Cover Page

Title: Integration of Standard Dermatology Outcome Measures in Electronic Medical Records to treat Atopic Dermatitis (ISDOM)

Grant ID number: NA

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Abstract:
The overall goal is to test the integration of simple and practical measurement tools designed for robust outcomes assessments of patients with atopic dermatitis (AD) in routine clinical practice. This project seeks to address the "lack of integration of severity assessment into electronic medical records (EMR)" as a barrier to achieving appropriate assessment of AD severity. With an iterative approach hinged on the Plan-Do-Study-Act cycle of the Model for Improvement, we propose three phases to implement a set of simple standardized dermatology outcome measures into the EMR without interrupting clinical workflow and providing useful information to providers (target population) treating AD patients at the time of service.

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Response to Reviewer Comments

Comment: "While most review panel members were interested by your program and look forward to reading your full proposal, there is a desire to better understand the PRO tools and if the project is scalable."

Response: We have provided details and a pictorial representation of the PRO tools in the body of the proposal. We feel that the project is scalable because we will provide the factors for success and barriers to completion of each iteration of the project. We will articulate how we addressed the barriers in order to progress to the next iteration. Other groups can utilize these "helpful hints" as they implement the project to their institution.

Main Section of the proposal
Overall Goal & Objectives:
The overall goal is to test the integration of simple and practical measurement tools designed for robust outcomes assessments of patients with atopic dermatitis (AD) in routine clinical practice. The goal aligns with the RFP in that it identifies the "lack of integration of severity assessment into electronic medical records (EMR)" as a barrier to achieving appropriate assessment of AD severity.

AD is a common and impactful disorder. Its impact on patients is complex and nuanced, resulting in a mixture of symptomatic, emotional, aesthetic, and functional ramifications. A number of tools have been proposed to capture the spectrum of impacts. These have been validated and used primarily within the context of formal study environments, where availability of resources (time, money, and people) is quite different from routine care environments.

It is both a challenge and vitally important to develop approaches and tools which will allow for capture of comparable information in environments of routine care of patients with AD. It is simply unrealistic to believe that the same resources can be deployed in routine care contexts that are deployed in study environments. However, we are still obligated to develop approaches to help us identify whether our attempts to add value to the lives of patients with diseases such as atopic dermatitis are successful, both in individual patients and in populations.

We hypothesize that simple standardized dermatology outcome measures (SDOM) can be integrated into EMR without interrupting clinical workflow and providing useful information to providers treating patients with AD at the time of service. The target population is the dermatology provider. The objectives are to:

1. Assess the feasibility of the integration by measuring provider, nursing, and patient satisfaction, clinical workflows, and overall clinic duration.
    a. Hypothesis 1a: Providers and nurses will not find integration of SDOM disruptive
    b. Hypothesis 1b: Patients will be satisfied with usage of the SDOM measures in the clinic visit
    c. Hypothesis 1c: Overall clinic duration will not exceed more than an additional 5 min per patient as measured by time stamps
2. Assess data completeness of the visit at each stage of implementation of the SDOM. There is a core set of information and outcome measures that we deem necessary for evaluation and management of AD.
    a. Hypothesis 2: During the course of taking a medical history, providers may not capture all relevant information to make adequate assessments and plan. This core set of information includes atopic history, exposures, quantification of disease severity by patient reports (itch score, impact on function), patient and/or physician global assessment, assessment of treatment adequacy, and assessment of iatrogenic injury. At each stage of implementation of the SDOM, we expect more complete capture of such information.

3. Ultimately, we want to assess the impact of SDOM implementation on clinical care and long-term outcomes. This goal is out of scope of the current proposal.
    a. Hypothesis 3: We propose that the implementation of SDOM will lead to quicker and more durable relief in itching for AD patients.

Current Assessment of need in target area

Currently, there is not a standard manner in which dermatologists capture severity or quality of life impact from AD in the EMR. These data are important in the management of patients. Dr. Swerlick (co-PI) was an inaugural member of the American Academy of Dermatology (AAD) Ad hoc Task Force on Data Collection which in turn catalyzed the development of DataDerm, the AAD project to create a national patient data registry. He now co-Chairs this effort, which has identified this massive gap. In order to convince dermatologists on a national level to collect standardized data for atopic patients, the feasibility of such an effort and the benefit of the information must be demonstrated. We thus propose a pilot project, based at a single institution, as a start. For our pilot project, we propose that we utilize iterative quality improvement processes to define and refine a compact PRO and ultimately incorporate this tool into a tablet based electronic data collection tool which will allow for a robust, efficient, and streamlined data collection process to enhance responding to individual patient needs. Once this pilot can demonstrate feasibility and benefit, next iterative steps to broaden to other electronic medical record systems and other provider groups can take place.

Initial metrics will be quantified for clinic duration (Hypothesis 1c) and for data completeness (Hypothesis 2). Hypothesis 1a and 1b will consist of surveys, which do not need initial, baseline metrics.

Clinic duration will be measured both in terms of number of minutes for each patient visit as well as the overall clinic. We will define the visit as starting when the patient is brought back to the examination room. We will define the visit end as when the patient leaves the room. We will have a quality improvement coordinator document the times in which the patient enters and leaves the room, as well as when the nurse, learner, and provider enter and leave the room. Such data will be collected for a minimum of 2 clinics per provider before implementation of Phase I so as to establish a baseline (initial metrics) average duration per patient and per clinic.

Clinic duration extends also to charting time, what we colloquially term, “pajama time” for after-hours charting. We will capture duration of pajama time as an initial, baseline metric. These data can be obtained from the clinical data warehouse.

Data completeness will be defined as the percentage of pre-specified data points completed per medical note. Initial metrics will consist of a data pull and chart review for a 3-month period of time from general dermatology clinics at Emory prior to Phase I. Emory dermatologists document their clinic visit for AD in one of two ways: (1) free text using both dictation and dot-phrases or (2) completing a "rash templated note" consisting of structured fields, called Powernote in Cerner (Figure 1). We will review the electronic medical record note for those that were documented by free text. For the rash template, we will pull the data from the clinical data warehouse. We propose to establish a baseline data capture rate from which we can compare our iterative interventions.

History of Present Illness	Risk Factors+ / Total Body Skin Exam"Spot Check"/suspicious lesions+ / Rash or skin symptom+ / Eczema+ / Acne+ / Warts/Molluscum+ / AKs+ / Alopecia+ / Birthmark+ / Urticaria pigmentosa+ / Isotretinoin+ / Vitiligo+ / OTHER
Rash, Eczema or Skin Symptom*	
Onset	Date=== / ==days / ==weeks / ==months / ==years / OTHER
Initial location	Localized+ / Generalized / OTHER Comment: OTHER
Itch Severity	Itch: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / Worse at night / OTHER M Close contacts itching: Yes / No / OTHER Comment: OTHER
Associated Other Symptoms	Pain: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / OTHER M Fatigue: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / OTHER Fever: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / OTHER Burning: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / OTHER M Stinging: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / Constant / Intermittent / OTHER M Comment: OTHER M
Functional/QOL Impact	None / Minimal / Impacts sleep / Impacts work / Impact school / Mood changes / Impacts social functioning / OTHER M
Previous Treatments	None / OTHER M Local: Topical Antibiotics / Calcineurin inibitors / Prescription Moisturizers / Weak Topical Corticosteroids / Mid potency Topical Corticosteroids / High potency Topical Corticosteroids / Intralesional Corticosteroids / Topical Antifungals / OTHER M Systemic: Antihistamines / Anti-leukotrienes / Corticosteroids / Oral antibiotics / Oral corticosteroids / MTX / Azathioprine / MMF / CSA / Dapsone / Intramuscular corticosteroids / Steriods / Antifungals / OTHER M Light Therapy: UVB / PUVA / Laser / OTHER M Comment: OTHER
Major concern	Treatment / Reassurance / Symptom control / OTHER M
Family history of atopy	Yes / No / OTHER
Previous hospitalization for skin	Yes / No / OTHER
Previous Diagnosis and Plan	OTHER
Patient assessment of response	Minimal / Partial / Near complete / Complete / Adequate / Not adequate / OTHER
Complications of disease	Weakness / Malaise / Headache / Mood changes / Confusion / Indigestion / Nausea / Vomiting / Diarrhea / Visual disturbance / Cough / SOB / Chest pain / Skin irritation / Worsening rash / Sun sensitivity / Itching / Joint pain / Somulence / OTHER
Complications of treatment	Weakness / Malaise / Headache / Mood changes / Confusion / Indigestion / Nausea / Vomiting / Diarrhea / Visual disturbance / Cough / SOB / Chest pain / Skin irritation / Worsening rash / Sun sensitivity / Itching / Joint pain / Somulence / OTHER

Figure 1: Partial screenshot of "rash template" in Cerner

1. **Target Audience:**

The target audiences are the care teams who care for patients with AD. We believe that the patient reported outcome (PRO) information will be useful for such providers. The PRO will allow collection of information during routine clinical care which will facilitate the quantification of the disease severity and quality of life impact, displayed in a concise format for providers to quickly peruse and incorporate into their assessment and plans.

Potential participants will be Emory Dermatology providers, which will include both physicians as well as advanced practice providers. These providers use the Cerner electronic medical record. We will target those providers who are (1) already using the electronic medical record (not just scanning a written medical note), (2) seeing adult general dermatology patients (vs. procedural clinics) to ensure patient with atopic dermatitis. Some of our providers are charting with the free-texting system while others are documenting with the "rash template", described above. We will include both types of users so as to broaden the impact of our project. We know that electronic medical records other than Cerner are used by dermatologists, but these EeMRs do use either templated notes with structure fields or a free-texting system. We intend for other dermatology providers, beyond those at Emory and beyond those who use Cerner, to be able to implement the same SDOM by following the "helpful hints" elucidated from this project.

Both Drs. Chen and Swerlick are in leadership roles at the Emory Clinic and in the Department. As chairman and vice-chair, they will be able to engage willing faculty. As clinical directors, they will be able to engage the nursing staff.

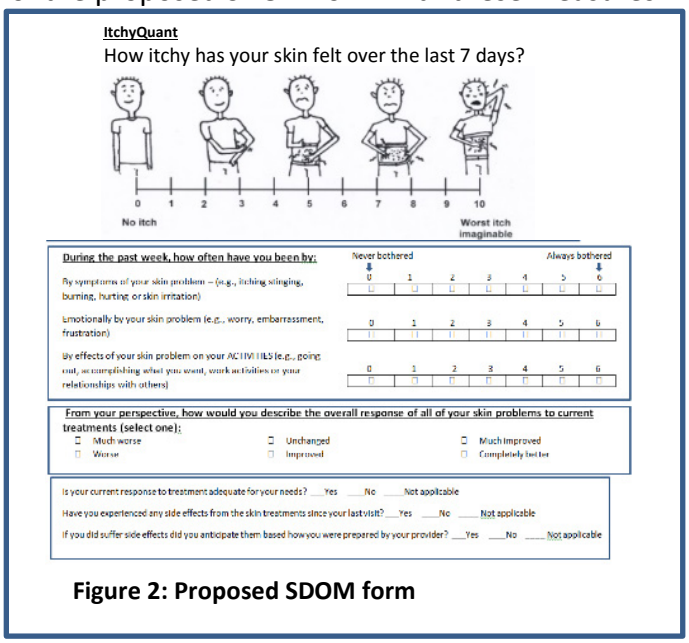
Beyond the primary target (providers), the patients will benefit from the project outcomes too. With implementation of the SDOM, we anticipate that patients will be more satisfied with care at the point of contact because they will be engaged in the assessment using patient reported outcome measures. We also anticipate that they will find relief sooner and with a more durable therapeutic regimen.

Project Design and Methods

Tools to be used

We have already begun these efforts with the development of and validation of streamlined data collection tools based upon PRO models. The proposed standardized PRO are the following. Figure 2 is a representation of the of the proposed SDOM form with these measures.

1. ItchyQuant[1]: cartoon-annotated numeric rating scale of itch severity as reported by the patient with "0" representing "no itch" and 10 representing "worst imaginable itch". The cartoon annotation allows for better understanding of the instructions and meaning of the numbers. The ItchyQuant was developed by Dr. Chen and the copyright is held with Emory University. All non-profit entities and academic institutions can use the ItchyQuant at no cost; only for-profit and pharmaceutical companies are charged a licensing fee.


ItchyQuant

How itchy has your skin felt over the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

No itch — Worst itch imaginable

During the past week, how often have you been by: Never bothered (0) — Always bothered (6)

By symptoms of your skin problem – (e.g., itching stinging, burning, hurting or skin irritation) 0 1 2 3 4 5 6

Emotionally by your skin problem (e.g., worry, embarrassment, frustration) 0 1 2 3 4 5 6

By effects of your skin problem on your ACTIVITIES (e.g., going out, accomplishing what you want, work activities or your relationships with others) 0 1 2 3 4 5 6

From your perspective, how would you describe the overall response of all of your skin problems to current treatments (select one):

Much worse — Unchanged — Much improved

Worse — Improved — Completely better

Is your current response to treatment adequate for your needs? ___Yes ___No ___Not applicable

Have you experienced any side effects from the skin treatments since your last visit? ___Yes ___No ___Not applicable

If you did suffer side effects did you anticipate them based how you were prepared by your provider? ___Yes ___No ___Not applicable

Figure 2: Proposed SDOM form

2. SkinDex-Mini: The SkinDex-Mini is a global quality of life instrument that measures skin disease impact in symptom, emotional, and functional domains using three questions. The Skindex-Mini is built upon the Skindex 16 in that each of the three questions are given with examples drawn from the Skindex 16. Preliminary validation data indicates high correlation between the Skindex 16 and the Skindex-Mini. Drs. Chen, Swerlick and Chren are co-authors of the Skindex-Mini and will license in a similar fashion to that of the ItchyQuant.
3. Patient global assessment – This one-item question is answered on a 6-point Likert scale ranging from "much worse" to "completely better".
4. Treatment sufficiency - Using a single question we query patients whether the outcome of the use of their current treatment regimen is sufficient to meet their needs. The answer is dichotomous (Yes, No)
5. Harm assessment- We utilize two questions, both of which the answers are dichotomous (Yes, No). First, we query patients whether they suffered any harm from treatment and then whether this harm was anticipated.

Project design (strategy, methodology, and analyses)

It has been our experience that while electronic data collection tools are what we ultimately aim to develop, it is difficult-to-impossible to fully understand up front what approaches and questions will be optimal. Instead, an iterative approach, initially using low-technology and nimble practices to discern the issues of content and deployment, is more efficient. This iterative approach is hinged on the Plan-Do-Study-Act cycle of the Model for Improvement, one of the core elements of quality improvement.[2] The Model was developed by the Associates in Process Improvement, and a general-purpose heuristic for learning from experience and guiding purposeful action. It is a tool used in various quality improvement paradigms.[3] We thus plan for three phases of the project (Figure 3).

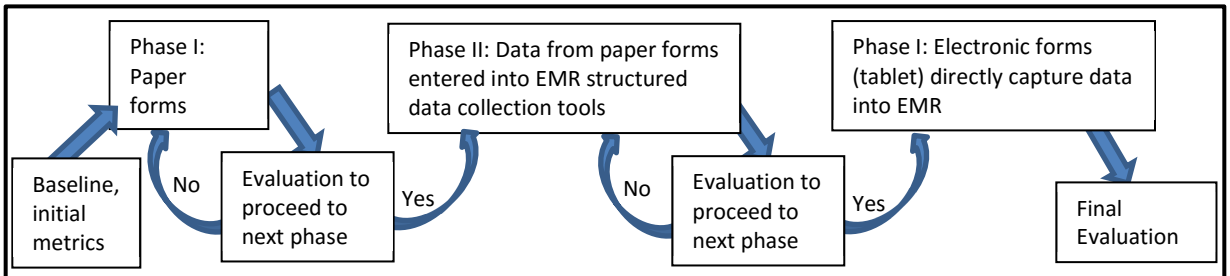


Figure 3: Overall schema of project

In **Phase I**, we will use paper forms to pilot questions and workflows, allowing for agile and iterative approaches to test acceptance of change in busy clinical environments. Quality assessment coordinators will ask patients to complete the SDOM on paper, all prior to the provider interaction. The completion of the SDOM may be done in a research waiting room with privacy, or in the clinical room, after the nurse has finished her portion of the visit but prior to when the provider enters. The completed forms will be given to the provider to use as an intake form.

Phase II will consist of creating a structured data collection tool within our EMR. While the paper questionnaires are efficient and nimble, the information entered into the EMR is not readily queried. The Cerner system allows for Powerforms, which are standardized electronic forms with structured fields. We have already worked with Emory Information Technology to create various Powerforms and they have agreed to create the "Standardized Dermatology PRO" Powerform which will allow us to capture the PRO scores in structured and queriable fields within our data warehouse. We can develop reports which can graphically display PRO data over time. Such reports, displaying changes in Itch Severity scores, SkinDexMini scores, and treatment adequacy, will be presented to providers at the time of service, when key treatment decisions are made.

Thus, for this phase, we will use a hybrid approach, maintaining the use of the paper forms for patients to complete prior to their interaction with the provider as in Phase I. Then quality improvement coordinator will enter the PRO data into the Powerform. The provider can then

use the SDOM data via the Powerform to make decisions, and also as documentation in their medical note.

Phase III of the project will move all data collection to purely electronic tools. The interface for the SDOM Powerform will be developed such that it can be completed either on a tablet and web based questionnaires which can be filled out by patients before, during, or after clinical encounters. All Emory patients receive a reminder (telephone and/or text) about their upcoming appointment. Patients will be asked at the time of their reminder call/text to complete the SDOM form online. At the day of the visit, the quality assessment coordinator will ask them if they have completed the form. If not, they will be given a tablet with the SDOM electronic form. The data from the electronic form (either from the tablet or the online interface) will be downloaded onto a tablet and given to the provider at the time of the visit.

To **evaluate each phase** of the project, to determine whether the study will move to the next phase, four outcomes will be assessed. If the assessments do not meet the targeted threshold (e.g., majority of providers do not accept the implementation as a benefit), then the study will not move to the next phase and factors contributing to the negative assessment will be investigated and corrected for another iteration of the same phase.

Target audience (feasibility and engagement)

We have 18 providers who have general dermatology clinics, ranging from 9 to 15 patients per clinic. We have deliberately omitted surgical clinics. In any given week, we have 60 eligible clinics, translating to 600-900 patients seen. We are confident that with this volume, the proposed project is feasible. We will assess level of engagement of the providers using the surveys (Hypothesis 1a). We will be asking the providers and nurses questions to determine whether the SDOM were disruptive and/or helpful. Whether or not the providers and nurses complete the survey will allow us a first-pass insight into their level of engagement. The type of comments that they provide in the survey will allow us more insight into their level of engagement.

Innovation (assurance that project idea is original)

We know that our specific project idea is original because the ItchyQuant and Skindex-Mini are copyrighted and need approval of the principal investigators for usage. We are aware that the overall idea of incorporating patient-reported outcomes into clinical workflow is not novel. However, our iterative approach using one of the core elements of quality improvement, the Plan-Do-Study-Act cycle is novel.

Evaluation Design

To evaluate each phase of the project and determine whether the study will move to the next phase, four outcomes will be assessed.

1. Assessment of clinic flow by measuring duration of clinic, accounting for number of patients, both AD and total, as well as number of learners (medical student and residents). We know from past implementation research that learners will increase the duration of the

clinic. Before implementation of the first phase, we will measure clinic duration in terms of number of minutes for each patient visit as well as overall clinic time (see above, "Current assessment need, initial metrics") The study will progress to the next phase if the clinic is not extended more than 5 minutes per patient from baseline. We will also capture duration of "pajama time" after-hours charting (see above). If after-hours charting is extended by more than 30 minutes, we will need to revisit factors contributing to the extension. Factors will be corrected for another iteration of the same phase.

2. Assessment of provider and staff acceptance of clinical work flow and value provided. A brief questionnaire will be administered after each clinic, querying providers about the impact of questionnaire deployment on overall clinic flow and on care delivery effectiveness. We will administer similar questionnaire to nursing staff to assess manpower and workflow issues. All provider and nurse interviews will be conducted with paper forms, which will be transcribed into spreadsheets. Data will be analyzed using descriptive statistics. If the majority of the responses are negative, the study will not move to the next phase and factors contributing to the negative assessment will be investigated and corrected for another iteration of the same phase.

3. Assessment of patient acceptance – as part of the depart process already in place, patients will be asked whether they believe the questionnaire use impacted their care at that visit either positively or negatively. If negative, we will ask them to free-text their comments and impressions. If the majority of the responses is negative, the same study pause and assessment will be implemented for another iteration of the same phase.

4. Assessment of data completeness – We will assess data completeness by determining the number of pre-specified pieces of relevant clinical information (see above and Figure 1) completed. We will calculate the proportion of completion. We will perform a chi-square analysis to compare proportions between iterations.

<u>Dissemination of information:</u>
Each stage of the project will be presented and vetted by the AAD DataDerm task force and other AAD venues to determine if the practice gap (i.e., the lack of standardized dermatology measures usable in clinics) is being addressed for dermatology providers. Results will be published in peer reviewed journals for dissemination and presented, where accepted, at national meetings. We will make ourselves available to other groups to troubleshoot their individual efforts to implement the SDOM in their institutions.

Detailed Work plan and Deliverables Schedule:

Deliverables: Each phase will have a report consisting of a summary of the surveys collected from providers, nurses, and patients, clinic duration, and proportion of data completeness.

I. <u>Anticipated Project Timeline</u>	Month 1	2	3	4	5	6	7	8	9	10	11	12
Protocol training and baseline metrics	x											
Phase I implementation & evaluation		x	x	x								
Phase II implementation & evaluation					x	x	x					
Phase III implementation & evaluation								x	x	x		
Manuscript preparation and dissemination of findings											x	x

Overall work plan: One month will be devoted at the start of the project to train staff on the protocol as well as to obtain baseline metrics by chart review and data pulls from the clinical data warehouse, as well as to perform time stamps in clinic. Each of the three phases will be allocated approximately 3 months to implement, capture and analyze data. We will allow two months at the end of the year to summarize our findings into manuscripts and reports. We will also submit abstracts to national meetings to disseminate our findings.

Detailed work plan: In each of the three iterations, we plan to implement the project in two simultaneous clinics. With two project personnel in each clinic, we will perform time stamps and administer the surveys. The time stamp person will stand in the hallway to mark the time that the patient, clinical staff, and learners enter and leave the room. The survey administrator will give the survey to the patient (iteration 1 and 2: paper survey, iteration 3: via tablet). The research interviewer will tabulate the survey results in iteration 1 while the patient is being assessed. In iteration 2, the research interviewer will be entering the data from the paper into the Powerform and sending the tabulated results to the providers. Note that in iteration 3, there will not be a need for the research interviewer to handle the data because the patient completes the survey directly into the tablet. As the patient leaves, project personnel will be administering a brief survey to the patients to assess their impression of the workflow and the survey information. At the end of each clinic, project personnel will administer a survey to the providers and nursing staff to assess their evaluation of the clinic workflow. On a weekly basis, the research interviewer will be entering all data into secure electronic spreadsheets not already captured during the clinical sessions. This includes the time stamps and the surveys.

After two weeks of data acquisition or 20 clinics, whichever occurs first, the clinical data warehouse team will pull all structured data from the warehouse. Project personnel will perform a chart review for those data that were not entered into a structured template. The biostatistician will compile the data for the team to assess. Any changes to the process will be implemented and the cycle will repeated until no changes are needed. At this point, the project

will proceed to the next phase. We are optimistic no more time in addition to the three months will be needed for each phase.

References

[1] Haydek CG, Love E, Mollanazar NK, et al. Validation and Banding of the ItchyQuant: A Self-Report Itch Severity Scale." J Investig Dermatol; 137(1):57-61.

[2] Langley GJ, Nolan KM, Nolan TW,et al. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* 2nd ed. San Francisco: Jossey-Bass; 2009.

[3] Scoville R, Little K. *Comparing Lean and Quality Improvement*. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2014. (Available at ihi.org)