A Case Comparison in Costs Between Establishing Local, Independent, Research Collections to the Utilization of an Established Biorepository to Fulfill Research Needs in a Longitudinal Study

Ann B. Tran, Amber L. Sexton, MPA
Global Alliance to Prevent Prematurity and Stillbirth (GAPPS)
Seattle, Washington, USA

ABSTRACT

Background:
The progress of medical research is hindered by its lack of long-term secure funding and availability of high-quality human biospecimens. Such limitations, particularly prevalent in longitudinal studies like pregnancy research, have led to the needed development of maternal-neonatal biorepositories. Although the potential benefits of biobanks are endless, the limited cost data associated with utilizing biorepositories greatly impedes their full potential uses.

Methods:
This discussion aims to provide a cost comparison, from a researcher’s standpoint, between developing an independent collection and utilizing an established biorepository. University Researcher A, studying prematurity, needs data and biospecimen collections from a local clinic across town, modeled after a typical WA clinic. To reach the study needs of 31 preterm and 31 control pregnancy cases, the researcher needs 407 participants. The assumption is that the recruiting clinic population is similar to that of the US, as the sampling distribution proportion is 11.73% preterm births in the US. University Researcher B, researching the exact same study, is seeking her study needs through an established biorepository.

Results:
Researcher A’s total costs in developing and maintaining the collections needed for his research is ~$1,018,260. This represents regulatory costs, data capture components, collection site set up, kit costs, and clinical pathology costs. Researcher B’s study, however, costs $199,330. By acquiring the needed biological and data collections from an established biorepository, Researcher B only spends a fifth of what Researcher A would spend collecting the same specimen and data samples independently.

Conclusions:
The utilization of biorepositories in longitudinal clinical studies is significantly more economical for researchers than developing an independent data and biospecimen collection. Using biobanks also provides access to more diverse participants. Historically, researchers have hesitated using biobanks, associating their use with sacrificing control in specimen procurement and processing. Developing dynamic repositories are a solution to such concerns. Dynamic biobanks can set up customized prospective collections, allowing researchers to influence and oversee the collection process. The scalability, flexibility, and economic benefits of biorepositories provide an advantageous resource, particularly in this unstable funding climate.

RESEARCHER PROFILE

<table>
<thead>
<tr>
<th>Description</th>
<th>Researcher A</th>
<th>Researcher B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Institute</td>
<td>A University</td>
<td>A University</td>
</tr>
<tr>
<td>Research Topic</td>
<td>Pregnancy research: Causes of Premature Birth</td>
<td>Pregnancy research: Causes of Premature Birth</td>
</tr>
<tr>
<td>Lab Site Location</td>
<td>At the University</td>
<td>At the University</td>
</tr>
<tr>
<td>Clinic Collection Profile</td>
<td>Collecting from one external local clinic across town,</td>
<td>Utilizing prospective collection approach from a multi-site biorepository</td>
</tr>
</tbody>
</table>

STUDY CRITERIA

- Study requirements: 31 Preterm Births; 31 Full-term Controls
- Sample size: 407*
- Study Duration: 1 year

* Assumption that the clinic population is similar to that of the United States, as the sampling distribution proportion is 11.73% preterm births in the entire US.

QUALITATIVE FACTORS

- Collection Kit Design
- Collection Kit Assembling
- Specimen Collection and Processing
- Quality Control
- Data Management and Quality Control
- Clinical Staff project integration
- Sample collection and processing training (data and biological specimens)

CONCLUSION

- In utilizing an established biobank for specimen and data samples, Researcher B saves five times more money than Researcher A.
- Significant benefits of convenience: Given the time consuming process of developing collection materials, establishing clinical relationships, and completing regulatory commitments, Researcher B saves dramatically more time and energy.
- Established biorepositories can guarantee data and specimen quality.
- Multi-site biobanks contain larger participant populations and therefore have access to more diverse participants.

DATA NEEDS

- Questionnaire Data: data characterizing environmental conditions, health history, reproductive history, etc.
- Maternal Age
- Gestational age
- Abstracted medical record report

INDEPENDENT SAMPLE PROCUREMENT COSTS

- Cost comparison between developing local, independent research collections and utilizing an established biorepository.

SPECIMEN NEEDS

<table>
<thead>
<tr>
<th>Collection Type</th>
<th>1st Trimester</th>
<th>2nd Trimester</th>
<th>3rd Trimester</th>
<th>Delivery</th>
<th>Post-partum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Serum</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Vaginal Swabs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Amniotic Fluid</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Whole Blood (Cryo protected: DMSO)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cord Blood (Cryo protected: DMSO)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>