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A Cluster Randomised Trial to Support Screening and Treatment for Unhealthy Alcohol Use in Aboriginal Community Controlled Health Services

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Declaration of originality

This is to certify that to the best of my knowledge, the content of this thesis is my own work, except as acknowledged in the author contribution statement. I hereby declare that I have not submitted this material, either in full or in part, for a degree at this or any other institution.

Monika Dzidowska 31 January 2022

Authorship attribution statement

This thesis contains three published papers. For all of these, I was involved in all aspects, from conceptualisation to publication. I am lead and corresponding author on all three publications. Throughout my candidature I was also involved in project management of the overarching trial (including ethics and governance, budget management, management of trial documentation and compliance with funding rules).

Chapter 2 of this thesis is published as: Dzidowska M, Lee KSK, Wylie C, Bailie J, Percival N, Conigrave JH, et al. A systematic review of approaches to improve practice, detection, and treatment of unhealthy alcohol use in primary health care: a role for continuous quality improvement. BMC Family Practice. 2020;21(1):33. https://doi.org/10.1186/s12875-020-1101-x

> **My contributions to this paper were as follows:** conceived the systematic review, designed search strategy and protocol, undertook abstract and full text screening, extracted data, drafted all sections of the paper including figures, synthesised and refined after co-authors' comments.

My co-authors' contributions to this paper were as follows: Lee: contributed to protocol development, screening process, reviewed drafts of paper; Wylie: independently undertook abstract and full text screening, reviewed draft of paper; Bailie: reviewed drafts of paper and interpretation of findings with regards to CQI; Percival: reviewed drafts of paper and interpretation of findings with regards to CQI; J Conigrave: reviewed draft of paper; Hayman: reviewed draft of paper; K Conigrave: contributed to protocol development, screening process, oversaw the scientific integrity of the study, reviewed drafts of paper.

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My contributions to this paper were as follows: proposed the analysis for the 'any treatment' variable, developed the code and conducted all analyses in R statistical software, drafted all sections of the paper including figures, synthesised co-authors' comments.

My co-authors' contributions to this paper were as follows: Lee: contributed to the development of the paper and reviewed drafts; J Conigrave: supervised the analysis and provided statistical mentoring, reviewed drafts; Dobbins: as lead statistician of the trial, led the statistical analysis design of the original trial, oversaw the statistical integrity of the analysis and interpretation of results; Hummerston: reviewed drafts and consulted on aspects of the routinely collected data and practice software; Wilson, Haber, Gray: reviewed draft of paper; K Conigrave: conceived the

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My co-authors' contributions to this paper were as follows: Raubenheimer: supervised the analysis and provided statistical mentoring, reviewed drafts; Lee: contributed to the development of the paper and reviewed drafts; Dobbins: as lead statistician of the trial, oversaw the statistical integrity of the analysis and interpretation of results, contributed to analysis development; Hayman, Haber, Vnuk: reviewed draft of paper, informed team on practical aspects of primary care; Conigrave: oversaw the scientific integrity of the study, reviewed drafts of paper.

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Katherine Conigrave

4 January 2022

Abstract

Background: Evidence-based management of unhealthy alcohol use in primary health care has been advocated since 1979 but implementation has proved challenging. There are few studies on the effectiveness of implementation strategies to improve alcohol screening and treatment in Indigenous primary health care, despite greater harms from alcohol in that population group.

Aims: To examine: (i) the approaches used to improve screening and treatment for unhealthy alcohol use in primary care internationally; and (ii) the effects of the 24-months' multifaceted support offered to 22 Aboriginal Community Controlled Health Services on screening and treatment for unhealthy alcohol use.

Methods: The systematic review (Study 1) uses summary statistics to describe strategies to improve alcohol screening and treatment in primary care and investigates if they employed elements of continuous quality improvement.

Studies 2 and 3 use multilevel logistic modelling to test the effect of the 24-month support on: (i) rates of screening and any alcohol treatment provision; and (ii) recommended frequency of screening.

Results and discussion: Study 1 found that most implementation strategies focussed on screening and/or brief intervention but not on treatments for the full spectrum of unhealthy alcohol use. About 20% of the studies employed the essential elements of continuous quality improvement. Study 2 showed that the 24-month support significantly improved the odds of screening. The effect on provision of any treatment as well as on individual treatment types was not clear and varied greatly between participating services. Study 3

was not able to show significant increases in the odds of first-time or annual screening. There were 841 (2%) clients who were screened four or more times annually.

Conclusion: Support provided to Aboriginal Community Controlled Health Services over 24 months can improve the rates of alcohol screening. However, more focus is required on screening frequency for individual clients. Further support for the delivery and accurate recording of alcohol treatment is needed. The thesis discusses practice, policy, and research recommendations for future directions in improving screening and treatment for unhealthy alcohol use.

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Table of contents

Table of figures and tables

Chapter 1

Chapter 2

Section 2.2

Chapter 3

Section 3.2

Section 3.3

Chapter 4

Chapter 5

Section 5.2

Section 5.10

Abbreviations and definitions

Terminology for Aboriginal and Torres Strait Islander peoples

This thesis follows the Public Health Association Australia's Aboriginal and Torres Strait Islander Guide to Terminology (1). As such, every effort has been made to use 'Aboriginal and Torres Strait Islander peoples' as the primary term both in the thesis manuscript and the published chapters. The use of this term aims to respectfully acknowledge the diversity of nations and language that continues to exist in Australia and the Torres Straits, and that each nation has their own names that they use to refer to themselves and others (2).

Where the use of the primary term is not possible, the term First Nations Australians or Australia's First Nations people is used. The term Indigenous (adjective, capitalised) is used to describe matters relating to First Nations peoples of countries other than Australia, and in the phrase 'non-Indigenous' to indicate populations other than First Nations peoples. 'Indigenous' is also used when it forms part of a formal name of an organisation or in previously published literature.

Other abbreviations and definitions

AA-TRIP	**Accelerating Alcohol Screening – Translation of Research into Practice** A 2-year randomised controlled trial of an intervention to improve alcohol screening and brief intervention rates in hypertensive clients; conducted in 21 primary care practices located across 16 states of the US
ABCD	**Audit for Best Practice in Chronic Disease** The largest Australian continuous quality improvement (CQI) project aiming to assist Aboriginal and Torres Strait Islander primary health care services to improve their systems for delivery of best practice care focussing on chronic disease
ABCDE	**Audit for Best Practice in Chronic Disease Extension** An extension of the ABCD project aiming to examine factors that influence update and sustainability of a quality improvement project in Australia's First Nations primary care organisations

ABS **Australian Bureau of Statistics**
Australia's national statistical agency providing official statistics on a wide range of economic, social, population and environmental topics

ACCHS **Aboriginal Community Controlled Health Services**
Incorporated Aboriginal health organisations initiated, managed by, and based in a local Aboriginal or Torres Strait Islander community

AIDS **Acquired Immunodeficiency Syndrome**
The most advanced stage of the human immunodeficiency syndrome, characterised by the development of certain cancers, infections, and other severe long-term clinical manifestations

AUDIT **Alcohol Use Disorders Identification test**
A 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviours, and alcohol-related problems

AUDIT-C **Alcohol Use Disorders Identification - Consumption**
An abbreviated 3-item form of AUDIT that focusses on assessing alcohol consumption

BIC **Bayesian Information Criterion**
A criterion for model selection used in multi-level logistic modelling. Models with the lowest BIC are preferred.

BP **Systolic blood pressure**
The pressure exerted on arterial wall when ventricles contract and blood is ejected from the heart into the arteries (measured in mmHg). For the purposes of this study acceptable range of values is defined as 60 - 230 mmHg. Hypertension defined by WHO is 140 or higher.

CI **Confidence Interval**
A range of values of sample means that is likely to include a population mean with a certain degree of confidence

CQI **Continuous Quality Improvement**
An ongoing cycle of gathering and analysing information on how well organisational systems are functioning (by comparing against standards or benchmarks) and developing or refining improvements in response to this information

DALY **Disability-Adjusted Life Year**
A measure of the burden of disease. One DALY represents one year of life lost due to ill health, disability, or early death

DSM-5 **Diagnostic and Statistical Manual of Mental Disorders (version 5)**
Fifth edition of the Manual of Mental Health Disorders published by the American Psychiatric Association

GGT **gamma-glutamyltransferase**
GGT is a liver enzyme, normally present in blood at low levels; increased levels indicate liver injury or obstructed bile flow. Higher levels occur in chronic heavy drinkers but not with lower consumption (less than 3 drinks per day or occasional heavy (binge

drinking). Reference range is Male: 5 – 50 U/L; Female: 5 – 35 U/L. Actual values in chronic drinkers can be extremely high: values of 4000 are plausible

HbA1c **haemoglobin A1c**
HbA1c is a measure of glycosylated red blood cells. It is reported either as a percentage of total red blood cells or in SI units of mmol/mol. It represents a 3-month average of blood sugar levels. Normal range is 4-6.0%. Value of 6.5% (48 mmol/mol) or higher indicates diabetes

HIV **Human Immunodeficiency Virus**
A lentivirus which, over time, causes acquired immunodeficiency syndrome (AIDS)

ICC **Intraclass Correlation Coefficient**
In multilevel modelling, ICC is a measure of homogeneity of an outcome within clusters. It is expressed as a proportion of between-cluster variation in the total variation (between- plus within-cluster variations)

ICD-11 **International Classification of Diseases (11th revision)**
A health conditions classification tool for epidemiology, health management and clinical purposes. It is maintained and published by the World Health Organization

MBS **Medicare Benefits Schedule**
A list of health professional services subsidised by the Australian federal government under the universal health insurance scheme, Medicare

NACCHO **National Aboriginal Community Controlled Health Organisation**
The national leadership body for Aboriginal and Torres Strait Islander health in Australia. NACCHO represents 144 Aboriginal Community Controlled Health Organisations (ACCHOs) that form its membership

NHMRC **National Health and Medical Research Council**
Australian federal government agency administering funds for health and medical research

ODHIN **Optimizing Delivery of Health Care Intervention (ODHIN)**
A stepped cluster randomized trial conducted in 5 European countries that tested if training and support, financial reimbursement, and option of referring screen-positive patients to an internet-based method of giving advice could increase delivery of screening with AUDIT-C and brief intervention in primary care

OR **Odds ratio**
A measure of association between an exposure and an outcome. OR is the ratio of odds of an outcome occurring given a particular exposure to odds of outcome occurring in absence of this exposure

PPRNet-TRIP **Practice Partner Research Network-Translating Research into Practice project**
A cluster randomized trial conducted in the US to assess the impact of the PPRNet-TRIP model on alcohol screening, brief intervention, and prescription of medication for alcohol use disorders in patients with diabetes or hypertension

RACGP **Royal Australian College of General Practitioners**
Australia's largest professional general practice organization

SBIRT **Screening, Brief Intervention, Referral to Treatment**
A public health framework approach used to identify and deliver services to those at risk for substance-use disorders including alcohol, depression, and other mental health conditions

SE **Standard Error**
A standard deviation of a sample mean

US **United States**
Refers to United States of America

VACCHO **Victorian Aboriginal Community Controlled Health Organisation**
Peak body of Aboriginal Community Controlled Organisations in the state of Victoria, Australia

WHO **World Health Organization**
An agency of the United Nations dedicated to promoting health worldwide

CHAPTER

1

INTRODUCTION

1.1 Epidemiology of unhealthy alcohol use

1.1.1 Unhealthy alcohol use worldwide

The World Health Organization (WHO) Global Status Report on Alcohol and Health 2018 states that about 2.3 billion people consume alcohol, and 2.8 million deaths were attributable to alcohol in 2016 (2.2% deaths among females and 6.8% in males) (3). This accounts for more deaths than tuberculosis, HIV/AIDS, or diabetes (3). Of these alcohol attributable deaths, 29% were from injuries, 21% gastrointestinal conditions, 19% cardiovascular disease, 13% infectious diseases and 13% cancer deaths (4). Globally, consumption among younger adults is of particular concern with alcohol being the leading cause of years lost from death and disability in people aged 15-49 (3).

Unhealthy alcohol use (Box 1.1) has a complex aetiology and resulting harms are strongly influenced by drinking volume and frequency (3). Intoxication can lead to poisoning, accidental injuries, and violence, while alcohol dependence is also associated with psychosocial issues, violence, and self-harm (3). Chronic consumption over recommended limits is associated with tissue damage (5). For example, recent research has shown that even low to moderate consumption over a long period of time is associated with harms such as increased risk of cancer (6, 7).

Box 1.1 Classification of unhealthy alcohol use

Two classification/definition schemes are primarily used in alcohol research: the Diagnostic and Statistical Manual for Mental Disorders, which concentrates on alcohol use disorders, currently in 5th edition (DSM-5); and World Health Organization's International Classification of Diseases (current edition: ICD-11), which also covers hazardous use (8, 9). In addition, other terms such as 'alcoholism' are common and originate from older classification schemes or public use (10, 11).

For the purposes of this thesis **unhealthy alcohol use** encompasses the full spectrum of alcohol use above recommended levels (Box 1.2). Using definitions in ICD-11 (8), unhealthy alcohol use comprises any one of the following:

Hazardous (risky) use– consumption of alcohol at levels that have the potential to cause physical or mental health harm to the user or to others and warrants an intervention from health professionals.

Harmful alcohol use – alcohol consumption patterns that have already caused harm to the user or others. These include physical illness and accidents, psychological problems, or social harms.

Alcohol dependence – this term describes an individual who is unable to control their alcohol consumption, prioritises alcohol over other activities despite experiencing harm or negative consequences, and will typically experience cravings, and may experience withdrawal symptoms when they reduce or stop drinking.

In peer reviewed literature the term **alcohol use disorder** is often used. Alcohol use disorder is a DSM-5 diagnostic term for a pattern of alcohol use leading to clinically significant impairment or distress (12). It is subclassified mild, moderate, or severe (10). The term alcohol use disorder is also often used to describe a variable that encompasses either harmful alcohol use or alcohol dependence (ICD-11 terms). In this thesis the term alcohol use disorder is used only when discussing results of other studies that use this term.

1.1.2 Unhealthy alcohol use is an Australia-wide problem

In Australia, where alcohol is the most commonly consumed psychoactive substance (13), drinking patterns follow global trends. The Australian Bureau of Statistics (ABS) reported that in 2017-18, 78.8% of the adult population 18 years and older (84.5% of men and 73.3%

of women) consumed alcohol in the previous year and 16.1% exceeded the national lifetime risk guideline of two standard drinks per day that was recommended[1] at that time (14).

Although the number of people aged 14 and over who exceed this lifetime risk guideline has declined from 21% in 2001 to 16.8% in 2019, there has been little change between 2016 and 2019 (from 17.2% to 16.8%). Furthermore, the proportion of individuals aged 14 or older who exceeded single occasion risk guidelines[1] (more than four drinks per occasion) has remained stable (26% in 2016, 25% in 2019) (15). Alcohol contributed 4.5% of the total burden of disease and injury in 2015 and was the highest contributor to the burden in males aged 15-44 (16).

1.2 Aboriginal and Torres Strait Islander peoples' unhealthy alcohol use in the context of colonisation

Alcohol has been identified as a priority concern by Aboriginal and Torres Strait Islander communities and the interaction between alcohol and the socio-economic disparities is complex (17). Aboriginal and Torres Strait Islander peoples are more likely to abstain from drinking than non-Indigenous Australians (31% and 23% respectively in 2016) (18). However, episodes of drinking in this population often involve large amounts of alcohol, with a median of 78g of ethanol consumed per occasion (19). This far exceeds the Australian recommendation of 40g per occasion to reduce short-term harms such as injury (20). Prevalence of alcohol dependence among Aboriginal and Torres Strait Islander peoples is estimated to be 2.2%, which is similar to the general Australian population (21).

[1] The 2009 Australian guidelines to reduce health risks from drinking alcohol discussed here were superseded by a new version in December 2020, which make a different recommendation. See box 1.2 and section 1.3.3.

Alcohol-related health outcomes in Aboriginal and Torres Strait population follow the globally observed but poorly understood alcohol harm paradox (22). This is the paradox wherein populations with greater socioeconomic disadvantage suffer disproportionately greater harms from alcohol than advantaged groups, even when taking into account differences in drinking patterns (22). Aboriginal and Torres Strait Islander peoples are particularly vulnerable to alcohol-related harm. For example, between 2013 and 2017 Australia's First Nations people had 23.8 alcohol-related deaths per 100,000, which is more than five times the rate for non-Indigenous Australians (23). Alcohol contributes significantly to the health gap between Aboriginal and Torres Strait Islander peoples and their non-Indigenous counterparts, accounting for 8.1% of that gap in 2011 (measured by the Disability Adjusted Life Years (DALY) rate difference between these two groups) (24).

Greater harms from unhealthy alcohol use among Aboriginal and Torres Strait Islander Australians have to be understood in the context of the effects of colonisation. Through this process Aboriginal and Torres Strait Islander peoples were systematically removed from their land, were subject to discrimination and racism in all aspects of life, and were robbed of their autonomy (25). As a result, like Indigenous peoples of other countries that have a history of British colonisation, Aboriginal and Torres Strait Islander peoples experience poorer social determinants of health such as greater poverty, malnutrition, and lower standards of living than the general population (26). This has led to poorer physical and mental health outcomes (26). For example, Aboriginal and Torres Strait Islander people are 2.1 times and 3.9 times more likely to be hospitalised for coronary heart disease or diabetes receptively, than the general Australian population (27).

Since alcohol was a feature of the Australian colonisation from the beginning, First Nations Australians were given easy access to alcohol while the erosion of their self-determination was occurring (13). Alcohol was also used at times by First Nations Australians as a means of escape from historical and contemporary traumas (28), leading to heavy consumption, and exacerbation of psychosocial and physical health problems (13).

Because of its harms to the individual, families, and communities, addressing unhealthy alcohol consumption is a matter of priority in Aboriginal and Torres Strait Islander communities.

1.3 Policies and guidelines to address unhealthy alcohol use

There is heterogeneity of policies and practices across countries relating to alcohol consumption and treatment of unhealthy alcohol use. This includes definitions of standard drinks and recommended safe drinking levels (Box 1.2), as well as treatment guidelines, and laws and policies designed to limit access to alcohol.

Box 1.2 How are standard drinks and recommended drinking limits defined?

Standard drink: The definition of a standard drink differs from country to country. The Australian National Health and Medical Research Council (NHMRC) defines a standard drink as containing 10g of alcohol, equivalent to 12.5mL of pure alcohol (29). This is consistent with the WHO's definition in screening and brief intervention guidelines (30, 31). Alcoholic beverages are often sold and served in sizes containing more than one standard drink (32).

Recommended drinking limits are defined using epidemiological evidence of association between consumption levels and short- and long-term harms. Recommendations differ between countries and may be different for men and women (5). Current Australian guidelines (updated in 2020) stress that there are no 'safe' drinking levels and recommend no more than 4 standard drinks daily and no more than 10 weekly for men and women aged 18 and over; no alcohol consumption for people age under 18 and for pregnant people (20).

1.3.1 International guidelines

WHO states that alcohol is the only substance with psychoactive and dependence-producing properties that has significant global impact on population health, but is not controlled at the international level by legally-binding regulatory frameworks (4). Furthermore, international trade treaties have increasingly focussed on facilitating trade and investment in alcohol, often resulting in minimising the effects of barriers imposed by national control measures (e.g., supply and demand control efforts) (33). It is therefore even more important to address unhealthy alcohol use in the context of health.

WHO's Global Strategy to Reduce the Harmful Use of Alcohol was agreed to by member states in 2010 and remains the most comprehensive global framework for minimising harms from alcohol consumption (4, 34). This global framework specifies 10 target areas for policy options and actions, which are complementary and supportive of each other. This includes health service response as well as responses in areas such as leadership, marketing, pricing, harm reduction and community action. The framework recommends that as part of the health service response, governments support screening and brief intervention for hazardous and harmful drinking in primary care (defined in Box 1.3), increase capacity to deliver prevention, treatment and care for alcohol use disorders, and that these be provided in a culturally sensitive manner (34). However, to maximise success, the health service response needs to be implemented alongside responses in other action areas (34).

Box 1.3 What defines primary care?

Australian Government's Department of Health defines **primary care** as the first point of contact a person has with Australia's health system. It relates to the treatment of patients who are not treated at a hospital and includes care provided in the home or in community-based settings (e.g., general practice, community health centres, Aboriginal Community Controlled Health Services). It can be delivered by clinicians such as nurses, allied health professionals, midwives, pharmacists, dentists, and Aboriginal health workers (35).

1.3.2 Recommendations and policies for primary care

Alcohol screening and treatment (Box 1.4) in primary care has been advocated by the WHO since 1980 (36). The recommended evidence-based approach includes annual screening with a validated tool to detect and assess the severity of unhealthy alcohol use, followed by brief intervention if indicated (30, 31). A recent review of 17 national and international guidelines in English on managing harmful alcohol use in primary care settings found that all recommended screening and brief intervention because of their effectiveness and cost-effectiveness. However, not all guidelines made recommendations for treatment of the full spectrum of unhealthy alcohol use in primary care, including for both dependent and non-dependent drinkers (37).

In primary care, treatments are most commonly delivered in the context of the SBIRT approach (Screening, Brief Intervention, Referral to Treatment) (38). SBIRT advocates for the delivery of screening and brief intervention within the primary care service, and referral to specialist services when harmful use or dependence are suspected. This approach helps to ensure effective pathways for referral between primary care and specialist services or external providers when more intensive treatment is needed (38).

Box 1.4 Overview of screening and treatment for unhealthy alcohol use

Screening is recommended for all adults aged 18+. A number of validated instruments have been developed, including the 10-item Alcohol Use Disorders Identification test (AUDIT) developed and recommended by WHO (31). The 3-item AUDIT-consumption (AUDIT-C) is its shorter version, which has been validated for use in primary care settings (39). Literature however highlights the broad application of the term "screening", which ranges from simply asking about alcohol to the use of validated screening tools.

Brief Intervention, also referred to as brief counselling. It is usually delivered as part of regular consultations and can be 5 – 30 minutes in duration (40). Brief interventions tend to employ a patient-centred, motivational interviewing approach (41, 42) rather than just providing advice. A brief intervention can include feedback on alcohol use and health-related harms, identifying motivations to change in drinking behaviour, identification of high-risk situations for unhealthy drinking, and the development of a personal plan. Brief intervention is generally considered of most benefit to those who drink at hazardous levels. There is also some recent evidence that it could of some benefit to individuals who are dependent on alcohol and in younger adults who drink at harmful levels (40).

Psychological and supportive therapies – this type of treatment includes psychosocial interventions such as counselling, behavioural therapies, self-help programs and mutual support groups (43).
Pharmacotherapies – there are several medications used to treat alcohol dependence in primary health care settings. These are used mainly to reduce relapse ('relapse prevention') once a person has successfully completed alcohol withdrawal. The most widely accepted medications are naltrexone, acamprosate and disulfiram. Others used, in some regions or in trials, include baclofen and topirimate (10, 44).

The SBIRT approach has come under criticism in recent times as research indicates that the 'referral' component of the SBIRT approach often does not result in treatment access and thus misses the opportunity to address more severe drinking problems in the health care system (45).

Despite being generally accepted as best-practice and being adopted into policies and guidelines, screening and treatment for unhealthy alcohol use remains poorly implemented

(46). For example, representative data from household surveys in the United Kingdom (2014) found that just 6.5% of people who drank excessively (score of 8 or higher on the Alcohol Use Disorders Identification Test (AUDIT)) recalled receiving related advice when visiting a general practice in the previous year, compared to 50.4% of those who smoked tobacco (47). The Optimizing Delivery of Health Care Intervention (ODHIN) – a five-country cluster randomized factorial trial (conducted 2012-13), found that 6% of presenting clients were screened for alcohol consumption at baseline (48).

1.3.3 Primary care guidelines in Australia

In Australia, the Department of Health and Ageing guidelines for the treatment of alcohol problems recommend screening with structured questionnaires, including AUDIT-C (Box 1.5) (49). The Australian guidelines on alcohol consumption at the time the study was conducted[2] recommended no more than four standard drinks on any day to reduce short-term harms from alcohol, and (an average of) no more than 2 standard drinks per day to reduce long-term harms (29). The Royal Australian College of General Practitioners' (RACGP) population health guide to behavioural risk factors (SNAP guidelines) advises that AUDIT-C scores of 3 or more for females and 4 or more for males are considered as exceeding recommended (low-risk) levels (50). The same cut-off scores are used when assessing alcohol consumption in Aboriginal and Torres Strait Islander peoples (51).

Australian alcohol treatment guidelines recommend that clients who drink above recommended levels should be offered brief intervention in primary care settings (49). Those identified as drinking at moderate- to high-risk levels should be assessed further for

[2]In 2020, the recommended maximum consumption to reduce long-term harms was reduced to 10 standard drinks per week (20). See box 1.2.

more intensive treatments (e.g. psychosocial interventions, pharmacotherapies, mutual-help approaches, withdrawal management) (49). These guidelines are not explicit about provision of more intensive treatments such as pharmacotherapy for relapse prevention in primary care settings.

RACGP guidelines on the other hand are not always consistent in treatment recommendations. The Guidelines for Preventive Activities in General Practice mention only brief interventions and recommend referrals to specialist treatment for more severe alcohol problems, including dependence (52). The SNAP guidelines advise considering prescription of pharmacotherapies for relapse prevention following successful withdrawal management, which could also be managed in community (i.e., while patient lives at home rather than in a residential or in-patient treatment centre) (50).

Box 1.5 The AUDIT-C screening tool

AUDIT-C consists of three questions on consumption, each with five possible response options. The score for each response is indicated in parentheses (). Maximum possible score is 12 (39).

1. How often do you have a drink containing alcohol?
- □ Never (0)
- □ Monthly or less (1)
- □ 2-4 times a month (2)
- □ 2-3 times a week (3)
- □ 4 or more times a week (4)

2. How many drinks containing alcohol do you have on a typical day when you are drinking?
- □ 1 or 2 (0)
- □ 3 or 4 (1)
- □ 5 or 6 (2)
- □ 7 to 9 (3)
- □ 10 or more (4)

3. How often do you have six or more drinks on one occasion?
- □ Never (0)
- □ Less than monthly (1)
- □ Monthly (2)
- □ Weekly (3)
- □ Daily or almost daily (4)

Primary care guidelines for Aboriginal and Torres Strait Islander people

The National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (co-published by The National Aboriginal Community Controlled Health Organisation (NACCHO) and RACGP) recommends screening for all people aged 15 or more, during the annual health assessment for First Nations Australians (53-55)[3], or opportunistically (56). More frequent screening is recommended for high-risk groups, which include:

- Adolescents and young adults (15-24 years)
- Women who are pregnant or planning for pregnancy
- People who use illicit drugs or who misuse other substances
- Clients with a family history of alcohol dependence
- People with mental illness
- People with medical conditions that may be worsened by alcohol consumption (e.g., cardiovascular disease, arrhythmia, liver disease, diabetes, hypertension)

Recommendations include brief interventions to reduce alcohol consumption as a first line of treatment and extended clinical care or referral for more severe use or dependence (56). Use of pharmacotherapies or other more intense therapies is not mentioned in these guidelines.

[3] An annual health assessment for Aboriginal and Torres Strait Islander adults. This is a preventive health check available to this population to no cost and is covered under Australia's Medical Benefits Scheme. It aims to identify lifestyle and other risk factors early to prevent the development of chronic conditions. It also checks for early signs of disease. This health check takes up to 1 hour to administer.

1.3.4 Adoption of screening and treatment in Aboriginal Community Controlled Health Services

In Australia, Aboriginal and Torres Strait Islander Community Controlled Health Services (ACCHS) provide primary health care services to Aboriginal and Torres Strait Islander peoples (57). ACCHS are owned and operated by the local First Nations Australian community. This allows the Aboriginal and Torres Strait Islander communities to determine, make decisions about, and act on their own health priorities, thus enabling self-determination (58). The first ACCHS was established in 1971 in Sydney's inner-city suburb of Redfern, in New South Wales (57). There are 143 ACCHS operating in Australia in urban, regional and remote areas and they vary in size and type of service provided (59). ACCHS adopt an integrated health care model and have a unique and close relationship with the community they serve. They are integral to meeting the Aboriginal and Torres Strait community's holistic view of health (Box 1.6). Involving the ACCHS as Australian First Nations primary care experts in co-design of service improvement strategies is therefore important for successful uptake.

Evidence also suggests that ACCHS can contribute to improvement of Aboriginal and Torres Strait Islander people's health outcomes more effectively than mainstream services (60). A study of communities in the Australian city of Brisbane found that Aboriginal people considered ACCHS to be positive determinants of health (60). A review of literature by Campbell et al found evidence of ACCHS contributing to improvement of health outcomes, particularly in the areas of immunisation and child and maternal health (57, 60). Yet adoption of screening and treatment for unhealthy alcohol use in ACCHS follows similar patterns to those observed globally – the rates are generally low and vary greatly between individual services. For example, baseline data from the cluster randomised trial on which

this thesis is based found that the 12-month rate of screening among participating ACCHS ranged between 6.5% and 10.4% (61).

Box 1.6 How is 'Aboriginal and Torres Strait Islander health' defined?

National Aboriginal Community Controlled Health Organisation states that *'Aboriginal health is not just the physical well-being of an individual but refers to the social, emotional and cultural well-being of the whole Community in which each individual is able to achieve their full potential as a human being thereby bringing about the total well-being of their community. It is a whole of life view and includes the cyclical concept of life-death-life.'* (62)

1.4 Efforts to improve global uptake of screening and treatment

Poor adoption of alcohol screening and treatment is caused by well-documented barriers. These include lack of time and resources, competing priorities, gaps in clinician's knowledge and training, and taboos around alcohol use (63). Many implementation studies to address these barriers have been conducted but previous systematic reviews showed that the evidence base tended to concentrate on implementation of screening and brief intervention (64-67). Due to the heterogeneity of the designs of both the implementation strategies and the studies in the published literature, it is not clear what combination of approaches works best to improve the rates of alcohol screening and treatment in primary care. Just one meta-analysis on alcohol screening and brief intervention implementation studies has been published. It showed that implementation strategies that were multifaceted and involved multiple organisational levels as well as those with durations of at least 12 months appeared to be associated with better outcomes (67).

However, since primary care services can differ greatly in organisation, in practice setting and workforce and in the communities they serve (68), strategies also need to be flexible and responsive to changing service needs. One approach that affords this flexibility is

Continuous Quality Improvement (CQI). Adopted in healthcare since the 1990s, CQI programs use recognised change methods such as Plan-Do-Study-Act and Six-Sigma to identify areas in need of improvement, design a response and monitor its effects through iterative cycles (69). The key philosophy of CQI is that it involves everyone in the organisation in reviewing the processes of delivering care and planning and executing improvement (70, 71).

A consensus study by Rubenstein et al. defined three essential CQI elements, which must be present for a program to be a CQI strategy:

1. Using 'systematic data guided activities' to identify problems and achieve improvement
2. 'Designing with local conditions in mind'
3. Using an 'iterative development and testing process'

CQI is widely used in health service quality improvement (72). There is also a growing body of academic literature in quality improvement science, but evidence for effectiveness is variable (73). However, there is evidence that CQI may be particularly suited as a primary care service improvement strategy, with significant results from studies in paediatric preventive care, diabetes care, colorectal cancer screening, practice improvement and cost reduction (73).

1.4.1 CQI in First Nations Australian primary health care

Aboriginal and Torres Strait Islander primary health care in Australia has been an early adopter of CQI. This is likely because the principles of CQI are compatible with strategy characteristics that have been shown to be important when implementing changes in the

Indigenous settings. These include culture-centred approaches, community engagement, systems thinking that addresses the complexity of local contexts, and co-design with end-users with the aim of transferring knowledge and ensuring sustainability (74). The National Appraisal of Continuous Quality Improvement Initiatives in Aboriginal and Torres Strait Islander Primary Health Care (75) reports that between 2010 and 2012 more than 200 health centres nation-wide, including ACCHS, were involved in the largest initiative - One21Seventy. This program is also known as Audit for Best Practice in Chronic Disease (ABCD and ABCDE). Several other CQI programs have been in operation in Aboriginal and Torres Strait Islander primary care (70).

CQI has been successful in improving adherence to best practice guidelines, client attendance and resulted in the rise of CQI workforce, system supports and improvement in engagement of stakeholders such as community members and organisations (76).

In 2020 the National Aboriginal community Controlled Health Organisation (NACCHO) launched the National Framework for Continuous Quality Improvement in Primary Health Care for Aboriginal and Torres Strait Islander People, 2018-2023 (from here on referred to as the National CQI framework) (70).

The principles of CQI within this national framework could potentially increase the effectiveness of service delivery strategies in the ACCHS setting. However, at the time of commencing this research it was not known how extensively CQI was used to effect improvements in the delivery of alcohol care either in ACCHS or in primary health services internationally. There were no systematic reviews that investigated whether CQI principles or CQI programs were employed in improving screening and treatment for unhealthy alcohol use.

1.5 Aims and objectives

This body of work aims to examine the approaches used to improve screening and treatment for unhealthy alcohol use in primary care services and how these apply in the context of healthcare provision to Aboriginal and Torres Strait Islander peoples of Australia. It will then examine the effects of a 24-month, service-wide support model offered to 22 ACCHS as part of a cluster randomised trial to improve screening and treatment of unhealthy alcohol use. The objectives of the thesis are:

1. **To investigate strategies used to improve implementation of alcohol screening and treatment in primary care internationally (Study 1, Chapter 2).**

   A systematic review will examine the different strategies that have been used since the 1990s to improve screening and treatment for unhealthy alcohol use in primary care in general and in Indigenous populations. Given the uptake of CQI for improvement of service delivery in Aboriginal and Torres Strait Islander healthcare, the review will also examine if elements of CQI are used in these strategies internationally.

2. **To investigate the effects of the model of support on alcohol screening and treatment rates in participating ACCHS over 24 months of implementation (Study 2, Chapters 3 and 4).**

   This study will use multilevel logistic modelling to test the change in odds of clients receiving screening and various types of treatment over 24 months of implementation of the support model (in the treatment arm when compared to a waitlist control arm).

3. **To investigate whether the support model resulted in clinically useful patterns of screening that are in keeping with recommendations for Aboriginal and Torres Strait Islander peoples in Australia (Study 3, Chapter 5).**

   The study uses multilevel logistic modelling to investigate if services, which were receiving the support (treatment arm), achieved a higher rate of first-time screening and regular annual screening of clients, compared to controls. It also investigates if the implementation model resulted in very frequent screening of clients (screened four times or more in any 12-month period).

4. **To consider the implications of the results for practice, policy, and research (Discussion, Chapter 6)**.

   The discussion will reflect on the results of the three studies as a whole and make recommendations for practice and policy for: client/community, clinician, services and the primary care sector. The discussion will also consider what role CQI could have in further work to improve implementation of alcohol screening and treatment. It will then reflect on research gaps identified in these studies and make suggestions for future directions.

1.6 Overview of research methods

1.6.1 Systematic review

The review will examine the different strategies that have been used since the 1990s to improve screening and treatment for unhealthy alcohol use in primary care. It will also investigate whether three elements of CQI were employed in these strategies. The time limit of 1990 for the systematic review was chosen as it marked the first decade after WHO's recommendations on alcohol screening with AUDIT and on the use of brief

intervention. It also marks the beginnings of adoption of the principles of CQI in healthcare delivery.

The search strategy was developed using the following steps:

- A broad search was conducted, and a 20% sample screened against selection criteria
- Included articles were reviewed independently by two reviewers to arrive at a sentinel article set.
- The sentinel article set was used in an iterative process of refinement to build and refine the search strategy.
- The search strategy was reviewed by an independent external reviewer and further suggestions incorporated.

Article selection followed commonly accepted review methods of abstract and full text screens, followed by data extraction. Due to the high volume of search results a semi-automated step of title-only screen was added.

The protocol for the systematic review was registered in the systematic reviews database PROSPERO. Although a risk of bias assessment was planned at the time of registration, it was not conducted due to the large number of included articles, high heterogeneity of study designs and time limitations of the PhD candidature. The registered protocol is presented in Appendix A with reformatting for the purposes of this thesis.

1.6.2 Cluster randomised trial

The focus of this thesis is part of a larger cluster randomised trial of a multifaceted, service-wide support model to improve screening and treatment of unhealthy alcohol use in ACCHS.

Ethical considerations

In line with the National Health and Medical Research Council's Guidelines on Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities (77), the development of the trial followed the six core values. The first value - spirit and integrity - demonstrates commitment in carrying out all the other five values: cultural continuity, equity, reciprocity, respect, and responsibility. This approach ensured that the research was culturally respectful and relevant to the Aboriginal and Torres Strait Islander communities:

- **Spirit and integrity** – the trial concept was initiated by the Aboriginal Health Council of South Australia and was co-designed with peak Aboriginal and Torres Strait Islander health organisations (in South Australia and New South Wales). The recruitment process was preceded by an extensive engagement with the services prior to formal consent to participate. This involved multiple opportunities to discuss the study, thus allowing the services to determine if participating in the trial might add value to their existing practices. The 22 ACCHS that consented to participate were also involved in refining the study design. During the first national workshop the services contributed insights about barriers and facilitators in relation to provision of alcohol care and contributed ideas for tailoring of the support model to their needs. The points below demonstrate in detail how the project addressed the five core principles.
- **Cultural continuity** – designing the study with peak Aboriginal and Torres Strait Islander health organisations and providing mechanisms that allowed the ACCHS' input into tailoring and refinement of the support model, ensured

culturally respectful design approach. This also enabled the communities to have input into the project throughout its trajectory. The study design drew on strengths within ACCHS as experts on working culturally with their people. The support model's training was informed by 44 in-depth qualitative interviews of ACCHS staff members, conducted and analysed by Kristie Harrison, a Wiradjuri woman and health professional (this report is being published separately). Kristie also co-designed and co-presented the training sessions. The training and the second monthly teleconference components had an emphasis on sharing their current knowledge and experience.

- **Equity and reciprocity** – the 22 ACCHS that participated in the study executed memoranda of understanding with the University of Sydney. They received reimbursement for time required to provide data to the project. Training offered during the study was available to all service staff. The waitlist design of the trial ensured that all 22 services received the support offered by the trial. The project prioritised engaging Aboriginal staff and postgraduate research students whenever possible. Two Aboriginal women have been engaged in postgraduate research studies in relation to other data from this study. Four other Aboriginal women have been involved in the research administration team for the project.
- **Respect and Responsibility** – the trial sought ethical and governance approval from appropriate Aboriginal and Torres Strait Islander ethics committees, and from the participating services. To preserve the services and clients' anonymity, outcomes data is aggregated in a way that prevents identification. In line with data sovereignty principles, the ACCHS remained in

control of the routinely collected practice data. The provision of specific data items was discussed and agreed with the services. Services gave authorisation for data extraction and could withdraw from the study at any time (including withdrawing data). Data provision was formalised through executing of a memorandum of understanding. Researchers did not have direct access to practice data. Data extraction and provision was carried out either by the ACCHS or by a data manager from the Aboriginal Health Council of South Australia (AHCSA). The ACCHS retained joint IP rights to the research dataset that resulted from aggregating and curating their individual data contributions. ACCHS have been consulted on all report drafts prior to dissemination of findings via peer-reviewed publications. Contribution of the ACCHS was acknowledged on all publications without identifying individual services.

Flexible multifaceted model with consistent core elements

The support model consisted of eight components including:

- formal agreements between services and the University of Sydney
- nomination of champions for each service
- a national workshop
- on-site training
- financial support for tools to support their work on alcohol
- support with practice software modification if needed
- bi-monthly data-audit-and-feedback, and champion teleconferences
- online resource and communication platform.

Implementation of the model occurred in two phases: active support and maintenance support, each 12 months in duration. The support model and its implementation will be described further in sections 3.3 and 5.2.

The model employed features consistent with the three essential CQI elements and this gave the services a high level of flexibility in how they chose to use the support offered, while the core elements of support remained consistent. For example, on-site training components were tailored to the needs communicated by each service and services chose if and how they wished to modify their practice software to support the improvement efforts. The data audit-and-feedback and service champion teleconferences were conducted in bi-monthly cycles, allowing the services and their champions to share their experiences and discuss barriers and facilitators to improving alcohol screening and treatment.

Data and outcomes

The trial outcomes were measured using routinely collected data from the participating services' practice software, Communicare. Deidentified data was provided by services as bi-monthly data downloads and combined into a single file by the study's data manager.

Outcomes data comprised the following records in the Communicare practice software database:

- demographic data
- whether AUDIT-C screen occurred
- Whether advice related to alcohol of less than 20 minutes (brief intervention) was provided
- Whether counselling related to alcohol was provided

- Prescription of relapse prevention pharmacotherapies (naltrexone, acamprosate or disulfiram)
- Biomarkers affected by alcohol (systolic blood pressure, haemoglobin A1c or gamma-glutamyltransferase)

Analysis

Due to the hierarchical nature of the data (visits nested within clients and clients nested within services) multi-level logistic modelling was used in the analyses presented in this thesis. Further details of the analytical methods are presented in Chapters 3 and 5.

The protocol of the trial and 12-month outcomes for screening and brief intervention have previously been published by other authors (78, 79). Those publications do not form part of this thesis.

This thesis examines screening and brief intervention over the entire 24-month implementation period (Chapter 3) and looks at outcomes of provision of any treatment, pharmacotherapies for relapse prevention and any talking therapies (Chapters 3 and 4). It also considers outcomes related to the appropriateness of screening frequency following implementation, or whether the implementation might have induced overscreening of certain individuals.

1.7 Thesis orientation

OBJECTIVE 1

Investigate implementation strategies (study 1)

Chapter 2. Systematic review: improvement strategies for screening and treatment of unhealthy alcohol use

OBJECTIVE 2

Effects on screening and treatment (study 2)

Chapter 3. Effects of the support model on screening and treatment for unhealthy alcohol use

Chapter 4. Effects of the support model on talking therapies and pharmacotherapies

OBJECTIVE 3

Effects on clinically useful screening patterns (study 3)

Chapter 5. Effects of the support model on AUDIT-C screening patterns

OBJECTIVE 4

Implications and future directions

Chapter 6. Discussion

CHAPTER

2

SYSTEMATIC REVIEW: IMPROVEMENT STRATEGIES FOR SCREENING AND TREATMENT OF UNHEALTHY ALCOHOL USE

2.1 Introduction

As outlined in Chapter 1, while screening and treatment, particularly brief intervention, have been accepted as best practice in management of unhealthy alcohol use in primary care, there is poor uptake globally (46). The principles of CQI offer a flexible approach to improve service delivery, that has been promoted in Aboriginal and Torres Strait Islander primary care by a national framework recently published by NACCHO (70).

Many strategies have been described in peer-reviewed literature to implement screening and treatment for unhealthy alcohol use. However, there is no consensus on which approaches work best in general and in Indigenous populations. As noted in Chapter 1, implementation strategies tend to focus primarily on screening or on screening and brief intervention with other treatments being offered by referral out of primary care. It is not known if CQI approaches are being used to improve screening and treatment for the full range of unhealthy alcohol use.

Prior to the commencement of this systematic review, there were just two reviews on implementation of screening and treatment for unhealthy alcohol use in primary care (the most recent published in 2011). These showed that alcohol-focussed, multifaceted programs, targeting multiple organisational levels with duration of at least 12 months did better than programs that did not have these features (64, 67). None of these reviews addressed the full spectrum of unhealthy alcohol use or all available types of treatment.

This chapter aims to synthesise strategies used to improve screening and treatment of unhealthy alcohol use and their main characteristics, including whether they addressed screening and treatment for the full spectrum of alcohol use, or used elements of CQI in their design. In addition, the review also aims to investigate whether the service

improvement strategies resulted in improvement in patient outcomes and assess the extent of available evidence for alcohol screening and treatment implementation in Indigenous primary care. The review will include evidence from a wide range of study designs in pragmatic settings, i.e., being delivered in settings in which evidence-based clinical procedures are integrated into the routine practice of the clinical setting and administered primarily by regular service providers rather than research staff. The included studies range from randomised controlled trials to natural experiments involving monitoring of trends in routinely collected data following government-level changes such as implementation of financial incentives for service provision.

2.2 Published article

This chapter was published as a peer reviewed, open access article in the journal BMC Family Practice as:

Dzidowska M, Lee KSK, Wylie C, Bailie J, Percival N, Conigrave JH, et al. A systematic review of approaches to improve practice, detection, and treatment of unhealthy alcohol use in primary health care: a role for continuous quality improvement. BMC Family Practice. 2020;21(1):33.

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BMC Family Practice

RESEARCH ARTICLE Open Access

A systematic review of approaches to improve practice, detection and treatment of unhealthy alcohol use in primary health care: a role for continuous quality improvement

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Abstract

Background: Unhealthy alcohol use involves a spectrum from hazardous use (exceeding guidelines but no harms) through to alcohol dependence. Evidence-based management of unhealthy alcohol use in primary health care has been recommended since 1979. However, sustained and systematic implementation has proven challenging. The Continuing Quality Improvement (CQI) process is designed to enable services to detect barriers, then devise and implement changes, resulting in service improvements.

Methods: We conducted a systematic review of literature reporting on strategies to improve implementation of screening and interventions for unhealthy alcohol use in primary care (MEDLINE EMBASE, PsycINFO, CINAHL, the Australian Indigenous Health InfoNet). Additional inclusion criteria were: (1) pragmatic setting; (2) reporting original data; (3) quantitative outcomes related to provision of service or change in practice. We investigate the extent to which the three essential elements of CQI are being used (data-guided activities, considering local conditions; iterative development). We compare characteristics of programs that include these three elements with those that do not. We describe the types, organizational levels (e.g. health service, practice, clinician), duration of strategies, and their outcomes.

Results: Fifty-six papers representing 45 projects were included. Of these, 24 papers were randomized controlled trials, 12 controlled studies and 20 before/after and other designs. Most reported on strategies for improving implementation of screening and brief intervention. Only six addressed relapse prevention pharmacotherapies. Only five reported on patient outcomes and none showed significant improvement. The three essential CQI elements were clearly identifiable in 12 reports. More studies with three essential CQI elements had implementation and follow-up durations above the median; utilised multifaceted designs; targeted both practice and health system levels; improved screening and brief intervention than studies without the CQI elements.

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(Continued from previous page)
Conclusion: Utilizing CQI methods in implementation research would appear to be well-suited to drive improvements in service delivery for unhealthy alcohol use. However, the body of literature describing such studies is still small. More well-designed research, including hybrid studies of both implementation and patient outcomes, will be needed to draw clearer conclusions on the optimal approach for implementing screening and treatment for unhealthy alcohol use. (PROSPERO registration ID: CRD42018110475).

Keywords: Alcohol, Unhealthy alcohol use, Alcohol use disorders, Implementation, Primary health care, Continuous quality improvement, Screening, Treatment, Brief intervention

Background

Unhealthy alcohol use involves a broad spectrum of conditions from hazardous or risky drinking to the diagnosis of alcohol use disorder. ICD-11 defines hazardous drinking as use that increases the risk of harmful physical or mental health consequences to the user or to others, while disorders due to alcohol involve use patterns that have already caused harm or dependence [1]. Evidence-based management of unhealthy alcohol use in primary health care (PHC), particularly the use of screening and brief intervention (SBI), has been advocated since the World Health Organization (WHO) called for the development of strategies and guidelines for SBI applicable in PHC settings [2–5]. SBI is now widely accepted as best practice and recommended by both national and international guidelines [6].

Meta-analyses of studies of implementation of alcohol screening and treatment have shown that multi-faceted programs with longer duration and alcohol-focused programs are better at achieving improvements. Specifically, programs oriented towards multiple-organizational levels, as well as studies longer than 12 months were associated with significant effects on improvement of implementation of screening and/or brief intervention compared to single strategy programs [7, 8]. Programs combining strategies that targeted the clinician, organization and patient were more effective in decreasing alcohol consumption than clinician-only strategies [8]. However, sustained and systematic implementation of evidence-based care for alcohol use in PHC continues to be a problem [6, 9–12]. Furthermore, there is little evidence of significant effects of implementation strategies on patients' alcohol consumption [8]. Barriers, such as time pressures, staff retention, lack of training and leadership, as well as the clinicians' perception of alcohol discussions as sensitive, have been identified [6, 11, 13]. To improve detection and treatment of unhealthy alcohol use, more work is needed to develop and test approaches that are sensitive to facilitators and barriers in an individual PHC setting.

Continuous quality improvement (CQI) in health care has been defined as "*a structured organizational process for involving people in planning and executing a continuous flow of improvement to provide quality health care that meets or exceeds expectations*" [14]. Originating from industrial process improvement approaches, this approach has been used in health care since the 1990s [14, 15]. CQI is designed to improve health care by using data to identify where services are doing well and not so well, implementing and monitoring corrective action and then reviewing its effectiveness, in continuous improvement cycles. Studies, including the largest CQI program in Australia [16], have shown that with consistent policy and infrastructure it can facilitate ongoing improvement of PHC service delivery and subsequently, better health outcomes [16–19]. This largest program includes research in Aboriginal community controlled primary health care services [16]. However, to our knowledge, there is no literature review specifically on the use of CQI strategies in improving service provision for unhealthy alcohol use in the PHC setting.

This systematic review aims to: 1) describe types, levels and duration of implementation strategies to improve screening and treatment for unhealthy alcohol use in PHC, and their outcomes, as available in peer-reviewed literature; 2) investigate to what extent elements of CQI are being used in these strategies; 3) compare characteristics of programs with all CQI elements with programs that do not have these elements.

Methods

We performed a systematic review of peer-reviewed literature from January 1990 to September 2018 (referred to from here on as 'reports'). The year 1990 was chosen because it marked the beginning of the decade following the WHO's first release of guidelines for alcohol screening and brief intervention, as well as the beginnings of CQI in health care [3, 14, 15].

Search strategy

To construct the search strategy, we first conducted a broad text-word search in MEDLINE.

From this search (14,764 results) we identified a set of representative reports that met the inclusion criteria (a sentinel set; $n = 25$) by systematically screening 20% of the search results for abstracts that met the inclusion criteria. Medical Subject Headings (MeSH) and keywords of the 25 sentinel

articles were then used to progressively refine the search strategy: subject headings and subheadings not already in the original search strategy were identified and used to modify the search strategy. Retention of the sentinel set was checked with each modification. The strategy was then further refined through an independent review by an expert in drug and alcohol health services research. The resulting final strategy consisted of three groups of search terms reflecting the problem (e.g. alcohol, binge drinking), setting (e.g. primary care, general practice), and intervention (e.g. program. strategy) of interest to this review. A summary of the strategy is presented in Table 1. This strategy was applied to MEDLINE, EMBASE and PsycINFO with modifications made as required. An adapted set of search terms was used in CINAHL and the Australian Indigenous Health InfoNet. Search results were restricted to English language. Hand searches were performed on reference lists of 21 major reviews, sourced from Cochrane (including Cochrane EPOC and Cochrane Drugs and Alcohol Review Group) and the above literature search. The final set included for analysis was checked for any additional reports. A detailed protocol and search strategy are available in the international prospective register of systematic reviews, PROSPERO (ID CRD42018110475), https://www.crd.york.ac.uk/prospero/.

Reports were included if they described experimental or observational studies that: (1) were conducted in a pragmatic PHC setting, that is the strategies were integrated into routine practice and delivered primarily by existing PHC staff [20]; (2) described an intervention/initiative/program designed to improve service provision or improve evidence-based practice to address unhealthy alcohol use; (3) reported original data; and (4) reported quantitative outcomes related to provision of service or change in practice for unhealthy alcohol use. Reports that utilized clinician self-reported outcome measures were included only if they quantified the change in service provision. Exclusion criteria comprised non-original data reports, reviews, commentaries and editorials, method reports, a citation without abstract available, and conference abstracts.

Data extraction

Literature searches were downloaded into Endnote X8.2 and duplicates removed. Irrelevant reports and ineligible publication types were removed at the stage of the title screen. Titles and abstracts of the resulting set were independently reviewed for inclusion criteria by two reviewers (MD, CW). Where agreement could not be reached a third reviewer (KC or KL) was consulted. Full text review was performed by MD and CW with further discrepancies discussed with KC. Data from the final set was extracted by MD in consultation with KC and KL.

We extracted the following data:

- information on study design and setting
- description of the improvement strategy including targeted clinical actions
- whether strategy was multifaceted (that is they employed more than one component [e.g. training plus financial incentive] to target implementation barriers and achieve improvement)
- organizational levels targeted by the strategy, defined as:
  - National – targeting the health care system for an entire population
  - Health system – targeting organizational structures within a health system (e.g. local, state-based, or private health insurance company)
  - Practice – targeting individual primary care practices
  - Clinician – targeting clinicians working within PHC practice settings
  - Patient – targeting the patient or population being served by the practices
- details of follow-up
- type of outcome measure and outcomes.

Identifying CQI elements

Because in academic literature, CQI methodology is not always clearly identified [15, 21, 22], we screened for the presence of three essential CQI elements defined by Rubenstein et al. [22]:

(i) Using 'systematic data guided activities' to identify problems and achieve improvement
(ii) 'designing with local conditions in mind'
(iii) using an 'iterative development and testing process'

Table 1 Summary of the final search strategy (MEDLINE)

Search term group (number of search terms[a] entered)	Examples of search terms
Implementation strategies and treatments (38 terms)	Mass Screening; Counseling; Evaluation Studies as Topic; Delivery of Healthcare; Total Quality Management; PDSA; Pharmacotherapy.mp; Health Check*.mp; organi* interv*.mp
Alcohol drinking (5 terms)	Alcohol*mp; Alcoholism; Binge Drinking; Alcohol Drinking; Alcoholic Intoxication
Primary Health Care (7 terms)	Primary Health Care; Preventative Health Services; commun$ health.mp; Physicians, Family; Physicians, Primary Care; Family Practice; General Practice

[a]Number of search terms entered represents the number of unexpanded MeSH subject headings and text key words entered into MEDLINE search. All MeSH subject headings were expanded

We defined element (i) as present if there was clear indication that the improvement strategy included systematic use of data to conduct assessment of the problem to be addressed and/or to diagnose improvement and a response to this data that modified the improvement strategy. We defined element (ii) as present if there was clear indication of designing and/or allowing adaptation of strategies to fit the special characteristics of the local setting. Element (iii) required evidence that the data collection and response in element 1 was conducted in at least two cycles. The elements were coded as 'present', 'absent' or 'unclear'. For the purposes of descriptive analyses below any instances of 'unclear' were treated as absent.

Descriptive analysis was performed on all reports that met the selection criteria as well as on the subset of reports describing initiatives that included all three CQI elements.

Results

Fifty-six reports representing 45 studies were included in the review (Fig. 1). Of these, 24 reports were randomized controlled trials (RCTs) [23–46], 12 were controlled designs [47–58] and 20 were before/after and other designs [59–78]. Thirty-five were alcohol-specific, while 21 focused on broader prevention (Table 2).

All studies were conducted in member countries of the Organization for Economic Co-operation and Development (OECD) and all countries but one were part of the Group of Twenty (G-20). Twenty-four reports represented projects conducted exclusively in the United States of America (USA), 12 in Australia, seven in the United Kingdom, seven in individual European countries and one in Canada. Three reports were from the Optimizing Delivery of Health Care Interventions (ODHIN) trial, which reported on aggregated outcomes in five European countries, and two reports from the international WHO Collaborative Project. The clinical setting was predominantly a generalist, general practitioner-led PHC service; however, four reports [28, 35, 52, 57] representing three projects were conducted in nurse-led community health centres. Likewise, populations served by these were general, except two in adolescent PHC

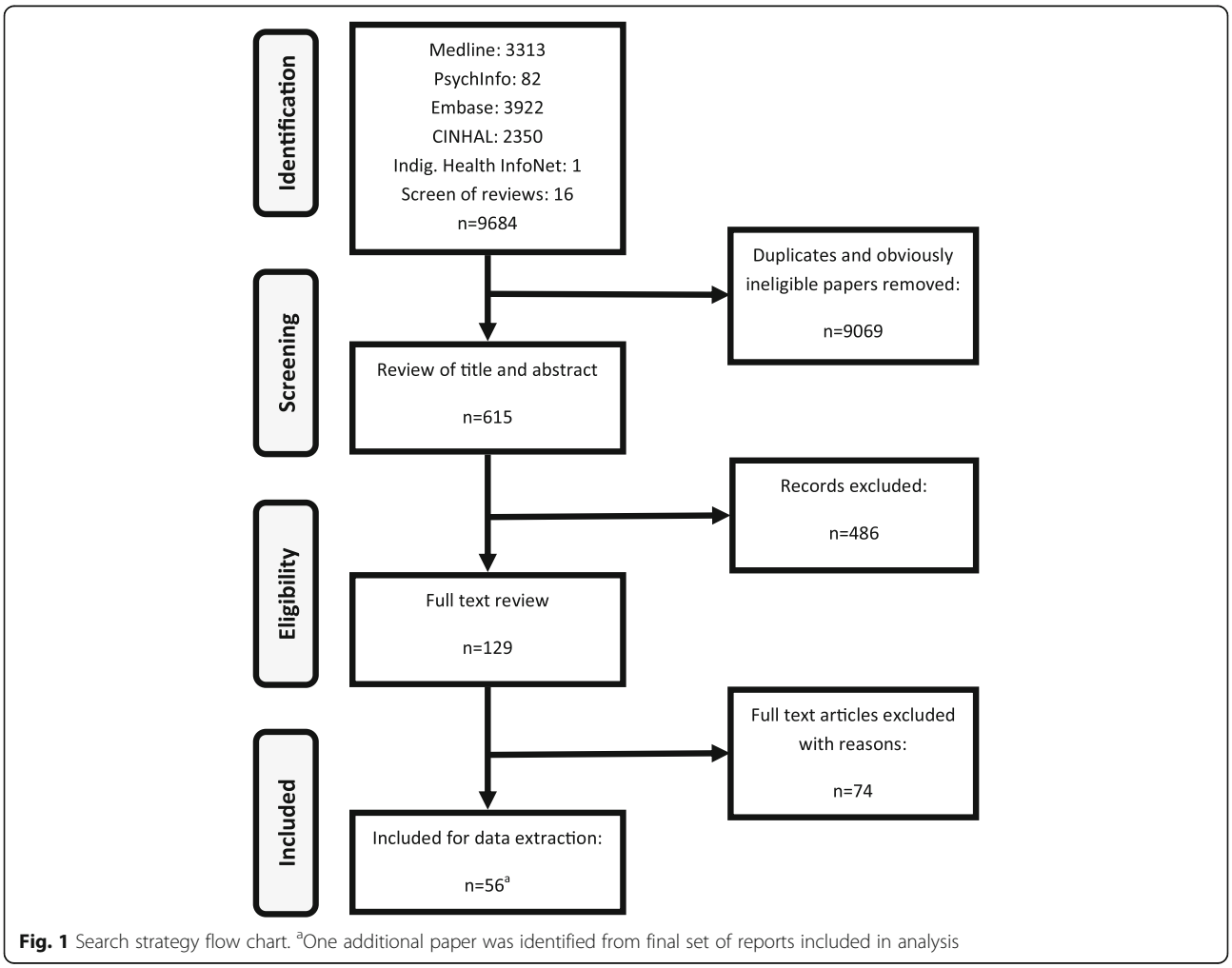

Fig. 1 Search strategy flow chart. [a]One additional paper was identified from final set of reports included in analysis

Table 2 Characteristics of studies included in the review

Study ($n = 56$)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Randomized controlled trials											
WHO collaborative Project (Phase 3)											
Gomel 1998 AUS Alcohol [33]	94,481	Phase 1: 628 Phase 2: 161 (1 per site)	628 161	Phase 1: mailout (c); telemarketing; academic detailing. Phase 2: written guidance (c); training; training + min support; training + ongoing support	**S, BI**	3,4	Y	Higher uptake if academic detailing or telemarketing; higher screening in training or training + max support cf. other arms; advice significantly higher in max support arms	N	N	N
Hansen et al. 1999 DNK Alcohol [34]	na	143	na	Phase 1 only	**S,** BI	4	N	Higher uptake if academic detailing or telemarketing. No significant differences control cf. intervention arms	N	N	N
Kaner 1999 GBR Alcohol [39]	11,007	128	128	Phase 2 only (excluding the training + min support arm).	**S, BI**	4	Y	Increased implementation, screening and intervention in training + support.	N	N	N
Funk 2005 AUS, BEL, DNK, NZ, ESP, GBR Alcohol [32]	60,989	Phase 1: 3436, Phase 2: 727 (1 per site)	3436 727	Phase 1 & 2 (excluding the training + min support arm)	**S, BI**	3,4	Y	Increased uptake if academic detailing or telemarketing. Increased screening and advice giving if training or training + support.	N	N	N
Anderson 2004 AUS, BEL, ESP, GBR Alcohol [25]	na	Phase 1: 2924; Phase 2: 632 (1 per site)	2924 632	Phase 1 & 2 (excluding the training + min support arm)	**S, BI**	3,4	Y	Sub-analysis of Funk 2005: Increased screening and BI if physicians secure and committed in working with drinkers	N	N	N
ODHIN											
Anderson 2016 ESP, GBR, NLD, POL, SWE Alcohol [23]	Mean: 1500 consults/site (baseline)	746	120	Country guidelines summary (c); training and support (TS), Financial reimbursement (FR), access to referral to eBI and combinations of these	**S,** BI	3,4	Y	During 12-week imple mentation: Increased screening in TS arm and FR arm. Increased intervention (screening or advice) in TS, FR, TSFR and TSFReBI. No effect on giving advice to screen positive pts.	N	N	N
Bendtsen 2016 ESP, GBR, NLD, POL, SWE	As above	350	60	As above	S, **BI**	3,4	Y	No association between eBI and increase in screening. Increased	N	N	N

Table 2 Characteristics of studies included in the review *(Continued)*

Study ($n = 56$)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Alcohol [26]								proportion of screen-positive pts. given BI. Low pt. and provider uptake rates of eBI			
Anderson 2017 ESP, GBR, NLD, POL, SWE Alcohol [24]	As above	746	120	As above	S**, BI**	3,4	Y	At 9 months follow-up: Increased intervention rates in TS. Reduction of intervention rates in all arms but reduction in TS arm was smaller.	N	N	N
CN SNAP											
Chan 2013 AUS Broad prev [28].	na	129	4	Training (5As); Integrating assessment/prompts into initial visits; referral directory; resources including. Guides for nurses, action plans for each risk factor.	**S,** BI, RT	3,4	Y	Increased self-reported screening at 6 and 12 months (validated scale). No effect on self-reported management or referral.	N	N	N
Harris 2013 AUS Broad prev [35].	804	na	4	As above.	BI, **RT**	3,4	Y	Increase in pt-reported referrals in intervention group at 3 months cf. baseline. No significant changes in self-reported alcohol consumption.	N	?	N
Other RCTs											
Bonevski 1999 AUS Broad prev [27].	2917	19	na	Computerized feedback system: guidelines, goal setting for GPs, GP feedback on performance in other health screening (not alcohol).	**na**	4	Y	Although not targeted by intervention, at 3-month follow-up classification of hazardous/harmful drinkers more accurate in intervention arm cf. controls.	N	N	N
Dubey 2006 CAN Broad prev [30].	1117	38	4	Gender based preventative checklist prompt with evidence-based recommendations.	**S**	4	N	Significant increase in alcohol history intake between baseline and follow-up in intervention arm. Increase significantly associated with intervention.	N	N	N
Chossis 2007 Switzerland Alcohol [29]	260	27	2	Training; summary checklist, textbook and pt. education materials.	**BI**	4	Y	Intervention residents conducted more components of BI: more	N	N	N

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
								likely to explain safe drinking limits provide feedback, seek pt. opinions on drinking limits, after training but not at follow-up; no effect on pt. drinking patterns.			
Friedmann 2006 USA Alcohol [31]	164	18	2	Maintenance care training for alcohol problems in remission (5As); follow-up academic detailing; booster training; materials for pts. and clinicians; pt. record prompt (paper).	**S,** BI**, RP, RT**	4	Y	Intervention pts. more likely to report clinician took alcohol history. Intervention clinicians who took alcohol history more likely to assess prior and planned alcohol treatment, offer of prescriptions and referral.	N	N	N
Harris 2015 AUS Broad prev [36].	21,848	122	32	Training of practice staff and QI facilitators; audit and feedback; site visits with goal setting; pt. education and referral materials; implementation support; facilitator support.	**S**	3,4	Y	At 12 months follow-up increase in odds of alcohol recording of alcohol consumption in the intervention compared to control. No significant change in the level of risk factors based on audit data.	Y	Y	Y
Haskard 2008 USA Broad prev [37].	2196	156	3	Physician training; pt. training.	**BI**	4,5	Y	Significant upward trend in counselling to quit alcohol at time 6-months post training after initial expected drop at 1-month post training.	N	N	N
Kaner 2003 GBR Alcohol [38]	5541	na	212	Phase 1: mailout (c); telemarketing; academic detailing. Phase 2: written guidance (c); training; training + ongoing support (directed at nurses).	S, **BI**		Y	Increased implementation in training and training + support. Increased BI in training and training + support. Fewer pt. management errors in controls.	N	?	N
Krist 2016 USA Broad prev [40].	2913	156	18	MOHR: self-administered health behaviour questionnaire; MOHR summary and feedback for pts.; a summary of positive MOHR for clinicians;	**S, BI,** RT	3,4	Y	Significantly higher screening for alcohol and goal setting to reduce risky drinking in intervention arm compared to control. No	N	Y	N

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
				optional training for clinicians; freedom of method of implementation.				significant changes in referrals. No significant changes in alcohol consumption.			
Ornstein 2013 USA Alcohol [43]	26,005	77	20	Pre-intervention visit; electronic screening/ intervention prompt and resource template; network meeting to discuss facilitators and barriers and to develop implementation plans; performance feedback; on-site support visits.	**S, BI, RP**	3,4	Y	Early Intervention (EI) phase: increased odds of screening and BI in EI cf. delayed intervention (DI); performance stable at DI phase. DI phase: increased odds of screening in DI pts. cf. EI phase. Increased prescription of AUD medication in EI pts. at DI phase.	Y	Y	Y
Mertens 2015 USA Alcohol [41]	420,946	554	54	Physician (PCP), Non-physician providers (NPP), Medical Aid (MA) arms. Training: PCP trained in all of SBIRT, MAs trained to ask screening question, NPPs trained to ask weekly drinking questions, AUD screener and BI and RT. All arms: Screening + automated prompts added to electronic health record; implementation support; audit + feedback.	**S, BI, RT**	3,4	Y	Higher screening rates in NPP, MA and PCP cf. controls. Higher BI and referrals in PCP cf. other arms (No difference between NPP, MA and controls).	N	Y	Y
Navarro 2012 AUS Alcohol [42]	155,170	na	20	Feedback letter to GP: prescription + community dependence rates, information on pharmacotherapies + behavioural interventions; recommendation to increase prescribing to reduce heavy alcohol consumption.	**RP**	4	N	Increased acamprosate but decreased naltrexone prescribing cf. controls.	N	N	N
Rose 2008 USA Alcohol [44]	27,591	na	22	NIAAA screening guidelines; instructions to develop/adapt screening template in electronic MRs; performance feedback and review; on-site visits with	**S, BI, RT**	2,3,4	Y	Screening, counselling odds higher in intervention cf. controls. Improvements over time greater in intervention arm. Reduced PB in pts.	Y	Y	Y

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
				training, development of action plan; network meetings. Screening template (5As with AUDIT-C + question / diagnosis/recording prompts).				given brief counselling or referral but No significant reduction for intervention cf. controls.			
Saitz 2003 USA Alcohol [45]	212	41	1	Clinical prompt: Results of CAGE assessment + recommendations attached to pt. record.	**BI,** RT	4	N	Faculty physicians in intervention arm more likely cf. controls to give advice, discuss associated problems. No significant difference in outcomes for residents in intervention cf. control arm. At 6-months, intervention arm pts. who saw residents had fewer drinks/drinking day but no between group differences.	N	N	N
van Beurden 2012 NLD Alcohol [46]	1502	124	82	3 components targeting: [1] professionals: training, guidelines, reminder cards [2]; organization: feedback report, facilitation of external specialist support, implementation support [3]; Pt-directed: letters, leaflets, self-help booklets, poster, personal feedback based on consumption.	S, BI	3,4,5	Y	No difference in improvement in screening or BI in intervention cf. control.	?	Y	N
Non randomized controlled studies											
Bradley 2002 USA Alcohol [47]	68	34	2	Clinical prompt: pt-specific positive screening result at each visit.	**BI**	4	N	Intervention group more likely to discuss alcohol use cf. controls.	N	N	N
Hamilton 2014 GBR Alcohol [48]	211,834	na	30	Pay-for-performance scheme (QOF+) to extend alcohol screening; computer templates; in-practice training.	**S, BI,** RT	2	Y	Increased screening in eligible and Non-eligible group cf. baseline. Eligible pts. more likely to receive ASBI and full AUDIT than Not eligible.	N	N	N

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Harris 2017 USA Alcohol [49]	2952	199	3	3 components targeting [1] Local champion: training + support, monthly teleconferences, access to national champions, website, pt. dashboard [2]; Providers: training + support, website, access to local champions, pt. dashboard, reminder emails [3]; Pt education + activation: mailed materials.	**RP**	2,3,4, 5	Y	Increased odds of filling a prescription during implementation in the three sites, however not significant at one site when stratified by site. No significant changes cf. matched controls.	N	?	N
Khadjesari 2017 GBR Alcohol [50]	261,424	na	na	Pay-for-performance scheme for specific clinical areas.	**S**	1,2	N	Increase in alcohol recording rate ratio over 13 years in case group cf. control group.	N	N	N
Mason 1997 GBR Alcohol [51]	1417	na	4	Nurse-counsellor providing counselling services to practices + training to physicians.	**S, BI,** RT	3	Y	Increase in: recording of consumption and identification of problem drinkers (all intervention sites), identification of pts. drinking above recommended limits and advice (2 sites). No increases in referrals.	N	N	N
McElwaine 2014 AUS Broad prev [52].	1989	570	17	Local leadership engagement, electronic MR modification, training, implementation support, audit + feedback.	S**, BI,** RT	2,3,4	Y	Increase in odds of provision of Brief Advice from baseline to follow-up in intervention cf. controls. No changes in screening or referrals.	Y	?	Y
O'Donnell 2016 GBR Alcohol [53]	106,700	99	16	Two pay-for-performance schemes: National (DES) - for each newly registered pt. screened; Local (LES) - for each new pt. over 16 positive for risky drinking + received BI.	**S, BI**	1,2	N	Rates of short screening (FAST or AUDIT-C) or AUDIT lowest in non-incentivised and highest in DES. Rates of alcohol intervention lowest in non-incentivised and highest in DES. Significance Not reported.	N	N	N
Onders 2014 USA Broad prev [54].	23,000 visits/ year Indigenous	10	1 (cf national service)	Electronic clinical reminders (CR) using PDSA: [1] data-driven ID of need [2]; Pilot test CR [3]; Expand to all	**S**	3,4	Y	Increased screening from 35 to 70% cf. IHS (smaller increase 40–48%) cf. other IHS.	Y	Y	Y

Table 2 Characteristics of studies included in the review *(Continued)*

Study ($n = 56$)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
				providers [4]. audit + feedback [5]; Delegation of CR to other staff.							
Ozer 2005 USA Broad prev [55].	$T_0 = 226$(i), 246(c); $T_1 = 551$(i), 260(c); $T_2 = 940$(i), 405(c) Adolescents	76	4	Clinician training; facilitated implementation of screening and charting forms tailored to local conditions. (Setting: paediatric PHC).	**S, BI**	3,4	Y	Increased screening and counselling post implementation both elements (intervention cf. controls). Increases associated with post training. No additional increases post tool implementation.	N	?	N
Thomas 2014 SWE Broad prev [56].	T1 = 888 T2 = 994	T1 = 120 T2 = 132	6	Implementing screening for risky behaviour + BI and referrals to in-house multidisciplinary team; compulsory components: multidisciplinary teams + managers, meetings, in-house referral workflows.	S, BI	3,4	Y	No difference in alcohol consumption discussion rates in intervention cf. control at 3 years. Significantly higher alcohol discussion rates in control cf. intervention at 5 years.	N	?	N
Wiggers 2017 AUS Broad prev [57].	5369	~ 1400	56	Policy + leadership engagement; modifying information systems; training; audit and feedback; implementation support, information and resources.	**S, BI,** RT	2,3,4	Y	Increased alcohol consumption assessment and advice cf. control (stepped wedge). No increases in referrals.	Y	Y	Y
Wilson 1992 GBR Broad prev [58].	4471	16	10	Increased consultation booking time from 6 to 10 min per pt.	**na**	3	N	Increased recording of alcohol education and in pt-reported discussion about alcohol.	N	N	N
Before/after and other designs											
Healthy Habits											
Seale 2005a USA Alcohol [77]	3387	35	1	Formation of lead committee (monitoring + recommendations); strategy development, modification of pt. record + workflows to include SBI; clinician training.	**S, BI,** RT	3,4	Y	Increased screening + intervention. Clinicians intervened more often when prompted with AUDITs. Periodic evaluation resulted in modifications, which resulted in progressive increases in screening.	Y	Y	Y

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Seale 2005b USA Alcohol [76]	1052	38	1	Formation of leading committee (monitoring + recommendations); strategy development, modification of pt. record + workflows to include SBI; clinician training.	S, **BI**	4	Y	No significant differences in problem drinking (PD) identification before and after intervention. After training, greater increase in advice giving in residents cf. faculty.	Y	Y	Y
Johnson 2013 USA Alcohol [69]	288	na	1	SBI workflow additions to protocols implemented above: Single Alcohol Screening Question (SASQ); checkbox in pt. record for BI; booster training.	**S,** BI	3,4	Y	Screening rates using AUDIT-C plus SASQ exceeded 90% but no significant changes. Increased identification of UAU at 6 weeks and 6 months.	?	?	?
VA program											
Lapham 2012 USA Alcohol [70]	6788	na	na	Health system-wide incentives-linked performance measure (PM) + BI electronic clinical reminder (CR); freedom of adaptation but core PM components required; BI clinician training optional.	**BI**	2,3,4	Y	Recording of advice increased continuously from baseline year, after PM announcement, PM implementation, and CR dissemination.	N	Y	N
Chavez 2016 USA Alcohol [62]	225,912	na	na	As above.	**BI**	2,3,4	Y	Increased pt-reported advice to pts. with moderate-severe alcohol misuse from baseline with plateau in two final years.	N	Y	N
ABCD											
Si 2007 AUS Broad prev [78].	360 Indigenous	na	12	Single intervention cycle includes: initial systems audit + records audit; identify priorities + design improvement strategy; audit + feedback to monitor + identify new priorities.	BI	3	Y	Alcohol counselling/advice increased significantly at Year 2 audit.	Y	Y	Y
Gibson-Helm 2016 AUS Broad prev [65].	2220 (Indigenous Pregnant women)	na	50	As above.	S, BI	3,4	Y	Increased odds of screening and BI with each cycle. Evidence of a trend in increased number of CQI cycles and increase in BI.	Y	Y	Y
Other											

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Aalto 2003 Finland Alcohol [59]	1449	24	2	Collaborative BI implementation development; training; implementation support; reminders in local and professional publications; distribution of AUDIT to all households.	S, BI	2,3,4, 5	Y	No statistically significant differences.	N	?	N
Aspy 2008 USA Broad prev [60].	600	30	9	Audits + feedback; training; practice facilitation/support; meetings between participating practice teams; Nurses, medical assistants, trained in screening and very brief interventions (VBI) e.g. referrals and handouts. Clinicians trained in BI.	S, BI	2,3,4	Y	No significant changes in alcohol screening or VBI or BI cf. baseline. Pts less likely to screen positive for UAU at end of study cf. baseline. Screening increased if alcohol was the target in first two cycles. Addition of more than two target behaviours appeared to negatively impact previous targets.	Y	Y	Y
Bobb 2017 USA Alcohol [61]	53,133	na	3	3 strategies: [1] Enabling teams: recruitment + CQI training of site champions, development + implementation support, regular education on CQI, SBI + AUD treatment, information sharing between sites [2]. Support via electronic health record: screening, BI, AUD prompts [3]; Monitoring + feedback: PDSA; meetings.	**S,** BI, RP, RT	2,3,4	Y	Increased screening and assessment post-implementation cf. baseline. Effects sustained 1 year later + increased new AUD diagnoses. Increased treatment within 30- and 90-days post diagnosis (driven mainly by one site).	Y	Y	Y
Clifford 2013 AUS Alcohol [63]	9322	na	4	Training; treatment guidelines; electronic assessment tool; implementation support	**S, BI**	3,4	Y	Increased records of screening. Increased records of BI overall but Not significant in individual ACCHS.	N	Y	N
Cowan 1994 USA Alcohol [64]	910	11	1	Clinician training.	**Y S**	4	N	Significant increase in recording of drinking histories.	N	N	N
Gilkes 2017 AUS Broad prev [66].	2608	35	na	Clinical audit + feedback by medical students to GP supervisors.	**S**	4	N	Increased record of alcohol consumption.	N	N	Y
Gowin 2012 POL Broad prev [67].	1060	106	na	Regional training program.	**S**	2,4	N	Increased screening.	N	N	N

Table 2 Characteristics of studies included in the review *(Continued)*

Study (***n*** = 56)[a]	Sample size			Strategy	Targets			Main outcomes	CQI elements[c]		
	Patients	Clinicians	Sites		Clin.action[b]	Org. level	M/ faceted		1	2	3
Holtrop 2009 USA Broad prev [68].	1965	na	20	Record audits + practice assessment; choice of improvement plan based on 5As, priority risk behaviour or both; support in planning + implementation; audit + feedback at end of study.	S, BI	3,4	Y	No practice chose alcohol as target. However, increased alcohol screening but non-significant when adjusted for clustering.	Y	Y	?
Lawner 1997 USA Alcohol [71]	297	15	1	Training of faculty members to give performance feedback to residents with a feedback form.	**S**	4	N	Increased record of alcohol consumption. Increased use of CAGE.	N	N	N
Lustig 2001 USA Broad prev [72].	532 (Adolescents)	63	3	Clinician training (Setting: paediatric PHC).	**S,** BI	4	N	Increased screening.	N	N	N
Marco-Garcia 1999 ESP Broad prev [73].	(1500–2000/ doctor, 42 doctors)	84	3	Formation of task force; collaborative program development; consensus on indicators + evaluation criteria; regular audit; action in response to audit.	**S**	3,4	Y	Increased recording of alcohol consumption.	Y	Y	Y
Olfson 1992 USA Alcohol [74]	884	110	1	Clinical prompt: addition of CAGE to health form completed by first-time pts. prior to first consult.	**S**	4	N	Alcohol problem detection (either problem drinking or abuse) increased cf. baseline.	N	N	N
Seale 2015 USA Alcohol [75]	1318	na	4	Partial funding for coordinator; coordinator + clinician training; implementation committees; implementation guide + freedom to adapt to local setting; progress feedback.	**S, BI,** RP, RT	3,4	Y	Increased record of any screening or validated screening. Increased identification of risky users. Increased record of BI.	?	Y	?

[a]Author, year, country (as three-letter ISO 3166 country codes), focus and citation are given; [b]significant positive result for clinical action is indicated in bold; Y – Yes, N – No; S – screening; BI – brief intervention; RP – relapse prevention medicines; PT – psychosocial therapies; RT – referral to treatment; Strategy targets: Clin. Action – clinical action, Org. level – organisational level (1 = National, 2 = Health System, 3 = Practice, 4 = Clinician, 5 = Patient), M/faceted – multifaceted; [c]CQI elements: 1- Using 'systematic data guided activities' to identify problems and achieve improvement; 2 - 'designing with local conditions in mind' i.e. adapting and or designing strategies to fit the special characteristics of the local setting; 3 - using an 'iterative development and testing process'; na – not available in article; (c) – control; (i) – intervention; pt. – patient; MR – medical record, eMR electronic medical record,.? – unclear; cf. – compared with

and four in PHCs predominantly serving Indigenous peoples [54, 63, 65, 78].

Targeted clinical actions

The majority of reports (52/56) examined improvement in rates of screening or brief intervention (BI) and/or referral to treatment. Twenty-four reports recommended or reported on the use of a validated screening measure, with 14 using either AUDIT (Alcohol Use Disorders Identification Test), its shorter version, AUDIT-C or both. Other validated screening tools included Single Alcohol Screening Question (SASQ), Fast Alcohol Screening Test (FAST), CAGE (an acronym for its four questions) and Short Michigan Alcohol Screening Test (sMAST). There was a wide range of terms used to describe screening and BI. For example, asking about alcohol consumption, eliciting alcohol history, 'assessment' of alcohol consumption or similar was used for screening; 'brief advice', 'brief counselling', and discussing alcohol was used for BI. Only six reports addressed improvement in rates of pharmacotherapy uptake for relapse prevention [31, 42, 43, 49, 61, 75]. None included implementation of psychosocial therapies, though referral to such therapies was mentioned as a treatment option.

Characteristics of improvement strategies

Types and levels of implementation

A variety of strategies were employed to improve screening and treatment for unhealthy alcohol use. These targeted one or more different organizational levels. Of the 56 reports, none targeted all five levels, and only two were targeted at four levels. The majority of reports (50/56) included clinicians as targets, followed by the practice (35/56), with 32 reports targeting both. Of those, only nine reports also targeted the health-system level, and two reports targeted four levels, including the patient. Table 3 summarizes strategies by implementation level. Most implementation strategies (42/56) were multifaceted. Of these, 33 targeted two or more organizational levels.

Duration of implementation and follow-up

For studies where it was possible to extract these data, the median duration of the implementation phase was 28.2 weeks (IQR = 40, n = 50), and median duration from commencement of implementation to last data collection was 52 weeks (IQR = 52, n = 53). Of the 49 reports, where both types of duration data were available, 20 had their last data collection event after the end of implementation phase, indicating a follow-up period.

Reports with CQI elements

Of the included reports, 22 described strategy components that were consistent with at least one of the three essential CQI elements (Table 4) [23]. An attempt to design or allow adaptation of implementation strategies to fit local conditions was the most commonly identified element (n = 20), followed by the use of iterative development and testing processes (n = 14). Using 'systematic data guided activities' to identify problems and achieve improvement, such as responding with corrective actions to regular practice audit reports and monitoring implemented changes,was identified in 13 reports.

All three essential CQI elements were clearly identifiable in 12 reports. Of these, three were RCTs and seven were focused on broader prevention of risky behaviours (rather than being solely focused on unhealthy alcohol use). All examined screening and/or BI. Two also examined relapse prevention medicines. In contrast to other reports, more studies with all CQI elements targeted health system practice and clinician levels for implementation strategies and all were multifaceted (Table 5).

Table 3 Types of strategy components employed by level of implementation

Organizational level	Strategy components	Reports
National	Pay-for-performance schemes, computer templates, grants for training initiatives	[50, 53]
Health system	Network meetings, audit and feedback, performance measures, changes to information systems, training, policy and leadership engagement, implementation committees, pay-for-performance schemes	[44, 48–50, 52, 53, 57, 59–62, 67, 70]
Practice	Training, telephone and on-site support, written and electronic materials, practice procedures and workflow changes, financial incentives, audit and feedback, involvement of staff other than clinicians, local champions and implementation committees, introduction of specialist staff, change to consultation booking time, systems audits and support in design of improvement strategies, information sharing between sites	[23–26, 28, 32, 33, 35, 36, 40, 41, 43, 44, 46, 49, 51, 52, 54–63, 65, 68–70, 73, 75, 77, 78]
Clinician	Training, telemarketing, letters to prescribers, academic detailing, written and electronic materials/guidelines, clinical prompts, audit and feedback, facilitation of referrals	[23–47, 49, 52, 54–57, 59–77]
Patient	Patient activation by: pre-appointment self-assessment +/−personalized feedback, information/resource mailouts	[37, 46, 49, 59]

Table 4 Distribution of CQI elements

Element (i) Data-guided	Element (ii) Local tailoring	Element (iii) Iterative process	Number of reports (*N* = 56)
–	–	–	34
–	–	Y	1
–	Y	–	6
–	Y	Y	1
Y	Y	–	1
Y	Y	Y	12

(i) Using 'systematic data guided activities' to identify problems and achieve improvement; (ii) 'designing with local conditions in mind' i.e. adapting and or designing strategies to fit the special characteristics of the local setting; (iii) using an 'iterative development and testing process'

Studies with all CQI elements also had higher median implementation duration.

Outcomes in relation to type of implementation strategy

The majority of reports (*n* = 51, 91.1%) showed a statistically significant increase in utilization of at least one clinical action. Significant increases in implementation were shown most often for screening and least often for referrals (Table 6). Only five reports (8.9%) included patient outcomes [29, 35, 40, 44, 45]. Of those, one [44] reported on changes in blood pressure and the rest on patient-reported changes in alcohol consumption. No significant between-group differences in these outcomes were shown, although there were some significant within-group outcomes in two reports [44, 45].

The proportion of reports with any positive outcome was similar in the 12 reports that included all three essential CQI elements, compared with the 44 reports that did not (91.7% compared to 90.1%). However, a higher proportion of the reports with three CQI elements achieved a significant improvement for two of the examined clinical actions: 81.8% for screening, 66.7% for brief intervention (compared with 75.6 and 57.6% respectively). Of the two reports with all CQI elements that aimed to examine pharmacotherapies, one reported a significant improvement and the other did not report results specific to this action. Of the five reports that presented patient outcomes, one [44] had all three CQI elements and reported a significant within-group improvement of systolic blood pressure but not between-groups.

Discussion

This is the first systematic review to investigate incorporation of CQI elements into strategies to improve implementation of screening and treatment for unhealthy alcohol use in primary care. There was much variation in the studies' design and delivery and studies concentrated mainly on screening and brief intervention for non-dependent alcohol use. There was little work on implementing onsite management of alcohol dependence, for example, pharmacotherapy for relapse prevention. Only 12 studies included all three CQI elements

Table 5 Key characteristics of reports with three CQI elements compared to other reports

Characteristic	Number of reports		
	Reports with 3 CQI elements (%), *n* = 12	Other reports (%), *n* = 44	All reports (%), n = 56
Multifaceted	12 (100)	30 (68.2)	42 (75.0)
Randomized	3 (30.0)	21 (45.7)	24 (42.9)
Alcohol-specific	5 (41.7)	30 (68.1)	35 (62.5)
Studied patient outcome	1 (8.3)	4 (9.1)	5 (8.9)
Included patient as target level	0 (0.0)	4 (9.1)	4 (7.1)
Health-system + practice + clinician as target level	4 (33.3)	5 (11.4)	9 (16.1)
Implementation duration (weeks)[a]:	(*n* = 11)	(*n* = 39)	(n = 50)
Median	52.0	21.7	28.2
Interquartile range	39	35.7	40
Implementation to end of data collection (weeks)[a,b]	(*n* = 11)	(*n* = 42)	(n = 53)
Median	104.0	38.3	52.0
Interquartile range	65	64.3	84

[a]Some data were missing due to lack of detail in reports
[b]this duration was defined as beginning of implementation until the last data collection event

Table 6 Reports with significant positive implementation outcomes by clinical action

Clinical action	Reports with 3 CQI elements ($n = 12$)		Other reports ($n = 44$)	
	Examining action	Reporting increased utilization(% reports)	Examining action	Reporting increased utilization(% reports)
Screening	11	9 (81.8)	33	25 (75.6)
Brief Intervention	9	6 (66.7)	33	19 (57.6)
Pharmacotherapies	2	1 (50.0)	4	3 (75.0)
Referral	4	0 (0.0)	10	3 (30.0)

considered core to the CQI approach, while 22 studies incorporated at least one CQI element.

General practitioners are most often the first point of contact with healthcare for any drinkers. Therefore, it is important that PHCs are equipped to deal with the full spectrum of unhealthy alcohol use. Currently, screening and brief intervention are widely advocated as an effective secondary prevention approach for hazardous or harmful alcohol use in PHC settings [6]. If more severe alcohol problems are detected during the course of screening and brief intervention, referral to treatment away from the PHC service is often used. However, there is little evidence that this approach actually leads to effective linking with specialised services for patients who need them [79]. Furthermore, in many settings referral to specialist healthcare may not be an option due to costs, geographic isolation, long waiting periods or associated stigma. Thus, prescription of relapse prevention medicines in PHC rather than by referral to specialist centres may result in increased patient engagement at the point of detection or when the patient may be motivated and open to change.

Yet in the large volume of literature reviewed, only six studies included pharmacotherapies for relapse prevention as a target of implementation strategies. Only four of these also included BI for non-dependent (hazardous or harmful) drinkers, thus addressing the full range of unhealthy alcohol consumption.

Types, levels and duration of strategies used to improve implementation

Strategies that are alcohol-specific, multifaceted and target multiple organizational levels have previously been shown to be associated with improved implementation outcomes [7, 8]. While the reviewed reports all tended to display some combination of these characteristics, reports with all three CQI elements more commonly utilized multifaceted designs and targeted the practice and health system levels (33.3%) than reports without these elements (11.4%). Overall, fewer studies incorporated the patient-level action as a target of implementation (none of the reports with three CQI elements and four of the other reports). This warrants more attention as there is evidence that strategies that include patient-oriented components of action (e.g. mailouts) in combination with other levels may be better at decreasing alcohol consumption than clinician-oriented strategies alone [8].

We found that details of study duration were often lacking in the included reports either due to omission or the nature of the study design. It was often difficult to distinguish the duration of individual phases of the study: baseline, implementation and follow-up, making systematic data extraction challenging. We therefore used the duration from start of strategy implementation to end of data collection as a proxy for study duration. When the end of data collection was later than duration of implementation, this was considered as an indication of follow-up. The median study duration for studies with all three CQI elements was much higher than for studies without these (104 and 38.2 weeks respectively). In addition, only 20 reports had a clear indication of follow-up after the conclusion of active implementation. While there is evidence that study duration of 12 months or more is a significant predictor of improvement in BI implementation [8], it is not clear whether this is due to longer duration of implementation or longer follow-up. The lack of consistent duration data on implementation and follow-up is an important gap in the evidence-base as these are likely to influence the uptake of the implementation strategy, its sustainability and effects on both service-level and patient outcomes. For example, longer duration of implementation may be necessary to implement more complex treatment regimens and to allow for late adopters. Insufficient duration and frequency of follow-up may also lead to loss of information about potential improvements in patient outcomes as well as optimal length of strategy implementation to ensure sustainability.

While studies with all three CQI elements appear to have more favourable design characteristics than studies without these, it is less clear if this leads to better outcomes in improving delivery of screening and treatment for unhealthy alcohol use. A higher proportion of reports with three CQI elements improved screening outcomes and, to a lesser extent BI outcomes. However, they did not improve uptake of pharmacotherapies. These results need to be interpreted with caution, given the small number of reports with all three CQI elements, and even smaller number ($n = 2$) of these that investigated use of pharmacotherapies.

It is notable that three of the four reports on studies in indigenous settings included all essential CQI elements. These represented two CQI studies (in Australia and US), both set in community controlled health services. This perhaps reflects CQI's suitability to facilitate efficient service improvements in settings where lack of adequate resources and multiple health priorities can be a challenge and where stakeholder-driven, culturally relevant programs are crucial [80]. Finally, very few implementation studies ($n = 5$) reported patient outcomes and those that did were unable to demonstrate significant reductions in patient alcohol consumption [8]. Just one report considered patient outcomes other than alcohol consumption. The demonstrated lack of evidence of significant effect on patient outcomes may be due to not enough consideration being given to the complexity of studies that test implementation strategies as well as effectiveness of clinical interventions [81, 82].

Recommendations for practice and research

Improving screening and treatment uptake in PHC

Given the dearth in evidence, there is a need for more implementation studies on treatment for the full spectrum of unhealthy alcohol use, particularly the use of pharmacotherapies to treat dependent drinkers. This is particularly important in low-income countries where alcohol-attributable mortality is highest [83], where specialist services may be limited, but where few such studies are conducted.

The effectiveness of implementation strategies may depend on how well they fit the services' own circumstances, address the barriers to implementation and how they can co-exist with existing local enablers in a specific service. Furthermore, studies rarely analyse the contribution of individual components of the studied strategies to the overall effect on service-level outcomes. This detail could help services tailor their approaches to improving screening and treatment for unhealthy alcohol use. The fact that uptake of screening and treatment for unhealthy alcohol use in PHC remains low [84] suggests that future research effort should concentrate on "service-friendly" strategies as they may increase uptake and sustainability of effect.

The CQI approach provides a framework for how to carry out an improvement process systematically and on an ongoing basis. What activity is carried out to achieve the improvement and how it is measured is left up to the services to decide. Services can work towards a national benchmark or choose their own implementation goal. If implemented well, the CQI approach can offer the advantage of being sensitive and responsive to local conditions, and to newly arising challenges. The Plan-Do-Study-Act of the CQI cycle can facilitate the identification of the optimal combination of strategy components for a particular clinical setting. It is compatible with reflective learning and change to enable interventions to adapt to complex environments [85]. However, there may be barriers to implementation of CQI itself, including staff time and resources [86].

CQI in implementation research

The ultimate goal of implementing and improving service delivery is to improve patients' health, but evidence for this in relation to screening and treatment of unhealthy alcohol use is lacking. One approach to closing this evidence gap could be to simultaneously test implementation strategies and the effectiveness of clinical interventions through hybrid designs. This approach is thought to enable a more rapid generation of evidence base for the clinical interventions in "real life" settings than the traditional stepped processes: efficacy-effectiveness-implementation [81, 82].

Implementation research utilizing hybrid designs and quality improvement research can complement each other, with the former contributing more rigorous, scientifically robust summative evaluation and the latter providing information to enable a systematic refinement of the studied implementation strategy [87]. Inclusion of CQI in implementation research, particularly in hybrid designs thus has the potential to provide the optimal study design: flexible and responsive implementation strategies, scientific rigor to detect improvements in both service and patient-level outcomes, and ability to simultaneously provide information of value to healthcare managers and policy makers.

Limitations

Due to the volume of work and logistic constraints the search was limited to English language and only peer-reviewed literature was included in this study. Some health organization-based programs are published only in annual and commissioned reports and so would not have been included. However, a review of grey literature was out of scope of this review.

It has been previously noted that CQI studies are not easily identifiable in the academic literature as these are often not reported clearly or consistently [15, 22, 88]. Furthermore, the word and formatting limits of peer reviewed journals may contribute to underreporting and imprecise reporting of CQI methods [15]. Data extraction in this review was done by single person (MD) because of resource constraints. This may have introduced bias to the coding of key characteristics of strategies, particularly the three CQI elements. However, a priori definitions and clear criteria were used to reduce subjectivity.

Future meta-analysis of these studies may offer deeper insights into the benefits of incorporating elements of CQI into implementation research in alcohol service delivery. However, the heterogeneity of the studies, gaps in

reporting and generally low numbers of reports that meet the inclusion criteria will pose challenges.

Conclusions

The uptake of screening and treatment of unhealthy alcohol use in PHC continues to be low despite national and international guideline recommendations. Many studies of implementation strategies have yet to show significant improvement in patient outcomes. There remains a lack of implementation studies for treatment for the full spectrum of unhealthy alcohol use. There is also a lack of information in the effectiveness of particular components of multifaceted strategies, or inclusion of patient-level implementation strategies and outcomes. Incorporating CQI elements into implementation strategies may offer promise as an approach to deliver flexible and responsive solutions for sustained implementation of alcohol care. However, further well-designed research, including hybrid studies of both implementation and patient outcomes are needed to draw clearer conclusions on the most effective way to implement screening and treatment for unhealthy alcohol use in PHC.

Abbreviations

AUDIT: Alcohol Use Disorders Identification Test; BI: Brief intervention; CAGE: Alcohol screening tool; abbreviation in an acronym for its four questions; CQI: Continuous Quality Improvement; EPOC: Effective Practice and Organisation of Care; FAST: Fast Alcohol Screening Test; G-20: Group of Twenty; ICD11: International Classification of Diseases, 11th Revision; MeSH: Medical Subject Headings; ODHIN: Optimizing Delivery of Health Care Interventions; OECD: Organization for Economic Co-operation and Development; PHC: Primary health care; RCT: Randomized controlled trial; SASQ: Single Alcohol Screening Question; SBI: Screening and brief intervention; sMAST: Short Michigan Alcohol Screening Test; WHO: World Health Organization

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Authors' contributions

MD: designed search strategy and protocol, undertook abstract and full text screening, extracted data, drafted paper, synthesised co-authors' comments. KL: chief investigator on the grant supporting this work; contributed to protocol development, screening process, reviewed drafts of paper. CW: contributed to planning of the review; independently undertook abstract and full text screening, reviewed draft of paper. JB: reviewed drafts of paper and interpretation of findings with regards to CQI. NP: reviewed drafts of paper and interpretation of findings with regards to CQI. JC: contributed to planning of the review; reviewed draft of paper. NH: chief investigator on the grant supporting this work; informing team on practical aspects of primary care delivery; reviewed draft of paper. KC: chief investigator on the grant supporting this work; contributed to protocol development, screening process, oversaw the scientific integrity of the study, reviewed drafts of paper. All listed authors have reviewed the manuscript and approved the submission.

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Availability of data and materials

The search strategy used to generate the initial systematic review search result is available in PROSPERO (protocol ID CRD42018110475). https://www.crd.york.ac.uk/prospero/. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Not applicable.

Consent for publication

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Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

CHAPTER

3

EFFECTS OF THE SUPPORT MODEL ON SCREENING AND TREATMENT FOR UNHEALTHY ALCOHOL USE

3.1 Introduction

In the previous chapter, the results of a systematic review (Chapter 2) demonstrated the high level of heterogeneity between strategies for screening and treatment implementation for unhealthy alcohol use. This review found that few studies address the implementation of all types of treatment for unhealthy alcohol use that are suitable for delivery in primary care. Studies were less successful in improving treatment rates than screening and there was a particular lack of evidence for increasing the use of relapse prevention pharmacotherapies. Of the included records, just four studies were conducted with Indigenous populations. Implementation of strategies to improve screening and treatment for unhealthy alcohol use tended to be offered for a mean duration of approximately 28 weeks. Also, there was some evidence that elements of CQI are being used to improve uptake of screening and treatment for unhealthy alcohol use in primary care, and that these strategies result in statistically significant improvements in screening and treatment rates more frequently than other approaches.

This chapter reports on the effects of a support model for ACCHS to improve uptake of screening and treatment for unhealthy alcohol use. The model features some of the key characteristics of successful implementation studies identified by the systematic review: (i) the three essential CQI elements (section 1.4) were used in its design; (ii) Implementation occurred over 24 months; (iii) Design was developed in collaboration with ACCHSs; iv) the model supports screening and for treatment of the full spectrum of unhealthy alcohol use.

The published paper describes the study design, methods, results of the analysis and discussion. The details of the multifaceted support model and further details of the methods are included in the published supporting materials (section 3.3).

3.2 Published article

This chapter was published as a peer reviewed, open access article in the journal Addiction as:

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SHORT REPORT

ADDICTION SSA

Support for Aboriginal health services in reducing harms from alcohol: 2-year service provision outcomes in a cluster randomized trial

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Abstract

Background and aims: There is a higher prevalence of unhealthy alcohol use among Indigenous populations, but there have been few studies of the effectiveness of screening and treatment in primary health care. Over 24 months, we tested whether a model of service-wide support could increase screening and any alcohol treatment.

Design: Cluster-randomized trial with 24-month implementation (12 months active, 12 months maintenance).

Setting: Australian Aboriginal Community Controlled primary care services.

Participants: Twenty-two services (83 032 clients) that use Communicare practice software and see at least 1000 clients annually, randomized to the treatment arm or control arm.

Intervention and comparator: Multi-faceted early support model versus a comparator of waiting-list control (11 services).

Measurements: A record (presence = 1, absence = 0) of: (i) Alcohol Use Disorders Identification Test—Consumption (AUDIT-C) screening (primary outcome), (ii) any-treatment and (iii) brief intervention. We received routinely collected practice data bimonthly over 3 years (1-year baseline, 1-year implementation, 1-year maintenance). Multi-level logistic modelling was used to compare the odds of each outcome before and after implementation.

Findings: The odds of being screened within any 2-month reference period increased in both arms post-implementation, but the increase was nearly eight times greater in early-support services [odds ratio (OR) = 7.95, 95% confidence interval (CI) = 4.04–15.63, $P < 0.001$]. The change in odds of any treatment in early support was nearly double that of waiting-list controls (OR = 1.89, 95% CI = 1.19–2.98, $P = 0.01$) but was largely driven by decrease in controls. There was no clear evidence of difference between groups in the change in the odds of provision of brief intervention (OR = 1.95, 95% CI = 0.53–7.17, $P = 0.32$).

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Conclusions: An early support model designed to aid routine implementation of alcohol screening and treatment in Aboriginal health services resulted in improvement of Alcohol Use Disorders Identification Test—Consumption screening rates over 24 months of implementation, but the effect on treatment was less clear.

KEYWORDS
Alcohol, alcohol screening, AUDIT-C, brief intervention, continuous quality improvement, Indigenous, primary care, training and support, treatment

INTRODUCTION

Indigenous peoples that have been colonized, including Australia's Aboriginal and Torres Strait Islander peoples, are more affected by alcohol-related harms than general populations [1–4]. Harms of colonization, including intergenerational trauma, combined with introduction of mass-produced alcohol, underpin this disparity [5].

Regular screening for unhealthy alcohol use (drinking above recommended guidelines, including alcohol use disorders) is important for timely detection. Cost-effective brief intervention (BI) can then be provided to those with unhealthy drinking who are not dependent [6]. Clients with dependence can be treated in primary care settings, including with pharmacotherapies or referred to specialist services, if appropriate.

Recent systematic reviews [7,8] found only four studies of implementation strategies to increase the uptake of both screening and the full spectrum of treatment for unhealthy alcohol use [7]. While they consistently showed improvement in screening, their impact on treatment provision was variable. None were conducted in Australian or other Indigenous populations.

This report describes the outcomes of a cluster randomized trial to assess whether a service delivery support model, designed for Aboriginal and Torres Strait Islander Community Controlled Health Services (ACCHS), can produce a sustained increase in uptake of screening and appropriate treatment for unhealthy alcohol use. The first 12 months (active phase) of support resulted in a significant increase in screening in any 2-month period over that time [odds ratio (OR) = 5.52, 95% confidence interval (CI) = 4.31–7.07] [9]. However, there was no significant increase in the odds of BI. That analysis did not assess provision of a broader spectrum of treatment.

Previous studies have shown that longer implementation was associated with better outcomes [10]. In this analysis we examine the effects of the support on screening and provision of alcohol treatment over the full 24 months of implementation (active and maintenance phases), and investigate if the effects of provision of BI over 24 months differed from 12-month results. We hypothesized that over the 24 months there would be an increase in the odds of: (i) screening; (ii) provision of any alcohol treatment; and (iii) provision of BI for unhealthy alcohol use.

METHODS

The full study protocol was retrospectively registered (ACTRN12618001892202) and published [9,11]. This paper was prepared using the Consolidated Standards of Reporting Trial (CONSORT) extension for cluster randomized trials [12].

Study design and recruitment

The study is a cluster randomized trial of 22 ACCHS across Australia, with an equal allocation to treatment (early-support) and waiting-list control arms. During recruitment there were approximately 140–143 ACCHS in Australia [13,14]. Of these, 132 were assessed for eligibility. ACCHS were eligible if they: (i) used Communicare practice software; and (ii) provided care for 1000 or more unique clients per year.

Sample size and randomization

Sample size was calculated to detect 13% increase in treatment for unhealthy alcohol use, as this would require the larger sample than for screening alone (Supporting information, Section S1). Eleven ACCHS were recruited per arm [11]. Randomization of ACCHS, stratified by remoteness (based on the road distance to the nearest urban centre; Table 1) [15], was performed by the study statistician (TD) in SAS statistical software, using coded identifiers to ensure blinded allocation.

Implementation strategy

The 24-month support model (Fig. 1) consisted of eight core components (Supporting information, Table S1) designed to aid routine implementation of alcohol screening and appropriate treatment. Support was delivered to the early-support arm services in two 12-month phases: active (components c1–c8) and maintenance (c4–c8). Waiting-list control services operated as normal and had contact with the research team only when providing data. Following both phases in early support, the waiting-list control arm received their support. Services received $AUD100 each as staff-time reimbursement after each provision of data in phases when they were not receiving support.

TABLE 1 Service characteristics by trial arm at the end of 12-month baseline period (52 678 clients; 142 519 observations).[a]

Characteristic	Early support	Waiting-list controls
Services		
n	11	11
Mean clients per service (SD)	3166 (2045.4)	1623 (586.7)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
n	34 829	17 849
Mean age of clients (years) (SD)	37.4 (16.0)	37.8 (16.4)
Number of female clients (%)	19 578 (56.2)	10 009 (56.1)
Mean observations[b] per client (SD)	2.7 (1.8)	2.7 (1.7)
Clients screened with AUDIT-C (%)	5435 (15.6)	3626 (20.3)
Mean AUDIT-C score[c] (SD)	3.5 (3.6)	3.3 (3.5)
Clients with an AUDIT-C > 0[c] (%)	3017 (55.5)	2133 (58.8)
Clients recorded as receiving treatment for UAU[d] (%)	199 (0.6)	162 (0.9)
Clients recorded as receiving brief intervention (%)	70 (0.2)	109 (0.6)

[a]Baseline period: from 29 August 2016 to 30 August 2017, inclusive;
[b]An observation appeared in the data set for a client if they attended their service for a consultation in the preceding 2-month reference period at least once;
[c]mean score among clients who had at least one recorded AUDIT-C score;
[d]UAU = unhealthy alcohol use; treatment as recorded in Communicare (i.e. advice recorded using selected clinical items or pharmacotherapies prescribed).
SD = standard deviation; AUDIT-C = Alcohol Use Disorders Identification Test—Consumption.

Study outcomes

We analysed data collected over 3 years (12 months baseline, 24 months implementation). Services extracted de-identified, routinely collected clinical data from their practice software, Communicare, using SQL commands every 2 months. Clients' records were matched through client IDs [11]. If a client attended in a 2-month period this resulted in an observation, which included age, gender and outcome variables.

The outcomes were a recording (yes/no) of each of the following in each 2-month period:

- screening with the Alcohol Use Disorders Identification Test—Consumption (AUDIT-C); primary outcome (Supporting information, Section S2);
- any treatment: advice/BI or counselling for unhealthy alcohol use or prescription of naltrexone, acamprosate or disulfiram; secondary outcome; and
- BI: advice/BI for unhealthy alcohol use; secondary outcome.

Analysis

We tested whether the support model improved the clients' odds of each outcome being recorded at least once in any 2-month period. To account for the effects of clustering by service and client, we used multi-level logistic modelling ('lme4' package [16] in R statistical software version 4.0.2 [17]). All models focused on testing the following fixed effects:

- 'condition': early support arm (condition = 1); waiting-list controls (condition = 0);
- 'post-implementation': whether an observation occurred on or after the start of implementation—taken as the date when service champions returned from the national workshop, 31 August 2017 (yes = 1, no = 0); and
- 'intervention': effect of support model, given by the interaction between 'condition' and 'post-implementation'. Interaction represents relative change in the odds for the early support arm when compared to the waiting-list controls, post-implementation.

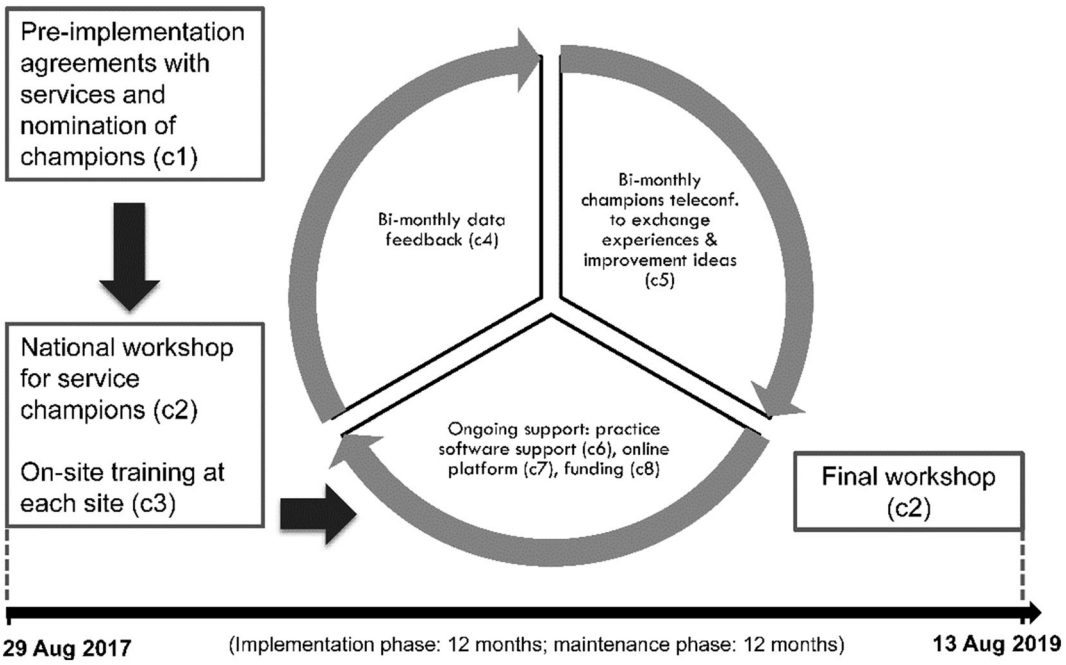

FIGURE 1 Graphic summary of the support model trialled during this study. c1 – c8: eight components of the support model. Detailed description is provided in Supporting information, Table S1. Implementation is considered as commencing on 31 August 2017, when service champions returned to their services following the workshop. Implementation ended on the last day of the final workshop on 15 August 2019

We tested a range of random effects. Model selection is detailed in Supporting information, Sections S3 and S4. We calculated:

- fixed effects and confidence intervals (Wald estimation);
- changes in odds over time for the early support arm (simple slope analysis) using the delta method ('car' package [18,19]); and
- adjusted intracluster correlation coefficients (ICC) to describe the proportion of variability explained by differences between clusters ('performance' package [20,21]).

We illustrated the fixed effects by plotting adjusted probabilities ('ggeffects' and 'ggplot2' packages [22,23]).

Missing data

As routinely collected data were used, we had no ability to detect if there were missing outcome data. When comparing demographic characteristics of arms at baseline we used complete-case analysis, as demographic data could be missing.

Aboriginal involvement and consent

Study methods were designed in consultation with two umbrella Aboriginal community-controlled health organizations (Supporting information, Table S2). The participating ACCHS were involved in refining study design. ACCHS' custodianship of study data was recognized: consent to participation and data release was sought from each ACCHS from authorized representatives and the board; ACCHS were provided with the results and the manuscript for comment before submitting for publication.

Ethics statement

This study received approval from eight ethics committees in Australian states where the participating services were located (Supporting information, Table S2). Three were Aboriginal-specific committees.

RESULTS

Description of sample

The 22 ACCHS contributed 83 032 client records between 29 August 2016 and 15 August 2019 (Fig. 2, Supporting information, Table S6). From January 2019, one waiting-list control service was unable to provide data due to change in practice software. Gender was missing for six clients. Service and client characteristics at baseline (Table 1) and at the end of the study (Supporting information, Table S6) show that sample composition remained broadly unchanged.

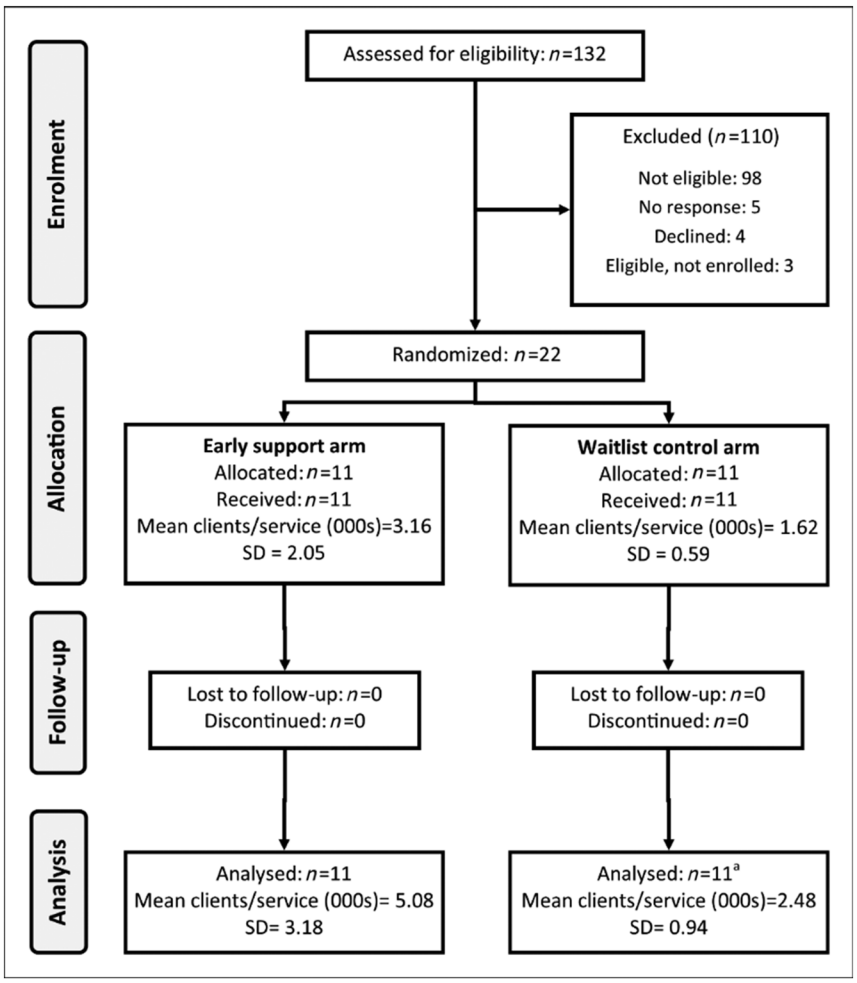

FIGURE 2 Flow diagram of participating services (*n* = number of services). [a]One service was unable to provide data from January 2019 onwards as they stopped using Communicare to log AUDIT-C results. Duration of follow-up was 24 months

TABLE 2 Detailed effects

	ICC (%)	OR	95% CI	Log-odds	SE	*P*
Screening	52					
(intercept)		0.02	(0.01–0.04)	−3.73	0.32	0.00
Post-implementation		5.09	(3.01–8.63)	1.63	0.27	0.00
Condition (early support)		0.13	(0.05–0.31)	−2.04	0.44	0.00
Intervention		7.95	(4.04–15.63)	2.07	0.35	0.00
Brief intervention	66					
(intercept)		0.00	(0–0)	−9.15	0.71	0.00
Post-implementation		0.88	(0.28–2.71)	−0.13	0.58	0.82
Condition (early-support)		0.79	(0.15–4.22)	−0.24	0.86	0.78
Intervention		1.95	(0.53–7.17)	0.67	0.66	0.32
Any treatment	33					
(intercept)		0.00	(0–0)	−6.28	0.21	0.00
Post-implementation		0.59	(0.41–0.85)	−0.52	0.19	0.01
Condition (early support)		1.01	(0.6–1.69)	0.01	0.26	0.98
Intervention		1.89	(1.19–2.98)	0.63	0.23	0.01

Intervention = effect of the entire 24-month support model given by the interaction between condition and post-implementation time-period. This interaction represents relative change in the odds for the early support arm when compared to the waiting-list control arm, post-implementation.
ICC = intracluster correlation coefficient; OR = odds ratio; CI = confidence interval; SE = standard error.

Outcomes

The odds of screening at baseline were lower for the early support arm than waiting-list controls. The odds of recorded BI and any treatment were negligible in both arms. Unadjusted smoothed rates by service and trial arm (Supporting information, Figs S1–S3) and adjusted ICCs (Table 2) demonstrate great variability in effects among the services. Detailed fixed effects results are presented in Table 2.

AUDIT-C screening

After implementation, the odds of screening increased in both arms, but the increase within the early support arm was much larger (simple slope: OR = 40.48, 95% CI = 17.82–91.97). This resulted in early support increase in odds nearly eight times greater (OR = 7.95, 95% CI = 4.04–15.63, $P < 0.001$) than controls. Probabilities of AUDIT-C screening adjusted for the effects of the support model are shown in Fig. 3.

Any treatment and BI

We found no clear evidence that the support model increased in the odds of having any treatment recorded in the early support arm (simple slope: OR = 1.12 95% CI = 0.74–1.68). However, odds reduced significantly for waiting-list controls (OR = 0.59, 95% CI = 0.41–0.85, $P = 0.01$). The reduction resulted in significantly greater odds of any treatment in early support services (OR = 1.89, 95% CI = 1.19–2.98, $P = 0.01$) than in controls.

The evidence that the model increased the odds of BI in the early support arm post-implementation was inconclusive (simple slope: OR = 1.71, 95% CI = 0.52–5.56), as was the evidence for the early support arm's increase in odds when compared to waiting-list controls (OR = 1.95, 95% CI = 0.53–7.17, $P = 0.32$).

However, adjusted probabilities for both any-treatment and BI remained extremely low (Figs 4 and 5).

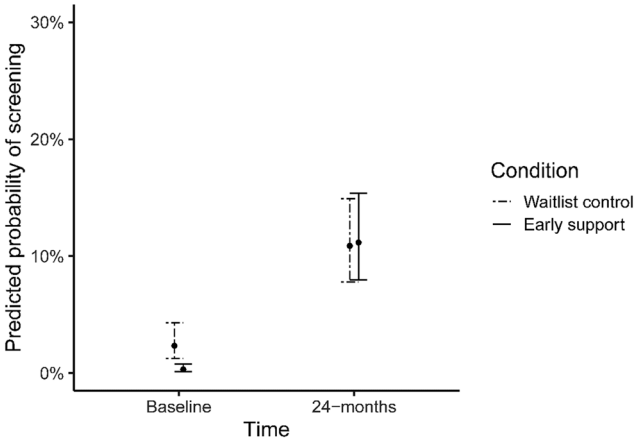

FIGURE 3 Predicted probabilities of screening in the early and waiting-list control arms at baseline and during 24 months of implementation

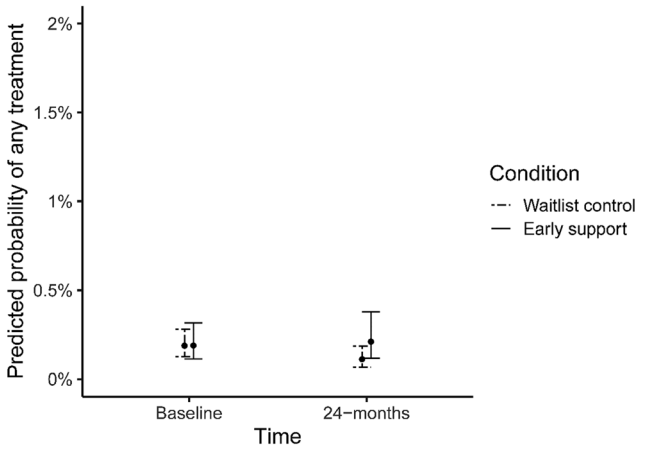

FIGURE 4 Predicted probabilities of receiving any treatment in the early and waiting-list control arms at baseline and during 24 months of implementation

DISCUSSION

This support model resulted in increased AUDIT-C screening over the 24 months of support and a higher likelihood of screening than during the 12-month active support phase [9]. However, the high variability in improvement between services [9] persisted until the end of implementation. Given this variability, and the lower baseline screening rates in early support arm, these results must be viewed with caution.

Consistent with the results during 12-month active phase [9], we were not able to show clear evidence that the support model improved the BI rates over 24 months.

The significant change in odds of any treatment in early support services when compared to waiting-list controls was driven mainly by a reduction of recorded treatment provision in controls. This result may indicate that the support prevented a drop-off in treatment provision in the early support arm. However, as the probability of treatment remained extremely low, the increase does not translate to a clinically meaningful result.

Alcohol consumption varies within and between Aboriginal and Torres Strait Islander communities [24]. The design of our model employed tailoring to local conditions, iterative support and using data to drive improvement. Longer duration of implementation (24 months) contrasted with past implementation studies where sites received support over 28 weeks on average [13]. These features may have made it possible for many services to implement improvements despite their highly variable context, ranging from settings where alcohol was freely available to others, where individuals had to drink outside the community.

Recommendations for policy, practice and research

The low implementation rates and high variability in effect sizes indicate that further effort is needed to see more consistent improvements in implementation. At service level, this might include periodic

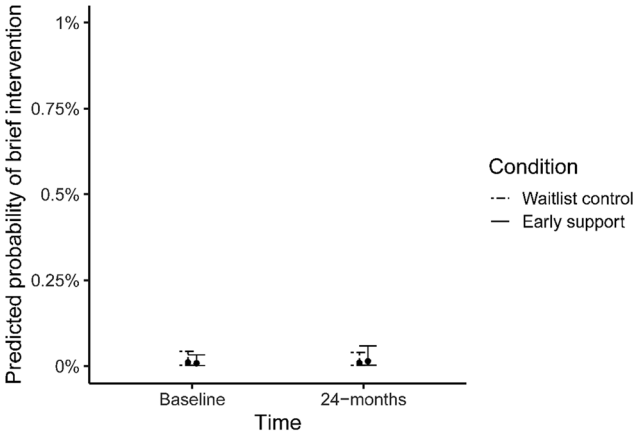

FIGURE 5 Predicted probabilities of receiving brief intervention in the early and waiting-list control arms at baseline and during 24 months of implementation

training for new and continuing staff involved in alcohol care and training, on how to improve and monitor service quality (e.g. continuous quality improvement). Screening in combination with other risk factors [e.g. using SNAP (smoking, nutrition, alcohol and physical activity)] may improve client acceptability [25]. Ensuring that practice software prompts recording of BI in response to a raised AUDIT-C score may help to raise treatment rates.

Previous studies have shown that multiple organizational levels need to be involved to optimize health service improvement efforts [7,26,27]. Furthermore, the ACCHS' work to sustainably improve Aboriginal and Torres Strait Islander health must be supported by both state and federal government. Efforts are needed to address systems-level barriers such as inconsistent, inadequate or siloed funding [28].

Limitations

The pragmatic setting of this implementation trial made the study vulnerable to factors beyond our control. Most significantly, introduction of AUDIT-C as a national key performance indicator for Aboriginal and Torres Strait Islander primary care in June 2017 [29] may have made early support services more receptive to the support. The effect of this policy change is reflected in the increased odds of screening post-implementation in both arms.

At service level recording of BI was unlikely to be consistent across sites, as clinicians had to search for and select the relevant clinical item in practice software. Some practices recorded counselling for alcohol by their specialized drug and alcohol staff in different software.

Resource constraints limited our ability to investigate the effect of individual components of the model on outcomes and to capture contextual information (e.g. how support components were used locally to achieve improvement) [26].

CONCLUSIONS

We have demonstrated that our flexible model of support, provided over 24 months, can result in improvement of AUDIT-C screening. Variability in outcomes indicate that the model was not uniformly successful in inducing gains in screening. Effects on treatment rates for unhealthy alcohol use are less clear. The longer duration of support facilitated successful delivery of the support model at all sites and appeared to be a factor in improving outcomes. Our study suggests that multi-faceted implementation strategies, which include data-driven tailoring as well as iterative monitoring and improvement processes, are well suited to the needs of ACCHS because of their flexibility and adaptability to local contexts.

DECLARATION OF INTERESTS

The authors have no conflicts of interest to declare.

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AUTHOR CONTRIBUTIONS

Monika Dzidowska: Conceptualization; formal analysis. **KS Kylie Lee:** Conceptualization; supervision. **James Conigrave:** Conceptualization; data curation; methodology. **Timothy Dobbins:** Formal analysis; supervision. **Beth Hummerston:** Data curation. **Scott Wilson:** Conceptualization. **Paul Haber:** Conceptualization. **Dennis Gray:** Conceptualization. **Katherine Conigrave:** Conceptualization; supervision.

TRIAL REGISTRATION

Australian New Zealand Clinical Trials Registry (ACTRN12618001892202): https://anzctr.org.au/Trial/Registration/TrialReview.aspx? ACTRN = 12 618 001 892 202.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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3.3 Additional materials

The content of this section was published as supplementary materials to the preceding article and includes a detailed description of the support model.

SUPPORTING MATERIAL

Support for Aboriginal health services in reducing harms from alcohol: 2-year service provision outcomes in a cluster randomized trial

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Table S1. Detailed description of the eight components of the support model

C1	Implementation agreements included memoranda of understanding outlining the aims of and design of the study, responsibilities of the research team and the services and what each party would provide as part of the study
C2	Two-day workshop with nominated service champions to familiarise them with the aims and methods of the study, to build a champions' network and introduce them to the support model. Training was provided on screening, brief intervention, and treatment of unhealthy alcohol use.
C3	On-site training: The program's core is a half-day face-to-face interactive training workshop. Themes included: harms from alcohol, alcohol use disorders; current evidence-base and guidelines for prevention, and treatment, using AUDIT-C to assess clients' drinking; using data to monitor improvements in screening and treatment; how to deliver brief intervention; use of relapse prevention medicines; community-driven actions to prevent harms from alcohol. Additional modules were available on topics such as Fetal Alcohol Spectrum Disorder (FASD) or more detailed coverage of medical treatments for alcohol dependence. Face-to-face workshops were delivered by an addiction medicine specialist and an Aboriginal health professional (for example, drug and alcohol worker or other health worker). Training content is aligned with Aboriginal and Torres Strait Islander cultural protocols such as gender appropriateness, kinship systems and cultural obligations.
C4	Bi-monthly data feedback report presented as a pdf file and emailed to the service champions and key contacts. Feedback was provided as a graphic representation of proportion of clients drinking at risky levels, as well as screening and treatment rates over time based on the bi-monthly data provided by the services.
C5	Bi-monthly teleconference for service champions to exchange improvement ideas and experiences
C6	Support to modify practice software, where needed, for example to include AUDIT-C in the Adult Health Check and other areas of the interface if requested.
C7	Online platform including a repository of electronic tools and resources, and a private chat platform for the champions.
C8	Services were offered financial support for purchase of resources to help their work on alcohol e.g., standard drink cups, FASD dolls; clinical handbooks, prevention materials.

Table S2 Ethics committees and key Aboriginal community controlled health organisations

Australian state or territory	**Ethics committee name**	**Approval number**
New South Wales (NSW)	The Aboriginal Health & Medical Research Council of NSW Ethics Committee	1217/16
Northern Terriory (NT)	Central Australian Human Research Ethics Committee Human Research Ethics Committee of Northern Territory Department of Health and Menzies School of Health Research	CA-17-2842 2017-2737
Queensland (Qld)	Central Queensland Hospital and Health Service Human Research Ethics Committee Far North Queensland Human Research Ethics Committee	17/QCQ/9 17/QCH/45-1143
South Australia (SA)	The Aboriginal Health Research Ethics Committee, South Australia	04-16-694

Victoria (Vic)	St Vincent's Hospital Melbourne Human Research Ethics Committee	LRR 036/17
Western Australia	Western Australian Aboriginal Health Ethics Committee	project 779
	Umbrella Aboriginal community controlled health organisation involved in consultation leading to study design	
South Australia (SA) New South Wales (NSW)	Aboriginal Drug and Alcohol Council SA Incorporated Aboriginal Health Council of South Australia (AHCSA), Aboriginal Drug and Alcohol Network, NSW Aboriginal Health and Medical Research Council, NSW	

SECTION S1 SAMPLE SIZE

The study was powered to detect and increase in both screening (the primary outcome) and in the offer of treatment for unhealthy alcohol use (the secondary outcome). As detecting an increase in treatment provision required a larger sample size than screening, it was the focus of sample size calculation. Treatment provision included brief intervention, counselling or pharmacotherapies for alcohol relapse prevention.

In a practice which sees 1000 clients per year, about 60% are likely to be aged 16 years or more (1). Of these clients, approximately 57% are likely to be screened in any 12-month period (2). Of the screened clients, at least 25% are likely to consume alcohol above the levels recommended by the National Health and Medical Research Council (NHMRC) of Australia (3, 4). In the control services 60% of people drinking above recommended levels were considered likely to have any intervention recorded (2). Assuming an intra-cluster correlation coefficient (ICC) of 0.04 (5, 6), a sample of 10 services per arm was found to be sufficient to detect 13% absolute increase in treatment provision in the intervention services (from 60% to 73%, 80% power and 2-sided significance of 0.05). This increase was considered of adequate clinical significance while allowing for a manageable number of services. To allow for possible service attrition, one extra service per arm was recruited. As outcomes in this study are obtained from de-identified, routinely collected electronic patient record data, patient consent is not required, only service consent, so sample size calculations did not incorporate non-consent rates.

SECTION S2. AUDIT-C

A record of Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) (7) was chosen as a screening frequency measure in this study because it is the most frequently used validated screening tool among Aboriginal Community Controlled Health Services. Acceptability studies and comparison studies with the full AUDIT have been conducted in Aboriginal and Torres Strait Islander populations. AUDIT-C was found to be more acceptable than other screening tools and compared favourably with AUDIT (8). The full AUDIT had previously been found to have good internal consistency, and correlation with another measure of alcohol consumption in an Aboriginal or Torres Strait Islander setting (9).

AUDIT-C screening is now used to estimate the proportion of the Aboriginal and Torres Strait Islander consuming alcohol above recommended levels as part of Indigenous primary health care national key performance indicators (10).

SECTION S3. MODEL SELECTION PROCESS

For all models, the fixed effects were condition + implementation + condition*post-implementation. We added a range of random effects including a random intercept for services, a random intercept for clients and a random slope of post-implementation by service, to the fixed effects model:

condition + implementation + condition*post-implementation

Of the models that converged (Tables S3-S5), the model with the lowest Bayesian information criteria (BIC), was considered best fitting (11). This model was compared with simpler, nested models using likelihood ratio testing. If the fit of a more parsimonious model was not significantly worse than the best fitting model, then the simpler model was preferred.

Table S3. Models for predicting odds of screening with AUDIT-C

Model	BIC	LogLik	Number of parameters
(A) Random intercept of service	272336.99	-136136.14	5
(B) Random slope of post-implementation by service and random intercept of service	265195.46	-132552.44	6
(C) Random intercept of service and client	272238.70	-136080.53	6
(D) Random intercept of service and client, random slope of post-implementation by service*	265102.92	-132499.69	7

*indicates best-fit model

Table S4. Models for predicting the odds of any-treatment for unhealthy alcohol use

Model	BIC	LogLik	Number of parameters
(A) Random intercept of service	17926.46	-8930.88	5
(B) Random slope of post-implementation by service and random intercept of service*	17741.41	-8825.41	6

*indicates best-fit model

Table S5. Models for predicting the odds of brief intervention

Model	BIC	LogLik	Number of parameters
(A) Random intercept of service	9706.00	-4820.65	5
(B) Random slope of post-implementation by service and random intercept of service	9610.57	-4759.99	6
(C) Random intercept of service and client	9574.67	-4748.51	6
(D) Random intercept of service and client, random slope of post-implementation by service*	9473.22	-4684.84	7

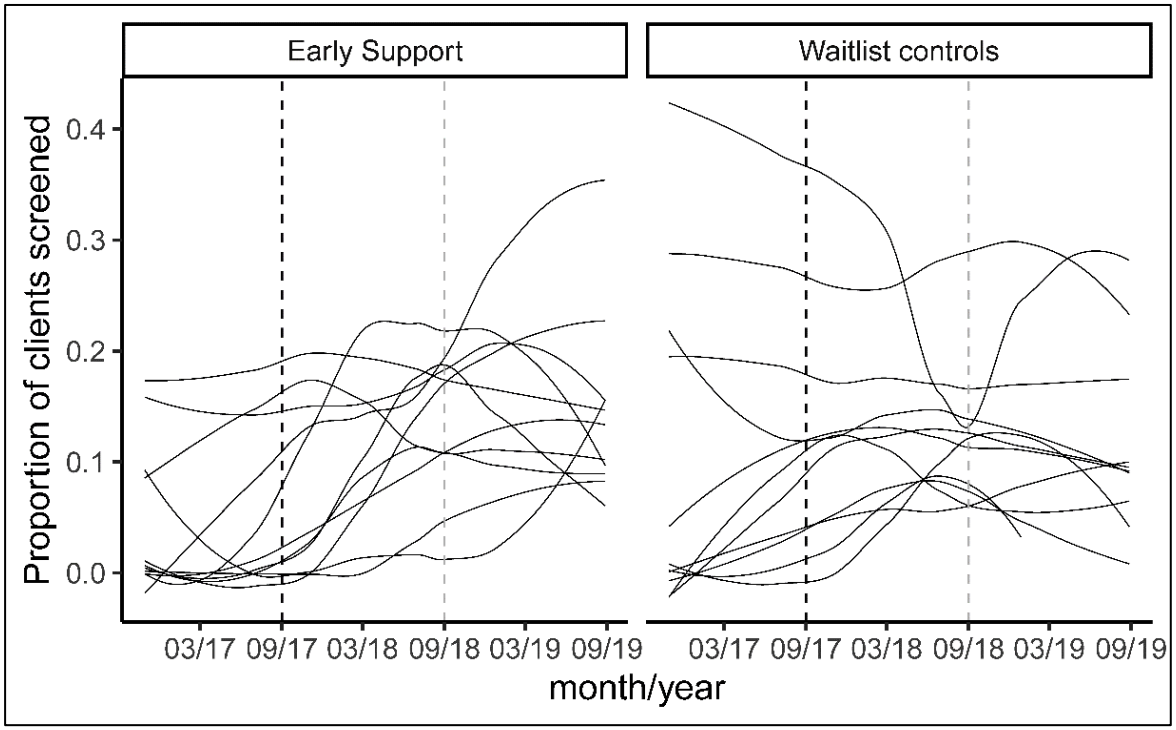
*indicates best-fit model

Table S6. Service characteristics by trial arm, over the study period[a] (83,032 clients; 417,228 observations)

Characteristic	Early support	Waitlist controls
Services		
N	11	11[e]
Mean clients per service (SD)	5,068 (3182.7)	2,480 (943.5)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
N	55,747	27,285
Mean age of clients (years) (SD)	36.9 (16.1)	37.2 (16.5)
Number of female clients (%)	30,658 (55.0)	14,891 (54.6)
Mean observations[b] per client (SD)	5.0 (4.7)	5.1 (4.7)
Clients screened with AUDIT-C (%)	19,077 (34.2)	9,193 (33.7)
Mean AUDIT-C score[c] (SD)	3.7 (3.6)	3.1 (3.5)
Clients with an AUDIT-C > 0[c] (%)	11,567 (60.6)	5,724 (62.3)
Clients recorded as receiving treatment for UAU[d] (%)	831 (1.5)	263 (1.0)
Clients recorded as receiving brief intervention (%)	569 (1.0)	168 (0.6)

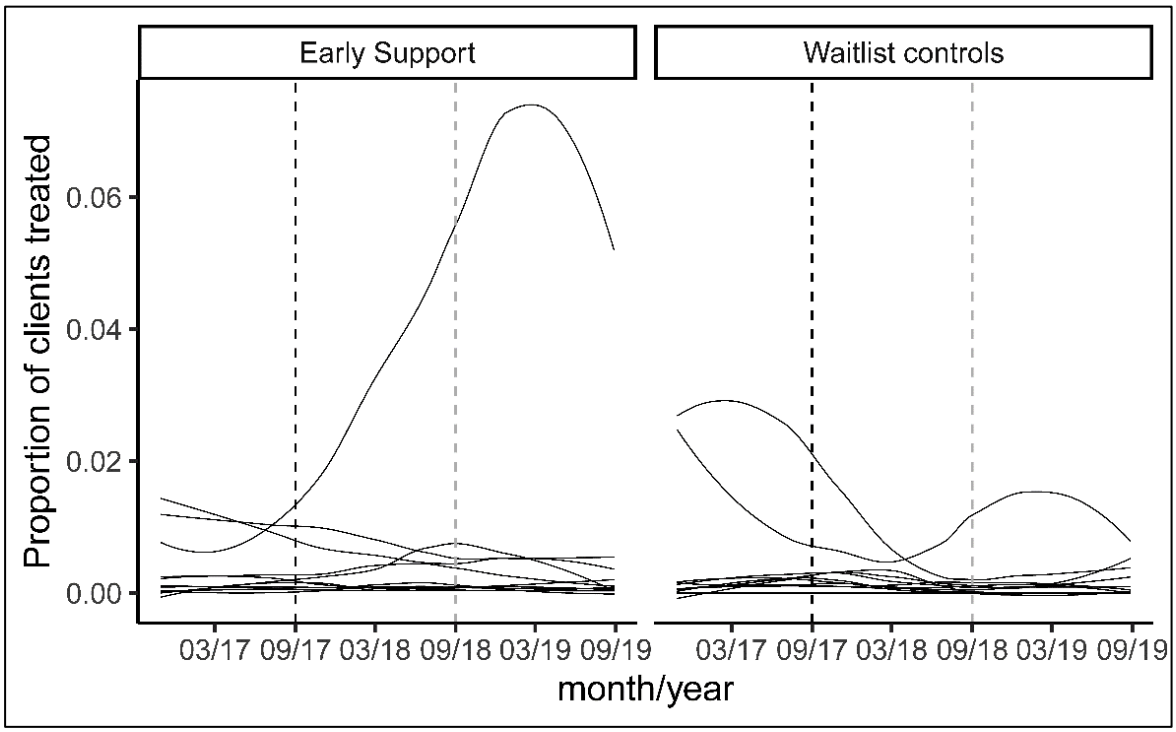
[a]Study period: from 29.08.2016 to 15.08.2019 inclusive. [b]An observation appeared in the dataset for a client if they attended their service for a consultation in the preceding two-month reference period at least once. [c]Mean score among clients who had at least one recorded AUDIT-C score. [d]UAU – unhealthy alcohol use; treatment as recorded in Communicare (i.e. advice recorded using selected clinical items or pharmacotherapies prescribed). [e]One service was unable to provide data from January 2019 onwards as they stopped using Communicare to log AUDIT-C results.

Figure S1. Unadjusted smoothed screening rates by service and trial arm



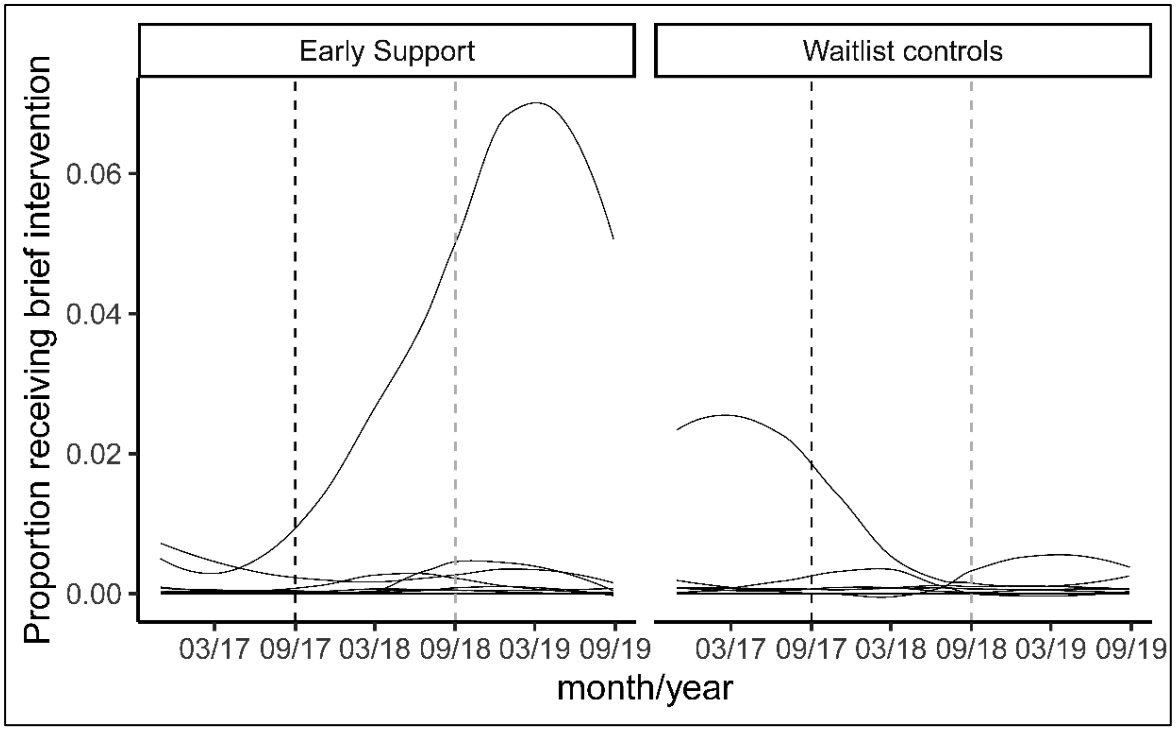
Rates are records of screening for a patient per two-month reference period. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase.

Figure S2 Unadjusted smoothed rates of any-treatment by service and trial arm



Rates are records of any-treatment for a patient per two-month reference period. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase.

Figure S3. Unadjusted smoothed rates of brief intervention by service and trial arm



Rates are records of any-treatment for a patient per two-month reference period. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase.

SECTION S4 ANALYSIS CODE: EXAMPLE OF PROCEDURE

Below is the procedure for analysis in R statistical package. This example is for the outcome of screening with AUDIT-C. The same procedure was followed for the outcomes of any-treatment and brief intervention.

DATA TRANSFORMATION

Load data and packages

```
library(plyr)
library(tidyverse)
library(lubridate)
library(optimx)
library(dfoptim)
library(performance)
library(car)
tx_monthly_data <- readRDS("tx_data.rds")
```

Set Seed

```
set.seed(42)
knitr::opts_chunk$set(cache.extra = knitr::rand_seed)
```

Subset data to consultations occurring before late support implementation

```
tx_monthly_data$last.visit<-as.Date(tx_monthly_data$last.visit, format = "%d/%m/
%Y")
tx_monthly_data<-tx_monthly_data%>%filter(last.visit<dmy("16-08-2019"))
```

Subset baseline data to one year pre-implementation (baseline: 29 August 2016)

```
tx_monthly_data<-tx_monthly_data%>%filter(last.visit>dmy("28-08-2016"))
```

Recode the variable: "condition" to numeric

```
tx_monthly_data$condition<-as.character(tx_monthly_data$condition)%>%
  mapvalues(c("Early","Late"), c(1,0))%>%
  as.numeric()
```

Create a new variable: Implementation date

```
tx_monthly_data$implDate<-dmy("31-08-2017")
```

Create a new variable: Is consult pre or post-implementation?

```
tx_monthly_data$postImpl<-ifelse(tx_monthly_data$last.visit<tx_monthly_data$impl
Date,0,1)
```

ANALYSIS

MODELS WITH RANDOM EFFECTS OF SERVICE

Random intercept of service

```
CIMpostImpl_scr<-glmer(audit~postImpl*condition+(1|service), data=tx_monthly_dat
a, family="binomial")
summary(CIMpostImpl_scr)
```

```
## Generalized linear mixed model fit by maximum likelihood (Laplace
##   Approximation) [glmerMod]
##  Family: binomial  ( logit )
## Formula: audit ~ postImpl * condition + (1 | service)
##    Data: tx_monthly_data
##
##       AIC       BIC    logLik  deviance  df.resid
##  272282.3  272337.0 -136136.1  272272.3    417223
##
## Scaled residuals:
##     Min      1Q  Median      3Q     Max
## -0.7302 -0.4177 -0.2832 -0.1824  8.1704
##
## Random effects:
##  Groups  Name        Variance Std.Dev.
##  service (Intercept) 0.6234   0.7895
## Number of obs: 417228, groups:  service, 22
##
## Fixed effects:
##                    Estimate Std. Error z value Pr(>|z|)
```

```
## (Intercept)        -2.39571    0.11726 -20.431  < 2e-16 ***
## postImpl            0.20728    0.01823  11.370  < 2e-16 ***
## condition          -0.53495    0.15419  -3.469 0.000521 ***
## postImpl:condition  0.59076    0.02330  25.354  < 2e-16 ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) pstImp condtn
## postImpl    -0.046
## condition   -0.552  0.026
## pstImpl:cnd  0.036 -0.771 -0.019
```

Random intercept of service and random slope of post-implementation by service

```
AIMpostImpl_scr<-glmer(audit~postImpl*condition+(1+postImpl|service), data=tx_monthly_data, family="binomial")
summary(AIMpostImpl_scr)
```

```
## Generalized linear mixed model fit by maximum likelihood (Laplace
##   Approximation) [glmerMod]
##  Family: binomial  ( logit )
## Formula: audit ~ postImpl * condition + (1 + postImpl | service)
##    Data: tx_monthly_data
##
##       AIC       BIC    logLik  deviance  df.resid
##  265118.9  265195.5 -132552.4  265104.9    417221
##
## Scaled residuals:
##    Min     1Q Median     3Q    Max
## -0.806 -0.454 -0.301 -0.082 62.802
##
## Random effects:
##  Groups  Name        Variance Std.Dev. Corr
##  service (Intercept) 9.863    3.141
##          postImpl    8.249    2.872    -0.98
## Number of obs: 417228, groups:  service, 22
##
## Fixed effects:
##                    Estimate Std. Error z value Pr(>|z|)
## (Intercept)        -3.70331    0.10096  -36.68   <2e-16 ***
## postImpl            1.62898    0.09232   17.65   <2e-16 ***
## condition          -2.04207    0.12657  -16.13   <2e-16 ***
## postImpl:condition  2.06773    0.09475   21.82   <2e-16 ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) pstImp condtn
## postImpl    -0.246
## condition   -0.500  0.081
## pstImpl:cnd  0.062 -0.342 -0.080
```

Comparing nested models

```
anova(CIMpostImpl_scr, AIMpostImpl_scr)
```

```
## Data: tx_monthly_data
## Models:
## CIMpostImpl_scr: audit ~ postImpl * condition + (1 | service)
## AIMpostImpl_scr: audit ~ postImpl * condition + (1 + postImpl | service)
##                 npar    AIC    BIC  logLik deviance  Chisq Df Pr(>Chisq)
## CIMpostImpl_scr    5 272282 272337 -136136   272272
## AIMpostImpl_scr    7 265119 265195 -132552   265105 7167.4  2  < 2.2e-16 ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

MODELS WITH RANDOM EFFECTS OF SERVICE AND CLIENT

Random intercept of service and of client

```
CIMpostImplID_scr<-glmer(audit~postImpl*condition+(1|service)+(1|id), data=tx_mo
nthly_data, family="binomial")
summary(CIMpostImplID_scr)
```

```
## Generalized linear mixed model fit by maximum likelihood (Laplace
##   Approximation) [glmerMod]
##  Family: binomial  ( logit )
## Formula: audit ~ postImpl * condition + (1 | service) + (1 | id)
##    Data: tx_monthly_data
##
##       AIC       BIC    logLik  deviance  df.resid
##  272173.1  272238.7 -136080.5  272161.1    417222
##
## Scaled residuals:
##     Min      1Q  Median      3Q     Max
## -0.8924 -0.4140 -0.2829 -0.1812  8.0431
##
## Random effects:
##  Groups  Name        Variance Std.Dev.
##  id      (Intercept) 0.06419  0.2534
##  service (Intercept) 0.62480  0.7904
## Number of obs: 417228, groups:  id, 83032; service, 22
##
## Fixed effects:
##                    Estimate Std. Error z value Pr(>|z|)
## (Intercept)        -2.42542    0.17165 -14.130   <2e-16 ***
## postImpl            0.20852    0.01860  11.208   <2e-16 ***
## condition          -0.53485    0.24506  -2.183   0.0291 *
## postImpl:condition  0.59309    0.02382  24.894   <2e-16 ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) pstImp condtn
## postImpl    -0.039
## condition   -0.579  0.022
## pstImpl:cnd  0.027 -0.779 -0.035
```

Comparing nested models

```
anova(CIMpostImpl_scr,CIMpostImplID_scr)
```

```
## Data: tx_monthly_data
## Models:
## CIMpostImpl_scr: audit ~ postImpl * condition + (1 | service)
## CIMpostImplID_scr: audit ~ postImpl * condition + (1 | service) + (1 | id)
##                   npar    AIC    BIC  logLik deviance  Chisq Df Pr(>Chisq)
## CIMpostImpl_scr      5 272282 272337 -136136   272272
## CIMpostImplID_scr    6 272173 272239 -136081   272161 111.23  1  < 2.2e-16 **
*
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

Random intercept of service and of client and random slope of post-implementation by service

```
AIMALTpostImplID_scr<-glmer(audit~postImpl*condition+(1+postImpl|service)+(1|id)
, data=tx_monthly_data, family="binomial")
summary(AIMALTpostImplID_scr)
```

```
## Generalized linear mixed model fit by maximum likelihood (Laplace
##   Approximation) [glmerMod]
##  Family: binomial  ( logit )
## Formula: audit ~ postImpl * condition + (1 + postImpl | service) + (1 |
##     id)
##    Data: tx_monthly_data
##
##       AIC       BIC    logLik  deviance  df.resid
##  265015.4  265102.9 -132499.7  264999.4    417220
##
## Scaled residuals:
##    Min     1Q Median     3Q    Max
## -0.982 -0.439 -0.302 -0.081 60.529
##
## Random effects:
##  Groups  Name        Variance Std.Dev. Corr
##  id      (Intercept) 0.06235  0.2497
##  service (Intercept) 9.86869  3.1414
##          postImpl    8.26193  2.8744   -0.98
## Number of obs: 417228, groups:  id, 83032; service, 22
##
## Fixed effects:
##                    Estimate Std. Error z value Pr(>|z|)
## (Intercept)         -3.7305     0.3206 -11.634  < 2e-16 ***
## postImpl             1.6280     0.2691   6.049 1.46e-09 ***
## condition           -2.0438     0.4388  -4.658 3.20e-06 ***
## postImpl:condition   2.0728     0.3451   6.007 1.89e-09 ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) pstImp condtn
## postImpl    -0.816
```

```
## condition    -0.256  0.029
## pstImpl:cnd  0.060 -0.087 -0.799
```

Comparing nested models

```
anova(AIMpostImpl_scr,AIMALTpostImplID_scr)
```

```
## Data: tx_monthly_data
## Models:
## AIMpostImpl_scr: audit ~ postImpl * condition + (1 + postImpl | service)
## AIMALTpostImplID_scr: audit ~ postImpl * condition + (1 + postImpl | service)
+ (1 |
## AIMALTpostImplID_scr:     id)
##                       npar    AIC    BIC  logLik deviance  Chisq Df Pr(>Chisq)
## AIMpostImpl_scr          7 265119 265195 -132552   265105
## AIMALTpostImplID_scr     8 265015 265103 -132500   264999 105.48  1  < 2.2e-16
##
## AIMpostImpl_scr
## AIMALTpostImplID_scr ***
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

INTRACLASS CORRELATION COEFFICIENT

```
performance::icc(AIMALTpostImplID_scr)
```

```
## # Intraclass Correlation Coefficient
##
##      Adjusted ICC: 0.531
##   Conditional ICC: 0.398
```

MEASURES OF EFFECT

Odds Ratios

```
summ<-summary(AIMALTpostImplID_scr)
ORtab_scr<-data.frame(coef(summ))
ORtab_scr$OR<-exp(ORtab_scr$Estimate)
ORtab_scr$OR
```

```
## [1] 0.02398105 5.09361652 0.12953887 7.94709635
```

Confidence Intervals - log(CI)

```
AIMALTpostImplID_scrW<-confint(AIMALTpostImplID_scr,level=0.95 ,method="Wald")
AIMALTpostImplID_scrW
```

```
##                          2.5 %    97.5 %
## .sig01                      NA        NA
## .sig02                      NA        NA
## .sig03                      NA        NA
## .sig04                      NA        NA
## (Intercept)        -4.358944 -3.102039
## postImpl            1.100501  2.155475
## condition          -2.903824 -1.183724
## postImpl:condition  1.396515  2.749099
```

SIMPLE SLOPES ANALYSIS

```
simp_scr<-
  car::deltaMethod(AIMALTpostImplID_scr,
                   g.=c("(b2+b4)"),
                   parameterNames=paste0("b",1:4))%>%
  data.frame()
simp_scr
```

```
##           Estimate       SE   X2.5..  X97.5..
## (b2 + b4) 3.700795 0.418706 2.880146 4.521443
```

Simple slopes OR

```
ORtab_simp_scr<-exp(simp_scr)
ORtab_simp_scr
```

```
##           Estimate       SE   X2.5..  X97.5..
## (b2 + b4) 40.47946 1.519993 17.81688 91.96824
```

Simple slopes table

```
write.csv(ORtab_simp_scr,"ORtab_simp_scr.csv")
```

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CHAPTER

4

EFFECTS OF THE SUPPORT MODEL ON PHARMACOTHERAPIES AND TALKING THERAPIES

4.1 Introduction

The importance of addressing the full spectrum of unhealthy alcohol use in primary care has been highlighted in the systematic review as this may be the most frequent, and often only, opportunity a health practitioner has to offer treatment (Chapter 2). For example, in Australia 86% of people accessed a general practitioner in 2015-2016 and made five visits on average (68). However, very few projects globally have studied implementation of alcohol treatments in Indigenous primary care settings (80). Addressing low uptake of treatment provision in primary care is important as these populations suffer significant harms from alcohol, exacerbated by harms caused by colonisation (26).

The support model trialled in this study included training on treating the full spectrum of unhealthy alcohol use. The analysis of the cluster randomised trial over 24 months (Chapter 3) showed a significant increase in the relative odds of receiving any treatment in services that were supported compared to wait-list controls, though this was mainly driven by a reduction of treatment provision in the controls. There was no clear statistical evidence that the increase in the relative odds of brief intervention was due to the effects of the support model.

This chapter investigates the effects of the support model on other treatments that comprised the variable 'any treatment', not studied in Chapter 3 (prescription of relapse prevention medicines, counselling). However, because of the nature of consultations in primary care and the likely lack of accurate distinction by clinicians between brief intervention and longer counselling (section 4.1.2), these will be considered together. This chapter is thus an in-depth investigation of two aspects of treatment: the effect of the

model on pharmacotherapies and on all 'talking therapies' (counselling or brief intervention).

4.1.1 Pharmacotherapies

Australian pharmacotherapy prescription rates for alcohol dependence in the general population are estimated to be less than 3% among those with dependence (81). However, the systematic review (Chapter 2) found that few studies have attempted to increase the prescription of pharmacotherapies for alcohol relapse prevention in primary care.

In this trial, the training component of the support model advocated the use of pharmacotherapies for relapse prevention (naltrexone, acamprosate or disulfiram) and training for their role in treatment of alcohol dependence. Their prescription would be of particular importance in many of the settings where ACCHS operate. In these settings access to specialist services can be limited (e.g., in rural and remote areas) or there could be barriers to accessing them (e.g., long waiting times for appointments, client's lack of trust in specialist services, stigma or shame) (82). It is therefore important to investigate the effects of this support model on provision of pharmacotherapies for relapse prevention.

4.1.2 Talking therapies

Primary care rates of providing talking therapies (e.g., education, brief intervention) for unhealthy alcohol use are generally low (47, 83, 84). In an Australian primary care survey, provision of this type of treatment in 2015-2016 was estimated to occur in 0.4% of primary care encounters but these estimates are reliant on the participating practitioners' accuracy of recording (85). Depending on which definitions are adopted, brief interventions can range from about 5 to 30 minutes and be delivered in one or multiple sessions (30, 40). The trial

defined the duration of brief intervention as one lasting less than 20 minutes. This duration was thought as more feasible in a busy primary care service. Accordingly, during the support model's training sessions, staff were advised to use the 'advice' field to record any discussion about alcohol that was less than 20 minutes in duration, and longer sessions in the field 'counselling'. The trial protocol defined brief intervention as the variable recorded in the field 'advice' and this was hence used in the analysis of the 24-months outcome (Chapter 3).

However, as highlighted in Chapter 3, the practice software Communicare, was not set up well to record brief intervention accurately. Differentiating between brief intervention and counselling first required the clinician to note the duration of their conversation on alcohol and then to search for a relevant clinical item (none of which were labelled 'brief intervention'). Brief intervention and other talking therapies may therefore have been interchangeably recorded in the fields 'advice' or 'counselling'. It was not possible to verify from other Communicare records whether these treatment events were recorded correctly.

Given normal consultation time available in the primary care setting, it is likely that any 'talking therapy' recorded either under 'advice' or 'counselling' would be in line with the aims and duration of a brief intervention. Therefore, combining the two 'talking therapy' variables may also be a useful way to examine these as a single outcome. This approach has precedent in some previous studies using practice software data, where a combination of counselling or education-style treatment fields was used as a record of brief intervention (83, 86, 87).

4.2 Aims

This chapter presents a supplementary analysis of the effects of the support model on the prescription of pharmacotherapies for relapse prevention, which was not presented separately in Chapter 3. It will also analyse the effects of the support model on receiving at least one talking therapy.

4.3 Methods

The analysis follows the methods described in Chapter 3. The outcomes were documentation of the following events in Communicare practice software within the any 2-month period:

- Pharmacotherapies: record of prescription of naltrexone, acamprosate or disulfiram
- Talking therapies: record of either advice or counselling for unhealthy alcohol use

In line with the analysis presented in Chapter 3, the following fixed effects were tested:

- 'condition': early support arm (condition = 1); waiting-list controls (condition = 0).
- 'post-implementation': whether an observation occurred on or after the start of implementation—taken as the date when service champions returned from the national workshop, 31 August 2017 (yes = 1, no = 0); and
- 'intervention': effect of support model, given by the interaction between 'condition' and 'post-implementation'. This interaction represents the relative change (from pre-to post implementation) in the odds (of clients

receiving pharmacotherapy / talk therapy) for the early support arm, when compared to the waiting-list controls' change over the same period, post-implementation.

4.4 Results

4.4.1 Pharmacotherapies for relapse prevention

There were only 479 consultations (involving 253 clients) that had a record of prescription of at least one of the three pharmacotherapies for relapse prevention. Of the 22 participating services, 21 had records of prescription. Unadjusted rates of pharmacotherapies by service are shown in Figure 4.1.

Of the three models that converged (Table 4.1), the model incorporating the random intercepts of service and client had the best fit based on lowest Bayesian Information Criterion (BIC) and was used in the analysis. Grouping structure accounted for 98% of the variance in the odds of receiving pharmacotherapies (Table 4.2).

The odds of receiving pharmacotherapy prescription were negligible in both arms prior to implementation of support (Table 4.2). After implementation, there was no clear evidence of change in the odds of receiving pharmacotherapies in the early-support arm (simple slope OR=0.76, 95%CI=0.56 – 1.03), but there was a significant reduction in the waitlist control arm (OR=0.47, 95%CI=0.30 - 0.75, p>0.01). There was also no clear evidence that there was a difference in the odds of receiving pharmacotherapy between early-support arm and controls (OR=1.61, 95%CI=0.92-2.80, p=0.1). Probabilities of having a record of pharmacotherapy prescription, adjusted for the effects of the support model are shown in Figure 4.2.

Table 4.1 Models for predicting odds of treatment with pharmacotherapies for relapse prevention

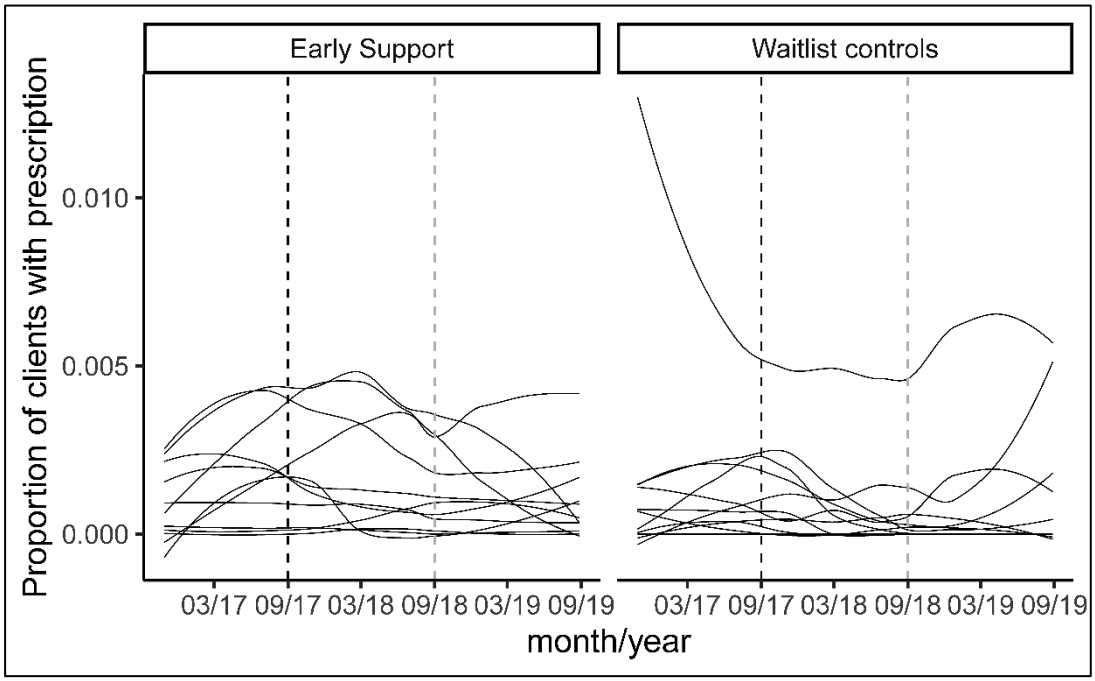
Model	BIC	Log Likelihood	Number of parameters
(A) Random intercept of service	7119.51	-3527.40	5
(B) Random slope of post-implementation by service and random intercept of service	7136.51	-3522.96	6
(C) Random intercept of service and client*	3569.90	-1746.13	6

*Indicates best fit model; BIC – Bayesian Information Criterion

Table 4.2 Fixed effects of the support model on the odds of receiving pharmacotherapies for relapse prevention

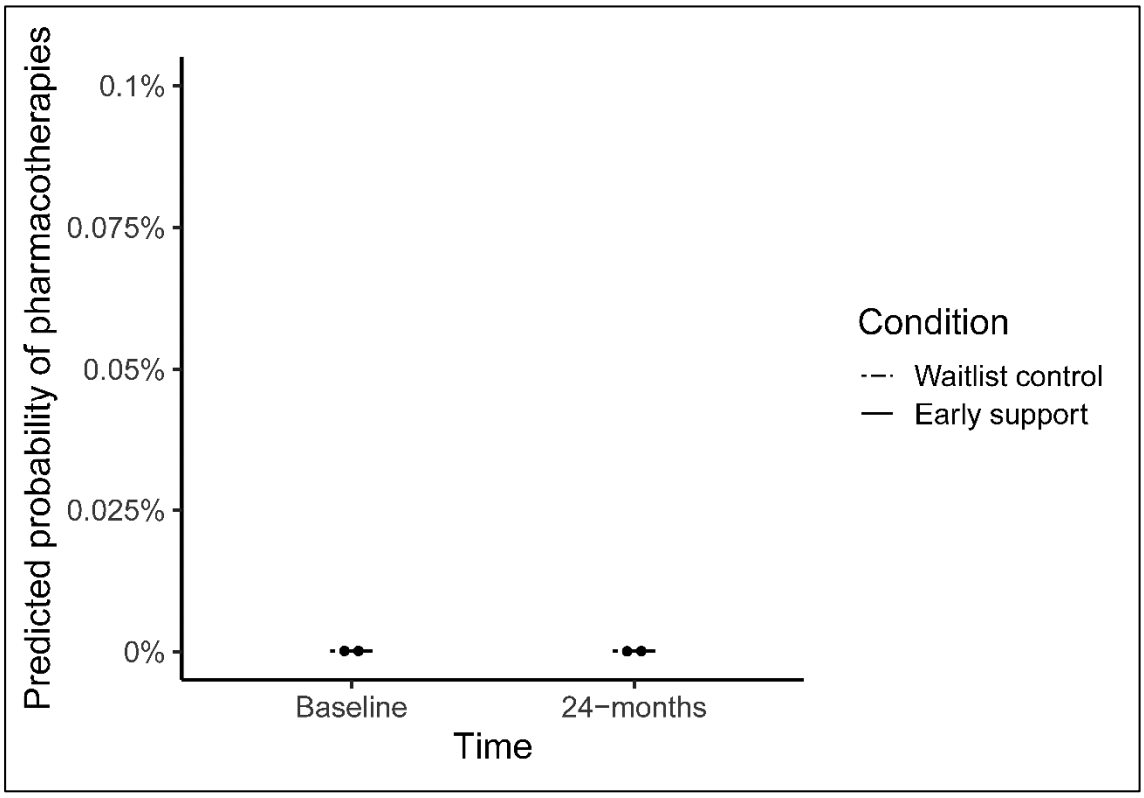
Effect	OR [95% CI]	lnOR	SE	p
(Intercept)	0.00 [0-0]	-13.81	0.42	<0.001
Post-implementation	0.47 [0.30-0.75]	-0.75	0.24	<0.01
Condition (Early-support)	1.04 [0.43-2.52]	0.04	0.45	0.94
Intervention	1.61 [0.92-2.80]	0.47	0.28	0.10
Intracluster correlation coefficient (ICC)	0.98			

Figure 4.1 Unadjusted smoothed rates of pharmacotherapies by service and trial arm



Rates are records of all pharmacotherapies for a patient per two-month reference period. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase.

Figure 4.2 Predicted probabilities of receiving pharmacotherapies in the early and waitlist control arms at baseline and during 24 months of implementation



4.4.2 Talking therapies

The model incorporating random intercepts of service and client was found to have the best fit based on BIC. Accordingly, it was chosen to investigate the effect of the support model on the odds of having a record of talking therapies for unhealthy alcohol use (Table 4.3). The grouping structure accounted for 54% of the variance in the odds of clients receiving talking therapies within two-month reference periods (Table 4.4). Unadjusted rates of talking therapies by service are shown in Figure 4.3. At baseline the odds of talking therapies being recorded were negligible in both arms (Table 4.4).

Over the study period, there were 945 clients with a record of talking therapies. The odds of a client having a record of receiving talking therapies within a two-month reference period doubled for the early-support arm (simple slope OR=2.08, 95% CI=1.74-2.49). The odds

again decreased for waitlist controls (OR=0.27, 95% CI=0.21-0.36, p<0.001). The change in the odds of having a record of talking therapies following implementation was 7.6 times greater in the early-support than waitlist controls (OR=7.60, 95% CI=5.54-10.42, p<0.001). This relatively large increase in odds of talking therapies was mainly due to the substantial decrease in recording talking therapies observed in the waitlist control services. Probabilities of having a recorded talking therapy, adjusted for the effects of the support model are shown in Figure 4.4.

Table 4.3 Models for predicting odds of talking therapies

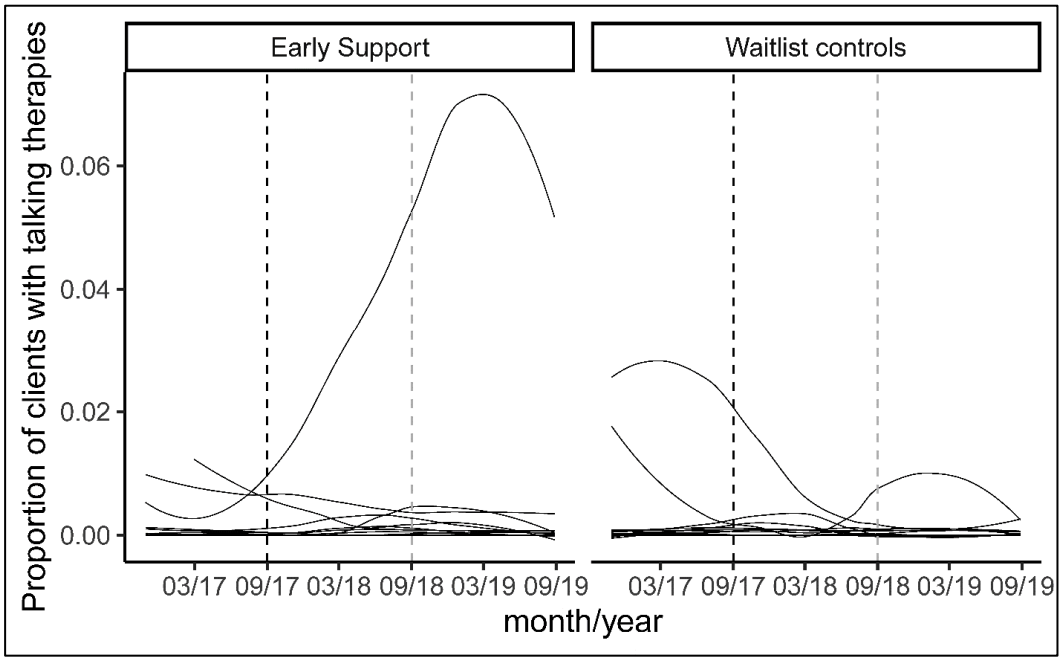
Model	BIC	Log Likelihood	Number of parameters
(A) Random intercept of service	12892.46	-6413.88	5
(B) Random slope of post-implementation by service and random intercept of service	12646.79	-6278.10	6
(C) Random intercept of service and client*	12411.04	-6166.70	6

*Indicates best fit model

Table 4.4 Fixed effects of the support model on the odds of receiving talking therapies

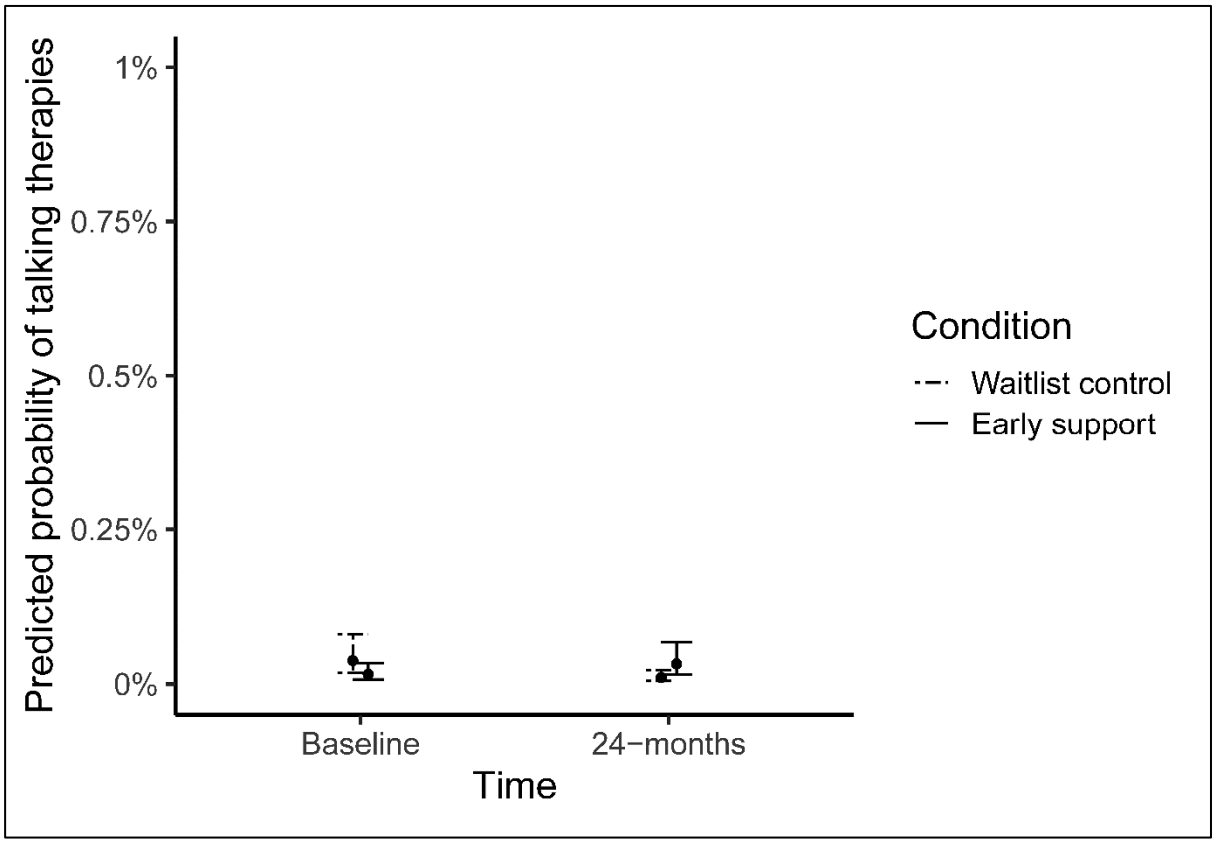
Effect	OR [95% CI]	lnOR	SE	p
(Intercept)	0.00 [0-0]	-7.88	0.38	<0.001
Post-implementation	0.27 [0.21-0.36]	-1.29	0.13	<0.001
Condition (Early-support)	0.41 [0.15-1.15]	-0.88	0.52	0.89
Intervention	7.60 [5.54-10.42]	2.03	0.16	<0.001
Intracluster correlation coefficient (ICC)	0.54			

Figure 4.3 Unadjusted smoothed rates of talking therapies by service and trial arm



Rates are records of all talking therapies for a patient per two-month reference period. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase.

Figure 4.4 Predicted probabilities of receiving talking therapies in the early and waitlist control arms at baseline and during 24 months of implementation



4.5 Discussion

4.5.1 Effects on pharmacotherapies

The evidence for the support model's effect on the rate of prescription of pharmacotherapies for relapse prevention was inconclusive. This was due to very low baseline rates of pharmacotherapy records and very high level of heterogeneity (ICC=0.98). There were very few records of prescriptions in this sample – only 253 clients of the 83,000 (0.3%) had a record of prescription at least once during the trial. Prevalence of alcohol dependence among Aboriginal and Torres Strait Islander peoples is estimated to be 2.2% (88). Therefore, the pharmacotherapy rates observed in this study, are likely to represent a very small fraction of clients who could benefit from pharmacotherapies in the study population.

Studies show that clinician barriers to prescribing pharmacotherapies in alcohol dependence include lack of knowledge and experience in prescribing these medications and belief that administering this form of treatment for dependence can only be done by addiction specialists (81, 89). Anecdotally there have been efforts over many years to increase training of Australian medical students in use of these medications, and there have been several articles providing guidance on use of these medicines for practising primary care practitioners (90, 91). According to the Australian alcohol treatment guidelines treatment of alcohol dependence for Aboriginal and Torres Strait Islander peoples should occur at the point of detection if possible, due to many barriers associated with seeking specialist treatment (e.g., stigma, access difficulties) (49). For this population the most common point of contact with health services are the ACCHS. However, the use of pharmacotherapies does not appear to be consistently recommended in guidelines specific to primary care. While the

RACGP (Royal Australian College of General Practitioners) SNAP guidelines[4] mention the option of pharmacotherapy prescription (50), neither the National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (56) nor the RACGP Guidelines for Preventative Activities in General Practice (92) mention the possibility of treatment of dependence in primary care. Instead, they recommend referral to a specialist service. Considering general practitioners' perception that alcohol pharmacotherapy prescription requires specialist care, inconsistent inclusion of pharmacotherapies in formal general practice guidelines is likely reinforcing that belief.

4.5.2 Effects on talking therapies

The support model improved the odds of clients in the early-support arm having a record of talking therapies after implementation when compared to waitlist controls (Table 4.4). This significant increase in the odds was due to two factors: (i) an increase in the odds of talking therapies within early-support arm after implementation, and (ii) the consistent post-implementation drop in the records of all talking therapies in the waitlist controls. This decrease in treatment rates was also observed in waitlist controls for pharmacotherapies. As discussed in Chapter 3, this could indicate the support model prevented a drop in talking therapies in the early-support arm. It is not clear why the frequency of providing treatment dropped off at control services, but local policy decisions, staffing, and other changes at the waitlist control services may have contributed to this effect.

In contrast to the results obtained for talking therapies as a combined variable, significant increases were not obtained in the brief intervention outcome on its own (recorded in the

[4] SNAP guidelines address lifestyle risk factors of smoking, nutrition, alcohol, physical activity.

practice software as ‘advice’; Chapter 3). However, it must also be noted that the best-fit model for talking therapies as indicated by Bayesian Information Criterion (BIC) differed from that for brief intervention (Chapter 3), in that it contained no random slope by service. As the model for talking therapies contained only random intercepts, it may have been more susceptible to effects of large outliers, resulting in greater effect estimations.

Regardless, low predicted probabilities for both early-support and wait-list control services (Figure 4.4) mean that any relative increases in providing clients with talking therapies are probably not clinically meaningful.

The rates of recorded provision of ‘talking therapies’ in this study were very low. More than 60% of the screened clients (n=28,270) in both arms of the study had AUDIT-C scores that indicated drinking above recommended levels. However only 945 (3.3% of screened clients) had a record of having received ‘talking therapy’ by the end of the maintenance period. This is of concern as this type of treatment (brief intervention) is currently the accepted first line of treatment for unhealthy alcohol use in primary care for people who drink at hazardous (risky) levels.

However, challenges in recording of this type of intervention may have contributed to the observed low rates. The aim of this trial was to test the effectiveness of the support model on treatment in real-world settings. Therefore, while recommendations for improving recording of various types of treatment were made during the onsite training, treatment delivery and recording was left to the services and clinicians to manage as part of their clinical practice. As this was a pragmatic implementation trial, there were also no efforts to control or measure the quality or duration of talking therapies delivered (e.g., through audits of a sub-sample of consultations). It is therefore possible that brief interventions

could be longer or shorter than accepted in standard definitions. As discussed in the introduction to this chapter, it is also possible that they were not correctly allocated to the appropriate clinical item based on duration of the session.

As well as using the two clinical 'items' (or variables) 'alcohol advice' and alcohol counselling, clinicians also likely recorded talking therapies in free-text notes fields, that were not part of the data provided by the services. Also, based on consultation with services, the data provided typically reflects only what is done in the primary care section of the ACCHS. Several services had separate counselling, drug and alcohol or mental health and wellbeing units, which used different software to record interventions. Nonetheless, the data reflects the challenge of improving systematic recording, and probably implementation of talking therapies, in busy primary care settings serving populations with complex needs.

Globally, similar implementation trials that successfully increased brief intervention had diverse methods of recording this outcome. They achieved diverse results that seem to correspond to the level of control exerted in recording the outcome or the approach to extracting it as a variable in routinely collected data (see Chapter 6, Discussion section 6.2.3).

4.6 Recommendations

There is a need to help clinicians to deliver brief interventions and prescribe pharmacotherapies for unhealthy alcohol use when clinically indicated. Appropriate modifications in practice software would be helpful to remind clinicians to consider offering and to record these options. For example, a simple prompt for appropriate clinical action (e.g., brief intervention, pharmacotherapies) could be programmed to appear in the practice software in response to elevated AUDIT-C screening scores. A tick box could be used to

indicate that brief intervention was recorded. A link could be provided to clinical or patient resources. Similar approaches have been adopted in large alcohol care implementation trials including PPRNet-TRIP (86, 93, 94).

At a national level, alcohol treatment could be 'incentivised' by including it as a funded item under the Australian Medicare Benefits Schedule (MBS). Such items were included on the MBS for smoking cessation in July 2021 for both face-to-face and telehealth services, albeit only temporarily (until 30 June 2022) (95).

It is evident that much more work needs to be done to improve uptake of prescription of pharmacotherapies for alcohol dependence. Improvement of uptake would require a multifaceted approach. This could include clinician training and provision of support through links to specialist services where general practitioners could seek advice on treatment of dependence. The consistent inclusion of pharmacotherapies in primary care guidelines as a treatment option, and advocacy to promote treatment of dependence in primary care would also be important in changing the professional culture around treatment of dependence.

4.7 Conclusion

While improvement in talking therapy rates was achieved with this model of service-wide support, these gains were not clinically significant. Observed low rates could in part be due to problems with recording these types of treatment in practice software. The support model did not appear to have any effect on increasing the provision on pharmacotherapies.

More effort at multiple organisational levels is needed to improve alcohol treatment rates in ACCHS, and most likely in other primary care settings. These findings are likely to be

relevant to other services for culturally distinct populations with complex health needs, and to family practice more broadly.

CHAPTER

5

EFFECTS OF THE SUPPORT MODEL ON AUDIT-C SCREENING PATTERNS

5.1 Introduction

The results presented in Chapter 3 showed a large increase in the odds of clients being screened with AUDIT-C in any two-month period in the early-support (treatment) arm compared to waitlist controls. However, these results do not provide any information about the frequency of screening that an individual client might be receiving. This is also true of screening implementation studies generally. Of the studies identified in the systematic review (Chapter 2), all were concerned with an overall increase in screening events or clients screened, rather than the screening patterns experienced by individual clients. If screening patterns of individual clients are not monitored, efforts concentrating on increasing universal screening rates within the primary care service could in theory lead to underscreening of clients who seldom visit the service, while overscreening of those who have the need to visit frequently.

This published chapter investigates whether the support model tested in this cluster randomized trial influenced the patterns of screening: whether there was a higher proportion of previously unscreened clients receiving an AUDIT-C screen and whether clients were being screened annually. In addition, the chapter investigates how many clients were frequently screened within any year during which they presented at the service, and if such clients were likely 'high risk' as defined in the National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander people (56).

The published paper describes the study design, methods, results analysis, and discussion. The details of the sample construction and extended regression results are included in the published additional materials (section 5.3).

5.2 Published article

This chapter was published as a peer reviewed, open access article in the journal Addiction Science & Clinical practice as:

Dzidowska M, Raubenheimer JE, Dobbins TA, Lee KSK, Hayman N, Vnuk J, et al. Effects of service-wide support on regularity of alcohol screening of clients in Australian Aboriginal and Torres Strait Islander Community Controlled Health Services: a cluster randomised trial. 17, 13 (2022).

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Addiction Science & Clinical Practice

RESEARCH Open Access

Effects of service-wide support on regularity of alcohol screening of clients in Australian Aboriginal and Torres Strait Islander Community Controlled Health Services: a cluster randomised trial

Monika Dzidowska[1,2*], Jacques E. Raubenheimer[3], Timothy A. Dobbins[4], K. S. Kylie Lee[1,2,5,6], Noel Hayman[7,8,9], Julia Vnuk[10,11], Paul Haber[1,2] and Katherine M. Conigrave[1,2]

Abstract

Background: We have previously shown that service-wide support can increase the odds of alcohol screening in any 2-month period in a cluster randomized trial of service-wide support to Aboriginal and Torres Strait Islander Community Controlled Health Services (ACCHS). Here we report an exploratory analysis on whether the resulting pattern of screening was appropriate. Aim: we assess whether that increase in screening was associated with: (i) increased first-time screening, (ii) increased annual screening, (iii) whether frequently screened clients fell into one of four risk categories as defined by national guidelines.

Methods: Setting and participants: 22 ACCHS; randomized to receive the support model in the treatment ('early-support') arm over 24-months or to the waitlist control arm. Intervention: eight-component support, including training, sharing of experience, audit-and-feedback and resource support. Analysis: records of clients with visits before and after start of implementation were included. Multilevel logistic modelling was used to compare (i) the odds of previously unscreened clients receiving an AUDIT-C screen, (ii) odds of clients being screened with AUDIT-C at least once annually. We describe the characteristics of a sub-cohort of clients who received four or more screens annually, including if they were in a high-risk category.

Results: Of the original trial sample, 43,054 met inclusion criteria, accounting for 81.7% of the screening events in the overall trial. The support did not significantly increase the odds of first-time screening (OR = 1.33, 95% CI 0.81–2.18, p = 0.25) or of annual screening (OR = 0.99, 95% CI 0.42–2.37, p = 0.98). Screening more than once annually occurred in 6240 clients. Of the 841 clients with four or more screens annually, over 50% did not fall into a high-risk category. Females were overrepresented. More males than females fell into high-risk categories.

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Full list of author information is available at the end of the article

Conclusion: The significant increase in odds of screening observed in the main trial did not translate to significant improvement in first-time or annual screening following implementation of support. This appeared to be due to some clients being screened more frequently than annually, while more than half remained unscreened. Further strategies to improve alcohol screening should focus on appropriate screening regularity as well as overall rates, to ensure clinically useful information about alcohol consumption.

Trial Registration ACTRN12618001892202, retrospectively registered 16 November 2018 https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12618001892202.

Keywords: Alcohol, Training and support, Alcohol screening, Screening patterns, Indigenous, Aboriginal, Torres Strait Islander, Continuous quality improvement, AUDIT-C, Primary care

Background

In Australia, Aboriginal Community Controlled Health Services (ACCHS) provide culturally appropriate, holistic health care and make key contributions to improving health outcomes for Australia's Aboriginal and Torres Strait Islander peoples (also respectfully referred to as First Nations Australians) [1]. These services play an important role in addressing health inequalities experienced by their clients. The inequalities include significant harms from alcohol [2, 3]. Alcohol contributes to 8.1% of the health gap between First Nations Australians and other Australians [4]. This is despite the fact that more Aboriginal and Torres Strait Islander peoples than non-Indigenous are current non-drinkers [5], and prevalence of dependence (2.2%) is similar to the general population [6]. However, when First Nations Australians people do drink, they consume a median of 78 g of alcohol per occasion, well over the Australian recommended limit to reduce risk of short-term harms, like injury, from alcohol (40 g per occasion) [7]. These patterns of drinking and harms have roots in ongoing trauma from colonisation [8]. Other Indigenous peoples who have been colonised have suffered increases in harms from alcohol, however, there are very few studies addressing alcohol screening in Indigenous populations [9].

Australian guidelines [10] recommend that Aboriginal and Torres Strait Islander peoples are screened with a validated tool, such as the Alcohol Use Disorders Identification Test—Consumption (AUDIT-C) [11], 'as part of an annual health assessment, or opportunistically'. As part of this same guideline, more frequent screening is recommended for high-risk groups including adolescents and young adults, those with high-risk and harmful drinking levels, those with conditions exacerbated by alcohol, and women who are pregnant or planning pregnancy [10].

Implementation studies in general primary care aim to increase the absolute number of alcohol screening events or patients screened. A recent systematic review showed that 34 of 44 studies aiming to improve alcohol screening resulted in significant increases in rates [9]. However, none investigated whether such interventions resulted in appropriate screening frequency or regularity. These studies therefore do not provide information on whether screening was clinically appropriate. For example, recommendations for universal opportunistic screening could in theory lead to unnecessarily frequent screening of clients who attend clinics often. Conversely, people with health conditions exacerbated by alcohol or people who are dependent on alcohol may need more frequent than annual screening.

In this paper we report on a secondary analysis of a cluster randomized trial of a multi-component, service-wide support for ACCHS to increase universal alcohol screening and appropriate treatment. We have previously shown that the support model could increase the odds of a person being screened with AUDIT-C when attending the participating ACCHS in any 2-month period over 24 months of implementation. The increase in odds from baseline to 24 months post-implementation was nearly eight times greater in the treatment arm (OR = 7.95, 95% CI 4.04–15.63, $p < 0.001$) than in waitlist controls [12]. However, that study did not investigate whether this increase resulted in clinically appropriate screening frequency or regularity.

Here we explore whether this increase resulted in patterns of screening that are in keeping with recommended guidelines. We thus examined data to answer the following questions:

1. Were previously unscreened clients more likely to be screened with AUDIT-C after support commenced?
2. Were clients in the treatment arm more likely to undergo regular annual screening?
3. What proportion of clients was frequently screened within any 12-month period and did these clients fall into high-risk categories?

Methods

Ethical approval and consent

This study received approval from eight ethics committees in Australian states and territories where the

participating services were located: The Aboriginal Health and Medical Research Council of NSW Ethics Committee (1217/16), Central Australian Human Research Ethics Committee (CA-17-2842), Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (2017-2737), Central Queensland Hospital and Health Service Human Research Ethics Committee (17/QCQ/9), Far North Queensland Human Research Ethics Committee (17/QCH/45-1143), The Aboriginal Health Research Ethics Committee, South Australia (04-16-694), St Vincent's Hospital Melbourne Human Research Ethics Committee (LRR 036/17) and Western Australian Aboriginal Health Ethics Committee (Project 779).

Study design and recruitment

The full study protocol (Trial Registration: ACTRN12618001892202, retrospectively registered) has been published elsewhere [13]. Briefly, the study is a cluster randomised trial of 22 ACCHS located across Australia equally allocated to the treatment and waitlist control arms.

Implementation strategy

The multifaceted model of support for implementing screening and a full range of clinical responses for unhealthy alcohol use consisted of eight core components (Table 1). Screening was addressed in multiple components. Training and support emphasised annual screening of all clients aged 16 or older and discussed opportunities for screening (e.g., antenatal checks or when seeing a nurse or Aboriginal health professional), and when not to screen (e.g., in crisis situations).

The treatment arm received support first (the 'early-support' arm). The total duration of implementation in the early-support arm was 24 months, consisting of 12 months of active support (Table 1, components 1–8), followed by maintenance support of 12 months (Table 1, components 4–8). During that time the waitlist control services operated as normal and interaction with the researchers occurred only for collection of routinely collected data. At the end of that period, which marked the end of the randomised trial, the waitlist control arm began receiving the full support model [14]. Data from the waitlist control implementation phase is not reported here.

Collaboration with Aboriginal community Controlled Health Service

ACCHS are primary health care services managed and operated by local Aboriginal and/or Torres Strait Islander communities. The study was developed and conducted in partnership with ACCHS to build on strengths and uniqueness of each service and to enhance how alcohol care is delivered locally.

Table 1 Description of the support model, with detail on elements relating to screening[a]

Component	Description
1	A memorandum of understanding outlining the aims of and design of the study, responsibilities of the research team and the service
2	Two-day workshop with two nominated service champions to introduce aims and methods of the study, the support model, and to build a champions' network. Training included screening, brief intervention, and treatment of unhealthy alcohol use
3	On-site training: the core program was half-day, face-to-face workshop. Training included: harms related to alcohol; current evidence for screening; culturally secure and accurate administration and interpretation of AUDIT-C; use of annual AUDIT-C screening; responding to a positive AUDIT-C screen; and using service-wide screening data to monitor improvements in screening Implementation approaches incorporated cultural protocols of Aboriginal and Torres Strait peoples such as gender appropriateness, kinship systems and cultural obligations Face-to-face workshops were delivered by an addiction medicine specialist and an Aboriginal health professional (e.g., drug and alcohol worker or other)
4	Data feedback report, based on the bi-monthly data provided by services Graphic representation of proportion of clients screened; proportion drinking at risky levels as measured by AUDIT-C; as well as overall rate of screening over 2-month periods and the last 12-months; and recorded treatment provided Presented as a pdf file with graphics and emailed to service champions and key contacts
5	Bi-monthly teleconference for service champions to exchange improvement ideas and experiences
6	Support to modify practice software to facilitate screening such as inclusion of AUDIT-C in the Adult Health Check, and other electronic forms used for periodic and opportunistic health checks, e.g., over 50 s, pregnancy, pre-consult examination
7	A website with a repository of electronic tools and resources, including screening resources and standard drinks charts, and a private chat platform for champions
8	Financial support for purchase of agreed resources e.g., standard drink cups, clinical handbooks, prevention materials

[a] This table emphasises the screening-specific content of the support model. Fuller description, including elements supporting alcohol treatment, has been published elsewhere [12, 15]

Data collection

ACCHS provided routinely collected clinical data from their electronic medical record system, Communicare, without personal identifiers, every 2 months. Records of patients who were 15 years or older were eligible for extraction. A client observation was recorded if the client had attended in the 2 months preceding extraction. Each observation included the date of the last visit in the preceding 2 months, basic demographic and health information including AUDIT-C score and date of AUDIT-C screen; systolic blood pressure (BP); haemoglobin A1c (HbA1c); and the liver enzyme, gamma-glutamyl transferase (GGT). Baseline data for 18 months prior to implementation in the early-support arm (28 February 2016–30 August 2017) was obtained for all 22 services. Records for individual clients were matched using patient IDs (with no personal identifiers attached) [13].

Analysis

For this secondary analysis, records of patients were eligible if they had at least one visit before and one visit on or after the date when the support model started implementation (here described as 'current clients'). This was to capture individuals who attended the service with some regularity during the trial.

Question 1: Screening of previously unscreened clients after implementation

To address question 1, we tested whether the support model improved the odds of previously unscreened clients being screened for the first time (in the early support arm when compared to waitlist control), in the 24 months after start of implementation of the support model. For this sub-analysis, only records of patients who had not been screened in the baseline period were included (Fig. 1). The outcome measure was whether the patient had at least one recorded AUDIT-C screen on or after the start date of implementation.

Question 2: Systematic annual screening of clients after implementation

To address question 2, we tested if the support model improved the odds of receiving annual AUDIT-C screening post-implementation (for clients in the early versus waitlist control arms). The 18 months of available baseline data did not enable us to establish if clients were screened annually pre-implementation. However, as data from this trial showed very low rates of baseline screening [12, 15], and as AUDIT-C screening was only made a national key performance indicator for these services in mid-2017 [16], we assumed that in most services no annual AUDIT-C screening had occurred prior to implementation. Clients were eligible for inclusion in this analysis if their earliest and latest visits were at least 12 months apart. For each eligible client, consecutive 12-month intervals were constructed from the date of their earliest visit during the study. Each period was defined as occurring pre- or post-implementation based on the latest date of client visit within that period (Fig. 1 and Additional file 1: Figure S1). A 12-month period for a client with at least one AUDIT-C screen was defined as a 'screened' period. All other 12-month periods with at least one visit were considered 'non-screened' periods. Clients were considered 'annually screened' if all their annual periods that occurred post-implementation were screened periods.

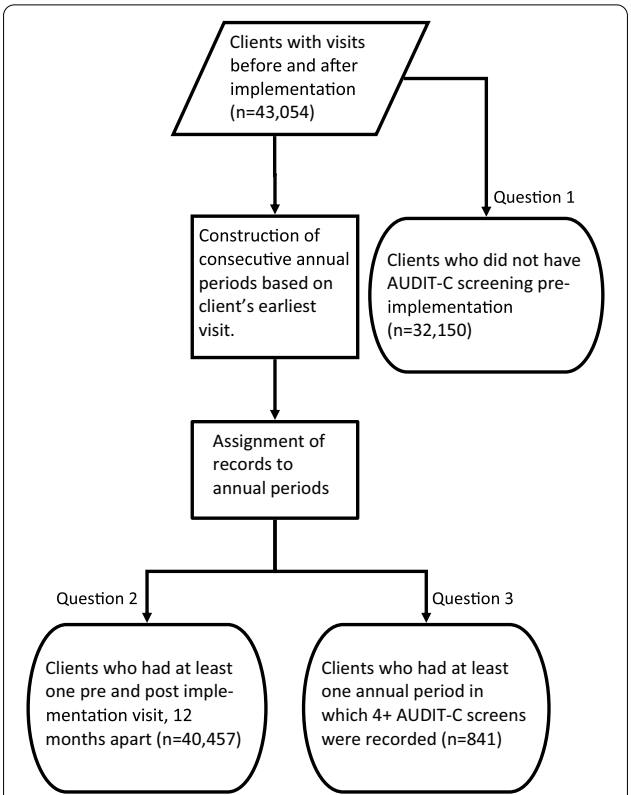

Fig. 1 Construction of analytical samples

Question 3: Frequent screening among low and high-risk clients

To address question 3, we investigated characteristics of clients who were frequently screened. We defined a client to be frequently screened if they had four or more AUDIT-C screens recorded in any 12-month period (Fig. 1 and Additional file 1: Figure S2). Clients were included if there was at least one annual period with visits, regardless of their timing relative to implementation. Clients' annual periods were classified as pre-, post-, or

spanning implementation based on their period start and end dates.

We investigated what proportion of these clients fell into a high-risk health category based on the clients' earliest record of AUDIT-C, systolic blood pressure (BP), haemoglobin A1c (HbA1c) and gamma-glutamyltransferase (GGT). Clients were considered 'high-risk' if at least one of these results was above recommended levels:

- AUDIT-C: for Aboriginal and Torres Strait Islander populations a score of 4 or higher for males and 3 or higher for females is used to suggest risky drinking [17].
- BP: systolic BP of 140 mmHg or higher is indicative of hypertension [18].
- HbA1c: levels of 6.5% or above are indicative of diabetes [19].
- GGT: 51 U/L or above for males, and 36 U/L or above for females, is considered an abnormal liver enzyme result [20].

Analyses were conducted on an intention-to-treat basis. For questions 1 and 2 outcomes for clients within the same service were likely to be correlated. Therefore, the effect of clustering was accounted for in the analysis. We conducted multilevel logistic regression using the 'lme4' package [21] in the R statistical software environment, version 4.0.2 [22].

Our model incorporated the fixed effect of 'condition' [whether a service was assigned to the early-support (condition = 1), or waitlist control arm (condition = 0)], the random intercept of service, and controlled for age and gender.

We calculated confidence intervals for the fixed effects using Wald estimation. We estimated the effect of implementation on the early-support arm (simple slope) using the delta method ('car' package) [23, 24]. Adjusted Intraclass Correlation Coefficients (ICC) were calculated using the 'performance' package [25, 26] to describe the proportion of variability explained by differences between clusters.

Preliminary analysis showed that only 10 of the 22 services were represented in the sample of clients who received four or more AUDIT-C screens in an annual period. Statistical significance testing was therefore not conducted. Accordingly, we used descriptive statistics to explore question 3.

Missing data

Clients were excluded from analysis if their gender or age were not recorded. Since the study used routinely collected practice data, it was not possible to determine whether any AUDIT-C screening data were missing.

Results

Description of sample

Twenty-two ACCHS were recruited to the study and randomised to either early or waitlist control arms. From January 2019 onwards, one service in the waitlist control arm was unable to provide data due to a change in practice software. For the present analysis, the trial sample was comprised of 89,788 individual clients with observations between 28 February 2016 and 30 August 2019. Of these, there were 43,054 current clients (attended at least once before and once after implementation). The 46,734 clients who were excluded from these analyses accounted for 18.3% (11,163) of all AUDIT-C screening instances recorded between 28 February 2016 and 30 August 2019 (61,075). The mean age and gender distribution in study arms remained the same as in the trial (see Table 2 and Additional file 1: Table S1), indicating that sample construction processes did not disrupt the gender balance in the trial arms established by randomisation.

Were more clients screened for the first time after implementation in the early-support arm?

Of the current clients, 32,150 had no AUDIT-C recorded pre-implementation. The baseline characteristics of this sub-sample are shown in Table 2. Two clients had missing gender and were excluded from analysis.

During the 24 months of support, 20,141 clients were not screened at all. Two in five (n = 8761 40.1%) individuals in early-support arm were screened for the first time as were 3248 (31.5%) in waitlist control arm. Controlling for age and gender did not have any significant impact on the fixed effect of condition, so the results of

Table 2 Unscreened sample at baseline[a]: characteristics by trial arm

Characteristic	Early support	Waitlist controls
Services		
n	11	11
Mean clients per service (SD)	1986 (1109)	936 (574)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
n	21,850	10,300
Mean age of clients in years (SD)	36.8 (15.9)	37.5 (16.2)
Number of female clients (%)	12,412 (56.8)	5859 (56.9)
Mean observations[b] per client (SD)	3.9 (2.6)	3.9 (2.6)

[a] Baseline period: from 28.02.2016 to 30.08.2017 inclusive

[b] An observation appeared in the dataset for a client if they attended their service for a consultation in the preceding 2-month reference period

the simpler model are presented. The odds of a client being screened for the first time in the waitlist control arm were 0.52 (95% CI 0.37–0.74, p < 0.001). Clients in the early-support had 33% greater odds than the waitlist controls of receiving a screen for the first time but this result was not significant (OR = 1.33, 95% CI 0.81–2.18, p = 0.25). There was modest variability in the effect, with service difference accounting for 10% of the variability in the odds of being screened for the first time (Additional file 1: Table S2).

Were more clients screened annually after implementation?

Of the current clients, 40,457 had at least one visit to their service in a post-implementation annual period. One client had missing gender and was excluded from the analysis. The baseline characteristics of this sample are shown in Table 3. Over the 24 months of support, 3091 (11.4%) in early-support arm and 1371 (9.9%) in waitlist controls were screened annually. Although the effects of age and gender were significant, they did not alter the effect of condition. Therefore, results from the simpler model are presented. The odds of annual screening for the waitlist-control arm were 0.08 (95% CI 0.04–0.15, p < 0.001). Clients in the early-support arm had the same odds as the waitlist controls of being annually screened (OR = 0.99, 95% CI 0.42–2.37, p = 0.98) over the support implementation period. Differences between services accounted for 24% of the variance in the odds of annual screening (Additional file 1: Table S3).

Table 3 Annually screened sample at baseline [a]: characteristics by trial arm

Characteristic	Early support	Waitlist control
Services		
n	11	11
Mean clients per service (SD)	2420 (1699)	1259 (521)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
n	26,614	13,843
Mean age of clients in years (SD)	37.2 (15.8)	37.6 (16.2)
Number of female clients (%)	15,261 (57.3)	7976 (57.6)
Mean observations[b] per client (SD)	4.6 (2.9)	4.7 (3.1)
Clients screened with AUDIT-C (%)	6382 (24)	4009 (29)
Mean AUDIT-C score[c] (SD)	3.9 (3.8)	3.3 (3.6)
Clients with an AUDIT-C score > 0[c] (%)	3665 (57.4)	2482 (61.9)

[a] Baseline period: from 28.02.2016 to 30.08.2017 inclusive

[b] An observation appeared in the dataset for a client if they attended their service for a consultation in the preceding 2-month reference period at least once

[c] The denominator is the number of clients who had at least one recorded AUDIT-C score

What proportion of clients were frequently screened in any 12-month period?

Of the 43,054 clients attending the services at least once before and once after the start of implementation, there were 6240 clients with two or more AUDIT-C screens per year (a total of 20,969 AUDIT-C records in 8173 annual periods). Of these, there were 841 clients (2.0% of the 43,054 clients) who had 1050 frequently screened annual periods (4 + screens per period) and these came from 10 of the 22 participating services. There were 5096 AUDIT-C screens within these periods, accounting for 10.2% of all AUDIT-C screens recorded for the 43,054 clients. The early-support arm appeared to have a lower proportion of frequently screened clients than waitlist control (Fig. 2).

Were frequently screened clients high-risk as indicated by AUDIT-C or biomarkers?

Among the 841 frequently screened clients, 181 did not have an HbA1c record, 81 did not have a GGT record, and one did not have a BP record. All clients had at least one of these three biomarkers recorded at least once. More than half (51.6%) had no record of an elevated biomarker or risky AUDIT-C levels, 25.3% had risky drinking, 32.9% had at least one elevated biomarker and 9.9% had both risky drinking and an elevated biomarker (Table 4).

There were nearly three times more females than males among the frequently screened group, and 2–3 times more females than males in this group had with a biomarker recorded. Males were older than females (median age: 47 and 32 years respectively). A greater percentage of males had one or more biomarkers above normal levels than females (35%, 22% respectively) and AUDIT-C above the cut-off (49%, 28% respectively) [17–20]. Males also had a higher proportion of individuals with elevated BP or HbA1c than females. However, both sexes had similar proportions of clients with elevated GGT (Table 5).

Discussion

Previous studies have shown that service-level implementation strategies can improve screening rates in primary care [9]. However, to our knowledge this is the first controlled trial to report on the effect of a service-level alcohol screening implementation program on screening regularity, in addition to screening rate. We previously showed that the odds of a patient being screened in any 2-month period significantly increased during the 24 months of implementation of support in this cluster

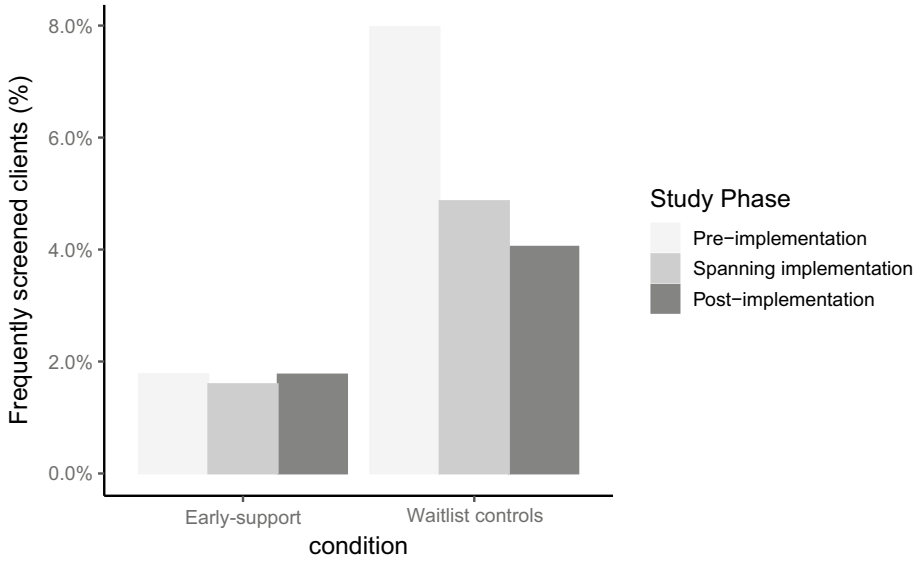

Fig. 2 Proportion of patients with frequently screened annual periods in each study phase ($n_{services} = 10$)[a]. [a]Figure shows data from 10 services where frequent screening occurred (at least one client had 4 + screens annually). Frequently screened annual periods: Pre-implementation = occurring before implementation date (31 August 2020); Spanning implementation = periods that include the implementation date; Post-implementation = entire period occurred after implementation date

Table 4 Frequently screened clients with at least one elevated biomarker by drinking risk (n = 841)

	Non-risk AUDIT-C drinking level (%)	Risky[b] AUDIT-C drinking level (%)	Total (%)
No record of an elevated biomarker[a] (%)	51.6	15.5	67.1
Record of 1 + elevated biomarker (%)	23.1	9.9	32.9
Total	74.7	25.3	100.0

[a] Here a biomarker refers to either GGT, BP or HbA1c above the reference range

[b] Risky AUDIT-C drinking level for Aboriginal and Torres Strait Islander populations: AUDIT-C 4 + in males and 3 + in females

Table 5 Characteristics of frequently screened[a] clients: gender by elevated AUDIT-C score or biomarkers (n = 841)

	Number of clients	
	Female	Male
n	625	216
Median age (IQR)	32 (28)	47 (22)
With AUDIT-C elevated* (%)	172 (28)	105 (49)
With 1 + elevated biomarker	137 (22)	76 (35)
With systolic BP record	624	216
BP elevated (%)	71 (11)	48 (22)
With HbA1c record	498	162
HbA1c elevated (%)	147 (30)	73 (45)
With GGT record	573	187
GGT elevated (%)	224 (39)	80 (43)

[a] frequently screened = clients with 4 + screens per annual period. Elevated indicates a result above a range that is considered normal: BP (systolic blood pressure) 140 mmHg and above; HbA1c (Haemoglobin A1c) 6.5% and above; GGT (Gamma-Glutamyl Transferase) male: 51 U/L and above, female: 36 U/L and above; AUDIT-C (Alcohol Use Disorders Identification Test—Consumption) for Aboriginal and Torres Strait Islander populations 4 and above in males and 3 and above in females

randomised trial [12]. However, in this report we show that this increase in screening rate was not reflected in an increase in odds of previously unscreened clients in the early-support arm being screened for the first time or of clients receiving regular annual screening when compared to controls. We have also found, in some instances, clients may have received unnecessarily frequent screening. For example, among the 2% of clients who were screened frequently (4 or more times annually), we found that there more women than men, and these women were younger than the frequently screened men. These results together show that service-level strategies successful in increasing overall alcohol screening rates may not lead to screening patterns that are in line with recommendations.

First-time screening and annual screening

Our sample of 43,054 current clients (i.e., those who attended their services both before and after the

implementation of support) accounted for most of the instances of AUDIT-C screening in the broader trial (81.7% or 49,912 instances). However, while over 24 months of implementation there was some increase in the odds of any one client being screened for the first time, this was not significant. There was also no effect on the odds of receiving regular annual screening. These results are explained by the distribution of screening records among the clients. Nearly half of these regular clients (20,141) had no AUDIT-C record at all. In contrast 14.5% (6240) had two or more screens in at least one annual period (accounting for 42% of the screens among the 43,054 clients). Mean AUDIT-C scores in screened individuals at baseline in both study arms of the overall trial (Additional file 1: Table S1) suggest that screening was not specifically targeting people known to drink heavily (early-support = 3.6, waitlist controls 3.3). This is in keeping with recommendations for universal screening. Repeated screening therefore was likely opportunistic—when the clients presented at the service for any reason or as part of scheduled health checks [27].

A range of factors may have contributed to the fact that the efforts of the services did not result in increased first-time or annual screening. Strategies and processes adopted by the services to increase screening differed. Some services reported trying to implement alcohol screening before a medical consultation for all clients, for example by an Aboriginal or Torres Strait Islander health worker or nurse. Screening approaches could also differ among individual clinicians. However, whether a client presents and the nature of their presentation influences whether the client is screened or not. For example, if a client presents in a crisis e.g., with severe asthma or bereavement, taking the opportunity to screen for usual alcohol use may be inappropriate. Also, if a client is known to have current severe alcohol dependence, then screening may be deemed unnecessary.

At a systems level, time pressures and high staff turnover prevalent in this health sector [28] may have contributed to the inconsistent alcohol annual and first-time screening observed in this study. While training resources were available on the website (component 7), the support did not itself include periodic retraining or training with new staff members.

Cultural barriers to screening may also play a role, particularly as alcohol can be a sensitive topic [29]. For example, Aboriginal and Torres Strait Islander peoples may be more comfortable to discuss private or sensitive issues with people of the same gender [30]. So, a male patient may be less comfortable talking with a female clinician. Further, cultural compatibility between clinician and client can be important when making clinical assessments relating to mental health of Aboriginal Australians [30]. So, some clients may be less willing to accept questions about alcohol from clinicians who are not Aboriginal or Torres Strait Islander, particularly if they do not know them well. On the other hand, community controlled services operate in closely knit communities so there may be instances in which family relationships or cultural restrictions impact on Aboriginal and Torres Strait Islander health workers undertaking screening with some clients, contacts or relatives [31] for drinking.

Was frequent screening appropriate?

National guidelines for preventative care for Aboriginal and Torres Strait Islander peoples recommend more frequent alcohol screening of high-risk groups [10]. However, there is no agreed definition of the appropriate frequency of screening. Aboriginal and Torres Strait Islander peoples experience higher rates of chronic diseases than the general Australian population [32]. Monitoring of alcohol consumption may be needed for clients with health conditions that can be exacerbated by alcohol, such as viral hepatitis. These conditions may also require more frequent visits, which present an opportunity for more frequent use of an alcohol screening tool. The 841 clients (2% of current clients) who were screened four or more times in at least one annual period accounted for nearly 11% of screens recorded for current clients. However, in most cases our data did not reveal why those clients were more frequently screened—less than half had elevated biomarkers or AUDIT-C levels.

Females were overrepresented in the frequently screened sample, even though a smaller percentage of females had elevated biomarkers and elevated AUDIT-C than males in this group. They also had a much lower median age. This could suggest that frequent screening was occurring in healthy females, possibly during regular antenatal or reproductive health consultations (e.g., for contraception). Other reasons for frequent health service contact in healthy women could be visiting with dependents, or a greater willingness to seek preventive care or routine health checks than males. Conversely, the higher proportions of individuals with elevated biomarkers in the smaller sample of frequently-screened males might reflect this group seeking healthcare for treatment or monitoring of health conditions more often than attending for a preventive health check.

Recommendations for policy, practice, and research

Annual screening allows the clinician to detect unhealthy drinking earlier and offer treatment or support, including brief intervention [10, 33]. Individuals' drinking patterns can vary over time [34, 35], including over relatively short periods [36]. Further, intermittent drinking patterns can be common among Aboriginal and Torres Strait Islander

peoples [7], with drinking triggered by events such as 'Sorry Business' (grieving after a bereavement). This means that annual screening rather than one-off is a better way to gain a picture of the individual's drinking.

In Australia, primary care services for Aboriginal and Torres Strait Islander peoples report on rates of risky drinking based on AUDIT-C scores as part of their national key performance indicators [17]. AUDIT-C is particularly suitable in this setting as it is brief and has been validated in primary care [11]. It has also been shown to be acceptable to Aboriginal and Torres Strait Islander peoples, though its delivery may need to be adapted for local culture and context [37]. However, regular screening with AUDIT-C or any other validated instrument is not otherwise mandated or widely promoted. For example, screening with a validated instrument such as AUDIT-C is not included in the Royal Australian College of General Practitioners' annual health check templates. Similarly, such screening is not required for the Medical Benefits Scheme to reimburse services for the conduct of the annual health assessment for Aboriginal and Torres Strait Islander peoples [27]. The health assessment uptake rates vary from about 20% per year in 15–24 year olds to over 40% in people aged 65 and older [38]. These rates are greater than the AUDIT-C screening rates shown in this study (12.7% based on 18-months' baseline, Additional file 1: Table S1). So, incorporating AUDIT-C in this assessment could improve detection and increase annual screening rates.

Refining strategies to reach unscreened adults should be considered. In addition to screening when clients present to the service, opportunities for outreach alcohol screening could be employed. For example, some ACCHS already engage their clients through activities outside of the clinic setting, which takes various forms, including camps or community gatherings [39]. Indeed, some participating services mentioned conducting screening in the community and updating records in practice software. Strategies to support these kinds of activities should be included in future designs.

Results of this analysis show that successful strategies designed to increase universal alcohol screening may lead to repeated screening of a particular group of clients rather than necessarily increasing screening in an unscreened or underscreened group. As alcohol use is a sensitive topic [29], broaching the subject too frequently could lead to the client becoming irritated or avoiding contact with the service. So, it is important that services and research studies clarify an optimal frequency of screening or monitoring for different clinical situations. Initiatives designed to improve screening and treatment for unhealthy alcohol use should ensure that training and monitoring of outcomes include consideration of the appropriate frequency and regularity of screening.

Identifying and addressing potential clinician and client barriers to screening, including those determined by cultural norms should be incorporated into improvement programs. Programs that incorporate audit-and-feedback cycles such as those based on continuous quality improvement (CQI), would be suited to this due to their iterative nature. After the initial cycle that aims to increase implementation of screening, these programs could then focus on screening regularity. Practice software can be an important tool in these efforts. Aside from its role in providing data for monitoring service improvement, services could choose to implement further modifications to help facilitate more appropriate screening frequency such as automated screening reminders based on clients' prior records [40–42]. However, services participating in this study have pointed out that too many reminders can interfere with clinical practice.

Limitations

This study is a post-hoc analysis of data from a larger trial [13], to explore potential unwanted effects of the intervention, and to scrutinize if the benefits were as significant as they appeared [13]. More than half of that clients from that broader study population were excluded from the analysis because they had not attended the service during the baseline period. A longer baseline could have allowed more clients to be included in analyses investigating first-time screening. The same limited availability of pre-implementation data prevented us from determining the levels of annual screening before implementation and therefore we had to limit this analysis to the comparison of study arms post-implementation. However, our assumption of the absence of regular annual AUDIT-C screening is supported by generally low screening levels at baseline.

While the training provided to services emphasised annual screening of clients as best-practice, several aspects of the support model may have resulted in efforts that prioritised increasing number of screening events rather than increasing annual or first-time screening. These included suggestions for opportunistic screening, including during pre-consultation examinations or antenatal checks. Further, regular feedback reports presented a graph of change in bi-monthly screening rates (as well as summary of screening in the last 12-months). They did not include details on first-time screening events, or over-frequent screening of clients. The duration of the trial would not have allowed for reporting on effect of the intervention on numbers of clients screened annually. Barriers and facilitators of appropriate screening

regularity were not specifically discussed during champion teleconferences.

Conclusions

Despite previously demonstrating a marked increase in the odds of screening occurring in any 2-month period with service-wide support, we were unable to show significant increases in clients screened for the first time or in annual screening of clients over 24 months of implementation of support. This appeared to be due to an uneven distribution of screening, with a small percentage of clients being screened more frequently than annually while nearly half clients were not screened at all. Females tended to be overrepresented among the more frequently screened clients. Further strategies to improve alcohol screening should focus on appropriate regularity as well as rate of screening in order to garner clinically useful information about alcohol consumption.

Abbreviations

ACCHS: Aboriginal Community Controlled Health Services (ACCHS); AUDIT-C: Alcohol Use Disorders Identification Test—consumption; BP: Systolic blood pressure; CI: Confidence interval; GGT: Gamma-glutamyltransferase; HbA1C: Haemoglobin A1c; ICC: Adjusted intraclass correlation coefficient.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13722-022-00294-6.

Additional file 1: Figure S1. Construction of client's annual periods for annual screening analysis (question 2). **Figure S2.** Construction of client's annual periods for a client screened four or more times annually (question 3). **Figure S3.** Unadjusted first-time screening rates for the 22 services over 24 months of implementation, by study arm and by service. **Figure S4.** Unadjusted annual screening rates for the 22 services over 24 months of implementation, by study arm and by service. **Table S1.** Full trial sample at baseline: characteristics by trial arm. **Table S2.** Fixed effects of the support model on the odds of screening in previously unscreened clients **A** without control variables; **B** with control variables of age and gender. **Table S3.** Fixed effects of the support model on the odds of receiving annual screening **A** without control variables; **B** with control variables of age and gender.

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Authors' contributions

MD: conceived and developed the study protocol, undertook the data preparation and statistical analysis, drafted paper, synthesised co-authors' comments. JR: supervised the study design and statistical analysis, reviewed analysis results and draft of paper. TD: chief investigator and lead statistician on the grant supporting this work; contributed to the development of analysis, reviewed drafts of paper. KL: chief investigator on the grant supporting this work; contributed to development of the manuscript, reviewed drafts of paper. NH: chief investigator on the grant supporting this work; informing team on practical aspects of primary care delivery in Aboriginal and Torres Strait Islander settings; reviewed draft of paper. JV: informing team on practical aspects of primary care delivery in Aboriginal and Torres Strait Islander settings; reviewed draft of paper. PH: chief investigator on the grant supporting this work; informing team on practical aspects of primary care delivery; reviewed draft of paper. KC: chief investigator on the grant supporting this work; contributed to protocol and manuscript development, oversaw the scientific integrity of the study, reviewed drafts of paper. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to ethics restrictions. Data can only be made available upon additional approvals from the ethics committees and consent from the 22 participating services.

Declarations

Ethics approval and consent to participate

This study has received ethics approvals from eight Australian human research ethics committees, which cover all 22 study sites. Consent for service participation was sought from each Aboriginal Community Controlled Health Service at institutional level, from authorised representatives and the board.

Consent for publication

Not applicable.

Competing interests

The author declares that he/she has no competing interests.

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Publisher's Note

5.3 Additional materials

The content in this section was submitted for publication as supplementary materials to the preceding article and includes a detailed description of sample construction.

EFFECTS OF SERVICE-WIDE SUPPORT ON REGULAR ALCOHOL SCREENING OF CLIENTS IN AUSTRALIAN ABORIGINAL AND TORRES STRAIT ISLANDER COMMUNITY CONTROLLED HEALTH SERVICES – A CLUSTER RANDOMISED TRIAL

ADDITIONAL MATERIAL

Monika Dzidowska[1,2], Jacques E Raubenheimer[3], Timothy A Dobbins[4], KS Kylie Lee[1,2,5,6], Noel Hayman[7,8,9], Julia Vnuk[10,11], Paul Haber[1,2], Katherine M Conigrave[1,2]

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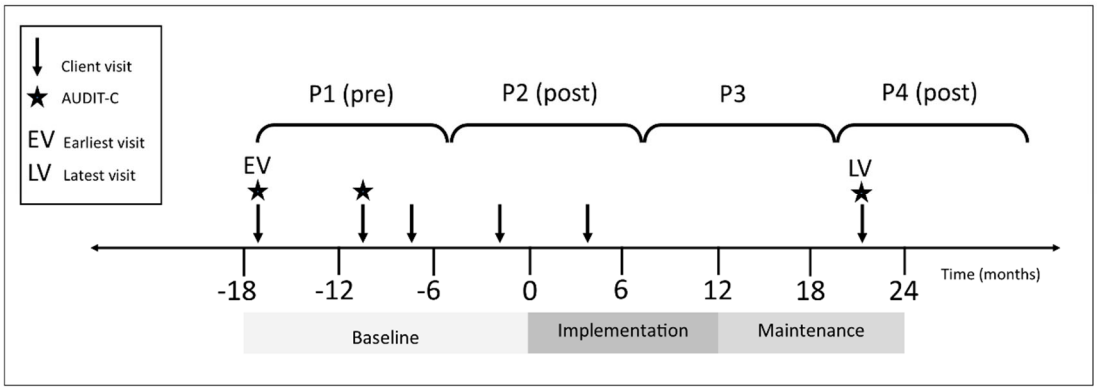
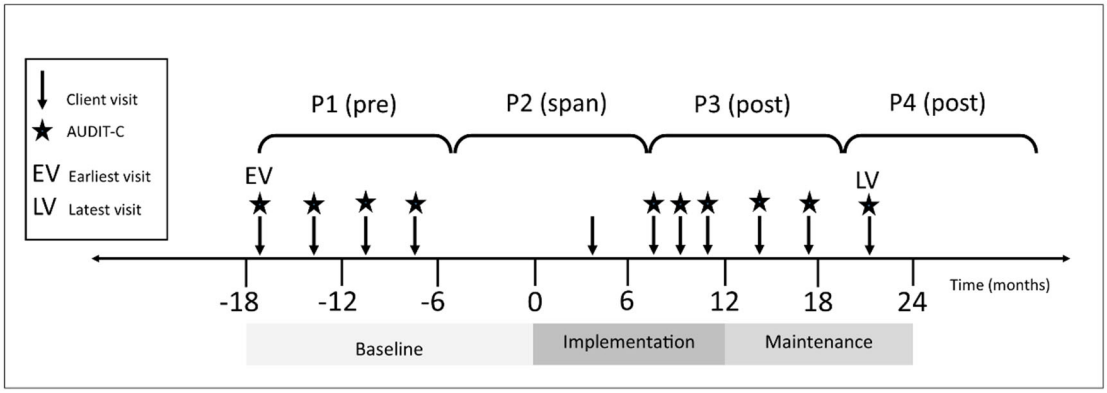
Figure S1. Construction of client's annual periods for annual screening analysis (question 2)



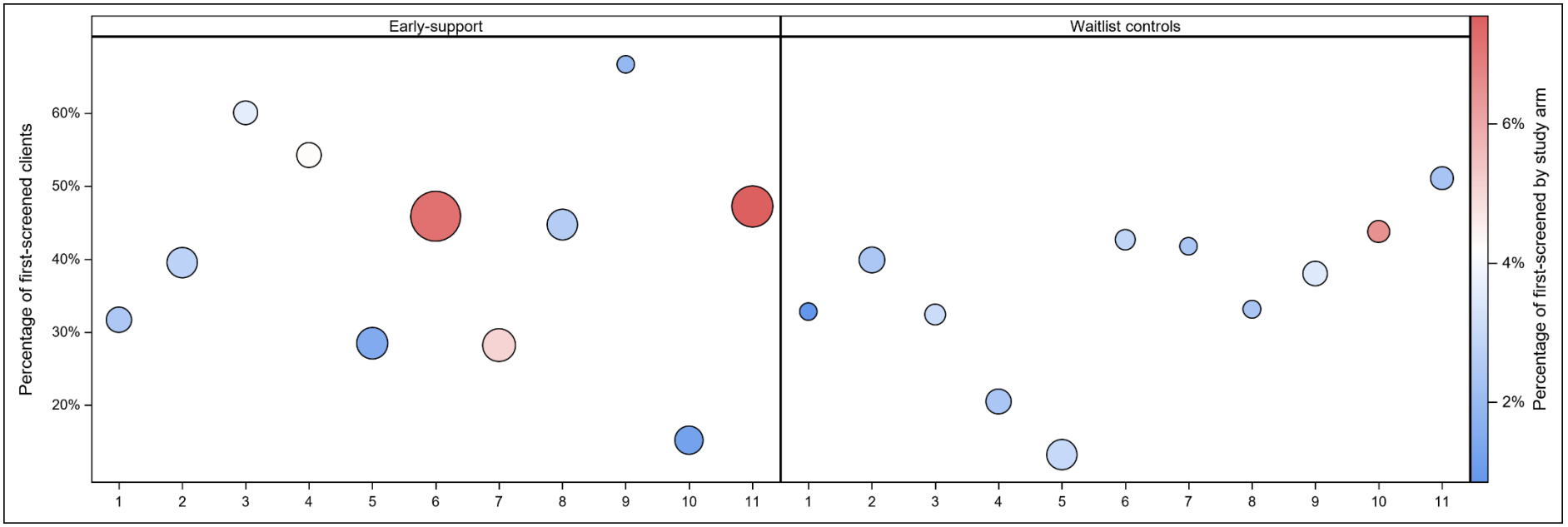
This figure illustrates construction and classification of four annual periods for a client with six service visits, three of which included AUDIT-C screening (designated with a star). Annual periods (P1 – P4) are constructed based on the earliest available client visit date (EV). A period is classified as occurring pre or post implementation based on the latest visit date within the period. Periods occurring pre-implementation are not used in the analysis. The client is classified as annually screened if all post-implementation periods with visits contain at least one AUDIT-C screen. Since this client presented to the service at two post periods (P2, P4) but only one contains AUDIT-C screening, they are classified as not annually screened.

Figure S2. Construction of client's annual periods for a client screened four or more times annually (question 3)



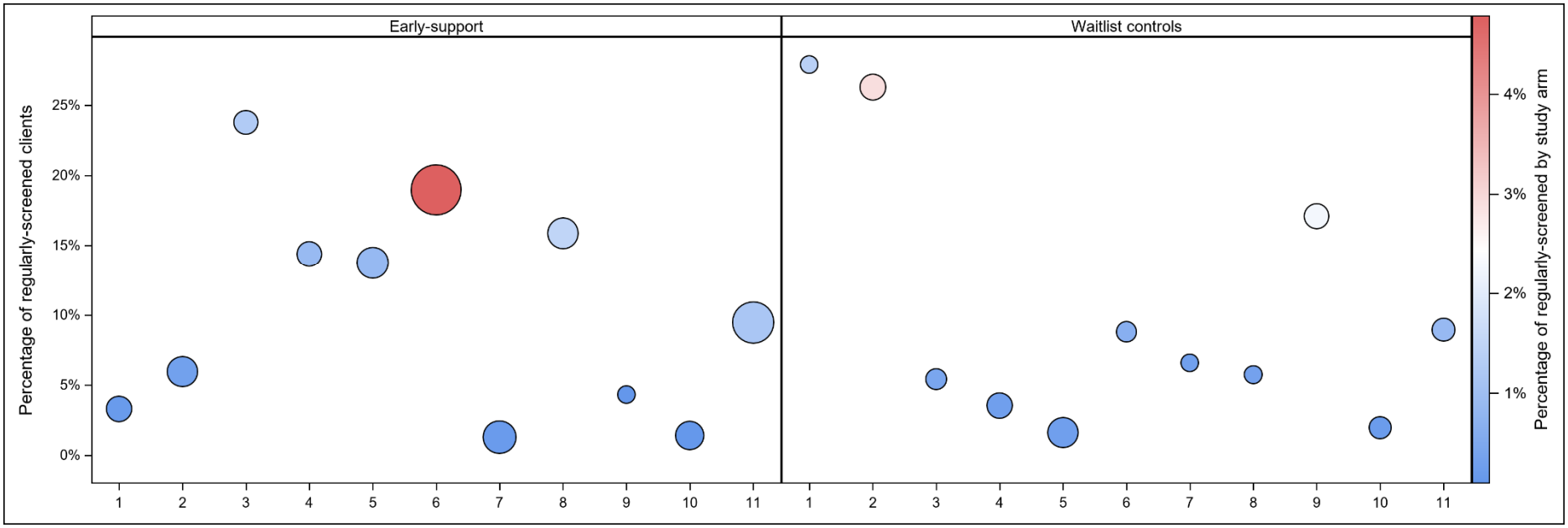
This figure illustrates construction and classification of four annual periods for a client with 11 service visits, 10 of which included AUDIT-C screening (designated with a star). Annual periods (P1 – P4) are constructed based on the earliest available client visit date (EV). A period is classified as occurring pre, span or post implementation based on the commencement and end dates of that period (i.e., the anniversary of EV). The client is classified as frequently screened if at least one period contains four or more visits with AUDIT-C screening. Since P1 and P3 contain four or more visits with AUDIT-C, this client is classified as frequently screened.

Figure S3. Unadjusted first-time screening rates for the 22 services over 24 months of implementation, by study arm and by service.



Services are represented by numbers 1-11 in each study arm (x-axis).
The size of the bubble represents the overall size of the service, based on the number of clients in the overall trial sample.
The vertical position of the bubble represents the percentage of first-screened clients in each service (denominator is the number of clients from that service that were included in sample for assessing first-screening). The corresponding y-axis is on the left.
The colour of the bubble represents the percentage of first-screened clients in that the service's study arm that were contributed by that service (denominator is the number of clients in that study arm that were included in the sample to assess first-screening). The corresponding y-axis is on the right.

Figure S4. Unadjusted annual screening rates for the 22 services over 24 months of implementation, by study arm and by service.



Services are represented by numbers 1-11 in each study arm (x-axis).
The size of the bubble represents the overall size of the services, based on the number of clients in the overall trial sample.
The vertical position of the bubble represents the percentage of annually screened clients in each service (denominator is the number of clients from that service that were included in the sample for assessing annual screening). The corresponding y-axis is on the left.
The colour of the bubble represents the percentage of annually screened clients in that the service's study arm that were contributed by that service (denominator is the number of clients in that study arm that were included in the sample to assess annual screening). The corresponding y-axis is on the right.

Table S1. Full trial sample at baseline: characteristics by trial arm

Characteristic	Early support	Waitlist control
Services		
N	11	11
Mean clients per service (SD)	3678 (2380)	1967 (791)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
N	40,459	21,631
Mean age of clients in years (SD)	37.1 (16)	37.4 (16.3)
Number of female clients (%)	22342 (55.2)	11938 (55.2)
Mean observations[b] per client (SD)	3.5 (2.6)	3.5 (2.6)
Clients screened with AUDIT-C (%)	7213 (17.8)	4601 (21.3)
Mean AUDIT-C score[c] (SD)	3.6 (3.6)	3.3 (3.4)
Clients with an AUDIT-C>0[c] (%)	4092 (56.7)	2811 (61.1)

[a]Baseline period: from 28.02.2016 to 30.08.2017 inclusive. [b]An observation appeared in the dataset for a client if they attended their service for a consultation in the preceding two-month reference period at least once. [c]The denominator is the number of clients who had at least one recorded AUDIT-C score.

Table S2. Fixed effects of the support model on the odds of screening in previously unscreened clients (A) without control variables; (B) with control variables of age and gender

A

Effect	Estimate [95% CI]	p
Odds of outcome in waitlist controls	0.52 [0.37-0.74]	<0.001
Odds Ratio: Condition (Early-support)	1.33 [0.81-2.18]	0.25
Intracluster correlation coefficient (ICC)	0.1	

B

Effect	Estimate [95% CI]	p
Odds of outcome in waitlist controls	0.51 [0.36-0.73]	<0.001
Odds Ratio: Condition (Early-support)	1.33 [0.81-2.19]	0.26
Odds Ratio: Gender (male)	0.96 [0.92-1.01]	0.13
Odds Ratio: Age	1.00 [1.00-1.00]	0.2
Intracluster correlation coefficient (ICC)	0.1	

Table S3. Fixed effects of the support model on the odds of receiving annual screening (A) without control variables; (B) with control variables of age and gender

A	Effect	Estimate [95% CI]	p
	Odds of outcome in waitlist controls	0.08 [0.04-0.15]	<0.001
	Odds Ratio: Condition (Early-support)	0.99 [0.42-2.37]	0.98
	Intracluster correlation coefficient (ICC)	0.24	

B	Effect	Estimate [95% CI]	p
	Odds of outcome in waitlist controls	0.08 [0.04-0.16]	<0.001
	Odds Ratio: Condition (Early-support)	0.99 [0.42-2.33]	0.98
	Odds Ratio: Gender (male)	1.12 [1.05-1.20]	<0.001
	Odds Ratio: Age	1.00 [0.99-1.00]	<0.01
	Intracluster correlation coefficient (ICC)	0.24	

CHAPTER

6

DISCUSSION

6.1 Novel contribution of this work

This thesis investigates approaches used to improve screening and treatment for unhealthy alcohol use in primary care services for Aboriginal and Torres Strait Islander peoples of Australia. A key strength of the study is its co-design with the ACCHS and key Aboriginal and Torres Strait Islander organisation to ensure suitability for diverse First Nations Australian contexts. It contributes new findings to the body of evidence for implementation of screening and treatment for unhealthy alcohol use globally. The systematic review of literature (Chapter 2) is the first to synthesise the evidence for implementation of screening and the full spectrum of treatment for unhealthy alcohol use in primary care. Before this study, available reviews concentrated on implementing either screening and brief intervention or just one form of treatment without also targeting screening (e.g., brief intervention or pharmacotherapies alone) (44, 64-67). Availability of treatment for the full spectrum of unhealthy alcohol use in primary care is important as these services are the most frequent, and often the only point of contact with healthcare for the general population. The review is the first to discuss the use of elements of CQI in strategies to improve screening and treatment for unhealthy alcohol use. It also sets out the limited evidence for implementation strategies within the setting of Australia's First Nations peoples.

Chapters 3, 4 and 5 reported results of a cluster randomised trial testing the effectiveness of a multifaceted support model for Aboriginal Community Controlled Health Services to increase the delivery of screening and treatment for unhealthy alcohol use. This is the first large scale trial conducted in First Nations primary care settings world-wide. This trial showed not only improvements in screening but also some evidence of improvement in the

rates of recorded treatment provision. Chapters 3 and 4 demonstrated that the support (provided over the implementation and maintenance phases of the trial) resulted in a significant increase in the odds of receiving AUDIT-C screening, in any two-month period during which a client visited their service when compared to waitlist controls. Chapter 5 contributes a novel investigation into the patterns of screening resulting from the implementation of the support, and whether these patterns were clinically useful and in line with available recommendations. At the time of writing, there appeared to be no other literature exploring the topic of screening patterns following an implementation trial.

6.2 Screening and treatment outcomes of the trial

6.2.1 Screening

The significant increase in AUDIT-C screening observed over 24 months of implementation (Chapter 3) is consistent with observations from large, randomised trials and cohort studies with similar multifaceted strategies in non-Indigenous populations. However, the size of effect can vary greatly. For example, the US PPRNet-TRIP trial observed an adjusted OR of 3.30 (95% CI=1.15-9.50) over 1 year of implementation, which remained unchanged following another year (93). The AA-TRIP achieved an OR of 8.1 among patients with hypertension (CI 1.7-38.2) over 2 years (94).

In these studies (and others identified in the systematic review), increases in screening rates were achieved in settings that were more conducive to an effective rollout of the implementation strategy at an individual practice and even at a clinician level. Common organisational structures (e.g., overarching governance, software infrastructure) enabled a much more systematic roll-out of strategy components in those studies, such as changes to practice software, incentive schemes and quality indicator requirements (86, 96). In

contrast, each ACCHS is independent. There is a variety of organisational structures, and large differences in resourcing were observed. This diversity is reflected in the heterogeneity of effect size among the services demonstrated in the 24-months outcomes (Chapter 3). Despite this, the support model achieved a significant increase in screening, sustained over 24 months.

6.2.2 Screening frequency

In contrast to the increase in screening overall, Chapter 5 investigated the patterns of screening among clients presenting to their services with some regularity (at least once both before and after implementation). The results did not show a significantly higher rate in screening of previously unscreened clients over the 24 months of implementation in the early-support arm compared with waitlist controls. In fact, of those unscreened before implementation, nearly two-thirds (62.7%) remained unscreened after. This is contrary to expectations. Clients attending with some regularity would be expected to benefit from efforts to increase screening coverage of the community since more frequent presentations give more screening opportunities.

Similarly, the support did not result in a significant increase in annual screening rates of clients in the early-support arm when compared to controls. Annual screening was defined as a record of at least one AUDIT-C screening event in any given year that the client attended the service, beginning with their earliest visit).

In their National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (56) NACCHO and RACGP recommend screening for unhealthy alcohol use during an annual health check or opportunistically. The first requires the client to present at the service annually for preventative care. The second approach requires screening when

the client visits the service for any reason. Both present challenges. Clients are more likely to attend primary care services to seek treatment rather than for prevention. To illustrate, free Annual Adult Health Assessments for Aboriginal and Torres Strait Islander people have been implemented for over 20 years, however uptake in 2018-19 was only 28.9% in people aged 15 years or older (54). Rates vary by gender (with females screened more often than males), and geographically (54, 97). Clients may not seek healthcare due to experience of barriers (e.g., previous trauma or lack of trust) or may not be aware that they are able to (or need to) seek preventive care. If they have no other reason to visit their health service regularly or even once per year, there may be limited opportunities for screening.

When clients do present to services, administering alcohol screening may not always be appropriate. For example, a client may present in a crisis, be reluctant to discuss substance use upon an initial meeting with the clinician, or there may not be time during a regular session (98). Conversely, if the approach is purely opportunistic (screening at every presentation), the small percentage of clients who visit the services frequently, for example to monitor pregnancy or a chronic health condition, may be screened more than necessary. The results presented in Chapter 5 support this: of the 43,054 clients who attended their services with some regularity, 6,240 clients had two or more AUDIT-C screens in any annual period, accounting for 42% of all screens.

Moreover, 841 clients received four or more AUDIT-C screens in at least one year in which they were visiting their service. More than half of these frequently screened individuals appeared not to have elevated biological indicators that can be linked to alcohol (elevated, systolic blood pressure, haemoglobin A1c or gamma-glutamyltransferase), or risky AUDIT-C levels, to warrant close monitoring.

Although the frequent monitoring of alcohol intake may be justified in some cases, these results could indicate that opportunistic screening may result in unnecessary burdens on both the client and the clinician. For example, young women appeared to be overrepresented in this frequently screened group, possibly in the context of antenatal screening. While monitoring of alcohol consumption during pregnancy is important, Australian preventative care guidelines recommend alcohol screening at every antenatal visit. Considering antenatal visits are monthly with the frequency increasing towards the end of pregnancy, this could result in monthly or more frequent screening on average. As discussed in Chapter 5, as alcohol is a sensitive topic, frequent broaching of the subject and direct questioning could lead to the client feeling frustrated, underreporting of risky drinking, and discouraged from attending antenatal care. Furthermore, AUDIT-C has not been tested on representative samples of pregnant women from different populations for sensitivity and specificity outside of the US (99). So, it is not clear how well it would perform in detecting risky drinking in Aboriginal and Torres Strait Islander women who are pregnant. On the other hand, it is important to note that AUDIT-C is a screening tool that that can potentially be useful in promoting preventive health conversations.

As well as ensuring appropriate regularity of screening, appropriate clinical responses are important where there is a score indicating the person is at risk because of their drinking. This may include more detailed screening with the full AUDIT, or a thorough clinical interview, brief intervention or other treatment if indicated.

6.2.3 Treatment provision

Chapters 3 and 4 investigated the effect of the support model on different types of treatment for unhealthy alcohol use. The analysis demonstrated a significant increase in

relative odds of a client receiving any treatment during a visit in any two-month period. However, rates of any recorded treatment at baseline were negligible so the relative increases in odds translate to extremely small and clinically insignificant increases in treatment rates (Chapter 3). Furthermore, the changes in treatment rates varied widely between individual services and seemed to be driven mainly by a few services, one of which experienced dramatic improvements. The statistical increase in the relative odds of any treatment was mainly driven by a decrease in odds in the waitlist controls after implementation in the early-support arm, which could indicate that the support model had at least some effect in preventing a drop-off in treatment.

Talking therapies

The increase in the odds of any treatment seemed to be driven by a combination of increases observed in the recording of both advice and counselling. When taken together as 'talking therapies', within-arm odds of recording of this type of treatment doubled in the early-support arm after implementation and the change in odds was 7.6 times greater in this arm when compared to controls (both increases were significant). In contrast, the trial did not show significant increases in odds of recording brief intervention (recorded as advice).

There are challenges associated with recording brief interventions in practice software, which was not designed to accurately record different types of psychosocial treatments. Globally, similar implementation trials that successfully increased brief intervention had diverse methods of recording it and correspondingly, diverse results. For example, the multi-national ODHIN trial of a multi-faceted support strategy (training, financial incentives, possibility of referral to electronic brief interventions) showed a small increase in the odds

of receiving brief intervention (1.61 95% CI, 1.24-2.10) during the 12 weeks of implementation training and support. This represented 11.72 per 1000 clients attending a consultation. ODHIN employed study-specific data capture instruments (tally sheets) and electronic records (83).

In contrast, the PPRNet-TRIP trial observed a 6-fold increase in brief intervention (OR = 6.58, 95% CI 1.69-25.7) over 12 months of implementation, with 58.1% of 1,278 eligible clients receiving this treatment. PPRNet-TRIP was a multi-faceted quality improvement intervention in 20 practices in the United States (included training and audit-and-feedback among other components). It used routinely collected data but exerted much more control over the recording of brief interventions as part of the implementation strategy. Electronic practice software at all intervention sites was modified to include intervention templates, which provided prompts for brief intervention, pharmacotherapies or other treatment recommendations based on the screening results (93). As a further example, a natural experiment study of the impact of financial incentives on the delivery of screening and brief interventions in Northern England also showed significant increases in rates of brief interventions (100). In this instance the outcomes were measured by pooling several electronic practice software codes, which included both brief and longer alcohol advice. In all cases there was inability to corroborate that the record was an accurate reflection of what was delivered or if brief intervention was delivered at all.

The rates of recorded provision of 'talking therapies' in this study were very low, even if considering underestimation due to poor recording. More than 60% the screened clients (n=28,270) in both arms of the study had AUDIT-C scores that indicated drinking above recommended levels (section 3.3, Table S6). However only 945 (3.3% of screened clients)

had a record of having received 'advice' or 'counselling' by the end of the maintenance period (section 4.4.2). This is of concern as brief intervention is currently the accepted first line of treatment for unhealthy alcohol use in primary care for people who drink at hazardous (risky) levels. There is some evidence that even young people who drink at harmful levels, and those who are dependent on alcohol may also benefit from brief interventions (40).

Pharmacotherapies for relapse prevention

Strategies to increase uptake of pharmacotherapies for relapse prevention in the Australian primary care setting have had limited study. The systematic review of international literature (Chapter 2) identified only one Australian study that included implementation of this treatment type (101).

The trialled support model did show a significant effect on the prescription of pharmacotherapies for relapse prevention. The low uptake of pharmacotherapies to treat alcohol dependence throughout this trial is consistent with global reports, though the rates were much lower (0.3%; see section 4.5.1). For example, among Veterans Health Administration patients in the United States, only 3.4% patients with alcohol use disorders received pharmacotherapies in 2009 (102). Slightly lower rates (less than 3%) have been estimated among people with alcohol dependence in Australia using prescription data (81).

Clinician barriers to prescribing pharmacotherapies in alcohol dependence have been studied and include lack of knowledge and experience in prescribing these medications and belief that specialist addiction treatment is required to treat dependence (81, 89). Clients' reluctance to recognise that they have alcohol dependence or willingness to enter treatment can also play a role (81).

The most recent Australian alcohol treatment guidelines advocate treatment of alcohol dependence for Aboriginal and Torres Strait Islander peoples at the point of detection as there can be many barriers that can prevent a First Nations Australian person from attending a specialist service (49). For this population the point of detection would most commonly be the ACCHS. However, the use of pharmacotherapies in primary care does not appear to be consistently recommended. While RACGP's SNAP guidelines mention the option of pharmacotherapy prescription (50), neither the RACGP and NACCHO National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (56) nor the RACGP Guidelines for Preventative Activities in General Practice mention the possibility of treatment of dependence. Instead, they recommend referral to a specialist service. In contrast, both guides recommend pharmacotherapies for smoking cessation.

Anecdotally there have been efforts over many years to increase training of Australian medical students in use of these medications, and several articles have been written for practising GPs on these medicines (91, 103). However, the inconsistent inclusion of pharmacotherapies in formal general practice guidelines may be contributing to their limited prescription.

6.3 A unique trial in the context of implementation research

6.3.1 A large-scale trial addressing gaps in evidence

This is the first large-scale cluster randomised trial world-wide to address screening and treatment for unhealthy alcohol use in First Nations primary care. The primary care services and their populations were likely to be reflective of Aboriginal and Torres Strait Islander primary care settings in that they were diverse geographically and captured routinely collected data from the entire adult client population who attended participating services

during the trial. Furthermore, comparisons with national key performance indicator data from the Australian Institute of Health and Welfare suggest that the 22 services participating in the trial represented about 15% of all Aboriginal Community Controlled Health Services in Australia, as well as about 15% of the clients accessing these services (104).

Primary care is the first and most frequent point of contact with healthcare, so improving detection and treatment of unhealthy alcohol use in this setting increases the opportunity to respond to unhealthy drinking. The support model trialled in this study aimed to improve the rates of screening as well as implementation of the full spectrum of treatment of unhealthy alcohol use, including pharmacotherapies. In contrast, few studies identified in the systematic review (Chapter 2) addressed the implementation of all types of treatment for unhealthy alcohol use suitable for delivery in primary care. Studies tended to concentrate on brief interventions, either alone or in combinations with screening and/or referral to treatment. There was a particular lack of studies into improving the use of pharmacotherapies with only six studies identified (41, 93, 96, 101, 105, 106), missing an important opportunity to initiate treatment for more severe forms of disorders due to the use of alcohol.

6.3.2 A flexible multifaceted design engaging whole organisations

It is evident from earlier literature reviews that multifaceted implementation strategies with durations of 12-months or longer, and those involving multiple organisational levels are more successful in improving rates of screening and treatment than single action strategies (64, 67). The systematic review (Chapter 2) showed that, broadly, engagement could occur at five organisational levels, national, health network/state, service/clinic, clinician/staff,

and client. It also showed that, although not widely used, strategies incorporating all three core elements of CQI were more likely to involve multifaced models of support and target multiple organisational levels.

The design of the trialled support model reflects many of these features. It offered an eight-component model to provide services with a wide range of support options. The approach was co-designed in consultation with peak community bodies (78) and strived to maximise entire health service participation. As mentioned in section 1.6.2, there was extensive engagement with the services to ensure that the trial would add value to their existing practices rather than replacing them. The 22 ACCHS that consented to participate were also involved in refining the study design. During the first national workshop the services contributed insights about barriers and facilitators of provision of alcohol care and contributed ideas for tailoring of the support model to their needs. Through this, the ACCHS were able to ensure that the support model was beneficial to them and their communities. This engagement also provided a strong basis for good ongoing collaborative relationship between the project team and the ACCHS. Engagement of the organisation throughout the study continued through a formal agreement with the service, availability of training and online support to all staff (not just clinicians), and provision of data feedback in the form of infographic reports that could be distributed to the entire service.

The support model also included the nomination of service champions whose role was to promote staff engagement in the efforts to improve alcohol screening and treatment rates. The champions were chosen by the ACCHS. Their primary role was to act as a liaison between the service and project team, disseminate the infographic data to their service and participate in bi-monthly teleconferences to exchange implementation experiences and

ideas with other service champions. Although not studied in this trial, the level of engagement of champions appeared to influence the improvement in trial outcomes.

To ensure that the services were able to implement improvement strategies that suited their settings, the support model incorporated design features consistent with the three essential elements of CQI (69). The model was designed to be flexible and to involve as many service staff as possible and thus give the services more control and ownership over the improvement process. Most components could be tailored to the needs of the services. The type of actions to achieve improvement in the rates of screening and treatment were left to up to the services. The infographic reports (78) allowed the services to check how they are tracking in two-monthly cycles. This then allowed the services to adjust their improvement actions in response to this information. As highlighted in Chapter 3, ongoing local monitoring of service provision is important as the ACCHS' dynamic operational environment is likely to continue to affect service provision in different ways over time.

The support model also offered longer than one year duration of implementation (24 months), which, at least in the case of screening and brief intervention, has been associated with better implementation outcomes (67). The duration was almost four times longer than the duration of implementation observed in the systematic review, which tended to be offered for approximately 28 weeks on average. Apart from allowing the services more time to implement and refine improvement strategies, longer duration facilitated the roll-out of the support at all sites.

Considering this, the support model could be expected to be more successful in improving systematic screening and increasing treatment rates than indicated by the outcomes of the trial. Personal communications with key staff at the participating services indicated that the

support model was well received. However, these communications and administrative trial data indicate that recommendations made during on-site training and support components were implemented with a considerable variability. For example, some services circulated their infographic reports widely, with anecdotal evidence that these were used to monitor and change alcohol service provision. Other services circulated them only to a small group of staff members and others did not seem to utilise them at all. Participation in bi-monthly conferences and uptake of financial support for resources was also variable. Some service champions attended regularly while others infrequently. Sometimes attendance was interrupted due to staff turnover. Some services did not feel they needed all the available resource support while others were slow to access due to lack of time. Several factors may have contributed to this inconsistent uptake, and these are discussed in sections 6.3.3 and 6.3.5.

6.3.3 Implementation barriers in the context of Australian primary care

It is evident that heterogeneity among the services is a major factor in the variability of outcomes. The services differ in terms of resourcing and practice management, electronic record keeping and the community they serve. There are also differences associated with settings in which the services operate. These range from communities where alcohol consumption is restricted or prohibited (mainly very remote settings) to those where alcohol consumption is controlled only by general measures such as taxation (e.g., urban areas).

This heterogeneity among services is not unique to ACCHS. The Australian general population's access to primary care occurs mainly through general practices, most of which are privately owned single or group practices (68). They operate independently and

therefore are likely to vary in the types of services, resources, and management practices. For example, access to primary care both in the general and Aboriginal and Torres Strait Islander population varies by remoteness with general practitioner numbers ranging from 110 per 100,000 population in major cities to just over 65 per 100,000 in very remote areas in 2017, which would have impacts on workload and time pressures (68).

However, there are also important differences between Aboriginal and Torres Strait Islander primary health care (including the ACCHS) and general population primary care in Australia. First, the proportion of Aboriginal and Torres Strait Islander services in areas where there are fewer general practitioners is greater. In this trial 55% of participating ACCHS were outer regional, remote, or very remote. This is somewhat lower than the overall proportion in Australia: in 2019-20, of the 196 organisations receiving government funding to provide primary care services to Aboriginal and Torres Strait Islander peoples, nearly 70% were classified as outer regional, remote, or very remote (107). The Australian Bureau of Statistics reports that nearly 40% of Aboriginal and Torres Strait Islander people live in outer regional, remote, or very remote areas in contrast with only 9.5% of the non-Indigenous populations (108). This means that a much greater proportion of First Nations Australians than non-Indigenous would be affected by lower availability of doctors.

Second, there are resourcing challenges. Australia's largest Aboriginal and Torres Strait Islander primary care quality improvement study reported many challenges to service improvement, including high staff turnover, need for skill development, decision support, inadequate electronic record systems and continuity of funding (109).

Furthermore, Aboriginal and Torres Strait Islander people experience a greater chronic disease burden than other Australians (110). Chronic diseases require more complex care

planning and this results in a higher workload, particularly for the fewer clinicians working in rural and remote settings (68).

A combination of service-level challenges and high disease burden among the Aboriginal and Torres Strait Islander population probably results in a diminished capacity to prioritise delivery improvements in some services. Individual and organisational stakeholder perceptions probably also play a role. If the community or service leadership sees alcohol as a priority, efforts to improve alcohol care are more likely to see uptake. Engagement of broad stakeholder groups as part of an implementation framework is seen as important to successful implementation (111).

The results of this study highlight the challenges associated with the great heterogeneity among the services and point to the need to approach future improvement efforts at multiple organisational levels to overcome the barriers associated with them.

6.3.4 CQI as a tool in improving alcohol screening and treatment uptake

CQI offers a systems-level approach that can help services recognise their own barriers and facilitators to improvement and respond dynamically. This approach has been shown to improve outcomes in diabetes care (112) and has been employed in addressing low uptake for screening and treatment for unhealthy alcohol use internationally (80). Globally, CQI has also been identified as a common characteristic in Indigenous primary care service delivery models (113).

While the support model trialled in this study incorporated features consistent with the three core CQI elements[5], it did not provide training on how to do continuous improvement. For example, the training did not include discussions of designing and monitoring improvement cycles. Improvement actions were also not systematically monitored, though champions were asked about what was working well during bi-monthly teleconferences. Including training on CQI techniques and monitoring improvement actions may have led to better trial outcomes.

CQI is widely accepted in ACCHS but if CQI is implemented at individual service level with little or no support at a higher organisational level (e.g., lack of resourcing or counter-productive policies at the level of regional or state network or association), the ACCHS may find it hard to implement and sustain improvements. For example, high staff turnover experienced by many ACCHS (109) could lead to loss of corporate knowledge on how to do CQI. Although it was co-designed with peak community bodies, the support model did not actively seek out and engage the umbrella organisations or systems above service level that might have facilitated implementation of service improvement activities in relation to unhealthy alcohol use.

6.3.5 Cultural factors in screening and providing treatment

For Aboriginal and Torres Strait Islander clients cultural factors such as gender separation (sensitive issues are often addressed in same-sex circles), 'skin' relationships (rules of association between different groups) or the client's traditional position within the

[5] As described is section 1.4, the three essential elements of CQI are: 1. Using 'systematic data guided activities' to identify problems and achieve improvement; 2. 'Designing with local conditions in mind'; 3. Using an 'iterative development and testing process'.

community relative to the clinician could also require consideration in the delivery of alcohol care (114). If clients are asked sensitive questions in an environment (the clinic) in which they don't feel comfortable, they may feel disempowered or guarded.

Furthermore, Aboriginal and Torres Strait Islander peoples' concept of health extends to the social, emotional, and cultural well-being of the whole community and the relationship between the well-being of the individual and the well-being of the community (62, 115). Implementation strategy components that focus on the client-community relationship are therefore highly likely to contribute to acceptance of any implementation program. The support model did not include direct engagement with the community as its focus was clinical service provision. However, the training did encourage the clinicians to consider the client in the context or family and community. It also included recommendations for community-based harm reduction and health promotion activities.

The systematic review (Chapter 2) revealed that even in general populations, client-oriented components can be important in designing successful multifaceted implementation strategies related to alcohol (67). Such components consist of actions that target potential primary care clients to raise awareness of and reframe the client's thinking about their alcohol drinking. For example, in a study in Finland, this kind of 'patient activation' was attempted by distributing AUDIT to all households in an urban site (116). Such initiative may improve acceptance of screening at clinical services, lead to empowerment of the community and perhaps even pro-active seeking out of preventive or therapeutic care.

Cultural barriers may also be encountered by Aboriginal and Torres Strait Islander health professionals. It has been previously noted that conflicts sometimes occur when the First Nations clinicians blend local cultural knowledge and practices with Western approaches

(117, 118). For example, there may be pressure not to deviate from a particular western method of delivering care for administrative reasons. The training provided through the support model was developed in partnership with Aboriginal health professionals and considered the cultural context of clinical interactions. Managers were also invited to the training. However, some barriers are likely still to have remained or could have re-emerged (e.g., with arrival of new staff who were not present at the training).

6.4 Key gaps this study did not address

The limitations of the data did not allow for analysis of the contribution of the model's individual components to the overall effect. The study also did not monitor the quality of screening or treatment delivered (e.g., adherence to AUDIT-C screening questions or quality and duration of brief intervention), or collect contextual information on acceptability, barriers, and facilitators to implementation. These limitations are also reflected in the broader literature, where the lack of evidence for what strategies work best in different contexts has been highlighted (Chapter 2). This leads to a gap in understanding in the relationship between the improvement strategies and their outcomes.

This study did not investigate if the support model resulted in benefits to patients' health or health-related behaviours, as patient outcomes were not the focus of the study design. There are also methodological challenges associated with designing studies to detect improvements in outcomes at both client and service level. However, garnering this evidence remains important as the systematic review (Chapter 2) showed that very few studies on the implementation of alcohol care report health outcomes, and fewer still showed any improvements.

These methodological challenges could be overcome by using the 'hybrid designs' approach proposed by Curran et al (119). The approach involves blending effectiveness and implementation designs, to accelerate evidence gathering for research translation or to fill research gaps. Three types of hybrid designs are proposed. Of those, 'Type 3' designs test an implementation strategy while at the same time collecting data on the effects of the clinical treatment and are most suitable to pragmatic trials (120).

Furthermore, as well as collecting data on both patient and implementation outcomes (summative evaluation), hybrid type 3 designs involve the use of data throughout the trial in order to detect barriers and refine the treatment and implementation processes while the trial is ongoing (formative evaluation) (121). This allows for gathering of contextual information, which is lacking in the current evidence-base. This is also compatible with the methodology employed by CQI, which use improvement cycles such as Plan-Do-Study-Act to refine process improvements (121).

6.5 Limitations

There are limitations arising from the nature of routinely collected practice data available to this study. This includes the inability to corroborate whether the clinical action was recorded correctly, whether it was recorded but did not occur or if action occurred but was not recorded (122). Some steps could have been included to ensure greater fidelity to the data entry requirements. These could have included modification of practice software to direct the clinician to this field (e.g., a screen prompt), or some form of periodic audit (e.g., using client exit interviews or surveys) to verify what was recorded in the software. This could have the added benefit of reinforcing the need to follow up positive screening with appropriate treatment. Alternatively, more accurate rates of brief intervention recording

could potentially be obtained by examining data from the free text fields containing clinical notes as well as the 'advice' and 'counselling' fields. However, this was not possible within the resources of this study.

Data on pharmacotherapy prescription was accurate because scripts are written in the practice software and automatically recorded. However, the data lacked contextual information such as whether the treatment was initiated within the service or was a continuation of treatment that had been started by a specialist service. A more detailed analysis of the client record, such as the free text notes, would have been useful, however this was not available due to privacy concerns and resource constraints. Prescription data also does not provide information about treatment adherence (i.e., whether the client took the medication).

The duration of baseline data (18 months) made it impossible to establish the rates of annual screening before implementation (Chapter 5). Thus, comparisons in regular annual screening rates between trial arms could only be made during the implementation and maintenance phases of the model. Given that more than half of the clients in the trial attended only after implementation, longer follow-up may have been useful in identifying regular screening patterns.

Data limitations did not allow for a detailed analysis of possible reasons for more frequent screening of some clients (Chapter 5). This information would be useful to contextualise the results observed in this study.

6.6 Recommendations for research and translation

The results of this study (Chapter 5) show that there is a need to improve regular as well as first-time screening rates. This would be facilitated by identifying (through collection of contextual data) and addressing the diverse barriers and facilitators that occur at each organisational level of the ACCHS. The results of this study also highlight the need to improve recording of treatment, particularly in the case of brief interventions, which can currently be recorded in multiple ways in Communicare practice software. Improvement of record keeping would be a crucial step to providing better information about whether implementation strategies influence service as well as client health outcomes. It will also ensure that services have accurate data that is needed to make practice adjustments during improvement efforts. Ongoing access to training and support of services in how to use these data in service improvement through techniques such as CQI is also important.

Recommendations for future research and practice will be made at the five organisational levels discussed in Chapter 2: client/community, clinician, practice, state/primary care sector and/or national.

6.6.1 Engaging clients and their community

As highlighted in this thesis (section 6.3.5), when cultural factors are not taken into consideration, barriers may arise for Aboriginal and Torres Strait Islander clients when alcohol is brought up in the context of primary care. Therefore, including culturally appropriate client- and community-oriented components in implementation strategies simultaneously with clinic and clinician-oriented components is important when designing service improvement strategies in Aboriginal and Torres Strait Islander settings. ACCHS already widely employ client engagement in the form of outreach in community, for

example, meeting clients in familiar places outside of clinical setting (e.g., parks, riverside, on the beach) or other culturally appropriate places. The engagement takes the form of informal 'yarns', during camps and walks or going fishing. It can also take the form of a community gathering with a short presentation followed by a social event like a barbeque, which gives the opportunity for an informal chat (123). Identifying and building on these existing methods of community and client engagement within ACCHS as part of the codesign process is important for the success of service improvement strategies. These methods could be included as discrete components of future implementation strategies. This would help to facilitate communication about alcohol between the clinician and the client.

Aboriginal and Torres Strait Islander peoples' concept of health includes the relationship between the well-being of the individual and the well-being of the community (62, 115). So, it is important that the community can drive service-level change and feel ownership of any resulting improvement programs. This could be done through direct engagement in co-design and refinement of implementation strategies as well as collection of acceptability data through post-implementation interviews, forums, or surveys. Better community engagement is likely to lead to greater acceptance of alcohol initiatives not only from individual clients but also clinicians, as broader society's attitudes to alcohol can have a big impact on whether and how clinicians deliver alcohol care. For example, a recent study of Australian general practitioners identified raising community awareness of harms from alcohol as a facilitator to using alcohol brief intervention in primary care (124).

6.6.2 Supporting clinicians

As evident in the systematic review (Chapter 2), most successful multifaceted implementation strategies include some form of clinician training on screening and

treatment for unhealthy alcohol use. Chapter 3 and 5 highlight the need for ongoing training for new staff and continuing staff members. However, given the possibilities presented by contemporary practice software, more could be done to support the clinician's day-to-day uptake of alcohol screening and treatment activities. Software could be modified to make administering and recording of screening and brief interventions easier. For example, the implementation strategy tested in this trial offered the services support in incorporating AUDIT-C into the adult health check template in the practice software, which has since become a routine inclusion. A similar strategy could be used for brief intervention. For example, a simple prompt for appropriate clinical response (e.g., brief intervention, pharmacotherapies) could be programmed to appear in the practice software in response to elevated screening scores along with a link to a resource screen. This type of approach has been adopted in large alcohol care implementation trials (86, 93, 94). Anecdotally, brief-intervention-specific practice software modifications (e.g., tick-box for brief intervention) have been implemented in some practice software for Australian general practitioners, however others including Communicare, Medical Director and Best Practice do not currently have them (K. Conigrave, personal communication).

RACGP and NACCHO have recently reviewed all health check templates for Aboriginal and Torres Strait Islander peoples with new versions trialled in 2021 (55). The new templates instruct the user to ask about quantity and frequency of alcohol but do not include specific wording or validated screening tools. Further, alcohol is combined with other substance use such as illicit drugs. Smoking on the other hand has a discrete section with structured questions, similar to the Fagerstrom test for nicotine dependence (125). In contrast to other sections (e.g., section on mood), no suggestion of alcohol screening tools is made within the

template. However, the general introduction page of the health check template does refer to the user to other clinical guides, which mention specific screening tools.

This illustrates that more could be done to encourage the clinician to screen. For example, the three-question AUDIT-C could be added to the template. However, the addition could increase the duration of administering the Adult Health Assessments (already up to 1 hour in duration). This could pose challenges to some understaffed services. Alternatively, a clear recommendation of AUDIT-C or names of other appropriate tools could be incorporated into the Adult Health Assessment template in a similar manner to that employed for mood.

Another option would be to use a self-administered screening tool. For example, the recently developed Grog App (19, 126) is not reliant on comfort with English language or literacy. Such solution may reduce the time burden on the clinician as well as providing extra privacy afforded by self-administration.

At a national level, alcohol screening and treatment could be 'incentivised' by including it as a funded item under the Medicare Benefits Schedule (MBS). Such items were included on the MBS for smoking cessation in July 2021 for both face-to-face and telehealth services, albeit only temporarily, until 30 June 2022 (95).

It is evident that much more work needs to be done to improve uptake of pharmacotherapies for alcohol dependence in order to improve patient access to this form of treatment (44). As discussed in section 1.3.3, these are not consistently included in either NACCHO or RACGP's guidelines and this is likely to contribute to them not being seen as part of primary care. While severe dependence on alcohol can have complex presentations and may require a more specialist treatment, not all cases are the same. For many clients, management of dependence with relapse prevention pharmacotherapy in primary care

settings may remove barriers such geographic distance to specialist centres, and stigma associated with specialist care (44, 82). For Australia's First Nations peoples these barriers are more significant due to socio-economic disadvantage and experiences of racism (26). Accordingly, as discussed in Chapter 4, treatment of dependence at the point of detection (if feasible) is particularly important for Aboriginal and Torres Strait Islander peoples (49).

Improvement of uptake would require a multifaceted approach. This could include clinician training on how to assess, identify and manage clients who would do well when treated while living in community, and provision of support through links to specialist services where general practitioner could seek advice on treatment of dependence. The consistent inclusion of pharmacotherapies in NACCHO and RACGP's guidelines as a treatment option, and advocacy activities to promote treatment of dependence in primary care would also be important in changing the professional culture around treatment of dependence.

6.6.3 Supporting services

As discussed in section 6.3.3, barriers to implementation of screening and treatment at clinician-level often involve multiple systems-level factors. Therefore, while training of clinicians in evidence-based screening and treatment and providing incentives and support is important, other systems-level barriers need to be identified and addressed simultaneously.

Strong relationships and mutual trust between non-Indigenous and Australian First Nations clinicians are important when adapting western treatments for culturally appropriate delivery (127). As noted in section 6.3.5, when these partnerships are not established, conflicts may arise when Aboriginal and Torres Strait Islander clinicians attempt to deliver programs in a culturally appropriate way. It is therefore important that non-Indigenous staff

receive cultural training, that programs are co-designed or co-adapted with Aboriginal and Torres Strait Islander clinicians and communities, and that service management foster a culture of trust, mutual support, and two-way learning when Australian First Nations and non-Indigenous staff work together.

More broadly, strategies to improve delivery of screening and treatment should include components that help identify service delivery barriers and facilitators particular to the setting, and to tailor service improvement actions to them. Implementation strategies could make use of existing improvement processes. For example, the Victorian Aboriginal Community Controlled Health Organisation (VACCHO) had a program of three-month improvement cycles delivered via webinars and supported by software infrastructure, training and support, resources, communities of practice and more (70). If improvement processes already are well-accepted, embedding alcohol screening and treatment efforts into these would help ensure engagement at health network/regional organisational level as well as clinic and clinician level. If these processes are not already in place, training and skill development components could provide support in this area by, for example, training in quality improvement techniques, such as Plan-Do-Study-Act cycles.

6.6.4 Supporting community controlled primary care through policy

Finally, for any of the efforts to alcohol screening delivery (or primary care service delivery) to Aboriginal and Torres Strait Islander peoples, governments need to address the systems-level barriers that are beyond control of the services such as reliance on multiple streams and inconsistent patterns of funding and high staff turnover (128). Anecdotally, services in this study often described siloed funding, short-term contracts, and lack of funding for drug

and alcohol workers as barriers to sustained alcohol care improvement. These systems-level barriers are reflected in the literature as outlined in section 6.3.3.

The ACCHS have decades of experience in successfully providing culturally-competent care to Aboriginal and Torres Strait Islander populations and are the largest private employer of Australia's First Nations peoples (129). Yet this expertise lacks recognition in government policies. In 2020, the RACGP called for the Aboriginal Community Controlled Health Organisations to be recognised as the preferred specialist provider of health services to Aboriginal and Torres Strait Islander peoples and for investment into the sector's physical infrastructure and the workforce, including training and financial incentives to attract and retain a highly skilled workforce (128).

Some Aboriginal and Torres Strait Islander communities, including some participating in this study, have already successfully adopted approaches for reducing harms from alcohol (e.g., providing alternative constructive activities for drinkers, supporting mobile assistance patrols, communities and individual households declaring themselves dry). However, the responsibility for developing and implementing alcohol policies is often devolved to state governments (130), where inclusion of First Nations Australians in policy-making is not systematic (131). This can result in successful local efforts undermined by overarching policies such as ambiguous pricing and discounting regulation, and lobbying from alcohol industry stakeholders for delays or dilutions of new regulatory measures (132). Governments should therefore ensure that any alcohol policies are developed with Australia's First Nations peoples. This will allow policymakers to build on local wisdom and experience so that so that new policies are not counterproductive to existing successful initiatives.

6.6.5 Providing evidence-base for implementation strategies

Research has a particularly important role in alcohol screening and treatment policies and practice are effective and feasible. This thesis has highlighted some important gaps in the evidence-base that were not able to be addressed by this study. There is a pressing need for studies to provide information on what approaches work in particular settings and why. The traditional step-wise progression of gathering evidence (efficacy-effectiveness-implementation), is time-consuming and contributes to the gap between discovery and implementation into policy and practice (133). When health issues are strongly driven by political or public agendas, the long time needed to produce the evidence-base may also lead to implementation before there is strong evidence from effectiveness or implementation trials (119). Implementation literature and current practices around alcohol screening and treatment in primary care appears to reflect such a situation: screening and treatment are advocated and incorporated into policies and guidelines (37) but uptake is still low (46); current approaches to delivery of screening and treatment are being called into question, particularly when addressing the full spectrum of unhealthy alcohol use as most recent evidence points only to modest reductions in alcohol consumption (40, 45, 134).

As discussed in section 6.4, hybrid type 3 study designs, which combine effectiveness and implementation studies would appear well-suited to alcohol treatment implementation research. They therefore should be considered when designing future studies, to address the evidence gaps both in service and patient-level outcomes. The use of existing CQI processes in Aboriginal and Torres Strait health services could be incorporated in this study design. This may contribute to a more complete picture of what works and what does not in

particular service settings. Since CQI is widely accepted, this approach could also lead to greater acceptance of implementation.

6.7 Conclusion

Few studies and no clinical trials have been conducted to address screening and treatment of for the full spectrum of unhealthy alcohol use in First Nations primary care settings world-wide. This thesis not only presents outcomes from first such trial in Aboriginal Community Controlled Health Services but also contributes a novel systematic analysis of alcohol care improvement strategies described in academic literature. The work described in this thesis therefore adds important evidence to the area of service improvement in alcohol care.

It is evident from the systematic review that a highly flexible, multifaceted strategy that considers local conditions of primary health care services is more likely to deliver positive service improvement outcomes. CQI is one such approach, which has been widely accepted among the ACCHS and formally adopted as the best-practice approach through the National CQI network.

The support model studied in this trial incorporated tailoring to local conditions, iterative audit-and-feedback, and providing data, to help the services to achieve service improvement. These components have been defined as the essential elements of CQI. As shown in this thesis, such a support strategy can successfully help the ACCHS over a period of 24 months to improve rates of alcohol screening. However, more focus is required on appropriate screening regularity to garner clinically useful information about drinking in this population.

This thesis has also shown that further support for the delivery and accurate recording of alcohol treatment is needed. Collecting contextual information to inform refinement of implementation strategies (e.g., how strategy components are used, barriers and facilitators to uptake and recording) will be important in both research and practice. This could be achieved by utilising quality improvement methodologies within hybrid design research models.

Lastly, efforts to improve screening and treatment for unhealthy alcohol use must be underpinned by support targeting each organisational level, ranging from the local community, though individual staff, service, professional associations, and governments.

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APPENDIX

A

REGISTERED SYSTEMATIC REVIEW PROTOCOL

The following document is the detailed systematic review protocol (Chapter 2). The reviews PROSPERO registration ID is CRD42018110475, https://www.crd.york.ac.uk/prospero/

Review title

Improving practice in detection and treatment of unhealthy alcohol use in Primary Health Care – does CQI make a difference? A systematic review.

Background

Evidence-based management of unhealthy alcohol use in Primary Health Care (PHC), particularly the use of screening and brief intervention (SBI) has been advocated since the World Health Organisation's Expert Committee report on problems related to alcohol consumption called for the development of strategies applicable to PHC settings (36) and subsequently guidelines for the use of AUDIT and brief intervention (30, 31, 135). SBI is now widely accepted as best practice and recommended by both national and international guidelines.(37)

An increasing body of literature now supports the effectiveness of SBI in PHC settings in reducing unhealthy alcohol use (40, 136). Several systematic reviews exploring the effectiveness of SBI implementation programs in PHC exist (65, 66). However, most studies report only short-term outcomes. Sustained and systematic implementation also continues to be a problem with various studies reporting on barriers to implementation (37, 63, 98, 137).

Furthermore, SBI is not known to be effective in more severe Alcohol Use Disorders (AUD).(45) Improvement of delivery of evidence-based treatments for AUDs in PHC once they are identified by SBI activities is a recognized gap. (38, 45)

Challenges in implementing evidence-based care for substance use in PHC including alcohol, such as time pressures and lack of training but also the sensitive nature of the problem have been identified (37, 98). There are particular challenges facing providers working with Indigenous peoples.(138, 139) In Australia, competing health priorities due to high morbidity, cultural differences between the provider and the patient and fear of destroying rapport with the patient as a consequence of addressing alcohol use have been highlighted as barriers to screening and treatment for unhealthy alcohol use (82).

Continuing Quality Improvement (CQI) in healthcare has been defined as "a structured organizational process for involving people in planning and executing a continuous flow of improvement to provide quality health care that meets or exceeds expectations". It originated from industrial process improvement approaches and has been used in HealthCare since the 1990s (71). The CQI process is designed to detect barriers and enables services to change and devise strategies to improve service delivery based on this knowledge. Studies have shown that CQI can improve aspects of PHC service delivery (140-142).

In Australian Aboriginal and Torres Strait Islander PHC, CQI initiatives have been shown to be effective in producing improvements in provision of care as well as having positive impact on organisational aspects of the PHCs (75, 143).

Previous systematic reviews concentrated on strategies designed specifically for the management of unhealthy alcohol use. However, in practice, screening, and treatment of unhealthy alcohol use in PHC is often embedded in broader initiatives such as chronic diseases and mental health. Furthermore, to our knowledge there is no literature

specifically exploring the use of CQI strategies in improving service provision for harmful alcohol use in PHC in general or in indigenous populations.

This work proposes to review the literature for evidence of programs incorporating strategies for improvement of screening and intervention for the full spectrum of unhealthy alcohol use in PHC. In particular, we will investigate whether implementation of CQI processes is more likely to lead to sustained improvement in detection and treatment of alcohol use in PHC. We will also review the subset of literature on evidence-based practice in screening and treatment for unhealthy alcohol use in Indigenous populations, as implementation of evidence-based care for unhealthy alcohol use can provide additional challenges in those settings. We will discuss implications for the design of future implementation strategies for reducing unhealthy alcohol use in general family care, and in Aboriginal and Torres Strait Islander settings in particular.

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Review question

Are strategies employing Continuing Quality Improvement elements associated with improved delivery of evidence-based screening and treatment for unhealthy alcohol use?

Development of the search strategy

Pilot searches revealed that strategies for service or systems-level improvement of evidence-based screening and treatment for unhealthy alcohol use are often embedded in broader programs where alcohol is not the sole focus. The search strategy therefore must be broader than targeting alcohol-specific studies.

To identify relevant search terms, list of relevant search terms for Alcohol, Primary Health Care and implementation strategy was developed and divided into three broad groups, reflecting the problem, population, and intervention of interest to this review (Table 1). The initial search was conducted in MEDLINE on 8 and 9 August 2018. All possible search terms were included both as MeSH terms and as keywords. Search terms within group were combined with the Boolean operator OR. The resulting groups were combined with the Boolean operator AND in MEDLINE. This yielded 14,764 articles from which we identified a set of sentinel papers by systematic screening of 20% of the search results for their match to the inclusion criteria (every first and fifth 100 articles per thousand, total of 2,900). Of these, 33 sentinel articles were identified, including “borderline” articles. The set was reviewed by two independent reviewers and further rejections were vetted by a third reviewer. Inclusion and exclusion criteria were refined during this process. The resulting sentinel set of 25 articles was used to refine the search terms: subject headings and subheadings not already in the original search strategy were identified and their scope notes reviewed, and either used to replace less specific text word searches or added into the system as new search terms. After each modification the resulting search was repeated and tested for the

presence of the sentinel set in its results. The modification process continued until most sentinel papers (23/25) were present and the total search result could not be decreased without losing the sentinel set. The resulting strategy was primarily comprised of exploded subject headings and subheadings. The strategy was independently reviewed, and suggested terms incorporated. The final set of Ovid Medline search terms is shown in Table 2.

The resulting strategy will be applied to MEDLINE EMBASE and PsycINFO with bibliographic modifications if required. An adapted set of search terms will be used in CINAHL and the Australian Indigenous Health InfoNet. The search results will be restricted to English language only and studies published from January 1990 until the date the searches are conducted. Hand searches will be performed on relevant Cochrane Reviews, other relevant systematic reviews and the final set of search results identified for content analysis.

Table 1. Initial search terms

Search terms for Alcohol drinking	**Search terms for PHC**	**Search terms for implementation strategies**
Alcohol drinking OR Alcohol OR Drink*	Aboriginal community controlled health services.mp. OR expPrimary Health Care OR family practice OR general practice OR community	Intervention OR program* OR training OR initiative* OR strategy OR improve* OR Key Performance Indicator* OR total quality management OR framework

Table 2 Final search strategy (MEDLINE)

Search number	Search terms	Search results
	Group: Implementation strategies and treatments	
1	exp Mass Screening/	117466
2	exp Evaluation Studies as Topic/cl, ec, mt, st, td [Classification, Economics, Methods, Standards, Trends]	38931
3	exp evidence-based practice/ or evidence-based medicine/	81463
4	exp Counseling/	40688
5	exp "delivery of health care"/ or exp culturally competent care/ or exp delegation, professional/ or exp "delivery of health care, integrated"/ or exp health care reform/ or exp health services accessibility/ or exp healthcare disparities/ or exp managed care programs/ or exp practice patterns, nurses'/ or practice patterns, physicians'/	981412
6	Preventive Health Services/mt, og, st, sn, sd, td [Methods, Organization & Administration, Standards, Statistics & Numerical Data, Supply & Distribution, Trends]	5955
7	exp Epidemiologic Methods/	5596476
8	exp guideline adherence/ or exp program evaluation/ or exp quality assurance, health care/ or exp quality improvement/ or exp quality indicators, health care/ or exp "utilization review"/	393294
9	health assess*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	7439
10	health check*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	4047
11	exp Total Quality Management/ or PDSA.mp.	12514
12	PDCA.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	234
13	naltrexone.mp. or exp NALTREXONE/	8905
14	acamprosate.mp.	740
15	disulfiram.mp. or exp DISULFIRAM/	4000
16	pharmacotherapy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	22929
17	organi* interv*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	464

18	organi* innov*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	23420
19	organi* effect*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	978
20	organi* mode*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	1405
	Group: Alcohol drinking	
21	alcohol*.mp.	345191
22	alcoholic intoxication/ or exp alcoholism/ or exp binge drinking/	83141
23	exp alcohol drinking/ or exp binge drinking/	63352
	Group: Primary Health Care	
24	exp physicians, family/ or exp physicians, primary care/	18514
25	exp Primary Health Care/	140221
26	exp Family Practice/ or exp General Practice/	72342
27	Preventive Health Services/mt, og, st, sn, sd, td [Methods, Organization & Administration, Standards, Statistics & Numerical Data, Supply & Distribution, Trends]	5955
28	commun$ health.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	74124
	Combined searches	
29	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20	6425307
30	21 or 22 or 23	345396
31	24 or 25 or 26 or 27 or 28	286054
32	29 and 30 and 31	4327

Condition or domain being studied

Implementation strategies for evidence-based screening and treatment for unhealthy alcohol use in Primary Health Care settings.

Participants/population

Inclusion criteria:

Primary Health Care services. Primary Health care is defined as a health service with its primary aim being the provision of general health clinical care in the community.

Exclusion criteria:

- Outpatient services
- Community services providing specialist care e.g., early childhood clinics, diabetes clinics
- Emergency services
- Rehabilitation services

Interventions, exposures

An intervention/initiative/program or any other strategy in the PHC setting designed to improve evidence-based primary care practice in relation to unhealthy alcohol use. Evidence-based practice will be defined as some form of screening and subsequent provision of appropriate care (at minimum: brief intervention) as defined by key English language guidelines on managing patients with harmful alcohol use in PHC settings (37, 43).

The strategy can be part of a wider program to improve health service delivery to the population, which the PHC services serve e.g., chronic diseases programs, preventive care programs.

Comparators/controls

Usual care provided in Primary Health Care services/no intervention directed at services or their staff; before and after comparisons are included.

Types of studies to be included

Included studies:

All experimental and observational studies designed to detect change in service provision in response to a strategy to improve service delivery in PHC setting as defined above, reporting primary data, and reporting a quantitative outcome related to provision of service for unhealthy alcohol use.

Excluded studies:

- Non-original data studies
- Reviews, commentaries, and editorials
- Methods papers
- Studies not published in English
- Studies without abstracts
- Conference abstracts
- Studies not including quantitative outcomes
- Case studies
- Studies with outcomes not indicating service delivery improvement (e.g., outcomes of training describing only improvement in provider competence)

Table 1 Descriptions of selection criteria

Study characteristic	Inclusion criteria	Exclusion criteria
Population	Primary Health Care services or service providers working within those services. Primary Health care is defined as a health service with its primary aim being the provision of general health clinical care in the community. Other names for this include family practice, general practice. PHC services providing general health clinical care to specific patient populations e.g., DVA PHC services, paediatric services, Aboriginal Community Controlled Health Services.	Outpatient services of hospitals Community services providing specialist care e.g., mother and baby clinics, diabetes clinics, STD clinics Emergency services Rehabilitation services
Setting	The delivery of the implementation strategy must occur in a pragmatic PHC setting, i.e., evidence-based clinical procedures (i.e., screening/treatment for unhealthy alcohol use) are to be integrated into the routine practice of the clinical setting and administered primarily by regular service providers rather than research staff.	Studies where strategies are not delivered in a routine practice setting
Strategy/intervention	An intervention/initiative/program or any other change in the PHC setting designed to improve service provision or improve evidence-based practice in unhealthy alcohol use. The initiative can be part of a wider program to improve health service delivery e.g., chronic diseases programs, preventive care programs, mental health	Studies which aim to only increase referrals to specialist alcohol services
Outcomes	Primary outcomes must include at least one of the following: Change in alcohol screening rates (e.g., change in proportion of providers who screened at least one patient; change in proportion of patients screened over a time period), Change in provision of appropriate care for unhealthy alcohol use (i.e., patients drinking in a hazardous way, who may or may not have an alcohol use disorder, e.g., rate of eligible patients receiving brief intervention) Uptake of evidence-based approaches of management of alcohol use disorders,	Papers with outcomes not indicating service delivery improvement (e.g., outcomes of training describing only improvement in provider competence should not be included) Papers where referral to specialist alcohol services is the only primary outcome Papers not identifying the required quantitative outcomes

	particularly the offer or prescription of relapse prevention pharmacotherapies An attempt must be made to statistically compare the primary outcomes e.g., between control and intervention groups or between baseline and post-implementation	
Time period	1990 onwards, until the date of the search	
Study types	Interventional or observational and quantitative, involving interventions/programs/initiatives designed to improve service delivery for/ evidence-based practice including improving access to brief intervention or treatment of alcohol use disorders	
Publication type	Original research papers published in peer reviewed journals	Commentaries Editorials Non-original data studies Methods papers Studies not published in English Studies without abstracts Conference abstracts Reviews*

*Reviews of literature, including Cochrane reviews will be used to identify further relevant literature but will not be included in this study.

Context

The delivery of the strategy must occur in a pragmatic PHC setting, i.e., being delivered in settings in which evidence-based clinical procedures are integrated into the routine practice of the clinical setting and administered primarily by regular service providers rather than research staff.

Primary outcomes

Change in alcohol screening rates (e.g., change in proportion of providers who screened at least one patient; change in proportion of patients screened),

Change in rate of provision of appropriate care for unhealthy alcohol use (e.g., rate of eligible patients receiving brief intervention)

Change in rate of utilisation of evidence-based approaches of management of alcohol use disorders, including relapse prevention approaches such as pharmacotherapies

Secondary outcomes

Improvement in alcohol-related health outcomes

Data extraction (selection and coding)

Selection procedure:

4. Literature searches will be performed and downloaded into a common library in Endnote
5. Duplicates will be removed using Endnote import function, duplicates function and checked with a manual search.
6. Automated search for obviously irrelevant titles as well as ineligible publication types will be removed using Smart Groups.
7. The resulting subset will be uploaded for review to an online systematic review tool Covidence
8. Titles and abstracts of the resulting set will be reviewed for inclusion criteria by two reviewers. Where agreement cannot be reached a third reviewer will be consulted.
9. Full text review will be performed by two reviewers and further possible exclusions will be discussed with the review team.
10. References of the resulting set will be checked for any potentially relevant literature and reviewed for inclusion criteria as per steps 3 and 4.
11. Data from the final set will be extracted

A form will be pilot tested, then used to extract data from the final set. Extracted information will include bibliographic information (title, author, year, country etc), details of study design and setting description, description of the intervention/implementation strategy and its aims; description of follow-up including outcome measures and time-points, evidence of the intervention/strategy employing CQI elements.

Eligible literature will be identified using the selection criteria listed in table 1 above.

Risk of bias (quality) assessment

If there are sufficient studies, we will use the QI-MCQS tool (144) to appraise the quality of CQI studies for the subset of studies identified as employing CQI. The assessment will be conducted independently by two reviewers. Discrepancies will be resolved by discussion and if necessary, referral to a third reviewer.

Strategy for data synthesis

Data analysis will be performed in two stages: in stage 1, descriptive analysis will be performed on all papers meeting the selection criteria as well as a subset of papers describing initiatives occurring in Indigenous population settings; in stage 2, papers found to contain the three essential components of CQI defined by Rubenstein et al(69), will be assessed for quality using the QI-MQCS tool. A descriptive analysis of the effectiveness of the CQI strategies in improving evidence-based management of unhealthy alcohol use will be undertaken.

We will provide tabled summaries of quantitative outcomes indicating increase in rate of screening, or provision of brief-intervention and other evidence-based treatments for unhealthy alcohol use.

We do not anticipate that there will be scope for meta-analysis as the implementation programs involve complex interventions with many components that are unlikely to be sufficiently similar in enough studies to allow meta-analysis.

Analysis of subgroups and subsets

A descriptive analysis of service improvement strategies in Primary Health Care services working with Indigenous populations in Australia and other countries with similar colonization history will be undertaken. It is anticipated that the body of literature will be small.

A descriptive analysis of the effectiveness of the intervention in improving management of unhealthy alcohol use, particularly improvement in:

- Screening rates
- Brief interventions
- Relapse prevention medicines