Alaska Area Specimen Bank

“A Resource for Improving the Health of Alaska Native People”

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Director

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Laboratory Team Lead

Arctic Investigations Program
Arctic Investigations Program (AIP)

- Infectious disease field station located on the Alaska Native Health Campus
- Infectious disease prevention and control through applied epidemiology, laboratory, and statistical sciences
Our Staff

• Epidemiology
  Medical epidemiologists
  Research nurses
  Surveillance epidemiologist

• Laboratory
  Microbiology
  Molecular Diagnostics
  Specimen Bank

• Statistics & data management

• Administration

Bullwinkle, our parking attendant
Mission

• To prevent infectious disease morbidity and mortality in peoples of the Arctic and Subarctic

• Special emphasis on diseases of high incidence and concern among indigenous peoples
What we do...

- Monitor Infectious Diseases
  - Alaska invasive bacterial infection surveillance
  - International Circumpolar Surveillance system
- Respond to emerging infectious diseases
- Reduce health disparities
- Respond to public health threats
  - Public health emergencies
  - Laboratory Response Network lab for bioterror threats
- Provide leadership in circumpolar health
Strategic Plan, 2016 - 2020

Priorities

The CDC Arctic Investigations Program has adopted the following top five Priorities for the period 2016-2020:

- Reduce the burden of disease and health disparities among Alaska Natives caused by respiratory infections, *Helicobacter pylori* gastric infections, viral hepatitis, and emerging invasive or antimicrobial-resistant infections.
- Strengthen infectious disease monitoring in the circumpolar north through enhancements to laboratory-based surveillance, use of electronic health records and biorepositories, and collaborations such as the International Circumpolar Surveillance system.
- Support efforts to improve access to in-home water and sanitation services for circumpolar populations.
- Provide leadership for domestic and international activities to promote improvements in health and well-being among Indigenous populations in the Arctic region and the U.S.
- Respond to infectious disease threats to Arctic and sub-Arctic populations caused by the rapidly changing climate and environment.

www.cdc.gov/ncezid/dpei/aip/
Alaska Area Specimen Bank (AASB)
Why have a Specimen Bank?

• Stored biologic specimens can help us
  • Understand disease prevalence and severity
  • Compare the past with the present
  • Investigate changes in diet, nutrition, exposures
  • Improve the health and well-being of populations

• Some examples:
  • Stored Alaska specimens allowed identification of alpha fetoprotein as a early marker of liver cancer
    • Used in care of hepatitis patients
  • Determined very high prevalence of Helicobacter pylori infections among Alaska Native persons
    • Cause of stomach ulcers and cancer
Alaska Area Specimen Bank

• Collection of biologic specimens from research done by
  • Arctic Health Research Center
  • Indian Health Service
  • Centers for Disease Control and Prevention
  • Tribal Health Organizations

• Includes
  • Human tissue (blood, biopsy, stool, urine, swab specimens)
  • Microbiologic organisms (bacteria, viruses, DNA)

• Co-management
  • CDC
  • Tribal health leaders and organizations
Alaska Area Specimen Bank, Two collections

- Active research
  - "Short-term" storage
  - Specimens kept for purpose defined in the protocol

- Historic specimens
  - "Long term" storage
  - Closed or historic research protocols
  - Specimens kept for future research
What is Banked in the AASB?

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th>Aliquots</th>
<th>Specimens</th>
<th>People</th>
</tr>
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<tbody>
<tr>
<td>Total</td>
<td>618,170</td>
<td>343,332</td>
<td>104,508</td>
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<tr>
<td>Specimen Types</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Serum</td>
<td>508977</td>
<td>277789</td>
<td>84404</td>
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<tr>
<td>Plasma</td>
<td>9131</td>
<td>6287</td>
<td>3378</td>
</tr>
<tr>
<td>Bacterial cultures</td>
<td>50518</td>
<td>33501</td>
<td>21138</td>
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<tr>
<td>Urine</td>
<td>2015</td>
<td>1212</td>
<td>1036</td>
</tr>
<tr>
<td>Cord blood</td>
<td>1805</td>
<td>1238</td>
<td>1233</td>
</tr>
<tr>
<td>NP/OP swabs</td>
<td>26184</td>
<td>26010</td>
<td>10725</td>
</tr>
<tr>
<td>DNA</td>
<td>11653</td>
<td>10714</td>
<td>6985</td>
</tr>
<tr>
<td>Other*</td>
<td>5342</td>
<td>4044</td>
<td>2017</td>
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*Other includes: body fluids, tissues, white blood cells and whole blood
Management of the AASB Policies and Procedures

• Defined in a research protocol, approved by:
  - Alaska Area and CDC Institutional Review Boards (IRB)
  - Alaska Native Tribal Health Organizations

• Purpose:
  - operations
  - priorities for use
  - conditions of informed consent
Management Objectives

- Secure storage
- Proper management
  - Follow best practices of the International Society for Biologic and Environmental Repositories (ISBER)
- Approval for secondary use is based on
  - Health concerns of Alaska Native peoples
  - Federal, Tribal and tribal health organization standards for
    - Individual privacy
    - Ethical approval
Management of the AASB Specimen Bank Committee

- Manage day-to-day operations
- Ensures that specimens are used in accordance with the Policies and Procedures
- Meets monthly
- Includes research staff from:
  - CDC’s Arctic Investigations Program
  - Alaska Native Tribal Health Consortium
Informed Consent

• Informed consent
  – Study participant agrees to have remaining specimen saved for future testing.

• Two parts:
  – Consent to be in a research study
  – Consent to store and test specimens at a later date

Example of a consent form

1. We would like to save any unused biological specimen in the Alaska Area Specimen Bank.
2. This biological specimen may be used for future testing.
3. Future tests on the biological specimen which use your name or other identifiers will not be done without your consent, including tests for HIV, family diseases, or drugs.
4. Any future anonymous testing will only be done with the consent of [insert name of your Alaska Native Tribal Health Organization].
5. You may request to have your biological specimen removed from the Specimen Bank at any future date by calling Dr. Karen Rudolph, Director, Alaska Area Specimen Bank at the Centers for Disease Control and Prevention (CDC). You may use this free telephone number 1-800-659-0767.
6. If you do not want to have your biological specimen kept, this would not change the care that you have a right to receive from your Alaska Native tribal health organization, or the Alaska Native Medical Center or prevent you from being in the study.

Check below:
I understand the biological specimen saving information as explained above and:
(  ) I agree to have my left over biological specimen from this study kept for possible future testing as explained above.
(  ) I do not agree to have my left over biological specimen from this study kept for future testing. These samples should not be used for anything but this research study, and the samples should be respectfully destroyed 12 months after the study ends.

<table>
<thead>
<tr>
<th>Participant (print)</th>
<th>Date of Birth</th>
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Signature of participant | Date  | Witness initials
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Signature of interpreter (if required) | Date
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Informed Consent - 2

• Specimens linked to participant and research protocol.
  – Anonymous specimens are not stored

• Three identifiers required:
  – Name, date of birth, medical record number, date collected

• Can participate in a study without having specimens stored long-term.

• Banked specimens can be discarded at request of consenting individual.
Informed Consent - 3

- New use of specimens
  - New research protocol

- Testing that requires personal identifying information
  - Needs individual consent.

- Banked specimens from deceased individuals
  - Tribal health organization provides guidance.

- Anonymous testing
  - Does not require individual consent
  - Needs tribal health organization approval
How do specimens get added?

- PI notifies AASB Director of intent to deposit specimens
- Proposal reviewed by AASB Committee
- Protocol Developed
- Space availability.
- Participant consent
- Supply needs
- Data requirements
- Collection/processing suggestions
- Specimens/long-term storage consents received
- Alaska Area IRB Approval
- Appropriate Tribal Approvals
How do specimens get used?

PI submits specimen request

Proposal reviewed by AASB Committee
Are specimens available
Review language in consent
Scientific validity
Depletion of specimens
Active vs. inactive protocol

Specimens are retrieved from the bank

Protocol Developed

PI completes specimen release form

Alaska Area IRB Approval
Appropriate Tribal Approvals

Specimen REQUEST (Withdrawal)
For more information:

“The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health.”

Alan Parkinson, Tom Hennessy, Lisa Bulkow and Sally Smith

*International J Circumpolar Health* 2013, 72:20607

AASB Policies and Procedures document available upon request.
Questions?
Specimen Bank Use - Examples

- High prevalence of Helicobacter pylori in the Alaska Native population and association with low serum ferritin levels in young adults.

- Estimating the date of hepatitis C Virus (HCV) infection from patient interviews and antibody tests on stored sera.

- Declines in traditional marine food intake and Vitamin D levels from the 1960s to present in young Alaska Native women.
AASB Inactive Specimens by Reason for Collection

Reason for collection

- Other hepatitis projects: 31%
- Hepatitis B statewide screen: 28%
- Hepatitis B Vaccine demonstration project: 12%
- Other infectious diseases: 14%
- Arctic Health Research Center: 3%
- Diabetes: 1%
- Other: 4%
How are Specimens Stored in AASB?

- Cryogenic vials
- Each tube has a unique number
- Data on each specimen
  - Person (name, DOB, MR#)
  - Specimen date
  - Specimen type
  - Protocol collected under (CLP)
- Container, Layer and Position (CLP)
-30°C Walk-in freezer

- Specimens
  - Serum
  - Plasma
  - Urine
  - Whole Blood
  - Bacterial DNA
-70°C Stand-alone Freezers

- 7 stand-alone freezers
- Specimens
  - Human genetic material
  - Whole blood
  - Tissues
  - Bacterial cultures
  - Nasopharyngeal swabs
  - Oropharyngeal swabs
AASB Costs

- Supported from CDC AIP’s base funds
- ANTHC funds specimen bank technician
- Investigators can help offset costs
  - direct costs in submitted budget
  - used to purchase consumables and equipment for the repository
- Not a requirement
Current Capacity of AASB

• AASB is a limited resource
  – Approximately 37% of the space is available in the -70°C freezers
  – Approximately 9.0% of the space in the -30°C walk-in is readily available

• More space is available by:
  • Increasing Rack sizes
  • Positions in the boxes
  • Implementing new technologies for storage
    – Ambient storage of nucleic acids