National Institute for Health and Care Excellence

Guideline version (Draft for Consultation)

Alcohol interventions in secondary and further education

NICE guideline: methods

NICE guideline <number>

Methods

February 2019

Draft for Consultation

Evidence reviews were developed by Public Health Internal Guideline Development team

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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ISBN:

Contents

Development of the guideline **5**
What this guideline covers 5
What this guideline does not cover 5
Methods **6**
Developing the review questions and outcomes 6
Reviewing research evidence 6
Data synthesis for intervention studies 7
Data synthesis for qualitative reviews 7
Appraising the quality of evidence 8
Intervention studies 8
Qualitative evidence 8
GRADE for interventional evidence 8
Presenting the evidence 9
Reviewing economic evidence 10
Appraising the quality of economic evidence 10
Health economic modelling 10
Resource impact assessment 11

Development of the guideline

What this guideline covers

This guideline covers the prevention and reduction of alcohol use through school-based interventions in secondary and further education. It looks at primary prevention through universal education as well as secondary prevention through targeted interventions delivered in schools for children and young people aged 11 to 18 and young people aged 18 to 25 with special educational needs and disabilities (SEND).

What this guideline does not cover

The guide does not cover interventions for children under the age of 11, children who are home-schooled, prevention interventions in the community or areas covered by other NICE guidance such as referral and treatment for alcohol misuse.

Methods

This guideline was developed in accordance with the process set out in 'Developing NICE guidelines: the manual (2014)'. A booklet, 'How NICE guidelines are developed: an overview for stakeholders, the public and the NHS' is available. In instances where the guidelines manual does not provide advice, additional methods are described below.

Declarations of interest were recorded according to the 2018 NICE conflicts of interest policy.

Developing the review questions and outcomes

This is an update of a previous guideline. The 4 review questions developed for this guideline were based on the key areas identified in the guideline scope. The key areas have changed since the previous guideline in that the scope no longer covers children under the age of 11 and now includes those with SEND aged 18-25 (in line with Children and Families Act 2014). Review questions to cover these key areas were drafted by the NICE Public Health Internal Guideline Development team, and refined and validated by the guideline committee.

The review questions were based on the following frameworks:

- population, intervention, comparator and outcome (PICO) for reviews of interventions

Full literature searches, evidence tables including critical appraisal for all included studies, tables of excluded studies with reasons for exclusion and evidence reviews were completed for all review questions.

Reviewing research evidence

The identification of evidence for evidence review in the guideline was conformed to the methods set out in chapter 5 of the "Developing NICE Guidelines: the manual" (2014). The purpose of the search was to identify the best available evidence to address review questions without producing an unmanageable volume of results.

Relevant databases and websites, (see Search strategies) were searched systematically to identify effectiveness, cost effectiveness and qualitative research evidence. The principal database search strategy is listed in Search strategies. The principal strategy has been developed in MEDLINE (Ovid interface) and was be adapted, as appropriate, for use in the other sources listed in Search strategies taking into account their size, search functionality and subject coverage. As this was an update of existing guidance, evidence relevant to the new protocols from the previous guideline was brought forward for assessment. To identify evidence published since 2006, the searches were limited from 2006 onwards. The committee decided that there was no need to search further back for studies on the new key area focusing on the SEND population because only studies published since the Children and Families Act 2014 would be relevant.

Randomised controlled trials were included if they evaluated interventions related to each specific review question. Systematic reviews of intervention studies were used

as a source for primary studies. Qualitative studies were included wherever exploring views and/or experiences children and young people, their parents/carers and people delivering alcohol interventions regarding the acceptability of the interventions.

Papers were excluded if they:

- were not published in the English language or were not carried out in OECD countries
- were only available as abstracts, conference proceedings, guideline/health technology assessment reports
- were published before the year 1990[a]

Data synthesis for intervention studies

1. The identified studies were considered heterogeneous and it was decided it would not be appropriate to conduct a meta-analysis. Therefore, the study results were presented individually in GRADE using the following process: Where individual RCTs reported an OR/RR or MD and 95% confidence intervals, this data was extracted and assessed in GRADE.
2. Where individual RCTs did not report an OR/RR or MD:
    a. the RR 95% CI was calculated using an excel calculator and
    b. the MD 95% CI was calculated using an online calculator.
3. Where cluster RCTs have statistically adjusted for the effects of clustering and have reported the adjusted OR/RR or MD and 95% confidence intervals, this data was extracted and assessed in GRADE.
4. Where cluster RCTs have not reported the adjusted OR/RR or MD but have reported raw data, the effective sample sizes were calculated using an intra-class correlation coefficient (ICC) (as described in chapter 16.3 of the Cochrane Handbook for Systematic Reviews of Interventions (2011). The ICC, if the data allowed, was taken from either:
    a. The study where reported
    b. The mean ICC from other studies reporting on the same outcome.
    c. An ICC reported in another single study on a similar outcome.
    d. The mean ICC of other studies in a similar outcome.
5. The effective sample sizes were then used to calculate an RR or MD using the calculators in steps 1 and 2.
6. All calculated RRs 95% CI and MDs 95% CI were assessed in GRADE.

For studies that did not report the data to allow for the steps above, for example, studies that did not report the number of people in each arm, were reported as in the paper and assessed in GRADE.

Studies that did not report raw data were not assessed in GRADE but were summarised in evidence statements.

Data synthesis for qualitative reviews

Where multiple qualitative studies were identified for a review question, information from these studies was summarise using a thematic synthesis. By examining the findings of each included study, descriptive themes were independently identified and coded. Once all of the included studies had been examined and coded, the resulting

a This was the cut-off date specified in the previous guideline

themes and sub-themes were evaluated to examine their relevance to the review questions, the importance given to each theme, and the extent to which each theme recurred across the different studies. The qualitative synthesis then proceeded by using these 'descriptive themes' to develop 'analytical themes', which were interpreted by the reviewer in light of the overarching review questions.

Appraising the quality of evidence

Intervention studies

Quality assessment for all included RCTs was conducted using the Cochrane Risk of Bias 2 tool (2016) for individual RCTs and cluster RCTs. The quality of each individual study was assessed at outcome level using this tool.

The quality was interpreted as follows:

- Low risk of bias – The true effect size for the study is likely to be close to the estimated effect size.
- Some concerns – There is a possibility the true effect size for the study is substantially different to the estimated effect size.
- High risk of bias – It is likely the true effect size for the study is substantially different to the estimated effect size.

Qualitative evidence

Individual qualitative studies were quality assessed using the CASP qualitative checklist. Each individual study was classified into one of the following three groups:

- Low risk of bias – The findings and themes identified in the study are likely to accurately capture the true picture.
- Moderate risk of bias – There is a possibility the findings and themes identified in the study are not a complete representation of the true picture.
- High risk of bias – It is likely the findings and themes identified in the study are not a complete representation of the true picture

GRADE for interventional evidence

GRADE was used to assess the quality of evidence for the selected outcomes as specified in 'Developing NICE guidelines: the manual (2014)'. Data from all RCT's were initially rated as high quality and the quality of the evidence for each outcome was downgraded or not from this initial point, based on the criteria given in Table 1

Table 1: GRADE

GRADE criteria	Reasons for downgrading or not downgrading confidence
Risk of bias	Randomised controlled studies and cluster randomised controlled studies The certainty of the evidence was downgraded if there were concerns about the design or execution of the study, including concealment of allocation, blinding, loss to follow up using the Cochrane Risk of Bias 2 tool for individually randomised controlled trials and cluster randomised controlled trials (2016); For example, limitations in the study design and

GRADE criteria	Reasons for downgrading or not downgrading confidence
	implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, healthcare professional or assessor) and attrition bias (due to missing data causing systematic bias in the analysis).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question. The certainty of the evidence was downgraded if there were concerns about the population, intervention and outcome in the included studies and how directly these variables could address the specific review question.
Inconsistency	Because the data was not pooled, it was not possible to measure inconsistency as only single studies were used.
Imprecision	Because the data was not pooled, imprecision was measured using the line of no effect. If a 95% CI crossed the line of no effect, the certainty of the evidence was downgraded by one for imprecision.
Other issues	None

Table 2: GRADE CERQual

CERQual criteria	Reasons for downgrading or not downgrading confidence
Methodological limitations	The certainty of the evidence was downgraded if there were concerns about the design or execution of the study including whether the research design and methods of data collection were appropriate to address the aims of the research, researcher reflexivity, ethical consideration and the clarity of findings.
Coherence	Assesses whether the review finding reflects the data from primary studies. The certainty of the evidence was downgraded if some of the data contradicts the review finding.
Adequacy	Assesses the degree of richness and the amount of data to support the review finding. The certainty of the evidence was downgraded if the data was not sufficiently rich or the number of studies of participant numbers were small.
Relevance	Assesses the extent to which the data from the primary studies supporting the review finding is applicable to its context. The certainty of the evidence was downgraded if the data available was not applicable to the review question.

Presenting the evidence

As there was heterogeneity with respect to participants and interventions the evidence reviews were presented to the Public Health Advisory Committee (PHAC) in forest plots annotated with study characteristics and in tabular form to allow the PHAC interpret the findings of the studies included in each review. Evidence was reported in the reviews as described previously.

Reviewing economic evidence

The PHAC is required to make decisions based on the best available evidence of both general effectiveness and cost-effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected benefits (that is, their 'cost-effectiveness') rather than the total implementation cost. Thus, if the evidence suggests that a strategy provides significant benefits at an acceptable cost per person treated, it should be recommended.

In order to assess the cost effectiveness of the key issues addressed in this guideline, the following actions were carried out:

- A systematic review of economic evidence in the literature was conducted, alongside the review of evidence on general effectiveness (see Reviewing research evidence)
- A de novo economic model was developed, in order to provide cost effectiveness evidence for a number of review questions

Literature review

The systematic reviewer:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts. Full papers were then obtained.
- Reviewed full papers against pre-specified inclusion and exclusion criteria to identify relevant studies.
- Extracted key information about the studies' methods and results into evidence tables (included in the relevant chapter for each review question)
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter for each review question)

Appraising the quality of economic evidence

Studies that met the eligibility criteria were assessed using the quality appraisal criteria as outlined in Developing NICE guidelines (NICE 2014).

Health economic modelling

As well as reviewing the published economic literature for each review question, as described above, a de novo economic analysis was undertaken for relevant research questions. The following general principles were adhered to in developing the analysis:

- Methods were consistent with the NICE reference case.
- The committee was involved in the design of the model, selection of inputs and interpretation of the results.
- Where possible, model inputs were based on the systematic review of the clinical literature, supplemented with other published data sources identified by the committee as required.

- When published data were not available committee expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.

Full methods for the de-novo modelling can be found in the Alcohol HE report.

Resource impact assessment

The resource impact team used the methods outlined in the Assessing resource impact process manual: guidelines.

The resource impact team worked with the guideline committee from an early stage to identify recommendations that either individually or cumulatively have a substantial impact on resources. The aim was to ensure that a recommendation does not introduce a cost pressure into the health and social care system unless the committee is convinced of the benefits and cost effectiveness of the recommendation. The team gave advice to the committee on issues related to the workforce, capacity and demand, training, facilities and educational implications of the recommendations.