



Review protocol

Interventions to prevent unintentional injury to children during outdoor play and leisure

PH Programme or PH Intervention process:	INTERVENTION
Name of Programme or Intervention:	Preventing unintentional injuries among under 15s: outdoor play and leisure
Programme Report No.:	N/A
CPHE Collaborating Centre:	PenTAG
Project led by:	Mark Pearson Research Fellow 01392 403056 mark.pearson@pms.ac.uk
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2. Title

Long title:

A systematic review of the effectiveness and cost-effectiveness of interventions which provide information, advice and education to prevent unintentional injuries among children and young people aged under 15 during outdoor play or leisure outside

Short title:

Preventing unintentional injuries among under 15s: outdoor play and leisure

3. Review team

This project will be conducted by a team from PenTAG. The team members, and their roles on the review, will be:

<p>Dr Mark Pearson, Research Fellow</p>	<p>Lead systematic reviewer. Project managing the delivery of the various parts of the project. Making key methodological choices within the systematic review of effectiveness studies, and the review of evidence about barriers and facilitators. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.</p>
<p><i>TO BE APPOINTED IN SEPTEMBER,</i> Associate Research Fellow</p>	<p>Second systematic reviewer. Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.</p>
<p>Dr Ruth Garside, Senior Research Fellow</p>	<p>Lead systematic reviewer for review of barriers and facilitators. Making key methodological choices within the review of qualitative studies (into barriers and facilitators). Screening, appraisal and data extraction of included studies. Writing and editing drafts and final report.</p>
<p>Tiffany Moxham, Information Specialist</p>	<p>Developing and conducting any formal searches (web-based, grey literature) for relevant reports. Writing up any relevant report methods sections.</p>
<p>Dr Rob Anderson, Deputy Director (PenTAG) and Senior Lecturer in Health Economics</p>	<p>Overall responsibility for delivery to NICE, ensuring report meets agreed protocol, discussing and agreeing with NICE any divergences from protocol. Leading any original economic analysis, and leading the systematic review of cost-effectiveness evidence. Writing and editing drafts and final report.</p>

4. Key deliverables and dates

Deliverable	Date (2009 unless otherwise indicated)	Comments back from NICE CPHE by:
1 st Draft review protocol	18 th August	25 th February
Revised review protocol	27 th August	28 th August
Draft search protocol & search strategy	1 st September	4 th September
Signing-off of review protocol	1 st September	
Signing-off of search protocol	8 th September	
Signing-off of search strategy	11 th September	
Interim progress meeting/ teleconference (1) – Including discussion of the feasibility, value and focus of a review of barriers and facilitators and any economic modelling	9 th October	
Interim progress meeting/ teleconference (2) – Including discussion of the nature of the emerging evidence and issues to do with how best to summarise and synthesise it	30 th October	
Draft Reports (Report 1: Reviews of effectiveness and cost-effectiveness studies, with draft evidence statements)	22 nd December	12 th January 2010
Draft Report ¹ (barriers & facilitators)	22 nd December	12 th January 2010
Draft Report ² (economic modelling)	22 nd December	12 th January 2010
Final Reports (main reviews with final evidence statements)	Midday 26 th January 2010	
Final report (Report 2 and Report 3: barriers & facilitators, and economic modelling)	Midday 26 th January 2010	

¹ Where a review of barriers and facilitators is agreed to be feasible and useful, via discussion between the Collaborating Centre and the relevant lead analyst and associate director at CPHE (see Interim progress meeting (1))

² Where an original economic analysis is agreed to be feasible and useful, via discussion between the Collaborating Centre and the relevant lead analyst and associate director at CPHE (see Interim progress meeting (1)). If no economic analysis is deemed to be feasible or useful, the timelines for the other reviews may be renegotiated.

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PHIAC 1 st meeting	12 th February 2010	
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5. Purpose of this document

This document describes the aims, scope and main methods of the evidence reviews and economic analyses which will be produced by the Collaborating Centre to support the development of related NICE Public Health Guidance.

Unless otherwise stated in this Review Protocol, these reviews and analyses, and the reports to summarise them, will be conducted according to the 1st Edition of the *Methods for the development of NICE public health guidance* (2006).

6. Clarification of scope

This protocol covers evidence reviews of the effectiveness, cost-effectiveness and barriers and facilitators, relating to interventions aimed at preventing unintentional injury to children and young people (aged under 15) during outside play and leisure. In addition, it describes the proposed approach to economic modelling related to this topic.

7. Review Questions

Question 1a: How effective are the different approaches to providing information, advice and education about safety and risk?

Question 1b: How cost-effective are the different approaches to providing information, advice and education about safety and risk?

Question 2: What are the barriers to, and facilitators of, the different approaches to providing information, advice and education about safety and risk?

8. Populations

8.1. Groups that will be covered

- Children and young people aged under 15, particularly those living in disadvantaged circumstances (for example, with families on a low income or with a lone parent).

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- Parents and carers of children and young people aged under 15, particularly those living in disadvantaged circumstances, where their children are the focus of research or where they are targeted by interventions aimed at reducing unintentional injury in their children.

8.2. Groups that will not be covered

Anyone aged 15 or older (unless they are the parents of targeted children).

9. Interventions /activities that will be covered

9.1. Activities/measures that will be covered

In parallel with this guidance for outdoor play and leisure, NICE will also be developing public health guidance (also developed using the intervention development process) to prevent unintentional injuries on the road and in the home. There will also be public health guidance (developed through the programme guidance process) focusing on the broader strategies, policies, and regulatory or legal frameworks which aim to prevent unintentional injuries in children.

The present guidance will complement these publications and will focus on:

Interventions aimed at reducing injuries in designated outdoor play and leisure spaces (for example, playgrounds and skateboard parks) and **other non-designated external environments** (for example, canals, construction sites, fields and farmyards).

It covers **the provision of information, advice and education on:**

- a. **safety and risk** (including risk assessment), and/or
- b. **safety clothing and protective equipment.**

The provision of information may be delivered via one or more of the following approaches (either separately or combined):

- one-to-one or group-based verbal information (planned or opportunistic)

- print media (for example, leaflets, posters and other printed information)
- new media: such as the Internet (including social networking sites), email and text messaging
- mass-media campaigns³

9.2. Activities/measures that will not be covered

- Play and leisure activities at home.
- Play and leisure activities on roads or pavements (including any bicycle helmet mass-media campaigns already covered by studies in the PDG 6 Programme review).
- Policy and legislation covering safety education, equipment and inspection standards.
- Design or modification of the physical environment, including environmental or engineering solutions to improve safety.
- Workforce training, support and capacity-building in relation to preventing unintentional injuries in children and young people under 15.
- National, regional or local media campaigns that focus on implementing or enforcing safety legislation, regulation and standards (which should be covered in the PDG 6 Programme review)
- Safety education that does not cover unintentional injury prevention related to play and leisure activities.
- Formal, competitive sports (where supervising adults are likely to be present).

³ Mass media campaigns are considered to be communication plans that use mass media to share messages with target audiences. Several media channels, such as television, radio, print, direct postal mail, and increasingly, the internet and other electronic media, may be used. Those which support strategies, policies and regulatory or legal frameworks, which will be covered by PDG6 of the PUIC Programme, will not be included.

- Any interventions which involve the provision of safety clothing and protective equipment, (unless they are delivered along side information, advice and education as outlined in Section 9.1).

10. Reports

It is envisaged that three reports will be produced for this project. The division of resources for the production of each of the reports will be finalised in discussion with the relevant lead analyst and associate director at NICE CPHE in accordance with what is deemed feasible and useful, and this is one of the main purposes of the planned interim progress meetings.

Report 1. Systematic reviews of the effectiveness and cost-effectiveness of educational interventions to prevent unintentional injuries among under 15s: outdoor play and leisure.

This will include two systematic reviews (one of effectiveness studies, and one of economic evaluations and cost analyses).

Report 2. A systematic review of qualitative studies relevant to understanding barriers to and facilitators of effective interventions to prevent unintentional injuries among under 15s: outdoor play and leisure (if it is to be included as a separate systematic review)

Report 3. Modelling to evaluate the cost-effectiveness of educational interventions to prevent unintentional injuries among under 15s: outdoor play and leisure

This will include an economic analysis of one or more types of intervention (again, if deemed feasible and useful).

Methods for these three reports are outlined below.

11. Reviews: Aims, key review questions and key outcomes

11.1. Report 1: Systematic review of effectiveness and cost-effectiveness studies

11.1.1. Aim

To identify, critically appraise, summarise and synthesise evidence relating to the effectiveness and cost-effectiveness of the specified types of interventions aimed at reducing unintentional injuries in children and young people aged under 15 during outdoor play and leisure.

11.1.2. Key review questions

Review 1: effectiveness

- a. What is the effectiveness of the different approaches to providing information, advice and education about safety and risk aimed at reducing injuries to children during outdoor play and leisure?
- b. What are the factors which either enhance or reduce the effectiveness of different approaches to providing information, advice and education about safety and risk aimed at reducing injuries to children during outdoor play and leisure? (examples might include the impact of training, methods and intensity of delivering the intervention, differential impact by class, age, ethnicity etc.)

Expected outcomes

- Changes in injuries and deaths in children and young people aged under 15.
- Changes in knowledge, attitude, skills and safety/risky behaviour in relation to preventing unintentional injuries among children and young people aged under 15 outside, and their parents/carers.
- Changes in the rates of use of safety clothing or protective equipment among children and young people aged under 15 outside.

Review 2: cost-effectiveness

- a. What is the cost-effectiveness of the different approaches to providing information, advice and education about safety and risk aimed at reducing injuries to children during outdoor play and leisure?
- b. What are the main causal relationships which seem to explain how the different combinations of resources (and levels of costs) of these interventions are related to intended outcomes?

In addition to the outcomes for the effectiveness review, the cost-effectiveness review will also report the following outcomes of included studies:

- costs and/or resource use
- cost-benefit estimates
- cost-effectiveness or cost-utility ratios

11.2. Report 2: Systematic review of evidence about ‘barriers and facilitators’

Production of a separate review of barriers and facilitators is conditional upon (a) the number of studies identified for inclusion in the effectiveness and cost-effectiveness reviews (the “main reviews”); and (b) the number of qualitative studies eligible for inclusion in a “barriers and facilitators” review. The number, range, and complexity of the identified studies will be discussed at the first interim progress meeting, with regard to the feasibility of producing a separate barriers and facilitators reviews. If the production of a set of high quality reviews under each of these headings is deemed unmanageable given the time and resources available, then a separate review of barriers and facilitators will not be conducted. However, in order to still answer the “barriers and facilitators” review question – it is proposed that relevant observations from the ‘Discussion’ and ‘Conclusion’ sections of all the included effectiveness papers will be extracted as part of that review of effectiveness studies (e.g. where authors try to explain why their evaluated outcomes differed from others, or differed from what they expected).

11.2.1. Aim

To identify, critically appraise, summarise and synthesise qualitative and/or quantitative evidence relating to contextual or other factors which either enhance or reduce the effectiveness of interventions which provide information, advice and education aimed at reducing injuries in designated outdoor play spaces and other external environments (for example, canals, construction sites, fields and farmyards).

11.2.2. Key review questions

What are the factors which either enhance or reduce the effectiveness of different approaches to providing information, advice and education about safety and risk aimed at reducing injuries to children during outdoor play and leisure)?

11.3. Methods

11.3.1. Identifying the literature: Overview

A single electronic search of relevant bibliographic databases, and also selected websites, will be conducted in order to identify relevant primary research (to be supplemented by communication with experts and/or organisations involved in the relevant research or policy areas).

This main search will serve all three planned systematic reviews.

11.3.2. Search process and methods

- To review published literature and relevant unpublished/grey literature in order to identify ineffective as well as effective interventions and approaches, as far as time and other resources allow.

- To include all relevant primary research that meet the inclusion criteria (see section 1.3).

- Databases to be searched and search terms will be detailed separately in the search strategy and protocol.

11.3.3. Study selection

Inclusion criteria (common to all reviews):

- Studies published from 1990
- Studies published in the English language
- Studies conducted in OECD countries

11.3.4. Criteria specific to the review of effectiveness

Inclusion criteria:

- Evaluations (prospective or retrospective) of interventions involving educational interventions (with or without the provision of safety equipment and protective equipment) using comparative designs (randomized controlled trials, non-randomized controlled trials, before and after studies, or natural experiments)

- Studies reporting the relevant outcomes listed in Section 11.1.2 in children (or in both adults and children but with the outcomes for children shown separately), or related to attitudes and knowledge in parents/ carers. This inclusion criteria will only be applied at full-text assessment stage. In other words, no papers will be excluded on the basis of age at the title and abstract screening stage. Where a study reports relevant outcomes related to an age range which overlaps with, but is not restricted to, the focus for this review (for example, aged 5-18 rather than under 15), it will be included only where the majority are of the appropriate age.

Exclusion criteria:

- Empirical studies which only document interventions and related outcomes without evidence regarding the outcomes listed in section 11.1.2 prior to or without the intervention.

- Empirical studies which do not separately report relevant outcomes for children or young people aged under 15 or in parents/carers for knowledge and attitudes outcomes (see above – this criteria will be applied at the full text stage only).

11.3.5. Criteria specific to the review of cost-effectiveness

Inclusion criteria:

- Full economic evaluations of relevant types of intervention, and costing studies of the relevant types of intervention conducted in OECD countries (either comparative or single intervention).

Exclusion criteria:

- Cost-of-illness studies, or other studies which do not involve assessing the costs and related benefits/effectiveness of particular interventions (or class of intervention).

11.3.6. Criteria specific to the review of barriers and facilitators:

Inclusion criteria:

- Primary qualitative research involving the analysis of written or spoken speech/evidence, regarding attitudes towards, or experiences of, the relevant interventions;⁴ OR

- Quantitative or qualitative surveys of attitudes towards, or experiences of the relevant interventions.

11.3.7. Study selection process

Assessment for inclusion will be undertaken initially at title and/or abstract level (to identify potential papers/reports for inclusion) by a single reviewer (and a sample checked by a second reviewer of at least 10%, more if resources allow), and then by examination of full papers. Where the research methods used are not clear from the

⁴ Primary qualitative research designs which use recognised methods of data collection and analysis (including, but not limited to, observational methods, interviews and focus groups for the former and grounded theory, thematic analysis, hermeneutic phenomenological analysis, discourse analysis etc. for the latter).

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abstract, assessment will be based upon a reading of the full paper. Any relevant systematic reviews will be used first as a further source of references for primary studies, but where there is a recent and high quality systematic review that substantively answers an aspect of the review question(s), we shall include the review, updating and extending it if it is considered feasible to do so. All such decisions regarding the utilisation of systematic reviews will be made in consultation with the NICE CPHE team.

If there are a large number of includable studies, such that a high quality review of them all would not be feasible within the time and resources available, then studies may be excluded from the full review on the basis of the study quality and/or applicability to the UK context. The reasons for such exclusions will be discussed and agreed with the CPHE team at the interim progress meeting (9th October).

11.4. Quality assessment and data extraction

All included studies for the **reviews of effectiveness and cost-effectiveness studies, and of qualitative research** will be quality assessed using the relevant quality assessment checklists in the Second Edition of *Methods for development of NICE public health guidance 2009*. Quality assessment will be undertaken by one reviewer and checked by a second reviewer.

Any proposed departures from the methods manual will be discussed and agreed with the NICE CPHE Team. Data extraction and quality assessment will be conducted by a single reviewer, and checked by a second reviewer.

11.5. Data synthesis and presentation, including evidence statements

Data synthesis and presentation, including evidence statements will be conducted according to the procedures outlined in the 1st Edition of *Methods for development of NICE public health guidance 2006*.

Key choices in how to synthesise the included evidence, or in how to develop evidence statements, will be discussed with the relevant analysts at CPHE.

11.6. Report 3: Economic analysis of a selected type of intervention

(IF FEASIBLE AND USEFUL)

11.6.1. Aim

For a selected type(s) of the defined educational intervention(s), to assess the relationship between the amounts and combinations of resources and costs, and the levels of resulting benefits and/or effectiveness (related to avoiding unintentional injuries to, and death in, children).(ie. To look at the costs and benefits of all impacts of an intervention in relation to unintentional injuries including death in children).

Also, where possible, to make assessments about whether the interventions evaluated would be judged as cost-effective from an NHS/PSS perspective (given the levels of willingness to pay for a QALY typically used by NICE to make judgements about the value for money of health technologies).

11.6.2. Perspective

The analysis will adopt a public sector perspective in relation to costs and benefits (*Methods for development of NICE public health guidance, 2006*). Wherever possible, injury-related health outcomes will be expressed in terms of QALYs or life-years gained/lost. If good data are available, and where appropriate, impacts in terms of other outcomes, such as lost school days may also be part of a broader cost-consequence approach to analysis.