

I. Title Page

Project Title: Identifying and addressing barriers to primary adherence with acne medications: development of a qualitative data-sourced toolkit

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Brief summary:

We propose a study to identify barriers for patient adherence with dermatology prescriptions (namely, systemic doxycycline and minocycline and topical retinoids for acne), such as the role of out-of-pocket cost to patients. Subsequently, we will create a provider toolkit for dermatologists and internal medicine physicians to improve primary adherence to these agents. Ultimately this will lead to development of a roadmap for implementing the toolkit broadly in practice to improve patient access to therapies.

II. Goals and Objectives

Currently, dermatology patients frequently do not fill their prescription medications. We hypothesize that this poor primary adherence (not filling a prescription for a new medication) reflects specific barriers to access, namely the frequently unpredictable and growing out-of-pocket cost to the patients and physicians' inadequate ability to screen and communicate with patients regarding the value of their medications. As an increasing number of patients carry high-deductible or tiered insurance plans, this problem will continue to grow.

Patient perceptions of barriers and facilitators that influence primary adherence to dermatologic medication are unknown. We propose a mixed methods study of patients with good and poor primary adherence to common dermatologic agents (specifically systemic doxycycline and minocycline and topical retinoids for acne), creating a body of evidence about patient perception of the trade-offs between benefits, cost, and barriers to adherence. We will then use these findings to develop a toolkit to help providers communicate about value and screen for barriers to primary adherence in this patient population.

Specifically, the goals of our project are to:

- * 1 - Identify barriers and facilitators of primary non-adherence with systemic doxycycline and minocycline and topical retinoids
- * 2 - Assess the role of out-of-pocket cost in patients' primary adherence and elicit optimal ways to screen for this barrier to adherence
- * 3 - Create a provider toolkit for dermatologists and internal medicine physicians to improve primary adherence
- * 4 - Develop a roadmap for implementing the toolkit in settings outside of the scope of this study (e.g., other dermatologic agents and other practice types)

III. Project Design, Methods, and Evaluation

1 - Identify barriers and facilitators of primary adherence

1a - IRB approval (months 1-2): Drs. Lipoff and Ryskina will write and submit an IRB application to the University of Pennsylvania IRB and will address any concerns and revise as needed to secure IRB approval of the study. The Penn Department of Dermatology Clinical Studies Unit will supervise IRB development and provide support (January-February 2016).

1b - Cohort identification (month 2, upon IRB approval): Dr. Ryskina will work with a programmer to develop an algorithm to pull data from Penn Data Store for dermatology and internal medicine patients who were started on medications of interest in the past month (the time frame may be shifted to capture 200 patients). Upon IRB approval, the algorithm will be applied to identify patients whose charts will then be reviewed selectively to identify likely good and poor adherence, narrowing the target sample. (February 2016)

1c - Data management (month 3): The sample data will be entered into a secure database that will be developed by study investigators and maintained by a trained research assistant. (March 2016)

2 - Specifically assess the role of out-of-pocket cost in patients' primary adherence and elicit patient-centered ways to screen for primary non-adherence

2a - Design data collection instrument/telephone script (months 1-2): Working with the experts at the Penn Mixed Methods Research Lab, Drs. Lipoff and Ryskina will develop and pilot telephone script instrument to ensure face validity (January and February 2016)

2b - Data collection (months 3-7): Penn Mixed Methods Research Lab experts will conduct telephone interviews of 30 patients who are adherent and 30 patients who are not adherent (of the 200 patient initial sample, assuming 30% yield) (March - July 2016).

2c - Data analysis (month 8-10): Qualitative data experts from the Penn Mixed Methods Research Lab will work with Dr. Ryskina and Dr. Lipoff to develop and revise a coding scheme using Grounded Theory approach. Common themes will be summarized in a final report and will be used to inform the development of the tool kit in Aim 3 below. (August-October 2016)

3 - Create and evaluate a physician-patient toolkit to improve adherence

3a - Design a toolkit (months 11-13). Experienced innovation designer (Davis Hermann, MiD) will work with study investigators to develop a toolkit using feedback gathered

from patients and with input from physicians. Toolkit form and function will be developed according to demonstrated stakeholder needs. (November 2016 - January 2017)

3b - Pilot toolkit (month 13): The designer will lead a small pilot for the toolkit, collect feedback, measure the impact, and make changes as needed. (January 2017)

3c - Implement toolkit (month 14): The toolkit will be rolled out and implemented in dermatology and internal medicine practices at Penn. (February 2017)

4. – Disseminate findings and develop a roadmap for implementing the toolkit in other settings

4a - Disseminate (month 15): Disseminate study findings and toolkit to a wider audience. Team will produce a roadmap for using this toolkit in settings outside of the University of Pennsylvania practices. (March 2017)

4b - Evaluate impact (future directions outside the scope of this 15-month project): Although evaluation of the impact of the toolkit on adherence is outside the scope of this study, we plan to explore the trends in primary adherence and physician and patient experiences with the intervention in a second phase of the project.

Goals of the project

In this study, our goal is to evaluate primary medication adherence (specifically with systemic antibiotics such as doxycycline and minocycline and topical retinoids) among dermatology patients to identify key factors in two phases and implement an intervention with recommendations based on our findings.

- * To identify factors for primary adherence with dermatology prescriptions (namely, systemic doxycycline and minocycline and topical retinoids)
- * To specifically assess the role of out-of-pocket cost in patients' primary adherence to these therapies
- * To create provider education deliverable to dermatologists and internal medicine physicians to improve awareness of costs and other factors important to patient adherence
- * To develop a road map for implementing this toolkit in other settings to improve patient access to therapies

Project Design (how the goals will be achieved)

The project will have three-pronged approach:

- * 1 - Secondary data analysis of prescribing information for patients of dermatology and internal medicine practices affiliated with Hospital of the University of Pennsylvania and Penn Presbyterian Medical Center
- * 2 - Qualitative study of patients with (1) good and (2) poor primary adherence to identify common barriers and facilitators of adherence. We hypothesize that medication costs represent an important barrier to adherence and will specifically evaluate this issue. The quantitative and qualitative information obtained in this study will inform intervention to improve medication adherence.
- * 3 - Intervention phase. In this final phase, we will design a toolkit to deliver to dermatologists (and other providers) specific information about the out-of-pocket costs and other factors that affect patient adherence. The toolkit will be developed with the assistance of an experienced health innovation designer with input from physicians and using feedback gathered from patients. Toolkit form and function will be developed according to demonstrated stakeholder needs. With time, we hope this resource will ensure optimized primary adherence with medications.

Participants

- * Jules Lipoff, MD, (primary investigator) Assistant Professor, Department of Dermatology, University of Pennsylvania
- * Kira Ryskina, MD, MS (co-primary investigator), Research Fellow, Division of General Internal Medicine, University of Pennsylvania and Attending Physician, PennCare Internal Medicine Associates, internal medicine faculty practice of the University of Pennsylvania
- * Christine Cabell, MD, President, Pennsylvania Academy of Dermatology
- * Jennifer Keeler, Executive Director, Pennsylvania Academy of Dermatology
- * Davis Hermann, Designer, Penn Medicine Center for Health Care Innovation

Delivered Project (what services you promise to deliver, to what population)

In the course of the project, we will produce the following deliverables:

- 1 - Report summarizing prevalence of primary non-adherence to doxycycline and minocycline in this diverse cohort of patients at a large academic medical center. This report will be used to develop a manuscript to be disseminated to researchers and thought leaders in dermatology to highlight the scope of the problem and potential solutions.
- 2 - Transcript summarizing thematic analysis about factors of patients' non-adherence, identifying ways to improve it. This will serve as the basis for developing a toolkit (see #3 below), which will be disseminated to researchers and clinician and policy audiences via a peer-reviewed manuscript in a high impact journal.
- 3 - Physician-patient toolkit aimed at clinical dermatologists, general internal medicine practitioners, and other relevant providers aimed at screening for barriers to adherence and reducing primary non-adherence to dermatologic medications.
- 4 - Roadmap for implementing this toolkit in settings outside of the scope of this study (such as other practice types).

Outcome Measures (how success or failure will be measured)

We will use the following measures to evaluate success of the project:

- * 1 - Enrollment rate of patients willing to participate in telephone interviews
- * 2 - Physician feedback about the toolkit materials
- * 3 - Physician adoption and use of the toolkit in practice
- * 4 - With time and future study, evaluation of primary adherence after implementation of our invention.

V. Budget

See attachment

VI. References

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