WHO EMRO | Adherence of preventive oral care products in the Syrian market to evidence-based interna

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D. Habes[1], R. Mahzia[2], K. Nakhleh[3] and E. Joury[4,5]

التزام منتجات العناية الوقائية بالفم في السوق السورية بالتوصيات الدولية المستندة إلى الأدلة

دعاء حابس، ريم محظية، كمال نخلة، استير جوري

: لم تقم أي دراسة بالتحري عن توافر منتجات العناية الوقائية بالفم في السوقالخلاصة السورية وعن التزامها بالتوصيات الدولية المستندة إلى الأدلة . ولذا فإن الدراسة المقطعية الحالية شملت جميع منتجات العناية الوقائية بالفم المتوفرة في السوق السورية، فجُمعت بيانات في عام 2012 - وحُدِّثت في عام 2016 - عن توافرها وخصائصها والتزامها بالتوصيات الدولية المستندة إلى الأدلة . فوُجد أن القليل من المنتجات الوقائية ملتزمة بالتوصيات . ولم يكن تركيز الفلوريد مذكوراً في 3 معاجين أسنان فلوريدية أخرى . وبصرف النظر عن الانخفاض الكبير في عدد منتجات العناية بالفم في السوق السورية - بسبب الأزمة السورية - فإن عدم التزام بعض المنتجات المتوفرة لا يزال قائماً . وثمة حاجة إلى نهج متعدد القطاعات على مستوى السياسات لمعالجة أوجه القصور الهامة هذه . فينبغي أن تقوم وزارة الصحة السورية بإصلاح القوانين المتعلقة بالمنتجات الفلوريدية كي تصبح خاضعة لأنظمة مراقبة الأدوية، ويجب على اللجنة العربية السورية للمقاييس والمعايير أن تحدِّث معاييرها، وينبغي أن تقوم الجمعية السورية لطب الأسنان العام بتوزيع كتيِّب وقائي على أطباء الأسنان .

ABSTRACT No study has investigated the availability and adherence of preventive oral care products on the Syrian market to evidence-based international recommendations. Data were collected in 2012, and updated in 2016, in terms of availability, characteristics and adherence to evidence-based international recommendations. Few preventive products adhered to the recommendations. Despite the large decrease in the number of oral care products on the Syrian market, due to the Syrian crisis, nonadherence of some of the available products is still present. A multisectorial approach at a policy level is needed to address such important limitations. The Syrian Ministry of Health should reform regulations for fluoride products to become subject to drug monitoring systems; the Syrian Arab Committee for Measurements and Standards needs to update its standards; and the Syrian General Dental Association should distribute a preventive booklet to dental practitioners.

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avec les recommandations internationales fondées sur des données probantes

RÉSUMÉ Aucune étude n'a examiné à ce jour la disponibilité et la conformité des produits de soins dentaires préventifs sur le marché syrien avec les recommandations internationales fondées sur des données probantes. Des données ont été collectées en 2012, et mises à jour en 2016, en ce qui concerne la disponibilité, les caractéristiques et la conformité de ces produits avec les recommandations internationales fondées sur des données probantes. Peu de produits préventifs étaient conformes aux recommandations. Malgré une forte diminution du nombre de produits de soins dentaires sur le marché syrien du fait de la crise actuelle dans le pays, la non-conformité de certains produits disponibles reste d'actualité. Une approche multisectorielle au niveau politique est nécessaire pour remédier à ces lacunes importantes. Le ministère syrien de la Santé doit réformer les réglementations existantes sur les produits à base de fluor afin que ceux-ci soient soumis à des systèmes de suivi des médicaments ; le Comité arabe syrien des mesures et des normes doit mettre à jour ses normes ; et l'Association de dentisterie générale syrienne doit distribuer une plaquette de prévention à l'intention des praticiens dentaires.

[1]Department of Orthodontics, Faculty of Dentistry, Damascus University, Damascus, Syrian Arab Republic. [2]Department of Oral Pathology, Faculty of Dentistry, Damascus University, Damascus, Syrian Arab Republic. [3]Angle House Orthodontics, London, United Kingdom. [4]Population and Patient Health, King's College London Dental Institute, University of London, London, United Kingdom. [5]

Department of Oral Medicine, Faculty of Dentistry, Damascus University, Damascus, Syrian Arab Republic (Correspondence to: easter.joury@kcl.ac.uk).

Introduction

Preventing oral diseases in the Middle East is of paramount importance. Oral health is an essential integral part of general health and has a profound impact on individuals' wellbeing and quality of life. The Middle East countries are facing a marked increase in the prevalence and severity of dental caries and periodontal diseases (1). Furthermore, the rates of dental caries in the Eastern Mediterranean Region are higher than in most industrialized countries (2,3). This relentless increase in the burden of oral diseases is observed across different age groups. Based on the WHO oral health data bank, the mean number of decayed, missing and filled deciduous teeth at 5 years of age in the Middle East is 5.7. There is a variation in this number across the region. For example, based on the aforementioned data bank, the mean number of decayed, missing and filled deciduous teeth is 1.7 in Saudi Arabia, 2.3–2.7 in the Syrian Arab

Republic and Kuwait and 3.4 in Jordan and Lebanon (4–6). Dental caries increases with age in Middle East countries (7). More than 90% of cases of dental caries throughout the Eastern Mediterranean Region remain untreated, leading to rising rates of edentulousness in older populations (8).

The above raises serious questions about the effectiveness and appropriateness of the traditional western-style, treatment-oriented oral health strategies and approaches adopted in Middle East countries to address the burden of oral diseases. The major limitations of such strategies, particularly in relation to their ineffectiveness and high requirement for human and financial resources, emphasize the urgency of reorienting oral health services to focus on prevention to address the growing burden of oral diseases. This view was endorsed by the World Dental Federation Vision 2020 (9).

One of the essential requirements for reorienting oral health services toward prevention is providing an evidence-based preventive toolkit for clinical teams (10). Such a preventive toolkit leads to a range of positive changes in dental professional practices and allows all patients equal access to modern preventive advice and interventions and improved methods of self-care. It includes, besides evidence-based guidance for primary dental care teams, lists of available preventive oral care products, such as fluoride toothpastes, high-concentration fluoride toothpastes, mouth rinses, fluoride varnish, and pit and fissure sealants. Such products might be the only means, in the majority of Middle East countries, to fluoridate the mouth to decrease the prevalence of dental caries. Despite the effectiveness of water fluoridation in decreasing dental caries (11), it is either impractical because of the poor infrastructure for piped water supplies, or undesirable in some Middle East countries that have high levels of natural fluoride (6). For example, in the Syrian Arab Republic, the majority of areas have low fluoride content in the water (>0.5 ppm), which is below the required level for caries prevention, whereas a few areas, such as Palmyra and Alhasaka, have elevated fluoride content (1.9 ppm) (12). Thus, it is clear that the main focus for fluoridating the mouth in the Middle East is to use the aforementioned preventive oral care products.

Developed countries, such as the United Kingdom, have developed a list of their preventive oral care products based on careful consideration of their adherence to evidence-based recommendations (10). Such a list helps dental professionals to give informed advice on preventive care and take appropriate actions. Also, the recommendations have prompted several manufacturers to reformulate their fluoride products with more effective and safe levels for caries control, and to include evidence-based labelling and instructions on how to use self-care products.

Although the above mentioned translational (applied) research is undertaken in the majority of developed countries, little has been conducted in developing countries. None of the countries in the Middle East has developed such an evidence-based preventive toolkit for oral health care. Thus, in the light of the lack of such important translational research in the Middle East, the present study aimed to investigate the availability and adherence of preventive oral care products on the Syrian market to evidence-based international recommendations.

Materials and methods

Study design and preventive oral care products

The current study adopted a cross-sectional design. We investigated all preventive oral care products available on the Syrian market, including self-care and professionally applied products. Control of caries and gum disease is related to tooth brushing with fluoride toothpaste and physical removal of plaque, respectively (13,14). Self-care products were manual and powered toothbrushes, interdental plaque control products (dental floss and tape and interdental brushes), toothpastes (fluoridated toothpastes, toothpastes containing ingredients that reduce plaque, gingivitis and bleeding gums, such as tin fluoride, triclosan with copolymer or zinc citrate) and mouth rinses (containing fluoride or antibacterial ingredients, such as chlorhexidine). The professionally applied preventive products included fluoride varnish/gels, and pit and fissure sealants.

Ethics and permissions

Ethical approval and permission to conduct the study were obtained from Damascus University Faculty of Dentistry Research Ethics Committee (no 1186/2012), the Syrian Ministry of Health and the Syrian Directorate of Medical Supplies.

Data collection

Data were collected between February and April 2012, and updated in March 2016, on the availability and characteristics of preventive oral care products on the Syrian market (Table 1).

We did not collect data on products related to dentures/removable appliances, such as brushes, pastes, disinfectant products, adhesives, dry mouth rinses, tooth powders, desensitizing, whitening and other types of toothpastes, and anaesthetic rinses. This was because these self-care products are not related to the prevention of dental caries and gum diseases. Also, data on fluoride supplements were not collected because these are no longer internationally recommended. This was based on the conclusion of a recent systematic review of fluoride tablets, drops, lozenges and chewing gums indicating that the evidence for the effect of these additional sources of fluoride on deciduous teeth is unclear (15).

Data collection procedures

A list of Syrian manufacturers and importers of preventive oral care products was prepared using the governmental records of the Syrian Ministry of Health in the Directorates of Pharmaceutical Affairs, Medical Supplies and Oral Health. Next, manufacturers and companies were contacted and asked to provide a full list of their manufactured or imported preventive oral care products. After developing an exhaustive list of oral care products available on the Syrian market, two researchers (DH and RM) undertook field visits to 36 pharmacies (including all central pharmacies in Damascus) and 12 dental supply stores to examine directly the products and extract relevant data. Relevant information was extracted from the packaging and instruction leaflets of the oral care products.

Evidence-based international recommendations on preventive oral care products

Data collected in the current study on preventive oral care products were checked against evidence-based international recommendations. The latter are summarized in Table 2 .

Data synthesis and analysis

The frequency distribution of preventive oral care products was calculated. The characteristics (features, concentrations of active agents and instructions for use) of available preventive oral care products were checked against evidence-based international recommendations.

Results

There were 216 self-care and 9 professionally applied preventive products available on the Syrian market in 2012.

There were 58 manual toothbrushes available (Table 3), of which, 44 were for adults and 14 for children. Only two of the 58 available toothbrushes adhered to evidence-based international recommendations, by having a small head and medium texture (Table 4). There were only two powered toothbrushes available and both had the required oscillating and rotating actions (Tables 3 and 4).

Both types of interdental plaque control products were available, namely, dental floss and tape (10 products) and interdental brushes (10 products) (Table 3).

Out of 103 available toothpastes (Table 3), only 83 contained fluoride, of which, 52 were formulated with NaF (the most effective form of fluoride). Furthermore, there were 22 toothpastes that contained active antibacterial agents (chlorhexidine or triclosan) and one that contained tin fluoride (Table 3).

Three fluoride toothpastes did not declare their fluoride concentration and another 22 declared their fluoride concentration in percentages, g or µg/g rather than ppm. Forty-three toothpastes had a fluoride concentration of 1350–1500 ppm and only three had a concentration of 1000 ppm (Table 3). None of the latter declared its exclusive indication for use in children aged up to 3 years (Table 4). There were 13 toothpastes that included ineffective concentrations of fluoride (i.e. 1500 ppm) were available, of which, only sixhad the recommended concentration (2800–5000 ppm) of fluoride and two exceeded the maximum recommended concentration (>5000 ppm). All 17 of these toothpastes were potentially toxic for children as they were indicated for daily use for all ages, including children younger than the evidence-based recommended age for use (Table 4).

Several fluoride toothpastes included instructions that contradicted the evidence-based recommendations. For example, the instructions for six fluoride toothpastes recommended rinsing the mouth with water after use. The instructions for three toothpastes with 1000 ppm fluoride recommended use in children aged more than 3 years (Table 4). In contrast, few fluoride toothpastes included instructions for use that were coherent with evidence-based recommendations. For example, 28 and 25 fluoride toothpastes recommended the use of a smear or pea-sized amount of toothpaste and parent supervision, respectively. Also, the instructions for seven toothpastes recommended not swallowing the toothpaste. For labelling language, 11 toothpaste instructions did not use Arabic.

There were 33 mouth rinses available (Table 3). Fifteen mouth rinses contained fluoride, of which, nine were formulated with NaF. Seven of the 18 antibacterial mouth rinses contained chlorhexidine. Fourteen fluoride mouth rinses included instructions that contradicted evidence-based recommendations, namely, use after tooth brushing (11 products) and rinsing with water after use (three products). Although 16 mouth rinses included a clear contraindication for use in children aged up to 6 years, 15 did not include such a clear contraindication (Table 4), and another six products did not use Arabic in their instructions for use.

Finally, with respect to professionally applied preventive care products, there were three fluoride gel products and six pit and fissure sealants. No fluoride varnish was available. One of the available fluoride gels was potentially toxic for children, as it was recommended for home use and its instructions included the use of fluoride trays (plastic trays to be filled with fluoride gel). All the available fluoride gels had fluoride concentrations less than the recommended level (2.2%) (Table 4).

The updated data in 2016 showed a large decrease in the number of oral care products available on the Syrian market. Nevertheless, nonadherence of some of the available products was still present (Tables 3 and 4).

Discussion

This is believed to be the first study in the Middle East to investigate the availability and adherence of preventive oral care products to evidence-based international recommendations. The present study was conducted on preventive oral care products available on the Syrian market. The findings indicate that products that adhered to evidence-based recommendations were either few in number or not available. For example, out of 58 manual toothbrushes, there were only two that had recommended features. Also, while three fluoride gels were available, no fluoride varnish was found. The latter is more effective than the former for prevention of dental caries (16).

The most worrying findings were the fluoride concentration and instructions for use in a number of fluoride toothpastes. Several products had fluoride concentrations that were low and thus ineffective in caries prevention, or high with potential long-term toxic effects in children. For example, 13 fluoride toothpastes claimed to have anti-caries effects although they had fluoride concentrations

Comparing the current study with other published studies is not easy. This is due to the paucity of published literature on the availability and adherence of oral care products available on the market to evidence-based international recommendations. To the best of our knowledge, the only published study is from the United Kingdom (published in 2009 and updated in 2014) (10). The United Kingdom applies strict measures to the oral care products available on its market, thus, all oral care products listed in that study were adherent to evidence-based international recommendations.

Despite the recent decrease in the number of oral care products available on the Syrian market,

due to the current political crisis in the country, some of the available products are still nonadherent.

Based on the findings of the current study, it is clear that the Syrian Ministry of Health should review its regulations and carry out necessary reforms for fluoride toothpastes, rinses and gels so that they become subject to drug monitoring systems. Also, because several preventive care products include instructions for use that contradict the evidence-based recommendations, the Syrian Arab Committee for Measurements and Standards should update its standards using current evidence-based international recommendations. The latest update took place in 1995.

Effective communication should be established so that Syrian manufacturers reformulate their preventive oral care products to have evidence-based effective and safe fluoride concentrations, labelling and instructions for use. They should also be encouraged to produce fluoride varnish. In addition, strict regulations should be imposed on imported preventive oral care products. All available self-care products should have instructions for use written in Arabic, so they can be read and understood by Syrian consumers.

Data collected in the current study were arranged in a user-friendly booklet to assist Syrian general dental practitioners implement evidence-informed preventive care. Similar to developed countries, such a booklet should be adopted by the Syrian General Dental Association and distributed to general dental practitioners.

In conclusion, few oral preventive products available on the Syrian market adhered to evidence-based international recommendations. Fluoride varnish was not available. Some fluoride products (30 toothpastes and three gels) had fluoride concentrations that were low and thus ineffective in caries prevention, or high, with potential long-term toxic effects in children. Another three fluoride toothpastes did not declare their fluoride concentration. A multisectorial approach is needed to address such important limitations at a policy level. The Syrian Ministry of Health should reform regulations for fluoride products to become subject to drug monitoring systems; the Syrian Arab Committee for Measurements and Standards needs to update its standards; and the Syrian General Dental Association should distribute a booklet for preventive care to dental practitioners.

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