

# Analysis of Adverse Reactions after Radiotherapy Treatment in Adults with Head and Neck Cancer

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*Análise de Reações Adversas após o Tratamento da Radioterapia em Adultos com Câncer de Cabeça e Pescoço*

*Análisis de Reacciones Adversas después del Tratamiento con Radioterapia en Adultos con Cáncer de Cabeza y Cuello*

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## Abstract

**Introduction:** Head and neck cancer consists of malignant tumors of the upper aerodigestive tract, located mainly in the oral cavity, larynx, pharynx and paranasal sinuses and increases its incidence with age. Radiotherapy treatment may induce adverse reactions. **Objective:** To analyze adverse reactions after radiotherapy treatment in adults with head and neck cancer. **Method:** Descriptive, exploratory, cross-sectional study with a quantitative approach, whose sample is non-probabilistic formed by adults with head and neck neoplasms undergoing radiotherapy treatment in the state of Sergipe during 2017 and 2018. **Results:** The main adverse reactions found were: pain, mucositis, nausea, vomiting, poor intake, dry mouth, dehydration, change in voice and pruritus. There were no significant differences between groups with less than 10 and more than 10 radiotherapy sessions according to adverse reactions. **Conclusion:** It is necessary that health professionals are aware of reactions to minimize and treat complications, in addition to continuous monitoring to reclaim the ideal health conditions, contributing to the patients' quality of life and self-esteem.

**Key words:** Radiotherapy/adverse effects; Mouth Neoplasms; Head and Neck Neoplasms.

## Resumo

**Introdução:** O câncer de cabeça e pescoço é composto por tumores malignos do trato aerodigestivo superior, localizados principalmente na cavidade oral, laringe, faringe e seios paranasais e aumenta a sua incidência com a idade. O tratamento radioterápico pode induzir reações adversas. **Objetivo:** Analisar as reações adversas após o tratamento da radioterapia em adultos com câncer de cabeça e pescoço. **Método:** Trata-se de um estudo descritivo, exploratório, transversal, com abordagem quantitativa, cuja amostra é não probabilística, composta por adultos com neoplasias de cabeça e pescoço em tratamento radioterápico no Estado de Sergipe, durante os anos de 2017 e 2018. **Resultados:** As principais reações adversas encontradas foram dor, mucosite, náusea, vômito, má ingestão, boca seca, desidratação, alteração na voz e prurido. Não houve diferenças significativas entre os grupos com menos de dez e mais de dez sessões de radioterapia, de acordo com as reações adversas. **Conclusão:** É necessário que os profissionais de saúde tenham conhecimento dessas reações para minimizar e tratar as complicações, além de acompanhamento contínuo com vistas ao resgate das condições ideais de saúde, contribuindo para a qualidade de vida e a autoestima dos pacientes. **Palavras-chave:** Radioterapia/efeitos adversos; Neoplasias Bucais; Neoplasias de Cabeça e Pescoço.

## Resumen

**Introducción:** El cáncer de cabeza y cuello está compuesto por tumores malignos del tracto aerodigestivo superior, ubicados principalmente en la cavidad oral, laringe, faringe y senos paranasales e aumenta la incidencia con la edad. El tratamiento con radioterapia puede inducir reacciones adversas. **Objetivo:** Analizar las reacciones adversas después del tratamiento con radioterapia en adultos con cáncer de cabeza y cuello. **Método:** Este es un estudio descriptivo, exploratorio, transversal con un enfoque cuantitativo, cuya muestra es no probabilística compuesta de adultos con neoplasias de cabeza y cuello sometidos a tratamiento de radioterapia en el Estado de Sergipe durante 2017 y 2018. **Resultados:** Las principales reacciones adversas encontradas fueron dolor, mucositis, náuseas, vómitos, ingesta deficiente, boca seca, deshidratación, cambio de voz y prurito. No hubo diferencias significativas entre los grupos con menos de 10 y más de 10 sesiones de radioterapia según las reacciones adversas. **Conclusión:** Es necesario que los profesionales de la salud tengan conocimiento de las reacciones para minimizar y tratar las complicaciones, así como un monitoreo continuo para recuperar las condiciones de salud ideales, lo que contribuye a la calidad de vida y la autoestima de los pacientes. **Palabras clave:** Radioterapia/efectos adversos; Neoplasias de la Boca; Neoplasias de Cabeza y Cuello.

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## INTRODUCTION

The head and neck cancer is a generic term defined by anatomy topographic bases for describing malignant tumors of the upper aerodigestive tract, which correspond to a numerous and heterogeneous group of tumors localized mainly in the oral cavity, larynx, pharynx and paranasal sinuses<sup>1</sup>. The epidemiologic evidences show that the incidence of head and neck cancer increases with age. In Europe, 98% of the patients is older than 40 years. Only 4% to 6% occur in younger individuals, but this incidence in several countries and the mechanisms involved in the carcinogenesis in this age-range are little known<sup>2</sup>.

Nearly 40% of the head and neck cancers affect the oral cavity, 15%, pharynx, 25%, larynx and other remaining locations (salivary glands and thyroid)<sup>3</sup>. Several other authors report the tongue, mouth floor and the lower lip as the most frequent regions for the occurrence of the oral cancer<sup>4-6</sup>. In relation to the histological type, the most frequent is the squamous cell carcinoma, prevalent in more than 90% of the cases<sup>3</sup>.

The most important treatment of the head and neck cancer is radiotherapy, which utilized electromagnetic or corpuscular ionizing energy, capable of provoking chemical and biological effects that block the replication of neoplastic cells<sup>7</sup>. This is considered the modality of choice to treat head and neck cancers and has been used in the treatment of malignant lesions of head and neck cancers with inhibition of metastases and improvement of the patients' survival<sup>8</sup>.

Usually, the effects of the radiations are well tolerated, if the principles of total dose of the treatment are considered and fractioned application in equal daily doses. Therefore, the biological effect reaches the greatest number of neoplastic cells and the tolerance of the normal tissues is respected<sup>8</sup>.

The objective of this study was to analyze the adverse reactions after the treatment of radiotherapy in adults with head and neck cancer and the possible associations with the number of sessions of radiotherapy.

## METHOD

Cross-sectional, descriptive, exploratory, quantitative approach whose sample is non probabilistic formed by adults with head and neck neoplasm in radiotherapy treatment in the State of Sergipe during 2017 and 2018. The treatment was conducted in the wards of radiotherapy treatment of the Oncology Center of the Hospital of Surgery and in the Oncology Sector of the Urgency Hospital of Sergipe (HSE), both in the city of Aracaju, Sergipe.

The patients were selected according to eligibility criteria: adults older than 18 years with histological diagnosis of head and neck cancer who had submitted to at least one treatment with radiotherapy; no brain metastasis or cognitive changes that compromise the understanding of the questionnaires proposed; charts correctly completed where the essential information about adverse reactions were possible to be obtained; patients who accepted to participate of the study by signing the Informed Consent Form (ICF).

It was utilized the Instrument of Sociodemographic and Clinical Characterization proposed by Sawada<sup>9</sup> to collect data about the sociodemographic, clinical and therapeutic characteristics containing the following variables: gender, age, International Classification of Diseases and Related Health Problems (ICD-10), time of diagnosis, extension of the disease, other illnesses, signs and symptoms, tobacco and alcohol. The sample was divided in two groups: Group 1, patients who submitted to up to ten sessions; Group 2, patients who submitted to more than ten sessions, adapted from Borrás et al.<sup>10</sup>.

To evaluate the adverse reactions to the treatment after radiotherapy, it was utilized the Common Terminology Criteria for Adverse Events (CTCAE), version 4.0, developed by the National Cancer Institute José de Alencar Gomes da Silva (NCI) and by the US National Institutes of Health (NIH) in May 2009<sup>11</sup>. The clinical variables analyzed were pain, bruise, fever, diarrhea, constipation, mucositis, nausea, vomiting, ill absorption, dry mouth, dehydration, dizziness, headache, somnolence, tremor, urinary retention, change in voice, dyspnea, alopecia, change in nails, pruritus, multiform erythema, hearing loss and tinnitus .

The data were obtained from the patients' charts and entered in the program *Statistical Package for the Social Sciences (SPSS Statistics 17)* for statistical analysis. Association between adverse reactions and the number of sessions was made through the chi-square test. Next, it was performed multivariate analysis by binary logistic regression, utilizing the hierarchical analysis. Through the established strategy of associations between the dimensions studied, clinicopathological and the number of sessions of radiotherapy, three explanatory models of binary logistic regression were elaborated, introducing the variables as blocks, remaining in the subsequent model the variables with statistical significance ( $p < 0.05$ ) in the previous model.

The exclusion criteria for all the variables introduced in each model was  $p < 0.10$ . Finally, it was reached a final model of regression with only those variables of greater statistical significance. For all the statistical tests utilized, it was considered a level of significance of 5% ( $p < 0.05$ ).

This study was approved by the Institutional Review Board of Federal University of Sergipe. The Informed Consent Form and the Confidentiality Agreement were elaborated in compliance with the Guidelines and Norms of Trials Involving Human Beings (Resolution CNS 466/12), with Certificate of Presentation for Ethical Review (CAAE): 62177416.2.0000.5546.

## RESULTS

Of the 34 patients evaluated who were in treatment with exclusive radiotherapy, 73.5% were males. Of these, 35.2% were treated with up to ten sessions and 38.2% with more than ten sessions of radiotherapy. In relation to females, 14.7% were treated with ten sessions of radiotherapy and 11.7% with more than ten sessions, totaling 26.4% of the patients.

The mean age of the patients with head and neck cancer in treatment with radiotherapy was 59 years ( $\pm 12.33$ ), with minimum age of 36 years and maximum of 86 years. Thirty-one patients (91.2%) reported tobacco addiction and 29 (85.3%), alcohol use.

The adverse reactions associated to the treatment were stratified in two groups: one with up to ten sessions and other with more than ten sessions of radiotherapy and the distributions of adverse reactions in the two groups are presented (Table 1). It was not observed statistically significant association among the sociodemographic variables with the number of radiotherapy sessions ( $p > 0.05$ ).

In the analysis through binary logistic regression, a regression model was achieved where none of the variables presented statistical significance ( $P > 0.05$ ) (Table 2).

## DISCUSSION

The literature describes tobacco addiction and alcoholism as risk factors well established for head and neck cancer. Although this neoplasm affects preferentially male patients, there was a remarkable increase of the incidence in women, which likely reflects change of habits similar to what was found in this study<sup>12,13</sup>.

**Table 1.** Distribution of adverse reactions presented by the individuals post radiotherapy treatment with less and more than ten sessions of radiotherapy. Sergipe, 2018

Adverse reactions	RXT <10 sessions	RXT >10 sessions	n (%)
Pain	12 (35.3%)	12 (35.3%)	24 (70.6%)
Bruise	4 (11.8%)	5 (14.7%)	9 (26.5%)
Fever	5 (14.7%)	1 (2.9%)	6 (17.6%)
Diarrhea	4 (11.8%)	3 (8.8%)	7 (20.6%)
Constipation	6 (17.6%)	9 (26.5%)	15 (44.1%)
Mucositis	17 (50.0%)	16 (47.1%)	33 (97.1%)
Nausea	10 (29.4%)	13 (38.2%)	23 (67.6%)
Vomiting	7 (20.6%)	12 (35.3%)	19 (55.9%)
Ill intake	10 (29.4%)	12 (35.3%)	22 (64.7%)
Dry mouth	16 (47.1%)	16 (47.1%)	32 (94.1%)
Dehydration	16 (47.1%)	16 (47.1%)	32 (94.1%)
Dizziness	8 (23.5%)	5 (14.7%)	13 (38.2%)
Headache	7 (20.6%)	9 (26.5%)	16 (47.1%)
Somnolence	4 (11.8%)	5 (14.7%)	9 (26.5%)
Tremor	6 (17.6%)	4 (11.8%)	10 (29.4%)
Urinary retention	0 (0.0%)	2 (5.9%)	2 (5.9%)
Change in voice	14 (41.2%)	17 (50.0%)	31 (91.2%)
Dyspnea	7 (20.6%)	4 (11.8%)	11 (32.4%)
Alopecia	4 (11.8%)	4 (11.8%)	8 (23.5%)
Change in nails	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pruritus	10 (29.4%)	9 (26.5%)	19 (55.9%)
Multiform erythema	1 (2.9%)	2 (5.9%)	3 (8.8%)
Hearing loss	2 (5.9%)	0 (0.0%)	2 (5.9%)
Tinnitus	5 (14.7%)	3 (8.8%)	8 (23.5%)

Captions: RXT: radiotherapy;  $p < 0.05$ .

Males with mean age close to 45 years are the most affected, like other studies<sup>13,14</sup>. Head and neck cancers develop from multiple lesions in different anatomic sites, that can be denominated “field cancerization”. This pattern is based in the constantly repeated exposure to risk factors for long periods as the carcinogenic present in alcohol and tobacco, leading to the development of other lesions<sup>15</sup>. In a study conducted by Castro-Silva et al.<sup>16</sup>, no case of

**Table 2.** Result of the multivariate analysis of logistic regression, final model of adverse reactions post radiotherapy. Sergipe, 2018

Variables	Reference	p (pain)	p (mucositis)	p (dehydration)	p (nausea)	p (dry mouth)	p (vomiting)	p (ill intake)	p (pruritus)	p (voice)
Gender	Male	0.763	0.543	0.382	0.449	0.382	0.549	0.077	0.777	0.611
Smoke	Yes	0.876	0.752	0.650	0.970	0.650	0.788	0.941	0.821	0.478
Alcohol	Yes	0.574	0.673	0.146	0.692	0.545	0.233	0.438	0.549	0.712

Caption:  $p < 0.05$ .

head and neck cancer was encountered in young males with approximately 30 years, being a clinical condition prevalent in older populations. Alcoholism and active tobacco addiction are the most frequent habits in males.

However, a global epidemiological study, which collected data of incidence of tongue carcinoma in more than 80 thousand patients in 22 countries, showed growth of the incidence and tendency of increase of this disease among younger patients with characteristics of world phenomenon. It is emphasized the annual increase in the rates of incidence of the spinocellular carcinoma of tongue among women in nearly all the regions studied<sup>17</sup>.

The growth of the incidence of tongue cancer in women, young and Caucasian is described in the results of a cohort conducted in the United States between 1973 and 2012. Caucasian women and men born after the decade of 1940 presented increasing incidence of tongue, oral and oropharyngeal cancer<sup>18</sup>. The Brazilian epidemiology contradicts the global tendency, but in despite of not being a national reality yet, new epidemiologic studies should be performed with the objective of verifying and updating the likelihood of introducing this new tendency in the country<sup>19</sup>.

The interruption of the treatment of patients submitted to radiotherapy in the head and neck region, in association with the continuous exposure to carcinogens, potentializes the risk of adverse reactions, such as mucositis, dry mouth dehydration, nausea and vomiting<sup>20</sup>.

The presence of pain was reported by the patients as in the study of Bragante et al.<sup>21</sup>. This indicates the importance of the evaluation for the early identification of the pain and its mensuration as well as the effective treatment in each case. The fact of not measuring correctly the pain or undertreat it can cause physiologic alterations, limitations of the patients' daily activities, restrictions to interact with others, loss of sleeping quality and learning process<sup>22</sup>.

Because of the negative impact of the pain over the quality of life of the oncologic patient, it is of great relevance to identify and stimulate the use of effective strategies to minimize these painful sensations in the context of the assistance and, whenever possible, should be treated preventively to avoid the suffering associated to this condition<sup>11</sup>.

In relation to headache, it can be intense at each attempt of eating or drinking, mainly visualized in mucositis, which is still more accentuated when radiotherapy is utilized in association with chemotherapy in cancer treatment, with pain irradiating through the entire region of the head<sup>23</sup>.

Nausea described by the participants of this study is described in other studies is a subjective and unpleasant sensation characterized as redness, tachycardia and feeling

of vomiting<sup>24</sup>. The occurrence of nausea and vomiting in patients with cancer can be related to the clinical spectrum of the neoplasm itself or by the toxicity of the radiotherapy treatment.

The bad intake was described as reaction in this study sample. The location of the tumor in the patients with head and neck cancer can compromise the full capacity of food intake, the gastrointestinal functions and the absorption of nutrients. The tumors that compromise the upper digestive tract can cause dysphagia, odynophagia and partial and total obstruction, impairing the proper intake of nutrients<sup>25</sup>.

According to Gwede et al.<sup>26</sup>, the alterations of the post-radiotherapy mucous lining and other as salivary glands, teeth, bones and cartilage lead to conditions of pains that irradiate by the head as consequence of mechanic activity of feeding and drinking water. The authors observed that, during the six months of treatment, the patients reported pain in the mouth, throat, difficulty of speaking, mastication and deglutition, dry mouth and thick saliva.

Mouth opening is considered essential in the process of ingestion. In the cases where masticatory muscles or soft tissues around the temporomandibular articulation are included in the field of radiation, it is indicated the practice of exercises concomitant with the beginning of radiotherapy<sup>27</sup>. Sessions with orientation and monitoring of the exercises of mobility and mandibular traction to be performed three times a day by the patient during radiotherapy provide significant opening of the mouth of the most part of the patients with head and neck cancer in the oral cavity with minimization of the adverse reactions presented<sup>28</sup>.

Actions like these improve the clinical conditions of the patient through amelioration of deglutition and communication, contribute for better intake of water and food and increases the survival of these patients<sup>29</sup>. In the literature, it was observed that the patients report more comfort while eating with other persons, with the possibility of following a diet without restrictions, in addition to improvement in the work, communication and reduction of facial pain, demonstrating great impact in the quality of life of these persons<sup>29</sup>.

The incidence of mucositis in persons with head and neck cancer in treatment with radiotherapy is of approximately 85% when associated to chemotherapy, but all the individuals treated present some degree of oral mucositis. This is one of the main limiting factors in use of chemotherapy associated to radiotherapy for advanced neoplasm of head and neck; for persons submitted to bone marrow transplantation, the incidence reaches 75%<sup>30</sup>.

For Caccelli et al.<sup>31</sup>, the grade of mucositis, the chronology and duration are related to factors of the

treatment, as dimension of the tissue irradiated, total and daily doses, location of the lesion, type of radiation, interacting synergistically with environmental factors of the patient as tobacco and alcohol use, as well as xerostomia and existing infections. Xerostomia, dry mouth and mucositis can be aggravated on account of the loss of lubrication of tissues, dehydration of the mucosa and of the secondary infection of the mucosa.

It is worth mentioning that, in the clinical units studied in the State of Sergipe, several interruptions along the treatment with radiotherapy occur and determinant modalities in dental care followed by laser therapy are little used in the several grades of oral mucositis.

The use of modalities as laser therapy in patients with oral mucositis after radiotherapy have acknowledged capacity of provoking biological effects through biochemical and photophysical processes, accelerating the cellular metabolism because it stimulates the mitochondrial activity. The laser acts also as anti-inflammatory, analgesic and healer of mucosa lesions<sup>32</sup>. The energy emanated from laser is absorbed by a thin layer of adjacent tissue and also from the spot reached by the radiation, unchaining the epithelial proliferation and of fibroblasts as well as vascular and cellular alterations.

It is also verified the occurrence of the production of collagen and elastin, contraction of the wound, increase of phagocytosis by the macrophages and proliferation and activation of lymphocytes, in addition to the tension force which, consequently, accelerates the cicatrization. Consequently, laser acts in the prevention and treatment of oral mucositis for maintenance of the integrity of the patients mucosa<sup>33</sup>.

Eduardo et al.<sup>34</sup> encountered significant reduction of the severity and number of days of mucositis in patients in dental follow up and laser therapy in comparison with patients without these procedures at Albert Einstein Hospital during the period from 2004 to 2008. This reduction caused significant diminishment of the frequency of pain in the oral cavity, which is a positive repercussion in the quality of life of the patient<sup>35,36</sup>.

In relation to the occurrence of xerostomia, the larger salivatory glands are usually exposed or are close to the target of radiotherapy in the region of head and neck. The parotid glands are irradiated with doses of high radiation in conventional radiotherapy used to treat some types of cancer in the region as nasopharyngeal carcinoma<sup>37</sup>.

The literature also indicates the compromise of the cells because of selective damages in the plasmatic membrane, changing the transduction of signal that affects mainly the release of the aqueous secretion. Although the cellular composition of the submandibular gland and of the parotid gland are different, the response to

the lesion promoted by the radiation is very similar. The most likely mechanism of action to explain the acute effects is the disturbance of the plasmatic membrane. Further on, the injury appears to occur mainly because of the death of the progenitor cells, which reduces the capacity of substitution of the gland by secretory cells and by lesions in the extracellular environment, avoiding the proper functioning of the cell of salivary production leading to dry mouth and difficulty of food intake<sup>38</sup>. Consequently, radiotherapy with modulated intensity and the use of modalities as laser therapy can be valuable tools to minimize some of these symptoms<sup>39</sup>.

In relation to dehydration, it is observed in clinical practice that the effects of the adjuvant treatment can appear late being worse in severity and duration and compromises therapeutic results<sup>40</sup>. Among its principal complications, are malnutrition, dehydration itself, aspiration of the food into airways and pneumonia. These factors are closely related with the health status and quality of life of the patient<sup>41</sup>. Nutritional counseling is important to reduce weight loss and dehydration<sup>42</sup>.

Studies indicated that dehydration is one of the ten most common causes of hospitalization of the geriatric population<sup>43</sup>. The maintenance of the hydration status of the elderly patient is of great relevance in the medical context. Dehydration is a common finding in this population and increases during radiotherapy treatment that exposes the individual to acute intensification of the clinical conditions, such as: confusion state, *delirium*, acute kidney injury, infections, falls and constipation<sup>44</sup>. In that line, the intervention of the staff during the radiotherapy treatment allows the early identification of the possible reduction of water intake by the patient. This fact corroborates the prevalence of the present study and justifies the indication of nutritional and clinical follow up for dehydration, regardless of the complaints about skin or mucosa drying.

Caminero Cueva et al.<sup>45</sup>, in a prospective study, verified that 80% of the patients presented alteration of the vocal quality after one year of treatment with radiotherapy. Voice and swallowing changes can be justified by the alterations of the sensitiveness and mobility of the structures affected by the radiation resulting from edema, fibrosis and reduction of the larynx elevation<sup>46</sup>.

In a study about functional results of the treatment for advanced larynx cancer, where the functions related to communication and deglutition were evaluated, it was verified that the patients with this tumor do not develop well the spontaneous communication. The muscles exposed to the treatment can develop edema and fibrosis; however, the effects generated in the vocal quality are not well understood. This finding emphasizes the



importance of a treatment that preserves the organ with the objective of obtaining better rehabilitation, in addition to phono audiologist consultations to these patients and management of the clinical staff<sup>47</sup>.

Among the dermatological reactions, pruritus was presented by the participants. Naylor e Mallet<sup>48</sup> point out that the most common effects of the radiotherapy treatment are the acute skin reactions, referred as radiodermatitis. In the skin, the intensity of the reaction can vary from mild erythema and pruritus through dry or moist desquamation, which can lead to tissue necrosis.

Pruritus represents distinct sensation whose origin is the superficial layer of the skin, of the mucosa, including upper respiratory tract or conjunctive<sup>49</sup>. This reaction can be defined as an unpleasant sensation, referred as localized or diffuse in the skin or semi-mucosa characterized by leading to the desire to scratch and can or cannot be associated to the presence of cutaneous lesions<sup>50</sup>.

In the current study, pruritus varied in relation to the intensity of the reaction. It can range from a mild erythema and pruritus to a dry or moist desquamation and eventually to tissue necrosis and intense pain. As the protective barrier is lost where the skin microbiota is encountered, the region becomes more susceptible to infections, mainly by *Candida albicans*<sup>51</sup>.

It is noticed that the control of physical and psychological signs and symptoms the oncologic diseases present is a challenge for the entire health team involved in the management of the patient with head and neck cancer. The proper assistance can be the most significant factor in the determination of the quality of life of these patients and follow up of the reactions presented during the radiotherapy treatment.

## CONCLUSION

The main adverse reactions were pain, mucositis, nausea, vomiting, ill intake, dry mouth, dehydration, voice change and pruritus. Significant differences were not verified in the groups with less than ten and more than ten sessions of radiotherapy according to the adverse reactions.

The health professionals must be aware of the adverse reactions to minimize and treat them, in addition to promoting continuous follow up for reclaiming the ideal health conditions, contributing for the quality of life and self-esteem of these patients.

## CONTRIBUTIONS

All the authors contributed substantially for the conception, design, collection, analysis of the data, wording and approval of the version to be published.

## DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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