Aligning patient recruitment with clinical pathways in an observational study in an acute cardiology setting

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Background

The recruitment of patients to clinical research in acute settings presents a number of challenges. It is important that approaches adopted, minimise disruption to patient care and also allow recruitment of patients who are representative of the target population. Historically women have been under-represented in cardiovascular research, which usually comprises a predominantly male study population. Furthermore, despite the prevalence of cardiovascular disease increasing with age, the older population are also not proportionally represented in cardiovascular research.

Aims

1. Establish an effective approach to recruit patients with confirmed ST elevation Myocardial Infarction (STEMI) who present directly to the coronary catheterisation lab for emergency Percutaneous Coronary Intervention (PCI) and patients with Non-ST Elevation Myocardial Infarction (NSTEMI) who receive inpatient angiogram.
2. Determine if the research population was representative of the wider STEMI and NSTEMI populations of patients undergoing PCI, in particular with respect to women and over 65s.

Methods

Before commencing the study, time was spent with clinical teams to build relationships and develop a clear understanding of the patient journey. This is important to allow the alignment of the research recruitment process with current patient pathways and processes.

A new research approach was adopted, involving the incorporation of recruitment steps into the clinical environment, with planned Kết

Recruitment was reviewed regularly to monitor progress and address any changes in the numbers of patients recruited. Clinical data for NSTEMI and STEMI patients undergoing coronary angiogram during the 9 month research period was collected. Baseline characteristics of the study population was compared to the wider patient population to establish if women and over 65s were represented proportionally.

Results

- 30 STEMI and 67 NSTEMI patients were recruited to the study.
- Recruitment of STEMI patients undergoing emergency PCI was reliant on clinical staff notifying the research team of eligible patients. Omission of this step is perhaps the primary reason for poor recruitment in this group.
- Women were proportionally represented in the study in comparison to the patient population undergoing planned or emergency PCI (Table 1).
- Conversely patients over the age of 65 were not proportionally represented within the research population, particularly the NSTEMI cohort (Table 1).

Table 1: Proportion of females and over 65s

<table>
<thead>
<tr>
<th>STEMI</th>
<th>NSTEMI</th>
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<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>Patient Population</td>
<td>301</td>
</tr>
<tr>
<td>Research Population</td>
<td>30</td>
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Discussion

- Only 5% of the STEMI population were recruited to the study.
- Review of the STEMI recruitment process identified areas for improvement. The process was altered and CCU nurses were asked to notify the research nurse of incoming STEMI patients, however this did not improve recruitment.
- This is not necessarily due to a lack of staff engagement as staff were often very supportive of recruitment and the research sampling procedures. This may be due to the prioritisation of clinical procedures over research activities.
- An increased research nurse presence within the clinical area improved the recruitment of STEMI patients.
- Fewer women were recruited than men, however on review the proportion of male to female patients in the study population was similar to the patient population undergoing planned or emergency PCI (Table 1).
- The over 65s population were underrepresented in the research study. Recruitment hours were limited and possibly more elderly STEMI patients were admitted out of hours. Age was not recorded on screening logs, however elderly patients may have more comorbidities and decline the burden of additional research samples.

Conclusion

It is important to work with clinical teams to map recruitment procedures with clinical pathways and to include regular review and feedback of study progress. Despite maintaining relationships with clinical staff and providing regular study prompts, clinical staff often failed to notify the research team of eligible patients. An exploration into clinical staff perceptions of the research project may provide an insight into why this step was missed and how future recruitment could be improved. Women were proportionally represented in this study, however the research population was predominantly under the age of 65. Restricted recruitment may have underrepresented these patients in the research population. Recording if patients are over the age of 65 on screening logs may determine if more of the elderly population decline research participation.