Abstract: Aims: Gestational diabetes (GDM) and Type 2 diabetes pose tremendous health and economic burdens as worldwide incidence increases. Primary care-based systematic diabetes screening and prevention programs could be effective in women with previous GDM. GooD4Mum aimed to determine whether a Quality Improvement Collaborative (QIC) would improve postpartum diabetes screening and prevention planning in women with previous GDM in general practice.

Methods: Fifteen general practices within Victoria (Australia) participated in a 12-month QIC, which consisted of baseline and four quarterly audits, guideline-led workshops and Plan-Do-Study-Act feedback cycles after each audit. The primary outcome measures were the proportion of women on local GDM registers completing a diabetes screening test and a diabetes prevention planning consultation within the previous 15 months.

Results: Diabetes screening increased with rates more than doubled from 26% to 61% and postpartum screening increased from 43% to 60%. Diabetes prevention planning consultations did not show the same level of increase (0% to 10%). The recording of body mass index improved (51% to 69%) but those with normal body mass index did not.

Conclusions: GooD4Mum supported increased diabetes screening and the monitoring of high risk women with previous GDM in general practice.
Dear A/Professor Blackberry,

**GooD4Mum: a general practice-based quality improvement collaborative for diabetes prevention in women with previous gestational diabetes**

We would like to thank the reviewers for their time and expert feedback. We appreciate the interest in our paper and feel the observations have enhanced the manuscript’s clarity. We have endeavoured to clarify the areas of weakness identified and revised the manuscript accordingly. We have taken the reviewer comments and responded to them individually in the response to review document.

My co-authors and I would be grateful for your consideration of our study as an original research paper in Primary Care Diabetes. The author for correspondence is at the address listed above, email Sharleen.oreilly@ucd.ie

Yours sincerely,

Sharleen O’Reilly, PhD, AdvAPD, RD
Dear A/Prof Blackberry,

We would like to thank the reviewers for their time and expert feedback. We appreciate the interest in our paper and feel the observations have enhanced the manuscript’s clarity. We have endeavoured to clarify the areas of weakness identified and revised the manuscript accordingly. We have taken the reviewer comments and responded to them individually below.

**Reviewer 1**

**General comments:**
The authors have presented data from an analysis of Australian women with previous GDM and found that GooD4Mum brought significant improvements in the postnatal diabetes screening and diabetes prevention planning consultation among women with GDM in general practice. The analysis presented in this manuscript consists of two parts. First, the authors presented the influence of external factors on the planned activity over time. In the second part, the authors calculated the numbers and the rates of women for every measure included in this project at each stage. Though the aim of this paper is clearly elucidated and the topic is important, the study design and results are weak and did not support the conclusion.

**Response:**
Thank you for your comments. We appreciate that the quality improvement methodology through the use of Collaboratives is a quasi-experimental design and has inherent issues. The methodology is however well described in the literature and our study does meet the SQUIRE standards for the method. We have reframed our conclusions to better reflect the data.

We now state “**Conclusions:** GooD4Mum supported increased diabetes screening and the monitoring of high risk women with previous GDM in general practice.”

**Major comment 1**
The study lacks a control group at the same period to check whether the GooD4Mum can increase the rate of participation in the diabetes screening and in the monitor of BMI and other risk factors, due to the possible improvement in awareness over time.

**Response:**
Clinical guidelines for the follow-up of women who have had GDM exist in many counties but follow-up rates remain obstinately low.\(^1,2\) Awareness increasing over time is an unlikely explanation because screening rates have been low despite reminders sent to the women and their GPs from a National Gestational Diabetes Register.\(^3\)

These guidelines represent the systematic review of randomised trials about **what** should be done but not **how**. e.g. NICE\(^4\). The Institute for Healthcare Improvement in Boston developed Collaboratives to improve the uptake of evidence. Collaboratives have been used in many countries. They were adapted by Prof Sir John Oldham in UK for use in primary care.\(^5\) He trained the Australian Government-funded Australian Primary Care Collaboratives team which has have been successful.\(^6,7\)

By using Collaboratives methodology we were following a decade of Australian Government policy on how to improve the uptake of evidence in primary care. Collaboratives do not include a control group and we acknowledge that this results in a quasi-experimental design.
We have amended the text to include this aspect:

“This quasi-experimental research project sought to apply QIC methods to the care of women with previous GDM...”

We have also provided more clarification in the methods on the activities:

“For women with previous GDM, this was engaging in annual diabetes screening and having a consultation where their lifestyle-related modifiable diabetes risk was assessed.”

References


Major comment 2

Despite an increased rate of women screened for DM, the rate of participation in the diabetes prevention planning is not significant different. It is quite weak to believe that the increased screening of DM is attributable to diabetes prevention planning consultations.

Response:

The general practices viewed the screening as a separate activity to the diabetes prevention planning consultation, which is why we have treated them as such in our analysis. Diabetes screening requires a small amount of GP time (asking a woman to take a test request slip to the nearest phlebotomy service or doing the blood test then and there) while the other activity required a much larger amount of time. The prevention planning session was usually booked in as a separate consultation and/or it was delivered by practice nurses often on a separate day.

We have additional qualitative data that was collected as part of the study from practices but not reported in this paper due to space constraints. We have decided to include a component of this data to add context to the data already included.
The methods now includes:

“The qualitative interviews and focus groups were conducted in each practice upon completion of the QIC activity to explore barriers and enablers to the intervention.”

“The qualitative data was analysed thematically by an experienced qualitative researcher (SOR) and coded transcripts were checked by the participants for accuracy of interpretation.”

The results now includes:

“The qualitative data proposed several barriers to conducting the diabetes prevention planning consultation: 1) it was only emphasised in the final six months of GooD4Mum and therefore had less time to become embedded within daily practice activity; 2) organising it within normal practice workflows was challenging; 3) women were reluctant to attend it for financial and time reasons; 4) limited lifestyle modification referral options existed; and 5) some GPs and practice nurses lacked confidence to engage in a lifestyle modification consultation.”

The discussion now includes:

“Diabetes screening and BMI monitoring in GooD4Mum aligns well with previous QIC diabetes prevention initiatives [15] but providing a diabetes prevention planning consultation was the more challenging component of the project - it had low uptake by both practice staff and women and practice staff reported several barriers to engaging in the activity. In looking at the QIC activities as behaviours that need to be changed and using the Theoretical Domains Framework[25] to map them, the screening activity required minor environmental restructuring to ensure GPs knew which women needed screening alongside some education and training with modelling promoted via teleconferences. These were easier behaviours to change because staff already know they will get reimbursed for doing the blood test and that HbA1c is a useful diabetes indicator. The prevention planning activity was a new process for the practices and required substantial behaviour change. Within the theoretical domains framework it called for: cognitive and interpersonal skills (training practice nurses to perform the tasks and support women to engage in lifestyle change), belief about capability and consequences (both staff and woman), environmental restructuring (needed patient and staff resources plus space to conduct consultation), education and training, persuasion and enablement to influence practice nurses and GPs optimism that the prevention planning consultations was worthwhile. It may simply be that providing a diabetes planning consultation to all women with a history of GDM is not appropriate and that providing the consultation in a more targeted fashion would yield better results. This should be explored in further work.”

Major comment 3

Many major confounders in this study were not adjusted in the analysis, e.g. social economic status. Besides, it is still unrevealed whether the characters of the study population at each audit stage are different over time.

Response:

The reviewer points to an important difference between an epidemiological study or a controlled trial and improvement work. The population does change over time as more women are entered into the register and a higher proportion are recalled. Numerator and denominator are both changing.

For these reasons, the standard tool in improvement work is the run chart developed by the Institute of Healthcare Improvement1. Its purpose is to help improvement teams formulate aims by
depicting how well processes are performing. It helps the practice teams determine when changes are true improvements by displaying a pattern of data that they can observe as they make changes. Run charts also indicate the direction of work on improvement and the value of particular changes.

For instance, if the run chart showed 100% follow up, there would be no need to look at SES or ethnicity affecting performance. If the run chart was obstinately at 80%, it might prompt thought about the demographic of the non-attenders.

In the absence of individual-level SES data, the best we could do is describe the area-level SES conditions where the practice is located which would not be useful for adjusting for SES. Supplementary Table 2 and Supplementary Table 3 provide a summary of outcomes by location and practice size – any analyses beyond these summaries is limited due to the sample size.

Reference


Major comment 4

The conclusion mainly stemmed from Table 2, but this table failed to give clear information, including: (a) it is better to point out which groups have statistical difference, if the difference assessed by ANOVA is significant; (b) the total number of women registered is far less than the numbers documented in text (N=481) and is also not consistent with the numbers showed in the supplementary table 2 and table 3, which are simply divided in different ways.

Response:

Thank you for this suggestion. There is an extra column added to Table 2 that highlights the pairwise differences.

The discrepancy described is between the total number of women (n=481) and the total number of practices that participated over the length of the study (n=14). The numbers presented in the Supplementary Table 2 and Supplementary Table 3 provide summary statistics of the outcome measures classified by location (rural v metro) and practice size (small, medium and large based upon the number of GPs in each practice). We considered this important to include to provide the readership with some context around these issues. Due to the small numbers, no attempt has been made to test for significance between groups and we believe the 95% CIs presented are sufficient.

Minor comments:

Some errors in text and tables need to be corrected. For example, .....location and size was explored descriptively (Supplementary Tables 2 and 3), rather than Supplementary Tables 1 and 2. (Line 173)

Response:

Thank you for highlighting these minor errors, we have edited the text accordingly.
Reviewer 2

Concluding statements:

How did it support diabetes prevention if diabetes prevention planning was little improved? Only 1 in 10 presented for diabetes prevention planning. Even if every one of them adopted the necessary interventions, it still leaves 90% of potentially vulnerable individuals not undertaking necessary prevention strategies.
Was it perhaps effective in detecting those with T2D or those with pre-diabetes rather than preventing diabetes?

Response:

Thank you for your feedback. We agree that our abstract conclusions needed to be framed better to reflect our findings.

We have now revised it to say “GooD4Mum supported increased diabetes screening and the monitoring of high-risk women with previous GDM in general practice.”

Our study was focused on delivering guideline-led diabetes prevention care, which detail regular diabetes screening and supporting women to achieve a healthy weight, diet and regular exercise through behaviour change (prevention planning) as the core activities that need to be completed to prevent diabetes. It is these activities that need to be enacted to deliver guideline-led care and what we focus on in this study. As a result, we are unable to make any conclusion as to its effectiveness in detecting women with T2DM or prediabetes versus preventing diabetes but it would be an important consideration in future research. We have edited the discussion limitations to include:

“Patient level data were not collected within GooD4Mum due to ethics approval restrictions, which limited our ability to explore the impact of factors such as age, blood glucose measurement values, education level or socioeconomic status as potential modifiers of engagement with the general practice and consequently the QIC activity.”

We provide additional information on the diabetes prevention planning session issues to Reviewer 1 above. We have added additional qualitative data to address this concern (see above).

Typographical errors:
Line 53
Line 127

Response:

These have been amended, thank you.

Results:

It would be interesting to know what the pickup rate for diabetes and prediabetes was in the screened population. Is this data available? Could it be included in this publication? This might inform, for example, the reasons for the low rates of diabetes prevention consultations.

Response:

As in a Collaborative, we do not have access the actual values for the diabetes screening tests. The data collection was focused on the rate of the screening rather than the biochemical result. We do not have ethical clearance to access this information.
We have added further detail on this as a limitation to the discussion section:

“Patient level data were not collected within GoD4Mum due to ethics approval restrictions, which limited our ability to explore the impact of factors such as age, blood glucose measurement values, education level or socioeconomic status as potential modifiers of engagement with the general practice and consequently the QIC activity.”

and additional information in the methods section:

“The standard of care provided to patients was aligned with guidelines and no personal or identified data was shared outside the general practice.”

We have additional qualitative data that was collected as part of the study from practices but not reported in this paper due to space constraints. We have decided to include a component of this data to add context to the data already included. We have detailed the exact text above in response to a Reviewer 1 query.

Discussion:
Some discussion re cost effectiveness would be interesting. Many people involved. (both practices and PHNs)- How resource intensive is this project- is it sustainable? Financial costs: Funding for the projects, and costs to the women in time and money.

Response:
We agree that this information would be useful. We have included the following additional information:

In the methods:

“Cost information was captured throughout the intervention from a QIC and intervention perspective. The cost data was collected from women and practices participating using cost diaries alongside recorded project expenses.”

“The cost data were analysed using a pathway approach and only cost descriptions could be provided.”

In the results:

“Total GoD4Mum intervention costs were estimated at $AUD 52,923, comprising project coordination $AUD 11,573, QIC Local Program Officers time cost $AUD 1,919, GP and practice staff time cost $AUD 14,172, materials development and production $AUD 24,405 and website resources $AUD 854. The average cost per practice was estimated at $AUD 3,528 during the QIC project. However, more than one third of total costs were associated with the handbook and material development, which would not be required for future implementation. Excluding the research and development costs, it was anticipated to deliver the intervention to one general practice would cost $AUD 2,166. Healthcare costs were collected from women with a GDM history in the participating general practices. However, the results were not representative due to a very small sample size (N=3 pre-intervention and N=10 post-intervention) and not reported as a result.”

In the discussion:

“Similarly GoD4Mum represented a modest investment to improve diabetes screening and risk monitoring amongst a high-risk population. Further research using a full economic evaluation is needed to assess the value for money of this type of intervention.”
Highlights

- GooD4Mum is a quality improvement study for diabetes prevention after gestational diabetes
- 15 general practices in Victoria, Australia participated in GooD4Mum collaborative study
- Diabetes screening rates doubled (30% to 60%) and 20% increase in BMI monitoring
- Improving screening and monitoring of women with previous gestational diabetes is feasible
GooD4Mum: a general practice-based quality improvement collaborative for diabetes prevention in women with previous gestational diabetes

RUNNING TITLE: Postpartum diabetes prevention in primary care

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**GooD4Mum**: a general practice-based quality improvement collaborative for diabetes prevention in women with previous gestational diabetes

**RUNNING TITLE**: Postpartum diabetes prevention in primary care

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GooD4Mum: a general practice-based quality improvement collaborative for diabetes prevention in women with previous gestational diabetes

Abstract

Aims Gestational diabetes (GDM) and Type 2 diabetes pose tremendous health and economic burdens as worldwide incidence increases. Primary care-based systematic diabetes screening and prevention programs could be effective in women with previous GDM. GooD4Mum aimed to determine whether a Quality Improvement Collaborative (QIC) would improve postpartum diabetes screening and prevention planning in women with previous GDM in general practice.

Methods Fifteen general practices within Victoria (Australia) participated in a 12-month QIC, consisting of baseline and four quarterly audits, guideline-led workshops and Plan-Do-Study-Act feedback cycles after each audit. The primary outcome measures were the proportion of women on local GDM registers completing a diabetes screening test and a diabetes prevention planning consultation within the previous 15 months.

Results Diabetes screening increased with rates more than doubled from 26% to 61% and postpartum screening increased from 43% to 60%. Diabetes prevention planning consultations did not show the same level of increase (0% to 10%). The recording of body mass index improved overall (51% to 69%) but the number of women with normal body mass index did not.

Conclusions GooD4Mum supported diabetes prevention in general practice through increasing diabetes screening and the monitoring of high risk women with previous GDM in general practice.

Abbreviations: gestational diabetes, GDM; glycated haemoglobin A1c, HbA1c; quality improvement collaborative, QIC; general practitioner, GP; body mass index, BMI.
Highlights

- GooD4Mum is the first quality improvement collaborative study focused on increasing diabetes screening and diabetes prevention planning consultations in general practice for women with previous gestational diabetes.
- Using established collaborative methods in 15 general practices, we found diabetes screening rates doubled and a 20% increase in body mass index monitoring.
- Though challenging, this study suggests that improving screening activity and monitoring of high risk women with previous gestational diabetes in a primary care setting is feasible.

Word count

2827
The prevalence of diabetes is growing worldwide [1] and a history of gestational diabetes (GDM) confers increased risk of developing Type 2 diabetes [2]. The incidence of GDM in Australian women is 6% [3] and is higher for some ethnic and socio-economic groups. For women who develop GDM, their risk of developing Type 2 diabetes within 5-10 years is sevenfold higher than for women who have not had GDM [2]. In 2011 Australia started a National Gestational Diabetes Register (Register) to help women manage their diabetes risk by providing them with information booklets and regular screening reminders [4]. Women with GDM typically have their 6-8 week postpartum check-up with their general practitioner (GP) [5, 6]; although the Register provides screening reminders around this time, postpartum screening rates do not appear to be increasing and remain low - around 30% over three years [7, 8]. Significant barriers exist for mothers and general practitioners (GPs) around diabetes screening and lifestyle change [5, 6, 9]. The main screening barriers are time pressures, losing laboratory request forms, and arranging transport and childcare [6, 10], while those for lifestyle modification are apathy towards change, time pressures and mixed messages [6]. Screening appears to be the main stumbling block in supporting this population to reduce their risk of diabetes as regular screening will help identify those at higher risk of developing diabetes and enable their engagement in effective diabetes prevention lifestyle interventions [11] earlier.

Quality improvement Collaboratives (QIC) is a methodology developed by the Boston Institute for Healthcare Improvement that can be applied to achieve system change within an organisation or its teams [12]. QICs differ from randomised controlled trials because they aim to implement existing evidence, usually a clinical guideline based on systematic review [13, 14], and they are concerned with external and internal validity; randomised controlled trials are primarily focused on internal validity [13]. QIC has shown measurable health care improvements in specific areas, for example diabetes treatment and diabetes prevention in older adults [15]. This quasi-experimental research project sought to apply QIC methods to the care of women with previous GDM based on prior
Australian QIC success [15] and the fact that the woman and GP identify general practice as the desired location for care delivery [6]. The aim of this project was to determine whether a QIC based in general practice would improve postpartum diabetes screening, weight monitoring and diabetes prevention planning in women with previous GDM.

Methods

Context

Approximately 300,000 women give birth each year in Australia and at least 17,000 are diagnosed with GDM [3]. The broad adoption of the WHO diagnostic criteria has increased GDM prevalence to 10% [16]. General practices in Australia receive support from Primary Health Networks, which are government-funded and independent organisations. Almost a quarter of all general practices have participated in a QIC project [15] and the Primary Health Networks provide QIC support through QIC Local Program Officers.

The basic QIC constituents are: 1) convening an Expert Reference Panel to define the quality improvement aim and measures, and approving the handbook; 2) identifying change principles and ideas to address underlying causes of the evidence-to-practice gaps; 3) developing the intervention, action periods and learning workshops to support the quality improvement process; and 4) using small local tests of change through Plan-Do-Study-Act cycles. This QIC project was called GooD4Mum and the Expert Reference Panel consisted of diabetes experts, general practice health professionals (practice nurse, GP, dietitian), QIC experts and guideline developers. Victorian Primary Health Networks agreed to participate in GooD4Mum and identified general practices with QIC experience from their catchment areas they felt were suitable for recruitment. There was no funding attached to GooD4Mum participation. Out of the 26 general practices identified and approached, 15 consented to participate (rural N=3, urban N=12). The reasons for declining were insufficient capacity (N=6) and lack of staff interest (N=5).
The GooD4Mum project team consisted of: a project manager, who is an implementation science trained research dietitian; general practice leads, who ranged from practice managers to GPs to practice nurses; QIC Local Program Officers; and the advisory group with key stakeholder representation including women with previous GDM. Each participating general practice initially identified a small GooD4Mum project team (typically a doctor and another staff member) to drive the project activities and nominated a lead to engage with the project manager. The Primary Health Networks nominated their QIC local program officers to engage with the project manager during GooD4Mum. The project manager provided each QIC Local Program Officer and general practice leads with one-to-one project training prior to the project starting. GooD4Mum registered with the Royal Australian College of General Practitioners for Category A Continuous Professional Development, which was important for GP participation. The QIC methods were unfamiliar to three practices, these practices required additional support from the project manager and QIC Local Program Officer.

GooD4Mum was divided into four three-monthly activity periods. During each activity period, general practice teams used the Model of Improvement (three improvement questions and mini quality improvement cycles using the Plan-Do-Study-Act approach). A minimum of one Plan-Do-Study-Act cycle report was required for each activity period. Women with a previous or current GDM diagnosis were identified through a combination of practice software and manual patient record searches to form local general practice GDM registers, which were audited using the quality improvement measures prior to each learning workshop. QIC Local Program Officers assisted general practices with conducting audits, creating and maintaining local practice registers, reinforcing learning workshop messages and providing guidance on completing Plan-Do-Study-Act cycles. The project manager collected, analysed and fed-back quality improvement measures to general practices.
and Primary Health Networks through emailed quarterly report cards. Similarly, Plan-Do-Study-Act cycles were formally collated and shared among general practice teams at six monthly intervals.

General practice teams and QIC Local Program Officers attended four 90-minute online learning workshops (webinars), facilitated by the project manager. The webinars provided interactive learning on the change principles, quality improvement process and guidelines. The audit data from each practice was shared during the webinar and a core component was sharing ideas and collaborative problem solving. Webinars had a prescribed format (welcome, learning outcomes outlined, reflection and discussion of audit data, learning topic with guest presenter/s, sharing ideas, question time and review of learning outcomes, reminders) and the topics were progressive (webinar one: creating and cleaning a local GDM register, webinar two: the practicalities of postpartum screening, webinar three: lifestyle modification for diabetes prevention, webinar four: sharing success through case studies). Each webinar recording was made accessible via the project website for all participants; the website also hosted a discussion board, non-identified Plan-Do-Study-Act report cards and quarterly newsletters.

**Study of Intervention**

The approach chosen for assessing the impact of the intervention was assessing the guidelines and determining what objective actions would reflect them being put into practice. For women with previous GDM, this was engaging in annual diabetes screening and having a consultation where their lifestyle-related modifiable diabetes risk was assessed. For diabetes screening, the issue of whether the test type (arduous oral glucose tolerance test versus quicker fasting blood glucose or Haemoglobin A1c (HbA1c) influenced observed outcomes was questioned but the Expert Reference Panel deemed any change in screening activity would be sufficient evidence that the intervention was driving the behaviour because of the previously low level of engagement of women in screening over time [7, 8]. Also any changes in the first 3 months postpartum diabetes screening were specific to changes in oral glucose tolerance testing, which would differentiate the effect of different
diabetes screening tests. For the diabetes prevention consultation, a specific project form was required to be printed for each woman and this enabled general practices to differentiate intervention consultations from standard ones. Cost information was captured throughout the intervention from a QIC and intervention perspective. The cost data was collected from women and practices participating using cost diaries alongside recorded project expenses. Qualitative interviews and focus groups were conducted in each practice upon completion of the QIC activity to explore barriers and enablers to the intervention.

Measures

The outcome measures were decided by the Expert Reference Panel based on guidelines [17], previously used QIC diabetes prevention measures and measures that were readily extractable from clinical software within a busy clinical setting. All data were aggregated at the practice level and non-identifiable. The general practice lead conducted the manual data extraction every three months. Audit data were manually checked against patient records to ensure counts were accurate and complete. The primary outcome measures were the proportions of women on individual general practice audits: 1) who completed a diabetes-screening test; and 2) who engaged in a diabetes prevention planning consultation within the previous 15 months. The 15-month timeframe was chosen to allow for local variation in appointment scheduling and return of screening results.

Additional secondary outcome measures included oral glucose tolerance test screening rates by three months postpartum and distribution of normal body mass index (BMI) within the practice audit. BMI measurement was identified as a critical measure to identify high-risk women within the register. The change in measures were calculated as average percentage change over time.

Analysis

Run charts were used to report the results of changes in measures over the 12 month intervention (Supplementary Table 1 details each measure). Repeated-measure ANOVA was used to determine if
measures differed significantly between audits. A Greenhouse-Geisser correction was applied where
the assumption of sphericity was violated and post-hoc tests were corrected for multiple
comparisons using the Bonferroni method. The cost data were analysed using a pathway approach
and only cost descriptions could be provided. The qualitative data was analysed thematically by an
experienced qualitative researcher (SOR) and coded transcripts were checked by the participants for
accuracy of interpretation.

Ethical considerations

GooD4Mum had ethical approval provided by Deakin University (HEAG-H 167_2014). The project
was managed and data were analysed by an external person to remove the influence of power
relationships. The standard of care provided to patients was aligned with guidelines and no personal
or identified data was shared outside the general practice. Each general practice consented to
inclusion and there were no funding incentives provided to participate.

Results

Fifteen general practices participated and fourteen completed the project work. One practice was
acquired by a larger provider during the project and subsequently withdrew, they were excluded
from the analysis as a result. The Expert Reference Panel determined that a three-monthly audit
frequency was appropriate due to the relatively low prevalence of GDM in general practice
populations and the period being sufficient to allow women time to engage in diabetes screening, or
attend an appointment for a diabetes prevention planning consultation, or both. The submission of
audits ranged from 100% to 93% each quarter and the number of women on registers with screening
within three months of delivery grew from 43% to 60%. Approximately 481 women with a history of
GDM were involved in the GooD4Mum project. Thirty-eight Plan-Do-Study-Act cycles were reported
over the 12-month project and an average of three cycles were reported per general practice.
There was a general trend of improvement in variables measured over the duration of the project, reflected in the main by shifts in screening practices and BMI monitoring (Table 1). The average number of women per practice with a diagnosis of GDM was 26 (Table 2). At baseline, the average level of screening occurring was 26%, rising to 61% at 12 months (P=0.002). BMI monitoring increased from 51% at baseline to 69% at 12 months (P=0.003). The postpartum diabetes screening and diabetes prevention action planning consultations rose over the course of the project (from 43% to 60% for screening, P=0.066; from 1% to 10% for consultations, P=0.183). The impact of practice location and size was explored descriptively (Supplementary Table 2). The average rate of conversion to Type 2 Diabetes was 6% (±7 SD) over the 12 months but 2 general practices have missing data for this variable.

The qualitative data proposed re are several potential reasons barriers to conducting the diabetes prevention planning for the low uptake of the consultation: 1) it was only emphasised in the final six months of GooD4Mum and therefore had less time to become embedded within daily practice activity; 2) organising it within normal practice workflows was challenging; 3) women were reluctant to attend it for financial and time reasons; 4) limited lifestyle modification referral options existed; and 5) some GPs and practice nurses lacked confidence to engage in a lifestyle modification consultation.

The planned intervention activity was influenced by several external factors (Table 1). Briefly, during the project’s first quarter, glycaated haemoglobin (HbA1c) became a government funded (Medicare) screening test for high-risk individuals and women with a history of gestational diabetes were eligible. At the time, HbA1c was not present in any GDM-specific guidelines and the expert reference panel recommended that HbA1c screening was not recommended for first postpartum screening test but suitable thereafter. Primary Health Networks were restructured by the Australian government at the halfway point of the project, impacting the capacity of Local Program Officers to be involved and the project manager assumed responsibility for this activity during the final part of
The general practice software had initial limitations extracting data for some measures, but this was resolved within the first 2 quarters. The lifestyle modification program used for diabetes prevention in Victoria (State-funded and run by Diabetes Australia, Victoria) had a period of funding uncertainty in quarter three. During that time, GPs were unable to refer their patients into the program and alternative referral plans were developed. When the program was funded again in the final quarter, these alternative plans were rescinded.

Total Good4Mum intervention costs were estimated at $AUD 52,923, comprising project coordination $AUD 11,573, QIC Local Program Officers time cost $AUD 1,919, GP and practice staff time cost $AUD 14,172, materials development and production $AUD 24,405 and website resources $AUD 854. The average cost per practice was estimated at $AUD 3,528 during the QIC project. However, more than one third of total costs were associated with the handbook and material development, which would not be required for future implementation. Excluding the research and development costs, it was anticipated to deliver the intervention to one general practice would cost $AUD 2,166. Healthcare costs were collected from women with a GDM history in the participating general practices. However, the results were not representative due to a very small sample size (N=3 pre-intervention and N=10 post-intervention) and not reported as a result.

Discussion

The Good4Mum QIC was able to demonstrate improved diabetes screening and BMI monitoring in women with previous GDM – the rate of screening doubled and a twenty percent increase in BMI monitoring occurred. Diabetes prevention QICs work by screening the practice population aged over 40 and largely identify people aged 50-69 [15] but the average age for GDM diagnosis is 30 years [18], which means these women will generally be overlooked by diabetes prevention efforts and go unnoticed in general practice. The creation and regular maintenance of a local GDM register enables practices to promote awareness of this growing population and embed diabetes prevention within routine care.
Although several studies have reported the outcomes of interventions to improve postpartum screening rates or lifestyle modification programs to reduce T2DM risk in women with previous GDM [19-22], only two screening reminder studies have been located in general practice [20, 23] and none has addressed both outcomes together. Most have limited generalisability due to being conducted in a single organisation and few used a multimodal approach, which is known to be a critical aspect for supporting change in health behaviour [24]. Participating GooD4Mum general practices had varying levels of experience with QIC methods, had different practice sizes and were located in urban and rural areas – all of which adds to the external validity of the findings.

QICs are multifaceted interventions that bring together many of the successful approaches identified in systematic reviews for professional behaviour change (educational meetings, educational outreach, local opinion leaders, audit and feedback, computerised reminders and tailored interventions), which can yield changes in the order of 50% of participants [14]. Diabetes screening and BMI monitoring in GooD4Mum aligns well with previous QIC diabetes prevention initiatives [15] but providing a diabetes prevention planning consultation was the more challenging component of the project and it had low uptake by both practice staff and women and practice staff reported several barriers to engaging in the activity. In looking at the QIC activities as behaviours that need to be changed and using the Theoretical Domains Framework[25] to map them, the screening activity required minor environmental restructuring to ensure GPs knew which women needed screening alongside some education and training with modelling promoted via teleconferences. These were easier behaviours to change because staff already know they will get reimbursed for doing the blood test and that HbA1c is a useful diabetes indicator. The prevention planning activity was a new process for the practices and required substantial behaviour change. Within the theoretical domains framework it called for: cognitive and interpersonal skills (training practice nurses to perform the tasks and support women to engage in lifestyle change), belief about capability and consequences (both staff and woman), environmental restructuring (needed patient and staff resources plus space to conduct consultation), education and training, persuasion and enablement to influence practice
nurses and GPs optimism that the prevention planning consultations was worthwhile. There are several potential reasons for the low uptake of the consultation: 1) it was only emphasised in the final six months of GooD4Mum and therefore had less time to become embedded within daily practice activity; 2) organising it within normal practice workflows was challenging; 3) women were reluctant to attend it for financial and time reasons; 4) limited lifestyle modification referral options existed; and 5) some GPs and practice nurses lacked confidence to engage in a lifestyle modification consultation [25]. It may simply be that providing a diabetes planning consultation to all women with a history of GDM is not appropriate and that providing the consultation in a more targeted fashion would yield better results. This should be explored in further work. Similarly GooD4Mum represented a modest investment to improve diabetes screening and risk monitoring amongst a high-risk population. Further research using a full economic evaluation is needed to assess the value for money of this type of intervention.

Limitations

GooD4Mum was a small-scale, uncontrolled QIC conducted in a single State in Australia. While the changes in the measures could be attributed to epiphenomena, we know that usual care during the same timeframe was not producing change in diabetes screening [7, 8] or lifestyle modification rates [21]. Similarly the changes in diabetes screening could be attributed solely to the availability of HbA1c as a Medicare funded item and easier test to undertake, yet the change seen in postpartum screening was only due to increased oral glucose tolerance testing, pointing to GooD4Mum stimulating a increase in screening activity across the board. The 6-8 week postpartum screening audit lacks complete data for audit one and two so a full picture cannot be seen for the whole project, a clear limitation as this information would have provided a more nuanced picture of the change in postpartum quality of care. Patient level data were not collected within GooD4Mum due to ethics approval restrictions, which limited our ability to explore the impact of factors such as age, blood glucose measurement values, education level or socioeconomic status as potential modifiers.
of engagement with the general practice and consequently the QIC activity. The small sample size limited the level of insight that could be gained from the QIC project. Only three Plan-Do-Study-Act cycles were reported on average per practice, which is low for QIC projects and a possible limitation. Staff turnover was the main reason for practices missing Plan-Do-Study-Act cycles and some practices wrote up several Plan-Do-Study-Act activities within a single report, which reduced the number of Plan-Do-Study-Act reports they submitted. It is possible that a cluster randomised controlled trial approach with more refined measures would address the majority of the limitations identified.

Conclusions

This QIC project demonstrates significant improvements in type 2 diabetes screening and BMI monitoring but further improvements are possible, particularly around diabetes prevention planning consultations. Future practice needs to build upon the learnings of this project and ensure that a systems approach is taken to improve outcomes for women with previous GDM.

Funding

This work was supported by the Greater Green Triangle University Department of Rural Health, Flinders University and Deakin University and the NHMRC Translating Research Into Practice Fellowship (1069254 to S.L.O’R.). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgements

The MAGDA study group contributors were Rob Carter (Deakin University), Jeremy Oats (University of Melbourne), Timothy Skinner (Charles Darwin University), Micheal Ackland (Monash University),
Paddy Phillips (South Australia Health), Alison Nankervis (The Womens Hospital), Greg Johnson
(Diabetes Australia), John Catford (Epworth Healthcare), Bill Jeffries (Lyell McEwin Hospital), John
Rasa (Networking Health Victoria), Liza Kelsall (Department of Health and Human Services Victoria),
Douglas Boyle (University of Melbourne), Bill Hague (University of Adelaide), Ken Sikaris (Melbourne
Pathology), Wendy Scheil (South Australia Health), Craig Bennett (Diabetes Australia), Peter
Baghurst (University of Adelaide).

We sincerely thank all GooD4Mum participants and organisations especially the general practices,
Medicare Locals and Primary Health Networks which participated in the study; Dino Asproloupos for
senior project management; Expert Reference Group; Dr Sue Phillips, CEO Therapeutics Guidelines;
and Dr Siew Lim for manuscript review. The concept of the study was contained within a National
Health and Medical Research Council (NHMRC) Partnership project grant (ApplID: 533956) called
Mothers After Gestational Diabetes In Australia (MAGDA).

The contents of this publication are solely the responsibility of the individual authors and do not
reflect the views of the NHMRC.
References


D. Oliver, David Oliver: Should practical quality improvement have parity of esteem with evidence based medicine?, BMJ, 357 (2017).


Table 1. Diabetes prevention collaborative for women with previous gestational diabetes in general practice and its evolution over time.

<table>
<thead>
<tr>
<th>Aim</th>
<th>100% women with previous GDM within participating general practices to have a diabetes screening test within the past 15 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% women with previous GDM within participating general practices to be provided with the opportunity to receive a consultation discussing a diabetes prevention action plan within the past 15 months</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Planned activity</th>
<th>External influences</th>
</tr>
</thead>
</table>
| Jul-Sep 2014 | • Handbook preparation  
• Expert Reference Panel meeting – change principles and measures  
• Handbook finalised and endorsed by Expert Reference Panel, provided to all general practices  
• General practice recruitment to quality improvement collaborative | • Australian government announced HbA1c as a screening test under Medicare funding (Late Nov)  
• Handbook materials, audit support and education materials updated to reflect change and delivered to general practice  
• General practice audit software data extraction coding issue, negotiation with several software providers to resolve issue |
| Oct-Dec 2014 | • Audit 1 where the program manager and Local Program Officer supported practices to perform initial audit and form the baseline register of women with previous GDM  
• Learning workshop 1 occurred  
• Plan-Do-Study-Act cycle/s undertaken in general practice and records provided to program manager | |
| Jan-Apr 2015 | • Audit 2 performed with continued support  
• Learning workshop 2 occurred  
• Plan-Do-Study-Act cycle/s undertaken in general practice and records provided to program manager | • General practice software patch rolled out to fix coding issue (Jan/Feb) |
| May-Aug 2015 | • Audit 3 performed with continued support  
• Learning workshop 3 occurred  
• Plan-Do-Study-Act cycle/s undertaken in general practice and records provided to program manager | • State-wide diabetes prevention program places freeze on new participants due to funding renegotiation, practices unable to refer women with previous GDM  
• American Diabetes Association and NICE revise guidelines to include HbA1c as screening test for women with previous gestational diabetes  
• Australian government restructure of Primary Health Networks reduces Local Program Officer capacity |
<p>| Sep-Dec | • Audit 4 performed with continued support | • State-wide diabetes prevention |</p>
<table>
<thead>
<tr>
<th>Year</th>
<th>Support</th>
<th>Audit/Program Refund</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>- Learning workshop 4 occurred&lt;br&gt;- Plan-Do-Study-Act cycle/s undertaken in general practice and records provided to program manager&lt;br&gt;- Final audit performed</td>
<td>program refunded and new participants accepted</td>
</tr>
</tbody>
</table>
Table 2. Summary of means and 95% confidence intervals from the general practices completing Good4Mum (N=14).

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Women registered (N)</td>
<td>26.7 (8.6, 44.8)</td>
<td>23.4 (6.3, 40.5)</td>
<td>29.6 (12.6, 46.6)</td>
<td>31.1 (14.5, 47.8)</td>
<td>34.4 (17.2, 51.5)</td>
<td>Audit 1 v Audit 4; Audit 2 v Audit 4</td>
</tr>
<tr>
<td>Women screened for diabetes (N)</td>
<td>9.1 (1.4, 16.9)</td>
<td>10.8 (2.3, 19.3)</td>
<td>14.9 (5.4, 24.4)</td>
<td>16.4 (6.0, 26.8)</td>
<td>20.0 (9.1, 30.9)</td>
<td>Baseline v Audit 3; Baseline v Audit 4; Audit 1 v Audit 4</td>
</tr>
<tr>
<td>Women screened for diabetes (%)</td>
<td>26.1 (11.6, 40.7)</td>
<td>32.9 (16.1, 49.7)</td>
<td>53.4 (38.9, 68.0)</td>
<td>54.2 (39.4, 69.0)</td>
<td>61.0 (48.6, 73.4)</td>
<td>Baseline v Audit 5</td>
</tr>
<tr>
<td>Women with BMI recorded (%)</td>
<td>50.7 (28.1, 73.3)</td>
<td>55.9 (34.7, 77.1)</td>
<td>65.6 (48.9, 82.2)</td>
<td>69.6 (55.1, 84.0)</td>
<td>68.8 (53.4, 84.2)</td>
<td>Baseline v Audit 3; Baseline v Audit 4</td>
</tr>
<tr>
<td>Women with normal BMI recorded (%)</td>
<td>19.1 (4.7, 33.4)</td>
<td>22.1 (9.4, 34.9)</td>
<td>31.3 (15.0, 47.6)</td>
<td>32.8 (16.5, 49.1)</td>
<td>33.2 (16.6, 49.9)</td>
<td>No significant comparisons</td>
</tr>
<tr>
<td>Women with diabetes prevention action planning consultation (%)</td>
<td>0.9 (-1.0, 2.7)</td>
<td>5.6 (-5.7, 16.8)</td>
<td>7.3 (-3.8, 18.4)</td>
<td>9.1 (-3.4, 21.7)</td>
<td>10.3 (-3.0, 23.5)</td>
<td>No significant comparisons</td>
</tr>
<tr>
<td>Women screened for diabetes within first three months postpartum (%)</td>
<td>Data incomplete</td>
<td>Data incomplete</td>
<td>42.3 (22.4, 64.2)</td>
<td>46.6 (23.8, 69.5)</td>
<td>59.9 (39.5, 80.3)</td>
<td>No significant comparisons</td>
</tr>
</tbody>
</table>
Supplementary Table 1. GooD4Mum quality improvement collaborative measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDM Register</td>
<td>The number of women within the clinical database that are coded with a diagnosis matching the GDM definition</td>
</tr>
<tr>
<td>T2DM Screening</td>
<td>The number of women on the GDM Register who have had an OGTT/FPG measurement recorded within the previous 15 months</td>
</tr>
<tr>
<td>T2DM diagnosis</td>
<td>The number of women on the GDM Register who have had a diagnosis of T2DM recorded</td>
</tr>
<tr>
<td>T2DM Prevention Care</td>
<td>The number of women on the GDM Register who had the GooD4Mum diabetes prevention action plan printed out</td>
</tr>
<tr>
<td>Postpartum Follow Up of Gestational Diabetes</td>
<td>The number of women on the GDM Register who gave birth within the previous year and had an OGTT measurement recorded within 3 months of delivery</td>
</tr>
<tr>
<td>Body Mass Index (BMI) - Recorded</td>
<td>The number of women on the GDM Register with recorded weight and height OR BMI</td>
</tr>
<tr>
<td>Normal Body Mass Index (BMI)</td>
<td>The number of women on the GDM Register where BMI is &lt; 25</td>
</tr>
</tbody>
</table>
Supplementary Table 2. Summary of means and 95% confidence intervals from the general practices completing Good4Mum divided into metropolitan and rural areas using Accessibility/Remoteness Index of Australia (ARIA).

<table>
<thead>
<tr>
<th></th>
<th>Metro (n=11)</th>
<th>Rural (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total register</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>25.5 (4.1, 46.8)</td>
<td>31.3 (-57.9, 120.5)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>25.9 (3.6, 48.2)</td>
<td>14.3 (-3.6, 32.3)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>32.2 (10.3, 54.1)</td>
<td>20.0 (-10.2, 50.2)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>32.8 (11.2, 54.4)</td>
<td>25.0 (-8.4, 58.4)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>36.3 (14.2, 58.2)</td>
<td>27.3 (-10.3, 65.0)</td>
</tr>
<tr>
<td><strong>Diabetes screened (% register, 95%CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>24.5 (8.8, 40.2)</td>
<td>32.3 (-58.5, 123.1)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>28.1 (9.1, 47.1)</td>
<td>50.7 (-23.5, 124.9)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>55.4 (38.0, 72.8)</td>
<td>46.3 (-19.1, 111.8)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>53.7 (35.2, 72.3)</td>
<td>56.0 (0.1, 109.9)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>61.0 (44.9, 77.1)</td>
<td>61.0 (35.8, 86.2)</td>
</tr>
<tr>
<td><strong>Diabetes prevention consultation (% register, 95%CI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>1.1 (-1.3, 3.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>7.1 (-7.6, 21.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>8.9 (-5.6, 23.5)</td>
<td>1.3 (-4.4, 7.1)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>10.7 (-5.7, 27.1)</td>
<td>3.3 (-5.4, 12.1)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>12.3 (-5.0, 30.0)</td>
<td>3.0 (-4.5, 10.5)</td>
</tr>
</tbody>
</table>
Supplementary Table 3. Summary of means and 95% confidence intervals from the general practices completing Good4Mum divided into practice size, using number of effective full-time general practitioners employed at baseline.

<table>
<thead>
<tr>
<th></th>
<th>Small practice (n=2)</th>
<th>Medium practice (n=4)</th>
<th>Large practice (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total register (n, 95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>5.5 (-39.0, 50.0)</td>
<td>17.5 (-0.9, 35.9)</td>
<td>36.6 (4.5, 68.8)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>6.5 (-50.7, 63.7)</td>
<td>16.8 (-0.8, 34.3)</td>
<td>31.0 (-0.3, 62.3)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>7.0 (-31.1, 45.1)</td>
<td>22.0 (19.1, 24.9)</td>
<td>39.0 (8.6, 69.4)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>8.0 (-42.8, 58.8)</td>
<td>22.0 (19.1, 24.9)</td>
<td>41.5 (12.3, 70.7)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>9.5 (-60.4, 79.4)</td>
<td>26.5 (17.7, 35.3)</td>
<td>44.5 (14.6, 74.4)</td>
</tr>
<tr>
<td><strong>Diabetes screened (% register, 95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>22.0 (-257.5, 301.5)</td>
<td>18.5 (-6.4, 43.4)</td>
<td>31.0 (6.3, 55.7)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>41.0 (-480.0, 562.0)</td>
<td>19.5 (7.3, 46.3)</td>
<td>37.6 (13.6, 61.6)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>75.0 (-242.7, 392.7)</td>
<td>48.0 (17.0, 79.0)</td>
<td>50.8 (28.9, 72.6)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>66.5 (-143.2, 276.2)</td>
<td>36.0 (-5.1, 77.1)</td>
<td>60.3 (40.1, 80.5)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>68.5 (-166.6, 303.6)</td>
<td>46.8 (12.0, 81.6)</td>
<td>66.3 (49.9, 82.7)</td>
</tr>
<tr>
<td><strong>Diabetes prevention consultation (% register, 95%CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit 1</td>
<td>0 (0)</td>
<td>3.0 (-6.6, 12.6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Audit 2</td>
<td>36.5 (-427.3, 500.3)</td>
<td>1.3 (-2.7, 5.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Audit 3</td>
<td>36.5 (-427.3, 500.3)</td>
<td>3.5 (-3.4, 10.4)</td>
<td>1.9 (-1.4, 5.2)</td>
</tr>
<tr>
<td>Audit 4</td>
<td>41.5 (-485.8, 568.8)</td>
<td>3.5 (-3.4, 10.4)</td>
<td>3.9 (-0.1, 7.9)</td>
</tr>
<tr>
<td>Audit 5</td>
<td>43.5 (-509.2, 596.2)</td>
<td>3.5 (-3.4, 10.4)</td>
<td>5.4 (-1.0, 11.8)</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Location</td>
<td></td>
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<td>--------------------------</td>
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<td></td>
</tr>
<tr>
<td>Title</td>
<td>Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)</td>
<td>1-2</td>
<td></td>
</tr>
</tbody>
</table>
| Abstract                 | a. Provide adequate information to aid in searching and indexing  
|                          | b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions            | 31-47    |
| Introduction             | Why did you start?                                                                                                                                                                                           |          |
| Problem description      | Nature and significance of local problem                                                                                                                                                                   | 64-68    |
| Available knowledge      | Summary of what is currently known about the problem, including relevant previous studies                                                                                                                                 | 70-79    |
| Rationale                | Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work | 80-88    |
| Specific aims            | Purpose of the project and of this report                                                                                                                                                                  | 89-90    |
| Methods                  | What did you do?                                                                                                                                                                                             |          |
| Context                  | Contextual elements considered important at the outset of introducing the intervention(s)                                                                                                                      | 93-110   |
| Intervention             | a. Description of the intervention(s) in sufficient detail that others could reproduce it  
|                          | b. Specifics of the team involved in the work                                                                                                                                                              | 113-149  |
| Study of intervention    | a. Approach chosen for assessing the impact of the intervention(s)  
|                          | b. Approach used to establish whether the observed outcomes were due to the intervention(s)                                                                                                                   | 151-162  |
| Measures                 | a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability  
|                          | b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost  
|                          | c. Methods employed for assessing completeness and accuracy of data                                                                                                                                       | 164-175  |
| Analysis                 | a. Qualitative and quantitative methods used to draw inferences from the data  
|                          | b. Methods for understanding variation within the data, including the effects of time as a variable                                                                                                         | 177-182  |
| Ethical considerations   | Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest | 184-188  |
| Results                  | What did you find?                                                                                                                                                                                           |          |
| Results                  | a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project  
|                          | b. Details of the process measures and outcome  
|                          | c. Contextual elements that interacted with the intervention(s)                                                                                                                                             | 190-221  |
d. Observed associations between outcomes, interventions, and relevant contextual elements
e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).
f. Details about missing data

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Data Statement

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