XEROSTOMIA VOICE OF THE PATIENT REPORT

From the

Externally-Led Patient Focused Drug Development (EL-PFDD) Meeting

Meeting Date: Thursday, 19 August 2021

10 a.m. – 3 p.m. U.S. Eastern Time (Virtual Meeting)

Report Date: 27 January 2022

Meeting co-hosted by Head and Neck Cancer Alliance (HNCA), the National Foundation of Swallowing Disorders (NFOSD), Support for People with Oral and Head and Neck Cancer (SPOHNC), and the THANC (Thyroid, Head and Neck Cancer) Foundation.

Report Submitted to the U.S. Food and Drug Administration (FDA).

XEROSTOMIA VOICE OF THE PATIENT REPORT

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XEROSTOMIA Voice of the Patient Report

The Xerostomia Externally-Led PFDD (EL-PFDD) meeting was co-hosted by Head and Neck Cancer Alliance (HNCA), the National Foundation of Swallowing Disorders (NFOSD), Support for People with Oral and Head and Neck Cancer (SPOHNC), and the THANC (Thyroid, Head and Neck Cancer) Foundation. This meeting was held to advance our collective mission to address the unique needs and challenges of patients living with xerostomia and their families, by helping to provide a deeper understanding of the symptoms and burdens associated with xerostomia in daily life, as well as the unmet needs of the community. The meeting was a key component of realizing the objective of capturing patient and caregiver insights to set the context for FDA benefit-risk considerations. The information gathered from this meeting may also be used to develop clinically meaningful endpoints for current and future clinical trials, as well as encourage additional manufacturers to investigate this condition.

This Voice of the Patient report was prepared by the above organizations as a summary of the input shared by people living with xerostomia during the EL-PFDD. This meeting was hosted virtually on August 19th, 2021.

Authors and Collaborators

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Consultants

James Valentine, JD, MHS, and Larry Bauer, RN, MA, from Hyman, Phelps & McNamara, P.C. were engaged for the meeting planning, implementation, facilitation, and provided review of the Voice of Patient report. Chrystal Palaty, PhD from Metaphase Health Research Consulting Inc. assisted in the creation of this report.

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James Valentine and Larry Bauer are employed by Hyman, Phelps & McNamara, P.C., a law firm that represents sponsors who are developing new drugs as well as patient advocacy organizations.

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Our appreciation goes to the U.S. Food and Drug Administration for giving us permission to hold this meeting and to the many FDA staff members who made the time to attend. A special thank you to Shannon Cole, from the patient focused drug development staff of the FDA, who guided us through this process. Thanks also to the many representatives from government agencies, non profits and industry as well as scientists and healthcare providers who attended and listened.

We thank Dr. Kendall Marcus, Director of the Division of Dermatology and Dentistry at the FDA, for providing her perspective on the patient focused drug development process and the role of the FDA in regulating therapies for xerostomia. Thank you to Dr. James J. Sciubba, consultant to the Johns Hopkins School of Medicine and President of SPOHNC for the thorough and interesting clinical overview of xerostomia. We are grateful to you both for supporting us with your time and expertise.

Thank you to everyone whose work ensured that our voices were heard. Thank you to Dudley Digital Works, especially John Dudley, Kyle Rhoderick and Eric Quigley for their help with the technical aspects of this meeting. We want to thank James Valentine and Larry Bauer and our planning committee staff, especially Erika Rauscher and the THANC team, Mary Ann Caputo (SPOHNC), Elizabeth Lipton (NFOSD) and Amanda Hollinger (HNCA).

We sincerely thank our industry supporter, MeiraGTx, whose support allowed this important meeting to take place. Finally, we wish to acknowledge and thank the many non-profit partners who supported this meeting including the International Society of Oral Oncology, the Sjögren's Foundation, the American Board of Swallowing Disorders, the Dysphagia Research Society, the Foundation for Voice Restoration, ThyCa - Thyroid Cancer Survivors' Association, Inc., Curaden and Side Effect Support.

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Introduction and Meeting Overview

The Xerostomia Externally-Led PFDD (EL-PFDD) meeting was co-hosted by Head and Neck Cancer Alliance (HNCA), the National Foundation of Swallowing Disorders (NFOSD), Support for People with Oral and Head and Neck Cancer (SPOHNC), and the THANC (Thyroid, Head and Neck Cancer) Foundation. This meeting was held to advance our collective mission to address the unique needs and challenges of patients living with xerostomia and their families, by helping to provide a deeper understanding of the symptoms and burdens associated with xerostomia in daily life, as well as the unmet needs of the community.

This EL-PFDD meeting was modeled after the work of the FDA's Patient-Focused Drug Development (PFDD) initiative. PFDD is a systematic way of gathering patient perspectives on their condition and on available treatments. The information gathered at the meeting is presented in this *Voice of the Patient* report. The information in this report will be used to guide drug and technology development and inform the FDA's benefit-risk evaluations when reviewing technologies and therapeutics to address xerostomia. The hope is that this information will ultimately catalyze significant improvements for the health and quality of life for people living with xerostomia.

Clinical Overview of Xerostomia[1]

Xerostomia, or dry mouth, results from salivary gland dysfunction and is characterized by reduced or absent salivary flow. Xerostomia is not a specific disease but a multifactorial condition that occurs as a side effect of certain medical conditions or from the treatment of systemic diseases. Xerostomia is often caused by radiation therapy used to manage oral and head and neck cancer. Radiation therapy to the head and neck region can diminish saliva production by 60-70%. Xerostomia can be secondary to Sjögren's syndrome, an autoimmune disease characterized by dryness of the mouth, eyes, and other body systems. Xerostomia may also be secondary to treatment of other diseases including rheumatoid arthritis, depression, diabetes, hypertension, and others. Although rare, xerostomia can be caused by gland obstruction. Many medications used in the aging population can increase the risk of xerostomia, which is prevalent in 5 – 46% of this population subset.

Three sets of glands are responsible for producing saliva: the parotid glands on the side of our face, the submandibular glands located under our lower jaw, and the sublingual glands under the tongue. These glands produce one and a half liters of salivary fluid each day. In addition to water (98%), saliva contains a complex mix of biologic substances including histatins, cystatins, secretory IgA antibodies, glycoproteins, gustins, statherins, enzymes (including amylase, ribonuclease, lipase), electrolytes (including bicarbonate and phosphate ions), minerals

[1] Summary extracted from the original Letter of Intent submitted to the FDA and from the Clinical Overview of Xerostomia presentation by James J. Sciubba, DMD, PhD, Professor (Ret), The Johns Hopkins University School of Medicine and the Department of Otolaryngology, Head and Neck surgery. Dr. Sciubba reviewed this summary prior to publication of report.

(including calcium), small organic molecules, glycoproteins, mucins and growth factors, with their antibacterial, antifungal and antiviral activities.

An essential overall biological function of saliva is to maintain oral homeostasis or balance. Saliva lubricates the mouth to help wash away food and debris, and helps to solubilize food, preparing it for digestion. Saliva helps preserve the integrity of the teeth, and maintain mucous membranes of the mouth, throat and oropharynx, and preserves a neutral pH in the oral cavity.

Unfortunately, there are no disease modifying therapies to address the underlying causes of xerostomia. Xerostomia management strategies consist of disease prevention and symptom relief. While some of these treatments offer temporary relief, none are universally and completely effective. Currently therapies are being developed and tested which include gene transfer therapy and genetically modified components directly delivered into the salivary gland, that may potentially improve water channel (aquaporin) function in the membranes of salivary secretory cells.

Meeting Summary

The August 19, 2021 Xerostomia EL-PFDD meeting was the 48th EL-PFDD and due to the ongoing COVID-19 pandemic, was the 15th fully virtual EL-PFDD meeting. While this meeting was held virtually for participant's health and safety due to the COVID-19 pandemic, the virtual platform increased accessibility by enabling participation from across the United States and from around the world.

The demographics of the meeting attendees living with xerostomia were determined using online polling. Results are summarized below and in **Appendix 1**. Most poll respondents (92%) were individuals living with xerostomia, and the remainder (8%) were relatives or care partners. Most (92%) poll respondents were located across the continental U.S., predominantly in the Eastern Time Zone, with representation from Hawaii, Mexico, Canada and Europe. Participants were split between female (52%) and male (48%). Most attendees identified as Caucasian (86%), with the rest identifying as other (7%), African American (5%) or Hispanic, Latin or Spanish (2%).

This meeting brought together the full spectrum of affected individuals with xerostomia. Poll respondents were all over 31 years of age, with the greatest representation in the 61-70 age bracket (39%), followed by those who were 71 years and older and those in the 51–60-year range (25% and 23%, respectively). There were fewer attendees in the 31–50-year age range (14%). Attendees reported first experiencing symptoms of xerostomia across the age spectrum, however most (72%) reported that they experienced their first symptoms of xerostomia between the ages of 31 to 60 years of age, while a quarter (25%) experienced their first symptom over the age of 61 and a very few (4%) experienced their first symptom between 0 and 30 years. Most attendees (75%), experienced xerostomia as the result of radiation therapy, followed by other causes (7%), Sjögren's syndrome (5%), surgery on a head or neck tumor (5%), diabetes (3%), drug reaction/side effects (2%), unable to determine the cause (2%) and unsure (2%). Radioactive iodine (RAI) should have been included as a response option on this poll and we apologize for the oversight.

This meeting brought together diverse members of the xerostomia stakeholder community. Of the 282 who attended on the day of the meeting, 136 were people living with xerostomia and 13 were caregivers and friends. The meeting was attended by 17 FDA representatives, 64 health care providers including speech and language pathologists, 21 representatives from industry, 9 scientists, 12 members of non-profit organizations as well as several others.

The Xerostomia EL-PFDD meeting was structured around two main topics. The morning session addressed Topic 1, *Symptoms and Daily Impacts of Living with Xerostomia* while the afternoon session addressed Topic 2, *Current and Future Treatment for Xerostomia*. The meeting agenda is in **Appendix 2**, and the meeting discussion questions are in **Appendix 3**.

The meeting was opened with remarks from co-moderator, Amanda Hollinger, the Executive Director of the Head, Neck Cancer Alliance, who was speaking on behalf of the National Foundation of Swallowing Disorders (NFOSD), Support for People with Oral and Head and Neck Cancer (SPOHNC), and the THANC (Thyroid, Head and Neck Cancer) Foundation as well as many other organizations. She welcomed all meeting attendees and thanked them for their participation.

Dr. Kendall Marcus, the Director of the Division of Dermatology and Dentistry in the Office of New Drugs at the FDA, welcomed meeting participants. She explained the role of her division which is to review drugs for the prevention and treatment of dermatologic and dental conditions, including xerostomia. She described the different roles of the FDA and drug companies in the development of new drugs, explained how the balance of benefits and risks of new therapeutics are evaluated, and emphasized the importance of patient input to determine xerostomia's impacts on daily life and what patients value in potential new treatments for xerostomia. Dr. James J. Sciubba, retired professor and consultant at Johns Hopkins University School of Medicine and the Department of Otolaryngology, Head and Neck surgery provided a clinical overview of xerostomia.

The first session, *Topic 1*: *Symptoms and Daily Impacts of Living with Xerostomia* featured five pre-recorded panelists who described their health experiences that resulted in xerostomia, their ongoing symptoms and health concerns, and the impact that xerostomia has had on their lives. They talked about their xerostomia-related worries for the future. Many described how persistent their xerostomia symptoms are. Meeting attendees were asked to participate through the online polling, by calling in, and by submitting online written comments. James Valentine moderated a discussion between the live Zoom panel and those who dialed in by phone. Amanda Hollinger read selected comments that were submitted through the online comment submission form. The results of online polling results for Topic 1 are included in **Appendix 4**. The names of panelists and callers are listed in **Appendix 5**.

The second session, *Topic 2: Current and Future Treatment for Xerostomia* opened with another pre-recorded panel. Five people living with xerostomia described the medications and other strategies that they use to try to alleviate their symptoms. Again, meeting attendees were provided with an opportunity to have their voices heard through online polling, by calling in and by submitting written comments about the issues discussed, and their voices were added to the moderated discussion by Amanda Hollinger and James Valentine. People living with xerostomia described the challenges of unmet treatment needs and made many suggestions for what they

wanted in potential new treatments. The results of online polling results for Topic 2 are included in **Appendix 6**. The meeting concluded with a summary of the key meeting points by Larry Bauer and was closed by Amanda Hollinger who thanked all the participants and attendees for their valuable contributions.

The online comment submission portal was open for 30 days before and after the meeting to include as many voices as possible. All submitted comments are included in a separate PDF with selected comments also included in the body of this report. The final *Voice of the Patient* report, online comments, the meeting transcript and a recording of the meeting can be found at: www.thancfoundation.org, www.swallowingdisorderfoundation.com, www.headandneck.org, www.spohnc.org. According to YouTube statistics, the meeting has been streamed 738 times (as of 26 January 2022).

Report Overview and Key Themes

This report provides a high-level summary of the perspectives generously shared by people and their families living with xerostomia who participated in the August 19, 2021, EL-PFDD meeting, and includes selected comments submitted through the online portal. HNCA, the NFOSD, SPOHNC, and the THANC Foundation have provided this report to the FDA and have made it publicly available for all xerostomia community stakeholders.

The input received from the August 19, 2021, EL-PFDD meeting reflects a range of experiences with, and perspectives on xerostomia and xerostomia management. The participants at this meeting may not fully represent the diverse population and the many varied perspectives of people living with xerostomia. The terms used in this report to describe specific symptoms and treatment experiences reflect the words and language used by meeting participants during the meeting and in submitted comments. The quotes that were selected to appear in this report were intended to create a better understanding of (a) the health concerns and burdens of xerostomia in daily life, both common and more rare experiences that exist, and (b) the challenges and trade-offs in selecting and using an appropriate treatment.

Key Insights from the Xerostomia EL-PFDD Meeting

1. **Xerostomia is a systemic condition. Considering xerostomia as just "dry mouth" vastly underestimates its impact.**

- Xerostomia affects all aspects of oral systemic health, including teeth, bones, trachea and the entire gastrointestinal tract including digestion. Oral infections can spread through the entire body.

2. **Most people living with xerostomia experience many health concerns. Some are severe and persistent.**

- Xerostomia is more severe than most patients would have ever anticipated, it is persistent and can become worse with time.
- The most common health concerns include trouble swallowing, chewing and/or solids sticking to teeth, dental cavities and altered taste and difficulties communicating. Some of the most disturbing xerostomia-related health concerns include tooth loss, periodontal disease, and digestive impairment.

- While many health concerns are xerostomia-related, others are side effects of cancer treatment, Sjögren's syndrome or other conditions. These health concerns are interrelated, interact and together contribute to disease burden and low quality of life. Attributing the exact cause of these health concerns is unnecessary.

3. Living with xerostomia is a daily battle and leads to a reduced quality of life.

- People living with xerostomia experience challenges eating, are unable to enjoy food or sleep soundly. Many are unable go out to eat, communicate clearly, or to participate in sports or recreational activities. Many people living with xerostomia described experiencing social isolation and being unable to participate in family celebrations or traditions.
- The secondary and tertiary effects of xerostomia impact all activities of daily living and diminish quality of life. Impacts such as sleep loss, lack of exercise and malnutrition exacerbate or contribute to other health problems. Xerostomia-related malnutrition can be life threatening.
- People living with xerostomia worry about the worsening of their disease including increased difficulties eating, not knowing how the disease will progress, and choking. They also expressed many worries about deteriorating dental health.

4. There are no effective and long-lasting xerostomia treatments.

- Most people living with xerostomia have tried many or all approaches available to them. Existing medications, medical treatments and solutions are ineffective at addressing the symptoms of xerostomia and at best provide only temporary relief.
- Current xerostomia treatments - saliva substitutes and moisturizers, lozenges and cholinergic agonists - focus on ways to replace saliva and to moisten the oral cavity. Other treatments, including prescription fluoride and antifungals, address the secondary effects of tooth decay and candidiasis.
- People living with xerostomia must drink a great deal of water every day to swallow every bite of food and to speak. This has secondary effects such as frequent urination, sleep interruptions and hyponatremia.
- Most people living with xerostomia have had to make major eating, social and lifestyle adaptations (including extensive dental care) to live with their disease.

5. People living with xerostomia are hopeful for better treatment approaches in the future.

- The top treatment wishes selected by people living with xerostomia include increased saliva production, help with chewing and swallowing and the prevention of cavities.
- People living with xerostomia would like more effective and longer lasting treatments. They suggested developing preventative approaches to avoid radiation treatment damage.
- Many are very open to new approaches and would like to participate in clinical trials and several described participating in gene therapy trials.
- Accepted or coordinated treatment algorithms or management guidelines for xerostomia do not exist. Many patients described how they were left on their own to find solutions.

Topic 1: Symptoms and Daily Impacts of Xerostomia

> *"Xerostomia affects the whole body. It's oral systemic health…. Whatever happens in the oral cavity can spread into the bloodstream and trigger systemic inflammation … there is more than just the oral cavity that's being affected."* – Hank

During the Xerostomia EL-PFDD meeting, people living with xerostomia described what it was like to have a dry mouth. Jeffrey said, "*My mouth is constantly very dry. I wake up during the night and in the morning, with my mouth and throat feeling parched. My tongue sticks to the roof of my mouth, my voice gets hoarse, and even on my best days, I have constant uncomfortable dryness, with trouble swallowing. … I often cough and choke, and my family is afraid I'll stop breathing."*

Recurring themes emphasized by people living with xerostomia during the meeting:

Many people living with xerostomia experience a heavy disease burden. While many health concerns are directly related to xerostomia, some are side effects of cancer treatment, Sjögren's syndrome, or other conditions. These health concerns interact and profoundly impact all activities of daily living and quality of life.

Most have already been through a great deal. Xerostomia is challenging, especially for those who have already survived an extensive and debilitating diagnosis and treatment journey for cancer and other chronic diseases.

***Xerostomia was unexpected*.** Redora said," *I was never informed about xerostomia before the radioactive iodine treatments."*

Ada said "*Saliva production is a normal bodily function that we all take for granted. And I really didn't think it would be a big deal to lose some of this functionality. I also thought it was going to be temporary. In hindsight, I was more focused on beating this illness than worrying about the side effects along the way*."

***Xerostomia is continuous, persistent and for many, becomes worse with time*.** Thad described, "*My body and spirit have healed in many ways, but unfortunately my salivary function is still impaired and likely always will be*."

For Janet R., "*Over the years, the dryness has become much more problematic. An increase of thrush, an increase of yeast infections, an increase of cracking, greater issues with choking, greater pain, which leads to a reduction in activities, a reduction in food choices*."

People with xerostomia experience a high number of health concerns but trouble chewing, swallowing, altered taste and dental cavities are most troublesome.

Meeting attendees used online polling to select all of their health concerns, with poll respondents recording an average of seven different health concerns each. Attendees were then asked to select their top three symptoms. The lists of the most frequently experienced and the most troublesome health concerns correlated closely, with trouble chewing, swallowing, altered taste and dental cavities topping both lists. Poll results are presented in **Appendix 4, Q1** and **Q2**, and health concerns are listed in descending order below, along with selected quotes.

Additional symptoms identified during the meeting and in the online comments are also described.

Trouble swallowing

Trouble swallowing was experienced by 78% of poll respondents and was selected as one of the top three most troublesome xerostomia-related health concerns by 72% of the poll respondents. During the meeting many people described how trouble swallowing interfered with eating and made them cough, gag, and choke. Without lubrication from saliva, Ada, "*can no longer enjoy crusty breads or thick foods because I could literally choke…these types of foods stick to the side of my mouth and throat, making for some very uncomfortable eating and swallowing*." She described how she has experienced incidents of painful swallowing, "*as there doesn't seem to be enough liquid in my mouth to propel or lubricate the food down my throat*."

Eating is challenging. Many people shared the challenges they have when eating and how this impacts their social lives, e.g. not wanting to go to restaurants with friends or attending family social gatherings. Ron described that, **"***I still have difficulties swallowing certain foods. Baked goods, no matter how moist, tend to change the quality of my saliva to a very thick and sticky form that turns a mouthful of food into a ball of glue. This is very difficult to swallow unless I wash down every small mouthful with liquid*."

***Choking is a very real threat*.** During the meeting several people living with xerostomia described challenges with swallowing medications. In addition, Anjali described that because of her choking, "*We've had numerous opportunities for our son to practice his Heimlich maneuver for scouting. … It's terrifying when you are going through that. … It's almost monthly, sometimes even more frequently than that, regardless of how small my food is cut up*."

Trouble chewing and/or solids sticking in teeth

Most poll respondents (85%) experience trouble chewing and/or solids sticking in teeth, and this was selected as one of the top three most troublesome xerostomia-related health concerns by 67% of poll respondents. In addition to trouble chewing, several people also mentioned problems with biting and sucking. Allan said, *"I have difficulty swallowing, biting, chewing, speaking, sucking".*

Cheryl described, "*I have a very dramatic dry mouth. [Food] turns into paste. I have to scrape it off my teeth every time I eat*."

For Anjali, it is her troubles with chewing that cause her to choke on her food. "*Oftentimes if it's something that's stuck, it's because it hasn't properly been cut up maybe because of my teeth, having the dental issues due to the dry mouth."*

Dental issues including caries or cavities

Although 75% of poll respondents reported experiencing cavities and 42% selected this as one of their top three most troubling health concerns, people living with xerostomia often described more extreme dental issues. Many experienced broken teeth, tooth loss, periodontal disease, the loss of gum tissue, and bone and jaw necrosis. Many require extensive and expensive dental work including extractions, bridges, dentures or implants. Many described meticulous oral hygiene and diligent monitoring and care by dental professionals. For many people living with xerostomia, the lack of saliva makes denture wearing difficult, and for some,

the loss of underlying bone makes dentures impossible. Tammy has lived with xerostomia for over a decade. "*I don't have a safe tooth in my mouth and I know I have very good hygiene. … It just baffled everybody why every time I would go to the dentist, I would have cavities. ... The teeth are cracked or they're all falling out one by one because they're so weak*."

Hank heartbreakingly described how xerostomia led to periodontal disease, the loss of implants, all his teeth, and the discovery of necrotic bone and tissue.

Altered taste

Altered taste was selected as a top three health concern by 31% with a total of 78% of poll respondents having experienced this. Thad described, "*I wasn't even aware that loss of taste was categorized as a xerostomia symptom, but apparently it is, and I definitely suffer from that. My taste was completely gone by the end of treatment, aside from everything tasting like battery acid. Some pieces came back salty, sour, and some bitter. My umami is decent, so I can taste some savory. Sweet is definitely the taste that forgot to come back so desserts don't have that much appeal for me anymore. And fruits are often sour when they shouldn't be*."

Some described their taste eventually returning. Tom said, "*Taste is coming back in sort of odd ways. Some things will be heavily overbalanced, like sour is very overbalanced for me. I used to really like spicy foods, hot flavors make my hair stand on end*."

Issues communicating verbally

This was the fifth most selected health concern, experienced by 64% of the poll respondents and selected as one of the top three by 20% of respondents. Participants described how thick saliva, coughing and a sore throat interfere with speech. Ron described how his saliva, "*is often very thick and sticky. This makes speaking difficult. Not only do I have to deal with adjusting my speech to compensate for the missing part of my tongue, but the dry mouth and sticky saliva, make my tongue stick to the roof of my mouth, and I start slurring my speech. Sometimes the sticky saliva closes the back of my throat, and I can't speak for up to a minute*." He described how this makes him feel. **"***This is really embarrassing, especially when it happens during a conversation or a presentation at work. I think people wonder if I'm choking or if I have Alzheimer's disease and just can't think of a word. The minute seems like hours of having people stare at me, and I feel helpless because I can't tell them what's going on*."

Fatigue

Fatigue is experienced by 58% of poll respondents and was selected as a top three health concern by 14%. Fatigue is often related to other impacts of xerostomia, difficulties sleeping, poor diet and malnutrition. Ron described how the fatigue from sleep loss impacts his social life. "*If I'm sitting with a group of friends in a casual conversation and I'm not really engaged and talking, I may just fall asleep in front of everybody. So now my friends either think I'm rude or that I'm really sick*."

Oral pain or burning

Oral pain and burning are experienced by 56% of poll respondents and were selected as a top three health concern by 14% of poll respondents. Many people living with xerostomia described having a burning sensation in their mouths. Susan S. described, "*My mouth felt like I just drank*

a cup of coffee and the pain never went away... It burned my whole mouth and it stayed there all the time. … I couldn't eat certain foods. Everything I did hurt me."

Ulcers of the tongue and mouth

Tongue or mouth ulcers are experienced by 24% of poll respondents and was selected as a top three health concern by 8% of poll respondents. Susan D. described deep fissures, pain, loss of taste," *This lasted for 3-4 weeks and was extremely disconcerting. I've never had these issues with such severity before."*

Mouth ulcers can lead to severe systemic infections. Hank described a complication of abscesses called Ludwig's angina. *"An infection that starts under the tongue, quickly spreads into the floor of the mouth and into the neck. Although Ludwig's angina is a rare complication, immune compromised patients can have life-threatening complications of airway obstructions, pericarditis, and other infections*."

Mood changes: depression or anxiety

Mood changes, including depression and anxiety are experienced by 42% of poll respondents and was selected as a top three health concern by 6% of poll respondents. With few treatment options and a low possibility of improvement, depression and anxiety are inevitable. As a result of xerostomia-related dental issues, Pam described how, "*My depression has just skyrocketed*."

Kathy H. explained how even trying new prescription products put her in a depression, because they are "*not going to be lifelong solutions, they're not going to help me forever."*

People living with xerostomia also experience panic, mood swings, frustration, grief and regret. Jeffrey described how, "*I often have choking and coughing spells. …Sometimes I feel a sense of panic because the food blocks my airway and I struggle to clear it*."

Kathy H. said, "*All of us face a grieving process. Having saliva is one of the things that makes us human. It helps us to function in the world and to be a part of the world. And you're not always aware of that, but you grieve for that loss."*

Some patients expressed regret about their cancer treatment. Nan said, "*If any of my doctors had mentioned [xerostomia] I never would have had radioactive iodine treatments*."

Oral candidiasis/infection

Oral candidiasis/infection is experienced by 27% of poll respondents and was selected as a top three health concern by 6% of poll respondents. Some described how the infections were extremely painful and dry. Ronnie said, "*I have dry mouth constantly and fight thrush about five out of seven days a week*."

Malnutrition

Malnutrition is experienced by 31% of poll respondents and was selected as a top three health concern by 3% of poll respondents. Many people living with xerostomia described losing a great deal of weight due to difficulties with swallowing.

Many are forced to eat very slowly. Scott described how with xerostomia, "*It takes more time to chew food, more time to eat. … I find at a certain point I'm just done eating because it's already twice or three times as long as a normal person. This results in not getting enough calories."*

Extra water interferes with appetite. Jamie said, *"I go through two gallons of water a day and at night 73 ounces. This took some time to have my body get used to this much water. I often felt full from so much water intake and I didn't want to eat. I lost even more weight, which concerned doctors and [there were] talks of a feeding tube."*

Xerostomia-related malnutrition can be life threatening. Some mentioned using a feeding tube either on a temporary basis or having a percutaneous endoscopic gastrostomy (PEG) feeding tube inserted into the abdominal wall, directly into the stomach. Ronald described how his PEG feeding tube, "*will be there for life because I cannot swallow."*

Halitosis or bad breath and cracked lips

Halitosis or bad breath is experienced by 31% of poll respondents and cracked lips is experienced by 29% of poll respondents. Both were selected as a top three health concern by 3% of poll respondents. Michelle said her, "*Most significant symptoms are consistent dry mouth and bad breath*."

Judy said, "*Often my mouth becomes so dry I can't enunciate clearly, and my lips become stiff and cracked*."

Other xerostomia-related health concerns

A quarter (24%) of poll respondents reported experiencing "Other" xerostomia-related health concerns and described these during the meeting and in the online comments. These include mucus accumulation, tracheostomy, coughing, gagging and throwing up not related to eating, gum sensitivity, sore throat especially at night or first thing in the morning, vocal changes, acid reflux, trismus, loss of electrolytes or hyponatremia, dried out eustachian tubes/ hearing impairment and leukoplakia. Meeting participants also described additional severe health concerns related to cancer treatment or Sjögren's syndrome.

Salivary gland infection

Salivary gland infection is experienced by 8% of poll respondents, but was not selected as a top xerostomia-related health concern. Tammy E. described, "*My saliva glands are always swollen and hard and tender*".

Xerostomia impacts all activities of daily living and quality of life.

> "*The Google definition of xerostomia is abnormal dryness of the mouth due to insufficient secretions. This doesn't give any idea of its impact. For me, the definition of xerostomia is abnormal dryness of the mouth due to insufficient secretions that affects speaking, eating, swallowing, sleep patterns and social relationships with my friends and work colleagues*." - Ron

People living with xerostomia experience a wide range of impacts from their disease. Kathy said "*Dry mouth doesn't sound so bad, but it is awful to live with it. …Xerostomia just affects every aspect of my life. Social, work, family, sleep and my ability to eat certain foods and even swallow it all. And eating used to just be such a fun part of life. So I am starting to lose hope that my quality of life can get better, that there will be solutions out there for me, as my dry mouth gets worse, and I have no saliva in the future*."

Living with xerostomia is a daily battle for many. Dave said, "*I finished my last radiation treatment … then the real battle began*."

For Jamie, "*Xerostomia is like that bad party guest, it just makes you cringe. They show up uninvited and it's all you can focus on."*

Meeting attendees used online polling to select the top three activities of daily living that were the most important to them that they were not able to do or that they struggled with due to xerostomia. Poll results are presented in **Appendix 4, Q3**. Impacts are listed in descending order below, along with selected quotes. Janet R. said, "*I had a hard time just picking my top three*."

Not enjoying food or eating

This was the top impact of xerostomia, selected by 79% of poll respondents. Impaired enjoyment of food or eating was discussed throughout the meeting and in online comments.

Xerostomia makes eating difficult. Judy described how, "*My ability to eat normally was severely impaired. I could chew on only one side of my mouth, I couldn't handle hard, crumbly, sticky or stringy foods and hot, spicy, and citrus food was painful, and left my mouth sore and the roof of my mouth swollen. In short, there were very few foods I could tolerate*."

Food choices are extremely limited. Ellen said, "*I have about six or eight things that I eat, and that's it."*

Kathie described, *"I can only eat very bland, very soft food. I might as well be like an 85-year-old. … If it has tomato, vinegar, garlic, or if it has anything that has even a little bit of acid or spice, and I will be on fire, my eyes will water and I'll suffer for days. So, it's just not worth it*."

Judy said,*" Never a meat eater, I could no longer eat my staple dishes; chicken, pasta, potatoes, green salads, fruits, and most breads. An avid lover of ethnic foods, Indian, Thai and Middle Eastern, I quickly abandoned those choices."*

Many people living with xerostomia no longer want to eat. As described previously, people living with xerostomia often have to eat slowly and the water they need to drink interferes with their appetite. Tom said, "*I really don't want to eat ever again. And that's pretty bad. … It's extremely hard for me to eat lots of things. … It's very hard for people who haven't gone through this to understand what it's like."*

Kathie agreed. "*Eating is now a chore. It's something that has to be done to stay alive*."

Inability to sleep soundly

According to polling results, sleep loss was selected as a top three impact by 56% of poll respondents and was mentioned often during the meeting and in the online comments. Jamie said, "*My giant jug of water is propped right next to me because during the night, my dry mouth is so bad, I wake up multiple times choking. I need water right away. … Waking up every hour and a half to take a drink does not make for a restful night*."

Dan described how, "*I really am up every night, at least four times, if not six times a night, either going to use the bathroom, or from dry mouth waking me up. So it's a combination of the two*." He described the impact of sleep loss. "*I take a lot of naps. I'm a napper. When I say a lot, at least one a day, which kind of offsets the interrupted sleep that I had the night before*."

Jeff described another negative effect. "*I had a serious memory issue which was caused by the lack of sleep due a painful dry mouth waking me up every two to three hours*."

Unable to go out to eat

The third most selected xerostomia impact was going out to eat, selected by 35% of poll respondents. People living with xerostomia described how having to eat slowly, carefully select what they eat and not finding foods that they can eat on the menu and embarrassment when eating, also impacted their social and family lives.

Eating slow. Ron said, "*I have to eat slowly, which means I'm always very careful of what I order when I'm out at a restaurant with friends. I try to find something easy and non-embarrassing to eat. Nevertheless, I'm always the last one eating while everybody else has to wait for me*."

Trying to find something on the menu. For Judy, "*After several embarrassing social occasions at restaurants where I could find nothing suitable on the menu, I started turning down friends' invitations, opting for home-based meals where I could control more my food choices. Restaurant based parties and social gatherings were, and continue to be an embarrassment, since I feel awkward rejecting everything that is offered. Friends try to be helpful and make suggestions, but seldom are they suitable."*

Many described embarrassments when eating out. Donna D. described how she, "*Can't eat in front of others with the coughing, clearing my throat and sometimes choking*."

Challenges with public speaking

Almost a third (31%) reported that their public speaking ability was impacted by xerostomia. Judy described how public speaking is yet another challenge she faces. "*As a college professor I did a lot of lecturing. Though now retired, I often get invitations to participate in workshops and conferences. When I need to talk aloud for extended periods of time, the spoken words become unclear, and I struggle to keep going*."

Jeffrey explained how, "*I became well-known as a speaker and gave hundreds of lectures and seminars, many of them in Asia and Europe. The xerostomia gives me a dry mouth and throat, and a hoarse voice. That interferes with my speaking, so I had to reduce my commitment to teaching and traveling. It was an enormous blow to my career as a professor and a teacher*." He stated that his xerostomia made him nervous about giving his short presentation during the meeting.

Interfering in participating in social engagements and events

Almost a third (29%) reported that xerostomia made it difficult to participate in social engagements and public events and described this impact throughout the meeting. Judy described how because of her xerostomia, "*I find that I eat alone a lot. I think others see me as a social liability. Picnics are a special challenge. Turning down burgers and hot dogs is awkward, and when I also reject potato salad, I feel like a total social misfit*."

Social isolation was a key theme that was highlighted throughout the meeting. Kathie described how xerostomia, "*Has destroyed my social life because I turn down all invitations that involve eating in front of people because I don't want any questions, because if they ask the questions*

about why I can't eat things, or if I start to choke, then I have to tell my cancer story, and I don't want to tell my cancer story. So, it's just basically... Just taking me out of my life."

Reduced participation in sports/recreational activities/exercise

A quarter of participants found it difficult to participate in sports, recreational activities and exercise due to xerostomia. Some described how they had to give up favorite hobbies or described having to adapt. For Janet O., "*My dry mouth makes running unpleasant - I need to stop every few minutes to take sips of water to wet my mouth. Horseback riding is impossible - I can't carry water or stop often enough to sip*."

For Ellen, "*My hobby, all of my adult life, has been cooking.... I still cook a lot. I enjoy cooking for other people, but I have to have tasters around me to let me know if things are spiced appropriately*."

Other activities of daily life impacted by xerostomia include travel and dating/sex

A total of 13% described that xerostomia impacted their ability to do other activities. They described travel. Judy explained how she needs to bring water with her everywhere. "*Airports present special challenges as they require that you relinquish all liquids prior to reaching the security checkpoint."*

With regards to sex and dating, Mike said *"The mouth is a sex organ. Xerostomia is a major issue for dating and kissing/oral sex."*

Tammy D. agreed*. "Xerostomia is a huge turn off. Nobody wants to kiss someone with cracked lips, bad breath, sores in their mouth, etc."*

Interacting with family members

Although only 6% of poll respondents picked interacting with family members as one of their top three impacts of xerostomia, their stories were heart-breaking. For Hank, his xerostomia symptoms have created awkward relationships with his grandchildren, "*As they came to view me as this monster in the room when they came to visit*".

Attending school or having a job

Attending school or having a job was selected as a top three impact by 4% of poll respondents. People described how xerostomia-related speech difficulties, burning mouth, memory loss and physical impacts interfered with their work. Thad said, "*I also speak at industry events usually for an hour or more. And maintaining moisture in my mouth during that time is a huge challenge. Having a decent amount of water or tea on hand is a lesson I learned the hard way.*"

Jeff's xerostomia-related sleep loss and memory issues impact his work. *"As a working musician, drummer, performing live gigs and session work I experienced the inability to recall how the song started or the name of the song to the beat. These are not good problems to have on a live gig."*

Pam described that, "*I constantly have a cracked mouth and bleeding no matter what I do, and that's really humiliating when you're on a Zoom call, and it looks like you have major issues or gross things going on*."

Top three worries for the future include increased difficulties eating, the stress of not knowing how xerostomia will progress and choking.

Using online polling to select their top three worries for the future, people living with xerostomia selected increased difficulties eating, the stress of not knowing how xerostomia will progress and choking as the clear top three fears. Poll results are presented in **Appendix 4, Q4.**

Increased difficulties eating

Increased difficulties eating was selected as a top three worry by 61% of poll respondents. Hank said, **"***My wife and I rarely go out to eat or socialize with friends if a meal is involved, due to the swallowing issues with xerostomia. The need to take constant sips of water, no ice, to help get the food down, having to use a harsh swallowing technique when food gets stuck is embarrassing.*" He described how, "*Eating is an exhausting experience by itself, making it hard to have good conversation and enjoy food at the same time as enjoying good friends*."

The stress of not knowing how xerostomia will progress

At 58%, the stress of not knowing how xerostomia will progress ranked as a close second choice as a the top three worry for the future. Bob said, "*Not knowing what looms ahead is unsettling and actually worse than the xerostomia, trismus or other side effects I currently have*." Many people especially described worries for their teeth.

Kathie said, "*I'm seven years out, and I thought, 'Well, it can't get any worse, can it? '… I was always a stickler for my teeth. My teeth were very healthy. And the first thing that my dentist said to me after I told him about my diagnosis was, 'You're going to lose all your teeth. 'And I just thought, 'Oh my God*.'"

Choking

Choking was selected as a top three worry by 56% of poll respondents. Ellen said, "*My doctors informed me that swallowing, it's a big problem, especially as I age, that's something I'll have to be very careful about. So, that is a fear, as with many, that I'll suffer a choking episode and maybe die*."

Anjali said," *I worry about being home alone, and choking, and trying to figure out ways that I can navigate that*."

Not having the energy to work and live as I want to

This was selected as a top three worry by 25% of the poll respondents. Jeffrey explained, "*As I get older, I worry about what will happen to me. I'm incredibly frustrated by all these limitations in my life. I already need to use a cane when I walk. In the future, will I be able to walk at all? Will I be able to eat a normal meal? Will I be able to eat in public? Will I lose my voice? Will I wake up parched and uncomfortable every single day? I'm frightened of becoming more disabled, but I know it's inevitable*."

Difficulties with communication

A quarter (24%) selected difficulties with communication as a top worry. Susan S. said, "*What I fear the most about my xerostomia is if I were to be rendered unable to talk (ie: coma, life support, ventilator), that my caretakers/nursing staff would not know of my condition, of my*

discomfort/distress and that no one would provide me with the moisture (whether it be lubricant or liquid) for my parched lips, mouth and throat."

Memory issues related to sleep deprivation

One fifth of attendees (20%) selected this as a top worry for the future.

Other worries for the future

A total of 15% of poll respondents selected having "other" worries for the future and described these during the meeting and in online comments. Ada described her list of her worries. "*Along with the fear of cancer recurrence, I fear for my dental health and my nutrition, and most importantly, my sleep. These are important factors for a healthy life, especially as one ages."*

Losing family and/or social connections and not knowing if I can support myself/family financially.

These two worries were each selected as a top worry by 8% of the poll respondents.

Topic 2: Current and Future Treatments for Xerostomia

> **"***Many suggestions were made to help with symptoms of xerostomia: drink water frequently, use XyliMelts at bedtime, humidifier to moisten the air, brush after every meal, floss after every meal, chew sugarless gum, eat soft foods, avoid caffeine, use a spray bottle to moisten mouth.*" - Jamie

During the second half of the meeting, people living with xerostomia described the different technologies, strategies and approaches that they used to manage their xerostomia and related health concerns. A key point repeatedly emphasized was that there is no cure for xerostomia, only relatively ineffective and temporary methods to manage symptoms. People living with xerostomia described how well the different approaches worked for them, some of the downsides they experienced as well as suggestions for ways things can be improved in the future. Meeting participants used online polling to respond to specific questions, the results of which are in **Appendix 6**.

Most people living with xerostomia have tried many available medications and medical treatments.

> *"I've tried a wide array of treatments. Aside from just staying really well hydrated, I've used sprays, lozenges, bitters before eating to bump salivary production, chewing gum, and even facial massage."* - Thad

When asked to select all of the medications and medical treatments that they have used, poll respondents selected an average of three different treatments. These are presented in **Appendix 6, Q1** and described below along with comments made during the meeting and in the online comments. Many of the drawbacks of specific medications described by meeting attendants are included in this section as well.

Saliva substitutes and moisturizers

The majority, 76% of poll respondents reported using saliva substitutes and moisturizers to address their symptoms and described using a number of different types of products during the

day, before meals and before bed to allow them to sleep. These products included tablets, gels, sprays and mouthwashes. Many described a wide range of experiences, with the biggest drawback being their temporary nature. Jeff said, "Biotène® *mouthwash and spray and Spry spray and gel are very helpful getting through the day. These work well when out and about*."

Jan agreed. "*I did Xylimelt discs. I thought those were very helpful. They lasted me about 45 minutes. And when I was working outside the home, 45 minutes was a big deal. I could talk with a moist mouth for that period of time, but I would love to have a solution to this."*

Cheryl described, "*I used this product called SalivaMAX. It's a saliva substitute that you can buy, … you need a prescription for it."*

Ronnie relies on, "*MEDActive® Patient- Friendly™ Oral Relief Spray. That product was helping me and working for me. They had a product that was a natural spring flavour, without any citrus. It didn't burn my mouth and was very helpful. I resorted to it a lot*."

Thad described xylitol-based sprays, which "*just require a couple spritzes directly under your tongue and then swishing it around in your mouth. I've generally found them to be useful, right before a meal, as they seem to help saliva production and promote swallowing for 15 to 30 minutes after you use them*."

Hal liked XyliMelts for mouth dryness and sore throat at night. "*I started using the XyliMelts and amazingly, I wake up lubricated. I don't want to say moist, but I don't have the sore throat. This has been an amazing product for me that's very, very low in cost."*

Products that work for some, don't work for everyone. Dave described how Biotène® gel was too temporary, "*but the best thing I'd tried so far to get a little moisture in my mouth."* He tried many other alternatives. *"I kept coming back to Biotène® gel and lots of water*."

Jamie said, "*I tried the XyliMelts and since my salivary glands are dead, they were awful. … They stuck to my dried gums and they did not dissolve. They sat there all night. One time I started to choke on one*. *Nope, this was not a solution to a long-term problem."*

Dave tried, *"An oil-based spray for xerostomia. It was supposed to last much longer than water-based products. It did require a prescription which wasn't covered by my insurance, but I gave it a try. You could tell there was oil in the spray, but the effects lasted minutes, not hours. I could buy five tubes of Biotène® gel for every bottle of spray, so I stopped using that*."

Prescription fluoride

More than half of poll respondents, 60%, used prescription fluoride to treat xerostomia symptoms. Don described that, "*I just keep on brushing and flossing and putting fluoride in little trays*."

Lozenges

More than half of poll respondents, 60%, used lozenges to treat xerostomia symptoms. For Thad, "*I sometimes use them when I have speaking engagements or for very long meetings. They're also very good for travel since they're easy to pack and water on travel can often be limited*."

Ronnie highlighted a challenge. Because he has very little feeling left in his mouth, the lozenges "*get lost and I choke on them. …My solution for that is to soak the lozenges in some warm water*

until they dissolve." He pours the dissolved lozenges in a spray bottle to spray in his mouth. "*The dissolved lozenges seem to keep my mouth and my throat moist for longer periods of time. They allowed me to do those things and go and speak because I love that, I enjoy giving back*."

Antifungal medications

Almost a third, or 31% of poll respondents have used antifungal medications such as fluconazole to treat oral fungal infections such as thrush, sometimes prophylactically. David said, "*I take 150 mg fluconazole weekly as a prophylaxis against oral candidiasis*."

Cholinergic agonists

Cholinergic agonists increase the amount of saliva produced through nerve stimulation. Almost a third, or 29% of poll respondents tried pilocarpine (Salagen®) and 11% tried cevimeline (Evoxac®). Unfortunately, these medications have side effects. Janet W. described, "*Despite pilocarpine, I still lack enough saliva to make my mouth comfortable*."

Dave experienced an increased heart rate from pilocarpine. "*I thought to myself, not a problem. I can handle that. After a few days, my heart was racing like a speeding train. My hands were shaking, and I could not sleep."* He also tried cevimeline with the hope that it would make his saliva less slippery and more like water. "*I tried it for a few months, but all it did for me was to make me sweat profusely*."

Valerie said, "*I take cevimeline 4x daily. It works okay."* The effects are only temporary. *"I can tell when I need the next pill*."

Katie said, "*Cevimeline is a pill that helped me, but with a lot of side effects. … Sweating, weight gain, tiredness, dizziness, don't drive a car when you take it. I mean, I literally passed out at the office the first week that I was on it. It did help with the choking. And that no longer happens, but it's not good enough. I don't think it's effective enough*."

Other medications

A total of 16% of poll respondents reported using other medications not listed in the poll. Some of these medications included both over the counter and prescription pain relievers (Tylenol [acetaminophen], Lidocaine), antacids (Maalox), antihistamines (Benadryl), anticonvulsants (Neurontin [gabapentin]), Lyrica [pregabalin], Lamictal (lamotrigine)) to help with coughing and nerve pain, benzodiazepine (Clonazepam) antipsychotic medications (Quetiapine), rituximab for autoimmune diseases, beta-blockers for atrial fibrillation (Metoprolol), blood clotting medications (Xarelto).

Two meeting participants described using combinations of anticonvulsants and other drugs off label. Susan S.'s doctor prescribed a combination of off-label treatments to treat her burning mouth. "*He must've tried 20 different drugs from Gabapentin to Lyrica…. Finally, we tried a combination of …an anticonvulsant and an antipsychotic together at a very high dose. And that seems to help the burning mouth, not the dry mouth at night. I won't say it takes it all away, but I can function. I was ready to pull my hair out. I couldn't stand the pain*."

Counseling or therapy

This approach was used by 13% of respondents. They specifically described using speech, neck and swallow therapy. Jeff said that the technique shown to him by the swallow tech has helped

to minimize his swallowing and aspiration issues. Hank said that, "*extensive speech and swallow therapy, barium swallow tests every few years… are part of my life now*."

Clinical trial enrollment

Only 9% of poll respondents have enrolled in a clinical trial. Ed described how he volunteered for a phase 1 gene therapy trial with the National Institutes of Health. He said, *"I won't achieve full recovery and I will still have xerostomia",* however he was hopeful that,*" If phase one is successful, they will go to a phase two program with the hope of being able to help head and neck cancer survivors and also women with Sjögren's syndrome*."

Thad expressed some apprehension about a gene therapy trial. "*[It] sounded a little scary primarily because I didn't fully understand what they would be manipulating and what the potential outcomes would be. But the xerostomia has enough of an impact on my day-to-day life that I would be willing to take some risks if that meant the impact might be lessened."*

Natrol Dry Mouth Relief or Antibiotics

A total of 7% of poll respondents used Natrol Dry Mouth Relief and 4% of respondents reported using antibiotics including penicillin or erythromycin to treat xerostomia-related symptoms, but there were no related comments made during the meeting.

No treatments

Very few (4%) respondents reported not using any medications or medical treatments, however this highlighted an important point of the meeting, which is that: **many people living with xerostomia were not presented with any medical treatment recommendations**. Allen described his long treatment journey as an oral, head and neck cancer survivor and said that for xerostomia, *"I haven't tried treatments. I wasn't aware that there were possible treatments."*

Hal commented that, "*I've been to my primary care physician, my oncologist, my dentist, nobody really has, in my doctors, nobody's really recommended something. They all seem mystified, like'I've heard about this, but I've heard it doesn't work. I'm just shocked that there's not more and that my doctors have not said, 'Hey, try this. Try that.*'"

Kathy described her unsatisfying search for a solution to burning mouth syndrome. "*I don't know if this has happened to anybody else, but I've been to my usual round of endocrinologist, dental oncologists, and they all say, 'There's nothing I can give you for that. Just drink ice water.'"*

Antidepressant or antianxiety medication

Only 2% reported trying antidepressant or antianxiety medication, which is very low considering that 42% reported experiencing depression or anxiety as a health concern.

Most people with xerostomia drink lots of water and have tried a wide number of different approaches and strategies.

Online polling was used to capture all the strategies, products and approaches used to manage xerostomia. Again, poll respondents each selected an average of three different treatments. These are presented in **Appendix 6, Q2** and described below along with additional approaches that were raised during the meeting and in online comments.

Drinking water

Drinking water is a strategy used by 93% of poll respondents to help to resolve the feeling of dry mouth. Most people living with xerostomia require water to communicate and to eat. Many described the large quantities of water that they needed to consume and how necessary it was for them to carry water with them everywhere they went. Edward explained how much he needs water." *During the daytime, I continuously take small sips of liquid, which prevents choking, which can be quite violent. I wear a medical notification bracelet, which says if found awake and choking, give small sips of water."*

Jamie described the amount of water she drank. "*I carry water with me everywhere. I can't talk more than three minutes without having a sip of water. I go through two gallons of water a day and at night 73 ounces. This took some time to have my body get used to this much water*."

Some individuals rely on other fluids to keep their mouth moist. Ken keeps Gatorade on his nightstand instead of water, "*For some reason coke helps. Water doesn't. Gatorade does."*

Downsides of water already mentioned in the report include low blood sodium and other electrolytes and disturbed sleep from having to wake up and go to the bathroom at night. Meeting participants described how water only helps a short time, how it affects the oral health and that they have to take it with them everywhere.

Kathy said, "*It seems like a first go-to for all of us is to sip on water. Well, that lasts in my mouth maybe 45 seconds, and then the three times I have to go to the bathroom afterwards. It just creates a major burden."*

Gum or hard candy

Just over half, or 53% of poll respondents use gum or hard candy to manage xerostomia symptoms. Robert said, *"I have found Brach's Sugar Free Lemon Drops work very well to stimulate saliva. ...The Xylitol Chewing Gum works well to clean out mucus that accumulates in the morning."*

Scott described how in addition to water and Tylenol, he uses gum with xylitol. "*I find that it definitely helps as an ongoing treatment, even when not talking, just driving, just doing my daily chores or what I do daily, having gum in my mouth to keep from getting dry helps a lot."*

Avoiding foods that irritate the mouth: sugary or acidic foods, alcohol and tobacco as well as caffeine

Avoiding sugary or acidic foods is a strategy used by 42% of poll respondents, while 33% avoid alcohol and tobacco to help manage their xerostomia symptoms. In addition, several mentioned avoiding caffeine. Hank described how eating for him involves, "*Not being able to enjoy coffee, tea or soft drinks because of the caffeine that dries out the mouth, and staying with a soft, liquid menu choice*."

Air humidifiers and diffusers

Almost a third (29%) of respondents reported using an air humidifier to manage symptoms. Jamie mentioned using an air diffuser. "*I have two humidifiers running at night and a diffuser. This is to help moisten the air at night, which worked for a little bit, but not long-term*."

Jeff described a downside. "*A humidifier does help give you some relief when sleeping, but it does nothing to increase the saliva*."

Acupuncture

Acupuncture is used by 20% of poll respondents to help manage xerostomia symptoms. This was very successful for some, including Hank.*" My xerostomia symptoms have been reduced since I started using acupuncture. I manage to increase how much saliva I produce and get a boost when I need it. … I now go every three months for a treatment and it's helped tremendously*."

Valerie mentioned downsides. "*Acupuncture worked well for me, but my insurance would not continue paying past six months, and it needs to be ongoing forever."*

For others, acupuncture was less successful. Dave said, "*After the procedure was complete, I did not notice anything different, but my acupuncturist said it may take a while with some people. I was not one of them*."

Increased nonverbal communication

Due to challenges with communicating orally, 18% of poll respondents described having to write notes and texts to communicate with others.

Other approaches

Almost one fifth (18%) of respondents reported using other strategies or approaches to manage xerostomia symptoms. Jeff described a wide variety of approaches that worked for him. "*Over the past 10 years, I've tried many methods of increasing saliva or decreasing dry mouth issues. I use different mouth rinses and home brew concoctions like honey, olive oil, almond milk, vegetable oil, lemon, and herbal teas sucking on mineral stones, using humidifiers, acupuncture, lymphedema, massage, neck massage, and homeopathy. A few of these methods provided some relief and saliva has increased a bit. Oils, honey milk and teas provide temporary belief, but it's difficult to have them on you all the time…. I had to find a solution and I'm very grateful that these alternative methods work so well*."

Other approaches mentioned at the meeting include taking the best care of themselves and their teeth, adapting how they eat, adapting their lifestyles and attitudes, hyperbaric treatments, electronic saliva replacement or stimulation technology including the Voutia and Salipen products, homeopathy, Traditional Chinese Medicine, keeping mouth closed to minimize mouth drying out, consuming astringent or bitter foods to stimulate salivation, mouthwashes and homemade rinses, neck/facial massage, CPAP.

Dietary supplements including nutritional drinks and smoothies

A total of 13% of poll respondents used dietary supplements including high calorie nutritional drinks and smoothies, not only to increase calories, but to replace electrolytes and to calm mouth irritation. Barbara said,*" I'm drinking the shakes and I've invented some of my own shakes, which I think are a little bit healthier than Boosts."*

David described how he eats *"High calorie smoothies fortified with a weight gain powder, and I add avocado oil to my coffee in the mornings*."

Stress management

A total of 7% of poll respondents reported using stress management strategies including mindfulness techniques to manage xerostomia symptoms. Jeffrey described how he dealt with the sense of panic he experiences when choking, ”*I can usually control the panic by mindfulness techniques. I tell myself to relax and just wait for it to get better. That usually takes care of it.*”

Not doing anything to manage symptoms and glycerin swabs

Only 2% of poll respondents reported not using any approaches to help manage their symptoms, and none of the poll respondents used glycerin swabs to manage their symptoms.

Current xerostomia treatment approaches are ineffective, temporary and costly.

While 54% of poll respondents reported that their current regimen controls their xerostomia “somewhat”, 31% reported that it controls it “very little” and only 15% reported that their current regimen controls it “to a great extent”. None of the poll respondents reported that their current regimen “does not control xerostomia at all”, and none reported “not using anything to control xerostomia”. Results are in **Appendix 6, Q3**.

People living with xerostomia not only described the direct downsides of their medications and treatments but the second and third order effects as well. Online polling results revealed that the leading downside of current treatments is that they are not very effective. The remaining polling results were quite evenly split between the remaining choices and are presented in **Appendix 6, Q4**. Many quotes and comments regarding the downsides of different medications and approaches were already captured in the previous sections of the report.

The biggest drawback to current approaches: not very effective

When asked to describe the three biggest drawbacks of their current approaches, 71% selected “not very effective”, which received more than twice as many votes as any other option. Kathy summarized the situation by saying, “*the reason we're trying all these things is that nothing really works.”*

A big reason for the lack of effectiveness is that most xerostomia solutions are only temporary. Thad summarized his treatment experiences by saying, “*all these treatments have provided a brief but temporary solution*.”

High cost or copay, not covered by insurance

This was selected as a drawback by 33% of poll respondents. People living with xerostomia described the expensive secondary costs of therapy including special equipment and the cost of dental work. Many described requiring extensive dentistry. Hank indicated that, *“The cost of treatment, not covered by insurance, is prohibitive and has caused a financial burden*.”

Helga said, “*I think it's worth pointing out that "dental insurance" is a bit of a misnomer. Most plans have a low maximum benefit amount (i.e. $1K-2K). It's more of a discount plan rather than insurance. As a result, it's not unheard of for people living with xerostomia to rack up massive dental bills.”*

Other drawbacks

A total of 27% of poll respondents selected "other drawbacks" when describing some of their therapies. They described having an oral sensitivity to mint, candies and lozenges can cause cuts in the mouth, they described their frustration at a lack of effective therapies. Many people living with xerostomia mentioned learning new approaches from others at the EL-PFDD meeting or at patient support group meetings.

Requires too much effort/time commitment

This option was selected by a quarter (25%) of poll respondents. During the meeting many people living with xerostomia described the large amount of time spent caring for their teeth. They also described the challenges in remembering to take medications.

Side effects

This option was selected by a quarter (25%) of poll respondents and the side effects were mostly from the cholinergic agonists, pilocarpine and cevimeline. Others reported being allergic to xylitol, a principal component of Biotène®.

Limited availability or accessibility and not applicable/not using any treatments

Limited availability or accessibility was selected as a top drawback by 23% of poll respondents and 17% selected not applicable or not using any treatments.

Increased saliva production, help with chewing and swallowing and preventing cavities are the most important goals for a possible new xerostomia drug or device treatment.

"What I would like to see in a development is something that comes available soon, without side effects or without it causing another problem. Make it affordable, and easy to obtain. Patients need relief and are suffering." - Charles

The clear top three choices for a possible new drug or device treatment included increased saliva production, help with chewing and swallowing and the prevention of dental caries or cavities. Poll respondents selected these three aspects much higher than all the others. Poll results are shown in **Appendix 6, Q5** and described below, along with comments.

Increased saliva production

Increased saliva production was selected by most, or 87% of poll respondents. Les said, "*An ideal treatment would be a saliva substitute that's effective and easy to use*."

Help with chewing and swallowing

Help with chewing and swallowing was chosen by 62% of poll respondents. This was important for Jeffrey who said, "*If there was one symptom of xerostomia that I could eliminate, it would be the dysphagia. I never know when I will start coughing and choking*."

Prevent dental caries or cavities

Prevention of cavities was selected by 51% of poll respondents. Kathy said that she wanted "*protection for the teeth that I have, and for the lining of my mouth, the mucosal lining. I don't want to lose my teeth. And if I do lose my teeth, I want to know that there are some solutions that would work*".

Other aspects of xerostomia management were selected with lower priority.

The other selected options and the percentage of people who selected them (in brackets) include: improved altered taste (13%), help with the ability to speak (13%), reduce oral pain or burning (11%), slow or stop progression (9%), prevent oral candidiasis (9%), help with mood changes: depression or anxiety (6%), reduce fatigue (6%), improve communicating verbally (6%), help with ulcers of the tongue and mouth (6%), help with halitosis or bad breath (2%), help with cracked lips (2%), and prevent salivary gland infection (0%).

Other unmet needs which were brought up during the meeting included: treatments that would decrease teeth/gum sensitivity, that would not affect the tastebuds, that would help with the ability to sleep at night, mucus blockers with a thinning element for mucus, treatments with few or no side effects, and more research.

People living with xerostomia want longer lasting solutions. This was mentioned many times. Kathy said, "*If I couldn't have complete resolution of the dry mouth and the consequences of that, …, I'd want something that's long lasting, not something that's so short lived like we, I think almost everybody has mentioned at some point*."

Injectable treatment options as opposed to pills. Katie noted that, "*we're talking about a group of people that have a lot of trouble swallowing and issues with their throat and saliva. So why are we taking so many pills a day*?...I *would prefer either an infusion or a shot that was a more systemic approach."*

Gene therapy for salivary gland replacement. Kathy is hopeful for gene therapy. "*We no longer have healthy tissue. We have just damaged tissue that can't function and no drug can make it function. ...I am so hopeful for gene therapy, and I just wish we could get something on the market before I'm 100 and in time to really help me*."

Preventative approaches: radiation alternatives or treatments to mitigate the negative side effects of radiation or iodine. Daria said, *"It would be ideal if there was a way to protect the saliva glands before radioactive iodine treatment."*

Michelle B. is looking for a treatment to, "*Block or prevent radiation's deleterious effect on the salivary glands, cells; anything that could be taken or used during and/or after radiation treatment to improve the integrity of healthy tissue and the ability of the body to continue to function with regard to saliva production*."

Jeff discussed an alternative to radiation. "*Another hopeful approach is a use of immunotherapy. I was fortunate to have had immunotherapy treatment to address my metastatic head and neck cancer. And I'm here because of it. If this can be used instead of radiation as a first-line treatment, that would be a dry mouth game changer."*

Better patient education or a Xerostomia treatment algorithm. Many people living with xerostomia mentioned being given few treatment options, forcing them to find out what worked through trial and error and having to learn about these options from other patients. Having better patient education materials about the experience of xerostomia (what to expect), a treatment algorithm showing all the different options including a full list of treatment lifestyle suggestions and adaptations is needed.

Incorporating Patient Input into a Benefit-Risk Assessment Framework

The FDA uses a Benefit-Risk Assessment Framework which provides an important context for drug regulatory decision-making, including valuable information for weighing the specific benefits and risks of a particular medical product under review. The Framework includes analysis of condition, current treatment options, benefit, risk and risk management as decision factors.

Table 1 serves as the proposed introductory framework for the Analysis of Condition and Current Treatment Option rows. The information presented captures the perspectives of people with xerostomia presented at the August 19, 2021, meeting, as well as polling results and comments submitted before, during and after the meeting through the online portal. Note that the information in this sample framework is likely to evolve over time.

Ultimately, this table could be adapted and incorporated in the FDA's Benefit-Risk Assessment to enable a comprehensive understanding of xerostomia for key reviewers in the FDA Centers and Divisions that would be reviewing new treatments. This information might also help inform the development of clinically meaningful endpoints for current and future clinical trials, as well as encourage additional manufacturers to investigate xerostomia treatments.

Table 1 speaks to the challenges faced by people living with xerostomia.

TABLE 1 Xerostomia Benefit Risk Table

	EVIDENCE AND UNCERTAINTIES	CONCLUSIONS AND REASONS
ANALYSIS OF CONDITION/ IMPACTS ON ACTIVITIES OF DAILY LIVING	**Symptoms.** Considering xerostomia as just "dry mouth" vastly underestimates its impact. The most troublesome xerostomia symptoms include trouble swallowing, trouble chewing and/or solids sticking to teeth, and cavities. The most severe health concerns include tooth loss, periodontal disease, and digestive impairment. Xerostomia-related malnutrition can be life threatening. **Impacts on activities of daily life.** People living with xerostomia have challenges eating, are unable to enjoy food or sleep soundly. Many can't go out to eat, communicate clearly, or participate in sports or recreational activities. Many are socially isolated.	**Symptoms** - Xerostomia affects all aspects of oral systemic health, including teeth, bones, trachea and the entire gastrointestinal tract. Xerostomia is often more severe than anticipated, persistent and can worsen with time. People living with xerostomia worry about increased difficulties eating, not knowing how the disease will progress, choking and losing their teeth. **Impacts on activities of daily life.** Living with xerostomia is a daily battle and leads to a reduced quality of life. Most people living with xerostomia have had to make major eating, social and lifestyle adaptations. Xerostomia- related sleep loss, lack of exercise and malnutrition exacerbate or contribute to other health problems.
CURRENT TREATMENT OPTIONS/ PROSPECTS FOR FUTURE TREATMENTS	**The unmet need**. Current treatments do not address the root causes of xerostomia, but instead focus on addressing symptoms: temporarily replacing saliva and moistening the oral cavity with saliva substitutes and moisturizers, lozenges and cholinergic agonists. Secondary effects of tooth decay and candidiasis are treated with prescription fluoride and antifungals **Patient preferences for future treatment.** Patients reported that they need: preventative approaches to avoid radiation treatment damage; treatment algorithms and management guidelines; patient education materials about what to expect.	**The unmet need**. Effective and long-lasting xerostomia treatments are lacking. Most patients tried all existing medications, medical treatments and solutions available; at best these provide temporary relief. Many patients have had to find their own solutions and reported learning about new approaches at patient support meetings. **Patient preferences for future treatment.** New and longer lasting treatments are needed for xerostomia. Treatment priorities include increased saliva production, help with chewing and swallowing and the prevention of dental cavities. ***See the voice of the patient report for a more detailed narrative.***

Conclusion

> "*Hopefully the input from actual patients will help develop a new treatment that can somehow activate the salivary glands or a product that at least gets close to the properties of saliva. I'm cautiously optimistic that one day I will be drooling over that half pound cheeseburger and fries, or at least be able to eat without choking or drinking a half gallon of water to wash it down*." - Dave

The August 19, 2021 Xerostomia EL-PFDD meeting brought together the full spectrum of xerostomia-affected individuals. This meeting provided an opportunity to hear directly from people about their experiences of living with xerostomia, the impact of xerostomia on their activities and daily lives, and their worries related to their xerostomia. Meeting participants described the different medications, technologies, strategies and adaptations that they had used to address their xerostomia. They identified unmet needs and shared their preferences and perspectives for future technologies and therapies to better inform the FDA, academic investigators, physicians and nurses, as well as providers from academic institutions, regional hospitals, and private clinics.

This was also a day of education, with at least 64 health care providers in attendance, who attended to learn more about the disease.

What we heard: most meeting attendees have already been through a great deal, including extensive and debilitating diagnosis and treatment journeys for cancer and other chronic diseases. The people living with xerostomia who attended this EL-PFDD demonstrated that xerostomia is not just an oral condition but has many secondary and tertiary effects and impacts all activities of daily living and quality of life. They expressed frustration at the lack of effective treatments for xerostomia and are hopeful about future treatments.

People living with xerostomia shared their stories of resilience. For Gail, "*What I've learned to do is try to manage it all with … a sense of humor as best I can*."

Ada said, **"***I do my best to try to maintain a positive attitude and I continue to seek relief*."

Jeff described, "*My wife and I have gained new respect towards resourcefulness. We never stop looking for alternatives. We never stop asking questions and we never accept unreasonable answers."*

Not only were voices heard, but solutions were shared. Although Hal's doctors could not recommend many solutions for his dry mouth, because of attending this meeting, he heard about many new things he wanted to try. Allen said, *"I am grateful to learn what I can because anything that may help any of my issues may help me live with the other ones."*

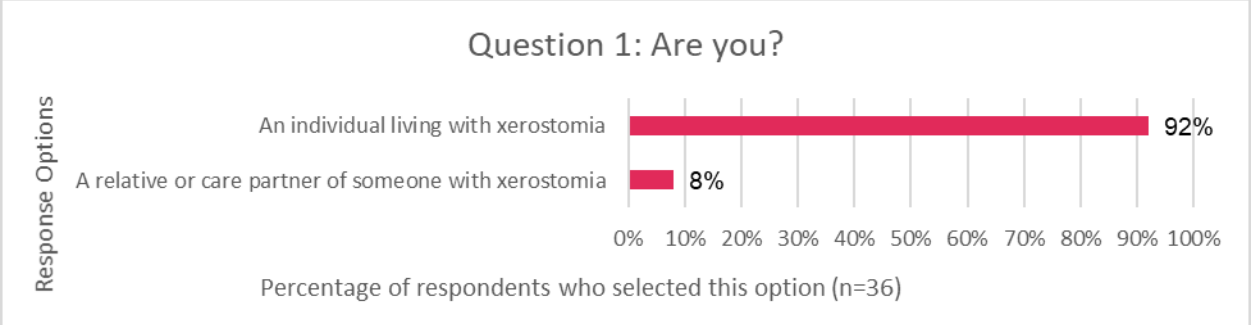
Head and Neck Cancer Alliance (HNCA), the National Foundation of Swallowing Disorders (NFOSD), Support for People with Oral and Head and Neck Cancer (SPOHNC), and the THANC (Thyroid, Head and Neck Cancer) Foundation are grateful for this opportunity to share our community's voices through this *Voice of the Patient* report and, in turn, educate and inspire others to find better solutions to improve the health and quality of life for those living with xerostomia.

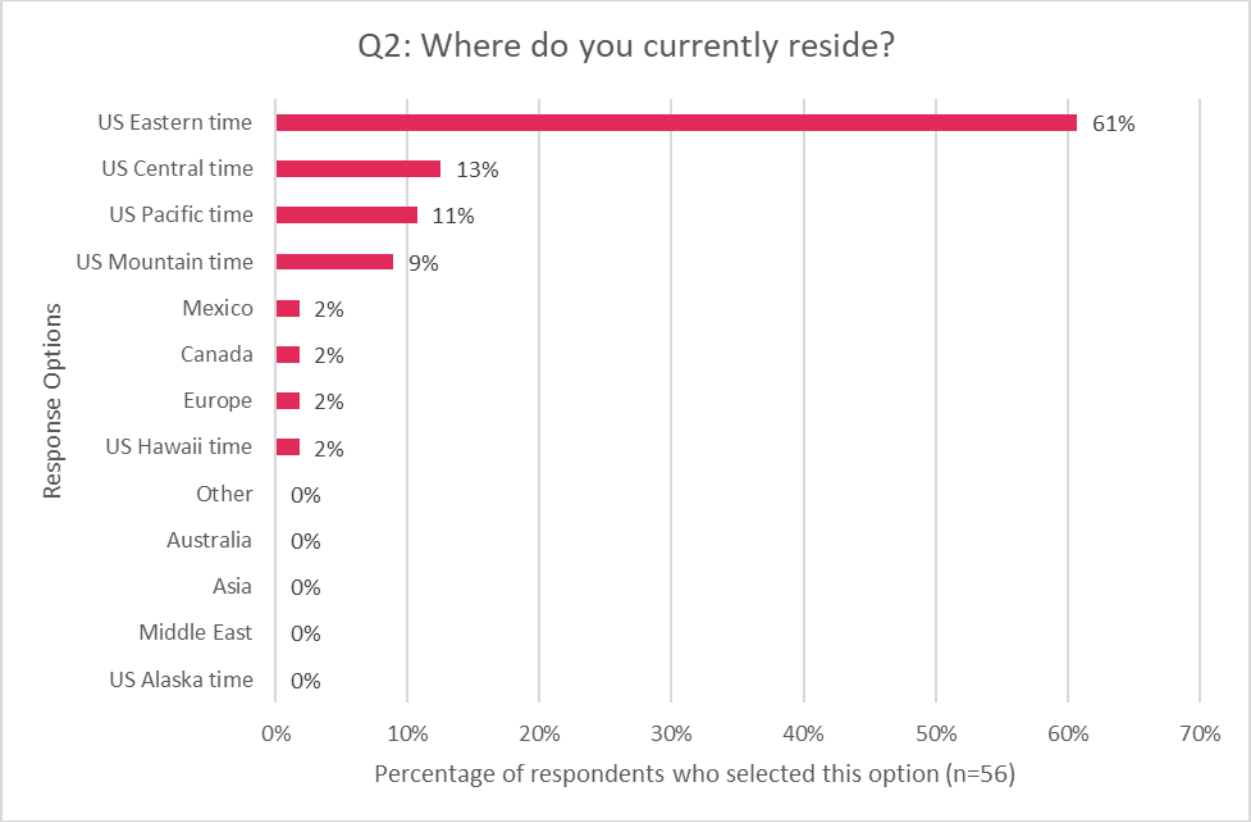
"I never give up hope that medical research will someday find better treatments for my xerostomia." - Jeffrey

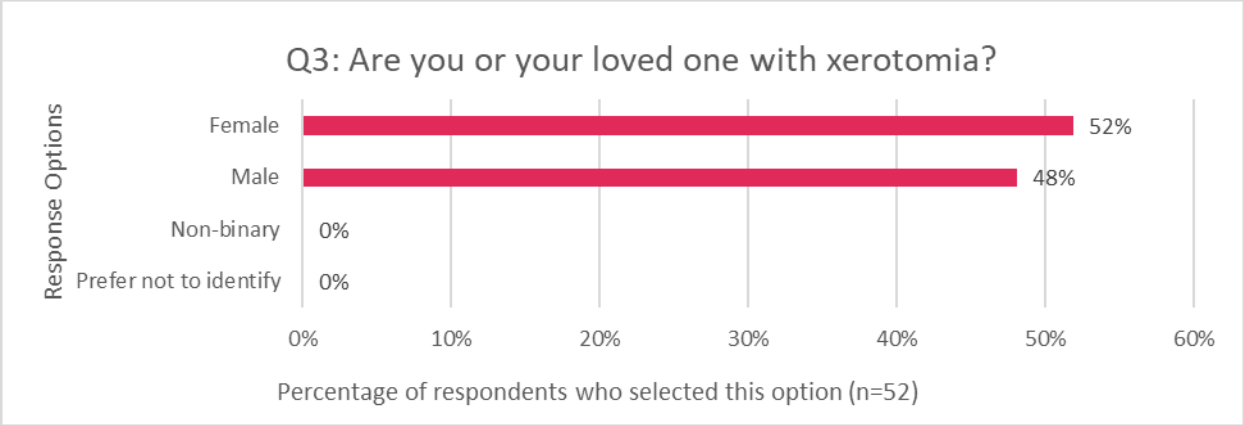
Appendix 1: Meeting Demographics

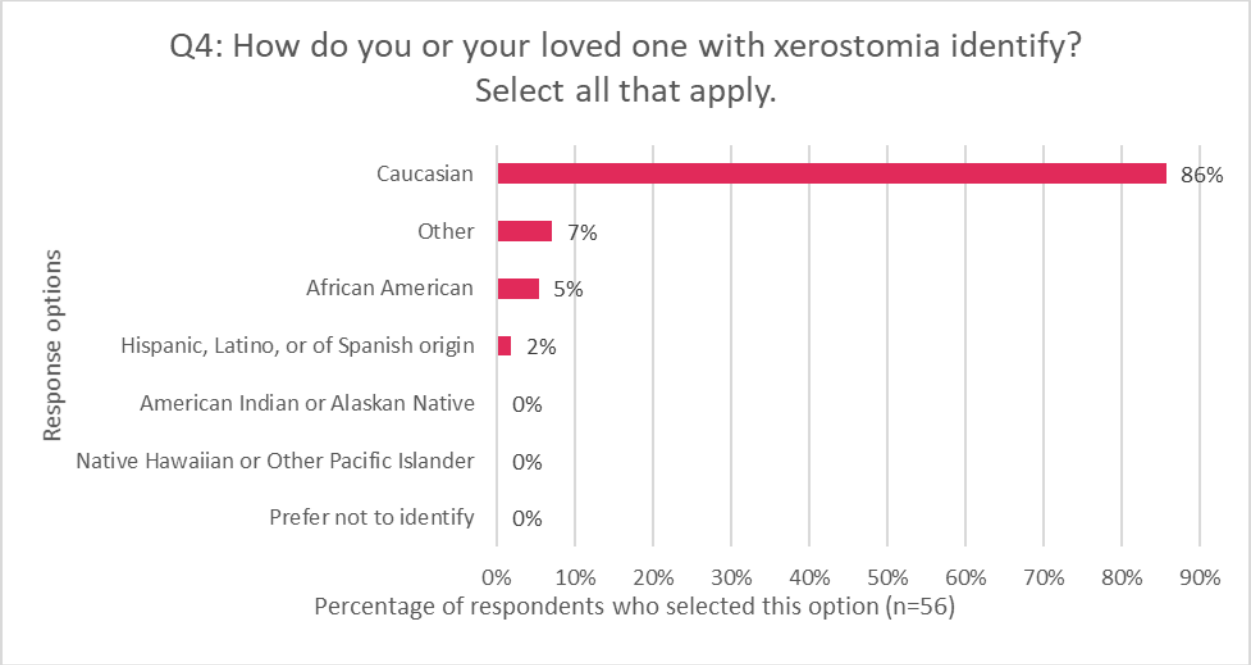
These graphs include those attendees who chose to participate in online voting. The number of patients who responded to each polling question is shown below the X axis (n=x).

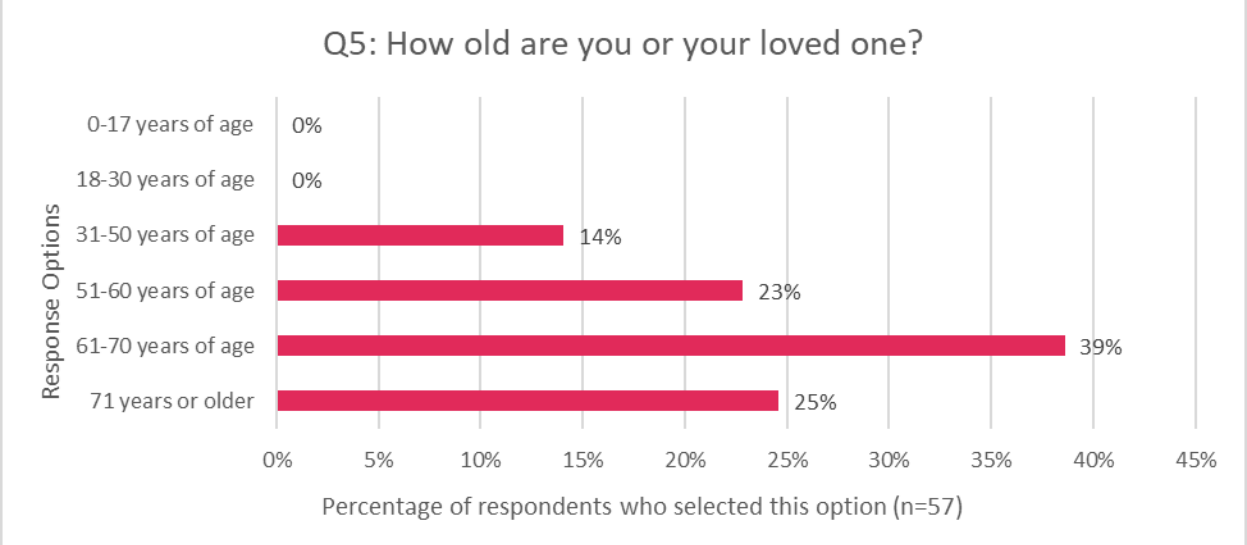
While the response rate data for these polling questions is not considered scientific data, it provides a snapshot of who participated in the EL-PFDD meeting and is intended to complement the live and pre-recorded comments throughout the meeting.

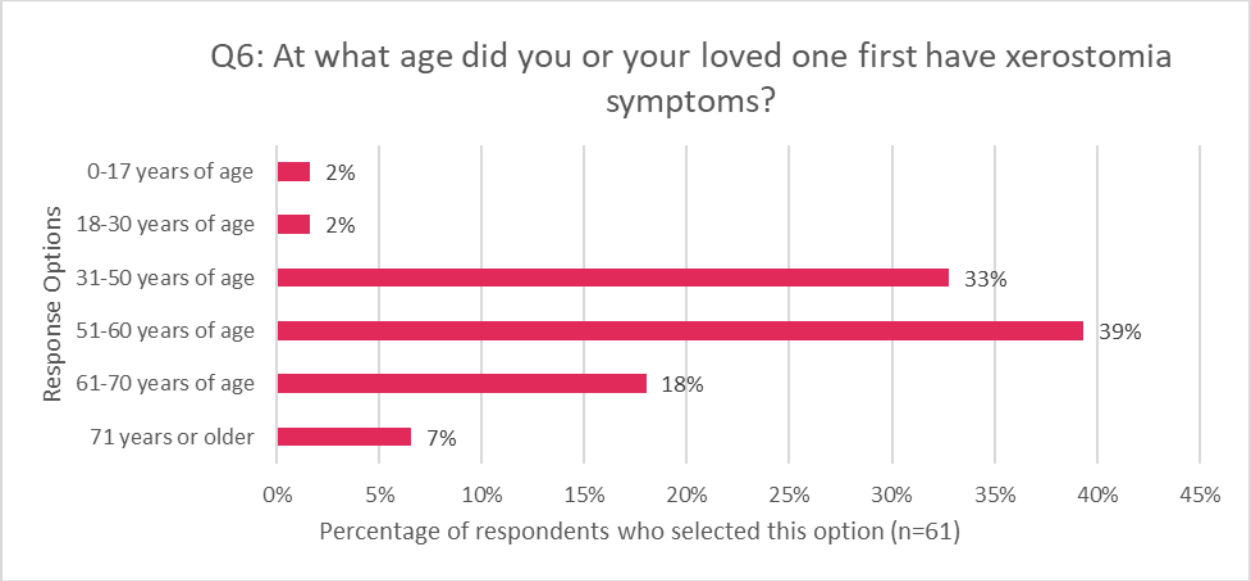


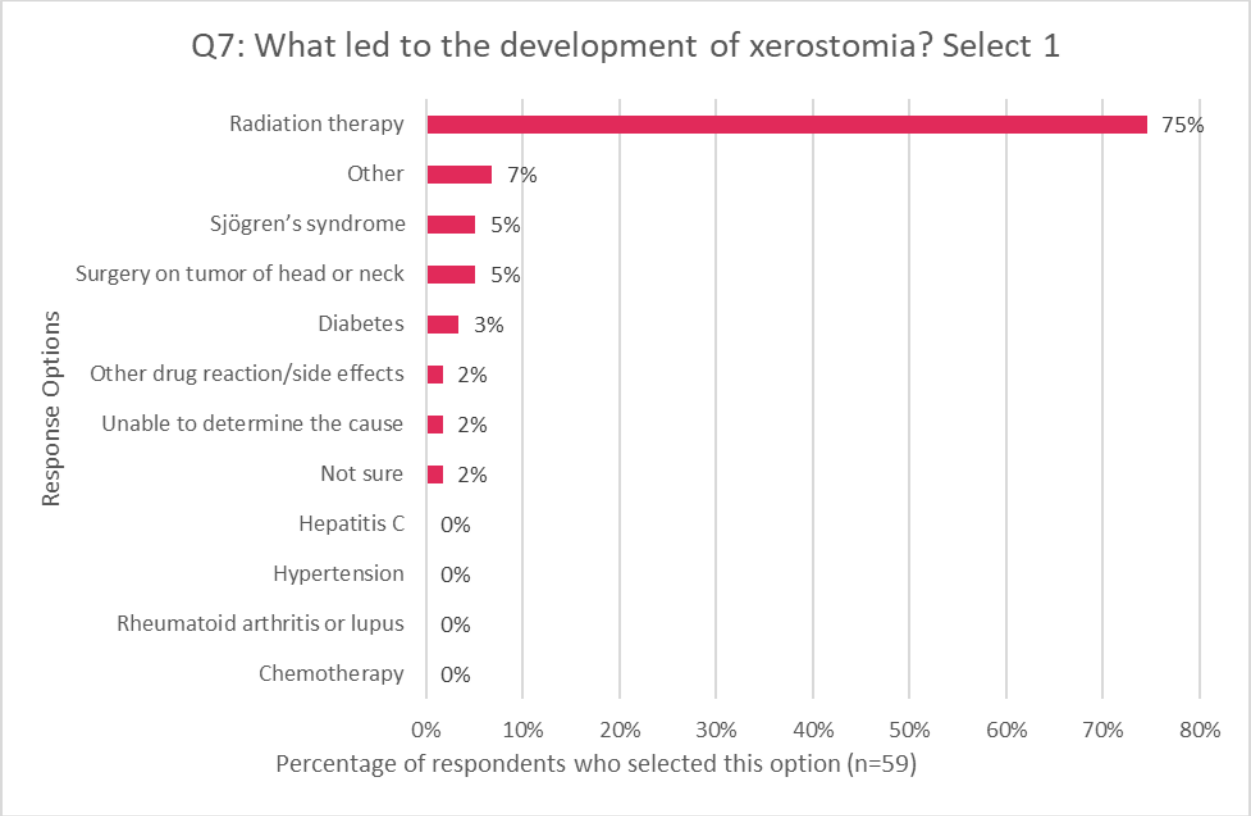



Q3: Are you or your loved one with xerotomia?
Response Options
Female
Male
Non-binary
Prefer not to identify
52%
48%
0%
0%
0%
10%
20%
30%
40%
50%
60%
Percentage of respondents who selected this option (n=52)


Q4: How do you or your loved one with xerostomia identify?
Select all that apply.
Response options
Caucasian
Other
African American
Hispanic, Latino, or of Spanish origin
American Indian or Alaskan Native
Native Hawaiian or Other Pacific Islander
Prefer not to identify
86%
7%
5%
2%
0%
0%
0%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
Percentage of respondents who selected this option (n=56)


Q5: How old are you or your loved one?
Response Options
0-17 years of age
18-30 years of age
31-50 years of age
51-60 years of age
61-70 years of age
71 years or older
0%
0%
14%
23%
39%
25%
0%
5%
10%
15%
20%
25%
30%
35%
40%
45%
Percentage of respondents who selected this option (n=57)


Q6: At what age did you or your loved one first have xerostomia symptoms?
Response Options
0-17 years of age
18-30 years of age
31-50 years of age
51-60 years of age
61-70 years of age
71 years or older
2%
2%
33%
39%
18%
7%
0%
5%
10%
15%
20%
25%
30%
35%
40%
45%
Percentage of respondents who selected this option (n=61)


Q7: What led to the development of xerostomia? Select 1
Response Options
Radiation therapy
Other
Sjögren's syndrome
Surgery on tumor of head or neck
Diabetes
Other drug reaction/side effects
Unable to determine the cause
Not sure
Hepatitis C
Hypertension
Rheumatoid arthritis or lupus
Chemotherapy
75%
7%
5%
5%
3%
2%
2%
2%
0%
0%
0%
0%
0%
10%
20%
30%
40%
50%
60%
70%
80%
Percentage of respondents who selected this option (n=59)

Appendix 2: Meeting Agenda

Externally-Led Patient Focused Drug Development (PFDD) Meeting on Xerostomia

Location: Virtual Date: August 19, 2021 Time: 10:00 am – 3:30 pm EST

9:45–10:00 Log on

https://thancfoundation.org/xerostomia-meeting-2021/

10:00–10:05 Welcome & Opening Remarks

Amanda Hollinger, MPA // Executive Director, *Head & Neck Cancer Alliance*

10:05–10:15 FDA Introduction to PFDD

Kendall Marcus, MD // Director, Division of Dermatology & Dental Products in the Center for Drug Evaluation & Research, *Food & Drug Administration*

10:15–10:30 Clinical Overview of Xerostomia

James J. Sciubba, DMD, PhD // Professor (Ret.), Consultant to *The Johns Hopkins School of Medicine*; President, *Support for People With Oral And Head And Neck Cancer (SPOHNC)*

10:30–10:40 Meeting Overview

James Valentine, JD, MHS // Meeting Moderator

10:40–10:45 Demographic Polling

Session 1 Xerostomia Symptoms & Daily Impacts

10:45–11:10 Patient Testimonials

11:10–12:30 Moderated Audience Discussion & Polling

James Valentine, JD, MHS // Meeting Moderator

12:30–1:00 Lunch Break

Session 2 Current & Future Xerostomia Treatments

1:00–1:25 Patient Testimonials

1:25–2:40 Moderated Audience Discussion & Polling

James Valentine, JD, MHS // Meeting Moderator

2:40–2:50 Meeting Summary

Larry Bauer, RN, MA // *Hyman, Phelps, & McNamara, P.C.*

2:50–3:00 Next Steps & Closing Remarks

Amanda Hollinger, MPA // Executive Director, *Head & Neck Cancer Alliance*

Appendix 3: Living with Xerostomia Discussion Questions.

Session 1: Symptoms and Daily Impacts

1. Of all the symptoms of xerostomia, which 1–3 symptoms have the most significant impact on you or your loved one's life?
2. How does xerostomia affect you or your loved one on best and on worst days?
3. How have you or your loved one's symptoms changed over time? How has the ability to cope with the symptoms changed over time?
4. Are there specific activities that are important to you or your loved one that you or they cannot do at all or as fully as you or they would like because of xerostomia?
5. What do you fear the most as you or your loved one gets older? What worries you most about you or your loved one's condition?

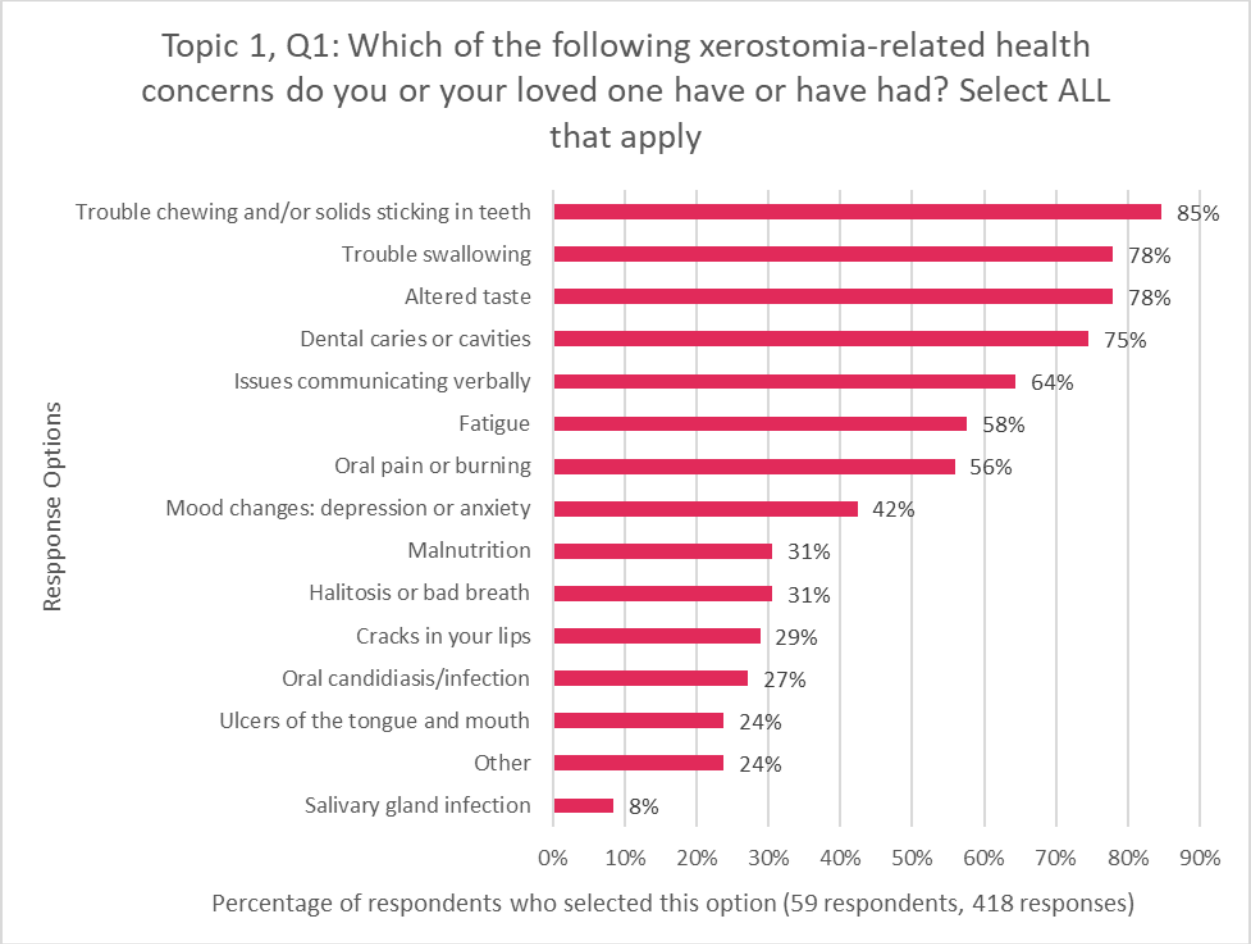
Session 2: Your Perspective on Treatment Approaches

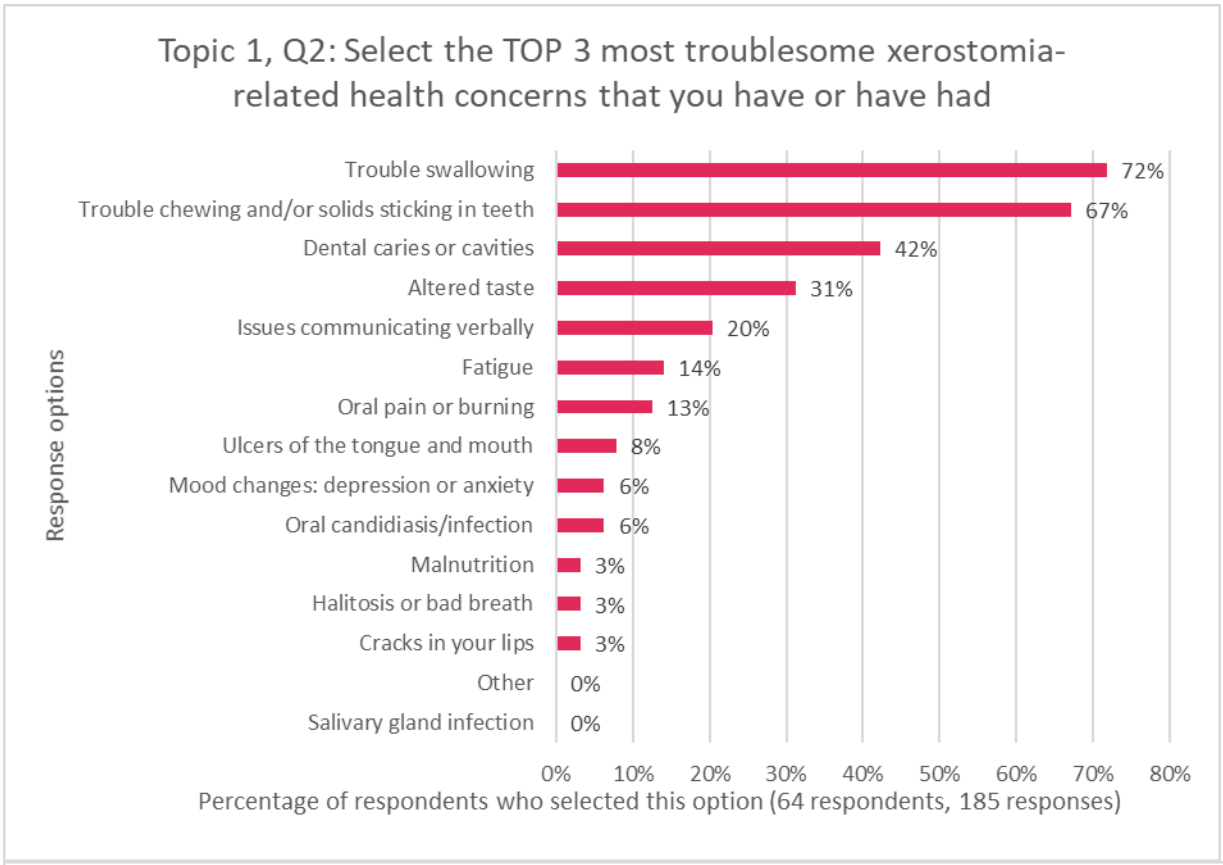
1. What are you currently doing to manage you or your loved one's xerostomia symptoms?
2. How well do these treatments treat the most significant symptoms of xerostomia?
3. What are the most significant downsides to you or your loved one's current treatments and how do they affect daily life?
4. Short of a complete cure, what specific things would you look for in an ideal treatment for xerostomia? When considering a new treatment, what factors are important to you?

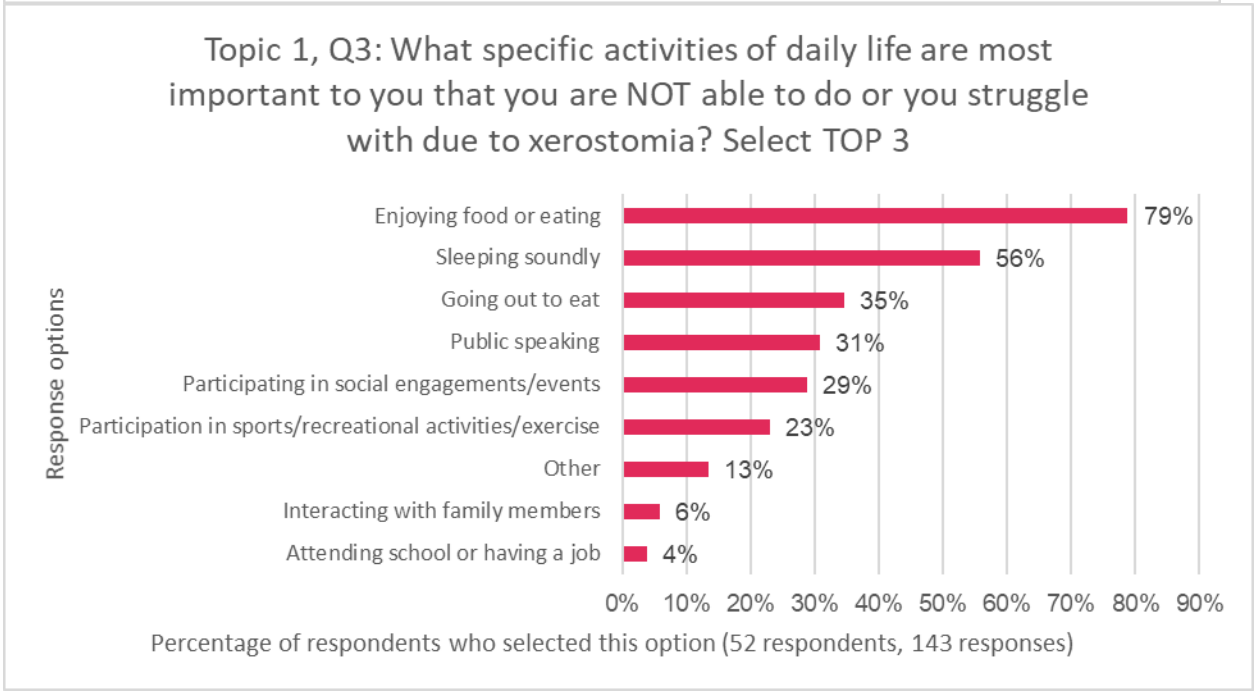
Appendix 4: Topic 1 Online Polling Results

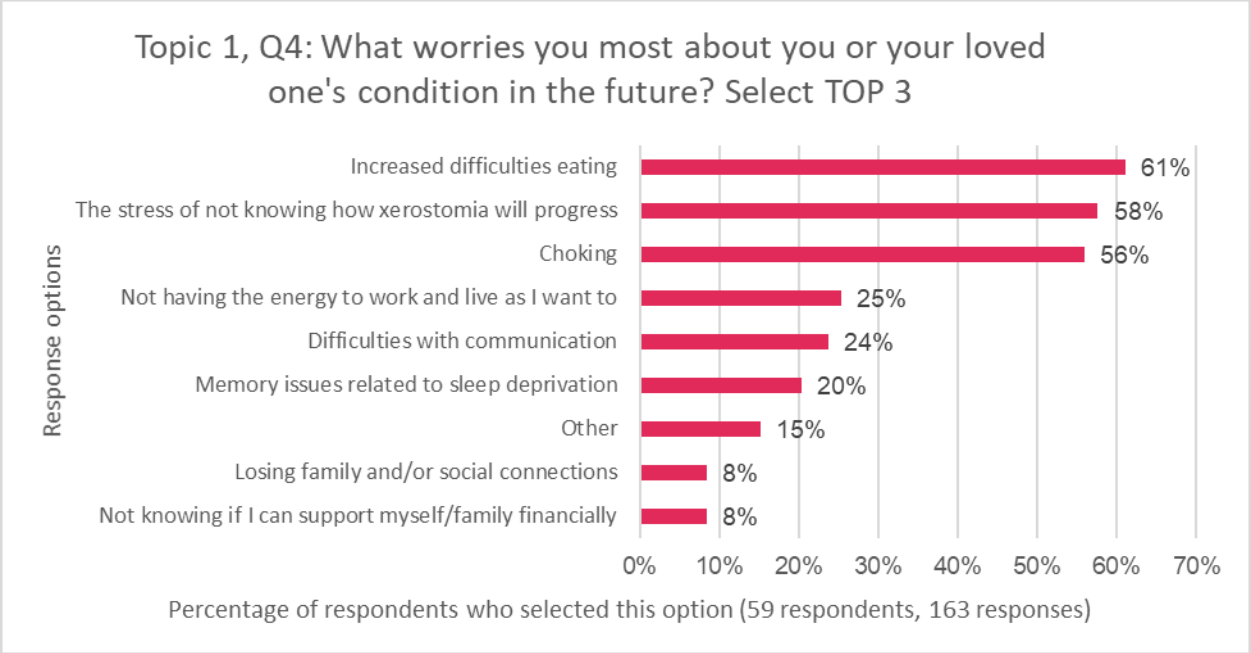
These graphs include those attendees who chose to participate in online voting. The number of patients who responded to each polling question is shown below the X axis. For most questions, poll respondents could select more than one response. The total of poll responses is also shown below the X axis.

While the response rate data for these polling questions is not considered scientific data, it provides a snapshot of who participated in the EL-PFDD meeting and is intended to complement the live and pre-recorded comments throughout the meeting.




Topic 1, Q2: Select the TOP 3 most troublesome xerostomia-related health concerns that you have or have had
Response options
Trouble swallowing 72%
Trouble chewing and/or solids sticking in teeth 67%
Dental caries or cavities 42%
Altered taste 31%
Issues communicating verbally 20%
Fatigue 14%
Oral pain or burning 13%
Ulcers of the tongue and mouth 8%
Mood changes: depression or anxiety 6%
Oral candidiasis/infection 6%
Malnutrition 3%
Halitosis or bad breath 3%
Cracks in your lips 3%
Other 0%
Salivary gland infection 0%
0% 10% 20% 30% 40% 50% 60% 70% 80%
Percentage of respondents who selected this option (64 respondents, 185 responses)


Topic 1, Q3: What specific activities of daily life are most important to you that you are NOT able to do or you struggle with due to xerostomia? Select TOP 3
Response options
Enjoying food or eating 79%
Sleeping soundly 56%
Going out to eat 35%
Public speaking 31%
Participating in social engagements/events 29%
Participation in sports/recreational activities/exercise 23%
Other 13%
Interacting with family members 6%
Attending school or having a job 4%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90%
Percentage of respondents who selected this option (52 respondents, 143 responses)


Topic 1, Q4: What worries you most about you or your loved one's condition in the future? Select TOP 3
Response options
Increased difficulties eating
61%
The stress of not knowing how xerostomia will progress
58%
Choking
56%
Not having the energy to work and live as I want to
25%
Difficulties with communication
24%
Memory issues related to sleep deprivation
20%
Other
15%
Losing family and/or social connections
8%
Not knowing if I can support myself/family financially
8%
0%
10%
20%
30%
40%
50%
60%
70%
Percentage of respondents who selected this option (59 respondents, 163 responses)

Appendix 5: Names of panelists and callers

The second initial was included only if there were multiple meeting participants with the same name.

Prerecorded Zoom Panel 1

Ron

Ada

Hank

Jeffrey

Judy

Live Zoom Panel 1

Gail

Tom

Dan

Janet R.

Barbara

Topic 1 Callers

Ellen

Pam

Carrie

Kathie

Kathy

Redora

Scott

Anjali

Prerecorded Zoom Panel 2

Edward

Dave

Jamie

Thad

Jeff

Live Zoom Panel 2

Katie

Scott

Hal

Kathy

Topic 2 Callers

Ronnie

Susan S.

Cheryl

Allen

Tammy D.

Jan

Hank

Appendix 6: Topic 2 Online Polling Results

These graphs include those attendees who chose to participate in online voting. The number of patients who responded to each polling question is shown below the X axis. For most questions, poll respondents could select more than one response. The total of poll responses is also shown below the X axis.

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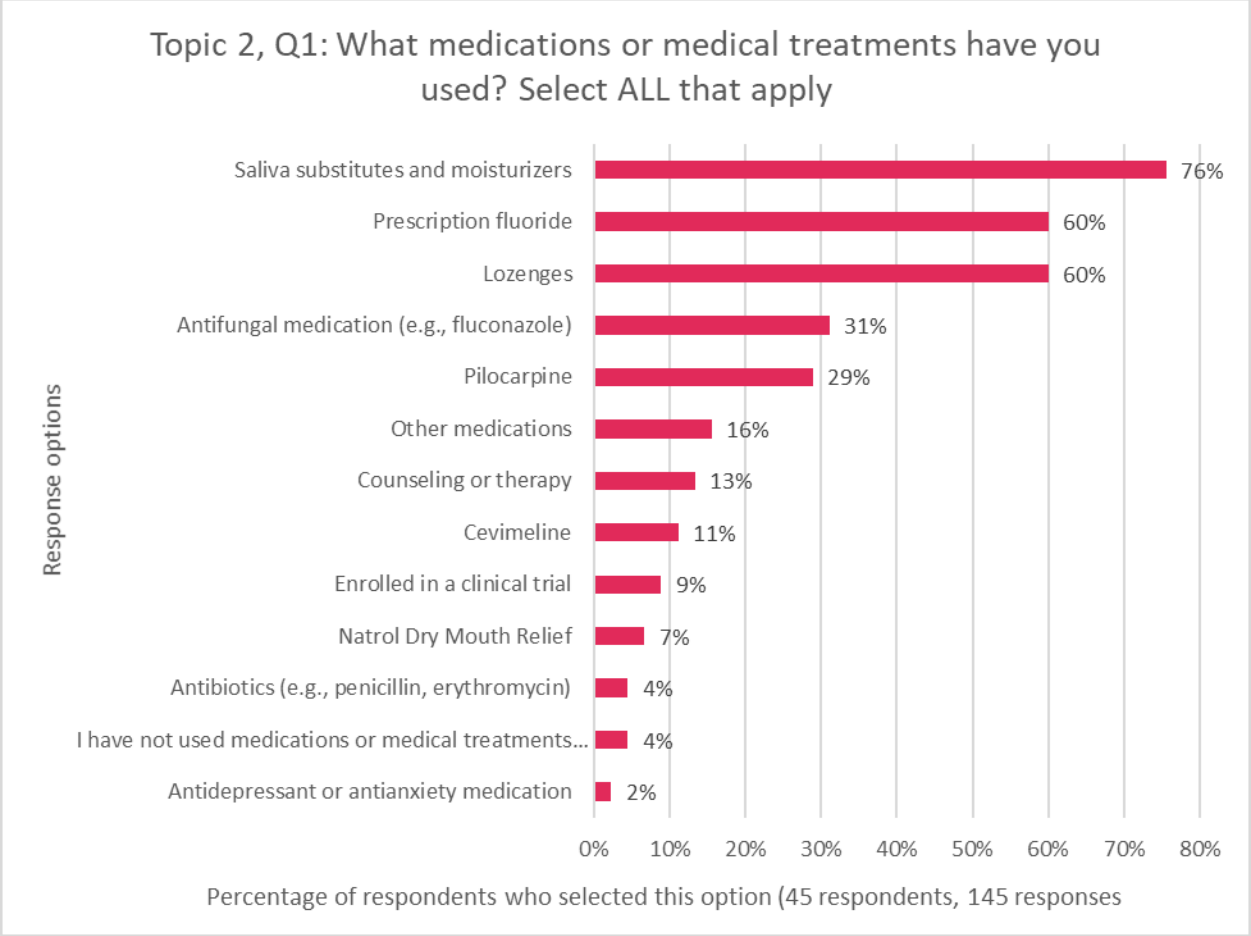
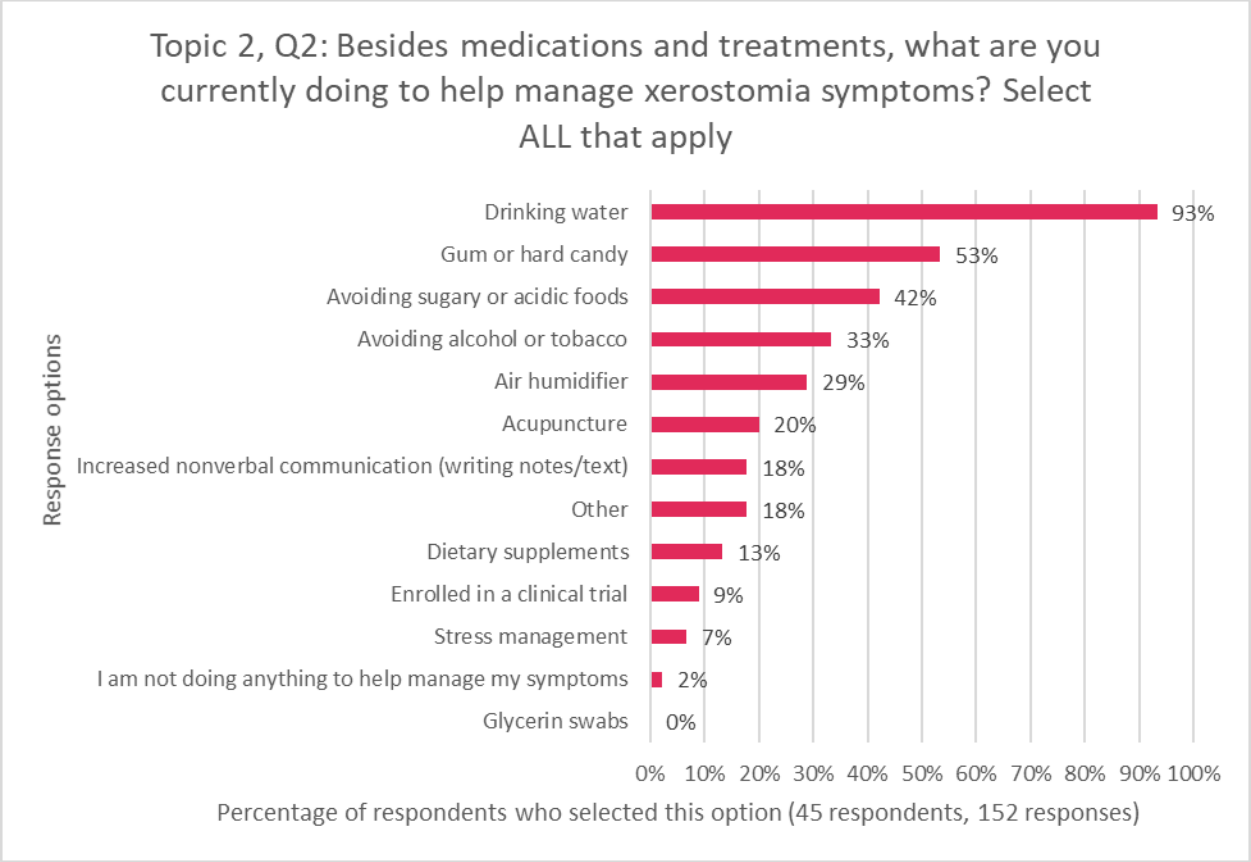
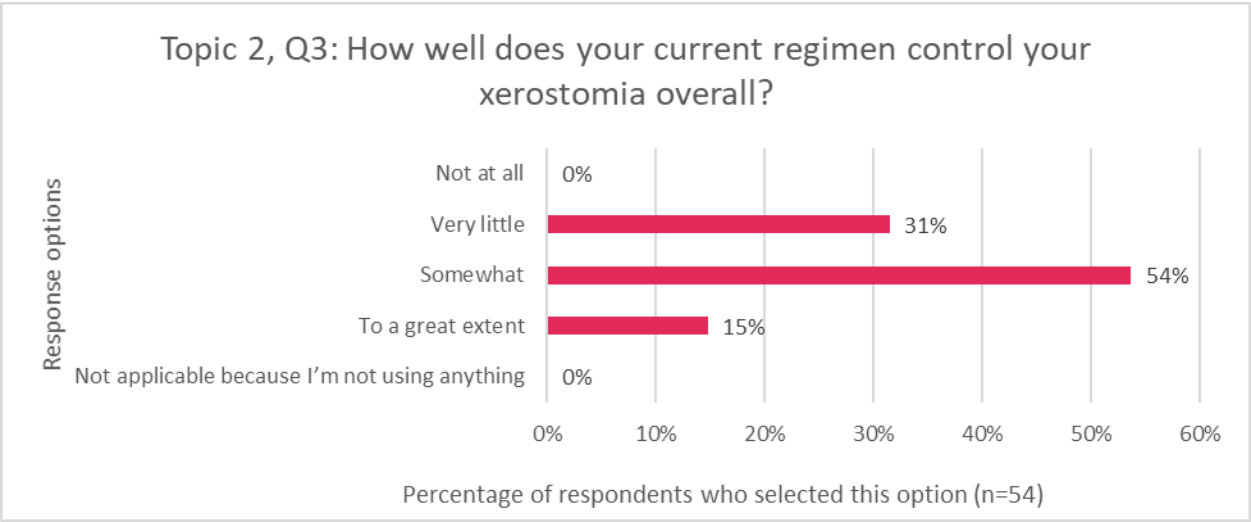
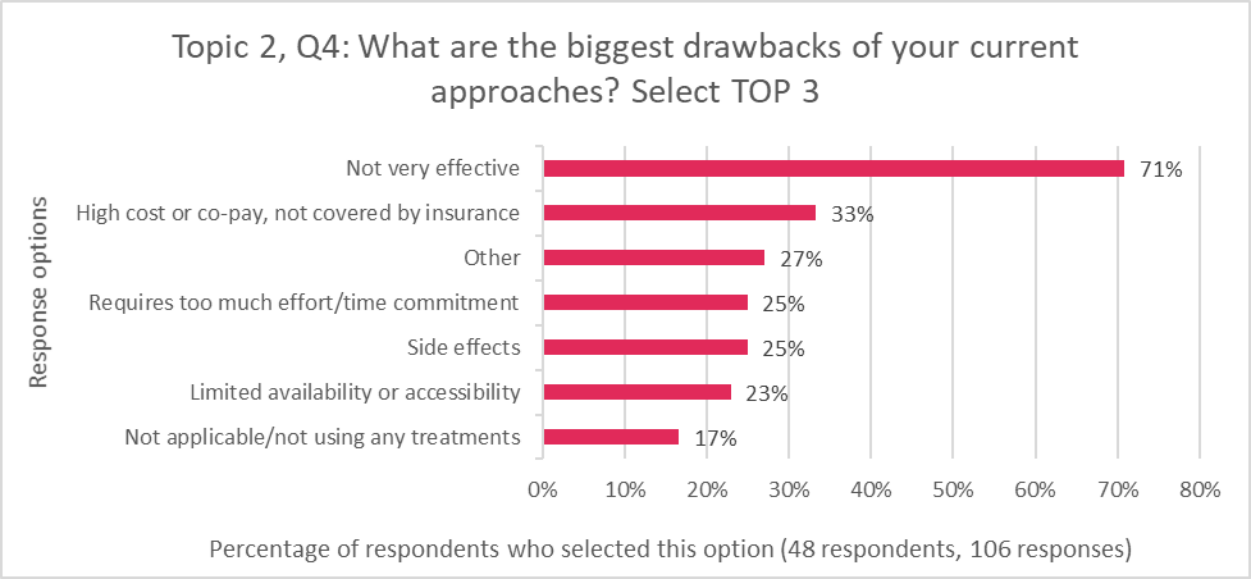
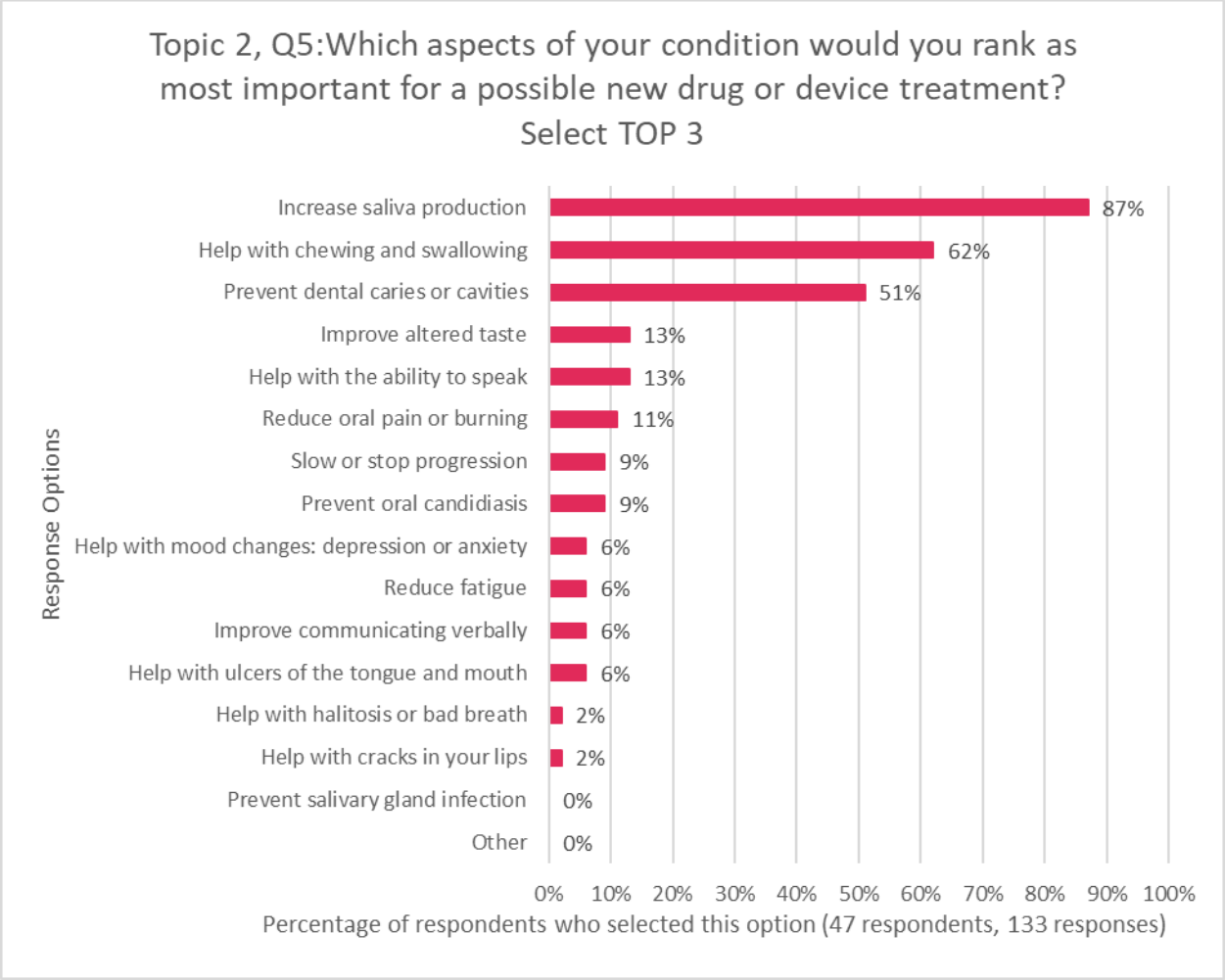



Topic 2, Q2: Besides medications and treatments, what are you currently doing to help manage xerostomia symptoms? Select ALL that apply
Response options
Drinking water 93%
Gum or hard candy 53%
Avoiding sugary or acidic foods 42%
Avoiding alcohol or tobacco 33%
Air humidifier 29%
Acupuncture 20%
Increased nonverbal communication (writing notes/text) 18%
Other 18%
Dietary supplements 13%
Enrolled in a clinical trial 9%
Stress management 7%
I am not doing anything to help manage my symptoms 2%
Glycerin swabs 0%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Percentage of respondents who selected this option (45 respondents, 152 responses)


Topic 2, Q3: How well does your current regimen control your xerostomia overall?
Response options
Not at all 0%
Very little 31%
Somewhat 54%
To a great extent 15%
Not applicable because I'm not using anything 0%
0% 10% 20% 30% 40% 50% 60%
Percentage of respondents who selected this option (n=54)


Topic 2, Q4: What are the biggest drawbacks of your current approaches? Select TOP 3
Response options
Not very effective
High cost or co-pay, not covered by insurance
Other
Requires too much effort/time commitment
Side effects
Limited availability or accessibility
Not applicable/not using any treatments
71%
33%
27%
25%
25%
23%
17%
0%
10%
20%
30%
40%
50%
60%
70%
80%
Percentage of respondents who selected this option (48 respondents, 106 responses)


Topic 2, Q5:Which aspects of your condition would you rank as most important for a possible new drug or device treatment? Select TOP 3
Response Options
Increase saliva production
Help with chewing and swallowing
Prevent dental caries or cavities
Improve altered taste
Help with the ability to speak
Reduce oral pain or burning
Slow or stop progression
Prevent oral candidiasis
Help with mood changes: depression or anxiety
Reduce fatigue
Improve communicating verbally
Help with ulcers of the tongue and mouth
Help with halitosis or bad breath
Help with cracks in your lips
Prevent salivary gland infection
Other
87%
62%
51%
13%
13%
11%
9%
9%
6%
6%
6%
6%
2%
2%
0%
0%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage of respondents who selected this option (47 respondents, 133 responses)