1. Introduction
In 2016, a systematic review was published looking at design, implementation and reporting strategies to reduce the instance and impact of missing patient reported outcome (PRO) data. Recommended strategies included: standardised administration procedures for local sites with initial and ongoing PRO training, reminders about upcoming PRO assessments, central monitoring of PRO compliance in real time, active communication and intervention with poorly performing sites. The review emphasised the importance of recording rates and reasons for missing PRO data.

POSNOC is an international multi-centre randomised controlled trial to determine whether axillary clearance / radiotherapy can be avoided safely in women with early breast cancer and one or two involved sentinel nodes who receive standard care with systemic therapy. It is centrally coordinated at Nottingham Clinical Trials Unit (NCTU) with PROs on quality of life (QoL) and long term side effects of axillary treatment managed by Sussex Health Outcomes Research & Education in Cancer (SHORE-C).

The trial opened to recruitment in August 2014 with the strategies listed above already in place.

2. Methods
- PROs are collected from patients entered from the United Kingdom
- QoL and arm morbidity questionnaires: FACT B+4, LBCQ, QuickDASH
- Anxiety questionnaires: STAI Y1/Y2
- Health economics questionnaire: EQ-5D-5L
- All PROs are completed in clinic at baseline prior to randomisation
- Follow up FACT B+4, EQ-5D-5L, STAI Y1 are posted to patients from SHORE-C
- Follow up LBCQ, QuickDASH are administered by local site staff in clinic or by telephone

3. Discontinuation of postal PROs
- Patient driven
  - Patient withdrawal from trial
  - Patient chooses to discontinue questionnaires
- Local site / SHORE-C driven
  - Local site advises that questionnaires should be discontinued
  - PROs not returned at three successive time points

4. Baseline PRO data collection strategies
- Prior to patient recruitment:
  - Nottingham CTU site initiation visit in person followed by SHORE-C telephone training
  - Staff trained to check questionnaires for missing items with patient present
- During recruitment:
  - Individual site training offered to all new local site staff (NCTU slides, SHORE-C telephone call)
  - Liaison with sites to determine most convenient way to supply further baseline questionnaires (hardcopies supplied or site prints them locally)
  - Prompt chasing of baseline questionnaire data by NCTU and SHORE-C
  - Problems with data addressed promptly with local sites

5. Follow up PRO data collection strategies
- NCTU:
  - Individual patient PRO data collection schedule available from POSNOC database
  - Clinic PRO data collection conducted in clinic or by telephone to fit in with local site pathway
  - Prompt query and chasing of clinic PRO data
- SHORE-C:
  - Liaison with local site regarding health status and current contact details prior to posting questionnaires
  - Liaison with local site to collect follow up PRO data from patients who require assistance or did not consent for SHORE-C to hold contact details
  - Liaison with patient or local site if postal questionnaires not returned
- NCTU & SHORE-C:
  - Reminders and tips regarding PRO data collection addressed in trial newsletters and monthly update memos
  - Detailed review of PRO data at each TMG meeting to identify problems and devise solutions (Example: additional SHORE-C reminder to local sites to collect clinic PRO data introduced in September 2016 following TMG over clinic compliance)

Follow up questionnaire sets received
- Follow up time point
  - Clinic PROs
  - Postal PROs

<table>
<thead>
<tr>
<th>Follow up time point</th>
<th>Clinic PROs</th>
<th>Postal PROs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. received / expected (%)</td>
<td>No. received / expected (%)</td>
</tr>
<tr>
<td>3 months</td>
<td>-</td>
<td>1065 / 1173 (91%)</td>
</tr>
<tr>
<td>6 months (August 2016)</td>
<td>206 / 251 (82%)</td>
<td>1001 / 1082 (93%)</td>
</tr>
<tr>
<td>6 months</td>
<td>986 / 1101 (90%)</td>
<td>1001 / 1082 (93%)</td>
</tr>
<tr>
<td>12 months</td>
<td>859 / 950 (90%)</td>
<td>855 / 930 (92%)</td>
</tr>
<tr>
<td>24 months</td>
<td>586 / 671 (90%)</td>
<td>560 / 634 (88%)</td>
</tr>
<tr>
<td>36 months</td>
<td>304 / 362 (84%)</td>
<td>292 / 328 (89%)</td>
</tr>
</tbody>
</table>

Reasons why questionnaires are not completed at individual time points are collected where possible

6. Conclusion
Our current PRO data indicate that implementation of these strategies together with close collaboration between the whole study team and local sites can achieve high rates of PRO data return and therefore deliver accurate reporting of the effect of the different POSNOC trial treatment allocations on QoL and arm morbidity.

Acknowledgements:
Members of the Nottingham CTU POSNOC trial management team:
- Mickey Lewis, Sebastian Moody, Clare Upton, Alan Montgomery, Beki Haydock

This project is funded by the National Institute for Health Research (NIHR project reference 12/35/17)

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health