	X	X	X	
Social support for health	Health literacy questionnaire (scale 4)	Self-report questionnaire	X	X	X	
Healthcare provider engagement	Health literacy questionnaire (scale 6)	Self-report questionnaire	X	X	X	
Navigating the healthcare system	Health literacy questionnaire (scale 7)	Self-report questionnaire	X	X	X	
Cardiac self-efficacy	Cardiac Self-efficacy Scale	Self-report questionnaire	X	X	X	
Physical activity	International Physical Activity Questionnaire – short form	Self-report questionnaire	X	X	X	
Medication adherence	Medication Adherence Rating Scale (MARS-10)	Self-report questionnaire		X	X	

*Within 30 days after hospital admission for MI.
EQ-5D-5L, EuroQol-5 Dimension-5 level; HLS19-Q12, European Health Literacy Survey-Q12; HRQoL, health-related quality of life; MBS, Medicare Benefits Schedule; MI, myocardial infarction; NDI, National Death Index; PBS, Pharmaceutical Benefits Schedule; VAED, Victorian Admitted Episodes Dataset; VEMD, Victorian Emergency Minimum Dataset.

Box 1   Major cardiac ICD-10 codes

11-I13 (Selected hypertensive diseases)
⇒ I11: Hypertensive heart disease
I20-I25 (Ischaemic heart disease)
⇒ I20: Angina pectoris
⇒ I21: Acute myocardial infarction
⇒ I22: Subsequent myocardial infarction
⇒ I23: Certain current complications following acute myocardial infarction
⇒ I24: Other acute ischaemic heart diseases
⇒ I25: Chronic ischaemic heart disease
I34-36, I42, I44, I46-I51 (Selected other forms of heart disease)
⇒ I34: Non-rheumatic mitral valve disorders
⇒ I35: Non-rheumatic aortic valve disorders
⇒ I36: Non-rheumatic tricuspid valve disorders
⇒ I42: Cardiomyopathy
⇒ I44: Atrioventricular and left bundle-branch block
⇒ I46: Cardiac arrest
⇒ I47: Paroxysmal tachycardia
⇒ I48: Atrial fibrillation and flutter
⇒ I49: Other cardiac arrhythmias
⇒ I50: Heart failure
⇒ I51: Complications and ill-defined descriptions of heart disease
I70-I77 (Selected diseases of arteries, arterioles, and capillaries)
⇒ I70: Atherosclerosis

Primary outcome

The primary outcome of this study will be all-cause, unplanned hospital admissions within 6 months of index admission. This will be a binary outcome (yes/no) and will be ascertained retrospectively through data linkage with the Victorian Admitted Episodes Dataset (VAED), with these data collected 12 months post-index admission. This primary outcome was selected as there is currently no evidence for the relationship between health literacy and readmission rates following MI beyond 30 days.[34] Readmission rates at 12 and 24 months will also be measured as secondary outcomes, and findings may provide the basis for further research to understand the relationship between health literacy, secondary prevention behaviour and health outcomes in the longer term.

Secondary outcomes

Cardiac-related hospital admissions

Rate of cardiac-related hospital admissions (both unplanned and planned) at 30 days, 6, 12 and 24 months following index admission will be ascertained from retrospective linkage with the VAED. Cardiac-related hospital admissions will be determined using the relevant ICD-10 codes detailed in box 1.

All-cause hospital admissions

Rate of unplanned or planned hospital admissions within 30 days, 12 and 24 months following index admission will be ascertained from the VAED.

ED presentations for chest pain

Rate of ED presentations for chest pain (ischaemic or non-ischaemic) within 30 days and 6 months following index admission will be collected via retrospective linkage with Victorian Emergency Minimum Dataset (VEMD).

Mortality

Mortality rate at 30 days, 12 and 24 months post index admission will be ascertained from retrospective linkage with the National Death Index (NDI) database. Relevant variables will include date of death; and underlying cause of death (labelled as ICD-10 codes).

Health-related quality of life

HRQoL will be assessed via survey at baseline, and at 6 and 12 months using the validated EuroQoL questionnaire (EQ-5D-5L).[35] The EQ-5D-5L utility index scores will be calculated using Australian time utility weights from general Australian population samples.[36]

Cardiac rehabilitation attendance

Attendance and completion rates of cardiac rehabilitation (CR) will be collected via participant self-report and/or from CR coordinators. Adherence to CR will be defined as attending ≥75% of recommended sessions.[37]

Healthcare costs and productivity loss

Health service use and costs during the 12 months post-index hospital admission will be collected via retrospective data linkage. As well as hospital costs (ED presentations and acute/subacute admissions collected via linkage with VAED and VEMD), additional variables will include subsidised prescription medicines for the Pharmaceutical Benefits Scheme (PBS) and subsidised outpatient and medical services ascertained from the Medicare Benefits Schedule (MBS); both ascertained from linkage with Services Australia. Productivity loss related to absenteeism from work due to the participants' MI will be collected via self-report survey at 6 and 12 months of follow-up.

Predictor variable

Health literacy will be observed as a predictor variable and will be determined using the 12-item version of the European Health Literacy Survey (HLS-Q12).[38] This instrument is derived from the widely used 47-item European Health Literacy Survey (HLS-EU-Q47),[39] which has previously been used in patients with heart failure and hypertension.[40 41] The HLS-Q12 was validated in a random sample of 900 Norwegian adults and is shown to have strong psychometric properties.[42] The HLS-Q12 scale has a 4-point rating scale; very difficult [1] to very easy [4], where higher total scores indicate higher health literacy proficiencies.[43] Validated cut-off points have been provided to group total scores into three health literacy categories (low, medium, high).[44] The instrument represents health literacy across the domains of accessing, understanding, appraising and applying health information.[39 43] Questions in the HLS-Q12 relate to whether people can find information

about health, whether they can judge the quality and relevance of that information, and whether they can understand information well enough to make decisions about their health.

Potential mediators of the association between health literacy and outcomes

We will also explore associations among certain variables that may act as mediators of the relationship between health literacy and primary and secondary outcomes. Based on these findings, a mediation analysis may be undertaken in the future. Selection of these variables was based on the causal pathways model by Paasche-Orlow *et al*[28] which describes three distinct points at which health literacy influences health outcomes (use of healthcare, patient–provider relationship and self-care). Social support for health was also included given the strong evidence for its role as a mediator between health literacy and health outcomes.[45] Variables used in this analysis will be collected via validated survey instruments, and include the following:

► *Health system interaction* comprising:
  – Ability to navigate the health system assessed using Scale 7 (Navigating the healthcare system) of the Health Literacy Questionnaire (HLQ).[46]
  – Healthcare provider engagement assessed using HLQ Scale 6 (Ability to actively engage with healthcare providers).[46]
► *Confidence and motivation* comprising:
  – Patient motivation assessed using HLQ Scale 3 (Actively managing my health).[46]
  – Cardiac self-efficacy measured using the Cardiac Self-Efficacy Scale.[47]
► *Social support to manage health* assessed using HLQ Scale 4 (Social support for health).[46]
► *Health behaviours* comprising:
  – Physical activity levels measured using the International Physical Activity Questionnaire (IPAQ-7) short form instrument.[48]
  – Medication adherence assessed using the Medication Adherence Rating Scale (MARS-10).[49]

Potential confounding variables
Sociodemographic variables
These include demographic variables (age, sex, marital status, lives alone), socioeconomic variables (education level, income, employment, postcode, healthcare card, private health insurance), and cultural and linguistic variables (country of birth, language spoken at home, years lived in Australia). These data will be collected at baseline via survey.

Internet use
Internet use for health will be assessed via baseline survey using a three-item scale developed by the researchers which includes questions about use of the internet as a source of health information (*Q1: Have you ever searched for health information online? Q2: If yes, how often do you search*

for health information online? Q3: Where do you usually find information about your health?).

Clinical data
Variables related to the index cardiac admission will include MI type (STEMI or NSTEMI), Killip class and electrocardiograph changes. Laboratory tests will include cardiac biomarkers (initial and peak), initial creatinine and lipids. Other variables will include in-hospital procedures/interventions, TIMI (Thrombolysis in Myocardial Infarction) flow, LVEF and major in-hospital events. Discharge data will include medication and referral to cardiac rehabilitation. Selected variables will be used to calculate the GRACE (Global Registry of Acute Coronary Events) 2.0 risk score, which has been validated as a predictor of death or death/MI in patients with acute coronary syndrome.[50] Variables related to previous medical history include prior cardiac history, risk factors and comorbidities. These data will be collected at baseline from hospital medical records. Additional medical data will include depression and anxiety, measured using the 2-item Patient Health Questionnaire (PHQ-2) and the 2-item Generalised Anxiety Disorder (GAD-2), respectively, at baseline, 6 and 12 months. These questionnaires are derived from the PHQ-9 and GAD-7 and in cardiac patients are shown to have similar sensitivity and specificity as these longer and highly validated questionnaires.[51]

Study procedures
Surveys
All survey data will be collected at three time points: baseline (within 30 days of MI), and 6 and 12 months postdischarge from the index hospital admission (figure 2). Given the variation in treatment trajectories following MI, different options for baseline survey data collection will be offered. For participants who prefer to complete the survey during their admission, paper-based surveys will be read aloud by the RN or completed by the participant themselves. For participants who have been discharged home, the baseline survey will be administered either online (via REDCap)[52] or via telephone, depending on the participant's preference. For 6-month and 12-month survey data collection, participants will be offered the option of completing it online or via telephone, as above. All surveys will be translated into the five languages listed above.

Data linkage
Data on hospital admissions will be collected via linkage with the VAED. The VAED is a database held by the Victorian Department of Health & Human Services that contains a comprehensive record of all admitted patients from Victorian public and private acute hospitals including causes, effects and nature of illness, and the use of health services.[53] Data linkage with the VAED will be undertaken at 12 and 24 months post-discharge from index admission.

Recruitment and consent
- Invitation and explanatory statement given whilst inpatient
- Written consent whilst inpatient (or after discharge if required)

Baseline data collection (within 30 days of MI)
- Medical history collected via hospital medical records audit
- Baseline survey whilst inpatient OR after discharge (phone or online)

Follow-up #1 (6-months post-index admission)
- 6-month follow-up survey via phone or online (via email)
- Cardiac rehabilitation (CR) data through CR coordinators

Follow-up #2 (12-months post-index admission)
- 12-month follow-up survey via phone or online (via email)
- Data linkage with VAED, VEMD, NDI and Medicare

Follow-up #3 (24-months post-index admission)
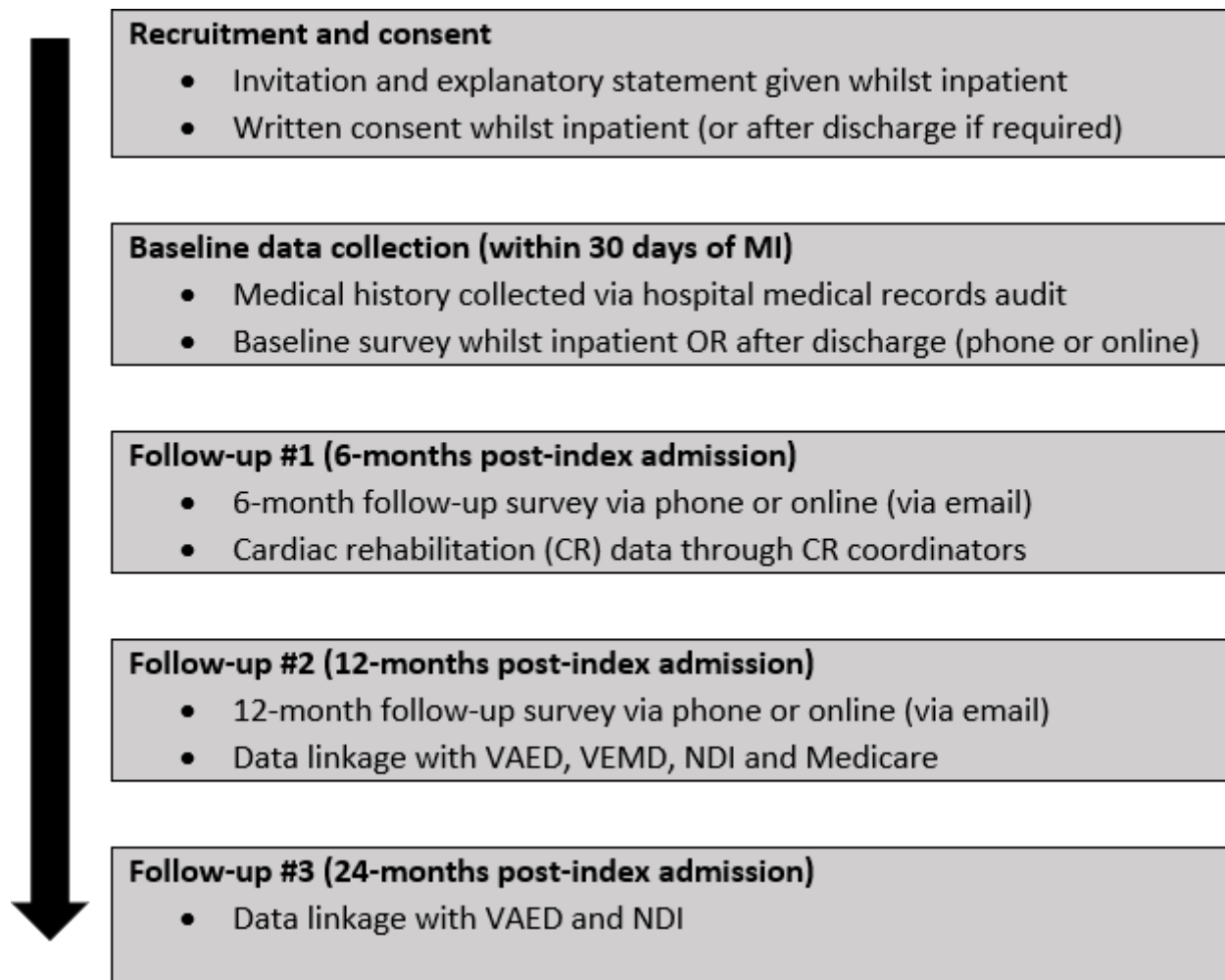- Data linkage with VAED and NDI

Figure 2 Overview of study steps. MI, myocardial infarction; NDI, National Death Index; VAED, Victorian Admitted Episodes Dataset; VEMD, Victorian Emergency Minimum Dataset.

Data on ED presentations will be collected via linkage with the VEMD. The VEMD is a database held by the Victorian Department of Health & Human Services that comprises clinical data on all ED presentations at Victorian public hospitals.[54] This will be undertaken at 12 months post-discharge from index admission and will include retrospective data on 30-day and 6-month presentations.

Mortality data will be collected via linkage with the NDI—a Commonwealth database that contains records of deaths registered in Australia[55]—at 12 and 24 months. Linkage with Services Australia for Medicare and PBS data will be undertaken at 12 months post-discharge (figure 2).

Statistical analyses
The analysis and reporting of results will follow the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting of observational studies.[56] Scores from the HLS-Q12 will be grouped three health literacy categories (low, medium, high) using previously validated cut-points.[41] Descriptive statistics will be used to compare the baseline characteristics of patients by health literacy status. The binary primary and secondary outcomes will be compared between the lowest and highest health literacy groups using log-binomial regression to estimate risk ratios and 95% CIs. Should the log-binomial model fail to converge, modified Poisson regression with robust standard errors will be used. Adjustment will be undertaken for baseline differences in potential confounding variables mentioned above. The difference in medians for the secondary outcome HRQoL utility index scores at 6 months and 12 months will be compared between the health literacy groups using median regression and will be adjusted for the baseline HRQoL utility index score.[57] Associations between each of the potential mediators (figure 1) with health literacy and the various health outcomes will be explored using regression methods.[58] Adjusted analyses will be undertaken to consider any potential confounders of these associations. A statistical analysis plan will be finalised prior to database lock.

The cost analysis will be undertaken from the health sector perspective and a limited societal perspective (reference year will be 2021). Analysis of healthcare costs

will include (1) hospital costs for public and private inpatient services (for all-causes including unplanned and planned admissions); (2) ED admissions for ischaemic/non-ischaemic chest pain and all other causes; (3) total MBS costs, including costs for General Practitioner and specialist consultations related to cardiac health and all other causes; and (4) total PBS costs for cardiac-related medications and all other medications. Hospitalisation costs will be valued using the National Hospital Cost Data Collection for each admitted Australian refined diagnosis-related group. Costs for MBS and PBS will be calculated as the sum of all subsidies paid by Medicare or Services Australia for each participant, and any out-of-pocket costs accrued by participants. Productivity costs will be estimated using self-reported data on absence from work due to ill health and valued using mean wages. Early retirement from the workforce due to ill health will be valued using the Friction Cost Approach which considers the cost to employers of replacing workers.

Study status
Participant recruitment started in November 2021 and is anticipated to be completed in June 2023.

Patient and public involvement
The patients and the public were not involved in the design or conduct of the study. The patients and the public will not be involved in the dissemination or reporting of the study results.

ETHICS AND DISSEMINATION
Ethics approval for this study has been received from the relevant human research ethics committees (HREC) at each of the participating health services (lead site Monash Health HREC; approval number: RES-21-0000-242A) and Services Australia HREC (reference number: RMS1672). Informed written consent will be sought from all participants.

We will use a variety of methods to ensure that our work will achieve maximum visibility. Publication of our study protocol provides an important first step in this direction. The study results will be published in peer-reviewed journals (three manuscripts are currently planned) and presented at scientific conferences. Findings will also be collated in reports for participating health services and Monash University and in 3-monthly newsletter updates to participants (should they choose to receive these updates). No individuals will be identified, and findings will be presented in such a way that identification of participants is not possible.

The study has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621001224819).

DISCUSSION
The American Heart Association recently highlighted the significance of health literacy for cardiac secondary prevention and noted that further exploration of its role in long-term behaviour change is warranted.[29] However, no previous studies have examined the long-term relationship between health literacy and post-MI hospital readmissions, nor explored the potential mechanisms by which poor health literacy leads to adverse outcomes following MI. Furthermore, no longitudinal studies have evaluated whether health literacy is associated with uptake and adherence of CR. The ENHEARTEN study will address these evidence gaps by establishing a cohort study to explore associations between health literacy, health outcomes and potential mediators in adults with incident MI.

Outcomes and significance
The ENHEARTEN study directly targets the challenge of long-term cardiac secondary prevention through the platform of health literacy—a concept which has national and international relevance to public health and is increasingly being recognised as a key factor for consumer empowerment and health-related decision-making.[59 60] Despite this interest, health literacy still remains an emerging area of research within cardiovascular disease and there are significant gaps in knowledge. A key outcome from this study will be new evidence for the significance of health literacy as a contributing factor for cardiac health outcomes. Understanding how health literacy is associated with a number of adverse health outcomes post-MI (ie, exploring potential mediating factors) may identify key points for cardiac secondary prevention interventions.

This study will also provide an understanding of the role of health literacy in the uptake of CR. Previous studies examining associations between health literacy and participation in CR show mixed results; however, these studies included small sample sizes and were likely to be underpowered.[61–63] Calculation of healthcare costs and productivity loss associated with lower health literacy has rarely been undertaken. Findings from this study may strengthen existing evidence for the economic burden associated with inadequate health literacy.[15]

Inclusion of culturally and linguistically diverse groups and/or those living with socioeconomic disadvantage will also provide much-needed evidence for health literacy barriers to secondary prevention in vulnerable populations. Initiation and long-term maintenance of cardioprotective behaviours after an MI can be challenging, especially for patients experiencing socioeconomic and/or cultural or language barriers. Studies examining the determinants of health literacy suggest a number of socioeconomic factors that may influence an individual's health literacy, including low income and education, ethnicity, age and rural location.[64–66] Participants in this study will be recruited from three public health services in Victoria, Australia (two metropolitan and one rural). Both metropolitan services are located in economically disadvantaged areas of Victoria with high proportions of culturally and linguistically diverse patients. The rural health service provides care for patients from inner

regional, outer regional and remote geographical areas, who are known to be at greater risk of heart disease.[67] It is therefore anticipated that recruitment through these three health services will allow for representation of many of the socioeconomic factors associated with low health literacy.

Limitations

There may be missing data due to inability to link to government databases (VAED, VEMD, NDI, MBS, PBS). The VAED and VEMD are comprehensive datasets of hospital admissions and ED presentations in public and private hospitals in Victoria, and therefore, we will not be able to capture data for participants who access health services outside Victoria. However, the sample size is inflated to account for this; these participants will be excluded from analyses that rely on data linkage but will be included in analyses of other outcomes. Additionally, healthcare costing data will be limited to those who provide consent for linkage to Services Australia. The NDI, MBS and PBS datasets are national datasets, and the above limitation will not apply. Convenience sampling will be used, and there may be potential bias in this study, in particular that people with lower health literacy or those from diverse cultural and linguistic backgrounds may be less likely to participate. To help overcome this limitation, recruitment and consent materials use plain language wherever possible. The study assumes that a person's health literacy does not change between baseline and 6 months; however, this will be assessed within the study. Findings will contribute to the limited evidence for health literacy trajectories in cardiac patients over time.

Study implications

In summary, there are significant gaps in knowledge about the role of health literacy in cardiovascular disease. Findings from the ENHEARTEN study will address this knowledge gap and inform development of future interventions that directly target pathways between health literacy and cardiac outcomes following MI.

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