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There is a lack of evidence for benefit of any specific treatment for Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).[1] The purpose of this study is to survey North American dermatologists and burn surgeons in order to estimate the minimally clinical important difference (MCID) in key outcomes for assessing treatment efficacy in SJS/TEN. MCID provides a measure of the smallest change in a specific treatment outcome that clinicians perceive as important and practice-changing. MCID are needed to effectively evaluate treatment efficacy in a clinically meaningful way for physicians. Establishing the MCID is the first step in designing rigorous randomized controlled trials to evaluate treatments for SJS/TEN. There is a lack of clinical trials for these life-threatening conditions, and this study lays the essential groundwork for future trial design.

A survey was designed to estimate MCID values for: (1) length of time to achieve full re-epithelialization (complete healing); (2) length of time before cessation of disease progression; (3) length of hospital stay; and (4) rate of mortality. The confidential and anonymous survey was electronically disseminated to a total of 928 dermatologists and burn surgeons who specialize in SJS/TEN care across North America. Participants were identified through registries from specialty-specific associations including the Canadian Dermatology Association, American Burn Association, and contact lists of North American physicians from previous survey efforts on SJS/TEN. A total of 190 physicians completed the survey using SurveyMonkey (response rate of 20.5%). Weighted means with standard deviations and standard errors of the mean were used. Demographics of survey participants are summarized in Table 1.

The estimated MCID for full re-epithelialization (complete healing) was 3.2 ± 1.8 days (SEM 0.7). The estimated MCID for time to cessation of disease progression was 2.1 ± 1.5 days (SEM 0.7). The estimated MCID for time reduction in length of hospital stay was 2.7 ± 1.6 days (SEM 0.7). The estimated MCID for reduction in rate of mortality falls in between 2- 5% and 6- 10% range; hence, the estimate was no greater than 10% and no less than 2%.

With this survey data, we define a set of MCID estimates for treatment outcomes specific to SJS/TEN. Our study estimated the MCID values from weighted means with standard deviations to provide a clinically meaningful consensus estimate (Figure 1). As perceived by physicians, these values would constitute clinically important changes required to change practice in the management of SJS/TEN.

The strengths of the study are the large size of cohort, high response rate, representativeness, and reproducibility of the survey. However, MCID estimates are not easily verifiable against external objective measures. In addition, the cross-sectional survey design can introduce biases such as recall bias.

Our study is the first to estimate the MCIDs in treatment outcomes for SJS/TEN. This study defines consensus parameters that are necessary to (1) calculate samples size for prospective studies and (2) evaluate treatment outcomes for SJS/TEN. These findings are necessary to design randomized trials and interpret their results in a clinically meaningful way that can ultimately influence clinical practice.

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Table 1. Demographics of 190 physician survey participants

Variable	Value, No. (%)
Field of specialty	
Dermatology	78 (44.3)
Burn Surgery	93 (52.8)
Other	5 (2.84)
Critical Care	4 (2.27)
Pediatric Critical Care	1 (0.57)
Number of years in practice	
1 – 9	77 (44)
10 – 19	35 (20)
20 – 29	31 (17.7)
30 – 39	23 (13.1)
40 – 49	8 (4.57)
Other	1 (0.57)
>60	1 (0.57)
Number cases in past 1 year	
1 – 4	46 (29.3)
5 – 9	50 (31.8)
10 – 14	40 (25.5)
15 – 19	14 (8.92)
20 – 24	5 (3.18)
Other	1 (0.64)
>24	1 (0.64)

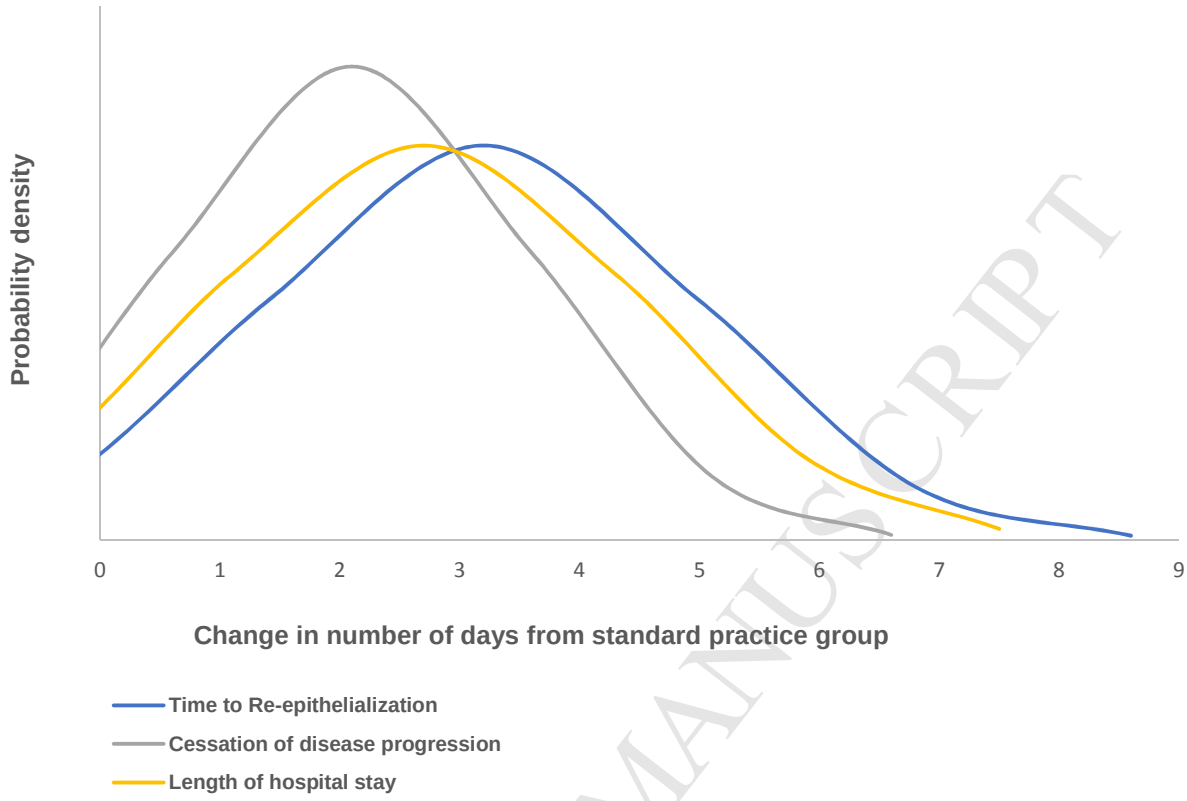
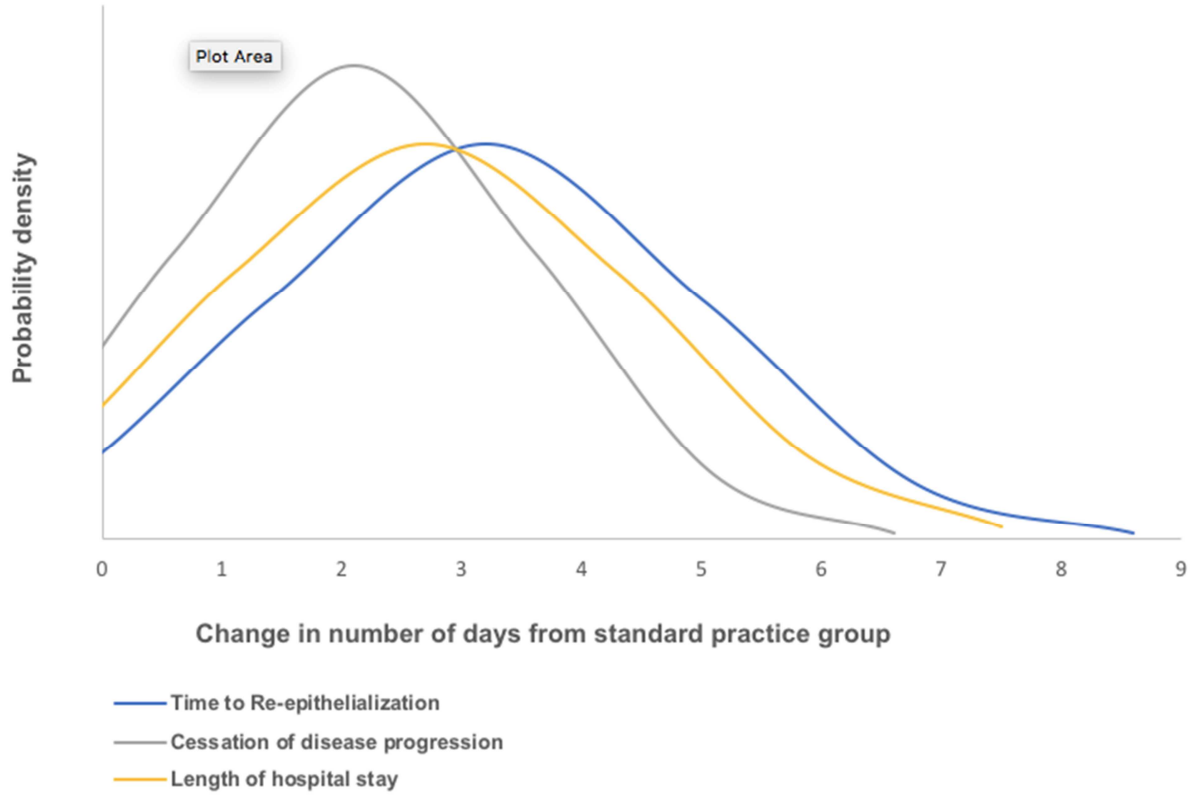


Figure 1. Standard curves for time to re-epithelialization, cessation of disease progression, and length of hospital stay



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