Alaska Area Specimen Bank

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

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Arctic Investigations Program (AIP)

- Field station of CDC located on the Alaska Native Health Campus
- Infectious disease prevention and control research studies through applied epidemiology, laboratory, computer and statistical sciences
AIP Staff

• Epidemiology
  Medical epidemiologists
  Research nurses
  Surveillance epidemiologist

• Laboratory
  Microbiology
  Molecular Diagnostics
  Specimen Bank

• Statistics & Information Management

• Administration

Bullwinkle, our parking attendant
AIP’s 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
AIP’s Priorities

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 Alaskans 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.
Alaska Area Specimen Bank (AASB)

Outline

• Introduction
• Management
• Informed consent
• Utilization of specimens
• Costs
• Current holdings
• References
Introduction

• Human health research in Alaska addresses:
  • Health disparities
  • Improves health of all Alaskans

• Conducted by agencies of the Public Health Service
  • Arctic Health Research Center
  • Alaska Area Native Health Service (AANHS)
  • Indian Health Service (IHS)
  • CDC

• Currently being conducted by
  • Alaska Native Tribal Health Organizations (THOs)
  • Academic, government and other tribal partners of THOs
  • CDC’s Arctic Investigations Program (AIP) and other CDC programs
Introduction

• Testing of previously collected biologic specimens can:
  • Allow assessment of disease prevalence
  • Contribute to the understanding of the natural history of disease
  • Benefit the health and well-being of populations

• Some examples include:
  • Used of stored specimens allowed identification of alpha fetoprotein as a pre-diagnostic marker of hepatocellular cancer
  • Determination of the prevalence of infections with *Helicobacter pylori* – has served as a starting point for research into prevention and control measure
Management of the AASB

History

- Prior to 1999, specimen bank co-managed by CDC’s AIP and AANHS.

- Use of stored specimens governed by ANNHS guidelines and serum bank protocol.

- Public Law 93-638 (1975):
  - Alaska Native peoples assumed responsibility for their health care
  - AANHS and IHS activities transferred to Alaska Native Tribal Health entities

- Specimen bank became known as the Alaska Area Specimen Bank
Management of the AASB Policies and Procedures

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

• Purpose:
  - conditions of informed consent
  - health priorities of Alaska Native peoples
  - principles of good scientific methods

• Ownership
  - Individual ownership vs. THO ownership
Management of the AASB Policies and Procedures

• Objectives:
  - secure storage
  - proper management
  - approval for secondary use is based on:
    - health concerns of Alaska Native peoples
    - in accordance with health-related missions
    - meet Federal, Tribal and THO standards for privacy, ethics and protection of human subjects
Management of the AASB
Alaska Area Specimen Bank Work Group

• Oversight provided by the AASB Working Group
  – Formulates policies and procedures regarding the collection and storage of biological materials.
  – Meets annually
  – Includes representation from
    • CDC Arctic Investigations Program
    • Alaska Native Tribal Health Organizations
    • Health Research Review Committee
    • Alaska Area Institutional Review Board
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
Management of the AASB Specimen Bank Committee

- **Specimen Bank Committee responsibilities:**
  1. Reviews new/renewed protocols, consent forms
  2. Specimen collection, processing, shipping
  3. Ensures
     - specimens are of high quality
     - complete information
     - privacy and confidentiality are protected
  4. Oversees
     - accessioning, data management, quality control/quality assurance
     - specimen withdrawals
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 1-800-699-0767].
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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of participant</th>
<th>Date</th>
<th>Witness initials</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Signature of interpreter (if required)</th>
<th>Date</th>
</tr>
</thead>
</table>
Informed Consent - 2

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

• Minimum of three identifiers required:
  – Study participant’s name, Date of birth (or medical record number), Date of specimen collection

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

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

• Future testing – related or not related to original study
  – Requires amendment and approvals
  – New research protocol

• Banked specimens linked to personal identifying information requires individuals to provide consent.

• Banked specimens from deceased individuals – THO provides guidance.

• Anonymous testing – does not require individual consent; needs THO approval
Utilization of the AASB Research Studies

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

Protocols

PI completes specimen release form

Protocol Developed

Alaska Area IRB Approval
Appropriate Tribal Approvals

Specimen REQUEST (Withdrawal)
Utilization of the AASB
Clinical and participant requests

• Specimen requests – clinical purposes
  – assist with diagnosis or care
  – requires signed consent from patient and letter from requesting physician

• Participant requests
  – have specimens removed from long-term storage at any time
  – specimen will be discarded in a manner similar to other clinical specimens
Utilization of the AASB Specimen Deposits

PI notifies AASB Director of intent to deposit specimens

Proposal reviewed by AASB Committee

- Space availability
- Participant consent
- Supply needs
- Data requirements
- Collection/processing suggestions

Protocol Developed

Specimens/long-term storage consents received

Alaska Area IRB Approval

Appropriate Tribal Approvals
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
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
- Container, Layer and Position (CLP)
What is Currently Banked in the AASB?

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th>Aliquots</th>
<th>Specimens</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>618,170</td>
<td>343,332</td>
<td>104,508</td>
</tr>
<tr>
<td>Specimen Types</td>
<td></td>
<td></td>
<td></td>
</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>
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<tr>
<td>Bacterial cultures</td>
<td>50518</td>
<td>33501</td>
<td>21138</td>
</tr>
<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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</table>

*Other includes: body fluids, tissues, white blood cells and whole blood
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.
For more information:
The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health.


Also – AASB Policies and Procedures document available upon request.
Questions?