

## OPINION PIECE

### Evaluating the Utility of Self and Clinical Skin Examinations to Screen for Skin Cancer: The Importance of Considering Publications of All Levels of Evidence

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In the recent updates to their evidence-based recommendation statements on the utility of clinical skin examination (CSE)<sup>1</sup> and self-skin examination (SSE)<sup>2</sup> for skin cancer primary prevention, the United States Preventative Services Task Force (USPSTF) concluded that there was insufficient evidence to recommend for or against both CSE and SSE. These statements have evoked considerable confusion, frustration, and controversy in the dermatology community.

Understanding the controversy at the heart of this situation requires a close look at the basic tenets of evidence-based practice, and how they have evolved. The term “evidence-based medicine,” as it was originally described, referred to the critical appraisal of the literature by the individual clinician to aid in decision making and patient counseling.<sup>3</sup> This has since grown into a more expansive concept that emphasizes the development of overarching guidelines and recommendation statements by working groups assigned to appraise the primary

literature. While guidelines certainly have great potential if properly comprised, this process has in many cases decentralized the role of the individual practitioner in evaluating the literature directly.

Rather than follow any recommendation statement blindly, it is imperative that the astute clinician reviews the underlying methodology prior to determining how and to what degree the guidelines will be incorporated into daily practice. In the case of the recent USPSTF recommendations, such an exercise will reveal several methodological flaws, but the critical drawback (and the focus of this editorial) is the task force’s overreliance on individual studies’ “level of evidence.” This is an increasingly pervasive problem in the modern medical landscape and underscores the scientific community’s misinterpretation of the original intent of the evidence-based medicine movement.

To grade the strength of their recommendations, the USPSTF uses a

scale based on the level of evidence inherent to the designs of the individual studies that they review. The critical error in their methodology, however, is that they place an disproportionately high value on results from meta-analyses and randomized controlled trials (RCTs) while giving much less consideration to prospective cohort studies and often completely discounting any existing evidence from retrospective cohort studies, case-control studies, and cross-sectional studies. For example, in their recommendation on SSE, they state that there is a lack of evidence linking this practice to lower incidence of skin cancer or other outcomes such as decreased mortality. However, multiple observational studies demonstrating material benefits to SSE exist, including a widely-cited case-control study by Berwick, et al. which revealed the potential of self-examination to reduce melanoma-related mortality by as much as 63%.<sup>4</sup>

Failing to include all study designs is a major oversight. The original tenets of evidence-based medicine make it clear that the practice should not be limited to meta-analyses and RCTs alone.<sup>3</sup> Although these studies are important because they can eliminate confounding and demonstrate causality, other study designs have merit as well and should not be completely discounted. While there is value in recognizing the hierarchy of evidence, sole reliance on study design is a flawed tactic. Rather, close assessment of all aspects of each individual study is important. After all, the results of a poorly constructed, heavily biased RCT are undoubtedly less useful than those of a well-designed retrospective cohort study, but the USPSTF's methods would place significant weight on the former while potentially discounting the latter altogether.

Furthermore, there are some cases in which an RCT cannot feasibly be performed due to ethical concerns or other prohibitively challenging circumstances. In such instances, it would be foolhardy to ignore evidence from observational studies. This point is expertly illustrated by a satirical "study" by Smith and Pell, who after attempting a meta-analysis of RCTs examining the benefits of parachute use during free fall, humorously concluded that there was insufficient evidence to recommend parachute use when jumping from an airplane due to the lack of RCTs examining this intervention.<sup>5</sup> Similarly, there surely are no trials randomizing cardiac arrest patients to cardiopulmonary resuscitation (CPR) versus no intervention. Does that mean that we should publish guidelines concluding insufficient evidence to recommend for or against the use of CPR in patients who suffer cardiac arrest? Another example, pertinent to the dermatology community, is the surgical treatment of skin cancer. One would be hard-pressed to find a study randomizing patients with biopsy-proven melanoma to observation versus surgical excision, yet clearly the former treatment course would be considered unfathomable in all but the most extreme of circumstances. These examples may seem radical, but they illustrate the point. When one considers the exorbitant costs (due to the large number of patients that would need to be followed for many years to demonstrate a significant difference), ethical problems (of withholding screening) that would lead to low enrollment, and bias issues (how could we ensure that patients randomized to no intervention were not looking at their own skin?), it becomes clear just how prohibitive conducting a high-quality RCT of CSE and/or SSE in this realm would be.

Although we applaud the USPSTF's efforts to generate evidence-based guidelines on skin examination, the current system has material deficiencies that may impact any conclusions which they draw. Until they revisit their methods and deliver recommendations that more appropriately consider all existing evidence, providers of dermatologic care must continue to advocate the importance of CSE and SSE in the prevention of skin cancer. We encourage groups like the USPSTF to better integrate observational and anecdotal evidence so that skin exams (like parachutes and CPR) will no longer continue to be under threat of denouncement as a viable life-saving option.

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