BEING EQUALLY WELL

BETTER PHYSICAL HEALTH CARE AND LONGER LIVES FOR PEOPLE LIVING WITH SERIOUS MENTAL ILLNESS

TECHNICAL REPORT 2021.03
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Morgan, M; Peters, D; Hopwood, M; Castle D; Moy, C; Fehily, C; Sharma, A; Rocks, T; Mc Namara K; Cobb, L; Duggan, M; Dunbar, JA; Calder, RV.

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ABOUT THE PROJECT

This has been a collaborative project between the Mitchell Institute at Victoria University, the Australian Health Policy Collaboration and Equally Well Australia to answer the question: '*What needs to change at the front lines of clinical care and how can the changes be supported?*' to reduce the premature mortality and high rates of poor physical health of people living with serious mental illness.

ABOUT US

The Mitchell Institute for Education and Health Policy at Victoria University is one of the country's leading education and health policy think tanks and trusted thought leaders. Our focus is on improving our education and health systems so more Australians can engage with and benefit from these services, supporting a healthier, fairer and more productive society.

The Australian Health Policy Collaboration is led by the Mitchell Institute at Victoria University and brings together leading health organisations and chronic disease experts to translate rigorous research into good policy. The national collaboration has developed health targets and indicators for preventable chronic diseases designed to contribute to reducing the health impacts of chronic conditions on the Australian population.

Using a collective impact approach Equally Well Australia brings together more than 90 organisations who are committed to make improving the physical health of people living with mental illness a priority at all levels: national, state and territory, and regional. Supported by the National Mental Health Commission, Equally Well Australia undertook an extensive consultation process to develop the Equally Well National Consensus Statement. Launched in July 2017, implementing the actions of the Equally Well Consensus Statement has become a priority action of The Fifth National Mental Health and Suicide Prevention Plan, and a priority reform and 'start now' reform of the Productivity Commission Mental Health Inquiry report.

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CONTENTS

INTRODUCTION

The problem of poor physical health and premature mortality for people living with mental illness exists globally. The World Health Organization (WHO) in 2018 produced international guidelines for the physical health care of people living with serious mental illness recognising that people with serious mental illness have "a two to three times higher average mortality compared to the general population, which translates to a 10-20 year reduction in life expectancy… (with) …the majority of deaths amongst people with serious mental illness (-) attributable to physical health conditions" (World Health Organization, 2018).

A recent comprehensive publication by the Lancet Psychiatry Commission summarised the issue as:

The high rate of physical comorbidity, which often has poor clinical management, drastically reduces life expectancy for people with mental illness, and also increases the personal, social and economic burden of mental illness across the lifespan.

The Lancet Commission objective was to summarise advances in understanding of the problem of poor physical health in people with mental illness, and to "present clear directions for health promotion, clinical care and future research". An extensive body of meta-research affirmed that the most common physical health conditions associated with mental illnesses are cardio-metabolic diseases and conditions with a risk of obesity, diabetes and cardiovascular diseases between 1.4 to twice as high as in the general population (Firth et al., 2019).

In the Australian context, considerable effort has been made through recent years to improve the physical health of people living with mental illness. In 2015 and 2016, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) published a series of reports that examined barriers to health care for people living with both mental and physical health conditions and outlined what could be done to reduce these. The 2015 report noted the extensive international evidence of the higher rates of physical illness among people with serious mental illness. The report highlighted the complex factors in health care that contribute to the poor health outcomes for people with serious mental health conditions:

The health system is fragmented and frequently unaffordable with a lack of integration between physical and mental health care. Frequently, people with both serious mental and physical illness fall through the gaps between physical and mental health systems.

When consumers with mental illness report physical health symptoms, all too often they are not addressed because clinicians focus on mental illness to the exclusion of other health problems or symptoms, a phenomenon called 'diagnostic overshadowing'.

Furthermore some psychiatrists and others working in the mental health field do not recognise the treatment of physical symptoms as a key part of their role. Conversely, other doctors and clinicians don't feel confident to manage physical health problems in people with mental illness. The result is that this group can miss out on essential services altogether (The Royal Australian and New Zealand College of Psychiatrists, 2015).

A 2016 report for the RANZCP said that the lifespan gap for this population group:

represents a failure of health policy and practice – and presents a substantial challenge for both policy makers and health care providers.

That report assessed the economic cost of concurrent physical and mental health comorbidities as at least $15 billion annually in Australia (The Royal Australian and New Zealand College of Psychiatrists, 2016).

Equally Well Australia (EWA) was established in 2017 to lead and support collaborative work nationwide to make the physical health of people living with mental illness a priority at all levels: national, state/territory and regional. Supported by the National Mental Health Commission, EWA is a collective representing consumers, carers, professional colleges, Aboriginal and Torres Strait Islander organisations, Primary Health Networks (PHNs), peak bodies, community managed organisations, private health providers, non-government organisations and governments.

The Equally Well National Consensus Statement 2016 (National Mental Health Commission, 2016) provides guidance to health service organisations on what is required to provide health care that is safe, collaborative and effective in recognizing and responding to the health needs of people with serious mental illness. The Statement was supported by the National Mental Health Commission. Subsequently, the Fifth National Mental Health and Suicide Prevention Plan (Commonwealth of Australia, 2017) cited the Consensus Statement as strong guidance for how governments "can work together to better address the physical health of people living with mental illness".

The Plan states that:

systems are needed to measure continuity of care between primary care and specialist services, the quality of physical health care for people with severe and complex mental illness, and experiences of stigma or discrimination in general health settings. Better information is needed on the full range of clinical and community supports which underpin a connected and contributing life. New data collections established by PHNs and the NDIS may allow development of additional indicators on these issues, and priority will be given to ensuring that these collections align with existing state and territory data collections.

The Australian Institute of Health and Welfare has provided a summary of data and international evidence on the physical health of people living with mental illnesses in the national report Australia's Health 2020 (Australian Institute of Health Welfare, 2020). AIHW notes the lack of a national data set on the physical health of people living with mental illness and the lack of consistency in data collected across jurisdictions and different health settings.

The Productivity Commission undertook an inquiry during 2018-20 into the role of mental health in supporting economic participation, enhancing productivity and economic growth. The Inquiry was asked to make recommendations, as necessary, to improve population mental health, so as to realise economic and social participation and productivity benefits over the long term.

The Commission's final report in June 2020 included in its priority recommendations that: "Australian State and Territory Governments should agree to an explicit target to reduce the gap in life expectancy between people with severe mental illness and the general population, and develop a clear implementation plan with annual reporting against the agreed target" (Productivity Commission, 2020, p. 73).

More recently, the Royal Commission into Victoria's Mental Health System (State of Victoria, February 2021) found that physical and mental health services are poorly integrated for people living with mental illness. The Royal Commission report recommends a "responsive and integrated system with community at its heart" through six levels of service provision – from services for the largest number of people with mental health needs through to statewide services for the smallest number of people with needs. Each level is to work with the others providing integrated services and integrated support for individuals. The role of primary physical health care is identified – and integration will require system linkages between Commonwealth government subsidized primary health care services and state funded mental health services.

This recent history indicates that the need to do better is well recognized. Through the 5th National Mental Health Plan, Australian Governments have a shared aim to achieve system changes to support better physical health outcomes for those with mental illness. To do so requires strategies and structures that address the reasons why people living with serious mental health conditions die prematurely and have poorer physical health compared to the

general population. There are barriers to accessing appropriate healthcare for people living with mental illness and their carers; there are barriers that confront health care providers including information barriers, resource insufficiency, resource distribution, resource inflexibility and timing (Knapp et al., 2006). Contributing factors to these barriers for both consumers and healthcare providers include payment systems that rely on fees for services and effectively limit the potential for care to be planned and managed over time. Payment systems that are focused on single points of contact inhibit the capacity of health service providers to focus on prevention of deterioration and crisis. The 'system' is based on supply rather than demand, with poor integration and poor accountability for quality and safe health care for people with significant mental health needs (Duggan et al., 2020).

Without a systematic strategy aimed at prevention, early risk management and long term integration of health care of coexisting physical and mental health conditions, the current rates of premature mortality for people living with serious mental illness will be likely to continue unchecked, representing a scandalous failure of health care in Australia; an unacceptable level of harm to vulnerable individuals and preventable adverse impacts on health expenditure and the broader economy.

How can we do better?

There have been successive initiatives at differing levels of health care service provision that have aimed at improved health outcomes for individuals through system redesign, quality improvement, data utilisation. None has achieved widespread implementation and the poorer health status and life span gap for people with serious mental illness is persistent. Policies often fail at implementation as a top-down approach does not provide for frontline staff engagement and ownership. In a federated nation, local area and even state level initiatives may deliver improvements without influencing other similar services elsewhere, and many such initiatives, if not built from within the infrastructure at all levels of the service system, can atrophy as leadership, priorities and pressures shift.

In October 2019, a national symposium hosted by the Australian Health Policy Collaboration (AHPC)[1] and Equally Well Australia (EWA)[2], brought together academic experts and leading health professionals to identify the evidence-based interventions that would improve the physical health of people with mental health conditions.

This work follows on from that symposium and has been an interdisciplinary collaboration to develop policy and practice actions for clinical care systems and services that are evidence based, implementable and affordable.

The project reports

There are two reports from this work. The technical report, of which this is Volume 2, presents the comprehensive, evidence-based and practical changes that have been identified by multi-disciplinary experts involved in this work. It details systematic changes in policy and practice that are designed to deliver better physical health care for individuals, within the existing health services infrastructure. This volume 2 provides the appendices of the data and evidence that has informed much of the work reflected in the technical report volume 1.

A second report, *the National Policy Roadmap to Being Equally Well* (the *Roadmap*) provides practitioners, service providers, health service system supporting agencies, funders and policy-makers with a summary of the suite of changes proposed, changes that are evidence-based, implementable and affordable.

1 A national network of health organisations, health professionals and academic experts working to provide policy leadership on strategies to reduce preventable chronic disease in the Australian population. The Collaboration is supported by the Mitchell Institute, Victoria University and the Australian Government Departmnent of Health.

2 Equally Well is a collaborative network established to support those with mental illness to live loinger and have a good quality of life. Equally Well is supported by the National Mental Health Commission and provides resources that have been collected, collated and curatged to assist consumers, carers, professionals and service providers.

GLOSSARY OF TERMS

aCVR: absolute Cardio Vascular Risk assessment.

HbA1c: a blood test used to help diagnose and monitor people with diabetes.

CVD: cardiovascular disease.

Chronic physical diseases: Chronic physical diseases (also referred to as non-communicable diseases or long-term conditions) include a range of conditions that are non-infectious, long-lasting, and diminish health status due to disease symptoms, functional impairment and disability, and can reduce healthy life expectancy and cause premature deaths.

Clinical Quality Registry (CQR): are datasets that draw from existing health care data sources and platforms and are designed to report timely, actionable and risk-adjusted benchmarked data back to clinicians, health providers and other stakeholders for the purposes of quality improvement.

Clinical microsystems: are the small, functional front line units that provide most healthcare to most people. For this project they are described as follows:

- **Micro-system:** the teams at the front lines of care where patients and their families meet the health system. These teams include General Practice, acute and community mental health services
- **Meso-system:** Primary Health Networks (PHNs), Local Health Networks/Districts (LHN/Ds), professional and industrial bodies
- **Macro-system:** federal, state and territory governments; NMHC, AHMAC, private health insurance

General Practice Registers: are a dedicated register and recall system for people with specific health conditions needing ongoing monitoring and support.

Local Health Networks/Districts (LHN/Ds): are independent organisations that directly manage groups of public hospital services and their budgets and are directly responsible for hospital performance (Australian Institute of Health Welfare, 2021).

Medicare Benefits Schedule (MBS): MBS is a listing of the Medicare services (subsidised treatment by health professionals, such as doctors, specialists, optometrists and, in specific circumstances, dentists and other allied health professionals).

Mental and physical comorbidity: Is defined by the presence of at least one diagnosed mental health condition and one or more physical health conditions.

Multimorbidity/comorbidity: Multimorbidities are a growing concern worldwide, driven by population ageing and improvement of public health leading to lower mortality rates (United Nations, 2017). Multimorbidity is commonly defined as the presence of two or more chronic medical conditions in an individual (Fortin et al., 2007). However, multimorbidity has no single definition and is often given other names, including comorbidity and multiple morbidity. For the purpose of this paper, multimorbidity and comorbidity are used interchangeably.

Pharmaceutical Benefits Schedule (PBS): PBS is a list of medicines subsidised by the Australian Government.

Primary Health Networks (PHNs): 31 PHNs are independent primary health care organisations throughout Australia that commission services and support to primary health care and general practice (Commonwealth of Australia, 2018).

Primary Care Practices: principally general practices that are the entry point into the health care system that include care by general practitioners and can include nursing care, allied health care, midwifery, pharmacy, dental and Aboriginal health care (Commonwealth of Australia, 2018).

Serious/severe mental health conditions: the terms serious mental health conditions and serious mental illness are predominantly used in this paper. Severe mental illness is the term used in some working group reports and whenever the reported discussion is drawn from a referenced report or publication. The project working definition of serious mental illness has included conditions requiring antipsychotic therapy, those requiring shared care provided between psychiatrists and GPs and thought disorder conditions rather than neuroses.

Thematic analysis: a methodology that provides a rigorous and transparent process to identify the themes emerging and consolidating through the project process.

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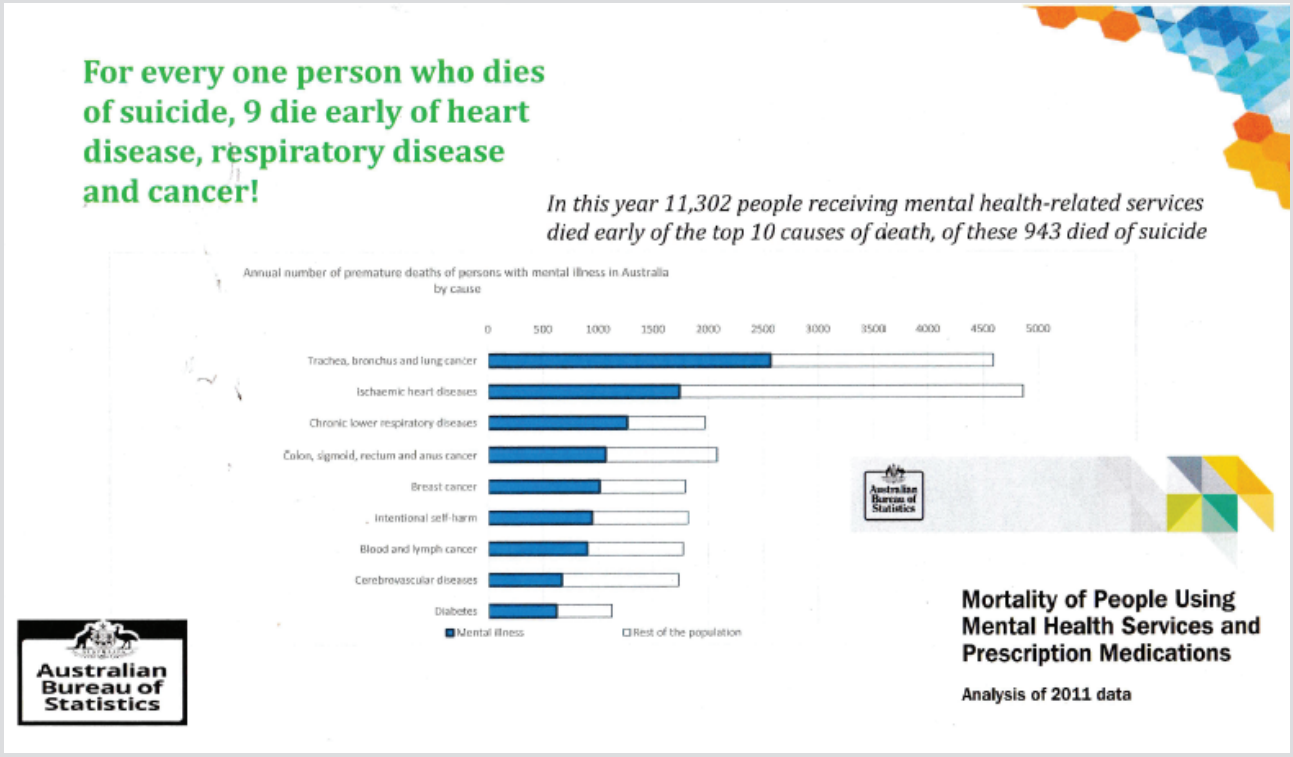
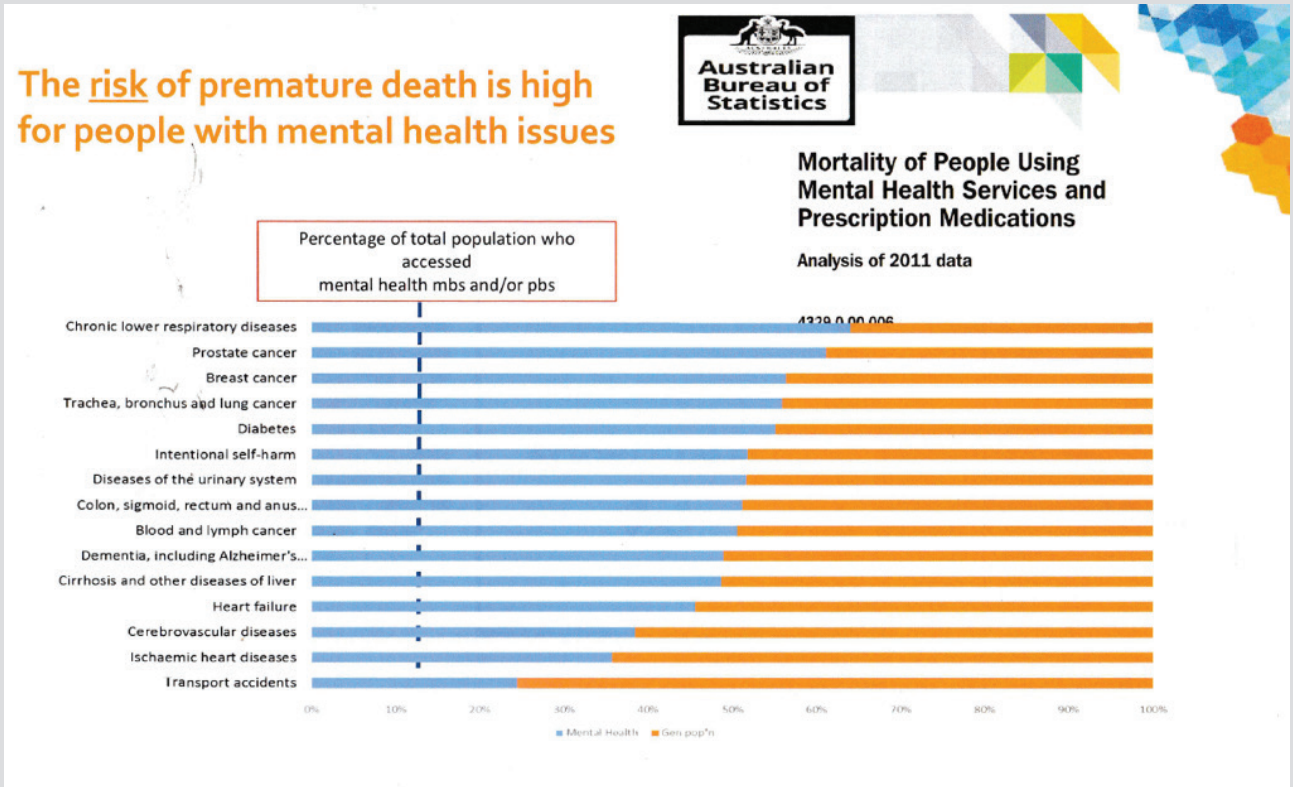
Fortin, M., Soubhi, H., Hudon, C., Bayliss, E. A., & Van den Akker, M. (2007). Multimorbidity's many challenges. British Medical Journal, 334(7602), 1016.

United Nations. (2017). *World Population Ageing 2017*. Retrieved from New York: http://www.un.org/en/development/desa/population/publications/pdf/ageing/WPA2017_Report.pdf

APPENDIX A: THE STARK DIVIDE

Australian Bureau of Statistics, 2017





APPENDIX B: THE USE OF PHARMACOTHERAPY TO REDUCE CARDIOMETABOLIC RISK IN PATIENTS WITH SEVERE MENTAL ILLNESS.

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Objective

To review current evidence relating to the use of antidiabetic medicines for the prevention of weight gain and cardiometabolic disease in patients with severe mental illness.

Background

There is considerable concern about the cardiometabolic risks associated with severe mental illness (SMI), particularly those patients who are also using antipsychotic medication. Not only are such patients more likely to have an increased baseline risk of various chronic diseases and poorer health behaviours than the general population, they are also at increased risk as a result of adverse effects associated with use of antipsychotic agents (Currie et al., 2019). Particular concern relates to the increased propensity for weight gain and subsequently increased diabetes risk associated with use of newer antipsychotic agents including olanzapine, clozapine and risperidone, aripiprazole, amisulpride and quetiapine (Castle et al., 2021). Among these, it has been identified that clozapine and olanzapine confer a high level of metabolic risk generally, followed by risperidone, quetiapine and paliperidone which have a moderate level of risk (De Hert et al., 2012; Liao et al., 2021).

There have already been many systematic reviews, and some comprehensive narrative reviews, examining the potential efficacy and effectiveness of using medicines to prevent the onset of cardiometabolic adverse events that arise from the use of antipsychotic medicines (see Box 1).

BOX 1. FOCUS OF REVIEWS EXAMINING USE OF ANTIDIABETIC MEDICATIONS FOR ANTIPSYCHOTIC INDUCED WEIGHT GAIN

Broad explorations of pharmacological agents

- Oral antidiabetic medicines for treatment of weight gain among adults taking any antipsychotic medicine (Hiluy et al., 2019)
- Pharmacologic interventions generally in the management of weight gain in patients with severe mental illness
- Pharmacologic interventions generally for the management of general cardiometabolic side effects in patients with schizophrenia using antipsychotic agents (Mizuno et al., 2014) generally, or more specifically second-generation antipsychotics (Das et al., 2012; Kanagasundaram et al., 2021)
- Pharmacological interventions generally to improve glycaemic control (in patients with or without diabetes) (Cernea et al., 2020; Taylor et al., 2017)
- Pharmacological interventions generally for clozapine-induced weight gain (Whitney et al., 2015)

Metformin use

- Metformin to prevent and/or treat weight gain in adults, and in children and adolescents (Ellul et al., 2018; Shin et al., 2009), using antipsychotics generally (Björkhem-Bergman et al., 2011; Bushe et al., 2009; de Silva et al., 2016; Hendrick et al., 2017; Zheng et al., 2015; Zhuo et al., 2018), or specifically second-generation antipsychotics (Ellinger et al., 2010; Hasnain et al., 2010; Khan et al., 2010; Lee & Jeong, 2011; Newall et al., 2012)
- Metformin for treatment of olanzapine-induced weight gain (Praharaj et al., 2011)

- Metformin for treatment/prevention of metabolic syndrome and metabolic abnormalities associated with antipsychotic use (Bushe et al., 2009; Jesus et al., 2015; Zheng et al., 2015)
- Efficacy and tolerability of metformin in combination with lifestyle measures to prevent weight gain for people for AP-related weight gain in schizophrenia
- Metformin to change weight and metabolic syndrome profile among people without diabetes who are taking clozapine (D. J. Siskind et al., 2016)

Other key medicines

- Glucagon-like peptide-1 (GPL-1) receptor agonists for antipsychotic-induced metabolic risk factors (D. Siskind et al., 2019)
- Topiramate for weight loss among patients with schizophrenia who use antipsychotics generally (Goh et al., 2019; Zhuo et al., 2018), or specifically second generation antipsychotics (Ellinger et al., 2010)

Metformin trials and systematic reviews – overview

Metformin appears to have considerably more evidence behind it than other pharmacological therapies relating to its use for weight loss among people with severe mental illness – in particular those using second generation antipsychotics. Nonetheless, most trials of metformin with adult participants reported in these systematic reviews have involved relatively small numbers of participants (e.g. 30-70 per trial) and short follow up periods, usually up to 3 or 4 months. A small number of RCTs have either a larger sample (>100 participants) or longer period of follow up (24-26 weeks), but not both. The total number of participants and trials identified was considerably increased in reviews where Chinese language databases were searched: in fact often the majority of trials and participants in such reviews were from Chinese-language trials. However, one systematic review identified that shortcomings in a number of Chinese language studies included lack of intention to treat data, failure to specify funding sources, and lack of double blinding; overall, few Chinese studies were considered high quality (D. J. Siskind et al., 2016; Zheng et al., 2015). Zheng et al., and others, also identified substantially greater reductions in mean weight loss and BMI among participants in Chinese RCTs compared with non-Chinese trials (Zheng et al., 2015). It is unclear if this difference relates to younger age of participants, study design, or other factors.

Trials examining the impact of metformin on weight gain have explored its role both as a preventative therapy for weight gain induced by antipsychotic agents and also to manage and reverse weight gain already accrued, up to a year after initiation of the antipsychotic agent. An increasing amount of evidence over the past 10-12 years has also examined broader cardiometabolic risk factors including lipid profile and blood sugar control/ diabetes onset, in addition to cholesterol, blood sugar and weight; and also outcomes for a broad variety of nationalities and ethnic groups, as well as sex-specific effect. Mostly trials have recruited participants already taking or about to commence second-generation antipsychotic agents (i.e. those with greatest propensity to cause weight gain), particularly olanzapine or clozapine. Therefore, results must be considered from the perspective of having less evidence related to conventional antipsychotics (with less propensity for weight gain), or individuals who may not be using antipsychotic therapy. The evidence seems to span a range of ethnic groups (Bushe et al., 2009; D. J. Siskind et al., 2016).

Metformin trials and systematic reviews – meta-analysis outcomes

Table 1 presents relevant key meta-analytic findings from a broad variety of systematic reviews involving metformin, topiramate or glucagon-like peptide-1 receptor agonists as the key pharmacological intervention. While the specific populations of interest, antipsychotic of interest, antidiabetic of interest, and trial parameters such as timeframe for outcome measure varies, the key message across reviews remain relatively consistent for metformin:

- Metformin seems to be an effective and relatively safe option to prevent or reverse some of the weight gain associated with antipsychotic use[3]. Reviews suggest a mean of 3-5kg weight loss is achieved on average compared with placebo/usual care – see Table 1.
- Metformin with or without adjunctive lifestyle modification achieved a net weight loss across multiple reviews, however the combination may be more effective than metformin alone (Goh et al., 2019; Hiluy et al., 2019). Despite the absence of definitive evidence, the general conclusion is that

3 While metformin is relatively safe and does not cause hypoglycaemia, caution should still be applied with use in some patients, particularly among those with renal insufficiency who are more at risk of lactic acidosis.

careful consideration of use is warranted on an individual basis, particularly if lifestyle modification has not been effective.

- Factors that might suggest an increased potential for benefit include the use of a second-generation antipsychotic (greater risk of weight gain), younger patients, and initiation of metformin very early, or prior to, initiation of antipsychotic therapy (de Silva et al., 2016; Hiluy et al., 2019). That said, analysis by Björkhem-Bergman et al. questions this general consensus, and suggests potentially negligible difference in impact if metformin is initiated as a preventative measure or to address established weight gain.
- Several reviews have further examined other cardiometabolic risk factors, particularly waist circumference, fasting sugar, insulin resistance, blood pressure diabetes onset and lipid profile. The evidence in favour of metformin appears, perhaps unsurprisingly, consistently positive for outcomes that are directly related to its primary indications such as BMI, waist circumference, HbA1c and fasting blood glucose (Table 1). The evidence is somewhat more conflicting for other cardiometabolic risk factors such as blood pressure and various lipid parameters. The potential for significant benefits around these broader cardiometabolic factors therefore remains less clear.

Clinical implications and context

Our guidance with respect to diabetes prevention is very much in keeping with recommendations regarding the role of metformin, outlined by the Australian Diabetes Society (ADS) in their position statement *The prevention and management of type 2 diabetes in the context of psychotic disorders (*Chen et al., 2017), published in 2017.

The ADS position statement clearly sees a potential role for metformin in achieving weight loss (and therefore also possibly diabetes prevention) in people commencing antipsychotics:

"The efficacy of pharmacotherapy to attenuate antipsychotic induced weight gain has been investigated (78, 82-86), with metformin being the most studied to date. The results of various meta-analyses suggest that if a pharmacological agent is to be considered, that metformin is likely to be the most suitable agent for the prevention and treatment of weight gain associated with SGA medication (83-85). These results though also need to be interpreted with some caution (90)

*The efficacy of pharmacotherapy to attenuate antipsychotic induced weight gain has been investigated (78, 82-86), with metformin being the most studied to date. The results of various meta-analyses suggest that if a pharmacological agent is to be considered, that metformin is likely to be the most suitable agent for the prevention and treatment of weight gain associated with SGA medication (83-85). These results though also need to be interpreted with some caution (90).**The (ADS Statement) Page 13 role of appropriate lifestyle interventions may account for at least some of the reported beneficial effect of metformin in this setting (88)*

Studies indicating that metformin has no beneficial effect on patients' body weight have involved relatively older cohorts, with longer disease and treatment durations, while the more 'significant studies', that have suggested a beneficial effect from metformin, have involved younger individuals, with shorter histories of psychotic illness (86). A recent meta-analysis indicated that the beneficial effects of metformin appeared to be greatest in those with first episode psychosis (87). In an analysis of 40 studies, where pharmacotherapy was considered to attenuate weight gain, the most substantive evidence of benefit was with metformin usage (3.17kg weight difference as compared to placebo). Drugs such as topiramate and reboxetine have also been studied as weight loss agents in this setting but these carry the possibility of significant side effects and the potential for drug interactions.

Female patients who are prescribed metformin should be advised about the possibility of resumption of menstruation if periods have been irregular, and a potential increase in fertility (91,92). In Australia, metformin is neither TGA-registered nor listed on the Pharmaceutical Benefits Scheme for indications other than the treatment of diabetes. If metformin is to be considered for use, it should only be considered after consultation with a physician and after a detailed discussion with the patient regarding the indications, contraindications, precautions and cost (private script so not subsidised).

Overall, the potential value of lifestyle measures should not be underestimated, particularly in light of diabetes prevention studies (98-100) which have highlighted the benefits of physical activity and appropriate dietary modifications among those with impaired glucose tolerance [ADS Statement pp 12,13] (Chen et al.)".

Metformin – interpreting the outcomes evidence

A further caveat of the evidence in systematic reviews for metformin and other individual agents is that not all have undertaken subgroup meta-analysis for those without (and with) diabetes at baseline. However Taylor et al.'s subgroup analysis did examine this for antidiabetic medication generally (including metformin) and found no significant improvement for either HbA1c or fasting glucose (although the combined group did show a significant improvement in HbA1c). This may in part be due to small numbers of participants in subgroups (Taylor et al., 2017). Others such as Siskind et al. (2016) and Björkhem-Bergman et al. (2011) included only participants without diabetes at baseline when examining the impact of metformin on BMI and metabolic syndrome components for those taking clozapine – both of these reviews identified a significant reduction in weight following metformin therapy.

Likewise, while several systematic reviews included trials with participants taking any antipsychotic therapy (or none), in reality most data were derived from participants taking the atypical antipsychotics clozapine and olanzapine, and use alongside conventional antipsychotic should be considered in this context.

Other medications – evidence from systematic reviews

There is evidence for some other pharmacological agents relating to weight gain and other cardiovascular risk factors among individuals with severe mental illness. The most notable of these in terms of number of trials identified and suggested benefit for weight is topiramate (Hiluy et al., 2019). This has been the subject of a smaller number of trials and systematic reviews – results have been positive for weight gain but there has been little examination of a role for topiramate directly on diabetes onset, or for other metabolic outcomes such as cholesterol. A further note of caution in addition to the distinct lack of a substantive evidence base is the fact that it is centrally acting. Although general psychotic symptoms may not be adversely affected, this remains an area for further exploration (Goh et al., 2019). A separate concern is the potential for increased risk of suicide ideation – this has been a concern with use of topiramate for a variety of interventions including weight loss (Wilding et al., 2004), and was a major source of therapy discontinuation in a recent observational study examining topiramate and other agents for reduction of metabolic risk for patients with severe mental illness in Australia (Tham et al., 2021). Drug interactions and possible direct actions may adversely affect control of mental health conditions such as schizophrenia (Goh et al., 2019; Hiluy et al., 2019). The short-term nature of most studies makes it difficult to evaluate long-term safety, hence even a quite recent systematic review involving 10 trials and 905 patients identifies the need for larger and more definitive studies (Goh et al., 2019).

In terms of other antidiabetic therapies, the data seems promising, but again there does not appear to be enough published outcomes of substantive trials to allow any firm conclusions. For example, systematic reviews of trials involving Glucagon-like peptide-1 (GLP-1) receptor agonists are only just emerging. Siskind et al. (2019) identified significant improvements in weight, waist circumference, body mass index, HbA1c, fasting glucose and visceral adiposity, but it was on the basis of only three trials with a combined 194 participants, an average of only 16 weeks follow up, and a majority who were using the second generation antipsychotic agents olanzapine or clozapine. There was also a very high prevalence of nausea within the intervention groups compared with control group participants (54% vs 27%). A subsequent pilot RCT (n=47) using high dose liraglutide (3mg) vs placebo suggests the possibility of increased weight loss and HbA1c reduction at 6 months when GLP-1 RAs are used at higher doses – although increased rates of gastrointestinal side effects may also be present, and there was a high rate of participant withdrawal/loss to follow up (Whicher et al., 2021). The highly promising results appear to be supported by an Australian observational study of adults managed for metabolic syndrome over 52 weeks, with various pharmacotherapy options alongside lifestyle modification and cognitive behavioural therapy support (Tham et al., 2021); among the 87 patients taking liraglutide at study completion, alone or in combination, there were substantial reductions in weight and waist circumference, and lipid profile improvements. There was equally no evidence of deterioration in mental health symptoms (and possibly minor improvements). However, there were high rates of GI side effects in particular (nausea, constipation, abdominal pain), with constipation in particular being cited as a key reason for liraglutide discontinuation. Hence there remains much work to be done before any strong conclusions could be drawn about generalisability, or long-term efficacy and safety.

Summary

In summary, metformin appears highly promising as a therapeutic option for the prevention and management of weight gain associated with antipsychotic use, and related to this. diabetes prevention. There is also significant reason to think that it may be beneficial for related cardiometabolic risk factors. However, use remains off-label for these purposes in individuals without diabetes, and there remains an absence of a large definitive trial with long periods of follow up (>6 months). Furthermore, trials have tended to focus on outcomes related to risk management rather than clinical endpoints. Therefore, consideration of use is warranted but requires careful consideration of the clinical and social context for the patient. The evidence does not seem strong enough for other pharmacological agents to contemplate their use in routine practice at this time, but as noted there appears to be quite promising data emerging to support GLP-1 receptor agonists. However, perhaps the most important medication issue in addressing weight gain is to select the most appropriate antipsychotic agent for management of severe mental illness at the outset. There is a compelling rationale that the prescribing of such agents should be on the basis of 'first do no harm'. This may help to avoid the considerable adverse event burden in patients with severe mental illness (English & Castle, 2021).
In patients with established weight gain, consideration of antipsychotic switching might also be of use (Taylor et al., 2017). Clearly a thorough consideration of potential impact on mental health and broader potential for adverse events is warranted first. The potential impact may also depend on the medications involved – evidence seems to suggest that switching from a drug with high levels of metabolic risk to amisulpride or ariprazole (both with low levels of risk) demonstrates potential benefits for weight and blood glucose within 4-8 weeks that remains evident at 52 weeks. However, there remains a high degree of discontinuation of switching (Liao et al., 2021).

Review	Changes observed, compared with non-medicated/placebo comparator group								
	N (meta-analysis)	T	Weight	Waist circumference	TC	TG	HbA1c	FG	Other
METFORMIN*									
Kanag-asundaram et al. (2021)	565		**Significant** -2.01 kg (95% CI -2.88, -1.14) (n=565)	**Not significant** -1.10 cm (95% CI -2.32 cm, 0.12 cm) (n=364)	**Significant** -14.40 mg/dL (95% CI -26.51 mg/dL, -2.28 mg/dL) (n=419)	**Significant** -21.01 mg/dl (-32.39, -9.64 mg/dL (n=565)	**Significant** -0.08% (-0.14%, -0.03%) (n=272)		**Significant** BMI -0.76 (-1.04, -0.48) (n=385) Mean blood insulin -4.97 (-6.96, -2.98) (n=521) HOMA IR -1.15 (-1.65, -0.64) (n=375) **Not significant** HDL 2.46 mg/dL (-1.15, 6.06 mg/dL) (n=565) LDL -12.52 (-35.86, 10.82 mg/dL) (n=419) BGL 0.15 mg/dL (-2.85, 3.15) (n=565, unclear if fasting or not) SBP -2.25 mmHg (-7.23 mmHg, 2.74 mmHg) (n=146)
Hiluy et al. (2019)[SMI]	843		**Significant** -3.27 kg (95% CI, -4.49 to -2.06)						
Zheng et al. (2015)[AP]	732		**Significant** Metformin plus lifestyle inter-vention versus metformin alone n = 64, WMD: – 1.50 kg [95% CI: – 2.98, – 0.02] (2) Metformin plus lifestyle intervention versus lifestyle intervention – 3.30 kg [95 % CI: – 4.78, – 1.82]	**Not significant** Metformin plus lifestyle versus metformin alone -2.33cm (-5.90cm, 1.25cm) NS (n=191) Metformin plus lifestyle versus lifestyle inter-vention -2.10cm (-2.83cm, -1.38cm) (n=343) Metformin plus lifestyle interven-tion vs. placebo -2.4 (-5.87, 1.05) (n=124)					**Significant** Metformin plus lifestyle versus metformin alone: BMI (n = 191, WMD: – 1.08 kg/m2 [95% CI: – 1.97, – 0.19], (2) Metformin plus lifestyle versus life-style intervention BMI (3 RCTs, n = 343, WMD: – 1.45 kg/m2 [95 % CI: – 1.93, – 0.97]
Zhuo et al. (2018)[AP]	763		**Significant** -2.50 kg (95% CI: -3.21, -1.80)						

Table 1. Key meta-analysis results measuring the effects of metformin, topiramate, and glucagon-like peptide-1 receptor agonists on weight and other cardiometabolic risk factors among patients with severe mental illness, 2010-2021

Review	Changes observed, compared with non-medicated/placebo comparator group								
	N (meta-analysis)	T	Weight	Waist circumference	TC	TG	HbA1c	FG	Other
Taylor et al. (2017)[SMI]	Not stated (sub-group analysis)						**Significant** -0.08%; 95% CI, [-0.14%, -0.03%]	**Significant** -0.15 mmol/L (95% CI, -0.29 mmol/L, -0.01 mmol/L)	
Siskind et al. (2016)[CL]	478		**Significant** -3.12kg, 95%CI -4.88kg, -1.37kg (n=306)	**Significant** -1.69cm (95%CI -3.06cm, -0.32cm)			**Significant** -0.17mmol/L (95% CI -0.30mmol/L, -0.03mmol/L) (N=284)	**Significant** -0.60mg/dL (95% CI -1.03mg/dL, -0.17mg/dL) (N=478)	**Significant** BMI (-1.18kg/m2, 95%CI -1.76kg/m2 to -0.61kg/m2 (n=306) Insulin -5.63 mU/L (-9.57 mU/L, -1.68 mU/L) HOMA -0.89 (-1.06, -0.72) **Not significant** HDL +0.015 (95% CI -0.02, 0.16) (n=282) SBP 0.07 (-0.51, 0.66) (n=146) DBP -0.23 (-0.79, 0,33) (n=146) LDL -0.10 mmol/L (95% CI -9.57 mmol/L, -1.68 mmol/L) (N=227)
Zheng et al. (2015)[AP]	1547		**Significant** (n=1279) -0.91 (95% CI, -1.40 to -0.41) [prevention] -0.66 (CI, -1.02 to -0.30) [yr 1] -0.50 (CI, -0.73 to -0.27) [chronic] –0.54 (–0.81 to –0.26) [high quality trials, n=611]	**Significant** -0.35 cm (95% CI -0.66 cm, -0.44cm) (n=575)	**Significant** –0.34 (95% CI –0.55 to –0.12) [high quality trials, n=335]	**Significant** –0.28 (95% CI –0.48 to –0.07) [high quality trials, n=364]	**Significant** -0.38 mmol/L (95% CI -0.69 mmol/L, -0.07 mmol/L) (n=3838)	**Significant** FBG -0.65 mmol/L (95% CI -0.95 mmol/L, -0.35 mmol/L)	**Significant** BMI -0.67 (95% CI –1.00 to –0.34) [high quality trials, n=611] Fasting insulin -0.64 µIU/mL (95% CI -1.03, -0.25) (n=787) HOMA IR -0.74 (-1.11. -0.40) (n=780)

Table 1. Key meta-analysis results measuring the effects of metformin, topiramate, and glucagon-like peptide-1 receptor agonists on weight and other cardiometabolic risk factors among patients with severe mental illness, 2010-2021

Review	Changes observed, compared with non-medicated/placebo comparator group								
	N (meta-analysis)	T	Weight	Waist circumference	TC	TG	HbA1c	FG	Other
Mizuno et al. (2014)[AP]	757		**Significant** -3.17 kg (95% CI: -4.44, -1.90 kg)		**Significant** -5.38 mg/dL (95% CI: -26.59 mg/dL, 15.82 mg/dL) (n=255)		**Significant** -0.08% (95% CI: -0.13%, -0.03%) (n=264)	**Significant** -3.18 mmol/L [(95% CI: -6.33 mmol/L, -0.03 mmol/L] (n=679)	**Significant** Fasting Insulin (, -7.47 µIU/L [-11.02 µIU/L, -3.91 µIU/L] (n=672) HOMA-IR -1.85 [-2.75, -0.96] (n=526) **Not significant** LDL-Cholesterol (-4.43 mg/dL (-34.23 mg/dL,+25.36 mg/dL) (n=255)
Gierisch et al. (2014)[SMI]			**Significant** –4.13 kg; 95% CI, –6.58 to –1.68						Unable to access full text for glucose- and lipid-related +topiramate results
Das et al. (2012)			Y						Unable to access full text
Björkhem-Bergman et al. (2011)[AP]	328 (adults)		**Significant** Overall: -4.8% (95% CI -1.6%, -8.0%) Subgroup with >10% wt gain: -7.5% (95% CI -2.9 to -12.0)						
Praharaj et al. (2011)[OL]	105		**Significant** -5.02% (95% CI -3.93%, -6.10 %)	**Significant** -1.42 (95% CI -0.29, -3.13) cm					**Significant** BMI -1.82 (95% CI -1.44, -2.19)
de Silva et al. (2016)[AP]	645 (adult sub-group)		**Significant** -3.24 kg (95 % CI -1.76kg, -4.72kg)					**Not significant** FBG –2.48 mg/dl (95 % CI –5.54 mg/dl to 0.57 mg/dl)	**Significant** BMI [-1.11 kg/m2 (95 % CI -1.62 to -0.60) Insulin resistance index -1.49 (95% CI -2.40, -0.59)

Table 1. Key meta-analysis results measuring the effects of metformin, topiramate, and glucagon-like peptide-1 receptor agonists on weight and other cardiometabolic risk factors among patients with severe mental illness, 2010-2021

Review	Changes observed, compared with non-medicated/placebo comparator group								
	N (meta-analysis)	T	Weight	Waist circumference	TC	TG	HbA1c	FG	Other
TOPIRAMATE									
Hiluy et al. (2019)[SMII]	512		**Significant** -5.33 kg (95% CI, -7.20 to -3.46)						
Goh et al. (2019)[AT]	905		**Significant** All: -3.76kg; 95% CI, -4.82kg to -2.69kg) Double blind RCT subgroup: -1.17 kg; 95% CI, -1.56 kg, -0.77 kg;	**Significant** -1.70cm (95% CI, -2.83 to -0.57cm) (n=331)	**Not significant** -0.75 mmol/L [-1.58 mmol/L, 0.07 mmol/L] (n=187)	**Significant** -0.68 mmol/L [-1.24 mmol/L, -0.13 mmol/L] (n=268)		**Not significant** -0.43 mmol/L [-1.00 mmol/L, 0.15 mmol/L] (n=369)	**Significant** Overall BMI -1.62; 95% CI, -2.13 to -1.12 (n=608) [Double blind RCTs, BMI -1.08; 95% CI, -1.55, -0.61] Fasting blood insulin -0.61 [95% CI -1.10, -0.12] (n=67) Insulin resistance -1.27 [95% CI -1.79, -0.74] (n=67) SBP -0.78 mmHg [95% CI -1.28 mmHg, -0.28 mmHg] (n=67) LDL -0.80 mmol/L [95% CI -1.06 mmol/L, -0.53 mmol/L] (n=247) **Not significant** HDL -0.07 mmol/L [95% CI -0.58 mmol/L, 0.44 mmol/L] (n=247) DBP -0.45 mmHg [95% CI -0.93 mmHg, 0.04 mmHg] (n=67)
Zhuo et al. (2018)[AP]	358		**Significant** -3.07 kg (95% CI: -5.57, -0.48)						
Das et al. (2012)			Y						Unable to access full text

Table 1. Key meta-analysis results measuring the effects of metformin, topiramate, and glucagon-like peptide-1 receptor agonists on weight and other cardiometabolic risk factors among patients with severe mental illness, 2010-2021

Review	Changes observed, compared with non-medicated/placebo comparator group								
	N (meta-analysis)	T	Weight	Waist circumference	TC	TG	HbA1c	FG	Other
GLP-1 RA									
Zhuo et al. (2018)[AP]	168		**Significant** - 3.71 kg (95% CI = -2.44 - -4.99 kg)	**Significant** –3.00cm (SE 0.68 cm); p<0.001		**Not significant** TG -0.24 mmol/L (SE 0.12, p= 0.055)	**Significant** –3.25 mmol/L (SE 0.66 mmol/L; p<0.001)	**Significant** –0.45 (SE 0.09 mmol/L, p<0.001)	**Significant** BMI –1.19 (SE 0.22, p<0.001) 0.218 HDL LDL -0.17 (95% SE 0.08, p=0.03) Visceral fat -177.5g (SE68.7, p=0.011) **Not significant** HDL -0.01 (SE 0.02), p=0.566) SBP -1.89 (SE 1.61, p=0.241) DBP -1.91 (SE 1.17, p=0.104) HOMA -0.58 (SE=0.59, p=0.723) Insulin 4.59 pmol/L (SE 12.93, p=0.723)

* Includes metformin in isolation or with lifestyle. Where there are separate trial arms with and without lifestyle modification, results for 'with' are presented

Abbreviations:

DBP, diastolic blood pressure;

FPG, fasting plasma glucose (mg/dL = mmol/L*18); HbA1c, haemoglobin A1c (NGSP = (0.09148*IFCC) + 2.152);

HDL, high-density lipoprotein cholesterol (mg/dL = mmol/l*38.6);

HoMA, homeostatic model assessment insulin (mU/L = pmol/L*0.144);

IFCC, International Federation of Clinical Chemistry;

LDL, low-density lipoprotein cholesterol (mg/dL = mmol/l*38.6);

NGSP, National Glycohaemoglobin Standardization Programme;

SBP, systolic blood pressure;

TGs, triglycerides (mg/dL = mmol/L*88.5)

OL = Olanzapine;

AI = any atypical/second generation ansipsychotic;

AP = receiving antipsychotic treatment;

SMI = any patient with severe mental illness (+/- medication).

Table 1. Key meta-analysis results measuring the effects of metformin, topiramate, and glucagon-like peptide-1 receptor agonists on weight and other cardiometabolic risk factors among patients with severe mental illness, 2010-2021

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APPENDIX C: A BRIEF HISTORY OF THE CLINICAL MICROSYSTEMS APPROACH

Maria Duggan PhD[1] and James A Dunbar MD[2], February 2021

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2. Deakin Rural Health, School of Medicine, Faculty of Health, Deakin University. Clinical and Research Advisor, Australian Health Policy Collaboration.

The landmark report by the Institute of Medicine, *Crossing the Quality Chasm*, recognised that hierarchical bureaucratic (top-down) approaches to quality of care were not working. The report identified the need to address these deficiencies in part by optimising the way that small clinical teams - *microsystems* - function.

The idea was not new. W. Edwards Deming, the father of quality improvement and James Brian Quinn taught us that systems by their nature must have an aim and their subcomponents must work synergistically to achieve that aim.

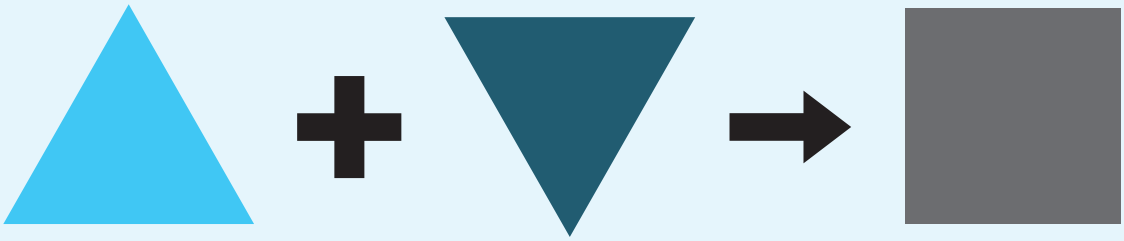
Quinn observed that top performing companies were successful as a result of their focus on the *smallest replicable units* of their business. These top performing companies achieved their performance by *empowering frontline teams*.

Successful companies recognise that their workers are the link between the organisation and the customer as is also the case in the healthcare system for clinicians, patients or consumers and carers. Consequently these frontline teams are best suited to redesign workflow to meet the customer's ever-changing needs.

Professors Paul Batalden and Eugene Nelson at Dartmouth College Medical School pioneered the application of *Clinical Microsystems thinking* to healthcare.

Formula for improvement

Engage the microsystem with the peer-reviewed literature.
Provide support as microsystem takes "intelligent action" (i.e. targeted changes) in clinical practice.



Generalisable Knowledge

What the evidence suggests from the scientific literature?

Context knowledge

What do we learn from each other, and from understanding the clinical situation?

Improvement knowledge

What measures demonstrate improvement?

So what's new?

What is new is bringing the *context knowledge of the frontline staff* to bear on the problem of improving the quality of care.

In the case of physical conditions among people with serious mental illness, much of the generalisable knowledge is already known to most if not all of the working groups.

The key element of the *Being Equally Well* project is to bring to bear the context knowledge of those of you at the frontline where clinicians and consumers meet. Context knowledge can and must drive policy. Without it, top down policy is at best based on incomplete evidence and usually unimplementable.

Our challenge is to produce policy that is implementable at the front lines of care.

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APPENDIX D: NATIONAL EQUALLY WELL QUALITY IMPROVEMENT COLLABORATIVE – DISCUSSION PAPER

Kimberley Fitzpatrick, February 2021

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Introduction: The Value of Collaboratives

No one would dispute that the system of care in many countries shows the determination to advance quality and safety in care was a fundamental commitment from the majority of systems throughout the world.

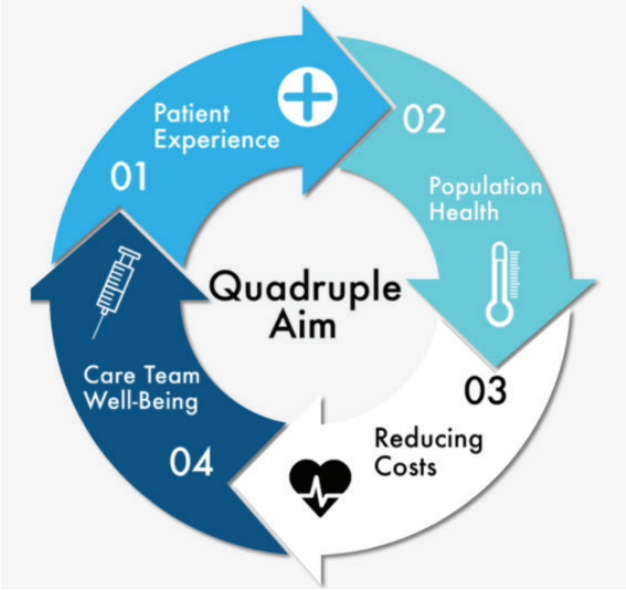
In this introduction I want to start at the point in time when The Quality Chasm report was published in the U.S. it was never the intention of the authors to give this title to their work. What emerged was not a series of gaps but a systemic chasm in the evidence and reliable measurable quality and safety. The report left us with what became the six aims of health care, that health care can be safe, effective, patient centred, timely, efficient, and equitable.

The report concluded that the system was not designed to deal effectively with the burden of chronic disease. The system is poorly designed. Care for even a single condition is fragmented across many clinicians and settings with little coordination or communications and some needs remain undetected or unmet. This is a feature of many health care systems in the developed world and relevant to the subject of this paper.

The paper refers to the Early Years Collaborative in Scotland. What emerged was real understanding of the method of improvement from a holistic approach not just pathogenic. The Early Years Collaborative in Highland brought agencies together, not just statutory but also voluntary, to improve lives of those with mental health and physical health vulnerabilities.

That is the essence, Collaborative is a noun not an adjective.

Quality Improvement Approach: Quadruple Aim, Model for Improvement and Collaboratives



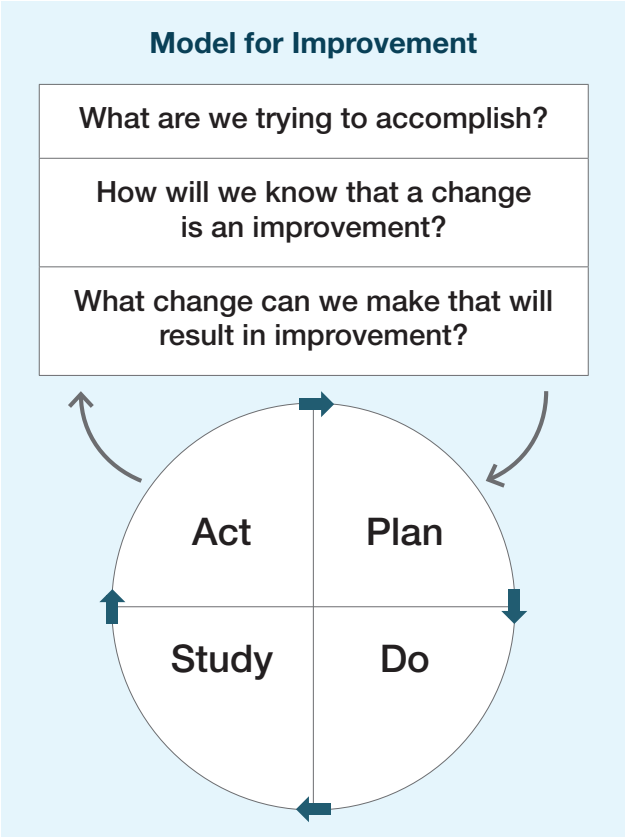
Quality improvement aims to make a difference to patients by improving safety, effectiveness, and experience of care by using understanding of the complex healthcare environment, applying a systematic approach, and designing, testing, and implementing changes using real time measurement for improvement.

In 2006, Nolan and Whittingham, US Primary Care Physicians, described the triple aim. Previous attempts recognised singular aims appropriate for acute based care, however care delivery in primary care and community settings requires simultaneous pursuit of three aims:

- improving the experience of care,
- improving the health of populations, and
- reducing per capita costs of health care.

(Nolan, Whittingham & Berwick, 2012).

But the Triple Aim does not explicitly acknowledge the critical role of the workforce in healthcare transformation. We propose a modification of the Triple Aim to acknowledge the importance of physicians, nurses and all employees finding joy and meaning in their work. This 'Quadruple Aim' would add a fourth aim: improving the experience of providing care (Sikka, Morath & Leape, 2015).



The IHI's Model for Improvement provides a methodology for developing, testing and implementing changes leading to improvement. Using plan-do-study-act (PDSA) cycles enables testing changes on a small scale, building on the learning from these test cycles in a structured way before systemwide implementation.

The Model for Improvement asks three questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in improvement?

The IHI Breakthrough Collaborative is an improvement method pioneered by the US Institute for Healthcare Improvement that relies on spreading and adapting existing knowledge of best practice care to multiple settings for a common aim. The goal of a Collaborative is to achieve results, and to close the gap between evidence-based medicine and evidence-based delivery.

A Breakthrough Series Collaborative is a short-term (6- to 15-month) learning system that brings together a large number of teams from hospitals or clinics to seek improvement in a focused topic area.

There is significant evidence that this methodology delivers results in terms of patient outcomes on a wide range of healthcare problems across many countries. The method involves the following key elements:

- Formation of an Expert Panel
- Three face-to-face learning sessions
- Monthly Reviews of process during action periods
- Regular coaching and advice.

Support for enrolled teams

To gain the most from the Learning Sessions and Action Periods it is essential that there is robust preparation in advance. An "Equally Well Collaborative Improvement Team" will support enrolled teams to:

- Identify their local physical health improvement team
- Map their local baseline data
- Prepare for and gain maximum benefit from the Learning Sessions,
- Determine local tests of change to implement the evidence-based bundle
- Utilise measurement tools by which to assess their progress during the life of the Collaborative
- Share results from their rapid change tests with peers and learn from successes and challenges.

The project will also assist participating teams to spread their achievements across their own hospital, clinic or health service.

History and Success of Collaboratives

Since 1995, IHI has sponsored over 50 such Collaborative projects on several dozen topics involving over 2,000 teams from 1,000 health care organizations. Collaboratives range in size from 12 to 160 organisational teams. Each team typically sends three of its members to attend Learning Sessions (three face-to-face meetings over the course of the Collaborative), with additional members working on improvements in the local organisation. Teams in such Collaboratives have achieved dramatic results, including reducing waiting times by 50 percent, reducing worker absenteeism by 25 percent, reducing ICU costs by 25 percent, and reducing hospitalizations for patients with congestive heart failure by 50 percent. In addition, IHI has trained over 650 people in the Breakthrough Series methodology, thus spawning hundreds of Collaborative initiatives throughout the health care world, sponsored by organizations other than IHI. (IHI, 2003)

Formation of an Expert Panel

The role of the Expert Panel is to identify and agree on the evidence-based interventions known to improve processes and outcomes and minimise harm; and establish the measurement framework that will be used during the Collaborative by all participating clinical units. These data measures provide the organisation with the effectiveness of the learning system at the micro, meso, and macro level to monitor and evaluate the reliability and sustainability of the system improvement on a continuous improvement basis.

Three face to face learning sessions

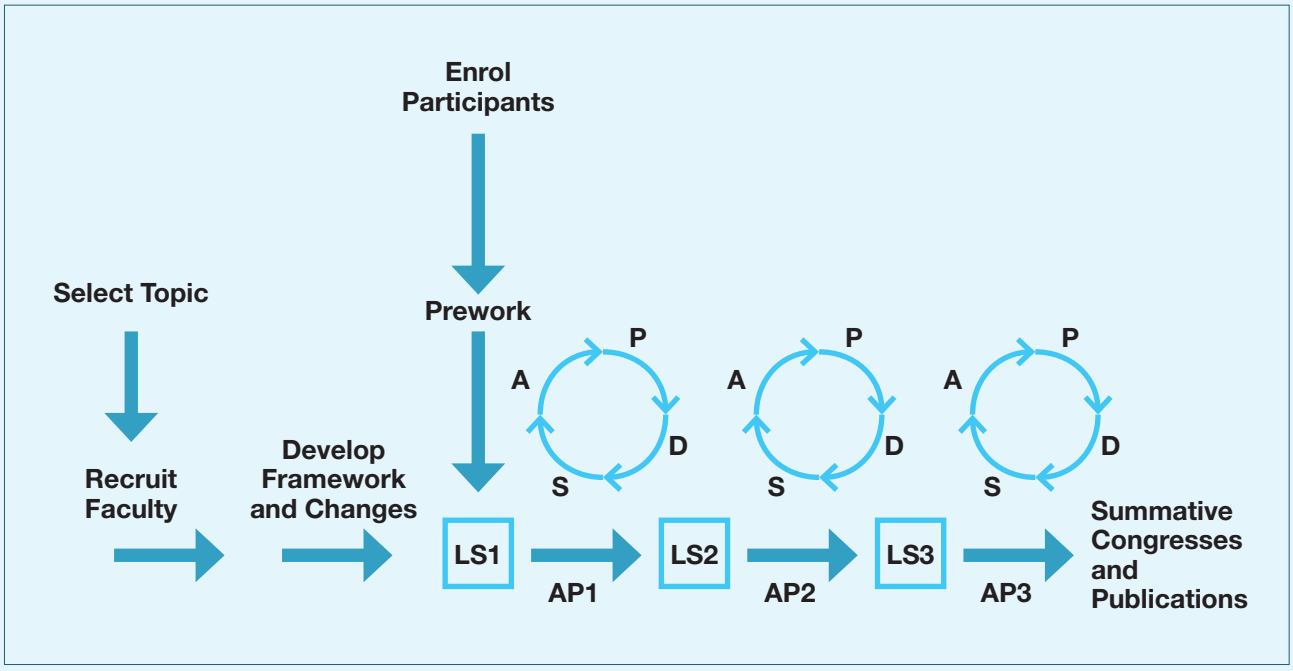
These two (2) day meetings support participating teams to develop their understanding and capacity of improvement science and help them to share with one another rapid cycle testing of change strategies and consolidate reliable system design. The meetings facilitate cross fertilisation of ideas; establish a robust and critical communication network; and significantly build staff morale and experience.

Monthly reviews of progress during 'Action Periods'

This is done through web conferences with peer teams. The Action Periods are where the work of improvement takes place in individual hospitals, supported by regular sharing of data and learnings with other teams. Measurement data is collected and recorded throughout this period by the participating team members.

Regular coaching and advice

This is provided by experts in improvement science, as well as regular access to peers in other teams to resolve common challenges and share learnings. This capacity and capability building in improvement science within hospitals or clinics, has additional long-term benefits for topics beyond the focus of the Collaborative and the life of it.



LS1: Learning Session
AP: Action Period
P-D-S-A: Plan-Do-Study-Act

Supports:
Email • Visits • Phone Conferences • Monthly Team Reports • Assessments

Collaboratives have demonstrated reduction in harm and improved wellbeing. Theses short-term team-based learning systems have resulted in a high degree of participants' involvement in QI activities and showed improvement in project measures, often occurring after completion of the program with majority of teams and beyond completion of the Collaborative. (O'Leary, 2018)

Some successful Collaboratives are detailed in Appendix C and summaries of these achievements are noted below.

Scottish Patient Safety Program Breakthrough Series Collaborative demonstrated a reduction of harm, including:

- 14% reduction in adjusted mortality rate in three years
- 21% reduction in mortality from sepsis since 2012
- 31% reduction in the cardiac arrest rate in hospitals 2013
- 31% reduction in the most severe pressure ulcers (Grade 2-4) since 2015
- SPSP has contributed to a 19.5% reduction in the rate of stillbirths since 2013
- 89% reduction in Paediatric Ventilator Associated Pneumonia to date
- 20% reduction in self harm in acute mental health settings (Healthcare Improvement Scotland, 2018).

Early Years Collaborative reported:

- 19% reduction in stillbirth rates by the end of 2015, surpassing the aim of 15%.
- increased access to financial advice for pregnant women on low incomes, helping to increase income by up to £5,000 per family
- increased uptake of the 27 to 30-month Child Health Review, resulting in children's developmental needs being identified and responded to earlier
- found effective ways of engaging vulnerable families in early years and family centres, helping to build parenting confidence and skills
- increased children's literacy and numeracy skills in nurseries and primary schools in areas of deprivation.

Safety and Improvement in Primary Care (SIPC) Pilot Collaborative in Scotland demonstrated improvements in care bundle data collection methods and the reliability of related systems were reported by most practices over the course of the program.

Queensland Health Mental Health Clinical Collaborative (MHCC) Physical Health & Mental Health reported improvement in the physical health assessment clinical indicator was demonstrated across the state over a 3-year period with an increase in the number of physical health assessments recorded from 12% to 58%.

Proposal for a National Equally Well Collaborative

Why focus on improving physical health of consumers with mental health concerns?

Mental illness is very common, with nearly half of all Australians developing a mental illness at some point in their lives. The cost of treating mental illness is significant in Australian society. The reciprocal relationship between more severe and persistent mental illness and poor physical health, including cardiovascular disease and diabetes, is increasingly clear. Consequently, the physical health care of people with severe and persistent mental illness has been identified as a serious public health challenge. The national survey, People living with psychotic illness 2010, found that for one quarter of participants, their physical health was one of the biggest challenges (Morgan et al 2012).

There is international recognition that the gap in life expectancy between people with a serious mental illness and the general population must be acted upon. The life expectancy for people experiencing severe mental illness is reduced by 15 to 20 years – largely due to cardiovascular disease and cancer rather than suicide – and the gap is widening (Lawrence, Hancock & Kisley 2013).

Whilst death from suicide contributes to this life expectancy gap, the predominant causes are physical health conditions such as cardiovascular disease, respiratory disease and cancer.

Despite improvements in physical health and longevity in the general population through better lifestyle and medical advances, people with severe mental illness have not shared in these benefits. They often experience economic and social marginalisation, including from health care professionals and systems, in addition to severe metabolic consequences from antipsychotic medication. While steps have been taken to ensure that we reduce the number of premature deaths, more needs to be done to ensure that people with severe mental illness have the same life expectancy, and equal expectations of life, as those without mental illness (Hunter Institute for Mental Health, 2015) .

Significantly improving the physical health of mental health consumers is becoming a priority area for clinicians and policymakers, yet the practical steps needed to achieve this are less clear. The common themes evident in national and state mental health commission reports include:

- integration, the need for a holistic, Collaborative and co-ordinated approach
- addressing the side effects of antipsychotic medication
- education
- the need to overcome the physical/mental dualism that is typically experienced by consumers.

Despite ongoing attempts to address the poor physical health of mental health consumers, much remains to be achieved. Recognition of the importance of bringing mental health and physical health care together is at the core of providing holistic care for people with a mental illness.

Further evidence for improving the physical health of people living with mental illness can be sourced through the NSW Mental Health Commission Physical Health and Wellbeing publication.

Data for Improvement - measuring progress in managing people with serious mental illness and physical conditions

Measurement – Data for Improvement

Establishing a measurement and evaluation framework prior to the commencement of the Collaborative is a critical factor to the success the whole Collaborative.

Both qualitative and quantitative data are critical for evaluating and guiding improvement. A family of measures, incorporating outcome, process, and balancing measures, should be used to track improvement work. Time series analysis, using small amounts of data collected and displayed frequently, is the gold standard for using data for improvement (Shah A. BMJ 2019;364:l189).

"Some is not a number, soon is not a time, hope is not a plan"

Don Berwick

Drawing on the expertise of the Equally Well Collaborative Expert Panel, a framework of measures that will include:

- Outcome measures – <identify outcome measure/s>
  - Improved physical health of people with mental health concerns
- Process measures – <identify process measures based on evidence derived from the Equally Well Expert Panel, and could include:>
  - Metabolic syndrome
  - Prediabetes and diabetes
  - Smoking cessation
  - Social prescribing
- Balancing measures – <identify balancing measures, the unintended consequences>
- Consumer and Carer Reported Experience & Outcomes Measures – <identify any patient reported measures>.

In the Equally Well Collaborative, consumers and frontline practitioners, using their professional expertise, identify where they consider changes could be made that could lead to improved outcomes for people with mental illness and their carers and families. Using the Model for Improvement and starting by making small tests of change, they are able to measure whether their theory is correct before scaling it up.

Quality Improvement Data System (QIDS)

The Quality Improvement Data System (QIDS) has been designed to give easy access to information at all levels of the organisation, for the purpose of improving the quality and safety of health service delivery.

National Perineal Tears Collaborative and NSW Falls Prevention Collaborative have utilised QIDS for teams to develop and manage:

- General Project information, settings and team members
- Driver Diagram: create and edit driver diagram with aim, primary drivers, secondary drivers, and interventions
- Interventions: Manage the interventions and change ideas
- PDSA Cycles: The Plan-Do-Study-Act (PDSA) cycle is a 'trial-and-learning' method that allows you to temporarily test and evaluate ideas for change

- Measures: manage process measures, outcome measures and balance measures. Link measure to charts
- Charts: design QI charts including run chart, control chart, pareto chart, histogram, etc
- Team document: upload and share the team documents
- Resource: managed by leading team. Other users can view and download project resources
- Chat Room: a place where ideas and views on a particular issue can be exchanged.

Conclusion

Collaboratives are designed to achieve sustained reliable improvement for patients and to decrease harm. Collaboratives operate on adult learning principles; require focused work by each team to adapt effective changes to their setting; use methods for accelerating improvement; and capitalise on shared learning and collaboration.

Internationally, there is demonstrated success of Collaboratives in acute and non-acute settings, and consideration should be given to the Equally Well Quality Improvement Program, tutilise the Collaborative model, based on the Model for Improvement methodology, focusing on the four dimensions of the Quadruple Aim.

Case Studies

Scottish Patient Safety Programme – Breakthrough Series Collaborative

Launched in NHS Tayside in January 2008, the Scottish Patient Safety Programme was delivered through a Breakthrough Series Collaborative approach, with regular learning sessions alternating with action periods. The SPSP Breakthrough Series Collaborative demonstrated a reduction of harm, including a 14% reduction in adjusted mortality in three years.

Each NHS board had a nominated SPSP program manager. They played a key role as part of the leadership, coordination and delivery at board level, with responsibility for embedding continuous quality improvement as an integral part of planning and delivery of care. Monthly reports were produced for each of the teams in each of the hospitals. Good quality data was crucial and as SPSP was generating more data, it started creating credence and integrity of the program which led to a greater belief that it was working.

In 2013 the program evolved to support improvements within Mental Health, Primary Care, Maternity and Children, Medicines, and Healthcare Associate Infections. More recently the Primary Care program has expanded beyond General Practice to include Care Homes, Dentistry, Pharmacy, and Community and District Nursing.

Following a decade of dedicated effort and collaboration at all levels of the system to support a culture of safety and learning, is evident through the sustained improvements being reported across the country:

- 21% reduction in mortality from sepsis since 2012
- 31% reduction in the cardiac arrest rate in hospitals 2013
- 31% reduction in the most severe pressure ulcers (Grade 2-4) since 2015
- SPSP has contributed to a 19.5% reduction in the rate of stillbirths since 2013
- 89% reduction in Paediatric Ventilator Associated Pneumonia to date
- 20% reduction in self harm in acute mental health settings (Healthcare Improvement Scotland, 2018).

Early Years Collaborative

The Early Years Collaborative (EYC) is the world's first national multi-agency quality improvement program. It is a coalition of Community Planning Partners (CPPs) including social services, health, education, police and third sector professionals that are committed to ensuring that every baby, child, mother, father and family in Scotland has access to the best support available.

The Early Years Collaborative commenced in Glasgow in January 2013 at Learning Session 1 where around 800 people working in children's services from each of the 32 local authorities in Scotland came together to hear about a methodology which could improve outcomes for children aged pre-birth to 5 years.

The work of the EYC is being delivered across four workstreams that relate to ages and stages in the early years.

- Workstream 1 - To reduce by 15% the rates of stillbirth and infant mortality by 2015.
- Workstream 2 - 85% of all children within each CPP have reached all of the expected developmental milestones at the time of 27-30 month health review by the end of 2016.

- Workstream 3 - 90% of all children with in each CPP have reached all of the expected developmental milestones by the time the child starts primary school, by end of 2017.
- Workstream 4 - To ensure that 90% of all children within each CPP have reached all of the expected developmental and learning milestones by the end of 2020.
- Workstream 5 - Multi-agency Leadership Group.

Early Years Collaborative together with MCQIC reported a 19% reduction in stillbirth rates by the end of 2015, surpassing the aim of 15%.

Other achievements included:

- increased access to financial advice for pregnant women on low incomes, helping to increase income by up to £5,000 per family
- increased uptake of the 27 to 30-month Child Health Review, resulting in children's developmental needs being identified and responded to earlier
- ensured more families on low incomes get Healthy Start Vouchers so that pregnant women and children get the nutrition they need
- helped dads in prison understand their children's needs and build positive family relationships
- helped pregnant women recovering from substance misuse to change their lifestyle, resulting in improved birth weights and fewer social work interventions
- found effective ways of engaging vulnerable families in early years and family centres, helping to build parenting confidence and skills
- engaged more parents in their children's early learning in nurseries and primary schools, so that they are more able to support their children's development
- improved multi-agency partnership working in health and social care services, making it easier for families to navigate and access services
- increased children's literacy and numeracy skills in nurseries and primary schools in areas of deprivation
- raised the aspirations, attendance and attainment of secondary school pupils through targeting and mentoring.

Safety and Improvement in Primary Care (SIPC) pilot Collaborative in Scotland

Qualitative evaluation of the Safety and Improvement in Primary Care (SIPC) Pilot Collaborative in Scotland: perceptions and experiences of participating care teams

Improvements in care bundle data collection methods and the reliability of related systems were reported by most practices over the course of the program (see online supplementary Appendix 2 for examples), but this was an evolving process that was strongly dependent on closer working arrangements between clinical and administrative staff. A majority of practices reported that they were now gradually providing safer, more reliable care for patients with heart failure or left ventricular systolic dysfunction (LVSD).

QH Mental Health Clinical Collaborative (MHCC) Physical Health & Mental Health

Queensland Physical Health Collaborative was established October 2005 with the aim to apply Collaborative breakthrough series methodology to Mental Health.

It undertook an applied quality improvement Collaborative to increase the number of physical health assessments conducted with consumers diagnosed with schizophrenia in adult community mental health services across Queensland.

Sixteen adult mental health service organisations voluntarily took part in the statewide Collaborative initiative to increase the number of physical health assessments completed on persons with a diagnosis of schizophrenia spectrum disorders managed through the community mental health service.

Improvement in the physical health assessment clinical indicator was demonstrated across the state over a 3-year period with an increase in the number of physical health assessments recorded from 12% to 58%.

Significant improvements were made over a 3-year period by all mental health services involved in the Collaborative, supporting the application of a quality improvement methodology to drive change across mental health services. (Plever et al 2016)

The vision of the Early Years Collaborative is to make Scotland the best place in the world to grow up in by improving outcomes, and reducing inequalities, for all babies, children, mothers, fathers and families across Scotland to ensure that all children have the best start in life and are ready to succeed.

APPENDIX E: INFLUENCE OF DIETARY CHANGES ON PHYSICAL HEALTH OF INDIVIDUALS WITH SERIOUS MENTAL ILLNESS

Rocks T[1], Fehily C[2], Young C[1], Howland G[1], Kelly B[3], O'Neil A[1], Calder R[4], Dunbar J[5]

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3. Library, Deakin University, Geelong, Australia.
4. Mitchell Institute, Victoria University
5. Deakin Rural Health, School of Medicine, Faculty of Health, Deakin University. Clinical and Research Adviser; Mitchell Institute, Victoria University

Compared to the general population, people living with serious mental illness (SMI) have a significantly increased risk of developing metabolic syndrome – a combination of obesity, high blood pressure, dyslipidaemia (blood lipid levels that are too high or low, contributory factors for CVD) and hyperglycaemia (an excess of glucose in the bloodstream, often associated with diabetes mellitus).(Vancampfort et al., 2015) This cluster of risk factors has been associated with the prevalence of cardiovascular disease (CVD) and premature mortality among people with SMI. (Correll et al., 2017) Dietary management of CVD in the general population is well supported by extensive research.(Dinu et al., 2020) For people living with SMI dietary modifications have also been proposed as an attainable and safe approach to manage comorbid physical conditions, including the metabolic syndrome.(Teasdale et al., 2018)

The Being Equally Well Consumer and Carers consultation working group has identified dietary management of health in people with SMI as one of its points of interest. Our research group has undertaken a review of the literature to synthesise the available evidence on the use of dietary intervention in treatment of physical outcomes in people living with SMI. We searched the peer reviewed literature for the papers published in English from January 2010 to March 2021. We also checked references in identified studies for further trials. We included trials of interventions where nutrition-related components were either a stand-alone intervention or embedded within broader programs for participants living with schizophrenia, schizoaffective disorders and other psychosis, major depressive disorder, and bipolar disorder. We only considered trials that used a control group (for example, 'treatment as usual' or 'standard care', or non-dietary active (e.g. social support) and reported body composition (e.g. weight, BMI), blood pressure, cholesterol, low-density lipoproteins, high-density lipoproteins, triglycerides, and glucose as their primary outcomes. All review stages (abstract, full text screening, and data extraction) were completed by two independent reviewers.

This summary includes 27 controlled trials with varying sample size conducted mostly in adult outpatients (n=4,604 total participants). Out of these 27 trials, only two comprised diet or nutrition as the sole component of their intervention: a 3-month RCT that investigated the effect of the Dietary Approaches to Stop Hypertension (DASH) diet on metabolic syndrome in Croatian inpatients with schizophrenia;(Soric et al., 2019) and a 12-month three-arm RCT that examined the effect of nutritional education on weight and other metabolic parameters in Japanese outpatients with schizophrenia.(Sugawara et al., 2018)

The DASH diet-based intervention was conducted with 67 hospitalised adult men and women. The intervention included a prescribed dietary menu, based on the standard hospital diet with energy intake reduced by approximately 1700kJ per day. This was supported by nutritional education that was delivered to both the intervention and control group. The results of this trial showed that the intervention resulted in a significant improvement in diet quality, such as higher consumption of dietary fibre and lower consumption of cholesterol and sodium in the DASH-diet group in comparison with the standard hospital diet group. Despite this, both groups showed similar modest improvements in weight, BMI, and waist circumference at the end of the intervention with no significant between-group differences reported. This lack of difference was attributed to various factors, including participants' awareness of the study, consumption of non-prescribed food items purchased

separately by the intervention group participants, and a short duration of the study.(Soric et al., 2019)

In contrast, the Japanese study of outpatients living with schizophrenia showed that nutritional education provided by an accredited dietitian was highly effective in supporting weight loss and significantly reducing prevalence of metabolic syndrome.(Sugawara et al., 2018) In this 12-month study, participants were randomised to either standard care, doctor's weight loss advice, or individual nutrition education with an accredited specialist (comprising monthly one-on-one educational sessions). Compared with the other two groups, participants who received the nutrition intervention, lost most weight, averaging over 3kg, with a greater proportion of those who lost >7% and >5% of their baseline body weight.(Sugawara et al., 2018)

Two other publications (Erickson et al., 2017; Erickson et al., 2016) reported outcomes of a multimodal behavioural intervention "Lifestyle Balance" that was adapted from the Diabetes Prevention Program (The Diabetes Prevention Program, Research Group, 2002) specifically to the SMI population. Lifestyle Balance was delivered by a registered dietitian and ran for 12 months. It included weekly group classes that covered a range of foundational topics related to healthy eating in the first two months and provided on-going monthly activities for the remaining 10 months. These were supported by individual sessions that assessed dietary intake, specific nutritional requirements, and provided encouragement and feedback using cognitive behavioural therapy and motivational interviewing. Participants and their caregivers maintained accountability resources, such as food journals, which were regularly reviewed by the program's dietitians to identify challenges. Participants also received cooking classes, and tours of restaurants and grocery stores. Motivation to participate was enhanced by achievement rewards, such as small gift certificates and prizes. In addition, the program offered an optional exercise component which included group exercise classes along with general recommendations for physical activity.(Erickson et al., 2016)

Lifestyle Balance was tested as a single-facility trial and then implemented in three additional locations. Both studies included outpatients of the Veteran Affairs Health Care System in California recruiting individuals with BMI >25kg.m^{-2} (or an increase of >7% of body weight) and taking second-generation antipsychotic medication. In the former single-centre trial, 122 participants were randomised to receive either Lifestyle Balance intervention (n=60) or usual care (n=62) that included self-help resources on nutrition, exercise, and weight-loss, and regular study visits to match the intensity of the intervention group. Results showed that after the 12-month program, 33% of the Lifestyle Balance group participants lost 5% of their body weight compared with 19% of the usual care group, albeit this difference did not reach statistical significance.(Erickson et al., 2016) Nevertheless, repeated measures analysis showed significant differences in the predicted trajectory for mean weight change between the study groups with participants from the Lifestyle Balance group projected to lose an average of 4.6kg whilst participants in the usual care were projected to gain an average of 0.6kg during the same period.(Erickson et al., 2016) In the multi-site extension of the single-facility trial, (Erickson et al., 2017) 121 volunteers were randomised to either Lifestyle Balance program (n=62) or to usual care (n=59). Results showed significant reduction in waist circumference and body fat percentage in the intervention group by comparison with the usual care group. Interestingly, both groups recorded a modest reduction in body weight compared to baseline. (Erickson et al., 2017)

Twenty three out of the 27 studies reviewed were broader lifestyle interventions that included exercise, nutrition, and other components such as sleep or stress management, delivered in a variety of modes: individually and in groups, in person and online. (Attux et al., 2013; Bartels et al., 2013; Bartels et al., 2015; Brown et al., 2011; Cordes et al., 2014; Curtis et al., 2016; Daumit et al., 2013; Detke et al., 2016; Errichetti et al., 2020; Green et al., 2015) (Goldberg et al., 2013; Holt et al., 2018; Iglesias-García et al., 2010; Jelalian et al., 2019) (Kilbourne et al., 2013; Looijmans et al., 2019; Lovell et al., 2014; Magni et al., 2017; Masa-Font et al., 2015; Methapatara & Srisurapanont, 2011; Osborn et al., 2018; Sylvia et al., 2019) (Verhaeghe et al., 2013) The length of the interventions varied from three to 18 months. Commonly, interventions were delivered in stages, commencing with an intense or active period comprising of regular, often individual, support sessions; and then following up with a less intense maintenance period that included intermittent support with group activities or short individual sessions. The reported outcomes were mixed, with nine out of 23 (Attux et al., 2013) (Bartels et al., 2015; Brown et al., 2011; Curtis et al., 2016; Daumit et al., 2013; Errichetti et al., 2020; Green et al., 2015; Magni et al., 2017; Methapatara & Srisurapanont, 2011) stating significant improvements in the primary measures of interest, such as body weight and other measures of body composition, systolic blood pressure, or HbA1c; and a further three trials (Jelalian et al., 2019; Kilbourne et al., 2013; Verhaeghe et al., 2013) described improvements in some of the

measured parameters. The remaining trials reported no significant differences between intervention and control groups in the outcomes owing to the implemented programs.

Overall, it is challenging to ascertain the impact of dietary modifications on metabolic syndrome outcomes, as the reviewed studies provided limited description of the dietetic component of their interventions. Furthermore, only 11 out of 27 studies (Attux et al., 2013; Bartels et al., 2013; Bartels et al., 2015; Curtis et al., 2016; Erickson et al., 2017; Goldberg et al., 2013) (Holt et al., 2018; Lovell et al., 2014; Masa-Font et al., 2015; Osborn et al., 2018; Verhaeghe et al., 2013) described diet-specific measures, such as overall energy intake, intake of specific macronutrients (e.g. fat or fibre), food groups (e.g. fruit or vegetables), or dietary behaviour (e.g. consuming sugary foods), and any changes in these after interventions. Therefore, post-intervention outcomes of broader lifestyle programs could be attributed to the impact of several components, for instance, exercise. There is evidence that increasing physical activity could be an effective adjunct to manage physical health in the SMI population. (Stubbs et al., 2018) Interestingly, almost all studies that included an accredited nutritional professional (dietitian) in the design and delivery of interventions (9/27) (Attux et al., 2013; Brown et al., 2011; Cordes et al., 2014; Curtis et al., 2016; Erickson et al., 2017; Erickson et al., 2016; Errichetti et al., 2020; Soric et al., 2019; Sugawara et al., 2018) reported successful outcomes for most of their primary measures (e.g. decrease or attenuation of increase in weight and BMI, reduction in blood pressure, improvement in diet quality). Earlier research showed dietitian-led interventions have a greater impact in addressing cardiovascular risks in the general population (Ross et al., 2019) and in people with SMI. (Teasdale et al., 2018) Therefore, we support previous recommendations for incorporating specialised nutritional professionals in diet-based interventions to address the complexity of the lifestyle needs and socioeconomic challenges often experienced by people living with SMI.

Another aspect that should be considered is poor adherence and notable attrition of intervention participants described by the reviewed studies. Although most groups reported completion by a significant proportion of participating individuals, commonly, considerably smaller numbers completed all or most of the assigned activities. For example, in the Lifestyle Balance program described above, half of the participants completed the full 12 months of the intervention (42% in the single-site trial (Erickson et al., 2016) and 53% in the multi-site study (Erickson et al., 2017). Other trials reported much more modest adherence (e.g. only 23% of participants attended all intervention activities in the STEPWISE group intervention by Holt and colleagues (Holt et al., 2018). The high attrition was notable despite inclusion of more stable participants. In most of the reviewed trials, common criteria for exclusion were recent hospitalisation and substance abuse. When analyses were re-run to account for adherence as, for example, in the intervention by Verhaeghe et al. (2013), outcomes suggested a dose-response relationship with higher participation rates corresponding with greater changes in primary outcomes, such as weight and other body composition measurements, a common finding in lifestyle modification programs. Attrition in complex behavioural interventions is prevalent including in the general population and has been previously associated with mental health issues, for instance, depression.(Ponzo et al., 2020) For individuals with SMI, challenges of behavioural changes are exacerbated by the effect of medications and by the impact of socioeconomic circumstances; therefore, additional assistance is essential to promote motivation and compliance. This assistance needs to come from trained professionals with a specialised skill set to recognise and harvest the readiness to change. Successful dietary and other behavioural change in people with SMI will require long-term follow-up in real-life settings. For example, outcomes of one of the trials showed that although it was unsuccessful in improving cardiometabolic outcomes of the intervention group, such as BMI or waist circumference, 12 months of intervention significantly increased readiness to change dietary behaviour. (Looijmans et al., 2019) Therefore, continuous follow-up in general practice could ensure timely referral to specialised care could be made for patients who are motivated to change.

Importantly, none of the reviewed trials reported any harm which could be directly associated with dietary or lifestyle interventions that were undertaken by the participants. On the contrary, outcomes of at least one study showed significantly fewer medical hospitalisations in their lifestyle intervention group, with 7% of intervention participants undergoing medical hospitalisation compared with 19% of controls over the 12-month intervention period. (Green et al., 2015)

Conclusion

This review of the literature showed limited evidence of the use of dietary intervention in treatment of physical outcomes in people living with SMI. Only four of the identified studies contained diet or nutrition as their main component with the rest of the studies embedding these as part of a broader lifestyle

treatment. Although the outcomes of the studies were mixed, none reported any harm that was directly associated with diet- or lifestyle interventions. Optimal nutrition and healthy dietary behaviours are essential to manage comorbid physical health challenges of people living with SMI. Continuous efforts in providing well-adapted routine dietary support for these individuals is critical; therefore, future research should focus on improving the available intervention models to establish the most effective approaches. The aim is to reduce the components of the metabolic syndrome which in turn would reduce CVD and diabetes. Much could be gained by applying lessons learnt from lifestyle modification programs for diabetes particularly as none of the trials showed evidence of harmful effects among people with SMI. These lessons for lifestyle modification applicable to the general population can be used in designing programs for people with SMI.

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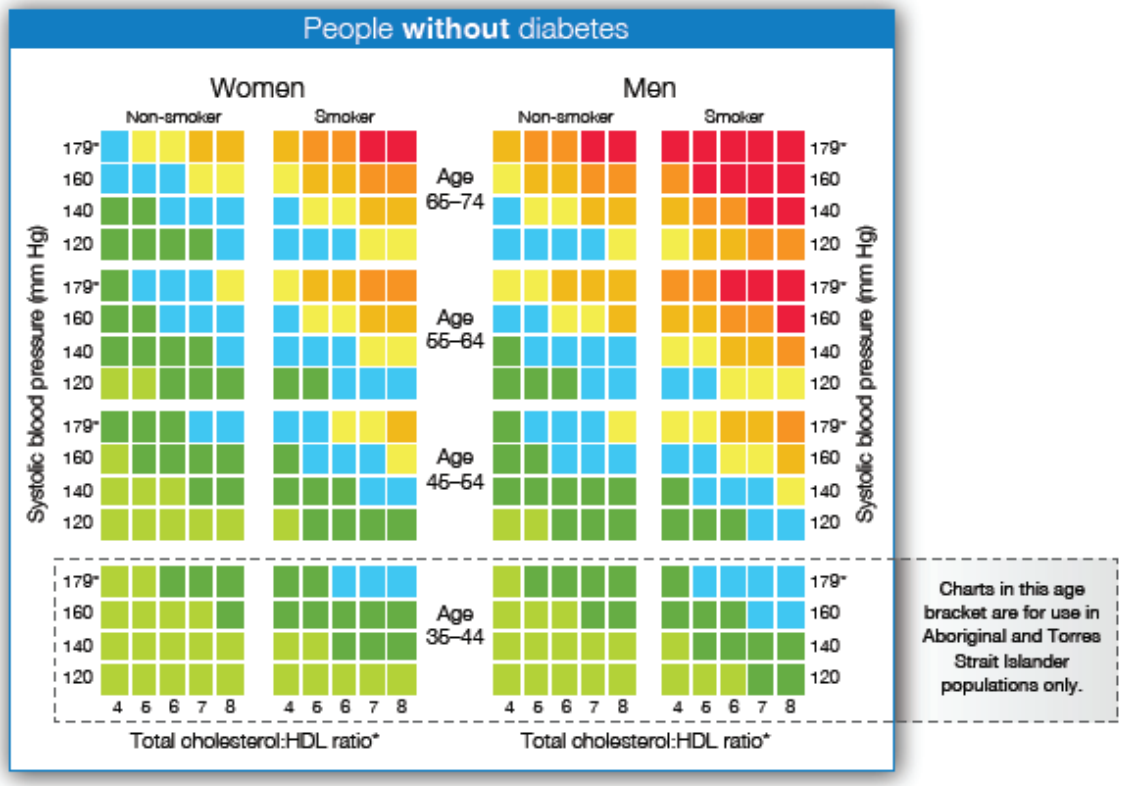
APPENDIX F: ABSOLUTE CARDIOVASCULAR RISK (ACVR) CHART

National Vascular Disease Prevention Alliance, 2012

Australian cardiovascular **risk charts**



*In accordance with Australian guidelines, patients with systolic blood pressure ≥180 mm Hg, or a total cholesterol of >7.5 mmol/L, should be considered at clinically determined high absolute risk of CVD.

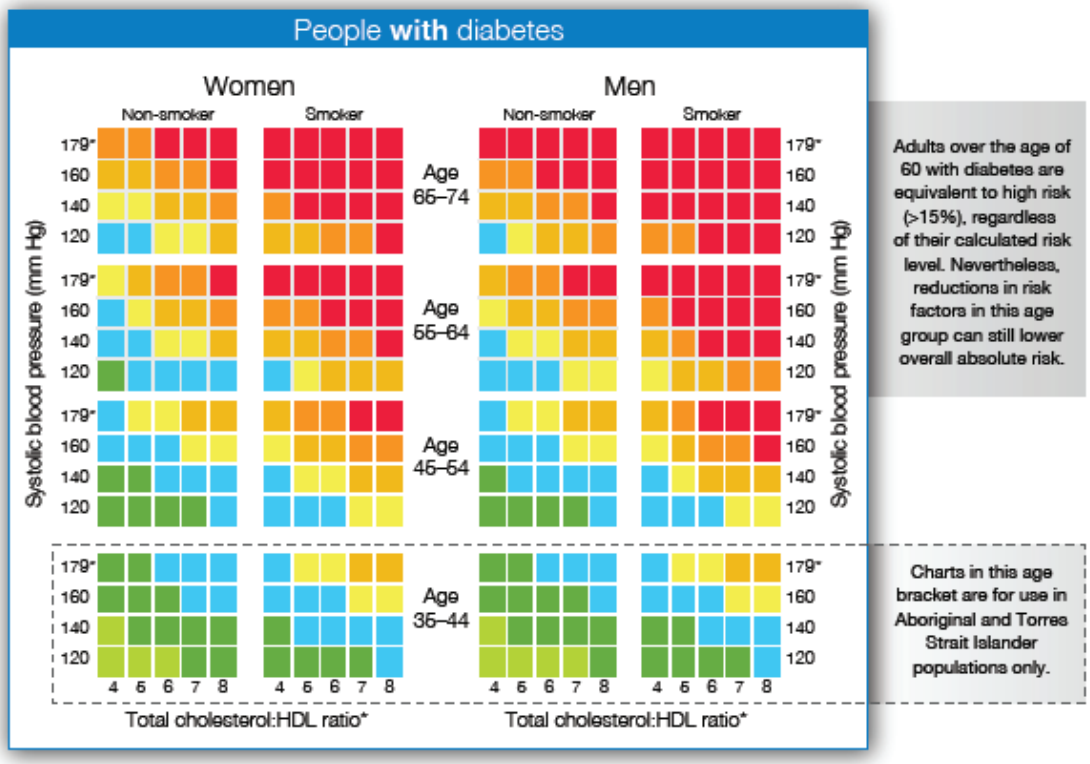
Risk level for 5-year cardiovascular (CVD) risk

High risk	Moderate risk	Low risk
≥30%	10–15%	5–9%
25–29%		< 5%
20–24%		
16–19%		

How to use the risk charts

1. Identify the chart relating to the person's sex, diabetes status, smoking history and age. The charts should be used for all adults aged 45 years or over (and all Aboriginal and Torres Strait Islander adults aged 35 - 74 years) without known history of CVD and not already known to be at clinically determined high risk.
2. Within the chart choose the cell nearest to the person's age, systolic blood pressure (SBP) and total cholesterol (TC):HDL ratio. For example, the lower left cell contains all non-smokers without diabetes who are 34-44 years and have a TC:HDL ratio of less than 4.5 and a SBP of less than 130 mmHg.
3. The colour of the cell that the person falls into provides their five year absolute cardiovascular risk level (see legend above for risk category). People who fall exactly on a threshold between cells are placed in the cell indicating higher risk.

Australian cardiovascular **risk charts**



*In accordance with Australian guidelines, patients with systolic blood pressure ≥180 mm Hg, or a total cholesterol of >7.5 mmol/L, should be considered at clinically determined high absolute risk of CVD.

Risk level for 5-year cardiovascular (CVD) risk

High risk	Moderate risk	Low risk
≥30%	10–15 %	5–9%
25–29%		<5%
20–24%		
15–19%		

Notes: The risk charts include values for SBP alone as this is the most informative of conventionally measured blood pressure parameters for cardiovascular risk.

For specific groups, additional guidance includes:
The Framingham Risk Equation has not been validated for all population groups, the assessment score should be interpreted with caution in the following groups:

- The Framingham Risk Equation may **underestimate CVD risk** in Aboriginal and Torres Strait Islander peoples (EBR Grade D); adults with diabetes aged between 45 and 60 years (EBR Grade C); adults aged over 74 years (CBR) however, available evidence suggests that this approach will provide an estimate of minimum cardiovascular risk.
- The Framingham Risk Equation is likely to **underestimate CVD risk** in adults with socioeconomic deprivation (an independent risk factor for cardiovascular disease) (PP) or depression (PP).
- The predictive value of the Framingham Risk Equation **has not been specifically assessed** in adults who are overweight or obese (EBR Grade D).
- The **increased risk of cardiovascular events and all-cause mortality**, in addition to thromboembolic disease including stroke, should be taken into account for adults with atrial fibrillation (particularly those aged over 65 years) (PP).

Charts are based on the NVDPA's *Guidelines for the assessment of absolute cardiovascular disease risk* and adapted with permission from New Zealand Guidelines Group. New Zealand Cardiovascular Guidelines Handbook: A Summary Resource for Primary Care Practitioners. Second edition. Wellington, NZ: 2009. www.nzgg.org.nz

APPENDIX G: MANAGEMENT OF RISK FACTORS IN GENERAL PRACTICE

James A Dunbar[1]. Advised by Dr Alan Cohen[2]

1. Clinical and Research Advisor for the Australian Health Policy Collaboration and was Director of the Greater Green Triangle University Department of Rural Health, Flinders and Deakin universities.
2. GP (retired) and Inaugural Chair of the Clinical Group, Equally Well UK

Will Management of Risk Factors in General Practice work? The Quality and Outcomes Framework: Experience from the NICE Audit of Diabetes Care

The National Institute for Health and Care Excellence (NICE) provides evidence-based recommendations and audits for the NHS in England and Wales. It has looked at the effect of the Quality and Outcomes Framework (QOF) on parity of outcomes among people with serious mental illness and diabetes.

The QOF was a voluntary reward and incentive program for UK GP practices for the quality of care they provide to their patients and helps standardise improvements in the delivery of primary care. Almost all GPs participated. Most practices got a significant proportion of their income through the QOF. The results are published every year.

In the 2004 contract a general practice could accumulate up to 1050 'QOF points', depending on level of achievement for each of the 146 evidence-based indicators.

A typical clinical indicator would be the proportion of patients with coronary heart disease who had cholesterol measured in the financial year, or the number of patients with depression who have answered a standard questionnaire on severity.

Dr Alan Cohen, GP and Inaugural Chair of the Clinical Group of ***Equally Well*** UK has been involved with the NICE audit of care processes for diabetes. He says:

"I think it would be fair to say that the QOF (or financial incentives) improved the parity in processes of care for people with SMI, for both CVD and Diabetes.

Outcomes are a bit harder, as although the National Diabetes Audit shows similar outcomes, the expert advisory group are concerned that this finding doesn't mirror clinical experience - which is that managing diabetes in people with SMI is generally more complex than with other groups."

Care Processes

• To update

All people with diabetes aged 12 years and over should receive all of the nine NICE recommended care processes[1,2,3,4,5] and attend a structured education programme shortly after diagnosis.

Table 2: Nine Annual Care Processes for all people with diabetes aged 12 and over

Responsibility of Diabetes Care providers (comprising the NDA 8 Care Processes)	
1. HbA1c (blood test for glucose control)	**5. Urine Albumin/Creatinine Ratio** (urine test for risk of kidney disease)
2. Blood Pressure (measurement for cardiovascular risk)	**6. Foot Risk Surveillance** (examination for foot ulcer risk)
3. Serum Cholesterol (blood test for cardiovascular risk)	**7. Body Mass Index** (measurement for cardiovascular risk)
4. Serum Creatinine (blood test for kidney function)	**8. Smoking History** (question for cardiovascular risk)
Responsibility of NHS Diabetes Eye Screening (NHS England, Public Health England)*	
9. Digital Retinal Screening (photographic eye test for early detection of eye disease)	

1,2,3,4,5. Please see full list of footnotes in the definitions and footnote section
* The screening registers are drawn from practice registers but the outcomes are recorded in screening management systems that presently cannot export data to the NDA

Definitions

Diabetes

Diabetes is a condition where the amount of glucose in the blood is too high because the pancreas doesn't produce enough insulin. Insulin is a hormone produced by the pancreas that allows glucose to be used as a body fuel and other nutrients to be used as building blocks. There are two main types of diabetes: Type 1 diabetes (no insulin); Type 2 diabetes (insufficient insulin).

Urine Albumin-to-Creatinine Ratio (UACR)

UACR is a ratio between two measured substances urine albumin and urine creatinine. Unlike a urine dipstick test for albumin, UACR is unaffected by variation in urine concentration.

Specialist Service

This is a service (often hospital based but sometimes delivered in a community setting) which includes diabetes specialists working in multidisciplinary teams. These teams usually comprise physicians (diabetologists), diabetes specialist nurses and dieticians; it may also include clinical psychologists.

Annual Review

This is a GP appointment where the annual NICE recommended Care Processes are undertaken

Care Processes (NICE recommends all of these at least once a year)

Blood Pressure is a measurement of the force driving the blood through the arteries. Blood pressure readings contain two figures, e.g.130/80. The first is known as the systolic pressure which is produced when the heart contracts. The second is the diastolic pressure which is when the heart relaxes to refill with blood.

BMI measurement – Body Mass Index is calculated from weight and height and used to classify body weight as low, normal, overweight and obese.

Serum creatinine – this is a blood test used to measure kidney function.

Urinary albumin – this urine test detects the earliest stages of kidney disease.

Cholesterol - this blood test measures a type of fat that can damage blood vessels.

Foot check - this examination checks the blood supply and sensation (feeling) in the feet. Loss of either is a risk for foot disease.

Smoking Status - this records whether the person is a smoker. Smoking increases the diabetic risk for heart attacks and stroke.

HbA1c – this is a blood test for average blood glucose levels during the previous two to three months.

Treatment Targets (NICE defines target levels to reduce risks of complications for people with diabetes)

HbA1c - the closer this is to normal (less than 42mmol/mol) the lower is the risk of all long term complications of diabetes.

Cholesterol – reducing cholesterol levels lowers the risk of heart attacks and strokes.

Blood Pressure – high levels are a risk for heart attacks and strokes; they also drive progression of eye and kidney disease.

Primary prevention of CVD – the prescription of statins for people with diabetes aged 40 to 80 years with no history of heart disease to reduce the risk of cardiovascular disease.

Secondary prevention of CVD – the prescription of statins for people with diabetes (any age) with a history of heart disease to reduce the risk of cardiovascular disease.

Combined prevention of CVD – the prescription of statins for people with diabetes that fall into either of the primary or secondary prevention groups.

Meeting all 3 treatment targets –
Old – having HbA1c ≤58mmol/mol, cholesterol <5mmol/L and blood pressure ≤140/80.

New – having HbA1c ≤58mmol/mol, cholesterol <5mmol/L and for people falling in the combined prevention CVD group: receiving statins.

For both measures patients under 12 years of age meeting all 3 is defined as HbA1c only.

Care Processes: Severe Mental Illness

Figure 2: Percentage of people with diabetes receiving all eight NICE recommended care processes[7] by diabetes type and SMI diagnosis, England and Wales, 2019-20

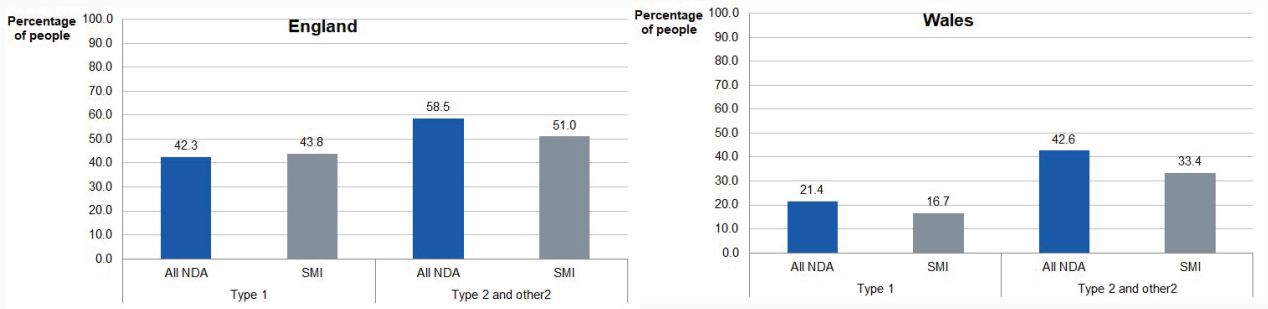
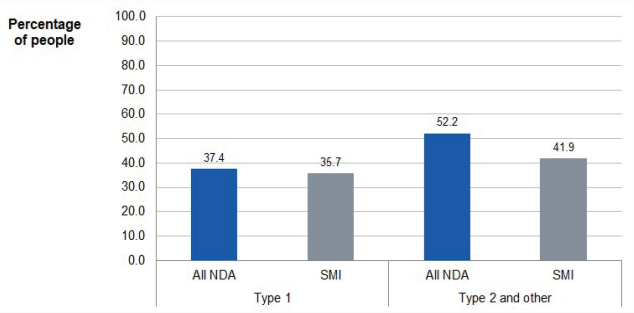


Figure 2a: Percentage of people with diabetes receiving all nine NICE recommended care processes[7] by diabetes type and SMI diagnosis, England, 2019-20

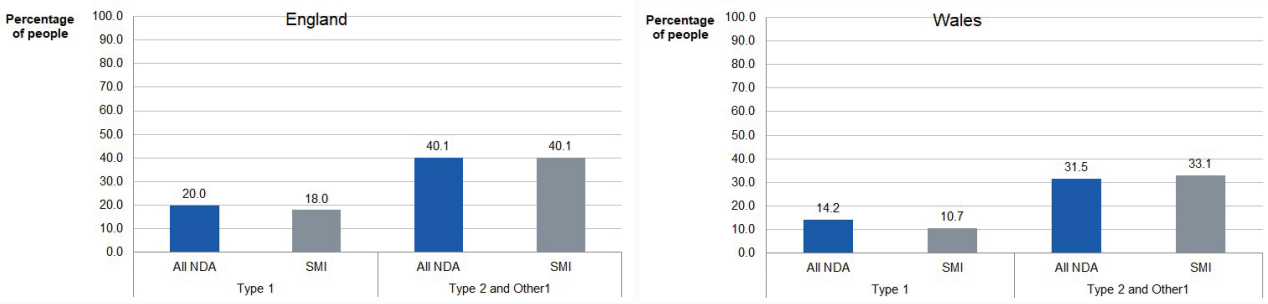


- 9CPs for England only due to no retinopathy data for Wales.
- Discussion for AG: how to report 8/9CP measures.

7. Please see full list of footnotes in the definitions and footnote section

Treatment Targets: Severe Mental Illness

Figure 7: Percentage of people with diabetes achieving their treatment targets NEW*, by diabetes type and SMI diagnosis, England and Wales, 2019-20



*Meeting All Three Treatment Targets NEW and Meeting All 3 Treatment Targets OLD are defined in the Definitions Section

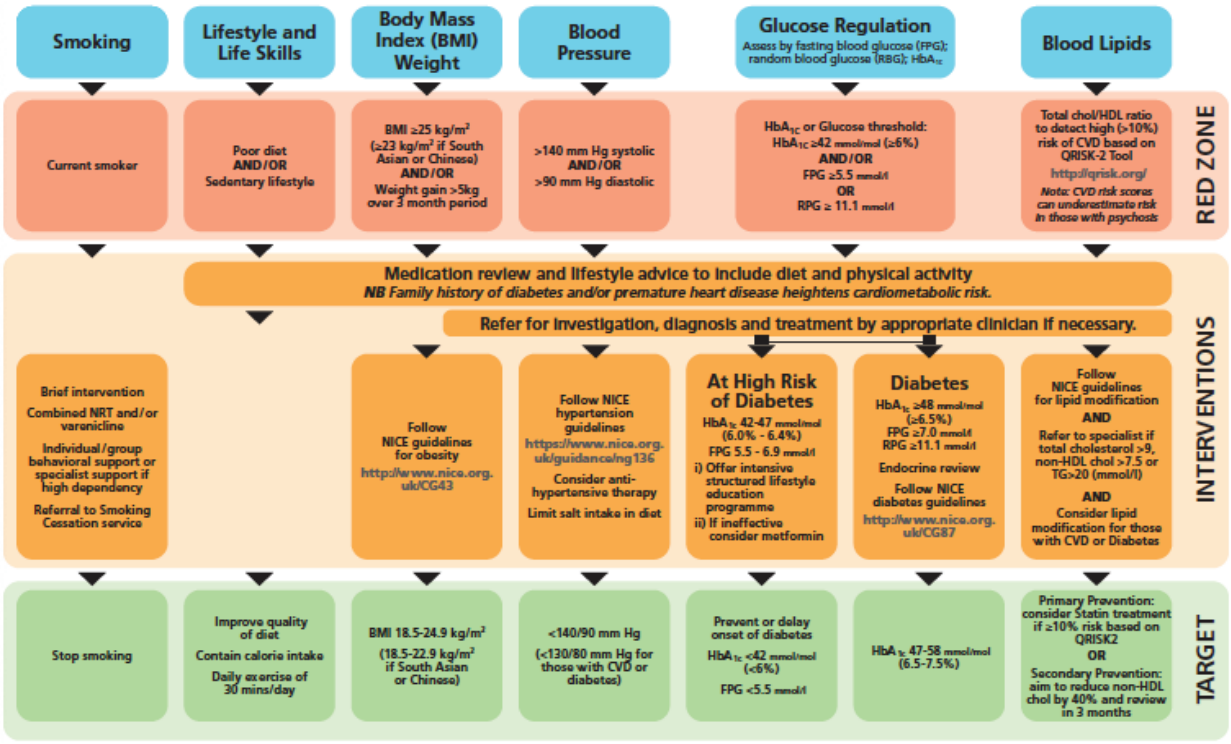
APPENDIX H: POSITIVE CARDIOMETABOLIC HEALTH RESOURCES

Adapted for use by the RCGP/ RCPsych. With permission from Curtis J, Newall H, Samaras K. © HETI 2011 | June 2014 | 1.0

Lester UK Adaptation | 2014 update

Positive Cardiometabolic Health Resource

An **intervention framework** for people experiencing **psychosis** and **schizophrenia**



FPG = Fasting Plasma Glucose | RPG = Random Plasma Glucose | BMI = Body Mass Index | Total Chol = Total Cholesterol | HDL = High Density Lipoprotein | TRIG = Triglycerides

History and examination following initiation or change of antipsychotic medication

Frequency: Normally supervised by the psychiatrist. As a minimum review those prescribed a new antipsychotic at baseline and at least once after 3 months.
Weight should be assessed weekly in the first six weeks of taking a new antipsychotic, as rapid early weight gain may predict severe weight gain in the longer term.
Subsequent reviews should take place annually unless an abnormality of physical health emerges. In these cases, appropriate action should be taken and/or the situation should be reviewed at least every 3 months.

At review

History: Seek history of substantial weight gain (e.g. 5kg), especially where this has been rapid (e.g. within 3 months). Also review smoking, exercise and diet. Ask about family history (diabetes, obesity, CVD in first degree <55 yrs male relatives and <65 yrs female relatives) and gestational diabetes. Note ethnicity.
Examination: Weight, BMI, BP, pulse.
Investigations: Fasting estimates of plasma glucose (FPG), HbA1c, and lipids (total cholesterol, non-HDL, HDL, triglycerides). If fasting samples are impractical then non-fasting samples are satisfactory for most measurements except for triglycerides.
ECG: Include if history of CVD, family history of CVD; where examination reveals irregular pulse (if ECG confirms atrial fibrillation, follow NICE recommendations http://guidance.nice.org.uk/CG36); or if patient taking certain antipsychotics (See SPC) or other drugs known to cause ECG abnormalities (eg erythromycin, tricyclic anti-depressants, anti-arrhythmics – see British National Formulary for further information).
Chronic Kidney Disease*: Screen those with co-existing diabetes, hypertension, CVD, family history of chronic kidney disease, structural renal disease (e.g. renal stones) routinely:

1. Monitor renal function: a) urea & electrolytes
   b) estimated glomerular filtration rate (eGFR)
2. Test urine: a) for proteinuria (dip-stick),
   b) albumin creatinine ratio (laboratory analysis)

*Presence of chronic kidney disease additionally increases risk of CVD: follow appropriate NICE guidelines on chronic kidney disease.

Monitoring: How often and what to do

Applies to patients prescribed antipsychotics and mood stabilizers.

	Baseline	Weekly first 6 weeks	12 weeks	Annually
Personal/FHx	■			■
Lifestyle Review[1]	■		■	■
Weight	■	■	■	■
Waist circumference	■			■
BP	■		■	■
FPG/HbA$_{1c}$	■		■	■
Lipid Profile[2]	■		■	■

[1]Smoking, diet, and physical activity [2]If fasting lipid profile cannot be obtained, a non-fasting sample is satisfactory

Monitoring table derived from consensus guidelines 2004, J clin. psych 65:2. APA/ADA consensus conference of 2004 published jointly in Diabetes Care and Journal of Clinical Psychiatry with permission from the Ontario Metabolic Task Force.

Specific lifestyle and pharmacological interventions

Specific lifestyle interventions should be discussed in a collaborative, supportive and encouraging way, taking into account the person's preferences:

- **Nutritional counselling:** reduce take-away and "junk" food, reduce energy intake to prevent weight gain, avoid soft and caffeinated drinks and juices, and increase fibre intake.
- **Physical activity:** structured education-lifestyle intervention. Advise physical activity such as a minimum of 150 minutes of 'moderate-intensity' physical activity per week (https://bit.ly/37sPxXZ). For example suggest 30 minutes of physical activity on 5 days a week.

If the patient has not successfully reached their targets after 3 months, consider specific pharmacological interventions:

Anti-hypertensive therapy: Normally GP supervised. Follow NICE recommendations https://www.nice.org.uk/guidance/ng136.
Lipid lowering therapy: Normally GP supervised. (If total cholesterol >9, non-HDL chol >7.5 or TG>20 (mmol/l), refer to metabolic specialist.) Follow NICE recommendations http://www.nice.org.uk/nicemedia/pdf/CG67NICEguideline.pdf.
Treatment of diabetes: Normally GP supervised. Follow NICE recommendations http://www.nice.org.uk/CG87.
Treatment of those at high risk of diabetes: FPG 5.5-6.9 mmol/l; HbA$_{1c}$ 42-47 mmol/mol (6.0-6.4%)
Follow NICE guideline PH 38 Preventing type 2 diabetes: risk identification and interventions for individuals at high risk (recommendation 19) – http://guidance.nice.org.uk/PH38.

- Where intensive lifestyle intervention has failed **consider a metformin trial** (normally be GP supervised).
- Please be advised that **off-label** use requires documented informed consent as described in the GMC guidelines, http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp. These GMC guidelines are recommended by the MPS and MDU, and the use of metformin in this context has been agreed as a relevant example by the Defence Unions.
- Adhere to British National Formulary guidance on safe use (in particular ensure renal function is adequate).
- Start with a low dose e.g 500mg once daily and build up, as tolerated, to 1500–2000mg daily.

Review of antipsychotic and mood stabiliser medication:
Discussions about medication should involve the patient, the general practitioner and the psychiatrist.
Should be a priority if there is:

- Rapid weight gain (e.g. 5kg <3 months) following antipsychotic initiation.
- Rapid development (<3 months) of abnormal lipids, BP, or glucose.

The psychiatrist should consider whether the antipsychotic drug regimen has played a causative role in these abnormalities and, if so, whether an alternative regimen could be expected to offer less adverse effects:

- As a first step prescribed dosages should follow BNF recommendations; rationalise any polypharmacy.
- Changing antipsychotic medication requires careful clinical judgment to weigh any benefits against the risk of relapse of the psychosis.
- An effective trial of medication is considered to be the patient taking the medication, at an optimum dosage, for a period of 4-6 weeks.
- If clinical judgment and patient preference support continuing with the same treatment, then ensure appropriate further monitoring and clinical considerations are carried out regularly.

It is advised that all side effects to antipsychotic medication are regularly monitored, especially when commencing a new antipsychotic medication (GASS questionnaire http://mentalhealthpartnerships.com/resource/glasgow-antipsychotic-side-effect-scale/), and that any side effects, as well as the rationale for continuing, changing or stopping medication is clearly recorded and communicated with the patient.
The Psychiatrist should maintain responsibility for monitoring the patient's physical health and the effects of anti-psychotic medication for at least the first 12 months or until the person's condition has stabilised, whichever is longer. Thereafter, the responsibility for this monitoring may be transferred to primary care under shared care arrangements. Discuss any non-prescribed therapies the patient wishes to use (including complementary therapies) with the patient, and carer if appropriate. Discuss the safety and efficacy of the therapies, and possible interference with the therapeutic effects of prescribed medication and psychological treatments.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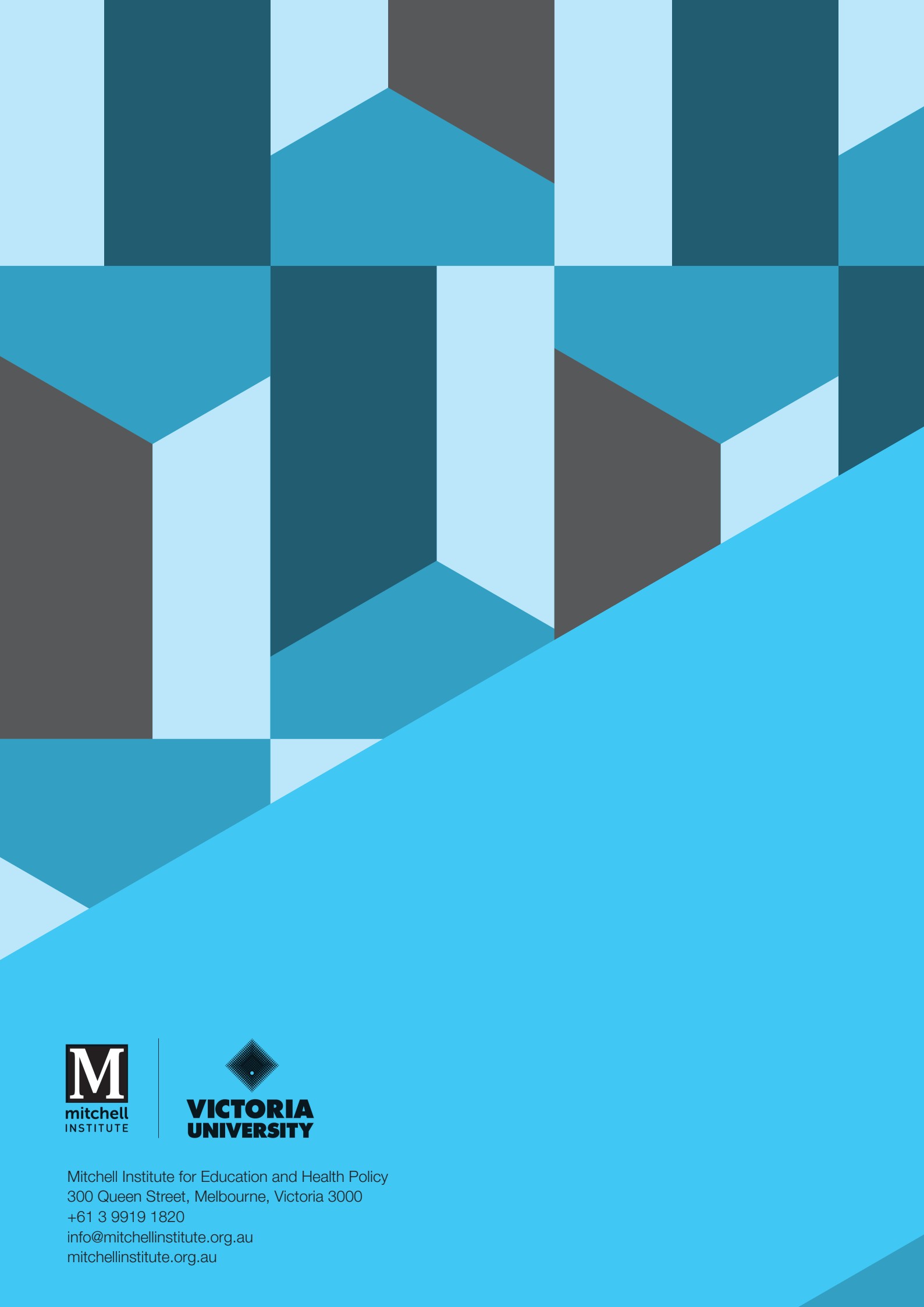

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