Q2 Evidence Profile

Recommendation Question 2: Should an oral care protocol be recommended to improve outcomes for persons and health providers?

Population: Adults 18 years of age and older
Intervention: Oral care protocol
Comparison: No oral care protocol
Outcomes: Ventilator-associated pneumonia, hospital-acquired pneumonia, knowledge and confidence of health providers in ability to assess changes in oral health status
Setting: Health service organizations and academic settings
Bibliography: 102, 1431, 2336, 2507, 2549, 3138, Mori et al. (2006)

Quality assessment							Study Details		No. of participants		Summary of Findings	Certainty	References
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Oral Care Protocol	Intervention	Control	Reported effects/ Outcomes		
Knowledge and confidence of health providers in ability to assess changes in oral health status (assessed with: Carer Activation Measure [CAM]) (Follow up: 6 months from baseline)													
1	Quasi-Experimental	Serious [a]	Not serious	Not serious [b]	Serious [c]	None	Australia	Health providers participated in a training program led by a dentist specialized in caring for individuals with special needs. The training program educated health providers on the implementation of an oral care protocol which included: completion of an oral health assessment using modified Oral Health Assessment Tool (OHAT), development of an oral care plan, providing oral health care as per the plan (e.g., tooth brushing, denture care) and assessing the need for a dental referral.	N=16 Mean CAM: *pre-training* = 50.9 (6.1) *Post-training* = 57.1 (5.7), p<0.001, effect size = 1.22 Mean CAM-Knowledge: *pre-training* = 14.4 (2.3) *Post-training*= 17.4 (1.9), p< 0.001, effect size = 1.43 Mean CAM-Confidence: *pre-training* = 23.4 (3.5) *Post-training*= 26.1 (3.0), p <0.003, effect size = 0.89 Mean CAM-Skill: *pre- training* = 13.1 (1.5) *Post-training*= 13.6 (1.3), p<0.261, effect size = 0.29	No comparator	An increase in the mean score of the Carer Activation Measure was seen overall after health provider training. Specifically, significant increases were seen for the knowledge domain and the confidence domain. Although the skill domain was not significant, scores were trending up.	⊕⊕◯◯ Low	3138: Pradhan, Keuskamp & Brennan (2016)
Aspiration													

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№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Oral Care Protocol	Intervention	Control	Reported effects/ Outcomes		
-	None	-	-	-	-	-	-	-				-	-
SURROGATE OUTCOME: Ventilator Associated Pneumonia (assessed with: Clinical Pulmonary Infection Score (CPIS) Criteria; Diagnostic Criteria of the CDC and confirmed by a pulmonologist) (Follow up: 3 days – 1 year)													
1	RCT	Very serious [d]	Not serious	Serious [e]	Serious [f]	None	Iran	*Intervention:* The protocol included: the use of the Beck Oral Assessment Scale (BOAS) to determine oral health and frequency of oral care. Nurses also had to: ensure the endotracheal tube cuff pressure was set at 25 mmHg, internal and external surfaces of teeth were brushed using rotational motion from top to bottom, teeth were rinsed with normal saline and mouth suctioning performed for 30s, teeth, gum, tongue and mucosa were sprayed with a syringe containing 5cc of chlorhexidine 0.2%, and then mouth and lips were moistened. *Control:* Routine oral care (brushing teeth with toothpaste once a day, washing mouth with chlorohexidine 0.2% twice a day)	N = 50 ***Mean incidence rate of pneumonia:*** Day 3: 3.9 (1.12) 2/50 participants (4%) Day 5: 4.68 (1.44) 5/50 participants (10%)	N = 50 ***Mean incidence rate of pneumonia*:** Day 3: 4.06 (1.3) 5/50 participants (10%) Day 5: 5.06 (1.8) 7/50 participants (14%)	For every 1000 people who received the oral health protocol, 4 fewer people developed VAP at day 5 of the protocol (ranges from 20 fewer people to 12 more people based on 95% confidence intervals).	⊕◯◯◯ Very Low	102: Haghighi, Shafipour, Bagheri-Nesami, Gholipour Baradari, Yazdani Charati (2017)
4	Quasi-experimental	Serious [g]	Not serious	Serious [h]	Not serious	None	1431: China 2507: United States of America 2549: United States of	1431: An oral care protocol was implemented which included: (1) checking endotracheal tube cuff pressure (20–24mmHg) every 8 hours and according to the Oral Assessment Guide (OAG); (2) mouth care	1431: N=99 *No VAP:* n=95/99 = 96% vs. *Yes VAP*: n=4/99 =4.0% 2507:	1431: N= 100 *No VAP:* n=82/100 = 82% vs. *Yes VAP:* n=18/100 18% 2507:	All three studies showed a decrease in VAP rates. In Liao et al. (2014), for every 1000 people who received the oral care protocol, 13 fewer people would develop VAP. (ranges from 33 fewer people to 6	⊕⊕◯◯ Low	1431: Liao, Tsai, & Chou (2014) 2507: Conley, McKinsey, Graff, & Ramsey (2013)

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							America Mori et al. (2006) as cited in 2724: Japan	performed at least 5 min in each session; (3) 0.2% chlorhexidine (15–20 mL) was used with a soft children's toothbrush; and (4) patients placed in semi-recumbent positions (positions of HOB were more than 30◦). 2507: Nurses were educated on how to perform the protocol. The protocol included: gathering of oral health supplies; performing a nursing assessment of patient's tongue, oral mucosa, teeth, and lips; brushing teeth, tongue and oral mucosa for 1-2 min; suction (if necessary); CHG solution 0.12% to oral cavity and tongue with oral sponge swabs 30-60sec after brushing and suction excess; for dentures: remove and clean with denture-cleaning tabs, swab oral cavity and tongue with CHG solution 0.12%, and suction. The nurses were then expected to document completion of the protocol. 2549: An oral care protocol was implemented by nurse specialists and registered dental hygienist (RDH). The protocol included: (1) a bedside oral exam (BOE) which determined the frequency of oral care and	N=75 VAP Rate of 1.1 per 1,0000 ventilator days at 12-month follow-up and one year after study ended (protocol continued) there was 0 VAP over 218 ventilator days 2549: N = Not reported Mori et al. (2006) as cited in 2724: N=1248 Episodes of VAP per 1000 ventilator days: 3.9	National Health and Safety Network (NHSN) report for 2009 reported a rate of 1.5 per 1,000 ventilator days. 2549: N= Not reported Mori et al. (2006) as cited in 2724: N = 414 (historical controls) Episodes of VAP per 1000 ventilator days: 10.4	more people based on the confidence intervals) (1431). Study 2507 did not demonstrate a significant difference in VAP rates when intervention results were compared to 2009 NHSN reports in VAP rates, but there was a decrease. In study 2549, there was a decrease in VAP rates after protocol implementation from 4.21 per 1000 ventilator days in 2011 to 2.1 per 1000 ventilator days in 2012 (p = 0.04). In Mori et al. (2006) as cited in Hilier et al. (2013), episodes of VAP in the intervention group were 3.9 per 1000 ventilator days, compared to 10.4 per 1000 ventilator days in the control group (p < 0.001). There was a 3.96% less risk of developing VAP in the intervention group (ranges from (2.2% less risk to 6.2% more risk based on 95% confidence intervals).		2549: Prendergast, Kleiman, & King (2013) Mori et al., (2006) as cited in 2724: Hilier, Wilson, Chamberlain & King (2013)

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								whether the use of an oral rinse was necessary; (2) tooth brushing or mucosal care, incl tongue scraper, electric toothbrush, oral moisturizer; (3) list of oral care supplies; and (4) denture care. Staff received laminated double sided handouts illustrating and detailing information about oral assessment and protocol. Mori et al. (2006) as cited in 2724: In the study, a multi-component oral care protocol was implemented which consisted of: (1) adjustment of tracheal tube pressure to 100 mmHg and suctioning; (2) positioning patient's head to the side, opening their mouth and performing an oral assessment of the soft and hard tissues; (3) oral rinse with diluted povidone-iodine; (4) toothbrushing and rinsing with weakly acidic water; (5) repeat cleansing using swab soaked in 20-fold diluted poviodine-iodine gargle; (6) suctioning. This was performed three times daily or once per nursing shift (Mori et al., 2006).					
SURROGATE OUTCOME: Hospital Acquired Pneumonia (assessed with: AMMI Canada Guidelines – chest x-ray + 2 of WBC count, pyrexia, positive sputum culture) (Follow up: study occurred over 6 months)													
1	Quasi-experimental	Serious [i]	Not serious	Not serious [j]	Serious [k]	None	Canada	Patients were provided with oral care kits, and nurses were trained on mouth assessments, toothbrushing and swabbing with toothbrushes and swabs	N = 32 Number of HAP events = 2/32 patients over 6 mths (6.3%)	N (retrospective data) = 51 Number of HAP events = 13/51 over 6 mths	For every 1000 people who received the protocol intervention, 19 fewer people developed HAP over 6 months (ranges from 57 fewer people to 18 more people based on 95% confidence	⊕◯◯◯ Very low	2336: Robertson & Carter (2013)

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								impregnated with sodium bicarbonate, oral rinsing with 1.5% hydrogen peroxide solution, and mouth and/or tracheostomy suctioning.		(25.5%)	intervals).		

CI: Confidence interval

Explanations

a. There was no control of the confounding variables, either with a statistical analysis or randomization. Despite visits by the dental hygienist to reinforce oral care that carers were providing, 61% of participants dropped out of the study; thus, deviations from intended interventions is likely. Moreover, the reliability and validity of the CAM was not assessed, and the post-CAM results could have been influenced by knowledge of the training intervention. Downgraded by 1.

b. Although the intervention and outcome was relevant to the PICO question, the specific carer characteristics (e.g., type of provider, years of experience, etc.) was not provided Moreover, the population of patients in the included studies were those with advanced airways or at risk of aspiration. Therefore, the results may not be generalizable to all patient populations. . Downgrade by 1.5

c. Only 16 carers were included in the analysis of the data, which is less than the optimal 400 participants. Downgrade by 1.

d. High risk of bias suspected due to deviations from intended intervention. Downgraded by 1 for study design.

e. The population of patients in the included studies were those with advanced airways or at risk of aspiration. Therefore, the results may not be generalizable to all patient populations.. Furthermore, surrogate outcome was used. Downgrade by 2 for indirectness.

f. Less than 300 participants. Downgrade by 1 for imprecision.

g. Moderate to critical risk of confounding bias with little to no appropriate analysis. Furthermore. Downgrade by 1 for risk of bias.

h. Study 2549 provided no information about population, and there was a slight difference in interventions. Moreover, the population of patients in the included studies were those with advanced airways or at risk of aspiration. Therefore, the results may not be generalizable to all patient populations. Downgrade by 2 for indirectness.

i. There were serious concerns of the confounding variables , moderate concerns for deviations from the intended interventions. Downgrade by 1.

j. The population of patients in the included studies were those with advanced airways or at risk of aspiration. Therefore, the results may not be generalizable to all patient populations. Moreover, a surrogate outcome was required because there were no studies identified that measured aspiration risk as an outcome of interest. Downgrade by 1.5.

k. There were only 83 participants across the three studies, which is less than the optimal 400. Downgrade by 1.5.