Review and Special Articles

Reducing Ultraviolet Radiation Exposure to Prevent Skin Cancer

Methodology and Measurement

Karen Glanz, PhD, MPH, Joni A. Mayer, PhD

Abstract: Skin cancer is the most common type of cancer, and is also one of the most preventable. This paper builds on an evidence review of skin cancer prevention interventions that was conducted for the *Guide to Community Preventive Services* (n =85 studies), and summarizes the state of knowledge about research methodology and measurement in studies of the effectiveness of interventions to reduce ultraviolet radiation (UVR) exposure. As this field advances, researchers should strive to minimize threats to validity in their study designs, as well as to consider the balance between internal and external validity. There is a need for more longer-duration interventions, and follow-up periods that make possible conclusions about the potential of these interventions to affect intermediate markers of skin cancer or at least sustained behavior change. Also, more work is needed to minimize attrition and characterize nonresponders and study dropouts. Verbal report measures of behavior are the most widely used measures of solar protection behavior. Given their limitations, investigators should routinely collect data about reliability and validity of those measures. They should also increase efforts to complement verbal data with objective measures including observations, skin reflectance, personal dosimetry, skin swabbing, and inspection of moles. Measures of environments and policies should incorporate observations, documentation, and direct measures of ambient UVR and shade. This article places the data derived from the evidence review in the context of needs and recommendations for future research in skin cancer prevention.

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Introduction

Skin cancer is the most common type of cancer in the United States.[1] In 2003, >1 million people were diagnosed as having the two most common types of skin cancer—basal cell carcinoma and squamous cell carcinoma—and about 2200 people will die from both cancers combined.[2] Between 1973 and 1999, the annual incidence rate for melanoma more than doubled, and the rate of melanoma deaths increased by about 40%, from 1.6 to 2.7 per 100,000 people.[3]

High levels of exposure to ultraviolet radiation (UVR) increase the risk of all three major forms of skin cancer, and approximately 65% to 90% of melanomas are caused by UV exposure. Other risk factors for skin cancer include fair skin, hair, and eyes (typically correlated with race/ethnicity); and a large number of moles or nevi.[4] While skin cancer is among the most common cancers, it is also one of the most preventable. Behaviors that reduce skin cancer risk include limiting or minimizing exposure to the sun during midday hours; wearing protective clothing; and using a broad spectrum sunscreen when outside.[5] Sunscreen use is considered an important adjunct to other types of UV protection, although sunscreen's role in preventing melanoma has not been unequivocally shown and remains complex.[6–8]

A variety of intervention strategies has been proposed for changing behaviors related to UVR exposure and their determinants, including educational programs, media campaigns, and changes in sun-protective environments and policies. The *Guide to Community Preventive Services* conducted an evidence-based review of the efficacy of sun-protection interventions in varied segments of the population across various implementation settings.[9–11] The evidence review process examined research methodology to determine whether studies had sufficient suitability of design and quality of execution to be included in the review, and also to inform the determination of whether the evidence was sufficient to recommend a particular intervention.[12,13]

This paper summarizes the state of knowledge about research methodology and measurement in studies of

From the Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University (Glanz), Atlanta, Georgia; and Graduate School of Public Health, San Diego State University (Mayer), San Diego, California

Address correspondence and reprint requests to: Karen Glanz, PhD, MPH, Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University, 1518 Clifton Road NE, Atlanta GA 30322. E-mail: kglanz@sph.emory.edu.

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the effectiveness of interventions to reduce UVR exposure among various groups in order to prevent skin cancer. This article also places the data derived from the evidence review in the context of needs and recommendations for future research in skin cancer prevention.

Methods

The *Community Guide* Evidence Review

A series of systematic evidence reviews of the effectiveness of interventions for reducing UVR exposure, in order to prevent skin cancer, was conducted for the *Guide to Community Preventive Services*.[9] These reviews examined behavioral, educational, policy, and environmental strategies for changing behaviors in order to reduce skin cancer risk and improve health.[10,11] The evidence reviews covered nine different categories of interventions. Six reviews focused on distinct settings: healthcare settings and healthcare providers, occupational settings, recreation and tourism settings, secondary schools and colleges, primary schools, and childcare centers. Three other reviews focused on a target population—children's parents and caregivers—and broad types of interventions, including media campaigns and community-wide multicomponent interventions. The focus was strictly on **prevention**, not on detection or patient education related to cancer treatment.

Studies were identified for the review by a comprehensive search of three databases (MEDLINE, PsychINFO, CINAHL) for primary investigations of interventions, published in English from 1966 to 2000, that compared outcomes among persons exposed to interventions with persons not exposed or less exposed to the interventions. A systematic review in which >6000 titles and citations were screened, 159 articles reviewed, and 85 studies included in the skin cancer prevention review.[9,10] Four studies with only one data set were double-counted because they fit into two different categories (e.g., occupational settings and recreation and tourism), resulting in a net total of 81 separate studies. Additional studies published after 2000 were included if they became available through a call for input that was sent to active skin cancer prevention researchers.

Following the standard *Community Guide* methodology,[12] each study was evaluated using a standardized abstraction form and was assessed for suitability of study design and threats to validity. Two abstractors evaluated each study, and the abstractions were reviewed, and reconciled when necessary, by a multidisciplinary team of scientists. A conceptual model, or analytic framework, was developed to show the relationship of the interventions to relevant intermediate outcomes (e.g., knowledge, attitudes, intentions regarding sun-protective behaviors), and to behaviors and reduction in skin cancer incidence. Outcome data extracted from the studies were aligned with the analytic framework to answer specific research questions.

Methodology and Measurement in the Evidence Review

To be included in the reviews of effectiveness, studies had to be primary investigations of interventions (rather than, e.g., guidelines or reviews); and compare outcomes among groups of persons exposed to the intervention with outcomes among groups of persons not exposed or less exposed to the intervention (i.e., include a concurrent or before-and-after comparison).[9] Studies also had to meet minimum standards for suitability of study design and quality of execution.[12,13]

Research designs included a range of methodologies, such as prospective randomized experiments (randomized controlled trials, or RCTs), nonrandomized trials (comparison groups), time series, and pre–post test designs. Other key design and execution factors of interest included the duration of the intervention, duration of follow-up, sample size, and description, and response rates or attrition.

With respect to outcomes, the focus of the review was primarily on sun-protective behaviors—avoiding peak sun (seeking shade and sun avoidance), covering up (hats, shirts, pants), and sunscreen use—and on key health outcomes (sunburn and nevi).[9] The review team also examined individual-level intermediate outcomes that were believed to be associated with sun-protective behaviors (e.g., knowledge, attitudes, intentions) and change in sun-safety environments and policies (e.g., increasing available shade, providing sunscreen, posting skin cancer prevention information).[9]

Sources and Methods for this Review

The primary sources of information for this article are the 81 studies included in the *Community Guide* skin cancer prevention evidence review.[9,10] In the process of developing this paper, we reviewed both the detailed abstraction forms and the original articles from those studies. In addition, we reviewed reports of relevant descriptive research that was conducted as part of several of the intervention trials; new publications released since the completion of the evidence review (in 2003 and 2004); work in progress; and descriptive reports that provide unique information regarding measurement of relevant outcomes. The review of measures also builds on an earlier review by one of the present authors.[14]

Study Design and Quality of Execution

Several research design and execution factors were noted throughout the evidence review. Matters of particular interest to the field include research design, including comparison groups; the nature of assessment samples; duration of the interventions and follow-up; and sample size and response rates or attrition. We created summary tables regarding these issues for the 81 included studies (available on request from the authors). In this section, we describe the highlights of our findings, and illustrative examples. Table 1 summarizes the number and proportion of the 81 studies in the evidence review with each characteristic.

Research Design

Of the 81 studies reviewed for all categories, more than half used experimental designs and many involved group-randomized trials; most of these were setting-specific interventions. Several studies used nonrandomized trials that involved comparison groups, and nearly a quarter of the studies used pre–post test designs. The four studies that used time series designs were community-wide interventions. While all of the designs have important strengths and weaknesses, the randomized controlled trials (RCTs) ensure the greatest internal

Table 1. Research design and execution factors in skin cancer prevention studies in *Guide to Community Preventive Services* evidence review (n=81 studies)[a]

Factor	*n*	%[b]
Research design		
Randomized controlled trial	46	56.8
Nonrandomized trial	14	17.3
Pre–post test design	17	21.0
Time series	4	4.9
Control/comparison groups		
None (one group)	25	30.9
No treatment control/comparison only (including delayed control group)	25	30.9
Attention-matched control	9	11.1
Three-group design	14	17.3
Crossed factorial, four or more groups	8	9.9
Measurement strategies[c]		
Verbal report	76	93.8
Observation	7	8.6
Skin reflectance	3	3.7
Other measures (non-verbal) of sunscreen use	7	8.6
Personal dosimetry[d]	1	1.2
Visual inspections of moles[d]	1	1.2
Other	2	2.5
Study sample comparison groups		
Point in time	18	22.2
Cohort	51	63.0
Repeated cross-sections	11	13.6
Cohort and cross-sections	1	1.2
Duration of intervention		
One-shot or one session	25	30.9
2 hours to 1 week	11	13.6
>1 week to 1 month	9	11.1
>1 month to 3 months	13	16.0
>3 months to 1 year	12	14.8
≥1 year	11	13.6
Duration of follow-up		
Not reported	5	6.2
<1 week	10	12.3
>1 week to 1 month	19	23.5
>1 month to 3 months	17	21.0
>3 months to 1 year	19	23.5
>1 year	11	13.6
Sample size (at follow-up)		
Not reported or indeterminate	3	3.7
<100	10	12.3
101–500	46	56.8
501–1000	10	12.3
>1000	12	14.8
Response rate (at follow-up)		
Not reported or indeterminate	31	38.3
<50%	3	3.7
50% to 75%	13	16.0
76% to 90%	22	27.2
>90%	12	14.8

[a]Four studies with only one data set per study were counted twice in the *Guide* evidence review[9,10] in different categories (e.g., occupational settings and recreation and tourism). This table counts those studies only once, resulting in a denominator of 81 studies instead of 85.
[b]Percentages may not add up to 100% due to rounding.
[c]Some studies used more than one type of measurement strategy.
[d]Reported for the Kidskin study, which was included in *Community Guide* evidence review,[15-17] in publications released after completion of the evidence review.[64,67]

validity. In the school-based intervention category, there were enough RCTs and pre–post test studies to allow for a comparison of effect sizes. Over all, the effects were smaller in the RCTs, suggesting that simpler before-and-after designs without control groups may have overestimated intervention effects. On the other hand, time series designs have some advantages compared to RCTs, especially for community-wide interventions. These include less chance of contamination and greater external validity, because their populations may be less highly selected than the participants in RCTs.

Control/Comparison Groups

The most-often used designs involved either a single no-treatment control/comparison group, or no control or comparison group. Nine studies used attention-matched control groups, such as high- versus low-intensity strategies, tailored versus generic messages, and sun protection compared to a parallel injury prevention program. These design features help to control for the attention aspect of interventions and make it possible to make more finely tuned comparisons across strategies. Because the majority of studies were testing multicomponent intervention strategies, two-group designs limited the potential to discern or dismantle the effects of specific components or strategies (such as lectures and audiovisual materials, or education and provision of sunscreen). Fourteen studies (17.3%) used three-group designs, which often involved a control group, a minimal- or low-intensity intervention, and a higher-intensity intervention. In some cases, three-arm trials allowed for the testing of additional components; for example, a control group versus education only versus education plus environmental strategies.[18]

More complex designs with four or more study groups, often in crossed factorial designs, were used in eight studies. Most of these studies are best described as "message testing" studies that compared various types of persuasive strategies, emotional appeals, and/or message framing.[11] Because of the categorization scheme used for the *Guide* evidence review, these studies were grouped with other studies in the settings where they were conducted (e.g., college students, beaches).

Measurement Strategies

Nearly all of the studies used verbal report measures such as surveys and interviews. The next most commonly used types of measures were observation (8.6%) and nonverbal measures of sunscreen consumption or use (8.6%). A very small minority of studies used other measurement strategies. The use of verbal report alone is an important limitation in the literature; in a later section of this paper, we will discuss in more detail the available alternatives as well as the importance of establishing reliability and validity for verbal report measures.

Study Sample Comparison Groups

Most studies followed cohorts of study participants over time, to allow for assessment of change within subjects as well as between groups. This type of design has the potential threat to validity of repeated measures, where the measurement process itself might stimulate behavior change. In contrast, 18 studies used point-in-time samples, usually post-test only. This procedure cannot control for baseline characteristics, and is commonly used to evaluate media campaigns by using comparison groups after the media strategy has been implemented. Alternatively, 11 studies that used repeated cross-sectional samples took place mainly in population-based or large community settings. Some of these studies found negative trends in control groups,[19–21] underscoring the importance of studying appropriate controls.

Duration of Interventions

We assessed the duration of interventions in the studies included in the *Guide* evidence review. The primary descriptor shown in Table 1 refers to the length of exposure of subjects to the interventions (as opposed to the number of hours of an intervention program), because most interventions included various communication modalities, such as lectures, print brochures, and interactive activities, and because the time spent on segments of some interventions (such as reading materials and online training courses) varies across individuals. Nearly one third of the interventions were either one-shot activities or a single session in length, about 40% continued for between 2 hours and 3 months, and another 28% occurred over >3 months. Only 11 studies (13.6%) had interventions that continued for >1 year. Because it is unlikely that short-term interventions can produce sustained long-term results, prevention research will need to study longer-lasting interventions or combinations of interventions as the field matures.

Duration of Follow-up

Over 40% of the evaluations followed subjects for <1 month. The studies with very short follow-up periods included most of the "message testing" studies and many school-based and health provider interventions. These types of studies are important to building the case for the initial efficacy of skin cancer prevention strategies; however, their eventual public health impact can only be tested over longer periods of time. Only 11 studies (13.6%) followed up on study participants over periods >1 year. Most of the studies with longer follow-up had longer-lasting interventions as well (see above). They were mainly mass media and community-wide interventions, and often used time series analysis. Given the seasonality of sun-protective behaviors and the importance of encouraging habitual as opposed to short-term behavior change to achieve prevention goals, a longer follow-up is crucial. Multiyear interventions and longer follow-up periods would be important improvements.

Sample Size

More than 80% of the studies used sample sizes (for analysis at follow-up) of >100 subjects. Also, the studies that used cluster randomized trial designs usually accounted for clustering in their statistical analyses. This indicates movement in a positive direction, with few studies including sample sizes too small to permit useful analyses. There were a few studies that included very large samples of >10,000 in recreation and tourism settings.[22,23] These studies used designs with one-time data collection strategies with little or no characterization of nonresponse or of the overall population sampling frame. Few of the articles provided information on power calculations, although we are aware that a number of investigators (including ourselves) planned their research to have sufficient power to detect anticipated changes in behavior.

Response Rates

Most of the studies reported on response rates at the last follow-up point, although only 11 studies (13.6%) described response to the baseline surveys or consent to participate. The most common range of response rates was between 76% and 90%, and 12 studies reported response rates >90%. These response rates are quite good and certainly comparable to those found in many health behavior intervention studies. However, these apparently high response rates were almost always calculated as the percentage of respondents to the previous data collection. So, for example, if 78% of those invited completed a baseline survey, and 78% of baseline respondents completed a follow-up assessment, the net response rate would be only 60.8% (or 0.78×0.78). Future research reports should describe the initial response (or consent) rate, and also identify novel strategies to maximize participant retention throughout the research.

Measures of UVR Protection/Exposure Behavior: Uses, Validity, and Reliability

This section describes the key UVR exposure/protection measurement strategies, suggests the best uses for each strategy, and summarizes recent progress in evaluating validity and reliability. The focus of this section is on measuring UVR protection and exposure at the individual level; measurement of sun-safety environments is addressed in a later section. Moreover, this review emphasizes measures of behaviors, (e.g., wearing a hat), as well as measures of UVR exposure that may be a consequence of behavior (e.g., level of tanness). It is outside the scope of this paper to address measures of skin cancer prevention–related knowledge, attitudes, and intentions.[24] Further, this review is confined to the measurement of solar protection/exposure, and therefore does not include behaviors related to indoor tanning.

Table 2 lists the key sun-protective behaviors and UVR exposure indicators and the applicable measurement strategies. With the exception of skin swabbing and visual inspection of moles, each of the strategies was described in detail in an earlier review[14] of measurement strategies for UVR exposure in children (see Creech and Mayer[14] for additional background information and progress related to each measure prior to 1997). Table 3 presents the types of psychometric data for each measure, that if collected, would advance the field; it is a methodologic wish list.

Verbal Report

As shown in Table 1, the majority of intervention studies used some form of verbal report to measure outcome. Table 2 indicates that verbal report of one's own or another's behavior is widely applicable across all sun-safety behaviors. Paper-and-pencil questionnaires and telephone interviews continue to be the most frequently used measures in sun-safety studies, likely due to their relative ease of administration and lower cost. The most common self-report or verbal report measures ask about habitual or typical behaviors, although a few studies

Table 2. Sun-safety behaviors and UVR exposure indicators: applicable measurement strategies

Key sun-safety behaviors	Measurement strategies					
	Verbal report (self or other)	Observations	Skin reflectance[a]	Personal dosimetry[b]	Swabbing[c]	Visual inspection[d]
Wear protective clothing	X	X				
Wear sunscreen	X				X	
Reduce time outdoors	X			X		
Use shade	X	X		X		
Use multiple protection strategies (composite)	X					
UVR exposure indicators						
Tanness	X		X			
Sunburn	X		X			
Mole development						X

[a]Measured via colorimeters or spectrophotometers.
[b]Using polysulphone film.
[c]Entails swabbing the skin, and then analyzing the materials on the swab using a spectrophotometer.
[d]Counting moles directly from the skin or from a photograph.
UVR, ultraviolet radiation.

have used multiple-day diary measures of sun exposure and solar protection.[20,25–27]

Internal Consistency

Several recent sun-safety intervention studies that used questionnaires have included data on internal consistency of composite scales based on multiple sun-protection behaviors (e.g., wear hats, wear sunscreen, seek shade). The majority of the measures used items with Likert-type scales of frequency, ranging from never to always. Alpha values reported have varied widely, mostly in the good to excellent range. They include alphas of 0.55 for parents reporting on protective practices for the family[28]; 0.67 for recreation staff[29]; 0.68 for a combination of parents and soccer coaches[30]; 0.82 for parents' protective behavior of their young children[31]; and 0.93 and 0.92 for parents and children, respectively.[32] Internal consistencies for multiple-item measures of individual behaviors also have been reported, with an alpha of 0.76 for a sunscreen behavior index administered to college students,[33] and alphas for elementary school children ranging from 0.71 to 0.78 for a sunscreen use subscale, 0.64 to 0.76 for a lip balm use subscale, and 0.61 to 0.75 for a hat use subscale.[34]

Internal consistency data are relatively easy to obtain. However, researchers attempting to measure UVR behavior may wish to consider the following. First, although composite scores that subsume several sun-safety behaviors may have the advantages of reducing the number of statistical tests and providing a global indication of an individual's protection, they may obscure some important details. More specifically, composite scores may mask behavior-specific changes due to an intervention,[11] and/or interactions between demographic variables and specific behaviors (e.g., males more likely to wear hats, females more likely to wear sunscreen). Consequently, investigators using composite scales should also analyze individual UVR protection behaviors in secondary analyses.

Criterion Validity

Few studies using verbal report of sun-safety behaviors have used previously validated measures or presented validity data for their own (author-developed) measures.[14] The Solar Protection Behavior Diary developed by Girgis et al.[20,25] in Australia in the early 1990s continues to be one of the only self-report instruments that was validated against an objective measure. In a recent report that assessed the validity of a modified version of that diary using UV monitors, results indicated that middle-school children accurately reported time outdoors and protective clothing use.[35] We will highlight the existing data.

Table 3. Data on UVR protection/exposure measures that would advance the field

Measurement strategy	Relevant methodologic data			
	Criterion validity	Test–retest reliability	Inter-rater reliability	Intra-rater reliability
Verbal report	X[a]	X		
Observations			X	X
Skin reflectance			X	X
Personal dosimetry	X			
Swabbing	X		X	X
Visual inspection			X	X

[a]Including comparison between different types of verbal reports (surveys, diaries, recalls).
UVR, ultraviolet radiation.

In a recent study, Oh et al.[36] validated Likert-type scale questionnaire items measuring the frequency (past 5 days while delivering mail) of U.S. Postal Service letter carriers' ($n=1036$) use of various forms of protective clothing; response options ranged from never (1) to always (5). When compared with direct observations of carriers' clothing as they delivered mail, self-report (dichotomized by always vs all other responses) was found to have good agreement, with kappas of 0.51 for sunglasses, 0.60 for any hat, 0.62 for wide-brim hat, 0.71 for long-sleeved shirt, and 0.83 for long pants. These findings are encouraging, since many researchers have used comparable survey items.

Several studies have attempted to validate parents' report of their child's UVR exposure against a more objective measure. For example, in an interim evaluation of the Kidskin trial, the correlation between paper-and-pencil questionnaire items (combined in a composite index of child's sun exposure) and skin reflectance measured with a spectrophotometer was −0.17 ($p<0.001$), indicating that children whose parents reported more exposure were more tanned.[15] Somewhat larger associations (r=0.30 and r=0.37) were found in an observational study comparing parental report and skin reflectance of children measured with a colorimeter.[37] Another study found that infants' time outside over a 4-day period, as reported by mothers, had a statistically significant association with a polysulphone film UVR dosimeter wristband worn by the infant (r=0.34, $p<0.001$).[38] In an observational study, Dwyer et al.[39] obtained data on the validity of habitual sun exposure survey items for 125 14- and 15-year olds. Correlations between self-report and dosimeter readings were statistically significant (r=0.32 and r=0.38).

Test–Retest Reliability

Test–retest reliability for the parent-reported sun-exposure composite index in the Kidskin study mentioned above was 0.79.[15] Also, test–retest reliability data were presented for a visual analog scale that assessed sunscreen use in fifth-graders. A range of 0.59 to 0.85 was given, although the authors did not specify the reference points for the range.[40] In a study comparing survey and diary measures of sun exposure and sun protection among 62 adults, Glanz[27] found significant test–retest reliability correlations for all key survey measures, with Spearman rho coefficients between 0.30 for shirt use and 0.84 for sunscreen use. Test–retest reliability coefficients for the diary measures were all statistically significant, and ranged from 0.52 for shirts to 0.74 for hat use.

Concurrent Validity

Few studies have undertaken comparisons between different types of verbal report, or self-report, measures, or of behavioral reports with reports of health outcomes (e.g., sunburn). This type of research is common in other fields of health behavior such as nutrition and physical activity, given the advantages and limitations of various types of measures. As mentioned earlier, the most often-used verbal report measures ask about habitual, or usual, sun exposure and protective behaviors. Some surveys have used multiple-day recalls after a weekend, which were significantly associated with sunburn in a sample of 1655 adults in Melbourne, Australia over 13 successive summer weekends.[5]

As part of a trial of tailored communications for skin cancer prevention, Glanz[27] conducted a measurement study among 62 adults to compare the concurrent validity and reproducibility of a sun habits survey and a 4-day sun-protection diary (including 2 weekend days). They found statistically significant correlations between the two instruments on three sun exposure indicators: weekly average hours outside (r=0.28, $p<0.05$), weekday hours outside (r=0.47, $p<0.01$), and weekend hours outside (r=0.26, $p<0.05$). They also found strong significant correlations for three sun-protection behaviors: sunscreen use (r=0.56, $p<0.01$), hat use (r=0.67, $p<0.01$), and shade (r=0.29, $p<0.05$). The correlation between covering up responses on the two instruments was 0.16, and was not significant.[27]

Limitations of Verbal Report Measures

In the *Community Guide* evidence review, reliance on self-report measures of behavior was the most frequently and consistently noted limitation to the quality of study execution. The potential limitations of verbal report measures are discussed in numerous textbooks and research papers.[41] Nevertheless, given the current state of the UVR measurement field, they will be reiterated here. Verbal report data may be inaccurate due to a variety of factors, including, but not limited to: poor recall, difficulty in estimating the frequency of routine behaviors, and social demand biases. Assessment of older children's and adolescents' UVR exposure and protection behaviors probably should be conducted using self-report rather than parental report, since parents may be less aware of older children's activities. Given these potential limitations, and the high likelihood that verbal report will remain the most widely used UVR measurement strategy, researchers are strongly encouraged to generate data that characterize the criterion validity and reproducibility of their UVR behavior verbal report measures.

As discussed in later sections, some of the objective measures appropriate for validating verbal report are relatively labor-intensive or expensive. To address this, investigators should consider collecting validity data on a (preferably random) subsample of study participants and/or sharing expensive resources (such as spectrophotometers and colorimeters) across research groups. Test–retest procedures also can be burdensome for both research staff and subjects. Nevertheless, we believe that the value of data on the reproducibility of UVR behavioral items will far exceed the expense. In short, until more research is generated addressing the criterion validity and reproducibility of verbal report measures of UVR protection/exposure, the field will not be able to advance.

Observational Strategies

Visual observation is a potentially useful and feasible strategy for measuring UVR protection behaviors, with the exception of its limited utility for measuring sunscreen use. Researchers have used observations both as an outcome and as a "gold standard" to validate less objective measures, such as verbal report (see above). Data from observations may be recorded manually in vivo or coded at a later time from photographs or videotapes. Some observational systems have been used to characterize the behavior of inhabitants of a particular environment, without linking the data of interest to individuals or to characteristics such as sun sensitivity. Other systems have been able to identify individuals.

In general, the strengths of observational measures of UVR behaviors include their direct nature (with greater potential for accuracy), their potential for unobtrusiveness, which may minimize subject reactivity, and their applicability for efficiently assessing the UVR behaviors of a large number of individuals within a specified environment. On the other hand, observational measures usually detect point-in-time behavior, and may not reflect habitual behaviors or sustained behavior changes. They also may be labor-intensive and expensive, and are vulnerable to biases and errors made by observers and coders or due to time sampling. Below are examples of observational systems for which at least some reliability data were reported.

Observation of hat use by child visitors as they exited two zoological parks was a primary outcome measure in one intervention study, in which two observers independently monitored over half of the 17,245 total observations.[22] For both protective hat (vs other categories) and any hat (vs other categories), kappa values were in the excellent range (>0.75); the specific values for percent agreement and kappa were not presented. In a pilot study that preceded the Kidskin intervention trial, children's use of hats on the playground was videotaped and later coded.[42] The intraclass correlation for two different coders for the percent of children wearing protective hats was 0.98, and intrarater agreement also was 0.98.

Use of sun-protective clothing items and sunscreen at poolside was observed by using a systematic behavioral mapping system.[43] Before the study, three observers independently recorded these measures. Percent agreement among observers was 100% for shade use and zinc oxide, 98% for shirts, 93% for hats, and 87% for sunglasses. Agreement among observers was based on the overall proportion of pool patrons engaging in the behaviors at a particular time point, rather than the behavior of **individuals**. In another pool-based intervention, observations of whether lifeguards were wearing hats and shirts served as a secondary outcome measure.[21]

Two observers independently recorded clothing items worn by 270 U.S. Postal Service letter carriers as they delivered mail.[36] Perfect agreement (with kappas of 1.0) were found for any hat, any wide-brimmed hat, and long pants. For sunglasses and long-sleeved shirts, kappas were 0.90 and 0.86, respectively.

As a primary outcome measure in a community-based sun-protection trial, observations at lakeside beaches were conducted of individual children's skin protection.[44] Accuracy checks were performed throughout the study, with an inter-rater agreement rate of at least 85%.

In sum, observations offer important advantages for measuring UVR exposure/protective behaviors, but require careful planning and execution, and are subject to limitations of interpretation due to group versus individual assessments and time sampling. Generally, the inter-rater reliability levels reported by investigators using observational systems are respectable. However, limitations or omissions in the descriptions of the data collection and analysis procedures temper our enthusiasm. Ideally, reliability data should be collected **throughout** the main trial. Second, most of the articles omitted the number of observations used to compute reliability; this number is essential for interpreting the stability of the estimates. Moreover, if inter-rater reliability was computed on a subset of the total study observations, specifying how the subset was selected is important for determining whether the estimates are unbiased. Randomly selecting the observations would be preferable. Third, some of the papers lacked information on exactly how reliability estimates were computed. Related to this, some studies reported percent agreement and others reported kappa values. It would be useful if authors would report both.

Skin Reflectance

Spectrophotometers and colorimeters emit light and then measure the level of reflectance/absorbance of the target surface. Each has been used to quantify skin color.[14] In theory, the instruments can be used to measure changes (within study participants over time and/or between groups of participants) in cumulative UVR exposure by quantifying the level of color associated with "tanness." The ability to measure tanness objectively is appealing because: (1) the data may reflect actual UVR exposure of participants, due to performing (or not performing) one or more of the recommended protective behaviors; and (2) it may be possible to capture the by-product of sun-safety behaviors performed over a relatively long time period. A more in-depth discussion of these instruments can be found in an earlier review article.[14]

To our knowledge, only three skin cancer prevention intervention trials have used skin reflectance measures as outcomes.[15,34,37] Of these, only two articles reported reliability estimates. Colorimeter data were used as one of the outcomes in an aquatics class–based intervention with children ($n = 169$).[37] Pearson correlation coefficients (for inter-rater reliability) for the six body sites measured ranged from 0.85 to 0.99 for the L* scale (black to white dimension) and 0.73 to 0.95 for the b* scale (blue to yellow dimension); all p values were statistically significant. Intrarater reliability also was high, with Cronbach alphas of 0.96 to 0.99.

A spectrophotometer was used to measure one of the interim outcomes in Kidskin, a 5-year, school-based sun-protection intervention for first-graders.[15] Inter-rater reliabilities were 0.93 for the back, 0.92 for the forearm, and 0.95 for the inner arm. Intrarater reliabilities were 0.94 for the back, 0.97 for the forearm, and 0.98 for the inner arm.

The data from these intervention studies and from a methodologic study[45] suggest that with proper training of data collectors, skin reflectance of children is a highly reliable measure. Its relatively infrequent use in skin cancer prevention/sun-safety research likely has been a function of the expense of the instruments and its relative labor intensity, especially when compared with paper-and-pencil questionnaires. Further concerns include the question of how sensitive skin reflectance data are to change, their usefulness in nonwhite samples, and whether they corroborate self-report data from the same research.[37] The results of a study in progress (with U.S. Postal Service letter carriers) will help address whether skin reflectance measured with a colorimeter is as reliable with adults, and whether this measure is sensitive to changes in UVR exposure among nonwhite racial groups

(G Galindo, San Diego State University, personal communication, 2003).

Personal Dosimetry

Objective measures of UVR exposure for individuals for ≥1 days by personal dosimetry can be used to assess reduced time in the sun and the use of shade. In laboratory, observational, and intervention studies, personal dosimetry through the use of polysulphone film badges has been shown to be a useful measurement strategy among children and adults.[38,46–49] These methods typically require assessment of personal UVR and concurrent measures of ambient UVR in order to adjust for environmental circumstances.[46,50] Observational studies have found concurrent validity between film badges and verbal report.[39]

We found only one example of the use of personal dosimetry in an intervention study—in the Kidskin study in Australia, shade use was measured using polysulphone badges worn by a random sample of children. A pilot study confirmed the feasibility of this method; however, the correlation between the calculated variable "proportion of ambient exposure" or PAE, and principals' estimates of the percentage of children who played in the sun at lunchtime was small and nonsignificant at 0.15.[46] Outcomes using the polysulphone film badges to assess shade use in the Kidskin study were recently reported; the investigators found that differences between study groups in mean PAE were small and nonsignificant.[51]

A review of earlier methodologic studies on using polysulphone film with children, as well as a discussion of strengths and limitations, may be found in an earlier paper.[14] The use of personal dosimetry in the Kidskin intervention trial can be taken as proof of concept, and future studies should consider other options for comparison to assess criterion validity. The lack of effect found may indicate the lack of efficacy of the intervention on the shade use outcome, or may reflect measurement issues that remain to be addressed in further research. With the emergence of new technology, future opportunities to use personal and environmental sensors, time–date stamps,[50] and real-time data transmission (S Intille, Massachusetts Institute of Technology, personal communication, 2004) can increase the opportunities to objectively assess sun exposure.

Skin Swabbing and Other Strategies for Verifying Sunscreen Use

For at least two reasons, there have been challenges to measuring sunscreen with any strategy other than verbal report. Because sunscreen is applied relatively quickly, and often before going outside, observations may not "capture" the behavior even when it is performed in public settings. Second, most sunscreens are not visible on the skin, which precludes being able to observe sunscreen once it is applied.

One promising strategy that is able to objectively verify whether sunscreen has been applied involves a swabbing procedure.[52] The skin is swabbed using an alcohol-free "baby wipe." The swab subsequently is placed in ethanol to elute any residues from the swab. The eluted washings are then analyzed with a spectrophotometer. In a field study with blinded data collectors, both the sensitivity and specificity of the spectrophotometric analysis for detecting sunscreen on 12 children were 100%.[52] A recent study replicated and extended the earlier research in a sample of 30 adult office workers. In that study, the swabbing technique consistently distinguished sunscreen from control swabs for up to 6 hours, and found no differences between groups that had sunscreen reapplied from those who did not.[53] To our knowledge, this swabbing technique has not yet been used in a sun-safety intervention study. An advantage of the swabbing procedure is its feasibility for use in the field: the sunscreen is removed from the skin and analyzed later using a spectrophotometer, which is a common laboratory instrument.

The results of several laboratory studies suggest that a technology using fluorescence spectroscopy can accurately quantify the thickness of sunscreen application.[54–57] This technology has limited portability, but may be useful in laboratory and clinical settings. Because sunscreen must be applied at a certain thickness to reach its stated SPF,[58,59] sun-safety research and practice would benefit from a measurement strategy that could be used in applied settings to quantify application thickness.

Several other strategies have been used to objectively evaluate sunscreen use. For example, at beaches, when caretakers of children reported that the child was wearing sunscreen, the data collector requested to see the container.[44] Eighty-three percent who said sunscreen had been applied had the bottle available. While this procedure helped to verify sunscreen use, the presence of a container cannot be considered a "gold standard" because (1) respondents reporting no sunscreen application also may also have had a container available, and (2) sunscreen may have been applied before arriving at the beach. Consumption of sunscreen has served as a primary or ancillary outcome measure in six sun-safety intervention studies.[22,40,43,60,61] However, none of these papers reported validity or reliability data for the measures.

Visual Inspection of Moles

The number of moles (i.e., nevi) is a strong risk factor for melanoma.[62] This relationship may be due to the impact UVR exposure has on both mole development and melanoma and/or the development of some melanomas from moles.[4,62] Results of epidemiologic studies suggest that most infants have few moles[63]; the number of moles increases significantly during childhood,[64] and the number of moles in children is strongly associated with the amount of UVR exposure.[65] Therefore, for skin cancer prevention interventions with young children that are designed to follow participants for at least 2 years, mole counts may provide a particularly strong measure of outcome.[16,66,67]

To date, only two intervention studies that used mole counts as a primary outcome have been published.[16,66] Both papers included reliability data. The first study was a randomized controlled clinical trial which tested the effects of a broad-spectrum sunscreen on mole development in 309 first- and fourth-graders, with an interval of approximately 3 years between baseline and follow-up.[66] The authors reported that effect of the counter contributed to <5% of the variance in mole counts.

In the Kidskin school-based intervention trial mentioned earlier,[16] mole counts on the children's (n =1432) backs at the end of the study constituted a main outcome of the study (along with behavioral endpoints reported earlier).[15,17]

Slides were taken of each child's trunk at pre- and post-intervention. These pairs of slides were then viewed simultaneously at the post-test by a trained (blinded) observer, who recorded all preexisting and new moles. As a secondary outcome, observers directly counted (in vivo) moles on each child's face and arms. Reproducibility, which was based on data obtained on randomly selected subsamples of participants, was high: The intrarater correlation coefficients ranged from 0.93 to 1.0, and the inter-rater correlation coefficients ranged from 0.82 to 0.89. After adjusting for baseline mole counts and other potential confounders, no significant differences in mole counts were found on any body sites among the three groups (i.e., high- and low-intensity intervention groups and control group).

Data from these two studies indicate that moles can be counted reliably. This, along with the epidemiologic links among moles, UVR exposure, and melanoma, provides a strong rationale for using mole counts as an outcome in interventions targeting children. However, other factors to be considered include (1) the relative cost and labor intensity of the measures[68]; and (2) the length of the follow-up period, number of participants, and intervention effect size needed for adequate statistical power. Regarding statistical power and design efficiency, it would be valuable to know the window of time during childhood in which the largest number of new moles develops. Prospective epidemiologic data to address this would be useful. Finally, the feasibility and reliability of using mole counts as an outcome with nonwhite participants is not known; both trials included only white participants in analyses.

Measures of Sun-Safety Environments and Policies

An important intermediate outcome in the evidence review of interventions to reduce UVR exposure is change in sun-safety environments and policies (e.g., increasing available shade, providing sunscreen, posting skin cancer prevention information).[9] These types of factors were considered either intermediate outcomes—that is, intended to influence behavioral and health outcomes—or secondary outcomes for populations and organizations such as schools, workplace settings, and recreation venues. They differ from measures of individuals' behaviors or outcomes because they occur at the level of organizations or geographically distinct settings. Still, in many ways, measures of environments and policies parallel those of individual behaviors and health outcomes. This summary focuses primarily on reports of assessments in intervention studies, and is augmented by some data from descriptive survey research, often conducted to inform intervention studies.[69,70]

Typically, these measures have focused on assessments in two categories: (1) environmental supports—mainly availability of shade and sunscreen, and posted information about sun protection; and (2) sun-protection policies—including policies to require or recommend covering up with hats and/or shirts; sun avoidance for outdoor activities (e.g., scheduling to avoid peak time); standard provision of sun-protection education; and comprehensive sun-protection policies. (See previous publications[11,71] for detailed definitions and discussion of the distinctions between policy and environmental interventions.)

Verbal Reports

These measures have usually involved yes/no questions asked in the two main categories: (1) environmental supports, and (2) sun-protection policies. Some studies have used individual items as separate indicators and others have created composite scores.

The most often-used measures of sun-safety environments and policies are surveys of key informants such as child care center directors[28,72]; school principals[73–75]; and aquatic directors and pool managers.[69,76] A second common source of reported sun-safety environments and policies has been potential beneficiaries of environmental changes (e.g., parents, pool users, community members).[18,21,77,78] Only a few studies have reported internal consistency data for measures of sun-protection policies and supports, with a study in outdoor recreation settings finding an alpha of 0.80 for parent-reported policies and supports, and staff-reported policies and supports with an alpha of 0.62.[18,29,78] A four-item measure of parent-reported sun-protection policies had an alpha of 0.82 in a pool-based intervention study.[21]

In several intervention studies in the United States, verbal reports of sun-safety environments and policies by study participants have been shown to be sensitive to change following interventions.[18,21,29,75] This appears to be due in part to the low levels of policies and supports at the time of baseline surveys.

Observations and Documentation

Given the limitations of verbal reports of these measures, some investigators have attempted to corroborate self-report measures using observations of sun-protection environments and other forms of documentation. In a study in child care centers, information from a center directors' survey was supplemented with observations of outdoor play, and a review of policies listed on enrollment materials, such as requiring permission slips to use sunscreen.[28] No psychometric data were reported in this study. Another study of 177 child care centers in Australia found that 97% of center directors reported having a written sun-protection policy, but only 5% of the policies were deemed comprehensive by written review.[72] The latter study underscores the notion that response to yes/no questions may not always distinguish the extent of a written policy, nor how well it is implemented and monitored.

In the Pool Cool sun-safety trial, repeated observations of elements of the pool environment (e.g., shade, availability of sunscreen, sun-safety signs) were found to corroborate the changes found using parent and lifeguard reports of policies and environments.[21] This analysis involved comparing pool-level (observation) data with clustered individual-level (survey) data; however, specific agreement coefficients were not reported.

In the Kidskin intervention trial in Australia, observations and videotapes were used to assess the implementation of "no hat, no play" policies and schools' efforts to reduce sun exposure at lunchtime.[46,51] These indicators were compared with principals' estimates of the proportion of children who played in the sun at lunchtime, but the correlations were not significant.[46] This study also used direct measures of sun-protection environments, which are described below.

Direct Measures of Ambient UVR and Shade

As noted above, measures of ambient UVR levels can be measured by polysulphone dosimeters, placed on stable objects in various sun and/or shade locations.[50,79,80] These measures have only been reported only once in the context of an intervention trial, as a partial indicator of shade in the Kidskin study.[46] The Kidskin trial also measured shade provision using aerial photographs of schools. The photographs were carefully timed and taken on clear summer days, and analyzed using maps and geographic information systems technology.[46] This method of measuring percentage of shade had high reproducibility with a correlation of 0.98 between two sets of photographs, but the correlation between the photographic measures and principals' reports was not statistically significant.[46]

Future Directions in Measuring Sun-Safety Environments and Policies

From a public health perspective, improved sun-protection environments and policies are an efficient and potentially powerful way to reduce UVR exposure and possibly to prevent skin cancer.[11] Measures of environments and policies are less well developed than are measures of individuals' behaviors, but a few studies have offered innovative advancements beyond merely obtaining verbal reports from key informants. Future studies should, at a minimum, include corroborating verbal reports from study participants; and should strive to use documentation and observations in a nonreactive manner whenever possible.

Discussion

There is increasing sophistication and diversification of research in skin cancer prevention. As this field of research advances, researchers should strive to minimize threats to validity in their study designs, as well as to consider the balance between internal and external validity. There is a need for more longer-duration interventions, and follow-up periods that make possible conclusions about the potential of these interventions to affect intermediate markers of skin cancer, or at least about sustained behavior change. Although none of the studies we examined reported on mediation analyses, this approach should be considered in order to improve our understanding of factors influencing "how" skin cancer prevention interventions work.[81,82] Also, more work is needed to minimize attrition and characterize nonresponders and study dropouts, to help frame the interpretation of research findings. The use of measurement strategies other than verbal report alone, and establishing reliability and validity of measures, should be considered in future research.

One of the most-often repeated critiques is related to the quality of study execution.[12,13] A key quality limitation was insufficient description of study samples and other methodologic details. To address this concern, investigators—and journal editors—should renew their attention toward improving the quality of published research reports. The CONSORT Statement (Consolidated Standards of Reporting Trials)[83] and TREND Statement (Transparent Reporting of Evaluations with Non-randomized Designs)[84] provide guidance for reporting both RCTs and studies with nonrandomized designs. The use of devices such as flow diagrams and the checklists suggested in these authoritative statements will improve reporting and make it easier to recognize the strengths and limitations of the accumulating evidence base.

Like any young field, skin cancer prevention research needs more scientific rigor in critical areas such as study design, quality of execution of research, establishing the reliability and validity of measures of behavioral and health outcomes, analytic methods, and reporting and replication of results.[85] The field of behavior change for skin cancer prevention has progressed significantly in the past decade, but important areas for further advancement exist. As outlined above, these include design, measurement, better description of interventions, development of a better understanding of how environmental and policy interventions work, and studies in multiethnic populations. The use of new communication technology and international collaborations can make significant contributions in these areas. The recent evidence review should be updated periodically, to help monitor the findings of skin cancer prevention research as well as methodologic advancements. The availability of systematic reviews that identify both progress to date and the remaining gaps will help to reduce the gaps in available research.

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