Methodology Checklist 4: Case-control studies

Study identification  \((Include\ author,\ title,\ year\ of\ publication,\ journal\ title,\ pages)\)

Guideline topic:  

Key Question No:

**Before completing this checklist, consider:**

1. Is the paper really a case-control study? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: Reason for rejection: 1. Paper not relevant to key question □  2. Other reason □  (please specify):

Checklist completed by:

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In an well conducted case control study:</th>
<th>In this study the criterion is:</th>
</tr>
</thead>
</table>
| 1.1 The study addresses an appropriate and clearly focused question | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

**SELECTION OF SUBJECTS**

| 1.2 The cases and controls are taken from comparable populations | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

| 1.3 The same exclusion criteria are used for both cases and controls | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

| 1.4 What percentage of each group (cases and controls) participated in the study? | Cases:  
| Controls:  
| 1.5 Comparison is made between participants and non-participants to establish their similarities or differences | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

| 1.6 Cases are clearly defined and differentiated from controls | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

| 1.7 It is clearly established that controls are non-cases | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |

**ASSESSMENT**

| 1.8 Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment | Well covered  
| Adequately addressed  
| Poorly addressed  
| Not addressed  
| Not reported  
| Not applicable |
### 1.9 Exposure status is measured in a standard, valid and reliable way

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

### CONFOUNDING

1.10 The main potential confounders are identified and taken into account in the design and analysis

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

### STATISTICAL ANALYSIS

1.11 Confidence intervals are provided

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise the risk of bias or confounding?

*Code ++, +, or −*

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

2.4 Notes. Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question.

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The following section is provided for non-SIGN users of this checklist and is being developed to conform to the standards set by the Guidelines International Network Evidence Tables Working Group.

*Members of SIGN guideline groups do not need to complete this section.*

### SECTION 3: DESCRIPTION OF THE STUDY

**PLEASE PRINT CLEARLY**

3.1 Do we know who the study was funded by?

- Academic Institution
- Healthcare Industry
- Government
- NGO
- Public funds
- Other

3.2 How many centres are patients recruited from?

3.3 From which countries are patients selected? (Select all those involved. Note additional countries after “Other”)

- Scotland
- UK
- USA
- Canada
- Australia
- New Zealand
- France
- Germany
- Italy
- Netherlands
- Scandinavia
- Spain
- Other:
<table>
<thead>
<tr>
<th>3.4</th>
<th>What is the social setting (ie type of environment in which they live) of patients in the study?</th>
<th>□ Urban □ Rural □ Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5</td>
<td>What criteria are used to decide who should be cases?</td>
<td></td>
</tr>
<tr>
<td>3.6</td>
<td>What criteria are used to decide who should be controls?</td>
<td></td>
</tr>
<tr>
<td>3.7</td>
<td>What exposure or risk factor is investigated in the study? (Include dosage where appropriate)</td>
<td></td>
</tr>
<tr>
<td>3.8</td>
<td>How long were patients followed-up for?</td>
<td></td>
</tr>
<tr>
<td>3.9</td>
<td>List the key characteristics of the patient population. Note if there are any significant differences between different arms of the trial.</td>
<td></td>
</tr>
<tr>
<td>3.10</td>
<td>Record the basic data for each arm of the study. If there are more than four arms, note data for subsequent arms at the bottom of the page.</td>
<td></td>
</tr>
<tr>
<td>Cases:</td>
<td>Exposure:</td>
<td>Cases:</td>
</tr>
<tr>
<td>Sample size:</td>
<td></td>
<td>Sample size:</td>
</tr>
<tr>
<td>No. analysed</td>
<td></td>
<td>No. analysed</td>
</tr>
<tr>
<td>With outcome:</td>
<td></td>
<td>With outcome:</td>
</tr>
<tr>
<td>Without outcome:</td>
<td></td>
<td>Without outcome:</td>
</tr>
<tr>
<td>3.11</td>
<td>Notes. Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question. (Much of this is likely to be contributed by GDG members).</td>
<td></td>
</tr>
</tbody>
</table>