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RESEARCH
TRANSLATION
FACULTY

CASE FOR ACTION- PROPOSAL TO NHMRC

Obesity prevention through preventing excess weight gain during pregnancy and postpartum

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Submitted by the Research Translation Faculty Obesity Steering Group (September 2014)

OBESITY

The National Health and Medical Research Council (NHMRC) Research Translation Faculty (the Faculty) was established as a key advisory forum in 2012. The primary work of the Faculty for the 2013-15 Triennium has been to help NHMRC accelerate the translation of research by identifying the most significant gaps between research evidence and health policy and practice in each of the major health areas in the NHMRC Strategic Plan, and to propose to NHMRC possible action it could consider taking to address that gap – these are called Cases for Action. In April and May 2013, fourteen Faculty steering groups were established as NHMRC working committees to each oversee the development of a Case for Action.

The Faculty's Obesity Steering Group is comprised of a range of experts and includes primary (1˚) and secondary (2˚) representatives of NHMRC Health Care Committee (HCC), Prevention and Community Health Committee (PCHC) and Research Committee (RC). Further information is available at: www.nhmrc.gov.au/research/research-translation/research-translation-faculty/research-translation-faculty-steering-groups.

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Declaration of interests

The declarations of interests of Steering Group members, authors and contributors are available at Appendix 3.

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NHMRC Research Translation Faculty

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Title: *Obesity prevention through preventing excess weight gain during pregnancy and postpartum*

Submitted to NHMRC for consideration: September 2014

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Case for Action in Obesity – NHMRC Research Translation Faculty

Obesity prevention through preventing excess weight gain during pregnancy and postpartum

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Rationale and Summary

Obesity presents a major public health and economic burden worldwide. Prevention of weight gain is feasible and requires minor lifestyle adjustments(1), whereas addressing established obesity requires intensive, multidisciplinary and costly treatment with poor efficacy and sustainability (2). Prevention of weight gain is a therefore a high priority.

Young reproductive age women are at high risk of excess weight gain driving obesity and related major reproductive and metabolic complications (3). Pregnancy contributes, with most women exceeding recommended gestational weight gain (GWG), and retaining a mean 2-5kg per pregnancy (4-8). Excess GWG increases pregnancy risks for mothers and babies, and is directly related to long-term maternal obesity across all weight categories (9), with longitudinal data in over 2000 women showing a 300% increase in obesity risk long term if GWG exceeds guidelines (5). Further, excess GWG in pregnancy, independent of potential confounders and mediators and after adjustment for pre-pregnancy maternal BMI, is a key predictor of childhood obesity. Excess GWG in mothers within the normal BMI range preconception has the most pronounced impact on child health, with an odds ratio of 1.79 (95% CI, 1.32–2.43) for obesity in childhood (10). Hence, excess GWG drives long term maternal and childhood obesity and subsequent chronic disease (5).

Lifestyle intervention: A comprehensive systematic review of lifestyle intervention studies in 7278 women (see attached), has shown effective prevention of excess GWG. Lifestyle intervention also reduced preeclampsia and shoulder dystocia and the more intense dietary interventions also prevented gestational diabetes (GDM) (11). There was no impact on birth weight, nor any safety concerns (11). As confirmed in the recent LIMIT study there were no adverse psychological impacts of regular weighing in pregnancy or of lifestyle intervention. Success factors included focusing on diet or combined diet and exercise interventions, rather than exercise alone. However, poor compliance with exercise prescription attenuates the effects of most exercise interventions. Behavioural strategies such as self-monitoring and motivational interviewing, as well as modern technology, are important components of successful intervention programs (11-14).

Evidence of successful lifestyle interventions in pregnancy in the Australian setting include the Monash behavioural Healthy Lifestyle Program (HeLP-her). This program, initially published in the BMJ, started as the first community-based successful weight gain prevention trial in non-pregnant women (15). Now with evidence across different settings and populations, it has established efficacy in high risk pregnancy (HeLP-her HRP) with demonstrated cost savings (net saving between ~$80/participant - submitted)(16). It is now being trialled across 42 rural towns (NHMRC funded); targeting mothers of young children and scale-up is being funded by the Victorian government (fig 1). Another Australian multidisciplinary study focused on continuity of care and also prevented excess GWG (17). The LIMIT lifestyle study, a large NHMRC funded lifestyle study in pregnancy, targeted prevention of large for gestational age (LGA) births, but failed to achieve the primary end-point. This is consistent with other literature showing lifestyle intervention in pregnancy does not impact on LGA (11). This study however was run externally to routine antenatal care had suboptimal engagement and notable attrition rates. In this context, not surprisingly, the LIMIT intervention did not effectively modify lifestyle or GWG (18).

Translation: The creation of knowledge does not, of itself, lead to widespread implementation and positive impacts on health. Knowledge must be translated into changes in practice and policy. With an imperative for action and demonstrated efficacious lifestyle interventions, there is now a clear need for a staged pragmatic implementation/translation program (11, 19)(20). This will take

existing evidence and inform efforts to change practice and scale up healthy lifestyles in pregnancy. An implementation program will address implementation questions for clinicians, health services and governments. As noted in the BMJ, implementation programs are vital for linking efficacy research to broad scale effectiveness and health care impact (19).

Barriers to implementation of healthy lifestyle initiatives in pregnancy include limited knowledge and inaccurate perceptions (among women and health professionals). Misperceptions relate to the importance of prevention of excess GWG and to appropriate gestational weight gain targets. There is inadequate health professional training and staff time to support lifestyle change (21). Sociocultural challenges for health professionals and women are problematic and there are limited available resources. There is also no systematic approach to healthy lifestyle in pregnancy with gaps at all levels of the antenatal health care system. Staged implementation is needed to address these barriers and inform scale up. Enablers of weight gain prevention in pregnancy include the *"teachable moment"*, with motivation for adoption of healthy behaviours. Also we have an existing health care system for pregnancy care with a health care workforce in place. Our group and others have also shown strong engagement in antenatal care across different socioeconomic and disadvantaged groups including Indigenous and refugee women (22-25).

Solutions: This CFA is prepared by an internationally recognised team with expertise in public health, obstetrics, midwifery, dietetics, exercise physiology, health economics, biostatistics, policy and systems approaches. We bring backgrounds in research, implementation and scale-up. We propose a series of actions and an implementation program to reduce GWG, pregnancy complications and prevention of longer term obesity. In this comprehensive evaluation we will identify system level leverage points in this unique setting and target group which will drive translation of evidence into practice to inform policy and change practice to improve health (19).

Aims of staged implementation program

To translate evidence into policy and practice, we recommend support and engagement activities, staged implementation of an evidence based lifestyle program into routine pregnancy care (including aiming to improve adherence to GWG recommendations), and a birth registry as a key platform for evaluation.

Specifically we recommend:

1. NHMRC to provide evidence-based advice to Commonwealth, state and territory departments of health in support of effective lifestyle interventions to prevent GWG including:
    - set out the existing evidence and highlight additional ongoing scoping activities
    - make a case for implementation of a national program, based on the evidence presented in the CFA
    - broadly set out the steps that would be involved in a systematic staged approach to national implementation
2. NHMRC to review the evidence and current recommendations on the prevention and management of GWG and produce national advice based on this review.
3. NHMRC to work with relevant stakeholders to promote the benefits of a birth registry and identify opportunities for its establishment.

Detailed background

Preventing weight gain is a key public health issue as illustrated by the following international and national priorities:

- WHO highlighting weight gain prevention, across the BMI range;
- NIH funding ($20M USD) to manage excess weight in pregnancy;
- Prevention of weight gain prioritised by the Australian Government through the National Preventive Health Agency, *Taking Preventative Action report*, *Preventative Health Taskforce Strategy* and Women's Health Policy;
- Coalition of Australian Governments Partnership Agreements on Preventive Health to hold the rise in adult unhealthy weight to 5% of baseline by 2013 returning to baseline by 2015;

This CFA proposal aligns with these agendas, targeting a high risk group with learnings relevant to the general population. It focuses on staged implementation to change policy and ultimately practice, to deliver tangible health and economic outcomes.

Health implications and rationale for general prevention of weight gain: Trends predict a 65% increase in Australian obesity prevalence by 2025, with <30% predicted to be healthy weight. Weight accumulates at ~700gms/year in young Australian women, with gain inversely proportional to BMI (3). Non-obese women gain more weight than obese women and 20% progress to higher BMI categories within five years (26, 27). While prevention is feasible, and requires minor energy balance adjustments (~220kJ/day)(1), established obesity requires intensive, multidisciplinary, costly treatment, with poor efficacy and sustainability (2). Prevention is also preferable because health impacts do not always reverse with weight loss (28).

Health implications of weight gain are major and risks increase per kilogram gained across all weight categories. Infertility and pregnancy complications occur and diabetes risk increases from a BMI of 22 kg/m^2 (29), with a lifetime risk of 18% in normal weight, 35% in overweight and 75% in obese women (29). Cardiovascular disease, the number one killer in Australian women, increases by 3% for each kilogram gained (30). As 55% of deaths are lifestyle related, the imperative for preventative public health interventions is critical (31).

Rationale for targeting women: Obesity prevention is vital for all. We target women here:

- as there are significant reproductive implications of obesity in women
- pregnancy offers a defined life stage for women with specific enablers for lifestyle change including engagement with the health care system
- benefits of lifestyle change in pregnancy offer benefits to mothers and babies
- targeting women has broader benefits for families and the community
- evidence based interventions are available

Rationale for prevention of excess GWG in pregnancy: Most Australian women exceed international GWG recommendations (4, 8, 32, 33) retaining ~2-5kg per pregnancy (8, 27). Excess GWG has major implications, with every kilo above recommended associated with ~10% increase in adverse outcomes (34), including foetal malformations, miscarriage, preeclampsia, gestational diabetes, labour complications and increased costs (35, 36). GDM affects 5% of normal weight and 18% of obese pregnancies (37, 38). Importantly, excess GWG is a strong predictor of long-term maternal obesity across all weight categories (9), with longitudinal data showing a 300% increase in obesity long term, if GWG exceeds recommendation (5). GWG also independently contributes to childhood obesity with children of women who exceed recommended GWG, having a 46% increase in overweight/obesity. The odds ratio [OR] was 1.46; 95% CI 1.17–1.83) after adjusting for maternal pre-pregnancy BMI, race/ethnicity, age at delivery, and other potential confounders). The risks of childhood obesity were strongest in women with a normal pre-pregnancy BMI (OR 1.79, 1.32–2.43) (10). Prevention of obesity is important lifelong, yet pregnancy offers double impact for mother and baby/child health, is evidence based and targets a life stage where motivation is high and where health system engagement is strong. Also 5% of all hospital admissions in Australia are related to pregnancy and the majority of Australian women experience at least one pregnancy with >98% attending antenatal care enabling broad capture of the population at a defined high risk life stage.
There is a clear imperative to prevent excess GWG to improve health for mothers and babies and to reduce maternal and childhood obesity and their long term complications.

Lifestyle interventions in pregnancy: Lifestyle studies in pregnancy generally improve GWG and postpartum weight retention (11, 13, 39-43). On meta-analysis, preeclampsia (OR 0.39 - 0.74) and shoulder dystocia (OR 0.39) were reduced, with a trend to reduced GDM (OR 0.78, CI 0.57-1.08) (11). There is no discernible impact on birth weight (5278 newborns on systematic on systematic review), but a trend towards reduced large for gestational age babies (11). Learnings include that diet or combined interventions are better than exercise alone. Is has also emerged that weight monitoring can facilitate healthy GWG, but that weight monitoring alone, without intervention is ineffective (44). Alignment with, or integration into, routine antenatal care facilitates engagement and reduces attrition (15). Table 1 summarises the relevant systematic reviews. Also data six years post antenatal lifestyle intervention shows mothers weight was 4 kg less in the antenatal intervention vs control groups supporting long term benefit of antenatal lifestyle intervention (45).

The LIMIT study has reported since these systematic reviews. This was an RCT of a low intensity lifestyle intervention, primarily targeting obese pregnant women, with two visits not integrated into routine care (85 and 77% attendance respectively), phone coaching and no electronic support. Unlike most GWG interventions, LIMIT was ineffective (40gm difference between groups), yet did yield some health benefits including improved diet quality, reduced number of babies >4000gms and >4500gms and reduced length of hospital stay. There was no adverse impact on mood or quality of life for mothers in the intervention who were weighed regularly and no adverse effects for the babies. Low intensity interventions are less effective in obese women, who make up 18% of Australian pregnancies and may need additional intensive intervention. Intervention in obese pregnancies is being investigated by the NIH with a current $20M study.

Despite evidence of effective interventions to prevent GWG in pregnancy and potential enablers in the antenatal care system, there are significant gaps that still need to be addressed. These include, but are not limited to little workforce or organisational engagement in healthy lifestyle in antenatal care and inadequate quality measurement of outcomes. To address these this proposal focuses on staged implementation to address these gaps moving beyond the individual intervention level to address local systems issues. The recommended implementation program builds on an innovative workforce up-skilling/ strategies and includes sustainability components with integration into the existing health system as outlined below. Learnings here can also draw upon parallel evidence from other effective systems wide change in this setting including breastfeeding initiatives.

The overall intention of this CFA population based strategy is therefore to limit GWG in the majority of non-obese women (82% pregnancies), delivering health benefits and reduced obesity in mothers and children long term. We deliberately target the antenatal care setting which provides significant enablers to prevent obesity and does not duplicate other activity in the area.

Key learnings from systematic reviews and literature include:

1/ Lifestyle intervention is effective in reducing gestational weight gain during pregnancy and postpartum weight retention with more success noted in dietary focused interventions compared to physical activity alone
2/ Interventions have nominal impact on birth weight, but may reduce births over 4000gms
3/ Interventions decrease maternal pregnancy complications
4/ Evidence from reviews summarising behavioural components suggest key enablers for prevention of excessive GWG include self-monitoring and motivational interviewing
5/ Monitoring weight alone, without active intervention appears ineffective
6/ Modern technology is emerging as a promising tool to improve intervention success
7/ Interventions appear safe and do not appear to cause harm

The research and implementation team preparing this CFA are involved in the current UK funded international individual patient meta- analysis on lifestyle interventions in pregnancy, including the Australian HeLP-her intervention. This will strengthen evidence synthesis in this area with results available in 2015.

Summary: Pregnancy is a high-risk time for excess GWG as a driver of obesity longer term. GWG increases health risks and costs for mothers and babies. There is a clear imperative to prevent excess GWG in pregnancy and reduce obesity and its complications. With evidence based interventions ready for implementation and scale-up, it is now time to translate the existing evidence into practice to prevent obesity and deliver health and economic benefits at a population level.

Author	Study Selection	Search Cut Off Date	Studies & Women Included	Main Outcomes	Main Findings
Thangaratinam et al, 2012 BMJ	RCTs dietary, physical activity or mixed approach No BMI limit	Jan 2012	44; *n* 7278 (inc 34 studies for GWG)	• Gestational weight gain	• -1.42kg with any intervention (-0.95,-1.89kg) • -3.84kg with dietary intervention (-2.45, -5.22kg). • No effect on IOM within recommendations.
				• Foetal birth weight	• No effect
				• Maternal: pre-eclampsia, GDM, hypertension, caesarean section, labour induction,	• Pre-eclampsia: 26% reduction overall, 33% reduction with dietary intervention. • GDM: 61% reduced risk with dietary intervention.
				• Foetal: birth trauma, hyperbilirubinaemia, shoulder dystocia	• Shoulder dystocia: 61% reduced risk with any intervention
Muktabhant et al, 2012 Cochrane Review	RCTs dietary, physical activity or mixed approach No BMI limit; results presented separately for general and high-risk populations	Oct 2011	27 ; *n* 3964	• Gestational weight gain	• -1.39kg with behavioural (3 studies) • -2kg with exercise (1 study)
				• Risk of macrosomia (>4000g)	• No effect
				• Maternal: pre-eclampsia, caesarean section, labour induction, postpartum complication	• No effect
				• Foetal: associated macrosomia complications	• No effect
Sui et al, 2012 Acta Ob Gynecol	RCTs Exercise only Overweight/obese only	2011	7; *n* 276	• Gestational weight gain	• -0.36kg with intervention
Hill et al, 2013 Obesity Reviews	Studies to prevent excess GWG No BMI limit	Nov 2012	21; *n* 3823	• Gestational weight gain	• -1.54kg compared to control • Better results with dietary intervention compared to exercise or mixed approach
Tanentsapf et al, 2013 BMC	RCTs Dietary interventions only No BMI limit	March 2011	13; *n* 1802	• Gestational weight gain: total and % exceeding IOM	• -1.92kg compared to control
				• Macrosomia (>4000g)	• No effect
				• Maternal: postpartum weight retention, pre-eclampsia, GDM, caesarean section	• -1.90kg weight retention at 6 months postpartum • Reduced risk caesarean section

Healthy Lifestyle Program for her (HeLP-her) (proposed as NHMRC recommended intervention): Here we build on HeLP-her interventions as an effective and cost effective intervention and on learnings from comprehensive evidence synthesis (table 1) (11). HeLP-her targets weight gain prevention. Published in the BMJ, an RCT of ~250 community dwelling mothers prevented weight gain over a year. HeLP-her includes simple dietary and activity messages, is based on established behavioural theory and self-management and uses personalised goals and approaches for feasible lifestyle changes (46, 47).

Figure 1: The evidence supporting HeLP-her including populations, settings and funding

HeLP-her involves goal setting, problem solving, relapse prevention, self-monitoring, phone coaching and SMS messages (15, 48). Dietary messages are informed by systematic review and national guidelines including increasing unprocessed grains, fruits, vegetables, with monitoring including food diaries (11). HeLP-her was the only intervention cited by the Preventative Taskforce, won the Public Health care (Vic) and a national BUPA award. HeLP-her was adapted to high risk pregnancies (HeLP-her HRP), preventing GWG in a low-mid socioeconomic, multiethnic population in an internationally funded RCT (7, 16, 49). Greatest efficacy was noted (3 fold reduction in postpartum weight retention) in women non obese pre-pregnancy. HeLP-her is also funded via a $1M NHMRC project grant for a cluster RCT across 42 rural towns (50). For that trial HeLP-her was adapted to integrate within existing local prevention systems. Recent analysis of results demonstrate efficacy at 1 year, with 2 year data collection underway. HeLP-her is now being scaled-up and implemented with support of Government as an integrated component of local prevention systems for non-pregnant women in the "Healthy Communities Victoria" (51) demonstrating implementation capacity of the CFA team (fig 1) and engagement of government. Funded by strategic grants across two states, HeLP-her has been integrated into ambulatory care settings including in remote Indigenous services, with recent positive evaluation. HeLP-her also underpins a short listed Global health NHMRC grant for roll out in India, Sri Lanka and Bangladesh, a short listed NHMRC CRE application in women's health and several submitted project and partnership implementation grants. The Victorian Government has recently funded resource adaptation and translation (4 key languages) targeting the pregnancy setting and committed to a partnership grant ($210,000 cash) along with all major maternity services in Victoria to progress the implementation of HeLP-her in pregnancy.

Overall, systematic review evidence supports the role of effective lifestyle interventions in prevention of GWG and HeLP-her is the most rigorously tested of these interventions with efficacy shown in studies of >1100 Australian women across a range of settings (rural, urban, schools, workplaces) and populations (rural, metro, immigrant, low SES) including in pregnancy (33, 49, 50, 52-54).

Economic Impact: HeLP-her is simple, low cost, pragmatic and implementation informed. Integration into routine antenatal care enables broad reach without additional infrastructure. It involves up-skilling of the existing antenatal workforce and low skill requirements. Resources are simple and include novel IT components with a focus on self-monitoring and self-management. These features reduce cost and enhance acceptability, affordability and sustainability. Cost effectiveness analyses have been completed to inform on both the potential savings if GWG complications including GDM were prevented to indicate the budget available for prevention. Cost effectiveness analysis has also been completed on HeLP-her intervention based on prevention of GWG and its complications including GDM and suggests cost savings. Within trial health economic analysis is underway, relevant manuscripts have been submitted for publication and further information is available on request[1](55).

[1] For additional information please contact Prof Helena Teede (helena.teede@monash.edu)

Broader impact: Successful completion of this CFA will see consistent national recommendations for healthy gestational weight gain with implementation and scale up of an evidence based lifestyle intervention. This will deliver health and economic benefits and drive obesity prevention for both mothers and babies. Australia will become a leader in the broad scale implementation of population based interventions in pregnancy, informing the field internationally. More broadly it will inform translation of evidence into practice including staged implementation, scale-up and evaluation for continuous improvement.

Summary: HeLP-her is an evidence-based, simple, implementation informed lifestyle intervention successful in a range of settings and populations, including in pregnancy. Cost effectiveness analyses suggest potential cost savings. If implemented and scaled-up successfully the program will prevent GWG and limit obesity and reduce related pregnancy and health complications for mothers and babies. Successful scale-up has broader implications delivering learnings in evidence translation across implementation, scale-up and evaluation linked to continuous improvement.

NHMRC Context: Obesity is a national Health Priority area for the NHMRC. There are many opportunities for action in this area. However the NHMRC Faculty for Translation Obesity Steering Committee has determined, based on collective expertise and a national consultation process, that promoting healthy GWG is a compelling CFA.

Recommendations in this CFA are consistent with the NHMRC strategic plan and priorities:

- Create new knowledge through support of research.
- Accelerate research translation so health care and prevention is based on evidence.
- Maximise benefits to Australia's health and prosperity from the work of NHMRC

CFA framework for action: This CFA is framed around an iterative implementation and knowledge to action cycle that underpins the activity of the Monash Centre for Health Research and Implementation and is based on the Canadian knowledge to action cycle including:

a) Consolidating knowledge through evidence synthesis

b) Implementation including implementation research and a staged pilot program. This is needed to inform how to maximise reach, effectiveness and sustainability through the testing and use of strategies to facilitate transfer and scale up of evidence-based approaches into practice in real-world settings. Piloting/ implementation research is an important phase of implementation to test and refine strategies and inform and enable broader scale-up.

c) Dissemination via distribution of information and resources to spread knowledge and use of evidence-based interventions

d) Scale-up as the development of organisational and system wide capacity for sustained, widespread use, evaluation and monitoring of uptake and rollout (56, 57). This is the remit of government and health services.

Actions for NHMRC to support and progress this CFA include:

The process of CFA selection and prioritisation in itself will provide significant impetus and strategic positioning to drive and enable translation of evidence into practice on prevention of GWG. It is anticipated that it will support the "significance" of implementation research in applications through routinely accessible NHMRC research funding streams including partnership, project and CRE schemes. It is also anticipated that it will facilitate engagement of stakeholders, funders and government.

Specific NHMRC actions recommended include:

1. NHMRC to provide evidence-based advice to Commonwealth, state and territory departments of health in support of effective lifestyle interventions to prevent GWG including to:

a) Set out the existing evidence and highlight scoping activities (currently underway):
This includes engagement of policy makers to share and inform on the need for action and the evidence for efficacy of interventions through current established structures, such as COAG and NHMRC reporting lines to government. The NHMRC could highlight current scoping activities through COAG and other channels. This includes the work by the CFA team encompassing scoping and feasibility of current practices, policies and initiatives within the healthcare system in a funded contract with the Victorian government. This would enable the CFA team to advocate broadening these nationally. Results to date demonstrate that there is no consistent and systematic approach to healthy lifestyle in pregnancy and that there are implementation gaps to be addressed across the antenatal health care system.

b) Make a case for a staged implementation of a national program, based on the evidence presented in the CFA
Prevention of excess GWG is an active area of research with our group (15) and others demonstrating positive outcomes with lifestyle intervention during pregnancy (Table 1). Yet, the key challenge is how to best adapt these otherwise isolated efficacy studies into routine antenatal care (19). Here, staged implementation is important and development of implementation strategies are vital to capitalise on investment in efficacy studies, translate evidence into and practice (19) and deliver programs ready for scale-up to deliver broader public health impact. This will involve a complementary mix of an implementation program strengthened/ underpinned by implementation research. Elements of research would include formative research to refine resources (noted below), input into implementation design and formal evaluation, including cost effectiveness.

Principles/ steps in implementation should include:

- Use of an evidence based lifestyle intervention with efficacy in the Australian setting
- Incorporation of interventions into routine antenatal care within current health systems
- Refinement of evidence-based resources/tools to target health professionals, women, and health services, to address enablers and barriers to implementation. As the intervention transitions from efficacy studies to implementation it will involve staff training, targeting up-skilled champion midwives (as demonstrated in an adaptation of a 2 day training program already available for community health workers for implementation in non-pregnancy settings). This will be supported by simple online programs to up-skill general antenatal health professionals, with low staff skill requirements. These strategies limit costs and address clinical time constraints. For women, complimentary resources should include contemporary technology (websites, live chat, SMS, phone apps (22)), designed for broad scale roll-out. Manuals, website, SMS content and apps are already developed. Whilst core elements and content will be retained, these resources will require adaptation, which will be the subject of implementation activities.
- An implementation resource for health services should apply evidence based improvement principals with minimum standards, measureable processes and outcomes and flexible implementation in the local context, co-designed with stakeholders. This process will link to other systems components (e.g. local policies, staff education programs and service health promotion initiatives) and is being developed by the CFA team.
- Completing detailed health economics analysis on the implementation pilot
- Overall with growing demands, interventions must be cost effective, feasible, generalisable and sustainable (21), principles which underpin HeLP-her and the planned implementation program.

- Pilots should include initial implementation across multiple sites, different levels of hospital care, regional areas, models of care (midwifery led, obstetric led, shared care and private hospital based care) and multicultural and Indigenous populations with inbuilt evaluation. These should use opt-out rather than opt-in engagement strategies and target vulnerable populations (e.g. HeLP-her).
- Core elements will be retained with adaptation to optimise implementation and scale-up. Implementation projects will be powered for both GWG and hard clinical endpoints including prevention of pre-eclampsia and GDM (as per the current NHMRC submitted partnership project).
- Use of evidence based frameworks for evaluation of the implementation pilots: including RE-AIM are essential to optimise Reach, Efficacy, Adoption, Implementation, and Maintenance (23). Further data on cost effectiveness is also essential.
- Engagement of national and state-funded knowledge translation and exchange units will be important in this process

It is anticipated that this work would be funded through a range of strategies including, government and health services support. However some of this work fits under the implementation research banner and could be funded through NHMRC current funding streams with elevated significance based on the CFA. Government funding for roll out is essential and is likely to be state based given that care is provide and savings applicable to the hospital setting. It is not anticipated that a targeted call for research is required, but rather that the CFA team in collaboration with other leaders in the field nationally will leverage off NHMRC endorsement of the CFA as a priority area in knowledge translation in obesity to apply through usual channels including partnership (with government and health services) and project funding to undertake implementation research and inform scale up.

National scale up: Existing evidence, implementation research and the pilot implementation program, will then inform policy makers and stakeholders on national scale-up. It is envisaged that scale-up activity would rest with policy makers and stakeholders and is no longer under the remit or influence of the NHMRC, other than to assist in evaluation through data analysis related to the birth registry and to ongoing quality improvement.

2. NHMRC to review the evidence and current recommendations on the prevention and management of GWG and produce national advice based on this review.

There are currently no Australian recommendations for healthy GWG in pregnancy. Disparities exist in current available recommendations for monitoring and managing GWG (see appendix 1). Development of Australian recommendations would be informed by a) existing IOM guidelines from the US –widely adopted but not formally endorsed in Australia b) an extensive systematic review and meta-analysis of international data on refining healthy GWG targets, expanding beyond the US IOM data, which is already underway within CFA team (complete in early 2015) c) future data from the proposed birth registry. *Australian recommendations* could be driven by the NHMRC in consultation with stakeholders. This step is fundamental to implementation.

3. NHMRC to work with relevant stakeholders to promote the benefits of a birth registry and identify opportunities for its establishment.

A detailed discussion of the role, value and processes needed to establish a birth registry is beyond the scope of this CFA. A summary of the justification and process for a registry are included in appendix 2. In summary *"Science tells us what we can do; Guidelines what we should do; Registries what we are actually doing*." (Ralph Brindis, MP MPH, FACC, Immediate past CMO and chair, ACC National Cardiovascular Registry). They have a defined target group**,** QA framework and clinical governance structure, secure funding stream, opt-out consent with 97% data acquisition and extension to longer term outcomes.

They enable data linkage, benchmarking opportunities, evaluation of clinical change such as this CFA proposes and they drive improvement in clinical practice. The CFA team is preparing a business case for a birth registry under the auspices of the School of Public Health, Monash University as a recognised Centre of Excellence on registry science. Here we will engage the NHMRC in this work and provide a complete rationale, staged implementation process and funding case as this work unfolds. It is not proposed that the NHMRC fund this process. However NHMRC may be able to assist communication on the evaluation role of the registry through channels such as the new data reference committee, which includes members of the CFA team. NHMRC strategies to promote the birth registry could include: 1) Engagement of stakeholders on the role of registries and large data sets generally and 2) Communication on potential benefits of a birth registry through existing channels including links to the new national data referencing committee

Summary

Obesity is increasing in prevalence and prevention is a key national and international priority. Pregnancy is a high risk time for excess weight gain. Excess gestational weight gain (GWG) drives adverse pregnancy outcomes and long term obesity in both mothers and children. Evidence synthesis demonstrates that antenatal lifestyle interventions including the Australian HeLP-her intervention, is successful, especially if integrated into routine pregnancy care. These interventions prevent excess GWG, improve pregnancy outcomes for mothers and babies, reduce postpartum weight and prevent weight gain and obesity long term. There is also emerging data on cost effectiveness suggesting cost savings. Enablers include optimal motivation for lifestyle change during pregnancy and population wide engagement in antenatal care including disadvantaged groups. Barriers include a lack of consistent GWG recommendations, health professional knowledge and resources. Overall, there is a clear imperative to prevent excess GWG, improve health for mothers and babies and reduce maternal and childhood obesity**.** Here we present a compelling case for NHMRC action working with government and including stakeholder engagement and national GWG recommendations. We recommend a staged process with implementation research and a pilot implementation program. We also outline a comprehensive evaluation plan through the implementation phase including expansion of cost effectiveness data and ultimately a birth registry to evaluate, inform and drive continuous improvement in the scale up phase.

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Appendix 1: Current status of national guidelines on weighing and GWG management

The Royal Australian and New Zealand College of Obstetrics and Gynaecologists (RANZCOG) and the Australian Department of Health (DoH) recommend healthy GWG, based on IOM guidelines. DoH Clinical Practice Guidelines (2012) advise restriction on frequent antenatal weight gain monitoring to cases where it will influence clinical obstetric management, while RANZCOG recommends "weight gain should be discussed and monitored regularly during antenatal care" (58, 59). Clinical Practice Guidelines in Antenatal care do not make recommendations for lifestyle intervention or limitation of excess GWG in women with a normal pre-pregnancy BMI, despite evidence of excess GWG, high postpartum weight retention and increased maternal and childhood obesity in this group. There is non-specific reference to healthy eating in pregnancy in the recent 'Healthy Eating When You're Pregnant' or Breastfeeding guidelines, based on the 2013 NHMRC Australian Dietary Guidelines 'Eat for Health'. Other guidelines increase ambiguity (60), contributing to variation in knowledge and practice. This was demonstrated in a recent survey of practice where just 4% of comprised of obstetricians and midwives had accurate knowledge of GWG recommendations across all BMI categories; 81% either did not weigh or only weighed once during pregnancy and 78% believed training related to GWG was inadequate (20).

Appendix 2: Brief outline of the case for a birth registry

"*Science tells us what we can do; Guidelines what we should do; Registries what we are actually doing*." (Ralph Brindis, MP MPH, FACC, Immediate past CMO and chair, ACC National Cardiovascular Registry). Key elements of a registry include targeting an identified cohort (pregnant women). They have a QA framework, are embedded in clinical care with a clinical governance structure and have a secure funding stream. They also have extension beyond current data bases to longer term outcomes and are linked to evaluation of clinical change. They have opt-out consent (most run at 96-98% engagement and include all population groups), identified cases to enable data linkage and identified organisations to optimise benchmarking opportunities and drive improvement in clinical practice.

Here a birth registry will advance significantly on the current incomplete, inconsistent data collection, where cases are not identified outside institutional data sets, organisations are not identified to enable benchmarking and public health trends, areas of quality concern and impact of practice change cannot be evaluated. Hence there is currently a compelling case for a birth registry as an independent registry with accurate data collection.

Relevant to this CFA, a birth registry would objectively measure trends in maternal BMI and the impact of maternal BMI and GWG as our key public health challenges in pregnancy. It will also inform on adherence to new NHMRC GWG advice, allow quality benchmarking across institutions and populations and measure the impact of the national implementation and scale up program for healthy GWG. Considerable work has already occurred with stakeholder engagement and support for a registry, and seed funding sources have been identified to progress this agenda with the CFA team in a lead role.

Appendix 3

Obesity Case for Action - Declarations of Interests

The declarations of interests of Steering Group members, authors and contributors to this Case for Action are listed below.

Name and Role(s)	Interest(s) declared
Prof Wendy Brown • Steering Group Chair • Author	**Board Membership** • Director (national Board member) of Sports Medicine Australia and a former Queensland Board member of the Heart Foundation. Both have an interest in healthy weight and obesity prevention - but not in a commercial sense as far as I know. **Consultancy fees/honorarium** • Received consultancy and research funds from the Australian (Departments of Health, Department of Families, Community Services & Indigenous Affairs, Veterans' Affairs etc) and Queensland governments, as well as from non-government (eg Diabetes Australia, Heart Foundation), community based (eg Blue Care) and corporate (eg MBF) agencies. In all cases these have been paid through the University of Queensland (UQ) rather than to me directly. **Grants** • Has received grants from NHMRC, ARC and other funding agencies. Holds several research grants and expect that these will continue during the period of Steering Group membership. **Support for travel/accommodation** • Occasional support from corporate sponsors to attend and speak at national or international conferences (including from the footwear and food industries). **Meals/beverages** • Occasional meals provided by corporate sponsors of conferences (eg by Asics footwear for Sports Medicine Australia), usually in my role as a conference organiser. **Gifts or gratuities** • Has received numerous small gifts from conference sponsors as part of their marketing/trade promotions at conferences (eg walking shoes from Asics and books from Human Kinetics). **Speeches/lectures** • Has spent the last 15 years or more publishing or speaking (including advocacy and public debate, as well as university lectures) about matters related to human movement, weight management, the obesity pandemic etc. This is the core focus of my work. **Relationships** • Is associated with numerous organisations and agencies with an interest in the health impacts of obesity. These include government and non-government agencies, as well as corporate research partners. Projects in development stages include partnerships with Linfox, Suncorp, QLD government etc. All relationships are organised through my work at UQ.
Prof Neville Owen • Steering Group member	**Grants** • Holds NHMRC grants and Fellowship and may apply for NHMRC grants throughout the period of Steering Group membership. **Support for travel/accommodation** • United States Centres for Disease Control and Prevention travel support. **Gifts or gratuities** • Standing desk from furniture company. **Speeches/lectures** • United States National Institutes of Health speech and policy advice.

Appendix 3

Name and Role(s)	Interest(s) declared
Prof Hugh Barrett • Steering Group Member	**Consultancy fees/honorarium** • CSL 2010-2011, Sanofi-Genzyme Advisory Board, 2012, Amgen Advisory Board, 2012-present. **Grants** • NHMRC: Fellowships and project grants since 2002 • National Heart Foundation: Fellowships and project grants • Amgen PCSK9 research contract. **Meals/beverages** • Associated with Advisory Board meetings. **Speeches/lectures** Chair and presented at local and international meetings: • Arteriosclerosis, Thrombosis and Vascular Biology, American Diabetes Association, Japan National Conference, XVI International Symposium on Atherosclerosis, International Atherosclerosis Society. **Publications** • School of Medicine & Pharmacology - Publications related to dyslipidemia in populations at risk of cardiovascular disease, including obesity, the metabolic syndrome and diabetes.
Prof John Wakerman • Steering Group member • Health Care Committee (HCC) primary contact	**Employment** • Associate Dean Flinders NT, Flinders University. **Board Membership** • Deputy Chair, Central Australian Health Service Board • Member, Health and Hospitals Fund Board • Member, Australian Therapeutic Goods Advisory Council.
Prof Samar Aoun • Steering Group member • Prevention and Community Health Committee (PCHC) secondary contact	**Employment** • Professor of Palliative Care, and Associate Dean of Research, Faculty of Health Sciences, Curtin University. **Grants** • Past and current NHMRC and ARC grants and possibly future ones.
Adj Prof Nikolajs Zeps • Steering Group member • Research Committee contact	**Employment** • Paid as Research Director to increase health and medical research for St John of God HealthCare • Curtin University of Technology, Adjunct Professor in the School of Health Sciences • Adjunct Professor in School of Medicine, Fremantle, The University of Notre Dame • Adjunct Professor, Centre for Comparative Genomics, Murdoch University. **Board membership** • Australian Clinical Trials Alliance (ACTA), interim member of Executive. ACTA aims to promote clinical research in Australia • Clinical Oncology Society of Australia, peak body promoting cancer research and clinical practice. **Consultancy fees/honorarium** • Merck Serono Pty Ltd, Pfizer Pty Ltd, Roche Pty Ltd, Novartis Pty Ltd. Honoraria and travel support. **Support for travel/accommodation** • Australasian Gastro-intestinal Trials Group. Cooperative clinical trials group, member of the Scientific Advisory Committee and Annual Scientific Meeting organising committee. **Publications** • Adjunct Associate Professor in the Schools of Surgery and Pathology and Laboratory Medicine, The University of Western Australia.

Appendix 3

Name and Role(s)	Interest(s) declared
Prof Louise Baur • Steering Group member • PCHC primary contact	**Grants** • Chief Investigator or Associate Investigator, on a range of NHMRC grants, largely related to clinical or population health aspects of obesity and obesity-related chronic disease. I intend to continue to apply for NHMRC funding in future years as part of my work at the University of Sydney and The Children's Hospital at Westmead. **Board membership** • Member of the following Boards: World Vision Australia; Sydney Children's Hospitals Network. **Support for travel/accommodation** • Has received travel support to attend the World Vision Australia meetings. **Consultancy fees – honorarium** • Honoraria received as Member, Ramaciotti Foundations Scientific Advisory Committee.
Prof Helena Teede • Steering Group member • HCC secondary contact • Author	**Employment** • Employee and senior academic of Monash University – since 1997 funded by NHMRC fellowships and Monash University • Employee of Monash Health. **Board membership** • Board member, Diabetes Australia, Victoria – voluntary position 2009- 2014. **Consultancy fees/honorarium** • Novo Nordisk – educational organising committee 2013 • Sanofi – educational organising committee • Practice: practising endocrinologist in private and public practice. Primary appointment at Monash Health. **Grants** • Funding: NHMRC, National Heart Foundation (NHF), Diabetes Australia Research Trust (DART), Department of Health-Victorian Government, International Diabetes Federation (IDF), Buckland, Perpetual Trustees, Lew Carty and Helen McPherson Trust, Brockhoff Trust, Cancer Australia Industry partnership with funds to the institution • Industry funding – pharmaceutical trials funded on a per patient basis.
Dr Cheryce Harrison • Author	**Non-financial interests** • Researched, published and presented on health pregnancy and prevention of excess weight gain.
Dr Catherine Lombard • Author	**Financial interests** • Employed as a senior research fellow, by Monash University. **Non-financial interests** • Has researched and published on pregnancy and prevention of excess weight gain • Has presented research findings related to pregnancy and excess weight gain at conferences.
Dr Jacqueline Boyle • Author	**Financial interests** • Global Advisory board to Pfizer 2014 • Education consultant to Jean Hailes for Women's Health. **Non-financial interests** • Member, Women's Health Committee – Royal College of Obstetricians and Gynaecologists • Has participated in research, published and presented on health pregnancy and prevention of excess weight gain.
Prof Christine East • Author	Nil to declare.