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Promotional or educational? Analysis of the evidence supporting industry-authored oral health education targeted at acute care clinicians

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Abstract

Objectives: To assess the nature, quality, and independence of scientific evidence provided in support of claims in industry-authored educational materials in oral health.

Design: A content analysis of educational materials authored by the four major multinational oral health product manufacturers.

Setting: Acute care settings.

Participants: 68 documents focused on oral health or oral care, targeted at acute care clinicians and identified as “educational” on companies’ international websites.

Main outcome measures: Data were extracted in duplicate for three areas of focus: a) products referenced in the documents, b) product-related claims, and c) citations substantiating claims. Claim-citation pairs were assessed to determine if information in the citation supported the claim. Social network analysis was conducted to analyze the interrelationships among cited authors and companies.

Results: Documents ranged from training videos to posters to brochures to continuing education courses. The majority of educational materials explicitly mentioned a product (59/68, 87%), a branded product (35/68, 51%), and made a product-related claim (55/68, 81%). The majority (91/147, 62%) of claims were unsupported by the accompanying reference, largely due to over-interpretation. References used to support claims most often represented lower levels of evidence: only 9% were systematic reviews (7/76) and 13% were randomised controlled trials (10/76). We found a network of 20 authors to account for 37% (n=77/206) of all references in claim-citation pairs; 60% (12/20) of the top 20 cited authors received financial support from one of the 4 sampled manufacturers.

Conclusions: Resources to support clinicians’ ongoing education are scarce. However, caution should be exercised when relying on industry-authored materials to support continuing education for oral health. Evidence of sponsorship bias and reliance on key

opinion leaders suggests that industry-authored educational materials have promotional intent and should be regulated as such.

Keywords

pharmaceutical industry; medical device industry; continuing education; nursing; oral health; acute care; content analysis

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Strengths and limitations

- We sampled all documents explicitly labelled as “educational” from the websites of the four major manufacturers of oral care products
- All data were extracted in duplicate and judgments about whether evidence substantiated a claim was made by two independent reviewers
- We included a novel evaluation of the independence of the evidence cited by manufacturers by assessing relationships among cited authors and the companies
- We do not know whether or how these educational materials are used by clinicians and thus the impact on practice is unknown

Introduction

With increased scrutiny and regulation of the influence of industry within medical research and practice, companies and commentators sometimes argue for the educational value of industry information and industry-clinician interaction.¹ Industry continues to be a major source of sponsor of clinicians' continuing education in the form of conferences, dinner meetings, journal clubs, grand rounds, and trainings.^{2,3}

In particular, nurses rely on industry representatives and information for educational support of their practice.⁴⁻⁷ For example, pharmaceutical and medical device representatives provide education in the form of contracted in-services, educational seminars in clinical and non-clinical settings, conference and event sponsorship, and also materials to support the use of their products in nursing care.⁴ Products commonly used in nursing care, such as wound dressings, often lack high-quality clinical trials demonstrating efficacy prior to market approval. Nurses are, therefore, often reliant on manufacturers rather than independent scientific experts for guidance on product use and outcome evaluation.^{8,9} Thus, industry is often a principle – or sole – source of information about nursing-related products.

Research suggests that information communicated to health professionals about pharmaceuticals and devices in the form of product advertisements and sales visits fails to provide adequate safety information, or to communicate an appropriate balance between benefits and harms.¹⁰⁻¹² The focus of research has been on advertising and other promotional activities directed at health professionals; less is known about the nature, quality, or impact of industry activities that are presented as educational. For example, for medical devices, sales representatives are frequently present in clinical settings, ostensibly for educational purposes such as the provision of device-related training and support.¹³ However, the presence of industry representatives in clinical settings is associated with increased uptake of newer, high-cost devices and increased procedural cost.¹⁴ Industry representatives also distribute

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product samples and supporting materials to frontline clinicians and administrators.^{5,15,16} Educational materials in many jurisdictions are not subject to the same regulation as advertising, thus, may not undergo regulatory review for inclusion of appropriate safety information, for example.¹⁷ Reliance on industry as the principal source of information on product efficacy and novelty may also create marketing feedback loops whereby clinicians, persuaded by perceived expertise located within industry, consequently adopt high-cost products into practice with no or limited evidence of safety or efficacy.⁵

The goal of this study was to evaluate the nature and quality of industry-authored educational materials from the perspective of evidence-based practice. We selected education related to oral health in acute care settings as the case study for three key reasons. First, oral diseases affect over half of the world’s population, including untreated dental caries, which globally, is the most prevalent health condition.¹⁸ As inadequate oral hygiene is a risk factor for healthcare-acquired pneumonia, an important source of morbidity, mortality and growing healthcare costs, nurses face increasing expectations to deliver safe and effective oral care.¹⁹ Second, clinicians consistently experience insufficient pre-and post-licensure education in oral health care,²⁰ which is consistent with the siloing of oral health by health systems, policymakers, and medicine more broadly.²¹ Third, oral health represents an opportunity to examine a variety of commercial determinants of health as it is characterised largely by a downstream, interventionist and technology-focused approach.²¹ In acute care settings, the increased interest by hospital administrators and health systems in addressing patients’ oral health has placed a spotlight on the selection and use of efficacious tools and pharmaceuticals for oral care. Thus, the aim of this content analysis was to assess the nature, quality, and independence of scientific evidence provided in support of product- and practice-related claims made in educational materials authored by oral health product manufacturers.

Materials and methods

Design and sampling frame

We identified companies through expert consultation (CD), previous research on nurse-industry interactions,⁴ Google searches for oral care product brands, and examination of the regulatory filing (SEC 10-K form) for the dominant manufacturer (Sage Inc.), which identified the major competitors in the company's medical division. We excluded companies that were at the start-up phase or supported exclusively through grants, and that only distributed and did not manufacture oral health products. Our sampling frame thus included educational materials authored by:

- Sage Products (publicly traded manufacturer, a subsidiary of Stryker, a Fortune 500 company, United States)
- Medline Industries, Inc. (privately held manufacturer and distributor, United States)
- Intersurgical (privately held manufacturer, United Kingdom)
- Avanos (publicly traded manufacturer, United States)

Ethics

Per the University of Toronto Health Research Ethics Board guidelines, this study was exempt from research approval as all data were publicly available and no human subjects were involved.

Patient and public involvement

This research was done without patient or public involvement.

Data sources

Two investigators independently sampled all educational materials from the four company's international websites; thus, all content was in English. We defined "educational material" as documents produced and authored by the company, focused on oral health conditions and/or care practices, targeted at clinicians, and explicitly identified as

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“educational” (e.g. located under website headers “clinical education,” or identified as a “course” or “training”). There were no restrictions on document format. We captured screenshots of all included web pages and downloaded all available PDFs. Two investigators independently screened the full texts of sampled documents according to these inclusion criteria with a third investigator reviewing any discrepancies. Documents were excluded if they were required by a regulator (e.g. Material Data Safety Sheet), intended for purchasing (e.g. catalogue, order form), hosted and/or authored exclusively by a third-party, or targeted patients, family caregivers, or clinicians working outside of acute care (e.g. dentists).

Data extraction

Based on previous analyses of evidentiary support for promotional claims in pharmaceutical and medical device advertising,^{11,12,22} we created a data extraction tool in Redcap²³ that comprised three main sections: identification of products, identification and assessment of product-related claims, and identification and assessment of supporting evidence (File S1). Identification of products included assessing the number and type of unique products mentioned or depicted. We extracted all product- or practice-related claims, defined as statements made about the efficacy, safety, cost-effectiveness, convenience, or other value of an oral care product (e.g. toothbrush) or clinical practice involving a product (e.g. toothbrushing), along with any accompanying citation(s). We distinguished product-related claims from normative claims, which suggested what should or must be done, but did not refer to effectiveness, for example.

We categorized claims using an adapted typology from a previous investigation of pharmaceutical advertisements¹¹: unambiguous (i.e. clinical comparison or outcome that is clear and measurable); vague or non-clinical (i.e. lacks a comparison, clear efficacy outcome, or clinical outcome); process-related (i.e. related to workflow, convenience or compliance

concerns); and emotive/immeasurable (i.e. evoked feelings and no measurable outcome identified) and noted whether the claim contained risk reporting.

We extracted all citations, then classified citations accompanying claims by type (e.g. journal article, conference abstract, data on file) and level of evidence according to the criteria for treatment efficacy from the Oxford Centre for Evidence-Based Medicine.²⁴ We determined whether a citation identified a primary outcome and data were extracted on the citation's funding sources and author conflicts of interest.

We piloted the instrument on a subset of sampled documents until we reached an acceptable level of agreement. Two investigators then independently extracted data on the entire sample; discrepancies were discussed and resolved with a third author.

Data analysis

Two independent investigators assessed claim-citation pairs, which involved a claim and accompanying citation, to determine if information in the citation supported the claim (Table 1). Investigators classified citations deemed "unsupportive" according to an adapted classification from a study of claim-citation pairs in wound care advertising,¹² choosing the reason that best described why the citation was unsupportive. Reasons included: the citation was unrelated, exaggeration or over-interpretation of the findings, different study population, in-vitro or animal study, the claim was not based on the study's primary outcome, the study findings were not statistically significant, or the citation did not meet an appropriate level of evidence for the accompanying claim. We calculated descriptive statistics on all frequencies and proportions using SPSS 25.

Table 1. Sample extraction and analysis of claim-citation pairs.

Extracted: Claim (citations)	Analysis: Unique claim-citation pairs
Claim 1 (citation 1)	Claim 1 + citation 1
Claim 2 (citation 1; citation 2; citation 3)	Claim 2 + citation 1 Claim 2 + citation 2 Claim 2 + citation 3

Network analysis

In addition to the level and quality of evidence used to substantiate claims, we assessed the independence of the evidence presented using social network analysis. We sought to analyse two facets of independence: 1) the degree to which industry-authored educational materials cited the work of authors who work independently from one another (i.e. authors who are not co-authors); and 2) the extent of referenced authors’ relationships with the sampled companies and industry more broadly.

We manually extracted the listed authors and co-authors for all publications referenced in the sample, excluding sampled documents with no citations and non-authored citations (e.g. data on file, federal register, no listed authors). We calculated the number of times each publication was cited in substantiation of a claim and the number of times each publication was cited overall. Then, we ranked authors by the number of cited publications they authored or co-authored in substantiation of a claim. To analyse the interdependence of authors, we derived the network of co-authorship relations derived from these references.

Role of the funding source

This study was supported by a Bloomberg Summer Research Scholarship from the Lawrence S. Bloomberg Faculty of Nursing at the University of Toronto and the Toronto Mobility Scheme of the University of Sydney’s Office of Global Engagement.

Results

We included 68 documents from the 4 manufacturers (Figure 1). Nearly 2/3 (43/68, 64%) were authored by Sage, Inc. (owned and operated by Stryker Corporation), the dominant manufacturer in this market. Document characteristics are outlined in Table 2. Sampled documents included brochures, flyers, web pages, and courses containing information about oral care (e.g. “Evidence-based practices for comprehensive oral care workshop”), oral disease (e.g. “Colonization of dental plaque and importance of brushing for

hospitalized patients”), or sequelae of missed oral care or oral disease (e.g. “Protecting your patients from ventilator-associated pneumonia”). Sampled documents also included templates for educational posters, and oral care assessment or care protocols designed to be customised by users. The majority of documents mentioned an oral care product (59/68, 87%) and 51% mentioned a branded oral care product (35/68), which included pharmaceuticals (e.g. oral rinse), medical devices (e.g. toothbrushes, suction devices), or pre-packaged kits containing a combination of oral care products and pharmaceuticals. The majority of documents made at least one product-related claim (55/68, 81%). We extracted 252 claims across the sampled documents; however, claims were frequently repeated verbatim across the 68 documents, resulting in 204 unique claims (204/252, 79%).

Figure 1. Industry-authored educational materials sampling flow diagram (n=68)

Table 2. Characteristics of industry-authored educational materials (n=68)

Variable	Sage Inc. n (%)	Intersurgical n (%)	Avanos n (%)	Medline Inc. n (%)	Total n (%)
No. of documents	43	10	9	6	68
Document format					
Brochure, flyer, webpage	31 (72)	8 (80)	8 (89)	4 (67)	51 (75)
Protocol template	7 (16)	2 (20)	0	0	9 (13)
Course (accredited)	2 (5)	0	1 (11)	2 (33)	5 (7)
Course (non-accredited)	2 (5)	0	0	0	2 (3)
Other ^a	1 (2)	0	0	0	1 (2)
No. with product mentions	36 (84)	8 (80)	9 (100)	6 (100)	59 (87)
No. branded ^b mentions	22 (51)	5 (50)	5 (56)	3 (50)	35 (51)
No. pharmaceutical mentions	22 (51)	7 (70)	4 (44)	2 (33)	35 (51)
No. device mentions	28 (65)	5 (50)	4 (44)	2 (33)	39 (57)
No. combination kit mentions ^c	20 (47)	5 (50)	6 (67)	4 (67)	35 (51)
No. with product-related claims	34 (79)	7 (70)	8 (89)	6 (100)	55 (81)

^aOther format was a webpage containing information about a ‘customer information department’

^b“Branded” mentions were those that referenced a product’s specific brand name

^cPre-packaged kits containing a combination of oral care products and pharmaceuticals

Evidentiary support for claims

The majority of claims (124/204, 61%) referred to an outcome that was vague and/or non-clinical (see Table 3). Only 12% (24/204) of claims contained risk reporting; upon examination of the accompanying citation, we determined the majority of claims containing risk reporting (18/24, 75%) reported relative risk, while 6 (25%) did not present sufficient information to determine the type of risk reporting.

Table 3. Nature of outcome reporting in claims

Type of outcome referenced in claim (n=204)	n (%)	Examples
Vague and/or non-clinical	124/204 (61)	The BALLARD turbo-cleaning catheter is the only catheter that retracts within a unique isolated turbulent cleaning chamber, which results in a cleaner catheter tip compared to a standard closed suction system
Unambiguous and clinical	39/204 (19)	A published 4-year study using an oral care protocol including Toothette® Oral Care Systems saw . . . fewer vent days, shorter length of stay and decreased mortality rates
Process-related	35/204 (17)	New space-saving design and bedside bracket help improve compliance
Emotive or immeasurable	6/204 (3)	We are preventing pneumonia and saving lives, one clean mouth at a time

Of the 204 unique claims, 56% (115/204) were accompanied by one or more citations, resulting in 147 unique claim-citation pairs. For the majority of claim-citation pairs, we judged the claim to be unsupported by the accompanying citation (91/147, 62%). The most prevalent reasons for judging a claim-citation pair as unsupportive were that the claim exaggerated or over-interpreted the cited study’s findings or that we were unable to access the cited study (e.g. the claim cited data on file with the manufacturer). Table 4 provides details about reasons citations were judged as unsupportive and illustrative examples.

Table 4. Nature of evidentiary support or non-support of claims

Reasons citation was unsupportive (n=91)	n (%)	Example	Citation	Explanation ^a
Claim exaggerates or over-interprets citation's findings	21 (23)	"Intervention led to 89.7% reduction in VAPs from 2004-2007."	Hutchins et al. Ventilator-associated pneumonia and oral care: A successful quality improvement project. <i>Am J Infect Contr.</i> 2009;37(7):590-597	Citation is a quality improvement study, with no control group, which stated "the ventilator bundle and an oral care protocol intervention with CPC (changed to 0.12% CHG in January 2007) and hydrogen peroxide. . . may have led to the 89.7% reduction in the rate of VAP in mechanically ventilated patients from 2004 to 2007"
Unable to access citation's full text (e.g. 'data on file')	21 (23)	"Clinician success at delivery of a suction catheter to ETT cuff: 99% with Sherpa Suction Guide, 0% with suction catheter alone."	Clinician experience in simulated test models, Data on File at Ciel Medical	Data not publicly available
Difficult to see how claim derived from citation	12 (13)	"In fact, two separate studies using our Q-Care Oral Cleansing and Suctioning Systems as part of a comprehensive oral care protocol saw VAP reductions of 42% and 60%."	Vollman et al., <i>AACN News.</i> Aug 2005;22(8):12-6.	The risk reporting in the claim cannot be found in the cited study.
Citation does not meet an appropriate level of evidence for outcome in claim	10 (11)	"Toothbrushes are the most effective means of removing plaque and stimulating mucosal tissue."	Editorial Staff, Oral care update: From prevention to treatment, <i>Nurs Mngt.</i> May 2003;34(5) Suppl 3.	The claim references a comparative, efficacy outcome, however, the citation is a narrative review and no additional studies are cited in the review to support this statement.

Citation not related to claim	8 (9)	"One facility had a VAP rate of zero for 3 straight years after implementing an oral care protocol that included Q care systems"	Quinn, B. et al. Basic nursing care to prevent nonventilator hospital-acquired pneumonia, <i>J Nurs Scholarsh</i> , 2014, 46:1, 11-19	The cited study examines prevention of non-ventilator hospital-acquired pneumonia, while the claim cited improvements in ventilator-associated pneumonia.
Citation's findings not statistically significant	7 (7)	"A published 4-year study using an oral care protocol including Toothette® Oral Care Systems saw a 33% reduction in VAP, plus fewer vent days, shorter length of stay and decreased mortality rates."	Garcia et al. Reducing ventilator-associated pneumonia through advanced oral-dental care: A 48-month study. <i>Am J Crit Care</i> . 2009;18(6):523-532.	The cited study states, "During the intervention period, VAP rates decreased by 33.3%, although the result was only marginally significant (12 vs 8 cases per 1000 ventilator days, P=.06)."
Study population or intervention differs from population or intervention in cited study	4 (4)	"TOOTHETTE® SUCTION TOOTHBRUSH: Helps remove dental plaque, debris and oral secretions, all known to harbor potential respiratory pathogens."	Pearson LS, Hutton JL, <i>J Adv Nurs</i> . 2002 Sep;39(5):480-9	The cited study compared toothbrushes (not suction toothbrushes) and foam swabs.
Claim not based on citation's primary outcome	4 (4)	"The physical removal of bacteria-laden dental plaque may play an important role in VAP risk reduction."	Needleman IG, et al. Randomized controlled trial of toothbrushing to reduce ventilator-associated pneumonia pathogens and dental plaque in a critical care unit. <i>J Clin Periodontol</i> 2010;38:246-52	The cited study's primary outcome was, "colonization of supragingival dental plaque by VAP-associated bacteria. The secondary outcome was dental plaque amount." The study did not measure risk reduction.
Other ^b	4 (4)	"Mechanically ventilated patients are at a	Lloyd, R. Oral care of the mechanically ventilated patient:	Citation is a conference poster with insufficient

		particularly high risk of pneumonia even after discharge. Yet oral care protocols have been shown to make a positive difference in ventilator-associated pneumonia (VAP) risk."	You can make a difference in five minutes. [cited at the State of Illinois Critical Care Conference]. March, 2002.	detail to assess methods or results.
Study in-vitro or in animals	0	--	--	--

^a All bolded text is added by authors for emphasis

^bIn general, these were citations that were not a high level of evidence and did not provide enough supporting evidence to verify the cited information

Nature and level of evidence

Documents referenced a mean 6.62 citations (SD=11.89). We extracted 437 citations from the 68 documents; 31% of the citations (134/437) appeared in multiple documents, resulting in 303 unique citations in the sample of 68 documents (Table 5). However, only 29% (88/303) of the unique citations were used to substantiate claims made about oral health products or processes (i.e. as part of a claim-citation pair). Rather, the majority were used as citations for statements unrelated to oral health or related to general facts (e.g. "Every 4–6 hours 20 billion bacteria duplicate in the oral cavity"). We were unable to access the full text of 14% (12/88); thus, we categorised 76 citations by level of evidence. Cited studies generally represented lower levels of evidence: less than 20% were systematic reviews (7/76, 9%) or randomised controlled trials (10/76, 13%). About half the cited studies provided a conflict of interest statement (43/76, 57%) and/or a funding statement (36/76, 47%). Of the cited studies that made such disclosures, 23% (10/43) disclosed financial relationships between authors and oral health product manufacturers and 33% (12/36) reported industry sponsorship of the study.

Table 5. Characteristics of cited studies

Variable	n (%)
Total citations (n=68 documents)	437
Total unique citations	303/437 (69)
Number of unique citations accompanying claims	88/303 (29)
Unique citations with full text accessible	76/88 (86)
Full text not accessible	12/88 (14)
Type of unique reference with full text accessible (n=76)	
Journal article	51/76 (67)
Other ^a	16/76 (21)
Poster	5/76 (7)
Clinical practice guideline	4/76 (5)
Level of evidence (n=76)	
Systematic review	7/76 (9)
Randomised controlled trial	10/76 (13)
Observational study	27/76 (36)
Opinion	24/76 (32)
Mechanistic	1/76 (1)
Other ^b	7/76 (9)
References with conflict of interest statement (n=76)	43/76 (57)
Presence of conflict of interest with manufacturer ^c	10/43 (23)
References with funding statement (n=76)	36/76 (47)
Study funded by manufacturer	12/36 (33)

^aArticles in non-peer-reviewed magazines/journals, FDA regulation notices, USA Department of Public Health document, informational webpages, textbook chapters

^bObscure references that either do not appear to be searchable or that were missing necessary identifying information, data on file with manufacturer, presentation abstracts, and unpublished reports from private company.

^cA manufacturer includes one of the four sampled companies

Independence of evidence

Figure 2 displays the co-author network derived from references used in substantiation of a claim within sampled documents. The nodes represent individual authors, joined by ties that indicate they co-authored at least one citation in the sample. The size of the node represents the number of citations the individual authored within the sample that were used to substantiate claims. Nodes coloured dark blue highlight the top 20 authors ranked by the number of citations; light blue nodes indicate authors that are directly or indirectly linked (though shared co-authors) to the top 20 authors.

Figure 2. Network of authors and co-authors referenced by claims

These top 20 authors occupy central positions in the network, connecting and collaborating with many of the author groups whose work companies cited to provide an

evidence base for the educational materials. The top 20 authors (in terms of the number of times their authored or co-authored citations were used to substantiate a claim) represented 2.5% of all authors in the overall sample of cited authors. Collectively, they accounted for 37.4% of all citations used within claim-citation pairs (n=77/206, including claim-citation pairs repeated across documents).

We investigated the industry ties of these top 20 authors (Table 6). Overall 60% (12/20), including the top 5 authors, had at least one financial relationship with one of the 4 sampled oral health product manufacturers, which included receipt of personal payments for speaking or consulting and/or study funding. Among these top 20, only 1 author (5%) had no financial ties to industry.

Table 6. Top 20 authors' financial ties to industry

Author name	Author profession	No of cited studies authored in sample	Total citations of authored studies in sample	Total citations of authored studies by claims	Disclosed study funding within sample citations	Disclosed personal payments within sample citations	Evidence of industry ties beyond sample
Quinn B	Clinical nurse specialist	8	26	18	C	C	C
Baker DL	Registered nurse, researcher	7	24	17	C	C	C
Garcia RA	Infection control	6	23	15	MW	C	C
Lima CA	Registered nurse, researcher	2	16	12	C		
Parise C	Scientist	2	16	12	C		
Scannapieco FA	Periodontist, researcher	4	13	9			I
Colbert L	Infection control	3	10	8	MW		
Jendresky L	Infection control	3	10	8	MW		
Greene LR	Registered nurse, infection control	5	13	7		I	
Bailey A	Registered nurse	2	9	7	MW		
Schleder B	Clinical nurse specialist	4	18	6	C	C	C
Lloyd RC	Researcher	2	14	6	C	C	
Stott K	Registered nurse	2	14	6	C	C	

Vollman KM	Clinical nurse researcher	4	11	6		C	C
Cohen S	Nurse practitioner, researcher	1	8	6	C		
Majumder M	Physician	1	8	6	MW		
Munro CL	Registered nurse, researcher	5	8	6			
Stewart JL	Clinical nurse educator	1	8	6	C		
Zaman M	Physician	1	8	6	MW		
Kollef MH	Physician	6	13	5		I	C

C= financial ties to company authoring documents (Sage, Avanos, Intersurgical, Medline)
I= financial ties to industry including pharmaceutical or medical device company (other than 4 oral care manufacturers)
MW = disclosed professional medical writing and editorial assistance, but did not disclose the funding source

Discussion

Oral health product manufacturers have produced a wide range of educational materials targeted at nurses ranging from product training videos to courses. However, these educational materials may be largely characterised as “education in support of a product”⁴: the majority mentioned an oral health product, half mentioned a branded product and over 80% made a product-related claim. Given that oral health is the product of a complex interplay among social (e.g. socioeconomic status, marginalisation, access to dental care) and commercial determinants (e.g. promotion of high-sugar products),¹⁸ the educational focus on product-related practices suggests a downstream approach to oral health and may constitute an agenda bias in educational content and the underlying research.²⁵

Educational materials authored by these companies presented as evidence-based, containing on average nearly 7 citations per document and suggested they represented the findings of curated scientific literature (i.e. titles such as “What the Experts Say”). Only half of claims were accompanied by a citation and the majority were not substantiated by the underlying evidence. In general, the level of evidence was low and relied heavily on narrative reviews or opinion pieces; however, most claims related to vague or non-clinical outcomes,

thus, the level of evidence required to support such statements is also lower. Most commonly, claims over-interpreted the accompanying evidence, which constitutes a form of ‘spin,’ defined as reporting practices that mislead readers by presenting results in a more favourable light.²⁶

The companies relied on a small network of oral health experts in marshalling evidence in support of claims and educational materials more generally, many of whom had existing or subsequent financial ties to the companies or industry more broadly. These recognized and respected experts are examples of key opinion leaders, who are engaged by pharmaceutical or medical device companies as speakers or consultants for their ability to influence their peers.²⁷ Companies may also approach key opinion leaders to serve as investigators on company-sponsored projects or as authors on company-led research.²⁸ Key opinion leaders are valuable to companies because they project an appearance of independence and integrity, while serving as ‘product champions’; however, companies carefully manage key opinion leaders through training programs and by offering targeted research funding, speaking platforms, and authorship opportunities.²⁷ Our findings suggest that companies identify and cultivate nurses, in addition to physicians and scientists, as key opinion leaders by engaging them as speakers and consultants and providing platforms through which to disseminate their work.

Companies also sponsored or were involved in nearly half of the highly cited studies suggesting sponsorship bias, where industry funding is associated with results and conclusions favourable to the sponsor,²⁹ may also be of concern. Regardless of the educational value and integrity of the underlying research, our network analysis illustrates how companies can strategically cite, often repeatedly, and thus amplify, perspectives that are favourable to commercial aims. This may be another facet of sponsorship bias consistent with

previous research that found articles with positive conflict of interest disclosures are more likely to be published in high impact journals or to receive more media attention.³⁰

Strengths and limitations

We analysed a purposive sample of publicly available educational materials sampled from the websites of four manufacturers of oral health products. It is unknown whether these documents are representative of those produced by other oral health manufacturers, nor whether these findings can be generalised to other product categories. However, the sampled companies are market leaders and two (Sage Inc. and Medline Inc.) have diverse product portfolios suggesting that these findings may be indicative of industry-authored educational materials more broadly. We sampled educational documents targeting nurses from company websites, thus it is unknown whether and how these educational materials are used and their impact on educational or clinical outcomes. Identifying educational materials and extracting claims required interpretation, thus we opted for duplicate sampling and data extraction at all stages.

Conclusion

The sustainability of health systems worldwide is under strain and resources to support nurses’ ongoing practice-based education are scarce. The findings of this study, however, suggest that caution should be exercised when relying on industry-authored educational materials to support product training and continuing clinical education in oral health and in clinical practice, more broadly. To support the use of oral health products in clinical practice, clinicians should seek industry-authored materials that conform to regulatory standards related to labelling (i.e. instructions for use) and otherwise, seek education that is independent from manufacturers.

The findings of this study call into question whether industry-authored materials are educational or promotional, which carries regulatory implications. Evidence of sponsorship

bias affecting the focus, substantiation of claims, and curation of expert recommendations suggests that industry-authored educational materials has promotional intent and should be regulated as such.

Figure legends

Figure 2 displays the co-author network derived from references used in substantiation of a claim within sampled documents. The nodes represent individual authors, joined by ties that indicate co-authorship with at least one citation in the sample. The size of the node represents the number of citations the individual authored within the sample that were used to substantiate claims. Nodes coloured dark blue indicate authors ranked in the top 20 authors ranked by the number of citations; light blue nodes indicate authors that are directly or indirectly linked (though shared co-authors) to the top 20 authors.

Author contributions

Quinn Grundy: Conceptualisation; Methodology; Investigation; Formal Analysis; Writing - Original Draft; Funding Acquisition; Supervision. **Anna Millington:** Investigation; Formal Analysis; Project Administration; Writing – Review & Editing; **Clodna Cussen:** Investigation; Formal Analysis; Writing – Review & Editing; **Fabian Held:** Formal Analysis; Visualisation; Writing – Review & Editing; **Craig Dale:** Methodology; Supervision; Writing – Review & Editing.

Data availability

The full dataset is available as a CSV file from the authors upon reasonable request.

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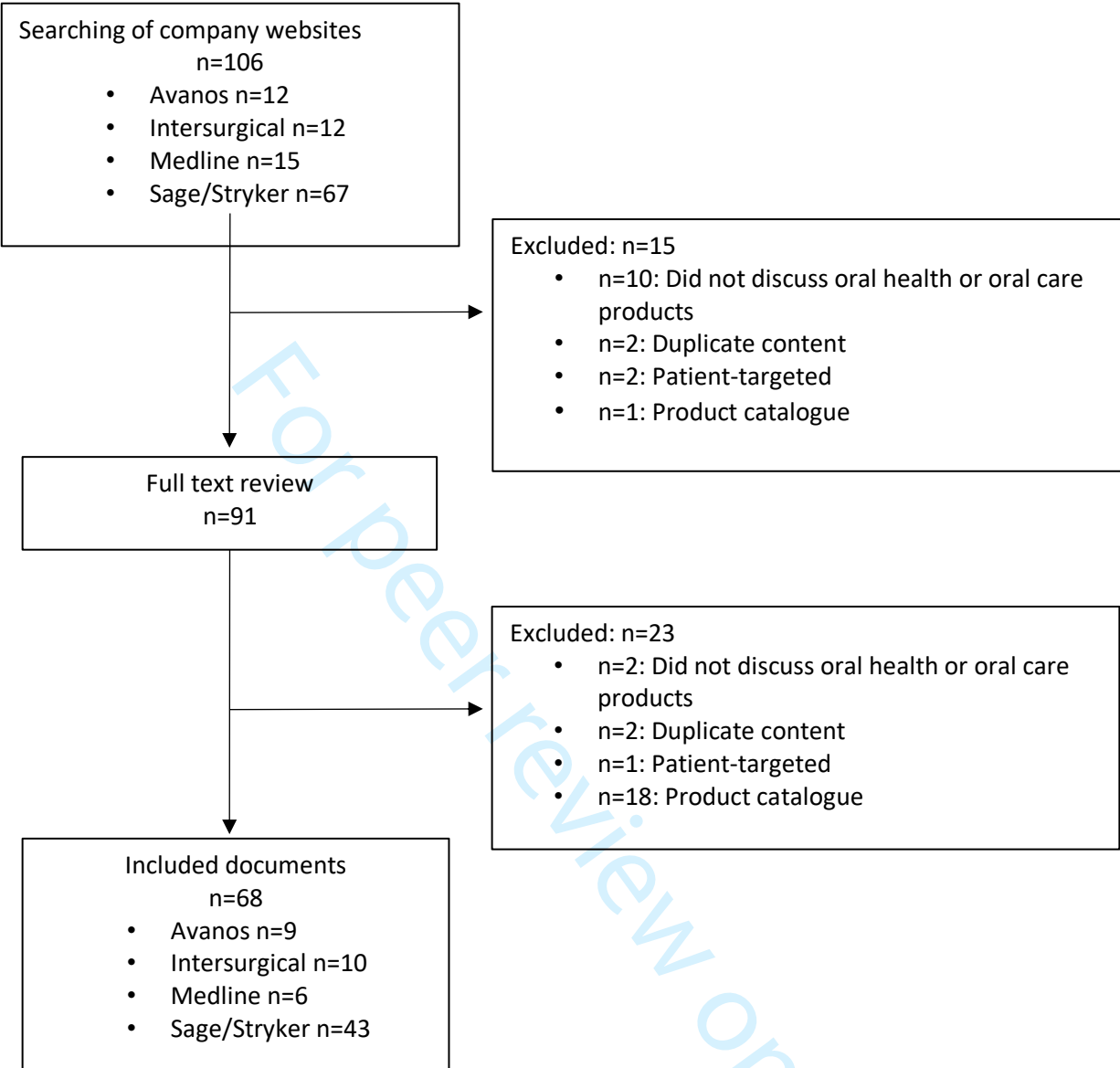
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Figure 1. Industry-authored educational materials sampling flow diagram (n=68)





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Promotion or education? A content analysis of industry-authored oral health educational materials targeted at acute care nurses

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Promotion or education? A content analysis of industry-authored oral health educational materials targeted at acute care nurses

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Abstract

Objectives: To assess the nature, quality, and independence of scientific evidence provided in support of claims in industry-authored educational materials in oral health.

Design: A content analysis of educational materials authored by the four major multinational oral health product manufacturers.

Setting: Acute care settings.

Participants: 68 documents focused on oral health or oral care, targeted at acute care clinicians and identified as “educational” on companies’ international websites.

Main outcome measures: Data were extracted in duplicate for three areas of focus: a) products referenced in the documents, b) product-related claims, and c) citations substantiating claims. We assessed claim-citation pairs to determine if information in the citation supported the claim. We analyzed the interrelationships among cited authors and companies using social network analysis.

Results: Documents ranged from training videos to posters to brochures to continuing education courses. The majority of educational materials explicitly mentioned a product (59/68, 87%), a branded product (35/68, 51%), and made a product-related claim (55/68, 81%). Among claims accompanied by a citation, citations did not support the majority (91/147, 62%) of claims, largely because citations were unrelated. References used to support claims most often represented lower levels of evidence: only 9% were systematic reviews (7/76) and 13% were randomised controlled trials (10/76). We found a network of 20 authors to account for 37% (n=77/206) of all references in claim-citation pairs; 60% (12/20) of the top 20 cited authors received financial support from one of the 4 sampled manufacturers.

Conclusions: Resources to support clinicians' ongoing education are scarce. However, caution should be exercised when relying on industry-authored materials to support continuing education for oral health. Evidence of sponsorship bias and reliance on key opinion leaders suggests that industry-authored educational materials have promotional intent and should be regulated as such.

Keywords

pharmaceutical industry; medical device industry; continuing education; nursing; oral health; acute care; content analysis

Strengths and limitations

- We sampled all documents explicitly labelled as “educational” from the websites of the four major manufacturers of oral care products
- All data were extracted in duplicate and judgments about whether evidence substantiated a claim was made by two independent reviewers
- We included a novel evaluation of the independence of the cited evidence by assessing relationships among cited authors and the manufacturers
- We do not know whether or how these educational materials are used by clinicians and thus the impact on practice is unknown

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Introduction

Industry continues to be a major source of sponsor of clinicians’ continuing education in the form of conferences, dinner meetings, journal clubs, grand rounds, and trainings.^{1,2} Nurses frequently rely on industry representatives and information for guidance on product use and outcome evaluation in the practice setting.³⁻⁵ Products commonly used in nursing care, such as wound dressings, often lack high-quality clinical trials demonstrating efficacy prior to market approval.^{6,7} Thus, manufacturers are often a principle – or sole – source of information about nursing-related products.

However, information communicated to health professionals about pharmaceuticals and devices in the form of product advertisements often fails to provide adequate safety information, or to communicate an appropriate balance between benefits and harms.⁸⁻¹⁰ Less is known about the nature, quality, or impact of industry-authored materials that are characterized as “educational.” Educational materials in many jurisdictions are not subject to the same regulation as advertising, thus, may not undergo regulatory review for inclusion of appropriate safety information, for example.¹¹ Thus, the goal of this study was to evaluate the nature and quality of industry-authored educational materials from the perspective of evidence-based practice.

We selected oral health in acute care settings as the case study for this analysis for three reasons. First, oral diseases affect over half of the world’s population, including untreated dental caries, which globally, is the most prevalent health condition.¹² Second, oral health represents an opportunity to examine a variety of commercial determinants of health as it is characterised largely by a downstream, interventionist and technology-focused approach.¹³ Third, inadequate oral hygiene represents a serious risk factor for healthcare-acquired pneumonia, which is an important source of morbidity, mortality and growing healthcare costs.¹⁴ Thus, there is increased

interest by hospital administrators and health systems in addressing patients' oral health, which has placed a spotlight on the selection and use of efficacious tools and pharmaceuticals for oral care.

Consequently, nurses face increasing expectations to deliver safe and effective oral care.^{14,15} Oral care is a fundamental care practice for which nurses are primarily accountable and occurs within complex clinical and technical environments in order to prevent associated adverse health and quality of life outcomes including pneumonia, painful oral diseases such as periodontitis and tooth loss.^{14,16,17} However, nurses consistently experience insufficient pre-and post-licensure education in oral health care,¹⁸ which is consistent with the siloing of oral health by health systems, policymakers, and medicine more broadly.¹³ Given these educational gaps, in this content analysis, we focus on educational materials authored by the manufacturers of products used to perform oral care in acute care hospital settings including toothbrushes, foam swabs, lip moisturizer, oral rinses, and oral suction (see Supplementary Table 1). We aimed to assess the nature, quality, and independence of scientific evidence provided in support of product- and practice-related claims.

Materials and methods

Design and sampling frame

We identified manufacturers of oral care products (see Supplementary Table 1) through expert consultation (CD), previous research on nurse-industry interactions,⁴ Google searches for oral care product brands, and examination of the regulatory filing (SEC 10-K form) for the dominant manufacturer (Sage Inc.), which identified the major competitors in the company's medical division. We excluded companies that were at the start-up phase or supported

exclusively through grants, and that only distributed and did not manufacture oral health products. Our sampling frame thus included educational materials authored by:

- Sage Products (publicly traded manufacturer, a subsidiary of Stryker, a Fortune 500 company, United States, manufacturer of Q•Care® Oral Cleansing & Suctioning Systems)
- Medline Industries, Inc. (privately held manufacturer and distributor, United States, manufacturer of Medline brand toothbrushes, swabs, Yankauers, mouthwashes, and DenTips® Oral Swabsticks)
- Intersurgical (privately held manufacturer, United Kingdom, manufacturer of OroCare™ 24 hour day kits)
- Avanos (publicly traded manufacturer, United States, manufacturer of Ballard® Oral Care kits)

Data sources

Two investigators independently sampled all educational materials from the four companies’ international websites; thus, all content was in English. We defined “educational material” as documents produced and authored by the company, focused on oral health conditions and/or care practices, targeted at clinicians, and explicitly identified as “educational” (e.g. located under website headers “clinical education,” or identified as a “course” or “training”). There were no restrictions on document format. We captured screenshots of all included web pages and downloaded all available PDFs. Two investigators independently screened the full texts of sampled documents according to these inclusion criteria with a third investigator reviewing any discrepancies. We excluded documents if they were required by a regulator (e.g. Material Data Safety Sheet), intended for purchasing (e.g. catalogue, order

form), hosted and/or authored exclusively by a third-party, or targeted patients, family caregivers, or clinicians working outside of acute care (e.g. dentists).

Data extraction

Based on previous analyses of evidentiary support for promotional claims in pharmaceutical and medical device advertising,^{8,9,19} we created a data extraction tool in Redcap²⁰ that comprised three main sections: identification of products, identification and assessment of product-related claims, and identification and assessment of supporting evidence. Identification of products included assessing the number and type of unique products mentioned or depicted. We extracted all product- or practice-related claims, defined as statements made about the efficacy, safety, cost-effectiveness, convenience, or other value of an oral care product (e.g. toothbrush) or clinical practice involving a product (e.g. toothbrushing), along with any accompanying citation(s). We distinguished product-related claims from normative claims, which suggested what should or must be done, but did not refer to effectiveness, for example.

We categorized claims using an adapted typology from a previous investigation of pharmaceutical advertisements⁸: unambiguous (i.e. clinical comparison or outcome that is clear and measurable); vague or non-clinical (i.e. lacks a comparison, clear efficacy outcome, or clinical outcome); process-related (i.e. related to workflow, convenience or compliance concerns); and emotive/immeasurable (i.e. evoked feelings and no measurable outcome identified) and noted whether the claim contained risk reporting.

We extracted all citations, then classified citations accompanying claims by type (e.g. journal article, conference abstract, data on file) and level of evidence according to the criteria for treatment efficacy from the Oxford Centre for Evidence-Based Medicine.²¹ We determined

whether a citation identified a primary outcome and data were extracted on the citation’s funding sources and author conflicts of interest.

We piloted the instrument on a subset of sampled documents until we reached an acceptable level of agreement. Two investigators then independently extracted data on the entire sample; discrepancies were discussed and resolved with a third author.

Data analysis

Two independent investigators assessed claim-citation pairs, which involved a claim and accompanying citation, to determine if information in the citation supported the claim (Table 1). Investigators classified citations deemed “unsupportive” according to an adapted classification from a study of claim-citation pairs in wound care advertising,⁹ choosing the reason that best described why the citation was unsupportive. Reasons included: the citation was unrelated in terms of content, study population or intervention; exaggeration of benefits; citation reported an in-vitro or animal study; distorted reporting of study findings (e.g. the claim was not based on the study’s primary outcome, the study findings were not statistically significant, or the citation did not meet an appropriate level of evidence for the accompanying claim); or cited data were unpublished (e.g. ‘data on file’). We calculated descriptive statistics on all frequencies and proportions using SPSS 25.

Network analysis

In addition to the level and quality of evidence used to substantiate claims, we assessed the independence of the evidence presented using social network analysis. We sought to analyse two facets of independence: 1) the degree to which industry-authored educational materials cited the work of authors who work independently from one another (i.e. authors who are not co-

authors); and 2) the extent of referenced authors' relationships with the sampled companies and industry more broadly.

We manually extracted the listed authors and co-authors for all publications referenced in the sample, excluding sampled documents with no citations and non-authored citations (e.g. data on file, federal register, no listed authors). We calculated the number of times each publication was cited in substantiation of a claim and the number of times each publication was cited overall. Then, we ranked authors by the number of cited publications they authored or co-authored in substantiation of a claim. To analyse the interdependence of authors, we derived the network of co-authorship relations derived from these references.

Patient and public involvement

There was no patient or public involvement in this study.

Results

We included 68 documents from the 4 manufacturers (Figure 1). Nearly 2/3 (43/68, 64%) were authored by Sage, Inc. (owned and operated by Stryker Corporation), the dominant manufacturer in this market. Document characteristics are outlined in Table 1. Sampled documents included brochures, flyers, web pages, and courses containing information about oral care (e.g. "Evidence-based practices for comprehensive oral care workshop"), oral disease (e.g. "Colonization of dental plaque and importance of brushing for hospitalized patients"), or sequelae of missed oral care or oral disease (e.g. "Protecting your patients from ventilator-associated pneumonia"). Sampled documents also included templates for educational posters, and oral care assessment or care protocols designed to be customised by users. The majority of documents mentioned an oral care product (59/68, 87%) and 51% mentioned a branded oral care product (35/68), which included pharmaceuticals (e.g. oral rinse), medical devices (e.g.

toothbrushes, suction devices), or pre-packaged kits containing a combination of oral care products and pharmaceuticals (Supplementary Table 1). The majority of documents contained at least one product-related claim (55/68, 81%). We extracted 252 claims across the sampled documents; however, claims frequently recurred verbatim across the 68 documents, resulting in 204 unique claims (204/252, 79%).

Figure 1. Industry-authored educational materials sampling flow diagram (n=68)

Table 1. Characteristics of industry-authored educational materials (n=68)

Variable	Sage Inc. n (%)	Intersurgical n (%)	Avanos n (%)	Medline Inc. n (%)	Total n (%)
No. of documents	43	10	9	6	68
Document format					
Brochure, flyer, webpage	31 (72)	8 (80)	8 (89)	4 (67)	51 (75)
Protocol template	7 (16)	2 (20)	0	0	9 (13)
Course (accredited)	2 (5)	0	1 (11)	2 (33)	5 (7)
Course (non-accredited)	2 (5)	0	0	0	2 (3)
Other ^a	1 (2)	0	0	0	1 (2)
No. with product mentions	36 (84)	8 (80)	9 (100)	6 (100)	59 (87)
No. branded ^b mentions	22 (51)	5 (50)	5 (56)	3 (50)	35 (51)
No. pharmaceutical mentions	22 (51)	7 (70)	4 (44)	2 (33)	35 (51)
No. device mentions	28 (65)	5 (50)	4 (44)	2 (33)	39 (57)
No. combination kit mentions ^c	20 (47)	5 (50)	6 (67)	4 (67)	35 (51)
No. with product-related claims	34 (79)	7 (70)	8 (89)	6 (100)	55 (81)

^aOther format was a webpage containing information about a ‘customer information department’

^b“Branded” mentions were those that referenced a product’s specific brand name

^cPre-packaged kits containing a combination of oral care products and pharmaceuticals

Evidentiary support for claims

The majority of claims (124/204, 61%) referred to an outcome that was vague and/or non-clinical (see Table 2). Only 12% (24/204) of claims contained risk reporting; upon examination of the accompanying citation, we determined the majority of claims containing risk reporting (18/24, 75%) reported relative risk, while 6 (25%) did not present sufficient information to determine the type of risk reporting.

Table 2. Nature of outcome reporting in claims

Type of outcome referenced in claim (n=204)	n (%)	Examples
Vague and/or non-clinical	124/204 (61)	<p>“The BALLARD turbo-cleaning catheter is the only catheter that retracts within a unique isolated turbulent cleaning chamber, which results in a cleaner catheter tip compared to a standard closed suction system.”</p> <p>“Our oral care products are designed to help promote oral health to address the risk of hospital acquired pneumonia.”</p> <p>“Oral care given q2-q4 appears to provide greater improvement in oral health”</p>
Unambiguous and clinical	39/204 (19)	<p>“A published 4-year study using an oral care protocol including Toothette® Oral Care Systems saw . . . fewer vent days, shorter length of stay and decreased mortality rates.”</p> <p>“A 2-year study at 11 nursing homes found pneumonia risk was significantly reduced in patients receiving oral care. In fact, mortality due to pneumonia was about half that of patients not receiving oral care.”</p> <p>“Twice a day application of 2% and 0.12% chlorhexidine gluconate to the oral cavity with a 2-hour time period from brushing has reduced VAP rates.”</p>
Process-related	35/204 (17)	<p>“New space-saving design and bedside bracket help improve compliance.”</p> <p>“The Sherpa Suction System ensures 100% of all ICU-</p>

		ventilated patients have daily access to above-the-cuff suctioning.” “Product ease-of-use resulted in my ability to provide more frequent oral cleansing.” “OroCare™ day kits: ensuring compliance with hospital guidelines for VAP prevention.”
Emotive or immeasurable	6/204 (3)	“We are preventing pneumonia and saving lives, one clean mouth at a time.” “Tooth brushing is essential component of oral care” “Oral hygiene is critical in the fight against VAP with good brushing techniques and suctioning being important tools.” “Data-driven best practices for oral care may allow healthcare providers to protect ventilated patients with a higher level of confidence.”

Of the 204 unique claims, 56% (115/204) were accompanied by one or more citations, resulting in 147 unique claim-citation pairs. For the majority of claim-citation pairs, we judged the claim to be unsupported by the accompanying citation (91/147, 62%). Most often, citations did not provide adequate support for the claim because citations were unrelated in terms of content focus, study population or intervention; the underlying evidence was inaccessible to a frontline clinician; or claims exaggerated the benefits of the cited findings. Table 3 provides illustrative examples of citations that provided insufficient support to claims.

Table 3. Nature of evidentiary support or non-support of claims

Reasons citation was unsupportive (n=91)	n (%)	Example claim	Accompanying citation	Explanation ^a
Citation unrelated to claim	25 (27)	“One facility had a VAP rate of zero for 3 straight years after implementing an oral care protocol that included Q care systems.”	Quinn, B. et al. Basic nursing care to prevent nonventilator hospital-acquired pneumonia, <i>J Nurs Scholarsh</i> , 2014, 46:1, 11-19.	The cited study examines prevention of non-ventilator hospital-acquired pneumonia, while the claim cited improvements in ventilator-associated pneumonia.
		“TOOTHETTE® SUCTION TOOTHBRUSH: Helps remove dental plaque, debris and oral secretions, all known to harbor potential respiratory pathogens.”	Pearson LS, Hutton JL, <i>J Adv Nurs</i> . 2002 Sep;39(5):480-9	The cited study compared toothbrushes (not suction toothbrushes) and foam swabs.
		“Pneumonia risk can be significantly reduced by performing oral care. • In a 2-year study, mortality due to pneumonia was about half that of patients not receiving oral care”	Yoneyama, T., Yoshida, M., Ohrai, T., Mukaiyama, H., Okamoto, H., Hoshiba, K., ... & Mizuno, Y. (2002). Oral care reduces pneumonia in older patients in nursing homes. <i>Journal of the American Geriatrics Society</i> , 50(3), 430-433.	The document containing the claim is targeted at oral care in adult acute care, however, the citation reports research conducted in a long term care facility.
		“Having set oral care protocols that are followed by healthcare personnel may help decrease poor oral health outcomes of patients, thus improving overall health.”	Handa, S., Chand, S., Sarin, J., Singh, V., & Sharma, S. (2014). Effectiveness of oral care protocol on oral health status of hospitalised children admitted in intensive care units of selected hospital of Haryana. <i>Nursing and Midwifery Research Journal</i> , 10(1), 8-15.	The document containing the claim is targeted at oral care in adult acute care populations, however, the citation reports findings from a study of hospitalized children.
Distorted interpretation of citation findings	24 (26)	“Oral care removes microbes and is proven to significantly reduce NV-HAP.”	Quinn, B., & Baker, D. (2015). Comprehensive oral care helps prevent hospital-acquired nonventilator pneumonia. <i>American Nurse Today</i> , 10(3), 18-23.	The claim implies causality but cites a narrative review.

		<p>“A published 4-year study using an oral care protocol including Toothette® Oral Care Systems saw a 33% reduction in VAP, plus fewer vent days, shorter length of stay and decreased mortality rates.”</p>	<p>Garcia et al. Reducing ventilator-associated pneumonia through advanced oral-dental care: A 48-month study. <i>Am J Crit Care</i>. 2009;18(6):523-532.</p>	<p>The cited pre/post (non-randomized) study states, “During the intervention period, VAP rates decreased by 33.3%, although the result was only marginally significant (12 vs 8 cases per 1000 ventilator days, P=.06).”</p>
		<p>“Maintaining oral hygiene has been proven to help reduce healthcare-acquired pneumonias (HAPs), including ventilator-associated pneumonia (VAP) and aspiration pneumonia.”</p>	<p>Vollman K, Garcia R, Miller L, AACN News. Aug 2005;22(8):12-6.</p>	<p>The claim implies causality but cites an observational study.</p>
Exaggerated benefits	21 (23)	<p>“Intervention led to 89.7% reduction in VAPs from 2004-2007.”</p>	<p>Hutchins et al. Ventilator-associated pneumonia and oral care: A successful quality improvement project. <i>Am J Infect Contr</i>. 2009;37(7):590-597</p>	<p>Intervention is a quality improvement study, with no control group, which stated “the ventilator bundle and an oral care protocol intervention with CPC [cetylpyridinium chloride] (changed to 0.12% CHG chlorhexidine gluconate) in January 2007) and hydrogen peroxide. . . may have led to the 89.7% reduction in the rate of VAP in mechanically ventilated patients from 2004 to 2007.”</p>
		<p>“In one study, Continue Care led to \$1,720,000 in avoided costs and 500 extra hospital days averted.”</p>	<p>Quinn, B., Baker, D. L., Cohen, S., Stewart, J. L., Lima, C. A., & Parise, C. (2014). Basic nursing care to prevent nonventilator hospital-acquired pneumonia. <i>Journal of Nursing Scholarship</i>, 46(1), 11-19.</p>	<p>Findings were due to the implementation of an "enhanced oral care nursing protocol" (including provider education, protocol, improved equipment). Continue Care products were also not explicitly mentioned in the article although it was stated that the authors received an unrestricted grant from Sage.</p>

		“Oral care removes microbes and is proven to significantly reduce NV-HAP.”	Fox J, Frush K, Chamness C, et al. (2015). Preventing Hospital-Acquired Pneumonia (HAP) Outside of the Ventilator-Associated Pneumonia Bundle. <i>Prevention Strategist</i> , 3, 45-48.	The citation does not provide any statistics nor raw data to be able to interpret the significance of the results.
Evidence cited not accessible for verification	21 (23)	“Clinician success at delivery of a suction catheter to ETT cuff: 99% with Sherpa Suction Guide, 0% with suction catheter alone.”	Clinician experience in simulated test models, Data on File at Ciel Medical	data on file with the manufacturer and not publicly available
		“Mechanically ventilated patients are at a particularly high risk of pneumonia even after discharge. Yet oral care protocols have been shown to make a positive difference in ventilator-associated pneumonia (VAP) risk.”	Lloyd, R. Oral care of the mechanically ventilated patient: You can make a difference in five minutes. [cited at the State of Illinois Critical Care Conference]. March, 2002.	citation is a conference poster with insufficient detail to assess methods or results.
		“Antiseptic Oral Rinse: Helps reduce chance of infection in minor oral irritation...[and] promotes healing by reducing bacteria known to cause most oral dysfunction.”	Nisengard RJ, Dept of Periodontics & Endodontics, Sch of Dent Med, SUNY Buffalo, 2000 Dec.	citation refers to an individual and not a study.
Study in-vitro or in animals	0			

^aAll bolded text has been bolded by authors for emphasis

Nature and level of evidence

Documents referenced a mean 6.62 citations (SD=11.89). We extracted 437 citations from the 68 documents; 31% of the citations (134/437) appeared in multiple documents, resulting in 303 unique citations in the sample of 68 documents (Table 4). However, the majority of unique citations (71%, 215/303) accompanied statements unrelated to oral health or general statements of fact (e.g. “Every 4–6 hours 20 billion bacteria duplicate in the oral cavity”). Only 29% (88/303) of unique citations occurred as part of a claim-citation pair. We were unable to identify or access the full text of 14% (12/88) because citations were incomplete (e.g. AACN Manual, 2015) or data were unpublished (e.g. data on file with manufacturer, presentation abstracts, and proprietary reports). Thus, we categorised 76 citations by level of evidence. Cited studies generally represented lower levels of evidence: less than 20% were systematic reviews (7/76, 9%) or randomised controlled trials (10/76, 13%). About half the cited studies provided a conflict of interest statement (43/76, 57%) and/or a funding statement (36/76, 47%). Of the cited studies that made such disclosures, 23% (10/43) disclosed financial relationships between authors and oral health product manufacturers, 33% (12/36) reported industry sponsorship of the study; 2 studies reported both author conflicts of interest and industry funding for the study.

Table 4. Characteristics of cited studies

Variable	n (%)
Total citations (n=68 documents)	437
Total unique citations	303/437 (69)
Number of unique citations accompanying claims	88/303 (29)
Unique citations with full text accessible	76/88 (86)
Full text not accessible ^a	12/88 (14)
Type of unique reference with full text accessible (n=76)	
Journal article	51/76 (67)
Other ^b	16/76 (21)
Poster	5/76 (7)
Clinical practice guideline	4/76 (5)
Level of evidence (n=76)	
Systematic review	7/76 (9)
Randomised controlled trial	10/76 (13)

Observational study	28/76 (37)
Opinion	24/76 (32)
Narrative review	4/76 (5)
Other ^c	2/76 (3)
Mechanistic	1/76 (1)
References with conflict of interest statement (n=76)	43/76 (57)
Presence of conflict of interest with oral health product manufacturer	10/43 (23)
References with funding statement (n=76)	36/76 (47)
Study funded by oral health product manufacturer	12/36 (33)

^aIncomplete citations or unpublished data (e.g. data on file with manufacturer, presentation abstracts, and proprietary reports).

^bPolicy documents, organizational web pages, non-peer-reviewed magazines and textbooks

^cRegulatory documents (e.g. Food and Drug Administration notice of rulemaking)

Independence of evidence

We identified 796 unique authors of citations referenced in the sampled documents; 38% (304/795) were authors of citations used to substantiate a claim. Using social network analysis, we examined the degree to which authors of citations accompanying claims were independent from one another (i.e. authors who are not co-authors). Within sampled documents, a small group of individuals authored and co-authored a disproportionate number of citations used to substantiate claims.

Figure 2 displays the co-author network derived from citations used to substantiate a claim within sampled documents. The nodes represent individual authors, joined by ties that indicate they co-authored at least one citation in the sample. The size of the node represents the number of citations the individual authored within the sample that were used to substantiate claims. Nodes coloured dark blue highlight the top 20 authors ranked by the number of citations; light blue nodes indicate authors that are directly or indirectly linked (through shared co-authors) to the top 20 authors.

Figure 2. Network of authors and co-authors referenced by claims

These top 20 authors occupied central positions in the network, connecting and collaborating with many of the author groups whose work companies cited to provide an evidence base for the educational materials. The top 20 authors (in terms of the number of

times their authored or co-authored citations were used to substantiate a claim) represented 2.5% of all authors in the overall sample of cited authors (20/796). Collectively, they accounted for 37.4% of all citations used within claim-citation pairs (n=77/206, including claim-citation pairs repeated across documents) (Table 5).

We investigated the industry ties of these top 20 authors (Table 5). Overall 60% (12/20), including the top 5 authors, had at least one financial relationship with one of the 4 sampled oral health product manufacturers, which included receipt of personal payments for speaking or consulting and/or study funding. Among these top 20, only 1 author (5%) had no financial ties to industry.

Table 5. Characteristics of top 20 authors

Characteristic	N	%
Citations within sample by top 20 authors ^a	270/437	62%
Citations accompanying claims by top 20 authors ^a	77/206	37%
Author discipline (n=20)		
Nursing	11	55%
Infection control	3	15%
Medicine	3	15%
Dentistry	1	5%
Epidemiology	1	5%
Disclosures (n=20)		
Study funding		
From oral health manufacturer ^b	9	45%
Use of professional medical writer ^c	6	30%
Personal payments		
From oral health manufacturer ^b	8	40%
From other industry	3	15%
Both study funding and personal payments from oral health manufacturer ^b	5	25%
Any financial relationship with oral health manufacturer ^b	12	60%
No financial ties to industry	1	5%

^aAuthorship included principal, senior, and co-authorship
^bIncluded companies producing the educational materials (i.e. Sage Products, Avanos, Intersurgical, Medline Industries)
^cAuthors disclosed using the services of a professional medical writer, but otherwise did not disclose the source of study funding

Discussion

Oral health product manufacturers authored a wide range of educational materials targeted at nurses ranging from product training videos to courses. However, these educational materials may be largely characterised as “education in support of a product”²⁴: the majority mentioned an oral health product, half mentioned a branded product and over 80% made a product-related claim. Given that oral health is the product of a complex interplay among social (e.g. socioeconomic status, marginalisation, access to dental care) and commercial determinants (e.g. promotion of high-sugar products),¹² the educational focus on product-related practices suggests a downstream approach to oral health and may constitute an agenda bias in educational content and the underlying research.²²

Educational materials authored by these companies presented as evidence-based, containing on average nearly 7 citations per document and suggested they represented the findings of curated scientific literature (i.e. titles such as “What the Experts Say”). Just over half of the unique claims (115/204, 56%) were accompanied by a citation and the majority were not substantiated by the underlying evidence. In general, sampled documents presented a low level of evidence and relied heavily on narrative reviews or opinion pieces; however, most claims related to vague or non-clinical outcomes, thus, the level of evidence required to support such statements is also lower. Commonly, claims presented a distorted interpretation or exaggerated the benefits of the accompanying evidence, which constitutes a form of ‘spin,’ defined as reporting practices that mislead readers by presenting results in a more favourable light.²³

The companies relied on a small network of oral health experts in marshalling evidence in support of claims and educational materials more generally, many of whom had existing or subsequent financial ties to the companies or industry more broadly. These recognized and respected experts are examples of key opinion leaders, who are engaged by

pharmaceutical or medical device companies as speakers or consultants for their ability to influence their peers.²⁴ Companies may also approach key opinion leaders to serve as investigators on company-sponsored projects or as authors on company-led research.²⁵ Key opinion leaders are valuable to companies because they project an appearance of independence and integrity, while serving as ‘product champions’; however, companies carefully manage key opinion leaders, including nurses, physicians, and scientists, through training programs and by offering targeted research funding, speaking platforms, and authorship opportunities.²⁴

Companies also sponsored or were involved in nearly half of the highly cited studies suggesting sponsorship bias, where industry funding is associated with results and conclusions favourable to the sponsor,²⁶ may also be of concern. Regardless of the educational value and integrity of the underlying research, our network analysis illustrates how companies can strategically cite, often repeatedly, and thus amplify, perspectives that are favourable to commercial aims. This may be another facet of sponsorship bias consistent with previous research that found articles with positive conflict of interest disclosures are more likely to be published in high impact journals or to receive more media attention.²⁷

Consequently, industry-authored educational should be characterized as “promotional” and regulated as advertising. Regulators have issued industry guidance to enable assessment of the distinction between “promotional” and “non-promotional” activities, which includes assessing whether materials directly or indirectly promote the sale of a health product and whether the manufacturer or sponsor has influence over the content.^{11,28} In practice, however, medical device industry-authored educational materials likely receive little regulatory scrutiny. Though certain high-income countries such as Canada, Australia, the United States, and the European Union have specific laws that govern pharmaceutical and medical device advertising, these regulators are under-resourced and

most jurisdictions rely on voluntary, industry self-regulation through codes of practice to regulate promotion.^{29,30}

Strengths and limitations

We analysed a purposive sample of publicly available educational materials sampled from the websites of four manufacturers of oral health products. It is unknown whether these documents are representative of those produced by other oral health manufacturers, nor whether these findings can be generalised to other product categories. However, the sampled companies are market leaders and two (Sage Inc. and Medline Inc.) have diverse product portfolios suggesting that these findings may be indicative of industry-authored educational materials more broadly. We sampled educational documents targeting nurses from company websites, thus it is unknown whether and how these educational materials are used and their impact on educational or clinical outcomes. Identifying educational materials and extracting claims required interpretation, thus we opted for duplicate sampling and data extraction at all stages.

Conclusion

The sustainability of health systems worldwide is under strain and resources to support nurses' ongoing practice-based education are scarce. The findings of this study, however, suggest that caution should be exercised when relying on industry-authored educational materials to support product training and continuing clinical education in oral health and in clinical practice, more broadly. To support the use of oral health products in clinical practice, clinicians should seek industry-authored materials that conform to regulatory standards related to labelling (i.e. instructions for use) and otherwise, seek education that is independent from manufacturers.

The findings of this study call into question whether industry-authored materials are educational or promotional, which carries regulatory implications. Evidence of sponsorship

bias affecting the focus, substantiation of claims, and curation of expert recommendations suggests that industry-authored educational materials has promotional intent and should be regulated as such.

Figure legends

Figure 2: Network of authors and co-authors referenced by claims: The nodes represent individual authors, joined by ties that indicate co-authorship. The size of the node represents the number of citations the individual authored within the sample that were used to substantiate claims. Nodes coloured dark blue highlight the top 20 authors ranked by the number of citations; light blue nodes indicate authors that are directly or indirectly linked (through shared co-authors) to the top 20 authors.

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Conflict of interest: The authors have no conflicts of interest.

Data Availability: All data are available in CSV format from the authors upon reasonable request.

Author contributions: QG conceived of the study, acquired funding, supervised all aspects of the work and wrote the first draft; AM and CC conducted sampling, data collection and analysis, and critically revised the manuscript; FH conducted network analyses, performed data visualisation and critically revised the manuscript; CD contributed to study design, supervised all aspects of the work and critically revised the manuscript.

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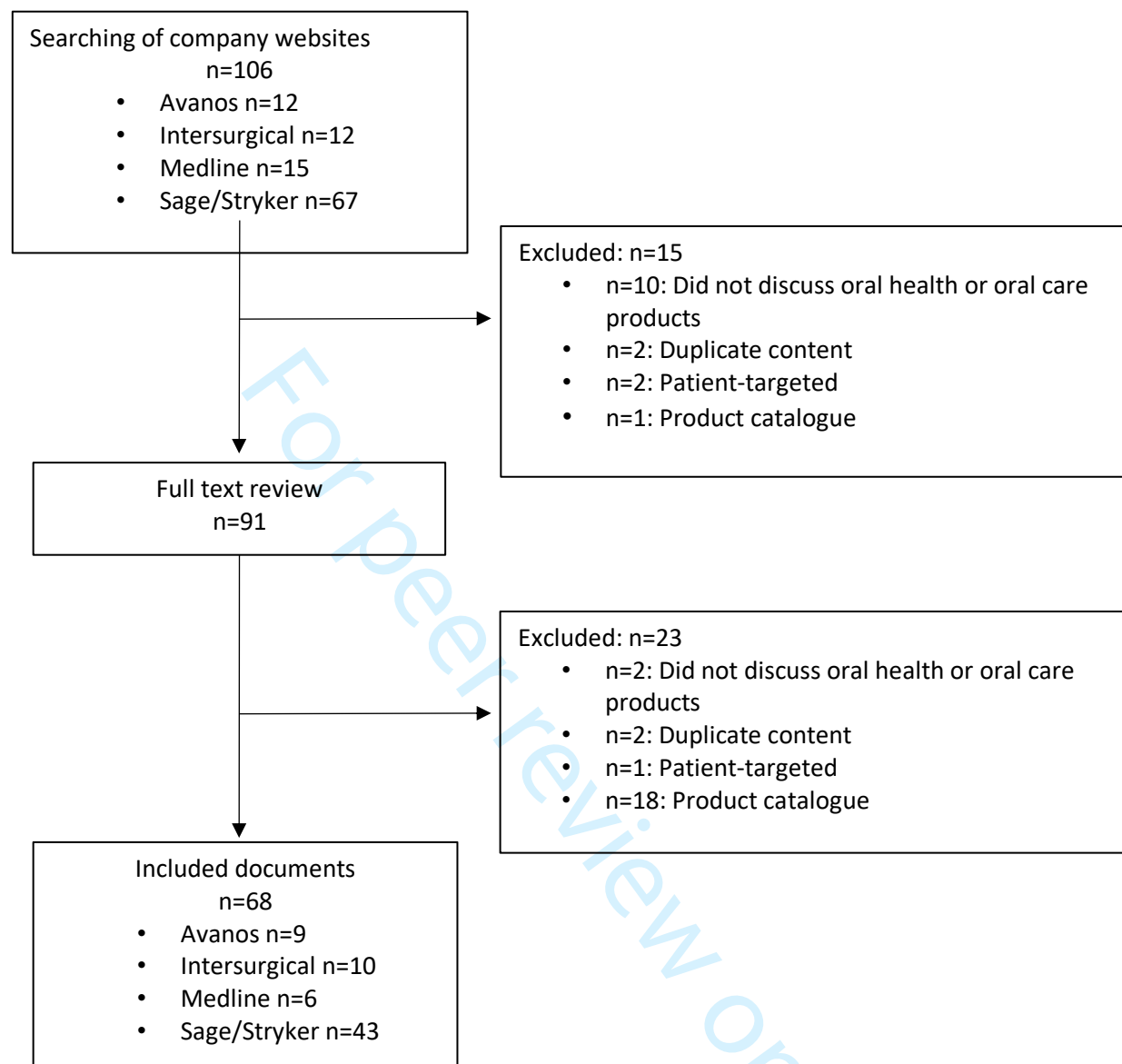
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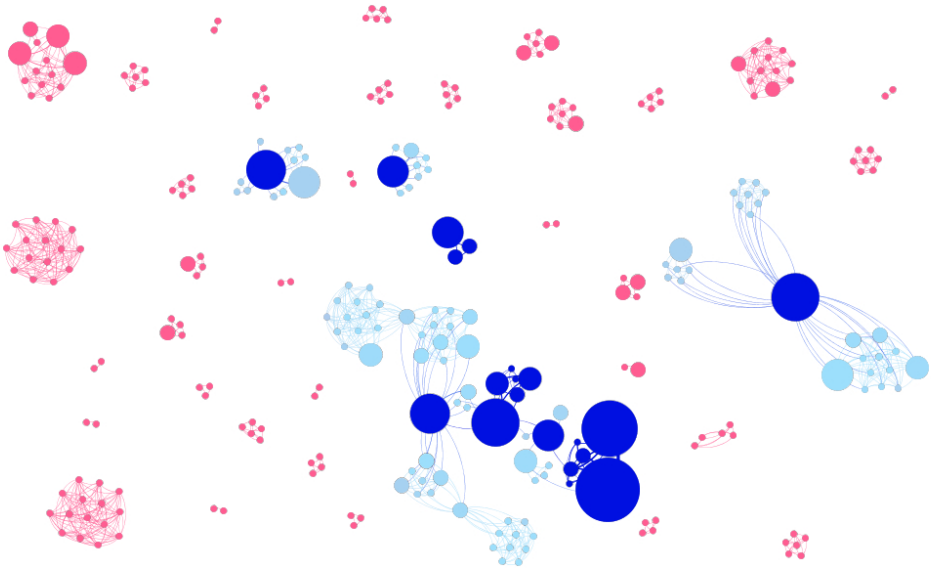
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For peer review only

Figure 1. Industry-authored educational materials sampling flow diagram (n=68)



Network of authors and co-authors referenced by claims: The nodes represent individual authors, joined by ties that indicate co-authorship. The size of the node represents the number of citations the individual authored within the sample that were used to substantiate claims. Nodes coloured dark blue highlight the top 20 authors ranked by the number of citations; light blue nodes indicate authors that are directly or indirectly linked (through shared co-authors) to the top 20 authors.

361x361mm (72 x 72 DPI)

Supplementary Table 1. Example oral care products for acute care settings

Category	Sub-category	Product	Use	Example products ^a
Pharmaceuticals	Antiseptics	Chlorhexidine rinse	<ul style="list-style-type: none"> Control of oral bacteria overgrowth 	Perox-A-Mint® Solution (Sage Products, active ingredient: hydrogen peroxide)
		Povidine iodine rinse		
		Triclosan rinse		
		Peroxide rinse		
		Antibiotic gel/pastes		
	Oral rinses	Non-alcohol based rinse	<ul style="list-style-type: none"> “Mouth wash” Odor control; symptom relief 	Corinz® Antiseptic Cleansing & Moisturizing Oral Rinse (Sage Products, active ingredient: cetylpyridinium chloride)
		Alcohol-based rinse		
	Pastes	Tooth paste	<ul style="list-style-type: none"> Plaque removal Fluoride delivery Caries prevention 	OroClean tooth gel (Intersurgical product)
	Lip Protector	Balm or ointment	<ul style="list-style-type: none"> Lip integrity; symptom relief Atmospheric barrier 	No examples identified in sample
		Petrolatum		
	Oral moisturizers	Gel or cream moisturizer	<ul style="list-style-type: none"> Oral tissue hydration (i.e., mucous membranes, tongue, etc.) Symptom relief (dryness) 	Toothette® Mouth Moisturizer (Sage product)
		Spray moisturizer		
Devices/tools	Suction tools	Hard catheters	<ul style="list-style-type: none"> “Yankauer” Removal of oral secretions Prevention of 	BALLARD* Turbo-Cleaning Closed Suction System (Avanos product)
		Flexible catheters		

			aspiration	
	Swabs	Disposable swabs	<ul style="list-style-type: none">• Oral application of liquids, gels, moisturizers and antiseptics• Oral-dental cleaning	Toothette® Plus Swabs – Untreated (Sage product)
		Suction swabs		DenTips® Oral Swabsticks (Medline product)
	Tooth brushes	Manual tooth brush	<ul style="list-style-type: none">• Debridement of plaque/biofilm• Tongue cleaning	Orocare™ Aspire suction toothbrush (Intersurgical product)
		Manual suction brush		
		Power brush		Toothette® suction toothbrush
	Oral hygiene kits	Single use kit	<ul style="list-style-type: none">• Composite tool set	Assisted Care 24 Hour Oral Care Kits (Avanos product)
		Multi-hour kit		OroCare™ 24-hr day kit – q4 (Intersurgical product) Q•Care® Oral Cleaning and Suction System q2 (Sage product) 24-Hour Oral Care Bag Kit (Medline product)
	Bite block	Bite block	<ul style="list-style-type: none">• Prevention of biting• Mouth opening; prevention of mouth closure	No examples identified in sample
		Oral prop		