

## Cost-effectiveness landscape analysis of treatments addressing xerostomia in patients receiving head and neck radiation therapy

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Head and neck (H&N) radiation therapy (RT) can induce irreversible damage to the salivary glands thereby causing long-term xerostomia or dry mouth in 68%-85% of the patients. Not only does xerostomia significantly impair patients' quality-of-life (QOL) but it also has important medical sequelae, incurring high medical and dental costs. In this article, we review various measures to assess xerostomia and evaluate current and emerging solutions to address this condition in H&N cancer patients. These solutions typically seek to accomplish 1 of the 4 objectives: (1) to protect the salivary glands during RT, (2) to stimulate the remaining gland function, (3) to treat the symptoms of xerostomia, or (4) to regenerate the salivary glands. For each treatment, we assess its mechanisms of action, efficacy, safety, clinical utilization, and cost. We conclude that intensity-modulated radiation therapy is both the most widely used prevention approach and the most cost-effective existing solution and we highlight novel and promising techniques on the cost-effectiveness landscape. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116:e37-e51)

In the United States (US), 24 million persons are suffering from xerostomia, or dry mouth, of which, 8 million present with moderate to severe symptoms.<sup>1,2</sup> More than 400 medications are known to be associated with xerostomia as a side effect.<sup>2,3</sup> This is the leading cause of xerostomia which affects in majority the elderly, a population more likely to suffer from chronic diseases necessitating polymedication.<sup>3</sup> Other medical etiologies, such as immune syndrome (e.g., Sjögren's syndrome) and poorly controlled diabetes, can also lead to xerostomia. Xerostomia is the most common complaint of head and neck (H&N) cancer survivors that have received radiation therapy (RT), with a prevalence of 93% during RT and 74%-85% following RT.<sup>4</sup> Importantly, in those cases, xerostomia cannot be

attributed to concomitant chemotherapy (CHT), often used to treat advanced stage cancers, as CHT-induced xerostomia has been shown to be reversible at the end of treatment.<sup>4</sup> Given 75,000 new H&N cancer patients per year,<sup>5</sup> 90% of which receive RT<sup>6</sup> and 85% of which consequently develop xerostomia,<sup>7-9</sup> the incidence of xerostomia as a consequence of H&N RT in the US can be estimated to 30-50,000 new patients each year.

Xerostomia is clinically defined as the subjective complaint of dry mouth and can be related to salivary gland hypofunction, the objective evidence of decrease in salivary secretion (unstimulated whole mouth salivary flow rates <0.1 mL/min or stimulated salivary flow rates <0.7 mL/min).<sup>4,10</sup> However, studies are contradictory as to whether there is an actual relationship between the patient's subjective perception of dry mouth and the clinician's objective measure of salivary flow rates.<sup>11</sup> Patients might experience xerostomia even without clinical evidence of mouth dryness or hyposalivation, perhaps due to a change in saliva composition.<sup>3</sup> There have been several attempts in the literature to define mild, moderate, and severe xerostomia, according to various subjective and/or objective evaluation criteria (Table I). Despite those attempts, the

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### Statement of Clinical Relevance

Xerostomia is the major complaint of patients receiving H&N RT. This manuscript is a practical and comprehensive review of solutions for prevention and treatment of radiation-induced xerostomia with emphasis on cost-effectiveness to help guide clinical treatment decisions.

**Table 1.** Measures of xerostomia

<i>Type of measure</i>	<i>Name</i>	<i>Year</i>	<i>Performed by</i>	<i>Description</i>	<i>Scale</i>	<i>Ref.</i>
Subjective	Vanderbilt Head and Neck Cancer Survey	2010-2012		28-Item questionnaire, with 5 symptom subscales: "Nutrition," "Pain," "Voice," "Swallow," and "Mucous/Dry Mouth"	Score from 0-10	12,13
Subjective	Groningen Radiotherapy-Induced Xerostomia questionnaire (GRIX)	2010	Patient	14-Item questionnaire, with 4 subscales: xerostomia during day and night and sticky saliva during day and night	Cronbach's $\alpha$ calculated for all subscales is converted to a 0-100 score, higher scores = worse xerostomia	14
Subjective	Visual Analog Scale (VAS)	2002	Patient	Mouth burning and/or pain intensity is evaluated on a 10-cm long VAS	0-10 cm scale, 10 cm being the highest toxicity	15,16
Subjective	Xerostomia-related QOL questionnaire (XQoLQ)	2001	Patient	Five questions relating xerostomia to QOL	Scale from 0-10	Several studies referenced in <sup>4</sup>
Subjective	Eisbruch's Xerostomia Questionnaire (XQ), also called University of Michigan XQ (UMXQ)	2001	Patient	8-Item questionnaire evaluating dryness while eating or chewing and while not eating or chewing	0-100 score, higher scores = worse xerostomia	17
Subjective	Xerostomia Inventory (XI)	1999	Patient	11-Item survey	Below 14.5: normal 55: worse toxicity	18,19
Subjective	Patient Benefit Questionnaire (PBQ)	1999	Patient	8-Item questionnaire: difficulty speaking and eating, sleep problems, use of oral comfort aids or fluids, mouth and tongue soreness, and mouth dryness	1-10 Likert scale: 1 = severe negative impact; 10 = no negative impact	18,20
Subjective	Functional assessment of cancer therapy-head and neck (FACT-H&N) questionnaire	1997	Patient	38-Item survey on QOL, 11 of these questions are specific to H&N cancer	QOL score based on the sum of question scores, each rated 0-4 on a Likert scale	18,21
Subjective	Oral Impacts on Daily Performance (OIDP)	1997	Patient	8 Items (eating and enjoying food; speaking and pronouncing; cleaning teeth; sleeping and relaxing; smiling; laughing and showing teeth without embarrassment; maintaining one's usual emotional state; carrying out one's major work or social role and enjoying contact with people)	Likert scale for each question, that is summed to a score for each of the 8 categories	22,23
Subjective	Oral Health Impact Profile (OHIP): long form (OHIP49) and short form (OHIP14)	1994, 1997	Patient	49-Item or 14-item (short version) survey, in 7 domains (functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap)	Questions are scored on a 5-point Likert scale and then added to a normalized score	23-25

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