



Determining appropriate inclusion criteria for reviews of public health interventions: skin cancer prevention as a case study

Catriona McDaid, Amanda Sowden, Fiona Paton
Centre for Reviews and Dissemination, University of York (catriona.mcdaid@york.ac.uk)

Background

We undertook a systematic review to inform guidance being developed by the Centre for Public Health Excellence at NICE. We evaluated the effects of provision of sun protection resources and/or physical changes to the environment, combined with information provision, in the primary prevention of skin cancer attributable to UV exposure.¹ The remit was to interpret resource provision and physical change in the widest sense e.g. provision of free sunscreen or clothing, changing the timing of outdoor activities, provision of purpose-built shade. Broad inclusion criteria were applied; there were no restrictions by study design or quality. Due to limitations in the included studies it was difficult to determine the contribution of the various intervention components to outcome. This raised the question of whether it is appropriate to adopt broad inclusion criteria for answering a policy relevant question.

Methods

This systematic review was used as a case study to explore the challenges in evaluating complex interventions in the context of answering a policy relevant question that required the adoption of broad inclusion criteria. We investigated the impact on review conclusions of varying the inclusion criteria for multi-component interventions. Three sets of inclusion criteria were applied: i) studies with appropriate assessment of the contribution of resource/physical change and information components (stringent); ii) studies where the main intervention components (resources/physical change and information) were of at least equal importance (pragmatic) and iii) the original broad criteria. Classification of equal importance was determined by the emphasis placed on each of the components in terms of detail of description, theoretical basis, and the process measures and outcomes reported.

Findings

Three challenges were identified in synthesising the evidence. First, it was difficult to determine the contribution of the resource element to outcome due to limitations in study design. Second, the resource components were poorly defined in most studies (Table 1). Third, was the failure of most studies to use outcome or process measures directly related to resource provision (Table 1).

Applying the narrowest set of inclusion criteria resulted in a single included study which was designed to determine the contribution of resource provision to the overall effect (Table 2, Bauer 2005). The second set of inclusion criteria resulted in an additional four included studies (Table 2). Three were three-armed studies. Although they had an arm with a substantive resource provision component, participants in this arm also received additional information over and above that provided to the information only group. Given that there was no evidence of additional benefit in arm a (Table 2) in these studies, it would seem reasonable to conclude that neither the resource provision component nor the enhanced information contributed any extra benefit. This was not the case in the fifth study (Mayer 2007, Table 2). There was evidence of benefit with the multi-component intervention compared to control. It was not possible to draw conclusions about the relative contribution of resource and information provision, though the findings suggested it was worthy of future investigation. Twenty-seven studies were included in the original synthesis, using the broadest criteria. The additional studies did not contribute any additional useful data.

Concluding remarks

The review would have been less resource intensive if either of the restricted sets of inclusion criteria had been applied. Arguably, the commissioner would not have had access to the same breadth of evidence, regardless of its limitations. Where there is a paucity of good quality evidence to underpin decision-making, there is a strong rationale for including all available evidence. This would suggest moving beyond using the "stringent" criteria (i) to the more "pragmatic" approach (ii). However, there was an element of subjectivity in applying the second set of criteria. The best available evidence approach is

reasonably straightforward to apply in relation to study design and study quality but this is not the case when restricting based on the content of complex interventions.

It is important to be able to assess the effectiveness of the key strands of complex interventions so that the appropriate key aspects can be implemented. This is especially true when the key strands are likely to have different mechanisms of effect or, where assessing cost-effectiveness, have different costs attached. A number of methods have been suggested to identify the active ingredients of complex interventions such as the use of taxonomies to classify interventions for analysis in a meta-regression. However, the contribution such methods can make within the context of a systematic review is heavily reliant on relevant and sufficient information being reported in the primary studies.

Table 1: Reporting of resource provision components and related outcomes

Resource provision component of intervention	Details provided of resource component	Was resource use or other related outcome assessed?
Sunscreen (25 studies)	SPF 32% Quantity 40%	Quantity of sunscreen used from communal containers or number of bottles used (n=4) Use of discount vouchers for sunscreen (n=1)
Hat (12 studies)	Shape/style 33%	Use of the broad-brimmed hat provided (n=1) Use of use of discount vouchers for hats (n=1)
Clothing or sunglasses (9 studies)	Shape/style 44%	No
Shade (5 studies)	Description of structure 0%	No

Table 2: Studies meeting (i) stringent or (ii) pragmatic inclusion criteria

Author	Study design	Reviewer conclusion
Bauer, 2005	a) 800ml SP25 sunscreen +information 3 times/year b) Information 3 times/year c) One information session	No evidence of benefit
Barankin, 2001	a) 800ml SP25 sunscreen +information 3 times/year b) Information 3 times/year c) One information session	No evidence of benefit for a compared to b
Glanz, 2000	a) Resource provision and enhanced information + information and incentives b) Information and incentives c) No intervention	No evidence of benefit for a compared to b
Milne, 2006	a) Low cost protective swim wear + enhanced information b) Information b) General health information	No evidence of benefit for a compared to b
Mayer, 2007	a) Protective hats and sunscreen + information b) Delayed intervention	Evidence of benefit for a

References

- McDaid C, Paton F, Wright K, Rice S, Maund E, Sowden A. *Sun protection resources and environmental changes to prevent skin cancer: a systematic review*. Centre for Reviews and Dissemination, 2010. <http://www.nice.org.uk/nicemedia/live/11871/49660/49660.pdf>.

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