



# Melanoma Prevention & Early Detection

## Background

Melanoma, a potentially lethal form of skin cancer, is the second most common type of cancer in males in the U. S. military. Furthermore, its incidence and mortality rates in all patients worldwide have continued to rise dramatically over the last four decades. For a total budget of \$183,100.00, this proposal is designed to scientifically evaluate digital imaging systems as they apply to the care of patients at high-risk for melanoma and to develop and deploy a DII/COE-compliant, secure, web-accessible database for accessing and archiving these images. The proposed project duration is eighteen months. Major Peter Ehrnstrom, Chief of Dermatology at Elmendorf AFB, will serve as the Principal Investigator. Major Emily Garscadden, Chief of Pathology at Elmendorf AFB, will be a Co-Investigator. Other dermatologists, both within the DoD and in civilian institutions, will be recruited as image evaluators. The site of this project is Elmendorf AFB, Alaska.

Although there are a handful of current DoD initiatives in the fields of telemedicine and teledermatology, to our knowledge none are disease-specific and none are designed primarily for longitudinal care of patients. This project is both. We seek to design an easily reproducible approach for image studies of the patient most at risk for melanoma and eventually incorporate this database of images into existing DoD goals of a system of medical information systems and the electronic patient record.

## Project Plan

### Project Narrative

In 1996, the lifetime risk of a person in the United States developing melanoma was 1:87. This number represents a greater than 1000% increase over the past 50 years and the yearly increase in the incidence rate of this disease in the U. S. is approximately 6%. The same risk for a white male in the U.S. is even higher—approaching 1:60. Two published studies of these rates in U. S. military populations show equivalent risks, and melanoma is rapidly becoming the most common cancer in males on active duty (second to testicular cancer in a 1990 published report). These rises in incidence rates are not due to merely increased awareness and detection, for despite increasing survival percentages for all stages of this disease, the overall mortality rate from melanoma in the U. S. has also continued to rise. Although melanoma still carries a very poor prognosis in its advanced stages, fortunately it is frequently detectable and curable in its earlier phases.

Because populations of patients at relatively high risk for developing melanoma are identifiable, dermatologists have long practiced taking pictures of these patients in order to identify the nevus in evolution toward a melanoma or the melanoma arising *de novo*. While this practice may work well in community-based, civilian practices, because of the mobility and transient nature of military patient populations, this practice has had little success within the DoD. Currently, there is no standard for imaging patients at high risk for melanoma, and in those offices in the DoD where such pictures are taken, problems regarding the legal issues surrounding the storage of this portion of the patient record are commonplace. Often the package of pictures is handed to the patients when they PCS presuming that the new station will agree with the methods used at the former and that the new station will have a process in place for archiving the photographs. Unfortunately, because of these faulty presumptions, often the utility of these imaging studies is negated when the patient moves within the DoD. Finally, there is no standard process in place to be able to view histologic studies of previously biopsied nevi in the patient at high risk for melanoma. When a pigmented lesion arises in a patient at the site of a previous biopsy, for example, reevaluation of the histology of the original lesion can be crucial in the decisions about the care of that patient. Again, the transient nature of our population and the variable methods by which pathology departments store and share their tissue sections present obstructions to using these studies in future decision analyses of patient care.

### Research Question

This study proposes to identify the patient at relatively high risk for melanoma, develop standards for taking digital images of these patients, develop standards for taking digital images of histologic sections of atypical pigmented lesions, and to develop and deploy a secure, web-accessible, DII/COE-compliant

database for the archival and future access of these images. Although this project will take place at Elmendorf AFB, the overall aim is to create a process and the tools necessary to carry out that process anywhere within the DoD. All database design will conform to DII/COE standards and, therefore, would have the potential of being incorporated into the future electronic patient record.

There are currently a few telemedicine, teledermatology, and telepathology projects active within the DoD. Examples include the Theater Telemedicine Prototype Project (T2P2), the Pacific Island Healthcare Project, the teledermatology project in active in Region 1, and telepathology at the Armed Forces Institute of Pathology. While each one of these endeavors allows for digital imaging of patients and/or pathology samples and for the archival of those images, they differ greatly from this proposal in three important ways. First, this project is disease-specific and, therefore, highly structurable. The patient population at relatively high risk for melanoma can be defined well by personal and family medical history as well as physical examination. Similarly, the potential users of this database, by virtue of the content of the images contained therein, would likely be limited to dermatologists and pathologists. (Evaluation of macro images of pigmented lesions and their histologies by other healthcare providers would be of limited utility.) Secondly, none of the aforementioned projects are aimed at the longitudinal care of the patient. Optimally, this proposed project is preventative in nature. It would allow for the detection and removal of an atypical pigmented lesion prior to its full evolution into a melanoma. Even if a melanoma develops *de novo*, these images and this approach toward melanoma patient care would allow dermatologists to detect these tumors when they are most amenable to cure. Thirdly, there are some questions regarding the DII/COE standards-compliance of some of the databases used in some of the existing projects. Because the aim of this project is to develop a potential portion of the electronic patient record, its development will remain consistent with current DoD goals regarding medical information systems of the future.

#### **Project Purpose**

The purpose of this project is to create a process to identify the patient at relatively high risk for melanoma, develop standards for taking digital images of these patients, develop standards for taking digital images of histologic sections of atypical pigmented lesions, and to develop and deploy a secure, web-accessible, DII/COE-compliant database for the archival and future access of these images. The ultimate goal of such a process is to prevent melanoma in this high-risk population or at least allow for its early detection, thereby decreasing its impact on the individual and on the DoD healthcare system.

#### **Significance to DoD in the Pacific**

The 6% annual increase in the incidence rates of melanoma observed over the last few decades represents a true epidemic of melanoma in the U. S. and around the world. In addition to the implied imperative to act against this potentially lethal disease, there is special significance for this disease in the Pacific regions for the DoD. The most significant environmental risk factor for the development of melanoma is prolonged exposure to the sun. Published studies show that a patient's individual risk for melanoma may be increased nearly five-fold by moving from higher latitudes (northern U. S., for example) to lower ones for a period as short as one year. This risk is especially important in those people who make such a move prior to the age of 10. Because active duty members in the DoD and their families are often displaced to latitudes providing more sunlight than was the case in their indigenous environment, as incidence rates continue to increase, our patient population may be especially vulnerable.

#### **Project Feasibility**

Approval to conduct this project in the Dermatology section and the Pathology Department at Elmendorf AFB has been given by the ad hoc IRB at Elmendorf. All patients involved in the project will give their informed consent to be photographed. The primary investigator, Dr. Peter Ehrnstrom, and the co-investigator, Dr. Emily Garscadden, are the chiefs of Dermatology section and the Pathology department at Elmendorf AFB, respectively. Each has an active duty service commitment and a projected date of change of station which are longer than the proposed length of this study. Dr. Ehrnstrom has served as a clinical consultant in the design of the Theater Telemedicine Prototype Project since November 1997, and was the chief photographer and director of the dermatology clinical photographic archive at Yale during his residency. Dr. Emily Garscadden has extensive experience in the use and firsthand knowledge of the strengths and shortfalls of the 3 CCD camera-equipped microscopes, which until recently the AFIP had deployed for telepathology at Elmendorf AFB.

#### **Technical Approach/ Methodology**

The first portion of this study is to scientifically evaluate the hardware and software currently available for capturing digital images as they apply to our patient population. Three digital cameras differing in their capabilities with regard to image resolution, ease of data transfer, accessory availability, and cost will be chosen. Dermatologists will then compare the outputs of these cameras in a single-blinded fashion and will compare them to images acquired with a traditional film camera (used as a gold standard).

The number of images and the number of image evaluators will be decided prospectively so as to achieve statistical significance of the outcomes. Care will be taken to match photographic techniques including lighting, lens focal lengths, and distance to subject as closely as the equipment will allow. Likewise, the method of comparing these digital images with one another will be designed to minimize any effects that the computer hardware used to view these images may have on the study's outcome. The images will be provided on CD-ROM and image manipulation by the evaluators will be limited to "zooming" only. The results of this scientific study will be applicable not only to this project but to many endeavors in teledermatology in general, so we will submit a manuscript to the medical literature for consideration for publication. The proposed length of this phase is six months to allow for acquisition of the photographic and computer equipment, the collection of the images, the evaluation of the images, the collation of the data, and the preparation of the manuscript for publication.

The final output of the camera and accessories chosen will be a JPEG image for storage in our database. Similarly, the image acquisition hardware and software for the pathology portion of this project will be chosen to optimize the characteristics and usefulness of the JPEG image generated from the histologic sections.

The second portion of this project (to run parallel with the first portion) is to secure a vendor to create a secure, web-accessible, DII/COE-compliant database for the storage and later retrieval of the clinical and pathological images. Mechanisms for the storage of applicable pathology reports will also be included. Although demographic data may need to be entered manually during the lifetime of this project, we will also explore the possibility of being able to directly download such information from CHCS or CHCS II in the future. For the purposes of this project the network will consist of a central main server and two workstations (at the Dermatology and Pathology sites). This design will allow for the demonstration of appropriate access and data-transfer capabilities of the system. The proposed length of this phase is six months after the vendor has been chosen.

The next phase of this project involve populating the database with images from patients identified at relatively high risk for developing melanoma. Hopefully, this will include return visits from patients showing some evolution of previously imaged nevi. The proposed length of this portion of the project is eight months.

The final stage in this project will be a demonstration of the fully functional and searchable database.

#### DoD Coordination

In addition to Dr. Ehrnstrom's direct participation in the Theater Telemedicine Prototype Project, we have made efforts to familiarize ourselves with current projects of similar nature throughout the DoD. We have spoken with those directly involved with the web-based teledermatology system in Region 1 and are familiar with the technical capabilities of that system, the T2P2 system, and the remote site telepathology systems currently used in the DoD. For the reasons delineated in the last paragraph of the Project Narrative section above, we believe that this project will augment rather than duplicate any current DoD initiatives in telemedicine. With the eventual possibility of inclusion into the electronic patient record, every effort will be made to develop this database in conjunction with current DoD information system goals.

#### Deliverables and Milestones

