Supporting Statement A For:

Solar Cell: A Mobile UV Manager for Smart Phones (NCI)

5/31/2012

Patricia Weber, DrPH
Program Director
National Cancer Institute
SBIR Development Center
6116 Executive Blvd, Suite 402
Rockville, MD 20852

Phone: 301-594-8106
Fax: 301-480-0482
weberpa@mail.nih.gov

Table of Contents

LIST OF APPENDICES

The small business conducting the research hopes to begin information collection at the end of May when ultraviolet radiation (UV) in sunlight is at its highest. The overall primary objective of this project is to produce, deploy, and evaluate the effectiveness of a state-of-the-art software application for smart phones (i.e., mobile application), *Solar Cell*. This software application supports decision-making related to sun protection and exposure by Americans to reduce the risk of developing skin cancer attributable to chronic and severe UV exposure and developing other cancers attributable to vitamin D deficiency.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 412 (42 USC § 285a-1) and Section 413 (42 USC § 285a-2) authorizes the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention, and treatment. The mission of the SBIR Development Center is to support research and development efforts of small businesses working in any of these areas. One way of carrying out this mission is by supporting small businesses that are developing consumer oriented tools designed to assess and mitigate cancer risk factors, which may include sun exposure.

This application is being submitted by NCI's Small Business Innovation Research (SBIR) Development Center. The SBIR Development Center is under the Office of the Director of the NCI and manages all SBIR and Small Business Technology Transfer (STTR) grants and contracts awarded by the NCI. The SBIR Program was established under the Small Business Innovation Development Act of 1982 (P.L. 97-219). Most recently in December 2011, the National Defense Reauthorization Act of 2012 (NDAA) Hr. 1540 was approved by Congress, and the bill was signed by the President. The bill extends the SBIR and STTR programs through September 30, 2017. The NCI SBIR program was created to strengthen the role of small, innovative companies

in federally-supported research and development. The study to be performed by Klein Buendel also fits the mission of the Health Communication and Informatics Research Branch of NCI's Division of Cancer Control and Population Sciences which is to support basic and translational research across the cancer continuum that will benefit consumers, patients, caregivers and health care professionals; from prevention to treatment, through survivorship, and end of life.

In this project, a new intervention, *Solar Cell*, a mobile application for smart phones will be evaluated. It is a unique sun protection intervention because it leverages the technological capabilities of smart phones (e.g., ability to detect time and location, access UV Index forecasts over the Internet, and tailor advice based on user input) and American's choice to carry mobile phones with them at all times to provide simple, actionable advice on sun protection and vitamin D in real time, when and where people need it. Mobile applications have not yet been tested extensively for disease prevention. Instead, studies have focused mainly on applications for monitoring caloric balance and detecting falls, clinical applications for reference materials, dosage calculators, and medical records, and disease management applications (e.g., diabetes self-management).[42-46] SMS text messaging has been successful in disease prevention but it is more simplistic and less interactive than a mobile application.[47-57]

Skin cancer incidence and mortality is a significant burden in countries with high ultraviolet (UV) levels and a large, light-skinned population such as the United States.[1] North America has a high age-standardized incidence rate of melanoma (16.4 for males, 11.7 for females).[2,3] In 2010, 38,870 U.S. men and 29,260 U.S. women were diagnosed with melanoma and 8,700 people will die from it.[4] Non-melanoma skin cancers (NMSC) are the most common form of cancer diagnosed in the United States and very costly to the health system,[5] even

though they are readily treatable.

Ultraviolet exposure is the most preventable cause of skin cancer.[6,7] Total lifetime UV exposure is positively associated with squamous cell cancer and possibly melanoma.[8-11] Intermittent, severe exposure may be linked to melanoma and NMSC.[12-19] Prevention relies on reducing chronic and severe UV exposure by wearing sunscreen, wide-brimmed hats, protective clothing, and sunglasses, using shade, and limiting midday exposure.

Effective methods are needed to help Americans protect their skin from the sun to reduce the prevalence of skin cancer. To take precautions effectively, individuals need to consider the level of UV for their time and location.[20-23] Protection is advised during midday (10 am – 4 pm) when daily UV peaks and during spring, summer and fall when UV levels are elevated.[24] UV is higher at lower latitudes than at higher latitudes and in regions with abundant sunlight, dry climates with little cloud cover, and at high elevation, and on reflective surfaces.[23,25-28] People also need to understand how their skin reacts to sun exposure. Persons at highest risk for skin cancer have skin types that sunburn with shorter exposure times.[29] They also need to know how various sun protection practices work, i.e., sun protection factor (SPF) of sunscreens, ultraviolet protection factor (UPF) of clothing, and ways of maximizing protection by sunscreen by pre- and re-application.

At the same time, there is emerging evidence of the health benefits of vitamin D for preventing chronic diseases, including several cancers, among them melanoma.[30-34] Unfortunately, several populations may have low vitamin D levels (e.g., the elderly).[35-37] The cheapest, most abundant natural source of vitamin D is exposing skin to UV in sunlight and some health authorities now advise people to receive routine small doses of UV from the sun

on unprotected skin to obtain vitamin D.[35,38,39] Thus, Americans should use sun exposure to produce vitamin D while taking precaution to not receive high doses of UV that can damage the skin. Fortunately, people can obtain considerable vitamin D with short non-sunburning doses of sunshine,[40,41] but many Americans may not realize this or use the need for vitamin D as an excuse to avoid taking precautions when outdoors in the sun.

Collecting information on US adults' sun protection in community settings is essential for testing *Solar Cell*. It will provide a "real world" test of the mobile application which is needed to be sure that Americans can download and use the application, will routinely use it, and when available derive benefit from the mobile application by reducing sunburn and increasing sun protection. A randomized trial with baseline and posttest assessment **(Appendix A and B)** in which a group of adults who receive *Solar Cell* is compared to a group who serve as untreated controls will provide a strong evaluation of the effectiveness of the *Solar Cell* application.

A.2 Purpose and Use of the Information

Information will be collected on the usability and use of the *Solar Cell* mobile application. Usability testing was requested under OMB No. 0925-0642 (NCI Fast Track Generic) and approved on 2/16/2012. Respondents will rate the overall usability of the mobile application, overall evaluation of *Solar Cell*, and the usefulness of various types of advice displayed by *Solar Cell*. They will also report whether they would use the mobile application again or recommend it to a friend. Scripts running on the web server that delivers the UV Index forecasts to the mobile application will record each time that the application is initialized and requests the UV Index forecast.

The information collected will be used in three ways:

1) Scientifically, it will be used to test the hypothesis that the *Solar Cell* mobile application will reduce sunburn prevalence (primary outcome) and increase frequency of sun protection behavior (secondary outcome) by adults. Findings will be published in peer-reviewed academic journals to inform other researchers about the potential utility of smart phone applications for improving cancer and disease prevention.

2) Practically, the findings will be used by the research team and programmers to improve the *Solar Cell* mobile application usability during final production of the Android and iPhone versions.

3) Commercially, the information will be used by the research team and staff to design and implement a dissemination plan for the *Solar Cell* mobile application. Currently, none of the smart phone applications for sun protection available in the Android Marketplace or iPhone App Store provide evidence of effectiveness from scientifically-rigorous trials. The information on *Solar Cell's* effectiveness should be a value-added feature of *Solar Cell* and improve its uptake by consumers.

A small business, Klein Buendel Inc., will be collecting, analyzing and storing the information for this research study as well as marketing and selling the finished application. Klein Buendel's research group has extensive experience collecting data to evaluate sun protection interventions with adults in community settings (**Appendix K**). The NCI SBIR program is sponsoring a research-based intervention that will benefit consumers, patients, caregivers and health care professionals.

Pre-testing and pilot testing was conducted with OMB approval of a generic sub-study (OMB No. 0925-0642-04, approved 2/16/2012) to specifically conduct beta testing, usability testing, cognitive testing, focus groups and interviews. A study design of the content of the sub-study and this main study is outlined in the **Appendix J**, Study Diagram.

The baseline and posttest surveys for the proposed project will utilize questions from previous studies; however, the surveys themselves will be unique and created just for this project. Several measures will be collected on sun protection. This includes two self-report

measures of sunburn prevalence, a dichotomous measure (yes/no) and a count of the number of sunburns in the past 3 months. Additionally, the frequency of practicing sun protection behaviors (i.e., use of SPF 15+ sunscreen, applying sunscreen, wearing hats, particularly wide-brimmed, protective clothing and sunglasses, and using shade) will be obtained by asking respondents to report how many days and hours they were outdoors in the sun over the past three months and the number of hours they spent practicing each sun protection behavior. A summed sun protection index will be created. Finally, at posttest, sun protection while outdoors on the previous weekend (Saturday or Sunday, selected at random) will be obtained (i.e., weather conditions, type of activity, use of sunscreen, hats, protective clothing, shade, and staying indoors) and summarized into a single index of sun protection.

Variables that may potentially moderate the success of the *Solar Cell* application and those that theoretically should mediate its effects will also be collected. Potential moderators include sun tanning behavior and attitudes, home latitude (obtained from home zip code), skin sun sensitivity, demographic characteristics (i.e., age, education, ethnicity, race, and gender), and personal and family history of skin cancer.[1]

Theoretical mediators include assessment of sun protection and sun tanning norms and intentions, outcome expectations for sun protection, and self-efficacy (confidence) for sun protection.

A.3 Use of Improved Information Technology and Burden Reduction

Data collection will be conducted using Knowledge Network's online electronic survey system through its secure, password-protected web servers using Secure Socket Layer (SSL)

[1]* Race, ethnicity, age and gender will be collected by Knowledge Networks (KN), a sub-contractor, and thus these questions do not appear in either the screener or pretest. KN will draw a sample to meet the race, ethnicity, age and gender target enrollment criteria (Appendix I). De-identified information will be conveyed to the contractor (Klein Buendel) and NCI.

encryption. Participants will be tracked from pretest to posttest through this system. The use of the Knowledge Networks system is an efficient way to recruit a sample of U.S. adults and the online electronic survey system is a low-cost and low-disruption means for them to respond to the pretest and posttest surveys. A Privacy Impact Assessment (PIA) is not needed because the data is being collected, held, and stored by a non-Governmental institution. NCI will not receive any data, or even a summary of the data.

A.4 Efforts to Identify Duplication and Use of Similar Information

The *Solar Cell* mobile application is a unique intervention for improving the sun protection of Americans. Recently, a search of the iPhone App Store and Android Market identified 18 mobile applications that provided information on sun protection; however none of them provided all of the features and advice in *Solar Cell*. A search of published literature on disease prevention interventions found no previous studies of smart phone mobile applications for sun protection. In fact, there have been very few studies on mobile applications for disease prevention, with only a few studies examining weight loss outcomes. Most published evaluations of mobile interventions have used text messaging, an older mobile technology. Klein Buendel recently completed a trial testing a smart phone application to support smoking cessation, but this study was performed only with smokers aged 18-30 and did not address sun safety.[69] This is the first trial to specifically test a mobile intervention to improve sun protection.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this trial.

A.6 Consequences of Collecting the Information Less Frequently

The information collection will be minimized to a 3-month period during the summer and is hoping to start information collection at the beginning of June. UV in sunlight is highest in summer months. Reducing the number of tests to a single posttest will weaken the trial because they would be unable to adjust for pre-existing sun protection habits and eliminate threats to internal validity such as history and maturation. Also, a recent trial on validity of sun protection measures identified three months as an optimal recall period (**Appendix K**).

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The project fully complies with all the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on January 27, 2012 (77 FR 4334). No public comments were received.

The *Solar Cell* mobile application for smartphones was developed through NCI's collaboration with: Klein Buendel Inc., University of Colorado and the University of New Mexico. During the development of *Solar Cell*, an External Working Group met twice to discuss the needs and interests of potential users and provide advice to the project.

A number of experts have been consulted to ensure that the impact of *Solar Cell* is measured effectively and efficiently. Drs. Berwick and Lantz have provided technical expertise, supported data collection efforts, and contributed to reports throughout the contract. Dr. Cutter has provided statistical analysis support throughout the contract and the existing

contract. Dr. Dellavalle has provided technical expertise throughout the contract. Dr. Hillhouse has provided support for survey development in the existing contract. Details for each can be found in **Appendix C**.

A.9 Explanation of Any Payment or Gift to Respondents

To maximize completion of the pretest and posttest surveys, Knowledge Networks will send email remainders **(Appendix D)** and make telephone calls to non-responding sample members to encourage them to complete the surveys. Participating adults will receive $5 for completing the pretest and another $5 for completing the posttest, to maintain high response.

A.10 Assurance of Confidentiality Provided to Respondents

Knowledge Networks, a sub-contractor, maintains two separate databases, one with personally identifiable information about their panel and another with survey responses. Personally identifying information will not be provided to the contractor (Klein Buendel) or NCI. Staff members who work with the personal information database never interact with the survey database and vice versa. Knowledge Networks will provide the contractor with data that is only identified by an identification number and will never reveal any personally identifying information about any participant in this study. It will place identification numbers in the pretest and posttest data files to link them over time. The data will be kept secure to the extent provided by law.

Knowledge Networks will maintain quality control/assurance of data from the participants using standard data management routines that ensure the accuracy of the data collected and delivered. Once Knowledge Networks transfers pre and posttest data files to the contractor's managers, well-established data management methods will be used to prepare

data for analysis. Real-time editing and coding will be used (valid value ranges; internal checks among codes set) to insure data quality. The contractor's data managers will review the data. All missing responses will be identified and staff will check that a question was not intentionally skipped. If missing responses occur, analyses will be done on data collected, i.e., case-wise deletion and imputation of missing data. While unlikely because of the automated nature of the data collection, data may not be missing at random (NMAR). All lost individuals will be assigned to extreme category, in either direction and perform multiple imputations utilizing Markov Chain Monte Carlo – Data Augmentation Method, a 2-step iterative procedure to obtain $P(\theta|Y_{obs})$ that can handle various amounts of missing data and use covariates and propensity scores.

Participants assigned to the treatment group will be given a link at the completion of their pretest that will include their identification number. When they follow this link on their mobile phone to download the *Solar Cell* application, their identification number will be linked to their mobile phone number to allow their survey data to be linked to their application usage data. Phone numbers will be maintained in a secure server environment with access only being granted to programmers and data managers. Usage data will be stripped of mobile numbers and only identified with identification numbers before being given to researchers for analysis.

Data on use of *Solar Cell* will be tracked through the contractor's secure web server, which will host the website from which the *Solar Cell* mobile application is downloaded and the website from which *Solar Cell* obtains the UV Index forecast data. The contractor's data managers will link *Solar Cell* use data to the pretest and posttest survey responses through the identification numbers provided by Knowledge Networks.

Participation in the study is voluntary and participants have the right to not answer any questions without consequences. The NIH Privacy Act Officer has stated that this information will be not be covered by the Privacy Act, and thus a Systems of Record Notice is not needed **(Appendix E)**. Klein Buendel's IRB, the Western Institutional Review Board (WIRB; DHHS IRB Reg. Number IRB0000053), has reviewed and approved this project **(Appendix F)**.

A.11 Justification for Sensitive Questions

Personally identifiable information will be collected in the form of name, age, gender, race, ethnicity, education, personal and family history of skin cancer, address, zip code, home and cell telephone numbers, personal email address. This information is collected by a sub-contractor so participants can be located and scheduled. De-identified information will be conveyed to the contractor (Klein Buendel) and NCI.

The only PII that would be considered "sensitive" are related to the questions regarding whether they or a family member has been diagnosed with skin cancer because past skin cancer diagnosis might moderate the effect of the *Solar Cell* intervention.

Participants will be asked to provide their home zip code since it will be used to code the latitude of their home residence, a proxy measure for the annual UV level in which they live, in order to test whether home UV level affects sun protection behavior and effectiveness of the *Solar Cell* intervention. Participants randomized to the intervention condition will provide their mobile phone numbers when they download the *Solar Cell* application in order for the mobile application to communicate with the smart phone. This information also will be used to track usage of *Solar Cell* and test the relationship of *Solar Cell* use and changes in sun protection behavior.

A.12 Estimates of Annualized Burden Hours and Costs

Data collection activities for all participants involve completion of a telephone screener **(Appendix G)** and a pre- and post-test survey **(Appendix A and B)** completed on a smart phone. It is estimated that there will be 1,875 participants screened annually, and a total of 3,750 participants over the course of two years of data collection. Of the 3,750 participants who are screened, meet the criteria, and consent to participate, 490 respondents will complete the pre- and post-tests over two years of information collection. The surveys are anticipated to take anywhere from 20 minutes to 40 minutes to complete and this means the estimated annual burden hours amounts to 308, and over the course of two years it will be a total of 616 hours see Table A.12-1).

Table A.12-1. Estimated Annual Burden Hours

Type of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Total Burden Hours
Adults	Screener (Appendix G)	1,875	1	2/60	63
	Pre-test (Appendix A)	245	1	20/60	82
	Post-test (Appendix B)	245	1	40/60	163
Totals					308

The cost burden to respondents is essentially the time required to read the Research Subject Information and electronically consent to participate in the study **(Appendix H)**, complete the screener, pre- and post- tests. The annualized cost to the respondents is

estimated to be $6,565, calculated at the mean hourly wage of $21.35 (U.S., Department of Labor, Bureau of Labor Statistics, May 2010, All Occupations[2]) (see Table A.12-2). The total cost to respondents is estimated to be $13,130 over a 2-year period of information collection.

[2] http://www.bls.gov/oes/current/oes_nat.htm

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The annualized cost to the Federal Government is estimated to be $63,846, and over the course of two years of information collection, a total of $127,692 (see Table A.14-1).

Table A.14-1. Annual Cost to the Federal Government

	TOTAL	ANNUAL AVERAGE
Contractor Costs	$67,652	$33,826
Data Collection Costs	$48,870	$24,435
Analysis	$9,500	$4,750
NCI Contracting Officer Technical Representative (COTR) costs	$1,670	835
Grand Total	$127,692	$63,846

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Statistical Power Calculations: The latest nationwide estimates from the Behavioral Risk Factor Surveillance Survey (2004) showed a sunburn prevalence of 34% in American adults.[70] In

a previous trial on personal protection education in the North American ski industry, the intervention reduced sunburn prevalence by 14% pre to post.[62] Thus, the statistical power of the evaluation of *Solar Cell* amounted to a difference of 14% in the experimental condition compared to no change in the not-treatment control condition. A two group test with a 0.050 2-sided significance level will have 80% power to detect the difference between the experimental group proportion of 0.340 and the control group proportion of 0.200 at posttest (odds ratio of 1.918) when the sample size is 160 adults in each group. To achieve this sample, Knowledge Networks will initially recruit 490 adults from its KnowledgePanel® and randomly assign half to the experimental group and half to the untreated control group. Knowledge Networks expects that 75% of adults to complete the posttest, yielding 165 adults with complete data in both groups.

Statistical Analysis: The trial is designed to test the hypothesis that the *Solar Cell* mobile application will reduce sunburn prevalence (primary outcome) and increase frequency of sun protection behavior (secondary outcome) by adults. The primary outcome measure of sunburn prevalence will be a dichotomous measure (any sunburn v. no sunburn). The number of sunburns in the past three months will also be analyzed. Pre-post change in sunburn prevalence will be tested. Frequency ratings of sun protection behaviors (i.e., use of SPF 15+ sunscreen, applying sunscreen, wearing hats, particularly wide-brimmed, protective clothing and sunglasses, and using shade) will be summed into a sun protection index and analyzed for pre-post change, as a secondary outcome. A summed secondary outcome score on the previous weekend day sun protection measure will include these behaviors plus pre-application and reapplication of sunscreen, and be analyzed in a posttest-only fashion. The analyses of these

primary and secondary outcomes will consist of the basic comparisons of means using a general linear model and categorical techniques (Proc Logistic) in SAS version 9.2, with $p<0.050$ (2-tailed). The primary outcome variable, sunburn prevalence, will be tested using Poisson Regression modeling to take into account the expected low number of events. The model will include the condition (*Solar Cell* application v. no-treatment control) and allow for the addition of pretest value and other variables as covariates to assess the basic hypothesis and more complicated relationships. The assumptions of the models will be assessed. The frequency of sun protection behavior is a summative score. If it is not normally distributed, Poisson Regression techniques will be utilized as well. However, if there is over-dispersion a negative binomial regression will be used. The posttest-only sun protection behavior measure is a count variable, just like sunburn, so this will be analyzed using Poisson regression techniques as described above.

Three sets of ancillary tests will be conducted. First analysis will include the potential effect moderators on the success of the *Solar Cell* application to reduce sunburn and improve sun protection by examining 2-way interactions between condition and effect moderators. The designed the sample size will need to be of a large size to be detected for these ancillary tests of these interactions. Second, mediation of change in sunburn and sun protection will be explored by applying regression techniques from Judd and Kenny[71] and MacKinnon.[72] Significance of mediation will be determined via interval estimation of mediated effect using the asymptotic variance derivation of Sobel.[73] Conclusions about mediation are weakened by the lack of an interim assessment of the mediators, but it would be difficult and disruptive to perform an interim survey during the relatively short 3-month intervention period (June –

August). Thus, these are ancillary tests, too. Finally, the effect of use of the *Solar Cell* mobile application on sunburn prevalence and frequency of sun protection behavior will be tested by examining the meditational effect of number of times the *Solar Cell* contacts the contractor's server, using analysis techniques described previously. Use of *Solar Cell* is not being randomly assigned, which could introduce a third-variable threat, so potential third variables (e.g., age, gender, education) will be included as covariates. Also, the statistical power of the exposure analyses is reduced because they are only conducted within the experimental condition.

Project Time Schedule: It is hoped that information collection can begin in shortly after OMB approval in late May/early June. Information collection is estimated to take 1-5 months, and this will occur during the peak of the solar activity. An extra year is requested in this submission to allow for unexpected events, should something occur and information collection cannot begin until May/June of 2013.

Investigators will prepare a manuscript describing the development of *Solar Cell* and results of the usability testing and randomized trial evaluating *Solar Cell* by Month 24 and submit it for publication in a peer-reviewed scientific journal. A presentation will be prepared on the development and evaluation of *Solar Cell* and demonstrate the mobile application at an NCI SBIR Development Center/Division of Cancer Control and Population Sciences-sponsored Product Showcase by Month 24. Finally, a final report will be created on the research that includes a summary of the *Solar Cell* product, its features, and potential user groups in Month 24.

Table A.16–1. Project Time Schedule

Activity	Time Schedule
Emails sent to respondents	**1 month after OMB approval**
Pretest Survey	**1 month after OMB approval**
Posttest Survey	**4 - 5 months after OMB approval**
Validation	**5 - 6 months after OMB approval**
Analyses	**7 - 10 months after OMB approval**
Publication	**24 months after OMB approval**

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The study will not require exemption from displaying the expiration date of OMB approval. Any reproduction of the data collection instrument will prominently display the OMB approval number and expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The Solar Cell Randomized Trial does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).

Reference List

1. Armstrong B. How sun exposure causes skin cancer: An epidemiological perspective. In: D.Hill, D.R.English, M.Elwood, editors. *Prevention of Skin Cancer*.Dordrecht: Kluwer Academic Publishers; 2004.

2. Parkin DM, Bray F, Ferlay J, Pisani P. Global cancer statistics, 2002. *CA Cancer J Clin.* 2005;55:74-108.

3. International Agency for Research on Cancer (WHO), International Association of Cancer Registries. Cancer Incidence in Five Continents. Lyon: International Agency for Research in Cancer; 2002. Report No.: VIII.

4. Columbia University. Go Ask Alice! *Columbia University's Health Question and Answer Internet Service.* http://www.goaskalice.columbia.edu/. 2003.

5. Australian Institute of Health and Welfare. Health System Expenditures on Cancer and Other Neoplasms in Australia. Canberra: Australian Institute of Health and Welfare; 2005.

6. Fears TR, Scotto J, Schneiderman MA. Mathematical models of age and ultraviolet effects on the incidence of skin cancer among whites in the United States. *Am J Epidemiol.* 1977;105(5):420-427.

7. Gallagher RP, McLean DI, Yang CP et al. Suntan, sunburn, and pigmentation factors and the frequency of acquired melanocytic nevi in children. Similarities to melanoma: The Vancouver Mole Study. *Arch Dermatol.* 1990;126(6):770-776.

8. Armstrong BK, English DR. Cutaneous malignant melanoma. In: Schottenfeld D, Franmeni JF, editors. *Cancer Epidemiology and Prevention*. 2nd ed. New York: Oxford University Press; 1996. 1282-1312.

9. Emmett EA. Occupational skin cancer: A review. *J Occup Med.* 1975;17(1):44-49.

10. Marks R. Nonmelanotic skin cancer and solar keratoses. The quiet 20th century epidemic. *Int J Dermatol.* 1987;26(4):201-205.

11. Rosso S, Zanetti R, Martinez C et al. The multicentre south European study 'Helios' II: Different sun exposure patterns in the aetiology of basal cell and squamous cell carcinomas of the skin. *Br J Cancer.* 1996;73(11):1447-1454.

12. Koh HK, Kligler BE, Lew RA. Sunlight and cutaneous malignant melanoma: Evidence for and against causation. *Photochem Photobiol.* 1990;51(6):765-779.

13. Kricker A, Armstrong BK, English DR, Heenan PJ. Does intermittent sun exposure cause basal cell carcinoma? A case-control study in Western Australia. *International Journal of Cancer.* 1995;60:489-494.

14. MacKie RM, Aitchison T. Severe sunburn and subsequent risk of primary cutaneous malignant melanoma in Scotland. *Br J Cancer.* 1982;46(6):955-960.

15. Marks R, Jolley D, Lectsas S, Foley P. The role of childhood exposure to sunlight in the development of solar keratoses and non-melanocytic skin cancer. *Med J Aust.* 1990;152(2):62-66.

16. National Health and Medical Research Council of Australia. Primary Prevention of Skin Cancer in Australia: Report of the Sun Protection Working Party. Sydney, Australia; 1996.

17. Weinstock MA, Colditz GA, Willett WC et al. Nonfamilial cutaneous melanoma incidence in women associated with sun exposure before 20 years of age. *Pediatrics.* 1989;84(2):199-204.

18. Weiss J, Bertz J, Jung EG. Malignant melanoma in southern Germany: Different predictive value of risk factors for melanoma subtypes. *Dermatologica.* 1991;183(2):109-113.

19. Bakos L, Wagner M, Bakos RM et al. Sunburn, sunscreens, and phenotypes: Some risk factors for cutaneous melanoma in southern Brazil. *Int J Dermatol.* 2002;41(9):557-562.

20. Reiter R, Munzert K, Sladovic R. Results of 5-year concurrent recording of global, diffuse, and UV radiation at three levels in the Northern Alps. *Theor Appl Climatol.* 1982;30(1-2):1-28.

21. Blumthaler M, Ambach W. Human ultraviolet radiant exposure in high mountains. *Atm Environ.* 1988;22(4):749-753.

22. Elwood JM, Koh HK. Etiology, epidemiology, risk factors, and public health issues of melanoma. *Curr Open Oncol.* 1994;6(2):179-187.

23. Calbo J. Empirical studies of cloud effects on UV radiation: A review. *Rev Geophys.* 2005;43(2).

24. World Health Organization, World Meterological Organization, United Nations Environment Programme, International Commission on Non-Ionizing Radiation Protection. Global Solar UV Index: A Practical Guide. Geneva: WHO; 2002.

25. Blumthaler M, Ambach W, Ellinger. Increase in solar UV radiation with altitude. *Jounral of Photochemistry and Photobiology B.* 1997;39:130-134.

26. Blumthaler M, Ambach W. Solar UVB- Albedo of various surfaces. *Photochem Photobiol.* 1988;48:85-88.

27. Feister U, Grew R. Spectral albedo measurements in the UV and visible region over different types of surfaces. *Photochem Photobiol.* 1995;62(4):736-744.

28. Bodecker GE, McKenzie RL. An algorithm for inferring surface UV irradiance including. *J Appl Meterol.* 1996;35:1860-1877.

29. Fears TR, Guerry D, Pfeiffer RM et al. Identifying individuals at high risk of melanoma: a practical predictor of absolute risk. *J Clin Oncol.* 2006;24(22):3590-3596.

30. Heenan PJ, English DR, Holman CD, Armstrong BK. Survival among patients with clinical stage I cutaneous malignant melanoma diagnosed in Western Australia in 1975/1976 and 1980/1981. *Cancer.* 1991;68(9):2079-2087.

31. Berwick M, Armstrong BK, Ben-Porat L et al. Sun exposure and mortality from melanoma. *J Natl Cancer Inst.* 2005;97(3):195-199.

32. Numberg B, Schadendorf D, Gartner B et al. Progression of malignant melanoma is associated with reducted 25-hydroxyvitamin D serum levels. *Experimental Dermatology.* 2008;7:627.

33. Rosso S, Sera F, Segnan N, Zanetti R. Sun exposure prior to diagnosis is associated with improved survival in melanoma patients: results from a long-term follow-up study of Italian patients. *Eur J Cancer.* 2008;44(9):1275-1281.

34. Newton Bishop J, Berwick S, Jackson S et al. Vitamin D and survival from melanoma. *Melanoma Res.* 2006;16:S26-S27.

35. Holick MF. Vitamin D deficiency. *N Engl J Med.* 2007;357(3):266-281.

36. Nesby-O'Dell S, Scanlon KS, Cogswell ME et al. Hypovitaminosis D prevalence and determinants among African American and white women of reproductive age: third National Health and Nutrition Examination Survey, 1988-1994. *Am J Clin Nutr.* 2002;76(1):187-192.

37. Park S, Johnson MA. Living in low-latitude regions in the United States does not prevent poor vitamin D status. *Nutr Rev.* 2005;63(6 Pt 1):203-209.

38. Reichrath J. The challenge resulting from positive and negative effects of sunlight: how much solar UV exposure is appropriate to balance between risks of vitamin D deficiency and skin cancer? *Prog Biophys Mol Biol.* 2006;92(1):9-16.

39. Webb AR, Engelsen O. Calculated ultraviolet exposure levels for a healthy vitamin D status. *Photochem Photobiol.* 2006;82(6):1697-1703.

40. Samanek AJ, Croager EJ, Giesfor Skin Cancer PP et al. Estimates of beneficial and harmful sun exposure times during the year for major Australian population centres. *Med J Aust.* 2006;184(7):338-341.

41. Webb AR, Engelsen O. Ultraviolet exposure scenarios: risks of erythema from recommendations on cutaneous vitamin D synthesis. *Adv Exp Med Biol.* 2008;624:72-85.

42. Tsai CC, Lee G, Raab F et al. Usability and Feasibility of PmEB: A Mobile Phone Application for Monitoring Real Time Caloric Balance. *Mobile Networks and Applications.* 2007;12(2-3):173-184.

43. Sposaro F, Tyson G. iFall: An android application for fall monitoring and response. IEEE Engineering in Medicine and Biology Society. September 2009.

44. Innocent K. Mobile apps for nurses. *Nursing Critical Care.* 2010;5(5).

45. California Health Foundation. How Smartphones Are Changing Health Care for Consumers and Providers. 2010.

46. Mougiakakou S, Kouris I, Ilipoulou D, Vazeou A, Koutsouris D. Mobile technology to empower people with Diabetes Mellitus: Design and development of a mobile application. *Information Technology and Application in Biomedicine.* 2009.

47. Cole-Lewis H, Kershaw T. Text Messaging as a Tool for Behavior Change in Disease Prevention and Management. *Epidemiol Rev.* 2010.

48. Levine D, McCright J, Dobkin L, Woodruff AJ, Klausner JD. SEXINFO: a sexual health text messaging service for San Francisco youth. *Am J Public Health.* 2008;98(3):393-395.

49. Lim MS, Hocking JS, Hellard ME, Aitken CK. SMS STI: a review of the uses of mobile phone text messaging in sexual health. *Int J STD AIDS.* 2008;19(5):287-290.

50. Terry M. Text messaging in healthcare: the elephant knocking at the door. *Telemed J E Health.* 2008;14(6):520-524.

51. Brendryen H, Kraft P. Happy ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction.* 2008;103(3):478-484.

52. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *Am J Prev Med.* 2009;36(2):165-173.

53. Gammon D, Arsand E, Walseth OA, Andersson N, Jenssen M, Taylor T. Parent-child interaction using a mobile and wireless system for blood glucose monitoring. *J Med Internet Res.* 2005;7(5):e57.

54. Holtz B, Whitten P. Managing asthma with mobile phones: a feasibility study. *Telemed J E Health.* 2009;15(9):907-909.

55. Krishna S, Boren SA, Balas EA. Healthcare via cell phones:A systematic review. *Telemed J E Health.* 2009;(3):231-240.

56. Park MJ, Kim HS, Kim KS. Cellular phone and Internet-based individual intervention on blood pressure and obesity in obese patients with hypertension. *Int J Med Inform.* 2009;78(10):704-710.

57. Patrick K, Raab F, Adams MA et al. A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res.* 2009;11(1):e1.

58. Buller DB, Andersen P, Walkosz BJ et al. Compliance with sunscreen advice in a survey of adults engaged in outdoor winter recreation at high elevation ski areas. *JAAD*. In press.

59. Andersen PA, Buller DB, Walkosz BJ et al. Environmental cues to ultraviolet radiation and personal sun protection in outdoor winter recreation. *Archives of Dermatology.* 2010;146:1241-1247.

60. Walkosz BJ, Buller DB, Andersen PA et al. Increasing sun protection in winter outdoor recreation: a theory-based health communication program. *Am J Prev Med.* 2008;34(6):502-509.

61. Buller D, Shane J, Borland R, Bader A. A study of the feasibility of delivering support for smoking cessation using a smart phone mobile application. Society for Research on Nicotine and Tobacco. Annual Meeting of the Society for Research on Nicotine and Tobacco. 2010.

62. Buller DB, Andersen PA, Walkosz BJ et al. Randomized trial testing a worksite sun protection program in an outdoor recreation industry. *Health Educ Behav.* 2005;32(4):514-535.

63. Walkosz BJ, Voeks J, Andersen P et al. Randomized trial on sun safety education at ski and snowboard schools in western North America. *Pediatric Dermatology.* 2007;24(3):222-229.

64. Andersen PA, Buller DB, Walkosz BJ et al. Expanding occupational sun safety to an outdoor recreation industry: A translational study of the go sun smart program. *Translational Behavioral Medicine*. In press.

65. Buller DB, Reynolds KD, Ashley JL et al. Motivating public school districts to adopt sun protection policies: A randomized controlled trial. *Am J Prev Med.* 2011;41(3):309-316.

66. Buller DB, Andersen PA, Walkosz BJ et al. Enhancing industry-based dissemination of an occupational sun protection program with theory-based strategies employing personal contact. *Am J Health Promot*. In press.

67. Yaroch AL, Reynolds KD, Buller DB, Maloy JA, Geno CR. Validity of a sun safety diary using UV monitors in middle school children. *Health Educ Behav.* 2006;33(3):340-351.

68. Glanz K, Yaroch AL, Dancel M et al. Measures of sun exposure and sun protection practices for behavioral and epidemiologic research. *Arch Dermatol.* 2008;144(2):217-222.

69. Buller D, Shane J, Borland R, Bader A. A study of the feasibility of delivering support for smoking cessation using a smart phone mobile application. Society for Research on Nicotine and Tobacco. Annual Meeting of the Society for Research on Nicotine and Tobacco. September 2010.

70. Saraiya M, Balluz L, Wen XJ, Joseph DA. Sunburn prevalence among adults--United States, 1999, 2003, and 2004. *MMWR Morb Mortal Wkly Rep.* 2007;56(21):524-528.

71. Judd C, Kenny D. Process analysis: Estimating mediation in treatment evaluations. *Evaluation Review.* 1981;5:602-619.

72. MacKinnon DP. Analysis of mediating variables in prevention and intervention research. In: Cazares A, Beatty LA, editors. *Scientific Methods for Prevention Intervention Research*. U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse; 1994.

73. Sobel ME. Asymptotic Confidence Intervals for Indirect Effects in Structural Equations Models. In: Leinhart S, editor. *Sociological Methodology*.San Francisco: Jossey-Bass; 1982. 290-312.