Biobanking for NEC: Challenges & Opportunities

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Image source: L. Rubenstein/Broad Institute

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Audience Poll

• Raise your hand if your center collects samples from babies with NEC?

Image source: Susies Heart Photography
Objectives

• Discuss the purpose of the biorepository
• Define samples interested in collecting
• Discuss infrastructure for biorepository
• Review database capabilities
• Discuss specimen procurement
• Review funding opportunities
• Discussion
Biorepository

• **Definition:** Biologic materials repository that collects, processes, stores and distributes biospecimens to support future scientific investigation.

• **Purpose:** To maintain biological specimens and associated info for future use.

• Biorepository assures the quality and manages the accessibility and distribution of the samples.

Image source: Pediatric Research Alliance
NEC Biorepository

- NEC Society Meeting UC Davis April 2017
- Focus group convened to discuss interest, challenges, and opportunities
- This group has a shared vision to advance the state of the science to combat NEC
Biorepository Aims

• **Aim 1:** Develop and maintain a NEC specimen biorepository with linked clinical metadata accessible to investigators across multiple institutions within/outside the US.

• **Aim 2:** Develop and maintain the infrastructure to execute large observational studies utilizing NEC specimens across multiple institutions within/outside the US.
Biorepository Aims

• **Overarching goal:** To promote, facilitate, and accelerate basic and clinical-translational observational studies of NEC in humans.

Image source: EPL Archives Biorepository
Who is involved?

• A team of investigators dedicated to advancing the field of NEC research.
• Several investigators from the NEC Society Research Collaborative.
What are centers currently collecting?

• Several centers currently collecting:
  – Intestine
  – Stool

• To a lesser extent:
  – Blood
  – Urine

• Rarely:
  – Gastric aspirates
  – Saliva
  – Maternal breast milk
What are we interested in collecting?

- Blood, stool, and intestine
- Intestine only
- Blood and stool
- Stool and intestine
- All the bodily fluids listed on previous slide
What are we interested in collecting?

• All the bodily fluids listed on previous slide
Infrastructure

• **IRB approvals**, standardized informed consents and protocols

• **Research coordinator and/or staff for consenting**

• **Surgeons/pathologists** on board

• **Team** of tissue collectors with access

• **SOPs**: Specimen notification

• **SOPs**: Tissue/sample handling

Image source: Genecure.org
Tissue Procurement

• Intestinal resections for NEC and “Non-NEC” tissue from stoma closures, atresias, SIPs, strictures.

• Detailed procedures for tissue procurement, processing and storage are required.
Intestinal Resection SOP

• Once the resection comes into lab, it is cut up and banked as below:
  – RNA later for gene expression studies stored at -80
  – 4% PFA for histology, processed and sectioned
  – Snap frozen for microbiota 16S stored at -80
  – Snap frozen for a backup sample stored at -80
  – Snap frozen piece for Repository
  – Rest is processed fresh for ex vivo studies (i.e. isolating intestinal stem cells, making enteroids, etc.)
Other Specimens

- Blood
- Urine
- Stool
- Gastric or tracheal aspirates
- Breast milk
- Saliva
  - All stored in -80
Infrastructure

- **Equipment**: Dedicated freezers with temp monitoring, centrifuges
- **Consumables**: PPE, surgical instruments, tubes, racks, boxes, RNA later, formalin
- **Training and Compliance**: CITI modules, HIPAA, BBP
- **Archiving system**: Database, labeling, access to PHI
Infrastructure

- **Archiving system**: Barcoding system for ease of locating and specimen retrieval
- **Freezers**: Secure with alarms and procedures in place for loss of electrical power, minimize access
Infrastructure

• **Strict case definitions:** Review by site PIs and research coordinators

• **Consenting:** Standardized, rapid
  • Recent scrutiny surrounding saving samples

• **No consent:** If parents unavailable, ability to acquire NEC tissue fresh or stool until parents are available within 24 hrs
How do we start?

- Setting up the **infrastructure**.
- **Multi-center IRBs** for the virtual biorepository, database and sharing of samples/information between centers.
Database

• Using **REDCap** database for clinical information since it’s free and accessible everywhere.
What is REDCap?

• Research Electronic Data Capture
• A secure web application designed to support data capture for research studies.
• REDCap allows users to build and manage online databases quickly and securely.
• Developed at Vanderbilt University; used by >2000 institutions.
• Many centers are already using it and their CTSIs provide support on REDCap.
REDCap

• For more information on REDCap: http://project-redcap.org/
Accurate Recordkeeping

• Finalize clinical parameters to be obtained
  – Birth, feeding, antibiotic, drug, transfusion history

• Data repository quality
  – Timely entering of data after samples obtained

• International collaborations

Image source: Northwestern
Material/Data Sharing

- Investigators from all centers able to collaborate with the NEC Society Biorepository
  - Collaboration with a participating center required
- Application will be available online through the NEC Society website
- Biorepository scientific advisory board will review applications
Biorepository Maintenance

• **Funding**
  – Each center to obtain their own?
  – Internal, NIH, Foundations, PCORI

• **Protection of confidentiality across all centers**
  – Anonymous coding
  – Minimize individuals with access to coding identifiers
Summary

- NEC Society investigators are committed to the development of a national/international biorepository of biological samples from infants afflicted with NEC.
- Goal is to improve human specimen studies by individual NEC investigators and foster collaborations across multiple centers.
Summary

• It is the hope of all involved in the NEC Society Biorepository that we can improve, facilitate, and accelerate basic and clinical/translational studies of NEC.
Acknowledgements

- **NEC Society** for bringing all the investigators together for this amazing collaborative.

- Jennifer and Dr. Noah Canvasser
Thank you for your attention!
Questions?

Interested in being a part of the NEC Society Biorepository??
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