

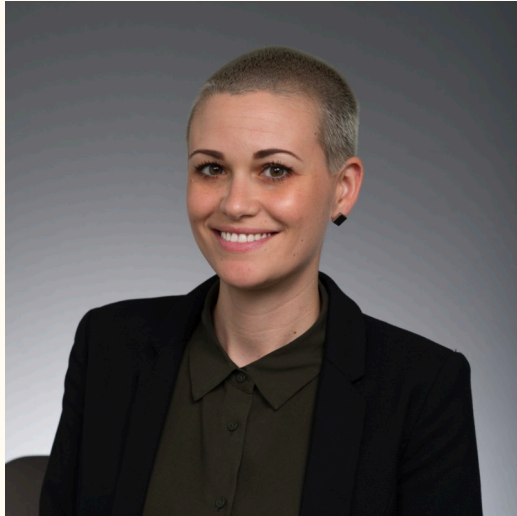
Chronic Graft-Versus-Host-Disease: Development of a Skin-Specific Patient- Reported Outcome Measure

Amol Jhala
University of Pennsylvania, Class of 2025
Wharton Dean's SUMR Scholar 2023

The Team

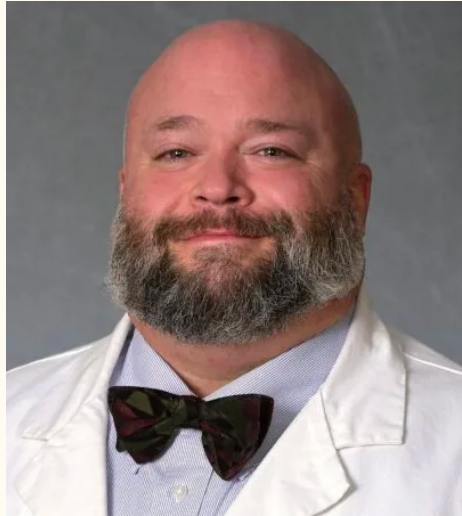
Andrea Bilger

Assistant Director, MMRL



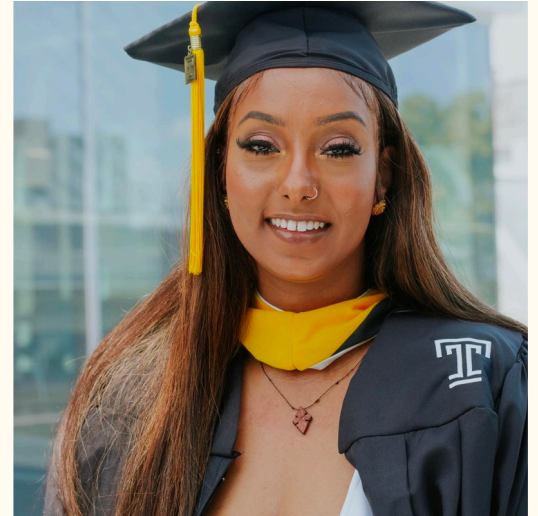
Dr. Peter Cronholm

Director, MMRL



Mika Mengesha

Research Coordinator, MMRL



Project Overview

Hematopoietic Stem Cell Transplantation (HSCT)

Also known as a bone marrow transplant

Life-saving procedure for malignant and non-malignant blood disorders

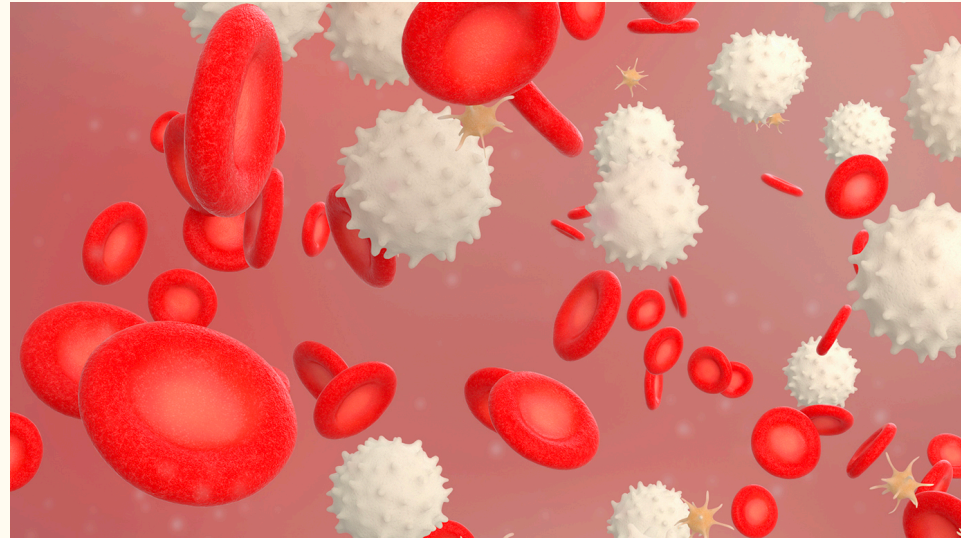


Chronic Graft-Versus-Host-Disease (GVHD): A Major Complication Post-Transplantation

Immune-mediated multisystem disorder

Direct cause of allogeneic HSCT

Observed in 30-50% of those who undergo transplantation (60-70% of this group develop skin involvement)



Significance of this Project

The NIH and the 2020 Recommendations

Limitations of the NIH Skin
Score - low interrater reliability
+ inability to register big
changes

2020 NIH Consensus
Committee - better tools for
skin GVHD



**National Institutes
of Health**

Emergence of Patient-Reported Outcome Measures (PROMs)

Rise of PROMs - endorsed by FDA for improving patient care

PROMs have various limitations despite their benefits

Development of a PROM specific to skin for GVHD



Aims

Project Aim and Initiative

Primary Goal:

Formulation and validation of enhanced tools for evaluating the severity and treatment response of chronic GVHD.

Outline of Initiative:

The establishment and validation of a disease-specific PROM for chronic cutaneous GVHD.

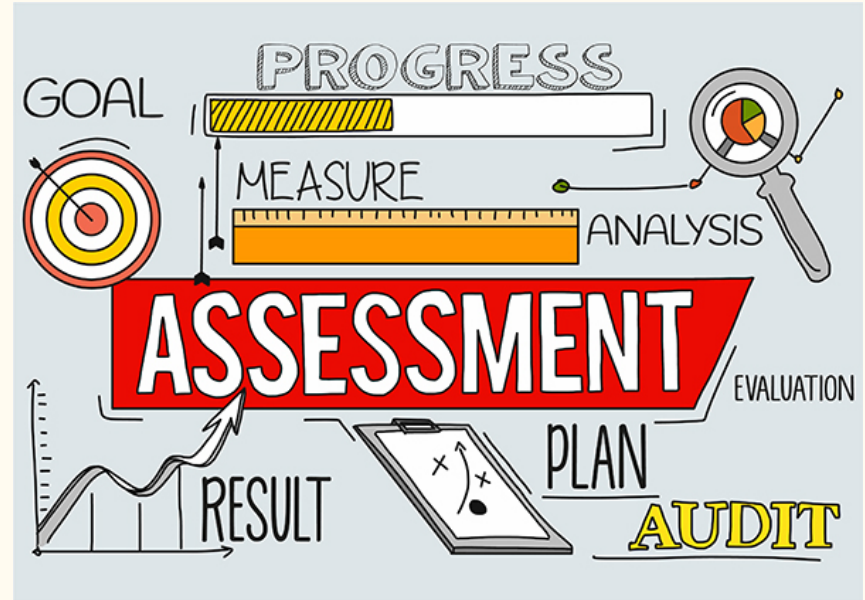


P R O J E C T
INITIATIVE;

Assessing the Novel PROM

Evaluation Strategy:

Assessment of the comprehensibility, comprehensiveness, and relevance of the newly developed PROM via cognitive interviews and expert reviews by dermatologists and transplant physicians.



Methods

Qualitative Assessment Plan

An in-depth qualitative examination of individuals with chronic cutaneous GVHD via qualitative interviews using a semi-structured interview design with a free-listing portion to assess health-related quality of life domains and to create items for a PROM.



Data Management and Analysis

Record, transcribe, and anonymize interviews; upload to NVIVO 12.0.

Analyze subsequent interviews using initial codebook, add themes as needed.

Conduct free listing analysis in R after interviews completed.



Findings

Preliminary Findings and Key Themes

Preliminary findings are still being defined due to the project's ongoing nature.

However, key themes emerging during the cleaning and coding stages inform specific codebook development for our qualitative analysis in NVivo.



The Codebook

GVHD CODEBOOK

	Code	Definition/When to use	When NOT to use	Examples	Possible Sub-codes
1	Symptoms	Descriptions of disease-related symptoms. Can include direct physical symptoms or secondary symptoms that occur as a result of primary symptoms. Also can include mentions of triggers to symptoms.	When side effects of medications are described	<p><i>Stiffness, pain, shortness of breath, respiratory issues, skin hardening, cracked skin, burning, etc.</i></p> <p>Primary- skin related Secondary-insomnia, feeling unbalanced, weakness</p> <p><i>"Well, it's very sore. It's itchy." "... the skin is very hard, but there's sores on it that we have to treat, we have to do special raps because the area between my kneecap and my groin is just very itchy and sleeky GVHD and my stomach and my chest, there's lots of crack skin, flaking skin." "The stiffness and the pain" "The main thing is the insomnia that's annoying..."</i></p>	<ul style="list-style-type: none"> - <i>Primary</i> - <i>Secondary</i> - <i>Triggers:</i> References of triggers to symptoms. Can include activities or environments that can cause symptoms to get worse or flare. Must specifically state that flares are a direct result of the trigger.
2	Disease location	Descriptions of the anatomic location of disease on the body Can include references of internal vs. external location		<p><i>"On legs, trunk, arms" "Internal scarring" "No, it's obvious on my legs." "Yeah, I mean, I've had superficial GVHD. Just a dermatitis that went away with the ointment..."</i></p>	
3	Physical functioning	References to physical actions that are affected by the disease		<p><i>Going up the stairs, walking, exercising, hobbies, working, impact on daily functioning (sleep, brushing/hitting against something, etc.) "...It's hard to do the things that I would normally do just like walking or exercising."</i></p>	

The Codebook

	Code	Definition/When to use	When NOT to use	Examples	Possible Sub-codes
				<i>"Well, I don't exercise as much. I don't walk as much. I'm not likely to do housework and even getting in and out of the car is difficult, because I'm likely to glance my calves against the car or something and that hurts."</i>	
4	Psychological/Emotional impact	Descriptions of the psychological or emotional impact of the disease. Includes mentions of oriented fear and worry about disease or disease course.	Does not include psychological or emotional changes related to treatment.	<i>Isolation, lack of motivation, helplessness, laziness, emotions around coping with disease, fear of the future, fear of disease trajectory</i> <i>"And during the day when I get a flare up, it's a matter of just not feeling motivated to do anything. Not wanting to move around, not wanting to go outside. So it's very inhibiting and isolating."</i> <i>"And also I have some fear of falling and that has to do with the stiffness."</i> <i>"It's depressing. There's so much uncertainty. You don't know when it's going to come, when it's going to go away."</i>	
5	Social interactions	References to others perceptions of self and self perception to others. Includes difficulties in being social or interacting with others.		<i>"embarrassed to go to the gym"</i> <i>"It's ugly."</i> <i>"They don't even notice it."</i> <i>"it's a whole pattern of not wanting to go out"</i>	

The Codebook

	Code	Definition/When to use	When NOT to use	Examples	Possible Sub-codes
6	Symptom analogy	Used to capture analogies that are used when describing disease symptoms		<p><i>"...like wearing a girdle"</i></p> <p><i>"washed out"</i></p> <p><i>"...my whole body, it was like I was wrapped in tape."</i></p> <p><i>"they were just like of the mummy's."</i></p>	
7	General perception of self	Descriptions of perceived current health status. Can include comparisons of self pre-disease vs post-disease.		<p><i>"50% of self"</i></p> <p><i>"life-changing situation"</i></p> <p><i>"...makes me feel very frail and vulnerable, because I'm used to being active. I'm used to doing exercise and things that I used to do very easily and undoable."</i></p> <p><i>"Because I look so different than I used to look. And it's sounds vain but, it sucks."</i></p>	
8	Treatment perceptions	Descriptions of feelings and attitudes towards medications or treatment effectiveness or importance. Can include requirements of treatment (eg time)		<p><i>"frustrated, not seeing improvements"</i></p> <p><i>"comfortable"</i></p> <p><i>"nothing has worked"</i></p> <p><i>"I don't like the creams"</i></p>	-
	Treatment side effects	Descriptions of side effects experienced due to medications	<p>Do not use when remembering a side effect of a medication that was given before skin GVHD.</p>	<p><i>"Well, one of the drugs that I'm on is prednisone and prednisone has caused lots of swelling in my body, especially my face and neck. So it's embarrassing. Because I look so different than I used to look. And it's sounds vain but, it sucks."</i></p>	-

The Codebook

	Code	Definition/When to use	When NOT to use	Examples	Possible Sub-codes
	Treatment response	Physical or emotional changes or lack thereof caused by treatment		<i>"I used to be a regular exerciser and now I can barely use my shoulders. So, there's fear about it getting even worse now that they have me back on steroids."</i>	-
9	Support	References to support received by others or mentions of reliance on others for assistance due to disease-related inability or impairment. Includes support from healthcare providers.		<i>"I have to get my husband involved in putting ointment on my legs and on my back sometimes. Also with putting on socks..."</i> <i>"My wife keeps track of all my medications"</i>	
10	Lifestyle impact	References to changes to behavior or environment as a result of disease. Can include intentional modifications or unintentional consequences.	Do not use when describing physical limitations from the disease (i.e. climbing stairs)	<i>Avoiding sun, maintaining low temperatures by using overhead fan/windows, avoiding short-sleeved shirts or shorts, increasing use of moisturizers, can't work because of so many appointments</i> <i>"I try to get as much coolness in the room as possible, because it's like a burning sensation. So I have the overhead fan on and I open all the windows."</i> <i>"That's one thing I don't like is, if I wear shorts too much the sun makes it flare up. So I don't wear shorts too often"</i>	
11	Disease understanding	Used when capturing instances of confusion on symptoms or other aspects of disease pre-diagnosis or during disease.		<i>"you don't know what's just dry skin and what's disease"</i> <i>"It was like a rash on my lower leg. I couldn't explain where it came from"</i> <i>"I said, is this poison Ivy? I looked at it and it didn't look like poison Ivy. It wasn't a wet rash or dry rash. Nobody knew what it was."</i>	

My Role and Moving Forward

My Role

Cleaning and preparing the transcripts for coding.

Open coding to develop the codebook.

Inter-rater reliability (IRR) during coding using NVIVO 12.0 – ensure a 0.75 kappa score.



Moving Forward

Finish coding all interview transcripts.

Utilize R to conduct a free listing analysis.



Lessons Learned

Effective communication

Teamwork

Perseverance

NVivo and qualitative analysis

Qualitative vs. quantitative
research



Thank You!



Dr. Peter Cronholm, MD, MSCE, CAQHPM

Andrea Bilger, MPH

Mika Mengesha

Hilena Gebru

Dr. Matthew Kearney, PhD, MPH

Joanne Levy, MBA, MPC

ChiChi Nwadijobu, MLA

SUMR 2023 Cohort

Questions?

ajhala@sas.upenn.edu

[linkedin.com/in/amol-jhala/](https://www.linkedin.com/in/amol-jhala/)