



Guideline Adherence and Management System

Cognuse White Paper
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INTRODUCTION

Despite the widespread adoption of quality improvement programs, adverse events continue to cause patient harm, generate unnecessary cost and produce extra burden in hospital settings.

In recent years, checklists have become a widely advocated solution to the ongoing problem. Successfully deployed in aviation, the expectation is for these simple tools to improve clinical task decision-making, process and memory leading to a reduction in unnecessary medical errors and unwarranted care variations.

Yet despite the hype and some positive outcomes, checklist use has been inconsistent and their efficacy questionable . As a result, critics argue for a) more research into the factors influencing their adoption, use and impact and b) greater consideration of their integration with clinical guidelines and workflows, especially for more complicated, infrequent and context-dependent tasks.

In this white paper, we describe how the **Cognuse CoNurse** application helps to overcome the shortcomings of checklist-driven and -dependent care quality improvement initiatives. In it, we:

- Examine briefly why harmful adverse events occur, with a particular focus on understanding the nature of medical errors and their causal factors
- Describe the potential and adoption of checklists as a "panacea" to resolve these errors
- Summarise the factors that are limiting the adoption and usefulness of checklists
- Explain how the CoNurse solution can address these factors by improving adherence to guidelines, and the need to go beyond checklist-thinking-as-solution alone
- Provide an overview of the evolution, prototyping and experience of CoNurse across Europe

First, we go "back to basics" to explore quickly the cost, incidence and causes of patient harm and adverse events in hospital settings.

THE PROBLEM EXPLORED

The burden of in-hospital adverse events

Adverse events (AEs) continue to negatively impact patient safety, the quality of care and staff morale in hospitals. Despite variations in their definition and recording, all studies confirm the significant scale of the problem as the summary data in Figure 1 testifies.

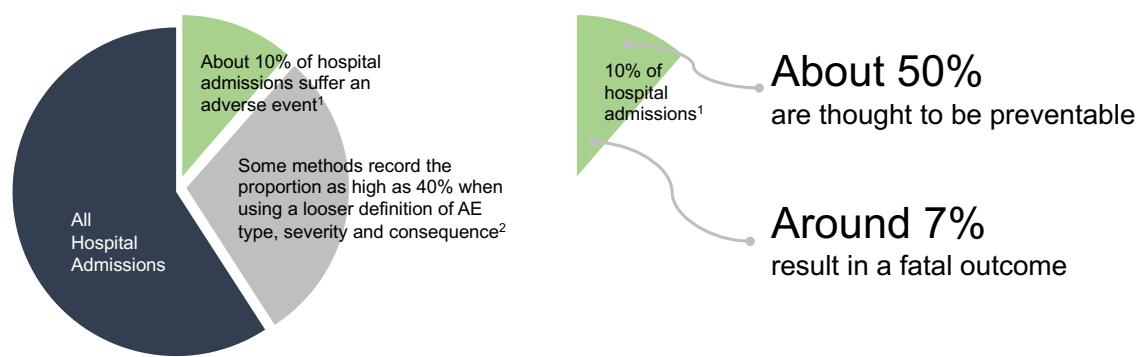


FIGURE 1: PERCENTAGE OF IN-HOSPITAL ADMISSIONS THAT INCUR AN ADVERSE EVENT¹

Notes: 1 - Recording of Adverse Events using the Harvard Method; 2 -Recording of Adverse Events using the Global Trigger Tool

In terms of cost, one respected study estimates that AEs add an additional 17.2 billion dollars of unnecessary spend to the US healthcare system².

Without question, AEs incur high direct and indirect costs, distract from care priorities, place burden on patients, their families and staff, and can cause reputational damage to hospitals.

But what can and is being done to reduce them? First, we suggest we must start by better understanding their causes.

¹ Based on data in Schwendimann, René et al. (2018) The occurrence, types, consequences and preventability of in-hospital adverse events – a scoping review. BMC Health Services Research. 18 (1) 521

² Van Den Bos J, Rustagi K, Gray , Halford M, Ziemkiewicz E, Shreve J. The \$17.1 billion problem: the annual cost of measurable medical errors. Health Aff (Millwood). 2011;30(4):596–603

Medical errors, adverse events and causal factors

When seeking to reduce adverse events and improve patient safety, it is important to consider the causal factors of AEs very carefully. To do so, we must make a distinction between AEs arising from standard, planned or intended care and AEs arising from medical errors of various kinds (see Figure 2).



FIGURE 2: MEDICAL ERROR-RELATED ADVERSE EVENTS AS A SUBSET OF ALL ADVERSE EVENTS

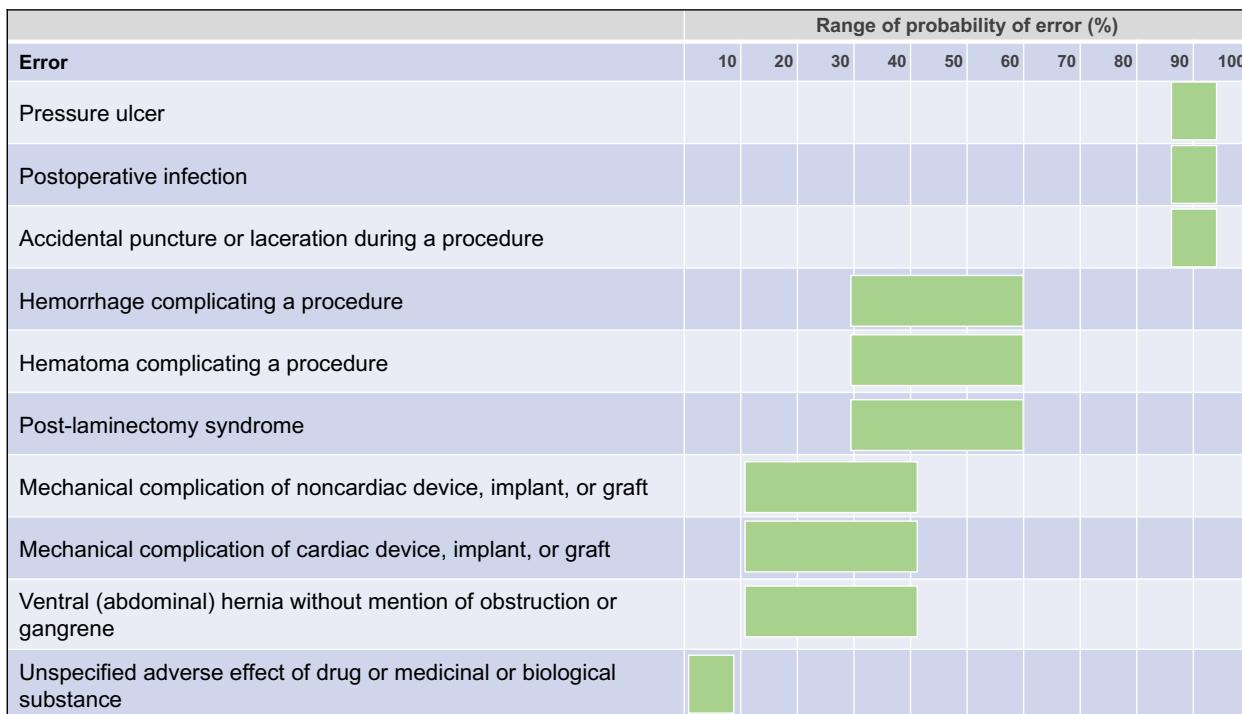
Unfortunately, distinguishing adverse events that arise from warranted and/or standard care and those that occur due to medical error is not easy. This lack of distinction has important implications when designing interventions to prevent AEs and reduce patient harm. It is particularly relevant when thinking about the potential of checklists as a quality improvement tool, as we shall describe later.

Next, we look at the actual evidence of medical error-related adverse events.

Medical errors and common adverse events

In a major study of medical errors in the US (using insurance claims data, seen as a reliable method), the authors were able to identify and rank specific medical errors (see Table 1). They found that pressure ulcers were the most common AE caused by medical error, followed by postoperative infections and post-laminectomy syndrome. Together, they calculate that ten errors account for 69 percent of the total medical cost for measurable medical errors. Postoperative infections were the costliest error, followed by pressure ulcers.

TABLE 1: MOST COMMON IN-HOSPITAL PREVENTABLE MEDICAL ERRORS, US 2008



Source: Shreve J, Van Den Bos J, Gray T, Halford M, Rustagi K, Ziemkiewicz E. The economic measurement of medical errors [Internet].

Denver (CO): Society of Actuaries; 2010 Jun [cited 2011 Mar 2]. Available from: <http://www.soa.org/files/pdf/research-econ-measurement.pdf>. NOTES Pressure ulcer is a Medicare “never event,” explained in the text. Postlaminectomy syndrome is pain following back surgery. A Hemorrhage complicating a procedure could be hemorrhage that occurs during (intraoperative) the surgical procedure due to inadvertent laceration of an organ or vessel or bleeding that occurs or becomes evident after the surgical procedure is completed (postoperative). The latter (postoperative) may be due to inadequate hemostasis during surgery (intraoperative) as the result of overlooked bleeding vessels or failure to appropriately suture or cauterize bleeding vessels.

What may be the cause of medical errors leading to the above adverse events? In the next section, we explore their underlying factors.

CONTEXTS AND CAUSES

In a recent meta-review of studies of preventable medical errors, the authors concluded that,

"the most frequent errors result from rather common medical services for which cost-cutting efforts compromise patient safety. That is, the majority of medical errors leading to in-hospital AEs are not caused by poorly performing physicians, nurses, or other clinicians. More commonly, they arise from care delivery problems that result from conditions at the level of the individual patient or staff member, the task or the health care team. They may even be rooted in the overall work environment."³

Such care delivery and task, workflow or environment-related problems include those shown in Figure 3.

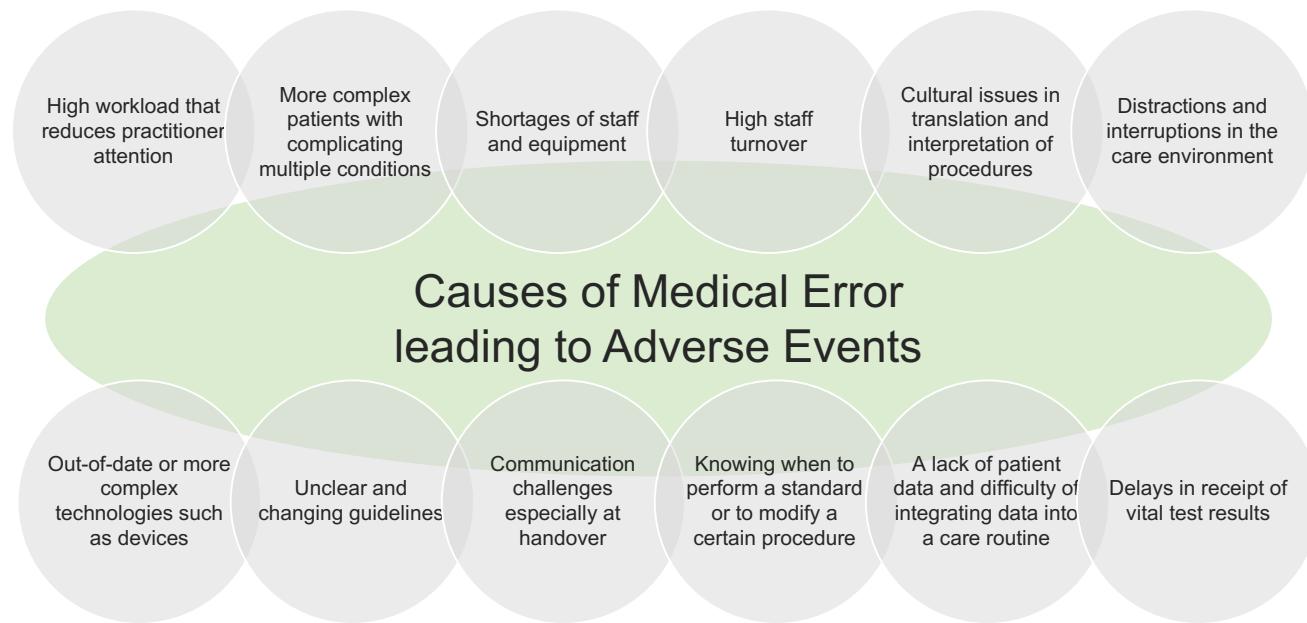


FIGURE 3: CAUSES OF MEDICAL ERRORS LEADING TO ADVERSE EVENTS

They denote a wider set of socio-technical causal factors that surround and influence clinical tasks and procedures in any given hospital setting, and which can lead to medical error.

These include:

- Staff (experience, shortages, turnover, workload)

³ Schwendimann, René et al. (2018) The occurrence, types, consequences and preventability of in-hospital adverse events – a scoping review. BMC Health Services Research. 18 (1) 521

- Material resource (quality, availability, cost, performance)
- Interaction (culture, communications, interruptions, information sharing, departmental)
- Workflow and guidelines (adherence, relevance, recency, ease) and last but not least,
- Patient factors (status, changes in status, complexity, involvement in care).

To address the cause and burden of preventable and identifiable medical errors leading to AEs, research into the above factors, their relations and influence continues. Checklists are increasingly viewed as one important solution, and form one major strand of such an effort.

In the next section, we review these tools and explore their limitations. Specifically, we ask the question: Are checklists really the panacea to the AE problem?

CHECKLISTS AS PANACEA?

Checklists are regarded as a relatively simple solution to address in-hospital AEs. Advocates, including the World Health Organisation, have developed and hope to implement checklists at a wider scale. In 2008, The Surgical Safety Checklist (SSC), introduced by WHO together with Atul Gawande (MD), a pioneer of the checklist movement, has been introduced in many hospitals around the world^{4,5}. In 2015, WHO introduced The Safe Childbirth Checklist (SCC) and embarked on a major program to implement it around the world^{6,7}.

Without question, checklists can help by improving or modifying a healthcare practitioner's cognitive capacities when planning or performing a particular healthcare task (see Figure 4).

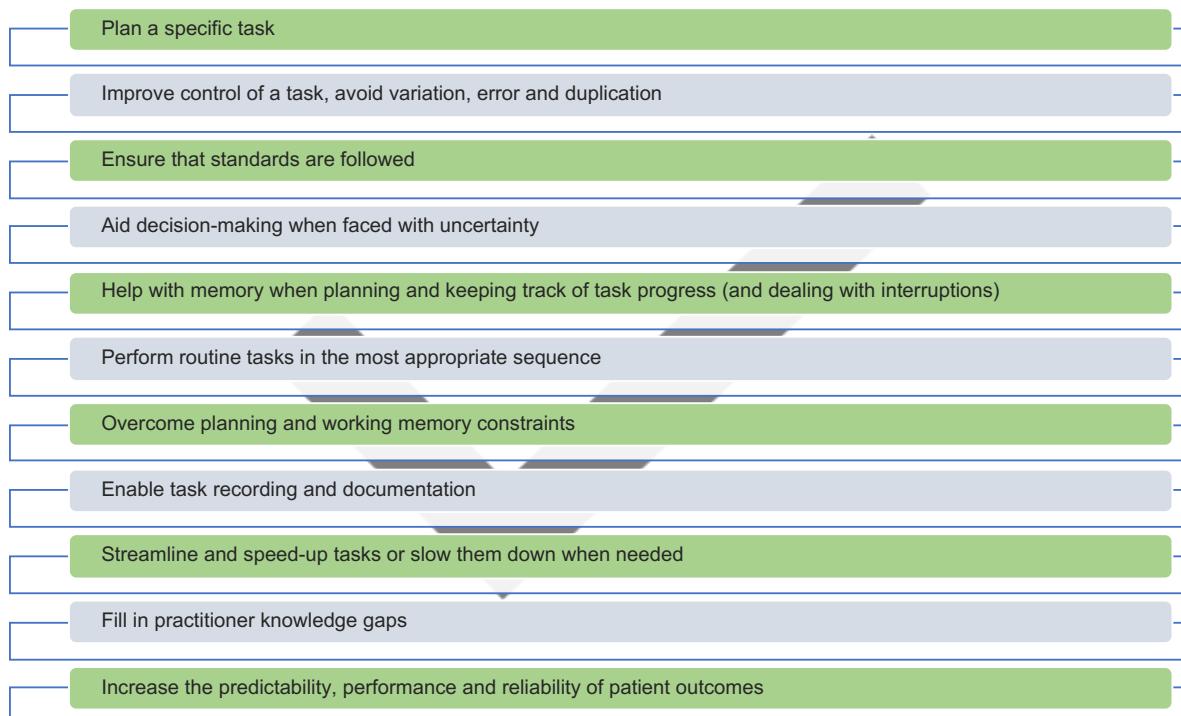


FIGURE 4: COGNITIVE CAPACITIES OF CHECKLISTS

⁴ Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *The New England Journal of Medicine*. 2009; 360(5): 491–99.

⁵ Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. Introduction of surgical safety checklists in Ontario, Canada. *The New England Journal of Medicine*. 2014; 370(11): 1029–38.

⁶ Amaya AAC, Cortés Díaz ML, Gomez LM, Eslava-Schmalbach J. Effectiveness of three intervention programs designed to implement WHO Safe Childbirth Checklist in Colombia. *International Journal for Quality in Health Care*. 2016; 28(1): 47–48.

⁷ Semrau KE, Hirschhorn LR, Delaney MM, Singh VP, Saurastri R, Sharma N, Tuller DE, Firestone R, Lipsitz S, Dhingra-Kumar N, Kodkany BS, Kumar V, Gawande AA. Outcomes of a Coaching-Based WHO Safe Childbirth Checklist Program in India. *The New England Journal of Medicine*. 2017; 377(24): 2313-24.

While early checklist introduction and use resulted in many positive and evidenced outcomes including a decreased amount of infection rates^{8,9}, reduction in the rates of death and readmissions¹⁰, and less in-patient complications due to surgical procedures¹¹, not all checklist implementations have been successful.

This variation in performance has led to some disappointment and increased questioning of the assumption of effectiveness in improving patient safety. For example, one study¹² re-examined the impact of the implementation of surgical safety checklists across a large number of acute care hospitals in Canada. It found that none of the targeted surgical outcomes improved; a finding in stark contrast to an earlier study that reported reductions in morbidity and mortality following checklist implementation.

Due to the inconsistency of results from checklist deployment, there is some concern that many are “neither clinically helpful nor widely used”¹³. Even though the use of checklists has increased substantially, resistance to their use continues. Next, we ask why is that and offer an explanation.

⁸ Bion J, Richardson A, Hibbert P. 'Matching Michigan': a 2-year stepped interventional programme to minimize central venous catheter-bloodstream infections in intensive care units in England. *BMJ Quality Safety*. 2013; 22: 110–23.

⁹ Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, Sexton B, Hyzy R, Welsh R, Roth G, Bander J, Kepros J, Goeschel C. An intervention to decrease catheter-related bloodstream infections in the ICU. *The New England Journal of Medicine*. 2006; 355: 2725–32.

¹⁰ McCarroll ML, ZulloG MD, Roulette D, Mendise TM, Ferris E, Zolton J, Andrews SJ, Gruenigen VE. Development and implementation results of an interactive computerized surgical checklist for robotic-assisted gynecologic surgery. *Journal of Robotic Surgery*. 2014; 9(1): 11–18.

¹¹ Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *The New England Journal of Medicine*. 2009; 360(5): 491–99.

¹² D.R. Urbach et al., Introduction of surgical safety checklists in Ontario, Canada, *N. Engl. J. Med.* 370 (11) (2014) 1029–1038.

¹³ G.D. Schiff, D.W. Bates, Can electronic clinical documentation help prevent diagnostic errors?, *N Engl. J. Med.* 362 (12) (2010) 1066–1069.

THE LIMITATIONS OF CHECKLISTS

At Cognuse, we believe that checklists (and their advocates) take an overly narrow view of the cause and nature of medical errors leading to adverse events. Then, when checklists are implemented, their use and efficacy is too often constrained by the many complicated, unplanned and unknown contextual factors and influences present in diverse in-hospital environments.

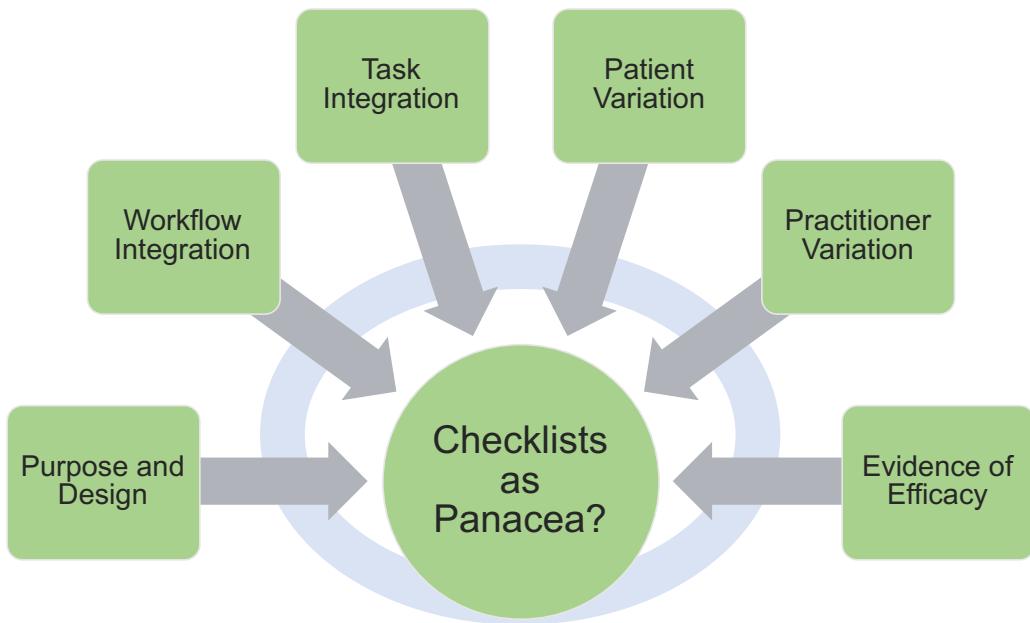


FIGURE 5: CHECKLISTS AS PANACEA? FACTORS INFLUENCING CHECKLIST USE AND EFFICACY

In short, we identify that the provision, compliance and usefulness of checklists in hospitals is often compromised by a number of influencing factors. These relate closely to the diverse, inter-related causes of medical errors described above. At Cognuse, we identify six categories of the factors that limit the use and efficacy of checklists. These are shown in Figure 5 and are listed in Table 2.

TABLE 2: FACTORS DIMINISHING THE USE AND EFFICACY OF CHECKLISTS IN HEALTHCARE

Factor of Use and Efficacy	Issue
PURPOSE AND DESIGN	<ul style="list-style-type: none"> ○ Lack of effective and standardised guidelines for checklist design and use ○ Guidelines cannot always be reduced to a linear task flow ○ Not all tasks are routine, or tasks may need to diverge from routine ○ Uncertain purpose: Planning, memory, decision-aid or flowchart? ○ When is a checklist a checklist? A guideline guide or a single task?
WORKFLOW INTEGRATION	<ul style="list-style-type: none"> ○ Lack of proper consideration and integration with all components of the clinical / non-clinical work system ○ Resources required to use checklists may reduce other resources available to perform other tasks ○ Lack of effective and standardised methodologies for checklist implementation ○ May require organisational changes, e.g., staff roles
TASK INTEGRATION	<ul style="list-style-type: none"> ○ May reduce staff communication when performing task (assumes a 1:1 clinician-task relationship) ○ Format and content may misalign with task ergonomics, e.g., manual dexterity, cognitive difficulty, vital data capture, patient documentation and recording, task recommendation, etc. ○ Difficulties when using more than one checklist (integration, sequence) ○ Cumbersome paper-based checklist designs
PATIENT CONTEXT	<ul style="list-style-type: none"> ○ Complicating patient situation and factors may require a non-standard procedure; may force unnecessary standardisation ○ Can detract from need for patient dialogue interaction ○ May create a false sense of patient safety and reduce the need to look at the holistic picture of the whole patient
PRACTITIONER CONTEXT	<ul style="list-style-type: none"> ○ Resistance to use based on familiarity, ego and/or experience ○ Competes with individual routines of habit and familiarity, cognitive bias or clinical judgement ○ Reliance on intuition when to use or not use a checklist ○ Risk of checklist fatigue
EVIDENCE OF VALUE	<ul style="list-style-type: none"> ○ Lack of consistent measures and standards for checklist evaluation ○ Uncertainty as to what is being measured? Adherence to procedure? Or clinical outcomes? Not performing care at all? Not using a checklist where it should be used, or an error arising when using a checklist?

One solution to address the above factors is digital checklists. Undoubtedly, the conversion from paper to digital formats can improve their use and efficacy¹⁴. Yet problems remain, especially concerning their

¹⁴ Kramer HS, Drews FA. Checking the lists: A systematic review of electronic checklist use in health care. Journal of Biomedical Informatics. 2017; 71: 6-12.

integration into wider care guidelines and workflows, and their capacity to adapt to variations in patient and practitioner context. In our view, if these critical factors are not addressed, then digital versions merely shift the problem of use and efficacy onto a different platform.

Next, we explain how CoNurse from Cognuse addresses the above limitations.

THE CoNurse SOLUTION FROM COGNUSE

What is CoNurse?

CoNurse from Cognuse is a voice-guided application for improving quality and reducing avoidable medical errors and patient harm in hospital settings. The solution is seamlessly integrated into clinical workflows to help ensure that procedural protocols and guidelines are followed each and every time by supporting nurses' memory to remember over 300 protocols.

CoNurse is not a checklist creation and process tool, but rather a guidelines deployment and adherence system enacted through voice-based technology at the point of patient interaction.

CoNurse runs on a standard smartphone (both iOS and Android are available) and is controlled through a Bluetooth headset, ensuring that the user-experience is entirely hands-free, thereby aligning with hospital hygiene and infection control measures.

Guideline management can be improved by providing pre-set templates for the quality department to adapt and adjust regarding to the hospital's specific needs.

How CoNurse works

The flow chart in Figure 6 summarises how CoNurse works.

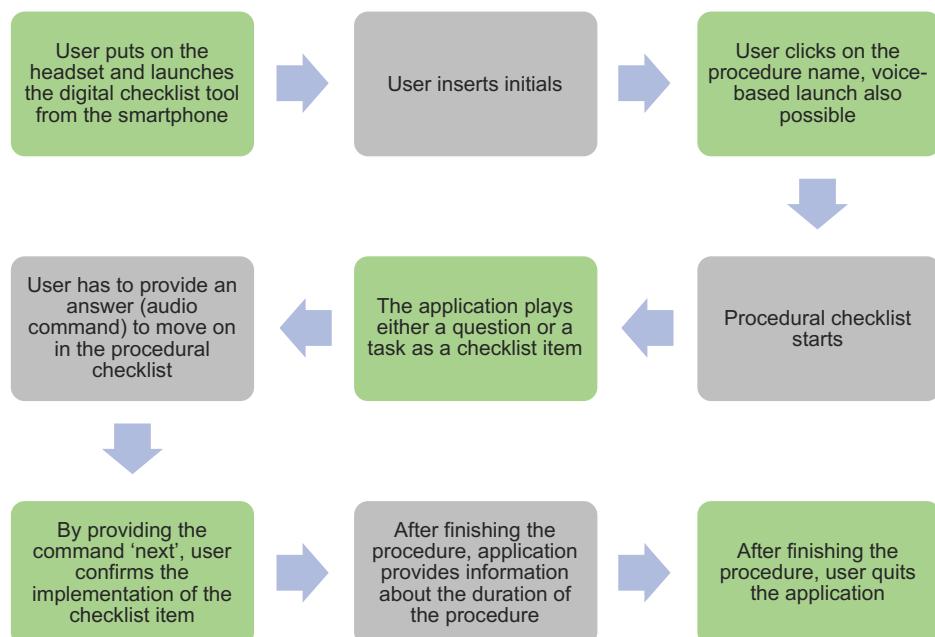


FIGURE 6: HOW CONURSE WORKS

History and piloting

A digital prototype

The development of CoNurse started in a collaboration between Cognuse and North-Estonia Medical Centre (NEMC) in March 2017. During the initiation phase, a prototype of a digital checklist tool was developed. This first prototype incorporated seven procedural nursing guidelines that were processed into a digital sequence of actions to be usable in clinical workflows. Six different procedural guidelines were chosen from the total of 400 nursing guidelines that currently exist at NEMC. These are shown in Figure 7:



FIGURE 7: THE SIX CoNurse PROCEDURAL GUIDELINES DEVELOPED WITH NEMC

In each protocol, guidelines were split into procedural steps. The inclusion and exclusion of certain tasks from the guidelines to be deployed in the application were discussed and agreed with the departmental chief nurse and quality leader. The main objectives of the development of the digital prototype were to:

- Bring distant and therefore inaccessible guidelines closer to the clinical staff
- Convert clinical guidelines to a simplified sequence of actions, making them usable and actionable during clinical work
- Standardise nursing procedures through active usage of procedural guides during clinical work
- Help mitigate problems arising from the work environment such as interruptions and communications challenges
- Improve patient outcomes through reduction of medical errors and complications

The procedures were performed randomly on patients who required the intervention and where it was possible to use the tool. The users could choose when to use the tool. No data were captured on the control state (procedures done without the tool), nor the baseline.

Four of the largest hospitals in Estonia piloted the solution during summer 2018. During the pilots, the solution was tested in 14 different departments by approximately 100 nurses. Altogether, the participating hospitals provided Cognuse with 60 different guidelines for nursing procedures. Each were processed, instructionally designed, reviewed and then converted into corresponding checklist and voice-guided audio formats. Besides nursing procedures, procedures for nursing assistants and caregivers were included in the procedure package of one the hospitals.

Benefits

The following summarises the benefits of the prototype, as expressed by nurses and team leaders:

- Good tool for learning purposes, with junior nurses benefiting the most
- Suitable for patients in intensive care
- Supports experienced staff members while recalling the actions within a procedure or while performing infrequent procedures
- Excellent for procedures involving preparatory steps and setting up medical devices

Challenges

The following are the challenges experienced by users of the prototype:

- Audio guidance causes issues with divided attention between the patient and guidelines, when patient is awake
- Patients need to be better informed about the purpose of the application to avoid them forming a negative perception of the nurses' knowledge and skill levels
- Speech recognition has to be flawless (99% correct) to avoid drop off

Current Use Cases

Various application areas for CoNurse were validated in the pilot phase. Among them, three primary procedural scenarios were identified, standard, critical and infrequent.



Standard procedures

Suitable for nurses who are starting their career. The general feedback towards the tool is that it is suitable for training purposes and/or for the nurses, that are yet unfamiliar with hospital procedures. CoNurse supports junior nurses while learning hospital-specific procedures in the beginning of their career. The use of CoNurse by all the nurses that start working in a specific ward ensures higher level of care standardisation and less care variation. As the content on the tool is periodically revised and therefore up-to-date, young nurses start performing the procedures in a scientifically proven way, not in a way that experienced nurses are used to. An added benefit is reduced stress of inexperienced or newer nursing staff, and reduced need for senior mentoring and oversight. During night shifts especially, more junior nurses are more confident while working.

Critical procedures

One of the most critical procedures that nurses have to perform is blood transfusion. This is a procedure where, if a nurse makes a mistake, the patient can die. Use of CoNurse as a support for blood transfusion helps to avoid situations where blood product is given to a wrong patient. It also ensures that patient identification is done as many times as stated in clinical guidelines. The latest development is addition of the blood scanner functionality to the solution.



The integration with the hospital IT system provides nurses with a powerful tool which can be used for identifying whether a certain blood product is meant for the right patient.



Infrequent procedures

Modern working culture means that nurses often have to work in different wards and hospitals. Some procedures might be done only a couple of times in certain wards. CoNurse guidelines for infrequent procedures support nurses that are not familiar with those activities. Standardising infrequent procedures is an effective way to reduce unwarranted care variation.

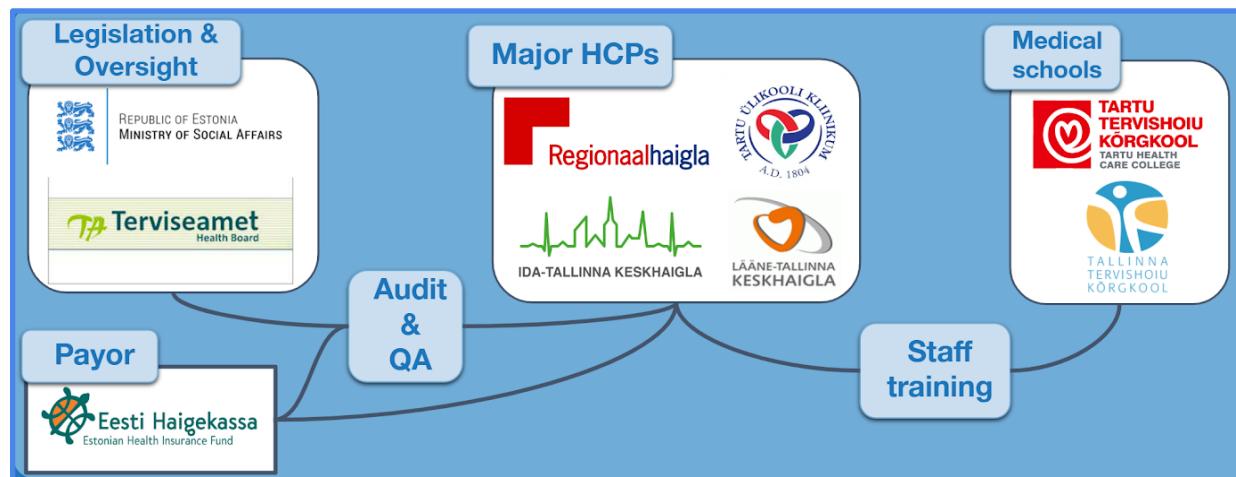
Pilot learning and recommendations

Depending on the particular healthcare system at hand and whether our focus is on national efforts or a more local, smaller set of hospitals, it is beneficial to include as many actors as possible in the overall ecosystem when dealing with aspects of patient safety, centralized guidelines and overall quality of care.

Medical schools are the primary source of nursing professionals for the hospitals and often employ simulation environments and supply digital aids to enhance the learning process. Facilitating an effective back and forth transfer of relevant and validated nursing content is key to reducing variations in comprehension and subsequent nursing practice.

Furthermore, in national healthcare systems one also has to include in the discussions the legislative, oversight and insurance or the payers.

In the case of CoNurse, this was achieved in Estonia with four of the largest hospitals, two medical schools as well as the Ministry of Social Affairs, the Health Board and the national health insurance. The below schema outlines the collaboration and embedded interests of the aforementioned parties.



In order to avoid any bias when piloting a solution in a single ecosystem of 4 large hospitals in Estonia, the Cognuse team took considerable efforts to provide external piloting and validation opportunities for the CoNurse solution. Below we have outlined developments in Denmark and an EU-wide initiative curated by EIT Health.

ProVaHealth (Denmark)

The solution was also tested in a living lab in Denmark. CoLab Denmark is a partnership and cooperation between the Health Innovation Centre of Southern Denmark, the hospitals and municipalities in the region and private companies. CoLab Denmark consists of six Living Labs (so called CoLabs).

The test took place in the room with hospital settings in CoLab Plug & Play. Two nurses were testing CoNurse one person at a time. Normally the nurses do not use audio guides. Instead they carry a booklet in their pockets, which includes guidelines for the most common guidelines procedures. The tested procedures were measurement of Glasgow Coma scale, blood transfusion, and respiratory rate assessment.

Both the nurses believed that an audio guide as CoNurse could be very useful for setting up new medical devices at the unit. They suggested to expand the use of CoNurse for setting up medical devices and believed that the tool would be useful for training or as a working aid for inexperienced nurses.

EIT Health Bridgehead Programme (UK; Germany; Spain; Italy)

CoNurse was awarded a grant from EIT Health to explore further its clinical and commercial model validation options across its partner sites in the EU during 2019. The CoNurse solution will be tried in two European countries with hand-picked clinical sites that have explicitly expressed interest in working with the Cognuse team on the following criteria:

- Settings that experience care variation issues and are exploring new methods, beyond paper or digital checklists, to mitigate them
- Specific patient safety challenges and adverse events
- Staff burnout and turnover problems
- A desire to create a supportive work environment
- A wish to develop a continuous learning, certification and auditing framework

SUPPORTING YOUR PILOT IMPLEMENTATION

The adoption of any new digital solution by hospital staff presents several challenges. A plethora of solutions already exists at most hospitals and there are important barriers to overcome. Moreover, each hospital is different. Even when part of a larger health system or network, the departmental and individual conventions, working methods and work flows can differ considerably.

It is important to consider early all aspects of deployment that any new technology solution must address. Especially, though centralized from the solution architecture standpoint, a solution such as CoNurse must deliver a personalized experience on the institutional, departmental and even individual levels when and where required.

Our structured implementation approach ensures CoNurse is not only introduced seamlessly into any hospital, but also when live, can adapt to changing practices and protocols and expand to include new ones.

The following are the summary steps we recommend are adopted when planning and making an implementation of CoNurse.

1. Review of past quality improvement programmes
2. Identification of influencing contexts, performance factors and patient outcome and clinical targets
3. Assessment of cost impact of meeting targets
4. Identification of critical guidelines and options for piloting CoNurse
5. Collaborative specification of key benchmark and criteria
6. Design of pilot programme
7. Execution of pilot programme
8. Audit of pilot programme





C O G N U S E

Cognuse Inc is a digital health company. The company was founded in 2014 and had offices both in the EU and the USA. Cognuse provides software solutions for hospitals across the globe with a main focus on applications for critical care environments, patient safety and the continuum of care for critical illness. The Cognuse team strongly believes that patient safety can and should be improved with digital technologies and human errors can be minimized with the help of simple and accessible technology.

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