Australian Government
Australian Institute of Health and Welfare

Request for linkage of national data: technical assessment

(AIHW V5: August 2019)

Note for researchers

The AIHW Data Linkage Unit is committed to working together with researchers to:

- ensure that data requested for linkage will answer the proposed research questions
- ensure that study aims are achievable using the proposed linkage methodology
- successfully obtain AIHW Ethics Committee approval for their project.

To achieve these goals, all requests for linkage will undergo a technical assessment by the AIHW Data Linkage Unit.

Please complete the **purple sections** of this technical assessment and return to linkage@aihw.gov.au.

To avoid duplication, please read the form in its entirety before you begin completing each section.

Please do not attach a separate study protocol with your application. Please make sure all important study information is captured in this Technical Assessment form.

Following sign-off by the Data Linkage Unit, researchers are invited to submit their projects to the AIHW Ethics Committee to ensure that their project complies with relevant legislation and requirements under the *National Statement on Ethical Conduct in Human Research*.

Please note that the AIHW Ethics Secretariat will not accept applications for AIHW Ethics Committee approval unless a technical assessment has been completed.

AIHW use:	
DLU project number	819
EO number	-
DLU Project Manager	Alice Crisp
Date feasibility completed	7 November 2019
Datasets to be linked by AIHW	NBSCP, PBS, MBS, MEF, ACD, NDI

Project Details	
Project Title	What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness?
Date of application	07/11/19

Document version history: please update version number and date in footer				
Version	**Date of change**	**Brief description of change/s e.g. amendment to variable lists; scope**	**Author**	**AIHW use: EC approval date**
1.0	07/11/19	Ready for AIHW Ethics Committee review	Research team	

Contact details		
Contact person		
Title and name	Ms Andrea McMurtrie BN	
Institution	The University of Queensland	
Institution address	Public Health Building 288 Herston Road (corner of Herston Rd and Wyndham St) The University of Queensland, Herston QLD 4006, Australia	
Work email	a.mcmurtrie@uq.edu.au	
Phone	Work: 07 3346 5244	Mobile: 0407 148 776
Investigators		
Please list all investigators involved in this project. These investigators should be **the same** as those listed on the NHMRC Human Research Ethics Application form. Please indicate whether the investigator requires access to national data at the unit record level – these investigators are required to sign an *Undertaking of Confidentiality (s.29)* form. **Please add rows to include other investigators as required.**		
Principal Investigator		
Title and name	Professor Steve Kisely	
Institution	School of Medicine, The University of Queensland	
Institution address	Level 4, Building 1, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, QLD 4102	
Position title	Chief Investigator/Researcher	
Work email	s.kisely@uq.edu.au	
Phone	Work: 07 3176 5859	Mobile:
Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29? **NO** ☐ **YES** ☒
Project activity (e.g. analyst)	Oversight of the project, designing and supervising the analyses investigating the association between Severe Mental Illness and cancer screening, intervention, treatment and outcomes, drafting related papers.	
Qualifications, relevant skills and experience	CI Prof Steve Kisely (MB ChB, MD, PhD, DMedRes, FRANZCP, FRCPsych, FAFPHM, FFPH, FAChAM, DFCPA) is an expert on physical & psychiatric co-morbidity, epidemiology, and health services research with over 256 full-length publications in the area. CI Kisely has been a principal or chief investigator on research and infrastructure grants at national and state level worth $10.3 million, as well as co- or associate investigator on grants worth an additional $3million. He has significant experience in the use of administrative data for research.	
Investigator 1		
Title and name	Associate Professor Susan Jordan	
Institution	The University of Queensland	
Position title	Lead Investigator/Researcher	
Work email	s.jordan@uq.edu.au	
Phone	Work: 07 3365 5473	Mobile: 0438 690 215
Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29? **NO** ☐ **YES** ☒
Project activity (e.g. analyst)	She will provide guidance on the process for obtaining the data as well as contributing to the analytic plan, reviewing and interpreting the results and the writing up of manuscripts for publication.	

Qualifications, relevant skills and experience	A/Prof Susan Jordan (MBBS (Hons), FRACGP, PhD) associate professor of epidemiology at The School of Public Health, the University of Queensland, Brisbane. She is a medically qualified cancer epidemiologist with experience in a range of study designs. She currently leads two projects using linked administrative data (including 1 million & 12 million women respectively) She brings to this project her expertise in cancer epidemiology and methods, particularly in the design and conduct of large-scale data linkage studies and data analysis.		
Investigators continued			
Investigator 2			
Title and name	Professor David Lawrence		
Institution	University of Western Australia		
Position title	Lead Investigator/Researcher		
Work email	david.lawrence@uwa.edu.au		
Phone	Work: 08 6488 3017	Mobile:	
Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29?	**NO** ☐ **YES** ☒
Project activity (e.g. analyst)	He will contribute to the analytic plan, review and interpret the results and contribute to drafting of papers for publication.		
Qualifications, relevant skills and experience	Prof David Lawrence (BSc, PhD) is Senior Statistician at the University of Western Australia. David has many years of experience analysing linked administrative data. He is an internationally acknowledged expert in multi-level modelling methods for analysis of complex population data. He has published widely on the physical health of people with mental illness including the BMJ and British Journal of Psychiatry.		
Investigator 3			
Title and name	Associate Professor Grant Sara		
Institution	System Information & Analytics Branch, NSW Ministry of Health		
Position title	Director, InforMH department		
Work email	Grant.Sara@health.nsw.gov.au		
Phone	Work: 02 8877 5132	Mobile:	
Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29?	**NO** ☐ **YES** ☒
Project activity (e.g. analyst)	He will provide guidance on the process for obtaining the NSW data as well contributing to the analytic plan, reviewing and interpreting the results and the writing up of manuscripts for publication.		
Qualifications, relevant skills and experience	A/Prof Grant Sara (MBBS, MMed, MMed(Psychotherapy), FRANZCP, PhD) is Director of InforMH, the unit responsible for data collection, analysis and reporting for NSW Mental Health and Drug and Alcohol services and is Clinical Associate Professor in the School of Psychiatry, University of Sydney. As well as working as a clinical psychiatrist, he has extensive experience in the use of linked datasets for clinical epidemiological research. His program of research has used large administrative datasets and data linkage approaches to examine population and public health issues affecting Australians with mental health problems.		
Investigator 4			
Title and name	Associate Professor Bradley Kendall		
Institution	Princess Alexandra Hospital, Brisbane		
Position title	Clinical academic Gastroenterologist and Cancer Epidemiologist.		
Work email	bradley.kendall@uq.edu.au		

Phone	Work: 07 3176 2613		Mobile:
Accessing national unit records?	**NO** ☒ **YES** ☐	If 'YES', signed s.29?	**NO** ☐ **YES** ☐
Project activity (e.g. analyst)	He brings expertise in gastroenterology and will contribute to the analytic plan, reviewing & interpreting the results and drafting papers for publication.		
Qualifications, relevant skills and experience	A/Prof Bradley Kendall (MBBS, PhD, FRACP, AGAF) is currently a Senior Staff Gastroenterologist at the Princess Alexandra Hospital, Brisbane with over 30 years of experience in clinical practice. He has a PhD in Cancer Epidemiology from the University of Queensland. He is actively involved in ongoing research into the epidemiology of pre-malignant and malignant gastrointestinal diseases via his clinical appointment and appointments as an Associate Professor in the School of Medicine at the University of Queensland and a Visiting Affiliate at the QIMR Berghofer Medical Research Institute. He has been a chief investigator on research grants at state and institutional level including funding from the Queensland Cancer Fund, Translational Research Institute, Princess Alexandra Research Foundation and the Gallipoli Research Foundation.		
Investigator 5			
Title and name	Associate Professor Lisa Brophy		
Institution	University of Melbourne		
Position title	Centre for Menal Health, Melbourne School op Population and Global Health and Principal research fellow Mind Australia		
Work email	lbrophy@unimelb.edu.au		
Phone	Work: 03 94792387		Mobile:
Accessing national unit records?	**NO** ☒ **YES** ☐	If 'YES', signed s.29?	**NO** ☐ **YES** ☐
Project activity (e.g. analyst)	She will provide guidance on obtaining the qualitatative data as well as contributing to the analytic plan, reviewing and interpreting the results.		
Qualifications, relevant skills and experience	A/Prof Brophy (BBSc, BSW, MPolLaw, PhD) has a professional background in Social Work and her PhD focused on good practice with people on Community Treatment Orders and she has been involved in local and international collaborations regarding mental health law and its implications for policy, law reform and direct practice. She has extensive experience in the use of qualitative research methods. She is a community member of the Victorian Mental Health Tribunal. Dr Brophy has been in a full time mental health research role for the last 7 years. Her focus has been on improving interventions for recovery and social inclusion and reducing coercive practice. Dr Brophy has undertaken multiple research projects involving consumer researchers and has published those studies in peer reviewed journals. Her research has been successful in engaging people with SMI and those with multiple and complex needs. As Principal Research Fellow at Mind, Lisa assists to develop Mind's research profile and engagement in research and evaluation activities through a strong partnership with the University of Melbourne.		
Investigator 6			
Title and name	Associate Professor Dan Siskind		
Institution	School of Medicine, University of Queensland		
Position title	Clinical Academic Psychiatrist		
Work email	dan_siskind@qcmhr.uq.edu.au		
Phone	Work: 07 3317 1040		Mobile:

Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29?	**NO** ☐ **YES** ☒
Project activity (e.g. analyst)	He will assist in the analysis and interpretation of the data relating to severe mental illness (SMI). He has particular expertise in the physical health of people with SMI, and its management. He will contribute to the analytic plan, review and interpret the results and contribute to drafting of manuscripts for publication.		
Qualifications, relevant skills and experience	A/Prof Dan Siskind (MBBS, MPH, PhD, FRANZCP) is a Clinical Academic Psychiatrist at the Metro South Addiction and Mental Health Service (MSAMHS) in Brisbane, Queensland, and an Associate Professor at the School of Medicine, University of Queensland. MSAMHS provides 0.5 FTE of protected research time. He has over 80 peer reviewed publications, including 2 1st author in the highly ranked BJPsych and 1 1st author in Diabetes Obes Metab, and has over $4.1 million in research grants in the past 5 years, including as a CI on an NHMRC Project Grant. A/Prof Siskind's research skills are directly related to this study proposal. He researches and publishes in areas including severe and persistent mental illness (SPMI), and the physical health of people living with mental illness.		
Investigator 7			
Title and name	Doctor Melinda Protani		
Institution	University of Queensland		
Position title	Researcher and lecturer in Epidemiology		
Work email	m.protani@uq.edu.au		
Phone	Work:	Mobile: 0431 592 831	
Accessing national unit records?	**NO** ☐ **YES** ☒	If 'YES', signed s.29?	**NO** ☐ **YES** ☒
Project activity (e.g. analyst)	Dr Protani will provide her expertise in cancer epidemiology and patterns of cancer care and work alongside CI Jordan to perform analyses and write manuscripts for publication. She will contribute to the analytic plan, assist with analyses and contribute to writing manuscripts.		
Qualifications, relevant skills and experience	Dr Melinda Protani (BSc, MPH, PhD, GCHEd) is an early-career epidemiologist with expertise in epidemiological methods and data analysis. She has particular expertise in cancer epidemiology with experience in the investigation of factors that influence cancer survival (including data linkage with the National Death Index), studies of patterns of care in cancer, and cancer aetiology. She is currently a chief investigator on projects examining patterns of care in breast cancer management, and radiation use during cardiac catheter procedures. Dr Protani is a lecturer in epidemiology at the University of Queensland. Most of her work has focussed on patterns of cancer care including use of cancer screening services.		

Brief project summary

Please provide a brief summary description of the project (limit 200 words)

Cancer is one of the major causes of death among people with a psychiatric illness. Our previous research has shown that cancer incidence rates in people with severe mental illness (SMI - i.e.those with schizophrenia or bipolar affective disorder) are similar to those in the general population, but that cancer mortality is higher in those with SMI than those in the general population. Lifestyle factors, such as diet or alcohol use, are unlikely to be the explanation. Other reasons could include: 1) Poor cancer screening participation rates in those with mental illness; 2) delays in diagnosis leading to more advanced disease at diagnosis; and 3) sub-optimal post-diagnosis management.

Australia's National Bowel Cancer Screening Program (NBCSP) provides a unique opportunity to determine where the major barriers to optimal cancer care for those with SMI occur. We propose a data linkage study using Commonwealth data (NBCSP, Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, Australian

Cancer Database & the National Death Index) to compare bowel cancer screening participation in people with SMI to those from the general population. We will additionally link these to the NSW cancer registry and hospital data to examine care pathways from diagnosis through treatment and end-of-life care. We have decided to focus on NSW for this part of the study as it is the only large jurisdiction that holds data on estimated cancer stage at diagnosis. People with SMI will be defined using the Pharmaceutical Benefits Scheme (PBS) streamlined authority system. Second generation antipsychotics, the mainstays of treatment for SMI, require an indication-specific authority code for subsidy through the PBS. These are used almost solely for treatment of either schizophrenia or bipolar affective disorder. We will also include Lithium prescriptions, for which the specific indication is bipolar affective disorder. Barriers to participation in screening will be explored in consultation with people with experience of SMI & colorectal cancer. We hypothesise that people with SMI will have lower sceening rates & be more likely to present with more advanced cancer. They will also be less likely to receive the appropriate specialist surgical procedures, chemotherapy or radiotherapy.

Lead institution details	
Please complete this section if the lead institution is a **state or federal government agency**	
Name of lead state or federal government agency	N/A
Please complete this section if the lead institution is a **university, research institute, or government health service (e.g. public hospital)**	
Name of lead university, research institute or government health service	The University of Queensland
Please describe this organisation's security policies and governance arrangements (including confidentiality agreements) relating to data access and storage: i.e. are researchers required to sign undertakings to comply with the university's IT policy? Describe any training in confidentiality and privacy that are required.	
Please note that you will be asked to describe your data storage and access arrangements in your AIHW Ethics Committee application.	
All linked data will be stored in the Secure Unified Research Environment (SURE – Sax Institute Sydney) and accessed remotely by our research team. Any data removed from SURE will be in aggregate form only and will have to be curated out of the SURE space with data custodian approval. Any data removed from SURE as a result of the proposed research project will be managed according to UQ's Research Data Management Policy. This policy was developed to ensure that research data is properly managed according to recommendations made in The Australian Code for the Responsible Conduct of Research and applicable legislation. The University's Code of Conduct guides the behaviour of all UQ staff members and defines the standards of behaviour required of all staff. UQ staff are required to undertake online training including Employment contracts, Code of conduct, Cyber security awareness, and Privacy and agree to comply with UQ terms and conditions, and policies and procedures. Staff members have a general duty to maintain the confidentiality, integrity and security of the University's information and of third-party information provided to the University under an obligation of confidentiality.	
Please complete this section if the lead institution is a **private sector health service or other organisation**	
Name of lead private sector health service or other organisation	N/A

Other agencies requiring access to the linked dataset	
Name all other agencies associated with this project and describe the nature of their involvement	
N/A	
Please complete this section if <u>any consultants</u> will have access to the linked dataset	
Name of consultancy firm	N/A
Data storage sites	
Please list all the sites where any project-related data will be stored	
Secure Unified Research Environment (SURE) at the Sax Institute.	
Do you intend to transfer any data outside Australia?	**YES** ☐ **NO** ☒

Research proposal

Please provide details of your research or evaluation project (no word limits)

The details outlined in this proposal should be the **same** as those approved or submitted for approval to an NHMRC-accredited human research ethics committee.

Study cohort and **control group details,** and **data flow** are addressed in subsequent sections.

Privacy, dissemination of results, and data security will be addressed in the **AIHW Ethics Committee** application.

Background

Mortality rates in patients with psychiatric illness are much greater than in the general population,[1-17] yet only 10% of the excess is explained by suicide.[1,2] Most excess mortality is due to chronic physical diseases such as cancer. [8,10,11]

CI Kisely & Lawrence's previous research in Canada and Australia across a range of cancers showed that mortality rates are higher in patients with mental illness than in the general population, but that cancer incidence is similar. Of the cancers they investigated, CRC was second only to lung cancer as a cause of cancer death and patients with mental illness were 60% more likely to die from CRC than people from the general population although incidence rates were almost identical.[6-8] It is unlikely that this pattern can solely be explained by lifestyle, such as diet or alcohol use, which have relatively little effect on CRC survival. It is likely therefore that factors associated with accessing optimal care play a role and it is important that we determine the relative contributions of these.

Cancer screening: Previous work in the United States indicates that members of marginalised groups, such as recent immigrants or those with fewer years of education were the least likely to report having screening procedures such as Faecal Occult Blood Testing (FOBT) or endoscopy within the past five years.[19] Similar disparities were reported for colonoscopy/sigmoidoscopy rates among those with lower levels of education or income.[20] There is less high quality information on screening in people with mental illness, but people with mental illness tend to be less likely to be screened or treated for their physical health problems.[14] For instance, when seen by a GP, patients with psychiatric illness were less likely to have a physical examination (e.g., weight, blood pressure)[15] or be assessed or treated for hyperlipidaemia.[21, 22] They are also less likely to be screened for breast or cervical cancer.[4] However, there are no comparable data for CRC even though screening reduces CRC mortality.[23]

The National Bowel Cancer Screening Program (NBCSP): The NBCSP has implemented staged population-based CRC screening using FOBT for all Australians from the age of 50 years. At 5-yearly intervals from age 50 years people are sent a kit to collect stool specimens that are then returned for FOBT testing. From 2015, there was a phased introduction of biennial screening. The program started on 1 August 2006 & it is unknown if access to CRC screening for people with SMI has improved since then, stayed the same or even worsened relative to the general population. A 2011 study evaluated the effectiveness of the NBCSP in reducing morbidity and mortality in the general population. The project demonstrated the feasibility of the linkage of data from the NBCSP register, cancer registries and the National Death Index (NDI) to evaluate NBCSP outcomes. Of the 2,609 people in the NBCSP group with a CRC diagnosis, 298 (11.4%) had died of CRC before 2012. Of the 10,080 controls with a CRC diagnosis, 1,973 (19.6%) had died of CRC by the same date giving a 68% increased risk of CRC-specific death in those not part of the program compared to those invited to participate in the NBCSP. After correcting for

potential lead-time bias, the result was still statistically significant (15% higher risk in the controls).[18] When diagnosed, the NBCSP participants had less advanced cancer.

There is evidence from Australia & overseas that people of lower socio-economic status or self-reported Indigenous status are less likely to participate in CRC screening programs.[25,26] However, there are no data on participation rates in people with SMI. This evidence is required to determine whether additional measures are required to improve screening rates in people with SMI.

Cancer treatment: CIs Kisely & Lawrence previously found that West Australians (both men and women) with CRC and any type of mental illness were less likely to have a colorectal resection.[6] They also received significantly fewer chemotherapy cycles (mean=10.3; 95% CI: 9.1-11.4) than the general population (mean=12.1; 95% CI: 11.6-12.7) and were less likely to receive radiotherapy for CRC (1.6%; 95% CI: 0.6-2.6% vs. 3.9%; 95% CI: 3.6-4.2%; $p<0.05$).[6] There are several limitations to these findings. Firstly, the information above is about people with mental illness in general, and there is little comparable information on people with severe mental illness. These studies were also limited by the lack of information on cancer staging. It may be that some of the differences in treatment rates are due to the cancer being at a more advanced stage at time of diagnosis. This is because symptoms of physical illness are more likely to go unrecognised in people with severe mental illness.[12] Patients with psychoses tend to be less likely to report a medical complaint and have more difficulty interpreting physical symptoms, or distinguishing them from symptoms of their mental illness.[12] They may also be less able to problem-solve and care for themselves.[13] Treating doctors may also be inclined to attribute emerging somatic complaints to the psychiatric disorder, in what is termed "diagnostic shadowing". It's thus particularly important that people with severe mental illness are engaged in formal disease screening programs.

Summary: People with SMI may be dying unnecessarily because of reduced access to medical or surgical interventions commonly received by the general community.[6] The effect of the NBCSP on people with SMI is unknown in terms of participation, uptake of colonoscopy, stage of disease at presentation, access to cancer care, and cancer-related mortality. Depending on the relative levels of participation in people with SMI and the general population, the existing disparities in outcomes could improve, remain the same or even worsen. Our study will investigate these factors to further understand the effect of the NBCSP in this very disadvantaged population.

References

1. **Lawrence D**, Hancock KJ, **Kisely S**. The gap in life expectancy from preventable physical illness in psychiatric patients in Western Australia: retrospective analysis of population based registers. BMJ. 2013 May 1;346:f2539. doi: 10.1136/bmj.f2539.
2. **Kisely S,** Smith M, **Lawrence D**, Maaten S. Mortality in individuals who have had psychiatric treatment: population-based study in Nova Scotia. *Br J Psychiatry* 2005; **187**: 552-8.
3. Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? *Arch Gen Psychiatry* 2007; **64**: 1123-31.
4. Weinstein LC, Stefancic A, Cunningham AT, Hurley KE, Cabassa LJ, Wender RC. Cancer screening, prevention and treatment in people with mental illness. CA Cancer J Clin 2016;66:133-151.
5. Brown S, Inskip H, Barraclough B. Causes of the excess mortality of schizophrenia. *Br J Psychiatry* 2000; **177**: 212-7.
6. **Kisely S**, Crowe E, **Lawrence D**. Cancer-related mortality in people with mental illness. JAMA Psychiatry. 2013 Feb;70(2):209-17. doi: 10.1001/jamapsychiatry.2013.278.
7. **Kisely S**, Forsyth S, **Lawrence D**. Why do psychiatric patients have higher cancer mortality rates when cancer incidence is the same or lower? Aust N Z J Psychiatry. 2016 Mar;50(3):254-63. doi: 10.1177/0004867415577979. Epub 2015 Mar 31.
8. **Lawrence D**, Holman CD, Jablensky AV, Threlfall TJ, Fuller SA. Excess cancer mortality in Western Australian psychiatric patients due to higher case fatality rates. *Acta Psychiatr Scand* 2000; **101**: 382-8.
9. **Kisely S,** Sadek J, MacKenzie A, **Lawrence D**, Campbell LA. Excess cancer mortality in psychiatric patients. *Can J Psychiatry* 2008; **53**: 753-61.
10. **Lawrence D**, Holman CD, Jablensky AV, Hobbs MS. Death rate from ischaemic heart disease in Western Australian psychiatric patients 1980-1998. *Br J Psychiatry* 2003; **182**: 31-6.
11. **Kisely S**, Campbell LA, Cox M. The effect of study design on the reporting of mortality due to colorectal cancer in adults with mental illness in Nova Scotia. Can J Psychiatry. 2012 Jun;57(6):389-94
12. Goldman LS. Medical illness in patients with schizophrenia. *J Clin Psychiatry* 1999; **60** Suppl 21: 10-5.
13. Oud MJ, Schuling J, Slooff CJ, Meyboom-de Jong B. How do General Practitioners experience providing care for their psychotic patients? *BMC Fam Pract* 2007; **8**: 37.

14. Roberts L, Roalfe A, Wilson S, Lester H. Physical health care of patients with schizophrenia in primary care: a comparative study. *Fam Pract* 2007; **24**: 34-40.
15. Burns T, Cohen A. Item-of-service payments for general practitioner care of severely mentally ill persons: does the money matter? *Br J Gen Pract* 1998; **48**: 1415-6.
16. Jablensky A, McGrath J, Herrman H, Castle D, Gureje O, Evans M, et al. Psychotic disorders in urban areas: an overview of the Study on Low Prevalence Disorders. *Aust N Z J Psychiatry* 2000; **34**: 221-36.
17. Australian Institute of Health and Welfare 2016. Australian Cancer Incidence and Mortality (ACIM) books.
18. Australian Institute of Health and Welfare 2014. Analysis of bowel cancer outcomes for the National Bowel Cancer Screening Program. Cat. no. CAN 87. Canberra: AIHW.
19. Ward E, Jemal A, Cokkinides V, Singh GK, Cardinez C, Ghafoor A, Thun M. Cancer disparities by race/ethnicity and socioeconomic status. CA Cancer J Clin 2004;54:78-93.
20. Koh HK, Judge CM, Ferrer B, Gershman ST. Using public health data systems to understand and eliminate cancer disparities. Cancer Causes and Control 2005;16:15-26.
21. Kilbourne AM, Welsh D, McCarthy JF, Post EP, Blow FC. Quality of care for cardiovascular disease-related conditions in patients with and without mental disorders. *J Gen Intern Med* 2008; **23**: 1628-33.
22. Hippisley-Cox J, Parker C, Coupland C, Vinogradova Y. Inequalities in the primary care of patients with coronary heart disease and serious mental health problems: a cross-sectional study. *Heart* 2007; **93**: 1256-62.
23. Lin JS, Piper MA, Perdue LA, Rutter CM, Webber EM, O'Connor E, Smith N, Whitlock EP. Screening for colorectal cancer: updated evidence report and systematic review for the US Preventive Services Task Force. Jama. 2016 Jun 21;315(23):2576-94.
24. **Kisely S**, Smith M, **Lawrence D**, Cox M, Campbell LA, Maaten S. Inequitable access for mentally ill patients to some medically necessary procedures. CMAJ 2007; 176: 779-84.
25. Christou A, Katzenellenbogen JM, Thompson SC. Australia's national bowel cancer screening program: does it work for indigenous Australians?. BMC public health. 2010 Jun 25;10(1):373.
26. Von Wagner C, Baio G, Raine R, Snowball J, Morris S, Atkin W, Obichere A, Handley G, Logan RF, Rainbow S, Smith S. Inequalities in participation in an organized national colorectal cancer screening programme: results from the first 2.6 million invitations in England. International journal of epidemiology. 2011 Feb 17;40(3):712-8.
27. National Advisory Council on Mental Health (NACMH). *A Mentally Healthy Future for all Australians*.2010. http://www.health.gov.au/internet/mentalhealth/publishing.nsf/Content/8CF8540215E98930C A2574320019D4F8/$File/AMentallyHealthyFutureforallAustralians.pdf

Aims

Among people invited to participate in the NBCSP (50-74 years) we aim to:
1. Compare NBCSP participation rates between those with and without SMI
2. Determine whether people with SMI with a positive NBCSP screen have diagnostic colonoscopy as often as those from the general population
3. Calculate and compare CRC mortality rates in those with and without SMI
a. Overall; and
b. According to participation in the NBCSP
4. Amongst NSW residents diagnosed with CRC assess whether those with SMI
a. Are diagnosed at a later cancer stage
b. Receive surgery, or chemo- & radio-therapy, as often as those without SMI after adjusting for cancer stage at presentation
c. Experience any change in the above following the NBCSP

Research questions/hypotheses

We will test the following hypotheses:
1. With respect to the NBCSP, people with SMI
a. Have lower participation rates in screening
b. After a positive FOBT are less likely to receive a subsequent colonoscopy
2. With respect to CRC diagnosis, people with SMI
a. Are more likely to present with more advanced cancer
b. Are less likely to receive specialised interventions such as resection or chemotherapy.
c. Disparities in mortality will be less for people with SMI who participate in the NBCSP

Benefits to the community

This research project is directly focussed on identifying where access and/or treatment disparities exist along the colorectal cancer care pathway for people with SMI in order to improve access and service utilisation, and ultimately to improve cancer survival for this very disadvantaged group.
Chronic physical disorders cause more than 10 times as many excess deaths in people with mental illness as are due to suicide, yet receive far less attention. Cancer is one of the major causes of death among people with a psychiatric illness. Using the example of CRC, this project will investigate incidence and mortality patterns in people with SMI, and investigate where there are potential delays, or even a lack of appropriate treatment. The proposed research will investigate whether there are gaps in CRC care in people with SMI. Our study will investigate these factors to further understand the effect of the NBCSP in this very disadvantaged population. Results of our study will enable appropriately targeted interventions to be implemented to improve CRC screening and health outcomes of people with SMI and therefore aligns with the National Advisory Council on Mental Health's call for person-centred collaborative practice to address inequities in the physical health of people with mental illness. In addition, we will ask stakeholders about their experience to gain a more in depth understanding of the barriers that exist to obtaining timely screening, diagnosis and treatment. The results may indicate the actions required to decrease inequity and enhance this marginalised group's access to optimal care, thereby improving their health outcomes.

How data will be used to achieve study aims

For each research question or hypothesis, please list all (national and other) data collections that are required for analyses and describe why each dataset is required to deliver project outcomes.
The **variables** required from each data collection are to be listed in a subsequent section.

1. With respect to the NBCSP, people with SMI
    a. Have lower participation rates in screening
    b. After a positive FOBT are less likely to receive a subsequent colonoscopy

- **Medicare Enrolment File**: the study cohort will be drawn from this dataset, defined as all of those in the population eligible to participate in the NBCSP.
- **National Bowel Cancer Screening Program** (NBCSP): required to identify who has participated in the NCBSP
- **Pharmaceutical Benefits Scheme** (PBS): to identify who has SMI (those who have been dispensed items with authority codes that apply only to those with SMI)
- **National Death Index** (NDI): to identify who has died and censor their data in analyses.
- **Australian Cancer Database** (ACD): to identify whether individuals have had other cancers diagnosed so that we may adjust for these or exclude/censor in sensitivity analyses.
- **Medicare Benefits Scheme** (MBS): from this data set we will request information on medical consultations during participation in the cohort as a marker of medical access. We will also request information on faecal occult blood testing that occurs outside the NCBSP and on colonoscopies recorded in the MBS.

2. With respect to CRC diagnosis, people with SMI
    a. Are more likely to present with more advanced cancer
    b. Are less likely to receive specialised interventions such as resection or chemotherapy.
    c. Disparities in mortality will be less for people with SMI who participate in the NBCSP

- **National Bowel Cancer Screening Program** (NBCSP): Required to identify who has participated in the NCBSP
- **Pharmaceutical Benefits Scheme** (PBS): to identify who has SMI
- **National Death Index** (NDI): to identify who has died and when so their data can be censored in analyses.
- **Australian Cancer Database** (ACD): to identify all NSW participants diagnosed with bowel cancer (those who were and were not diagnosed through the NBCSP).
- **Medicare Benefits Scheme** (MBS): MBS data will be used to adjust for frequency of medical consultations as a marker of medical access during participation in the cohort.

- **NSW Central Cancer Registry**: obtain information on bowel cancer stage at diagnosis.
- **NSW Admitted Patient Data Collection**: for information on bowel cancer care after diagnosis

Analysis plan

Analyses will be conducted within the Secure Unified Research Environment (SURE) at the Sax Institute, which has the capacity for analyses of large datasets. We will investigate differences in screening rates in those with and without SMI, as well as cancer stage at diagnosis.

Incidence analyses:

We will use Poisson regression to calculate incidence rates and rate ratios (IRRs) for each outcome (FOBT, colonoscopy, cancer diagnosis, surgery, chemo/radiotherapy and mortality), comparing those with and without SMI and the effects of the NBCSP on these outcomes. Person-years will be calculated from 2006 (the year of commencement of the NBCSP), or from the year that people become eligible for screening (i.e. age 50), whichever occurs later. If an individual becomes eligible for screening before they are dispensed a medicine for an SMI then the years prior to the first prescription will be considered 'unexposed'. For NSW residents we will also assess for cancer stage at diagnosis. We will undertake sensitivity analyses of whether NBCSP participation by people with SMI reduces any disparity in mortality or cancer care outcomes (e.g. colonoscopy Australia-wide following a +ve FOBT in the NBCSP and surgery in NSW) compared to those over 50 years who participated in the program (Australia-wide), or everyone who was over 50 years old (NSW).

Adjusting for confounders: The models using only the national data will be adjusted for age, area-level socioeconomic status and state. We will also explore the possibility of adjusting for concessional status (holding a health care card or similar to receive further subsidisation on costs of medicines or health services) as a further marker of socioeconomic status. Data on the number and type of medical consultations for each person during the study period, (from Medicare) will be considered as mediators in the model. For analyses using NSW data we will also adjust for comorbidities by constructing a Charlson comorbidity score using principal and additional diagnosis codes from hospital morbidity data.

Consent for data linkage

Handy tip

The AIHW Ethics Committee expects that whenever feasible, participant consent is obtained particularly for any future recruitment.

If you are conducting a **prospective** study, a **Department of Human Services** (DHS) consent form can be used so that Medicare Benefits Schedule or Pharmaceutical Benefits Scheme data can be provided directly to researchers by the DHS. If no other data are required, these consent arrangements can be approved by the DHS' External Request Evaluation Committee.

Contact us (linkage@aihw.gov.au) to find out more.

Contact the DHS: statistics@humanservices.gov.au

Have study participants provided consent for linkage of their personal identifiers to other data collections?	**YES** ☐ **NO** ☒

You will be asked to provide details of consent arrangements in your AIHW ethics application.

Study cohort/s	
From which data collection/s or source will the study cohort be derived?	
The National study cohort will be derived from the PBS data set. The NSW cohort will be derived from the NSW Cancer Registry	
Please describe the inclusion criteria for the study cohort/s (including variables, dates)	
1. **National study cohort:** All men and women aged 50-74 years and over with severe mental illness (SMI). We will define people as having SMI if they have been dispensed two prescriptions for authority-only medications used specifically for SMI (ATC codes N05AH, N05AX, N05AE, N06AX) since 01/07/2002 (the commencement of the PBS dataset). We will include only people aged 50-74 years at 01/01/2006 or who turn 50 after this date or become Medicare eligible (and were 50-74 years) after this date. 2. **NSW cohort**: All men and women aged 50-74 years, registered on the NSW Cancer Registry with a new diagnosis of cancer of the colon or rectum after 01/01/2006.	
Estimated size	The estimated size of the 'National study cohort' is 124,974; the estimated size of the 'NSW cohort' is 53,000.
Other information about the study cohort/s	

Personal identifiers for cohorts provided to the AIHW for linkage	
For studies where the cohort/s are not created by the AIHW, please list the *personal identifiers* (e.g. names, date of birth, sex, full address) or *Statistical Linkage Key (SLK)* information that will be provided to the AIHW Data Linkage Unit	
Full name	Address
Date of birth	Postcode of residence
Sex	

Control/comparator group/s	
Is a control/comparator group part of your study?	**YES** ☒ **NO** ☐
If 'YES', who will create this group – e.g. AIHW, researchers, other linkage unit, other?	
AIHW will create the '**National comparator group**'.	
From which data collection/s will the control group/s be created?	
Medicare Enrolments File	
Please describe the inclusion criteria for the control group/s (including variables, dates)	
We are asking that the AIHW randomly select a sample of people on the Medicare Enrolments File selecting 1 in 4 people from the entire population aged 50-74 years at 01/01/2006 or who turn 50 after this date or become Medicare eligible (and were ≥ 50 years) after this date. This group will consist of people who have not been dispensed a prescription for one of the specified PBS medicines (ATC codes N05AH, N05AX, N05AE, N06AX) between 1/7/2002 to latest available.	

Estimated size	N= 1,630,000
Other information about the control/comparator group/s	
We considered whether these people could be ascertained from one of the other datasets however, we will want to ascertain these people irrespective of whether they were invited onto the NBCSP in a particular year or not. The Medicare Enrolment File appears to hold the most comprehensive set of those who would be eligible for our study and the selection of the comparator group from this data set is least likely to introduce bias.	
Personal identifiers for controls/comparators provided to the AIHW for linkage	
Please list only if these identifiers differ to those listed above for the study cohort	
N/A	

Data flow

Please outline the flow of 1) personal identifiers and 2) content data between data custodians, linkage unit/s and researchers
If you are unsure of the details, your Project Manager will help you complete this section.

Did you know…?

To minimise the risk of participant re-identification when data are to be stored in a secure research access environment, a data linkage team will remove any original personal identification numbers and replace them with a new project-specific person number (PPN).

The NSW linkage team CHeReL will:

- Select the 'NSW cohort' from NSW cancer registry data
- Assign a CHeReL_PPN to the members of the NSW cohort
- Link the NSW cohort to NSW Admitted Patient Data
- Transfer a file with CHeReL_PPN and personal identifiers for the NSW cohort to AIHW
- Extract content data for the NSW cohort from the NSW Cancer Registry and NSW Admitted patient data
- Use a map file provided by AIHW to attach the AIHW_PPN to the content data from the NSW Cancer Registry and NSW Admitted patient data, and load this content data to SURE.

AIHW will:

- Extract the 'National cohort' from the PBS.
- Select the 'National control group' from the Medicare Enrolment File.
- Link the NSW cohort, the National cohort and the control group to the MEF, ACD, NDI and NBSCP.
- Create an AIHW_PPN for all individuals in the NSW cohort, the national cohort and the control group.
- Send a PPN Map file to CHeReL with the CHeReL_PPN and AIHW_PPN.
- Extract content data from the MEF, PBS, MBS, ACD, NDI and NBSCP for the three study populations. AIHW will attach the AIHW_PPN and load these content datasets to SURE.

All data transfers will be via secure messenger service, with encrypted and password protected files.

Study datasets

Using the **Tables** on the next few pages, please:

- select the content data that are required from **national data collections**
- list the required content data from **state/territory government data collections**
- list the required content data from **other data sources.**

Please do not attach variable lists as separate documents. Lists of variables must be in Word format.

Please **list all variables and datasets** that will be accessed by the researchers.

If the variables of interest for the cohort differ to those required for the control group, please copy and paste dataset Tables as required (and clearly label).

Handy tip

Visit the AIHW website for more information about **Pharmaceutical Benefits Scheme, Medicare Benefits Schedule, National Death Index, Australian Cancer Database** and other national data collections: https://www.aihw.gov.au/about-our-data/our-data-collections.

Commonwealth dataset: Medicare Enrolment File (MEF)

Please select the MEF variables that are to be supplied to the researchers

Data requested for the period	01/01/2006 to latest available
Please provide justification for the use of these variables **If 'day of birth' or 'postcode' are requested, please provide a justification for release**	Age, sex and area level socioeconomic status and remoteness as potential confounders Postcode is requested to enable the derivation of SEIFA and ARIA categories for each person. We would like to have postcode during the whole study period so that we know whether people were residents of NSW at any time and so we can adjust as far as possible for up-to-date SEIFA and ARIA These are required to adjust for their potential confounding effects in analysis.

Handy tip

The Medicare Enrolment File is the best source of 'date of birth' and 'sex' information.

Requested MEF variables (☒ = selected variable)		☐ = specific justification for release required	
Year of birth	☒	Sex	☒
Month of birth	☒	Statistical Area 2 (SA2) (incomplete)	☐
Day of birth	☐	Postcode	☒
Age in years (time point =)	☐	Date range when postcode was current	☒

Commonwealth dataset: Pharmaceutical Benefits Scheme (PBS)	
Please select the PBS variables required from the PBS (available from 1/7/2002) **'Under co-payment' data are available from 1/4/2012** **Includes Repatriation PBS (RPBS), but veterans cannot be identified without additional DDVA HREC approval**	
Data requested for the period	01/07/2002 to latest available
Please provide justification for the use of the requested variables. **If any 'postcode' variable is requested, please provide a justification for its release.**	We would like the PBS item, the Repeat prescription indicator, the number of scripts and date of supply to enable estimation of the amount of medicine that has been dispensed. We would like information about the prescriber because we want to assess the types of health care providers that those with SMI are accessing. We would like the streamline approval number to validate that the script is for SMI and we would like the variables associated with payment as a measure of SES. We have requested 'pharmacy approval type' so that we can determine if a script was dispensed in a hospital pharmacy rather than a community pharmacy. This will be important particularly for ascertaining patterns of chemotherapy use.
Please list the specific PBS items or ATC codes that will define the scope of the PBS content extract. **Handy tip** **As new medications can be added to the PBS dataset, consider using only ATC codes to define the scope of the data extract. ATC codes will capture any newly listed PBS items.**	The following codes will be extracted for all three study populations: N05A – antipsychotics (N05AE, N05AX, N05AL, N05AH Lithium carbonate – all forms) N06A – antidepressants The following codes will be extracted for the 'NSW cohort': L01 – Anti neoplastic agents L03 – Immunostimulants L04 – Immunosupressants
Please justify the requested scope of PBS items or ATC codes **OR** **if all PBS medications are required, please provide a project-specific justification for this request.**	People with Severe Mental Illness will be defined using PBS data. We are requesting information on antipsychotic medicines so that we can use this to identify people with severe mental illness. In Australia, the most commonly prescribed medications for these conditions are lithium and second-generation antipsychotic agents. Second generation antipsychotics require an indication-specific authority code for subsidy through the PBS. These are almost solely for treatment of either schizophrenia or bipolar affective disorder hence will enable us to accurately identify the cohort of interest. The following ATC codes can be used to identify these [N05AE, N05AX, N05AL, N05AH, Lithium carbonate – all forms]. Our interest is in those who have had the medicines prescribed under the following streamlined authority codes: 4246 , 1589, 5907, 2272, C3841, 5856, 1589, 5869, 2044, 4304, 5773, 5719, 3935, 3936, 5611 5639, 2044, 2765, 5742, 3084. We will initially define our cohort as being anyone who has been prescribed one of the medicines of interest during the study period but will refine this further to create a more specific group that has received two presriptions of one of the medicines of

	interest within one year. We will use information on other antipsychotic medications and antidepressants to undertake sensitivity analyses to assess the effect of excluding those with prescriptions for these medications from the control population. PBS data is requested in order to analyse cancer treatment and outcomes for NSW colon or rectum cancer patients.

Handy tip

'ATC code' and 'Drug name' are not directly provided but can be mapped from the 'PBS item' number: http://www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop (scroll to 'Item code to drug mapping file').

'DDD' or defined daily dose and 'Form and strength' are not directly provided. This information can be found at the above link and also here: https://www.whocc.no/atc_ddd_index/ **OR** http://www.pbs.gov.au/info/statistics/asm/australian-statistics-on-medicines

'Form type code' is only provided if information about prescription authorisation is required.

Requested PBS variables (☒ = selected variable)		= specific justification for release required	
Patient postcode (PTNT_PSTCD)	☐	Prescriber speciality (MJR_SPCLTY_GRP_CD)	☒
Pharmacy postcode (PHRMCY_PSTCD)	☐	Prescriber type (PRSCRBR_TYP_CD)	☒
Prescriber postcode (PRSCRBR_MJR_PSTCD)	☐	Date of prescribing (PRSCRB_DT)	☐
PBS item (ITM_CD)	☒	Prescriber identifier (scrambled) (PRSCRBR_ID)	☐
Drug type (DRG_TYP_CD)	☐	Repeat prescription indicator (SRT_RPT_IND)	☒
Benefit amount (BNFT_AMT)	☐	Repeat order number (RPT_ORDR_NMBR)	☐
Patient contribution amount (PTNT_CNTRBTN_AMT)	☒	Previous supply number (PRVS_SPPLY_NMBR)	☐
Streamlined authority approval number (STRMLND_ATHRITY_CD)	☒	Number of scripts dispensed (always select) (PRSCRPTN_CNT)	☒
Under co-payment prescription type (UNDR_CPRSCRPTN_TYP_CD)	☒	Quantity supplied (always select) (PBS_RGLTN24_ADJST_QTY)	☒
CTG benefit amount (CTG_BNFT_AMT)	☐	Date of supply (SPPLY_DT)	☒
CTG co-payment eligibility code (CTG_CD)	☐	Patient category (derived) (PTNT_CTGRY_DRVD_CD)	☒
Pharmacy approval type (PHRMCY_APPRVL_TYP_CD)	☒	Form type code (FRM_TYP_CD)	☒
Pharmacy identifier (scrambled) (PHRMCY_ID)	☐	Regulation 24 indicator (RGLTN24_IND)	☒

Commonwealth dataset: Medicare Benefits Schedule (MBS)			
Please select the variables required from the MBS (available from 1/2/1984)			
Data requested for the period	01/01/2004 to latest available		
Please provide justification for the use of the requested variables. **If any 'postcode' variable is requested, please provide a justification for its release.**	We want to be able to adjust our analyses for frequency of medical contact as this may mediate or moderate associations between SMI and cancer screening. The selected variables will enable us to determine the number of medical practitioner consults and the type of practioner. We want to be able to adjust for these in our analyses to ascertain the effect of health care contact on use of the NBCSP.		
Please list the specific MBS items, categories, or groups for which content data are required.	The following MBS data is requested for all three study populations: All MBS items under Broad Type of Service (BTOS) groups 101 (Non-referred attendances GP/VRGP), 102 (Non-referred attendances - Enhanced Primary Care) and 103 (Non-referred attendances – Other) All MBS items under BTOS 200 (Specialist attendances) All MBS items under MBS groups M6 (clinical psychologist) and M7 (other psychologist/other health professional) and further items relating to psychologist services:10956, 10968, 81325, 81355, 82000, 82015 Sigmoidoscopy (32084, 32087) Colonoscopy (32090/32093) NBCSP colonoscopy (32088/32089) FOBT items (66764, 66767, 66770)		
Please justify the requested scope of MBS items, categories, or groups **OR** **if content data for all MBS items are required, please provide project-specific justification for this request.**	We want to be able to calculate a frequency of visits per year by specialty (GP, psychiatrists, oncologists, gastroenterologists, psychologists and other specialties grouped together) where possible. We will adjust for overall frequency of visits but will also want to test whether the influence of medical contact varies by the types of medical practitioner seen. We will also test the effect of seeing the same provider versus different providers over time. We want the Medicare colonoscopy numbers as they are more complete than what the NBCSP can supply. We are aware that the capture of colonoscopy/sigmoidoscopy will be incomplete because some colonoscopies done in public hospitals or done under Veteran's Affairs will not be included. However, we will will account for this in sensitivity analyses.		
Handy tip			
MBS item descriptions and categories can be found here: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/downloads **To help with analyses, it's a good idea to always include 'number of services performed by the provider'.**			
Requested MBS variables (☒ = selected variable)		= specific justification for release required	
Patient postcode (ENRPC)	☐	Current MBS item number (ITEM)	☒
Servicing provider practice postcode (SPRPC)	☐	Original MBS item number (AGGRITEM)	☒
Referring provider practice postcode (RPRPC)	☐	Hospital flag (INHOSPITAL)	☒

Servicing provider ID (scrambled) (SPR)	☒	Bulk-billing flag (BILLTYPECD)	☒
Servicing provider practice location (SPRPRAC)	☐	MBS category (MBSCAT)	☒
Servicing provider registered speciality at time of claim (SPR_RSP)	☒	MBS group (MBSGROUP)	☒
Number of services performed by provider (always select) (NUMSERV)	☒	MBS subgroup (MBSSUBGROUP)	☐
Referring provider number (scrambled) (RPR)	☐	Broad type of service (BTOS)	☒
Referring provider practice number (RPRPRAC)	☐	Amount of benefit paid (BENPAID)	☐
Referring date (RPDATE)	☐	Amount of fee charged (FEECHARGED)	☐
Date of service (DOS)	☒	Scheduled fee for item(s) claimed (SCHEDFEE)	☐
Date of processing (DOP)	☐	Predominant registered specialty for the provider, to be derived by AIHW	☒

National dataset: National Death Index (NDI)			
Please select the variables required from the NDI			
Handy tip			
NDI data are available from 1980 although prior to 1996, data quality is variable. 'Underlying cause of death' was classified using ICD-9 until 1996. 'Other causes of death' data are only available from 1997. From 1997, all causes of death are classified using ICD-10. Fact-of-death data are usually made available to AIHW within two months. Cause-of-death data may take about 18 months to become available to AIHW.			
Data requested for the period		01/01/2006 to latest available	
Please provide justification for the use of the requested variables **If the Regions or 'Indigenous status' variables are requested, please provide a justification for release**		Fact of death will allow censoring in analysis; cause of death will allow cause-specific mortality analyses.	
Are you seeking approval to undertake the clerical review?		**YES** ☐ **NO** ☒	
If 'YES', please list the personal identifiers you require to be released to you for clerical review			
Requested NDI variables (☒ = selected variable)		= specific justification for release required	
Fact-of-death		**Other**	
Date of death	☒	Indigenous status (incomplete)	☐
State/territory in which death registered	☒		
Year of death registration	☒	**Region**	
		Postcode	☐
Cause-of-death		SLA/SA2	☐
Underlying cause of death	☒	Country of birth (may not be reliable)	☐
Other causes of death	☒		

National dataset: Australian Cancer Database (ACD)			
Handy tip			
Researchers must seek approvals from data custodians/ethics committees as required within **each jurisdiction**. **As it may take more than six months, researchers are advised to begin the approval process as soon as possible.**			
Please select the variables required from the ACD (available from 1982)			
Date range requested		Earliest available year of diagnosis **to** latest available year of diagnosis ☒ **OR**	
		Earliest available year of diagnosis common to all relevant cancer registries **to** latest available year of diagnosis common to all relevant cancer registries ☐ **OR**	
		Other:	
Please provide justification for the release of standard variables		An outcome of colorectal cancer is a key outcome for our study so we will need to know fact of diagnosis as well as date and age at diagnosis, morphology/topography and whether the patient died of their cancer. We will also want to know whether people have been diagnosed with other cancers so that we can perform sensitivity analyses censoring at diagnosis of other cancer (as this may influence screening practices and treatments).	
Please provide justification for <u>each</u> of the requested non-standard variables			
Requested ACD variables (☒ = selected variable)		= specific justification for release required	
Standard variables		**Non-standard variables (cancer registries also require justification for these variables)**	
Sex	☐	State Registry Person id number	☐
Site/type of cancer (ICD-10)	☒	Name	☐
State of cancer registration	☒	Date of birth	☐
Most valid basis of diagnosis	☒	Date of birth accuracy indicator	☐
Date of diagnosis*	☒	Indigenous status	☐
Melanoma thickness (cutaneous melanomas)	☐	Country of birth	☐
Date of diagnosis accuracy indicator	☐	State Registry Tumour id number	☐
Size of tumour (breast cancers)	☐	Postcode at diagnosis	☐
Age at diagnosis	☒	Statistical Local Area (2006) at diagnosis	☐
Date of death*	☒	Statistical Local Area (2011) at diagnosis	☐
Age group at diagnosis	☐	Statistical Area Level 2 (2011) at diagnosis	☐
Age at death	☐		
Topography (ICD-O-3)	☒		
Age group at death	☐		
Morphology (ICD-O-3)	☒		
Underlying cause of death#	☒		
ACT Cancer Registry does **not** release person ID, name, tumour ID or date of birth. ACT Cancer Registry does not usually release postcodes. *ACT Cancer Registry usually only releases year of diagnosis and year of death. Month of diagnosis and month of death can be accessed if a strong justification is provided.			

#Cancer Registry-coded cause of death code.

As of 24 November 2015, Cancer Council Victoria ethics approval is no longer required if there is AIHW Ethics Committee approval.

Other Commonwealth/national dataset	
Name of other dataset:	**National Bowel Cancer Screening Program**
Data custodian:	Commonwealth Department of Health
Copy and paste this table to add additional datasets as required.	
Data requested for the period	01/08/2006 to latest available
Please provide a justification for the release of the requested variables	We will want to know who has been invited to screen, who has returned the tests, the results of the test and whether subsequent colonoscopy was undertaken. We will also want to know if a cancer was diagnosed.
Requested variables	
Person—sex, code X	Establishment-Australian state/territory identifier, code N (scrambled)
Person—age, total years N[NN]	Patient-colonoscope withdrawal time, total minutes NNN
Person—Indigenous status, code N	Patient colonoscope depth, anatomical site within the bowel code XX[XX]
Person-disability status, yes/no/not stated/inadequately described code N	Patient election status, code N
Person-Australian state/territory identifier, code N	Patient- sedation received indicator, yes/no code N
Person-geographic remoteness, classification (ASGS-RA) N	Patient-sedation type, code N
Person-disease screening program invitation date, DDMMYYYY	Patient-type of health professional who administers sedation, bowel canceer diagnostic assessment code N
Person–Disease screening invitation round count, total number N[N]	Patient-colorectal polyps found in colon indicator, yes/no code N
Person-first disease screening program participation indicator, yes/no code N	Patient-number of colorectal polyps found, N{NN}
Person-opted off from a disease screening program indicator, yes/no code N	Patient-colorectal polyps greater than or equal to 10mm indicator, yes/no code N
Person–suspended participation from a disease screening program indicator, yes/no code N	Patient-anatomical site of colorectal polyps, code XX[XX]
Person-cancer screening test indicator, yes/no code N	Patient-colorectal polyp type, code N[N]
Person-cancer diagnostic assessment indicator, yes/no code N	Patient-grade of colorectal polyps found, code N
Person-cancer screening test type, bowel cancer code N	Patient-adverse event, indicator, yes/no code N
Person-disease screening test completion status, bowel screening code N	Patient-type of adverse event, bowel cancer diagnostic assessment adverse event code N[N]

Person–disease screening test analysis date, DDMMYYYY	Patient–cancer staus, code N
Person-disease screening test results sent date, DDMMYYYY	Person with cancer-primary site of cancer, topography code (ICD-0-3) ANN.N
Person-cancer screening test result, bowel cancer code N[A]	GP-patient symptom code N
Patient-cancer diagnostic assessment date, DDMMYYYY	GP-patient referred for colonoscopy indicator, yes/no code N
Patient-cancer diagnostic assessment date, bowel cancer code N	GP-patient not referred code N

State or territory datasets	
Name of state or territory dataset:	NSW Central Cancer Registry
Data custodian:	Data Governance Manager Cancer Institute NSW
Copy and paste this table to add additional state or territory datasets as required.	
Data requested for the period	01/01/2006 – latest available
Requested variables	
Degree of spread at diagnosis	Remoteness 2006 (ASGC)
Month of diagnosis	Socioeconomic position – IRSD quintiles (ASGC)
Year of diagnosis	Performance status (ECOG)
Best basis of diagnosis	MDT date
Registry derived-stage (STaR)	Degree of spread at episode
Registry derived staging basis (STaR)	TNM staging group

State or territory datasets	
Name of state or territory dataset:	CHeRel - NSW Admitted Patient Data Collection
Data custodian:	Ray Messom, A/Director Demand Performance and Evaluation Branch Performance and Innovation Division, NSW Ministry of Health Locked Mail Bag 961 NORTH SYDNEY NSW 2059
Copy and paste this table to add additional state or territory datasets as required.	
Data requested for the period	01/01/2006 – latest available
Requested variables	
Hospital Type (public/private)	Referred to on separation
Age	Sex
Local Health District of facility	Source of referral
Procedure block number	Service related group
Clinical codeset	SRG version
Condition onset flags	Stay number (encrypted)
Country of birth (SACC)	LGA 2001 CODE
Days in psychiatric Unit	LGA 2006 CODE
Diagnosis codes	LGA 2011 CODE
Emergency status	LHD 2010 CODE
Episode end date (date)	PHN 2006 CODE
Episode length of stay	SA2 2011 CODE
Episode of care type	SA3 2011 CODE
Episode sequence number	LGA 2016 CODE
Episode start date (date)	RA 2011 CODE
Facility identifier (scrambled)	Days Sequence Number
Facility transferred from	Start Date
Facility transferred to	Start Time
Hours in ICU	End Date
Hours on mechanical ventilation	End Time
Involuntary days in psychiatric unit	
Major Diagnostic Category	
Mode of separation	
Procedure codes	

Participant re-identification risks	
Did you know…?	
The AIHW Ethics Committee is concerned with mitigating the risk of re-identification of study participants during analyses or in any reports or publications.	
Please list any variables that when combined may allow the re-identification of participants: e.g. date of birth, date of death, sex, ethnicity, country of birth, hospital names in rural areas, rare diseases in rural areas, postcode, personal unique characteristics.	
Age, sex, death date, area level socio-economic status, state, Indigenous status, disability, country of birth	
Why are these variables required to deliver project outcomes?	
We need age and sex and death date for analyses but CRC is not rare. Area is required to look at socio-economic status. We plan to investigate whether any associations that we observe are confounded or modified by socioeconomic status or other measures of disadvantage including Indigenous status, disability and country of birth outside of Australia.	
Did you know…?	
During analyses, participant re-identification may occur where researchers have provided cohort information or work in the same organisation as the data custodian or provider. In addition to the s.29 *Undertaking of Confidentiality*, further safeguards are required in these circumstances	
1. Where researchers have access to personal identifiers and content data for study participants, they will not access personal identifiers *and* content data at the same time for the duration of the project. 2. An independent data manager (not part of the research team) will be assigned and will be responsible for ensuring that personal identifiers and content data for participants are stored in separate data collections for the duration of the project. Please agree that these safeguards will be implemented for your study: **YES** ☐ Not applicable: ☒	
Please acknowledge that cell sizes less than five (5) will not be included in any report or publication: **YES** ☒	
If applicable to your project, please describe any other re-identification safeguards that you will implement	
Will any Commonwealth or national data approved by the AIHW Ethics Committee for a different project be included in this study?	
Name of data collection	**AIHW Ethics Committee approval number**
N/A	

Secure research access environments	
Did you know…?	
Where a project requires Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, Centrelink or certain other data, it is a data custodian requirement that the linked dataset must be stored and analysed within an approved secure research access environment (e.g. 'SURE')	
Complete the following section if your project requires a secure research access environment	
Where additional content data or the personal identifiers of study participants are held outside the secure research access environment, researchers will have their access to this information suspended while they are working in the secure environment. Please agree that this safeguard will be implemented for your study: **YES** ☐ Not applicable: ☒	
If 'YES', please describe the arrangments for suspension (e.g. IT access to researcher-held content data blocked for the duration of the study)	
Did you know…?	
If datasets are stored in a secure research access environment *and* outside a secure research access environment (e.g. a university network), personal identification numbers allocated by linkage units should be different. This ensures that it is not possible to make connections between the two environments and protects participant privacy.	
Will any data stored and analysed within the secure research access environment also be stored outside the secure research access environment?	**YES** ☐ **NO** ☒
If 'YES', please list the datasets that will be stored in the two environments	
If applicable to your project, please describe any other re-identification safeguards that you will implement	

Future linkages	
Handy tip	
For future linkages, the AIHW Ethics Committee expects that researchers will obtain consent where feasible.	
Will future linkages of datasets be required?	**YES** ☐ **NO** ☒

Funding
Please list all sources of funding for this project
Cancer Australia – awarded & confirmed

Principal Investigator declaration	
Please complete once the draft document has been finalised	
I have reviewed and approved this application for national data to undertake health- or welfare-related research or evaluation. **I declare that approval from an NHMRC-accredited human research ethics committee is current or being sought for this linkage project.** **I understand it is a data custodian requirement that once the secure research access environment workspace contains any Commonwealth data, the AIHW will have sole curation rights.**	
Print name: Andrea McMurtrie (on behalf of Steve Kisely)	**Date of approval**: 07/11/2019

AIHW use only:				
DLU check of ACD file prior to release: approved variables by jurisdiction against linked file				
Jurisdiction	**ACD Approval**	**Tick if required**	**Approval date**	**Expiry date (HREC approvals)**
	Home Institution HREC	☐		
AIHW	AIHW Ethics Committee	☐		
ACT	ACT Health HREC	☐		
ACT	Director of ACT Cancer Registry	☐		
ACT	ACD Variable Access Form	☐		
NSW	NSW Population and Health Services HREC	☐		
NSW	Director of NSW Cancer Registry	☐		
NSW	Chief Health Officer	☐		
NSW	Signed Data Confidentiality Undertaking	☐		
NSW	ACD Variable Access Form	☐		
NT	NT Health and Menzies School of Health Research HREC	☐		
NT	Chief Health Officer/Director of NT Cancer Registry	☐		
NT	ACD Variable Access Form	☐		
QLD	Director of QLD Office of Health and Medical Research	☐		
QLD	ACD Variable Access Form	☐		
SA	SA Health HREC	☐		
SA	Director of Epidemiology (SA Health)	☐		
SA	ACD Variable Access Form	☐		
Tas	University of Tasmania HREC	☐		
Tas	Director of Tasmanian Cancer Registry	☐		
Tas	ACD Variable Access Form	☐		
Vic*	ACD Variable Access Form	☐		
WA	WA Health HREC	☐		
WA	Director of WA Cancer Registry	☐		
WA	ACD Variable Access Form	☐		
*As of 24 November 2015, Cancer Council Victoria ethics approval is not required if there is AIHW Ethics Committee approval.				

AIHW use only: linkage technical notes				
Client Services checks				
Discussed with linker	**Name**	Elena Ougrinovski		
Linkage unit creating the master PPN	AIHW. Data flow sent to CHeReL on 31/10/19, no response yet			
Confirmation PPN with other nodes	**Email** ☐	**PHRN OAS** ☐	**Other** ☐	**N/A** ☐
Flow agreed by nodes?	**YES** ☐ **NO** ☐ **N/A** ☐			
Reminder - two PPNs may be needed if data are also stored outside the secure research access environment				

AIHW use only: National data custodian review		
Reminder: verify NMDS state hospital data custodian approval		
National data collection	**Data custodian name**	**Date reviewed**