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Investigation of perioperative work processes in provision of antibiotic prophylaxis: A prospective descriptive qualitative study across surgical specialities

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3 **1 Investigation of perioperative work processes in provision of antibiotic prophylaxis: A**
4 **2 prospective descriptive qualitative study across surgical specialities in Norway.**
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ABSTRACT

Objective

Surgical site infections are known postoperative complications, yet the most preventable of healthcare-associated infections. Correct provision of surgical antibiotic prophylaxis (SAP) is crucial. Use of the World Health Organization (WHO) Safe Surgical Checklist (SSC) has been reported to improve provision of SAP, and reduce infections postoperatively. To understand possible mechanisms and interactions in generating such effects, we explored the underlying work processes of SAP provision and SSC performance at the intersection of perioperative procedures and actual team working.

Design: An ethnographic study including observations and in-depth interviews. A combination of deductive and inductive content analysis of the data was conducted.

Setting: Operating theatres with different surgical specialities, in three Norwegian hospitals.

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3 40 **Participants:** Observations of perioperative team working (40 hours), and in-depth interviews
4 41 of 19 experienced perioperative team members were conducted. Interview participants
5 42 followed a maximum variation purposive sampling strategy.

6 43 **Results:** Analysis identified provision of SAP as a process of linked activities; sequenced, yet
7 44 disconnected in time and space throughout the perioperative phase. Provision of SAP had to
8 45 be handled in relation to several interactive factors; preparation and administration,
9 46 prescription accuracy, diversity of prescription order systems, patient specific conditions, and
10 47 changes in operating theatre schedules. However, prescription checks were performed, either
11 48 as formal SSC reviews of SAP items or as informal checks of relevant documents. In addition,
12 49 use of cognitive reminders and clinical experiences were identified as mechanisms used to
13 50 enable administration of SAP within the 60 minutes timeframe described in the SSC.

14 51 **Conclusion:**

15 52 Provision of SAP was identified as a complex process, yet mechanisms within the team were
16 53 identified in response to variations, enabling administration of SAP before incision. A key
17 54 element in provision of SAP was the given 60 minute timeframe of administration before
18 55 incision, provided in the SSC.

19 56
20 57 **Key words:**

21 58 Surgical Wound Infection, Antibiotic Prophylaxis, Qualitative Research, Preoperative Care,
22 59 Patient Safety.

23 60
24 61 **ARTICLE SUMMARY**

25 62 **Strengths and limitations of this study:**

- 26 63
- 27 64 • This study builds on previous work investigating the impact of WHO surgical safety
28 65 checklist implementation on perioperative work processes including provision of
29 66 antibiotic prophylaxis.
 - 30 67 • It shows perspectives on provision of antibiotic prophylaxis by all members
31 68 represented in the multidisciplinary perioperative team, using purposive sampling
32 69 strategy in selecting participants for single, in-depth interviews.
 - 33 70 • It provides detailed, first-hand observations of everyday work processes on antibiotic
34 71 prophylaxis across different surgical specialties, including WHO surgical safety
35 72 checklist antibiotic items.
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- 72 • The extent to which identified elements in the work processes of antibiotic
73 prophylaxis can be influenced and further lead to improved provision of prophylaxis
74 remains to be tested.
- 75 • The findings might not be generalisable across countries due to organisational and
76 cultural differences.

78 INTRODUCTION

79 Surgical site infections (SSIs) are associated with substantial morbidity and mortality,
80 prolonged hospital stay and increased costs.¹⁻³ Although SSI incidence is higher in low-and
81 middle income countries,⁴ SSIs remain the most common health care-associated infections in
82 the USA, and the second most frequent in Europe.^{5,6} The efficacy of surgical antibiotic
83 prophylaxis (SAP) in preventing SSIs is well established. Timely administration of
84 appropriate SAP is considered one of the most effective SSI prevention strategies⁵ as
85 recommended in the World Health Organization (WHO) global guidelines for prevention of
86 SSIs.⁷

87
88 Successful SAP requires administration of one or more antimicrobial agents at appropriate
89 time-points to achieve effective antibiotic concentrations at the surgical site at time of incision
90 and throughout surgery. Pharmacokinetic properties determine administration forms and
91 correct timing and intervals of antibiotic(s).⁵ Actual delivery of antibiotics for surgical
92 prophylaxis is commonly carried out within operating theatre (OT) premises. Provision of
93 optimal SAP may be influenced by a number of factors before, during and after surgery. Lack
94 of clarity concerning responsibility for the choice, dose, timing and duration of antibiotics
95 influences decision-making and proper prescription of SAP.⁸ Unresolved issues of workflow
96 and role perceptions have also been reported as obstacles to properly timed SAP.⁹ As a
97 consequence, SAP may be administered too early,¹⁰⁻¹² too late, or not at all,¹³⁻¹⁶ causing
98 unnecessary patient risks. Guidelines do not recommend prolonged SAP administration for
99 preventing SSI. However, prolongation of SAP for more than 24 hours remains prevalent.^{17,18}

100
101 Within the OT setting, the WHO Safe Surgical Checklist (SSC)¹⁹ includes evidence based
102 items for prevention of SSI. Use of the SSC has been reported to reduce mortality and
103 complications, including postoperative infections.^{20,21} In a previous study investigating
104 changes in perioperative care processes following WHO SSC implementation, we found
105 significant improvements in timely SAP provision preoperatively, before incision.²² This was

106 further associated with reduced risks of infections and wound rupture postoperatively. To
 107 understand possible mechanisms and interactions contributing to these effects, an
 108 investigation of the everyday work of SAP provision at different surgical settings is required.
 109 The aim of this study was therefore to map work processes of SAP provision, including SSC
 110 performance of SAP items at the intersection of preoperative procedures and actual team
 111 working. The following research questions were addressed: (1) How can SAP work processes
 112 be described? (2) What are the key elements in these work processes that influence provision
 113 of SAP?

115 METHODS

116 Design

117 An ethnographic design was used, where multi-professional perioperative teams were
 118 observed in action in OTs, followed by face-to-face interviews of key informants. This design
 119 is well suited to capture “everyday” routine behaviours in their natural settings.^{23 24}

121 Study setting

122 The study was conducted in three hospitals in one Regional Health Authority in Norway;
 123 surgical activity and hospital characteristics are described in table 1.

124
 36 **Table 1. Characteristics of hospitals included in the study of surgical antibiotic prophylaxis work processes**

Hospitals (N=3)	Hospital size*	Surgical activity**	Teaching status	Hospital level	Medical service	Organisational structure
1	1066	33584	University hospital	Tertiary referral hospital	National and regional referral hospital for medical and surgical care	22 specialised units
2	149	4769	Residency training approval	Secondary care hospital	General medical and surgical care	3 specialised units
3	244	7887	Residency training approval	Secondary referral hospital	General medical and surgical care	2 specialised units

54 The Regional Health Authorities have overall responsibility for the specialist health service. Hospital #1 and #3 are organised
 55 in two separate health trusts, while hospital #2 is a private, non-profit hospital on contract with the Regional Health
 56 Authority.

56 * 2016 Occupancy rate (Statistics Norway) = bed-days/available bed-days.

57 **2016 reported surgical hospital stays with one or more surgical procedure, based on the classification system of the
 58 Norwegian diagnosis related groups (N-DRG, Norwegian Patient Registry).

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3 126 The hospitals operate within separate organisational structures, and perioperative routines
4 127 vary accordingly. However, SAP use should be compliant with the implemented Norwegian
5 128 national guidelines of antibiotic use in hospitals.²⁵ Further, the WHO SSC had been
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7 129 implemented formally at all sites at the time of the study.
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11 131 **Data collection**

12 132 Data triangulation was used in collection of data across time, hospital settings and professions
13 133 to capture a more complete and contextualised portrait of the studied settings and to validate
14 134 conclusion of findings.^{26 27} Data collections were limited by available time frames for both
15 135 the observation- and interview time, although saturation of data was met in relation to
16 136 responsibility of prescription, preparation and, administration of SAP.
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23 138 *Perioperative observations*

24 139 Data were collected through 40 hours of non-participant observations of perioperative teams
25 140 in OTs, and through individual interviews of members of these teams (surgeons, operating
26 141 theatre nurses, anaesthesiologists, and nurse anaesthetists). Observations aimed to map routine
27 142 behaviours on: 1) antibiotic management and 2) team reviews of antibiotic items in the WHO
28 143 SSC. All team observations took place within local OTs, and followed the entire perioperative
29 144 phase from the patient arrival in the OT to post-operative delivery. Data were collected from
30 145 one hospital at a time, with team observations taking place prior to interviews. The
31 146 observations covered scheduled surgical procedures at dates agreed upon beforehand with the
32 147 service managers and teams. Three different surgical specialties/subspecialties were included
33 148 in order to cover different SAP regimes. Observations of team interactions- and
34 149 communications were noted and reviewed by the research team. These field notes were used
35 150 to develop the interview guide.
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47 152 Mapping work processes of how antibiotics were managed in a variety of surgical contexts
48 153 was essential. By “work processes” we included both the formal documentation for standard
49 154 procedures of antibiotic prophylaxis as well as the organisational roles and responsibilities,
50 155 together with informal roles and lines of communication. All observations and interviews
51 156 were performed by HVW (nurse anaesthetist, trained in qualitative research). ASH (senior
52 157 nurse anaesthetist, trained in qualitative research) also participated in some of the initial
53 158 observations (6 hours). Observation notes were compared and discussed between the two
54 159 observers to validate findings.
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161 *Interviews with members of the perioperative team*
162 Nineteen interviews were performed lasting from 27 to 48 minutes in duration, with a median
163 length of 33 minutes. The interview guide covered three topics: 1) antibiotic management, 2)
164 use of the WHO SSC (with specific focus on SAP items), and 3) teamwork experience
165 (interview guide in Supplementary file 1). All healthcare personnel in the perioperative teams
166 were considered key informants. Hence, a maximum variation purposive sampling strategy
167 was used to elicit all perspectives in the provision of SAP in the OTs.²⁸ Invitations to
168 participate were initially reviewed and approved by the Directors of the Department of
169 Research and Development at the respective study hospitals. Participants were recruited by
170 the local managers. Professionals with variable length of perioperative work experience were
171 targeted for sampling; their characteristics are described in Table 2.

172
173 The interviews were conducted between November 2015 and November 2016, and were
174 conducted in the OT departments, in areas free from distractions (e.g., meeting rooms). Each
175 participant was interviewed once. The interviews were audiotaped, transcribed verbatim, and
176 transferred to NVivo Pro 11.4 computer software (QSR International Pty Ltd. ABN
177 47006357213) for coding.

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TABLE 2. Characteristics of informants in the study of surgical antibiotic prophylaxis work processes

Participant profession	Number N = 19	Work – experience years qualified in profession - range	Sex female/ male	Participant work place		
				Secondary care hospital	Secondary referral hospital	Tertiary referral hospital
Nurses ¹ Nurse anaesthetist/ Operating theatre nurse	12	5 - 30	11/ 1	4	4	4
Physicians ² Consultant anaesthesiologist/ Consultant surgeon/Surgeon	7	3 - 30	0/ 7	0	4	3
Total	19	3 - 30	11/ 8	4	8	7

¹Authorisation requirements in Norway: 3-year bachelor degree in Nursing-180 ECTS* + either a 1,5-year Specialist education program-90 ETCS, or a 2-year Master's program-120 ECTS at a College University degree.
²Authorisation requirements in Norway: 6-year cand. med degree, 360 ECTS* + 6,5 years of specialist training before qualification as consultant. *European Credit Transfer and Accumulation System (ECTS) credits.

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182 **Analysis**
183 Data from observations and interviews were analysed using a content analysis approach,
184 combining deductive and inductive analysis elements. First, to identify the perioperative work
185 process of SAP, a deductive approach was applied using directed content analysis as

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3 186 described by Hsieh and Shannon.²⁸ The Norwegian national regulation framework for
4 187 medication management was applied as coding frame. This regulation framework requires
5 188 healthcare personnel to adhere to defined responsibilities in the three domains of medication
6 189 prescription, -preparation and -administration to ensure that the right medication and dose is
7 190 administered correctly to the right patient at the right time.²⁹ The deductive analysis
8 191 investigated specific SAP work processes in relation to these three domains of the medication
9 192 regulation framework, which is also a compulsory part of the curriculum- and training for
10 193 nurses and physicians in Norway. HVW, ASH, ES (consultant anaesthesiologist) and SH
11 194 (consultant in infectious diseases) participated in the preliminary analysis using group
12 195 consensus to strengthen coherence of the findings.³⁰ Second, to further explore the underlying
13 196 work processes, an inductive approach was applied with a thematic analysis according to
14 197 Graneheim and Lundman.³¹ This qualitative content analysis comprises descriptions of the
15 198 manifest content close to the text as well as interpretations of the latent content distant from
16 199 the text, yet still close to the participants' experiences.³⁰ Statements, observations and
17 200 interpretations that reflected participants' conditional actions and interactions were identified.
18 201 The following steps were used: HVW, ASH and SH read the transcribed interviews forming
19 202 units of analysis. HVW identified and coded transcript sections into 'meaning units', followed
20 203 by relating categories and theme, constituting the manifest content.³¹

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36 205 Observational data were used to support the interview data analysis, contributing to the
37 206 formation and interpretation of emerging themes. ASH and SH reviewed the coding and
38 207 interpretations. Preliminary themes, subthemes and quotes were then discussed amongst the
39 208 authors (HVW, AS, ES, SH). In addition, KA and SW (safety scientists, trained in qualitative
40 209 methods) also participated in finalising analysis of the latent content, the underlying meaning
41 210 of the text, and concluding themes. The finalised dataset is reported in categories and sub-
42 211 themes constituting the overarching descriptive theme, with verbatim quotes from the
43 212 interviews, and summarised field notes from the observations to support and illustrate each
44 213 category.

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215 **Patient and Public involvement statement**

216 There was no direct patient or public involvement in this study, although the object of study
217 and its relevance to patient has been discussed on several occasions with Head of Patient
218 Involvement Committee in the Western Norway Regional Health Authority. Both observers
219 had previously worked in OTs. The local managers informed all OT staff prior to case

220 observations, and cases where any staff member or the patient withheld consent were
 221 excluded.

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224 **RESULTS**

225 Analysis of observations and interviews identified provision of SAP as a process of linked
 226 activities, sequenced yet disconnected in time and space during the perioperative phase. The
 227 process involved interactions of the multidisciplinary team members before, under and after
 228 surgery. The deductive analysis identified the “who”, “where” and “when” in relation to
 229 initial- and follow-up prescription, preparation, and administration of SAP. These three
 230 domains, as described in the Norwegian regulation framework, constituted the formal steps of
 231 the work process. Participants described these steps in relation to the entire perioperative
 232 phase, although timing administration of SAP prior to incision was a target.

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234 The inductive analysis identified several challenges of competing demands and varying
 235 conditions, in the process of timing administration of SAP within the given timeframe of 60
 236 minutes prior to incision. The overarching theme describes provision of SAP as “a complex
 237 process of balancing timeliness whilst considering and responding to multiple, interacting
 238 factors”. The balancing of timeliness and interacting factors were further characterised by
 239 three sub-themes interpreted from nine categories, which were derived from codes of the
 240 deductive and inductive analysis, presented in table 3. In the following section, the three sub-
 241 themes and corresponding categories are presented in detail with representative illustrating
 242 verbatim quotes in italics.

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Table 3. Main findings from the study “Investigation of perioperative work processes in provision of surgical antibiotic prophylaxis: A qualitative study across different surgical settings”, presented as categories, sub-themes and overarching theme

Theme	Provision of antibiotic prophylaxis as a complex process of balancing timeliness by considering and responding to multiple interacting factors.								
Sub-theme	Handling surgical antibiotic prophylaxis in consideration of multiple, preoperative interacting factors					Timing administration of surgical antibiotic prophylaxis in relation to knowledge and clinical experience		Performing formal and informal checks	
Category	Formal work processes	Prescription accuracy	Diverse prescription order systems	Patient specific conditions	Changing schedules in operating theatre	Cognitive work task reminders	Importance of knowledge and clinical experience	Performance variety of Surgical Safety Checklist	Indirect and direct prescription validity checks
Codes	<ul style="list-style-type: none"> Roles Responsibility Location of performance Time 	<ul style="list-style-type: none"> Unclear prescriptions Lack of prescriptions Standardised prescription Electronic default settings 	<ul style="list-style-type: none"> Electronic, surgical planning system Electronic medication chart Paper-forms Wall poster in operating theatre 	<ul style="list-style-type: none"> History of allergies Type of surgery Adjusting dosage in relation to age Adjusting dosage in relation to weight (<ul style="list-style-type: none"> Order of scheduled patients Deviations from scheduled patient order Deviations from information in operating planning system Timing of incision 	<ul style="list-style-type: none"> After patient transport When positioning the patient During placements of electrocardiography electrodes When entering the operating theatre 	<ul style="list-style-type: none"> Local prescription systems Surgeons’ preferences Surgical procedures Selection of antibiotics according to procedures 	<ul style="list-style-type: none"> Interruption of workflow Responses Performance challenges Responsibility Identifies missed SAP administration 	<ul style="list-style-type: none"> Paper documents Electronic medication chart Electronic surgical planning system Prescribing signature

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			<ul style="list-style-type: none"> • Oral prescription • Pre-authorized prescription protocols 	Body Mass Index - BMI)	<ul style="list-style-type: none"> • Approximate time estimations 	<ul style="list-style-type: none"> • After induction of anaesthesia 	<ul style="list-style-type: none"> • Alternative antibiotics 		<ul style="list-style-type: none"> • Calling surgeons • Paging surgeons • Approaching in person
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Handling surgical antibiotic prophylaxis when considering multiple interacting factors.

The formal work processes included participants' perception of roles, responsibility, location- and timing of performance related to prescription-, preparation and administration of SAP.

Prescription of SAP (drug of choice, dosage, and duration) was as a rule ordered by the surgeon before the surgical procedure, although verbal prescriptions might also occur during surgery. The surgeon then had to confirm the SAP prescription by signing the anaesthesia and/or postoperative record. This prescribing responsibility was acknowledged by all members of the team. However, diverse prescription order systems were observed with different prescription practices. Some units used electronic surgical planning systems with embedded preoperative standardised SAP prescriptions with default settings.

Nurse anaesthetist: "SAP is to be prescribed in the patient's medication chart by the surgeon, if there is an indication. Sometimes, SAP is prescribed in the electronic surgical planning system as well".

Surgeon: "As long as the patient belongs to this department SAP is to be prescribed in the medication chart. In case it is not written in the medication chart, then it [the antibiotic] is not prescribed properly".

Other units had written pre-authorized standardised SAP protocols for certain types of surgery, and patient-bound signed pre-operative medical paper forms of SAP prescription for others. The different preoperative SAP prescription systems varied not only between sites, but also between surgical wards at one of the study hospitals. Nurse anaesthetists also described variations in prescription accuracy, particularly in cases with unclear prescriptions or lack thereof. Sometimes the anaesthesiologist might also be involved in prescription orders such as in endocarditis prophylaxis or when the anaesthesiologist was personally responsible for an interventional procedure, e.g. subcutaneous venous port implantations.

Anaesthesiologist: "Formally, the surgeon is in charge of the SAP prescription orders, no doubt of that! Within the premises of the operating theatres, I only prescribe SAP to patients if I'm in charge of the procedure, i.e.: subcutaneous venous port implantations"

279 Preparations of all SAP infusion(s) or injection(s) were done by nurses. The medication
280 infusions were mainly prepared in the OTs by nurse anaesthetists, but for surgery involving
281 combinations of two antibiotics infusions were prepared in the surgical ward.

282 *Nurse anaesthetist: "For orthopaedic surgery, and for some of the abdominal.....like the inguinal hernia*
283 *repairs, we prepare the SAP ourselves, although sometimes it gets a bit messy, due to suboptimal*
284 *localities... For some of the other abdominal surgeries.... I.e. cancer surgery, the SAP is prepared as 500*
285 *mL or 1000 mL infusions, and both preparations are made at the ward, and brought to the OT along with*
286 *the patients"*

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288 Administration was then started in the surgical ward or the operating holding area: The ward
289 nurse handed over the double controlled and signed infusion containers to the nurse
290 anaesthetist if the infusions were not completed before patient handover. SAPs with short
291 half-lives were both prepared and administered to patients by nurse anaesthetists within the
292 OT. Dosages and time points were documented in the patients' anaesthetic records, registered
293 at a precise time point (injections) or an explicit "start" and "stop" time (infusions).

294 *Operating theatre nurse: "The anaesthesia team is responsible for SAP administration. Medications,*
295 *anaesthesia, ... this is their responsibility"*

296
297 Considering patient specific factors were also described as important when handling SAP.
298 When in need of alternative antibiotic(s) due to patient allergies, adjustments in timely
299 administration of SAP had to be reconsidered, according to the pharmacokinetic property of
300 the alternative antibiotics, especially half-lives. This was not always clarified prior to the
301 patient's arrival in the operating theatre. Clarifications on the precise SAP dosages in cases of
302 elder, adipose or paediatric patients were also reported by informants as important, yet time
303 consuming considerations in the planning or preparation of SAP.

304 The type of surgery initially determined the SAP regimes. Hence, the OT scheduling of
305 patients also influenced SAP work processes. The scheduled order of the different surgical
306 procedures in the OT- with corresponding specific SAP regimes generated fluctuating SAP
307 work processes throughout the day. With the exception of the first patient admitted to the OT
308 the timings of incision for the remaining scheduled patients were based on approximate time
309 estimations with SAP being administered according to these estimations.

310 *Nurse anaesthetist: "It is much easier to provide right timing of SAP to the first scheduled patient of*
311 *the day, because we have an exact point of time scheduled for this patient. Throughout the day, it gets*
312 *more complicated, because it is difficult to predict the time of arrival- and administration of SAP, for*
313 *the next patients"*

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3 314 Participants described cases where information in the operating planning system, including
4 315 SAP prescriptions, deviated from agreed (or perceived as agreed) upon perioperative
5 316 standards. Furthermore, abrupt changes in preoperative scheduling, lack of signed
6 317 preoperative prescriptions and uncertain SAP indications also caused variations in the
7 318 preparations- and administration of SAP.

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14 320 **Timing administration of surgical antibiotic prophylaxis using clinical knowledge and**
15 321 **experience.**

17 322 The participants described how specific preoperative work tasks served as cognitive
18 323 reminders for SAP administration within the preferred timeframe. This was explained as
19 324 particularly helpful for the anaesthesia team as both preparation and administration of SAP
20 325 might easily be influenced by concurrent tasks, distracting them in timely provision of SAP.
21 326 This was confirmed through observations, especially during induction of anaesthesia. The
22 327 anaesthesia team explained how linking SAP administration concurrently to other specific
23 328 work tasks made it easier for them remembering to administer SAP within the recommended
24 329 timeframe of 60 minutes. Such work tasks included patient transport, patient positioning or
25 330 electrocardiography electrodes placement.

33 331 *Nurse anaesthetist: "For orthopaedic patients, they are first transported to anaesthetic room, for*
34 332 *application of anaesthesia. Then, there is a timespan where SAP may be administered, before the patient*
35 333 *is transported into the OT".*

334

335 SAP administration was also emphasised to be carried out at specific points of time in the
336 preoperative phase such as when entering the OT, when positioning the patient, or after
337 induction of anaesthesia.

338 *Anaesthesiologist: "As a routine, I believe that the SAP is administered during induction of anaesthesia,*
339 *just after we have inserted the central venous catheter".*

340

341 Use of the WHO SSC, with the item for specified timeframe of SAP provision within 60
342 minutes prior to incision, was also described as a reminder. Most of the nurse participants
343 reported that the WHO SSC implementation had made them more aware of this timeframe.
344 Knowledge and experience on surgical routines and workflow in the OTs, in addition to the
345 local SAP regimes, were also highlighted as important amongst the participants. This was
346 described as being experience gained on the standardised surgical procedures and the types of
347 antibiotics used as standard prophylaxis for the different procedures performed at their

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3 348 surgical unit. In addition, participants emphasised the need to have knowledge on alternative
4 349 SAPs used in cases of identified antibiotic allergies.

5 350 *Nurse anaesthetist: "When you have some experience, you know which type of surgeries that requires*
6 351 *SAP, and which types of surgeries that do not, because you recognise the indications, even though*
7 352 *prescriptions are not clear".*

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10 354 **Performing formal and informal checks**

11 355 Both formal- and informal SAP checks were carried out in the preoperative phase as
12 356 illustrated in Figure 1. The Surgical Safety Checklist constituted the formal, compulsory
13 357 check. Prior to incision the perioperative teams paused and performed a "Time-Out"
14 358 according to the WHO SSC with items questioning whether SAP had been provided read
15 359 aloud. Varying team-briefing responses as to these SSC SAP items were observed. Some team
16 360 responses concentrated on the timing of SAP administration, some reviewed if prescribed
17 361 dosages correlated to the actual administered SAP, and some left responses to the SSC items
18 362 out completely. When addressing these items during SSC team briefings, some of the OT
19 363 nurses felt like questioning aloud whether the anaesthesia team had performed their job or not.
20 364 If the anaesthesia team failed to respond, repetition of these SSCs items was then ignored.

21 365 *Operating theatre nurse: "My only worry- personally- is to ask the anaesthesia team whether they have*
22 366 *done their job or not. I really struggle with this checklist item [SAP]. I get this awkward feeling ... It's*
23 367 *like poaching on somebody's preserve".*

24 368

25 369 The informants also described episodes where surgeons did not wait (but carried on with
26 370 incision) despite the "Time-Out" briefings having identified missing or delayed SAP
27 371 administration. This was also confirmed by observations.

28 372 *Surgeon: "No, I don't think that I have ever experienced to stop and await incision, in cases where SAP*
29 373 *has not been fully administered".*

30 374

31 375 The physicians' responses were explained by an overall concern of delay causing surgical
32 376 program flow disruptions and prolonging time of anaesthesia. However, in cases where
33 377 surgery required application of a tourniquet, surgeons delayed incision in order to let the SAP
34 378 work appropriately.

35 379 *Operating theatre nurse: "No, the surgeons do not await incision if SAP is missing. Only if the tourniquet*
36 380 *is already applied, then they have to wait".*

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38 382 Informal SAP checks were performed by the anaesthesia teams to clarify which antibiotic to
39 383 administer, the dosages and duration. For the SAP to be administered by the nurse

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3 384 anaesthetists in the OT SAP prescription orders should have been documented and signed
4 385 preoperatively according to local prescription systems involved, i.e. written paper orders,
5 386 electronic orders or orders in the patient medical chart. The informants emphasised that SAP
6 387 prescriptions also had to be checked to ensure validity of the prescription order, as default
7 388 settings in the electronic surgical planning system might cause an unintentional or incorrect
8 389 SAP prescription.

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10 390 *Nurse anaesthetist: "Well, if SAP is not prescribed initially, and the surgeon arrives in theatre and*
11 391 *announces that we need to administer antibiotic prophylaxis....Then, I need to make the surgeon sign the*
12 392 *patient's medical record. I present the medical record to the surgeon and then...sign here, please!"*
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16 394 The surgeons in charge were contacted in cases of partial or missing SAP prescription orders,
17 395 or if anyone in the anaesthesia team was in doubt of whether or not to administer the SAP.
18 396 Surgeons were contacted by phone or pager or by approaching them when they entered the
19 397 OT. These actions were taken by members of the anaesthesia team themselves or by the
20 398 operating theatre nurses on behalf of the former.

21 399 *Anaesthesiologist: "Normally, the nurse anaesthetist calls the surgeon if SAP prescriptions are missing".*
22 400

23 401 **DISCUSSION**

24 402 This study has identified provision of SAP as a complex process of balancing timeliness by
25 403 considering and responding to multiple interacting factors. Our findings of the multiple
26 404 considerations and compensating mechanisms used particularly in the preoperative phase,
27 405 highlight the real-world balancing of professional judgements regarding patient, antibiotic,
28 406 and surgery-related factors as well as coordinating the OT scheduling and -work flow for SAP
29 407 to be administered in due time before incision. Even though perceptions of responsibility in
30 408 relation to SAP -prescription, -preparation and -administration were consistent among team
31 409 members, our results indicate ambiguities in ownership for SAP. This was seen especially at
32 410 intersections of prescription transfers to providers, where suboptimal use of the prescription
33 411 order systems or poorly completed SAP orders may provide unclear indications for SAP to its
34 412 actual providers. In addition, the team performances on the WHO SSC checks including
35 413 reviews of antibiotic items varied during the "Time Out" part of the SSC, also with a
36 414 reluctance to address SAP items. The nurse anaesthetist, surgeon and anaesthetist each seem
37 415 to have self-perceived defined roles in provision of SAP, and yet these roles did not seem to
38 416 be aligned or sufficiently understood through shared decision-making. Consequently, possible
39 417 risks of SAP failures were poorly understood or defined at each step in the preoperative
40 418 planning of surgery.

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5 420 Existing surgical workflow systems have previously been identified by surgeons and
6 421 anaesthesiologists as an obstacle to proper timing of SAP, also with work processes of SAP
7 422 being of low priority amongst their many perioperative responsibilities.⁹ Yet, studies
8 423 investigating predictors for appropriate antibiotic use found that patients were more likely to
9 424 receive an effective and timely first SAP dose when preoperative orders were written and
10 425 implemented in the OTs.^{32 33} We identified a number of interacting considerations which
11 426 might help to understand factors and situations influencing timely provision of SAP. One
12 427 contributor to delayed SAP administration was ignored identification of patients' allergies, or
13 428 the lack of such being properly addressed. This has also been reported by others, with
14 429 administration of an effective first prophylactic dose being less likely when a patient had a
15 430 beta-lactam allergy, increasing the risk of SSI.³³ Another identified contributor to delayed
16 431 SAP administration was the need to clarify the precise SAP dosages in cases of elder, adipose
17 432 or paediatric, especially neonate, patients. As these sub-groups of surgical patients (age < 60
18 433 weeks and > 75 years, obesity with BMI > 30, morbid obesity with BMI ≥40) are reported to
19 434 have an increased risk of developing SSIs based on their physical status, delayed SAP
20 435 administrations adds to these risks.^{25 34} The classification of patients' physical status (America
21 436 Society of Anesthesiologists classification) has previously been identified as a significant
22 437 predictor of SSIs.³⁵ Patients with an impaired physical status should therefore be given extra
23 438 attention during the planning and prescription of SAP. Although our findings describe the
24 439 surgeons as being responsible for SAP prescriptions, the anaesthesiologists have
25 440 responsibility for patient assessments as to potential allergies and physical status. This
26 441 imbalance of responsibilities might contribute to unclear SAP prescription orders with risks of
27 442 delayed SAP administrations.³⁶

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29 443
30 444 Suboptimal use of the prescription order systems or poorly completed SAP orders may
31 445 provide unclear indications for SAP to its actual providers. We found that the nurse
32 446 anaesthetist as a response performed additional informal SAP checks, and that the surgeons
33 447 were contacted when in doubt of SAP indication or the validity of the prescription order.
34 448 Nevertheless, the need to spend crucial minutes in the OTs to clarify prescription orders as
35 449 illustrated in Figure 1., inadvertently leaves a narrower timeframe for the nurse anaesthetist to
36 450 administer SAP on time (60 minutes prior to incision). A narrower timeframe in itself, in turn,
37 451 increases risk of SAP administration delays. A comparison on the risk of SSI with different
38 452 timing intervals of SAP was addressed in a recent meta-analysis.³⁷ The analysis showed that

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3 453 the risk of SSIs almost doubled when SAP was administered after incision compared to before
4 454 incision, and resulted in 25 more infections per 1000 treated patients.³⁷

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8 456 This study builds on previous research which reported significant improvements in timely
9 457 SAP provision preoperatively before incision following implementation of the WHO SSC.²²
10 458 The key novelty of our findings show how implementation of the SSC may facilitate resilient
11 459 mechanisms within the team, in relation to specific work processes of SAP. This is supported
12 460 by how timing administration of antibiotics was performed. We found that this was executed
13 461 mainly by nurse anaesthetists, in relation to their knowledge and clinical experience of
14 462 workflow in surgery, and the performance of prescription checks at different time points
15 463 before incision (Figure 1.). A key element that seems to drive tasks and behaviours related to
16 464 SAP administration was the given timeframe of 60 minutes prior to incision as provided in the
17 465 SSC. This suggests that the SSC might serve as a cognitive tool to drive SAP administration
18 466 to take place prior to incision. In addition, by being aware of this timeframe the providers of
19 467 SAP were able to respond to regular and irregular variabilities in prescriptions by questioning
20 468 uncertainties and adjusting timing of SAP administration according to disturbances in the OT
21 469 workflow.

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24 471 However, the identified various team responses during the “Time Out” part of the SSC as well
25 472 as a reluctance to address SAP items, indicates a lack of SSC quality performance at full
26 473 length. Moderate compliance rates of SSC utilisation as well poor performance quality, have
27 474 also been identified in previous studies.³⁸⁻⁴⁰ Furthermore, we found that identification of
28 475 missing or delayed SAP prescription or administration during time-out reviews, seldom
29 476 resulted in delays of incision, although this is recommended in guidelines.⁴¹

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32 478 Our findings indicate that the SSC is likely to identify missed SAP administrations, yet does
33 479 not prevent surgical incision to take place before SAP administration. However, having
34 480 established focus on the timeframe of completing SAP administration within 60 minutes prior
35 481 to incision through SSC use might have influenced SAP administration practise indirectly.
36 482 The nurse anaesthetist more likely responds in a prompt manner to unclear prescriptions, and
37 483 adjusts timing of administration in accordance with the SSC recommendations. To strengthen
38 484 SSC use as a safety barrier to minimise risk of SSI, we suggest that SAP prescription checks
39 485 should also be done by the nurse anaesthetist at the Sign-In in addition to the surgeons’
40 486 already established controls of SAP administration at Time-Out (Figure 1). This should also

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3 487 reduce risk of interfering with the time point for incision and possible delays in OT schedules.
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5 488 Such clarifications via preoperative team briefings have previously been associated with
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7 489 improved clinical practice of timely SAP administration.⁴²
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491 **Recommendations and further research**

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11 492 Antibiotic stewardship programs (ASP) are of particular importance to surgical specialties due
12 493 to their prominent role in prophylactic antibiotic usage and management of surgical
13 494 infections, and may serve as suitable frameworks to address correct provision of SAP.⁴³
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15 495 Multidisciplinary team roles and pathways specifying timing and sequence of responsibilities
16 496 are recommended to influence team-level communications and workflow.⁴⁴ Based on our
17 497 findings we advocate that objectives and measures of antibiotic stewardship programs in
18 498 surgery must include both nurse providers of SAP as well as the surgeon prescribers. Our
19 499 findings illustrate how nurses, particularly nurse anaesthetists, are important stakeholders in
20 500 SAP provision when responding to unclear prescriptions and adjusting time of SAP
21 501 administration according to the timeframe provided in the SSC. Nurses' role in antibiotic
22 502 stewardship practices in hospitals have previously been emphasised.⁴⁵ To our knowledge their
23 503 role and responsibility of SAP in the perioperative period has not been described before.
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26 505 Further research should investigate how the roles and responsibilities of nurses and nurse
27 506 anaesthetists regarding SAP management for surgical patients could be expanded. In addition,
28 507 antibiotic stewardship programs in surgery should test SAP delivery interventions, and
29 508 measure performance indicators of timely SAP administrations as well as prescription
30 509 adherence to guidelines. We suggest that education of SAP indications and the
31 510 pharmacokinetic properties of the antibiotic used as prophylaxis may further support SAP
32 511 providers to target SAP timing according to the half-life of the prescribed antibiotic. Also,
33 512 providing feedback on timeliness of SAP administration as performance indicator will allow
34 513 nurses and nurse anaesthetists to take ownership in improving provision of timely SAP.⁴⁴
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515 **Study limitations**

516 516 This study was conducted in surgical settings in Norway. Recommendations of SAP regimes
517 517 were based on the Norwegian national guidelines of antibiotic use in hospitals. The identified
518 518 work processes and mechanisms might therefore be limited to reflect practice in Norway.
519 519 However, international recommendations indicate that SAP should be initiated within 60-120
520 520 minutes prior to surgical incision, based on its pharmacokinetic property.⁵

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3 521 In order to achieve credible information on the SAP work processes, data triangulation was
4 522 used by collecting data across time, hospital settings and professions.²⁶ Also, combinations of
5 523 individual interviews and observations of team interactions in the OTs, made it possible to
6 524 collect data showing actual behaviours in their natural settings.^{23 24} Although all members of
7 525 the multidisciplinary surgical team were represented, interview selection bias was a
8 526 possibility. Despite our maximum variation purposive sampling strategy²⁸ a majority of the
9 527 informants turned out to be experienced clinicians (Table 2), which likely reflected and
10 528 limited the range of responses compared to if junior team-members had been involved. By use
11 529 of the ethnographic approach possible risks of SAP failures- and possible explanations of their
12 530 occurrence have been identified. Larger follow-up studies on procedures, work practices and
13 531 measures of SAP provision are required to achieve more generalisable findings.
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533 **CONCLUSION**

534 This study has explored SAP work processes in the pre-operative period and outlined how the
535 multitude of considerations in handling SAP may influence, and delay its administration. Yet,
536 a key element to proper SAP that supports timely provision is the given timeframe of
537 administration, focused on by SSC use. Thus, the introduction of SSC, emphasising SAP
538 administration 60 minutes prior to incision, is likely to have influenced administration
539 practice through the following mechanisms: 1) as a cognitive tool, in helping the nurse
540 anaesthetist to remember timing of SAP administration, 2) as an educational intervention,
541 facilitating resilience by making SAP providers able to respond promptly when in need of
542 clarifications of prescriptions, to ensure SAP administration before incision.
543

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552 study was endorsed by the National Advisory Unit for Antibiotic Use in Hospitals in Norway.
553

554 ***Author Contributions***

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3 555 HVW, IS, ES, SH, and ASH conceived of and designed the study. HVW carried out the data
4 556 collection, ASH participated in some of the observations. HVW, ASH, SH, ES performed
5 557 preliminary analysis, KA and SW participated in finalising the analysis, and provided input in
6 558 relation to methodology matter. All authors participated in interpretation of the study results,
7 559 assisted in manuscript revision, and approved the final draft.
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31 578 this study.
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580 ***Competing interest***

46 581 NS is the Director of London Safety and Training Solutions Ltd, which provides quality and
47 582 safety training and advisory services on a consultancy basis to healthcare organisation
48 583 globally.
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585 ***Ethics approval***

56 586 The study was reviewed by the Regional Ethics Committee, REK Vest, of the Western
57 587 Norway Health Region (2015/1741) prior to data collection, who recommended that the study
58 588 be reviewed by hospital management and data privacy ombudsman for research (DPO). The

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3 589 DPO reviewed and approved the study prior to data collection. All study participants gave
4 their informed, written consent to participate prior to the interviews, and could withdraw from
5 590 the study at any time.
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10 593 **Transparency statement**

11 594 HVW, SH, ASH and ES had full access to all of the data in the study and HVW affirms that
12 this manuscript is an honest, accurate, and transparent account of the study being reported.
13 595
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15 596

16 597 **Data sharing statement**

17 598 The datasets analysed during the current study are not publicly available due to confidentiality
18 599 issues, but can be made available (in Norwegian) from the corresponding author on
20 600 reasonable request.
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23 601

24 602 **Open Access**

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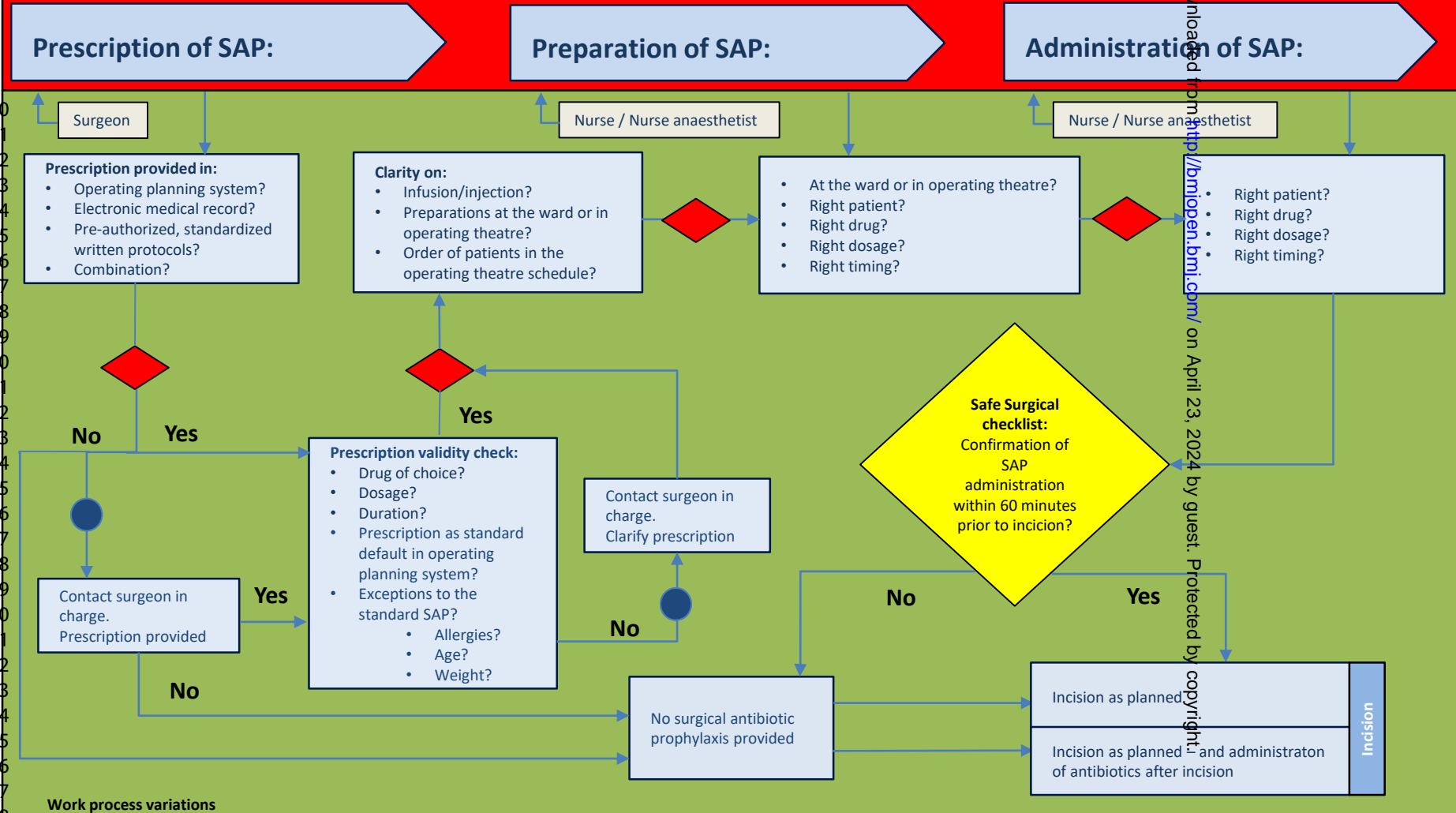
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The Norwegian National Regulation Framework for medication management



Interview guide

Interview number: _____

Setting: _____

Interview participant (profession): _____

Opening information to establish relationship with participants:

- Information on protection of anonymity of interview participants
- Clarification on role of the interviewer

Topic 1: Surgical antibiotic prophylaxis

Surgical antibiotic prophylaxis is crucial in the prevention of surgical site infections, and provision of antibiotic prophylaxis is standardized for many surgical procedures. In the following, I will ask questions related to the work processes surrounding provision of surgical antibiotic processes.

- Can you tell me how surgical antibiotic prophylaxis is prescribed?
 - (Pre-, per- and postoperatively)
- Can you tell me how surgical antibiotic prophylaxis is prepared?
- Can you tell me how surgical antibiotic prophylaxis is administered?
 - (When?)
 - (Who?)
 - (How?)
- In your opinion, what is challenging in relation to surgical antibiotic prophylaxis?
 - (Can you describe a challenging episode?)
- In your opinion, what works well in relation to surgical antibiotic prophylaxis?
 - (Can you describe a «well-functioning» situation?)

Topic 2: World Health Organization's Surgical Safety Checklist and teamwork:

The SSC has been introduced as a safety tool to enhance perioperative teamwork and information exchange, by systematically reviewing critical patient factors before the induction of anaesthesia, before the incision of the skin, and before the patient leaves the operating facility.

As (the relevant profession):

- In your opinion, do you think the SSC function as intended?
 - (How?)
 - (Why?)
- Can you describe a situation in which using the SSC has been useful or positive?
 - Any experiences in relation to surgical antibiotic prophylaxis?
- Can you describe a situation in which using the SSC has been difficult?
 - Any experiences in relation to surgical antibiotic prophylaxis?

Interview guide

Topic 3: Perioperative teamwork:

As (the relevant profession):

- How do you experience that the SSC influence the perioperative teamwork?
- Do you have any experiences in relation to “Time-Out” and the surgical antibiotic prophylaxis item?
- Have you experienced that the SSC may influence your professional role in the perioperative teamwork?
- Do you have any experiences in relation to “Time-Out” and the surgical antibiotic prophylaxis item?

Closing questions:

- Is there anything you would like to add, that you believe is of importance in relation to the topics we have discussed?
 - (Surgical antibiotic prophylaxis?)
 - (The Surgical safety checklist?)
 - (Perioperative teamwork?)
- Do you have any thoughts or feedback on this interview?

Thank you for your participation!

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

Investigation of perioperative work processes in provision of antibiotic prophylaxis: A 2 prospective descriptive qualitative study across surgical specialities in Norway.

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Investigation of perioperative work processes in provision of antibiotic prophylaxis: A 2 prospective descriptive qualitative study across surgical specialities in Norway.

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ABSTRACT

Objective

Surgical site infections are known postoperative complications, yet the most preventable of healthcare-associated infections. Correct provision of surgical antibiotic prophylaxis (SAP) is crucial. Use of the World Health Organization (WHO) Safe Surgical Checklist (SSC) has been reported to improve provision of SAP, and reduce infections postoperatively. To understand possible mechanisms and interactions in generating such effects, we explored the underlying work processes of SAP provision and SSC performance at the intersection of perioperative procedures and actual team working.

Design: An ethnographic study including observations and in-depth interviews. A combination of deductive and inductive content analysis of the data was conducted.

Setting: Operating theatres with different surgical specialities, in three Norwegian hospitals.

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3 40 **Participants:** Observations of perioperative team working (40 hours) and in-depth interviews
4 41 of 19 experienced perioperative team members were conducted. Interview participants
5 42 followed a maximum variation purposive sampling strategy.
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8 43 **Results:** Analysis identified provision of SAP as a process of linked activities; sequenced, yet
9 44 disconnected in time and space throughout the perioperative phase. Provision of SAP was
10 45 handled in relation to several interactive factors; preparation and administration, prescription
11 46 accuracy, diversity of prescription order systems, patient specific conditions, and changes in
12 47 operating theatre schedules. However, prescription checks were performed either as formal
13 48 SSC reviews of SAP items or as informal checks of relevant documents. In addition, use of
14 49 cognitive reminders and clinical experiences were identified as mechanisms used to enable
15 50 administration of SAP within the 60 minutes timeframe described in the SSC.
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18 51 **Conclusion:**

19 52 Provision of SAP was identified as a complex process. Yet, a key element in provision of
20 53 SAP was the given 60 minute timeframe of administration before incision, provided in the
21 54 SSC. Thus, the SSC seems beneficial in supporting timely SAP administration practice by
22 55 either being a cognitive tool and/ or as a cognitive intervention.
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24

25 56 **Key words:**

26 57 Surgical Wound Infection, Antibiotic Prophylaxis, Qualitative Research, Preoperative Care,
27 58 Patient Safety.
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30 60 **ARTICLE SUMMARY**

31 61 **Strengths and limitations of this study:**

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43 62 • This study builds on previous work investigating the impact of WHO surgical safety
44 63 checklist implementation on perioperative work processes including provision of
45 64 antibiotic prophylaxis.
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47 66 • It shows perspectives on provision of antibiotic prophylaxis by all members
48 67 represented in the multidisciplinary perioperative team, using purposive sampling
49 68 strategy in selecting participants for single, in-depth interviews.
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51 70 • It provides detailed, first-hand observations of everyday work processes on antibiotic
52 71 prophylaxis across different surgical specialties, including WHO surgical safety
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- 72 • The extent to which identified elements in the work processes of antibiotic
73 prophylaxis can be influenced and further lead to improved provision of prophylaxis
74 remains to be tested.
- 75 • The findings might not be generalisable across countries due to organisational and
76 cultural differences.

78 INTRODUCTION

79 Surgical site infections (SSIs) are associated with substantial morbidity and mortality,
80 prolonged hospital stay and increased costs.¹⁻³ Although SSI incidence is higher in low-and
81 middle income countries,⁴ SSIs remain the most common health care-associated infections in
82 the USA, and the second most frequent in Europe.^{5,6} The efficacy of surgical antibiotic
83 prophylaxis (SAP) in preventing SSIs is well established. Timely administration of
84 appropriate SAP is considered one of the most effective SSI prevention strategies⁵ as
85 recommended in the World Health Organization (WHO) global guidelines for prevention of
86 SSIs.⁷

87
88 Successful SAP requires administration of one or more antimicrobial agents at appropriate
89 time-points to achieve effective antibiotic concentrations at the surgical site at time of incision
90 and throughout surgery. Pharmacokinetic properties determine administration forms and
91 correct timing and intervals of antibiotic(s).⁵ Actual delivery of antibiotics for surgical
92 prophylaxis is commonly carried out within operating theatre (OT) premises. Provision of
93 optimal SAP may be influenced by a number of factors before, during and after surgery. Lack
94 of clarity concerning responsibility for the choice, dose, timing and duration of antibiotics
95 influences decision-making and proper prescription of SAP.⁸ Unresolved issues of workflow
96 and role perceptions have also been reported as obstacles to properly timed SAP.⁹ As a
97 consequence, SAP may be administered too early,¹⁰⁻¹² too late, or not at all,¹³⁻¹⁶ causing
98 unnecessary patient risks. Guidelines do not recommend prolonged SAP administration for
99 preventing SSI. However, prolongation of SAP for more than 24 hours remains prevalent.^{17,18}

100
101 Within the OT setting, the WHO Safe Surgical Checklist (SSC)¹⁹ includes evidence based
102 items for prevention of SSI. Use of the SSC has been reported to reduce mortality and
103 complications, including postoperative infections.^{20,21} In a previous study investigating
104 changes in perioperative care processes following WHO SSC implementation, we found
105 significant improvements in timely SAP provision preoperatively, within 60 minutes before

106 incision.²² This was further associated with reduced risks of infections and wound rupture
 107 postoperatively. We aimed to understand possible mechanisms and interactions contributing
 108 to these effects, in order to further improve SAP provision. The aim of this study was
 109 therefore to outline work flow of SAP provision, including SSC performance of SAP items at
 110 the intersection of preoperative procedures and actual team working. The following research
 111 questions were addressed: (1) How can SAP work processes be described? (2) What are the
 112 key elements in these work processes that influence provision of SAP?

114 METHODS

115 Design

116 An ethnographic design was used, where multi-professional perioperative teams were
 117 observed in action in OTs, followed by face-to-face interviews of key informants. This design
 118 is well suited to capture “everyday” routine behaviours in their natural settings.^{23 24}

120 Study setting

121 The study was conducted in three hospitals in one Regional Health Authority in Norway;
 122 surgical activity and hospital characteristics are described in table 1.

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Table 1. Characteristics of hospitals included in the study of surgical antibiotic prophylaxis work processes

Hospitals (N=3)	Hospital size*	Surgical activity**	Teaching status	Hospital level	Medical service	Organisational structure
1	1066	33584	University hospital	Tertiary referral hospital	National and regional referral hospital for medical and surgical care	22 specialised units
2	149	4769	Residency training approval	Secondary care hospital	General medical and surgical care	3 specialised units
3	244	7887	Residency training approval	Secondary referral hospital	General medical and surgical care	2 specialised units

The Regional Health Authorities have overall responsibility for the specialist health service. Hospital #1 and #3 are organised in two separate health trusts, while hospital #2 is a private, non-profit hospital on contract with the Regional Health Authority.

* 2016 Occupancy rate (Statistics Norway) = bed-days/available bed-days.

**2016 reported surgical hospital stays with one or more surgical procedure, based on the classification system of the Norwegian diagnosis related groups (N-DRG, Norwegian Patient Registry).

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3 125 The hospitals operate within separate organisational structures, and perioperative routines
4 126 vary accordingly. However, SAP use should be compliant with the implemented Norwegian
5 127 national guidelines of antibiotic use in hospitals.²⁵ Further, the WHO SSC had been
6 128 implemented formally at all sites at the time of the study.
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11 130 **Data collection**

12 131 Data triangulation was used in collection of data across time, hospital settings and professions
13 132 to capture a more complete and contextualised portrait of the studied settings and to validate
14 133 conclusion of findings.^{26 27} Data collections were limited by available time frames for both
15 134 the observation- and interview time, although saturation of data was met in relation to
16 135 responsibility of prescription, preparation and, administration of SAP.
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23 137 *Perioperative observations*

24 138 Data were collected through 40 hours of non-participant observations of perioperative teams
25 139 in OTs, and through individual interviews of members of these teams (surgeons, operating
26 140 theatre nurses, anaesthesiologists, and nurse anaesthetists). Observations aimed to map routine
27 141 behaviours on: 1) antibiotic management and 2) team reviews of antibiotic items in the WHO
28 142 SSC. All team observations took place within local OTs, and followed the entire perioperative
29 143 phase from the patient arrival in the OT to post-operative delivery. Data were collected from
30 144 one hospital at a time, with team observations taking place prior to interviews. The
31 145 observations covered scheduled surgical procedures at dates agreed upon beforehand with the
32 146 service managers and teams. Three different surgical specialties/subspecialties were included
33 147 in order to cover different SAP regimes. Observations of team interactions- and
34 148 communications were noted and reviewed by the research team. These field notes were used
35 149 to develop the interview guide.
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48 151 Mapping work processes of how antibiotics were managed in a variety of surgical contexts
49 152 was essential. By “work processes” we included both the formal documentation for standard
50 153 procedures of antibiotic prophylaxis as well as the organisational roles and responsibilities,
51 154 together with informal roles and lines of communication. All observations and interviews
52 155 were performed by HVW (nurse anaesthetist, trained in qualitative research). ASH (senior
53 156 nurse anaesthetist, trained in qualitative research) also participated in some of the initial
54 157 observations (6 hours). Observation notes were compared and discussed between the two
55 158 observers to validate findings.
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160 *Interviews with members of the perioperative team*
161 Nineteen interviews were performed lasting from 27 to 48 minutes in duration, with a median
162 length of 33 minutes. The interview guide covered three topics: 1) antibiotic management, 2)
163 use of the WHO SSC (with specific focus on SAP items), and 3) teamwork experience
164 (interview guide in Supplementary file 1). All healthcare personnel in the perioperative teams
165 were considered key informants. Hence, a maximum variation purposive sampling strategy
166 was used to elicit all perspectives in the provision of SAP in the OTs.²⁸ Invitations to
167 participate were initially reviewed and approved by the Directors of the Department of
168 Research and Development at the respective study hospitals. Participants were recruited by
169 the local managers. Professionals with variable length of perioperative work experience were
170 targeted for sampling; their characteristics are described in Table 2.

171
172 The interviews were conducted between November 2015 and November 2016, and were
173 conducted in the OT departments, in areas free from distractions (e.g., meeting rooms). Each
174 participant was interviewed once. The interviews were audiotaped, transcribed verbatim, and
175 transferred to NVivo Pro 11.4 computer software (QSR International Pty Ltd. ABN
176 47006357213) for coding.

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TABLE 2. Characteristics of informants in the study of surgical antibiotic prophylaxis work processes

Participant profession	Number N = 19	Work – experience years qualified in profession - range	Sex female/ male	Participant work place		
				Secondary care hospital	Secondary referral hospital	Tertiary referral hospital
Nurses¹ Nurse anaesthetist/ Operating theatre nurse	12	5 - 30	11/ 1	4	4	4
Physicians² Consultant anaesthesiologist/ Consultant surgeon/Surgeon	7	3 - 30	0/ 7	0	4	3
Total	19	3 - 30	11/ 8	4	8	7

¹Authorisation requirements in Norway: 3-year bachelor degree in Nursing-180 ECTS* + either a 1,5-year Specialist education program-90 ETCS, or a 2-year Master's program-120 ECTS at a College University degree.
²Authorisation requirements in Norway: 6-year cand. med degree, 360 ECTS* + 6,5 years of specialist training before qualification as consultant. *European Credit Transfer and Accumulation System (ECTS) credits.

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181 Analysis

182 Data from observations and interviews were analysed using a content analysis approach,
183 combining deductive and inductive analysis elements. First, to identify the perioperative work
184 process of SAP, a deductive approach was applied using directed content analysis as

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3 185 described by Hsieh and Shannon.²⁸ The Norwegian national regulation framework for
4 186 medication management was applied as coding frame. This regulation framework requires
5 187 healthcare personnel to adhere to defined responsibilities in the three domains of medication
6 188 prescription, -preparation and -administration to ensure that the right medication and dose is
7 189 administered correctly to the right patient at the right time.²⁹ The deductive analysis
8 190 investigated specific SAP work processes in relation to these three domains of the medication
9 191 regulation framework, which is also a compulsory part of the curriculum- and training for
10 192 nurses and physicians in Norway. HVW, ASH, ES (consultant anaesthesiologist) and SH
11 193 (consultant in infectious diseases) participated in the preliminary analysis using group
12 194 consensus to strengthen coherence of the findings.³⁰ Second, to further explore the underlying
13 195 work processes, an inductive approach was applied with a thematic analysis according to
14 196 Graneheim and Lundman.³¹ This qualitative content analysis comprises descriptions of the
15 197 manifest content close to the text as well as interpretations of the latent content distant from
16 198 the text, yet still close to the participants' experiences.³⁰ Statements, observations and
17 199 interpretations that reflected participants' conditional actions and interactions were identified.
18 200 The following steps were used: HVW, ASH and SH read the transcribed interviews forming
19 201 units of analysis. HVW identified and coded transcript sections into 'meaning units', followed
20 202 by relating categories and theme, constituting the manifest content.³¹

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36 204 Observational data were used to support the interview data analysis, contributing to the
37 205 formation and interpretation of emerging themes. ASH and SH reviewed the coding and
38 206 interpretations. Preliminary themes, subthemes and quotes were then discussed amongst the
39 207 authors (HVW, AS, ES, SH). In addition, KA and SW (safety scientists, trained in qualitative
40 208 methods) also participated in finalising analysis of the latent content, the underlying meaning
41 209 of the text, and concluding themes. The finalised dataset is reported in categories and sub-
42 210 themes constituting the overarching descriptive theme, with verbatim quotes from the
43 211 interviews, and summarised field notes from the observations to support and illustrate each
44 212 category.

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54 214 **Patient and Public involvement statement**

55 215 There was no direct patient or public involvement in this study, although the object of study
56 216 and its relevance to patient has been discussed on several occasions with Head of Patient
57 217 Involvement Committee in the Western Norway Regional Health Authority. Both observers
58 218 had previously worked in OTs. The local managers informed all OT staff prior to case

219 observations, and cases where any staff member or the patient withheld consent were
 220 excluded.

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223 **RESULTS**

224 Analysis of observations and interviews identified provision of SAP as a process of linked
 225 activities, sequenced yet disconnected in time and space during the perioperative phase. The
 226 process involved interactions of the multidisciplinary team members before, under and after
 227 surgery. The deductive analysis identified the “who”, “where” and “when” in relation to
 228 initial- and follow-up prescription, preparation, and administration of SAP. These three
 229 domains, as described in the Norwegian regulation framework, constituted the formal steps of
 230 the work process. Participants described these steps in relation to the entire perioperative
 231 phase, although timing administration of SAP prior to incision was a target.

232

233 The inductive analysis identified several challenges of competing demands and varying
 234 conditions, in the process of timing administration of SAP within the given timeframe of 60
 235 minutes prior to incision. The overarching theme describes provision of SAP as “a complex
 236 process of balancing timeliness whilst considering and responding to multiple, interacting
 237 factors”. The balancing of timeliness and interacting factors were further characterised by
 238 three sub-themes interpreted from nine categories, which were derived from codes of the
 239 deductive and inductive analysis, presented in table 3. In the following section, the three sub-
 240 themes and corresponding categories are presented in detail with representative illustrating
 241 verbatim quotes in italics.

242

Table 3. Main findings from the study “Investigation of perioperative work processes in provision of surgical antibiotic prophylaxis: A qualitative study across different surgical settings”, presented as categories, sub-themes and overarching theme

46 Theme	47 Provision of antibiotic prophylaxis as a complex process of balancing timeliness by considering and responding to multiple interacting factors.								
48 Sub-theme	Handling surgical antibiotic prophylaxis in consideration of multiple, preoperative interacting factors					Timing administration of surgical antibiotic prophylaxis in relation to knowledge and clinical experience		Performing formal and informal checks	
49 Category	Perceptions of antibiotic prophylaxis work processes (work as imagined)	Prescription accuracy	Diverse prescription order systems	Patient specific conditions	Changing schedules in operating theatre	Cognitive work task reminders	Importance of knowledge and clinical experience	Performance variety of Surgical Safety Checklist	Indirect and direct prescription validity checks
50 Codes	<ul style="list-style-type: none"> • Roles • Responsibility • Location of performance • Time 	<ul style="list-style-type: none"> • Unclear prescriptions • Lack of prescriptions • Standardised prescription • Electronic default settings 	<ul style="list-style-type: none"> • Electronic, surgical planning system • Electronic medication chart • Paper-forms • Wall poster in operating theatre 	<ul style="list-style-type: none"> • History of allergies • Type of surgery • Adjusting dosage in relation to age • Adjusting dosage in relation to weight (<ul style="list-style-type: none"> • Order of scheduled patients • Deviations from scheduled patient order • Deviations from information in operating planning system • Timing of incision 	<ul style="list-style-type: none"> • After patient transport • When positioning the patient • During placements of electrocardiography electrodes • When entering the operating theatre 	<ul style="list-style-type: none"> • Local prescription systems • Surgeons’ preferences • Surgical procedures • Selection of antibiotics according to procedures 	<ul style="list-style-type: none"> • Interruption of workflow • Unclear responses of antibiotic item • Performance challenges • Responsibility • Identifies missed SAP administration 	<ul style="list-style-type: none"> • Paper documents • Electronic medication chart • Electronic surgical planning system • Prescribing signature

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			<ul style="list-style-type: none"> • Oral prescription • Pre-authorized prescription protocols 	Body Mass Index - BMI)	<ul style="list-style-type: none"> • Approximate time estimations 	<ul style="list-style-type: none"> • After induction of anaesthesia 	<ul style="list-style-type: none"> • Alternative antibiotics 		<ul style="list-style-type: none"> • Calling surgeons • Paging surgeons • Approaching in person
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Handling surgical antibiotic prophylaxis when considering multiple interacting factors.

The formal work processes included participants' perception of roles, responsibility, location- and timing of performance related to prescription-, preparation and administration of SAP.

Prescription of SAP (drug of choice, dosage, and duration) was as a rule ordered by the surgeon before the surgical procedure, although verbal prescriptions might also occur during surgery. The surgeon then had to confirm the SAP prescription by signing the anaesthesia and/or postoperative record. This prescribing responsibility was acknowledged by all members of the team. However, diverse prescription order systems were observed with different prescription practices. Some units used electronic surgical planning systems with embedded preoperative standardised SAP prescriptions with default settings.

Nurse anaesthetist: "SAP is to be prescribed in the patient's medication chart by the surgeon, if there is an indication. Sometimes, SAP is prescribed in the electronic surgical planning system as well".

Surgeon: "As long as the patient belongs to this department SAP is to be prescribed in the medication chart. In case it is not written in the medication chart, then it [the antibiotic] is not prescribed properly".

Other units had written pre-authorized standardised SAP protocols for certain types of surgery, and patient-bound signed pre-operative medical paper forms of SAP prescription for others. The different preoperative SAP prescription systems varied not only between sites, but also between surgical wards at one of the study hospitals. Nurse anaesthetists also described variations in prescription accuracy, particularly in cases with unclear prescriptions or lack thereof. Sometimes the anaesthesiologist might also be involved in prescription orders such as in endocarditis prophylaxis or when the anaesthesiologist was personally responsible for an interventional procedure, e.g. subcutaneous venous port implantations.

Anaesthesiologist: "Formally, the surgeon is in charge of the SAP prescription orders, no doubt of that! Within the premises of the operating theatres, I only prescribe SAP to patients if I'm in charge of the procedure, i.e.: subcutaneous venous port implantations"

278 Preparations of all SAP infusion(s) or injection(s) were done by nurses. The medication
279 infusions were mainly prepared in the OTs by nurse anaesthetists, but for surgery involving
280 combinations of two antibiotics, infusions were prepared in the surgical ward.

281 *Nurse anaesthetist: "For orthopaedic surgery, and for some of the abdominal.....like the inguinal hernia*
282 *repairs, we prepare the SAP ourselves, although sometimes it gets a bit messy, due to suboptimal*
283 *localities... For some of the other abdominal surgeries.... I.e. cancer surgery, the SAP is prepared as 500*
284 *mL or 1000 mL infusions, and both preparations are made at the ward, and brought to the OT along with*
285 *the patients"*

286
287 Administration was then started in the surgical ward or the operating holding area: The ward
288 nurse handed over the double controlled and signed infusion containers to the nurse
289 anaesthetist if the infusions were not completed before patient handover. SAPs with short
290 half-lives were both prepared and administered to patients by nurse anaesthetists within the
291 OT. Dosages and time points were documented in the patients' anaesthetic records, registered
292 at a precise time point (injections) or an explicit "start" and "stop" time (infusions).

293 *Operating theatre nurse: "The anaesthesia team is responsible for SAP administration. Medications,*
294 *anaesthesia, ... this is their responsibility"*

295
296 Considering patient specific factors were also described as important when handling SAP.
297 When in need of alternative antibiotic(s) due to patient allergies, adjustments in timely
298 administration of SAP had to be reconsidered, according to the pharmacokinetic property of
299 the alternative antibiotics, especially half-lives. This was not always clarified prior to the
300 patient's arrival in the operating theatre. Clarifications on the precise SAP dosages in cases of
301 elder, adipose or paediatric patients were also reported by informants as important, yet time-
302 consuming considerations in the planning or preparation of SAP.

303 The type of surgery initially determined the SAP regimes. Hence, the OT scheduling of
304 patients also influenced SAP work processes. The scheduled order of the different surgical
305 procedures in the OT- with corresponding specific SAP regimes generated fluctuating SAP
306 work processes throughout the day. With the exception of the first patient admitted to the OT
307 the timings of incision for the remaining scheduled patients were based on approximate time
308 estimations with SAP being administered according to these estimations.

309 *Nurse anaesthetist: "It is much easier to provide right timing of SAP to the first scheduled patient of*
310 *the day, because we have an exact point of time scheduled for this patient. Throughout the day, it gets*
311 *more complicated, because it is difficult to predict the time of arrival- and administration of SAP, for*
312 *the next patients"*

1
2
3 313 Participants described cases where information in the operating planning system, including
4 314 SAP prescriptions, deviated from agreed (or perceived as agreed) upon perioperative
5 315 standards. Furthermore, abrupt changes in preoperative scheduling, lack of signed
6 316 preoperative prescriptions and uncertain SAP indications also caused variations in the
7 317 preparations- and administration of SAP.

318

14 319 **Timing administration of surgical antibiotic prophylaxis using clinical knowledge and**
15 **experience.**

16 320
17 321 The participants described how specific preoperative work tasks served as cognitive
18 322 reminders for SAP administration within the preferred timeframe. This was explained as
19 323 particularly helpful for the anaesthesia team as both preparation and administration of SAP
20 324 might easily be influenced by concurrent tasks, distracting them in timely provision of SAP.
21 325 This was confirmed through observations, especially during induction of anaesthesia. The
22 326 anaesthesia team explained how linking SAP administration concurrently to other specific
23 327 work tasks made it easier for them remembering to administer SAP within the recommended
24 328 timeframe of 60 minutes. Such work tasks included patient transport, patient positioning or
25 329 electrocardiography electrodes placement.

30 330 *Nurse anaesthetist: "For orthopaedic patients, they are first transported to anaesthetic room, for*
31 331 *application of anaesthesia. Then, there is a timespan where SAP may be administered, before the patient*
32 332 *is transported into the OT".*

333

334 SAP administration was also emphasised to be carried out at specific points of time in the
335 preoperative phase such as when entering the OT, when positioning the patient, or after
336 induction of anaesthesia.

337 *Anaesthesiologist: "As a routine, I believe that the SAP is administered during induction of anaesthesia,*
338 *just after we have inserted the central venous catheter".*

339

340 Use of the WHO SSC, with the item for specified timeframe of SAP provision within 60
341 minutes prior to incision, was also described as a reminder. Most of the nurse participants
342 reported that the WHO SSC implementation had made them more aware of this timeframe.
343 Knowledge and experience on surgical routines and workflow in the OTs, in addition to the
344 local SAP regimes, were also highlighted as important amongst the participants. This was
345 described as being experience gained on the standardised surgical procedures and the types of
346 antibiotics used as standard prophylaxis for the different procedures performed at their

1
2
3 347 surgical unit. In addition, participants emphasised the need to have knowledge on alternative
4
5 348 SAPs used in cases of identified antibiotic allergies.

6 349 *Nurse anaesthetist: "When you have some experience, you know which type of surgeries that requires*
7
8 350 *SAP, and which types of surgeries that do not, because you recognise the indications, even though*
9 351 *prescriptions are not clear".*

10 352

11 353 **Performing formal and informal checks**

12 354 Both formal- and informal SAP checks were carried out in the preoperative phase as
13
14 355 illustrated in Figure 1, which outline the workflow for SAP including different checkpoints.
15
16 356 The Surgical Safety Checklist constituted the formal, compulsory check. Prior to incision, the
17
18 357 perioperative teams paused and performed a "Time-Out" according to the WHO SSC with
19
20 358 items questioning whether SAP had been provided read aloud. Varying team-briefing
21
22 359 responses as to these SSC SAP items were observed. Some team responses concentrated on
23
24 360 the timing of SAP administration, some reviewed if prescribed dosages correlated to the
25
26 361 actual administered SAP, and some left responses to the SSC items out completely. During
27
28 362 performance of the formal SSC, and specifically when addressing SAP items during the SSC
29
30 363 team briefings, some of the OT nurses were reluctant, because they felt like questioning aloud
31
32 364 whether the anaesthesia team had performed their job or not. If the anaesthesia team failed to
33
34 365 respond, repetition of these SSCs items was then ignored.

34 366 *Operating theatre nurse: "My only worry- personally- is to ask the anaesthesia team whether they have*
35
36 367 *done their job or not. I really struggle with this checklist item [SAP]. I get this awkward feeling ... It's*
37 368 *like poaching on somebody's preserve".*

38 369

39
40 370 The informants also described episodes where surgeons did not wait (but carried on with
41
42 371 incision) despite the "Time-Out" briefings having identified missing or delayed SAP
43
44 372 administration. This was also confirmed by observations.

45 373 *Surgeon: "No, I don't think that I have ever experienced to stop and await incision, in cases where SAP*
46
47 374 *has not been fully administered".*

48 375

49
50 376 The physicians' responses were explained by an overall concern of delay causing surgical
51
52 377 program flow disruptions and prolonging time of anaesthesia. However, in cases where
53
54 378 surgery required application of a tourniquet, surgeons delayed incision in order to let the SAP
55
56 379 work appropriately.

56 380 *Operating theatre nurse: "No, the surgeons do not await incision if SAP is missing. Only if the tourniquet*
57
58 381 *is already applied, then they have to wait".*

59 382

1
2
3 383 Informal SAP checks were performed by the anaesthesia teams to clarify which antibiotic to
4 384 administer, the dosages and duration. For the SAP to be administered by the nurse
5 385 anaesthetists in the OT SAP prescription orders should have been documented and signed
6 386 preoperatively according to local prescription systems involved, i.e. written paper orders,
7 387 electronic orders or orders in the patient medical chart. The informants emphasised that SAP
8 388 prescriptions also had to be checked to ensure validity of the prescription order, as default
9 389 settings in the electronic surgical planning system might cause an unintentional or incorrect
10 390 SAP prescription.

11 391 *Nurse anaesthetist: "Well, if SAP is not prescribed initially, and the surgeon arrives in theatre and*
12 392 *announces that we need to administer antibiotic prophylaxis....Then, I need to make the surgeon sign the*
13 393 *patient's medical record. I present the medical record to the surgeon and then...sign here, please!"*

14 394
15 395 The surgeons in charge were contacted in cases of partial or missing SAP prescription orders,
16 396 or if anyone in the anaesthesia team was in doubt of whether or not to administer the SAP.
17 397 Surgeons were contacted by phone or pager or by approaching them when they entered the
18 398 OT. These actions were taken by members of the anaesthesia team themselves or by the
19 399 operating theatre nurses on behalf of the former.

20 400 *Anaesthesiologist: "Normally, the nurse anaesthetist calls the surgeon if SAP prescriptions are missing".*

21 401 22 402 **DISCUSSION**

23 403 This study has identified provision of SAP as a complex process of balancing timeliness by
24 404 considering and responding to multiple interacting factors. Our findings of the multiple
25 405 considerations and compensating mechanisms used particularly in the preoperative phase,
26 406 highlight the real-world balancing of professional judgements regarding patient, antibiotic,
27 407 and surgery-related factors as well as coordinating the OT scheduling and -work flow for SAP
28 408 to be administered in due time before incision. Even though perceptions of responsibility in
29 409 relation to SAP -prescription, -preparation and -administration were consistent among team
30 410 members, our results indicate ambiguities in ownership for SAP. This was seen especially at
31 411 intersections of prescription transfers to providers, where suboptimal use of the prescription
32 412 order systems or poorly completed SAP orders may provide unclear indications for SAP to its
33 413 actual providers. In addition, the team performances on the WHO SSC including reviews of
34 414 antibiotic items varied during the "Time Out" part of the SSC, also with a reluctance to
35 415 address SAP items, described by the OT nurses. The nurse anaesthetist, surgeon and
36 416 anaesthetist each seem to have self-perceived defined roles in provision of SAP, and yet these
37 417 roles did not seem to be aligned or sufficiently understood through shared decision-making.

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2
3 418 Consequently, possible risks of SAP failures were poorly understood or defined at each step
4 419 in the preoperative planning of surgery.
5
6 420
7
8 421 Existing surgical workflow systems have previously been identified by surgeons and
9 422 anaesthesiologists as an obstacle to proper timing of SAP, also with work processes of SAP
10 423 being of low priority amongst their many perioperative responsibilities.⁹ Yet, studies
11 424 investigating predictors for appropriate antibiotic use found that patients were more likely to
12 425 receive an effective and timely first SAP dose when preoperative orders were written and
13 426 implemented in the OTs.^{32 33} We identified a number of interacting considerations that might
14 427 help to understand factors and situations influencing timely provision of SAP. One contributor
15 428 to delayed SAP administration was ignored identification of patients' allergies, or the lack of
16 429 such being properly addressed. This has also been reported by others, with administration of
17 430 an effective first prophylactic dose being less likely when a patient had a beta-lactam allergy,
18 431 increasing the risk of SSI.³³ Another identified contributor to delayed SAP administration was
19 432 the need to clarify the precise SAP dosages in cases of elder, adipose or paediatric, especially
20 433 neonate, patients. As these sub-groups of surgical patients (age < 60 weeks and > 75 years,
21 434 obesity with BMI > 30, morbid obesity with BMI ≥40) are reported to have an increased risk
22 435 of developing SSIs based on their physical status, delayed SAP administrations adds to these
23 436 risks.^{25 34} The classification of patients' physical status (America Society of Anesthesiologists
24 437 classification) has previously been identified as a significant predictor of SSIs.³⁵ Patients with
25 438 an impaired physical status should therefore be given extra attention during the planning and
26 439 prescription of SAP. Although our findings describe the surgeons as being responsible for
27 440 SAP prescriptions, the anaesthesiologists have responsibility for patient assessments as to
28 441 potential allergies and physical status. This imbalance of responsibilities might contribute to
29 442 unclear SAP prescription orders with risks of delayed SAP administrations.³⁶ Further, our
30 443 findings indicate that suboptimal use of the prescription order systems or poorly completed
31 444 SAP orders may provide unclear indications for SAP to its actual providers. Especially the
32 445 nurse anaesthetist performed additional informal SAP checks, and the surgeons were
33 446 contacted when in doubt of SAP indication or the validity of the prescription order.
34 447 Nevertheless, the need to spend crucial minutes in the OTs to clarify prescription orders as
35 448 illustrated in Figure 1, inadvertently leaves a narrower timeframe for the nurse anaesthetist to
36 449 administer SAP on time (60 minutes prior to incision). A narrower timeframe in itself, in turn,
37 450 increases risk of SAP administration delays. A comparison on the risk of SSI with different
38 451 timing intervals of SAP was addressed in a recent meta-analysis.³⁷ The analysis showed that

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2
3 452 the risk of SSIs almost doubled when SAP was administered after incision compared to before
4 453 incision, and resulted in 25 more infections per 1000 treated patients.³⁷

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7
8 455 This study builds on previous research which reported significant improvements in timely
9 456 SAP provision preoperatively before incision following implementation of the WHO SSC.²²
10 457 The key novelty of our findings show how implementation of the SSC may facilitate resilient
11 458 mechanisms within the team, in relation to specific work processes of SAP. This is supported
12 459 by how timing administration of antibiotics was performed. We found that this was executed
13 460 mainly by nurse anaesthetists, in relation to their knowledge and clinical experience of
14 461 workflow in surgery, and the performance of prescription checks at different time points
15 462 before incision (Figure 1.). A key element that seems to drive tasks and behaviours related to
16 463 SAP administration was the given timeframe of 60 minutes prior to incision as provided in the
17 464 SSC. This suggests that the SSC might serve as a cognitive tool to drive SAP administration
18 465 to take place prior to incision. In addition, by being aware of the timeframe the providers of
19 466 SAP were able to respond to regular and irregular variabilities in prescriptions by questioning
20 467 uncertainties and adjusting timing of SAP administration according to disturbances in the OT
21 468 workflow.

22 469
23
24 470 However, the identified various team responses during the “Time Out” part of the SSC as well
25 471 as a reluctance to address SAP items, indicates a lack of SSC quality performance at full
26 472 length. In a previous study, we have identified how nurses utilised a variety of strategies to
27 473 adjust team involvement when encountering resistance to the SSC from members of the
28 474 surgical team.³⁸ This included avoiding completing the checklist entirely, or selectively
29 475 completing some items with specific team members. Both strategies resulted in decreased
30 476 quality of the SSC process. This shows that obstacles stemming from the SSC apply not only
31 477 to the content but also to psychological ownership³⁹ Moderate compliance rates of SSC
32 478 utilisation as well poor performance quality, have also been identified in previous studies.⁴⁰⁻⁴²
33 479 Furthermore, we found that identification of missing or delayed SAP prescription or
34 480 administration during time-out reviews, seldom resulted in delays of incision, although this is
35 481 recommended in guidelines.⁴³

36 482
37
38 483 Our findings indicate that the SSC is likely to identify missed SAP administrations, yet does
39 484 not prevent surgical incision to take place before SAP administration. However, having
40 485 established focus on the timeframe of completing SAP administration within 60 minutes prior

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3 486 to incision through SSC use might have influenced SAP administration practise indirectly.
4
5 487 The nurse anaesthetist more likely responds in a prompt manner to unclear prescriptions, and
6
7 488 adjusts timing of administration in accordance with the SSC recommendations. To strengthen
8
9 489 SSC use as a safety barrier to minimise risk of SSI, we suggest that SAP prescription checks
10
11 490 should also be done by the nurse anaesthetist at the Sign-In in addition to the surgeons'
12
13 491 already established controls of SAP administration at Time-Out (Figure 1.). This should also
14
15 492 reduce risk of interfering with the time point for incision and possible delays in OT schedules.
16
17 493 Such clarifications via preoperative team briefings have previously been associated with
18
19 494 improved clinical practice of timely SAP administration.⁴⁴

20 496 **Recommendations and further research**

21
22 497 Antibiotic stewardship programs (ASP) are of particular importance to surgical specialties due
23
24 498 to their prominent role in prophylactic antibiotic usage and management of surgical
25
26 499 infections, and may serve as suitable frameworks to address correct provision of SAP.⁴⁵
27
28 500 Multidisciplinary team roles and pathways specifying timing and sequence of responsibilities
29
30 501 are recommended to influence team-level communications and workflow.⁴⁶ Based on our
31
32 502 findings we advocate that objectives and measures of antibiotic stewardship programs in
33
34 503 surgery must include both nurse providers of SAP as well as the surgeon prescribers. Our
35
36 504 findings illustrate how nurses, particularly nurse anaesthetists, are important stakeholders in
37
38 505 SAP provision when responding to unclear prescriptions and adjusting time of SAP
39
40 506 administration according to the timeframe provided in the SSC. Nurses' role in antibiotic
41
42 507 stewardship practices in hospitals have previously been emphasised.⁴⁷ To our knowledge their
43
44 508 role and responsibility of SAP in the perioperative period has not been described before.

45
46 510 Further research should investigate how the roles and responsibilities of nurses and nurse
47
48 511 anaesthetists regarding SAP management for surgical patients could be expanded. In addition,
49
50 512 antibiotic stewardship programs in surgery should test SAP delivery interventions, and
51
52 513 measure performance indicators of timely SAP administrations as well as prescription
53
54 514 adherence to guidelines. We suggest that education of SAP indications and the
55
56 515 pharmacokinetic properties of the antibiotic used as prophylaxis may further support SAP
57
58 516 providers to target SAP timing according to the half-life of the prescribed antibiotic. Also,
59
60 517 providing feedback on timeliness of SAP administration as performance indicator will allow
518
519 518 nurses and nurse anaesthetists to take ownership in improving provision of timely SAP.⁴⁶

520 **Study limitations**

521 This study was conducted in surgical settings in Norway. Recommendations of SAP regimes
522 were based on the Norwegian national guidelines of antibiotic use in hospitals. The identified
523 work processes and mechanisms might therefore be limited to reflect practice in Norway.
524 However, international recommendations indicate that SAP should be initiated within 60-120
525 minutes prior to surgical incision, based on its pharmacokinetic property.⁵
526 In order to achieve credible information on the SAP work processes, data triangulation was
527 used by collecting data across time, hospital settings and professions.²⁶ Also, combinations of
528 individual interviews and observations of team interactions in the OTs, made it possible to
529 collect data showing actual behaviours in their natural settings.^{23 24} Although all members of
530 the multidisciplinary surgical team were represented, interview selection bias was a
531 possibility. Despite our maximum variation purposive sampling strategy²⁸ a majority of the
532 informants turned out to be experienced clinicians (Table 2), which likely reflected and
533 limited the range of responses compared to if junior team-members had been involved. By use
534 of the ethnographic approach possible risks of SAP failures- and possible explanations of their
535 occurrence have been identified. Larger follow-up studies on procedures, work practices and
536 measures of SAP provision are required to achieve more generalisable findings.

537

538 **CONCLUSION**

539 This study has explored SAP work processes in the preoperative period and outlined how the
540 multitude of considerations in handling SAP may influence, and delay its administration. Yet,
541 a key element to proper SAP that supports timely provision is the given timeframe of
542 administration, focused on by SSC use. Thus, the introduction of SSC, emphasising SAP
543 administration 60 minutes prior to incision, is likely to have influenced administration
544 practice through the following mechanisms: 1) as a cognitive tool, in helping the nurse
545 anaesthetist to remember timing of SAP administration, 2) as an educational intervention,
546 facilitating resilience by making SAP providers able to respond promptly when in need of
547 clarifications of prescriptions, to ensure SAP administration before incision.

548

549 **Legend to Figure 1:**

550 The clinical pathway of surgical antibiotic prophylaxis (SAP): an outline of the workflow for
551 SAP in perioperative care.

552

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1
2
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16

17 562

18 563 ***Author Contributions***

19
20 564 HVW, IS, ES, SH, and ASH conceived of and designed the study. HVW carried out the data
21
22 565 collection, ASH participated in some of the observations. HVW, ASH, SH, ES performed
23
24 566 preliminary analysis, KA and SW participated in finalising the analysis, and provided input in
25
26 567 relation to methodology matter. All authors (HVW, SH, ES, NS, IS, SW, KA, and ASH)
27
28 568 participated in interpretation of the study results, assisted in manuscript revision, and
29
30 569 approved the final draft.
31

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589

8 590 ***Competing interest***

10 591 NS is the Director of London Safety and Training Solutions Ltd, which provides quality and
11 592 safety training and advisory services on a consultancy basis to healthcare organisation
13 593 globally.

594

17 595 ***Ethics approval***

18 596 The study was reviewed by the Regional Ethics Committee, REK Vest, of the Western
19 597 Norway Health Region (2015/1741) prior to data collection, who recommended that the study
20 598 be reviewed by hospital management and data privacy ombudsman for research (DPO). The
22 599 DPO reviewed and approved the study prior to data collection. All study participants gave
23 600 their informed, written consent to participate prior to the interviews, and could withdraw from
24 601 the study at any time.

602

30 603 ***Transparency statement***

31 604 HVW, SH, ASH and ES had full access to all of the data in the study and HVW affirms that
32 605 this manuscript is an honest, accurate, and transparent account of the study being reported.

606

37 607 ***Data sharing statement***

38 608 The datasets analysed during the current study are not publicly available due to confidentiality
39 609 issues, but can be made available (in Norwegian) from the corresponding author on
40 610 reasonable request.

611

46 612 ***Open Access***

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617

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The Norwegian National Regulation Framework for medication management

Prescription of SAP:

Preparation of SAP:

Administration of SAP:

Surgeon

Nurse / Nurse anaesthetist

Nurse / Nurse anaesthetist

Prescription provided in:

- Operating planning system?
- Electronic medical record?
- Pre-authorized, standardized written protocols?
- Combination?

Clarity on:

- Infusion/injection?
- Preparations at the ward or in operating theatre?
- Order of patients in the operating theatre schedule?

- At the ward or in operating theatre?
- Right patient?
- Right drug?
- Right dosage?
- Right timing?

- Right patient?
- Right drug?
- Right dosage?
- Right timing?



No Yes



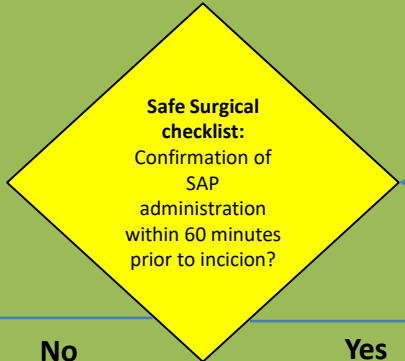
Yes

Prescription validity check:

- Drug of choice?
- Dosage?
- Duration?
- Prescription as standard default in operating planning system?
- Exceptions to the standard SAP?
 - Allergies?
 - Age?
 - Weight?

Contact surgeon in charge. Clarify prescription

No



Safe Surgical checklist: Confirmation of SAP administration within 60 minutes prior to incision?

No

Yes

Contact surgeon in charge. Prescription provided

Yes

No

No surgical antibiotic prophylaxis provided

Incision as planned	Incision
Incision as planned and administration of antibiotics after incision	

Work process variations

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SAP checks - Nurse / Nurse anaesthetist



SAP check - Surgeon



Follow-up

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Interview guide

Interview number: _____

Setting: _____

Interview participant (profession): _____

Opening information to establish relationship with participants:

- Information on protection of anonymity of interview participants
- Clarification on role of the interviewer

Topic 1: Surgical antibiotic prophylaxis

Surgical antibiotic prophylaxis is crucial in the prevention of surgical site infections, and provision of antibiotic prophylaxis is standardized for many surgical procedures. In the following, I will ask questions related to the work processes surrounding provision of surgical antibiotic processes.

- Can you tell me how surgical antibiotic prophylaxis is prescribed?
 - (Pre-, per- and postoperatively)
- Can you tell me how surgical antibiotic prophylaxis is prepared?
- Can you tell me how surgical antibiotic prophylaxis is administered?
 - (When?)
 - (Who?)
 - (How?)
- In your opinion, what is challenging in relation to surgical antibiotic prophylaxis?
 - (Can you describe a challenging episode?)
- In your opinion, what works well in relation to surgical antibiotic prophylaxis?
 - (Can you describe a «well-functioning» situation?)

Topic 2: World Health Organization's Surgical Safety Checklist and teamwork:

The SSC has been introduced as a safety tool to enhance perioperative teamwork and information exchange, by systematically reviewing critical patient factors before the induction of anaesthesia, before the incision of the skin, and before the patient leaves the operating facility.

As (the relevant profession):

- In your opinion, do you think the SSC function as intended?
 - (How?)
 - (Why?)
- Can you describe a situation in which using the SSC has been useful or positive?
 - Any experiences in relation to surgical antibiotic prophylaxis?
- Can you describe a situation in which using the SSC has been difficult?
 - Any experiences in relation to surgical antibiotic prophylaxis?

Interview guide

Topic 3: Perioperative teamwork:

As (the relevant profession):

- How do you experience that the SSC influence the perioperative teamwork?
- Do you have any experiences in relation to “Time-Out” and the surgical antibiotic prophylaxis item?
- Have you experienced that the SSC may influence your professional role in the perioperative teamwork?
- Do you have any experiences in relation to “Time-Out” and the surgical antibiotic prophylaxis item?

Closing questions:

- Is there anything you would like to add, that you believe is of importance in relation to the topics we have discussed?
 - (Surgical antibiotic prophylaxis?)
 - (The Surgical safety checklist?)
 - (Perioperative teamwork?)
- Do you have any thoughts or feedback on this interview?

Thank you for your participation!

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.