Subject Recruitment in the Acute Care Setting

Marjolein de Wit, MD, MS
Associate Professor of Medicine
Division of Pulmonary Disease and Critical Medicine
Department of Medicine
Acute Care & Inpatient Facilities

Fast Facts

<table>
<thead>
<tr>
<th>VCU Health System Statistics for 2010</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Licensed Beds</td>
<td>779</td>
</tr>
<tr>
<td>Inpatient Discharges</td>
<td>32,841</td>
</tr>
<tr>
<td>Adjusted Discharges</td>
<td>55,616</td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>84,990</td>
</tr>
<tr>
<td>Outpatient Clinic Visits</td>
<td>534,126</td>
</tr>
<tr>
<td>Total Surgeries</td>
<td>19,727</td>
</tr>
<tr>
<td>Virginia Premier member months</td>
<td>1,748,124</td>
</tr>
</tbody>
</table>

Things to Consider: Service Factors

• Patients are cared for by a variety of clinicians and services
  – Attending
  – Fellows
  – Residents and Interns
  – Midlevel Providers
    • Nurse Practitioners and Physician Assistants
  – Nursing staff
Things to Consider: Service Factors

• Inform services about the study
  – Make sure all members of service know about the study and understand basics of the study
    • Consider asking Attending about 5-10 min presentation during sit down rounds
    • Make sure Nurses and Nurse Managers are aware of the study
  – Cannot expect services to perform any part of study
    • Focus is on patient care
    • Time constraints
    • Unaware of study details
    • Conclusion: Need to contact services on daily basis
  – What researcher may wish to ask services
    • Determining if patient meets eligibility criteria
    • Monitoring for adverse events
Things to Consider: Patient Factors

- Consent
  - Assess for ability to obtain consent
    - Social factors
      » No family or legally authorized representative (LAR)
      » Severe social stresses on patients and LAR
  - Patient ability to provide consent
    - Delirium common among hospitalized patients
    - Patients/family may not understand consent process
  - Make sure healthcare team speaks with patient/family prior to you!
    - You don’t want to be the first person to inform family that patient is hospitalized
Things to Consider: Types of Consent

- Written informed consent
  - Patients/family provide consent prior to study commencing
- Delayed consent
  - May start study but immediately need to start evaluating how to obtain consent
    » Talk to healthcare providers
    » Make sure you do not contact family before healthcare providers speak with family
    » Inform family and healthcare team by having flyers and posters in units
Electronic Medical Record

- Cerner is the electronic medical record used
- Accessing medical records is electronically recorded
  - At this point no distinction between entering for research purpose or for providing patient care
- Cerner has section on clinical trials
### Clinical Trials

<table>
<thead>
<tr>
<th>Protocol Name</th>
<th>Enrolment ID</th>
<th>On Study Date</th>
<th>Off Study Date</th>
<th>Contact Info</th>
</tr>
</thead>
</table>

### Potential Clinical Trials/Studies for Patient

**Patient interest in pre-screening:**

- [PreScreen]

**Last run by:**

**Last run on:**

<table>
<thead>
<tr>
<th>Protocol Name</th>
<th>Pre Screened By</th>
<th>Pre Screened Date</th>
<th>Pre Screened Status</th>
</tr>
</thead>
</table>

### Potential Clinical Trials/Studies Referred/In Follow-up for Patient

<table>
<thead>
<tr>
<th>Protocol Name</th>
<th>Pre-Screened By</th>
<th>Pre-Screened Date</th>
<th>Pre-Screened Status</th>
<th>Referred By</th>
<th>Referred Date</th>
</tr>
</thead>
</table>


Sample Acquisition and Processing

• Research team should expect to do this
  – Again services are not focused on your study
  – Entering data/orders into Cerner
• Researchers should expect to do this
  – Hospital versus university reimbursement
Conclusion

• Large number of beds translates into large number of patients that can be evaluated for study eligibility

• Many clinicians providing patient care have little experience in research (clinical or basic science)

• Clinicians are focused on patient care and not research
  – Cannot expect that they perform research related responsibilities

• Researchers should contact services to inform and educate about a particular study

• Electronic medical record has section on clinical research
  – Documentation of consent
  – Entering study related orders