Assessment of surgical site infection after hospital discharge:

Validation of an outcome measure for patient report or observer completion

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on behalf of the Bluebelle study group
Assessing wounds for surgical site infection (SSI)

- SSI is an important outcome for research and routine surveillance
- Assessment is challenging - often SSIs occur after patient has left hospital
- Current tools have limitations
Analyses of existing clinical tools

Analyses of existing patient questionnaires

Interviews with patients and professionals

Designed & pre-tested new questionnaire

Macefield et al., 2017 Journal of Infection Prevention
The questionnaire

“Was there redness spreading away from the wound? (erythema/cellulitis)”

- 16 items:
  - 8 signs/symptoms
  - 8 wound care interventions
- Patient self-report or observer completion
Questionnaire validation study

To examine

- compliance and acceptability
- patient vs observer responses
- psychometric properties
- clinical application
Questionnaire validation study

**Design**
- cohort study (Aug 2015 to Jan 2016)
- pilot RCT (March 2016 to Nov 2016)

**Setting**
UK hospitals, 5 centres

**Participants**
general abdominal surgery & C-section
Design

Questions on feasibility & practicality
Test-retest sample

Patient wound assessment
postal questionnaire

Follow up assessment
face to face reference SSI diagnosis (CDC criteria)

Observer wound assessment
telephone

Recruitment
Data

- cohort study n=416
- pilot RCT n=394
- Follow up ended January 2017
- Database locked 2\textsuperscript{nd} March 2017
Compliance

- 537/752 (71%) response to postal questionnaire
- 562/802 (70%) patient self-assessments
- 597/802 (74%) observer assessments

Acceptability

- 91% patients completed questionnaire in <10 mins
- 94% no difficulty or assistance
- mean item omission 2.4% (range 0.7% to 3.9%)
Do patient and observer assessments agree?

- **Comparison of responses**

Example: “Was any part of the wound leaking fluid?”

<table>
<thead>
<tr>
<th>Patient report</th>
<th>Observer assessment</th>
<th>Not at all</th>
<th>A little</th>
<th>Quite a bit</th>
<th>A lot</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td>182</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>190</td>
</tr>
<tr>
<td>A little</td>
<td></td>
<td>21</td>
<td>56</td>
<td>1</td>
<td>2</td>
<td>80</td>
</tr>
<tr>
<td>Quite a bit</td>
<td></td>
<td>0</td>
<td>6</td>
<td>8</td>
<td>5</td>
<td>19</td>
</tr>
<tr>
<td>A lot</td>
<td></td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>205</td>
<td>73</td>
<td>11</td>
<td>15</td>
<td>304</td>
</tr>
</tbody>
</table>
Do patient and observer assessments agree?

• Generally fair to good agreement across all items

• Kappa values between 0.4 and 0.75 for 11/16 items

• Consistent pattern observed for all symptoms

• Patients seem more likely to rate things a little worse
Distribution of responses

“Was there redness spreading away from the wound? (erythema/cellulitis)”
Comparison of patients with/without SSI

- 417/802 (52%) follow up reference SSI diagnoses
- 80/417 (19%) with SSI of any type

“Was there redness spreading away from the wound? (erythema/cellulitis)”
Comparison of patients with/without SSI

• Cross-tabulations of responses to each item

“How has the wound been painful to touch?”

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>Quite a bit</th>
<th>A lot</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No SSI</td>
<td>115</td>
<td>117</td>
<td>15</td>
<td>8</td>
<td>255</td>
</tr>
<tr>
<td>SSI of any type</td>
<td>14</td>
<td>35</td>
<td>6</td>
<td>5</td>
<td>60</td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>152</td>
<td>21</td>
<td>13</td>
<td>315</td>
</tr>
</tbody>
</table>

Pearson chi² = 11.5917   p = 0.009

• Chi² tests

• Differences between SSI/no SSI for all items (p<0.01)
Summary & next steps

- Practical and feasible questionnaire
- Good response rates & few missing data
- Suitable for patient or observer completion

- Examination of questionnaire structure – scales / single items
- ROC curve analysis for SSI discrimination
Acknowledgements

- MRC Network of Hubs for Trials Methodology Research
  (www.methodologyhubs.mrc.ac.uk)

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