

Public Meeting on Patient-Focused Drug Development for Vitiligo

Monday, March 8, 2021

FDA will be streaming a live webcast of the meeting with the presentation slides, which is open to the public at: <https://fda.yorkcast.com/webcast/Play/46a8899c50914665b27d134db530bd421d>. The webcast recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting.

 #PFDD



Welcome

Robyn Bent, RN, MS | CAPT, U.S. Public Health Service

Director, Patient-Focused Drug Development Program

Office of Center Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration



Agenda

- Opening Remarks
- Setting the Context
 - Overview of FDA's Patient-Focused Drug Development Initiative
 - Overview of Vitiligo
 - Overview of Discussion Format
- Discussion Topic 1: Health Effects and Daily Impacts
- Break
- Discussion Topic 2: Current Approaches to Treatment
- Closing Remarks

Opening Remarks

Kendall Marcus, MD

Director

Division of Dermatology and Dentistry

U.S. Food and Drug Administration

Overview of FDA's Patient-Focused Drug Development Initiative

Theresa Mullin, PhD

Associate Director for Strategic Initiatives

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

What is Patient-Focused Drug Development (PFDD)?



PFDD is a systematic approach to help ensure that **patients' experiences, perspectives, needs, and priorities** are captured and meaningfully incorporated into drug development and evaluation.¹

¹<https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary>



Value of FDA's PFDD Meetings

- Patients are uniquely positioned to inform FDA understanding of the clinical context for drug review and regulatory decision making
- Prior to PFDD, available mechanisms for obtaining patient input were limited to discussions related to specific applications under review, such as Advisory Committee meetings and only a few patient representatives
- PFDD meetings provide a more systematic way to obtain patients' perspectives on severity of a condition, and its impact on daily life, and their assessments of available treatment options



PFDD Meetings Provide Key Stakeholders an Opportunity to Hear the Patient's Voice



CY2013

- Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis
- HIV
- Lung Cancer
- Narcolepsy

CY2014

- Sickle Cell Disease
- Fibromyalgia
- Pulmonary Arterial Hypertension
- Inborn Errors of Metabolism
- Hemophilia A, B, and Other Heritable Bleeding Disorders*
- Idiopathic Pulmonary Fibrosis
- Female Sexual Dysfunction

CY2015

- Breast Cancer
- Chagas Disease
- Functional Gastrointestinal Disorders
- Parkinson's Disease and Huntington's Disease
- Alpha-1 Antitrypsin Deficiency*
- Non-tuberculous Mycobacterial Lung Infections

CY2016

- Psoriasis
- Neuropathic Pain Associated with Peripheral Neuropathy
- Patients Who Have Received an Organ Transplant

CY2017

- Sarcopenia
- Autism
- Alopecia Areata
- Hereditary Angioedema*

CY2018

- Opioid Use Disorder
- Chronic Pain

CY2019

- None

CY2020

- Systemic Sclerosis
- Stimulant Use Disorder

CY2021

- Vitiligo

In addition, FDA clinical and statistical review staff have also attended over 40 other *Externally-Led PFDD* meetings to date, conducted by patient advocacy groups



Patients' Perspectives Inform FDA work in oversight of medical product development and evaluation

FDA's mission is to **protect and promote public health** by evaluating the **safety and effectiveness of new drugs**.

While FDA plays a critical role in drug development, it is just one part of the process. **FDA does not develop drugs nor conduct clinical trials.**

Review divisions at FDA (e.g., Division of Neurology, Division of Psychiatry, etc.) provide **regulatory oversight** during drug development, make decisions regarding **marketing approval for new drugs**, and **provide guidance** to regulated industry on clinical, scientific and regulatory matters.

PFDD meetings follow a **town hall style** discussion format



Overview
Clinical Background
and Current Available
Treatments



Symptoms and Daily Impacts

- Panel of patients and caregivers
- Facilitated group discussion



Current Treatment Options

- Panel of patients and caregivers
- Facilitated group discussion



Each PFDD meeting is tailored to the needs of the specific disease area

- FDA encourages patient advocates, researchers, drug developers, healthcare providers and other government officials to attend PFDD meetings
- However, our focus is on hearing directly from patients and their caregivers, so we ask that others remain silent in listening mode during the discussions since the meetings are a **platform to hear directly from patients, caregivers and patient representatives.**
- After the PFDD meeting, a **Voice of the Patient report** summarizes the input shared by patients and caregivers.



Resources are available on PFDD webpages

CDER Patient-Focused Drug Development Homepage

- Guidances
- COA Grant Program
- FDA-led PFDD Meetings
- Externally-led PFDD Meetings
- External Resources



- Browse upcoming meetings
- View past meeting materials
 - Slides, meeting recordings, transcript, agenda, summary report

Questions?

Email PatientFocused@fda.hhs.gov.

To get updates about CDER's Patient-Focused Drug Development programs, subscribe to our **free email subscription service** by clicking on the button near the top of the **homepage**.



Thank you!

An Overview of Vitiligo

Brenda Carr, MD

Medical Officer

Division of Dermatology and Dentistry

U.S. Food and Drug Administration



Overview of Talk

- Introduction
- Epidemiology
- Clinical Features
- Treatment
- Impact of Vitiligo

Introduction

- Vitiligo is an acquired disorder of pigment loss.
- Lesions are white patches with sharp margins.
- Vitiligo results from destruction of melanocytes.
 - Proposed theories include autoimmunity, genetics, oxidative stress, neural hypothesis.¹

¹Grimes PE. Vitiligo: Pathogenesis, clinical features, and diagnosis. In: UptoDate, Tsao H (Ed), UptoDate, Waltham, MA. (Accessed on February 1, 2021.)

Epidemiology

- Estimated prevalence is ~ 1% of the worldwide population²
- Nearly 50% have onset before age of 20 years³
 - Onset < 12 years old is common⁴
- Affects males and females equally³

²Whitton et al. Evidence-based management of vitiligo: summary of a Cochrane systematic review. Br J Dermatol 2016;174:962–969.

³Ezzedine et al. Vitiligo. Lancet 2015;386:74–84.

⁴Nicolaidou et al. Childhood- and later-onset vitiligo have diverse epidemiologic and clinical characteristics. J Am Acad Dermatol 2012;66:954-8.

Clinical Features

- Two major types:
 - *Non-segmental*: bilateral, symmetrical, unpredictable; most common; subtypes include localized, acrofacial, generalized, universal
 - *Segmental*: unilateral, stable
- Hair in affected areas may be depigmented
- Mucosa may be involved



Acrofacial

Rodrigues et al. New discoveries in the pathogenesis and classification of vitiligo. *J Am Acad Dermatol* 2017;77:1-13.



Generalized

Taieb A and Picardo M. Vitiligo. N Engl J Med 2009;360:160-9.



Generalized

Ezzedine et al. Vitiligo. Lancet 2015;386:74–84.



Universal

Rodrigues et al. New discoveries in the pathogenesis and classification of vitiligo. *J Am Acad Dermatol* 2017;77:1-13.



Segmental

Ezzedine et al. Vitiligo. Lancet 2015;386:74–84.

Treatment

- FDA-approved therapy: Monobenzone Cream
(no longer marketed)
 - “Indicated for final depigmentation in extensive vitiligo”



Topical

- Corticosteroids
- Calcineurin inhibitors
- Vitamin D analogs

Phototherapy

- Ultraviolet B (UVB):
 - Narrowband (NB-UVB)
 - Monochromatic excimer light (lasers, lamps)
- Psoralen plus ultraviolet A light (PUVA) photochemotherapy
 - topical or oral

Systemic

- Oral corticosteroids
- Limited information for other immunosuppressants⁵

⁵Rodrigues et al. Current and emerging treatments for vitiligo. J Am Acad Dermatol 2017;77:17-29.

Surgical

- Tissue grafts^{5,6}:
 - Punch
 - Suction blister
- Cellular grafts⁵:
 - Noncultured epidermal suspension
 - Cultured melanocytes

⁶Iannella et al. Vitiligo: Pathogenesis, clinical variants and treatment approaches. Autoimmunity Reviews 2016;15:335–343.



Camouflage

- Makeup
- Tattoos
- Self-tanning products

Other Measures

- Diet and supplements⁷
 - Investigation of possible adjunctive role for vitamins, minerals, botanicals

⁷Grimes PE and Nashawati R. The Role of Diet and Supplements in Vitiligo Management. *Dermatol Clin* 35 (2017) 235–243.

Impact of Vitiligo

- Vitiligo may significantly impact patients' psychosocial wellness.
 - “disempowerment and loss of self-esteem...a profound diminution” in the quality of life⁸
 - “worry, anger, shame and depression”; impaired social life⁹
- Economic

⁸Talsania et al. Vitiligo is more than skin deep: a survey of members of the Vitiligo Society. *Clinical and Experimental Dermatology*, 35, 736–739.

⁹Sampogna et al. Identification of categories at risk for high quality of life impairment in patients with vitiligo. *Br J Dermatol* 2008,59: 351–359.



Patient-Focused Drug Development

- The FDA is aware of unmet medical needs experienced by patients who have vitiligo.
- The FDA is conducting this public meeting to hear comments about the impact of vitiligo on patients, caregivers and family members.
- Thank you for taking the time to join us to share your experiences and unique perspectives.

Overview of Discussion Format

Robyn Bent, RN, MS | CAPT, U.S. Public Health Service

Director, Patient-Focused Drug Development Program

Office of Center Director

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Discussion Overview

Topic 1: Health Effects and Daily Impacts That Matter Most to Patients

- Health effects of vitiligo that have the most significant impact on your daily life
- How your vitiligo has changed over time
- What worries you most about your vitiligo

Topic 2: Current Approaches to Treatment

- Your experience with treating your vitiligo
- What approaches you use to treat your vitiligo
- What you have found to be most effective in helping you treat your vitiligo
- What factors you would consider when considering or seeking treatment



Discussion Format, continued

You will have a chance to answer polling questions

- Their purpose is to aid our discussion
- Participants can use the [mentimeter.com](https://www.mentimeter.com) link to answer polling questions
- Individuals or family members only, please

Participants can add comments through the webcast or by telephone

- Although they may not all be read or summarized today, your comments will be incorporated into our summary report



Send us your comments!

You can send us comments through the “public docket”

- The docket will be open until May 10, 2021
- Comments will be incorporated into our summary report
- Anyone is welcome to comment

Visit:

<https://www.regulations.gov/document?D=FDA-2020-N-0255-0054>

Or Search “patient-focused vitiligo”
on www.regulations.gov

And **Click Comment Now!**

The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with 'Home', 'Help', 'Resources', and 'Contact Us'. A search bar contains the text 'vitiligo'. The main heading is 'Patient-Focused Drug Development for Vitiligo; Public Meeting; Request for Comments'. Below this, there is a section for 'Action' with the text 'Notice of public meeting: request for comments.' and a 'Summary' section. A 'Dates' section indicates the public meeting will be held on March 8, 2021, from 10 a.m. to 2:30 p.m. Eastern Time. A 'Comment Now!' button is visible in the top right corner, with a red arrow pointing to it. A 'Document Information' sidebar on the right shows the ID: FDA-2020-N-0255-0054, the date posted: Jan 15, 2021, and the Federal Register Number: 2021-00932.

Participate in crowdsourcing!

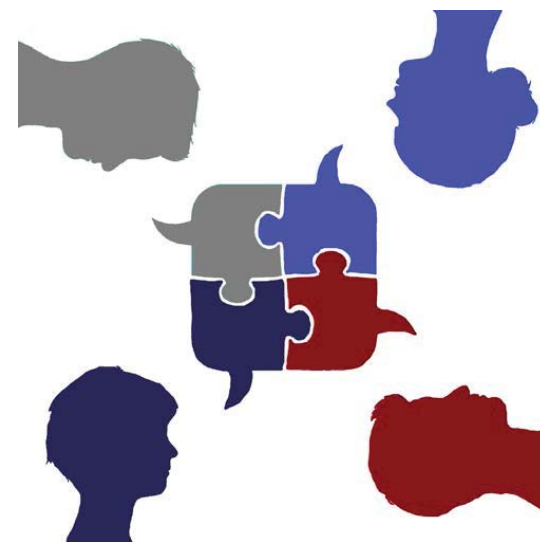
- Crowdsourcing is another way for the vitiligo community to engage and interact with each other and the FDA.

In addition to the docket, you can also send us comments through Crowdsourcing

Comments will be incorporated into our summary report

Anonymous Participation: There will be instructions on how to participate anonymously once you log in.

How do I join? We will send out an email with instructions and the link to the crowdsourcing site in a couple of days.





Discussion Ground Rules

- We encourage all individuals and family members to contribute to the dialogue
- FDA is here to listen
- Discussion will focus on vitiligo health effects and treatment
- The views expressed today are personal opinions
- Respect for one another is paramount

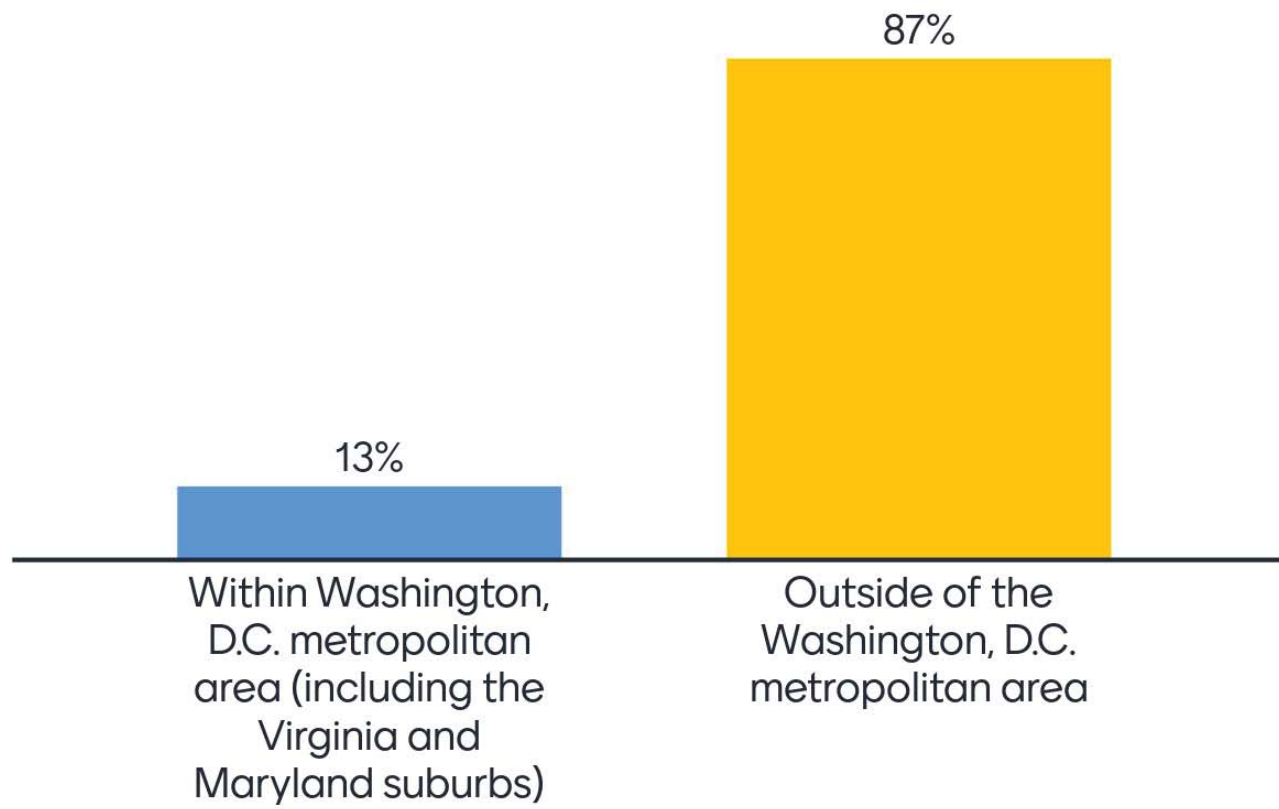


Where do you live?

- a. Within Washington, D.C.
metropolitan area
(including the Virginia and
Maryland suburbs)
- b. Outside of the
Washington, D.C.
metropolitan area

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Where do you live?



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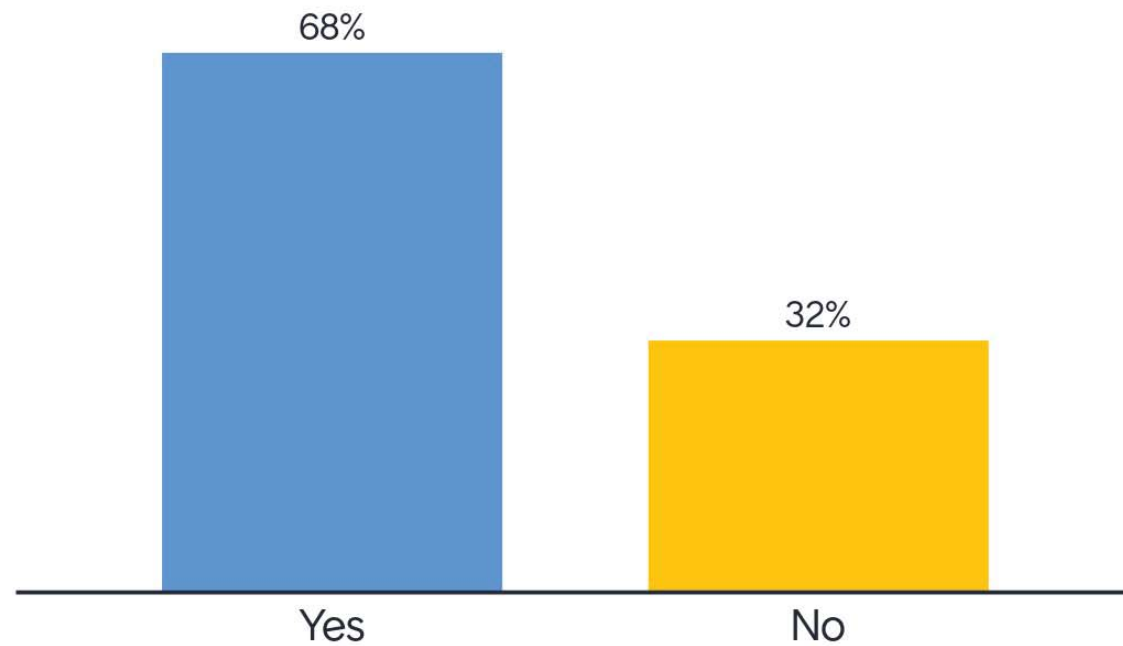


Have you or your loved one ever been diagnosed as having vitiligo?

- a. Yes
- b. No

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Have you ever been diagnosed as having vitiligo?



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We will ask that the remainder of the questions be answered by people who responded “yes” to Question 2. Please answer for the person diagnosed with vitiligo.

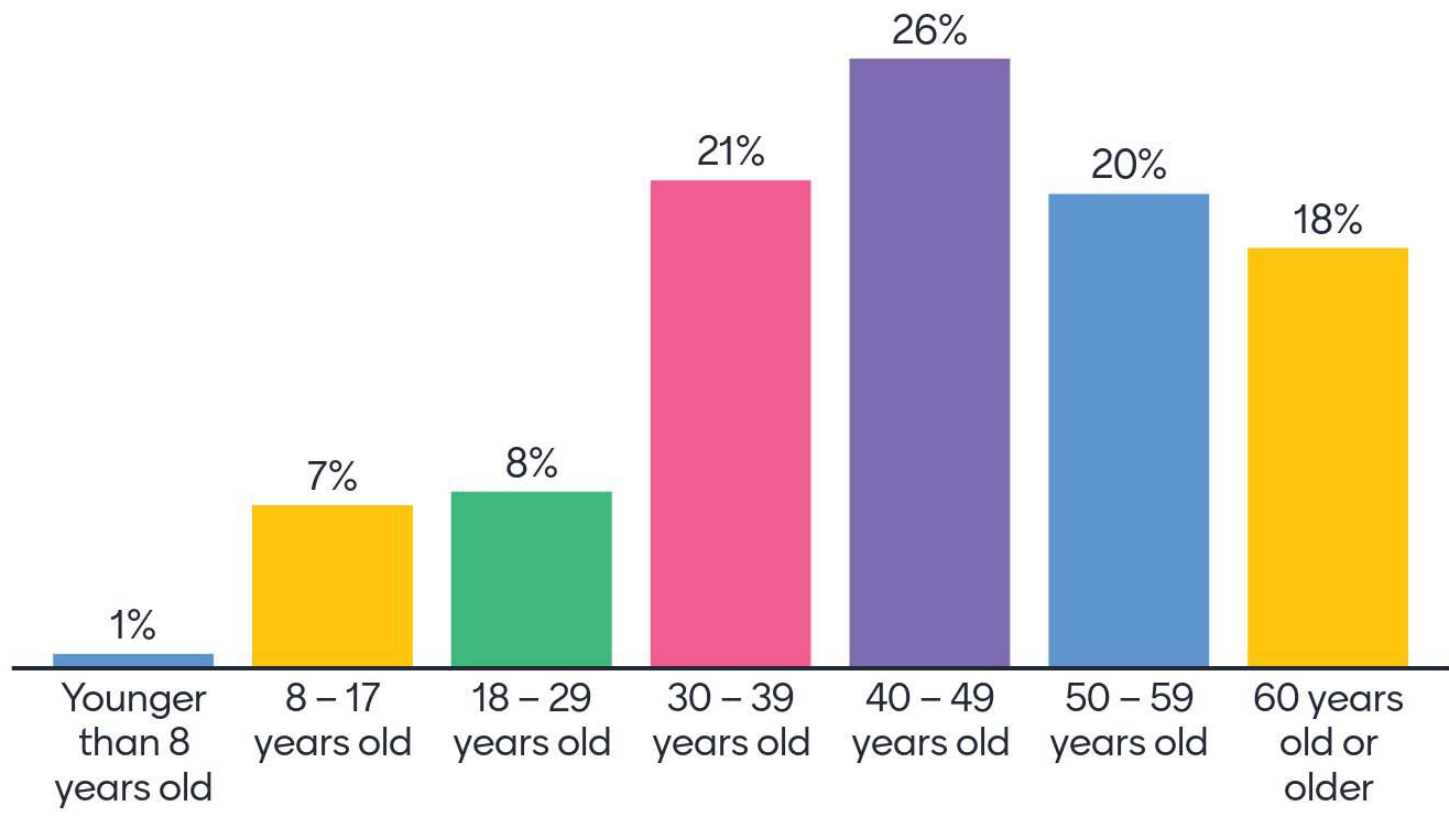


What is you/your loved one's age?

- a. Younger than 8 years old
- b. 8 – 17 years old
- c. 18 – 29 years old
- d. 30 – 39 years old
- e. 40 – 49 years old
- f. 50 – 59 years old
- g. 60 years old or older

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What is your age?



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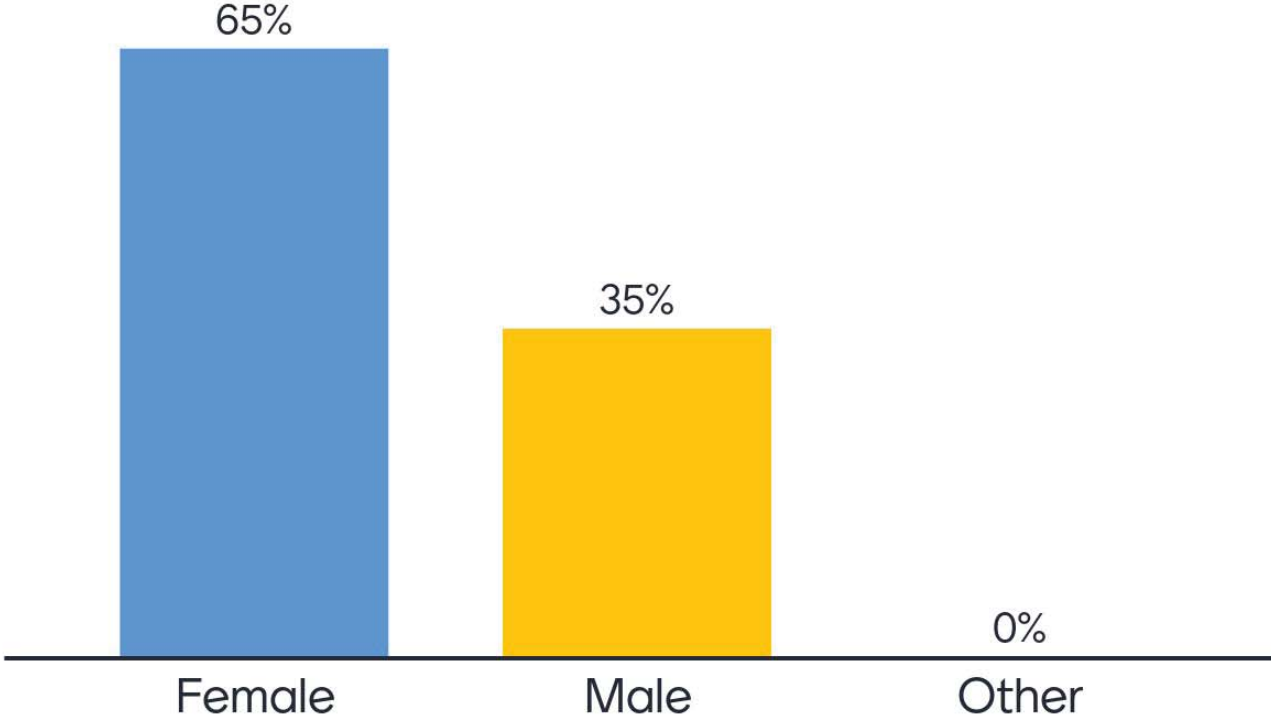


Do you/your loved one identify as:

- a. Female
- b. Male
- c. Other

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Do you identify as:



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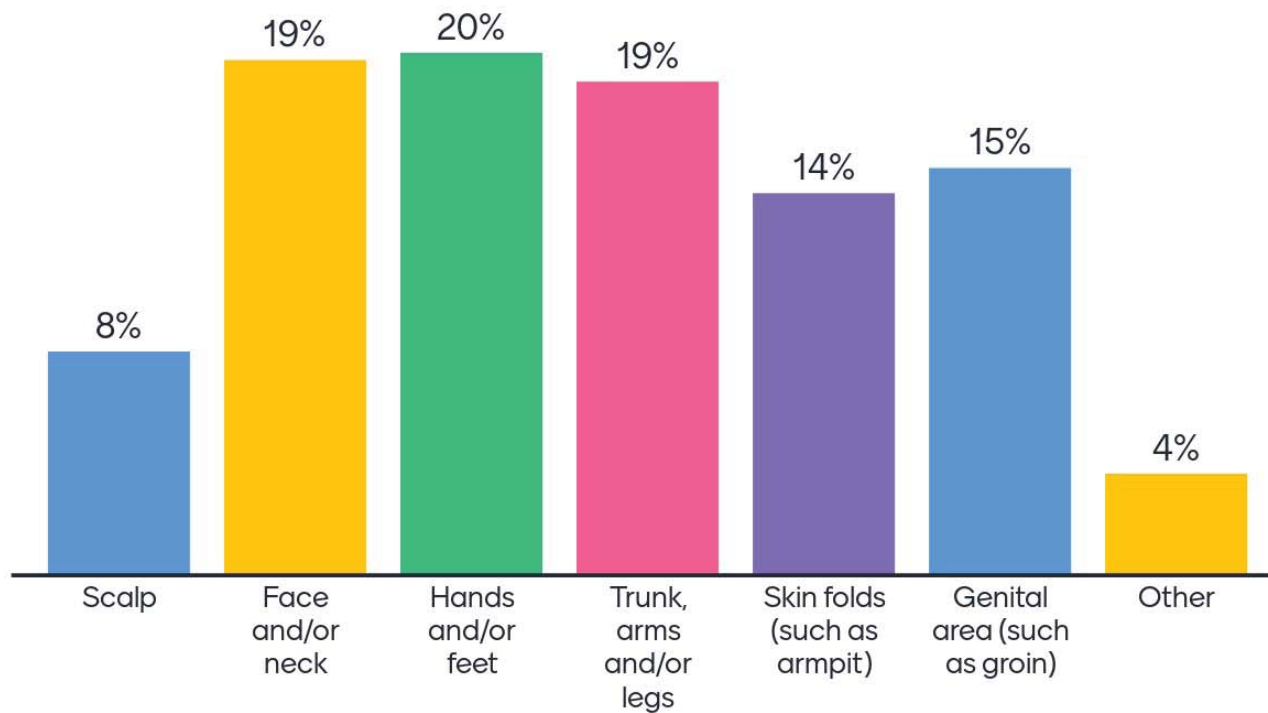


Where is your vitiligo located? **Check all that apply.**

- a. Scalp
- b. Face and/or neck
- c. Hands and/or feet
- d. Trunk, arms and/or legs
- e. Skin folds (such as armpit)
- f. Genital area (such as groin)
- g. Other areas not mentioned

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Where is your vitiligo located? Select all that apply.



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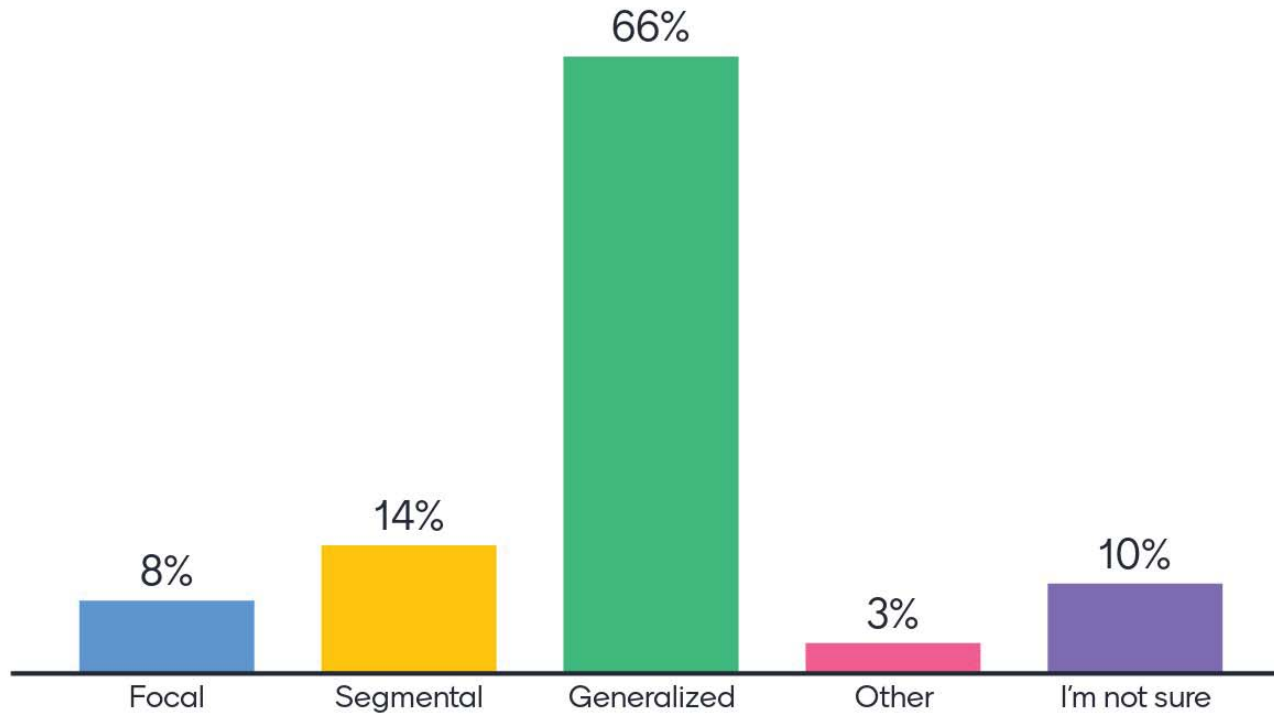


In what pattern does your vitiligo appear?

- a. Focal
- b. Segmental
- c. Generalized
- d. Other
- e. I'm not sure

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In what pattern does your vitiligo appear?



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Discussion Topic 1

**Health Effects and Daily Impacts of
Vitiligo**

Topic 1 Discussion Questions

1. Which **aspects** of vitiligo have the most significant impact on your life? (Examples may include depigmentation, itching, sensitivity to sunlight, etc.)
2. Are there **specific activities** that are important to you but that you cannot do at all or as fully as you would like because of your vitiligo? (Examples of activities may include participating in social events, sports, being outside in the sunlight, etc.)
 - a. How does your vitiligo and its impacts affect your daily life on the **best days**? On the **worst days**?
3. How has your vitiligo **changed over time**?
 - a. How has your vitiligo changed from childhood to adulthood (such as vitiligo severity, disease acceptance)?
 - b. Would you define your vitiligo today as being well-managed?
4. What **worries you** most about your vitiligo?
 - a. Is there a particular body area affected by vitiligo (such as face, body) that is of most concern to you?

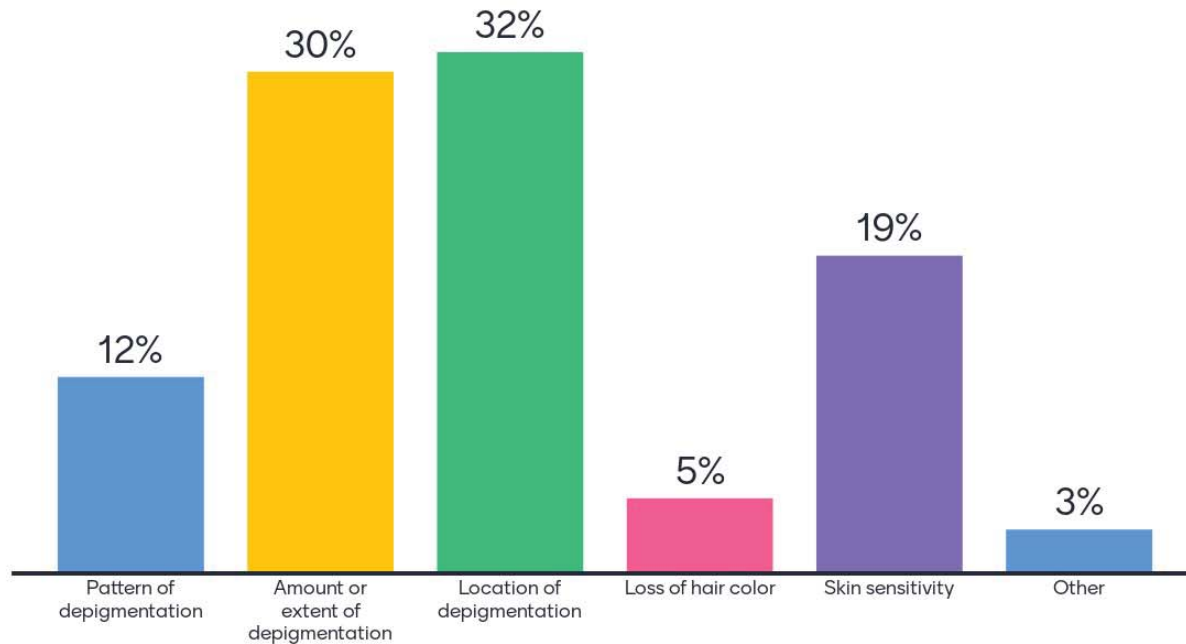


What aspects of your vitiligo are most bothersome to you? **Please choose up to three answers.**

- a. Pattern of depigmentation
- b. Amount or extent of depigmentation
- c. Location of depigmentation
- d. Loss of hair color
- e. Skin sensitivity
- f. Other effects not mentioned

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What aspects of your vitiligo are most bothersome to you? Please choose up to three answers.



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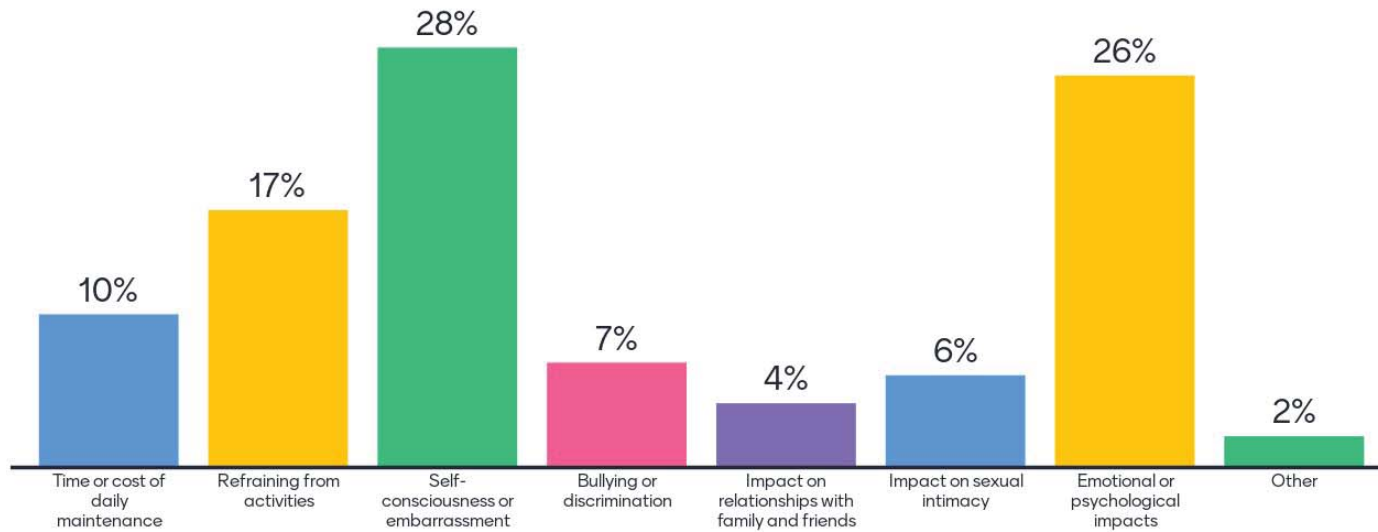


What do you find to be the most bothersome impacts of vitiligo on your daily life? **Please choose up to three answers.**

- a. Time or cost of daily maintenance
- b. Refraining from activities
- c. Self-consciousness or embarrassment
- d. Bullying or discrimination
- e. Impact on relationships with family and friends
- f. Impact on sexual intimacy
- g. Emotional or psychological impacts
- h. Other impacts not mentioned

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What do you find to be the most bothersome impacts of vitiligo on your daily life? Please choose up to three answers.



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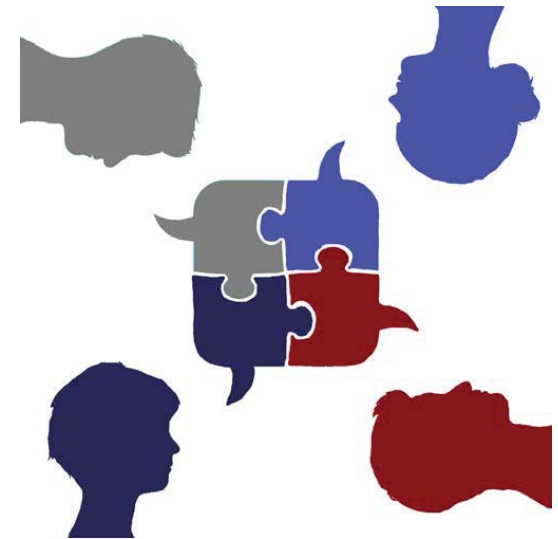
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Discussion Topic 2

Current Approaches to Treatment



Topic 2 Discussion Questions

1. **What are you currently doing** to help treat your vitiligo? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification.)
 - a. How has your treatment regimen changed over time, and why?
2. **How well** does your current treatment regimen treat the most significant aspects of your vitiligo? For example, how well do your treatments improve your ability to do specific activities?
3. What are the most significant **downsides to your current treatments**, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, depigmentation of affected area is more noticeable, going to the hospital for treatment, etc.)
4. Assuming there is no complete cure for your vitiligo, what specific things would you look for in an **ideal treatment** for your vitiligo?
 - a. Is there a particular body area affected by vitiligo (such as face, body) that you would prioritize for treatment?
5. What factors do you consider when making decisions about selecting a course of treatment?

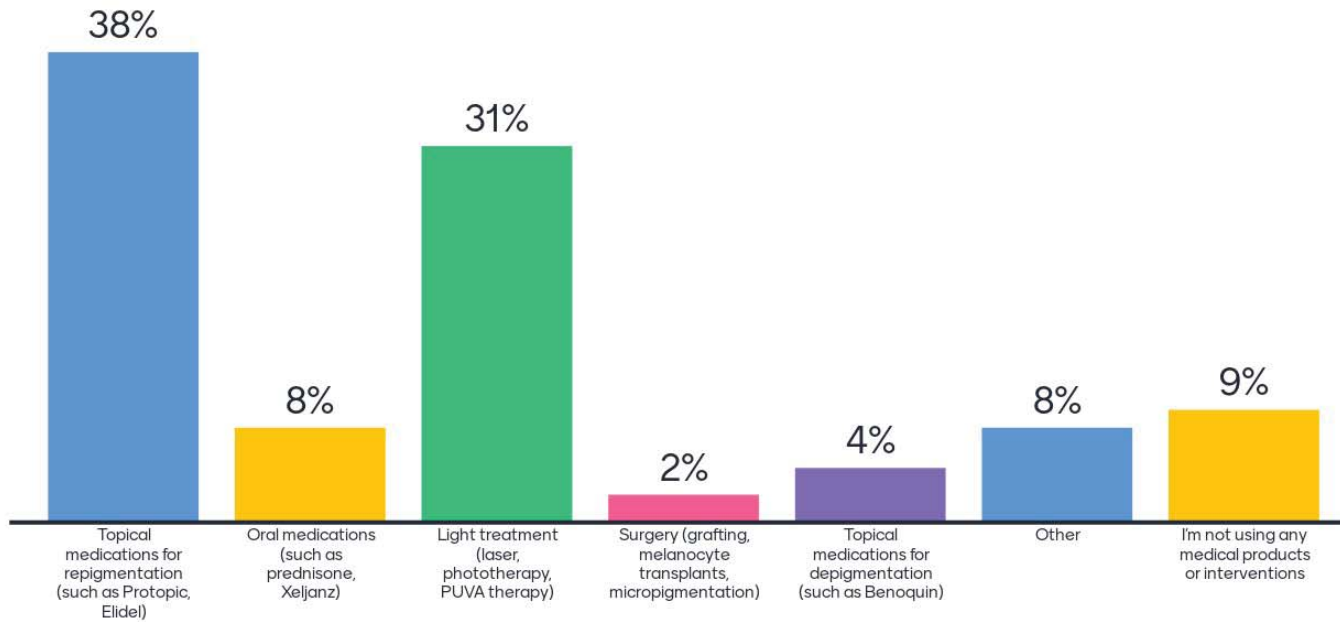


Have you ever used any of the following medical products (drug therapies or medical devices) or interventions to treat your vitiligo? **Check all that apply.**

- a. Topical medications for repigmentation (such as Protopic, Elidel)
- b. Oral medications (such as prednisone, Xeljanz)
- c. Light treatment (laser, phototherapy, PUVA therapy)
- d. Surgery (grafting, melanocyte transplants, micropigmentation)
- e. Topical medications for depigmentation (such as Benoquin)
- f. Other medical products or interventions not mentioned
- g. I'm not using any medical products or interventions

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Have you ever used any of the following medical products or interventions to treat your vitiligo? Check all that apply.



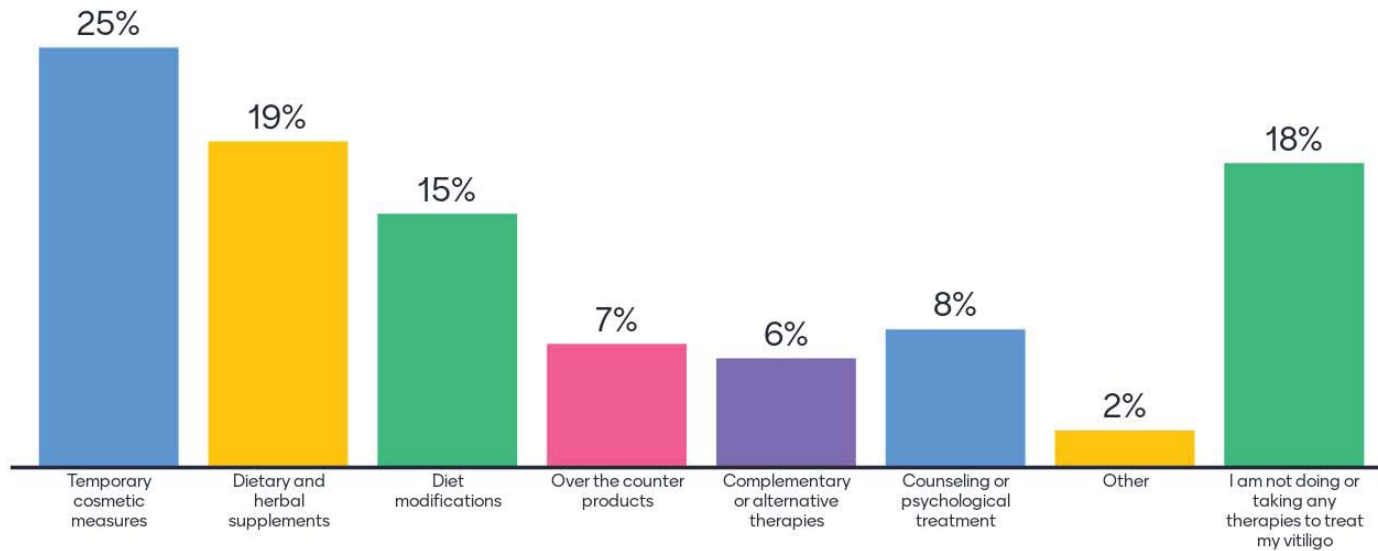
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Besides the medical products or interventions mentioned previously, what else are you doing to manage your vitiligo? **Check all that apply.**

- a. Temporary cosmetic measures
- b. Dietary and herbal supplements
- c. Diet modifications
- d. Over the counter products
- e. Complementary or alternative therapies
- f. Counseling or psychological treatment
- g. Other therapies not mentioned
- h. I am not doing or taking any therapies to treat my vitiligo

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Besides the medical products or interventions mentioned previously, what else are you doing to manage your vitiligo? Check all that apply.



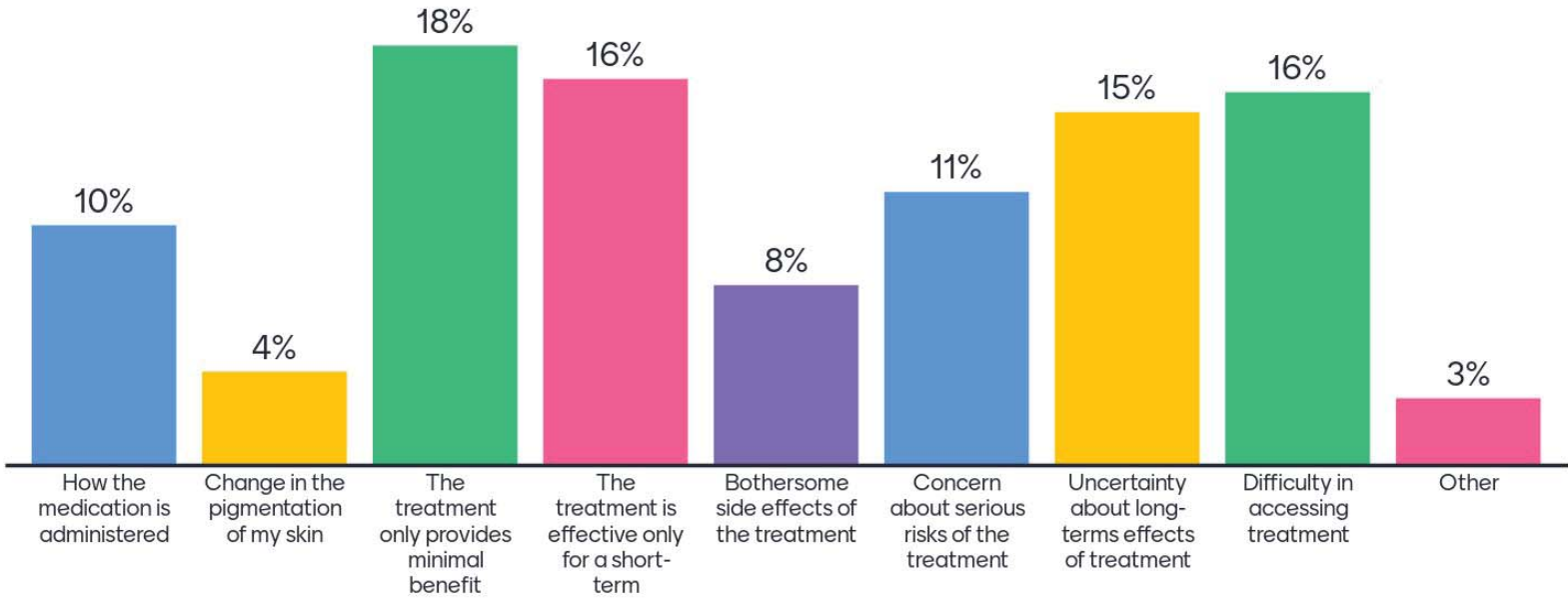
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For the medical products or interventions you use, what do you consider to be the most burdensome impacts? **Please choose up to three answers.**

- a. How the medication is administered
- b. Change in the pigmentation of my skin
- c. The treatment only provides minimal benefit
- d. The treatment is effective only for a short-term
- e. Bothersome side effects of the treatment
- f. Concern about serious risks of the treatment
- g. Uncertainty about long-term effects of treatment
- h. Difficulty in accessing treatment
- i. Other negative impacts not mentioned

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For the medical products or interventions you use, what do you consider to be the most burdensome impacts? Please choose up to three answers.



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Imagine that a new topical cream (not a steroid) indicated to treat vitiligo has recently been approved by FDA. Your doctor believes that you/your loved one may be a good candidate for this medication.

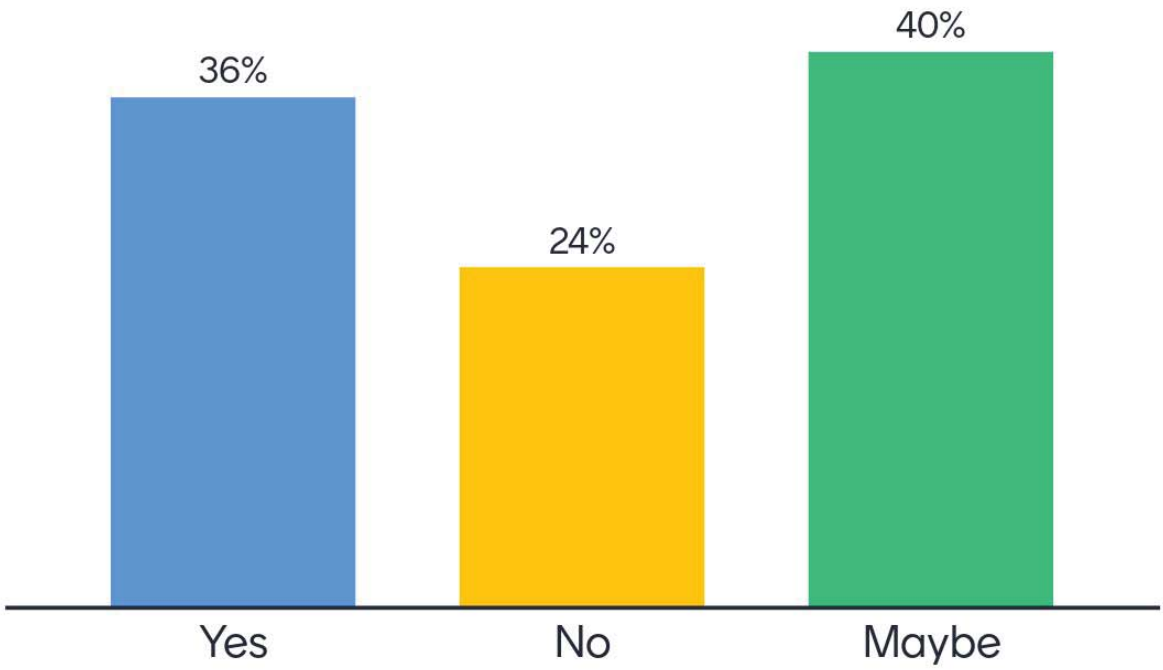
The topical cream needs to be applied once a day. Research in animals and people show that this treatment may improve pigmentation by up to 50% in some people. More common side effects of this therapy may include redness and irritation at the application site, mild acne, and burning. Rarer but more serious side effects may include fever, pain during swallowing, insomnia, nausea, and increased heart rate.

Given the risks and benefits, would you take this medication?

- a. Yes
- b. No
- c. Maybe

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Given the risks and benefits, would you take this medication?



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Imagine that you have been invited to participate in a clinical trial to study an experimental treatment for vitiligo. Your doctor believes that you may be a good candidate for this clinical trial.

This experimental treatment is an oral immunosuppressant. Early research in animals and people show that this treatment may improve pigmentation by up to 50% in some people after 1 year. The purpose of this study is to better understand how well this treatment works and its safety.

More common side effects of this therapy may include headache, diarrhea, and pain in the sinuses (such as nose, forehead, cheeks). Rarer but more serious side effects may include stomach/abdominal pain, liver problems, or cancer. This clinical study will last 18 months and clinic visits will occur every 3 months. Visits will involve routine blood work.

Based only on the information presented in the scenario, would you consider participating in this clinical trial? **Please choose one response.**

- a. Yes, I would consider participating in this study
- b. No, I would not consider participating in this study
- c. I'm not sure

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The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with 'Home', 'Help', 'Resources', and 'Contact Us'. A search bar contains the text 'vitiligo'. The main heading is 'Patient-Focused Drug Development for Vitiligo; Public Meeting; Request for Comments'. Below this, there is a section for 'Action' with the text 'Notice of public meeting: request for comments.' and a 'Summary' section. A 'Dates' section states: 'The public meeting will be held on March 8, 2021, from 10 a.m. to 2:30 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by May 10, 2021. See the SUPPLEMENTARY INFORMATION section for registration date and information.' On the right side, there is a 'Document Information' box with the ID 'FDA-2020-N-0255-0054', the date posted 'Jan 15, 2021', and the Federal Register Number '2021-00932'. A red arrow points from the bottom left towards the 'Comment Now!' button in the top right corner of the document information box.

Participate in crowdsourcing!

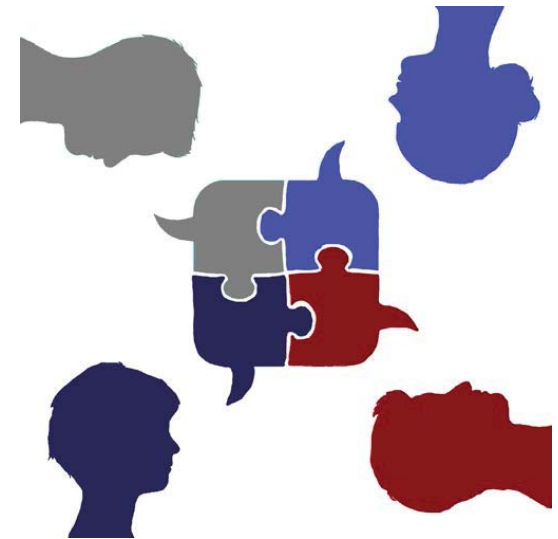
- Crowdsourcing is another way for the vitiligo community to engage and interact with each other and the FDA.

In addition to the docket, you can share your experiences through Crowdsourcing

Comments will be incorporated into our summary report

Anonymous Participation: There will be instructions on how to participate anonymously once you log in.

How do I join? We will send out an email with instructions and the link to the crowdsourcing site in a couple of days.



Closing Remarks

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Director

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U.S. Food and Drug Administration

