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Citation: Dombrowski, S. U., Prior, M. E., Duncan, E. M., Cuthbertson, B. H., Bellingan, G., Campbell, M. K., Rose, L., Binning, A. R., Gordon, A. C., Wilson, P., Shulman, R. and Francis, J. (2013). Clinical components and associated behavioural aspects of a complex healthcare intervention: Multi-methods study of selective decontamination of the digestive tract in critical care. *Australian Critical Care*, 26(4), pp. 173-179. doi: 10.1016/j.aucc.2013.04.002

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Article:	Clinical components and associated behavioural aspects of a complex healthcare intervention: Multi-methods study of selective decontamination of the digestive tract in critical care
Corresponding author:	Professor Jill J Francis
E-mail address:	Jill.Francis.1@city.ac.uk
Journal:	Australian Critical Care
Our reference:	AUCC203
PII:	S1036-7314(13)00122-7
DOI:	10.1016/j.aucc.2013.04.002

Correspondence to:

Professor Jill J Francis
 School of Health Sciences
 Room C332 Tait Building
 City University London
 Northampton Square
 England EC1V 0HB, UK
Jill.Francis.1@city.ac.uk

Clinical components and associated behavioural aspects of a complex healthcare intervention: Multi-methods study of selective decontamination of the digestive tract in critical care

Running title: Clinical components and behaviours for SDD

Stephan U. Dombrowski, PhD¹; Maria E. Prior, PhD²; Eilidh Duncan, PhD³; Brian H. Cuthbertson, MD⁴; Geoff Bellingan, MD⁵; M. K. Campbell, PhD⁶; L. Rose, PhD⁷; Alexander R. Binning, MB ChB⁸; Anthony C. Gordon, MD⁹; P. Wilson, MD¹⁰; Rob Shulman, DHC(Pharm)¹¹ Jill J. Francis PhD¹² and the SuDDICU UK study group

1. Research Associate, Newcastle University, Newcastle upon Tyne, UK.
2. Research Fellow, University of Aberdeen, Aberdeen, UK.
3. Research Fellow, University of Aberdeen, Aberdeen, UK.
4. Professor and critical care specialist, Sunnybrook Health Sciences Centre, Toronto, Canada.
5. Director of Intensive Care Unit, University College Hospital London, London, UK.
6. Director of Health Services Research Unit. University of Aberdeen, Aberdeen, UK.
7. Associate Professor of critical care nursing, University of Toronto, Toronto, Canada.
8. Consultant, Glasgow Western Infirmary, Glasgow, UK.
9. Senior Lecturer, Imperial College London, London, UK.
10. Senior Lecturer in Medical Microbiology, University College London, London, UK.
11. Lead Pharmacist – Critical Care, University College Hospital London, London, UK.
12. Professor of Health Services Research, City University London, UK.

Acknowledgments

We would like to thank all the clinical staff who provided their time and expertise by participating in this study. This project was funded by the UK National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. Visit the HTA programme website for more details www.hta.ac.uk/2299. ACG is a NIHR Clinician Scientists award holder, and is grateful for funding from the NIHR comprehensive Biomedical Research Centre funding stream. The Aberdeen Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Government Health Directorates. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Department of Health or the Scottish Government Health Directorates.

Authors' contributions

JJF and BHC designed the study. ARB and ACG assisted with recruitment of participants. SUD collected data. SUD and ED analysed the data. All authors provided critical comments on drafts of the analyses and contributed critically for important intellectual content to the manuscript. All authors read and approved the final manuscript and all those entitled to authorship are listed as authors.

Abstract

Background – This study sought to identify and describe the clinical and behavioural components (e.g. the what, how, when, where and by whom) of ‘selective decontamination of the digestive tract’ (SDD) as routinely implemented in the care of critically ill patients.

Methods – Multi-methods study, consisting of semi-structured observations of SDD delivery, interviews with clinicians and documentary analysis, conducted in two ICUs in the UK that routinely deliver SDD. Data were analysed within-site to describe clinical and behavioural SDD components and synthesised across-sites to describe SDD in context.

Results – SDD delivery involved multiple behaviours extending beyond administration of its clinical components. Not all behaviours were specified in relevant clinical documentation. Overall, SDD implementation and delivery included: *adoption* (i.e. whether to implement SDD), *operationalisation* (i.e. implementing SDD into practice), *provision* (i.e. delivery of SDD) and *surveillance* (i.e. monitoring the ecological effects). Implementation involved organisational, team and individual-level behaviours. Delivery was perceived as easy by individual staff, but displayed features of complexity (including multiple interrelated behaviours, staff and contexts).

Conclusions – This study is the first to formally outline the full spectrum of clinical *and* behavioural aspects of SDD. It identified points in the delivery process where complex behaviours occur and outlined how SDD can be interpreted and applied variably in practice. This comprehensive specification allows greater understanding of how this intervention could be implemented in units not currently using it, or replicated in research studies. It also identified strategies required to adopt SDD and to standardise its implementation.

Key words: behaviour, infection control, critical care

Introduction

Healthcare interventions are typically complex ¹ and involve two broad interacting categories of components: 1. *clinical components*, i.e., the clinical materials or equipment of the intervention and related features and 2. associated *behavioural aspects* i.e., the actual behaviours required to deliver the intervention in practice. Healthcare interventions are often specified clinically without explicitly addressing associated behavioural aspects required for successful delivery ^{2, 3}. Thus, interventions may be implemented differently across sites, potentially leading to variable effectiveness and resultant consequences for patient outcomes. The need to fully describe healthcare interventions has been widely recognised, together with the need to report interventions in such a way as they could be directly replicated by others ⁴.

Selective decontamination of the digestive tract (SDD) is an intervention that has been shown to reduce hospital acquired infection rates and mortality in critically ill patients⁵⁻⁷. SDD involves the application of antibiotics and antifungals to the mouth, throat and stomach combined with a short course of intravenous antibiotics ⁸. Despite considerable evidence supporting the benefit of SDD ⁵⁻⁷, adoption internationally is low ^{9, 10}. Amongst proposed reasons for this lack of adoption are controversies surrounding prophylactic use of antibiotics and associated risk of antibiotic resistance ^{11, 12} and purported difficulty of SDD implementation and delivery ¹³.

Considerable variation exists in the clinical components of SDD evaluated in trials and used in clinical practice. A recent systematic Cochrane review noted that trials used different SDD protocols and investigators use different definitions for SDD ⁶. In addition, behaviours related to the delivery of SDD have not been systematically described in the literature. As such, a standardised and fully specified protocol outlining both clinical components and associated behavioural aspects of SDD implementation and delivery in

practice does not exist but could be very beneficial in both widespread clinical adoption and future effectiveness or implementation trials.

This study sought to describe the clinical components and associated behaviours related to SDD implementation and delivery in clinical practice.

Methods

Study Design

An in-depth multi-methods study design ¹⁴ was used in two UK intensive care units (ICUs) where SDD was routinely administered - with the 'site' (unit of analysis) consisting of an ICU. Data were collected from three sources: direct observation of SDD delivery at the bedside; face-to-face semi-structured interviews with clinicians responsible for implementing and/or delivering SDD; and systematic assessment of written documentation (e.g., SDD protocols, training documents) (Figure 1).

Figure 1

Sampling and recruitment

All UK ICUs delivering SDD, identified from a recent national SDD survey ⁹, or known by the study investigators to deliver SDD were deemed eligible for inclusion (15 ICUs). Two ICUs were purposively selected to represent recent and more remote lengths of time since SDD adoption and different geographical locations (i.e. geographically dispersed ICUs to ensure different organisational profiles). For interviews we recruited a purposive sample of clinicians based on profession (i.e. intensivists, medical microbiologists, specialist clinical pharmacists and ICU nurses) and involvement in the implementation and/or delivery of SDD. This study was classified as service evaluation by the Research Ethics Committee

(10/MRE00/32) and was deemed by them not to require ethical approval. All participants observed and interviewed were aware of the study purpose and provided verbal consent prior to data collection.

Materials

Observations were conducted using an investigator-designed form to record all behaviours relating to ‘real time’ delivery of SDD. Additionally, the context (i.e. the physical environment where behaviours were performed), timing of procedures and physical presence of healthcare providers at time of delivery were recorded.

Semi-structured face-to-face clinician interviews were conducted in the study hospitals using a topic guide with pre-specified prompts to ensure consistent coverage of key issues including behaviours relating to SDD implementation and SDD delivery as well as barriers and facilitators of described behaviours.

Lastly, written documentation relating to SDD implementation and delivery (e.g. SDD protocols, training documents) were provided by the participating ICUs for systematic analysis.

Procedure

Data collection commenced with observation of SDD delivery performed by various ICU nurses to different patients at the bedside. Semi-structured interviews were conducted in parallel with observations. Observed nurses were included in the interview sample to gain an in-depth understanding of observed behaviours. With participants’ permission, interviews were audio-recorded, transcribed verbatim and anonymised. Written documentation from each ICU was examined following completion of all observations and interviews to minimise researcher bias during these stages.

Analysis

Data from the three sources were analysed *within-site* to describe the clinical components and behavioural aspects of delivery and synthesised *across-site* to identify emergent themes describing SDD implementation and delivery in context. The analytical process was guided by the study aims that included identification of the clinical components and behavioural aspects of SDD and exploration of the implementation and delivery of SDD in practice.

The three data sources were analysed separately and in reverse order to data collection (Figure 1). First, we systematically examined written documentation and extracted the clinical components and the associated behavioural aspects of SDD delivery. Clinical components were defined as the pharmaceutical regimens forming part of SDD including drug, dose, route, frequency and duration. Associated behavioural aspects were defined as any actions or behaviours that were/would be directly observable. We recorded the behaviours involved in delivering the clinical components and those not related specifically to drug administration. Second, we performed content analysis¹⁵ of interview transcripts to identify additional behaviours involved in SDD delivery (i.e., those not specified in the documents). Third, direct observations provided contextual ‘real time’ data¹⁴ and identified new and corroborative evidence on SDD clinical components and associated behavioural aspects, (i.e. data triangulation from multiple sources)¹⁴.

To identify features of SDD implementation and delivery across units, a thematic analysis of the interview data was conducted using a framework approach¹⁶. This involved coding the data for emergent themes relating to the behaviours and clinician groups involved. A single researcher (SUD) coded the data, a second researcher (ED) independently coded randomly selected portions of the dataset to identify clinical components and associated

behavioural aspects and three researchers (MP, JJF, LR) provided critical comments on analyses drafts.

Results

Site 1 implemented SDD 3.5 years prior to this study in response to increased hospital acquired infection rates and was the most recent adopter of SDD in the UK. Collected data comprised 4 observations; 8 interviews (intensivists [$n=3$], nurses [$n=3$], microbiologists [$n=1$], pharmacists [$n=1$]) and 3 SDD documents (protocol, prescription chart, training slides). Site 2 implemented SDD as part of an effectiveness trial 26 years prior to this study. Collected data comprised 3 observations; 8 interviews (intensivists [$n= 3$], nurses [$n= 3$], and pharmacists [$n= 2$]), and 1 document [protocol].

SDD Clinical Components and Associated Behavioural Aspects

Protocols documenting the specific clinical behaviours required for drug preparation and administration in the two ICUs are detailed in Table 1, demonstrating the degree of clinical complexity and also the variation encountered in clinical components of SDD. Documentation listed 9 different medications and a total of 13 different preparations as part of SDD in the two sites (Table 1). Several behaviours directly relevant for drug administration were identified in examined documentation.

Table 1

Aside from clinical components and associated behavioural aspects directly relevant to SDD delivery, documents from both sites revealed several additional delivery behaviours performed by multiple clinicians in various clinical and environmental contexts (Table 2). To complement understanding of associated behavioural aspects that are important in SDD delivery but not specifically mentioned in the examined documentation, Table 3 outlines

additional delivery behaviours identified through interviews and observations. Behaviours outlined in Table 2 and 3 were performed by various clinician groups (e.g. nurses, physicians, pharmacists) in a variety of clinical and environmental contexts (e.g. bedside, ICU nursing stations, pharmacy).

Tables 2 and 3

Participant interviews were provided most data relating to behavioural aspects; 49 components were identified through interviews, 22 in documentation and 12 via observations. Each data source gave rise to unique behaviours not mentioned in other sources, confirming the added value of analysing multiple information sources (28, 7 and 4 unique behavioural aspects for interviews, documentation and observations, respectively). Twenty-nine and 9 behavioural aspects, respectively, were unique to the two sites. Twenty-six behavioural aspects were common across ICUs, being identified in at least one data source for each site.

SDD Implementation and Delivery

Based on our analysis, SDD implementation and delivery was conceptualised as a complex procedure consisting of four overlapping processes each involving specific behaviours: *adoption*, *operationalisation*, *provision* and *surveillance*. *Adoption* concerned the decision to introduce SDD; *operationalisation* referred to the processes required to introduce SDD in to clinical practice. *SDD provision* included actions involved in delivery of the clinical components. *Surveillance*, mentioned in both sites, provided the foundation for adoption, operationalisation and provision by checking that SDD was effective in preventing infection.

Adoption & Operationalisation

For adoption, we identified that actions often occurred at the organisational and team level involving organisational and group processes as well as individual actions. As the implementation process moved from adoption to operationalisation, more behaviours emerged that were performed by individual staff (Tables 2 and 3). Although operationalisation was complete following SDD introduction, elements of operationalisation continued due to clinician staff turnover (e.g., although SDD was a standard procedure within the ICUs, the low national baseline adoption meant that additional training for clinicians new to these ICUs and SDD delivery was required).

Provision of SDD

Three themes emerged from the interviews on SDD provision: complexity/difficulty, protocol adaptation in practice and facilitators and barriers.

Complexity / difficulty

Reflecting the theme of complexity one intensivist and several nurses reported that SDD provision represented additional and time consuming work leading to unpopularity with staff. When examining the sequencing and flow of actions, we identified some evidence of complexity such as multiple clinicians being involved in managing various behaviours within multiple clinical and environmental contexts using a range of materials delivered in specific sequences in a continuing flow of action (see Box 1 for quotations). However, most nurses and doctors refuted the idea that SDD was complex and time consuming stating that SDD provision was performed effortlessly (see Box 1 for quotations). Low complexity / difficulty of SDD was supported by observational data that indicated administration of clinical components took no longer than 5 minutes, and often less, and was performed in a swift

sequence of actions. It is important to note, however, that these were highly practised actions and may require considerable skill development to achieve this high level of expertise.

Box 1

Protocol adaptation in practice

Protocol adaptation in SDD delivery was noted in observational and interview data. Preparation of antibiotics/antifungals varied suggesting some deviation from recommended practice. A further adaptation was evident in the provision of SDD oral components such as different ways of applying oral drug components and timing with other nursing interventions such as oral hygiene. Authorisation of SDD involved multiple staff and deviation from recommended practice was noted. Although documentation indicated patients should be routinely commenced on SDD, this was not always the case, due to more pressing clinical concerns. As a result, multiple layers of control to ensure protocol adherence were described (see text box 2 for quotations).

Box 2

Facilitators and barriers

Various facilitators and barriers to SDD delivery were evident across both sites (Box 3). One facilitating factor frequently reported was ‘dovetailing’ of SDD with other established and routine procedures. Thus, intensivists might include SDD delivery behaviours as part of the admission process. Nurses might include SDD as part of oral hygiene or other activities, and microbiologist and pharmacists dovetailed SDD actions within ward rounds. Dovetailing was evident in multiple interviews and in documentary data

on SDD provision for oral hygiene. Although barriers were commonly reported during interviews in response to specific prompts, these were often referred to as minor inconveniences, rather than significant obstacles to SDD delivery (see text box 3 for quotations).

Box 3

Infection Surveillance

Surveillance was specified in documentation outlining the SDD protocol in one of the sites, but not in the other, where it was part of the wider regimen to combat hospital acquired infections. Despite these differences, surveillance was integral to the provision of SDD, and included the performance of multiple behaviours of various clinicians in several clinical and environmental contexts.

Discussion

In line with frameworks for intervention development¹ and description,⁴ this study is the first to formally seek to describe the full clinical components and associated behavioural aspects of SDD and to describe how they impact on SDD implementation and delivery in practice. There are several advantages of describing an intervention behaviourally alongside clinical descriptions. First, it demonstrates procedural complexity and the situations in which complexity may be experienced. This information has direct relevance to clinicians and hospital decision-makers considering implementation of particular healthcare interventions. It also can inform the scale and content of implementation strategies to facilitate diffusion and adoption within specific contexts¹⁷. Second, behavioural specification identifies potential areas where behavioural variation in practice may occur and thus allows prior specification of acceptable limits of protocol adaptation. Thirdly it can identify whether formal training for,

and monitoring of, adherence to an expected standard of intervention delivery will be required. Fourthly, it may identify training needs to facilitate adherence to an expected standard. Finally, behaviour specification facilitates precision in protocols and training materials by describing what should be done, by whom, when and where.

We found variation in the clinical components of SDD, in terms of the drug regimen, mode of drug delivery and specification of components between the two study sites. This may be appropriate and could be the result of local tailoring to make the intervention simple and feasible to deliver. Various behaviours directly related to drug provision as well as relevant to the SDD intervention (e.g. authorisation of SDD delivery) were performed by multiple clinicians in differing contexts. Overall, SDD implementation and delivery comprised the interrelated phases of SDD adoption, operationalisation, provision and surveillance.

Additional behaviours to those specified in documentation were identified. These behaviours are essential for SDD delivery. SDD involved a range of healthcare professionals performing various behaviours in differing contexts. These findings emerged from the interview and observational evidence but were not always clearly specified in the documentation. Ensuring that these additional behaviours are specified in protocols, guidelines and the academic literature should lead to improvements in implementation, delivery and reproducibility of SDD ^{2,3}.

Various behaviours were identified in order to implement SDD, many at the organisational and team level and others at the individual level. Several features of operationalisation identified an on-going process (e.g. nurse training for SDD provision) due to staff turnover. SDD might be perceived as a simple and easy intervention from the individual behavioural perspective that becomes increasingly complex when focusing on the

flow of actions required at an organisational level for its delivery in practice. Consequently, some of the barriers and facilitators to SDD provision tended to centre on the environmental context and resource issues, rather than specific attitudinal (e.g. beliefs about SDD effectiveness) or skills barriers. Clinicians in ICUs not delivering SDD might include different views potentially preventing SDD rollout, requiring further research in this area ¹⁸.

Strengths and limitations

A limitation of this exploratory study is the potential lack of generalisability due to the use of only two sites. Additional clinical and behavioural components as well as alternative methods of SDD implementation and delivery may be evident if investigating SDD practice in a larger number of ICUs. However, the study was exploratory in nature with the goal of providing information-rich case studies that facilitate in-depth understanding of SDD in practice rather than a comprehensive picture of SDD across all UK ICUs. We recruited only one microbiologist, limiting the perspective from this profession. Lastly, clinicians in ICUs not delivering SDD may have different views about barriers to SDD implementation. This was investigated systematically in a larger programme of work ¹⁹, but was beyond the remit of the study reported here.

Conclusion

This study is the first to develop a formal description of the full clinical and behavioural components of SDD and to describe how they impact on SDD implementation and delivery in practice. We identified a wide range of behaviours involved in delivering SDD, several of which were not included in local SDD protocols. Significant protocol adaptations resulting from these behaviours were observed across sites – supporting the need for routine behavioural specification in SDD delivery protocols. Such routine specification

would greatly facilitate the subsequent detection of acceptable variations and those that might lead to significant differences in patient outcomes.

Competing interests

The authors declare that they have no competing interests.

References

1. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new Medical Research Council guidance. *Br Med J*. 2008;337:979-83.
2. Michie S, Johnston M. Changing clinical behaviour by making guidelines specific. *Br Med J*. 2004;328:343-5.
3. Michie S, Lester K. Words matter: Increasing the implementation of clinical guidelines. *Quality and Safety in Health Care*. 2005;14:367-70.
4. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: Explanation and elaboration. *Ann Intern Med*. 2008;148:295-309.
5. de Smet AM, Kluytmans JA, Cooper BS, Mascini EM, Benus RF, van der Werf TS, et al. Decontamination of the digestive tract and oropharynx in ICU patients. *N Engl J Med*. 2009;360:20-31.
6. Liberati A, D'Amico R, Pifferi S, Torri V, Brazzi L, Parmelli E. Antibiotic prophylaxis to reduce respiratory tract infections and mortality in adults receiving intensive care. *Cochrane Database Syst Rev*. 2009:000022.
7. Silvestri L, Van Saene HKF, Zandstra DF, Marshall JC, Gregori D, Gullo A. Impact of selective decontamination of the digestive tract on multiple organ dysfunction syndrome: Systematic review of randomized controlled trials. *Crit Care Med*. 2010;38:1370-6.
8. Stoutenbeek CP, Van Saene HKF, Miranda DR, Zandstra DF. The effect of selective decontamination of the digestive tract on colonisation and infection rate in multiple trauma patients. *Intensive Care Med*. 1984;10:185-92.
9. Bastin AJ, Ryanna KB. Use of selective decontamination of the digestive tract in United Kingdom intensive care units. *Anaesthesia*. 2009;64:46-9.

10. Shah R, Louw J, Veenith T. National survey on current practice of use of selective digestive decontamination in the United Kingdom. *Crit Care*. 2008;12:7.
11. Shibli AB, Milbrandt EB, Baldisseri M. Dirty mouth? Should you clean it out? Decontamination for the prevention of pneumonia and mortality in the ICU. *Crit Care*. 2010;14:314.
12. Zandstra DF, Petros AJ, Taylor N, Silvestri L, de la Cal MA, van Saene KF. Withholding selective decontamination of the digestive tract from critically ill patients must now surely be ethically questionable given the vast evidence base. *Crit Care*. 2010;14:443.
13. Jongerden IP, de Smet AMG, Kluytmans JA, te Velde LF, Dennesen PJ, Wesselink RM, et al. Physicians' and nurses' opinions on selective decontamination of the digestive tract and selective oropharyngeal decontamination: A survey. *Crit Care*. 2010;14:R132.
14. Yin RK. *Case study research, design and methods*. 3 ed. Newbury Park: Sage Publications; 2003.
15. Krippendorff K. *Content Analysis: An Introduction to its Methodology*. 2 ed. Thousand Oaks, California: Sage; 2004.
16. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. *Analysing Qualitative Data*. London: Routledge; 1994. p. 173–94.
17. Rogers EM. *Diffusion of Innovations*. New York: Free Press; 1983.
18. Cuthbertson BH, Francis J, Campbell MK, MacIntyre L, Seppelt I, Grimshaw J. A study of the perceived risks, benefits and barriers to the use of SDD in adult critical care units (The SuDDICU study). *Trials*. 2010;11:117.
19. Francis JJ, Duncan EM, Prior ME, MacLennan GS, Dombrowski SU, Bellingan G, et al. Selective decontamination of the digestive tract in critically ill patients treated in Intensive Care Units: a mixed-methods feasibility study (the SuDDICU study).. *Health Technol Assess*. in press.

Table 1: Protocolised or documented clinical components and behaviours involved in delivery of SDD medications in the two ICUs.

Drugs	Dose	Route	Frequency	Specific Behaviours (what)	Directions (how)	Frequency/duration (when)
<i>Site 1</i>						
Cefuroxime	1.5g (6 doses) over 3-5 minutes	intravenous	8 hourly	Prepare drug Administer drug	Dilute 1.5g in 15ml of water for injection Administer intravenously over 3-5 minutes	Immediately after obtaining all admission surveillance and diagnostic microbiological samples and then at 8 hourly intervals
Ciprofloxacin (if allergic to Cefuroxime)	400mg (4 doses) over 60 minutes	Intravenous	12 hourly	Prepare drug Administer drug	Administer 400mg intravenously over 60 minutes	Immediately after obtaining all admission surveillance and diagnostic microbiological samples and then at 12 hourly intervals
Nystatin	100,000 units/ml	Oral & gastric tube	8 hourly	Prepare drug Administer drug	Administer 5ml topical to mouth and 5ml via gastric tube. Use a new 30ml bottle every 24 hours. If gastric tube on free drainage, flush tube with 20ml sterile water and clamp for 30 minutes after administration of antibiotics/antifungals	3x daily after oral hygiene regimen
Vancomycin	500mg	Oral & gastric tube	6 hourly*	Prepare drug Administer drug	Reconstitute a 500mg vial with 10ml water for injections and administer 250mg into the mouth and 250mg via gastric tube.	4x daily after oral hygiene regimen
Colistin sulphate	250,000 units/ml	Oral & gastric tube	6 hourly*	Prepare drug Administer drug	Reconstitute a vial (licensed for injection) of 1 million units with	4x daily after oral hygiene regimen

					sodium chloride (NaCl) 0.9%. Dilute the reconstituted vial to a total of 40ml with NaCl 0.9%. This solution may be kept at the bed space for 24 hours. Administer 5ml (125,000 units) of this solution into the mouth & 5ml via gastric tube.	
Tobramycin	80mg	Oral & gastric tube	6 hourly*	Prepare drug Administer drug	Dilute one ampoule of 80mg (licensed for injection) in 10ml NaCl 0.9%. Give 5ml (40mg) into mouth and 5ml (40mg) by gastric tube	4x daily after oral hygiene regimen
Chlorhexidine gluconate 4% liquid soap	15ml	Topical	12 hourly	Administer body wash	Use 15ml for body wash with water	2x daily
Chlorhexidine gluconate 0.2% mouthwash	10ml	Topical	6 hourly*	Administer mouthwash	Not to be swallowed. Apply with pink sponge stick to teeth, gums, tongue and lining of the mouth as part of thorough mouth care	2x daily before each application of topical antibiotics
<i>Site 2</i>						
Tobramycin, Colistimethate sodium (colistin), Amphotericin B, prepared by Pharmacy	2% w/w of each constituent	Topical	6 hourly*	Administer gel to oropharynx	Apply gel to palate and buccal surfaces	Within 4 hours of admission 4x daily for duration of ITU admission Until discharge

Manufacturing

Unit

Tobramycin 27mg/ml liquid †	80mg	NG tube	6 hourly*	Administer solution /suspension	Deliver solution/ nasogastric tube	suspension	via	4x daily for duration of ITU admission
Colistimethate sodium (colistin) 50mg/ml liquid †	100mg	NG tube	6 hourly*	Administer solution/suspension	Deliver solution/ nasogastric tube	suspension	via	4x daily for duration of ITU admission
Amphotericin B 100mg/ml liquid †	500mg	NG tube	6 hourly*	Administer solution/suspension	Deliver solution/ nasogastric tube	suspension	via	4x daily for duration of ITU admission

Note. *Components typically administered at the same time, † Prepared separately by local Pharmacy Manufacturing Unit and drawn up by the nurse together into an oral syringe, prior to administration.

Table 2: Documented behaviours for delivery of SDD not related specifically to drug administration

Behaviour	Professional Group	Context	Site 1	Site 2
Clarifying SDD regimen (in ambiguous cases)	Nurse, Intensivist, Pharmacist, Microbiologist	ICU and bedside	X	X
Authorise SDD delivery	Intensivist, Pharmacist	ICU (admission) and bedside	X	
Prompt SDD authorisation	Nurse	ICU (admission) and bedside	X	
Judging SDD delivery in unclear cases	Intensivist	ICU (admission) and bedside	X	
Documenting SDD delivery	Nurse	ICU and bedside	X	
Discarding of antibiotics (when out of date)	Nurse	Bedside	X	
Storing reusable antibiotics	Nurse	ICU and bedside	X	
Labelling leftover antibiotics/antifungals	Nurse	ICU and bedside	X	
Check SDD is “continued and operating”	Intensivist, Pharmacist	ICU, bedside		X

Note. X = identified within site.

Table 3: Additional behaviours of SDD delivery identified in interviews and observations but not in written protocols or procedures.

Behavioural	Professional Group	Context	Site 1	Site 2
Check patient eligibility for SDD	Intensivist, Pharmacist	ICU (admission) and bedside	X*	X*
Review and optimise SDD delivery	Intensivist, Pharmacist, Microbiologist	ICU, bedside	X*	X*
Attend ward rounds (at which SDD discussed)	Intensivist, Pharmacist, Microbiologist	ICU, bedside	X*	X*
Dispose of SDD waste	Nurse	Bedside	X*, †	X†
Order SDD drugs from pharmacy	Nurse	ICU	X*	X*
Reassure patient/patient visitors before/during SDD administration	Nurse	Bedside	X†	X*, †
Reposition patient for SDD administration	Nurse	Bedside	X†	X†
Decision to discontinue SDD drugs	Intensivist, Pharmacist	ICU and bedside	X*	X*
Print SDD documentation	Ward clerk	ICU	X*	
Monitor for SDD drug reactions	Intensivist, Pharmacist	Bedside	X*	
Check stock and supply SDD drugs	Pharmacy Technician	ICU	X*	
Order SDD drugs from suppliers	Pharmacy Technician	ICU	X*	
Describe SDD during shift communication	Nurse	ICU and bedside	X*	
Handling contraindications	Nurse	Bedside	X†	
Collecting SDD drugs	Nurse	ICU and bedside	X*, †	
Preparation of antibiotics	Pharmacist	Production unit ²		X*

Order raw materials	Pharmacist	Analytic lab ²	X*
Check of antibiotics quality	Pharmacist	Quality Assurance Department ²	X*
Liaise with pharmacy production unit	Pharmacist	ICU	X*
Check naso/orogastric aspirate	Nurse	Bedside	X*, †

Note. X = identified within site; * = identified through interview, † = identified through observation

Box 1: Selected quotations on the level of difficulty / complexity of providing SDD.

Quotes supporting difficulty of providing SDD:-

“...there is extra work, four times a day,” Participant 1

“...it’s relatively unpopular with most of the nursing staff [...] because they see it as excess workload” Participant 10

“...delivery [...] can be difficult” Participant 5

“It only takes five/ten minutes, although that is another five/ten minutes added on to the other five/ten minutes for everything else that you have to do”, Participant 7

Quotes not supporting difficulty of providing SDD:-

*“...it’s a part of your routine already so I don’t find it difficult, it’s just finding ways of **how** to do it, I mean it’s not too difficult”* Participant 6

“[SDD provision] is really straight forward” Participant 7

“...very simple [...], a fairly straight forward thing to do” Participant 3

“... the main message to take across is that it’s, it works well. It is very easy to do”
Participant 13

“I don’t find it difficult” Participant 14

“It is not that hard. It is really straight forward.” Participant 15

Quotes supporting complexity of providing SDD:-

“[overall, SDD delivery] involves a large amount of co-operation between the microbiologists, the nursing staff and the medical staff to [...] maintain an appropriate antibiotic policy; it also involves [...] quite a lot of monitoring of what is involved with the patients [...] so that we can manage the infections appropriately [...] it involves applying some paste and some nasogastric SDD, but these are relatively minor parts of the whole. It is a system of which that is part.” Participant 11

Box 2: Protocol adaptation in practice.

“... although it says the dose is 500 mg I have been taught, in order to better manage my time, that I use [a] 1g bottle instead and instead of reconstituting it with 10ml I reconstitute it with 20ml” Participant 5

“I have different ways [...] because there are a lot of antibiotics” and he/she did not *“know if it’s a good thing to mix all 4 antibiotics in one go and put them orally in one go also”*, and that *“...others might do it differently”* Participant 14

“...it sometimes slips off the main agenda of the patient’s day...”, Participant 8

“I would ensure that all the relevant people get SDD”, Participant 17

“I just make sure it is being put on”, Participant 11

“if they haven’t prescribed it, I’ll ask them to prescribe”, Participant 14

Box 3: Facilitators and barriers reported to influence SDD implementation and delivery.

Facilitators

- Policies and protocols, e.g. *“We have an admission policy, so [patients] come in and we have a set of investigations and [...] they’ll get SDD and [...] that’s just part of the admission”*, Participant 10
- Patient state, e.g. *“patient is deeply sedated, it’s easier,”* Participant 1
- Perceived effectiveness, e.g. *“the fact that you have a very few incidents of pneumonia”*, Participant 17
- Colleague support, e.g. *“if you’re working side by side with a nurse, that nurse will help you”* Participant 5
- Dovetailing, e.g. *“you just tag it on with your aspirating stomachs,”* Participant 15

Barriers

- Workload, e.g. *“When it’s a really busy day then it gets a lot to do,”* Participant 5
- Patient state, e.g. *“if they’re intubated and they’re just maybe biting”* Participant 6
- Side effects, e.g. *“patients tend to get more diarrhoea when they are [on] SDD,”* Participant 1
- Staff changes, e.g. *“losing a senior microbiologist was a stress, he was very supportive,”* Participant 10
- Cost, e.g. *“The main challenges are the cost. The drugs themselves cost a lot of money”* Participant 10
- Materials, e.g. *“there’s been a few supply problems over the last couple of years. Sometimes [...] there can be national shortages which can be a bit of a problem,”* Participant 16

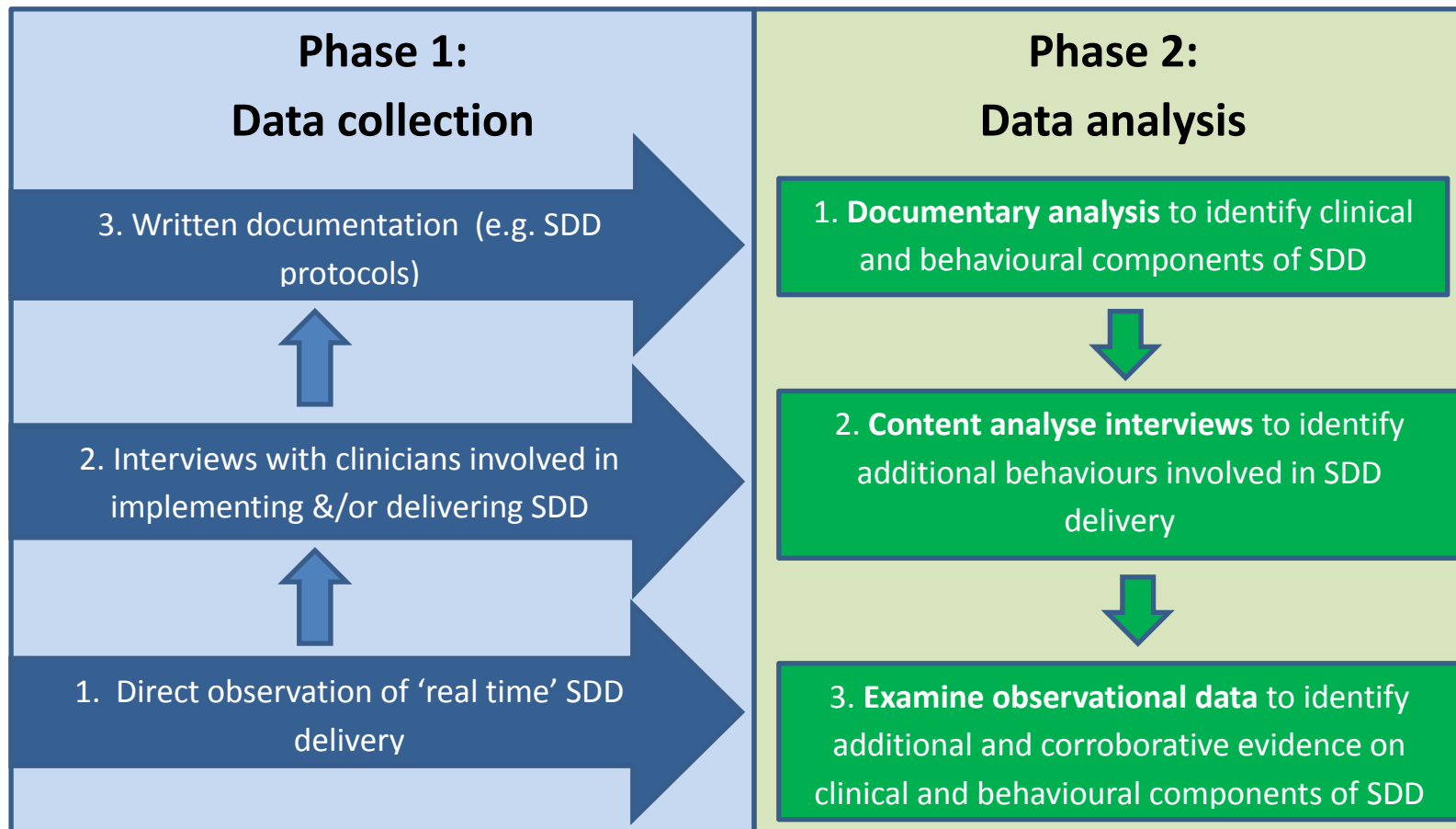


Figure 1: Diagram of the study procedures