

Biobanking for NEC: Challenges & Opportunities



Image source: L. Rubenstein/Broad Institute

Misty Good, MD, MS
Division of Newborn
Medicine

Department of Pediatrics
Washington University
School of Medicine

Audience Poll

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



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.



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.



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



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



Image source: L. Biologix



Image source: L. Rubenstein/Broad Institute

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



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

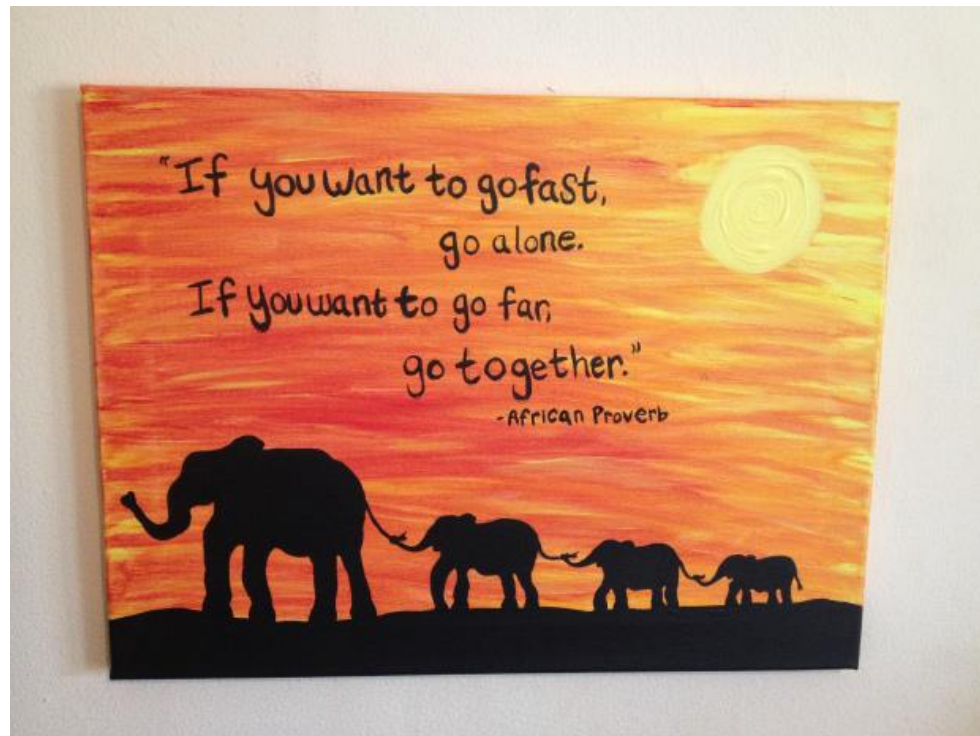


Summary

- 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??

Email:

mistygood@wustl.edu
jennifer@necsociety.org