Message

From: Melissa Givens [redacted]
Sent: 5/15/2012 3:12:09 PM
To: Daniel Edlin [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=daniel edlin]; melissa.givens@usafricom.mil
CC: Elizabeth Holmes [/o=theranos organization/ou=first administrative group/cn=recipients/cn=eholmes]; Christian Holmes [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=christian holmes]
Subject: RE: Theranos Demo Results

Greetings all,

It has been an extremely busy week for me so I have not had much time to devote to protocol writing.
I figured I can send you a shell of the protocol and let you work on filling in pertinent details while I flesh out the remainder of the protocol.

File attached has some highlighted areas in red where I could use your input - please provide references. I still have to generate the clinical scenarios and survey instruments.

How are things progressing in terms of customs clearance for shipping the cartridges?

I'm excited to get the initial concept down on paper. Not a very sophisticated study but should at least be proof of concept to deploy further systems and collect more robust data.

Regards,
Missy Givens

From: dedlin@theranos.com
To: Melissa.Givens@usafricom.mil; mgivens[redacted]
CC: eholmes@theranos.com; cholmes@theranos.com
Subject: Theranos Demo Results
Date: Wed, 2 May 2012 06:41:30 +0000

LTC Givens,

It was great meeting you this afternoon. Attached to this note are the results from the blood sample we drew. We are happy to answer any questions you might have.
We will be in touch soon with follow up from our conversation today, and we very much look forward to advancing our partnership.

Best regards,
Dan

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Protocol Name: Utility of portable enhanced laboratory device to support SOF forces in austere environments on the African continent

Research site(s): multiple locations within the SOCAFRICA area of operations to include the trans-Sahara region and sub-Saharan east Africa. Research sites will be remote areas occupied by SOCAFRICA forces without endemic medical facilities that meet Western standards.

Sponsor: None

Research Personnel:

Principle Investigator:
LTC Melissa Givens, MD, MPH
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Associate Investigator(s): TBD

1. Background

There is a paucity of Western standard medical facilities in Africa. Laboratories do not meet the certification standards of U.S. labs so it is difficult to know if results are reliable.
Service members deployed to Africa rely on host nation facilities for clinical laboratory evaluation. There is only one MTF on the African continent with clinical laboratory services in Djibouti. Obviously this lab cannot support service members deployed across the continent as the time, travel, and costs would be prohibitive. Currently most of the deployed members in Africa are in extremely austere locations and operate in small teams. The current deployable laboratory capabilities are designed to support much larger units with a significant footprint. Even the Special Operations Resuscitation team which is designed to provide stabilization and diagnostic support for SOF forces brings a significant footprint and logistical requirement that is not appropriate to support small teams.

Because units in Africa have minimal medical support (most often a team medic) it is not unusual for a patient to be transported significant distances to undergo diagnostics tests and receive care. This movement exposes the patient and medical escort to the risks inherent to travel in Africa. It also results in loss of unit capability due to reduced manpower and can also be a significant strain on logistical resources. Unfortunately, even these long evacuations rarely bring the patient to a level of care that is commensurate with Western standards.

Current DNBI data (SOCAFRICA DNBI 2011-12) reveals that host nation laboratory services are required about 3-4 times per week for every 100 service members in an operational environment. Host nation laboratories may or may not conform to regulatory guidelines for laboratory services and there is often not an option to seek out an accredited lab. Results from non-certified laboratories may be unreliable and laboratory error could result in increased morbidity among service members. A false positive test may lead to unnecessary treatment with possible side effects or unnecessary patient movement for further evaluation that exposes the SM to risk. False negatives may result in delayed treatment that can result in worsening of disease. In Africa, delays in care can be particularly devastating due to long evacuation times. Currently, SOCAFRICA practice is to evacuate personnel who require confirmatory laboratory testing when a certified host nation laboratory is not available. Review of 6 months of evacuation data for 100 personnel, revealed that 8 SMs were moved to the closest MTF solely for laboratory evaluation. At an aircraft fuel cost of $240/hr and an aircraft maintenance cost of $600/hr and an average 9 hour round trip flight, transportation costs alone for these 8 patients (using

SOCAFRICA managed air assets) is over $60,000. This cost does not include lost man hours and risks of travel. Once evacuated for further evaluation, the SM may not return to his unit for several days and often it takes over a week to arrange return transport. Forward positioned laboratory capability could decrease patient movement and reduce costs and lost man hours.

Africa is a unique operational environment with significant medical threats and SOCAFRICA forces are often living in working in the most unforgiving environments. The African continent harbors some of the most dangerous infectious disease processes in the world. Many of these diseases are difficult to diagnose without laboratory support as the symptoms are non-specific. Undifferentiated fever is just one example of a diagnostic dilemma that could represent something as simple as a minor upper respiratory illness or a life threatening diagnosis such as malaria or early manifestation of hemorrhagic fever. Because of the life threatening nature of many endemic diseases, it is often necessary to begin empiric therapy pending diagnosis to prevent morbidity and mortality. Unfortunately, empiric therapy can often complicate further diagnostic assessment or may clinically alter the disease progression such that further treatment decisions are compromised. Additionally, many of the pharmaceuticals used to treat high risk disease threat such as PEP for HIV exposure are very expensive. A single bottle of Combivir costs over $900. The ability to provide reliable laboratory testing at remote sites could help minimize the risks and costs of unnecessary medical treatment.

Theranos data pertinent to study: Cost of tests, deployability of system, QA controls, etc

The intent of this study is to establish operational functionality of Theranos laboratory systems and quantify impacts of utilizing these systems at forward deployed locations. If Theranos systems are shown to be operationally effective and have the capacity to improve patient care, reduce costs, and mitigate risks, service members throughout the organization will benefit by further deployment of these devices.

2. Objectives

The primary objective of this study is to deploy the Theranos system to austere locations on the African continent and demonstrate the ability to generate meaningful laboratory data without the physical presence of licensed medical providers to guide medical decisions made through remote consultation.

Secondary objectives include impact of Theranos systems on diagnostic certainty in austere environments, patient movement, patient care costs (to include traditional lab costs, cost of unnecessary treatment, and evacuation costs), treatment decisions, and man hours for lost duty due to patient movement.

Hypothesis: Theranos systems emplaced in austere troop locations on the African continent can effectively generate meaningful laboratory data that can improve diagnostic and treatment decisions, reduce unnecessary patient movement, reduce patient care costs and reduce lost man hours.

3. Study Design

- **a. Study design:** prospective observational study
- b. **Setting:** various austere locations throughout the SOCAFRICA area of operations
- **c. Interventions:**
    - i. Conduct laboratory panel on volunteers to demonstrate operability of equipment in various locations/environments
        1. Standard physical exam tests on 5 volunteers
            a. CBC, chemistry, liver panel, UA, lipids
            b. Will gather survey data on ease of laboratory assessment (likert scale), pain (0-10 pain scale)
    - ii. Conduct scenario based laboratory assessments using Theranos system on volunteers (see attached scenarios and assessment tools) and collect decision

tree data, treatment decisions, and evacuation decisions from on-site personnel and remote consulting medical provider.

1. Adult male with chest pain (1 volunteer)
2. Female with abdominal pain and vaginal bleeding (1 volunteer)
3. Walking blood bank scenario requiring donor screening (5 volunteers)

iii. Mock patient scenario requiring laboratory assessment with subsequent evacuation for confirmatory testing under current system. Scenario will be conducted simultaneously at two independent sites on 2 different volunteers performing the same scenario which would utilize the same laboratory testing facility, with the same level of provider. Data collected to include decision tree, further diagnostics, treatment decisions, and patient movement decisions. Volunteers will be assessed by provider and scenario will drive provider to take patient to host nation laboratory(control patient) or utilize Theranos system(intervention patient). Laboratory assessment will be conducted at host nation lab per provider orders. Photo documentation of encounter will be conducted by study personnel. Laboratory results will drive need for further confirmatory testing requiring patient evacuation for control patient. Medical evacuation processes according to SOCAFRICA SOP will be conducted and volunteer will be moved from assessment site to MTF in Djibouti. Once in Djibouti, laboratory assessment will be conducted appropriate to patient scenario and clinical disposition will be documented. Once laboratory assessment is complete, standard procedures for returning volunteer to duty will be undertaken according to SOCAFRICA SOP. For intervention patient, confirmatory testing will be performed on Theranos system on site and clinical decision tree will be documented. All pertinent timelines and costs will be collected as data points for duration of scenario until patient is returned to original duty station/status.

iv. All laboratory results will be artificially created to represent scenario results so no actual laboratory data will be collected on volunteers. All samples will be collected and run but actual results will not be utilized and destroyed upon reporting.

d. Equipment/instruments:

i. See attached surveys used for data collection
ii. Equipment: Theranos system
    1. Description
    2. Certifications
    3. Safety data

e. Subjects

i. Study population: Study subjects will be active duty U.S. service members over 18 years of age deployed to Africa in support of SOCAFRICA. All study subjects will be volunteers and only enrolled after informed consent is obtained.

ii. Number of subjects: The study will be conducted using a convenience sample of volunteers. Fourteen total volunteer encounter will be conducted but volunteers may participate in more than one scenario.

iii. Consent: Written informed consent will be documented for all volunteers prior to participation in the study.

iv. Blinding: volunteers to include those undergoing laboratory analysis and those making clinical decisions will be blinded to the scenarios with the exception of the 5 volunteers doing physical exam screening. The PI will not be blinded.

v. Compensation: No direct compensation

vi. Risk to subjects: The only risk to subjects is the discomfort associated with a fingerstick/venipuncture and the associated small risk of infection. No personally identifiable data will be collected other than demographic information to include age, gender, and location at time of enrollment. All clinical data will be notional

data, created as a scenario and will not represent any true condition of the research subject.

f. **Data collection:**
    i. Data will be collected by PI through direct observation. PI will accompany volunteer throughout course of study enrollment to capture all data points.
    ii. See attached data collection sheet for each scenario
g. **Data management:**
    i. Data will be de-identified. Volunteers will be given a study number to track all results.
h. **Statistics:**
i. **Budget:**
    i.