

Collection of Patient Reported Outcomes in Vitiligo: A Study Announcement by the VR Foundation

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Abstract

A six-month data collection project from Vitiligo Research Foundation (VRF) is set to begin on November 1, 2015. It involves academic institutions, small-to-medium sized clinics, patient organizations and service providers. A self-reported patient questionnaire structure, along with possible conceptual and methodological difficulties, is reviewed in this communication paper.

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Introduction

Vitiligo affects all ages, sexes and social groups and approximately 1–2% of the world population. It is typically characterized by smooth white patches in the midst of normally pigmented skin, which gradually expand over time. Besides skin manifestation, symptoms such as depression, anxiety, sleep disorders and suicidal thoughts are very common in people affected by this disease. Comorbidities with thyroiditis, diabetes and other diseases are frequently registered. Although primarily viewed as a benign skin disease, vitiligo has severe socioeconomic effects, which have a substantial impact on many aspects of physical, emotional, and mental well-being.

The traditional assessment of vitiligo relies primarily on visual assessment by a dermatologist, with or without using a Wood's lamp, but does not always capture certain aspects of a patient's health that may be important for research. Generally, questionnaires have been found to have a better correlation with other measures than interviews [1], but some patients require assistance, so flexibility in the method of administration is important to capture all relevant information.

Self-reporting by patients is increasingly valued as an outcome variable in vitiligo research studies [2]. The latest massive self-reported study of 1,023 patients with vitiligo was conducted in a nationwide German postal survey in 2009, using health-related quality of life (QoL) and willingness-to-pay (WTP) measures [3].

VRF routinely collects patient health data using a comprehensive, 120 question vitiligo patient record [4] through a network of participating clinicians in six countries. Now VRF aims to collect a substantial set of self-reported data, using a simple vitiligo questionnaire, from patients across the world. These two datasets

will be made freely available to qualified researchers for a range of vitiligo projects.

Questionnaire Structure

Our vitiligo questionnaire measures several aspects of health status in vitiligo patients and the cost of their treatment to date. It is self-administered, fully anonymous and features thirty questions in five sections. These cover biologic factors, symptom status, functional status, treatment outcome perception, and economic impact. The conceptual model was adapted from Wilson and Cleary [5]. The survey takes approximately 15 min to complete. After completion, it can also be used to produce a four-page self-assessment report for a patient's doctor. Templates with a range of translations are available online [6].

There is always a degree of measurement error in both subjective and objective assessments. Conceptual and methodological difficulties that include response and recall biases, the responder's socioeconomic status, timing and distribution may all lead to accumulated error. To minimize these effects, we have used measures that are reliable, sensitive to change, have good predictive validity, and are characterized by minimal measurement error.

A response bias is common to patient-reported outcome surveys, but by employing appropriate strategies we hope to minimize this. For example, using a simple set of 30 questions that asks patients to assess the disease triggers or outcomes of treatment is more efficient than administering a lengthy, interviewer-led vitiligo patient record with 120 questions [4].

A potential selection bias is mostly avoided because the majority of participating patient's lives in different countries and

climate zones and do not belong to the same self-help group or community.

The reporting of skin health events, possible triggers and treatment outcomes has been improved by questions that are designed to facilitate the recall process, i.e., direct questions about a specific treatment process.

The self-reporting format has its disadvantages as patients are known to overestimate their level of adherence. However, findings have suggested that patients find it easier to estimate general adherence (see question nineteen) than to report a specific number of missed interventions. Thus, we expect the adherence question to provide an overestimated but nevertheless valid data [7,8].

Whilst social desirability may be one factor leading to overestimation of adherence, other factors such as memory recall are equally important [9]. Combining temporal markers (see questions six and sixteen) or recall aid (see questions eight, fifteen and twenty-six) alongside a retrospective global report of the outcomes of treatment (see question twenty) helps us overcome some of the problems associated with recall and present state bias. The inclusion of a question probing the negative aspects of other medicines on vitiligo (see question twenty-one) will ensure that all features of experience are covered.

Questions that directly ask patients the extent to which an intervention has changed their skin condition (see question seventeen) may be less subject to bias than questions that

ask patients how satisfied they are with the outcome of their latest treatment.

Completing the questionnaire within the first few months post-intervention, or following the purchase of cosmetic or supplementary products for vitiligo, may minimize recall bias, reduce non-response bias, and thus produce a more representative data set.

We believe this approach will produce great variability and is less likely to be associated with patients' socio-demographic variables and their treatment expenses to date.

Acknowledgements

This data collection project is being undertaken by VR Foundation and its partners (academic institutions, small-to-medium sized clinics, patient organizations and service providers) and is completely self-funded. VR Foundation is the only 501(c) 3 non-profit organization that addresses every phase of vitiligo drug development. The project is due to start on November 1, 2015 and be completed on May 1, 2016.

Guidelines on Use

VR Foundation will provide guidance on how to distribute to and collect the questionnaire from the target audience, so that partners and practitioners alike apply it judiciously and responsibly for a given purpose. Direct any questions to the author – Yan Valle, CEO, VR Foundation - at yan@vrfoundation.org

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