Development and validation of surgical Patients' own Safety Checklist – PASC

A new tool to involve patients in safety

Kristin Harris

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
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Scientific environment

The Ph.D. candidate was accepted at the Department of Clinical Research (K1) at the University of Bergen and all the doctoral training was carried out here. The Ph.D. scholarship and project funding was granted from the Western Norway University of Applied Sciences, thorough the Patients-reported Outcomes and Patient Safety in acute and/or critical illness (POPS) research group. The Surgical Safety Checklist research group at the Department of Anaesthesia and Intensive care at Haukeland University Hospital, Bergen, Norway, the Centre for Implementation Science, Health Service & Population Research Department, King's College London, London, United Kingdom, and the Western Regional Norwegian Health Authority Network for patient safety research has been a vital part of the scientific environment throughout this doctoral project.

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This regional research project had a strong collaboration with multidisciplinary teams from six surgical departments; Breast & Endocrine; Ear, Neck, Throat (ENT)/Maxillo-Facial; Neuro; Thorax and Gastro surgical ward at Haukeland University Hospital, and General surgery at Førde Central Community Hospital. In addition, the general practitioners' representatives and the media and communication centre at the Department of Research and Development at Haukeland University Hospital assisted with the development and design of the surgical Patients' Safety Checklist.

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Abstract (in Norwegian)

Bakgrunn: Sjekklister for bruk av kirurgisk helsepersonell er vist å ha forbedret teamarbeid og pasientsikkerhet. Fremdeles opplever et stort antall pasienter feil som kunne ha vært forebygget. Verdenshelseorganisasjons globale pasientsikkerhetsplan (2021-2030) har som mål å eliminere alle feil som kan forebygges innenfor helsesektoren. De anerkjenner at for å nå dette målet må pasientene bli mere involvert i pasientsikkerhetsarbeid, et behov som også er anerkjent i forskning og av helseorganisasjoner, sykehus og helsearbeidere. Det er derfor behov for initiativ som styrker pasientinvolvering. En sjekkliste for kirurgiske pasienter er et slikt initiativ. I denne avhandlingen er en slik sjekkliste utviklet og validert, samt at sjekklistens gjennomførbarhet er undersøkt.

Mål:

1. Undersøke og beskrive risikoelementer og muligens innhold for en kirurgisk pasient sjekkliste før og etter kirurgi.

2. Utvikle og validere kirurgiske pasienters sjekkliste til bruk før og etter kirurgi.

3. Undersøke gjennomførbarheten av kirurgiske pasienters sjekkliste, ved å identifisere dens bruk, rekrutering, barrierer og drivere for videre implementering i en stegvis klynge-randomisert kontrollert studie.

Metode: Kvalitative og kvantitative metoder er brukt, med et rammeverk for komplekse intervensjoner som overordnet struktur. Alle data ble samlet inn på Haukeland Universitets sykehus, og Førde Sentralsykehus. I studie I, ble data samlet inn fra fem kirurgiske avdelinger (en fra Førde og 4 fra Haukeland universitetssykehus). I studie II og III, deltok en avdeling i tillegg, fra Haukeland universitetssykehus. Studie I hadde en kvalitativ tilnærming, mens både kvalitative og kvantitative tilnærminger ble brukt i studie II og III. Induktiv innholdsanalyse ble brukt i studienes kvalitative deler. I studie I, ble fokusgruppeintervju gjennomført med post-operative pasienter og helsearbeidere. Under sjekklistens utviklingsprosess, i

studie II, ble en konsensusmetode som inkluderte et ekspertpanel brukt for å oppnå enighet om innholdet i sjekklisten.

Det ble gjennomført en samlet datainnsamling fra de samme kirurgiske avdelingene i studie II og III, både for de kvalitative og kvantitative data. Tre fokusgruppeintervju ble gjennomført med post-operative pasienter som hadde brukt pasientenes kirurgiske sjekkliste. Her ble også kvantitative data samlet fra kirurgiske pasienter som hadde brukt sjekklisten. Dataen ble analysert med deskriptiv statistikk for å undersøke bruken av sjekkpunktene og rekruteringen. En kji-kvadrat test ble brukt for å sammenligne pasientkarakteristikken. I studie II, ble pasientene bedt om å skåre hvert sjekklistepunkt ved bruk av en valideringsindeks for innholdet. Reliabiliteten av pasientenes sjekkliste validering ble undersøkt med Intraclass Correlation Coefficient. For punktene som pasientene skåret lavt på relevans på valideringsindeksen, ble det gjort en risikovurdering av hvert enkelt punkt med Health Failure Mode Effect hazard skåring. Risikovurderingen ble utført for å sikre at punkter på sjekklisten som kunne ha høy risiko for feil ikke ble fjernet fra sjekklisten grunnet lav relevans på pasientenes valideringsindeks.

Resultat: I studie I, identifiserte pasienter og helsearbeidere riskområder som kunne brukes som innhold i kirurgiske pasienters sjekkliste. Mulige riskområder ble plassert under fire hovedkategorier som representerte når og hvilke informasjon pasientene bør få gjennom det kirurgiske forløpet. De fire kategoriene er; "Pre-operativ informasjon", "Pre-operativ forberedelser", "Post-operativ informasjon" og "Videre plan og oppfølging". I tillegg utrykte både pasientene og helsearbeidere et behov for en mer systematisk praksis for pasientinformasjon, før og etter operasjon.

I studie II, ble funnene fra studie I presenter for et ekspertpanel og gjennom en konsensusprosess ble det oppnådd enighet om innholdet i sjekklisten. 215 av 428 inviterte kirurgiske pasienter deltok i studien og validerte punktene på pasientenes sjekkliste. Pasientene var enige om relevansen av de fleste sjekklistepunktene, men fem punkter ble fjernet grunnet lav relevans og risiko for komplikasjoner. Seks punkter ble redesignet for å forbedre brukervennligheten. Scale-level Content Validity Index/Averages på sjekklistens to pre-operative og post-operative deler var

henholdsvis 0,89 og 0.93, som indikerer en god aksept av sjekklistens innhold. Intraclass Correlation Coefficient indikerte en utmerket reliabilitet av pasientenes validering med en skår på 0.97, og et smalt 95% konfidensintervall på 0.96-0.99. Funnene fra fokusgruppeintervjuene viste god face-validitet for innholdet i sjekklisten. I tillegg understøttet funnene de kvantitative resultatene som viste behov for å redesignet enkelte sjekklistepunkt.

I studie III, brukte 50.2% (428/215) (de samme pasientene som i studie II) den kirurgiske pasient sjekklisten og 86.5% (186/215) av pasientene svarte på mer enn 80% av sjekklistepunktene. Årsaker for ikke å bruke sjekklisten var for 24.1% (103/428) av pasientene relatert til kirurgisk strykninger, 19.1% (85/428) leverte ikke samtykke, 5.1% (22/428) mistet eller glemte å levere sjekklisten, og 0.7% (3/428) døde mens de var på sykehuset. Fokusgruppeintervjuene identifiserte barrierer og drivere for bruken og implementering av sjekklisten som; viktigheten av å la pasientene ha tid til å bruke sjekklisten, design (brukervennlighet), og viktigheten at helsearbeidere fremmet sjekklistebruken. Driverne for å bruke sjekklisten var at den ga støtte gjennom det kirurgiske forløpet og økte kommunikasjonen mellom pasient og helsearbeider.

Konklusjon: Kirurgiske pasienters sjekkliste ble utviklet gjennom studie I og II og dens gjennomførbarhet ble undersøkt i studie III, i forbindelse med en planlagt klinisk studie. Det er sterke bevis at den kirurgiske pasienters sjekklisten er relevant for pasientene og at den systematiserer pre-operativ og post-operativ informasjon. Det er også en indikasjon at kirurgiske pasientenes sjekklister er et steg i riktig retning for å øke pasientinvolvering i pasientsikkerhet, men det er behov for en klinisk studie for å undersøke dens effekter på komplikasjoner og dødelighet.

Abstract

Background: Checklists used by healthcare professionals in the surgical field have contributed to improved teamwork and patient safety. Still, the large number of patients experiencing preventable errors worldwide is unacceptable. WHO's Global Safety Action plan (2021-2030) aims to eliminate all preventable harm in healthcare. They acknowledge that patient involvement in safety must be more prominent to achieve this, a need which is also recognised in current research and by healthcare organisations, hospitals, and healthcare professionals. Therefore, patient involvement initiatives are warranted. The surgical patient's safety checklist is such an initiative. This thesis has developed and validated the surgical patients' safety checklist, and investigated its feasibility.

Aims:

1. To explore and describe the risk elements and perceived content for a safety checklist for patients before and after surgery.
2. To develop and validate a surgical patients' safety checklist before and after surgery.
3. To investigate the feasibility of the surgical patients' safety checklist usage, recruitment, barriers and drivers to implementation before a large-scale Stepped Wedged Cluster Randomised Controlled Trial.

Methods: Qualitative and quantitative methods have been applied, with a complex intervention model as an overarching framework. All data was collected at Haukeland University Hospital, and Førde Central Community Hospital. In study I, data were collected from five surgical wards (one from Førde, four from Haukeland University Hospital). In study II and III, an additional surgical ward participated from Haukeland University Hospital. A qualitative approach was applied in study I, while both quantitative and qualitative approaches were applied in study II and III. Inductive categorical content analyses were used for the qualitative parts in all three studies. In study I, focus group interviews were carried out with post-surgical patients and

healthcare professionals. The checklist development processes in study II, used expert panel consensus processes to achieve agreement on the checklist content.

In study II and III, qualitative and quantitative data were collected from the same sample of surgical patients. Three focus groups interviews were conducted with post-surgical patients who had used the patient's safety checklist. Quantitative data were also collected from surgical patients who had used patients' surgical safety checklists. The data were analysed using descriptive statistics on checklist item usage and recruitments, and a Chi-squared test to describe patient characteristics. In study II patients were asked to score each checklist item using an item content validation index, and Intraclass Correlation Coefficients were applied to assess the reliability of the patients' total PASC item validation scoring. Finally, Health Failure Mode Effect Hazard scoring was applied to the items that received a low patient item content relevance score to ensure that high-risk safety items were not removed from the checklist.

Results: In study I, patients and healthcare professionals identified patient risk areas that could be used for content in patients' surgical safety checklist. The possible risk areas were placed under four main categories that representing when the information should be given and type of information patients should receive throughout the surgical pathway. The four categories are: "Pre-operative information", "Pre-operative preparation", "Post-operative information", and "Further plans and follow-ups". In addition, both patients and healthcare workers expressed a need to systemise information given to the patients before and after surgery.

In study II, the findings from study I were presented to an expert panel through several meetings until consensus on the checklist content was achieved. Then, 215 of 428 invited patients, answered and validated each item of the patients' safety checklist. Most patients agreed on the importance of each item however, five checklist items were removed, due to low patient relevance scoring, while six items were redesigned to improve user-friendliness. The Scale-level Content Validity Index/Averages on the checklist before and after surgery were 0.86 and 0.93 respectively, indicating good patient acceptance of the checklist content. Further, Intraclass Correlation Coefficient

indicated excellent reliability of the patients' validation with a scoring of 0.97 and a narrow confidence interval of 0.96 - 0.99. The data from the focus group interview showed good face validity of the surgical patient's safety checklist, it also supported the quantitative findings regarding the need for redesigning some items.

In study III, 50.2% (428/ 215) patients used the checklist (same patients as in study II). Out of these, 86.5% (186/215) of the patients answered more than 80% of the checklist items. As to patients who did not return the checklist, 24.1% (103/428) were related to surgical cancellations, 19.1% (85/428) did not consent, 5.1% (22/428) lost or just forgot to return it, and 0.7% (3/428) died during hospitalisation. The qualitative interviews identified barriers and drivers for the checklist usage and implementation; such as the importance of allowing time to use the checklist, the design (user-friendliness), and healthcare professionals actively participating in the checklist usage. In Addition, the drivers for the checklist use was that it impetus communication and gave support throughout the surgical pathway.

Conclusion: The surgical patients' safety checklist has been developed through study I and II, and its feasibility has been investigated in study III, prior to an upcoming clinical trial. Overall, there is strong evidence that the checklist content is relevant for patients and that the checklist systemises pre-surgical and pre-discharge information. There is also an indication that a safety checklist for surgical patients is a step in the right direction for increasing patient involvement in safety. However, a clinical trial is necessary to study its effects on complications and mortality.

List of publications

Paper I

Harris K, Søfteland E, Moi AL, Harthug S, Storesund A, Jesuthasan S, Sevdalis N, Haugen AS. Patients' and healthcare workers' recommendations for a surgical patient safety checklist - a qualitative study. BMC Health Serv Res. 2020 Jan 16;20(1):43. doi: 10.1186/s12913-020-4888-1. https://pubmed.ncbi.nlm.nih.gov/31948462/

Paper II

Harris K, Søfteland E, Moi AL, Harthug S, Ravnøy M, Storesund A, Jurmy E, Thakkar B, Haaverstad R, Skeie E, Wæhle HV, Sevdalis N, Haugen AS. Development and validation of patients' surgical safety checklist. BMC Health Serv Res. 2022 Feb 25;22(1):259. doi: 10.1186/s12913-022-07470-z. https://pubmed.ncbi.nlm.nih.gov/35216592/

Paper III

Harris K, Søfteland E, Moi AL, Harthug S, Ravnøy M, Storesund A, Jurmy E, Skeie E, Wæhle HV, Sevdalis N, Haugen AS. Feasibility of implementing a surgical Patient Safety Checklist: Prospective cross-sectional evaluation. In manuscript.

Abbreviations

Apps = Mobile Applications

COVID-19 = Coronavirus Disease 2019

CVI = Content Validation Index

EPF = European Patients' Forum

ERAS = Enhanced Recovery after Surgery

HFMEA = Health Failure Mode Effect Analysis

ICC = Intraclass Correlation Coefficients

ICU = Intensive Care Unit

I-CVI = Item Content Validation Index

LOS = Length Of Stay

MI = Multiple Imputation

PASC = PAtients' Safety Checklist

PROMS = Patient Reported Outcome Measures

PSP = Patient Safety Program

REC West = Regional Ethics Committee, Western Norway

S-CVI/Ave = Scale-level Content Validity Index/Average

SURPASS = SURgical PAtient Safety System

SWCRCT = Stepped Wedge Cluster Randomized Controlled Trail

WHO = World Health Organisation

WHO SSC = World Health Organisations' Surgical Safety Checklist

Contents

1. Introduction

1.1 Background

The expression "*first do no harm"* (primum non nocere) has been identified in texts from Hippocrates dating back c. 460-370 BC,[1] and Florence Nightingale expressed the importance of not inducing harm to those who are ill in her book, "Notes on Hospital" in the 19th century.[2] In the 20th century, studies focusing on identifying types and frequencies of patient harm became more prominent. In 1964, the ground-breaking study "*The dangers of hospitalisation*" was published, with a classification of the severity of patient harm, and concluded that 20% of the study population experienced harm, with one-fifth of these being major.[3] This inspired similar studies and highlighted the need for health organisations and leaders to act on improving patient safety. Later, the report "*To Err is Human"* was published in 1999, emphasising the need for a shift from blaming individuals for errors to creating safety systems within healthcare organisations,[4] leading to WHO's establishment of the World Alliance for Patient Safety. The World Alliance for Patient Safety launched the first global challenges*" Clean care is safe care,"*[5] *"Safe Surgery Saves Lives,"*[6] and *"Medication without harm"*.[7]

In 2006, the first ground breaking checklist study was published by Pronovost et al.,[8] and 127 intensive care units in the state of Michigan participated. This checklist was designed based on evidence-based care processes and aimed to improve communication among Intensive care unit (ICU) clinicians.[9] Its design aimed to reduce bloodstream infections during catheter insertions in intensive care units, and it showed a significant reduction in catheter-associated infections.[8] Next the *"Safe Surgery Saves Lives" campaign* published guidelines to ensure surgical safety for patients worldwide. These guidelines were used to develop the WHO surgical safety checklists (WHO SSC).[6] WHO SSC is designed to improve operating-theatre teamwork, communication and consistency of care throughout surgical procedures.[10] The effects of using the WHO SSC have been rigorously studied in multi-centre and worldwide studies.[10-12] These generally show reduced complication and mortality rates, but there is an

indication that SCC is most effective if it is used correctly, with high compliance, and individualised to fit each specialty and local routines.[13 14]

Another checklist system within the surgical field is the SURPASS (SURgical PAtient Safety System) checklists,[15] which are completed by multidisciplinary teams. The SURPASS checklist consists of several checklists following the patients throughout the surgical pathway.[15 16] The implementation of the SURPASS checklists had a goal to mitigate morbidity and mortality. Use of these perioperative checklists have been associated with reduced surgical complications, reoperations, readmissions,[17 18] and mortality.[18]

Despite this extensive work on improving patient safety, far from all challenges have been overcome.[19] Annually, almost 313 million surgeries are carried out worldwide[20] with an overall 10% adverse events and mortality rate of 7.3%.[21] Most likely, 50% of these events are preventable, and the most common adverse events reported are procedural complications, post-op bleeding, infections, and medication errors.[21] Implementing checklists designed and used by healthcare professionals has been a step toward reducing errors and increasing the quality of care within the surgical field. However, there is a further need to improve patient safety in today's health care. The ultimate goal of the WHO's Global Safety Action plan (2021- 2030) is to eliminate all preventable harm in healthcare,[19] and the Norwegian national action plan for patient safety and quality improvement (2019-2023) aims to reduce the number of in-hospital patient injuries from 13.7% (2017) to 10.3 % by the end of 2023.[22] Patient involvement has been recognised as a key to achieve such goals.[19 23 24]

In 1986 the WHO published the Ottawa Charter for Health Promotion, emphasising the importance of patient involvement in healthcare. The publication stated that health promotion is a *"process of enabling people to increase control over, and to improve, their health"* and that health promotion does not solely lay within the health sectors but also includes each person's lifestyle choices.[25] In 2005, the WHO established the "*Patients for Patient Safety"* as one of the action area of the World Alliance for patient safety.[26] The *"Patient for Patient safety"* action areas is a central to the WHO's Patient Safety Program (PSP). It is designed to engage and empower patients to share

experiences and expertise to facilitate learning and improvement of patient safety.[26] Since then, the focus on patient safety has slowly shifted from the more traditional culture where healthcare professionals were responsible for patient safety to an approach where patients and their families are considered vital in actively managing patient safety. Despite this development, there are still calls for initiatives that facilitate patient and family involvement in safety within all areas of healthcare, including surgical checklists for patients to use.[19 27]

Checklists designed for surgical patients are rare, and those that exist only cover specific surgical areas or only parts of the surgical pathway.[28-31] Little information exists on the development processes, validations and effects of surgical patients' safety checklists.[32 33] However, some studies show promising results in reducing re-admissions and hospitalisation time in surgical and cancer patients.[33] Further development, validation, and testing of a safety checklist for surgical patients is warranted.[32] Such a checklist might increase patients' participation in surgical safety, ensuring that patients receive and understand the information they require throughout the surgical pathway.

1.2 Definitions

1.2.1 Patient harm and adverse events

Patient harm is considered synonymous with adverse events in healthcare and may be defined as *"unanticipated, unforeseen accidents (e.g., patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease"*.[34]

1.2.2 Medical error

Medical error was defined in 2005 by Grober & Bohnen as "*an act of omission or commission in planning or execution that contributes or could contribute to an unintended result".*[35] The cause of medical error is often divided into two parts in the literature*; Error of omission refers to a missing action and error of commission refers*

to a wrong action taken.[35] Medical errors may or may not lead to patient harm, but they expose the patient to a potential hazard. Medical errors are generally recognised to be preventable.[36]

1.2.3 Patient Risk

Risk is the probability of an incident occurring and the consequences if it occurs. Patient risk is defined as "probability of suffering harm".[37] The causes of risk can be multiple and the types of impact can be many, patient harm is one of the most significant types of impact. Patient risk relates to decision making and medical errors (e.g. wrong medication).[38]

1.2.4 Quality of care

Quality of care is often seen as an overarching term where patient safety belongs. In the 1980s, Donabedian recognised that quality of care is a complex and multidimensional indicator, defined according to individual dimensions or components: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy.[39] [40] Each of these dimensions represents partial views of quality of care when considered separately. Further, Campell et al.[41] propose that quality of care should be defined either at an individual level or at the population level. Quality of care for the individual person can be quite different to quality of care from the population. WHO uses Lohr's definition of quality of care which was first published in 1990; "*the degree to which health services for individuals and populations increase the likelihood of desired health outcomes*".[42] [43] In the 21st century the United States Institute of Medicine recognised that a focus on the dimensions or components of quality instead of indicators was needed.[44] Quality of care is; safe, effective, patient-centred, timely, efficient and equitable, and that these components are the foundation of patient safety.[44]

1.2.5 Patient Safety

WHO describes patient safety as a field that aims to prevent and reduce risks, errors and harm to patients receiving healthcare.[19] The Norwegian Directorate of Health defines patient safety as *"protection against needless harm following health care services or the lack of them"*.[45] There is a large number of definitions of patient safety. However, they all encompass the prevention of patient harm.[46 47 19]

Further, patient safety measures may be defined as having either a safety I or a safety II approach. Safety I measures aim to obtain *"the absence of unwanted outcomes such as incidents or accidents"* while Safety II measures seek to "*comprehend and learn from how things go right"*.[46]

1.2.6 Safety Checklists

Safety checklists have been utilised in industries such as aviation and construction.[48] In healthcare, a checklist may be defined as an algorithmic listing of items describing actions to be performed in a clinical setting or during a procedure to ensure that no step is forgotten to prevent errors.[49] There are commonly two types: ''read-do'' or ''challenge-confirm''. A ''read-do'' checklist is a list of items to evaluate or tasks to complete. The "read-do" checklist functions as a simple memory aid to complete a series of tasks. Such basic checklists can help to standardise procedures, and prevent error-inducing conditions.[50] The "challenge-confirm" checklists are often utilised by two or more individuals. They are often integrated into a formal procedure or task structure: One member of a team ''challenges'' the rest of the team to perform tasks or ''confirm'' already completed tasks. The team will answer with a reply that the information is understood or completed to avoid confusion.[10] Overall, a single checklist can contain both types of design, with the main goal to encourage a more systematic practice and to promote effective communication resulting in an improved safety culture.[33 50]

1.2.7 Patient involvement

Patients' involvement in healthcare is receiving increased attention. WHO promotes the notion that to further improve patient safety and quality of care, involvement of patients and their family's needs must be facilitated.[19] Higgens and colleagues define patient involvement as the *"desire and capability to actively choose to participate in care in a way uniquely appropriate to the individual in cooperation with a healthcare provider or institution for the purposes of maximising outcomes or experiences of care"*.[51] Patient involvement is described as multilevel, occurring at the level of direct care (Micro level), the level of organisational, design, and governance (Meso level), or at the level of policymaking (Macro level).[52] Despite this, there is no explicit agreement on the definitions of patient involvement or engagement in the literature, and the definitions are strongly interwoven with descriptions of patient empowerment.[19]

1.2.8 Patient empowerment

WHO acknowledges that patient empowerment is a key to patient involvement in today's healthcare.[19] The European Patients' Forum (EPF) has defined Patient Empowerment as *"a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important,"* and that collective empowerment is *"a process through which individuals and communities are able to express their needs, present their concerns, devise strategies for involvement in decision-making, and take political, social, and cultural action to meet those needs"*.[53] Patient empowerment represents patients' increased willingness and ability to be involved in their own care with good knowledge about their health and diagnoses. To achieve patient empowerment within healthcare, healthcare professionals have to facilitate interventions and measures that allow this to happen.

1.3 Checklist use within surgery

The use of perioperative checklists by healthcare professionals reduces complications, mortality, and hospitalisation time and improves teamwork.[8 10 17 18 54] Only a few studies report negative results considering implementation processes and personnel acceptances.[55 56] These are issues and barriers beyond the checklists themselves that need to be considered as implementation requires time and effort. If checklists are laboriously implemented within the surgical field in well-functioning health organisations their chances of improving the quality of care is large.[54 57] To expand on the checklist concept aiming to further reduce patient errors, patients' involvement in checklist usage needs to be explored.[58]

1.4 Patient involvement in safety

Following a growing awareness of patient safety, there is an ongoing shift from traditional treatment with patients having little to say towards a more patient-healthcare partnership where patients and healthcare personnel work together towards a common safety goal.[27] This thesis focuses on patient safety involvement at the level of direct care (Micro Level), where primary processes in healthcare occur. Here, patients are allowed direct participation in decision-making, self-management, and error prevention. Patients' willingness to take part in their safety is documented, still there are uncertainties on how they best should be taken in.[27 59-61] Patients are always at the centre of their own healthcare treatment, and they observe almost all the care processes themselves. Though they may not understand all the medical issues, procedures, or technical terms, they are the ones who are receiving and experiencing the delivery of care. Patients could potentially prevent errors throughout their own treatment pathway if provided with the proper support, information, and tools.[62] Not all patients can participate due to progressive diseases, cognitive deficits or lack of willingness. In such situations, close family, or caregivers could act on behalf of the patient to maintain safety.[63]

There are several patient involvement initiatives at the direct level of care developed by health organisations. The Joint Commission's Speak Up Initiative in cases of safety

concerns and several WHO and EPF informative initiatives as to awareness and knowledge of safety risks, close observation of medication and treatment, coordination of care, contributing to hygienic practices, self-management, and compliance are such initiatives.[64-67] Considerable research has been conducted within the area of patient involvement in safety. However, due to large variations in study designs and data, it seems complicated to conclude on which methods are most feasible for involving patients in safety and their effects.[27 68] A recent literature review and meta-analysis on original studies investigating the impact of patient and family involvement on safety gave an overview of existing interventions.[68] Patient involvement interventions identified in this review examined the prevention of post-operative complications, pressure ulcers, falls, urinary tract infections, medication errors, nosocomial infections, central line-associated bloodstream infections, safety-related incidents, unsafe situations, and vascular complications. The interventions comprised informative brochures/leaflets, posters, consultations, interviews, computer animations, and educational films, with overall findings that patient and family involvement interventions may reduce adverse events.[68] Recently, other initiatives such as patient-reported outcome data (PROMS) have also been increasingly used as a quality improvement strategy.[69] PROMS is a questionnaire filled out by patients which measures patients' health, health-related quality of life or various health-related constructs. PROMS used before consultations has been linked to improve the quality of clinical consultations across multiple healthcare services.[70]

Despite this, for these initiatives to affect patient safety, they largely depend on the healthcare professionals' efforts in providing information and encouraging their usage. Patients who receive treatment in healthcare often experience stress and information overload, which leads to difficulties in retaining information.[71] Although these initiatives show a positive trend towards improving patient safety and quality of care, more research is needed. Guidelines for implementing patient involvement in patient safety, increasing the research scope for which type of patient involvement initiatives are effective on patient safety, and lastly, the need for action plans on implement patient involvement effectively in practice.[27 68] In fact, patients and healthcare workers express the need for interventions that can increase patients' health literacy and

systematically provide them with the most crucial information that can prevent error and patient harm.[32 60]

1.5 Patient involvement in safety initiatives in surgery

Several initiatives aim to involve patients in their surgical safety. WHO has developed an information pamphlet, "*What You Need to Know Before and After Surgery"* this pamphlet contains questions patients themselves should ask healthcare workers before and after surgery and could potentially be a helpful tool.[65] Most patients would not be aware that such a pamphlet exists without healthcare professionals informing or providing it as part of their practice. In addition, there are several research interventions on involving patients more actively in education and preparation programs before surgery. The Prehabilitation and Enhanced Recovery After Surgery (ERAS) program and surgery "schools" for patients show positive results.[72-75] Other specific initiatives seem to effectively reduce site infections, such as actively involving patients in reducing surgical site infections and improving hand hygiene.[68] It has also been increasingly popular to use mobile applications (apps) to provide surgical patients with educational materials and guides to empower them to ask questions and prepare for surgery.[76 77] These apps might be helpful for the patients, but their use depends on the patient's ability and willingness to use a mobile phone or electronic devices and know about the app's existence. Another issue with current apps is that they are a one-way tool, not communicating with healthcare professionals. There are also suggestions that the apps need to be connected to personal medical records to affect and improve patient outcome.[78] This raises concerns of data security. Developing surgical safety checklists for patients might be a way to go, and such checklists might empower patient involvement in safety and improve the quality of care.[32 58 33]

1.6 Development and design of patient-completed safety checklists

Recommendations on how to design checklists for healthcare workers and other industries are well documented,[15 79-81] and how to transfer this knowledge to develop patients own safety checklists.[32 58] However, there is limited literature on methods to develop surgical patients safety checklists. Fernando and colleagues[32] describe how to develop customised checklists for patients based on the existing checklist methodology *"A checklist for checklists",*[79] presenting a template checklist on developing, drafting and validating a patient checklist. For each stage of the template checklist there are clear instructions on essential issues to consider in the three development phases. Harris and Russ[33] have just recently published an article where they explore the patient-completed checklists concepts, considerations, and recommendations, with a proposed development and implementation guide based on Fernando and colleagues' template and their own experiences in developing patients-completed checklists (Figure 1).[33]

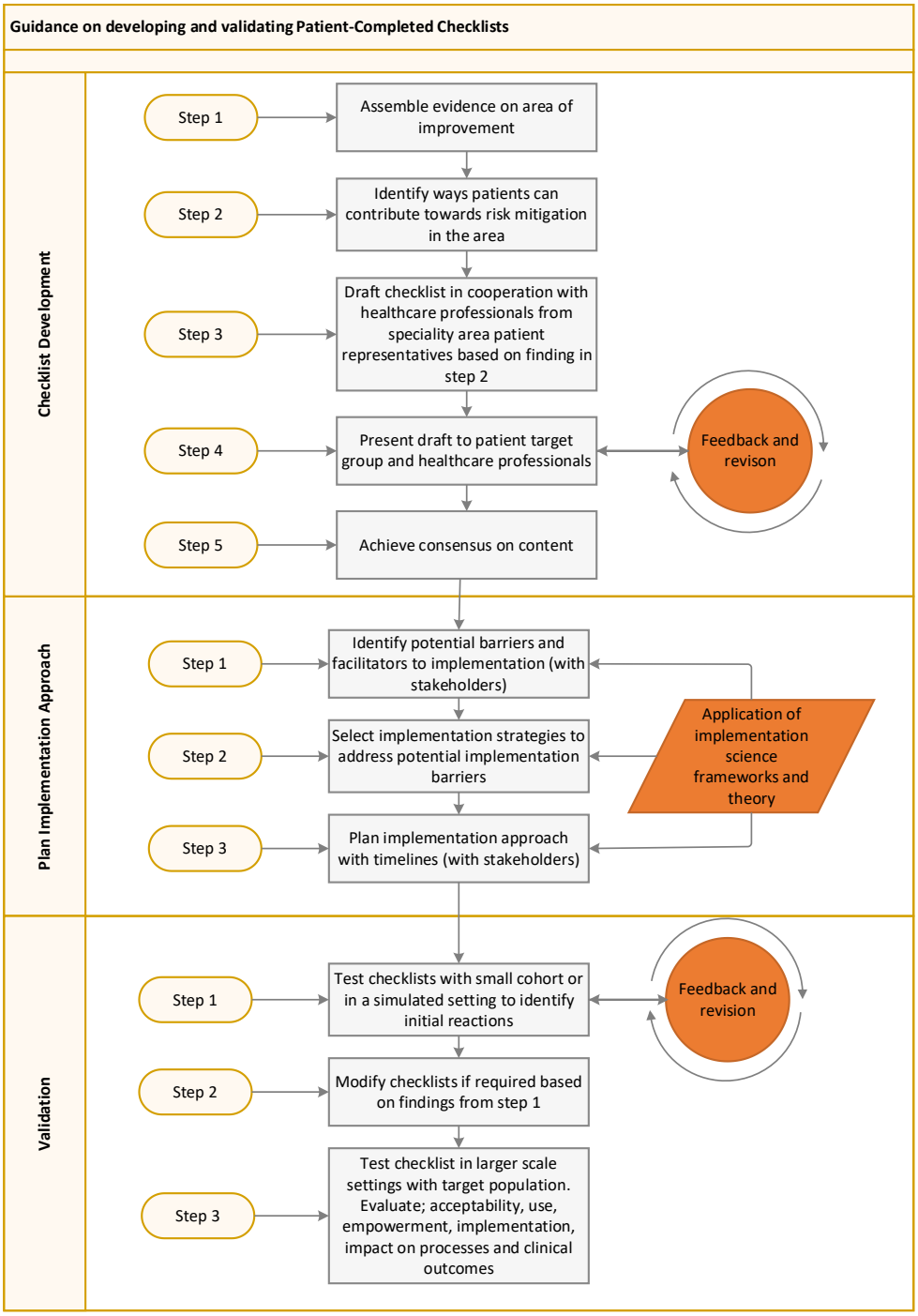

Figure 1: Guidance steps on developing and validating patient-completed checklists (based on the figure published by Harris & Russ[33])

1.7 Systematic review of patient-completed surgical checklists

Patient-completed surgical checklists might empower patients to be involved in surgical care and safety.[32] In order to assess the scientific knowledge on patient-completed surgical checklists and their effect, a systematic review of the literature was performed to identify studies that have either developed a patient-completed surgical checklist or investigated their effects. The search was limited from 1946 to 17 November 2021. The search was updated on May 3rd 2022, and a descriptive synthesis of the identified literature is included in Figure 2.

The keywords used to search the literature were MESH terms: surgical procedures, operative, preoperative or postoperative AND checklist, patient participation. To these search terms there was also combined with key words such as patient checklist, checklist for patients, patient driven checklists AND checklist completed by patient. The search was performed in Ovid MEDLINE, Embase, and CINAHL – EBSCO host (See appendix 8.1 for search links to search strategy). The reference lists of all the included studies were additionally screened to identify other eligible studies. The EndNote reference management software package version X9.3 (Carlsbad, CA, USA) was used to organise retrieved data. The review covered reading through titles, abstracts and original qualitative and quantitative design articles, reviews and systematic reviews. The inclusion criteria were any studies on checklists designed for patients and/or families prior to or post-surgical procedures. Exclusion criteria were checklists for healthcare workers, and checklists not used in the surgical setting.

The search identified 325 titles and abstracts, after removing duplicates. After reading titles and abstracts 308 articles were excluded because the surgical checklists were designed for healthcare professionals and not for patients. The overall searches and review processes are illustrated in a flow diagram, Figure 2. A total of five studies were identified each of a different methodical design: One cross-sectional survey, one retrospective cohort, one RCT, one non-randomised controlled trial, and one pilot RCT.

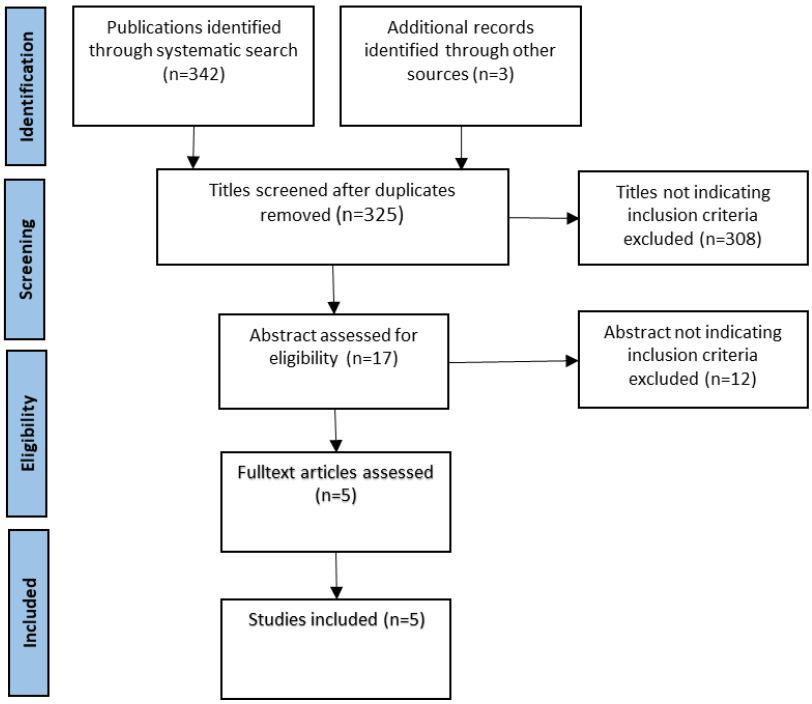

Figure 2: Prisma flow diagram of systematic literature review on patient-completed surgical checklists. (Modified from Page et al [82])

Two checklists have been designed for pre-surgery preparations, Fernando et al.,[31] and Shirley et al.[29] The three other checklists were designed to be used post-operatively before discharge Hardiman et al.,[28] and Trocchia et al.,[30] and one after discharge Huang et al.[83] All the five checklists aimed to increase patient or family understanding or engagement within a specific surgical area; Colorectal surgery (n=3),[28 30 83] ambulatory/day surgery (n=1),[31] and paediatric orthopaedic surgery (n=1).[29] All five studies were performed in hospitals settings in high-income countries; USA (n=4) and Australia (n=1). All five studies used patient-completed checklists in paper format.

Two single-centre studies on discharge checklists for colorectal surgery patients investigated effects of checklist use on readmission and length of stay in hospital. Hardiman and colleagues found a significant decrease in readmission rates in the

checklist group,[28] and Trocchia and colleagues found a significant reduction of in-hospital length of stay.[30] Further, one double centre study investigated the effect of utilising a patient-completed pain-relief checklist post-haemorrhoidectomy. In the checklist group, they found a significant reduction in mean pain score between day one post-operatively and day 14 post-operatively, but there was no significant difference in individual or overall mean pain experiences in both groups over the 14 days.[83]

The two last studies identified utilised surveys to investigate the patients' experiences and barriers for using patient-completed checklists.[29 31] One multicentre study on patient's checklist for ambulatory procedures found that both patients and providers were in favour of using a patient-completed checklist. However, some barriers were identified concerning its implementation, which included fear of confusing the patient, causing patients' to doubt the care, being time-consuming, and lack of resources.[31] Next was a small single centred study utilising a preoperative visit checklist to increase patients' understanding of the consent process. They found no significant difference in satisfaction, decisional conflict and knowledge between the checklist group and the control group and they observed a significant negative effect on nervousness in the checklist group.[29]

Table 1. Summary of a systematic literature review on patient-completed surgical safety checklists.

Authors	Design	Checklist design	Aim	Population/setting	Results
Fernando et al., 2015[31]	Cross-sectional study utilising a survey.	Patient's checklist for ambulatory procedures.	Improve patient education and engage patients in their own care.	35 ambulatory surgical patients and 56 ambulatory surgical providers in USA.	94% of patients and 83 % of providers believed the patient checklist was of benefit. 37% of providers indicated barriers to implementation.
Hardiman et al., 2016[28]	Retrospective cohort.	Postoperative self-care checklist.	Increase patients' understanding of how to care for their ileostomy prior to discharge, to reduce readmission.	Single centre study, USA. 226 in the control group and 204 colorectal surgical patients in the intervention group.	28% to 20% reduction in readmission after the introduction of the checklist (p=0.04).
Huang et.al 2020[83]	Randomised controlled trial.	Patient-completed checklist for pain management.	Improve pain management after haemorrhoidectomy.	Dual-centre, Australia, 28 surgical patients in the control group and 35 in the intervention group.	The intervention group reported a significant reduction in VAS pain score between day 1 and day 14 post-op compared to the control group ($p< 0.001$). There was no significant difference between mean pain in the two groups ($p= 0.07$).
Shirley et al., 2021[29]	Non-blinded randomised controlled trial utilising a survey.	Informative pre-consent checklist for family	Increase patients' understanding of the surgical consent process.	Single centre study, USA, 34 Paediatric orthopaedic patients, and parent/guardian control group and 27 in the intervention group.	No difference in satisfaction, decisional conflict, and knowledge were found. There were significant differences in increased nervousness in the intervention group.
Trocchia et al., 2020[30]	Pilot study (retrospective cohort)	Bedside goals to discharge checklist.	To facilitate patient engagement, optimise time of discharge, and reduce LOS	Single centre study, USA. 60 baseline and 60 colorectal surgical patients in the intervention group.	LOS in the intervention group was significantly less than the baseline with 2.66 vs. 3.13 days. (p=0.05).

Abbreviations: LOS = Length of stay

The few studies identified in this review were heterogeneous in patient-completed checklist design, implementation methods, and measured outcome, except for the two studies on pre-discharge checklists for colorectal surgical patients.[28 30] Overall, there is a positive indication in the literature that surgical patients might be willing to use patient-completed checklists. It could potentially empower patients' involvement in surgical care and safety. The findings in the two checklist studies on pre-discharge checklists for colorectal surgical patients reported a positive indication that if patient-completed checklists are designed to increase patient understanding and knowledge within a specific field, they might reduce the length of stay and hospital readmissions.[28 30]

Despite these findings, one study identified in this review challenges these results. This study failed to find any significant change in knowledge, and they concluded that the checklist might have worsened patients' experiences.[29] However, the authors acknowledged several weaknesses in this study, such as the sample size and site location limitation. There is a considerable risk of bias because the physicians were not blinded to the two study groups.[29]

In conclusion, the concept of patient-completed surgical checklists needs to be further investigated. A surgical checklist for patients to use preoperatively and postoperatively should be developed systematically and validated across surgical specialities. In addition, their impacts on patient involvement in surgical care and safety should be investigated.

2. Aims/objective

The overall aim of the thesis was to develop and validate a patients' own surgical safety checklist (PASC), and then to investigate PASC feasibility to prepare for a Stepped Wedge Cluster Randomised Control Trial (SW-CRCT). The individual study aims are described as follows:

Study I

Based on patients' and healthcare workers' experiences, this study aimed to explore and describe the risk elements and perceived content for a safety checklist to be used before and after surgery.

Study II

To develop and validate the surgical patients' safety checklist to use before and after surgery.

Study III

To investigate the feasibility of surgical patients' safety checklist usage, recruitment, barriers and drivers to implementation prior to a large-scale SW-CRCT.

3. Materials and Method

3.1 Study design

The overarching intention of the surgical Patients Safety checklists (PASC) is to empower the patients to be involved in their own safety, reduce patient harm and improve quality of care. PASC has been developed following the Complex Intervention Framework.[84-86] Complex interventions are defined as an intervention that includes several interacting elements.[85] The aspects of a Complex Intervention Framework are described in Figure 3.

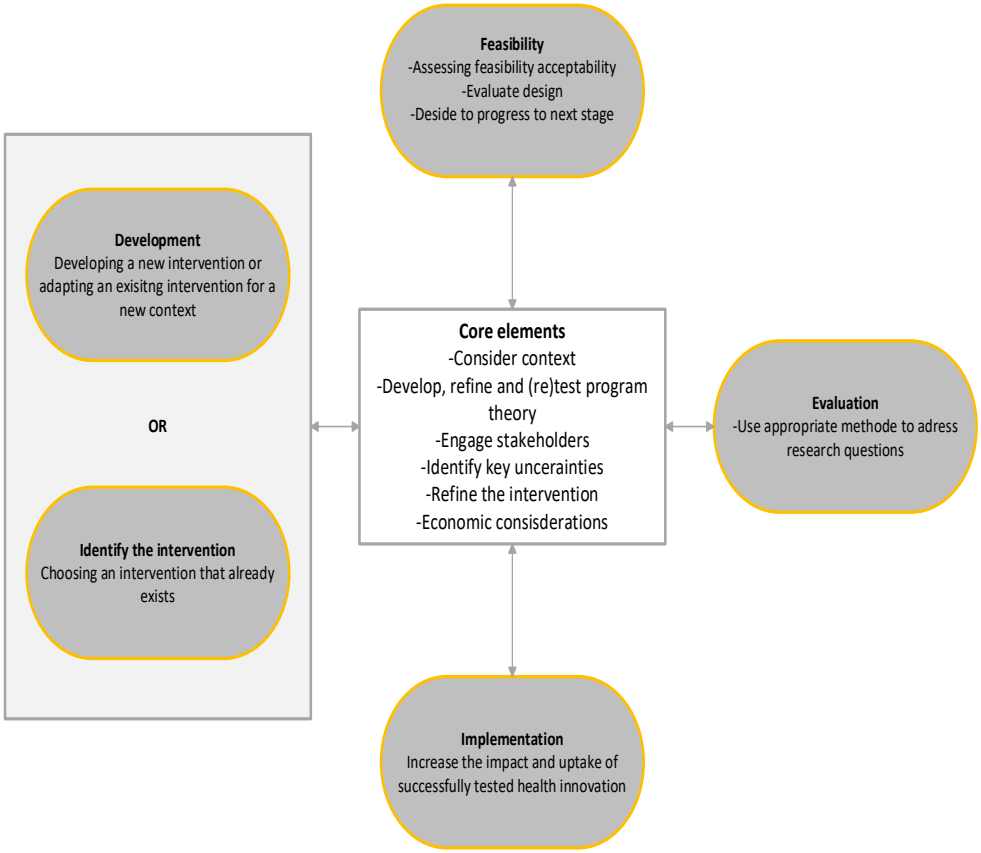

Figure 3: Key components of complex intervention studies (based on Craig et al. & Skivington et al.)[84 86]

The studies included in this thesis cover the development and feasibility phases of a complex intervention study. Both qualitative and quantitative methods have been utilised throughout, and the use of different methodological approaches are considered appropriate in the development and feasibility phase of complex intervention studies.[86 87]

Table 2. Overview of study design, settings samples, and outcomes for all three studies

	Qualitative Study	Development/validation study	Feasibility study
Study	I	II	III
Design	Qualitative focus group interviews	Prospective cross-sectional study utilising consensus processes, item-content validation index (I-CVI), and face validity focus group interviews	Prospective Cross-sectional study utilising quantitative and qualitative methods with focus group interviews
Settings	One tertiary referral and one secondary care hospital Five surgical wards	One tertiary referral and one secondary care hospital Six surgical wards	One tertiary referral and one secondary care hospital Six surgical wards
Sample	n=25 surgical patients n=27 healthcare professional	**Development**: Health professionals from 6 surgical wards and the patient representatives **Validation:** n=215* surgical patients and n=10* face validity	n=215* elective surgical patients n=10* post-surgical patients, focus group interviews
Outcome	To identify patients' risk areas throughout the surgical pathways that could be used as PASC items	To develop PASC through a consensus process. Finalising PASC based on patient validation data	Investigate PASC's feasibility prior to an SW-CRCT

* Data in study II and III were collected from the same sample

3.2 Ethics

Prior to the study start, this research project received ethical approval for all three studies from The Regional Committee for Medical and Health Research Ethics (REC West, 2016/1102) of the Western Regional Norwegian Health Authority (see appendix 8.2 for Ethical approval document). It followed the Helsinki declaration's research principles.[88] Final approval of the project was given by the hospitals' managers. The hospitals' (Haukeland University Hospital, Førde Central Community Hospital) Ombudsmen for data privacy on research reviewed the protocol to ensure the patients' data privacy (Ref: 1218-1218).

Verbal and written study information in Norwegian was given to all potential participants at the time of recruitment in all three studies. The participants were informed that participation in the studies was voluntary. Patient information and consent forms were pre-approved by REC West. The written information explaining the type of data planned to be collected, the aim, confidentiality, data-handling, and that they could withdraw at any time without consequences for their treatment. Patients were also informed that if any unidentifiable data were published before their withdrawal, this could not be removed. All participants signed an informed consent form.

The research protocol was registered as part of a clinical trial (ClinicalTrials.gov: NCT03105713).

3.3 Clinical settings

All three studies were conducted at Haukeland University Hospital and Førde central community hospital, with referrals for 1.1 million and 110,000 inhabitants, respectively.

Focus group interviews in study I were conducted at four surgical wards at Haukeland University Hospital: Ear, Neck, Throat (ENT)/Maxillo-Facial; Cardio-Thoracic; Neuro; Breast- and Endocrine; and the general surgical ward at Førde Central Community Hospital.

Prior to study II and III all eligible surgical wards at Haukeland University Hospital and Førde Central Community Hospital were listed in a randomised order to prepare for the later planned SW-CRCT. The six first wards in the randomisation were invited to participate in the study and accepted the invitation. The ward managements from Ear, Neck, Throat (ENT) /Maxillo-Facial; Cardio-Thoracic; Neuro; Breast and Endocrine; Førde General surgery; and Gastro surgery accepted the invitations.

3.4 Participants

In Study I, a total of six patient focus groups interviews (a total of 25 patients) and five focus group interviews with health professionals (a total of 27) were carried out, all recruited from the five surgical wards included in study I, with five to eight participants in each focus group interview.

Potential participants for patient interviews were recruited in cooperation with the ward nurses one to two days before discharge from the hospital. They were interviewed three to six weeks after discharge. One patient focus group interview was held per ward, except for the interview at the Neurosurgical ward. Here two interviews were held because only two participants met for the initially planned interview.

The healthcare professionals' interviews were conducted at the five surgical wards during work hours. The ward leaders performed recruitment and scheduled the interviews. The healthcare professionals interviewed consisted of one or two from the following profession; surgeons, ward doctors, nurses, and secretaries from each ward.

In study II, hospital service managers, surgeons, ward doctors, pharmacists and nurses, general practitioners, and patients' representatives participated in the development and consensus processes of the PASC. All health professionals were from the surgical wards included in the study; the general practitioners were from the practice consultants representatives at Haukeland University Hospital, and the patient representatives were from the Western Regional Norwegian Health Authority Trust Patient Advisory Board. In addition, experts on checklist development (safety officer from the aviation industry) and from media/communication (Haukeland University Hospital were consulted during the PASC development phase.

In the validation part of study II and the feasibility study III, all eligible surgical patients from the six surgical wards were invited to use and validate PASC. These patients were recruited in cooperation with the ward staff (nurses, surgeons, doctors). In the qualitative part of study II and III, three focus group interviews were conducted from 4 of the included wards (ENT/Maxillo-Facial, Cardio-Thoracic, Neuro, Breast- and Endocrine). Unfortunately, during the recruitment period of the interviews, patients from the two remaining surgical wards were lost due to the Coronavirus Disease 2019 (COVID-19) outbreak. In total, 24 patients were asked to participate and accepted. However, because of uncertainties due to the COVID-19 outbreak, 14 participants cancelled or did not attend on the scheduled interview days.

3.5 Inclusion criteria

In study I, inclusion criteria for the surgical patients focus group interviews were; post-surgical elective patients, who had surgery at one of the included wards, eligible to be interviewed 3-6 weeks after surgery, fluent in Norwegian, living no further away than 1 hour from the hospitals, not institutionalised (e.g., nursing home patients) and capable of participating in focus group interviews. The inclusion criteria for the healthcare professionals' focus group interviews were; permanently employed at one of the included wards and have at least five years of work experience within their specialty.

In study II and III, the inclusion criteria were: elective surgical patients aged 18 years or older, cognitively capable of answering the checklist, living at home, and fluent in Norwegian. Participants were to be recruited within two to twelve weeks before surgery to allow time for PASC use. We had the same inclusion criteria for the focus group interviews as in Study I, except that the patients had to have used both parts of PASC.

3.6 Data collection

3.6.1 Qualitative data

Qualitative data for study I were collected from February to June 2017 through focus groups. Two semi-structured interview guides were developed, for surgical patients and one for healthcare professionals. The interview guide development and conduction followed Kruger and Casey's recommendations for focus group interviews.[89] Open-ended questions relevant to the study aim were used (Appendices 8.3 and 8.4). The interview guides were piloted prior to the interviews to assess limitations and flaws. Only minor adjustments were made. Patient representatives participated in piloting the patient interview guide, and quality and risk managers participated in piloting the healthcare professionals' interview guide. KH conducted all the focus group interviews with one member of the research team present as a co-moderator. The interviews were digitally recorded and transcribed verbatim before analysis. All the focus group interviews were held at the hospitals and lasted up to 90 minutes each. The patients were invited to participate at a set time, with the interviews carried out 2-6 weeks after their surgery. Transport and parking expenses for the participants were covered by project funding.

Before the focus group interviews were started, all participants were informed of the purpose for the interviews and that all information obtained during the interviews should stay within the group and not be shared afterwards. Further, if sensitive information was given during the interview, this would be anonymised in the transcripts, and there were no right or wrong answers to the questions. The overall purpose of the focus group interviews was to allow participants to share their experiences about patient risk areas before and after surgery freely and to encourage discussions on the issue. An outline of the patients' and healthcare workers' semi-structured interview guide is shown in Tables 3 and 4, respectively.

Table 3. Outline of the interview guide for patients (Study I)

Introduction question	1. In relation to your latest surgery, can you tell us shortly about your experiences before surgery, after surgery, and after being discharged
Inductive discussion triggers -Information -	**2. Core trigger: what is important for you to be informed about before surgery?** 3. Additional trigger; Can you say which of these points mentioned are most important for you? 4. Did you miss any information before your surgery? 5. If yes, what kind of information did you miss? 6. Did this have any importance for you? Disadvantages, problems 7. Did you contact the hospital before your operation? If yes, what did you call for?
After surgery (still hospitalised, preparation for discharged)	**8. Core trigger: What information is important for you before discharge?** 9. Additional trigger; Can you say why this is important for you? 10. Was there any information missing before your discharge?

Table 4. Outline of the interview guide for healthcare workers (Study I)

Inductive discussion triggers -Information -	Intro/statement: **To develop patients' own checklist before and after surgery can contribute to increased patient involvement and insight into own treatment and reduce unwanted incidents.** 1. How can the patients contribute to reduce complications?
Inductive discussion triggers -Information – before surgery	The interview is divided into 3 parts, before admission, discharge, and after discharge; 2. **Core trigger**: **What do you think are the most important points patients need to know before surgery to avoid complications?** 3. Additional trigger: Information before surgery, medications, diagnoses, complications. 4. Have any of you experienced a patient not being prepared for surgery? Can you explain? 5. Do the patients contact the ward before their surgery? And what do they ask? 6. What type of written information do you give to the patients? 7. Do you believe the information the patients get is sufficient? If not, what is missing?

In study II and III, qualitative data collections were carried out with the same participants. Data were collected from December 2019 to August 2020. Patients who had used both parts of PASC during their surgery were asked to participate. A semi-structured interview guide (Appendix 8.5) was designed to explore PASC's face validity (study II) and barriers and drivers for its usage (study III). Again, patient representatives piloted the interview guide to identify faults and limitations, and only minor changes to the interview guide were made. This interview guide followed the same introductions and principles as in the patient interviews in study I. However, the COVID-19 pandemic was an established reality in March 2020, and necessary infection control measures had to be taken during the interviews. A member of the research team performed all interviews, and KH was present as a co-moderator. The interviews lasted for 50 to 60 minutes and the participants had access to PASC during the interview (paper version). An outline of the semi-structured interview guide is provided in Table 5.

Table 5. Outline of the focus group interview guide for patients (Study II and III)

Introduction question	1. In relation to your latest surgery, can you tell us briefly your experiences using patients' own surgical safety checklist?
Inductive discussion triggers Information -	2. **Core triggers: What was positive when using the checklist?** 3 Additional trigger; what could have been done different with the checklist? 4 Did the checklist prevent any misunderstandings or possible complications? Explain how. -did you experience any adverse events that could have been prevented with an additional point to the checklist? Please Explain? 5 How did checklist use influence the information received before your surgery? -Did you get your questions answered, please explain? -Did you need additional information, please explain? 6. How did the checklist influence your preparations before surgery? -Did you changes in your life style (smoking, alcohol, nutrition or exercise) please explain? -Did you learn the name of your medications/what they are for/ how they look and time you take them before admission to hospital, please explain? -Did you contacted your general practitioner or dentist before surgery, please explain?

3.6.2 Consensus data

The consensus process during the PASC development took place during a period of seven months, from December 2018 until July 2019. The consensus data collection involved several meetings with the same multidisciplinary teams at each surgical ward and patient representatives.

3.6.3 Quantitative data

Study II and III, collected data on patient validation and PASC use from the same population for a 14 months period (August 2019 to September 2020).The recruited patients received the PASC two to twelve weeks before surgery. The time for patients receiving the PASC before their surgery depended on their urgency for surgery. Patients returned the PASC on discharge from the hospital to either nurses or ward secretaries. If the PASC was not returned, a reminder was sent to their residential address with an enclosed prepaid envelope. The recruitment processes followed the randomisation order and the SW-CRCT design, as shown in Figure 4. The mapping of recruitment flow for study II and III is shown in Figure 5.

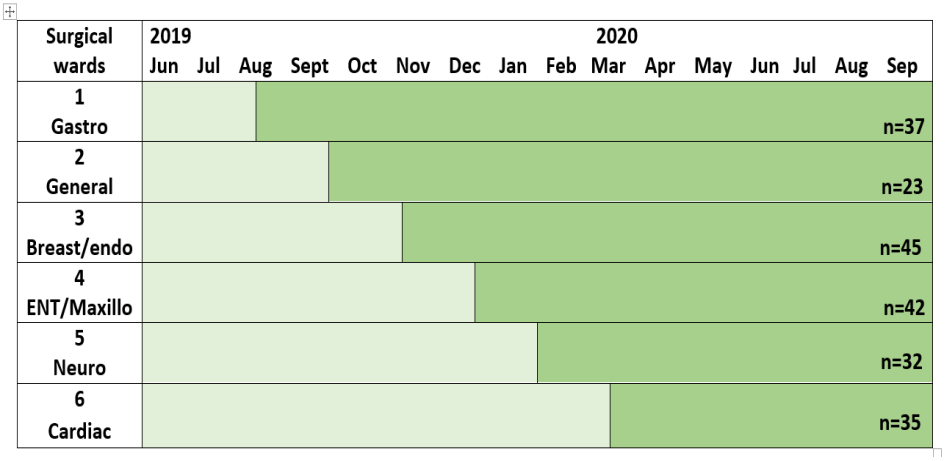

Figure 4: SW-CRCT recruitment randomisation order: The darker green area represents the recruitment period in study II and III and n=total patients per ward.

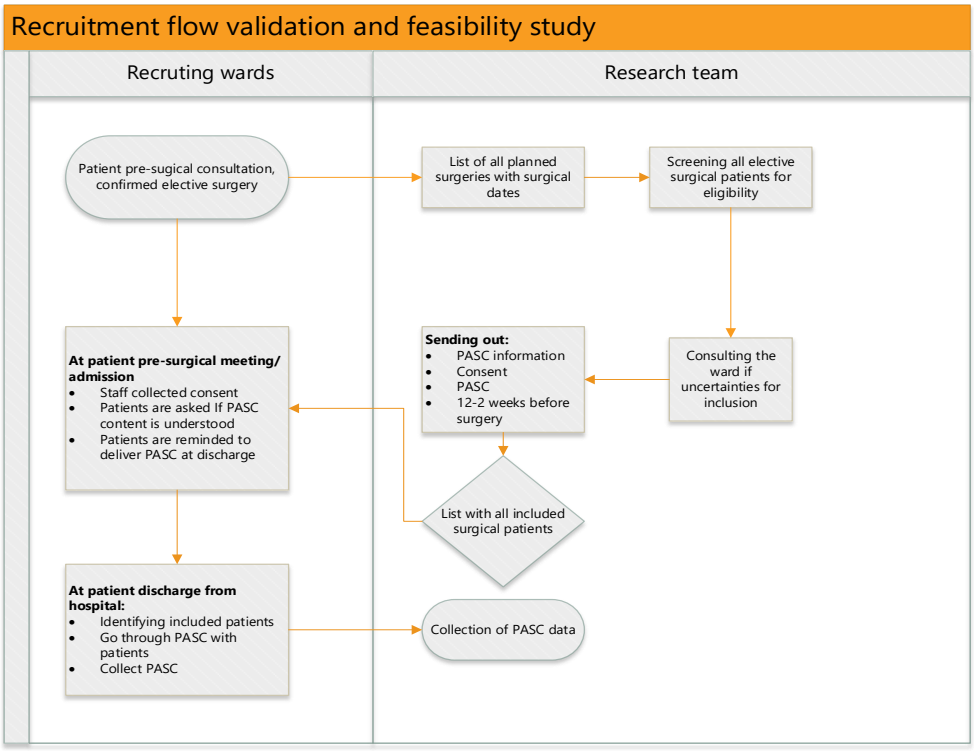

Figure 5: Mapping of planned recruitment for PASC validation (Study II) and feasibility (Study III)

3.7 Complex Intervention stages and core elements

3.7.1 Context of complex interventions

The existing evidence on patient-completed surgical safety checklists has been identified, and the rationale for the development is described (see section 1.7. Systematic review of patient-completed surgical checklists, pages 12-16). Additionally, an overview of the importance and the possible value of a patient safety checklist was gained during the focus group interviews in study I.

3.7.2 Stakeholders' involvement

Identifying and involving stakeholders is vital to success throughout a complex intervention study.[86] Stakeholders from healthcare professionals groups have been involved from the beginning of the PASC project, and have been a valuable knowledge resource throughout the PASC development.

Public Patient Involvement (PPI) is a group of stakeholders that has been crucial for the PASC project. PPI in research differs from patient involvement in healthcare, and it refers to including and engaging service users as collaborators within research processes.[90] Generally, active stakeholder involvement in research can increase the quality and relevance of the study by allowing them to contribute with their experiences.[91] and PPI is likely to increase chances for successful recruitment and retention in effect studies.[86]

Overall, the PASC project has a strong PPI. At the outset, the project evolved based on patient representatives' feedback from the introduction of WHO SSC and the SURPASS checklist.[17 54] Patient representatives from the Western Regional Norwegian Health Authority's Patient Advisory Board have been actively involved throughout the project by giving advice and feedback on the study design, interview guides, and the PASC development and consensus processes.

3.7.3 Development and Validation of PASC

The complex intervention framework recommend using the intervention guidance framework developed through the INDEX study.[92] The framework contains eleven actions for intervention development, and the PASC development process followed this framework, together with the recommendations for developing patients' own checklists.[32 92 86] The first six actions of this framework were considered during the development of the PASC project plan and therefore not included in this thesis. These six action areas are: planning the development processes, involving stakeholders, establishing a research team and decision-making processes, reviewing published evidence, drawing on existing theories and articulating program theory.[92] The remaining five steps, which is included in this thesis are: undertaking primary data

collection, understanding the context, attention to further intervention implementation, designed and refine the intervention and ending the development phase.[92] The steps are described in Figure 6 in line with the concepts for development of a customizable checklist for use by patients[32] and the PASC developing phases. The checklist concept describes the checklist development process in three stages; Development, Drafting, and Validation.[32] Each step has a detailed description of what needs to be in place before developing a patient checklist, design considerations, and validation processes.[32]

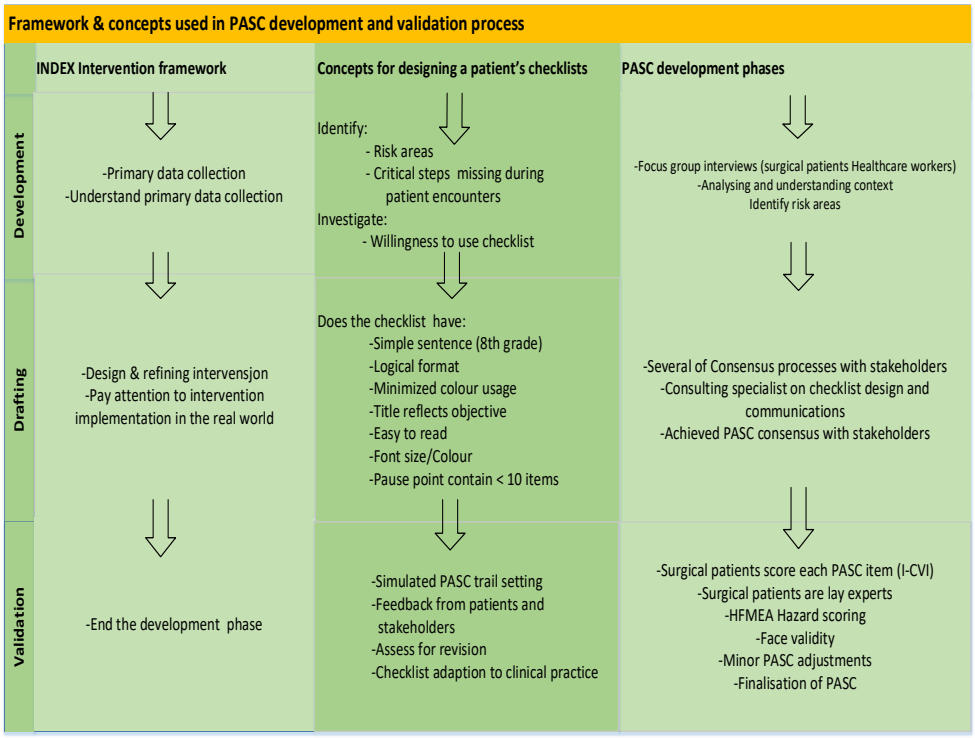

Figure 6: Frameworks applied to PASC development (based on the framework from O'Cathain et al.[92] and concepts from Fernando et al.[32])

3.7.4 Consensus on PASC development

To develop PASC, the findings in study I were identified as possible content for the checklist. The PASC was developed in study II, and an expert panel consensus process was applied to the data from study I. An expert panel consensus process is described as several structured meetings of experts, where the panel rates, discuss and re-rates a series of items.[93] Two consensus meetings were held with the multidisciplinary teams from each participating surgical, hospital patient representatives, and general practitioner hospital representatives. The identified risk areas were presented to the expert panel, and they reported on the importance of each risk area. Written and discussed feedback on the PASC content and design was given to the research team. An additional consensus meeting was carried out after the results of the patient's validation were completed. In addition to the consensus processes with the multidisciplinary team, other experts on communication and checklist experts were consulted on the checklist language and design to check for language and design errors. The whole PASC development process is described in Figure 1 in the published paper on study II.

3.7.5 Validation of PASC

Through the validation of PASC, Item Content Validity Index (I-CVI) was applied together with the Health Failure Mode Effect Analysis (HFMEA) hazard matrix scoring. Surgical patients were asked to rate each checklist item from 1 to 4 (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant, and 4 = highly relevant) as described by Polit et al.[94] The surgical patients were considered the lay experts during this validation process. I-CVI was calculated based on how many patients scored each item as 3 or 4 divided by the total number of patients who scored the item (see Appendix 8.6 for the full I-CVI dataset). I-CVI should not be less than 0.78 for acceptance. If it is less developers should consider keeping, redesigning or dropping the item.[95] Another consideration was that not all items would be relevant to all patients. Therefore a separate I-CVI calculation was made on items with patients who had answered yes to having other health-related issues or using medications. See

Figures 7 and 8 below for an example of the PASC checklist with the content validation.

ID:

Your checklist before surgery

HELSE VEST

To prevent complications that can occur throughout your surgery Use your checklist to cross off the relevant response to EVERY question	Each column under describes the relevance of each checklist question. Please cross off on each question how relevant you believe they are.			
If you require any clarification, or if any issues arise while you are using the checklist, contact, (ward name) on this telephone number:_____	Not Relevant 1	Somewhat Relevant 2	Quite Relevant 3	Highly Relevant 4
Important issues you should consider before your surgery **1. Are you using any medications?** ☐ No ☐ Yes, memorise the name of your medication, what they are for, how they look and the time you take them	☐	☐	☐	☐
2. Do you have a medication list with the latest changes? ☐ Yes. Remember to bring it to the hospital ☐ No. Contact your general practitioner and ask for a updated medication list	☐	☐	☐	☐
3. Are you using blood-thinning medications? ☐ No ☐ Yes. Have you been informed of when, or if you should stop them before your surgery? If not, contact the ward 2 weeks before your surgery to clarify	☐	☐	☐	☐
4. Do you have diabetes, high blood pressure, cardio- vascular or receiving treatment for other chronic conditions? ☐ No ☐ Yes, if you have not been for a control the last 12 months contact your general Practitioner	☐	☐	☐	☐

Figure 7: Example showing how patients validated PASC items before surgery

ID:

Your checklist after surgery

HELSE VEST

Use your checklist to cross off an answer to EVERY question **Remember to return the checklist before you go home!**	**Each column under describes the relevance of each checklist question. Please cross off on each question how relevant you believe they are.**			
What you need to know before your discharge home: Read the questions below before you talk to the doctor and nurse who is discharging you. Ask for missing information or written information if needed.	**Not relevant** **1**	**Somewhat Relevant** **2**	**Quite Relevant** **3**	**Highly relevant** **4**
Complications **33.** Are you informed about possible complications? ☐ YES ☐ NO. Ask for information from your doctor or nurse	☐	☐	☐	☐
34. Are you informed about what you should do if you experience complications or in an emergency? ☐ YES ☐ NO. Ask for information from your doctor or nurse	☐	☐	☐	☐
35. Are you informed if you need to take any special considerations after your surgery? ☐ No ☐ YES. Ask for information from your doctor or nurse	☐	☐	☐	☐
36. Are you informed if you need compression stockings ☐ No. Ask for information from your doctor or nurse ☐ YES	☐	☐	☐	☐
Aktivitet og restriksjon **37.** Are you informed about when you can drive after surgery? ☐ JA ☐ NEI. Clarify with your doctor or nurse	☐	☐	☐	☐

Figure 8: Example showing how patients validated PASC items after surgery

In addition to the I-CVIs, the total Scale-level index/Average (S-CVI/Ave) was calculated for both parts of PASC. S-CVI is defined in Waltz et al.,[96] as *"as the proportion of items given a rating of quite/very relevant by both rates involved,"* and S-CVI/Ave is calculated based on the I-CVI score divided by the number of items, here set with a lower limit for acceptability at 0.80.[95]

As described in the publication for study II and section 3.7.3 Development and Validation of PASC in Figure 6, page 31, after the validation of PASC, a last revision and consensus process was performed to ensure agreement with the consensus team. PASC content was also adjusted to fit each surgical ward's practice and routine. (See Appendices 8.7 and 8.8 for full versions of PASC in Norwegian and English)

3.7.6 Health Failure Mode Effect Analysis (HFMEA) hazard scoring

HFMEA is a systematic risk assessment method taken from high-risk industries.[97] HFMEA is designed in a 5-step process that uses a multidisciplinary team to proactively evaluate high-risk healthcare processes and identify potential failures

within the process activities. The team uses process flow diagramming and a hazard scoring matrix.[98]

Health Failure Mode Effect Analysis (HFMEA) hazard scorings were applied to the PASC items with a lower relevance for the patients (less than 78% of the patients scored the item as important). The complication risk per PASC item of importance was estimated on the probability of patient harm occurring and its severity within the research team. If a PASC item received a hazard score of 8 or higher, it was either kept or redesigned. HFMEA hazard scoring was applied in the patient validation process to ensure that PASC items that scored low on patient importance were only removed if they did not involve any or had a very low risk of patient harm.

Table 6. HFMEA hazard scoring matric (adopted from DeRosie et al.[98])

Probability of harm occurring	Consequences of harm occurring			
	Catastrophic	**Major**	**Moderate**	**Minor**
Frequent	**16**	**12**	**8**	**4**
Occasional	**12**	**9**	**6**	**3**
Uncommon	**8**	**6**	**4**	**2**
Remote	**4**	**3**	**2**	**1**

3.7.7 PASC Feasibility

Study III is a descriptive cross-sectional evaluation study investigating the feasibility of the PASC intervention and the recruitment processes to facilitate an effect and implementation study (Stepped Wedged Cluster Randomised Controlled Trial design). A feasibility study is defined as parts of research performed before a main study to evaluate if it can be implemented on a larger scale.[99] A feasibility study can cover either or both the feasibility of an intervention and the feasibility of the planned trial.[86] In study III the feasibility of both the intervention and the planned evaluation trial are investigated. The study followed the recommended assessments for feasibility studies

presented in the complex intervention framework (see section 3.1 Study design, Figure 3, page 18). The feasibility of the intervention was investigated by examining the PASC content optimality, mode of delivery, acceptability, adherence and unintended outcomes. The feasibility of the planned trial investigated the recruitment, retention, and sample size. Outcomes and outcomes analysis were not investigated because the research group has previously carried out more extensive studies on these measurements in similar settings.[11 17]

3.7.8 Stepped Wedge Cluster trial design

When this project was designed, it was planned to evaluate PASC's effect on reducing patient complications and quality of care in an SW-CRCT after the development, validation, and feasibility studies. In a stepped wedge design study, an intervention is implemented sequentially in clusters over several periods until all the clusters have received the intervention.[100 101] The cluster receiving the intervention first is decided by randomisation of the implementation order. Each cluster acts as its own control over a period until the intervention has been rolled out to all clusters.[101] The reason for choosing a stepped wedge cluster design was to ensure sound implementation processes of PASC within each cluster and to avoid biases between the control group and the intervention group, due to ethical considerations and external impact. All eligible surgical wards in this project were chosen by random, and followed the randomised order in the recruitment processes to test the feasibility (See section 3.6.3 Quantitative data, Figure 4, page 28). The statistical power was calculated for the planned SW-CRCT in the project protocol prior to study I. It was estimated to be a 5% reduction in surgical complications, re-admissions (30 days), and unwanted incidences, and it was calculated that 4200 patients had to be included in the trial. The calculations were based on a stepped wedged design with 6 clusters (surgical wards) over 14 months which indicated that an average of 50 patients had to be recruited in each ward per month.

3.8 Qualitative data analysis

The transcribed focus group interviews for study I, II, and III were analysed separately. Content analyses described by Graneheim and Lundeman,[102 103] were applied to the data with an inductive approach. In study I, the eleven patients' and healthcare professionals' interviews were first analysed separately to identify if there were any differences in view on patient risk areas. When there were established no major differences in the data between patients and healthcare professionals, all the interviews were combined to form the unit of analysis. Inductive content analyses were applied to the manifest content to describe the elements of surgical risk as perceived by the patients and healthcare workers in study I and study II, and III to confirm face validity and identify barriers and drivers for PASC. All the analyses were stopped at the category level and according to Graneheim & Lundeman.[103] Qualitative content analyses at category level describe participants' experiences of common phenomena, such as things, opinions, attitudes, perceptions, and experiences.[103 104] Figure 9 outlines the analyses process in study I, II, and III.

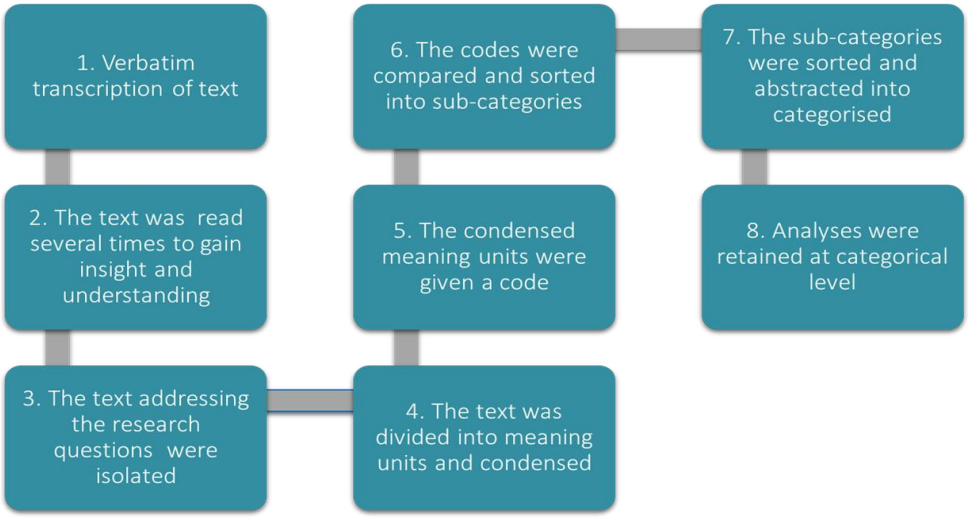

Figure 9: An overview of the inductive content analyses steps for study I, II, and III.

Each step in the analytic process is described in detail on next page.

Step 1: Transcription of text

In study I, II, and II, every word of the audio records were transcribed, including pauses to nonverbal sounds. This process allowed the researchers to get familiar with the data. All interviews were transcribed verbatim by KH in study I, and MR transcribed the interviews in study II and III while KH read listened to the audio recordings and read through the transcripts.

Step: 2: Familiarising with units of analysis

KH read thoroughly read through all interviews. Additionally, a selection of transcripts were read by four members of the research team (ASH, AS, ALM, and MR). This was done to create an understanding of the context within the research team.

Step: 3: Isolation of text

All transcribed interviews were transferred to NVivo 12 Plus software program (QRS International Pty Ltd Version 12. 2018). Excel spreadsheets and NVivo was used to organise text, and manage all data. The interviews were reread and all text addressing the research questions were isolated. Several research members (KH, ASH, ALM, AS and MR) participated in this process, first separately and then together as a team.

Step 4: Meaning units and condensed meaning units.

The text from the units of analysis addressing the research questions were considered meaning units and condensed by KH. The rest of the research team then controlled the condensation to ensure that the meaning was not lost.

Step 5: Assigning codes

The condensed meaning units were given a code, first separately by the same research members mentioned in step 2. Then the codes were discussed and compared. The coding had a descriptive approach striving to stay close to the text of analysis.

Step 6: Comparing codes and abstraction subcategories

Again, the codes representing each condensed meaning unit were assessed and compared by the research team included in the analysis processes. The codes were then abstracted based on differences and similarities and were in the surgical risks occurred. The codes were then placed under subcategories.

Step 7: Assessing the subcategories and creating categories

The Subcategories were discussed within the research group and given a temporary category. The categories were then discussed and finalised. The categories were labelled to describe the content, which is referred to as the manifest content or close to the text.

Step 8: Retaining analysis

Analysis stopped at the categorical level is seen as an expression of the manifest content within the text and answers the question *"What"*.[102] The final categories describe the possible content of PASC in study I. In study II they described the face validity of the checklist while in study III, barriers and drivers for PASC usage were identified.

3.9 Statistics analysis

Descriptive statistics were used in all three studies to describe participants' demographics. Additionally, study II used simple descriptive statistics to calculate the I-CVI's, and a chi-square test was carried out to investigate any demographic differences between the patients who used the checklist and those who did not use PASC.

Intraclass Correlation Coefficients (ICC) were also carried out in study II to assess the PASC reliability. ICC estimate and 95% confidence intervals were calculated based on a mean-rating, two-way random-effects model with absolute agreement.[105] The I-CVI scoring variables with missing values less than 50% were replaced with the mean values based on multiple imputations (MI).[106] Of a total of 215, 23 patients were

removed due to 50% or more missing values.[107] A total of 10.8 % (1207 missing ratings of 11135 possible ratings) were replaced with mean values based on multiple imputations.

In study III, descriptive statistics describe the return rates and percentages of PASC items used. In addition, the Chi-squared test (also performed in study II) was carried out to identify possible reasons for the different return rates between the surgical wards.

All analyses were carried out in STATA version SE 16.1. (StataCorp. 241 2019. College Station, TX: StataCorp LLC) except for the ICC estimate, which was carried out in SPSS Statistical Package Version 26 (SPSS, Inc, Chicago, IL).

3.10 Data Handling

The qualitative and quantitative data from the three studies were transferred to the research server provided by Haukeland University Hospital. All focus group interviews were deleted from the digital recorders once the data had been transferred to the research server. All contents of the transcribed interviews were ensured as anonymised before analysis. The whole research team performed quality assurance of the data and the analyses.

In study II and III, the checklists used by the patients were given a unique ID number with the identity key stored at the main research server, where only the Ph.D. candidate and the main supervisor had access. The paper versions of PASC are stored in a locked filing cabinet in an office at Haukeland University Hospital. The anonymised data from the PASC checklists were plotted in two separate Excel spreadsheet by two researchers and then doubled controlled in the spreadsheets compare program.

3.11 Ensuring transparency

Study I ensured transparency by reporting according to the Consolidated criteria for Reporting Quality Research (COREQ).[108] COREQ is a checklist designed to guide researchers to rapport on essential features such as research team, study method, context, findings, analysis, and interpretations.[108] The full coding tree from the analysis and a statement of data available upon request was included in the published version of study I.

Study II followed the consolidated criteria guideline for reporting intervention development studies (GUIDED).[109] GUIDED is a checklist designed to improve the quality and consistency of reporting intervention development in health research. The GUIDED checklist is recommended by the complex intervention framework when reporting an intervention development study. In addition, the complete I-CVI calculations per item/ward were published in study II as an appendix (Appendix 4) with a declaration that if further details are needed correspondent author can be contacted. Reporting of the qualitative data followed the COREQ checklist as described above.

Study III utilised the checklist for CONSORT extension for feasibility studies. The CONSORT extension for feasibility studies focuses on randomised pilot and feasibility trials. Study III is not a randomised feasibility trial. However, Lancaster and Thabane[110] recommend using the CONSORT extension to pilot and feasibility trails since it can be adapted by leaving out the items about randomisation. Reporting of the Qualitative data followed the COREQ checklist.

4. Summary of results

Study I

Post-surgical patients and healthcare workers shared their experiences regarding risk areas before and after surgery. The final categories represented the time of information delivery: “pre-surgical information” “Pre-surgical preparation”, “Post-surgical information” and “Further plans and follow-ups”. The subcategories represented the risk areas under each category. The risk areas identified pre-surgery were; The need for direct contact information (to the ward or coordinators), so that the patients could ask questions; Information about medication safety on what patients needed to know before surgery, and what they could do to prevent medication error; Information about own health status, and if there were issues they should address with their general practitioner before surgery; Information about how patients could optimise own health before a surgery; The importance of having a dental check before surgery; Reminder to read all information given to them; Information about important preparation two weeks before surgery; which information healthcare worker’s needed from the patients before their surgery; Plan their discharge; Information on the preparation they need to performed on admission to hospital and just before surgery.

The risk areas post-surgery was; Information on how to prevent complications and what to do if complication occurred; The importance of keeping to restrictions and being active; Addressing medication safety such as new or stopped medications; Addressing the need and usage of pain relief; Information about surgeries effect on stomach functions; and the need for information on further care and appointments. In addition, both patients and healthcare workers expressed the need to systematise patient surgical information and that a surgical safety checklist could be the right tool. It was imminent in the results that patient information and preparations before and after surgery are a key to improving patient safety. The time of information delivery was crucial to patients, and that stress often affected their ability to receive and understand information.

Study II

PASC development process resulted in consensus on a two-part patient checklist pre- (32 items) and one post-surgery (26 items). The checklist covers patient risks such as medication safety, optimisation of patient health, patient preparations, crucial information before and after surgery, and further treatment and follow-up after surgery. 215 surgical patients from six surgical wards scored each checklist item on a scale from 1 to 4 (I-CVI analysis). Most participants agreed on the item importance resulting in the removal of five items and redesign of six items on PASC. Before the revision, the total Scale-level index/Average (S-CVI/Ave) on pre-operative and post-operative PASC was 0.83 and 0.86, respectively. After revision, S-CVI/Ave increased to 0.86 and 0.93, respectively. After revising the I-CVI scoring and the HFMEA hazard scoring, PASC was shortened to 27 items pre-surgery and 20 items post-surgery. Patients' item scoring reliability (ICC) for both parts of PASC were 0.97 (95% confidence interval 0.96 to 0.98). In addition to item reliability, the item missing I-CVI scoring was also investigated. Most items with missing over 10 % were redesigned and kept or removed based on the I-CVI and HFMEA hazard scores. A full overview of missing I-CVI scoring per item can be found in appendix 8.9. PASC's face validity was assessed as good. Only small adjustments on the checklist items were needed to improve PASC's user-friendliness. However, during the focus group interviews, patients did express it was important that the patients received PASC at the right time and that healthcare workers participated in its usage. Full Norwegian (validated) and English (translated, not validated) versions of both parts of the patients' safety checklist can be found in appendices 8.7 and 8.8.

Study III

PASC usage and its barriers and drivers were identified. 50.2% (215/428) of surgical patients used PASC. Out of the 428 recruited patients, 24.1% (103/428) did not use PASC due to surgical or COVID-19-related cancellations. 29.9% (85/428) did not consent, and 5.1% (22/428) did not deliver PASC due to losing their checklist or forgetting to return it at discharge from the hospital. 0.7% (3/428) died during

hospitalisation. Four out of five patients who used PASC (186/215) answered ≥80% of the PASC items (see Figure 10) (se appendix 8.10 for full dataset on patient item usage). Barriers and drivers were identified through focus group interviews; Patients expressed the importance of having time to address the checklist items; Design was essential, especially the layout to avoid having to answer irrelevant items; Patients also expressed that the checklist was an impetus to communication and gave support throughout the surgical pathway. In addition, the findings also indicated that there was a need for more project funding to increase the numbers of clusters (Surgical wards) and the recruitment time to ensure a successful of a SW-CRCT.

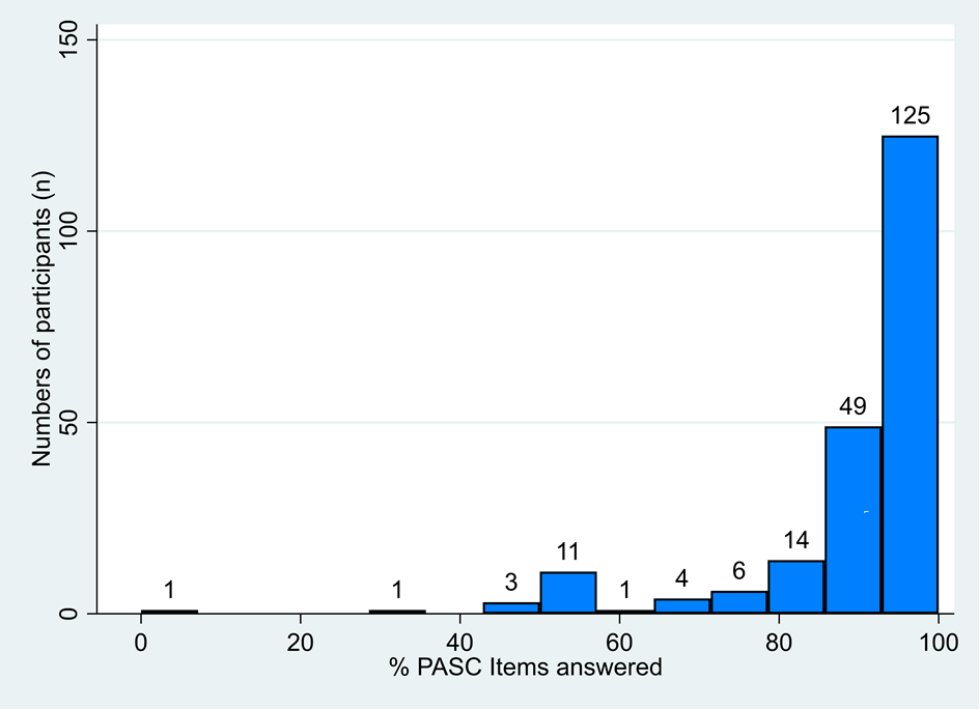

Figure 10: An overview of total PASC item usage.

5. Discussion

5.1 Methodological considerations

Qualitative and quantitative research methods have been used based on this thesis's overall aim and overarching study design (Complex Interventions). Qualitative methods have been used to interpret and understand phenomena around patients' surgical risk areas, identify the content and developing of PASC, and investigate PASC's feasibility. The quantitative methods have been used to describe the item content validation index and usage of PASC.

5.2 Qualitative approach

5.2.1 Study design

Phenomenology research design is preferred when searching to examine lived experiences of humans.[111] One should then seek to understand the "truths" in these experiences. Qualitative methods such as interviews (transcribed) with data analysing involving coding and categorising information are often used in phenomenological studies.[112] When content analyses are close to the manifest content with a concrete analysis level and a low interpretation degree, Graneheim et al.,[103] call this a phenomenological description of the data. Such a description is well suited to identify the patients' and healthcare professionals' experiences with patient risk areas and perceived contents for a surgical patient-completed safety checklist in study I. Similarly, a phenomenology description is also suited for the qualitative parts in study II and III, where focus group interviews are used to investigate face validity and the barriers and facilitators related to PASC use.

The qualitative parts of all three studies seeks experiences of surgical patients regarding risk areas related to surgery and the usage of PASC. The analyses were inductive, and the researchers searched for patterns related to surgical risk areas and

PASC usage. It has been argued that an inductive analyses might give superficial empirical summaries.[113] However, the qualitative analysis in this thesis aims to describe the content at the manifest level with a low degree of interpretations, which is recommended if the researchers seek to identify lists of risk areas related to a phenomenon.[103]

An additional challenge with qualitative methods is the researcher's pre-conception when conducting the interviews and analyses,[103] which raises questions of reflexivity and trustworthiness.

5.2.2 Reflexivity

Reflexivity is described as the process of critically reflecting on oneself as a researcher and how prior assumptions and experiences can influence the research results.[114 115] Peshikn[116] expressed the need for qualitative researchers to systematically identify their subjectivity throughout their research to establish rigour. The researchers' personal and intellectual biases must to be left outside the research to avoid affecting the data collection and interpretation.[115 117] As an ICU nurse with more than 18 years of clinical experience with critically ill surgical patients, I needed to be aware of my personal and intellectual biases related to my professional experiences regarding the topics addressed in study I. During the interviews and data analyses, I tried to avoid letting my own professional pre-conceptions influence the patients' and healthcare workers' experiences. At the same time it was essential to make use of my professional experiences on surgical risk areas to encourage discussions during the interviews. Study I aimed to identify surgical patients' risk areas before and after surgery that could be addressed in a patient checklist, which would benefit all parties. During the data collection, notes were taken, with either a supervisor or a co-researcher present during the interviews, and issues were discussed after each interview.

There was a risk of positive bias in study II and III because I had developed the checklist and with me having a possible need for the patients to give positive feedback

on PASC. To reduce risk of bias, a co-researcher who had not participated in the PASC development performed and drafted the interview guide together with me and the research team. I was only present as a co-moderator during the three interviews. Interviews were moderated by a co-researcher and the analysis was carried out by members of the research team, being aware of subjectivities and the above mentioned reflections.

5.2.3 Trustworthiness

Trustworthiness is described as a process of auditability where the reader can track and confirm the research processes.[118] The researchers are obliged to report the study so that the reader can accept it as trustworthy. Trustworthiness has been divided into five criteria; credibility, dependability, confirmability, authenticity and transferability, as described by Lincolon & Guba.[119]

Credibility refers to how the data and analyses address the research question, which involves two factors. The first factor, describes the decision processes of the study focus, study context, participants and data gathering.[119] Variation in participants' experiences, gender and ages contributes to a rich variation of the phenomena under investigation. The second factor is the data analysis process and how clearly the researchers can present the analysis in their report to ensure credibility.[102]

To address credibility, we emphasised to report clearly on the aims for the qualitative data collections. We conducted focus group interviews with post-surgical patients and healthcare workers to collect the qualitative data in study I and post-surgical patients in study II and III. Focus group interviews are suitable for collecting data in order to explore a range of opinions, perceptions, ideas, feelings about an issue, practice or idea.[89] In study I, we aimed to ensure that the interview objects represented variations of surgical experiences, ages and gender, by interviewing post-surgical patients (4-8 participants in each group) from five different surgical specialities from two hospitals. Likewise, variation was ensured in the healthcare professionals group, by conducting the focus group interviews from different surgical specialities. Each focus group interview with healthcare professionals (5-10 participants in each group) was

multidisciplinary; one or two representatives of the following professions participated in each focus group interview; surgeons, ward physicians, nurses, and secretaries. Members of the multidisciplinary teams (and team compositions) were chosen based on their roles, work experiences and level of patient contact.

In study II and III there were only three focus group interviews conducted, and there were limited numbers of participants in each interview (2-4 participants in each group). A total of 24 patients were invited for the three focus groups interviews across the five surgical wards at Haukeland University Hospital. Unfortunately, after the first interview, COVID-19 arrived in Norway and several participants from two wards (Gastro and General surgery) were lost due to community closedowns and uncertainties within our country. We acknowledge a weakness in credibility due to the low numbers of patients interviewed. However, no clear recommendations as to numbers of interviews or participants have been made. It is acknowledged that small studies with *"modest claims"* might achieve data saturation quicker than more complex studies.[120] Although the focus group interviews are minor parts of study II and III, the qualitative findings strengthened and confirmed the quantitative findings from 215 surgical patients related to PASC validation and feasibility.

To address the second issue of credibility (reporting the analysis clearly), we ensured all the meaning units chosen were related to possible patient surgical risk areas (study I), face validity (study II) and barriers and facilitators (study III). All the analyses were illustrated in text and tables or added as an appendix in the published studies. Four researchers read the data and the data abstractions were performed in collaboration with the research team. Any meaning units deemed to have more than one possible meaning were discussed within the research group before it was condensed and given a code. Non-condensed meaning units were displayed in both the text and analyses table to further ensure the credibility.

Dependability refers to change of data over time and adjustments done within the research's analysis process.[102] To address this issue, we ensured asking questions on the same areas in each focus group interview. Two semi-structured interview guides were used in study I, one for the patients and one for the healthcare professionals. In

study II and III, the same patient interview guide was utilised during the focus group interviews with the surgical patients who had used PASC. We designed each interview guide with a core trigger and under each core trigger, we had more specific questions (supporting questions) to help identify possible risk areas in detail, if further elaboration was needed during the interviews. The research team also had an open discussion on similarities and differences in the data, as recommended by Graneheim and Lundeman.[102] All patients' interviews were carried out two to eight weeks after surgery to ensure that the patients had a recent memory of the surgical event.

Confirmability refers to that the findings from the data abstraction represent actual information provided by the participants and that these results are not invented.[119 121] To achieve confirmability, all findings in the report should reflect the participants' voices and not the researcher's biases or perspectives.[121] Confirmability was ensured in all three studies by presenting a clear coding tree of the analysis and findings, including in the text quotations from the participants.

Authenticity describes to which degree the researchers present fairly and faithfully when reporting a range of realities.[121] Here we addressed the issue of authenticity, the lived experiences related to surgical patients' risk areas and PASC usage were described in the text with patient quotations within all three studies.

Transferability refers to transferring the findings to other settings or groups.[122] All qualitative data were collected from five surgical wards at two Norwegian hospitals. All patients interviewed in study I, were elective post-surgical patients that had been admitted to the hospital and undergone a surgical procedure. In study II and III, patients who had undergone elective surgery, validated and used PASC were interviewed. Study I findings in the post-surgical patient interviews clearly reflected the risk areas also identified by the healthcare professionals and as reported in existing literature (See the published paper in study I). Still, the patients' interviews gave additional insight into the patients' perceptions of risk areas and how they could participate themselves in reducing such risks. The findings were used to develop a surgical safety checklist for six surgical wards, and only minor customisations had to be performed to fit each ward's practice. Based on PASC development, the findings

may reflect the patient risk areas are similar within surgical units in the Norwegian hospital settings. Whether the results are transferable to other international settings is beyond this thesis and is yet to be explored.

5.2.4 PASC Consensus process

Consensus methods are often used in development research with limited statistical information. [93] Using a consensus method for instrument development research, researchers can gather a broader range of information compared to studies relying on only statistical data gathering.[93] In study II the research team applied an expert panel (multidisciplinary team with, patient representatives, general practitioners representatives, pharmacist, communication experts, and a safety officer from the aviation industry) to develop PASC. Then surgical patients validated its content and design. The final consensus round was applied with all the involved teams, discussing the results from the patient validation and the HFMEA hazard scoring was performed.

Ensuring that every clinical profession from each participating ward participated in the consensus proses strengthened the consensus process in study II.[93] However, data analysis from study I revealed that general practitioners also had to be included in this process, because the content of PASC expanded beyond the surgical speciality field. A possible bias in the consensus processes is the selection of participants for the expert panels, with the participants primarily expressing personal views.[93] Still, most healthcare workers are found to not only represent themselves, but also their co-workers' views.[123] To compensate for this issue of selection bias the checklist drafts were presented at each surgical ward staff meeting. The staff was allowed to voice their concerns and opinions regarding the patient safety checklist concept and its content and design.

5.2.5 Risk assessment Health Failure Mode Effect Analysis hazard scoring

HFMEA hazard matrix scoring was a part of the consensus process. It was applied to any items scoring low on the patients' I-CVI scorings (<0.78), in order to prevent elimination of potential PASC items addressing a risk to surgical patients. HFMEA

risk assessment consist of five steps and has a qualitative nature where multi-professional teams work together to identify potential healthcare risks.[124] HFMEA hazard matrix scoring is the second last step in the HFMEA risk assessment. In this step, a multi-professional team evaluates the risks probability and harm level according to the HFMEA hazard matrix scoring[98] (See section 3.7.6 Health Failure Mode Effect Analysis hazard scoring Table 6, page 35). This thesis only describes the HFMEA hazard matrix scoring (which is step 4 in the HFMEA risk assessment method) and not the whole HFMEA risk assessment method leaving out the following four steps; 1. Defining the topic, 2. Assembling the team, 3. Graphically describing the process and, 5. Identifying actions and outcome measures.[125] This might be a weakness, but we can in many ways say that the project has followed the five steps within the HFMEA risk assessment method. If we look at the PASC development process from the beginning to the end. It started with defining the topics where we identified areas where patients could potentially reduce risk before and after surgery (HFMEA step 1, study I). After analysing the data, findings were presented to multi-professional teams within the participating wards and stakeholders. The results were discussed, and each ward reported which risk areas PASC should address (HFMEA step 2, study II). Further, the admission and discharge practices at each surgical ward were mapped. The wards had very different routines when giving patients pre-surgical and discharge information. The main problem was that the patients did not remember, or understand the information given to them (HFMEA step 3, study I and II). After the patients had scored each PASC item, the hazard score analysis was applied to those who scored low (HFMEA step 4, study II). In the last HFMEA step, an intervention should be developed, and the outcomes measured (HFMEA step 5, study II and the planned SW-CRCT).

5.2.5 Face validity and Feasibility

In study II and III, the qualitative data were utilised to investigate the face validity and feasibility of PASC. Face validity has been described in several ways, and some interpret face validity as content validity.[126] This thesis, used the definition described in the paper: “Essential elements for questionnaire design and development”.[127] They

define face validity as assessing the design and likelihood for an instrument to be used and accepted. Face validity can evaluate the following in a questionnaire: readability, clarity of wording, layout, style and feasibility.[128] Face validity of an instrument is closely interwoven with its feasibility,[128] and therefore the qualitative data were collected simultaneously for study II and III.

Several qualitative methods can be used to collect face validity data. Face-to-face interviews with the target group members are recommended.[129] Face validity is an integral part of developing an instrument to ensure user-friendliness and that the instrument targets the areas it is attended for. Despite this, face validity is not seen as a strong method to ensure validity alone, but can contribute to strengthening instruments validity if combined with other content validity methods such as I-CVI.[121 130] In study III, the qualitative findings helped identify and understand the facilitators and barriers to PASC and its implementation. The results were an important addition to supporting and strengthening the quantitative data on PASC recruitment and usage. Overall, usage of qualitative methods in complex intervention studies is seen as a contribution and strength, to exploring issues related to the healthcare question of interest or context of the research, and developing and refining interventions.[87]

5.3 Quantitative approach

5.3.1 Study design

Study II and III had a prospective cross-sectional design. The cross-sectional design is characterised by data collection at a certain time point of a phenomenon under investigation and is often utilised to establish preliminary evidence when planning further studies.[121 131] It is the most relevant design in validation studies and reliability where the status of a phenomenon at a fixed point of time is described.[132] Cross-sectional design studies are either descriptive or analytical. The descriptive approach describes the phenomena, while the analytical approach compares exposed and non-exposed groups at a set time.[131] Hence, the cross-sectional descriptive design in study II and III, aimed to validate and describe PASC's feasibility. Cross-sectional designs

are recognised as the best way to determine the general use and acceptance of an intervention before a randomised controlled trial.[133] However, there are some disadvantages to using a cross-sectional design. It eliminates the possibility to investigate the effects of an intervention and only provides a snapshot of the results at a certain point in time, and the results in another timeframe might be different.[134] Other issues with the cross-sectional design are the sample selections and response rates. An optimal sample size for a cross-sectional study is taken from the whole population, which was not possible in study II and III.[134] Instead, a cluster randomisation was carried out as described in section 3.6.3 Quantitative data collection page 28. Sample size in study II and III was based on the power calculation for the planned SW-CRCT (REK 2016-1102). It was initially calculated that the PASC could give a 5% reduction of, complications. A total of 4200 patients (6 wards x 14 months x 50 patients per month) had to be included. However, descriptive studies do not rely on statistical power,[131] and the I-CVI method do not recommend a large amount of raters,[94] so for study II and III, the sample size was set at 50 patients per ward.

Non-responders are a common problem in survey studies and can cause bias. Biases may occur if the questions in the survey are related to the probability of having an outcome (e.g. disease).[134] Study II, was in many ways a survey where elective surgical patients were asked to rate the importance of each PASC item. However, the variation in each checklist item was not intended to be linked to specific outcomes. The purpose of the checklist items was to ensure that patients understood the importance of preparations for surgery and having received important information before and after surgery. To address the possible respondent bias, the reason for not returning or using PASC was documented in study III (same study population as in study II). Still, there might be a possibility of biases related to the patients' willingness to use the checklist.

Both study II and III, had no significant differences between gender in the responders' group and the non-responders, indicating a low risk of responder/non-responder bias. However, there were significant difference in the response rates between the surgical wards. One had a high response rate (72%), and the other had a lower rate (38.9%). This could have potentially given a loss-to follow up bias.[131] Taking a closer look at

this, there are indications that the healthier population (and having minor surgery) was less likely to use PASC than patients scheduled to have major surgery. Still, the data are limited, and it is too early to draw any conclusions.

5.4 Validity

5.4.1 Content Validity

After an instrument has been rigorously developed, the content validity of the measure must be investigated.[95] Content validity is described by Polit & Beck as "*the degree to which an instrument has an appropriate sample of items for the construct being measured"*.[122] Several methods exist to measure content validity, and in study II, Content Validity Index (CVI) was used. CVI has been widely used in scale developing research, and some weaknesses to the method have been described: CVI does not adjust for chance agreement.[135] Also the CVI method does ignore some relevance categories within the Item Content Validity Index (I-CVI) scoring. It only focusing on the two scores relevant/not relevant rather than all four scores described by Polit & Beck,[94] and that it does not capture the instruments comprehensiveness and are unable to measure the construct of interest.[95]

The method consists of two types, the I-CVI and the S-CVI. The I-CVI measures each item's relevance, while the S-CVI/Ave or the S-CVI/UA measures the total relevance of the entire construct.[95] In study II S-CVI/Ave was chosen as recommended by Polit and Beck,[95] because the S-CVI/UA method can be too stringent when there are many validation experts involved, making 100 % agreement improbable or impossible to obtain.[95 130]

How to calculate the I-CVI and S-CVI/Ave is generally agreed upon, but there is a discussion on how many experts should rate the content, with a current recommendation of minimum of three experts and no more than twenty. A large number of experts rating, the items limits any chance of agreement.[95 136] In study II, 215 patients rated the PASC items, with 22-45 patients per surgical ward (see demographics in study II). The total number of lay experts is above the recommended number of experts. Also, when considering each surgical ward separately, the numbers

are not deviating too much from the recommendations. It was important that each ward did their own validation of PASC to identify any differences and to be able to adapt PASC to each ward separately. In our analysis of the expert ratings we saw only minor differences in the item ratings and that the overall I-CVI ratings were in agreement. Therefore we concluded in study II that having such an extensive number of lay experts strengthened our I-CVI and S-CVI/Ave results additionally rather than weakened them as described in the literature.

Another discussed issue regarding I-CVI and S-CVI/Ave scorings is agreement on acceptance levels for when an item should be considered valid or not, with various I-CVI and S-CVI/Ave acceptance levels described, depending on the number of raters.[130] With a large number of raters, Polit & Beck and Davis describe the minimally acceptable level for I-CVI and S-CVI to be 0.78 and 0.80, respectively.[94 137] A S-CVI/Ave set at 0.80 is also most commonly mentioned as an acceptable limit for instrument developers.[94] Since study II had a large number of raters, the minimal levels of I-CVI and S-CVI were agreed upon in the research team.

One of the weaknesses in CVI is that it does not adjust for chance of agreement. Polit and Beck[94] suggest that Kappa statistics can be used to calculate the chance of agreement, but also dispute if it will actually add any value to the validation. However, in study II, there is an issue of a large number of rating experts, and a total consensus was then deemed unlikely. Instead we investigated the PASC items' reliability (internal consistency) as described under section 3.9 statistics analysis page 38.

5.4.2 Construct and criterion validity

Construct validity refers to whether an instrument actually measures the concept, and criterion validity investigate similar instruments' up against an instrument under validation to see if they measure the same variables.[138] These two types of validity are not applicable for study II. PASC use does not measure levels of disease or symptoms. Instead, it is designed to empower patients' involvement in safety, and the endpoint for measuring its construct validity (effects on reducing patient complications) will be the planned SW-CRCT.

5.5 Reliability

In instrument development, reliability relates to the consistency of a measure.[138] Reliability is defined "*as the extent to which measurements can be replicated"*.[139] There are three approaches to measuring instrument's reliability; internal consistency, stability and equivalence.[138] In study II, the reliability of the patients' validation ratings (I-CVI scorings) were investigated by evaluating internal consistency and equivalence. Internal consistency captures consistency through each item of an instrument, and equivalence examines the consistency among responders of an instrument.[117 138] Cronbach α is commonly used to report the internal consistency of an instrument.[121] However, as the PASC items are of an informative kind and do not inter-correlate, Cronbach α is not relevant as a reliability test for PASC, instead an Intraclass Correlation Coefficients (ICC) calculation was performed.

5.5.1 Intraclass Correlation Coefficients

ICCs are descriptive statistics that can measure consistency and reliability for larger sets of measurements from several raters,[140 141] and are widely used to measure raters' reliability when developing instruments or assessment tools.[105] Ten different ways of calculating ICC have been identified, and each method can yield different results from the same data set.[105] It is therefore vital that a researcher choses the appropriate method according to the dataset and report it clearly. If the information about the ICC method applied is unclear, its results become questionable.[140] The ICC method used here to assess the internal consistency of the patients' PASC rating was a mean-rating, two-way random-effects model with absolute agreement. The two-way random-effects ICC model is appropriate if subjects are randomly selected from a larger population of raters with similar characteristics,[105] such as the population in study II. Again, there two variants of this model which are described, either with "*consistency"* or "*absolute agreement".* Absolute agreement which is applied in this thesis, is described as when different raters give the same score to the same subject.[105]

To calculate ICC (in SPSS), we had to address missing data because ICC can only be calculated with complete cases. In the dataset for patients' validation scoring, there were few complete cases (100% compliance). However, the quality of the data set would be reduced if all cases with some degree of missing were removed and the results would be affected. Missing data is a known problem in quantitative data analysis. In settings such as medicine, the missing data can cause inhibitors for the analysis processes and the results.[142]

5.5.2 Multiple Imputation

MI is one of the commonly used simulation approaches dealing with missing data and is currently considered the best choice.[121] To address the issue of missing values, MI was applied to the cases where raters had less than 50% missing ratings, while cases with 50% or more missing ratings were removed from the dataset. MI creates multiple data sets and consists of three stages; First, MI creates multiple imputed data sets where each set is given reasonable values for the missing data. Next, a test model is added to each imputed data set, and the point, and standard error estimates from the analyses are pooled across imputations. Finally, the point standard error estimates for the model parameters is calculated and used to replace the missing values in the data set.[106 142] To be able to report reliability of patients PASC scorings, missing values had to either be removed or replaced. Otherwise, an ICC could not have been calculated. To avoid biases when replacing the missing data the research team considered MI as the most appropriate approach, applicable to all three missing data patterns; missing completely at random, missing at random and missing not at random.[121]

5.6 Discussion of results

The three studies in this thesis have described patient risk areas, and possible contents for a surgical patients' safety checklist, and the checklist development, validation, and feasibility have been investigated. PASC can act as a tool for patients that enhances their understanding of important information, and raises their awareness of what they can do to prevent complications related to their surgery.

5.6.1 Patient checklists and safety

Currently, the use of patient safety checklists to enhance safety is limited. From study I it was clear that there are many areas where patients can reduce the risk of complications and patient harm before and after surgery. However, there are few systematic approaches in place how to convey such information to surgical patients who are often stressed and anxious before surgery. Many patients experience information overload and struggle to retain information.[143] In fact, studies show that as low as 14% of any presented information is remembered correctly if given only orally, and that a combination of written and oral information is preferred.[71 144] Patients tend to focus on diagnostic information and often fail to remember practical instructions.[71] How information is communicated and the dialogue between the patients and healthcare professionals is crucial for patients' understandings and ability to feel empowered to participate in their own safety. Interventions designed to improve information conveyance and communication between patients and healthcare workers are shown to reduce hospital readmissions, and increase adherence to treatment and patient satisfaction.[28 145 146] Throughout the focus group interviews (study 1), it was identified that patients experienced confusion, information overload and uncertainty about what they could do to prevent complications before and after surgery. However, they did acknowledge that they had some responsibilities themselves, but were unsure how to contribute. Some patients felt it was difficult for them to participate in communication due to a lack of background knowledge, and some patients chose to let the healthcare workers take full responsibility for their safety. It was clear through study I that patients require a more systematic approach to encourage patient involvement in preventing complications and patient harm. In fact, the patients themselves mentioned that a checklist might be one of the solutions to the problem. These findings align with the current calls for systematic approaches to empower patient safety involvement.[27 32 58]

WHO has identified patient empowerment as the key to patient involvement in their own care and safety.[19] The main component to ensure patient empowerment is to provide them with accurate and high-quality information.[147] A surgical patient checklist might be the right way to provide patients with such information, and it can easily be adapted to fit different medical settings and practices.[32] At the same time a patient-completed checklist can increase surgical patients' understanding and knowledge, guiding the patients through the surgical pathway and directing them to access accurate and safe information. Research evidence indicates that patients who are accurately informed have increased health literacy and feel more empowered to be involved in their own care and safety.[63 148]

Further, patients are often unsure about their relationship with healthcare professionals. They are often afraid of asking confronting questions such as hygiene practices, marking of the right surgical site or usage of WHO SSC during surgery.[58] The patients' families should also be included in this. If close family members are an active part of the patients' healthcare, it might make it easier for patients to participate when experiencing this additional support.[63] Health organisations generally recognise benefits of involving patients and their families at all levels of healthcare and that it is their responsibility to facilitate this.[58] At the same time, there is an ongoing discussion that increasing patient involvement in safety may cause an unwanted shift of responsibility to the patients themselves.[27 33 53] Studies show that patients and families often blame themselves after a medical error.[149] However, patients do understand that they have a role in omitting and preventing errors, and that they might be a cause of error themselves.[27] To avoid patients or families blaming themselves, they must be made aware that error is an unfavourable outcome that healthcare workers strive to avoid and that all efforts to further reduce any chances of these are made. Therefore, it is vital to develop a tool that allows patients' involvement and to identify risk areas for error where the patients' own knowledge and understanding play central roles. This can empower patients increasing patient knowledge of the benefits of optimising their own health before surgery, having control over their medication usage or encourage

patients to ask for more information or request the use of other safety initiatives such as SCC.[63 149]

The PASC content addresses broad aspects of potential risk areas before and after surgery, with crucial information that the patients should receive before surgery and discharge from the hospital. This has been systemised in PASC, to guide surgical patients through the surgical pathway and empower them to prepare for surgery and also request any missing information. The first part of PASC encourages patients to ensure medication reconciliation and safety, optimising their own health, and ensures that they have understood information as to surgical preparation. The second part of PASC acts more as a check tool where patients can go through the checklist to ensure that they have received information about risks for complications, the importance of activity or any restrictions, new medications, pain relief and treatment plans after surgery.

Results from study I indicate that a checklist should address both patient risk areas within the hospital and risk areas as to lifestyle and existing health issues. Patients who optimise their own health before surgery reduce their chances of having surgical complications.[72 150-152] Items encouraging patients to address their medication usage, lifestyle issues and existing health problems were included in PASC after the consensus process and validation in study II. The expert panel and patients all agreed that general practitioners, as well as dentists have important roles here.

Medication errors are one of the most prominent problems in patient safety and are often underreported.[153 154] Several promising initiatives, such as electronic records, have been implemented to improve medications safety and reconciliation.[155] In Norway alone, 3372 medical errors were reported in 2016-2017 and that 68% of these errors occurred during admission, and 62% of the reported cases had harmful consequences for the patient, such as dosing errors, omissions, and wrong medication.[156] Patient involvement in medication safety is often under-recognised, with calls for measures.[156-158] Patients report that they lack knowledge on their

medications, especially any new ones, when they are discharged from the hospital,[157] Our findings in study I are in line with this, and the finalised version of PASC is a tool addressing medication safety, helping patients to understand the importance of having control over their own medication before surgery and empower them to ask for important information regarding new medicines and pain relief before discharge.

The qualitative findings in study I and II and III, showed that patients often experienced rushed discharge processes. In study I, patients often expressed that they received limited or did not remember information as to their discharge. This often made them feeling unsure as to complications, activity levels or restrictions, adverse effects, follow-ups and when to contact the hospital. These findings align with other recent studies on patient experiences at hospital discharge.[159 160]

5.6.2 Development, validation and implementation of PASC

The PASC has been developed and validated throughout this Ph.D. project, and the results indicate that patients and healthcare workers support the implementation of PASC. Existing research on safety involvement tools and initiatives indicates a positive impact on patient-healthcare professionals' communication, patient experiences and quality of care.[27 28 30] However, there is still a call for more systematic approaches to involve patients in their own safety, and the concept of implementing a patient safety checklist might be one answer to this. In fact, current literature has highlighted that there is a need for clear guidelines on how to implement patient safety involvement and more research that investigates how to best implement patient safety involvement in practice and its effect on patient outcome and quality of care.[27 58] Currently, there is limited research on the development processes of patient-completed checklists. In this thesis, the focus has been on patients' surgical safety checklists, still a few patients' checklist concepts exist outside surgery.[146 161] One checklist designed to improve medical patients discharge process, reports on the development method of the checklist but do not report on its validation. This checklist is more a practical checklist rather than a safety checklist.[161] Jones and colleagues[146] report briefly on developing a safety checklist App for cancer patients undergoing treatment. In addition

other development and validation studies exist on surgical checklists designed for healthcare professionals, such as the SURPASS and WHO's SCC.[15 16 81]
Together study I, II and III, show that it is possible to develop patient-completed surgical checklists. The methods used in study I and II might also guide other researchers to develop patient-completed checklists within other medical specialities. The development and validation of PASC should be a valuable addition to the existing patient safety involvement research and highlights the potential benefits of designing patient-completed safety checklists. However, with the safety checklist concept for surgical patients other issues arise such as access to the checklist, and its feasibility.

5.6.2 Feasibility of PASC

The topic of feasibility has arisen several times, from the early stages of PASC development to the final part of this thesis. Is it feasible to implement a patient checklist, and will it improve patient involvement in safety? In study III, our findings mostly supported PASC's feasibility, and four out of five patients who consented to use the checklist answered a majority of the items. To ensure success in further research it was essential to identify the feasibility of PASC and its implementation. The following issues were identified in study II and III: acceptability, accessibility, and practical issues related to the planned SW-CRCT.

Checklist acceptability

The acceptability of PASC has been investigated in study II and III. Overall, there is an acceptance of the checklist concept from both patients and healthcare professionals. However, there are indications of resistance to patient-completed checklists[162] and we know that previous SCC implementation has encountered resistance.[56] Some healthcare professionals do not believe that a checklist concept is transferable to patients and that they are unlikely to use such a checklist,[162] and others have a more general resistance based on the WHO SSC concept.[33 56] Also, patients are less likely to be involved in safety initiatives if they are asked to challenge the practice of healthcare

professionals.[163] This was taken into account during the development of PASC, while trying to avoid such items on the checklist and to design it as a mutual tool that could be beneficial both to patients and healthcare professionals.

Still, findings in study III, supports and strengthens the patient-completed checklist concept. However, a successful implementation of a patient surgical safety checklist is not straight forward, and a multifaceted approach, taking into account the local context, stakeholders, organisational structures, and dynamics is necessary to facilitate implementation and to minimise any resistance.[33 86]

Checklist accessibility

If a surgical safety initiative is only accessible to some patients, the ethical question of equal health for all may be raised. Study participants and patient representatives raised such concerns in study II and III. These concerns have also been raised by researchers studying patient involvement in safety, focusing on initiatives such Apps and checklists for patients.[59 61 146] They are concerned about digitalisation restricting patients' access to information, patients who have learning difficulties, language barriers, old age, dementia, visual or mentally impaired, and those with multimorbidity or are institutionalised. There is also an ongoing discussion of the role patients' personalities may play. Some patients might not use the checklist because they do not have time, or they have a passive attitude and avoid using the checklist or interactions with healthcare professionals.[59 61 164] When it comes to the patients' choice to use the checklist or not, is it ethical to make such a checklist mandatory? One way to encourage its use is to involve healthcare professionals, especially nurses, but also ward doctors and surgeons. Healthcare professionals' involvement was reported in our qualitative findings in study II and III, and the patients felt that it was more beneficial to use the checklist if the healthcare professionals actively asked if they understood the questions and went through both parts before surgery and discharge together with them.

Shirley and colleagues found that their checklist designed to improve a parent consent process for children increased the parents' feelings of nervousness and anxiety.[29] This

is an effect that a patient-completed checklist also might cause. However, in our studies, there were no indications of such effects on patients. On the contrary, the results from the focus groups in study II and III indicated the opposite effect**.** Patients felt more control over their own situation and were better prepared for surgery. These findings align with other initiatives where patients receive more comprehensive information and instructions before surgery.[72 77 164 165]

The findings in study II and III indicate that the time-point and –frame where the surgical patients receive the PASC before surgery matters as to the patients' willingness to use the checklist. If the patients received PASC too early, they were likely to forget it, and if they received it too close to surgery (one to two weeks), they were less likely to use it because of lack of time to go through all the items. The research team considers that a modification of PASC can potentially be a solution for the patients who have a short waiting time before their surgery and for those in need of urgent surgery. Similar problems applied to use of the he second part of PASC intended for patients before discharge from the hospital. Whereas the timing for when the patients' received the second part of PASC did not seem to be an issue, a lack of available time for the patient to complete PASC before discharge from the hospital was raised as a concern.

From the qualitative findings in study II and III, it was evident that, healthcare professionals have to be actively involved in PASC use to achieve optimal patient compliance. Patients expressed a need for healthcare professionals to encourage the importance of PASC, and ensure that patients understand the checklist content and have time to answer all the items (especially the second part before discharge). These findings are in line with current research on patient involvement. A patient safety involvement tool cannot solely rely on patients, healthcare professionals have to encourage its usage.[60 166]

Through study II and III, it was recognised that the user-friendliness of the checklist could be improved. These issues were related to item adjustments according to patients' answers, such as health history and medication usage (e.g. patients who do not use medications do not have to answer items regarding this). It is always important

to avoid long checklists and minimise the number of irrelevant items.[32 167] Next was the way the checklist items addresses the patient. If patients are not able to use it because of a disability or by choice, could the family members, carers or guardian use it on the behalf of the patient?[33] The current design of PASC is intended to be used by the patients themselves. However, the checklist items could easily be adapted to address family or other care takers. These are all issues that need to be carefully evaluated before the planned SW-CRCT and further implementation upscaling.

Other concerns raised during study III were recruitment processes and economic perspectives for our planned further studies. The patient recruitment was much slower at the central community hospital than at the university hospital. The overall recruitments at both hospitals were too slow if and when aiming to obtain success with our planned SW-CRCT. However, an additional successful funding application was submitted to the Research Council of Norwegian. This additional funding, will allow the future research team to employ more research staff and to increase the clusters from 6 to 7 surgical wards and recruitment time from 14 months to 22 months. It is crucial that the economic perspectives of doing research are investigated prior to a planned clinical trial, and according to the complex intervention framework.[86]

6. Conclusion and implications

6.1 Conclusion

Surgical patients' safety checklist have been developed, validated, and its feasibility has been investigated. Study I identified surgical patients' risk areas used as items in a surgical patients' safety checklist. Results here indicated that many surgical patients experienced confusion and stress before surgery. They were often unsure of which actions and preparations they themselves could do before and after surgery to avoid complications and preventable harm. Both patients and healthcare workers were positive towards designing a patient-completed safety checklist. In study II, PASC was

rigorously developed and validated. Consensus on the PASC content was achieved with patients, patients' representatives, and multidisciplinary healthcare professionals and then validated by patients through item content validation. A majority of patients asked to use PASC did in fact use it. Surgical patients who used PASC expressed that the checklist helped them gain better control of information and encouraged them to actively participate during consultations and throughout the surgical pathway. PASC is a feasible tool empowering patient involvement in their own safety throughout the surgical pathway.

This thesis contributes to new knowledge on how to develop and validate a patient-completed surgical safety checklist. It also indicates that a patient-completed surgical safety checklist is a positive step toward increased patient involvement by systemising information and empowering them to take actions for their own surgical safety.

6.2 Implication for clinical practice

Implementation of PASC can affect the practice of how information is given to surgical patients and provide information more systematically. PASC might guide surgical patients to be better prepared for surgery and recovery, which may reduce complications and increase the quality of care. Some PASC items encourage patients to contact their general practitioner before surgery to clarify existing medical issues or promote lifestyle changes. These might increase the contact between the patient and general practitioner before surgery. The study results suggest that for PASC to reach its full potential healthcare professionals must actively participate in its usage and ensure that the information is understood. Implementing PASC as a tool to involve patients in their own safety might change the current healthcare professionals' practice helping to systemise routines regarding how they inform patients before surgery and before discharge. PASC might also affect how patients communicate with healthcare professionals. Further, the concept of surgical patients' safety checklists could encourage other healthcare specialities to systemise patient information by creating patient-completed checklists. However, the three studies included in this thesis did not

aim to evaluate effects of PASC on patient safety, and potential implications are not identified. For this further studies are warranted.

6.3 Implication for further research

- A clinical trial needs to investigate the factors within PASC that can potentially prevent complications, patient harm and its effect on mortality, hospitalisation time and readmissions.
- Studies should be carried out on whether the implementation of PASC affects how healthcare professionals inform surgical patients before surgery and after surgery and if the checklist changes their current practice.
- Patients' experiences with using digital PASC should be investigated in detail.
- PASC might increase patients' health literacy, and a Health Literacy Questionnaire (HLQ) should be used to measure patients' health literacy as a part of a clinical trial.
- PASC implementation's effect on health economics should be investigated as a part of a clinical trial.
- Upscaling of PASC implementation and clinical effect. PASC should be implemented in more hospitals across Norway and overseas, where its impact on patient complications, preventable patient harm, mortality, hospitalisation time and readmissions should be investigated.
- The PASC concept transferability to other medical fields should also be investigated, such as in medical patient treatment, dental treatment and psychological treatments.

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8 Appendices

8.1 Search Strategy for systematic literature review

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to November 17, 2021>

1 exp Surgical Procedures, Operative/ 3345471
2 postoperative period/ or preoperative period/ 61655
3 1 or 2 3345471
4 Checklist/ 7539
5 Patient Participation/ 27953
6 4 and 5 52
7 (Patient* checklist* or "checklist* for patient*" or "patient driven checklist*").ti,ab,kf. 333
8 (checklist* adj2 complet* adj2 patient*).ti,ab,kf. 48
9 7 or 8 369
10 6 or 7 or 8 419
11 3 and 10 57
https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=7MOQnXR5VsMeYWayIoaD9r3toLCG6qVadyfDBQAgwojhUz7KYV7K27jK5vJVdJBZW

Embase (OVID) <1974 to 2021 November 17>

1 exp surgery/ 5205597
2 checklist/ 28847
3 patient participation/ 30619
4 2 and 3 118
5 (Patient* checklist* or "checklist* for patient*" or "patient driven checklist*").ti,ab,kf. 597
6 (checklist* adj2 complet* adj2 patient*).ti,ab,kf. 77
7 4 or 5 or 6 762
8 1 and 7 173
https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=4civX8haNHwArF7a4E02LNhQFGH2KtqoLxLXYcq9Jbf7CC7ewCTzHr8727Lo6oz0M

CINAHL - EBSCOhost Research Databases
Search Screen - Advanced Search–

S1 (MH "Surgery, Operative+") 705,390
S2 (MH "Checklists") 32,497
S3 (MH "Consumer Participation")22,028
S4 S2 AND S3 138
S5 TI ((Patient* checklist* or "checklist* for patient*" or "patient driven checklist*")) OR AB ((Patient* checklist* or "checklist* for patient*" or "patient driven checklist*")) 1,348
S6 TI (checklist* N1 complet* N1 patient*) OR AB (checklist* N1 complet* N1 patient*) 24
S7 S4 OR S5 OR S6 1,475
S8 S1 AND S7 191

https://search.ebscohost.com/login.aspx?direct=true&db=cin20&bquery=((MH+%26quot%3bSurgery%2c+Operative%2b%26quot%3b))+AND+((((MH+%26quot%3bChecklists%26quot%3b))+AND+((MH+%26quot%3bConsumer+Participation%26quot%3b)))+OR+((TI+((Patient*+checklist*+OR+%2

6quot%3bchecklist*+for+patient*%26quot%3b+OR+%26quot%3bpatient+driven+checklist*%26quot%3b)))+OR+(AB+((Patient*+checklist*+OR+%26quot%3bchecklist*+for+patient*%26quot%3b+OR+%26quot%3bpatient+driven+checklist*%26quot%3b))))+OR+((TI+(checklist*+N1+complet*+N1+patient*))+OR+(AB+(checklist*+N1+complet*+N1+patient*))))&type=1&searchMode=Standard&site=ehost-live

8.2 Ethical approval

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Camilla Gjerstad	55978499	21.09.2016	2016/1102/REK vest
			Deres dato:	
			12.09.2016	

Vår referanse må oppgis ved alle henvendelser

Arvid Steinar Haugen
Helse Bergen HF

2016/1102 Pasientens helsetjeneste: Effekt av å utvikle og implementere pasientenes egne sjekklister på forekomst av uønskede hendelser og komplikasjoner for, under og etter kirurgiske inngrep i sykehus

Forskningsansvarlig: Helse Bergen HF, Helse Førde HF
Prosjektleder: Arvid Steinar Haugen

Vi viser til din tilbakemelding om ovennevnte forskningsprosjekt. Tilbakemeldingen ble behandlet av leder av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) på fullmakt. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Pasientenes helsetjeneste medfører økt pasient-involvering. Helse Vest har mål om å redusere pasientskader som kan forebygges med minst 50%. Prosjektet bidrar til ny kunnskap om pasient-involvering og om pasienters bruk av sjekklister ved kirurgi kan forbedre kommunikasjonen med helsepersonell, forebygge pasientskader knyttet til innleggelse, før, under og etter sykehusopphold. Prosjektet vil identifisere risiko-områder for uønskede hendelser og komplikasjoner ved kirurgi gjennom fokusgruppeintervju med pasienter og helsepersonell. Sjekklistene utvikles etter en metode kjent fra høyreliabilitetsindustrier og pasientsikkerhetsarbeid (Healtcare Failure Mode and Effects Analysis). Sjekklistene vil bli testet og validert i en pilotstudie ved to sykehus i Helse Vest. I en større studie vil vi undersøke effekt av pasientenes egne sjekklister på uønskede hendelser og pasientskader knyttet til kirurgisk behandling i sykehus, med en gruppe-randomisert kontrollert studie.

Komiteen ba om tilbakemelding (vedtak av 05.09.16)
I studien er det søkt om fritak for samtykke for kontrollgruppen i delstudie 3. REK vest ber om tilbakemelding og redegjørelse på hvilke data som skal brukes, hvordan disse skal hentes ut og hvordan deltakerne i kontrollgruppen (n=2100) sin integritet best skal ivaretas.

Tilbakemelding fra prosjektleder
Data som blir samlet inn for kontrollarmen i studien vil være sykehusadministrative data, pasientdata for komplikasjoner og dødelighet. Data (sykehusadministrative og komplikasjon/mortalitet) vil hentes ut elektronisk ved etablerte systemer i Helse Bergen og Helse Vest – IKT. Det vil det være et elektronisk uttrekk av pasientdata, med behov for å verifisere opptil 30 % av ICD-10 kodene ved lesing av epikriser. Data aggregeres elektronisk ved sykehusenes etablerte IKT-systemer. Personidentifiserende data vil kun være tilgjengelig for prosjektleder, stipendiat og medarbeider som bidrar til å verifisere komplikasjonsdata.

For etterkontroll av data er det ønskelig å lagre personidentifiserende data i opptil fem år etter prosjektslutt.

Besøksadresse:
Armauer Hansens Hus (AHH),
Tverrfløy Nord, 2 etasje. Rom
281. Haukelandsvelen 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK vest og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK vest, not to individual staff

Deretter vil data slettes.

Vurdering av tilbakemeldingen
For at fritaket skal kunne innvilges, må lovkravene i helseforskningsloven § 35 være oppfylt, jf. vedtaksbrev av 05.09.16. REK vest finner at data er relevant og nødvendig for å nå forskningsformålet og at vilkårene for fritak i henhold til § 35 er oppfylt.

Tillatelsen til å behandle opplysningene gjelder til prosjektslutt 31.12.20. REK vest godkjenner videre at opplysningene lagres for etterkontrollformål i fem år etter prosjektslutt, for så å slettes.

Prosjektleder oppgir i tilbakemeldingen at kun anonymiserte forskningsdata vil bli delt med andre forskere og evt. tidsskrift dersom det er behov for det. REK vest forstår det slik at det gjelder kun deling av anonyme data der opplysningene ikke er mulig å knytte til en enkeltperson, verken direkte eller indirekte. REK vest har ingen innvendinger til dette.

Vedtak
REK vest godkjenner prosjektet i samsvar med forelagt søknad og tilbakemelding.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.06.2021, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg
Prof. Dr.med
Komiteleder

Camilla Gjerstad
kontorsjef

Kopi til: postmottak@helse-bergen.no; post@helse-forde.no

8.3 Focus group interview guide patients

Organisation and implementation of the interviews

- One person (first author) will perform all focus group interviews and one of the other three researcher will act as a moderator. One interviewer and one moderator participate in the focus group interviews. The interviews will follow the guide below with an inductive approach to the research question. It will focus on identifying risk areas to examine events and complications related to the surgical pathway.
- The ideal participant number in each interview would be 6 to 8 participants. The participants should have had surgery within one of the five included wards, and it should not be more than 2 months since their surgery.
- An information letter will be given to the patients with time and place for the interview. The participants will get a friendly reminder about time and place by text message 3 days before the interview if they agree to it.
- The participants will meet 5 min before the interview.
- Traveling cost to and from the interview will be covered.
- The participants should live within an hour drive, or have a control appointment at the hospital the same day if they live further away.
- Nursing home patients or patients with communication problems are excluded.
- Each interview will last up to 90 minutes. Current literature recommends that a focus group interview should last from 45-90 min, longer interviews are often not productive and it turns in to a burden for the participants
- The Moderator has the responsibility of keeping the time and taking field notes.
- Other preparations; we will serve coffee and tea, and fruit. We need pens, paper and recording equipment.
- Rooms has to be reserved.
- Piloting of the interviews guide will be performed before the interviews.

Interview steps	**Details**
Opening	• Welcome and thank you all for participating in this focus group interview. • We need to hear your thoughts and experiences about your surgery. The reasoning is that we will use your information to develop a checklist to surgical patients. • Provide written information **(Consent signed at the point of recruiting).**

	• Inform the participants why they are asked to participate in this project. • Inform that the interview is recorded, anonymised, transcribed and stored securely (research server). • We have limited time so if you move away from the area examined, I will interrupt. This is not because I don't want to hear what you have to say, but because it is important that we finish the interview to have enough information to develop the patient's own checklists.
Guidelines	• No answer is wrong, you are allowed to have different opinions • Please, turn of the sound on your mobile phone, if you have to answer leave the room and return as soon as possible • Researcher will ask the questions, moderator will guide the discussions. • Talk to each other. • One person speaks at the time. • If there is information you do not want to talk about in the group, you can inform us after the interview in person.
Group demographics (participant 1-8, start recording)	• Recording is started and we begin with a presentation round. Gender: 1_____2_____3_____4_____5_____6_____7_____8____ Age: 1____ 2____ 3_____ 4_____5_____6_____7_____ 8_____ Type of operation 1_____2_____3_____4_____5_____6_____7_____8____
Introduction question	11. In relation to your latest surgery, can you tell us <u>shortly</u> about your experiences before surgery, after surgery and after being discharged

Inductive discussion triggers **-Information -**	1. **Core trigger: what is important for you to be informed about before surgery?** 2. Additional trigger; Can you say which of these points mentioned are most important for you? 3. Did you miss any information before your surgery? 4. If yes, what kind of information did you miss? 5. Did this have any importance for you? Disadvantages, problems 6. Did you contact the hospital before your operation? If yes, what did you call for?
After surgery (still hospitalised, preparation for discharged)	7. **Core trigger: What information is important for you before discharged?** 8. Additional trigger; Can you say why this is important for you? 9. Was there any information missing before your discharge? 10. If yes, what information did you miss? 11. Did this have any importance for you? Disadvantages, problems? 12. Did you have any questions regarding your discharge while you were hospitalised?

After discharge	13. **Core trigger: What was important for you have information about at home in relation to your surgery?** 14. Additional trigger; Can you say which of these points mentioned are most important for you? 15. Did you miss any information after our discharge? 16. If yes, what did you miss? 17. Did this have any impact on you? Disadvantages, problems 18. Did you have to contact the hospital after discharge? If yes, why did you contact them? 19. Do you have any thoughts about what you can do to prevent complications before surgery and after? 20. We will analyse the information you have given us and use it to develop a patient's checklist. Is it right to call this a checklist for patients? Or do you have other suggestions?
Ending	21. Summarise the relevant findings through the interview. Is there anything we have forgotten or is there something that needs to be added?

8.4 Focus group interview guide Healthcare workers

Organisation and implementation of the interviews

- One person (first author) will perform all focus group interviews and one of the other three researcher will act as a moderator. One interviewer and one moderator participate in the focus group interviews. The interviews will follow the guide below with an inductive approach to the research question. It will focus on identifying risk areas to examine events and complications related to the surgical pathway.
- The ideal participant number in each interview would be 6 to 8 participants. The participants has to be employed at one of the requited ward. It is desirable with 3 registered nurses, 1-2 ward doctor, 1-2 surgeon and one secretary/patient coordinator.
- The participants will get a friendly reminder about time and place by text message or email 3 days before the interview.
- The participants will meet 5 min before the interview.
- The participants will be interviewed within working hours.
- Each interview will last up to 90 minutes. Current literature recommends that a focus group interview should last from 45-90 min, longer interviews are often not productive and it turns in to a burden for the participants
- The Moderator has the responsibility of keeping the time and taking field notes.
- Other preparations; we will serve coffee and tea, and fruit. We need pens, paper and recording equipment.
- Rooms has to be reserved.
- Piloting of the interviews guide will be performed before the interview

Interview steps	**Details**
Opening	• Welcome and thank you all for participating in this focus group interview. • We need to hear your thoughts and experiences about the patient's role in the surgical pathway. • Providing consent forms before the interview. • Inform about the aim and what the results are going to be used for; We aim to identify the most important risk areas that can be used to develop patients own surgical checklists. • Inform the participants why they are asked to participate in this project – they are employed within one of the 5 recruited surgical wards.

	• Inform that the interview is recorded, anonymised, transcribed and stored securely. (research server)
Guidelines	• No answer is wrong, you are allowed to have different opinions. • One person speaks at the time. • Please turn of the sound on your mobile phone, if you have to answer leave the room and return as soon as possible. • Researcher will ask the questions, moderator will guide the discussions. • Talk to each other. • If there is information you don't want to talk about in the group, you can inform us after the interview.
Gruppens bakgrunn (informant 1-6, Start opptak)	• Recording is started and we begin with a presentation round. Gender: 1_____2_____3_____4_____5_____6_____ Age: 1_____2_____3_____4_____5_____6_____ Profession: 1_____2_____3_____4_____5_____6_____ Experience in years: 1_____2_____3_____4_____5_____6_____

Inductive discussion triggers **-Information -**	Intro/statement: **This project seek to identifying risk areas of complications and for patients to be involved in reducing complication risks.** 22. What can the patients contribute with to reduce complications? And how?
Inductive discussion triggers **-Information – before surgery**	1. The interview is divided into 3 parts, before admission, discharge and after discharge; 23. Core trigger: **What do you think is the most important points that patients need to now before surgery to avoid complications?** 24. Additional trigger: Information before surgery, medications, diagnoses, complications. 25. Have any of you experienced that a patient was not prepared for surgery? Can you explain? 26. Does the patients ring before their surgery? And what do they ask? 27. What kind of written information do you give to the patients? 28. Do you believe the information the patient get is sufficient? If not what is missing?
After surgery (still hospitalised, preparation for discharged)	29. Core trigger: **What are the most important issues the patients have to be aware about before discharge?** 30. Additional trigger: medications, diagnoses, complications? 31. Have you ever experienced that the patients had to stay hospitalised of missing information/preparations? Can you tell me more about this?

	32. What do the patients request information about before discharge? 33. What kind of information routines do you have before discharge? Does the patient get any written information before discharge? 34. Do you believe this is enough? If not what is missing?
	35. Core trigger: **What is the most important things for the patients to know after discharge?** 36. Additional trigger: medications, diagnoses, complications etc? 37. Have you experienced readmission because of missing information? Please explain? 38. What does the patient contact the hospital about after discharge? 39. Do you believe patients own surgical checklists can reduce complications? And when do you think the patients need to receive the surgical checklist?
Ending	40. Summarise the relevant findings through the interview. Is there anything we have forgotten or is there something that needs to be added?

8.5 Focus group interview guide patients (Study II and III)

Organisation and implementation of the interviews

- One person (first author) will perform all focus group interviews and one of the other three researcher will act as a moderator. One interviewer and one moderator participate in the focus group interviews. The interviews will follow the guide below with an inductive approach to the research question. It will focus on identifying risk areas to examine events and complications related to the surgical pathway.
- The ideal participant number in each interview would be 6 to 8 participants. The participants should have had surgery within one of the five included wards, and it should not be more than 2 months since their surgery.
- An information letter will be given to the patients with time and place for the interview. The participants will get a friendly reminder about time and place by text message 3 days before the interview if they agree to it.
- The participants will meet 5 min before the interview.
- Traveling cost to and from the interview will be covered.
- The participants should live within an hour drive, or have a control appointment at the hospital the same day if they live further away.
- Nursing home patients or patients with communication problems are excluded.
- Each interview will last up to 90 minutes. Current literature recommends that a focus group interview should last from 45-90 min, longer interviews are often not productive and it turns in to a burden for the participants
- The Moderator has the responsibility of keeping the time and taking field notes.
- Other preparations; we will serve coffee and tea, and fruit. We need pens, paper and recording equipment.
- Rooms has to be reserved (large enough to adhered to COVID restrictions).
- Piloting of the interviews guide will be performed before the interviews.

Interview steps	**Details**
Opening	• Welcome and thank you all for participating in this focus group interview. • We need to hear your thoughts and experiences about your using the checklist. • Provide written information **(Consent signed at the point of recruiting).** • Inform the participants why they are asked to participate in this project.

	• Inform that the interview is recorded, anonymised, transcribed and stored securely (research server). • We have limited time so if you move away from the area examined, I will interrupt. This is not because I don't want to hear what you have to say, but because it is important that we finish the interview to have enough information to develop the patient's own checklists.
Guidelines	• No answer is wrong, you are allowed to have different opinions • Please, turn of the sound on your mobile phone, if you have to answer leave the room and return as soon as possible • Researcher will ask the questions, moderator will guide the discussions. • Talk to each other. • One person speaks at the time. • If there is information you do not want to talk about in the group, you can inform us after the interview in person.
Group demographics (participant 1-8, start recording)	• Recording is started and we begin with a presentation round. Gender: 1_____2_____3_____4_____5_____6_____7_____8____ Age: 1____ 2____ 3_____ 4_____5_____6_____7_____ 8_____ Type of operation 1_____2_____3_____4_____5_____6_____7_____8____
Introduction question	1. In relation to your latest surgery, can you tell us <u>shortly</u> about your experiences with using patients' own surgical safety checklist?
Inductive discussion triggers -Information -	**2. Core triggers: What was the positive aspects with using the checklist?** **3.** Additional trigger; what could have been done different with the checklist?

	4. Did the checklist prevent any misunderstandings or possible complications? Explain how? -did you experience any adverse events that could have been prevented with adding an additional point to the checklist? Please Explain? 5. How did the checklist influence the information before your surgery? -Did you get your questions answered, please explain? -Did you need additional information, please explain? 6. How did the checklist influence your preparations before surgery? -Did you changes in your life style (smoking, alcohol, nutrition or exercise) please explain? -Did you learn the name of your medications/what they are for/ how they look and time you take them before admission to hospital, please explain? -Did you contacted your general practitioner or dentist before surgery, please explain?
After surgery (still hospitalised, preparation for discharged)	**1. Core trigger: How did checklist influence the information after surgery?** 2. Additional trigger; Who or where did you get the information from? -Did you get clear answers to your questions? -How was your communication with the nurses/surgeons/doctors? 3. Was there any information missing before your discharge? -Did you need more information? What information was missing? 4. How did the checklist influence your preparations for discharge? -How well were you prepared regarding the information on the checklist? Complications, activity, medications, pain relief, stomach functions, further plans and follow-up? 5. Did the checklist lead to any actions from you?

	6. Would you have used the checklist if you were to have another surgery? And why?
Ending	7. Summarise the relevant findings through the interview. Is there anything we have forgotten or is there something that needs to be added?

8.6 I-CVI scoring of PASC

I-CVI scoring of preoperative PASC

Item number/ answer	Respondents (Total**)	Number of scores 3-4 per surgical ward (I-CVI)						
Yes/No*	n(%)	Gastro	General	Endo	ENT	Nevro	Cardiac	Total I-CVI
1 Yes/No	206	29 (0.70)	18 (0.90)	35 (0.81)	35 (0.83)	22 (0.73)	27 (0.82)	164 (0.80)
1 Yes	152	22 (0.88)	17 (0.89)	27 (1.00)	28 (0.97)	19 (0.86)	25 (0.86)	139 (0.91)
1 No	54	4 (0.33)	1 (1.00)	8 (0.50)	7 (0.54)	3 (0.38)	4 (0.50)	25 (0.46)
2 Yes/No	198	23 (0.58)	13 (0.72)	20 (0.51)	27 (0.71)	20 (0.69)	29 (0.85)	131 (0.67)
2 Yes	104	14 (0.82)	11 (1.00)	13 (93.0)	24 (0.92)	14 (1.00)	20 (0.95)	97 (0.93)
2 No	69	7 (0.54)	2 (0.33)	4 (0.22)	3 (0.33)	4 (0.33)	8 (0.80)	28 (0.41)
3 Yes/No	190	17 (0.50)	11 (0.58)	17 (0.44)	20 (0.57)	13 (0.48)	25 (0.76)	104 (0.55)
3 Yes	54	9 (1.00)	5 (1.00)	6 (1.00)	7 (1.00)	5 (0.83)	18 (0.90)	51 (0.94)
3 No	134	8 (0.32)	6 (0.43)	11 (0.33)	13 (0.46)	8 (0.38)	6 (0.50)	52 (0.39)
4 Yes/No	194	19 (0.58)	12 (0.63)	25 (0.63)	22 (0.58)	18 (0.62)	26 (0.76)	123 (0.63)
4 Yes	89	10 (0.77)	9 (1.00)	14 (93.3)	9 (0.90)	14 (0.93)	22 (0.85)	79 (0.89)
4 No	104	9 (0.45)	3 (0.30)	11 (0.44)	13 (0.46)	4 (0.29)	3 (0.43)	43 (0.41)
5 Yes/No	179	12 (0.37)	9 (0.50)	16 (0.41)	17 (0.47)	11 (0.41)	16 (0.55)	80 (0.45)
5 Yes	2	1 (1.00)	0	0	0	0	1 (1.00)	2 (100)
5 No	176	10 (0.35)	9 (0.50)	16 (0.41)	17 (0.47)	11 (0.41)	15 (0.55)	78 (0.45)
6 Yes/No	186	11 (0.33)	11 (0.61)	16 (0.42)	21 (0.57)	10 (0.35)	22 (0.71)	91 (0.49)
6 Yes	4	1 (1.00)	0	2 (1.00)	0	0	1 (1.00)	4 (100)
6 No	182	10 (0.31)	11 (0.61)	14 (0.54)	21 (0.57)	10 (0.35)	21 (0.70)	87 (0.48)
7 Yes/No	199	37 (0.95)	18 (0.90)	32 (0.83)	35 (0.85)	27 (0.90)	31 (0.97)	178 (0.90)
8 Yes/No	203	30 (0.83)	12 (0.60)	28 (0.67)	30 (0.73)	18 (0.62)	26 (0.79)	144 (0.72)
8 Yes	119	21 (0.84)	9 (0.75)	13 (0.68)	18 (0.72)	7 (0.58)	23 (0.88)	91 (0.77)
8 No	78	8 (0.80)	3 (0.25)	15 (0.68)	11 (0.73)	11 (0.69)	3 (0.43)	51 (0.65)
9 Yes/No	199	28 (0.76)	14 (0.74)	32 (0.80)	32 (0.80)	22 (0.73)	33 (100)	161 (0.81)
10Yes/No	193	27 (0.75)	11 (0.61)	27 (0.71)	29 (0.73)	23 (0.79)	26 (0.81)	143 (0.74)
11 Yes/No	200	36 (0.97)	19 (0.95)	39 (0.95)	42 (1.00)	29 (1.00)	33 (1.00)	196 (0.98)
12 Yes/No	177	15 (0.52)	10 (0.59)	19 (0.58)	18 (0.50)	16 (0.55)	27 (0.82)	105 (0.59)
12 Yes	117	11 (0.61)	7 (0.78)	14 (0.64)	13 (0.65)	11 (0.65)	26 (0.84)	82 (0.70)
12 No	48	4 (0.36)	3 (0.50)	4 (0.44)	5 (0.45)	5 (0.46)	0	21 (0.44)
13 Yes/No	178	28 (0.85)	14 (0.82)	31 (0.94)	37 (0.93)	24 (0.86)	21 (0.78)	155 (0.87)
14 Yes/No	192	26 (0.77)	6 (0.33)	31 (0.82)	30 (0.73)	17 (0.59)	22 (0.69)	132 (0.69)
14 Yes	116	20 (0.83)	3 (0.43)	28 (0.93)	21 (0.84)	10 (0.77)	13 (0.76)	95 (0.82)
14 No	74	6 (0.60)	3 (0.27)	2 (0.29)	9 (0.56)	7 (0.44)	8 (0.57)	35 (0.47)
15 Yes/No	177	17 (0.52)	12 (0.62)	21 (0.60)	27 (0.73)	14 (0.52)	19 (0.61)	107 (0.61)
15 Yes	22	1 (1.00)	1 (0.50)	6 (1.00)	7 (1,00)	4 (1.00)	2 (1.00)	21 (0.96)
15 No	155	15 (0.50)	11 (0.64)	15 (0.52)	20 (0.67)	10 (0.44)	17 (0.61)	86 (0.56)
16 Yes/No	194	31 (0.86)	16 (0.89)	37 (0.93)	39 (0.95)	26 (0.96)	30 (0.94)	179 (0.92)
17 Yes/No	196	29 (0.81)	16 (0.89)	35 (0.90)	37 (0.90)	27 (0.90)	30 (0.97)	175 (0.89)
18 Yes/No	193	28 (0.80)	11 (0.65)	40 (0.98)	31 (0.78)	22 (0.79)	21 (0.68)	154 (0.80)
19 Yes/No	180	23 (0.68)	10 (0.59)	34 (0.90)	24 (0.65)	21 (0.84)	21 (0.75)	134 (0.74)
19 Yes	78	14 (0.93)	4 (1.00)	18 (1.00)	16 (1.00)	10 (1.00)	14 (1.00)	77 (0.99)
19 No	98	7 (0.41)	6 (0.46)	14 (0.78)	8 (0.38)	11 (0.73)	7 (0.50)	53 (0.54)
20 Yes/No	174	12 (0.39)	7 (0.41)	11 (0.31)	9 (0.25)	5 (0.19)	13 (0.46)	57 (0.33)
20 Yes	9	4 (1.00)	1 (1.00)	0	1 (1.00)	0	3 (1.00)	9 (1.00)
20 No	163	7 (0.27)	6 (0.38)	10 (0.29)	8 (0.23)	5 (0.19)	10 (0.40)	46 (0.28)
21 Yes/No	181	21 (0.59)	5 (0.28)	23 (0.62)	13 (0.35)	17 (0.63)	27 (0.90)	104 (0.58)
21 Yes	30	5 (0.83)	0	1 (1.00)	1 (1.00)	4 (1.00)	15 (0.88)	26 (0.87)
21 No	150	14 (0.54)	5 (0.29)	21 (0.60)	12 (33.3)	13 (0.57)	12 (0.92)	77 (0.51)
22 Yes/No	182	27 (0.76)	14 (0.88)	34 (0.92)	29 (0.76)	23 (0.85)	24 (0.77)	149 (0.82)
23 Yes/No	187	35 (1.00)	17 (1.00)	36 (1.00)	40 (0.98)	27 (1.00)	30 (0.97)	185 (0.99)
24 Yes/No	188	36 (1.00)	19 (1.00)	37 (1.00)	39 (0.95)	27 (0.96)	30 (0.97)	184 (0.98)
25 Yes/No	170	11 (0.38)	5 (0.33)	17 (0.49)	10 (0.28)	10 (0.40)	9 (0.32)	62 (0.37)
25 Yes	46	3 (0.60)	2 (0.67)	6 (0.75)	7 (0.50)	9 (0.82)	4 (0.80)	31 (0.67)
25 No	122	8 (0.33)	3 (0.25)	11 (0.41)	3 (0.14)	1 (0.07)	5 (0.21)	31 (0.25)
26 Yes/no	185	19 (0.61)	13 (0.77)	30 (0.75)	25 (0.68)	22 (0.79)	25 (0.78)	134 (0.72)
26 Yes	34	5 (0.83)	3 (1.00)	10 (1.00)	5 (1.00)	6 (1.00)	4 (0.80)	33 (0.97)

26 No	151	14 (0.56)	10 (0.71)	20 (0.67)	20 (0.63)	16 (0.73)	21 (0.78)	101 (0.67)
27 Yes/No	185	25 (0.83)	14 (0.88)	32 (0.84)	34 (0.85)	26 (0.96)	30 (0.91)	162 (0.88)
28 Yes/No	179	13(0.42)	4 (0.25)	17 (0.46)	20 (0.53)	12 (0.43)	22 (0.73)	87 (0.49)
28 Yes	55	8 (0.80)	1 (0.33)	7 (0.58)	7 (0.64)	8 (0.89)	10 (1.00)	41 (0.75)
28 No	123	5 (0,24)	4 (0.23)	10 (0.40)	11 (0.46)	4 (0.21)	12 (0.60)	45 (0.37)
29 Yes/No	189	31 (0.89)	16 (0.94)	35 (0.90)	36 (0.92)	26 (0.96)	31 (1.00)	176 (0.93)
30 Yes/No	158	28 (0.90)	7 (0.44)	28 (0.93)	18 (0.56)	15 (0.68)	15 (0.56)	111 (0.70)
31 Yes/No	174	26 (0.87)	17 (1.00)	31 (0.97)	34 (0.90)	23 (0.89)	27 (0.87)	158 (0.91)
32 Yes/No	165	26 (0.87)	14 (0.88)	37 (1.00)	28 (0.93)	22 (0.96)	24 (0.83)	151 (0.92)

Abbreviations: Gastro = Gastrointestinal surgery; General = Førde Hospital general surgery; Endo = Breast/endocrine surgery; ENT = Ear, Neck, and Throat/Maxillo-facial surgery; Nevro = Neurosurgery; Cardio= Cardio-thoracic surgery; Yes/No* = respondents answer to PASC item question; Total** = Total respondents per PASC item.

I-CVI score of postoperative PASC

Item number/ answer	Respondents (Total**)	Number of scores 3-4 per surgical ward (I-CVI)						
Yes/No*	n(%)	Gastro	General	Endo	ENT	Nevrc	Cardiac	Total I-CVI
33 Yes/No	189	36 (100)	16 (1.00)	40 (1.00)	40 (0.98)	26 (1.00)	29 (0.97)	187 (0.99)
34 Yes/No	187	36 (100)	16 (1.00)	40 (1.00)	38 (0.95)	24 (0.96)	30 (1.00)	184 (0.98)
35 Yes/No	183	33 (100)	16 (0.94)	36 (0.92)	35 (0.88)	24 (0.96)	28 (0.97)	172 (0.94)
36 Yes/No	165	14 (42.2)	0	5 (0.15)	6 (0.18)	11 (0.50)	20 (0.69)	56 (0.34)
36 Yes	26	2 (0.50)	0	0	2 (1.00)	6 (0.86)	11 (1.00)	21 (0.81)
36 No	132	10 (0.37)	13 (1.00)	5 (0.16)	4 (0.13)	4 (0.29)	8 (0.47)	31 (0.24)
37 Yes/No	176	24 (0.73)	14 (0.88)	24 (0.71)	22 (0.58)	23 (0.89)	27 (0.93)	134 (0.76)
37 Yes	87	9 (0.90)	10 (1.00)	7 (0.70)	11 (0.69)	15 (0.88)	21 (0.92)	74 (0.85)
37 No	86	15 (0.68)	4 (0.67)	17 (0.71)	11 (0.52)	8 (1.00)	5 (1.00)	60 (0.70)
38 Yes/No	18	35 (0.97)	14 (0.88)	34 (0.94)	31 (0.82)	26 (1.00)	29 (1.00)	169 (0.93)
39 Yes/No	180	33 (0.94)	15 (0.94)	33 (0.92)	34 (0.82)	24 (1.00)	29 (0.97)	166 (0.92)
40 Yes/No	181	34 (0.94)	12 (0.75)	35 (0.95)	28 (0.74)	24 (0.96)	29 (1.00)	162 (0.90)
41 Q41 Yes/No	166	25 (73.5)	7 (0.50)	18 (0.60)	20 (0.57)	17 (0.68)	28 (1.00)	115 (0.69)
41 Q41 Yes	48	13 (100)	1 (1.00)	4 (1.00)	7 (0.88)	3 (1.00)	19 (1.00)	47 (0.98)
41 Q41 No	116	12 (60.0)	6 (0.46)	14 (0.54)	13 (0.48)	14 (0.64)	8 (1.00)	67 (0.58)
42 Q42 Yes/no	131	18 (62.2)	5 (0.42)	8 (0.38)	11 (0.37)	8 (0.53)	22 (0.92)	72 (0.55)
42 Q42 Yes	26	6 (100)	0	4 (1.00)	5 (1.00)	3 (1.00)	8 (1.00)	26 (1.00)
42 Q42 No	90	13 (0.57)	5 (0.45)	3 (0.23)	5 (0.22)	5 (0.63)	13 (0.93)	43 (0.48)
43 Q43 Yes/No	133	20 (71.4)	10 (0.78)	11 (0.52)	20 (0.65)	11 (0.69)	24 (1.00)	96 (0.72)
43 Q43 Yes	76	14 (93.3)	8 (1.00)	8 (0.80)	15 (0.83)	8 (1.00)	17 (1.00)	70 (0.92)
43 Q43 No	45	6 (54.5)	2 (0.50)	1 (0.04)	4 (0.33)	3 (0.60)	6 (1.00)	22 (0.50)
44 Q44 Yes/No	128	16 (61.5)	8 (0.62)	8 (0.40)	9 (0.31)	8 (0.50)	21 (0.88)	70 (0.55)
44 Q44 Yes	11	0	0	0	2 (1.00)	1 (1.00)	8 (1.00)	11 (1.00)
44 Q44 No	101	15 (0.65)	8 (0.67)	6 (0.43)	6 (0.26)	7 (0.64)	12 (0.80)	54 (0.55)
45 Q45 Yes/no	128	19 (73.1)	7 (0.54)	9 (0.45)	17 (0.55)	7 (0.50)	25 (1.00)	83 (0.65)
45 Q45 Yes	34	5 (100)	2 (1.00)	2 (1.00)	6 (0.86)	2 (1.00)	16 (1.00)	33 (0.97)
45 Q45 No	81	13 (68.4)	5 (0.50)	6 (0.46)	9 (0.41)	5 (0.56)	8 (1.00)	46 (0.57)
46 Q46 Yes/No	156	22 (0.73)	10 (0.67)	20 (0.66)	15 (0.50)	15 (0.71)	24 (0.83)	106 (0.68)
46 Q46 Yes	48	10 (1.00)	6 (1.00)	8 (1.00)	5 (1.00)	6 (1.00)	12 (0.92)	47 (0.98)
46 Q46 No	105	11 (0.58)	4 (0.44)	11 (0.50)	10 (0.37)	9 (0.64)	11 (0.75)	57 (0.54)
47 Q47 Yes/no	135	17 (0.57)	8 (0.62)	6 (28.6)	8 (0.30)	7 (0.39)	24 (0.92)	70 (0.52)
47 Q47 Yes	18	5 (0.83)	1 (1.00)	0	2 (1.00)	1 (1.00)	8 (1.00)	17 (0.94)
47 Q47 No	102	9 (0.47)	6 (0.54)	5 (0.31)	6 (0.25)	5 (0.33)	15 (0.88)	44 (0.43)
48 Q48 Yes/No	174	27 (0.82)	8 (0.57)	31 (0.85)	25 (0.71)	21(0.84)	25 (0.86)	137 (0.79)
48 Q48 Yes	99	21 (1.00)	3 (1.00)	23 (0.92)	15 (1.00)	13 (1.00)	22 (1.00)	97 (0.98)
48 Q48 No	74	5 (0.46)	5 (0.45)	8 (0.65)	10 (0.50)	8 (0.67)	3 (0.42)	39 (0.53)
49 Yes/No	165	25 (80.7)	11 (0.79)	34 (0.94)	26 (0.74)	19 (0.95)	28 (0.93)	142 (0.86)
50 Yes/No	166	26 (78.8)	12 (0.86)	30 (0.88)	24 (0.67)	20 (0.95)	27 (0.93)	138 (0.83)
51 Yes/No	177	36 (100)	15 (0.88)	32 (0.87)	20 (0.56)	15 (0.65)	30 (1.00)	146 (0.83)
52 Yes/No	184	34 (91.9)	12 (0.75)	39 (1.00)	35 (0.90)	22 (0.96)	30 (0.97)	171 (0.93)
53 Yes/No	176	34 (91.9)	12 (0.92)	37 (0.97)	35 (0.90)	18 (0.86)	28 (0.97)	163 (0.93)
54 Yes/No	158	21 (0.62)	7 (0.47)	23 (0.66)	6 (20.0)	7 (0.39)	19 (0.70)	82 (0.52)
54 Yes	23	3 (0.75)	0	10 (0.90)	1 (1.00)	2 (1.00)	3 (1.00)	22 (0.96)
54 No	132	15 (0.71)	6 (0.43)	13 (0.54)	5 (0.17)	5 (0.38)	15 (0.65)	58 (0.44)
55 Yes/No	174	34 (0.90)	13 (0.87)	34 (0.97)	30 (0.86)	20 (0.87)	25 (0.86)	155 (0.89)
56 Yes/No	167	22 (0.61)	7 (0.46)	26 (0.70)	22 (0.65)	14 (067)	17 (0.63)	106 (0.64)
56 Yes	78	14 (0.88)	3 (1.00)	19 (1.00)	17 (0.90)	12 (1.00)	9 (1.00)	74 (0.95)
56 No	83	7 (0.39)	3 (0.30)	6 (0.38)	5 (0.33)	2 (0.29)	8 (0.47).	31 (0.37)
57 Yes/No	165	23 (0.66)	7 (0.50)	22 (0.60)	23 (0.68)	12 (60.0)	17 (0.65)	103 (0.62)
57 Yes	86	15 (0.83)	6 (1.00)	17 (0.90)	19 (1.00)	9 (0.82)	13 (1.00)	79 (0.92)
57 No	68	7 (0.50)	1 (0.13)	4 (0.29)	4 (0.31)	3 (0.43)	4 (0.33)	23 (0.34)
58 Yes/No	171	18 (0.50)	8 (0.53)	18 (0.49)	14 (0.39)	13 (61.9)	13 (0.48)	83 (0.49)
58 Yes	36	2 (0.50)	2 (1.00)	13 (0.54)	5 (0.71)	7 (0,78)	5 (0.63)	25 (0.69)
58 No	132	15 (0.50)	6 (0.46)	5 (0.42)	9 (0.32)	6 (0.50)	8 (0.42)	58 (0.44)

Abbreviations: Gastro = Gastrointestinal surgery; Genera l= Førde Hospital general surgery; Endo = Breast/endocrine surgery; ENT = Ear, Neck, and Throat/Maxillo-facial surgery; Nevro = Neurosurgery; Cardio= Cardio-thoracic surgery; Yes/No* = respondents answer to PASC item question; Total** = Total respondents per PASC item.

8.7 PASC (Validated in Norwegian)

ID:

Din sjekkliste før operasjon

Målet med sjekklisten er å forebygge komplikasjoner som kan oppstå i operasjonsforløpet

Bruk sjekklisten aktivt ved å krysse av på JA eller NEI på sjekklistepunktene.

Har du spørsmål når du går gjennom sjekklisten, skriv dem ned og ta med til sykehuset.
Hvis nødvendig kontakt **sett inn avdelings kontakt informasjon her.**

Viktige punkter du bør tenke igjennom før operasjonen

1. Bruker du medisiner?
☐ NEI, **gå til punkt 4**
☐ JA, lær deg navn, utseende, tidspunkt du tar medisinene og hvorfor du tar dem

2. Bruker du blodfortynnende medisiner?
☐ NEI
☐ JA, er du informert om du skal stoppe eller når du skal stoppe med dem før din operasjon? Hvis ikke, ring 2 uker før operasjonen og avklar med avdelingen

3. Har du en medisinliste, med siste endringer?
☐ JA, husk å ta den med til sykehuset
☐ NEI, bestill time hos fastlegen og be om en ny medisinliste

4. Har du diabetes, høyt blodtrykk, hjerte- og karsykdommer, sår som ikke gror eller blir du behandlet for andre kroniske lidelser?
☐ NEI
☐ JA, hvis du ikke har hatt kontroll for dette de siste 12 månedene bestill time hos fastlegen.

5. Har du vært i utlandet de siste 12 månedene og hatt tannbehandling, medisinsk behandling, vært innlagt eller jobbet på sykehus?
☐ NEI
☐ JA, bestill time hos fastlegen og få tatt bakterieprøver av deg før innleggelse, ring avdelingen og informer

6. Er du informert om at opphør/avhold av røking og inntak av alkohol og andre rusmidler i god tid før operasjonen kan forebygge komplikasjoner?
☐ JA
☐ NEI, be om informasjon fra fastlege ☐ Ikke aktuelt

7. Er du informert om at det å være aktiv og ha et næringsrikt kosthold før operasjon kan redusere sjansen for komplikasjoner? (avklar med fastlegen om aktivitetsnivå)
☐ JA
☐ NEI, be om informasjon fra fastlege

Ta kontakt med din tannlege hvis behov

8. Går du til tannlege hvert år?
☐ JA
☐ NEI, tannlegekontroll anbefales før en operasjon

Les informasjon

9. Har du lest innleggelses brevet og annen informasjon du har fått?

☐ JA

☐ NEI, les all informasjon - det er viktig for deg.
Du kan også gå inn på www.helse-bergen.no. Her finner du informasjon om behandling og svar på praktiske spørsmål.

Forberedelser du må gjøre 2 uker før innleggelse

10. Vet du hvilken operasjon du skal ha og når du skal opereres?

☐ JA

☐ NEI, ring avdelingen og avklar (se telefon-nummer øverst på listen)

11. Har du fylt ut egenerklæringsskjema?

☐ JA,

☐ NEI, kontakt avdelingen

12. Råd: Det anbefales at du har med deg en fra nær familie eller venn, når du mottar informasjon om operasjonen. Eventuelt at de deltar over telefon.

13. Er du under utredning for andre sykdommer?

☐ NEI

☐ JA, ring avdelingen og gi beskjed tidligst mulig, hvis ikke du har informert kirurgen din

Informer om ny oppstått sykdom

14. Er du informert om hva du skal gjøre dersom du blir syk uken før innleggelse?

☐ JA

☐ NEI, gi avdelingen snarest beskjed hvis du blir syk før innleggelse

Planlegg din utskrivelse i møte med helsepersonell før operasjon

15. Er du informert om hvor lenge du skal være inneliggende?

☐ JA

☐ NEI, avklar med sykepleier hvor lenge

16. Har du noen som kan være hos deg første døgnet etter du har kommet hjem fra sykehuset?

☐ JA

☐ NEI, informer lege/sykepleier hvis du ikke har noen hjemme

17. Er det noe du trenger å ha klart hjemme (bandasjer, medisiner, hjelpemidler, hjemmehjelp)?

☐ NEI

☐ JA, avklar med sykepleier og eventuelt skriv ned hva du trenger

18. Har du fått tilbud om rehabilitering eller fysioterapi?

☐ JA

☐ NEI, avklar om du trenger det med sykepleier ☐ Ikke aktuelt

Innleggelsesrutiner før din operasjon

19. Har du fjernet alle ringer, smykker, piercinger, falske negler og neglelakk?

☐ JA

☐ NEI, fjern dem før du legges inn

20. Er du informert om når du skal stoppe å spise og drikke før operasjonen din?

☐ JA

☐ NEI, avklar med sykepleier

ID:

Din sjekkliste før utskrivelse

Bruk sjekklisten aktivt ved å krysse av på JA eller NEI på alle sjekklistepunkter.

Hva trenger du å være informert om før du reiser hjem? Les gjennom spørsmålene under før du snakker med legen og sykepleieren som skal skrive deg ut. Be om skriftlig informasjon ved behov.

Komplikasjoner

28. Er du informert om komplikasjoner som kan oppstå?

☐ JA

☐ NEI, be om informasjon fra legen som skriver deg ut

29. Er du informert om hva du skal gjøre hvis du får komplikasjoner eller blir akutt syk?

☐ JA

☐ NEI, be om informasjon fra legen som skriver deg ut

30. Er du informert om at du skal bruke støttestrømper?

☐ NEI ☐ Ikke aktuelt

☐ JA, avklar med sykepleieren din eller legen som skriver deg ut hvor lenge du skal bruke dem

Aktivitet og restriksjon

31. Er du informert om når du kan kjøre bil igjen?

☐ JA

☐ NEI, avklar med lege/sykepleier som skriver deg ut

32. Er du informert om at det er viktig at du er i aktivitet og når du kan begynne å trene?

☐ JA

☐ NEI, avklar med lege/sykepleier som skriver deg ut

33. Er du informert om aktivitetsrestriksjoner?

☐ JA

☐ NEI, avklar med lege/sykepleier som skriver deg ut

34. Er du informert om når du kan dusje igjen?

☐ JA

☐ NEI, avklar med lege/sykepleier som skriver deg ut

Medisiner

35. Skal du begynne med nye medisiner?

☐ NEI, gå til **punkt 40**

☐ JA, bruk sjekklistepunktene under og be om en gjennomgang med legen som skriver deg ut

36. Er du informert om mulige bivirkninger til de nye medisinene?

☐ JA

☐ NEI, avklar med legen som skriver deg ut

37. Er du informert om hvem du kan kontakte hvis du opplever bivirkninger?

☐ JA

☐ NEI, avklar med legen som skriver deg ut

38. Er det medisiner eller mat du ikke kan spise sammen med de nye medisinene dine?

☐ NEI

☐ JA, avklar med legen som skriver deg ut og skriv ned navnene

39. Har du fått en kopi av din nye medisinliste?

☐ JA

☐ NEI, be om en kopi fra legen som skriver deg ut

40. Er det medisiner (for eksempel blodfortynnende, blodtrykksmedisiner) som er stoppet i forbindelse med operasjonen?

☐ NEI

☐ JA, avklar med legen som skriver deg ut når du skal begynne å ta medisinen igjen

Smertestillende

41. Trenger du resept på smertestillende?

☐ NEI

☐ JA, be om resept fra legen som skriver deg ut

42. Er du informert om hvordan smertestillende skal brukes, og hvordan du skal slutte med dem?

☐ JA

☐ NEI, be lege/sykepleier som skriver deg ut om informasjonen

43. Er du informert om hva du skal gjøre hvis anbefalt dose smertestillende ikke virker?

☐ JA

☐ NEI, be om informasjon fra lege/sykepleier som skriver deg ut

Magefunksjon

44. Er du informert om at du kan få forstoppelse/treg mage og hva du kan gjøre for å unngå ubehag?

☐ JA

☐ NEI, be om informasjon lege/sykepleier som skriver deg ut

Videre plan og oppfølging

45. Er du informert om sårstell, bandasjeskift, fjerning av sting og hvem som kan hjelpe deg med dette?

☐ JA

☐ NEI, avklar med lege/sykepleier

46. Er du underernært eller i risiko for å bli underernært?

☐ Ja, be lege/sykepleier/klinisk ernæringsfysiolog om informasjon hvordan du kan bedre dette

☐ Nei

47. Skal du ha kontrolltime eller henvises til andre spesialister?

☐ NEI

☐ JA, be lege/sykepleier om dato eller når du kan forvente å få time

48. Vet du hvem du skal kontakte etter utskrivelse hvis du må etterlyse timer eller har spørsmål?

☐ JA

☐ NEI, avklar med lege/sykepleier

49. Har du fått sykemelding?

☐ JA

☐ NEI, avklar med lege/sykepleier som skriver deg ut ☐ Ikke aktuelt

8.8 PASC (Translated to English)

Your checklist before surgery

To prevent complications that can occur throughout your surgery

Use your checklist to cross off the relevant response to EVERY question

Write down any non-urgent questions you may have and bring them with you to the hospital so you can ask a healthcare worker

If you require any clarification, or if any issues arise while you are using the checklist, contact (ward name) on this telephone number:_____

Important issues you should consider before your surgery

1. Are you using any medications?

☐ No, **go to question 4**

☐ Yes, memorise the name of your medication, what they are for, how they look and the time you take them

2. Are you using blood-thinning medications?

☐ Yes. Have you been informed of when, or if you should stop them before your surgery? If not, contact the ward 2 weeks before your surgery to clarify

☐ No

3. Do you have a medication list with the latest changes?

☐ Yes. Remember to bring it to the hospital

☐ No. Contact your general practitioner and ask for a updated medication list

4. Do you have diabetes, high blood pressure, cardio- vascular, non-healing wounds or receiving treatment for other chronic conditions?

☐ No

☐ Yes, if you have not been for a control the last 12 months contact your general practitioner

5. Have you received dental treatment, medical treatment, or been hospitalised, or worked in hospitals overseas the last 12 months?

☐ No

☐ Yes, contact your general practitioner and take bacterial tests before hospitalisation and call number provided and inform the hospital ward

6. Have you been informed that stopping smoking, alcohol and substance abuse as early as possible before surgery can reduce chances of complications?

☐ Yes

☐ No, contact your general practitioner for Information ☐ Not relevant

7. Have you been informed that physical activity and a healthy diet before surgery can reduce chances for complications?

☐ Yes

☐ No, contact your general practitioner for information (clarify activity level)

Contact your dentist if needed

8. Do you go to your dentist yearly?

☐ Yes

☐ No. A visit to the dentist is recommended before surgery

Read Information

9. Have you read the admission letter and all other information given to you?

☐ Yes

☐ No. Read the information, it can be important for you

You can also access information about treatments and practical issues on the hospital's web page (Ad webpage link)

Preparations 2 weeks before your hospital admission

10. Do you know what type of surgery you are having and the time of your surgery?

☐ Yes

☐ No. Call the provided number and clarify

11. Have you filled out all required forms before admission to the hospital?

☐ Yes

☐ No. Fill them out and bring them with you to the hospital

12. Advice: We recommend that a family member or a close friend accompany you in person or over the phone while you get the information about your surgery

13. Are you under investigation for other diseases?

☐ No

☐ Yes. If you have not informed your surgeon, call the provided number and inform

Inform on any new illness

14. Have you been informed about what you should do if you get sick the week before surgery?

☐ Yes

☐ No. Contact provided number as soon as possible before your surgery and inform that you are sick

Plan your discharge together with a healthcare worker before your surgery

15. Have you been informed about how long you could expect to stay in hospital?

☐ Yes

☐ No. Clarify with your admitting nurse or doctor

16. Do you have family or a friend that can be with you the first night after you are discharged home?

☐ Yes

☐ No, inform your admitting nurse or doctor

17. Ask if there are some things you need to have ready at home (bandages, medications, assistance aid, homecare)

☐ No

☐ Yes. Clarify with your nurse or doctor, and write down if necessary

18. Have you been informed if you need rehabilitation or physiotherapy?

☐ No. Clarify with your nurse or doctor

☐ Yes ☐ No Relevant

Admission routine before your operation

19. Have you removed all rings, necklaces, piercing, fake nails and nail polish?

☐ Yes

☐ No, please remove them before hospitalisation

20. Have you been informed about when you should stop eating and drinking before your surgery?

☐ Yes

☐ No, clarify with the ward nurse the day before your surgery

21. Have you been informed about hygiene/showering routines before your surgery?

☐ Yes

☐ No, clarify with the ward nurse the day before your surgery

22. Are you allergic to any medication or medical equipment (latex)?

☐ No

☐ Yes, provide information to your nurse or doctor at admission to hospital

23. Do you use any herbal medication or nutritional supplements?

☐ No

☐ Yes, provide the name to your nurse or doctor and explain what you are taking them for

24. Have you been informed about expected pain after your surgery?

☐ No

☐ Yes, ask your nurse/doctor about expected pain

Preparations the day of your surgery

25. If relevant: have your operation site been marked?

☐ Yes

☐ No, inform your nurse or doctor ☐ Not Relevant

Advice

26. Avoid getting cold right before your surgery, it can lead to complications

27. Request the use of safe surgery checklist when you arrive at the surgical theatre. The surgical team should clarify your identity, type of operation and which side you should operate on (if you are having surgery on a side)

Your checklist before hospital discharge

What you need to know before your discharge: Read the questions below before you talk to the doctor and nurse who is discharging you. Ask for missing information or written information if needed. This can prevent complications for you.

Use your checklist to cross off the relevant response to EVERY question

Information about complications

28. Have you been informed about possible complications?

☐ Yes

☐ No. Ask for information from your doctor or nurse

29. Have you been informed about what you should do if you experience complications or in an emergency?

☐ Yes

☐ No. Ask for information from your doctor or nurse

Information about activity and restrictions

30. Have you been informed about when you can drive after surgery?

☐ Yes

☐ No. Clarify with your doctor or nurse

31. Have you been informed about the importance of being physical active and when you can begin to exercise?

☐ Yes

☐ No. Clarify with your doctor or nurse

32. Have you been informed about activity restrictions?

☐ Yes

☐ No. Clarify with your doctor or nurse

33. Have you been informed about when you can shower again?

☐ Yes

☐ No. Clarify with your doctor or nurse

34. Have you been informed if you need to take any special considerations after your surgery?

☐ Yes

☐ No. Clarify with your doctor or nurse

Information about medication safety

35. Are you starting on any new medications?

☐ No. **go to question 39**

☐ Yes. Use the checklist items under and ask your doctor to go through them with you

36. Have you been informed about possible side effects of your new medications?

☐ Yes

☐ No, clarify with your doctor or nurse

37. Have you been informed about whom to contact if you are experiencing side effects?

☐ Yes

☐ No. Clarify with your doctor or nurse

38. Have you been informed about medications or food you cannot eat/take together with your new medications?

☐ No

☐ Yes, clarify with your doctor or nurse

39. Have you received a copy of your new medication list?

☐ Yes

☐ No, ask for a copy from you discharging doctor

40. Have you stopped any medications (for example. blood thinners, blood pressure medications) in relation to your surgery?

☐ No

☐ Yes, clarify with your doctor when you are going to starting them again

Information about pain relief

41. Do you need a pain relief prescription?

☐ No

☐ Yes, ask for a prescription from your doctor

42. Have you been informed about how to use and when you should stop taking pain relief?

☐ Yes

☐ No, ask for information from your discharging doctor or nurse

43. Have you been informed about what you can do if recommended pain-relief dosage is not sufficient?

☐ Yes

☐ No, ask for information from your discharging doctor or nurse

Stomach functions

44. Have you been informed about that you can experience constipation after your surgery and what you can do for prevention?

☐ Yes

☐ No, ask for information from your discharging doctor or nurse

Further plans and follow-up

45. Have you been informed about wound care, bandage changes, removal of sutures and who can help you with this?

☐ Yes

☐ No, ask for information from your discharging doctor or nurse

46. Are you going to have a follow up appointment or referral to other medical specialists?

☐ No

☐ Yes, ask your doctor or nurse about a date or when to expect to get an appointment

47. Have you been informed about whom you can contact after discharge if you have any questions or need to make enquire about follow-up appointments?

☐ Yes

☐ No, ask for information from your discharging doctor or nurse

8.9 Missing per PASC item

Item number	Raters missing per item	Total raters	Percent missing per Item	Item questions
1	3	192	1.56	Are you using any medications?
2	10	192	5.21	Do you have a medication list with the latest changes
3	13	192	6.77	Are you using blood-thinning medications?
4	8	192	4.17	Do you have diabetes, high blood pressure, cardio- vascular or receiving treatment for other chronic conditions?
5	18	192	9.38	Do you have non-healing wounds?
6	13	192	6.77	Have you received dental treatment, medical treatment, or been hospitalised, or worked in hospitals overseas the last 12 months?
7	5	192	2.60	Are you informed that physical activity and a healthy diet before surgery can reduce chances for complications?
8	4	192	2.08	Are you informed that stopping smoking, alcohol and substance abuse as early as possible before surgery can reduce chances of complications?
9	4	192	2.08	Do you go to your dentist regularly?
10	9	192	4.69	Have you read the admission letter and all other information given to you
11	3	192	1.56	Do you know what type of surgery you are having and the time of your surgery?
12	21	192	10.94	Are you informed of when, or if you should stop your blood thinning medication before your surgery?
13	20	192	10.42	Have you filled out all required forms before admission to the hospital?
14	10	192	5.21	Do you have family or a close friend that can accompany you to get the information about your surgery?
15	20	192	10.42	Are you under investigation for other diseases?
16	8	192	4.17	Are you informed about what you should do if you get sick the week before surgery?
17	4	192	2.08	Are you informed about how long you could expect to stay in hospital?

18	8	192	4.17	Do you have family or a friend that can be with you the first night after you are discharged?
19	19	192	9.90	Ask if there are some things you need to have ready at home (bandages, medications)
20	22	192	11.46	Do you need homecare or other social services?
21	16	192	8.33	Are you informed if you need rehabilitation or physiotherapy?
22	17	192	8.85	Have you removed all rings, necklaces, piercing, fake nails and nail polish?
23	13	192	6.77	Are you informed about when you should stop eating and drinking before your surgery?
24	12	192	6.25	Are you informed about hygiene/showering routines before your surgery?
25	26	192	13.54	Do you have children under 18 years?
26	13	192	6.77	Are you allergic to any medication or medical equipment (latex)?
27	13	192	6.77	Are you using any medications permanent or in periods
28	17	192	8.85	Do you use any herbal medication or nutritional supplements?
29	8	192	4.17	Are you informed about expected pain after your surgery?
30	38	192	19.79	If relevant: have your operation site or side been marked?
31	22	192	11.46	Avoid getting cold, inform your nurse
32	31	192	16.15	Request the use of safe surgery checklist when you arrive at the surgical theatre. The surgical team should clarify your identity, type of operation and which side you should operate on (if you are having surgery on a side)
33	7	192	3.65	Are you informed about possible complications?
34	8	192	4.17	Are you informed about what you should do if you experience complications or in an emergency?
35	13	192	6.77	Are you informed if you need to take any special considerations after your surgery?
36	28	192	14.58	Are you informed if you need compression stockings

37	17	192	8.85	Are you informed about when you can drive after surgery?
38	14	192	7.29	Are you informed about the importance of being physical active and when you can begin to exercise?
39	16	192	8.33	Are you informed about activity restrictions?
40	14	192	7.29	Are you informed about when you can shower again?
41	27	192	14.06	Are you starting on new medications?
42	61	192	31.77	Are you informed about possible side effects of your new medications?
43	60	192	31.25	Are you informed about whom to contact if you are experiencing side effects?
44	65	192	33.85	Are you informed about medications or food you cannot eat together with your new medications?
45	65	192	33.85	Are you going to use your medication regularly?
46	37	192	19.27	Have you stopped any medications (for example. blood thinners, blood pressure medications) in relation to your surgery?
47	60	192	31.25	Have you received a copy of your new medication list?
48	20	192	10.42	Have you stopped any medications (for example. blood thinners, blood pressure medications) in relation to your surgery?
49	30	192	15.63	Are you informed about how to use and when you should stop taking pain relief?
50	30	192	15.63	Are you informed about what you can do if recommended pain-relief dosage is not sufficient?
51	19	192	9.90	Are you informed that it can take some time before your bowel motions are back to normal and what to do for prevention?
52	14	192	7.29	Are you informed about wound care, bandage changes, removal of sutures and who can help you with this?
53	19	192	9.90	Are you going to have a follow up appointment?
54	35	192	18.23	Are you referred to other medical specialities?
55	20	192	10.42	Are you informed about whom you can contact after discharge if you have any

				questions or need to make enquire about follow-up appointments?
56	28	192	14.58	Do you need a sick certificate?
57	28	192	14.58	Are you informed whom to contact if you need a sick certificate extension?
58	24	192	12.50	Are you informed about when you can travel after your operation?
Total	1207	11136	10,8 %	replaced with med missing amputations

Item kept if CVI ≥ 0.78
Item kept after hazard scoring and/or consensus and revision
Item reviewed and added to other items after hazard scoring and consensus
Item removed after hazard scoring

8.10 Patients item usage

Patient (n)	Missing items out of total (56)	Percent Missing
1	13	23.21
2	10	17.86
3	0	0.00
4	0	0.00
5	1	1.79
6	0	0.00
7	0	0.00
8	0	0.00
9	2	3.57
10	0	0.00
11	4	7.14
12	0	0.00
13	7	12.50
14	4	7.14
15	1	1.79
16	8	14.29
17	0	0.00
18	5	8.93
19	2	3.57
20	0	0.00
21	5	8.93
22	1	1.79
23	0	0.00
24	4	7.14
25	0	0.00
26	8	14.29
27	5	8.93
28	27	48.21
29	0	0.00
30	1	1.79
31	0	0.00
32	9	16.07
33	0	0.00
34	2	3.57
35	0	0.00
36	3	5.36
37	0	0.00
38	0	0.00
39	10	17.86
40	26	46.43
41	1	1.79
42	0	0.00

43	0	0.00
44	0	0.00
45	1	1.79
46	9	16.07
47	1	1.79
48	39	69.64
49	5	8.93
50	0	0.00
51	31	55.36
52	0	0.00
53	0	0.00
54	8	14.29
55	1	1.79
56	0	0.00
57	0	0.00
58	5	8.93
59	2	3.57
60	0	0.00
61	19	33.93
62	0	0.00
63	0	0.00
64	1	1.79
65	8	14.29
66	29	51.79
67	6	10.71
68	4	7.14
69	7	12.50
70	9	16.07
71	6	10.71
72	6	10.71
73	11	19.64
74	0	0.00
75	5	8.93
76	0	0.00
77	1	1.79
78	10	17.86
79	0	0.00
80	0	0.00
81	3	5.36
82	5	8.93
83	2	3.57
84	3	5.36
85	10	17.86
86	7	12.50
87	5	8.93

88	6	10.71
89	3	5.36
90	1	1.79
91	32	57.14
92	5	8.93
93	0	0.00
94	0	0.00
95	1	1.79
96	9	16.07
97	1	1.79
98	12	21.43
99	8	14.29
100	14	25.0
101	56	100.00
102	0	0.00
103	15	26.79
104	8	14.29
105	4	7.14
106	1	1.79
107	1	1.79
108	3	5.36
109	4	7.14
110	1	1.79
111	0	0.00
112	2	3.57
113	5	8.93
114	6	10.71
115	0	0.00
116	0	0.00
117	0	0.00
118	26	46.43
119	7	12.50
120	5	8.93
121	2	3.57
122	0	0.00
123	0	0.00
124	7	12.50
125	1	1.79
126	0	0.00
127	7	12.50
128	0	0.00
129	5	8.93
130	7	12.50
131	7	12.50
132	1	1.79

133	2	3.57
134	0	0.00
135	3	5.36
136	5	8.93
137	5	8.93
138	9	16.07
139	14	25.00
140	13	23.21
141	0	0.00
142	0	0.00
143	8	14.29
144	0	0.00
145	0	0.00
146	28	50.00
147	10	17.86
148	0	0.00
149	3	5.36
150	3	5.36
151	1	1.79
152	26	46.43
153	18	32.14
154	0	0.00
155	3	5.36
156	18	32.14
157	6	10.71
158	0	0.00
159	20	35.71
160	2	3.57
161	7	12.50
162	12	21.43
163	27	48.21
164	1	1.79
165	0	0.00
166	11	19.64
167	5	8.93
168	3	5.36
169	5	8.93
170	6	10.71
171	0	0.00
172	8	14.29
173	7	12.50
174	1	1.79
175	0	0.00
176	4	7.14
177	26	46.43

178	7	12.50
179	3	5.36
180	7	12.50
181	0	0.00
182	0	0.00
183	5	8.93
184	6	10.71
185	8	14.29
186	13	23.21
187	3	5.36
188	4	7.14
189	1	1.79
190	0	0.00
191	4	7.14
192	3	5.36
193	6	10.71
194	1	1.79
195	0	0.00
196	0	0.00
197	2	3.57
198	0	0.00
199	4	7.14
200	26	46.43
201	0	0.00
202	2	3.57
203	2	3.57
204	1	1.79
205	6	10.71
206	5	8.93
207	1	1.79
208	28	50.00
209	0	0.00
210	0	0.00
211	1	1.79
212	0	0.00
213	28	50.00
214	26	46.43
215	18	32.14

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Patients' and healthcare workers' recommendations for a surgical patient safety checklist – a qualitative study

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Abstract

Background: Patients' involvement in patient safety has increased in healthcare. Use of checklists may improve patient outcome in surgery, though few have attempted to engage patients' use of surgical checklist. To identify risk elements of complications based on patients' and healthcare workers' experiences is warranted. This study aims to identify what the patients and healthcare workers find to be the risk elements that should be included in a patient-driven surgical patient safety checklist.

Method: A qualitative study design where post-operative patients, surgeons, ward physicians, ward nurses, and secretaries from five surgical specialties took part in focus group interviews. Eleven focus groups were conducted including 25 post-operative patients and 27 healthcare workers at one tertiary teaching hospital and one community hospital in Norway. Based on their experiences, participants were asked to identify perceived risks before and after surgery. The interviews were analysed using content analysis.

Results: Safety risk factors were categorised as pre-operative information: pre-operative preparations, post-operative information, post-operative plans and follow-up. The subcategories under pre-operative information and preparations were: contact information, medication safety, health status, optimising health, dental status, read information, preparation two weeks before surgery, inform your surgical ward, planning your own discharge, preparation on admission and just before surgery. The subcategories under post-operative information, further plans and follow-up were: prevention and complications, restriction and activity, medication safety, pain relief, stomach functions, further care and appointments. Both healthcare workers and patients express the need for a surgical patient safety checklist.

Conclusion: A broad spectre of risk elements for a patient safety checklist were identified. Developing a surgical safety checklist based on these risk elements might reduce complications and unwanted errors.

Trail registration: The study is registered as part of a clinical trial in ClinicalTrials.gov: NCT03105713.

Keywords: Patient's surgical safety checklist, Patient surgical safety, Patient involvement, Patient surgical information

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Background

The World Health Organisation (WHO) and European patient organisations endorse patient involvement in safety [1, 2]. Patient involvement in self-care and safety is widely discussed [1, 3–7]. Patients are willing to participate, but this depends largely on the healthcare system creating opportunities that promote and allow patient involvement [2, 5, 8]. There are decision aids increasing patients' involvement in treatment processes by enhancing their knowledge of risks and benefits related to specific treatments [9, 10].

Systematic literature reviews on patient involvement in safety show that patients have an important role on their own safety, but evidence on effects of such involvement is limited [3, 11, 12]. There have been numerous attempts to facilitate use of patient-centred checklist pamphlets and apps [13–16]. These tools are often not aligned with different hospital administrative systems and the patients' medical records, limiting their potential as communication tools to prevent errors [17]. Several key elements that could potentially prevent medical and surgical complications, such as empowering the patients to request information, but also informing them on the importance of optimising their own health (e.g., before and after undergoing surgical procedures), have been identified. However, such interventions need to be initiated at the right time with the right tools to be effective [18].

Prehabilitation and Enhanced Recovery after Surgery (ERAS) is a multidisciplinary and multimodal perioperative program designed to optimise patient health before surgery, increase awareness in certain elements within the intraoperative phase as well as enhancing patient recovery and rehabilitation. With patient compliance, these programs have shown reductions up to 50% in complications, and 42% in mortality in patients [7, 19]. Further, one study having designed and implemented a patient checklist after colorectal surgery showed reduction of readmissions from 28% to 20% [16]. These findings might indicate that introducing a patient checklist before and after surgery can inform patients better about what they can do to prevent complications and enhance their safety knowledge.

Surgical checklists driven by healthcare providers have flourished within surgical care in the last decade. Checklists, such as the WHO Surgical Safety Checklist in operating theatres and the comprehensive Surgical Patient Safety System (SURPASS) throughout the surgical pathway, have been shown to improve patient safety by preventing medical errors and to reduce morbidity and mortality [20–23]. How patients can be involved in applying checklists has been recommended, but has not been significantly explored [3, 24]. A checklist for patients to use might enhance patient – physician communication, increase patient's participation in their own safety and optimise patient health [3, 6, 24].

Little is currently known about patient-driven checklist in surgery. It remains unknown whether patients would be comfortable and able to use a checklist as part of their own care. More importantly, which patient safety elements should be included in a checklist and which of these the patients themselves perceive as important, lacks investigation. Based on patients' and healthcare workers' experiences, this study aims to explore and describe the risk elements and perceived content for a safety checklist to be used before and after surgery.

Methods

The study has an exploratory qualitative study design, with focus group interviews involving healthcare workers and discharged surgical patients to gain patients' and healthcare workers' experiences and perspectives on preventable risk factors throughout the surgical pathway. When designing the study, patient representatives from the Health Trust Patient Advisory Board were consulted for their opinion on the study design and interview guide. In addition, we followed the Consolidated criteria for Reporting Qualitative Research (COREQ) checklist in reporting our research.

Settings and participants

Participants were recruited from surgical wards at two Norwegian hospitals, one tertiary teaching hospital and one community hospital, being referrals for 1.1 million and 110,000 inhabitants, respectively. The surgical specialties included were: Ear, Neck, Throat (ENT)−/Maxillo-Facial-; Cardio-Thoracic-; Neuro-; Breast- and Endocrine-; and General surgery. Eligible elective surgical patients from the participating wards were aged 18 years or older, without mental health conditions, independent in daily life and living within one hour's drive from the hospital, were asked if they were willing to participate in the study. Potential participants were recruited in collaboration with the ward nurses and there was no prior relationships with researchers before study start. Service managers recruited healthcare workers (surgeons, ward physicians, ward nurses, and secretaries) strategically, based on experience and type of profession, and the interviews were conducted within workhours. No quality or risk managers of the clinics participated in the focus groups interviews because they were involved with the project. One or two of each profession mentioned above participated in each health care workers' focus group interview. Five focus groups interviews of surgical healthcare workers and six groups of surgical patients were conducted with five to eight participants per group (25 patients and 27 healthcare workers, in total; participants' demographic data are presented in Table 1). One additional patient focus group interview was conducted due to too few participants in one of the

Table 1 Patients ($n = 25$) and healthcare personnel ($n = 27$) characteristics

	Age in years	Sex	Professional experience in years
Interview participants	Mean (SD)	Male n (%)	Mean (SD)
Healthcare personnel	43.0 (10.7)	7 (25.9%)	12.4 (9.3)
Patients	53.9 (15.1)	8 (32.0%)	–

Abbreviations: *SD* Standard deviation

groups. The patients were recruited one to two days before hospital discharge and interviewed three to six weeks after discharge.

Data collection

The interviews were conducted from February to June 2017. Two separate semi-structured interview guides were used, one for healthcare workers and one for patients. The interview guides were developed based on earlier research on safety checklists [3, 21, 25, 26]. Each interview guide was piloted in separate healthcare workers and patient focus group interviews. The interview guides were similar, but each adapted to the two groups of participants (Additional file: 1 and Additional file: 2). Healthcare workers were asked to identify measures the patients could do to reduce complications, and what information patients were supposed to have before surgery, after surgery and before discharge. Patients were asked to identify the information they needed before surgery, discharge and at home, as well as how they could contribute to reduce complications. The first author led all interviews with one of the other researchers as a moderator. The focus groups took place in quiet rooms at the hospital and the interviews lasted up to 90 min. All interviews were digitally recorded and transcribed verbatim.

Data analysis

Inductive content analysis was used to describe the elements of surgical risks as perceived by patients and healthcare workers [27]. Four of the authors read the interviews several times. Text revealing patient safety risk were collated and divided into meaning units, which then were condensed, assigned a code and sorted into sub-categories. The entire research team discussed the sub-categories and further abstracted and reorganised them into categories. In order to identify key elements, the analysis process was retained at a descriptive category level according to Graneheim and Lundman [27]. NVivo 12 Plus software program was used to organise text and manage the data [28].

Results

Four categories were identified throughout the analysis: pre-operative information, pre-operative preparations, post-operative information, post-operative plans and follow-up. These four categories represent the phases of information delivery, preparations and follow up. The four categories each had subcategories containing several of assigned codes, which could be identified as possible key elements for a future checklist (Table 2). However, it was also evident through our findings that the patients needed repeated information from healthcare workers and were struggling with remembering information and understanding its importance. Generally, we did not ask the healthcare workers or patients about the need for a checklist, but they both raised a need for a memory aid and clearly were positive to the idea of having patient checklists. The healthcare workers claimed that a patient checklist tool could be designed to encourage the patients to ask for information or give the healthcare staff any important information that may prevent complications or surgical cancelations. One nurse said:

> *"I feel that sometimes information slip and the surgery are cancelled, most likely it is because of missing information and lack of communication".*

In what follows, we present the four main categories and subcategories in detail, including representative quotes (translated from Norwegian) within each one.

Pre-surgical information

Patients expressed a need for a contact phone number to the surgical ward to call if important issues arose. Further, they also requested to be informed about writing down any non-urgent questions they might have and bring them along to the hospital, as a memory aid.

Both healthcare workers and patients indicated that obtaining correct medications are a major problem. Lack of an updated medical list caused a lot of frustration and time-consuming work for the physicians admitting the patients to surgery and in worst cases surgery had to be postponed or even cancelled. Often the physician had to use medication lists from an earlier admission because the patients had little or no overview over their own medications. They also experienced that patients were often unaware if they used anticoagulants and patients had not stopped all these medications. One patient expressed this as follows:

> *"We are not the experts here, how can I know what my medications contain? Everything on the medication package is "Greek" to me."*

Table 2 Key risk elements for a patient surgical checklist

CATEGORIES	SUB-CATEGORY	CODES	EXAMPLE
Pre-operative information	Contact	Direct phone number Ask questions Clarify information Write down information	***Nurse;*** *"That they have a number they can ring when they get back to them self after being informed about the surgery. Maybe it could be written a place that they get proper information under admission. I believe 90% of the patients do not remember anything.* ***Patient;*** *"Before the operation I had no idea who to contact. I got referred here and there and suddenly I got a letter informing me about an operation".*
	Medication safety	Lack of medication lists Updated medication list at general practitioners office Little insight in own medication Identify anticoagulants with their general practitioners Learn their medications	***Surgeon;*** *"I don't believe we always ask if they use anticoagulants and they don't always understand that it is anticoagulants they are using. Patients often relate to the medication name and misunderstandings can often happen".* ***Patient;*** *"I wonder what kind of information the nurses have. When I came to the ward after my surgery, I was offered some pain relief and I am allergic to certain medications. Luckily I asked her because I did not recognise those tablets and asked what they were and it turned out I was allergic to them".*
	Health status	Ensure correct treatment Diabetes High blood pressure Cardio-Vascular disease Chronic diseases Non Healing wounds Regular control at the general practitioners office Test for multi resistance bacteria	***Nurse;*** *"I am thinking about our own health. Say, that someone is overweight; they might have diabetes that are not under control. That the general practitioners consider these things before the patients comes in for an operation."* ***Nurse;*** *"We have talked a lot about it in our ward. I believe it is very important because some patients come in a such a bad state. So I think the elective patients should consider own health and the general practitioners should be involved earlier and help them".*
	Optimizing health	Patients responsibility Contact with general practitioner Inform patients Exercise Stop smoking Stop drinking/drugs Nutritional status	***Surgeon;*** *"We know that it's documented that if you quit smoking the chances of complications reduce, but there is now culture for informing patients about it.* ***Nurse;*** *"Most patients sit down in a chair and stay there, when they get informed about their surgery. I wish they could contact their general practitioner and ask how much activity they can have before surgery so they do not become passive. Because the whole thing is to optimize the patient health to prevent complications".*
	Dental status	Regular dental checks Recommend to check dental status Poor dental status Infections due to dental status Extraction of teeth day before surgery	***Surgeon;*** *"I remember we had a patient who had to remove half of her teeth before we could operate. I believe people don't understand how important it is that their teeth are well kept".* ***Surgeon;*** *"one patient had an old rote canal and at the bottom of the tooth there was a little thing that they had not manage to remove. He had to go to a specialist and it was not possible to get it done the week before the surgery".*
	Read information	Patient need for encouragement Accurate information Don't use google	***Nurse;*** *"I know there is a lot of the patients who don't read the information given to them"* ***Patient;*** *"When you receive all the papers before your surgery, it was too much I had no energy to read it all"*
Pre-operative preparations	Preparations 2 weeks before surgery	Type of surgery Time of surgery Bring close family/friend to information meeting Clarify when to stop anticoagulants Fill out required forms	***Patient;*** *"I should have stopped my blood thinners 2 days before my surgery, no one asked me so I stopped them the day before because I remembered it from my last operation, but it was too late".* ***Ward doctor;*** *"When you arrive at the hospital to the information meeting it is so important that the patients bring an up to date medication list so we know what kind of medication they are using and we don't have to wonder if they are using anticoagulants. Yes that they bring an updated list maybe this can be one of the preparations the patients need to do before their surgery".*
	Inform your surgical ward	Patient forget to inform about important information Don't think it's important Other medical investigations Cold our infections just before surgery	***Patient;*** *"If you use any form for medications or need something I believe we as patients' needs to take some responsibility to inform before surgery. Something can happen and if you have not informed about it before your surgery it is kind of your fault".* ***Nurse;*** *"Or they actually are under investigation of other diagnoses, they have to let us know or their operation might have to be cancelled".* ***Other Nurse:*** *"or if they get sick with throat infections and can't be operated on".*
	Plan your discharge	Length of hospitalisation Discharged before expected Prolonged hospitalisation due to not having someone at home Home care Aids/bandages/medication Planed discharge safer at home	***Nurse;*** *"the patients are very interested in the practical things before they come in, but we have to focus on the things that has to be ready before they get here and what they want after their surgery are they considering rehabilitation or do they live alone?"* ***Patient; "****You are going to be reduced and it is wise to have someone that can look after you at home and then you have the chance to inform the nurses that you are alone and might need an extra night in the hospital".*

Table 2 Key risk elements for a patient surgical checklist *(Continued)*

CATEGORIES	SUB-CATEGORY	CODES	EXAMPLE
	On admission to hospital	Need for a checklist on important info Patients can check and request missing info Remove rings, necklaces, piercings When to stop eating and drinking Pre surgery shower routines Allergies Updated medication list Natural medications or nutritional supplements Are you informed about expected pain	***Patient;*** *"It was own times on drinking clear fluids, I remember it from last time I had surgery. I was told that I could drink clear fluids until a few hours before my surgery. This time I did not receive any information so I was a bit unsure when I should stop eating and drinking".* ***Ward Doctor;*** *"We do have a journal system that is supposed to be updated with patients' current medicines but it's not always updated. We often use old admission notes because the patients don't have anything with them and the referral dose not usually contain a medication list".*
	Just before surgery	Are operational are marked correctly? Avoid getting cold Ask surgical team to use safe surgery	***Patient;*** *"The surgical team was ready and they started to look for the marked surgical site which was not there. They got a bit quiet and then they asked control questions before the operation started".*
Post-operative information	Preventions and complications	Information about complications Often unsure at home What is normal or not What to do in an emergency Special considerations	***Surgeon;*** *"It is very important that patients contact us if they experiences complications and that they adhere restrictions".* ***Patient;*** *"I thought this does not feel normal and I was walking around thinking Oh my god this is not good. I called the ward all the time because it was so swollen and warm. Oh my god this is not right but it apparently was all normal".*
	Restrictions and activity	When to start exercising Stayed in bed for weeks Confusion about restrictions	***Nurse;*** *"Patients own efforts in relations to mobilisation and what they can do themselves to reduce hospitalisation time after their operation".* ***Nurse;*** *"At the same time it is this about training, how much can they do, because they are so scared that they will damage something or do too much. But it is important that they exercise and don't sit down".*
	Medication safety	Start new medications Restart medications Don't remember information Rushed information Need a checklist Ask for missing information Medication side effects New medication list	***Surgeon;*** *"it is very important to inform the patients. I believe it is the core reason for them taking their medicine and understanding their disease and that they contact their general practitioners".* ***Patient;*** *"I believe the most important thing the doctor did was to line up all my medications. Some of them I knew from before and some I did not know. I explained to me very clearly, what each medicine was for and how long I was going to use them. This was very useful for me especially when you take 5–6 different medicines it is easy to mix them up".*
	Pain relief	Taking too little Taking too much Regular usage When to stop What to do if still in pain	***Patient;*** *"It is easy to forget when you are laying there and then suddenly you have to ouch!! You are in your own world and suddenly it is too painful and you take double the amount of pain relief you should".* ***Nurse;*** *"And it is reductions of pain relief, many patients have used large doses over longer time".*
	Stomach functions	Often experiences stomach pains Constipation Prevention/medication Worried something is wrong	***Surgeon;*** *"The day after it always take some time before the stomach functions work again. This is not a problem if the patients are informed about it".* ***Patient;*** *"I had problems with my stomach and I had to ask. I was informed that it was normal, I did not know that and it would have been good to know".*
Post-operative plans and follow-up	Further care	Wound care Removal of sutures Other treatment Test results Sick certificate When can I shower; Whom to contact for questions	***Nurse;*** *"Further plan, times for things, how to treat the wound, showering, precautions and whom to contact".* ***Patient;*** *"I showered with the bandage and did not change it. I looked if there was something yellow on it because I was told to. There was some wound discharge on it the first days which made me unsure".*
	Appointments	Expected time and date Referral to other specialities What to do if not received	***Nurse;*** *"It is not always patients feel a responsibility to enquire about missing follow-up appointments. They have to take some responsibility too".* ***Patient;*** *"kind of trust that you will get an appointment and you don't really think about it anymore. But of course if you had a checklist or something you would go Oh I haven't got my appointment".*

Healthcare workers suggested that if the patients were encouraged to learn their medications' names, how they look, when to take them, and learn what the medications are for before surgery, this could reduce potential errors. In addition, they stated the patients needed to contact their general practitioner if there had been changes on the medication list that was not updated, as well as help to identify if they are using anticoagulant medications.

Healthcare workers expressed the importance of assessing the patients' health status before surgery clearly. If they had diabetes, hypertension, cardiac or vascular diseases, non-healing wounds or other chronic health issues not having been controlled for the last months, they should contact their general practitioner to evaluate current treatment. One ward doctor said that:

"It is a common problem that a chronic disease is often not under control before surgery, which could potential cause complications and prolonged hospitalisation."

Furthermore, if patients had been abroad for the last 12 months and had received dental, medical treatment, or been hospitalised or worked in a hospital or clinic, healthcare workers expressed the need for information about the importance of taking bacterial swabs for multi-resitant bacteria, in accordance with national regulations.

Patients and healthcare workers agreed that the patients themselves could take more responsibility in optimising their own health before surgery, in cooperation with their general practitioners. Patients stated that they were not aware that improving their lifestyle before their surgery could significantly reduce chances of complications. A majority thought that it was too late to change their habits only months or weeks before surgery.

Patients specifically undergoing cardiac valve replacement are required to have their dental status checked before surgery. Some cardiac and cancer patients, who had not seen their dentist, experienced that teeth had to be sanitised or extracted the day before surgery. Healthcare workers all agreed that appropriate dentist consultations before surgery could potentially reduce complications. One surgeon expressed his view on this:

"We often have to refer the patients to get teeth sanitized in-hospital on the day before surgery, I'm not sure but I believe this is not ideal if we look at reducing the chances for infections. All our patients get informed before surgery to visit their dentist but most of them don't."

Patients experienced that they rarely read information before and after their surgery. They requested more emphasis on the need to read information, and to be referred to an accurate and updated information site online. They often ended up using Google to obtain information and ended up confused and scared.

Patient's preparations before surgery

Patients and healthcare workers expressed that the patients were often unsure about which preparations they needed to do before their surgery and that they often forgot to fill out important forms or bring along family to information meetings, as requested. Patients said that it would be very helpful to have a list were they could tick off the most important preparations. One patient exemplified the importance of bringing family along:

"I was so glad I had my son with me when they informed about the practical things and my surgery. I could not remember anything after the meeting, but it was not a problem because my son had also gotten the important information."

Furthermore, healthcare workers said that they often did not receive important medical information from the patients themselves. Either the patients did not consider crucial information important and therefore did not inform healthcare workers, or they simply forgot to inform. On occasions, healthcare workers themselves forgot to ask. Healthcare workers expressed the importance of the patients informing the surgical ward if they are under other medical investigations or if they get a cold or an infection the last week before planned surgery. In addition, patients had a great desire to have the information about when to stop eating and drinking, before their surgery – on a checklist, even though the healthcare workers mentioned this to the patients several times before their surgery. Both these points were agreed upon to potentially prevent delays or cancellation of surgery.

Healthcare workers frequently mentioned the importance of the patients having planned for their own discharge before surgery. At admission, patients often expected to be hospitalised for a longer period than planned. Many of the patients were dissatisfied when discharged earlier than expected, as theyhad not prepared for someone to stay with them the first night at home. Patients who were alone had to stay hospitalised longer because they had forgotten to organise to have someone with them the first day.

Preparations for home care is also part of the discharge planning and healthcare workers stated that the patients should be encouraged to evaluate and plan for their own need for home care or aids before admission.

Patients who were well informed beforehand and had planned their hospital discharge felt more prepared for their surgery.

Healthcare workers also expressed the importance of preparing the patients for what they need to be aware of on the day of surgery. They wanted the patients to be encouraged to inform staff if the operation site was not marked or if they got a cold before surgery, to prevent surgery on the wrong side or other complications.

Post-surgical patient information

Information about possible post-operative complications was mentioned in the interviews several times. Patients said that they often became unsure when at home, about what to expect and how to distinguish normal reactions from development of a complication. Patients and healthcare workers experienced that this caused numerous phone calls to the wards and patients travelling to and from the hospital. Some of the patients had experienced post-surgical bleedings and other complications where they had become seriously and acutely ill. Patients and their family members felt unprepared and unsure what to do in an emergency.

When it came to restrictions and activities, several patients were unsure about when they could start going for walks and exercise. Some had stayed in bed for weeks, others had been active from day one after their surgery. There was also confusion about when and how much weight they could lift after surgery, as exemplified by a patient:

> *"It was difficult for me to know when I could start to lift and how much I could lift. I was worried that I could cause damages to myself and it was especially difficult because I have a little toddler at home."*

Furthermore, patients who had to start on new medications or restart medications said that they mostly were only informed orally about their medications. In addition, they said that the information was often rushed with important points not being understood or remembered. One patient illustrated this:

> *"I did not know that I could not take warfarin and ibuprofen together. My wife just said ibuprofen is much better for pain than paracetamol and I took ibuprofen for over a month before I was aware of it."*

Pain relief was problematic for some of the patients even with written instructions on the packaging. Some patients had taken too much pain relief while others had taken too little. Healthcare workers stated that information on the importance of regular use and avoiding overuse had been provided before and after the surgery. However, it is still one of the most common questions received from patients after discharge:

> *"I was in agony the second night at home. I took the pain relief I was prescribed, but it did not help. I tried calling the ward to ask for help, but no one could give me an answer. I just wished I had been informed before discharge that I could have increased my dosage, and the importance of taking your pain relief regularly."*

According to healthcare workers many patients experience stomach pains and constipations after their surgery, and this was a common reason for the patients to call the ward. Patients were often worried that something had gone wrong even when they had been informed about the issue before and after their surgery.

Post-surgical plans and follow-up

Both healthcare workers and patients mentioned further plans and follow-up before discharge. Patients with more complex surgery and cancer patients expressed a great need for information about this, and who to contact in different situations. This was identified as a risk factor through the patient interviews. The patients who were informed on further plans and follow-ups were much less anxious and nervous than those who were unsure on the next steps in their treatment process. Patients who did not receive their follow-up appointment at the time of discharge became unsure when to expect appointments and some had even slipped through the hospital system and been forgotten about. One healthcare worker interviewed stated:

> *"It happens sometimes, that some patients fall out of the system and they do not receive their control appointment and that is very regrettable and can give serious consequences".*

Discussion

We identified categories and a broad spectrum of pre- and post-surgical sub-categories and codes. Our findings highlight risk elements where increased patient involvement can potentially prevent complications throughout the surgical pathway. Our main findings reflect patients' related safety concerns and the warrant of a surgical patient safety checklist; these findings were supported by healthcare workers. The key sub-categories and codes may stimulate the patients to ask safety related questions, enhancing patient interactions with healthcare workers, optimising patients' health before and after surgery to reduce health risks, and empowering the patients to request missing information and to be aware of

medication safety, and of further care and follow-up appointments. These are all elements to be considered and incorporated into a patient safety checklist for surgical patients.

Our findings indicate that patients would like to use a safety checklist. In fact, they explicitly wanted to name it a checklist. Patients' ability to absorb all the information provided by healthcare workers is weakened by stress and being in a vulnerable position [29]. Checklists may help focus on the most critical parts and enhance communication, as previously shown with the WHO Surgical Safety Checklist aimed at providers [21]. The patients wanted a tool to help them prepare for surgery and to remember important information when interacting with healthcare workers. A review of patient involvement in safety behaviour found that intra- and interpersonal and cultural relations between healthcare workers and patients might stimulate or limit patients' involvement in safety [18]. By developing patients' surgical safety checklists based on our findings, we could stimulate an interpersonal and cultural relation between the healthcare workers and patients, and encourage patient involvement. A patients' surgical checklist might also prevent errors and reduce complications either when used alone or together with existing surgical complication prevention programs.

Combining patient's surgical safety checklist with existing programs such as the ERAS program might improve patient's compliance to the program as well as further reduce complications, and hospitalisation time. Several surgical complication prevention programs are based on providers giving information and patients adhering to the programs [6, 7, 13–15, 19]. The aim for a patient's surgical safety checklist is to encourage patients to take more responsibility for their own safety, by ensuring that they have received and understood the information provided to them as well as helping them to prepare before and after surgery.

Our findings on health and personal care optimisation are in line with today's recommendations to prevent complications by improving patient information and preparations before surgery [3, 24]. Patients are rarely informed in a timely manner about the benefits of lifestyle changes [6] and most patients participating in this study believed it was too late to change lifestyle weeks before surgery. If patients optimise their own health before surgery by exercising, improving nutritional status, or discontinuing smoking, alcohol and other substances they can reduce complications [6, 7, 30, 31]. A major study on orthopaedic patients found that ceasing smoking six to eight weeks before surgery could reduce overall complications from 56 to 18% [32]. Other studies on alcohol misuse and nutritional status have also found fewer complications if these issues are addressed six to eight weeks before surgery [6, 33]. Screening for multi-resistant bacteria, quitting smoking, treatment of chronic diseases, nutritional status, perioperative showering and body temperature and wound care after surgery are other risk elements we found, which is in line with today's recommended key actions for patients to help prevent surgical site infections [34, 35]. Patient checklists containing elements taking into account such factors could be of great benefit.

We also identified medication safety as one of the major problems related to patient safety before and after surgery. This is also recognised as a challenge in several studies and by the WHO [14, 36, 37]. Including medication in a surgical safety checklist can help patients to be more aware of their medications and to guide them to ask the right questions to the healthcare workers before surgery and discharge which is coherent with WHO's five moments for Medication Safety [14] and recent literature [37]. Patient checklists with elements on medications might involve the patients more in improving medication safety and reducing adverse drug events and medication errors before surgery and discharge.

The purpose of a surgical patient safety checklist is not to replace any existing educational material or clinical data but to help the patient get a better overview on the important information and preparation before and after surgery, and to serve as a communication tool. A surgical patient safety checklist might help the patients being more active in preventing errors and complications [3, 16, 24].

Limitations and strengths

Initial focus group interviews of patients' personal surgical experiences and healthcare workers' expertise and knowledge are the recommended step in development of a patient checklist [24]. A limitation for this study would be that respondents only represented some surgical specialities and came from a small number of departments and institutions. Saturation in the data was achieved and no new categories emerged in the latest focus group interviews [25]. Strengths of this study are that the patients interviewed covered a large number of surgical procedures and there has been a multi-disciplinary team involved throughout the whole checklist content identification. Our findings were also in line with the current recommendations from WHO and other experts regarding involving patients in their own surgical safety [2, 13, 14, 34].

Implications for practice and future research

Patients will be challenged and need to get more involved in safety regarding their own surgical care throughout the surgical pathway. When patients become better informed and prepared for their surgery,

communication with healthcare workers should improve. Patients may consult general practitioners more often prior to surgery and less after surgery. Based on our findings a surgical checklist for patients is possible to be developed, but it will need to be designed, validated and tested before examining its effect.

Conclusion

A wide range of risk elements have been outlined in this study, which could be the content of a patient surgical safety checklist. It is evident that patients need help with remembering information and important preparations before and after surgery that can reduce complications and unwanted errors. Based on the identified risk elements it should be possible to develop patient's surgical checklists based on our findings.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-4888-1.

Additional file 1: Focus group interview guide patients

Additional file 2: Focus group interview guide healthcare workers

Abbreviations

COREQ: Consolidated criteria for reporting qualitative research; ENT: Ear, neck, throat; ERAS: Prehabilitation and enhanced recovery after surgery; REC West: The regional committee for medical and health research ethics of the western Norway; SD: Standard deviations; SURPASS: Surgical patient safety system; WHO: The World Health Organisation

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Author's contributions

Researchers who design the study were author number KH, ES, AS and ASH. The researchers conducting the data collection were author KH, ALM, AS, SJ and ASH. KH, ALM, AS, ASH performed the main analyses. KH, ES, ALM, SH, AS, SJ, NS and ASH took part in the final analyses and review of intellectual content of the article. KH, ES, ALM, SH, AS, SJ, NS and ASH approved the final draft.

Authors' information

KH is currently a PhD candidate with a Master's degree in critical care nursing, she has previously worked as a research coordinator, intensive care nurse at several medical/surgical intensive care units and as clinical nurse educator at an ENT and Maxillo-Facial ward. All authors have extensive training and experience in both qualitative and quantitative research within surgical patient safety.

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Availability of data and materials

The dataset used and/or analysed during this study are available in English from corresponding author on reasonable request.

Ethics approval and consent to participate

The study followed the Helsinki declaration's research principles [38]. The Regional Committee for Medical and Health Research Ethics (REC West) of the Western Norway Health Region (2016/1102) approved the study prior to study start. Patients were given verbal and written information about the study at recruitment. The participants were informed that their participation in the study was voluntary and that they could withdraw at any time without consequences. All participants signed an informed consent form.

Consent for publication

The participants gave consent for use of interview data in publications, including direct anonymised quotes from the interviews.

Competing interests

ASH represent the International Federation of Nurse Anaesthetists in the European Society of Anaesthesiologists' Patient Safety & Quality Committee. NS is also the Director of London Safety and Training Solutions Ltd., which provides quality and safety training and advisory services on a consultancy basis to healthcare organization globally. The other authors report no conflicts of interest.

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RESEARCH

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Development and validation of patients' surgical safety checklist

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Abstract

Background: Poor uptake and understanding of critical perioperative information represent a major safety risk for surgical patients. Implementing a patient-driven surgical safety checklist might enhance the way critical information is given and increase patient involvement in their own safety throughout the surgical pathway. The aim of this study was to develop and validate a Surgical Patient Safety Checklist (PASC) for use by surgical patients.

Method: This was a prospective study, involving patient representatives, multidisciplinary healthcare professionals and elective surgical patients to develop and validate PASC using consensus-building techniques in two Norwegian hospitals. A set of items intended for PASC were rated by patients and then submitted to Content Validation Index (CVI) analyses. Items of low CVI went through a Healthcare Failure Mode and Effect Analysis (HFMEA) Hazard Scoring process, as well as a consensus process before they were either kept or discarded. Reliability of patients' PASC ratings was assessed using Intraclass Correlation Coefficient analysis. Lastly, the face validity of PASC was investigated through focus group interviews with postoperative patients.

Results: Initial development of PASC resulted in a checklist consisting of two parts, one before (32 items) and one after surgery (26 items). After achieving consensus on the PASC content, 215 surgical patients from six surgical wards rated the items for the CVI analysis on a 1-4 scale and mostly agreed on the content. Five items were removed from the checklist, and six items were redesigned to improve PASCs' user-friendliness. The total Scale-level index/Average (S-CVI/Ave) before revision was 0.83 and 0.86 for pre- and post-operative PASC items, respectively. Following revision, these increased to 0.86 and 0.93, respectively. The PASC items reliability score was 0.97 (95% confidence interval 0.96 to 0.98). The qualitative assessment identified that patients who used PASC felt more in control of their situation; this was achieved when PASC was given to them at what they felt was the right time and healthcare professionals took part in its usage.

Conclusion: Multidisciplinary perioperative care staff and surgical patients agreed upon PASC content, the checklist ratings were reliable, and qualitative assessment suggested good face validity. PASC appears to be a usable and valid checklist for elective surgical patients across specialties.

Keywords: Surgery, Checklist, Patient safety, Patient's surgical safety checklist, Patient involvement

Background

In 2004, The World Health Organisation's (WHO) World Alliance for Patient Safety and the European Patient Forum emphasised mobilisation and empowerment of patients as one of six action areas in the

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'Patients for Patient Safety' program [1, 2]. Patients' participation in their own safety might reduce risk of medical errors by optimising patients' health and providing healthcare workers with crucial information such as allergies, medical history and medications usage [3]. Research suggests that patients are willing to participate in ensuring their own safety, but healthcare workers need to empower patients to do so [4–7]. Communication between patients and healthcare workers in primary and secondary care, as well as patient information and education, are important to improve patient safety [8, 9]. However, patients are often unaware that certain types of information is important to reduce errors in health care [3, 10]. Large volumes of patient information leaflets and similar materials exist, but several studies have reported that patients often have problems remembering and understanding crucial information given to them, which can affect their care in both primary and secondary healthcare settings [11, 12]. Beyond passive receipt of leaflets, several approaches to more proactive patient involvement exist – including: speaking up in case of safety concerns, increased awareness of safety issues pertaining to a patient's care (including involvement in medication administration and hygienic practices), use of patient safety apps and telemedicine educational applications for patients [10, 12–17]. Despite all these initiatives, there is still a need for implementable interventions that can effectively increase patients' involvement in preventing harm in their care [3, 5, 8, 10].

This study focuses on perioperative care and the proactive involvement of patients in their own safety. Surgical care may represent a major patient safety risk if critical information is missing and/or patient involvement is poor [10, 18]. Moreover, as the patient is unconscious during surgery, opportunities for patient engagement arise essentially prior to and following surgery. Over the past 10 years, the use of perioperative surgical checklists by healthcare workers throughout the surgical pathway and within operating theaters has resulted in reduced rates of complications [19, 20]. Recent recommendations suggest developing surgical checklists for patients to use themselves [10, 18]. Some studies have suggested that patients' use of their own checklists could further decrease complications, medical errors, length of hospital stay and readmissions [21–23]. However, there is a gap in the literature on checklists specifically developed with and validated for use by surgical patients. This study aims to address this gap. We report the development and validation of a safety checklist for patients to use before and after surgery.

Method

Study design

This study forms part of a research project focused on the development and implementation of 'surgical patient's safety checklist' (PASC). We have previously interviewed surgical patients and perioperative healthcare professionals and identified risk areas before and after surgery as well as how these risks can be reduced by patient participation [3]. The PASC content is based on the findings from our previous qualitative study, together with the development and validation process that we report here.

This was a prospective study consisting of the development and validation of PASC, and a reliability analysis of the checklist items. PASC was developed and validated in Norwegian, however for this publication it was translated into English to enable reporting and wider sharing globally. The English translation was performed by a person fluent in both languages and back translated into Norwegian by a healthcare professional and a surgical patient and only minor word differences were detected in the Norwegian back translation (which means the checklist as reported here is an accurate representation of the checklist evaluated in the study).

The development consisted of a consensus process including patients' representatives and multi-professional healthcare personnel. In the validation process, elective surgical patients from six surgical wards received PASC two to six weeks before surgery. The patients were asked to use the checklist as well as to score the importance of each checklist item; these scores were subsequently used to produce an item content validation index (I-CVI). A small number ($n=10$) of surgical patients were also interviewed in focus groups to investigate the face validity of PASC. The finalisation of PASC is based on the patients' I-CVI scores, risk assessment of items with low I-CVI score using Healthcare Failure Mode and Effect Analysis (HFMEA) hazard scoring and a consensus process [24]. The study followed the consolidated criteria guideline for reporting of intervention development studies (GUIDED) [25].

Setting and participants

Study participants were recruited from two Norwegian hospitals; one tertiary teaching hospital and one central community hospital, which cover populations of 1.1 million and 110,000 inhabitants, respectively. Among all eligible surgical wards at the two hospitals, six surgical specialties were invited to take part in the study. The selection of surgical wards was based on a randomization for an upcoming trial of the clinical effectiveness of PASC. This included Ear, Neck, Throat (ENT)/Maxillo-Facial; Cardio-thoracic; Neuro-; Breast- and Endocrine-;

Gastrointestinal; and General surgery. All departments agreed to participate.

Healthcare personnel included in the development consensus process were service managers, surgeons, ward doctors, ward nurses, and patients' representatives from the surgical wards included in the study. Additionally, anesthesiologists, nurse anesthetists, intensive care nurses, specialist dietitians, pharmacists and general practitioners were included. A safety expert from the aviation industry, and hospital communication advisors were also consulted on the wording, layout and design of the checklist.

In the content validation process, elective surgical patients having surgery in the same six surgical specialties were invited to participate. Inviting surgical patients as lay experts ensured that they were an integral part of the checklist development [26]. Inclusion criteria for the participants were: elective surgical patients aged 18 years or older, cognitively able to complete the checklist, living at home, able to give informed consent and fluent in Norwegian. Participants were recruited within a time period of two to twelve weeks before surgery, in cooperation with the nurses and surgeons at each ward. The time for when patients received the checklist before surgery depended on their severity of their disease and urgency of surgery. Patients returned the completed checklists before hospital discharge in collaboration with ward nurses and secretaries. If participants had forgotten to return PASC at the time of discharge, a reminder letter was sent to their home address with an enclosed prepaid envelope to return their completed PASC.

Checklist development

In a previous study, focus group interviews of patients and healthcare workers were utilised to identify risk areas for complications before and after surgery [3]. Subsequent PASC item development focused on the risk areas identified in that study.

To develop the checklist, we applied the recommended guidance for developing and validating checklists for patients [18]. The development process included a consensus-based process and a validation process with statistical testing of content validity and reliability. The checklist development and consensus process before the checklist validation lasted from December 2018 through June 2019. The steps of the PASC development and validation process are described in Fig. 1.

Content of preoperative PASC before content validation

The preoperative PASC included 32 items covering issues patients should consult their general practitioner for prior to surgery, such as medication usage, medical history, need for multi-resistant bacteria testing after overseas treatments and/or hospitalisation and lifestyle issues. This checklist also encouraged patients who have not seen a dentist in the previous 12 months to do so and to read all information given to them related to their surgery. Further, it included information and preparations for patients need to be aware of two weeks prior to surgery. Lastly, the preoperative PASC included issues patients need to be aware of the day before, and immediately before surgery.

Content of postoperative PASC before content validation

The postoperative PASC contained 26 items that included information about risk factors and complications that may arise, and what patients or families/relatives should do if such complications occur. Secondly, items relating to the importance of physical activity after surgery, and reminders to patients to adhere to important restrictions. Thirdly, this checklist included medication safety information before discharge from hospital and other information, like gastro-intestinal function, after surgery. Lastly, this checklist also covered further treatment plans and follow up after surgery.

Depending on a patient's answer (yes/no) to each item on PASC, they receive clear instructions on what actions should be taken if needed. Due to the checklists' large number of items, the items were structured into sections of no more than eight items for ease of completion. Each section had a heading that described the item content in each section, as recommended by the guideline for developing and validating checklists for patients [18]. The checklists were designed to follow the patient surgical pathway and to be used over 2-6 weeks before surgery and also before hospital discharge.

Content validity and reliability

After establishing the PASC content, elective surgical patients used the checklist (Norwegian version) and scored each item to content-validate the checklist [27]. The data on patients, checklist usage and I-CVI were collected over a period of 14 months (August 2019 to September 2020). Descriptive statistics were used to describe patient demographic information and a chi-squared test was performed to investigate any demographic differences between responders and non-responders. Participants were given PASC, consisting of two parts; one prior surgery and one before discharge. While using the two checklist parts (a total of 58 items) the patients rated each item from not relevant to very relevant on a four-point scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant) [27]. For each item, a final I-CVI was calculated by including the number of patients who rated the item 3 or 4 and dividing that number by the total number of experts rating each item [28]. I-CVI

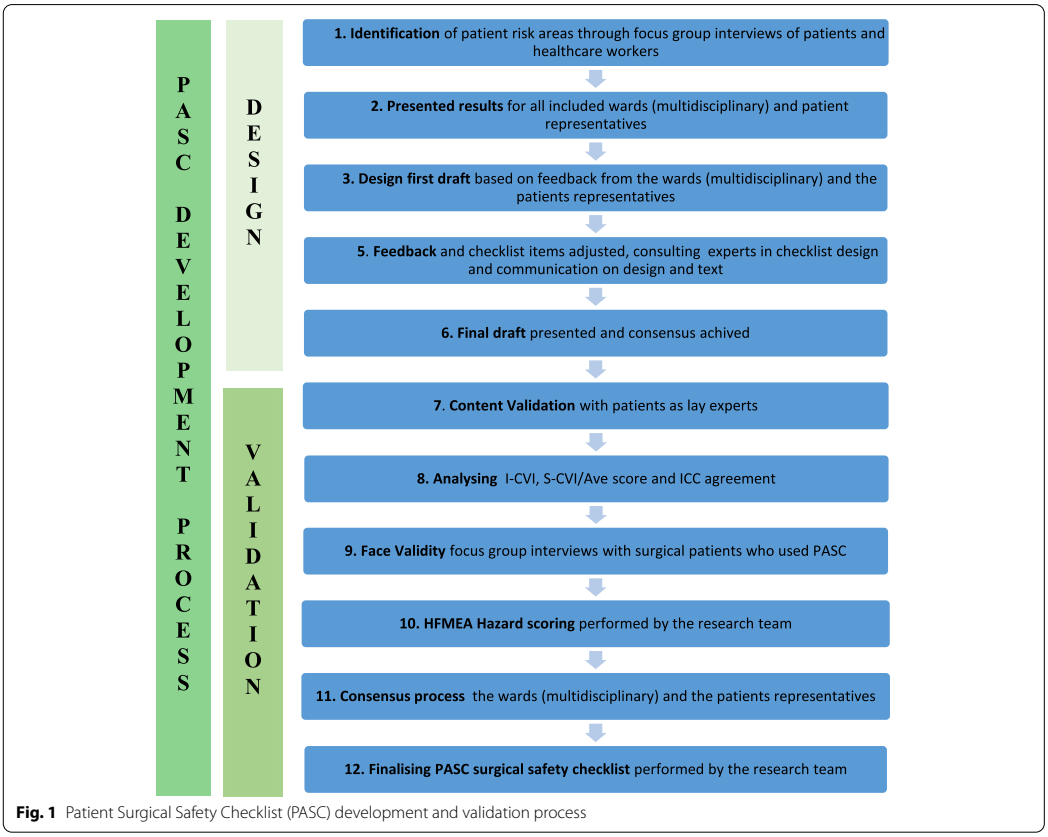

Fig. 1 Patient Surgical Safety Checklist (PASC) development and validation process

scores ≥0.78 were considered satisfactory; items that reached this score were kept unchanged in the final version of the checklists [29].

Items with scores <0.78 were subsequently risk-assessed by the research team using the HFMEA Hazard Scoring Matrix [24]. The risk of possible complications related to each reviewed item was estimated based on the rated frequency and the potential severity of the hazard. Hazard scores can range from 1 to 16, where 1- 4 indicates low frequency/impact and 8 to 16 indicates high frequency/impact, as described by the standard HFMEA Hazard Scoring Matrix [24]. Lastly, a final consensus and revision process on PASC items that received I-CVI > 0.78 and hazard scores < 8 was performed as recommended by Polit and Beck [29]. Tables 3 and 4 describe which items were kept unchanged; which items were revised due to hazard scoring and consensus; and which items were ultimately removed as a result of this development and scoring process.

To investigate the total content validity of the checklist, the Averaging Scale-level Content Validity Index (S-CVI/Ave) of items scoring 3-4 was calculated for both parts of the checklist before and after revision based on I-CVI. S-CVI/Ave was calculated by summing all I-CVI scores and then dividing by the total numbers of items [29] (Tables 3 and 4). Descriptive analyses of the I-CVI and S-CVI/Ave were performed in STATA version SE 16.1. (StataCorp. 2019. College Station, TX: StataCorp LLC).

Intraclass Correlation Coefficients (ICC) were used to assess the PASC checklist reliability (internal consistency). ICC estimates and 95% confidence intervals were calculated using SPSS Statistical Package Version 26 (SPSS, Inc., Chicago, IL) based on mean-rating, two-way random-effects model [30]. Variables with missing values >50% were removed from the ICC analyses ($n=23$), and

variables with missing values < 50% were replaced with mean values based on multiple imputation [31].

Face validity

After PASC was used and validated by surgical patients, ten patients were invited to attend small focus group interviews (two to five surgical patients in each group). The focus groups interviews lasted for up to 60 min and performed by one interviewer and one moderator (MR and KH). These consisted of a purposive sample of surgical patients three to eight weeks post-surgery from: Ear, Neck, Throat (ENT)/Maxillo-Facial; Cardio-thoracic; Neuro-; Breast- and Endocrine surgery. The focus group interviews were carried out in hospitals according to COVID-19 regulations. Focus group interviews were semi-structured, driven by a topic guide based on the checklist items, which was first piloted on patient representatives. They were recorded and transcribed verbatim for analysis. Qualitative content analysis was used to identify codes and categories from condensed patients meaning units to assess face validity as described in Fig. 2 under results [32].

Results

Of 428 patients asked to participate, 215 patients (50.2%) consented and were thereby eligible for the study. Participants' demographics are listed in Table 1. The gender distribution in responders and non-responders was not significantly different ($p = 0.599$). However, there was a difference between responders and non-responders in terms of the surgical wards they were in at the time of the data collection ($p = 0.006$). Patients having general surgery at the community hospital had the highest number of non-responders (61.0%). In contrast, breast/endocrine surgery patients had the highest number of responders (72.6%).

Preoperative PASC

Based on the I-CVIs, hazard scorings and the final consensus process described in Table 2, five items on the preoperative PASC were either removed or added to other revised items. Thirteen items on this checklist were redesigned, resulting in an overall reduction to 27-item checklist. We found I-CVI variations in some items between the surgical wards, especially on items covering medication usage, and health history and treatment. We therefore investigated the differences in the I-CVIs on the patients who had answered "yes" on the checklist for using medications, health history and other treatment related questions. The majority of patients who answered "yes" to these items rated them 3 or 4 ("quite relevant" or "highly relevant"), but those patients who answered "no" rated them mostly as 1 or 2 ("not relevant" or "somewhat relevant") (Table 2). The items related to medication, health history and treatment were kept based on the result of I-CVI from the patients answering "yes" to these items, and further based on hazard scoring and the final consensus process. We calculated the S-CVI/Ave on the preoperative PASC in two ways; one including the total I-CVI for all the wards, and one revised version excluding the CVI scoring from the patients who did not answer "yes" to using medications, having a medical or treatment history. The S-CVI/Ave scoring for the total PASC I-CVIs was 0.73 before and 0.77 after revision, respectively. The PASC S-CVI/Ave when including only the patients answering" yes" to the items described above was 0.83 before and 0.86 after revision, respectively (Table 2).

Table 1 Participants' demographics of the PASC validation

Surgical specialties	Patients per specialty	Age Mean (SD)	Sex Male n (%)
Gastrointestinal surgery	37	59.0 (12.8)	18 (48.6%)
General surgery	22	64.0 (14.7)	14 (63.6%)
Breast/endocrine surgery	45	59.8 (9.8)	2 (0.4%)
ENT/Maxillo-facial surgery	43	50.0 (15.8)	19 (44.2%)
Neurosurgery	32	54.0 (9.6)	15 (46.9%)
Cardio-thoracic surgery	36	62.8 (9.9)	30 (83.3%)
Total	215	58.0 (8.6)	98 (46%)

Abbreviations: *PASC* Patient Safety Checklist, *SD* Standard deviation, *ENT* Ear, Neck, and Throat

Postoperative PASC

The I-CVI and S-CVI/Ave, hazard scoring and final consensus process for the postoperative PASC are described in Table 3. Six items on the checklist were removed or added to other revised items. Nine items went through the hazard scoring/consensus process, thus shortening the checklist to 20 items. The S-CVI/Ave was calculated as for the pre-operative PASC. S-CVI/Ave was 0.75 and 0.81 before and after revision, respectively. When we only included the I-CVI's of the patients answering "yes" to using/starting medications, the S-CVI/Ave was 0.86 before revision and 0.91 after revision.

PASC checklist reliability

Reliability of patients' PASC ratings was assessed for both parts of the PASC and for the entire checklist with ICC (mean-rating, two-way random-effects model with absolute agreement). The ICC ratings were excellent for both parts of PASC and for the total rating (see Table 4).

Face validity of the PASC

The focus groups included participants from four of the six recruited wards, four women and six men with an age ranging from 30 to 70 years (mean age 50 years, SD 8.60). Several codes were identified from the condensed

Table 2 I-CVI Analysis of preoperative PASC items (Item actions are not included in this table)

Item number	n	Item question:	Total I-CVI	Total (yes)** I-CVI	Hazard score
23	189	Are you informed about when you should stop eating and drinking before your surgery?	0.99	0.99	-
11	202	Do you know what type of surgery you are having and the time of your surgery?	0.98	0.98	-
24	190	Are you informed about hygiene/showering routines before your surgery?	0.98	0.98	-
29	191	Are you informed about expected pain after your surgery?	0.93	0.93	-
16	169	Are you informed about what you should do if you get sick the week before surgery?	0.92	0.92	-
32	166	Request the use of safe surgery checklist when you arrive at the surgical theatre. The surgical team should clarify your identity, type of operation and which side you should operate on (if you are having surgery on a side)	0.92	0.92	-
31	176	Avoid getting cold, inform your nurse	0.91	0.91	-
7	201	Are you informed that physical activity and a healthy diet before surgery can reduce chances for complications?	0.90	0.90	-
17	198	Are you informed about how long you could expect to stay in hospital?	0.89	0.89	-
27	187	Are you using any medications permanent or in periods	0.88	0.88	-
13	180	Have you filled out all required forms before admission to the hospital?	0.87	0.87	-
22	184	Have you removed all rings, necklaces, piercing, fake nails and nail polish?	0.82	0.82	-
9	201	Do you go to your dentist regularly?	0.81	0.81	-
18	195	Do you have family or a friend that can be with you the first night after you are discharged?	0.80	0.80	-
1	208	Are you using any medications?	0.80	0.80	-
10	195	Have you read the admission letter and all other information given to you?	0.74	0.74	8 Frequent/ moderate
19	182	Ask if there are some things you need to have ready at home (bandages, medications)	0.74	0.74	4 Frequent/ Minor
26	187 33*	Are you allergic to any medication or medical equipment (latex)?	0.72	0.97**	9 Occasional/ Major
8	203 91*	Are you informed that stopping smoking, alcohol and substance abuse as early as possible before surgery can reduce chances of complications?	0.72	0.77**	9 Occasional/ Major
30	161	If relevant: have your operation site or side been marked?	0.70	0.70	8 Catastrophic /Uncommon
14	194	Do you have family or a close friend that can accompany you to get the information about your surgery?	0.69	0.69	8 Frequent/ moderate
2	198 97*	Do you have a medication list with the latest changes	0.67	0.93**	12 Frequent/ Major
15	179 21*	Are you under investigation for other diseases?	0.61	0.96**	9 Occasional/ Major
4	197 79*	Do you have diabetes, high blood pressure, cardio- vascular or receiving treatment for other chronic conditions?	0.63	0.89**	12 Frequent/ Major
12	179 82*	Are you informed of when, or if you should stop your blood thinning medication before your surgery?	0.59	0.70**	12 Frequent/ Major
21	183	Are you informed if you need rehabilitation or physiotherapy?	0.58	0.58	6 Occasional/ Moderate
3	190 51*	Are you using blood-thinning medications?	0.55	0.94**	12 Frequent/ Major
6	188 4*	Have you received dental treatment, medical treatment, or been hospitalised, or worked in hospitals overseas the last 12 months?	0.49	1.00 **	9 Occasional/ Major
28	181 41*	Do you use any herbal medication or nutritional supplements?	0.49	0.75**	9 Occasional/ Major
5	182 2*	Do you have non-healing wounds?	0.46	1.0**	9 Occasional/ Major
25	170	Do you have children under 18 years?	0.37	0.37	4 Frequent/ Minor
20	176	Do you need homecare or other social services?	0.33	0.33	9 Occasional/ Major
S-CVI/Ave					-
Total S-CVI/Ave before revision (Total 32 items)			**0.73**	**0.83**	-
Total S-CVI/Ave after revision (Total 27 items)			**0.77**	**0.86**	-

Abbreviations: I-CVI = item content validity index; S-CVI/Ave = mean sum score of content validity index; * = n for yes answer to item; ** = Total I-CVI for yes answer to medication usage, medical and treatment history

Color coding as follows:

Item kept if CVI ≥ 0.78
Item kept after hazard scoring and/or consensus and revision
Item reviewed and added to other items after hazard scoring and consensus
Item removed after hazard scoring

Table 3 I-CVI analysis of postoperative checklist items (Item actions are not included in this table)

Item numbers	n=	Item questions	Total I-CVI	Total (yes)** I-CVI	Hazard Score
33	192	Are you informed about possible complications?	0.99	0.99	-
34	190	Are you informed about what you should do if you experience complications or in an emergency?	0.98	0.98	-
35	186	Are you informed if you need to take any special considerations after your surgery?	0.94	0.94	-
38	184	Are you informed about the importance of being physical active and when you can begin to exercise?	0.93	0.93	-
52	187	Are you informed about wound care, bandage changes, removal of sutures and who can help you with this?	0.93	0.93	-
53	179	Are you going to have a follow up appointment?	0.93	0.93	-
39	183	Are you informed about activity restrictions?	0.92	0.92	-
40	184	Are you informed about when you can shower again?	0.90	0.90	-
55	177	Are you informed about whom you can contact after discharge if you have any questions or need to make enquire about follow-up appointments?	0.89	0.89	-
49	168	Are you informed about how to use and when you should stop taking pain relief?	0.86	0.86	-
50	169	Are you informed about what you can do if recommended pain-relief dosage is not sufficient?	0.83	0.83	-
51	180	Are you informed that it can take some time before your bowel motions are back to normal and what to do for prevention?	0.83	0.83	-
48	177	Do you need a prescription on pain relief medication?	0.79	0.79	-
37	179	Are you informed about when you can drive after surgery?	0.76	0.76	8 Uncommon/ Catastrophic
43	135 70*	Are you informed about whom to contact if you are experiencing side effects?	0.72	0.92**	12 Frequent/ Major
41	167 47*	Are you starting on new medications?	0.69	0.98**	12 Frequent/ Major
46	159 47*	Have you stopped any medications (for example. blood thinners, blood pressure medications) in relation to your surgery?	0.68	0.98**	12 Occasional/ Major
45	129 33*	Are you going to use your medication regularly?	0.65	0.97**	4 Frequent/ Minor
56	170	Do you need a sick certificate?	0.64	0.64	4 Frequent/ Minor
57	168	Are you informed whom to contact if you need a sick certificate extension?	0.62	0.62	4 Frequent/ Minor
44	129 11*	Are you informed about medications or food you cannot eat together with your new medications?	0.55	1.00**	12 Frequent/ Major
47	137 17*	Have you received a copy of your new medication list?	0.52	0.94**	12 Frequent/ Major
42	132 26*	Are you informed about possible side effects of your new medications?	0.55	1.00**	12 Frequent/ Major
54	160 22*	Are you referred to other medical specialities?	0.52	0.96**	9 Occasional/ Major
58	174	Are you informed about when you can travel after your operation?	0.49	0.49	4 Frequent/ Minor
36	167	Are you informed if you need compression stockings	0.34	0.34	4 Frequent/ Minor
S-CVI/Ave					**-**
Total S-CVI before revision (Total 26 items)			**0.75**	**0.86**	**-**
Total S-CVI after revision (Total 20 items)			**0.81**	**0.91**	**-**

Abbreviations: I-CVI = item content validity index; S-CVI/Ave = mean sum score of content validity index; * = n for yes answer to item; ** = Total I-CVI for yes answer to medication usage, medical and treatment history

Color coding as follows:

Item kept if CVI ≥ 0.78
Item kept after hazard scoring and/or consensus and revision
Item reviewed and added to other items after hazard scoring and/or consensus
Item removed after hazard scoring

Table 4 Assessment of PASC reliability as rated by surgical patients ($n = 212$) with Intraclass Correlation using mean measurement, absolute-agreement, two-way random-effects model

				95% Confidence Interval	
	Mean	**SD**	**Intraclass Correlation**	**Lower Bound**	**Upper Bound**
Preoperative PASC	3.04	1.10	0.97	0.96	0.99
Postoperative PASC	3.13	1.12	0.97	0.95	0.98
PASC Total	3.07	1.11	0.97	0.96	0.98

Abbreviations: *PASC* Patient Safety Checklist, *SD* Standard Deviation

meaning units derived from the transcripts; 'Increased systematising and reminder', 'adjust after patient situation', 'early delivery and involvement' and 'ask patients about checklist'. The codes formed the main thematic categories that we extracted – as follows: 'Help to systematise and keep focus', 'Improve user friendliness and delivery', 'Healthcare workers need to be involved in using the checklist'. Fig. 2 summarises the analysis process and findings.

Following the I-CVI and face validity analyses, most of the PASC content was kept as initially designed, but it was recognised that some parts of the PASC required editing. The final PASC (for pre- and post-operative usage) with all items and related instructions for patients to take action as required can be found in Additional files 1 and 2.

Discussion

The aim of this study was to develop and validate a patient-completed checklist to help surgical patients become involved, and empowered to take appropriate actions to reduce chances of complications and enhance

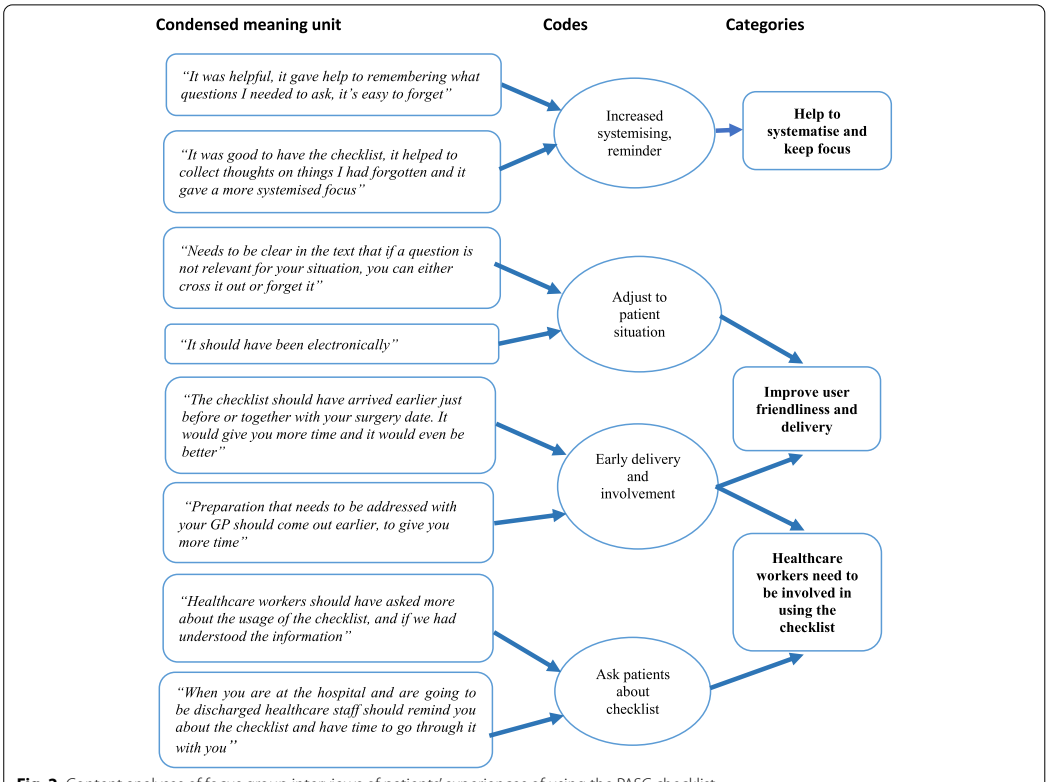

Fig. 2 Content analyses of focus group interviews of patients' experiences of using the PASC checklist

their own safety. The study achieved this and produced a usable checklist, with evidence for validity of content and consistency in scoring.

The results from the content validation of PASC show that patients across the six surgical wards largely agreed on the relevance of each set of checks. However, we observed some variance across surgical wards that might be explained by differences in types of surgery, medication usage and medical history. The checklist was initially designed without allowing adjustments to medication usage and medical history, because we aimed to design a checklist that can be used by most surgical patients. With the added necessary adjustments, depending on the patients' medication usage and medical history, the checklist will adjust and include only relevant items to patients using it. Further, some PASC items might not be directly linked to specific safety aspects, such as the item addressing the importance of filling in all forms patients are given. We acknowledge that perioperative care practices in Norway and other countries (and also between hospitals) will differ. In the context of this study, the forms referred to in the checklist do cover safety aspects, such as important information to the anesthetist and a form relating to the COVID-19 pandemic. Whilst most PASC content will be relevant for most elective surgical patients, some adaptations to PASC will be needed depending on local clinical routines and practice to ensure utility [18, 33].

Two PASC items were redesigned as recommendations rather than check items – because they did not quite fit as a checks; however, both could possibly prevent complications and both patients and perioperative staff requested they be kept [3]. The first item related to the need for having a close family member or friend present during consultations for surgery. Initially, it was recommended that surgical patients were accompanied by someone close to such consultations to ensure that information was understood and remembered [34]. However, due to COVID-19 the practice had to change and most surgical patients attended consultations on their own. The second item related to avoid getting cold before surgery, as evidence shows that patients that have a low bodytemperature before surgery have a larger risk of bleeding and infections [35, 36].

Patient-completed surgical checklists are currently rare [16, 21]. Those that exist, tend to be tailored to a specific type of surgery, sometimes offered as a mobile app to guide the patient through the surgical pathway. The PASC is designed to be a part of the patient's medical records and should be used by patients as they prepare for surgery and hospital discharge. PASC can guide patients to ask for important information and facilitate communication with healthcare professionals. However, it is important to acknowledge that to achieve uptake, healthcare professionals need to take an active role in implementing PASC and encourage patients to use it.

Our previous research suggested that in addition to hospital healthcare professionals, general practitioners also have an important role in helping patients to prepare for surgery [3]. This was taken into consideration when designing PASC. Items encouraging patients to establish contact with their general practitioners and other medical professionals have been included. Early patient contact with medical professionals opens up opportunities for optimising a patient's health before surgery [37]. Patients widely agree that such contact is important [3]. Current evidence shows that informing patients about the benefits of optimizing their health before surgery is of value and upcoming surgery can be a driver for positive lifestyle changes [37, 38]. Several initiatives show promising results here, such as the Pre-habilitation and Enhanced Recovery after Surgery (ERAS) program and 'surgery schools' for patients [39, 40]. Based on the experience of this study, we propose that PASC can either be used as an independent tool for surgical patients, or integrated with existing patient pre-habilitation and recovery programs.

Limitation and strengths

The main limitation of the study is that the checklist has not been evaluated clinically. As this is the first step of the evaluation of the checklist, clinical evaluation (feasibility and effectiveness) is yet to be carried out. The validation evidence collected reflects the views of patient users on its utility and relevance and does not tell us (yet) whether use of the PASC checklist in addition to the standard surgical checklists currently in use (WHO Surgical Safety Checklist and/or other) would actually improve outcomes. This remains to be tested. Further, since the checklist was developed in the context of a high-income country and culture that explicitly supports patient engagement (Norway), it remains to be seen how well it will fit with other systems and cultures globally [41].

Another potential weakness in this study is the 213 non-responder patients. Our analysis found no difference between genders on responding, however the central community hospital had higher number of non-responders. This pattern may indicate that the patients with more complex surgery and medical conditions were the ones who used PASC. The validation results would most likely not be influenced by the non-responders. It also has to be acknowledged that from March to end of May 2020 all surgical activity at both study hospitals was suspended due to the COVID-19 pandemic, and a large number of elective surgical patients were lost in

this period. A larger study with more equal representation of different hospital settings could address these shortcomings.

A major strength of the study is the comprehensive development and validation process of the PASC, across six surgical wards of two hospitals. This process included interviews of surgical patients and healthcare workers [3] and a consensus process with patients' representatives, a multi-professional healthcare team and general practitioners. Further, the validation process using surgical patients as lay experts has afforded surgical patients strong involvement and voice throughout the whole development of PASC. Another strength is the large total number of patients agreeing on the rating of each checklist item and the high ICC scores, which indicate very good content validity and reliability.

Conclusion

A patient-completed surgical safety checklist in the form of the PASC has been developed and validated in this study. PASC has been designed with the goal of helping surgical patients to be more aware of what actions they can take to prevent complications and to acquire control over which information they need throughout the surgical pathway. The development and validation process showed that a multi-disciplinary healthcare team and elective surgical patients across a range of surgical specialties agree on the PASC content. Surgical patients also indicated that they are willing to use such a checklist if it is user-friendly and provided in a timely manner. The PASC checklist is not designed to replace existing educational materials or replace existing surgical patient enhancement programs or surgical checklists. Further feasibility study and a definitive clinical effectiveness study of PASC effect on complications, mortality, morbidity and length of hospital stay are needed. In addition, qualitative studies exploring both patients and healthcare workers' experiences with application of PASC should be conducted across surgical specialties.

Trial registration

The PASC development and validation study is part of a trial registered in clinicaltrials.gov: NCT03105713. Registered 10.04.2017.

Abbreviations

WHO: World Health Organisation's; PASC: Patient's Safety Checklist; I-CVI: Item content validation index; HFMEA: Healthcare Failure Mode and Effect Analysis; GUIDED: Consolidated criteria guideline for reporting of intervention development studies; ENT: Ear, Neck, Throat; COVID-19: Coronavirus disease 2019; S-CVI/Ave: Averaging Scale-level Content Validity Index; ICC: Intraclass Correlation Coefficients; SD: Standard Deviation; ERAS: Prehabilitation and Enhanced Recovery after Surgery; REC West: The regional committee for medical and health research ethics of the western Norway.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-022-07470-z.

Additional file 1.

Additional file 2.

Additional file 3.

Additional file 4.

Additional file 5.

Additional file 6.

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Authors' contributions

Researchers who design the study were author number 1, 2, 3, 4, 6, 12 and 13. The researchers conducting the data collection were author number 1, 5, 7, 10, 11 and 13. Author's number 1, 5 and 13 performed the analyses of the data. All Authors participated in the interpretation of the data and review of intellectual content of the article and have extensive training and experience in both qualitative and quantitative research within surgical patient safety. All authors approved the final draft.

Authors' information

KH is currently a PhD candidate with a Master's degree in critical care nursing, she has previously worked as a research coordinator, intensive care nurse at several medical/surgical intensive care units and as clinical nurse educator at an ENT and Maxillo-Facial ward.

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Availability of data and materials

The dataset used and/or analysed during this study are available in English in Additional files 3 and 4. If more details are needed please contact corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study followed the Helsinki declaration's research principles [42]. The study was approved by the regional ethics committee for medical and health research and the data privacy ombudsman at 21.09 and 2016 (Ref: 2016/1102/REC/west) prior to study start. Patients were given verbal and written information about the study at recruitment. The participants were informed that their participation in the study was voluntary and that they could withdraw at any time without consequences. All participants signed an informed consent form.

Consent for publication

The participants gave consent for use of all anonymised data in publications, including direct anonymised quotes from the interviews.

Competing interests

Conflicts of interest: NS is the director of the London Safety and Training Solutions Ltd., which offers training in patient safety, implementation solutions and human factors to healthcare organisations and the pharmaceutical industry. ASH has received travel re-imbursement for representing the International Federation of Nurse Anaesthetists in the European Society of Anaesthesiologists and Intensive Care's Patient Quality and Safety Committee. The other authors declared no conflicts of interest.

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