

Written Testimony: Evaluating complex community-based interventions (CBIs) for obesity prevention

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Experience in CBI evaluation

This paper is a view from my experience of the current state of the evaluation of complex CBIs for childhood obesity prevention. The WHO Collaborating Centre for Obesity Prevention at Deakin University has been involved in the evaluation of 12 CBIs over the last 10 years.^{1,2,3,4,5,6} These have all been of 2-4 years in duration, typically involved about 1000 children in intervention and comparison communities, taken a community capacity-building approach, been in Australia, Fiji, Tonga and New Zealand, and involved multiple ethnic groups. Most have used quasi-experimental designs (one cluster RCT) with cross-sectional and longitudinal follow up. These have all been undertaken as demonstration projects to build the evidence, expertise and community/political support for larger scale community action to prevent childhood obesity. In addition, as part of the CO-OPS Collaboration (a knowledge exchange network for professionals working in Community Obesity Prevention Sites)⁷, we have developed a set of best practice principles for establishing CBIs.⁸ I have close knowledge of the largest existing CBI in Australia (the OPAL project in South Australia – over \$50m over 6 years⁹ because I chair the Scientific Advisory Council. Our team is also working very closely with the Victorian government which is currently developing its evaluation plans for its recently-launched Community Prevention Model – a \$150 investment over 6 years to take a systems-based approach to obesity prevention in the state.¹⁰ The evaluation budget is about \$8m and there will be dedicated evaluators in each of the 12 designated prevention areas. I have also been closely involved in the EPODE program and spent some time with their team to work through an analysis of the EPODE approach which has recently been published¹¹ in parallel with other publications arising from the European EPODE Network.¹² While I have not undertaken a review of evaluation approaches to CBIs, our experience has taught us many things about this rapidly changing field.

Overview of evaluation

I have developed a characterisation of 3 types or generations of evaluation to try to define the pros and cons of each. I have pasted the 3 key slides below (this work has not been published yet).

G1 'Package-testing' characteristics

- 'Package Testing' approach
- Conceived, developed and implemented by (academic) experts
- Practice experts and local implementers consulted
- Suits RCT (usually cluster) methods
 - High fidelity of package implementation
 - Very limited local adaptation
 - High internal validity
 - Sacrifices external validity
 - Efficacy outcomes
 - Needs further research to determine effectiveness
 - Not necessarily implementable or translatable
 - Usually single setting only
- E.g. cluster RCT of nutrition and PA interventions in middle school (42 schools, 4600 participants, \$38m USD) (Foster GD et al NEJM 2010)

G2 'Community-engaged' characteristics

- Build the evidence on 'what works for whom, why, in what contexts and at what cost?'
- 'Community-Engaged', participatory, capacity building approach
- Interventions conceived and developed in partnership with and implemented by practice and local experts
- Suits quasi-experimental or cluster RCT design
 - Attention to fidelity of processes and relationships
 - Significant local adaptation
 - Higher external validity
 - Risks to internal validity (intervention definition, design effects)
 - Create proof of principle for 'translation to scale'
 - Effectiveness outcomes
 - Needs further research to translate into real-world scale
 - Multiple settings usually possible

G3 'Integrated Systems' characteristics

- 'Integrated Systems' approach
- Interventions conceived and developed in partnership with and implemented by practice and local experts
- Suits systematic grounded, CQI, systems analysis methods (does not suit null hypothesis testing methods)
 - Attention to fidelity of processes and relationships
 - Significant local adaptation
 - High external validity
 - Internal validity applies to processes
 - Real world, scalable outcomes
 - Multiple settings and systems are integral

Current state of effectiveness evidence

The publication of the recent meta-analysis in the latest Cochrane review on interventions to prevent childhood obesity shows clear evidence of effectiveness of prevention intervention in children.¹³ This is markedly different to the conclusions from the previous review in 2005¹⁴ were largely that there was no convincing evidence that interventions worked. One conclusion of the most recent review is that it would be inappropriate to continue to do studies with a non-intervention comparison arm. Most of these studies were of the Generation 1 type studies. The attraction of these studies is that they are readily amenable to null hypothesis testing methods so that internal validity can be maximised with the focus of fidelity being on the delivery of a standardised package. They are often short term (matching research grant durations) and they are rarely translated to scale where they could make a material difference at the population level, although some studies do evolve into large-scale interventions (eg Planet Obesity in Massachusetts¹⁵)

In the Generation 2 studies we have conducted (including one long-term follow up¹⁶), the results can be summarised as:

- A community capacity-building approach¹⁷ reduces unhealthy weight gain in under 5s, primary school children and adolescents in white populations
- Interventions appear to have no negative consequences, several non-health benefits (eg educational, behavioural, developmental) and also may have greater effects in low SES groups, thus reducing the social gradients in obesity as well as their prevalence rates²
- Similar approaches in non-white populations (usually with high ethnic propensities to overweight) have not shown the same degree of success^{18,19,20,21}
- Spillover effects ('contamination') of non-intervention areas may be an important issue (a negative issue for comparative studies but a positive issue for health promotion). Some cluster RCTs are showing declines in obesity in both groups (eg

the Healthy Study in the US²² and Fun n Healthy in Moreland in Melbourne [unpublished]) and 3 years after the end of the first CBI we evaluated, the comparison areas had markedly increased community capacity, health promotion activities and both intervention and comparison areas reduced overweight and obesity prevalence by about 8 percentage points over the 6 years of the study and follow up.

- Under-5s seem particularly susceptible to interventions, probably because of the high environmental dependence of toddlers and high level of support for healthy eating among carers
- The analyses of these interventions are a challenge given the risks of type 1 and type 2 errors. We have analysed them in a variety of ways and I feel confident that we have been able to make firm conclusions about the outcomes (whether they are positive or null). This confidence comes analysing them in several different ways with different outcome measures and by analysing the changes measured through the logic pathways of influence (intervention dose, community capacity, environments, attitudes/knowledge, behaviours, and BMI and/or waist). The main caveat is that in some studies the behaviour changes are not detected even with BMI changes and I think this is because the instruments are quite blunt – we tended to have large numbers (over 1000 in each arm) so we could not use detailed methods (eg diet diaries) or objective measures (eg accelerometry) to be able to pick up more subtle changes. Also, if broad interventions proceed as planned, then the expectation may be that multiple small behavioural changes would occur below the sensitivity threshold of the measures.
- Countries with low capacity and little expertise in CBIs could take this G2 approach of whole-of-community demonstration projects to build the evidence, expertise and buy in. For countries like the UK, I think they should be going straight to G3, systems-type approaches.

CBI evaluation priorities into the future – moving towards generation 3 systems-approaches

The future priorities for CBI evaluation, in my view, are:

- **Culturally-centred demonstration interventions** in communities with high prevalence rates of obesity – these include populations from: the Pacific Islands, Middle Eastern countries, some Southern European countries, indigenous and marginalised populations, South Asians (who seem susceptible to obesity complications at lower BMI levels), and so on. In other words, we need innovative, culturally-centred approaches to show that such approaches can influence BMI. While these may be of the generation 2 type, I believe it is potentially valuable to view culture through a systems lens, taking it more into the generation 3 approach and we are applying for grants to do this at the moment using a church denomination as the system to influence cultural norms in Tonga towards being less obesogenic.
- **Analysis of existing large-scale systems-based programs.** The EPODE program grew from a successful generation 2 demonstration project in two French towns.²³ It has now scaled up to cover several countries and several hundred sites. It has many of the characteristics of a systems-based approach but the evaluation of this approach is only now occurring. The core components of the EPODE approach and how they

work together has been assessed by the EPODE team and its scientific committee and the EPODE European Network.^{11,12} The effectiveness of the program compared to some meaningful comparator (eg matched non-intervention sites or France as a whole) has not occurred because implementation and scale up have been the priorities and the main drivers of the program are not academics. A more in-depth retrospective assessment of the program theory of EPODE has been undertaken with a publication in press.²⁴ This has been very helpful in characterising the program theory that the EPODE team has been intuitively using. The development of the agreed logic model and its core elements and an overall program theoretical framework for the program will be very useful in thinking through scalable approaches to obesity prevention. Note that the 4 'pillars' of the EPODE approach are: Political commitment, resources, evidence, and support services.

- **Large-scale, intervention programs which explicitly take a systems approach.** This is where the generation 3 type approaches can thrive and the methodologies really progress. I can describe how we are planning to approach this within the Victorian Community Prevention Model¹⁰ and to a lesser extent in the South Australian OPAL program.⁹ Both programs have an original construction of intervention vs comparison areas in a cluster RCT and matched community design respectively, and this has been driven by the need to select places to target resources and to get some early evidence of effectiveness. However, the shortcomings of this approach are acknowledged are well recognised by the scientific teams because spillage/contamination will occur quite quickly and a large-scale, progressive approach will soon run out of comparison areas as they convert to intervention areas.

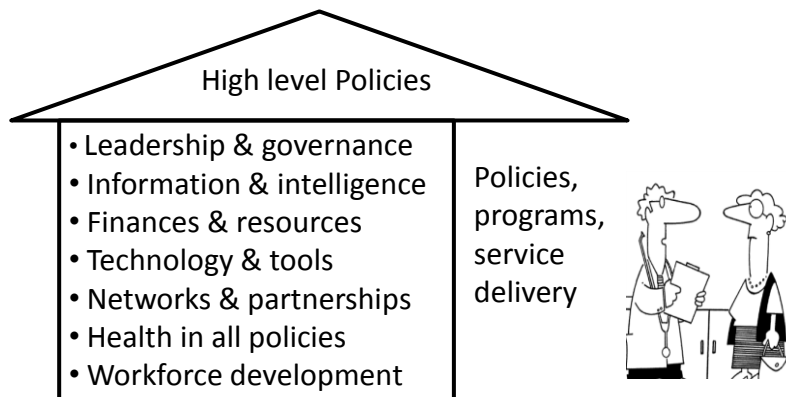
Some practical challenges (and potential solutions) for a systems-based approach

- **Articulating what a systems-approach means.** This is a major first hurdle because the terms are fuzzy, jargony, and mean different things to different people. In my communications, I tend to try to move people part of the way there by talking about the 'prevention house' (below). The usual interventions we try are the 'front-of-house' ones which interact with the population of concern and which we still need. The added value of a systems approach is to have an overarching 'Big P' policy to drive the initiative (which we have in OPAL and CPM) and then to focus on the 'systems building blocks' at the back of the house. These have come from several sources and have evolved in our thinking and some may be more relevant than others but we are keeping them all in at the moment. Then what is not shown is all the boxes and arrows which connect all these components to make it a true system – however this does not fit inside people's heads so I do not show them any representation of this (other than perhaps the Foresight Map to give them the idea). I think there are several strategies to fit a system into peoples' heads so that people are on the same map. Firstly, talk about systems related to the solutions and not the problems (even with a complex intervention, many of the boxes and arrows of the Foresight Map fall out). The various influences on information and intelligence within a secondary school setting are enormous but the levers for change are much fewer. Secondly, break it into chunks and talk about the systems of resource flow or information and intelligence flow within a setting/sector eg secondary schools.

Thirdly, only try to get a grip on the main bits of the system – enough so that everyone is on the same page with the main levers generally understood are taken into account in the plans for action. The partners within the secondary schools who know all the nuances and details of their system can work through it.

The Prevention House

Overarching big 'P' policies
 'Front of house' specific actions with end users
 'Back of house' capacity building blocks
 Systems are the arrows between components (not shown)



- **Achieving a common view on what the systems and its levers are.** This systems mapping process needs to be efficient (if it is to be done on a large scale) and so should not try to be too detailed. Our approach, which we have piloted in early childhood settings and will put to the test in secondary schools next month, is to sit down with key informants and go through the building blocks getting a rough map of the main system levers for change in each of them. These need to be well enough described or drawn so that the action plans and logic models include those levers.
- **Achieving a common view on how to change the systems.** Again this needs to be done efficiently and we are planning on using the ANGELO process we used for our CBIs²⁵ and create a SYS-ANGELO process whereby we help the participants in the workshop to create an evidence-informed, local practice-informed, systems-oriented action plan. We will condense the 'front-of-house' priority setting and focus on the 'back-of-house' system building blocks and include these more specifically in the action plan. For our CBIs these were there to some extent included in the compulsory first objective of the plans to 'Increase Community Capacity'. We will use the systems maps previously derived from the key informants to help guide the action statements at the workshop.
- **Measuring the effects of the actions.** Ideally, we should be taking a 'continuous quality improvement' approach to this rather the null-hypothesis testing approach for the reasons mentioned above – spillage and running out of comparison areas. To achieve this, good monitoring systems need to be in place so that the heterogeneity can be used to determine impact and to identify new and novel ways forward (from the leading areas) and to identify major barriers for those areas making the least progress. In Australia, we do not the monitoring systems in place to achieve this

which is why we have ended up with rather hybrid systems. In England, the childhood obesity monitoring systems and the regular surveys should allow this heterogeneity approach to be used.

- **Measuring the spillage/contamination to other areas.** After a decade of publicity and some actions, parts of the population (especially children) are poised to turn the epidemic around. We used to say that obesity was so resistant to change that 'contamination of the comparison group' was not a problem. I believe that it now is an issue and this is very good news for health promotion – indeed we need to work out how to promote the 'contamination/spillage' effect. Network analyses may well help in achieving this and we are looking at using this tool widely in the Victorian CPM. From our follow up work in the BAEW project, the comparison area did an amazing catch up job on their own by creating or grabbing programs and investing their own money (not outside 'project money' which has an end date) into action on obesity prevention. The 8 %-point reduction over 6 years in both intervention and comparison areas was a real surprise and we have postulated some potential explanations for this.
 - **Potential explanations for comparison area surge in activity and results**
 - ?Selection bias – more o/w kids not consenting to assessment
 - ?'Prevention virus' – spill over of effect from Colac BAEW project
 - ?'Project syndrome' – slump at project end in Colac
 - ?Disinvestment – prevention funding ↓ in Colac, ↑ in region
 - ?'Locus of stimulus' – internal stimulus more sustainable than external stimulus (\$\$)
 - ?'Reverse Hawthorne effect' – annoyance at being comparison group stimulates own action

Conclusions

We are at the early stages of putting theory around a systems approach in to practice and doing so is not a trivial undertaking. Over the next 12 months we will undoubtedly learn a lot on how to do this in Victoria. Other wealthy countries with the policy backing to undertake large-scale interventions should also try to convert the systems approaches into reality on the ground.

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