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Title: Implementing Selective Digestive Tract Decontamination in the intensive care unit: A qualitative analysis of nurse-identified considerations

Abstract

Objective: To describe factors senior critical care nurses identify as being important to address when introducing Selective Digestive Tract Decontamination (SDD) in the clinical setting.

Background: Critically ill patients are at risk of developing ventilator-associated pneumonia (VAP). SDD is one strategy shown to prevent VAP and possibly improve survival in the critically ill.

Methods: We performed a secondary analysis of qualitative data obtained from 20 interviews. An inductive thematic analysis approach was applied to data obtained from senior critical care nurses during phase two of a multi-methods study.

Results: There were four primary considerations identified that should be addressed or considered prior to implementation of SDD. These considerations included education of health care professionals, patient comfort, compatibility of SDD with existing practices, and cost.

Conclusions: Despite a lack of experience with, or knowledge of SDD, nurses were able to articulate factors that may influence its implementation and delivery. Organizations or

researchers considering implementation of SDD should include nurses as key members of the implementation team.

Key Words: antibiotic prophylaxis, critical illness, implementation, selective decontamination of the digestive tract, ventilator-associated pneumonia

Introduction

Critically ill patients are at risk of developing infectious complications [1] because of increased severity of illness, poor nutritional status [2] and the need for invasive devices. More than half of patients admitted to an intensive care unit (ICU) will develop an infection, the majority (80%) of which are endogenous infections caused by oropharyngeal or digestive tract microflora present on admission. [3] The most common infection acquired in the ICU is ventilator-associated pneumonia (VAP) with at least a quarter of all ICU patients affected. [4] The impact of VAP on patient outcomes is substantial. VAP is associated with prolonged length of ventilation, increased ICU and hospital stay, greater costs, and higher mortality. [5]

Selective Digestive Tract Decontamination (SDD) is a prophylactic strategy which aims to reduce infections and improve mortality in critically ill patients by eradicating potentially pathogenic microorganisms in the oropharynx and digestive tract. [6] SDD is a four stage process which includes: 1) a four day course of parenteral antibiotics to control potentially pathogenic microorganisms present on admission; 2) administration of non-absorbable antimicrobials (normally polymyxin E, tobramycin and amphotericin B) to the oral cavity and gastrointestinal tract; 3) continuation of standard hygiene measures to control exogenous infections; and 4) cultures of the throat and rectum on admission and then twice weekly to assess the efficacy of SDD and identify emergence of resistant bacteria. [7,8]

SDD, when fully implemented, has been shown to prevent VAP and, in some studies, improve survival. [9,10] The effectiveness of SDD has been demonstrated in numerous randomized controlled trials with results showing that SDD significantly reduces Gram-negative microorganisms in the oropharyngeal cavity [11] and reduces lower airway infections by 72%. [12] Although a 2006 meta-analysis of 36 randomized controlled trials did not find

evidence of antimicrobial resistance, [13] the use of SDD in clinical practice remains low because of the perception that this strategy will increase the development of resistant bacteria. Much of the SDD research has been conducted in Europe and in clinical environments with already low rates of resistant bacteria such as methicillin-resistant *Staphylococcus Aureus.* [14] Consequently clinicians who work in environments where resistant bacteria are present question the applicability of these data to their clinical context.

While there are divergent views on the use of SDD as a strategy to prevent the development of VAP, there is strong evidence that SDD significantly reduces the number of lower respiratory tract infections and mortality. [15] Recommendations to consider using SDD for patients ventilated for more than 48 hours has been included in the VAP prevention guidelines produced by The British Society for Antimicrobial Chemotherapy [16] and more recently in the Surviving Sepsis Campaign Guidelines. [17] It is likely with the growing body of evidence for SDD, and its inclusion within well-respected and implemented clinical guidelines, that nurses will soon be required to deliver SDD medications to critically ill patients. However, most critical care nurses are unfamiliar with SDD as a strategy to prevent infections in the critically ill. With a large international clinical trial planned and the inclusion of SDD as a recommendation within the most recent Surviving Sepsis Campaign Guidelines, [17] it is likely that SDD as a strategy to prevent infection may be introduced more widely into practice.

To explore why SDD has not been widely adopted in clinical practice we undertook a program of research to describe barriers to SDD implementation and identify what further evidence is required before full scale clinical implementation would be considered appropriate and feasible has been completed. [18] The, multi-methods study was undertaken in Canada, the United Kingdom (UK) and Australia/New Zealand (ANZ) from 2010-2012 to

develop an understanding of issues related to current lack of adoption of SDD and considerations for its implementation into clinical practice. The full study protocol has been published elsewhere. [18,19] Stage 2 of this research program was a Delphi study to identify the range of stakeholders' beliefs, views and perceived barriers relating to the use of SDD. The aim of this paper is to describe factors senior critical care nurses identified during the first Delphi as being important to address when introducing SDD in the clinical setting.

Methods

The Delphi technique was used to identify participant's self-reported knowledge of SDD as well as their beliefs, views and perceived barriers to adoption and implementation of SDD. The Delphi technique uses a structured, iterative process including anonymised feedback, in a series of sequential questionnaires or 'rounds'. We used the Delphi technique to assess levels of agreement on SDD within an expert group. [20, 21] The first Delphi round comprised semi-structured qualitative interviews with the interview topic guide based on the Theoretical Domains Framework [22] of clinical behavior change. The interview topic guide incorporated questions to elicit participants' views on the conduct and design of SDD research (Table 1).

One hundred and forty one participants completed the first Delphi round. Ethics approval was obtained from relevant institutional review boards and each participant gave informed consent prior to the conduct of the interviews.

The sub study of senior nurse participants

We conducted a secondary analysis of qualitative data collected from nurse participants during the first Delphi round. [18] This secondary analysis allowed us to explore in more detail factors senior critical care nurses identified as being important to address when introducing SDD in the clinical setting, which was not a specific focus of the first Delphi round. We

included data from all nurse participants (n=20), a sample size that is similar to that reported for other secondary analyses of qualitative data. [23] The majority of participants were female (85%; n=17) and worked in a tertiary level ICU (80%; n=16). The mean length of ICU experience was 22.1 years. (Table 2). All nurse participants were employed in management or educational leadership roles and were responsible for implementing practice change within the ICU.

We specifically analysed a subset of interviews from nurse participants in order to focus on a an aspect of the data which was not specifically addressed in the primary study and to specifically analyse data from one participant group who had shared characteristics that distinguished them from the larger sample. [23] This secondary analysis of the data allowed us to explore issues nurse participants identified as important for the implementation of SDD.

Data collection

During the first Delphi round research teams in each geographical region conducted interviews by telephone. Interviews lasted 20 to 60 minutes and were recorded and transcribed verbatim. All identifying information was removed to maintain privacy and confidentiality.

Data analysis

In conducting this secondary analysis we employed an inductive approach [24] where detailed readings of the raw data allowed for open coding, categorisation and abstraction of specific concepts and themes. [25] Although the interview guide was informed by the Theoretical Domains Framework, [22] we did not use this framework in our analytic approach and instead allowed the themes to emerge from the interview data. Interviews were read multiple times by three authors (AM, LW, LR) who each independently open coded the data.

Through discussion a consensus approach to abstraction allowed for identification of themes. Data were coded into themes using NVivo 9 software (QSR International, Doncaster, Australia).

Results

Nurse participants identified a number of factors they believed might impact the implementation of SDD in the clinical setting. Lack of knowledge about SDD was identified as an important barrier that would need to be addressed prior to implementing SDD in practice. Additional factors identified and thematically grouped were risk to the patient, the impact of SDD on nursing practice and the impact of SDD on the organization.

Knowledge

Of the 20 nurse participants, 15 were aware of SDD as an approach to prevent VAP. The level of SDD knowledge amongst participants was variable and only two participants explicitly referred to research about SDD. Four participants had experience in administering SDD although most reported a lack of SDD knowledge as being common amongst their colleagues. There were misconceptions regarding the rationale for SDD including the belief that SDD was used to "prevent gut-related infections" (UK4501) or used as "a bowel and gastric stimulant to…expedite the flow or the processes within the gastric system" (CA9). A distinction between SDD and the use of chlorhexidine for mouth care was not clear with some participants identifying chlorhexidine as a strategy to decontaminate the oral cavity.

Knowledge of the link between SDD and VAP prevention was not clearly articulated. Nevertheless, understanding the rationale underpinning clinical practice was perceived as important with one participant commenting that nurses like "to know why they're doing things…". (CA37)

Risks to the patient

All participants expressed concern about the potential for SDD to cause increased bacterial resistance. The participants were also concerned about the possible impact of SDD such as the possibility of the paste "staining the teeth" or a long term effect on tooth enamel (CA2). Adverse events, such as aspiration of oral paste or endotracheal tube dislodgement during paste application, were concerns particularly if the patient actively resisted paste application.

The potential discomfort for patients receiving SDD as a treatment was a key consideration for most nurse participants. The oral component was identified as the one aspect of SDD that had the potential to negatively impact patient comfort, with the application of paste to the oral cavity potentially uncomfortable and the taste of the oral paste unpleasant (CA22).

The risk of diarrhea was also a significant concern for most participants with a perception that SDD might make patients more susceptible to *Clostridium difficile* because "… you're potentially knocking out the flora in their gut, in which case they can get *Clostridium*, especially if they've had it before." (CA37) Diarrhea associated with SDD could contribute to the development of further complications such as perianal excoriation. If the diarrhea was significant then fecal management systems might be used which in turn might have longer-term consequences for patients.

Impact on nursing practice

Concern was raised that the number of care improvement initiatives currently in place left little scope for the introduction of a new practice as "people are saturated [but have] limited resources" and "there is so much in our face that we can't see the wood through the trees."

(ANZ212). However, the process of SDD administration was not viewed as challenging although some participants were conscious of the amount of time required to administer all SDD components and recognised that this might impact on nursing workload.

The impact of SDD on other aspects of nursing care was a consideration for some. Regular mouth care was viewed as fundamental for elimination of dental plaque and prevention of VAP. The concern that implementation of SDD might result in regular mouth care being over looked prompted the suggestion that there would need to be "a lot of work to ensure that mouth care is still of a very high standard and it [SDD] is not *instead* of mouth care" (UK1804).

The compatibility of SDD and enteral nutrition was raised as a potential factor that could influence the implementation of SDD with one participant suggesting SDD might be a possible "competing priority" (CA9) with enteral feeding. In addition, concerns were raised that food in the stomach might interfere with the SDD antibiotics. Participants also raised the issue of feed tolerance for some, but not all, critically ill patients and queried whether the gastric component of SDD administration was feasible in patients with intolerance to enteral feeds. For those patients where small bowel feeding was required for nutritional therapy, the ability to administer the gastric component of SDD was questioned if a nasogastric tube did not remain in place.

Impact on the organization

Participants perceived the most significant impact on the organization was the potential cost of SDD because "money is really tight" (CA31). This was a particular concern as many of the nurse participants were responsible for day-to-day management of ICU budgets and "the ones who pay for all the supplies and medications" (CA22). Additional costs associated with laboratory tests required for surveillance screening were considered a further economic

impost, especially for those ICUs where routine screening was not in place (ANZ 206). As few ICUs delivered SDD, the need for additional resources to educate nurses in the use of SDD was also identified.

A need for balance between costs and perceived benefit was highlighted and it was questioned whether VAP rates were sufficiently high to warrant the introduction of SDD. When other strategies were already established in practice and likely to be cheaper it was suggested that "you should address the more cost effective, simpler approaches first" (ANZ 201). However SDD implementation was also considered an economically sensible option if it resulted in improved outcomes for the patient and organization.

Discussion

Nurses knowledge and exposure to SDD

SDD is one strategy shown to reduce VAP rates and mortality in critically ill, ventilated patients [27] but is not widely practiced [28,29] outside the European context. [30,31] So it is not surprising that few participants in this study had direct experience with SDD and this likely explains the variability in participants' knowledge. Existing VAP guidelines refer to SDD as a treatment strategy, [32,33,34] however, familiarity with, and increased exposure to, SDD is likely to increase now that it has been included in the most recent Surviving Sepsis Campaign Guidelines. [17] Theoretical knowledge is an important component in the implementation of evidence-based practice [22] and for nurses both knowledge of the evidence and procedural knowledge are important for implementation of SDD.

In the process of supporting nurses to develop theoretical knowledge, it is important to focus on the distinction between decontamination of the oropharynx with the use of topical, non-absorbable antibiotics that feature as a component of SDD [12] with the use of

chlorhexidine as an antiseptic [35, 36] used in routine mouthcare. This will be particularly important for countries where the use of cholorhexidine is more widespread as a result of patient safety initiatives [26] that recommend oral decontamination with chlorhexidine is a key component of their VAP bundle.

Patient safety and comfort issues with SDD

Addressing concerns related to patient safety and comfort should be included in any implementation plan. All participants expressed concern regarding the potential for development of antibiotic resistance and, although debated, similar concerns are described in the literature and these concerns likely to contribute to low SDD adoption rates. [30, 37, 38] There is limited evidence regarding SDD and acquisition of resistant organisms [39] and further research in this area is warranted.

The potential for the antibiotic paste to stain the teeth or impact tooth enamel was highlighted as having potential to negatively impact the patient. The antibiotic paste used in the oral component of the SDD regimen contains polymyxin E, tobramycin and amphotericin B [12] which are not routinely administered orally because of poor oral absorption. Consequently, little is known about the effect these medications have on the oral cavity or tooth enamel.

Application of antibiotic paste to the oral cavity was considered potentially unpleasant for patients although one participant suggested very few patients refuse the treatment. Nurses who have administered SDD report that as many as 56% of non-sedated patients found application of paste to the oropharyngeal cavity bothersome and almost half (46%) of patients disliked the flavour of the oral paste. [40] There are no data available describing patients' perception of SDD administration highlighting a potential area for further research.

The risk of diarrhea as the result of SDD administration was a concern. There are few reports of increased rates of diarrhea in patients receiving SDD. One small study of severely burned children (n=23) receiving SDD reported higher rates of diarrhea in the SDD group (P=0.003) [41] and diarrhea caused by *Clostridium difficile* is uncommon and identified in fewer than 0.5% of patients receiving SDD. [9]

Issues for nursing practice

How the use of SDD might impact existing nursing practice was an important consideration. Mouth care is a well-established and important aspect of nursing practice [42] shown to reduce plaque biofilm, a known source of infection. [43] Some participants were concerned that the oral component of SDD might inadvertently lead to a decreased provision of mouth care. This emphasizes the need for a SDD implementation plan to clearly articulate the importance of maintaining regular mouth care practices. Such regular mouth care practice might include the use of chlorhexidine [26] and some participants questioned the potential for interactions between chlorhexidine and the oral paste used in SDD. The lack of data to address this concern highlights an important area for further research.

Administering SDD to patients receiving enteral nutrition was an area of practice requiring further clarification. One issue was the potential interaction between feeds and the enteral component of SDD which might increase, decrease or delay the bio-availability of antibiotics, however absorption of antibiotics is not intended with SDD. [3] The volume of the enteral component of SDD (10 mL suspension) [6] was a further consideration, particularly in relation to feeding tolerance however the total daily volume of enteral SDD delivered is 40 mL and would not significantly contribute to feeding intolerance. Current SDD protocols describe administration of the enteral component of SDD via a nasogastric tube [1,9] with no

recommendations for enteral SDD delivery to patients receiving small bowel feeding without a nasogastric tube in situ.

The perception of an increased nursing workload associated with SDD is consistent with reports in the literature. [6,40] In the context of a group-randomized, controlled, cross-over multicenter study of SDD, the estimated median time to deliver the full SDD protocol was five minutes, two minutes longer than either standard oral care or selective oral decontamination alone. With administration recommended four times per day [12] the introduction of SDD could potentially impact existing nursing workload, though not appreciably. However, many participants described feeling burdened by the implementation and monitoring of new practices in ICU and the capacity to absorb more change. Implementing practice change requires significant effort and needs to be appropriately resourced to be successful. [44] The introduction of SDD would require a significant educational component for nurses and their colleagues and this can be resource intensive.

The financial burden of SDD, including the medications, microbiological surveillance and increased nursing workload, is an important consideration when financial resources are already stretched. Estimated costs of SDD have been reported at 10€ or $13 USD per day [12] and in patients undergoing liver transplantation estimated at $3100 USD (1997) per patient, inclusive of medication and surveillance cultures. [45] However actual costs are not clearly described and likely to differ by region and product availability. The true cost associated with SDD implementation is unknown but cost concerns should be balanced against savings associated with a reduction in healthcare-associated infections. [6, 46-49] The need for more complete and transparent economic analyses of SDD is required particularly as costs will differ by region.

Limitations

The study contains certain limitations. Although we interviewed 141 participants in the parent study, this secondary analysis includes data from only 20 of these participants, all of whom were critical care nurses in leadership positions. The selection of interview data only from critical care nurses may have overlooked additional factors important to nursing practice identified by other members of the interprofessional team. In the first round of the Delphi study we purposefully selected nurse leaders who were positioned to contribute to decision making within the ICU and therefore did not accommodate the views of nurses directly responsible for SDD administration. While most of the nurse participants in this study had an awareness of SDD, only four had previous experience with its administration; therefore, the degree to which the issues identified in this study truly reflect the concerns of critical care nurses who are more familiar with SDD administration is unknown.

Implications for future research

Most of the research to date has focused on the clinical effectiveness of SDD as a treatment. There is an opportunity to add to the body of SDD literature by drawing attention to how such a treatment might influence patient comfort and safety. In future clinical trials of SDD there are opportunities for nurse researchers to concurrently examine such issues including the incidence of diarrhea in patients receiving SDD, the effect of SDD paste on tooth enamel, and patient experience of administration of the SDD oral component. The interaction of existing mouthcare solutions, such as chlorhexidine, with the SDD oral paste also requires further research.

Conclusions

The implementation of SDD in clinical practice may increase as a result of the recent Surviving Sepsis Campaign Guidelines including a recommendation for this preventative strategy. Implementation of SDD as a strategy will require a comprehensive education

program for nurses unfamiliar with SDD and the development of an implementation plan which addresses risk to the patient, the impact of SDD on nursing practice and the impact of SDD on the organization.

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Table 1 Delivery of SDD to patients in the Intensive Care Unit: Delphi Round 1 Topic Guide

Domain	Core Question	Possible Prompts
Knowledge	In your view, what are the components of SDD?	What are the possible variations in these components?
	What are the components of SDD as they are delivered in your unit? *Do you know about the unit SDD protocol?*	*What does the protocol say?*
General*	Is SDD delivered in your ICU?	What would you say is the main reason?
Motivation and goals	How important is the issue of SDD for you?	How does it fit with other priorities in the ICU? Is its priority for you related to your assessment of the evidence?
Professional role and identity	Do you sense whether there is general consensus in your profession about SDD?	What is the range of views?
		How does SDD fit with your own professional standards?
Emotion	Does anyone you work with have strong feelings about SDD?	(If Yes) Have you got a sense why they feel strongly about SDD?
Social influences	Would you say that your opinion on providing SDD has been influenced by your colleagues?	(If Yes) In what way? (If No) Why not?
Behavioral regulation	What else are you doing to prevent new infections in your unit? What would need to happen in order to adopt SDD in your Unit?	How would implementation of the protocol be monitored? If the decision was not to adopt SDD, what alternative procedures might you use instead?
	How is implementation of the SDD protocol monitored?	*Are there procedures or ways of working that make it easier or more efficient to deliver SDD?*
Beliefs about consequences	What would be *(are)* the benefits and downsides, of delivering SDD over and above what you are doing now?	What about the bigger picture. What might be the short/medium-term benefits and downsides compared to longer term consequences? Are there consequences of using SDD in ICU that may affect other patients in the ICU or hospital?
Skills	Are there any specific skills	Do you think members of your profession have

	needed for delivering SDD?	these skills? (In other words, would training be needed to deliver SDD?)
Nature of the Behavior	How difficult would SDD be in comparison to what you are doing already?	Do you think the complexity is an important barrier to adoption?
	Are the behaviors that make up SDD performed often enough to become routine?	*Is SDD well embedded within the daily routines of the unit?*
Environmental context and resources	What additional resources would *(does)* your Unit need in order to deliver SDD?	Any other resources?
		To what extent is the delivery of SDD influenced by physical or resource factors?
Beliefs about capabilities	How much influence do you personally have over whether or not your Unit adopts SDD?	Do you have responsibility for instigating changes?
	How difficult or easy is it for you to do the things that you are required to do as part of SDD delivery?	*What problems have you encountered? What would help them?*
Decision processes	How would you go about seeking agreement among your colleagues about whether or not to adopt SDD in your Unit?	How about individual clinical decisions - What would you consider when making the clinical decision whether or not to administer SDD to an individual? In which patient groups would you **not** administer SDD?
	What would you consider when making the clinical decision to administer SDD to an individual?	*In which patient groups would you **not** administer SDD?*
Further research	Do you think that further research would settle some of the issues surrounding SDD?	What type of research study do you think would be most informative for the future of SDD practice? Is further research ethical? Why? Or why not?
<u>Secondary focus 1</u>: Participation in an effectiveness trial	The purpose of this study is not to recruit you to a trial but if there was a study which randomised patients to a SDD group against a no-SDD control group would you be willing to recruit patients?	Why? Or why not?
<u>Secondary focus 2</u>: Participation in an implementation trial	If there was a study whose aim was to increase adoption of SDD in ICUs nationwide would you be willing to participate?	Why? Or why not?

Other	Is there anything else that you want to say that you haven't mentioned yet?	What do you think is the current state of the evidence about SDD? Any other ethical matters?
Diversity questions:	What ICU do you work in? How many beds are there in the ICU? How many years' experience do you have (within ICU/professional)?	

*For those units who do not deliver SDD

Italicised font depicts those questions modified for participants whose ICU delivers SDD.

Table 2 Participant details (n=20)

	ANZ (n=6)	Canada (n=8)	UK (n=6)
Female (n)	5	6	5
Median Age (IQR)	47 (38-51)	48 (47-52)	48 (45-49)
Working in a tertiary ICU (n)	4	4	8
Median (IQR) length of ICU experience (years)	24 (15-26)	20.1 (8.4)	23 (20-26)

ANZ – Australia and New Zealand

UK – United Kingdom

IQR – Interquartile range