

Accepted Manuscript

Title: Medicine Based Evidence for Individualized Decision Making: Case Study of Systemic Lupus Erythematosis

Author: Ashley E. Wivel, Kate Lapane, Christi Kleoudis, Burton H. Singer, Ralph I. Horwitz

PII: S0002-9343(17)30686-1

DOI: <http://dx.doi.org/doi: 10.1016/j.amjmed.2017.06.013>

Reference: AJM 14162

To appear in: *The American Journal of Medicine*



Please cite this article as: Ashley E. Wivel, Kate Lapane, Christi Kleoudis, Burton H. Singer, Ralph I. Horwitz, Medicine Based Evidence for Individualized Decision Making: Case Study of Systemic Lupus Erythematosis, *The American Journal of Medicine* (2017), <http://dx.doi.org/doi: 10.1016/j.amjmed.2017.06.013>.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Medicine Based Evidence for Individualized Decision Making: Case Study of Systemic Lupus Erythematosis

Running Head: Medicine Based Evidence In Systemic Lupus

Ashley E. Wivel MD^a, Kate Lapane PhD^b, Christi Kleoudis MS^c, Burton H. Singer PhD^d,
Ralph I. Horwitz MD^e

^aawivel@gmail.com, ^bUniversity of Massachusetts Medical School, Amherst, MA, ^cPAREXEL International, Waltham, MA, ^dUniversity of Florida, Gainesville, FL, ^eTemple University, Philadelphia, PA

Communicating Author: Ralph I. Horwitz, ralph.horwitz@temple.edu

Key words: Evidence Based Medicine; Medicine Based Evidence; Clinical Decision Making; Systemic Lupus Erythematosis

Funding Sources: None

Verification: All authors had access to the data and contributed to writing the manuscript.

Conflict of Interest: Drs. Wivel, Kleoudis and Horwitz were employed by GSK; Drs. Lapane and Singer were consultants to GSK

Clinical Significance

- Evidence to guide treatment decisions for a given patient is a multi-dimensional longitudinal profile incorporating biological, clinical, psychological and social environmental information idiosyncratic to the particular patient.
- We developed a taxonomy of lupus patient histories in the context of response to a new therapy that provides an example of how far more nuanced information than that customarily made available from RCTs can be tuned to the needs of clinical practice.

ABSTRACT

To guide management decisions of an index patient evidence is required from comparisons between approximate matches to the profile of the index case, where some matches contain responses to treatment and others act as controls. We describe a method for constructing clinically relevant histories/profiles using data collected but unreported from two recent phase 3 RCTs assessing belimumab in subjects with clinically active and serologically positive SLE. Outcomes were the SRI (SLE Responder Index) measured at 52 weeks. Among 1175 subjects we constructed an algorithm utilizing 11 trajectory variables including 4 biological, 2 clinical and 5 social/behavioral. Across all biological and social/behavioral variables, the proportion of responders based on the SRI whose value indicated clinical worsening or no improvement ranged from 27.5% to 42.3%. Kappa values suggested poor agreement indicating that each biological and patient reported outcome provides different information than gleaned from the SRI. The richly detailed patient profiles

Download English Version:

<https://daneshyari.com/en/article/8604198>

Download Persian Version:

<https://daneshyari.com/article/8604198>

[Daneshyari.com](https://daneshyari.com)