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INTRODUCTION:

The study is designed to test a community intervention that adheres to the Department of Defense clinical practice guidelines on tobacco use cessation. Originally, this study was developed to evaluate the efficacy of an intervention on smoking prevalence in the Air Force, Navy, Marines, and Army.

However, after numerous administrative delays which were out of the control of the project team (discussed below) and with the consent of the project funding agency, the Navy and Marines were removed from the study. In order to maintain the scientific integrity of the research, additional sites were selected from the Air Force and Army, for a total of eight sites from each branch. The project intervention combines state-of-the-art components from community trials with empirically supported clinical interventions to form a unique, comprehensive tobacco control program for military installations.

BODY:

At the end of the third year of the study, several milestones have been achieved which will benefit the military's efforts to reduce tobacco use. The following is a summary of our significant accomplishments to date.

1. Development and initial evaluation of tools and products which will be given to the DoD.

- a. DoD Comprehensive Community Tobacco Plan. The plan includes detailed guidance and resources for intervention in the following areas: (i) leadership and policy; (ii) community action teams, (iii) primary care and dentistry, (iv) junior enlisted, (v) community based tobacco intervention training, and (v) social marketing. The plan was developed with input from military leaders and tobacco control scientists and has been field tested on 2 military bases. This plan has the potential of forming the basis of tobacco control programs for military installations worldwide.
- b. A tailored website which houses resources including (i) articles addressing tobacco, (ii) power point presentations and speakers note's, (iii) access to a listserv, (iv) links to important tobacco web sites, (v) project materials, and (vi) links to emails of project investigators. Currently the website is password protected. However, it will be opened to all DoD personnel at the conclusion of the study. This website promises to serve as a valuable resource for military tobacco control efforts.
- c. A tailored training program consisting of three modules: (1) a set of "awareness raising" briefings – over 500 slides total; (2) A "Intervention and Referral" 2-hour skills building course, and (3) "Motivation and Assist" 2 hour skills building course.

2. We have successfully implemented the project at 4 Air Force installations (Whiteman, Tinker, Minot, and Hill). Progress has been made in each of the six areas of intervention outlined in the community plan. Key accomplishments have included:

- √ Reducing tobacco use a clear priority for installation
- √ An increase in the number and quality of tobacco related newspaper articles and information materials
- √ Medical personnel and leadership more keenly aware of DoD Tobacco Practice Guidelines
- √ Increased number of brief interventions occurring in primary care
- √ Engaging junior enlisted in tobacco control efforts
- √ Securing the consultation of media/marketing experts to design social marketing efforts which convince junior enlisted that tobacco use is inconsistent with military service

- √ Hundreds of installation personnel trained in brief tobacco interventions and tobacco control advocacy
- √ Highly visible leadership support for tobacco control efforts
- √ Produced a large volume of tobacco control briefings, tailored materials, informational sheets, and clinical materials for installation personnel
- √ Whiteman AFB established a walk-in clinic for smokers in primary care
- √ Sponsored conferences at military installations focusing on tobacco control

3. We negotiated and secured pharmacotherapy from pharmaceutical industry to support increased military installation interventions. We have developed an algorithm for ordering, shipping, and distribution of the both the nicotine gum and the nicotine patch.

4. Secured funding from the American Legacy Foundation to add an additional component to the study which will develop a marketing campaign targeting 18-24 year olds in the military. This additional funding allows us to conduct focus groups with several groups of individuals in order to identify key themes for our marketing campaign. Approval for these focus groups is pending, but is expected to occur within the month. Once approval is obtained, we will schedule these focus groups and begin immediately, as we have already developed the materials.

5. Successful recruitment of the following military installations into the study:

Table 1: Military Installations Selected for the STAR Project

Installation	First	Last	Phone	Email
Hill AFB	Carolyn S.	Bennett	801-777-1215	carolyn.bennett@hill.af.mil
Tinker AFB	Brenda	Irwin	405-734-5505	Brenda.irwin@tinker.af.mil
Whiteman AFB	Janet	Rudderham	660-687-1199	Janet.Rudderham@whiteman.af.mil
Minot AFB	Dianna	Skidmore	701-723-2990	dianna.skidmore@minot.af.mil
Hurlburt Field AFB	Kirk	Tresch	850-884-4292	Kirk.tresch@hurlburt.af.mil
Pope AFB	Nelta	Jean-Pierre	910-394-4292	Nelta.jean-pierre@popo.af.mil
Goodfellow AFB	Karen	Bartholomeo	325-654-5686	Karen.bartholomeo@goodfellow.af.mil
Altus AFB	Jeanine	Hatfield	580-379-5647	Jeanine.hatfield@altus.af.mil
Fort Lewis	Ernie	Stephenson	253-968-2937	erenst.stephenson@nw.amedd.army.mil
Fort Campbell	Kathrine	Richardson	270-956-0100	kathrine.richardson@se.amedd.army.mil
Fort Jackson	Patricia	Hick	803-751-5251	patricia.hick@se.amedd.army.mil
Fort Leonardwood	Cindy	Plank	573-596-0491	cynthia.planl@cen.amedd.army.mil

Fort Carson	Bridget	Minihane	719-526-3848	bridget.minihane@cen.amedd.army.mil
Fort Riley	Jennifer	Fenti	785-239-7520	jennifer.a.fenti@us.army.mil
Fort Wainwright	Vernell	Henderson	907-353-5692	Vernell.henderson@nw.amedd.army.mil
Fort Richardson	Rolland	Cabid	907-384-1401	rolland.cabid@nw.amedd.army.mil

6. Reconnaissance visits to each of the bases to brief leadership and assess tobacco control infrastructure. These trips were conducted with the experimental Navy and Marine sites in order to expedite the implementation of the intervention in January of 2003. Currently we are in the process of making these trips for the Army and newly identified Air Force sites. These trips included introduction to the community plan, motivating bases about the project, identifying the main point of contact, briefing the command, and touring the base. The presentation of the community plan was tailored to be service-specific. No intervention components or assessment instruments were implemented during the visit – it was informational and motivational only. We have learned that given the very long delays which occur from base recruitment until IRB approval, significant loss of installation motivation for the study occurs without the reconnaissance trips.

7. Publications and presentations at national and international scientific conferences.

1. Taylor, J.E., Poston, W.S.C., Pyle, S.A., Haddock, C.K., Lando, H., & Talcott, W.G. How well do health care providers document tobacco use? A Review of Medical and Dental Charts from the Air Force. *Proceeding of the 12th World Conference on Tobacco or Health*.
2. Lando, H., Haddock, C.K., Talcott, G.W., Schmidt, L.A., Muramoto, M.L., Xaverius, P.K., Poston, W.S.C., & Taylor, J.E. (November 2002). Department of Defense Comprehensive Tobacco Intervention Program: Project STAR. *Proceedings from the 2002 National Conference on Tobacco or Health, San Francisco, CA*, p. 128.
3. Lando, H., Xaverius, P., Haddock, C., Poston, C., Talcott, G., Schmidt, L. A comprehensive approach to reducing tobacco use among young adults in the military. Presidents' Symposium: Tobacco use by young adults: Challenges and opportunities for intervention. Society for Research on Nicotine and Tobacco, New Orleans, LA, February 2003.

8. Comprehensive media analysis of tobacco control messages on 24 military bases over 2 years (includes the Navy and Marine bases in addition to the newly selected sites). Using a structured and reliable coding system, we conducted a content analysis of health information in 12 military installation newspapers. We will continue this analysis in the newly recruited installations. This information will be used as process data to determine if the project impacts how tobacco-related information is disseminated. Table 2 provides information about the number of papers coded to date.

Table 2: Base newspapers coded to date

AIR FORCE	Number of Papers Coded	Publication Date of First Paper Coded **	Publication Date of Last Paper Coded **
Tinker Take Off	53	12/08/00	12/21/01
Whiteman Spirit	47	1/12/01	12/21/01
Northern Star	51	12/1/00	12/21/01
Hilltop Times	52	1/11/00	12/20/01
Total # of Air Force Papers Coded	203		
NAVY			
The Golden Eagle	49	1/4/02	12/20/02
The Dolphin	48	1/10/02	12/05/02
The Newport Navallog	45	1/4/02	1/10/03
The Jax Air News	45	1/24/02	
Flightline Aircraftsman*	27	8/8/01	10/24/02
Foc'sle*	20	1/11/02	10/2/02
Total # of Navy Papers Coded	234		
MARINES			
The Windsock	51	8/23/01	5/30/03
Observation Post	47	12/21/01	1/22/02
Total # of Marines Papers Coded	98		
Total newspapers Coded	535		

*Published bi-Monthly

** Month/day/year

In addition to the above milestones reached during year three, several conferences were hosted throughout the year to unite key researchers and discuss critical components of the project. These conferences included convening key members of the research team in November 2002 in San Francisco, CA during a conference to discuss progress to date and issues with the Navy and Marine IRB process. In December 2002 the entire research team met at Tinker AFB in Oklahoma City, OK to discuss the project and to see "first hand" how it was going. In February 2003, a group of key investigators discussed the project to date at a conference and presented a talk on the junior enlisted plan.

In the ongoing effort to monitor the progress of the grant, military and research representatives participate in a weekly teleconference.

Barriers to Research Accomplishment

Our project has experienced very significant delays which disabled us from implementing the project in any reasonable timeframe. The following provide an overview of these delays:

(1) September 11, 2001

- A DoD wide video teleconference was scheduled to unveil and discuss the new clinical practice guidelines for tobacco cessation within the military. This teleconference was rescheduled several months later due to the attacks on Sept. 11th

(2) IRB Demands

- In general every IRB that we have worked with to date, with the exception of Wilford Hall, has made demands (i.e. demands that are unrealistic and go well beyond the main responsibility of an IRB (i.e. human subject protection) and that has caused major delays for the project.

(3) Obtaining Addresses for Participant Surveys

- The process was extremely cumbersome and time consuming (i.e. numerous contacts and approvals were necessary) even though the project and the process were approved by the DoD.
- The data use agreement process was unnecessarily complex.
- The agency providing the participant addresses was overly cautious by only allowing one (1) person a total of 48 hours to abstract addresses based on our selection criteria. This task could have easily taken two weeks for a full-time person.
- The information we were provided was not the most accurate (even though we were promised accurate information). For example, at one of the installations, addresses were given for a dorm that had been torn-down almost a year earlier.

(4) Baseline Survey

- Initially, Fort Detrick wanted signed and witnessed informed consent. After several months (approximately 8 months) of debate, the IRB recognized that this demand would render the project unfeasible.
- At the IRB's request, the cover letter accompanying the baseline survey stated that "response could be reported to your supervisor." This statement contributed to the unusually low response rate among active duty personnel. After over a year of discussion with the IRB and DoD legal counsel, it was recognized that this statement could not be upheld and therefore it could be removed from the cover letter.

(5) General Fort Detrick IRB Issues

- Our original POC changed and it took several months to be notified that she was no longer serving as our POC. In addition, it took several months (approximately 6) to find a replacement POC for the project.
- Notification of the IRB's action regarding the submission of materials generally takes considerable time.
- We have sent materials for the IRB's consideration via FedEx (which were received according to FedEx) that were misplaced by the IRB. Upon our querying as to the status of the materials, we were informed that the materials were never received. During this time lag, there were two IRB meetings. The materials were immediately resent.

(6) Navy IRB

- All of the sites had to be selected prior to submitting the application to the IRB
- We were eventually informed that there were three separate IRB's for the installations that were chosen to participate in our study (Bethesda, San Diego, and Portsmouth).
- We were also told that obtaining approval from Bethesda was the first step and that the other IRB's would grant approval based on Bethesda's Approval
- An initial meeting between the PI and the Bethesda IRB was originally scheduled for July 02. However, a few weeks before this meeting was to occur, it was postponed by the IRB until September 02.
- At the September 12, 02 meeting, we were informed that there would be a few minor stipulations, but that essentially the study was approved. The IRB specifically praised the scientific merit of the study.
- However there were several "administrative items" before final approval could be granted.
- These "administrative items" were given to us in a linear fashion. For example, we were told that we needed some internal IRB paperwork completed by the bases (i.e. verification worksheets, an endorsement memo, a Resource request, NIH training certificates, and CV's). Once these were submitted, CRADA's and DoD Assurances were requested. Please keep in mind, all of these approvals were being requested in addition to the approvals we have already received (i.e. the DoD, the installation commander, etc.).
- This process continued for more than 1.5 years until we were granted permission by Fort Detrick to drop the Navy and Marines from the study.
- Inability to obtain IRB approval in a reasonable time frame was also experienced at the other Navy IRBs.
- Considerable project time and staff salaries were used during this process.

(7) Army

- Delays in getting initial recruitment letter out due to several reasons:
 - Change in POC due to PSCing.
 - Leadership turnover
 - Setting a precedent in who has the authority to sign the necessary documents.
- It took approximately 6 months for this letter to be signed and sent out.
- Could not go forward to an IRB until the sites have been selected.
- There was a poor response to our initial attempt at recruiting sites, so a more pro-active approach was undertaken and a sufficient number of sites were recruited.
- These delays cost considerable project time and resources.

(8) War and Deployment

- The Air Force sites slowed involvement with the project due to deployments and the Iraq war.
- IRB approval and base recruitment were significantly slowed due to involvement in the Iraq war.

(9) Final Comments

- We would like to note that we are required to approach each step in sequential fashion. For instance

- We cannot approach IRBs until we have all the bases agreement to participate
- We cannot go to Fort Detrick for overall approval until we have all of the service specific IRB approvals despite the fact that it is a common protocol
- We are at the end of our originally approved study and thus far we have been allowed to do our baseline survey in only one service.
- Of particular interest is the fact that we have spent more time responding to administrative issues and queries than we have been able to spend on conducting the project itself.
- This study was viewed as outstanding by a rigorous scientific review group.
- It was also seen as very high priority for the military.
- No IRB has suggested that the study poses significant risk to human subjects and indeed some IRBs have reviewed the study as exempt.
- It was our goal to demonstrate the effectiveness of a comprehensive tobacco reduction intervention that could subsequently be disseminated throughout the DoD system.
- It is of great importance to us to be able to complete the study in a rigorous and timely fashion.

- Although we have done everything we can to reduce our rate of spending and to obtain additional resources, we will now be forced to seek a substantial extension both in time and money.
- Fort Detrick has granted us a 12-month no-cost extension and has given verbal indication that they will view favorably a subsequent request for an additional 12-month no-cost extension.

REPORTABLE OUTCOMES:

1. Taylor, J.E., Poston, W.S.C., Pyle, S.A., Haddock, C.K., Lando, H., & Talcott, W.G. How well do health care providers document tobacco use? A Review of Medical and Dental Charts from the Air Force. *Proceeding of the 12th World Conference on Tobacco or Health*.
2. Lando, H., Haddock, C.K., Talcott, G.W., Schmidt, L.A., Muramoto, M.L., Xaverius, P.K., Poston, W.S.C., & Taylor, J.E. Department of Defense Comprehensive Tobacco Intervention Program: Project STAR. Presented at the 2002 National Conference on Tobacco or Health, San Francisco, CA, November 19-21, 2002.
3. Lando, H., Xaverius, P., Haddock, C., Poston, C., Talcott, G., Schmidt, L. A comprehensive approach to reducing tobacco use among young adults in the military. Presidents' Symposium: Tobacco use by young adults: Challenges and opportunities for intervention. Society for Research on Nicotine and Tobacco, New Orleans, LA, February 2003.

CONCLUSIONS:

Since the project is still ongoing, we do not offer any conclusions to report at this time. We can suggest, however, that IRB process be made easier to navigate when going through multiple branches of the military. We would specifically suggest convening of a multiservice IRB for projects conducted in more than one branch of the military.

APPENDICES:

None.