Proceedings of the 2011 AFMS Medical Research Symposium. Volume 5. Operational Medicine (In-Garrison Care) Track

Lieutenant Colonel Cherri Shireman (Editor), Welford C. Roberts, Ph.D. (Coordinating Editor)

The U.S. Air Force Medical Service presented the sixth annual Air Force Medical Research Symposium coordinated by the Air Force Medical Support Agency’s Research and Development Division (AFMSA/SGRS). The symposium was held 2-4 August 2011 at the Gaylord National Hotel & Convention Center, National Harbor, MD. The symposium featured two half-days of plenary sessions, one and a half days of scientific presentations, and a poster session. It was organized into five tracks to include: Operational Medicine (In-Garrison Care), Enroute Care and Expeditionary Medicine, Force Health Protection, Traumatic Brain Injury (TBI) and Psychological Health, and Healthcare Informatics. These proceedings are organized into six volumes to include one that provides a general overview and all presentation and poster abstracts; the other five each address a specific track. Volume 5 contains abstracts and presentation slides for the Operational Medicine (In-Garrison Care) Track.

US Air Force, Medical Service, Medical Research, Operational Medicine, In-Garrison Care

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2011 AFMS Medical Research Symposium
2-4 August 2011

Gaylord National
201 Waterfront Street
National Harbor, MD 20745
(1-877-677-9352)
Proceedings of the 2011 AFMS Medical Research Symposium
Volume 5. Operational Medicine (In-Garrison) Track
Abstracts and Presentations

Edited by: Lieutenant Colonel Cherri Shireman

Held
2-4 August 2011
at the
Gaylord National Resort Hotel and Convention Center
201 Waterfront Street
National Harbor, MD 20745
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The symposium was organized into several tracks to include Enroute Care, Force Health Protection, Healthcare Informatics, Operational Medicine (In-Garrison Care), and Psychological Health/Traumatic Brain Injury, as follows:

- **The Enroute Care Track** addressed science and technology targeted at the continuum of care during transport from point of injury to definitive care including, but not limited to: Casevac, Medivac; Aeromedical Evacuation; Critical Care Air Transport; and Patient Staging. Further areas addressed included: patient stabilization; patient preparation for movement; impact of in-transit environment on patient and AE crew physiology; human factors concerns for AE crew or patient population; AE/medical personnel training; infectious disease/control; burn management; pain management; resuscitation; lifesaving interventions; and nutrition research in the enroute care environment.

- **The Force Health Protection Track** focused on prevention of injury and illness and the early recognition or detection of emerging threats for in-garrison or deployed operations. Topics of interest include research in bio-surveillance, infectious disease, emerging threats (pandemic response), protective countermeasures, disaster response/consequence management, toxicology/health risks (e.g., particulates nanomaterials, radiation, etc.), monitoring disease trends, other areas of preventive medicine, public and environmental health relevant to the military workforce.

- **The Healthcare Informatics Track** focused on the use of innovative information management & technology solutions that enhance healthcare delivery at any point of the full spectrum of patient care to include medical simulation and training.

- **The Operational Medicine (In-Garrison Care) Track** focused on care delivered in the outpatient or inpatient in-garrison setting and on enhancing the performance of airman in challenging operational and expeditionary environments.

- **The Psychological Health/Traumatic Brain Injury Track** addressed topics pertaining to screening, diagnosis, and treatment of TBI and/or Psychological Health in the military community. Specific focus areas within Psychological Health included depression, substance use disorders, family functioning, and suicide prevention. Topics of special interest included field-deployable diagnostic tests for mild TBI (concussion), blast modeling, large epidemiologic studies of Psychological Health and TBI, and strategies for translating research into practice.

These proceedings are organized into five volumes, as follows:

- **Volume 1.** This volume is a general overview of the entire 2011 Air Force Medical Research Symposium and includes abstracts of all the oral presentations and posters. First presented is the symposium’s opening plenary session, followed by the abstracts from the four technical tracks, and then the closing plenary session. The abstracts associated with the poster session are in the last section of these proceedings. The agenda for the overall symposium is in Appendix A, attendees are listed in Appendix B, and continuing education information is in Appendix C of this volume. Appendices D-J are copies of presentation slides from the plenary sessions.

- **Volume 2.** This volume contains abstracts and presentation slides for the Enroute Care Track.

- **Volume 3.** This volume contains abstracts and presentation slides for the Force Health Protection Track.

- **Volume 4.** This volume contains abstracts and presentation slides for the Healthcare Informatics Track.

- **Volume 5.** This volume contains abstracts and presentation slides for the Operational Medicine (In-Garrison Care) Track.

- **Volume 6.** This volume contains abstracts and presentation slides for the Psychological Health/Traumatic Brain Injury Track.
The Armed Forces Institute of Regenerative Medicine: Bone and Nerve Regenerative Programs

AFMS/SG

Brig Gen Michael Yaszemski

The Armed Forces Institute of Regenerative Medicine (AFIRM) is a consortium of military medical treatment facilities, academic clinical and research institutions, and industry partners. The consortium's goal is to provide novel treatment modalities for our nation's wounded warriors in five broad areas: limb reconstruction and regeneration, burn treatment, scarless healing, craniofacial reconstruction and regeneration, and skin regeneration. Several of the AFIRM projects have reached human use, and several more are poised to do so as AFIRM enters its fourth year in the Summer of 2011. This presentation will cover the AFIRM bone and nerve regeneration programs. The nerve regeneration scaffold consists of a biodegradable polymer that is fabricated into a tube and lined with bioactive molecules. A clinical study of 6 cm nerve defects will begin this year. The bone regeneration scaffold to treat segmental bone defects consists of a structural polymer that is fabricated into a porous three dimensional scaffold, surface coated with a calcium phosphate material, and which delivers bone growth factors in a controlled fashion to direct the new bone growth. This treatment enters large animal testing in 2011.

This partnership is committed to providing tools for optimum treatment of those colleagues who have been injured in the service of our country.
The Armed Forces Institute of Regenerative Medicine: Bone and Nerve Regenerative Programs

Michael J. Yaszemski, M.D., Ph.D.
Brigadier General, USAF, MC, FS
AFMS/SG, Washington, DC
Professor of Orthopedic Surgery and Biomedical Engineering
Mayo Clinic, Rochester, MN

2011 AFMS Medical Research Symposium
National Harbor, MD
August 2, 2011

Outline
• The Armed Forces Institute of Regenerative Medicine (AFIRM)
• Clinical needs for bone and neurologic tissue regeneration
• Tissue Engineering: polymer and scaffold design, synthesis, and fabrication
• Preclinical bone and nerve studies, and translation to human use

Armed Forces Institute of Regenerative Medicine (AFIRM)
• Two consortia working together with the US Army Institute of Surgical Research (230 scientists)
27 Universities
114 investigators – 30% of which are clinicians
46 graduate students
70 post-docs

This is a great start, but we can do better.
Armed Forces Institute of Regenerative Medicine (AFIRM)

- Total 5 yr funding (2008-2013) of >$250M
- $100M US Government funding from Army, Navy, Air force, VA, and NIH
- $68M Matching funds from state governments and participating universities
- $109M in pre-existing government research projects directly related to the deliverables of the AFIRM

AFIRM Goal: To Heal our Wounded Warriors
Five Areas of Emphasis

- Craniofacial Reconstruction
- Scarless Healing
- Limb Salvage and Reconstruction
- Treatment of Compartment Syndrome
- Burn Repair

AFIRM Goal: To Heal our Wounded Warriors
Five Areas of Emphasis

Combat Injury Severity Relative to Civilian Trauma: Fractures

*Unrest, Harris et al. 2002
Salvetti and Andrus 2002
Burden of Injuries and Morbidity
19 January 2011 - 42167 battle injuries/ >50% Evac

Bedside to Bench and Back
- Begin with clear description of a clinically relevant unmet need for patient care.
- The solution to that need may span the range from basic research to product development.
- Multidisciplinary input is essential. Teamwork is an absolute requirement for effective translation of a novel idea to practice.
Tissue Engineering Strategy

Scaffold → Bioactive Molecules → Cells

Synthetic Biodegradable Polymers
- Chemical
- Mechanical
- Degradation
- Drug Release
- Tissue Formation
- Cellular Interaction
- Architecture

Controllable Properties

Polymer Scaffolds for Bone Regeneration
- Preformed
  - Appropriate for non-contained defects of specified shape
- Controllable internal microarchitecture
- Injectable
  - Appropriate for contained defects of arbitrary shape
  - Random internal microarchitecture
  - Minimally Invasive insertion
Nerve Regeneration

Challenges:
- Crossing gaps - injuries, tumor resections
- Distal regeneration from proximal injuries
- Accuracy of regeneration

Clinical Practice for Nerve Repair

- Autologous nerve graft (nural nerve)
- Disadvantages:
  - Donor site morbidity
  - Limited availability
  - Size mismatch
- Less than perfect recovery of function

Courtesy of Dr. R.J. Spinner
The Peripheral Nervous System

Some factors to consider

- 3-D architecture  
- tissue shape  
- extracellular matrix

- Surfaces/interfaces  
- shape  
- chemical composition  
- surface charge

- Mechanical properties  
- elasticity, deformability  
- flexibility  
- tensile strength

Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture  
- tissue shape  
- extracellular matrix

- Surfaces/interfaces  
- shape  
- chemical composition  
- surface charge

- Mechanical properties  
- elasticity, deformability  
- flexibility  
- tensile strength

Vacuum Molding Technique
Scanning electron microscopy of poly(lactic-co-glycolic) acid (PLGA)

Biomimetic design - mimicking properties of original tissue

Some factors to consider
- 3-D architecture
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- Surfaces/interfaces
  - shape
  - chemical composition
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- Mechanical properties
  - elasticity, deformability
  - flexibility
  - tensile strength

Effect of degradation on shape

PLGA 75:25
PLGA 75:25 after 12 weeks in vitro

PCLF
PCLF after 12 weeks in vitro
Effect of Surface Etching on Cell Attachment

Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture - tissue shape
- Extracellular matrix

- Surfaces/interfaces - shape
- Chemical composition
- Surface charge

- Mechanical properties
  - Elasticity, deformability
  - Flexibility
  - Tensile strength

Suture Pull-Out

Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture - tissue shape
- Extracellular matrix

- Surfaces/interfaces - shape
- Chemical composition
- Surface charge

- Mechanical properties
  - Elasticity, deformability
  - Flexibility
  - Tensile strength
**Dorsal Root Ganglion Explant Attachment and Neurite Outgrowth**

**Electrically Conductive Scaffolds**

- Motivation: direct electrical stimulation at the regeneration site
  - magnitude, frequency, interval
- Semi-interpenetrating polymer network of polypyrrole discontinuous phase within polycaprolactone continuous phase
- Initial studies: conducting polymer implant without imposed potential difference across it

**Electrically Conductive Scaffolds**

**Biomimetic design - mimicking properties of original tissue**

**Some factors to consider**

- 3-D architecture - tissue shape, extracellular matrix
- Surfaces/interfaces - shape, chemical composition, surface charge

**Mechanical properties**

- elasticity, deformability, flexibility, tensile strength
Nerve Tube Mechanical Properties

Measurement of Outcomes
- Retrograde axonal tracing
- Fidelity of motor re-innervation
- Nerve and muscle morphometry
  - Numbers of axons regenerating
  - Muscle fiber-type distribution
- Electrophysiology (sensory and motor NCV)
- Electrophysiological function
- Gait analysis
  - Integrated functional analysis

Compound Muscle Action Potential
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- Dr. L. Lu
- Dr. A. Nassr
- Dr. H. Wang
- Dr. S. Wang
- Dr. C. Yang
- Dr. A. Knight

Clinical Trial

- Clinical Equipoise
- Neuropathy Evaluation: Sural Nerve Biopsy
- Institutional Review Board
- FDA: IDE, GMP

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- Ms. K. Taylor
- Mr. Bob Brown
- NIH (NIAMS, NIBIB, and NINDS)
- DOD (AFIRM)
- Mayo Foundation
The Team

Thank you
Designing a Safer OR to ICU Hand-Off

81 MSGS/SGCX

Lt Col Broadus Atkins

Background: Clinical transfer of patient care from one medical unit/service to another is high-risk and error-prone. We examined a tertiary VA medical center’s current OR-to-ICU handover protocols, quality, and provider satisfaction and reviewed available literature on ICU patient transfers to redesign and standardize the handover process. Methods: After institutional approval, data were acquired through (1) observation of 50 OR-ICU handovers, (2) provider surveys eliciting perceived deficiencies and proposed modifications, and (3) 25 focus-group interviews evaluated with ‘open coding’ strategy. Methodical literature review was conducted using PubMed and ProQuest databases (keywords: ‘handover’, ‘handoff’, ‘patient transfer’ and/or ‘post operative’, ‘post anesthesia’, ‘anesthesia’, ‘surgery’, ‘operating room’, ‘ICU’, ‘critical care’, ‘intensive care’, ‘surgical intensive care’, ‘admission’, ‘communication’, and ‘team’). Results: 500 published manuscripts were reviewed; 30 (6%) focused on postoperative handovers; 14 manuscripts provided evidential support for proposed solutions to handover difficulties. Handover observations, survey reviews, and interview analysis revealed that technical handover processes were often compromised by ineffective communication (simultaneous conversations or task performance during handover, artificial distractions, inconsistent role participation, inattention due to time pressure), poorly coordinated task prioritization, and incongruous priorities of task performance and information exchanged between transferring and receiving teams. A new, standardized model for OR-ICU handover was devised. Conclusions: Previous OR-ICU handover processes were flawed and not uniformly conducted. Using these data, a redesigned handover, based on structured verbal reporting and establishment of a communication platform, was constructed. High-fidelity patient simulation will allow testing, staff training, and tool refinement prior to clinical introduction of the new handover process.
INTRODUCTION

1999 IOM report: To Err is Human: Building a Safer Health Care System.

- Up to 98,000 US pts/yr die from medical errors
- Updated estimate: 192,000 US pts/yr from med errors
- At least 80,000 pts die of blood stream infection/yr

- Marked med systems as focus of safety movement
  “…the biggest challenge to moving toward a safer health system is changing the culture from…blaming individuals…to one in which errors are treated…as opportunities to improve the system…”


INTRODUCTION

IOM Report

- Related medicine to other high-risk industries
- Suggested “Crew Resource Management” to make medicine highly-reliable org (airline, nuclear)
- Urged health care orgs to assess local safety climate and monitor improvements
- Heavily investigated area
- Spawned JCAHO Nat’l Hosp Pt Safety Goals;

One of 8 PSCIs funded by VA National Center for Patient Safety (2007)

- 2 - year study FY 2010 – FY 2011
- Recently extended for FY 2012
Durham VAMC Patient Safety Center of Inquiry

Investigations
Perioperative care
Acute and ICU care
Procedural care

VA National Center for Patient Safety
Moderate Sedation Toolkit for Non-Anesthesiologists
Facilitator's Guide

Durham VAMC Patient Safety Center of Inquiry

Principal Investigator: Jonathan B. Mark, M.D.
- Rebecca A. Schmieder, M.D. (Investigator, Associate Director)
- Aditi Barbetia, M.D. (Investigator)
- Rosa Segall, Ph.D. (Investigator)
- Bridget A. Alger, B.S. (Simulation Consultant)
- Jeffrey M. Tarkness, M.D. (HUMAN Factors Engineer Consultant)
- Michelle Wright, Ph.D. (Human Factors Engineer Consultant)
- Eason S. Riggs, B.S.N. (Quality Improvement Nurse)
- Sally S. Kellum, R.N., M.S.N. (Simulation Consultant)
- Gene Hobbs (Simulation Technician)
- Deborah De Corso, M.A. (Simulation Consultant)
- Sam B. Stilke, Ph.D. (Organizational Behavior Consultant)
- Jenn Haty, M.S. (Organizational Behavior Consultant)
- Richard W. Horton, M.D. (Organizational Behavior Consultant)
- Chris Jennings, M.A. (Organizational Behavior Consultant)
- Rebecca Perfect, R.N. (Clinical Trials Assistant)
- Talia Schwartz
- Mary Holtschneider (Nurse Educator / Simulation Consultant)

OBJECTIVE
To design a safer, more reliable process for OR-to-ICU patient handovers
**Patient Transfer, e.g. “Handover”**

"...transfer of responsibility between health care providers to ensure patient safety and continuity of care."

*The Joint Commission: 2008 National Patient Safety Guidelines*

**Critical & vulnerable period in pt care, especially OR>> ICU:**
- Complex patients/procedures
- Complex physical transfer (actually 2 transfers!)
- Multiple teams (traditions, hierarchies, different priorities)
- Time constraints

**Handover Characteristics**
- Increased in frequency since duty hour restrictions
- Informal, non-structured
- Not formally taught
- Subject to interpersonal conflicts

**Handover Problems**
- Information lapses lead to 1
  - Patient care delays (77%) 2
  - Wasted provider time (50%)
  - SAEs (33%)
- Key clinical info available in handover only 2/3 of time 2
- Handover deficiencies: most prevalent deficiency among closed med mal cases involving trainees 2
- ICU handovers: frequently accompanied by technical errors and info omissions 2

1 Williams RG et al. Am J Surg 2007; 244: 139
2 Pomeleu et al. Qual Saf Health Care 2009; 18: 248
3 Pickering BW et al. CIt Care Med 2009; 37: 2905

**CONSIDER....**
- Continuous ICU monitoring and intervention generates large quantities of information
- Information is the platform upon which medical decisions are made
- "Information corruption"
  - distortion and/or omission of patient info compared to med record
  - potential source of medical judgment errors

Communication Failures

- **Occasion** (36%): ineffective exchange due to timing
- **Content** (36%): missing/inaccurate information
- **Purpose** (25%): issues not resolved
- **Audience** (20%): key individuals were excluded

**STUDY DESIGN**

Gain a comprehensive understanding of issues and evidence of events surrounding OR-to-ICU handovers
The Setting

- Tertiary VAMC
- Affiliated with Duke University Hospital
- Comprehensive surgical care (CT, Vasc, Neuro, etc)
  - 2,500 surgical cases/year
- 12-bed SICU
  - Closed unit
  - 24 hour ICU attending, fellow, and intern coverage

Current Preparation

- Telephone Handoff
  - CT read, MRI read, OR read
- Telephone Status Call
  - Ongoing case status
- Computerized Patient Record (CPR) Handover Notes

Define the Problem

Literature Review

- Sources: PubMed, Medline, Proquest, AMQ
- Topics: Transfer, handoffs, handover, and patient transfer and combinations of these with the terms post-operative, post anesthesia, post-anesthesia, surgery, operating room, ICU, critical care, intensive care, surgical intensive care, administration, communication, and team

Methods:

- Titles were reviewed for possible inclusion
- All papers dealing with OR handovers were reviewed

Results:

- 45% included postoperative handovers

Recommendations from Literature:

- Complete urgent care tasks before visual handover
- Set aside time for handover communication
- Avoid performing other tasks during this time and limit conversations while performing tasks
- All relevant members of the surgical and receiving teams should be present during the handover and each specialty should take turns speaking
- Provide an opportunity to ask questions and voice concerns
- Document this handover
- Confirm handover completion and readiness of receiving team to accept responsibility for the patient
- Use structured checklists to public communication and ensure completeness of information. Use forms or reference cards as reminders
- Use protocols to standardize processes
- Provide formal team handover training
Determine Current Practice

Focus Interviews:
- Guided interviews conducted by clinician and non-clinician pairs
- Interviews recorded and commercially transcribed
- Analysis performed by three clinician/non-clinician teams
- Interview recorded and commercially transcribed
- Analysis performed by three clinician/non-clinician teams
- Open coding used to identify themes
- Inter-rater agreement achieved verbally
- Themes collected for further analysis by PSCI investigator

Field Observations:
- Two observers for cardiac surgical handovers
- One observer for all others
- 128 item checklist used
- N=50 cases observed

Interview Themes Identified:
- Ward Clerk Information Packet: unused if used, not current
- Procedure note: variable, unstructured, redundant, impacts prep, dictatorship, surgical moment
- OR CPRS: handwritten, unpopular, redundant, only viewed
- Other Info: no answers, forgotten, needs patient update
- Transfer: hallway obstructed, trolley
- Tasks: unstructured roles, disorganized process, room not ready
- Clinical handover: anesthesia chart missing, illegible, no handover, no thorough handover, highly variable, many omissions
- OR Resident: high resident attention demand, junior residents do not follow
- Staff: no standardized setup, reviewed met in every room
- PACU: no standardized setup, reviewed met in every room
- Steps: hard to follow cooperation between PACU and ICU, simplicity in report between ICU, unfamiliarity of surgical cases in ICU, CCU, unclear physician contacts
- ICU Resident: no standardized setup, reviewed met in every room
- Other issues: patient safety, OP Note in CPRS, inconsistent, Thorough

Solutions presented in interviews:
- OR nurse could call SlctJ with lines and ventilation
- Use phone report checklist
- Handover plan discussed in OR
- Techs to help with transport and stocking rooms
- Verbal handover after patient monitored
- Primary nurse could take report while other nurses settle in patient
- Exits could happen after settling in patient
- Receiving and delivering teams need to be present at handover
- Checklist for verbal handover
- Complete a form in the OR to give to the ICU nurse
- Electronic anesthesia chart
- Anesthesia provider could enter CPRS note in OR
- Provide opportunity to ask questions, be thorough
- Establish training on handovers
- Change underlying traditions, hierarchies. Accept change
- Exits could happen after settling in patient
- Put less acute patients in PACU or step-down unit
Develop and Implement New Handover

**Briefings**

- Fundamental to CRM
- Types:
  - Information-centered briefings
  - Administrative briefings
  - Debriefings
- Goals of briefings:
  - Promotes real-time exchange of information
  - Sets stage for communication and common understanding
  - Gives people permission to be frank and honest
  - Gets all on “same page” & provides structure for collaborative planning
Standardized multidisciplinary protocol improves handover of cardiac surgery patients to the intensive care unit

Brian F. Joy, MD; Emily Elliott, RN, MSN, CPNP; Courtney Hardy, MD; Christine Sullivan, MBA, MS; Carl L. Backer, MD; Jason M. Kane, MD, MS

Objectives: To determine whether the implementation of a standardized handover protocol could reduce the number of errors occurring during patient transfers from the operating room to the intensive care unit.

Setting: The cardiothoracic intensive care unit.

Subjects: Forty-four patient handovers from the operating room to the cardiothoracic intensive care unit after completed cardiac surgery were observed. A standardized handover checklist was developed and used by the surgical and ICU teams to perform standardized assessments of patient handovers. The standardized checklist was used in 30 of the 44 handovers. The continuity of care and execution of the checklist was evaluated by the surgical and ICU teams.

Conclusions: A formal, structured handover process for pediatric patients transitioning in the intensive care unit after cardiac surgery can reduce medical errors that occur during the transition process and improve handover among caregivers.
Evaluate Change

Five prospective methods (field observation, clinical data, physiological data, workload assessment, and culture survey) used to determine the current intervention was assessed to assess the impact of the intervention.

Can Aviation-Based Team Training Elicit Sustainable Behavioral Change?

Mary C. Sun, MD, Patrick Brown, RMD, Raymond J. Mayeski, MD, Robert J. Pauker, MD, Kathleen C. Hines, MD, Rebecca L. Beale, RN, MS, Sandra Colina, MSH

Objectives: To quantify effects of aviation-based crew resource management training on patient safety-related behaviors and perceived personal empowerment.

Design: Prospective study of aviation-based training. Elicited self-reporting and a 10-point safety empowerment survey of all participants in a crew resource management training intervention.

Setting: Simulation training at a military hospital.

Participants: There were 957 participants, the majority of whom were nurses (38%), followed by medical personnel (28%) and physicians (21%).

Main Outcome Measure: Prospective checklist was given to each member of the team to complete before and after the intervention. This included 10-point safety empowerment survey of attitudes and actions, prior to, immediately after, and 3 months after training.

Results: Since 1998, 35% of medical records did not include all or none of the checklist items for the intervention. Observations were conducted in 10 hospitals. The checklist increased from 15% to 15% of the checklist items completed.

Conclusions: Can aviation-based team training elicit sustainable behavioral change?

Arch Surg. 2008;143(2):133-137
Variations in the Management of Hypertension in Active Duty Airmen – JNC7 Revisited

AFMSA/SG6H

Dr. Celan Alo

A cross-sectional retrospective design was employed to describe the management of hypertension by estimating the patterns of use of antihypertensive agents and lifestyle modification (LSM) counseling in a cohort of hypertensive patients among active duty airmen (ADAF). We compared available data for 2003 and 2009. All eligible ADAF were screened and classified as having hypertension based on two elevated blood pressure (BP) readings, diagnostic information in the form of ICD 9CM codes, and prescription drug use from pharmacy dispensing records. All available BP data were extracted from the Preventive Health Assessment and Individual Medical Readiness (PIMR) files. For this study, we only included the most recent documented BP reading during the reporting calendar year. For each study year, we compared the its representative BP reading with the following year’s representative BP measurement to identify those with hypertension based on two elevated BP readings. Data show that the number of ADAF who were hypertensive or had BP in the hypertension range increased significantly from 7 percent in 2003 to 9 percent in 2009 (p<.0001). Of these, 91 percent are either diagnosed or treated and about 9 percent are untreated. About 33 percent of study subjects had any LSM counseling. Only 16 percent of study subjects who were receiving antihypertensive drugs were on thiazide diuretics while a large proportion was receiving ACE inhibitors (28 percent) followed by beta blockers (17 percent). Overall BP control rate was 80 percent.
Variations in the Management of Hypertension in ADAF – JNC7 Revisited

Colan Alo, MD, MPH
Lt Col David Carnahan, MD, MSCE
Healthcare Informatics Division, AFMSA/SG/CH

Rationale

- Costs: estimated at nearly $73.4 billion for 2009
  - Expanditures for medical services have been rising, especially prescription drug costs
- Available national data are mostly from cross-sectional surveys, epidemiological investigations, community studies, HMOs, and reports of physician office practices using different populations – none of these studies are using AF population data

Background

- Hypertension (HTN) is the most common primary diagnosis in the US with more than 46.3 million office visits annually
- HTN affects 1 in 3 American adults
- An estimated 76 million adults >20 years of age have HTN
- HTN is a significant risk factor for coronary heart disease, the leading cause of death in the US

JNC7 Features and Key Messages

- Adoption of healthy lifestyles
- Thiazide-type diuretics should be included in initial therapy
- BP control only occurs with motivated patients who trust their clinician
- Benefits of lowering BP
  - Incidence of stroke reduced by an average of 35-40 percent
  - Incidence of coronary events reduced by 20-25 percent
  - Incidence of congestive heart failure reduced by more than 50 percent

References:
Changes in Blood Pressure Classification

<table>
<thead>
<tr>
<th>JNC 6 Category</th>
<th>SBP/DBP</th>
<th>JNC 7 Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal</td>
<td>&lt;120/80</td>
<td>Normal</td>
</tr>
<tr>
<td>Normal</td>
<td>120-129/80-84</td>
<td>Prehypertension</td>
</tr>
<tr>
<td>Borderline</td>
<td>130-139/85-89</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Hypertension</td>
<td>≥140/90</td>
<td>Hypertension</td>
</tr>
</tbody>
</table>

Stage 1: SBP 140-149/90-99<br />
Stage 2: SBP 150-159/100-109<br />
Stage 3: SBP ≥160/110

Why Prehypertension

- Based on data from epidemiologic studies that demonstrated a linear relationship between BP and cardiovascular risk.
- The risk of cardiovascular disease (CVD), beginning at 115/75 mmHg, doubles with each increment of 20/10 mmHg.
- Individuals with BP levels in the prehypertension range are at increased risk of developing hypertension and CVD later in life compared with those with BP in the normal range.
- Identification of patients will allow early intervention such as health-promoting lifestyle modifications to prevent CVD.

AF Measured BP Study

JNC 7 Treatment Guidelines

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>SBP mmHg*</th>
<th>DBP mmHg</th>
<th>Lifestyle Modification</th>
<th>Drug Therapy**</th>
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<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>&lt;80</td>
<td>Encourage</td>
<td>No</td>
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<tr>
<td>Prehypertension</td>
<td>130-139</td>
<td>≥80-89</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Stage 1 HTN</td>
<td>140-149</td>
<td>≥90-99</td>
<td>Yes</td>
<td>Single Agent</td>
</tr>
<tr>
<td>Stage 2 HTN</td>
<td>≥150</td>
<td>or ≥100</td>
<td>Yes</td>
<td>Combo</td>
</tr>
</tbody>
</table>

* Treatment immediately required
**ADAF, CY99-99
U.S. AIR FORCE

**Lifestyle Modifications (LSM) To Prevent and Manage Hypertension**

### Recommendation | Modification | Approximate SBP Reduction (Range)
--- | --- | ---
Weight reduction | Maintain normal body weight (body mass index [BMI] 18.5 - 24.9 kg/m²) | ↓5-20 mmHg/10 kg weight loss
Adopt DASH eating plan | Consume a diet rich in fruits, vegetables, and low-fat dairy products with a limited amount of saturated and total fat | ↓5-10 mmHg
Limit sodium intake | Limit sodium intake to less than 150 mmol per day (2.3 grams on an 8-gram sodium diet) | ↓3-8 mmHg
Physical activity | Engage in regular physical activity such as brisk walking on most days of the week | ↓0-9 mmHg
Moderation of alcohol consumption | Consume alcohol in moderation, no more than 2 drinks per day for women and moderate-weight persons, no more than 3 drinks per day for men | ↓2-4 mmHg

---

**HTN Treatment Goal**

"THE GOAL IS TO GET TO GOAL"

<table>
<thead>
<tr>
<th>Hypertension</th>
<th>Diabetes or Renal Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;140/90 mmHg</td>
<td>&lt;130/80 mmHg</td>
</tr>
</tbody>
</table>

---

**METHODS**

**What we did**

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Integrity - Service - Excellence

---

Integrity - Service - Excellence
Data Sources

- PMIR – for BP measurements
- SADR, SIDR, and Purchased Claim Data – for coded diagnoses of hypertension
- Pharmacy Data (POTS) – for data on antihypertensive prescriptions
- Military Personnel Files (MIPS) – for demographic data
- SADR – to identify ADAF who were counseled in lifestyle modifications

Ascertainment of Study Subjects

- ICD-9 and CPT codes related to lifestyle modifications (LSM) counseling were identified from the Standard Ambulatory Data Record (SADR)
- Prescription fills for any antihypertensive drugs were identified from pharmacy records (POTS)
Analysis

- Describe the study subjects by age groups, gender, race and rank groups and comparing with the total ADAF population
- Proportion of study subjects who were counseled on any hypertension-related lifestyle modifications
- Distribution of drug classes among study subjects who were prescribed antihypertension drugs
- BP control rates (<140 mmHg SBP and <90 mmHg DBP) for those who had any counseling for lifestyle modifications and/or prescribed antihypertension drugs

RESULTS

Demographics

<table>
<thead>
<tr>
<th></th>
<th>7-year average</th>
<th>TOTAL ADAF</th>
</tr>
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<tbody>
<tr>
<td>AGE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>10.9</td>
<td>10.5</td>
</tr>
<tr>
<td>30-34</td>
<td>10.8</td>
<td>10.5</td>
</tr>
<tr>
<td>35-39</td>
<td>12.3</td>
<td>12.1</td>
</tr>
<tr>
<td>40-44</td>
<td>13.6</td>
<td>13.4</td>
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<td>45-49</td>
<td>13.9</td>
<td>13.7</td>
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<tr>
<td>50-54</td>
<td>16.4</td>
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<tr>
<td>55-59</td>
<td>20.2</td>
<td>19.8</td>
</tr>
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<td>60+</td>
<td>30.2</td>
<td>29.8</td>
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Systolic

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<tr>
<td>100</td>
<td>20.5</td>
<td>20.0</td>
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<tr>
<td>110</td>
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<td>24.5</td>
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<tr>
<td>120</td>
<td>29.0</td>
<td>28.5</td>
</tr>
<tr>
<td>130</td>
<td>33.0</td>
<td>32.5</td>
</tr>
<tr>
<td>140</td>
<td>38.0</td>
<td>37.5</td>
</tr>
<tr>
<td>150</td>
<td>47.0</td>
<td>46.5</td>
</tr>
<tr>
<td>160</td>
<td>52.0</td>
<td>51.5</td>
</tr>
<tr>
<td>170</td>
<td>60.0</td>
<td>59.5</td>
</tr>
<tr>
<td>180</td>
<td>70.0</td>
<td>69.5</td>
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Diastolic

<table>
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<tr>
<th></th>
<th>7-year average</th>
<th>TOTAL ADAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>80</td>
<td>20.5</td>
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<tr>
<td>90</td>
<td>25.0</td>
<td>24.5</td>
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<td>100</td>
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<tr>
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<td>34.5</td>
</tr>
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<td>130</td>
<td>45.0</td>
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<td>140</td>
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<tr>
<td>150</td>
<td>55.0</td>
<td>54.5</td>
</tr>
<tr>
<td>160</td>
<td>60.0</td>
<td>59.5</td>
</tr>
<tr>
<td>170</td>
<td>65.0</td>
<td>64.5</td>
</tr>
</tbody>
</table>

Overall Results

![Graph showing blood pressure control rates](Image)
Lifestyle Modification Counseling

### ANY HTN RELATED COUNSELING, %

<table>
<thead>
<tr>
<th>STUDY SUBJECTS</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicated and Coded Group</td>
<td>9.6%</td>
<td>21.5%</td>
<td>26.4%</td>
<td>32.0%</td>
<td>34.1%</td>
<td>32.5%</td>
</tr>
<tr>
<td>Neither Medicated nor Coded BP in the HTN range</td>
<td>26.7%</td>
<td>29.2%</td>
<td>29.5%</td>
<td>30.5%</td>
<td>22.9%</td>
<td>23.4%</td>
</tr>
</tbody>
</table>

Prescribing Patterns

Time Trends in Use of AntiHTN Drugs

BP Control Rates
Limitations

- Blood pressure data was taken within the PIMR system—we know there is variability in the performance of these BPs.
- Measured BPs were taken about 12 months apart.
- Administrative data.
- No medical record review.
- Could not ascertain intensity of and adherence to LSM intervention.
- Could not ascertain adherence to pharmacotherapy.

Overall Findings

- About 10 percent of total ADAF personnel are hypertensive or have BP in the hypertension range.
  - 23 percent are coded only.
  - 20 percent are medicated only.
  - 45 percent are coded and medicated both.
  - 11 percent are untreated.
- Substantial improvement in documentation of LSM counseling during the study period.
- 17% of study subjects who were receiving antihypertension drugs were on thiazide diuretics.
- A large proportion were receiving ACE inhibitors (27%), followed by BB (25%).
- Overall results showed that hypertension in ADAF personnel are very well controlled.

Background

- AF Hypertension Study Group.
  - Col Daniel Burnett, MD, MPH
  - Col Al Bonmusa, MD, MPH
  - Vince Fonseca MD, MPH
  - Susan Chao, MS

Questions
### Comparative Drug Trials in Patients with HTN*

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>Drug Comparison</th>
<th>Primary Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>HELT-S</td>
<td>Standard care vs. placebo</td>
<td>significant difference</td>
</tr>
<tr>
<td>HELT-P</td>
<td>Metyrapone 50 mg vs. metyrapone 100 mg</td>
<td>no significant difference</td>
</tr>
<tr>
<td>HELT-P</td>
<td>Metformin 2.0 mg vs. metformin 1.0 mg</td>
<td>no significant difference</td>
</tr>
<tr>
<td>HELT-P</td>
<td>Standard care vs. placebo</td>
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</tbody>
</table>

* HTN: Hypertension

**Primary Outcome**: Integrity - Service - Excellence
Readiness Optimization through Surgical Outcomes Surveillance

USAF MC

Lt Col John Tokish, MD

Disease and non-battle injuries (D/NBI) of the musculoskeletal system pose a threat to readiness at the unit and individual levels within the US Military. It is known that “in-garrison” musculoskeletal conditions are highest contributor to medical profiles, disability, and separation from military service. Conservative estimates of musculoskeletal D/NBI from 2002 – 2010 within the military active component were 75,000 in the knee and 40,000 in the shoulder. Additionally, 150,000 surgeries to correct these injuries were performed from 2004-2010. To date, a Department of Defense (DoD) surveillance program for musculoskeletal D/NBI or for the surgical outcomes to treat these injuries does not exist. A recent literature review found that cost-benefit studies (using return to duty as the outcome measure) which examine the efficacy of surgical interventions to treat D/NBI musculoskeletal injuries are lacking. In 2004, the Society of Military Orthopedic Surgeons sought to address this void in the literature and the persistent lack of evidenced-based medicine to support surgical decisions to treat musculoskeletal D/NBI; both within the context of the DoD mission. The DoD’s powerful electronic medical records within the Military Health System (MHS) afford the exceptional opportunity to develop a surveillance program for such. This presentation will encompass the development of such a surveillance program that is being led by the US Air Force. Included will be the regulatory and privacy requirements that have been met to establish this central database using health care data from MHS as well as future directions.
Readiness Optimization through Outcomes Research

John M. Tokich, MD
Tripler Army Medical Center
Orthopedic Surgery Residency Program Director
SOMOS Research Consortium Founder/Director

Scope

- This is a talk about Readiness as an outcome measure
- Cellars population has nothing like it
- "Return to activity" is subjective, self-limited, and for the most part, optional
- In contrast, physical fitness is an occupational necessity—peace time, physical fitness tied to advancement, promotion

But in War

- Physical fitness is paramount to survival
  - Individual
  - Unit
- In fact, "Readiness" is really just physical fitness on a population level
- Without it, we fight nothing

The Blast injury: The signature wound of GWOT

- GWOT: 2001-2011
- Emergence of the IED
- 14k amputations since 9-11
- Too many
Advances in Blast Care

- Solemn Obligation to the Wounded Warrior
- Changing attitudes about potentials
- Return to Duty and Readiness
- We have no more important mission

GWOT: The Blast Injury/Amputation

- Unbelievable progress in the care of the amputee/blast injured patient
- Congressional research
  - O
top 2006
  - $19.5 M
- PRORP 2008: $40M
- Centers for the Intrepid

But Take a Broader View
A Macro-Readiness Perspective

- What keeps our warriors off the field?
- What keeps them from returning to battle?
- What are the big threats to fielding a Battlefield team?

The ONBI: Readiness’ Silent Assassin

- Extremity injuries account for over 2/3 of all incident hospital costs and disability payments; warriors
- “In Garrison” musculoskeletal conditions are largest cause of profiles, disability, and separations from the DOD
- Posttraumatic osteoarthritis is single greatest cause of disability in the DOD (Cross, EWI 2010)
But Dr. Tokish, we remain a nation at war: let’s concentrate on battlefield injuries

- 60% of all battlefield injuries are musculoskeletal
- Goodman et al (SOMOS 2009) followed an Army Brigade Combat Team during the “Surge” in Afghanistan for injuries that removed soldiers from the battlefield
- 75% of injuries were non-battlefield related

Musculoskeletal DNBI

- In contrast to the 1,400 Warriors lost to the fight because of amputation consider:
  - ACL injury: 25,000 in the same time period
  - Chondral injury: 30,000
  - Shoulder labral injury: 20,000

But those are “minor” injuries that can be fixed and returned

- Scenario:
  - A commander has a troop who injures his ACL. He asks the orthopedic surgeon, “Will this soldier get back to duty, and how long will it take?”

- Answer:
  - Almost unanimous opinion of orthopedic surgeons:
    - Yes; will get back 90%
    - 4-6 months

This answer comes from CIVILIAN DATA

- If an “elite” athlete can get back 90% of the time, surely an “average soldier can do the same”
- But this has rarely been evaluated
- Is this true in a military population
Return to Duty, ACL injury 2005-2010

- Tokish, unpublished data
- ACL reconstructions done at single institution over 5 year period:
  - 56% remain MEDICALLY NOT READY (minimum 2 yr i/u)
  - For those who did return: only 39% did so by 6 months
  - Avg. return to duty was nearly 1 yr
  - And 16% were still on profile at 2 yrs

Look, there’s a limited pot of research money, and there are other groups that can do your “sports research”

- AOSSM, AANA- true
- But completely WRONG
- Because our population has RETURN TO FULL ACTIVITY NOT AS A HOBBY, BUT AS A JOB REQUIREMENT
- Can you imagine telling this guy “hey I need the day off- my patella tendon is super sore”

Can we really compare the knee blast injury to the knee “sports” injury

- Depends on your outcome measure
- If we look through the lens of RETURN TO DUTY/ READINESS
- The “sports knee” injury is a temporary setback and should get back, right?

Meet Jake C.

- 25 yo Army Infantry Officer
- Injured his knee in Unit fitness soccer game 2008
- ACL, bad medial meniscus tear
- ACL reconstruction, partial meniscectomy, standard stuff
Jake C

- Injured October
- November 2009: ACLR/med meniscectomy
  - 6 month profile for “rehab”
- May 2009: patellar tendinitis, extended profile 3 mos - missed deployment
- Sept 2009: stopped “heavy” and left knee go out
  - Sent to PT for 3 months, but no improvement, so MEB obtained
  - Released
- Jan 2010, Revision ACL recov, noted “grade 3 chondral damage” in knee.
  - Missed deployment, 3 month extension on profile
- Sept 2010: knee pain with running, diagnosed with “early arthritis”
- March 2011: Missed deployment, MEB
  - “Discharged due”
- May 2011: Pending separation

That’s too bad

- No, it’s too common.
- The ACL is only the beginning:
  - The majority of ACLs eventually develop arthritis
  - Especially if meniscal injury
  - This guy isn’t going back to duty
- 3000 of “these guys” every year

Meet Michael L.

- 22 yo Marine
- Knee pain “since basic”
- Diagnosed with chondral defect of the knee
- Seen by primary care
- Sent to PT 3 mos
- Continued pain
- MRI: dime sized defect

Bad problem for Michael, Bad problem for the military

- 2005-2010
- 13,000 + chondral procedures done in knee in US DOD
- What should we do?
When Can I get back, Doc?

- 6 weeks non-weightbearing
- At 3 mos, begin running
- 7-9 mos return to full activity
- Total time on profile: 12 mos so far...
- But then he and his 13000 counterparts go back, right?

ML: Already out 3 mos

- Referred to Orthopedics
- Confirmed diagnosis
- 3 basic choices:
  - Microfracture: simple, good pain relief, but may not be durable, tree
  - OATS: surgeon dependent, long recovery, but very good return to sports: $27K per surgery
  - ACI: Tech challenging, 2 procedures, not clear if better than other two: $10K per pop.

So how do we make this decision?

- Want the most cost effective way to maximize return to duty-readiness
- World literature addressing this question:

Bottom line:

- We have no idea what the return to duty rate is for ANY of these injuries- Because the outcome measure we must have isn’t tracked
- We therefore have no idea which approach to take to the chondral defect
- Cost analysis, disability, and most importantly, patient outcome
- Readiness
The SOMOS Research Collaborative

- 2004- SOMOS Annual meeting
- Goals:
  - Establish Standardized Outcomes measures
  - Establish a centralized IRB for multicenter research
  - Establish central database for combining data

SOMOS Research Collaborative

- Huge Homogenous population
- Single med record system
- Single Payor Health care system
- Culture of collaboration

SOMOS- Weaknesses

- Poor infrastructure
  - Need to ask a surgeon to do research if he’s busy typing his notes into stetha
  - No senior support for the guys in the trenches
- Frequent turnover
  - Commitments / PCS move: hard to establish patient base
- IRB process in the military
  - Safe, thorough, decentralised, difficult

Proof of concept: Pan Labral

- Tokish, JBJS 2009, 2010
- Collaborative effort of USAF Academy/ NMC SD
- AAOS annual award in Sports Medicine
- 41 patients (largest previous series: 7)
- Only 2 MTFs participated: imagine what we can do!
Prospective Comparisons testing hypotheses

- Databases: M2, DMED, DMSS, Army Physical Disability Program,
  - Aggregate demographics:
    - How many of which kind of surgery
  - Return to duty:
    - Profiles/ MEBs/ did they return, how long did it take?
  - What is the return to duty rate for Orthopedic Surgical Procedures?

Retrospective: what are current outcomes from “Standard of Care”

- Standardized data collection: traditional retrospective cohorts
- Improves on surveillance with validated outcomes measures
- What is quality of life, and patient related outcomes of Orthopedic Surgery in the military? How does it compare to the civilian population?

Must have standardized set of data:
- Validated outcomes scores:
  - Web based, PATIENT ENTERED subjective scores
  - Simple input from surgeon
  - Combinable and mergeable data sets
  - Modular and adjustable
Translational research: Team approach

- Science and Technology Division: The Engine
  - Deb Niemeyer - Chief Scientist: Engine builder
  - Rose Ramos - PhD Epidemiologist
- Reach out to experts who can help
  - Program management
  - Contracting/Logistics
  - Administrative Support
  - Informatics

Musts for success

- IRB processes - IRB net/ Single standardized system: multicenter collaboration
- Access to Databases - Learn to navigate
- All collect the same data - Hand/Peds/Spine?
- Prove the concept
- Build a program that outlives us

Final Goals

- Optimize Readiness
- Move beyond "expert opinion" to evidenced based outcomes
- Build an Research Engine that can answer questions no one else can even ask
- Make it Efficient, Applicable and Sustainable
- Our Warriors deserve nothing less

Thank you
**Prevention of Low Back Pain in the Military (POLM) cluster randomized trial**

**US Army-Baylor University**

**Lt Col John Childs, Associate Professor**

**BACKGROUND:** Effective strategies for the primary prevention of low back pain (LBP) remain elusive. The prevention of low back pain in the military (POLM) cluster randomized trial investigated whether core stabilization and/or brief psychosocial education were effective in preventing future LBP episodes.

**METHODS:** Companies of Soldiers were randomly assigned to receive a core stabilization exercise program (CSEP) alone, a CSEP with brief psychosocial education program (PSEP), a traditional exercise program (TEP) alone, or a TEP with PSEP. The randomly assigned programs were performed during 12 week Advanced Individual Training (AIT). Soldiers were followed monthly for 2 years to determine self-report (onset and severity) and health care utilization related to initial LBP episode. **FINDINGS:** Twenty companies consisting of 4,325 Soldiers were enrolled in the trial. There were no differences among the exercise and education programs for self-report of occurrence and severity of LBP during the subsequent 2 years. There was decreased health care utilization related to LBP from the PSEP. This effect was noted in both exercise programs resulting in an overall 3.3% decrease in LBP related health care utilization over 2 years (NNT = 30.3). **INTERPRETATION:** Results from the POLM trial suggest that exercise and education approaches may not offer protective benefit for the development of self-reported LBP. However, decreased health care utilization from LBP may be attainable with education programs that reduce the fear and threat of LBP. Future trials should investigate cost-benefit and determine if larger dosages of psychosocial education result in larger decreases in health care utilization.

**FUNDING:** Peer-Review Medical Research Program of the Department of Defense (PR054098).

Trial registration: NCT00373009
Prevention of Low Back Pain in the Military: A Cluster Randomized Trial

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Jessica L. Dugan, DPT
Michael E. Robinson, PhD

"Promoting Readiness Through Research"

Funding Source & Approval

Funding:
Peer Reviewed Medical Research Program (PRMRP) of the Congressionally Directed Peer-Reviewed Medical Research Programs (CDMRP)

Approval:
Brooke Army Medical Center (Feb 2006)
University of Florida (Jun 2006)

Registration:
http://clinicaltrials.gov
NCT00373009

Potential Conflicts of Interest

Contributing authors were independent from the study sponsor
Study sponsor had no role in data collection, analysis, interpretation of data, or writing of the paper
All contributing authors had access to all study data and take final responsibility for paper submission

Potential Conflicts of Interest

Minority stockholder in 2 private companies related to physical therapy
Evidence in Motion
Texas Physical Therapy Specialists
Neither entity played a role in the study design, funding, data collection, analysis, interpretation of data, or writing of the paper
### Background

- Low back pain (LBP) is one of the most common forms of chronic pain (Martin 2000, Luo 2004, Stewart 2003).
- Leading factor for medical board processing in the military (Sorger 2000).
- High cost of LBP:
  - Lifetime compensation cost (van Tulder 1997).
  - High tax payer dollars (Kaurman 2000).
  - Decrease mission readiness (Knapik 1993, Jones 1999).

### Purpose

- Determine whether a core stabilization exercise program (CSEP) in combination with a psychosocial educational program (PSEP) prevents low back pain incidence.
- The effect of the combined program will be compared to 3 other programs:
  - CSEP alone
  - Traditional Exercise Program (TEP) alone
  - TEP in combination with PSEP.
## Methods

**Exclusion Criteria**
- Prior history of LBP with all of the following:
  - Limited work or physical activity
  - Duration > 48 hours
  - Caused individual to seek medical care
  - Currently seeking medical care for LBP
  - Previous medical history including surgery for LBP
  - Currently unable to participate in unit exercise due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand
  - History of fracture (stress or traumatic) in hip and/or pelvis
  - Pregnant
  - Transferred from another AIT Company

## Subjects
- 4,325 Advanced Individual Training (AIT) US Army Soldiers (George, BMC Musculoskeletal Disord., 2007)
- Enrolled in POLM study
  - Healthy Soldiers between 18-35 years of age

## Cluster Randomization
- Cluster randomization of 20 companies
- TEP
- TEP+PSEP
- CSEP
- CSEP+PSEP

- Individual randomization was not utilized
- Detract from unit cohesion
- Inevitable contamination of treatment groups
- Burdensome for company instructors
Physical and Ultrasound Exam

- 371 out of 4,325 soldiers underwent a detailed examination.
- Physical Examination
  - Lumbar flexion and straight leg raise
  - Bilateral hip range of motion assessment
  - Trunk endurance tests
- Ultrasound Imaging
  - Lateral abdominals
  - Symmetry of multifidus muscles

Exercise Programs

- 2 exercise programs: TEP & CSEP
- Performed at unit physical training
- Frequency: 5 minutes/day, ≥ 4 days/week
- Led by Company instructors
- Company instructors were provided training and training aids by study personnel
- Study personnel routinely observed training
- Weekly meeting with Cadre to answer questions/concerns

### Exercise Programs

<table>
<thead>
<tr>
<th>Exercise</th>
<th>CSEP</th>
<th>TEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle</td>
<td>Lower load, less repetitions</td>
<td>Higher load, more repetitions</td>
</tr>
<tr>
<td>Activation</td>
<td>Shinew</td>
<td>Faster</td>
</tr>
<tr>
<td>Trunk movements</td>
<td>None to minimal</td>
<td>Full</td>
</tr>
<tr>
<td>Dosage</td>
<td>5 minutes/day</td>
<td>5 minutes/day</td>
</tr>
<tr>
<td>#1</td>
<td>Abdominal drawing-in</td>
<td>Traditional sit-up</td>
</tr>
<tr>
<td></td>
<td>maneuver crunch</td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td>Left and right horizontal side</td>
<td>Sit-up with left trunk rotation</td>
</tr>
<tr>
<td></td>
<td>support</td>
<td></td>
</tr>
<tr>
<td>#3</td>
<td>Hip flexor squat</td>
<td>Sit-up with right trunk rotation</td>
</tr>
<tr>
<td>#4</td>
<td>Supine shoulder bridge</td>
<td>Abdominal crunch</td>
</tr>
<tr>
<td>#5</td>
<td>Quadruped alternate arm and leg</td>
<td>Traditional sit-up</td>
</tr>
</tbody>
</table>

Table 1. Description of core stabilization (CSEP) traditional (TEP) and exercise programs

### Traditional Exercise Program (TEP)

- Commonly performed exercises in the military for physical training
- Targeted muscles: Rectus abdominis, internal and external oblique, and hip flexor muscles
Core Stabilization Exercise Program (CSEP)
- Evidence-based
- Targeted muscles: transverse abdominis, multifidi

Psychosocial Education Program (PSEP)
- 1,994 out of 4,325 Soldiers participated in a 45 minute seminar
- LBP prognosis
- Anatomical causes of LBP not likely
- Importance of decreased fear avoidance beliefs and pain in response to LBP
- Issued The Back Book
- Q&A with study personnel

Establishing LBP Incidence
- The Military Health System Management Analysis and Reporting Tool (M2)
- Maintained by the Tricare Management Activity (TMA)
- Contains a variety of health utilization data from both the direct care system (care provided in military treatment facilities) and network care (care provided to MHS beneficiaries at civilian facilities) worldwide

Establishing LBP Incidence
- M2 searched for relevant LBP-related International Classification of Diseases (ICD) codes for Soldiers enrolled in the POLM trial
- Utilized similar strategies to operationally define LBP as has been published in other studies using ICD codes to identify subjects seeking health care for LBP
- Geithorn, Spine, 2010
- Fritz, Med Care, 2007
Data Analysis

- No planned interim analyses/stopping rules
- All analyses performed using SAS, version 9 (SAS Institute Inc, 1996)
- Demographic and baseline levels of clinical variables compared between the 4 cluster randomized groups
  - Analysis of variance (ANOVA) for means
  - Chi-square tests for proportions

Data Analysis

- Variables that differed between the training groups considered in the final analyses
  - In addition to pre-specified covariates of gender and age
- LBP incidence data analyzed with a generalized linear mixed model (GLM)
  - Response variable - # of months in which a Soldier reported LBP

Data Analysis

- Company considered as a random effect since this was a cluster randomized trial
- Planned fixed effects were
  - Treatment group
  - Age
  - Gender
  - Any variables that differed between the clusters after randomization

Data Analysis

- Survival time to the first month a Soldier reported LBP investigated with a Cox proportional hazards model and log rank test to investigate treatment effects
  - Response variable - time to first month in which health care incidence for LBP was reported
- Predictor variables same as those included in the GLM
Results

CONSORT Flow Diagram

- Twenty companies consisting of 4,325 Soldiers were enrolled in the trial
- No adverse events reported
- Figure 1 provides information on study enrollment, participation, follow-up, and analysis for all stages of the POLM trial according to CONSORT guidelines

Baseline Characteristics

- Baseline differences across individuals in the four companies found in age, education, income, active duty status, time in army (P<.05) (Table 2)
- These differences were controlled for in subsequent analyses

Figure 1. Flow diagram for patient recruitment and randomization
LBP Incidence

- Over 2 years, the number of Soldiers captured in the M2 database was 4,147/4,325 (95.9%)
- 706 (17.0%) identified as having LBP
- Evaluable patient analysis indicated no differences in low back incidence between core stabilization and traditional exercise

LBP Incidence

- However, brief psychosocial education from the combined exercise and education (CSEP+PSEP and TEP+PSEP) prevented low back pain episodes
- Overall 3.3% (95% CI: 1.1 – 5.5%) decrease over 2 years (p=.007)
- NNT = 30.3 (95% CI: 18.2 - 90.9).

Survival Analysis

- Compared to no PSEP (exercise only), combined exercise and education (CSEP+PSEP and TEP+PSEP) groups experienced 0.49 (95% confidence interval: 0.003-0.983, p=0.048) fewer months in which a Soldier experienced LBP
- Time to the first month of LBP incidence demonstrated a similar pattern
- Preventative effect of PSEP was observed (Hazard ratio=0.90; Log-Rank test, p = 0.021).
Figure 3. Percent of Soldiers who reported incidence of low back pain by intervention group and days since enrollment.

Discussion

- In contrast, brief psychosocial education that reduced fear and threat of low back pain decreased 2-year incidence of LBP
  - NNT = 30.3 (95% CI: 18.2 - 90.9)
- Overall decrease in LBP from brief psychosocial education might be perceived as small (3.3%)
  - However, utilization of health care for LBP is very common, so even small decreases in LBP incidence could potentially lessen burden on a health care system

Limitations

- Additional sit-ups performed to prepare for fitness testing
- Rate at which additional sit-ups performed was equivalent across the 4 groups
- Did not track exercise performance after the 12 week training period
- Did not track if the LBP episode resulted in a medical board or evacuation from theater

First large scale trial to test the purported primary prevention effects of core stabilization alone, and in combination with psychosocial education, for LBP

Trial results suggest no benefit of core stabilization exercises for preventing LBP incidence in comparison to traditional abdominal exercises.
Conclusions

Potential importance for uniformed service members given high rates of evacuation due to musculoskeletal pain.

The PSEP was administered in a single, low-cost session, hence potential for similar education programs to be done in an efficient manner across large populations to yield incremental decreases in LBP incidence.

Conclusion

Potential application in general society because the education program could be adapted to civilian populations.

Future trials should investigate cost-benefit and determine if larger dosages of psychosocial education result in larger decreases in health care utilization.

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John Ney, Elizabeth Sonnenberg

Texas State University-San Marcos
Monica Montanez
Questions?
Spinal Injuries Following Ejection

81st AMDS/SGPF

Lt Col Richard Blair

Vertebral fractures are common in those ejecting from aircraft. High G forces experienced during ejection place significant loading on the vertebral column. The lower thoracic vertebrae are most commonly injured followed by lumbar vertebrae. Following is a case study a student pilot whom ejected from a USAF T-6 Texan training aircraft and sustained a compression fracture of the fifth vertebrae. Initial radiographic studies performed following ejection sequence failed to identify a compression fracture of the fifth thoracic vertebrae. The fracture was diagnosed two weeks later via MRI after patient complained of non-resolving mid back pain. The Royal Air Force identified compression fractures in 30-70% of those whom ejected from aircraft. Fractures suffered during ejection are stable in nature and treatment is conservative. The RAF routinely performs MRI of the spinal column on all those whom eject from aircraft. The USAF may be well served in the future to adapt a similar policy in order to avoid a delay in diagnosis of vertebral fractures in those ejecting from aircraft.
POST EJECTION SPINAL INJURIES AND SCREENING OF AIRCREW

Richard E. Blair, DO, MPH

306 AFRN
Nellis Medical Center, KAFB, MS

Post ejection spinal MRI

- Case Report
- Ejection forces
- Post ejection injuries
- Screening modalities
- Foreign Air Forces screening
- USAF post ejection policy
- Discussion and Recommendation

Case Study

Raytheon T-6 Texan II
Raytheon T-6 Texan II

USAF T-6 Texan II
- Routine training flight
- Inadvertent engine shutdown
- Unsuccessful restart
- Instructor (IP) and student (SP) ejected
- IP and SP immobilized at scene
- Transported to local ED via EMS
USAF T-6 Texan II
- 3 weeks later SP C/O back pain
- Referred to NS at BAMC
- MRI of Spine performed
- Dx: Compression fracture T-5
- Disposition: DNIF

T-5 Compression Fracture

Ejection Seat Forces

Ejection Seat
Ejection forces
- Ejection forces along spinal axis Gz
- Initial ejection Gz up to 25 G
- Sustained forces of 12-20 Gz
- Variable with altitude, temp, pressure, and speed
- Vertebral compression fracture as low as 10z
- Vertebral fracture common above 20z

Post ejection vertebral fracture
- Post ejection vertebral fracture in 40-70% of aircrew
- Lower thoracic spine compression fracture common
- Highest Gz loading per unit area

Location and type of bony injuries post ejection (n=33)

<table>
<thead>
<tr>
<th>Location</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Thoracic (T1-10)</td>
<td>7</td>
<td>21</td>
</tr>
<tr>
<td>Thoracolumbar (T11 to L1)</td>
<td>18</td>
<td>55</td>
</tr>
<tr>
<td>Lumbar (L2-L5)</td>
<td>6</td>
<td>18</td>
</tr>
</tbody>
</table>

Post ejection spinal imaging
- Spinal injuries may be ill defined on plane films
- Plane films 75% sensitive
- CT/MRI of spine preferable
- MRI sensitivity 100%
“all UK military personnel who eject from aircraft will have an MRI of their spine prior to returning to duty”

“the ejectee shall have a neurological assessment by a consultant neurologist or neurosurgeon at an approved specialist centre”
Indian Air Force

“all cases of aircraft ejection should undergo magnetic resonance imaging of the spine as MRI excels in evaluation of spinal injuries”

USAF

“Post ejection physical exam with particular attention directed to the spine”

Conclusion

- Ejection associated with high incidence of vertebral fracture
- Spinal fractures may not be evident on plain films
- MRI highly sensitive in diagnosis of compression fractures
- USAF should consider post ejection MRI for all aircrew

References

7. USAF Waver guide. Clinical Practice Guidelines For Abnormal Spine Curvature. Feb 00
A New Paradigm for Conducting Air Force Research

Air Force Diabetes and Obesity Research Working Group

59 MDOS/SG05E

Lt Col Mark True

INTRODUCTION: Diabetes mellitus is costly and presents a major burden on Military Treatment Facilities (MTFs). There are insufficient clinicians to effectively manage the 47,000 AFMS patients with diabetes mellitus, and over 100,000 patients with pre-diabetes. Research is needed to determine the optimal use of personnel and technology to affect the greatest good for these populations. METHODS: A call for multi-base participation in diabetes research occurred in April 2009, and attendees responded with great interest. AFMSA/SG9 contracted for research coordinators at six Air Force MTFs. Formal research priorities were established in Feb 2010, laying the groundwork for future activities. The Air Force Diabetes and Obesity Research Working Group was formally chartered in November 2010. Its membership consists of clinicians and research coordinators from Andrews, Keesler, Lackland, Nellis, Travis, and Wright-Patterson AFBs.

RESULTS: The working group produced a Research Development Document, which defines research priorities; Working Group Charter; Annual Plan; and Strategic Plan. The research priorities include: Primary Prevention of Diabetes, Technologies to bridge current resource gaps, Models of care to improve outpatient care, Inpatient diabetes care, Biomarkers to define diabetes populations, and Safety/operational concerns. The working group also established a coordinated framework by which research concepts are structured and pursued within these priorities. To date, over 10 new research projects have been established. Of note, 4 multi-base trials are underway. CONCLUSIONS: The Air Force Diabetes and Obesity Research Working Group can serve as a effective synergistic model for structuring, conducting, and accomplishing research within the Air Force Medical System.
AF Diabetes and Obesity Research Working Group

A New Paradigm for Conducting Air Force Research

Mark W. True, Lt Col, USAF, MC
Chair, Air Force Diabetes and Obesity Research Working Group

Overview

- Why diabetes and obesity research?
- Recent diabetes efforts in AFMS
- Establishment of Diabetes and Obesity Research Working Group (DORWG)
- DORWG Progress
- Challenges / Lessons Learned

Why diabetes and obesity research?

- Focus of AFMS should be on wartime priorities first and peacetime care of our beneficiaries second.
- We exist for wartime...this is why we wear the uniform.
- However, diabetes and obesity affects MORE of our patients than all physical wartime casualties combined!
- If we don’t control the diabetes and obesity epidemic, we will bankrupt the MHS and hinder our ability to focus on our primary wartime requirements.
- Additionally, we need to ensure that we have an optimum fighting force through diabetes prevention measures.

Obesity Trends* Among U.S. Adults


* "BMI ~30, or about 30 lbs. overweight for 5'4" person"

Centers for Disease Control and Prevention (CDC)
Diabetes Epidemiology

• US: 25.8 million diabetics, 79 million pre-diabetics
  - Endocrinology shortage: only 4,000 in clinical practice
  - Certified Diabetes Educators shortage: 30,000 diabetes educators (16,000 certified diabetes educators)
• USAF: 47,000 diabetics, >100,000 pre-diabetics
  - 8 endocrinologists, ~20 CDEs in dedicated positions
• Result: bulk of chronic diabetes care provided at primary care level

Estimated prevalence of diagnosed and undiagnosed diabetes in people aged 20 years or older, by age group, United States, 2007

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-39</td>
<td>2.6%</td>
</tr>
<tr>
<td>40-59</td>
<td>10.8%</td>
</tr>
<tr>
<td>60+</td>
<td>23.1%</td>
</tr>
</tbody>
</table>

CDC National Diabetes Fact Sheet, 2007

Source: 2003-2006 National Health and Nutrition Examination Survey estimates of total prevalence (both diagnosed and undiagnosed) were projected to year 2007.
Estimated number of new cases of diagnosed diabetes among people aged 20 years or older, by age group, United States, 2010

Source: 2007-2009 National Health Interview Survey estimates projected to the year 2010

Unique features of AF Medicine

- AF has unique patient population
  - Active duty population is forced to maintain fitness standards
  - There is great need to maintain fit force in order to maintain readiness capability
    - Diabetes prevention in this population is necessary
  - Majority of AF personnel retire in their 40's
    - Majority of diabetes cases occur at/after this time juncture
    - To reduce overall MHS, preventing diabetes here is crucial
- To study this population, other fitness standards are no longer imposed, presents great research opportunity
- Additionally, AF population is true cross-section of American society

Not just a problem for retirees

Weighing in on Type 2 Diabetes in the Military

Characteristics of U.S. military personnel at entry who develop type 2 diabetes

- Financial analysis performed to assess direct and indirect costs of tobacco, obesity/overweight, and alcoholism in TRICARE Prime population (under 65)

- Annual cost to system (2006 dollars)
  - Obesity/overweight — $1.1 billion
  - Diabetes — $300 million

TOBESAHOL Study

Importance in Pediatrics

A Message from America’s Rearmed Generals, Admirals, and Civilian Military Leaders.

As retired Generals, Admirals, and other senior leaders of the United States Armed Forces, we know firsthand that national security must be America’s top priority.

Recent statistics from the American Diabetes Association (ADA) indicate that more than 25.8 million people—8.3 percent of the population—have diabetes. This includes 5.7 million people who are unaware they have the disease.

According to the ADA, the prevalence of diabetes is increasing among the military population. Diabetic individuals in the military are at higher risk for complications such as cardiovascular disease, blindness, and kidney failure.

This situation presents a significant challenge for military medicine. The prevalence of diabetes among military personnel is expected to increase as more young adults enter the service.

AFMOA AFSO21

Strategic Management of Diabetes

AFMOA’s Problem Statement: The AFMS does not have a comprehensive, informed, and aligned strategy for diabetes care.

As evidenced by …

• Poorly characterized AFMS diabetes populations.
• AFMS has not defined an expected standard of diabetes care
• AFMS metrics of care and outcomes are not comprehensive
• Workflow management of diabetes is not standardized
• Inability to capture all necessary data for care obtained outside the MTFs
• MTF-level variation: some do well, others are challenged

Initial Diabetes Translational Research Mtg

2012 Vision

Several research areas of interest identified in diabetes technology/IT/primary prevention areas

Common Themes:

• Great interest in conducting research
• Inadequate research infrastructure/staff to effectively engage
Building AF Research Infrastructure

• AFMSA/SG9 contracted research coordinators specifically dedicated for diabetes research at six AF medical centers
  - Fuchsia Plan
    • 1 research coordinator at Keesler, Wright-Patterson, Nellis, Travis, Andrews
  - Blue Plan
    • 1 research coordinator at Lackland
• Good start!
• Needs to be broadened and continued,…

Diabetes Research HPT

• Feb 2010 – representation from Andrews, Keesler, Lackland, Nellis, Travis, and Wright-Patterson
• Product: Diabetes Research Development Document
• Research priorities were established:
  - Primary Prevention of Diabetes
  - Technologies to bridge current resource gaps in outpatient diabetes care
  - Models of care to improve efficacy of outpatient diabetes care
  - Inpatient diabetes care
  - Biomarkers to better define diabetes populations
  - Safety/operational concerns

Establishment of DORWG

• Nov 2010 – Charter established
• Multi-base participation, voting members
• Quarterly face-to-face meetings, monthly teleconferences

DORWG Membership

• Chair – Lt Col Mark True, Lackland
• Vice-Chair – Col Marcus Cranston, Keesler
• Voting membership from all six bases
  • Multi-disciplinary government (endocrinology, family medicine, internal medicine, diabetes educator, behavioral health)
• Non-voting membership
  • AFMSA/SG9 government
  • AFMGA government
  • CPRT contractor team
  • Clinical research coordinators (contractor)
**DORWG Mission**

- The Air Force Diabetes and Obesity Research Working Group mission is to promote and conduct diabetes research for prevention, identification, education and treatment of diabetes in all military beneficiaries.

**DORWG Duties**

- DORWG will:
  - Work with AFMS/AG to build and implement an Annual Plan
  - Submit, revise proposals
  - Conduct research projects
  - Work towards practice management change
  - Report research progress
  - Publish research outcomes
  - Advise and serve as subject matter experts on matters related to diabetes and obesity research within the Air Force

**Current Projects**

- 30+ projects total, 4 multi-base

**Annual Plan**

- Predominant focus this year
  - Finalization of planning documents: RDS, charter, strategic plan
  - Progress on current and new projects
  - Tracking established milestones for each project
  - Identification of research gaps to plan future projects
  - Progress will be documented and summarized in an Annual Report
Strategic Plan

- 5 year plan, still in development
- Large emphasis of strategic plan is survivability
  • Greater marketing of group’s efforts
  • Broader efforts to include grants external to AFMS
  • Infrastructure building
- Expanded research priorities to include greater emphasis on obesity-related subjects for future projects

Challenges / Lessons Learned

- Leadership recognition of the importance of diabetes and obesity research
  • Need to build convincing story, ... tell it often
- Instability of personnel to provide stable program longevity (deployments, contractors)
  • Need for more stable, permanent, civilian research staff
  • Until available, find interested parties and build team

Challenges / Lessons Learned

- Bureaucratic challenges (research leadership changes, role changes, multiple IRBs)
  • Clear leadership structure needed
  • Single IRB preferred
- Funding / rules of R&D funds and how they apply to desired projects
  • Standard, uniform guidance needed, perhaps in workshop or “how to” booklet format
  • 59 MOWST is building to this purpose

Conclusions

- Diabetes and obesity research represents a worthy investment within the AFMS research community
- DORWG has made significant progress in terms of defining research priorities, establishing a charter, annual plan, strategic plan, initiating and tracking projects within established priorities
  • DORWG model can serve as example for other research focus areas
- Continued support and guidance from AFMS research leadership is needed to continue this work
Comments/Questions?
Delivering a Diabetes Prevention Program in a Military Setting

59 MDOS/SGO5E

Maj Lisa Strickland

OBJECTIVE: Diabetes prevention is an important consideration for the military. Lifestyle coaches were trained by the University of Pittsburgh Diabetes Prevention Support Center to implement the Group Lifestyle Balance (GLB), an adaptation of the Diabetes Prevention Program intervention, in two US Air Force settings. Our objective was to determine if GLB delivered to military healthcare beneficiaries resulted in reduction of risk factors and program satisfaction.

METHODS: The GLB intervention was delivered by face to face group classes or through the GLB DVD over 12 weeks. Program goals are to achieve/maintain weight loss and increase activity. Anthropometric (height, weight, blood pressure, and waist circumference) and laboratory (fasting glucose, triglycerides, and HDL) were collected at baseline and 12 weeks. Satisfaction surveys were administered at 12 weeks.

RESULTS: Thirty-two participated in the face to face GLB; 55 in the GLB DVD interventions. Program attendance rates declined over time. Participants in the face to face lost a median 4.4 lbs; had an average BMI decrease 0.75 kg/m², both statistically significant. Participants in the GLB DVD intervention lost a median 8.9 lbs, had a decrease of BMI 1.5 kg/m², and median reduction in waist circumference by 3.81 cm, all statistically significant. There was high program satisfaction.

CONCLUSIONS: Albeit a limited time frame and sustained program attendance, GLB can be considered a viable evidence-based risk reduction program for eligible military beneficiaries. The GLB program is an effective tool to implement lifestyle change for diabetes prevention. Further research is needed to explore motivational tools to improve adherence.
**Type 2 Diabetes Prevention in the Military**

Lisa Strickland, M.D.
Major, USAF, Medical Corps
Director Diabetes Prevention
Diabetes Center of Excellence
Wilford Hall Medical Center

---

**Diabetes Statistics**

- 25.8 million diabetics in US
- 79 million pre-diabetics (35% of US population)
- Heart disease → 2-4x more likely
- Stroke → 2-4x more likely
- Blindness → 12-14k new cases each year
- Kidney failure/dialysis → 48k new cases yearly
- Nervous system disease → amputations → 65k/yr

*If diabetes is prevented, these problems are avoided!*

---

**County-level Estimates of Diagnosed Diabetes for Adults aged 20 years: United States 2007**

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**Obesity Trends Among U.S. Adults**


(*BMI ≥ 30, or about 30 lbs. overweight for 5'4" person)

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**CDC**

Provisioning Great Care, Building Warrior Medicine
Importance to Military

- Military must have a fit active duty force in order to maintain its readiness capability.
  - Active duty population must meet fitness standards.
  - Diabetes prevention in this population is necessary to preserve fighting strength of our force.

- Military health system (MHS) provides lifelong care for retirees and spouses.
  - Majority of personnel retire in their 40’s and 50’s.
  - Majority of diabetes cases occur during this time frame; after fitness standards are no longer imposed.
  - Preventing diabetes in retirees leads to healthier lives and it also reduces long-term costs.

American Diabetes Association

Position Statement

Primary prevention of diabetes
- Among individuals at high risk for developing type 2 diabetes, structured programs emphasizing lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 min/week) with dietary strategies including reduced calories and reduced intake of dietary fat can reduce the risk for developing diabetes and are therefore recommended. (A)

American Diabetes Association

Position Statement

Follow-up of all three large studies of lifestyle intervention has shown sustained reduction in the rate of conversion to type 2 diabetes, with 43% reduction at 20 years in the Da Qing study (30), 43% reduction at 7 years in the Finnish Diabetes Prevention Study (DFPS) (31) and 34% reduction at 10 years in the U.S. Diabetes Prevention Program (DPP) (32). A cost-effectiveness analysis suggested that lifestyle interventions as delivered in the DPP are cost-effective (33). Group delivery of the DPP intervention in community settings has the potential to be significantly less expensive while still achieving similar weight loss (34).

American Diabetes Association

Position Statement

Primary prevention of diabetes
- Among individuals at high risk for developing type 2 diabetes, structured programs emphasizing lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 min/week) with dietary strategies including reduced calories and reduced intake of dietary fat can reduce the risk for developing diabetes and are therefore recommended. (A)
• The DPP was a great success!

• GLB is an adaptation of the successful DPP lifestyle intervention

• Developed in 2004 by the Diabetes Prevention Support Center faculty of the University of Pittsburgh Diabetes Institute

• BMI ≥ 25
• Pre-diabetic
• CHCS consult:
  • “SAMMC Diabetes Prevention”
  • List patient contact information
  • Note if there are barriers to brisk walking

How To Enroll Patients

Lifestyle coach must complete training

Staffing Options

• PREFERRED
  • Nurse
  • Dietitian
  • Exercise Physiologist
  • Diabetic Educator
  • Behaviorist
  • Physician

• ACCEPTABLE
  • Physical Training Leaders (P TL)
  • Air Force Fitness Facility Center Trainers, Certified Personal Trainer (CPT)
  • Licensed Vocational Nurse
  • Medical Technician
Summary

- Diabetes CAN be prevented or delayed
- The GLB DVD program is a cost-effective means to implement evidence-based practice
- With this tool, you can build a diabetes prevention program at YOUR base to help our airmen live healthier lives now and into retirement

One Year Data

<table>
<thead>
<tr>
<th>Measured Item</th>
<th>Mean Baseline</th>
<th>Mean 3 Month</th>
<th>Difference</th>
<th>N</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Weight (kg)</td>
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<td>-29.93</td>
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<td>Waist Circum. (in)</td>
<td>41.33</td>
<td>26.91</td>
<td>-14.42</td>
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<td>Fasting Glucose (mg/dL)</td>
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<td>84.43</td>
<td>-17.31</td>
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<td>A1c (%)</td>
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<td>Total Cholesterol (mg/dL)</td>
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<td>172.81</td>
<td>-50.14</td>
<td>74</td>
<td>0.034</td>
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<tr>
<td>Triglycerides (mg/dL)</td>
<td>124.74</td>
<td>105.55</td>
<td>-19.19</td>
<td>74</td>
<td>0.011</td>
</tr>
</tbody>
</table>

Summary

- Currently up and running at six bases and counting
- Formal follow-up in the process of being developed in collaboration with UPMC
- Training for lifestyle coaches will be available online in the fall
Questions?

POC: Lisa.Strickland.1@us.af.mil
Obesity is an epidemic that cost Americans more than $168 billion dollars per year. The TOBESAHOL Study estimates the DoD’s annual medical cost of obesity and overweight at $1.1 billion. In 2007, 12.4 percent Air Force personnel had a body mass index 30 or greater. Active duty members are at risk for administrative discharge for being over body fat. In 1999, 600 airmen and women were discharged for being over body fat. The Diabetes Prevention Program and the Look Ahead Study show 7 to 10 percent sustained weight loss greatly improves health. The National Weight Control Registry (NWCR), with over 5,000 registrants, has shown long-term weight management is achievable. The average NWCR registrant lost 66 lbs and kept it off >5 years. Less than 5 percent used medication. In 2006, the Certification Board of Obesity Educators (CBOE) was established to promote continuing commitment to best practices, standards of care, and knowledge of obesity counseling and education techniques. Curriculum for the certification exam is under development. During this session I propose a pilot study where Air Force healthcare professionals (physicians, nurses, dieticians, social workers, and psychologists) are trained as obesity educators to assist Air Force personnel to lose weight and maintain a healthful weight.
"Wait a minute here, Mr. Crumbley. Maybe it isn't kidney stones after all."

Don't Miss The Obvious

The war against the obesity epidemic is...
“Only 3.5% of the obese population has been impacted by current initiatives.”

Dr. Lee Kaplan, MD
Professor of Medicine, Harvard Med School and Director of the MGH Weight Center and the Obesity Research Center Conference on Practical Approaches to Obesity Treatment 18 June 2011

CDC REPORT: 22 July 2011
Behavioral Risk Factor Surveillance System 2009 versus 2010

1. >30% prevalence rate: 9 states now 12 states
2. 16 states increased rate in one year
3. No state now <20% prevalence rate

OBESITY IN AIR FORCE: 2007
Overweight (BMI 25-29.9):
   Air Force - 44.4%
   AFSOC - 46.3% (highest in AF)
Obese (BMI 30 or higher):
   Air Force - 12.4%
   AFSOC - 12.6% (PACAF 13.4%)

AD DOUBLE JEOPARDY
Health cost: >$1.1 billion/DoD/2006
Career cost: Administrative discharge
UNPUBLISHED AFPC DATA

1999: 600 airmen/women discharged for over-body fat = failed PT
Enlisted: 96% (89% active force)
Female to male: 2:1

OVER BODY FAT = FAILED PT

22 y/o airman: WC 51 in/BMI 41
29 y/o airwoman: 45 lbs preg > WC 36 in
42 y/o MSgt (15 yrs AD); s/p back surgery
  - WC 42 in

THE AF OBESITY EDUCATOR PROGRAM

Strategic:
- Obesity: A Chronic Disease
- Focus on Obesity Prevalence
Tactical: Weight Management Wheel
  - The Process Wheel
  - The Program Wheel

STRATEGIC PRINCIPLES #1

Obesity is a Chronic Disease
It can be controlled, not cured!
ADIPOSE TISSUE: ENDOCRINE GLAND

- (-) Adiponectin: -Atherogenic, -Inflamm, -DM
- (+) Interleukin 6: +Inflammation, +DM
- (+) PAI-1: +Atherogenic, +Coagulant
- (+) TNF-alpha: +Inflamm, +Insulin Resistance
- (-) Angiotensinogen: +HTN
- (+) Endocannabinoid Recep: +Lipogenesis

Obesity’s impact on female cancers

As a woman’s BMI rises above the normal range (18.5 to 24.9), her risk of dying of breast, kidney, uterine, and several other cancers also rises. For example, the risk of dying of breast cancer is 34 percent higher for women who are overweight (BMI between 25.0 and 29.9) than for women who are normal weight. For men above average BMI (at or below 30 overweight), the risk of dying of breast cancer is nearly five times higher, and the risk of colorectal cancer is six times higher.


Obesity’s impact on male cancers

As a man’s BMI rises above the normal range (18.5 to 24.9), his risk of dying of colorectal, esophageal, kidney, and several other cancers also rises, though not as dramatically as it does for cancers of the breast or among women. In fact, the risk of dying of colorectal cancer in 20 percent higher for men who are overweight (BMI between 25.0 and 29.9) than for men who are normal weight. For men who are obese (BMI of 30 or higher), the risk is 60 percent higher.

Figure 1 Impact of obesity on risk of developing chronic diseases. Adapted from: Field et al.¹

Field, Arch Intern Med 2001; 161: 1581-1586

**OBESITY STEALS LIFE YEARS**

Framingham Heart Study – 3457

40 y/o overweight:
- Non-smoker: M - lost 3.1 years
  F - lost 5.3 years

40 y/o obese:
- Non-smoker: M - lost 5.8 years
  F - lost 7.1 years

40 y/o obese:
- Smokers: M - lost 13.7 years
  F - lost 13.1 years

(compared to normal weight/predicted after age 50 to 69)

Annals of Internal Medicine, 7 Jan 03

**STRATEGIC PRINCIPLE #2**

Outcome Focus: Prevalence Rate

Must attack wherever the disease is!
**CHRONIC DISEASES TREATED ALIKE**

*Therapeutic Lifestyle Changes > Lip Service*

Primary treatment most diseases is medication:
- HTN: 10 categories of medications
  - Over 60 choices of single/combo meds

**THE CALVARY AIN’T COMING**

*Redux: Pulled in 1997 – heart valve and pulmonary HTN*
  - 21 billion dollar compensation fund

*Rimonabant: 2009 – endocannabinoid receptor blocker*
  - Effective in weight loss. Studied 18,000 over 13 months > Reduction in MI/CVA/death. Increase: psychotic/suicide

*Lorcaserin: 2010 – BLOOM study: 47.5% vs 20% lost 5%*
  - Concern: breast/brain tumors in rats. Re-evaluated?

**CONTINUED**

*Qnexa (topiramate + phentermine)*
  - Effective: 3,700 sub -14.7% (52 weeks)
  - FDA rejected: psychiatric, liver, birth defects

*Sibutramine: On market 13 years > effective*
  - SCOUT study: 9,800 over 3.4 years
  - 14% increase non-fatal MI and CVA

**SURGERY NOT REDUCE PREVALENCE**

*Bariatric surgeries: >200,000 in 2008*
  - Average cost: $10,000 = $200,000,000

*Obese Americans: 72 million Americans*

*Surgery cannot slow, stop, reverse obesity*
POSITIVE LIFESTYLE IMPACT
Therapeutic Lifestyle Changes: TLC

- Hyperlipidemia: first line of treatment
  (Conn’s Current Therapy, 2009, p 649)

- HTN: 1600 mg Na + DASH diet = single therapy
  (JNC VII, JAMA 14 May 2003)

- Type II DM: Diabetes Prevention Program
  - 6 Aug 01 HHS Thompson: 58% v 31% RR reduced

WE MUST THINK DIFFERENTLY
(Personal Responsibility)

STUDY WINNERS, NOT RUNNERS

- 1954: Roger Bannister > John Lundy
- 2008: Hicham el Guerouj > 3:43:13

NATIONAL WEIGHT CONTROL REGISTRY

- Study the ‘winners, not just the runners’ of the race
  - 1954: Roger Bannister > John Lundy
- NWCR:
  - Over 5,000 registrants
  - Average member: 60 lbs / 5.5 years
  - Characteristics: self-monitor (weigh at least weekly)
    eat low-fat/high carbohydrate diet
    eat breakfast (78% daily, 95% - 4/7)
    exercise 60 minutes/day (91%)

STRATEGIC SUMMARY

Common language = chronic disease

United vision = attack wherever found
TACTICAL: TWO SIDES OF WHEEL

The Process: Inclusiveness

The Program: Personal Responsibility with assistance

TACTICAL #1: INCLUSIVENESS

Empowerment:
Each healthcare specialty

CERTIFICATION BOARD OF OBESITY EDUCATORS

VISION
Reduce the prevalence of obesity across all social and economic settings in America.
- Inclusive approach! -

(www.obesityeducator.org)

OBESITY EDUCATOR

Licensed/Certified Healthcare Professional

Physicians, Nurses, Social Workers, Psychologists, Health Educators, Nutritionists, Exercise Physiologist
AIR FORCE OBESITY EDUCATOR

A new beginning...

PATIENT-CENTERED
MEDICAL HOME FOCUS

The Process of Weight Management

TACTICAL #2: SELF-SELECTION

Bariatric surgeon:
“Looking for a few good patients.”
ENHANCE SELF-EFFICACY

Patient decides: “I’m In”

Selects therapeutic spokes

Referred to specialty with skill in that spoke

Clinic ‘obesity educator’ coordinates

AF OBESITY EDUCATOR RESEARCH PROPOSAL

Target population: AF who failed PT test

Phase I: Specialty consultants/IRB/training
Phase II: 6-month wgt loss phase with
         18 month maintenance
Phase III: Begin 2nd 6-month wgt loss phase

VALUE TO AIR FORCE

1. Healthcare cost savings
2. Retention of qualified airman
3. Become DoD/national leader in
effective weight management science
Discussion/Questions
Intraosseous Infusion Rates Under High Pressure: A Cadaver Study of Anatomical Site Comparisons

711 HPW/USAFSAM-ETS

Maj Joe Dubose

BACKGROUND: Modern combat injuries often involve injuries to the extremities and torso, limiting the ability of medics to obtain intravenous access for resuscitation. Therefore, combat medics are trained in the use of intraosseous (IO) devices for the delivery of resuscitative fluids after combat injury. However, the optimal site of insertion for these devices (tibia, humerus, or sternum) has not been well established.

HYPOTHESIS: The optimal site or sites for IO vascular access in humans, using devices and sites currently being employed in theater, can be objectively determined using a fresh cadaver model. METHODS: “Fresh” cadavers, flushed with intravascular detergent solution immediately after arrival to the morgue and stored in a holding area at 34-36 degrees Celsius until use within 24 to 48 hr, will be utilized for study. IO infusion devices will be sited in the proximal tibia, proximal humerus, and sternum. The FAST-1 (Pyng Medical Corp., Richmond, British Columbia, Canada) and EZ-IO (VidaCare Corp., San Antonio, TX), which are U.S. Federal Drug Administration approved for sternal (FAST-1) and humeral or tibial site (EZ-IO) and commonly employed in combat theaters by field medics, will be utilized. A 0.9% saline solution will be infused at each site in turn, where the volume infused over 5 min using a pressure infuser inflated to 300 mmHg will be measured. Mean flow rates for each site will be calculated and used to compare mean rates of flow achievable using the three sites of access in this model. This study will be completed in 8 months.
A Comparison of Infusion Rates Using Intraosseous Devices on Adult Fresh Cadavers

Major Joe DeBose, USAF, MC, FACS
Clinical Assistant Professor of Surgery
University of Maryland/R Adams Cowley Shock Trauma Center
Baltimore C-STARs, USAFSAM

Background

- Acute hemorrhage remains the leading cause of combat death
- Resuscitation
  - Blood products
  - Fluid
- Administration requires access

Peripheral Intravenous

- Extremity injuries prevalent after combat injury
- Difficult in setting of hypotension

Central Venous Access

- Advanced skill set
- Time dependent
**Venous Cut-Down**

- Surgical skill required
- Time/equipment dependent

**Intraosseous (IO) Infusion**

- Safe
- Effective
- Rapid

**IO Access**

- American Heart Association – Resuscitation Guidelines, 2005
  
  - The intraosseous route should be the first alternative to difficult or delayed intravenous access.

**IO Site Options**

- Tibia
- Humerus
- Sternum
- Distal Femur
Military Relevance

- IO devices presently being utilized in theaters of conflict
  - Prevalence of extremity injuries
  - Prehospital environment challenges

- Tactical Combat Casualty Care Committee
  - Policy oversight in prehospital setting
Best Site?

- Objective = rapid administration of resuscitative fluids/critical medications for combat casualties who critically need them
- By this definition, optimal site = unknown

Available Data

- Animal models
  - Lairot J - U.S. Army Institute of Surgical Research (USA ISR)
    - Humens better infusion rates than tibia in rabbits
    - Larger animal studies ongoing
  - Limited human skeletal correlation
  - Particularly sternum
- Small human case series
  - No comparison of sites
How Do We Study?

- Animals not ideal correlate
- Risks associated with human volunteers
- Randomization in theater problematic

Study Design

- Prospective, observational study
- “Fresh cadavers”
  - Intravascular detergent solution flush on arrival
  - Stored 34-36°C
  - Utilized within 24-48 h post-mortem
  - Decedent age 18-65

Exclusions

- Bony or myeloproliferative malignancy
- History of median sternotomy
- Known fracture or orthopedic operation at planned extremity site

Cadavers?

- Fresh cadavers (<24-48 h) utilized in trauma training at specialized civilian centers
  - UMM/R Adams Cowley Shock Trauma Center
- Osseous structure preserved
- Correlates with anatomy
- Capable of sustaining flow through central lines after vascular flushing with mild detergent solution
**Protocol**

- Protocol refinement - 4 cadavers
- Study conduct - 38 cadavers
- Surgical cut-down of internal jugular for measurement of central venous pressure (CVP) monitoring
  - To prevent bias due to overfilling, intravascular volume will be removed to maintain CVP < 10 cm H2O or < 5 cm H2O above initial baseline

---

**Measurements**

- Mean flow rate calculation
- Total infusion delivered determined by weight comparisons before/after infusion of bags of NS

---

**Protocol**

- Randomized order of IO placement/infusion
  - Initial confirmation via marrow aspiration
  - Infusion 0.9% normal saline (NS) X 5 min
  - Pressure infuser inflated to 300 mmHg

- Appropriate insertion confirmed by cut-down upon completion of all sites

---

**Data Analysis**

- Primary outcome variable:
  - Mean flow rate of 0.9% NS at 300 mmHg through each of three access sites in a fresh cadaver model
    - Sternal
    - Proximal Humeral
    - Proximal Tibial
Deliverables

- Prioritize site choice

- Standardization?
  - Training / supply simplification

Collaborators

- Baltimore C-STARS
  - Lt Col (sel) Joe DuBoise, USAF, MC
  - Maj Jon Casey, USAF, MC

- Cincinnati C-STARS
  - Maj Mike Petro, USAF, MC
  - Col Warren Dorfoc, USAF, MC

- St. Louis C-STARS
  - Maj Brian Holt, USAF, MC

- USA ISR
  - Maj Julio Lainet, USAF, MC

Questions?
Intraosseous hydroxocobalamin versus intramuscular hydroxylamine in a validated swine model of acute cyanide toxicity and shock

59 EMDS

Lt Col Vikhyat Bebarta

Background: Non-intravenous routes of cyanide (CN) antidotes are needed as an easily administered antidote for first responders and military troops. Objective: To compare the return to baseline of mean arterial blood pressure (MAP) between 2 groups of swine in acute CN toxicity and treated with IO HOC or IM HAM. Methods: 24 swine (48-52 kg) were intubated, anesthetized, and instrumented. CN was infused until severe hypotension. Animals were randomly assigned to IO HOC or IM HAM and monitored for 60 min.

Results: Baseline mean weights, time to hypotension, and CN dose at hypotension were similar between groups. At hypotension mean MAP (42, 42 mg Hg), blood CN (3.2, 2.9 mcg/ml) and lactate levels (7.4, 7.8 mmol/L) were similar. 12/12 animals in the IO HOC group and 9/12 in IM HAM group survived (p=0.11). IO HOC resulted in a faster return to baseline (p < 0.001). Bicarbonate, pH, and lactate, levels were similar. Methemoglobin (1.2% IO HOC, 12.8% IM HAM) and CN levels (0 in IO HOC, 15.5 mcg/ml in IM HAM) were greater in the IM HAM group (p < 0.001). Cerebral NIRS oxygenation decreased was similar in both groups after antidote (p=0.78). Serum nitrotyrosine rose during CN infusion in all animals, but was lower in the IO HOC group at 60 min (p=0.03). TNF-a, IL-1b, IL-6 and IL-10 were similar.

Conclusions: Intraosseous hydroxocobalamin led to a faster return to baseline mean arterial blood pressure compared to intramuscular hydroxylamine. Mortality with the intramuscular hydroxylamine group was greater.
Intraosseous hydroxocobalamin vs. intramuscular hydroxylamine for severe cyanide toxicity and shock

**Disclosure**
- My opinions and comments do not reflect the official policy or position of the Department of the Air Force or Navy, Department of Defense, US Government.
- Funding - USAF Office of the Surgeon General, NIH, US Army, Univ of Texas Health Science Center.
- No other financial disclosures. No industry support.

**Project title**
Intraosseous hydroxocobalamin versus intramuscular hydroxylamine in a validated swine model of acute cyanide toxicity and shock – a randomized trial.
Hypotension or cardiac arrest occur in > 50% of cases due to cyanide poisoning. Ingestion or fires lead to cyanide release. Cyanide antidote kit includes 3 drugs, each requiring complex dosing, and can have serious adverse effects.
Hydroxocobalamin and Sodium Thiosulfate Versus Sodium Nitrite and Sodium Thiosulfate in the Treatment of Acute Cyanide Toxicity in a Swine (Sus scrofa) Model

Hydroxocobalamin and Sodium Thiosulfate Versus Sodium Nitrite and Sodium Thiosulfate in the Treatment of Acute Cyanide Toxicity in a Swine (Sus scrofa) Model

Similar survival and blood pressure
Hydroxocobalamin - Improved
hurtle, pil, cyanide levels

2009 National Best Basic Science Award – SAEM

Is sodium thiosulfate alone effective?
Recommended as single agent¹
Sodium thiosulfate failed to reverse cyanide induced shock – 100% mortality
Hydroxocobalamin alone was effective

2011 National Best Basic Science Award – SAEM

Non intravenous route of cyanide antidotes are needed
Hypotension may not allow absorption for IM in shock

¹ Non intravenous route cyan ant are needed
Hypotension may not allow absorption for IM in shock
Cyanide antidote kit – IV only
Hydroxocobalamin – cannot be given intramuscularly
We found IO HOC as effective as IV for cyanide shock.

Hydroxylamine
Induces methemoglobinemia
Intramuscular route is effective against cyanide
Only 1 study reported

Study Objective
To compare the return to baseline of mean arterial blood pressure between 2 groups of swine in acute cyanide toxicity and treated with IO HOC or IM HA
Methods

Randomized comparative study

Swine

Approved by local IACUC

24 swine (48-52 kg)
Pulmonary artery catheter with continuous cardiac output
Continuous central arterial monitoring

Intubated, instrumented & acclimated

Weight based potassium cyanide infusion

Cyanide infused

Intubated, instrumented & acclimated

T: 50 min  T: 30 min  0 min  10 min  20  30  40  50  60

Cyanide infusion stopped

Cyanide infused

Intubated, instrumented & acclimated

50% of Baseline MAP

T: 50 min  T: 30 min  0 min  10 min  20  30  40  50  60
Hydroxocobalamin – 150 mg/kg (i.v. OR) OR Hydroxylamine 50 mg/kg IM

Cyanide infused

Intubated, instrumented & acclimated

30% of Baseline MAP

T:30 min T:30 min 0 min 10 min 20 30 50 60

Antidote bolus

T:30 min T:30 min 0 min 10 min 20 30 50 60

Antidote bolus

Key outcome measurements

Primary
Change in mean MAP after antidote until 60 min

Secondary
HR, CO, SVR, SVO2 over time
pH, lactate, bicarbonate, cyanide blood levels
Nitrotyrosine1-2
NIRS – near infrared spectrometry on brain, kidney
Inflammatory markers
Brain tissue microdialysis

1Gert H, Clin Toxicol, 2006
2Kan WH, J Appl Physiol, 2008

Necropsy
Verification of pulmonary artery catheter and other catheters
Data analysis

50% increase in MAP after induced hypotension
Clinically significant
Based on our previous data
12 animals per group for power of 0.8
Two-tailed alpha of 0.05
24 animals
Repeated measures ANOVA
Hemodynamic and biochemical measurements
Post hoc t-tests if differences found

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<th>Baseline Characteristics</th>
<th>Hydroxocobalamin</th>
<th>Hydroxylamine</th>
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<tr>
<td>Weight, kg</td>
<td>49±2</td>
<td>50±2</td>
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<tr>
<td>Heart rate, beats/min</td>
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<tr>
<td>Mean art pressure, mm Hg</td>
<td>91±6</td>
<td>98±8</td>
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<td>Cardiac output, L/min</td>
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<th>Characteristics at hypotension (MAP &lt; 50% of baseline)</th>
<th>Hydroxocobalamin</th>
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<td>Cyanide dose, mg/kg</td>
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<td>4.5±1</td>
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Deaths

<table>
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<th>Antidote</th>
<th>Hydroxocobalamin</th>
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<tr>
<td>Deaths</td>
<td>0/12</td>
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<tr>
<td>Survival</td>
<td>100% *</td>
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</tbody>
</table>

*p = 0.11

Blood cyanide over time

Systemic vascular resistance over time

Mean arterial pressure over time

HOC, Hydroxocobalamin
HA, Hydroxylamine
Error bars – 95% CI
Results

At 60 min
Cyanide level great in HA – 15.5 vs 0 mcg/ml
Methemoglobin greater in HA – 13% vs 1%

Results

Systolic and mean arterial blood pressure, SVR, SVO2 – greater in HOC group
Cardiac output – greater in HOC group early and in HA later (p=0.003)
Lactate, bicarb, pH – similar

Results – NIRS

Brain NIRS was similar (p = 0.78)
Kidney NIRS was greater in HA group (p = 0.01)
Paralleled hypotension

Nitrotyrosine

Results pending
In our previous studies
Similar at baseline in all 3 arms
Increased by 60% in all arms at hypotension
Discussion

IO HOC – 100% survival
  Reduced cyanide levels – neuro effects
HA – 75% survival
  High cyanide and methemoglobin levels
  Had improved cardiac output and NIRS kidney at study end
HA mechanism unclear – Improved MAP before methemoglobin levels rose
Nitrotyrosine may suggest mechanism

Limitations

Animal model
Intravenous vs. inhaled cyanide model
Short duration of observation
Neurological outcomes not measured

Conclusion

• Intraosseous hydroxocobalamin – faster return to baseline MAP compared to intramuscular hydroxyamine
• Methemoglobin and serum cyanide levels – greater in hydroxyamine arm
• Mortality, acidosis, and lactate – similar
• IM antidotes for cyanide shock may be effective

Acknowledgements

• Research team
  Vik Bebarta, MD (PI)
  Dave Tanen, MD (US NAVY; Captain)
  Rebecca Pitotti, RN, MSN
  Susan Boudreau, RN
  Patricia Dixon, MS
  Julio Lairet, DO
  Sandra Vaizier, PhD
  Anneke Bush, ScD, MHS

• USAF Office of the Surgeon General
Questions

Lt Col Vik Bebarta, MD
Wilford Hall Med Ctr/Brooke Army Med Ctr
vikhyat.bebarta@us.af.mil

Slides for questions

• Call for no IV routes (NIH and USAMRIC)
• Complicated, failure, higher skill level
• Cold CAK – no IO or IM
• HOC – no IO
• We conducted a study to IO vs IV is effective similarly
• What is hydroxylamine? Can state given IM
• Look at an IM route is as effective as IO HOC
Antidote dose

- **Hydroxocobalamin**
  - 150 mg/kg IV\(^1,2\)
  - Package insert – 10 grams (150 mg/kg)
- **Sodium thiosulfate**
  - 1.65 ml/kg of 25% solution IV – 413 mg/kg\(^3,4\)
  - Adult dose – 12.5 grams and repeat – 360 mg/kg

Lab interference

- No known interference for our labs
- Colorometric and co-oximetry mostly\(^1\)
- ALT, AST, amylase, bilirubin\(^1,3\)
- Creatinine, magnesium, iron, CK\(^1,3\)

Antidote infusion

- **Volume** – 200 ml for each arm\(^1\)
  - Hydroxocobalamin 180 ml
  - Sodium thiosulfate 20 ml
- **Rate** based on previous studies – 5 minutes\(^3\)
- 10 ml saline flush before and after each drug

Cyanide method

- Whole-blood cyanide levels were measured with spectrophotometry\(^1,2\)
- Diagnostic Center for Population and Animal Health, Michigan State University, Lansing, MI
- Generates hydrogen cyanide gas, converts it to a cyanogen chloride, and uses spectrophotometric determination of the barbituric acid complex\(^1\)
- Does not measure cyanide as cyanmethemoglobin or cyanocobalamin

---

\(^1\)Brower S, Crit Care, 2006
\(^2\)Erdman A, Medical Toxicology, 2004
\(^3\)Seibert, Ann Emerg Med, 2010
\(^4\)Brower, Ann Emerg Med, 2010
\(^5\)Brickerman, Semin Diagn Pathol, 2009
\(^6\)Carson SC, Ann Emerg Med, 1984
\(^7\)Seibert VS, Ann Emerg Med, 2010

---
Ongoing or future studies

- Completed – non intravenous routes
  - Intraosseous vs intravenous hydroxocobalamin
  - Intraosseous vs intramuscular methemoglobin inducer
- Ongoing
  - Intramuscular cobalt formulation for cyanide toxicity
- Future
  - Hydroxocobalamin for other toxins and shock states
- All studies are federally funded

Color interference with PA catheter

- Edwards Lifesciences Engineer
- Possibly SVO2
- SVO2 correlated well with clinical parameters
  - Mean arterial pressure, cardiac output

Nitric oxide and nitrotyrosine

- Nitric oxide directly
  - Colormetric chemiluminescent analyzer (Sievers Nitric Oxide Analyzer, GE, Boulder CO)
- Nitrotyrosine
  - ELISA (Northwest Life Science Specialties, Vancouver, WA)
Nitrotyrosine

• Nitric oxide relaxes vascular tone – hypotension\(^1,2\)
• Nitrotyrosine – downstream NO byproduct\(^2\)
• Cyanide decreased MAP, increased nitrotyrosine
• HOC increased MAP, and decreased nitrotyrosine
• Previous reports
  Cyanide not used in model and NO not measured\(^2\)

\(^1\)Samik, Crit Care Med, 2001
\(^2\)Kain, J Appl Physiol, 2008
\(^3\)North, Crit Care Med, 2006
Neurological outcomes

- No measurements in this study
- In our other studies
  - NIRS – brain and renal
  - Cerebral microdialysis
  - Cerebral Licox – Partial PO2

Hypotension as primary outcome

- Apnea used as outcome\(^1,2\)
- Oxygen/ventilation reverses cyanide toxicity\(^3\)
- Hypotension is common and predictor of death
- 50% MAP used in several swine studies\(^4\)

---

\(^1\) Borron, Clin Toxicol, 2006
\(^2\) Vick, Mil Med, 2000
\(^3\) Bacons, Ann Emerg Med, 2000
\(^4\) Bacons, Ann Emerg Med, 2000
Other slides

Universal antidote

EMS use
nucleophile and electrophiles
• Work in future studies and universal antidote
• Practice

Cyanide is a nucleophile (neg charge)
  - Chloride, ammonia, azide, organochlorines, organophosphates?
• Cobalamin is a electrophile (pos charge)

Non IV route
• Non IV route is important - cannot use for HOC
• Need route that requires less skill, simple
• Recommended by other agencies (NIH, USAMRIC)
• Intraosseous route
• Other antidotes

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Hydroxocobalamin</th>
<th>Cyanide antidote kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Few serious adverse effects</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Simplicity of use</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Number of drugs used</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
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### Characteristics Hydroxo-cobalamin Cyanide antidote kit

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<tr>
<td>Cost</td>
<td>✓</td>
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### Characteristics

<table>
<thead>
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<td>✓</td>
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<tr>
<td>Cost</td>
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<td>✓</td>
</tr>
<tr>
<td>Efficacy</td>
<td>?</td>
<td>?</td>
</tr>
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</table>

**Methemoglobinemia**

**Hypotension**

Elevated blood pressure, red color, rash, allergic
Is hydroxocobalamin alone effective?
FDA approved

Is sodium thiosulfate alone effective?

100% mortality in sodium thiosulfate alone

Combined Exposures

Committee on Combined Exposures to Hydrogen Cyanide and Carbon Monoxide in Army Operations
Committee on Toxicology
Board on Environmental Studies and Toxicology
Hydroxocobalam adverse effects

Elevated blood pressure, red color, rash, allergic

Simple, single, and few adverse effects

Table 1: Baseline characteristics of the animals

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Hydroxocobalamin</th>
<th>Hydroxocobalamin + Sodium Thiosulfate</th>
<th>Sodium Thiosulfate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, kg</td>
<td>49.2</td>
<td>51.2</td>
<td>49.2</td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
<td>92±14</td>
<td>81±6</td>
<td>67±13</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>107±13</td>
<td>112±11</td>
<td>104±7</td>
</tr>
<tr>
<td>Mean arterial pressure, mm Hg</td>
<td>84±10</td>
<td>94±9</td>
<td>80±5</td>
</tr>
<tr>
<td>Cardiac output, L/min</td>
<td>5.0±0.8</td>
<td>5.1±0.8</td>
<td>4.8±0.9</td>
</tr>
<tr>
<td>Systemic vascular resistance, dyn/cm²</td>
<td>1966±244</td>
<td>1515±282</td>
<td>1448±340</td>
</tr>
<tr>
<td>pH</td>
<td>7.4±0.05</td>
<td>7.4±0.01</td>
<td>7.4±0.05</td>
</tr>
<tr>
<td>Bicarbonate, mmol/l</td>
<td>29±12</td>
<td>29±12</td>
<td>28±1.0</td>
</tr>
<tr>
<td>Lactate, mmol/l</td>
<td>1.4±0.1</td>
<td>1.4±0.3</td>
<td>3.2±0.5</td>
</tr>
</tbody>
</table>

Data presented as means ± standard deviation.

Characteristics at hypotension (MAP < 50% of baseline)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Hydroxocobalamin</th>
<th>Hydroxocobalamin + Sodium Thiosulfate</th>
<th>Sodium Thiosulfate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cysteine dose, mg/kg</td>
<td>4.9±2</td>
<td>5.7±2</td>
<td>5.0±0.9</td>
</tr>
<tr>
<td>Time to hypotension, min</td>
<td>27±0±10±21</td>
<td>35±5±13±40</td>
<td>24±5±4±02</td>
</tr>
<tr>
<td>MAP at hypotension, mm Hg</td>
<td>4±0</td>
<td>4±0</td>
<td>4±2</td>
</tr>
<tr>
<td>Lactate, mmol/L</td>
<td>6.9±1</td>
<td>7.6±0.2</td>
<td>8.0±0.5</td>
</tr>
<tr>
<td>Cysteine level, mg/kg</td>
<td>3.4±0.7</td>
<td>3.4±0.9</td>
<td>3.5±1</td>
</tr>
<tr>
<td>pH</td>
<td>7.4±0.1</td>
<td>7.4±0.1</td>
<td>7.4±0.1</td>
</tr>
</tbody>
</table>
Is sodium thiosulfate alone effective?

— modern study...[comparing all 3] is needed

Hydroxocobalamin
Hydroxocobalamin
Sodium thiosulfate
Hydroxocobalamin and sodium thiosulfate
Sodium thiosulfate
Hydroxocobalamin and sodium thiosulfate


Sodium thiosulfate
Used and recommended as single agent
As effective as hydroxocobalamin as prophylaxis
Few side effects
However
Small or uncontrolled studies
Indirect outcomes

"modern study...[comparing all 3] is needed"
"modern study...[comparing all 3] is needed"

Hydroxocobalamin Hydroxocobalamin Sodium thiosulfate
and sodium thiosulfate

Is hydroxocobalamin alone effective?


Potentially synergistic\footnote{\textit{Kerns, B., Ann Emerg Med, 2008}}

Europe

However\footnote{\textit{Kerns, B., Ann Emerg Med, 2008}}

Case reports and small studies
No direct comparison reported\footnote{\textit{Kerns, B., Ann Emerg Med, 2008}}
Resuscitation with Hextend Leads to Diminished Inflammation as Compared to Hespan in Hemorrhagic Shock

711 HPW/USAFSAM-ETS
Dr. Timothy Pritts

PURPOSE: Hemorrhagic shock is the leading preventable cause of traumatic death. Recent studies have shown that hemorrhagic shock is associated with a dysfunctional inflammatory response and that this response can be affected by resuscitation strategy. CCR1 is a chemokine receptor that is important in inflammatory cell activation and recruitment. It is activated by both CCL3 (MIP-1α) and CCL5 (RANTES). Hetastarch (6%) is a colloid resuscitation fluid and is available dissolved in normal saline as Hespan or in Lactated Ringer’s as Hextend. We hypothesized that resuscitation with Hextend would lessen the inflammatory response to hemorrhagic shock as compared to Hespan.

METHODS: Mice underwent femoral arterial cannulation and hemorrhage using a pressure-clamp model to a mean arterial pressure of 25 mmHg. After 1 hr of hemorrhagic shock, mice were resuscitated with normal saline, Lactated Ringer’s, Hespan, or Hextend. The mice were then sacrificed at intervals to collect serum. Serum was analyzed by multiplex ELISA for cytokine analysis.

RESULTS: Mice resuscitated with Hextend had a lower level of CCL3 than mice resuscitated with Hespan at 30 min (112.3 vs. 606.3 pg/mL, p<0.05). At 4 hr, mice resuscitated with Hextend had a lower level of CCL5 compared to Hespan (54.6 vs. 203.8 pg/mL, p<0.05). In further investigation, this did not appear to be simply the result of carrier solution alone.

CONCLUSION: Mice resuscitated with Hextend had a diminished inflammatory response among the activators of CCR1 as compared to Hespan at both early and late time points. Resuscitation with Hextend in place of Hespan may decrease the inflammatory response to hemorrhagic shock.
Resuscitation with Hextend Leads to Diminished Inflammation as Compared to Hespan in Hemorrhagic Shock

Timothy A. Pritts, MD, PhD
University of Cincinnati

Every Airman a Force Multiplier
August 2011 AFMS Research Symposium

Hemorrhagic Shock

- 2nd leading cause of lethal traumatic injury
- Leading cause of preventable mortality
- 10,000-24,000 potentially preventable deaths annually in U.S.
- Global ischemia-reperfusion injury
- Dysfunctional systemic inflammatory response
- Infection, sepsis, organ failure, and late mortality

Every Airman a Force Multiplier

Background

- Hespan
- 6% hetastarch in normal saline
- Hextend
- 6% hetastarch in lactated Ringers
- Effect of either fluid on inflammation after resuscitation is unknown

Maddox et al. J Trauma 2011
}

Every Airman a Force Multiplier

128
Hypothesis

Resuscitation with Hespan vs. Hextend will differentially affect the systemic inflammatory profile.

Methods

Anesthesia
Cannulation
Hemorrhage
Resuscitation
Analysis

Shed Blood

Syntonic BP (mmHg)

<table>
<thead>
<tr>
<th>Time (minutes)</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
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<tbody>
<tr>
<td>NS</td>
<td></td>
<td>*</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>LR</td>
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<td></td>
</tr>
<tr>
<td>Hespan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hextend</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Volume (ml)

<table>
<thead>
<tr>
<th>Volumes (ml)</th>
<th>0.0</th>
<th>0.2</th>
<th>0.4</th>
<th>0.6</th>
<th>0.8</th>
<th>1.0</th>
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</thead>
<tbody>
<tr>
<td>NS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hespan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hextend</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Volume of Resuscitation**

- NS
- LR
- Hextend
- Hextend

**Metabolic Data**

<table>
<thead>
<tr>
<th></th>
<th>pH</th>
<th>CO₂</th>
<th>HCO₃⁻</th>
<th>BE</th>
<th>CI</th>
<th>Hgb</th>
<th>Lac</th>
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<tbody>
<tr>
<td>Sham</td>
<td>7.40</td>
<td>46</td>
<td>25</td>
<td>3.25</td>
<td>11.0</td>
<td>12.8*</td>
<td>1.31</td>
</tr>
<tr>
<td>NS</td>
<td>7.29*</td>
<td>60</td>
<td>29</td>
<td>2</td>
<td>11.2</td>
<td>9.4</td>
<td>1.90</td>
</tr>
<tr>
<td>LR</td>
<td>7.35</td>
<td>49</td>
<td>27</td>
<td>1</td>
<td>11.1</td>
<td>9.2</td>
<td>1.17</td>
</tr>
<tr>
<td>Hextend</td>
<td>7.30*</td>
<td>59</td>
<td>29</td>
<td>2.6</td>
<td>11.3</td>
<td>7.9</td>
<td>1.35</td>
</tr>
<tr>
<td>Hextend</td>
<td>7.32</td>
<td>59</td>
<td>31</td>
<td>4.75</td>
<td>11.1</td>
<td>8.1</td>
<td>1.15</td>
</tr>
</tbody>
</table>

**IL-6**

- Sham
- HES
- HEX
- HES
- HEX

**IL-10**

- Sham
- HES
- HEX
- HES
- HEX

---

Distribution Statement A: Approved for public release, distribution unlimited. Date Released: 03/09/2021, 15:00 EST.
Sham HE X HE X
30 minutes

MIP-2

Concentration (pg/ml)

S h a m H E S H E X
30 minutes

CCL3

Concentration (pg/ml)

Sham HE S HE X
30 minutes

CCL5

Concentration (pg/ml)

Sham HE S HE X
30 minutes

Myeloperoxidase Activity

Lung

MPO Activity/Protein Concentration

Sham HE S HE X
30 minutes
Histology

Sham | Hespan | Hextend

Conclusions

- Resuscitation with Hespan leads to greater systemic inflammation as compared to Hextend.
- This increase in inflammation may lead to increased end organ inflammation and complications.

Acknowledgments

Eric M. Campion, MD; Amy T. Makley, MD; Ritha Belizaire, MD; Lou Ann Friend, RVT; Alex B. Lentisch, PhD

NIH Training Grant T32 GM08478
U.S. Air Force FAB553-05-2-6519
Epidemiology of Respiratory Illness During Basic Cadet Training at the U.S. Air Force Academy: Implications for Future Research and Prevention

U.S. Air Force Academy
Lt Col Catherine Witkop

BACKGROUND: Respiratory symptoms are responsible for over half of all medical visits during Basic Cadet Training (BCT) at the U.S. Air Force Academy (USAFA) each year and can impact training and duty availability. Cough is the predominant symptom. Environmental conditions and infection have been proposed as possible etiologies. Our objective was to determine if a pathogen was associated with respiratory symptoms during BCT. METHODS: This cross-sectional study compared cadets in three groups: (1) FRI (febrile respiratory illness); (2) ARI (afebrile respiratory illness); (3) control (presenting with other than respiratory chief complaint). Each subject completed a questionnaire including demographics, pre-existing medical history, and current symptoms. Nasal wash and throat swab specimens were evaluated by PCR for detection of adenovirus, influenza, rhinoviruses, and other pathogens. Clinical information was abstracted from the medical record. Infection rates were calculated and compared between groups. RESULTS: 129 cadets were included. Cough was reported as a symptom in 115/129 cadets, including 10/12 FRI, 88/99 ARI, and 17/18 controls. Rhinovirus was detected in 56/129 (43.4%) of subjects, including 51/115 (44.3%) of those with cough and 5/14 (35.7%) of those without cough. Adenovirus was only detected in one cadet at levels consistent with possible infection. CONCLUSIONS: Rhinovirus was identified in almost half of cadets studied. It was not significantly associated with cough, although there were very few cadets without cough in this study. Further study is warranted to test for factors such as altitude, environment, and immune status and to evaluate possible preventive measures, with implications for deployed troops.
Epidemiology of Respiratory Illness during Basic Cadet Training at the U.S. Air Force Academy: A Molecular Approach

Lt Col Catherine Witkop
Preventive Medicine
US Air Force Academy

Disclaimer

- The opinions expressed in this brief are solely those of the authors and do not represent an endorsement by or the views of the United States Air Force Academy, the United States Air Force, the Department of Defense, or the United States Government.

- I have no financial disclaimers to disclose.

U.S. Air Force Academy

- Undergraduate military academy with over 4000 students (cadets)
- Four year institution of higher learning
- Successful cadets graduate as 2nd Lt with a Bachelor of Science Degree
- Cadets live in dorms with 2-3 to a room

Basic Cadet Training (BCT)

- Six week rigorous training
- BCT 1:
  - In dorms (sleep 2-3 to a room)
  - Academic, physical, military training
- BCT 2:
  - 14 days in Jacks' Valley
  - Field training
  - Sleep 12-15 to a tent
  - Obstacle, assault, confidence courses
  - Support operations also move to Jacks' Valley
What is "Jacks' Hack"?

- Lay term for the cough and other respiratory symptoms that occur during BCT at USAFA
- Most Basics get it and it can last for weeks
- Etiology is currently unknown but thought to be some combination of:
  - Environment (dry, dusty conditions in Jacks' Valley)
  - Altitude
  - Depressed immune system/stress
  - Respiratory pathogen

Respiratory symptoms are responsible for over half of all medical visits during BCT at USAFA each year and can impact training and duty availability.

Respiratory Illnesses

<table>
<thead>
<tr>
<th>Year</th>
<th>No. Total Visits for Resp. Illnesses</th>
<th>% of Visits Occurring During Real Training</th>
<th>No. Cadets with Resp. Illnesses</th>
<th>Total No. Cadets</th>
<th>% Cadets with Resp. Illnesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>871</td>
<td>48%</td>
<td>551</td>
<td>1296</td>
<td>42.5%</td>
</tr>
<tr>
<td>2008</td>
<td>802</td>
<td>55%</td>
<td>540</td>
<td>1356</td>
<td>39.8%</td>
</tr>
</tbody>
</table>
Respiratory Illnesses
BCT 2007-2008

Background

- Adenovirus has been implicated in respiratory illnesses among recruits at training bases
- Adenovirus generally peaks in weeks 3-5
- A study performed at USAFA in summer 2009 showed no positive results for adenovirus
- An nH1N1 outbreak during the study period precluded definitive conclusions about infectious etiologies
- Rhinovirus, however, was identified in a large subset of cadets

Objective

- The objective of this study was to determine if adenovirus, rhinovirus or another pathogen was associated with respiratory symptoms in Basic Cadets during BCT.
### Methods

- Cross sectional, descriptive design
- Participants: Male and female cadets aged 17 and above who presented for medical care at the USAFA cadet clinic or infirmary tent at Jacks’ Valley
- Time period: 24 Jun-6 Aug 2010

### Groups

- **Group 1 (FRI):** Cadets with temperature of 100.5 or greater and any upper respiratory symptom such as cough, sore throat, rhinorrhea
- **Group 2 (ARI):** Cadets with respiratory illnesses, but without fever
- **Group 3 (Control):** Cadets who present to the clinic/tent for care for symptoms other than respiratory symptoms (e.g. musculoskeletal injuries)

### Questionnaire

- The purpose of the study and the protocol were explained to each eligible cadet
- Signed informed consent (approved by USAFA and USUHS IRBs) was obtained
- Each subject completed a questionnaire:
  - Information regarding gender, race, region/state of residence, squadron, dorm room/tent, smoking history, pre-existing medical history, symptoms, previous visits, and missed training

### Specimen Collection

- Nasal wash and throat swabs were performed per standard protocol
- Clinical information about the encounter was abstracted from the subject’s medical record
- Specimens were shipped overnight to the Advanced Diagnostic Laboratory (ADL) at Lackland AFB
- Samples were processed at the ADL for detection and characterization of a variety of pathogenic and commensal organisms
Pathogens Tested by PCR

- Adenovirus (3, 4, 7, 11, 14, and 21)
- Influenza A (H1, H3, H5A, H5B)
- Influenza B
- Parainfluenza viruses (types 1, 2, and 3)
- Rhinovirus
- Respiratory Syncytial Virus (RSV)
- Human Metapneumovirus (HMPV)
- Bocavirus (NS1 and NP1)
- Epstein-Barr Virus (EBV)
- Coronavirus
- Streptococcus pneumoniae
- Streptococcus pyogenes
- Mycoplasma pneumoniae
- Chlamydia pneumoniae
- Bordetella pertussis I
- Bordetella pertussis II
- Legionella pneumophila
- Hemophilus influenza and subtyping

Real-time PCR Technology

- Each time a target DNA sequence is replicated, a fluorescent molecule is released
- The amount of fluorescence correlates to the amount of DNA

Cycle threshold value (CT): The replication cycle number at which the fluorescence level (shown as an amplification curve for each sample) crosses a set threshold line (green)

- The leftmost purple curve is the positive control. The 3 rightmost greenish curves are samples with CT values greater than 35, and are considered negative.
- The blue/purple lines in between are samples that are considered positive for rhinovirus, with CT values ranging from 26 to 34.
Validation of USAFA Biology Laboratory Techniques

- If nasal wash specimens contained >3 cc of washing, 0.5 cc was provided to the USAFA Department of Biology laboratory.
- Analyzed for the presence of influenza A, swine influenza H1, swine influenza A (as a confirmatory test to swine influenza H1), adenovirus, and rhinovirus.
- Analytical results were compared with results from ADL.

Results

- 129 cadets were included in the study.
  - 37 females
  - 92 males
- Mean temperatures among the ARI and control groups were not significantly different.
  - 97.86 ARI vs. 97.84 among controls.
- Mean temperature among those in the FRI group was 101.3 (p<0.05).
- Cough was reported as a symptom in 115/129.
  - 10/12 FRI, 88/99 ARI, and 17/18 controls.

Proportion of self reported symptoms of study participants

- The pan-screen for adenovirus was positive (Ct < 35) in only one subject.
- If a more liberal cut-off of Ct <40 is used, adenovirus was detected in 3/12 (25%) of FRI and 8/88 (9.1%) of ARI.
### Rhinovirus

<table>
<thead>
<tr>
<th>Outcome (n)</th>
<th>Rhinovirus (Ct ≤40)</th>
<th>Rhinovirus (Ct &gt;35)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>ARI (99)</td>
<td>61</td>
<td>61.6</td>
</tr>
<tr>
<td>FRI (12)</td>
<td>6</td>
<td>50</td>
</tr>
<tr>
<td>Control (18)</td>
<td>11</td>
<td>61.1</td>
</tr>
<tr>
<td>Cough as a symptom (115)</td>
<td>71</td>
<td>61.7</td>
</tr>
</tbody>
</table>

*Lab confirmed Nasal Wash or Throat Swab

### Conclusions

- Respiratory symptoms were common among cadets during BCT, including in those who presented with a non-respiratory complaint.
- Rhinovirus was identified in almost half of cadets studied.
- It was not significantly associated with cough, although there was a very small number of cadets without cough in this study.

### Bordetella Pertussis

- Several specimens positive for Bordetella species but negative for Pertussis.
- One positive for Pertussis; had been treated when results detected.
- Cadet left the Academy during the first week of training; no further cases.

- Lab confirmed Nasal Wash or Throat Swab
Conclusions

- Adenovirus may be a contributing factor in patients with FRI, but not in those with ARI.
- This finding was useful in helping determine policy for adenovirus vaccine administration at USAF.
- The use of real-time PCR technology can assist in the detection of pathogens in a particular population and potentially aid in the development of preventive measures.

Rhinovirus

- RNA virus in the picornavirus family.
- Symptoms: rhinorrhea, nasal congestion, sore throat, non-productive cough, sneezing, facial pressure and headache.
- Direct contact (e.g., sneezing or coughing of aerosolized particles) seems to be the most efficient mode of transmission.
- Can persist on door knobs, silverware, masks, etc.

- Symptoms typically occur within 16 hours of inoculation and last for a median of 9.5 to 11 days.
- The symptoms of "Jacks' Hack" are similar to findings in patients with rhinovirus infection.
Future Directions

- Further study is warranted to test for other factors such as altitude, environment, and immune status in this USAFA population.

BCT 2011 Study Protocol

- Add educational brief for all Basic Cadets on Day 1 of BCT
  - Focused on basic public health messages
  - Hand-washing, covering cough
  - Discussing possible role of an infectious agent in Jacks’ Hack
  - Educational campaign (signs) in the dormitories of half of the squadrons
  - Compare rates of respiratory illness diagnoses between 2010 and 2011
  - Compare incidence of rhinovirus in Squadrons A-E and F-J

Status of 2011 Study

- Study was in process when norovirus outbreak among Basic Cadets struck on 21 Jul

- The experiences at USAFA in BCT 2009 and 2011 highlight the need for field-deployable rapid diagnostic tests
  - In both cases, earlier identification of H1N1 and norovirus might have prevented lost training time
  - In deployed locations, such technology can be a force-multiplier

Future Directions

- Further study should also focus on potential preventive measures, such as education and supplements to help reduce the spread of rhinovirus

- We began to investigate that this year and, to give a sneak preview of our study from this year . . . .
Acknowledgements

- Advanced Diagnostic Laboratory
  - Lisa Lott, Matt McDonald and Team
- USAFA Department of Biology
  - Mel Groger, Michelle Wickersheim
- USUHS Preventive Medicine Residency Program
  - Shane Steiner
- Biostatistical Support
  - Katie Tastad

References

- Personal communication. Mr. Michael Love, Chief of Business Analysis, 10th Medical Group, U.S. Air Force Academy, January 2011.
Virulence and Resistance Trends of Staphylococcus aureus in an Outpatient Military Population

59 MCCS SGOBV
Capt Corey Falcon

Skin and soft tissue infections due to community-associated methicillin resistant Staphylococcus aureus (CA-MRSA) pose a clinical challenge due to their increasing incidence and virulence. This epidemiologic study was undertaken to determine the occurrence of virulence and resistance factors in S. aureus isolated from an outpatient population in San Antonio, TX. A total of 200 S. aureus isolates from samples submitted for culture from outpatient clinics over 5 months in 2009 were tested for the presence of mecA, mupA, TSST-1, and PVL genes using EVIGENE qualitative nucleic acid hybridization assays. Antibiotic susceptibility profiles for each of the isolates were obtained. Results show that 50% of the isolates were MRSA. The prevalence of PVL was 56%. 84% of the MRSA isolates were positive for PVL while 29% of the MSSA isolates demonstrated PVL. Only 4% and 7% of the isolates carried the mupA and tsst-1 genes respectively. The MRSA burden in our community is significant. The data suggests that Mupirocin remains an option for the elimination of S. aureus nasal carriage. There appears to be an increasing incidence of Panton-Valentine leukocidin in S. aureus strains, especially MRSA. Interestingly, the majority of isolates with toxic shock syndrome toxin were methicillin sensitive S. aureus. Ciprofloxacin, Levofloxacin, and Erythromycin should not be used to treat S. aureus infections in this population. There is a significant occurrence of inducible Clindamycin resistance in the MRSA strains. Bactrim and Tetracycline are viable antimicrobial options for treating S. aureus in our community.
Virulence and Resistance Trends of *Staphylococcus aureus* in an outpatient military population

COREY FALCON MD, CAPT, USAF, MC
2011 GRADUATE OF SAUSHEC PEDIATRIC RESIDENCY

**Background**

- Community-associated methicillin resistant *Staphylococcus aureus* (CA-MRSA)
- *mecA*,
- *TSST-1*
- *mupA*
- Panton-Valentin leukocidin (PVL)
- *lukS-PV & lukF-PV*

**Objectives of Study**

- Determine occurrence of virulence and resistance factors in *S. aureus* infections
- Discover prevalence of Methicillin-resistant *S. aureus*
- Determine USA typing for MSSA and MRSA strains using pulse field gel electrophoresis (PFGE)
- Determine effective outpatient treatment options for MRSA
- Evaluate for significant differences between isolates from children and adults
Materials & Methods

Evigene®:
- qualitative nucleic acid hybridization assay
- Results in 3 hours

Results

- 200 S. aureus isolates
- Tested each isolate for meca, mupA, Tsst-1, and lukS-lukF-PV (PVL) genes
- Positive and negative controls

Materials & Methods Part #2

- meca, tsst-1, mupA, and PVL PCR confirmatory test
- Broth microdilution and E-test for Mupirocin resistance
  - 8 mupA + and 22 controls
- Pulse field gel electrophoresis for 3A typing
Results #2

- **mecA** and **tst-1** PCR and Evigene correlate
- 7 of 8 **mupA** Evigene isolates positive for **mupA** on PCR
- 1 PVL + Evigene isolate negative for PVL on PCR and vice versa
- Majority of MSSA & MRSA type USA 300
Results

- S/7 mupA + PCR demonstrate mupirocin resistance on broth microdilution and E-test

Discussion

- CA-MRSA burden

- Evigene provides reliable, rapid detection of mecA and other virulence factors

- Pediatric isolates similar to adults
Discussion

- Mupirocin resistance
- USA type 300
- Bactrim and Tetracycline
- Clindamycin ???

Future Projects

- Possible utility of Evgene® in deployed settings and basic training
- Correlate laboratory markers of virulence with severity of disease

Contributors

- Ms. Donna Hensley, Civilian, 59th MDW Clinical Research Division
- Lt Col Deena Sutter MD, SAUSHEC Staff, Pediatric Infectious Disease
- Ms. Katrin Mende Ph.D, Civilian Microbiologist, BAMC
- Laboratory Support
  - Yadira Encina and Hermosilla Atamu

Questions?
Automation and Assessment of a Whole Blood Interferon Gamma Release Assay (IGRA) for LTBI Screening: The USAF-CDC TB Collaboration

711HPW/USAFSAM-PHR

Dr. Donald Goodwin

BACKGROUND: In 2006, a USAF-CDC TB Collaboration set out to enhance TB diagnostics. By April 2010 it had automated an IGRA (the QFT-GIT); completed three clinical trials to comparatively assess performance of the QFT-GIT with the TST; and, completed enabling SBIR software development efforts.

METHODS: The USAF led, multiple-sector, multiple-site, multiple-partner collaboration established laboratories at USAFSAM and at CDC’s Division of TB Elimination. Private sector partners were engaged with CRADAs and contracts. Three IRB approved clinical trials were subsequently completed. Centralized IT support enabled coordinated quality assurance monitoring which optimized data quality and analytic efficiencies. Use of on-site coordinators, weekly conference calls, periodic site visits, and data/specimen exchanges enabled synchronization of efforts, validation of observations, and timely problem solving.

RESULTS: Trial #1 automated the QFT-GIT and produced an experience-refined testing protocol used to support mass LTBI screening among 2,367 USAF basic military trainees. Problems identified in Trial #1 were addressed in Trials #2 and #3.

Trial #2 assessed reproducibility of the TST and QFT-GIT (automated and manual) and measured impacts attributable to: specimen collection; antigen mixing; processing variability; diurnal variation of IFN-Ɣ concentrations; serial testing; and, inter-laboratory variability (USAF, CDC, and Tripler AMC). Test concordance/discordance was described; and, boosting with serial testing assessed.

Trial #3 documented specimen volume variability impacts on clinical results, and a work-around assessed.

DISCUSSION: Assessments considered both statistical and clinical significance. The SBIR effort yielded a 21 CFR Part 11 compliant, automation-facilitating software usable on any automated ELISA platform for producing validated, electronically reportable QFT-GIT results.
Automation and Assessment of a Whole Blood Interferon Gamma Release Assay (IGRA) for LTBI Screening: The USAF-CDC TB Collaboration

MEASUREMENTS FOR 1 QFT-GIT: MANUAL DETERMINATION

1. Place blood sample into an IFN-gamma releasing assay system.
2. Add 100 μl of PPD antigen (10 ng/ml), 100 μl of control antigen (10 ng/ml), and 100 μl of blank solution (100 μl water) to each tube.
3. Incubate at 37°C for 16-24 h.
4. Measure IFN-gamma levels using an IFN-gamma release assay system.
5. Determine the presence or absence of a positive response.

TOTAL # of Measurements: 121

MEASUREMENTS FOR 1 QFT-GIT: AUTOMATED DETERMINATION

1. Place blood sample into an automated IFN-gamma release assay system.
2. Add 100 μl of PPD antigen (10 ng/ml), 100 μl of control antigen (10 ng/ml), and 100 μl of blank solution (100 μl water) to each tube.
3. Incubate at 37°C for 16-24 h.
4. Measure IFN-gamma levels using an automated IFN-gamma release assay system.
5. Determine the presence or absence of a positive response.

TOTAL # of Measurements: 107
USAF-CDC TB TRIAL #1: QFT-GIT AUTOMATION - Methods Overview

(FW/DEG/OE/DH, Maj. Dr. E. Goodwin, Dr. G. Mazurek)

OBJECTIVE: To automate the ELISA reading using a Triturus analyzer; to compare the TST versus the QFT-GIT in a mass screening setting.

STUDY SUBJECTS: 2,374 Basic Military Trainsees (BMT) at Lackland AFB.

METHOD: Used both TST & QFT-GIT to screen BMTs for LTBI; included completion of an epidemiological questionnaire. IRB-approved protocol.

QFT-GIT: RESULTS INTERPRETATION

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Nil</th>
<th>TB Response*</th>
<th>Mitogen - Nil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Nil</td>
<td>≥ 3.50 IU/mL and ≥ 25% of Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Negative</td>
<td>Nil</td>
<td>&lt; 3.50 IU/mL or &lt; 25% of Nil</td>
<td>≥ 0.5</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>Nil</td>
<td>&lt; 3.50 IU/mL or &lt; 25% of Nil</td>
<td>&lt; 0.5 Low Mitogen</td>
</tr>
</tbody>
</table>

*TB Response* is the IFN-γ concentration in plasma from blood stimulated with ESAT-6, CFP-10, & TB7.7, minus the IFN-γ concentration in plasma from unstimulated blood.
**USAF-CDC TB TRIAL-1: RESULTS**

**TST & QFT-GIT SPECIFICITY**

Limited to low-risk BMTs (Assumed not to have been infected)

- TST < 10 mm for 1,617 of 1,626 = 99.4%* (specificity)
- TST > 10 mm = 6/1,626 = 0.35%
- QFT-GIT < 0.35 IU for 1,503 of 1,588** = 93% (specificity)
- QFT-GIT ≥ 0.35 IU = 85/1,588 = 0.31%

*Difference is not statistically significant

**USAF-CDC TB TRIAL-1: RESULTS**

**TST & QFT-GIT ConCORDANCE/DISCORDANCE**

Evaluated: 2,076 (includes those with out-of-range volume and those with increased TB risk)

<table>
<thead>
<tr>
<th>Concordance</th>
<th>TST pos/QFT-GIT pos</th>
<th>1 (0.05%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TST neg/QFT-GIT neg</td>
<td>2,067 (99.08%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discordance</th>
<th>TST pos/QFT-GIT neg</th>
<th>13 (0.62%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TST neg/QFT-GIT pos</td>
<td>5 (0.24%)</td>
</tr>
</tbody>
</table>

Total 14 2,080 2,066

QFT-GIT/TST OR\(_{adj}\) = 0.427 (95% CI: 0.164 - 1.114)

57% fewer screen-positives with the QFT-GIT.

**USAF-CDC TB TRIAL-1: RESULTS**

**QFT-GIT Volume Problem Documented**

**BLOOD COLLECTION VOLUMES**

- In-Range Volumes (6.0 to 1.2 mL) 1,488 (62.3%)
- Out-of-Range Volumes* (<0.6 mL or >1.2 mL) 586 (37.3%)
- TOTAL 2,374

*INDETERMINATE tests (n=50) associated with out-of-range volumes.

**USAF-CDC TB TRIAL-2: Reproducibility**

**Objective & Methods Overview**

(FWDC1059828, PI: Dr. K. Weal, Dr. G. Mazurak)

**OBJECTIVE:** To compare QFT-GIT & TST performance under conditions that might impact test results.

**STUDY SUBJECTS:** 156 persons with a history of a positive TST.

**METHOD:** 6 visits; 12 QFT-GIT tests (36 tubes) & 3 TSTs; IRB approved.
METHODS

QFT-GIT performed as follows unless stated otherwise:

1. 1 ml of blood collected 8 a.m. to 9 a.m.
2. Mixed on “Rock & Roll” mixer and incubated for 1 h.
3. Incubated for 23 to 24 h at 37.0 ± 1.0 °C.
4. Centrifuged and stored at 6.0 °C.
5. ELISAs performed with automated ELISA analyzer within 24 h.
6. Interpreted as per CDC guidelines.

TST performed with Tuberculin PPD:

1. Incubation at 48 to 72 h.
2. Interpreted as + if ≥ 10 mm.
3. Different people placed and read TST on left and right.
4. Same person placed and read 1st and 2nd TST.

Research Questions & Results

1. What is the interassay QFT-GIT variability when performed with an automated ELISA analyzer?
   - **Method:** QFT-GIT performed as follows:
     - 1 ml of blood collected 8 a.m. to 9 a.m.
     - Mixed on “Rock & Roll” mixer and incubated for 1 h.
     - Incubated for 23 to 24 h at 37.0 ± 1.0 °C.
     - Centrifuged and stored at 6.0 °C.
     - ELISAs performed with automated ELISA analyzer within 24 h.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from 2 ELISA runs (p = 0.04)

2. What is the interassay QFT-GIT variability when performed manually?
   - **Method:** QFT-GIT performed as follows:
     - 1 ml of blood collected 8 a.m. to 9 a.m.
     - Mixed on “Rock & Roll” mixer and incubated for 1 h.
     - Incubated for 23 to 24 h at 37.0 ± 1.0 °C.
     - Centrifuged and stored at 6.0 °C.
     - ELISAs performed with automated ELISA analyzer within 24 h.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from 2 ELISA runs (p = 0.04)

3. What is the interassay QFT-GIT variability between automated vs. manual methods?
   - **Method:** QFT-GIT performed as follows:
     - 1 ml of blood collected 8 a.m. to 9 a.m.
     - Mixed on “Rock & Roll” mixer and incubated for 1 h.
     - Incubated for 23 to 24 h at 37.0 ± 1.0 °C.
     - Centrifuged and stored at 6.0 °C.
     - ELISAs performed with automated ELISA analyzer within 24 h.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from automated and manual ELISAs (p = 0.04)

4. What is QFT-GIT variability using blood collected 1 wk apart?
   - **Method:**
     - Blood collected 1 wk apart.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from automated and manual ELISAs (p = 0.04)

5. What is QFT-GIT variability using blood collected in morning vs. evening?
   - **Method:**
     - Blood collected in morning vs. evening.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from automated and manual ELISAs (p = 0.04)

6. What is QFT-GIT variability using blood incubated at 37.0 °C vs. 35.0 °C?
   - **Method:**
     - Blood incubated at 37.0 °C vs. 35.0 °C.
     - Interpreted as per CDC guidelines.
   - **Result:**
     - No significant difference between TB response from automated and manual ELISAs (p = 0.04)
Research Questions & Results

7) What is the effect of delaying blood inoculation on QFT-GIT results?
   - Concordant: 21
   - Concordant agreement: 33.7% (Kappa = 0.17)
   - Discordant: 21
   - Discordant agreement: 56.6% (Kappa = 0.81)
   - Intra-class correlation: 0.15
   - Between-subject standard deviation = 0.89
   - Significant boost if blood inoculation is delayed for 11-12 h

8) What is the effect of shorter blood inoculation on QFT-GIT results?
   - Concordant: 21
   - Concordant agreement: 56.6% (Kappa = 0.81)
   - Discordant: 21
   - Discordant agreement: 33.7% (Kappa = 0.17)
   - Intra-class correlation: 0.15
   - Between-subject standard deviation = 0.89

What is the effect of injecting PPD for TST on subsequent QFT-GIT results?
   Significant "boosting" of QFT-GIT results.

Concordance:
- PPD/Prep: 30 (23.5%)
- PPD/Post: 75 (52.1%)

Disconcordance:
- PPD/Prep: 39 (28.3%)
- PPD/Post: 1 (0.7%)

Kappa = 0.43 (95% CI 0.34-0.56)
McNemar’s p = <0.0001

Research Questions & Results

9) What is the interassay variability in simultaneous TSTs on right vs. left arms?
   - Concordant: 21
   - Concordant agreement: 81.7% (Kappa = 0.69)
   - Discordant: 21
   - Discordant agreement: 33.7% (Kappa = 0.17)
   - Within-subject standard deviation = 1.35 mm
   - No significant difference in TSTs on right and left arms, p = 0.10

10) What is the interassay variability when TSTs are performed 1 wk apart?
    - Concordant: 21
    - Concordant agreement: 81.7% (Kappa = 0.69)
    - Discordant: 21
    - Discordant agreement: 33.7% (Kappa = 0.17)
    - Within-subject standard deviation = 1.3 mm
    - Highly significant difference in TST responses, p < 0.0001

Demonstrated boosting of PPD TST by 56% in patients with negative initial TST become positive.

11) What is the effect of injecting PPD for TST on QFT-GIT performed 1 wk later?
    - Concordant: 39
    - Concordant agreement: 72.7% (Kappa = 0.62)
    - Discordant: 30
    - Discordant agreement: 25.6% (Kappa = 0.17)
    - Within-subject standard deviation = 1.35 mm
    - Boosting effect seen in TST responses, p = <0.0001

Demonstrated boosting of QFT-GIT by TST. 34% of those with negative initial QFT-GIT became positive.

USAF-CDC TB TRIAL-2: Reproducibility
Research Questions & Results

What is the effect of injecting PPD for TST on subsequent QFT-GIT results?
Significant "boosting" of QFT-GIT results.

Concordance:
- PPD/Prep: 30 (23.5%)
- PPD/Post: 75 (52.1%)

Disconcordance:
- PPD/Prep: 39 (28.3%)
- PPD/Post: 1 (0.7%)

Kappa = 0.43 (95% CI 0.34-0.56)
McNemar’s p = <0.0001

USAF-CDC TB TRIAL-3: Volume Study

OBJECTIVES:
- To assess the implications of out-of-range specimen volumes.
- To assess the effects (if any) of antigen: blood mixing methods.

STUDY SUBJECTS: 104 Wilford Hall Medical Center healthcare workers with a documented history of a positive TST.

METHOD: (next slide) IRB-approved research protocol.
USAF-CDC TB TRIAL-3: Volume Study
Methods Overview

**Rolling-Rocker mixer:**
- 10 mL
- 5 mL
- 1 mL
- 5 mL
- 10 mL
- 5 mL

**Heparin:**
- 300 U
- 10 mL

**Stirrer:**
- 0°C

**Paperwork:**
- Consent, HIPAA release.

(continued on next slide)

---

Research Questions & Preliminary Results

1) **What is the effect of mixing by shaking vs. rolling an QFT-GIT?**
   - **Correlation:** 0.697
   - **Agreement:** 90%
   - **Within-subject standard deviation:** 0.016
   - **No significant difference:** if blood shaken or mixed by “Roll & Rock” mixer.
   - **p < 0.05**

2) **What is the effect of transferring blood from a heparin tube to a QFT-GIT?**
   - **Correlation:** 0.679
   - **Agreement:** 80%
   - **Within-subject standard deviation:** ± 0.016
   - **No significant difference:** if blood is transferred from heparin to the QFT-GIT.
Research Questions & Preliminary Results

3) What is the effect of blood volume on IFN-γ in TUB tube of QFT-GIT?
   - $r^2 = 0.724 (P < 0.001)
   - Within subject observed deviations: ± 0.01 ng/mL
   - Significant range: IFN-γ in TUB tube if blood volume is 4.8 mL vs. 1.2 mL, $p = 0.02$.

4) What is the effect of blood volume on IFN-γ in NIL tube of QFT-GIT?
   - $r^2 = 0.312 (P < 0.001)
   - Within subject observed deviations: ± 0.01 ng/mL
   - Significant range: IFN-γ in NIL tube if blood volume is 1.8 mL vs. 1.2 mL, $p = 0.02$.

5) What is the effect of blood volume on TUB response of QFT-GIT?
   - $r^2 = 0.274 (P < 0.001)
   - Within subject observed deviations: ± 0.01 ng/mL
   - Significant range: TUB response if blood volume is 4.8 mL vs. 1.2 mL, $p = 0.02$.

Effect of Blood Volume on IFN-γ in TUB Plasma: Lower Volumes Yielded Higher Concentrations

Effect of Blood Volume on IFN-γ in NIL Plasma: Lower Volumes Yielded Higher Concentrations

Effect of Blood Volume on TUB Response: Lower Volumes Yielded Higher Concentrations
**USAF-CDC TB TRIAL-3: Volume Study**

**Research Questions & Preliminary Results**

What is the effect of volume on QFT-GIT results when comparing 0.5 to 1.5 ml?

<table>
<thead>
<tr>
<th>Concordance* (84.0%)</th>
<th>0.5 ml</th>
<th>1.5 ml</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 Pos/1.5 Pos: 10 (13.3%)</td>
<td>QFT-GIT pos</td>
<td>QFT-GIT neg</td>
<td>19</td>
</tr>
<tr>
<td>0.5 Neg/1.5 Neg: 53 (76.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discordance* (16.0%)</th>
<th>0.5 ml</th>
<th>1.5 ml</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 Pos/1.5 Neg: 9 (12.0%)</td>
<td>QFT-GIT pos</td>
<td>QFT-GIT neg</td>
<td>3</td>
</tr>
<tr>
<td>0.5 Neg/1.5 Pos: 3 (4.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Kappa = 0.53 (0.30-0.76)

**USAF-CDC TB TRIAL-3: Volume Study**

**Volume Problem Mitigation**

- **VOLUME PROBLEM VERIFIED**: QFT-GIT results may change as an artifact of the volume of blood used.

- **MITIGATION**: Control volume by using an indirect collection method.

- **MIXING - NO PROBLEM**: QFT-GIT results did not vary by mixing method, so either method is acceptable.

**Phase I (N=3):** Software concept

- Convert ELISA outputs into clinically interpretable results.
- Verification standards and QA performance.
- Model decision curve options.

**Phase II** (Coladon Laboratories, Hyattsville, MD; completed 16 Jan 2010)*

- Software developed, models built and tested, refinements made.
- Collaboration facilitated reporting of clinical results to medical record.
- Will work on any automated ELISA platform.

* IMMUNO-AT: http://www.coladonlabs.com/protocol_immune-at.htm

**USAF SBIR: Automation Enabling Software Development**

(FA8650-08-C-0071, SBIR Mgr: Dr. D. Goodwin)

**INTERLABORATORY VARIABILITY**

**OBJECTIVE**: To assess interlaboratory variability of the QFT-GIT.

**STUDY SUBJECTS**: 97 previously TST positive subjects at 2 sites.

**METHODS**:

- Blood drawn into 3 sets of QFT-GIT and incubated together.
- 1 set held at site, 2 sent to other labs (Brooks C-B; Tripler AMC; CDC).
- Automation ELISA performed 13-15 days later in 3 labs.
- 12 (12%) subjects found to have discrepant results:
  - 5 due to data entry errors (Tripler used manual reporting)
  - TB response for 6 within 0.25 IU/mL of cutoff (Tripler: 4 std vs CDC & USAF 8 std calibration curve, and within subject variation near assay cutoff)
  - Variability increased with increasing mean IFN-γ
USAF-ARMY-CDC INTERLAB VARIABILITY

Variability increased with increasing mean IFN-γ for both Nil and TB. Differences in Nil and TB were frequently in different directions.

*Whitworth, Hamilton, Goodwin, Campbell, Barnes, Rodner, Daniels, Chiu, & Naukak (2011). Within Subject Inter-Lab Variability of QFT-GIT Test Results.

USAF-CDC TB COLLABORATION: Summary of Accomplishments

- Successfully automated the QFT-GIT & produced a standard protocol.
- Compared performance of TST & QFT-GIT in a mass screening setting.
- Documented degree of TST & QFT-GIT concordance/discardance.
- Documented specificity for both TST & QFT-GIT (BMT screening).
- Documented reproducibility under a variety of scenarios.
- Documented impact of specimen volume on clinical results.
- Recommended mitigation methods for volume problems (2-step).
- Documented similarity of results using two antigen mixing methods.
- Documented interlab variability and identified sources of variation.
- Documented automation enabling software for electronic validation & report.
- Enabled USUHS-Army-CDC-USAF IGRA-TST assessment.
- Shared results with JPMIP to inform DoD TB screen & testing policies.

AFRL

SBIR OSD11-H05 (OSDDHF): Development of an Alternative Screening Method for Detecting Evidence of M. tuberculosis Infections

Thank you!

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Chief Scientist, USAF/AFRPH
Wright-Patterson AFB, OH
Donald.Goodwin@USAF.mil
Tel: 937.928-0416

*Whitworth, Hamilton, Goodwin, Campbell, Barnes, Rodner, Daniels, Chiu, & Naukak (2011). Within Subject Inter-Lab Variability of QFT-GIT Test Results.
How to Get Your Survey Approved

Lou Datko/Panel
Air Force Survey Office

No Abstract
What is Attitude and Opinion Research?

- Any methodology investigating, but not limited to, an individual's thoughts, feelings, impressions, agreement, satisfaction or interpretation of an event, policy, or phenomenon obtained through...
- Climate Assessments
- Polls
- Focus Groups
- Telephone Interviews
- Questionnaires and Surveys
- Program Evaluations (Active Duty Military/Civilians)

Targeted Population

- Use appropriate sample size
- Minimum number to represent population
- No contract employees
- Spouses, dependents, retirees are included
- Surveys to non-mil members require OMB coordination

AF Survey Program Mission

- Monitor and conduct attitude and opinion surveys
- IAW AFI 38-501, AF Survey Program
- AF representative IAW DoD 100-13, Surveys of DoD Personnel
- In CY 2010, reviewed 187 AF-wide survey requests
- Disapproved 51 – cost avoidance $500K, 13K man-hours
- Only Air Force agency with authority to manage and control surveys of Total Force members
- One of few survey hosting sites with DoD Certification and Accreditation (dot mil servers)
**Survey Questions/Topics**

- Should not be sensitive in nature, objectionable, or in bad taste
- Should not require a lot of time and effort to respond
- Should be grammatically correct and easily understood by respondents
- Likert-type response scales should be balanced – equal number on both sides of neutral point

**Exemptions**

- AF/AIP
  - Psychological/character assessments
  - Installation Commander (base-level or below)
  - If issues are within their control/purview
- AFAG
  - Surveys in conjunction with inspections
  - HQ AETC Occupational Measurement Division
  - Task Inventories and SKT Construction
  - Base-level customer satisfaction

---

**Survey Control Number Process**

Any type of research/questions to investigate attitudes and/or opinions of any AF member must go through SCN process

- Fill out SCN form
- Important! How will results be used?
- Submit questions for review
- Proof of Pentagon sponsorship
  - Must include all HAF sponsors if “crossing lanes”
- AF IRB submission, if required
- OPSEC, FOIA, Privacy Act, and non dot mil administration are sponsor’s responsibility
- 20 working days to review requests
- No student research

**AF IRB Process**

- IRB vs. AF Survey Review
  - Purpose of the IRB is to protect the individual involved in human research
  - Purpose of AF Survey Review is to protect the Air Force agencies involved in organizational research

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1.5M Targeted Annually
Sample AF Survey Topics

Approved CY 2011

<table>
<thead>
<tr>
<th>Topic</th>
<th>FY 11 AF Topic Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes in the Military</td>
<td>Immunization</td>
</tr>
<tr>
<td>Professional Development</td>
<td>Golf Loyalty</td>
</tr>
<tr>
<td>Performance Feedback</td>
<td>Uniform</td>
</tr>
<tr>
<td>Enlisted Aide Utilization Training</td>
<td>First Sergeant Utilization</td>
</tr>
<tr>
<td>Officer/Enlisted New Directions</td>
<td>IDEA Program</td>
</tr>
<tr>
<td>Smokes Tobacco Use</td>
<td>Airmen Resiliency Training</td>
</tr>
<tr>
<td>Field Evaluation Questionnaires</td>
<td>Where Airmen Get Information</td>
</tr>
<tr>
<td>Boston Globe</td>
<td>Alumni &amp; Student Supervisor</td>
</tr>
<tr>
<td>Post Event/Implementation</td>
<td>Combat Shield Assessment</td>
</tr>
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</table>

Survey Projects

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<tr>
<th>Title</th>
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<td>Customer Service Feedback</td>
</tr>
<tr>
<td>Tricare Inpatient/Outpatient</td>
<td>Recruit Oral Health</td>
</tr>
<tr>
<td>Post Deployment Health</td>
<td>Wounded, Ill and Injured Support</td>
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<td>Life After Deployment</td>
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Sample DoD Survey Topics

Active in CY 2011

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Health Related Behaviors

http://www.dmdc.osd.mil/surveys
**Issues**

- Survey research conducted without approval
- Lack of appropriate AF level sponsor
- Repeated survey questions on same topic and/or subject
- Survey overload is reducing participation rates for legitimate and needed surveys
- Contracts awarded and funded before surveys are approved
- Surveys hosted on non dot mil domain
- Requirement for digital signature on email invitation
- Protection of data
- Samples too large

Survey demand continues to grow dramatically!

**AF Senior Leader Guidance**

- SECAF
  - Initiative to reduce airmen's time spent on non-mission related workload
- CSAF
  - AF members experiencing survey fatigue/overload
  - Reduce number of surveys

**AF Survey Summit**

- SECAF/CSAF requested AFMA lead effort to reduce surveys
- Conducted Survey Summit in Jul 11 to reduce survey footprint
  - Met with survey principles from SAF/GCM, SAF/PAX, SAF/A&LON, AF/1A1, AF/SE, USAF A and AFIT
- Summit Purpose
  - Eliminate non-value added surveys
  - Encourage survey approval prior to contract/grant
  - Reduce outside entities (contracts, grants, etc.)
  - Encourage agencies to share existing survey results
  - Explore alternatives for collecting information and solving problems
  - Avoid duplication of topics thru improved coordination of HAF level functional managers; schedule large-scale surveys to avoid overlap
- Working follow-on action items
  - Policy, communication, exemptions, consolidation, cost savings
  - Recommendations will be provided to AF senior leadership Sep/Oct

**Survey Office Contact Info**

Air Force Manpower Agency
Performance Management Division
Performance Planning Branch
Air Force Survey Office
Randolph AFB, TX
af.surveys@us.af.mil
DSN 487-4773
Commercial 210-652-4773
Air Force AF Portal Web Link:

**Integrity - Service - Excellence**