TraceBook: the clinical proof of concept on the intensive care.

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Content

Summary

Background

The effectiveness of checklists is hampered by lack of acceptance and compliance. Recently, a new type of checklist with dynamic properties has been created to provide more specific checklist items for each individual patient. The proof of concept of this dynamic clinical checklist (DCC; BJA 2017 (DOI: 10.1093/bja/aex129)) was tested in a simulation trial with improved outcomes and high acceptance scores. Our purpose is to investigate if the outcomes of this real-life clinical proof of concept study are similar with the outcomes of the simulation trial for the intensive care unit (ICU) ward.

Method

A prospective single center (Catharina Hospital Eindhoven) controlled before-and-after study.
The before period will be used as control group in which ward rounds and nurse handovers will be observed by the investigators for two months. Then TraceBook will be introduced and clinicians, ICU doctors and nurses, will be able to use checklists of TraceBook for ward rounds, their shifts and handovers in which they will be observed for two months. The goal is at least 120 observations per period.

Endpoints

The primary outcome is the percentage of items that were checked per ward rounds and nurse handovers during the before and the after implementation period. Secondary outcomes will be clinical outcomes of admitted patients, pharmacist specific outcomes, specific checkable item related outcomes, and user experience and acceptance scores.

Hypothesis

TraceBook, with the use of digital dynamic checklists, improves compliance to care processes on the intensive care with a high user acceptance score.

1. Background and Rationale

In America, it has been estimated that the deaths of approximately 210.000 hospitalized patients are associated with preventable adverse events each year.[1] Medical record research in the Netherlands reported that each year approximately 10% of the deceased hospitalized patients had a preventable adverse event, of which 42% could have been easily prevented.[2] These large numbers can be explained if one considers that most medical procedures are still based on human memory and physicians also have to work with more sophisticated technologies.[2–4] To prevent these adverse events, a huge diversity of medical guidelines and protocols have been introduced, but it remains a challenge to implement them in daily practice. For example, only 56% of the patients in the Intensive Care Unit (ICU) are treated according to the best practice for which they are eligible.[5] To overcome these problems, a benchmark used in other high-risk industries, the checklist, has been tested as a method in medical care, with encouraging results.[6–11] Haynes et al. showed that the surgical safety checklist standardizes preoperative care, resulting in a cost-effective reduction of morbidity and mortality.[6] Likewise, De Vries et al. demonstrated that implementing multidisciplinary checklists in the surgical pathway, from admission to discharge, significantly reduced the proportion of patients with one or more complications from 15.4% to 10.6% in Dutch hospitals.[8]

However, numerous subsequent studies could not reproduce these beneficial effects, which could be due to the remaining challenge of checklist implementation in medical care, i.e. a lack of acceptance and compliance.[6 8 12–15] A possible cause could be that current static checklists negatively interfere with the daily workflow of caregivers because they do not provide contextual information that makes it easier to complete the checklist and they cannot include or exclude items based on the characteristics of a particular patient and caregiver.

In 2012 Nan et al. created TraceBook, a novel decision support system that integrates workflow management with the use of dynamic clinical checklists in a process-oriented and context-aware manner to make clinical processes more traceable and the people in it more accountable.[16] These new forms of intelligent checklists derive their dynamic property from being connected with the electronic health record (EHR) and other electronic medical databases. These checklists are therefore able to provide real-time relevant information and specific items of patients to the specific user. These hypotheses were tested by De Bie et al in a simulation study in 2014. They showed that the number of checked items per ICU ward round significantly improved and the number of pharmacists calls due to medication alerts would significantly decrease while the acceptance score of the ICU doctors for the dynamic digital checklist of the ICU ward round was high.[17] However, these outcomes were a proof of the concept in a controlled simulated environment and the question remains if these results are reproducible in a real life clinical setting. Our hypothesis is that TraceBooks' dynamic

characteristics can also ensure in real life practice a high satisfaction rate among clinicians while improving the compliance with agreed local care processes.

2. Aim & study endpoints

2.1 Goal/hypothesis

TraceBook, with the use of digital dynamic checklists, improves compliance to care processes on the intensive care with a high user acceptance score.

2.2 Primary endpoint

The efficacy of TraceBook based on the percentage of daily checked checkable items overall and items requiring an intervention per patient.

2.3 Secondary endpoints

2.3.1. Clinical outcomes of patients admitted to ICU will improve after implementation of TraceBooks' checklists for ICU staff:

- Decreased mortality: ICU, in-hospital, 30 and 90 days.
- Decreased length of stay (LOS): ICU, hospital.
- Decreased number of ventilator days.

2.3.2. Pharmacist specific outcomes will improve after implementation of TraceBooks' checklists for ICU staff:

- Decreased umber of daily ICU medication alerts for the pharmacist based on their ICU clinical rules.
- Decreased number of patients per day needing a telephone call by the pharmacists with the responsible clinician of the ICU based on medication alerts by GASTON.

2.3.3. Compliance to specific agreed local care processes will improve after implementation of TraceBooks' checklists for ICU staff:

- Decreased number of gastro-intestinal bleedings (hematemesis or melena), ventilator and hospital associated pneumonia and central-venous-catheter-related bloodstream infections (CRBSIs).
- Decreased number of days without prophylactic or therapeutic anticoagulation, proton pump inhibitors or SDD, if required based on the guidelines.
- Increased percentage of performed spontaneous breathing trials and sedation wake up calls.
- Decreased number of days with intravenous sedatives prescribed (Propofol, midazolam)

- Decreased number of days with opiates being prescribed.
- Decreased number of days with antibiotics being prescribed, while not required for treatment.
- Decreased number of complications registered.
- Decreased number of registered allergies within 24 hours of ICU admission.
- Increased number of days where the required amount of calories is prescribed when patient receives enteral feeding.
- Increased number of automatically or administratively checked items.

2.3.4. User experience outcomes:

- The Attrakdiff questionnaire (appendix 3) at the end of the before period and at the end of the after period to assess the pragmatic and hedonic quality of the electronic health record with paper checklists and TraceBook. Pragmatic factors are, for example, usefulness and usability. Hedonic factors include emotional needs, such as curiosity and identification (http://attrakdiff.de/index-en.html#hello; https://www.uid.com/en/publications/attrakdiff)
    - H1: Pragmatic factor will be better for TraceBooks' checklists compared to the electronic health record with paper checklists.
    - H2: Hedonic factor will be better for TraceBook checklists compared to the electronic health record with paper checklists.
- One questionnaire based on the Technology Acceptance Model 2 (TAM2) at the end of the intervention phase (figure 6 and appendix 4).[18–20]
    - H1: Perceived Usefulness is positively associated with clinicians' attitudes toward using TraceBook.
    - H2: Perceived Ease of Use is positively associated with clinicians' attitudes toward using TraceBook.
    - H3: the perception of perceived Ease of Use of TraceBook will have a positive effect on Perceived Usefulness.
    - H4: the perception of the subjective norm of TraceBook will have a positive effect on Perceived Usefulness.
    - H5: the perception of the subjective norm of TraceBook will have a positive effect on clinicians' attitudes toward using TraceBook.
    - H6: the perception of the Image of TraceBook will have a positive effect on Perceived Usefulness.

- H7: the perception of Job Relevance of TraceBook will have a positive effect on Perceived Usefulness.
- H8: the perception of Output Quality of TraceBook will have a positive effect on Perceived Usefulness.
- H9: the perception of Results Demonstrability of TraceBook will have a positive effect on Perceived Usefulness.
- H10: the perception of Facilitation of TraceBook will have a positive effect on clinicians' attitudes toward using TraceBook.

3. Study design

3.1 Design

Prospective single center (Catharina Hospital Eindhoven) controlled before-and-after study.

The estimated before period of two months for the control group will be: 04-06-2018 till 06-08-2018. The estimated after period of two months for the intervention group, TraceBooks'checklists are available for ICU staff, will be: 20-08-2018 till 22-10-2018.

3.2 Setting

This study will be conducted in the Intensive Care Department of Catharina Hospital Eindhoven, a tertiary hospital in The Netherlands.

4. Research participants

4.1 Participants

The participants will be the intensive care staff of the Intensive Care Department of Catharina Hospital Eindhoven. During the before period they will work as usual, while after introducing TraceBook they will be able to use this clinical decision support system that provides them digital patient specific checklists of patients who are admitted on the Intensive Care of the Catharina Hospital.

4.2 Recruitment of participants

ICU management will be informed about the study design. If management approves the design of this study then the floor manager and executive manager will sign this protocol document. The ICU staff will be informed about the study design and the fact that their participation in ward rounds and handovers may be observed. Information will be provided during a presentation before 01-06-2018 and a message in the newsletter about the concept of this study will be published before the start of the study. Participants can indicate that they do not want to be observed. If participants object observation than the ward rounds and shift handovers in which they participate will not be observed. Observations will only be done for this research objective.

4.3 Sample size calculation

Since there is no previous clinical study it is difficult to perform a sample size calculation based on clinical evidence. For this sample size calculation we will therefore use the outcomes from the pilot-simulation-study of De Bie et al.[21]

In the simulation study a significant difference was found in the percentage of checked items and critical items during ward round with 116 observed scenarios (60 observation in the control group and 56 in the intervention group). A power sample size calculation with G*Power (version 3.1.9.2.; Franz Faul, Universitiet Kiel,Duitsland) based on the median percentage of checked items during the simulation study (73.6% (IQR: 64.5–79.3) for the control group and 100% (IQR: 100.0–100.0) for the intervention group with a $p<0.001$ and z-score =7.74) shows that 44 observations are needed during both periods to achieve a power of 95% with an α of 0.05. In this study some flaws were incorporated in the simulation scenarios that generated some specific relevant items. However, this incorporation of flaws cannot be controlled in a clinical proof of concept study. Therefore we estimate that the number of observation must be more, aiming on 120 observations for both the before and the after group.

Based on the annual admission rate of patients on the IC in 2016 being reassessed for a period of 2 months we estimate to be able to perform at least 4 observations per working day, which is at least 160 observations in 2 months. However, since this is a before-after observational study we will try to perform as many observations as logistically possible.

5. Study conduct

5.1. Workflow of study groups

This is a controlled before-after study starting with two months of observation of local standard of care followed by the implementation of TraceBook on the ICU with two months of observation. During the before period members of the research team will perform observations of ward rounds and nurses' shift handovers. To overcome the Hawthorne effect as much as possible observations will be performed behind a computer, out of the sight of the observed clinicians, which shows footage of the room in which the ward round or shift handover is without any actual recording of footage. A headphone will be used to listen to the conversations without any recording.
The observation will be scored based on the number of items that are relevant for the patient. This number of items will be generated by TraceBook and printed on paper. During the before period the generated checklist items of TraceBook will only be available for the observers of the research team (figure 1). The observer then checks if an item is discussed or registered. The current used paper checklist will be available as usual.
After the introduction of TraceBook ICU clinicians will be able to use TraceBook and check items for the ward round and nurses's shifts and handovers for a period of two months. During this after period observations will be done and an item will be considered as checked if it is checked within TraceBook or is discussed in the room (figure 2). The current used paper checklist will still be available for clinician to use if desired.
A second opinion of the generated items by TraceBook will be performed by the observers of the research team for each patient during both periods. In the event that they decide a generated item by TraceBook was not applicable to the patient, an independent physician of the intensive care (not part of the research team) will arbitrate and a consensus will be reached on whether to include the item or not for analysis.

In addition, during both periods, each day pharmacists will count the number of alerts that were provided by GASTON based on predetermined pharmacological clinical rules for the ICU. They will also assess the number of patients for whom they have to inform the responsible clinician about the alert.

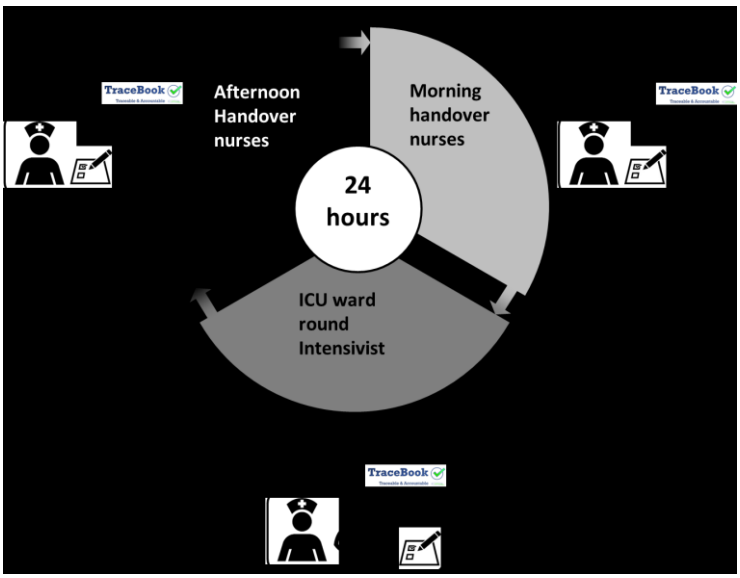


Figure 1. Standard operating procedure during before (control) period; TraceBook is only available for the research team (observers).

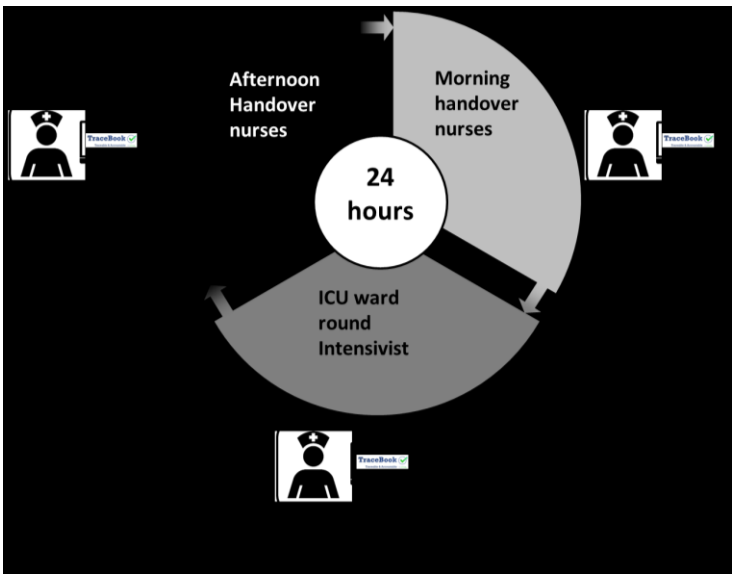


Figure 2. Standard operating procedure during after (intervention) period; TraceBook is available for ICU clinicians and the research team.

5.2 Data measurements

5.2.1 Tools used by observers

The following tools will be used to collect the described data in *"6.1 study parameters":*

Electronic health record (EHR):

Investigators of the research team will use the EHR to collect:

- Patient characteristics of patients admitted to ICU during the study.
- Clinical outcomes of patients admitted to ICU during the study.
- Registered complications and prescribed medication.
- Registered allergies in the EHR, within 24 hours after ICU admission.
- The calculated and prescribed amount of calories of enteral or parenteral feeding.

TraceBook:

TraceBook is a novel decision support system that integrates workflow management with the use of dynamic clinical checklists in a process-oriented and context-aware manner to make clinical processes more traceable and the people in it more accountable.[16 21] These new forms of intelligent checklists derive their dynamic property from being connected with the EHR and other electronic medical databases. These checklists are therefore able to provide real-time relevant information and specific items of patients to the specific user.[21] There will be two checklists available for the clinician:

1. TraceBook's ICU ward round checklist for physicians (appendix 1):

   The content is based on the currently available paper checklist (appendix 1A; with FASTHUGS mnemonic) and locally applied ICU related clinical rules (appendix 1B).

2. TraceBooks' nurses' handover and shift checklists (appendix 2):
   The content is based on the paper handover checklist (appendix 2A) and currently required administration within the EHR (appendix 2B).

With TraceBook the following parameters will be generated and collected:

- The number of checkable items per patient.
- The number of checked items:
  - Before period: completed by the observers based on their observation. The observer observes if the item is checked by registering on paper, in the EHR, or if it is only discussed in the room.
  - After period: completed by the ICU staff and observers based on their observation . The observer observes if the item is checked by registering on paper, in the EHR, or if it is only discussed in the room..

Attrakdiff esurvey:

To assess the pragmatic and hedonic quality of the EHR with paper checklists and TraceBook for daily use during ICU ward rounds and ICU nurses' shifts and handovers.

TAM-2 based questionnaire:

To assess the user acceptance of the EHR with paper checklists and TraceBook for daily use during ICU ward rounds and ICU nurse handovers. The questions of this questionnaire are based on the international accepted and validated Technology Acceptance Model 2 (TAM2). Questions will be presented to the participants with a survey on paper and a survey made with SurveyMonkey. Participants can only participate once.

5.2.2 Participant questionnaires

All ICU staff, physicians and nurses, will be asked to complete the attrakdiff esurvey and the TAM-2 survey during the study.

The Attrakdiff esurvey:

To assess the pragmatic and hedonic quality of the EHR with paper checklists and TraceBook for daily use during ICU ward rounds and ICU nurses' shifts and handovers. The model of the attrakdiff esurvey separates four essential aspects:

1. The product quality intended by the designer.
2. The subjective perception of quality and subjective evaluation of quality.

3. The independent pragmatic and hedonic qualities.
4. Behavioral and emotional consequences.

How the pragmatic and hedonic qualities influence the subjective perception of attractiveness giving rise to consequent behavior and emotions is illustrated in figure 3. The survey consists of 28 seven-step items whose poles are opposite adjectives. (site; http://attrakdiff.de/sience-en.html).

The attrakdiff esurvey will be send to all ICU staff during both periods:

- Before period: ICU physicians and nurses will complete this esurvey at the end of the after period (figure 5). The participation is voluntary and ICU staff receives the esurvey by email with a reminder after one week.
- After period: ICU physicians and nurses will complete this esurvey at the end of the second month of the after period (figure 5). The participation is voluntary and ICU staff receives the esurvey by email with a reminder after one week.

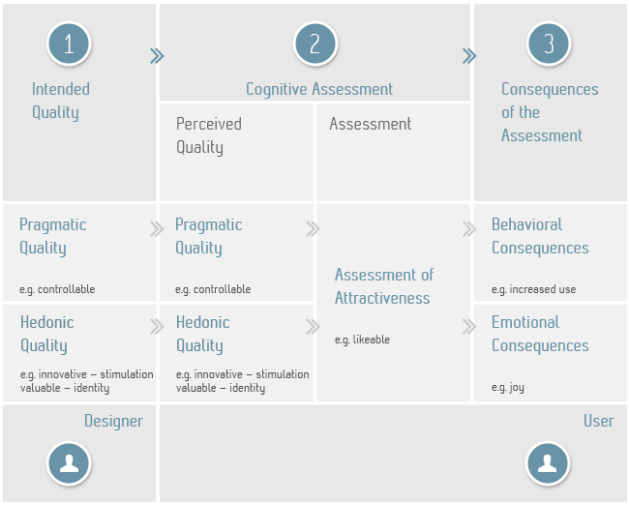


Figure 3: Model of the attrakdiff esurvey.

TAM-2 based questionnaire:

The TAM-2 model is used to assess the user acceptance the EHR with paper checklists and TraceBook. This model contains two key constructs, perceived usefulness and ease of use, with several variables, subjective norm, image, job relevance, output quality and results demonstrability, that influence the user acceptance of TraceBook (figure 4).[19] The definitions of the variables are described in table 1.The TAM-2 based questionnaire that assesses the user acceptance of TraceBook contains 58 questions on a 5-point Likert scale (with 1 totally disagree, 2 disagree, 3 neutral, 4 agree, and 5 totally agree) that cover all these key constructs and variables (table 2). The participation to complete the questionnaire is always voluntary. The TAM-2 based questionnaire will be send to all ICU staff by e-mail (SurveyMonkey), with a reminder after one week. It will also be available on paper on the ICU. Participants can only participate once.

Figure 4. *TAM-2 model:*

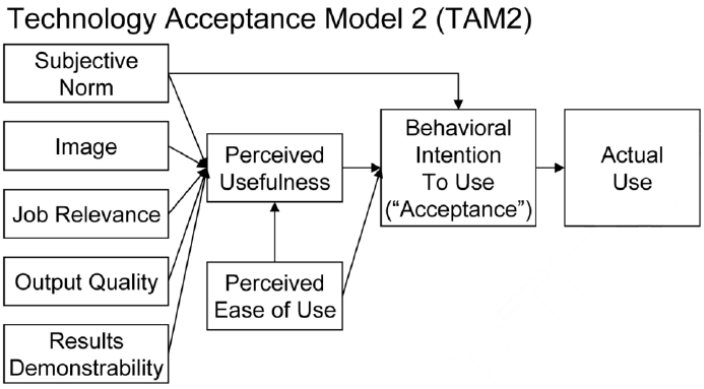


Table 1. Definitions of the key constructs and variables of TAM-2.[19]

Key constructs and variables	**Definitions applicable to TraceBook**
Perceived usefulness	A person's perception that using TraceBook will enhance job performance (HK)
Perceived Ease of Use	A person's perception that using TraceBook will be free of effort (HK)
Subjective norm	A person's perception that most people who are important to him think he should or should not use TraceBook (4)
Image	A person's perceived image of TraceBook that influence the perceived usefulness (HK)
Job Relevance	A person's perception regarding the degree to which TraceBook is applicable to his/her job (WU)
Output Quality	the degree to which an individual judges the effect of TraceBook. 20
Results Demonstrability	Tangibility of the results of using TraceBook 14

Table 2. Distribution of the questions in the TAM-2 questionnaire in the variables of the TAM-2 model:

Variable	Subvariable 2	Question
Age, experience, sex and job		Q1-3
Perceived usefulness	Subjective norm	T4-7; US10
	Image	U10, 14; US 1-9; G 3,7
	Job Relevance	U1, 13, 14; G2
	Output Quality	U2,3,4,8, 11; G1, 5
	Results Demonstrability	U5-7, 9, 12
Perceived Ease of Use	Ease of Use	EU 1-11; G4
Facilitation		T1-3, 8; EU 12-13
Other, not TAM-2 related questions.		G8

5.3 Withdrawal of consent

In this study participation of the ICU staff is completely voluntary. Participants can always abort participation or disagree to further observation at any moment during the study. The use of TraceBook is also not mandatory. They do not have to provide any reason for both issues. If a participant want to withdrawal all collected data till the moment of withdrawal will be available for analyses.

6. Methods

6.1 Study parameters

Primary endpoint:

Efficacy:

The efficacy will be determined by comparing the percentage of items, generated by TraceBook, that were vocally and/or administratively checked during the before period with the percentage of vocally or administratively checked items in TraceBook during the after period. The percentage per patient is used since the number of items can vary as TraceBook generates patient specific checkable items.

Secondary endpoints:

Patient characteristics of the patients who were admitted during the before and after period:

- Medical history: diabetes mellitus, recent surgery, number of chronic diseases, charlson comorbidity index.
- Severity of the disease at admission: APACHE IV, Standardized Mortality Ratio and qSOFA
- Age, sex
- Reason for ICU admission
- Laboratory measurement at admission: Hemoglobin, leukocytes, bilirubin, creatinine, urea, CRP, lactate, P/F ratio

Clinical outcomes of the patients who were admitted during the before and after period:

- Mortality; ICU, in-hospital, both 30 as 90 day.
- Length of stay (LOS) in ICU, LOS in hospital
- The number of ventilator days.

Pharmacist specific outcomes during both periods:

- Number of daily ICU medication alerts for the pharmacist based on their ICU clinical rules.
- Number of patients per day needing a telephone call by the pharmacists with the responsible clinician of the ICU based on medication alerts by GASTON.

Checkable item specific outcomes during both periods:

- Number of gastro-intestinal bleedings (hematemesis or melena), ventilator and hospital associated pneumonia and central-venous-catheter-related bloodstream infections (CRBSIs).

- Number of days without prophylactic or therapeutic anticoagulation, proton pump inhibitors or SDD, if required based on the guidelines.
- Number of days with intravenous sedatives prescribed (propofol, midazolam)
- Number of days with opiates being prescribed.
- Number of days with antibiotics being prescribed.
- Number of complications registered ICU clinicians in the EHR and by the observers (research team).
- Number of registered allergies within 24 hours of ICU admission.
- Number of days with the correct amount of required calories prescribed for enteral or parenteral nutrition.
- Number of automatically, or discussed and registered observed checked items per patient per day.

User experience outcomes:

- Attrakdiff esurvey (appendix 3) to assess the pragmatic and hedonic quality. [22 23]
- TAM-2 based questionnaire (appendix 4). [18–20]

6.2 Randomization and blinding

Participants will not be randomized since this is a controlled before-after observation study. Both participants and researcher can also not be blinded during both periods since the researchers need to use the TraceBooks' checklists during both periods and participants only during the after period.

6.3 Investigation procedure

The timeline of the study procedures is demonstrated in figure 5.

Before (control) period (2 months):

- ICU staff will perform their daily work by local standard of care, which also contains applying available paper checklists and EHR that can be used if desired (appendix 1 and 2).

- The daily ICU ward rounds and nurses' handovers are observed during working days by investigators of the research team out of sight of the ICU staff.

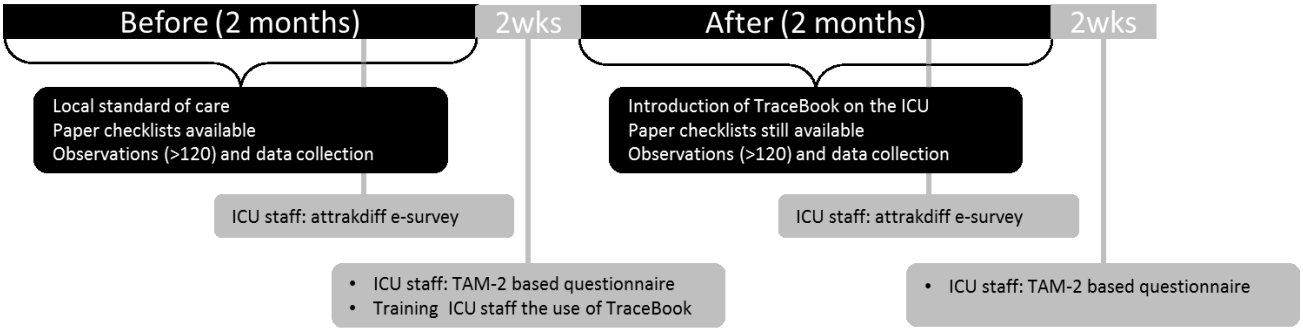
- In the second month ICU staff receives the Attrakdiff esurvey to assess the pragmatic and hedonic quality of the EHR (Chipsoft) with paper checklists. A reminder is send after one week if not being completed by then.

- After two months ICU staff receives the TAM-2 based questionnaire to assess the user acceptance of the EHR (Chipsoft) with paper checklists. A reminder is send after one week if not being completed by then.

After (intervention) period (2 months):

- ICU staff will perform their daily work by local standard of care, in which now also the checklists of TraceBook (content is based on currently applied paper checklist and clinical rules; appendix 1 and 2) are available besides the paper checklists and EHR. Both can be used if desired.
- In the second month ICU staff receives the Attrakdiff esurvey to assess pragmatic and hedonic quality of TraceBook. A reminder is send after one week if not being completed by then.
- After two months ICU staff receives the TAM-2 based questionnaire to assess the user acceptance of TraceBook. A reminder is send after one week if not being completed by then.

Figure 5: The timeline of the study.



6.4 Loss to follow up

ICU staff will be considered loss to follow up if they abort participation or disagree to further observations. The data till the withdrawal will be still available for analyses.

7. Ethics consideration

In the Netherlands this study falls outside the scope of the Medical Research Involving Human Subjects Act (WMO) since the participants, ICU staff, are not subjected to procedures or are required to follow rules of behavior. The CDSS TraceBook does not subject users to follow procedures or specific rules as it only advises the users on some topics. The users, ICU staff, always decide the procedure and can therefore decide to agree, or not, with the advice of a TraceBooks' checklist and can always decide to not use TraceBook as this is not mandatory. The advices of TraceBooks'checklists are also based on the local guidelines.
For this study we will only use (medical) data of admitted patients on the ICU that already needs to be registered as part of their treatment.

8. Statistical Analysis

Statistical analyses shall be performed with SPSS version 23.0/24.0 (IBM Corp. Armonk, NY, USA), AMOS 23 (IBM Corp. Armonk, NY, USA) or with Excel 2013 (Microsoft Office). The distribution of continuous variables will be assessed with Kolmogorov-Smirnov tests. The patient and participant characteristics will be described as descriptive statistics.

Normally distributed data will be analyzed with the following parametric tests: The chi-square test, independent-samples t-test, the Mann-Whitney U test shall be used to analyze the data if the data is not normally distribute, and a two-sided p-value less than 0.05 will be considered statistical significant.

The results of the TAM-2 based questionnaire will be analyzed with SPSS version 23.0/24.0 (IBM Corp. Armonk, NY, USA) and AMOS 23 (IBM Corp. Armonk, NY, USA). The correlation between variables will be measured by Pearson's correlation and regression tests. Internal consistencies among scale items will be calculated using Cronbach's alpha. Internal consistencies are given in table 3.
The Structural Equation Modeling (SEM) will be used to analyze the predicted paths. SEM is the preferred approach for analyzing interactions between multiple independent and depended variables, such as those used in this study. The proposed conceptual path model is described in figure 6. A p-value of less than 0.05 will be considered as statistical significant.

Cronbach's alpha	Internal consistency
$0.9 \leq \alpha$	Excellent
$0.8 \leq \alpha < 0.9$	Good
$0.7 \leq \alpha < 0.8$	Acceptable
$0.6 \leq \alpha < 0.7$	Questionable
$0.5 \leq \alpha < 0.6$	Poor
$\alpha < 0.5$	Unacceptable

Table 3: Internal consistencies base on Cronbach's alpha

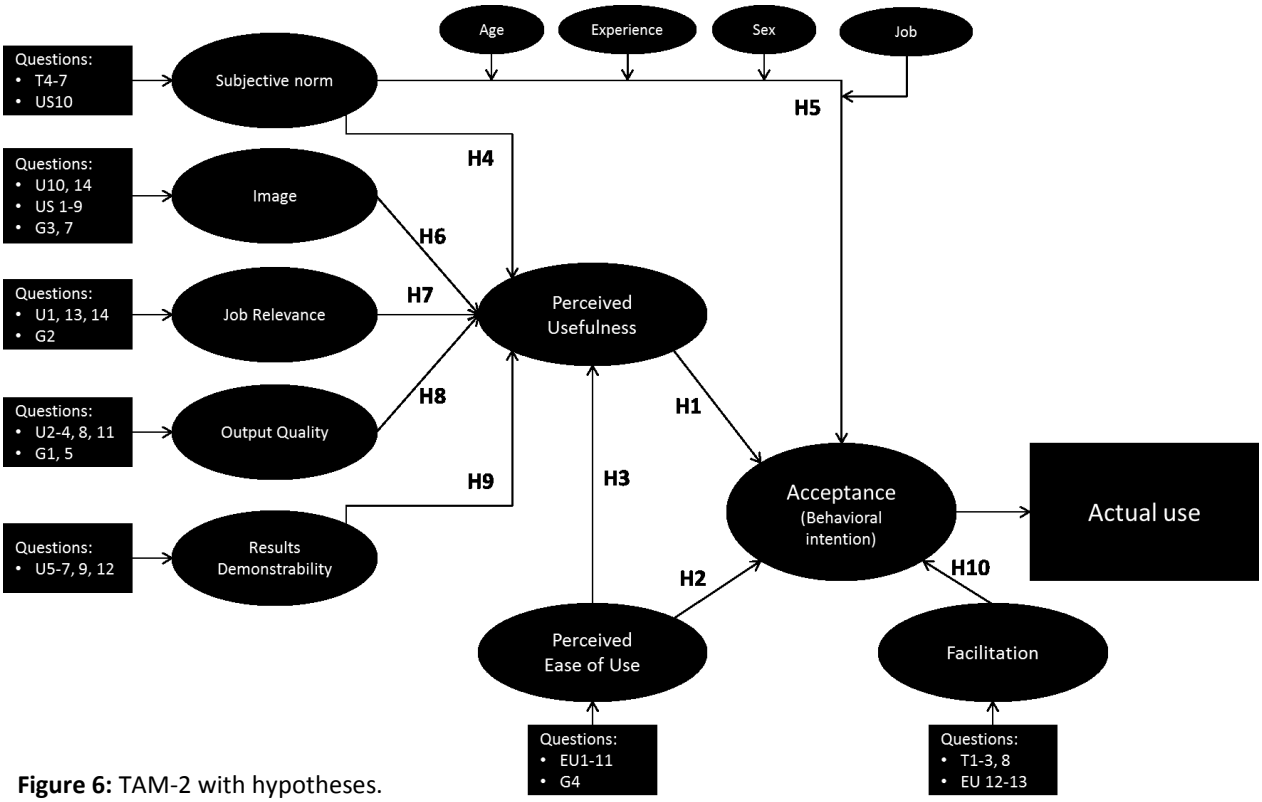


Figure 6: TAM-2 with hypotheses.

9. Consent & data protection

ICU management will be informed about the study design. If management approves the design of this study then the floor manager and executive manager will sign this protocol document. The ICU staff will be informed about the study design and the fact that their participation in ward rounds and handovers may be observed during the study at least one week before the study starts. Information will be provided during a presentation and a message in the newsletter about the concept of this study will be published before the start of the study. Participants can indicate that they do not want to be observed. If participants object observation than the ward rounds and shift handovers in which they participate will not be observed. Observations will only be done for this research objective.

All digital data will be stored in databases on a password-protected computer and can only be accessed by the local or principal investigators. Confidentiality of participants and patients will be protected by anonymizing all results. No identifiable details will be recorded as part of the study documentation.

The study will comply with the principles of the World Medical Association Declaration of Helsinki good clinical practice.

10. Administration

10.1 Administration and storage of research data

Research data will consist of digital completed checklists by observers (before period) and participants (after period) combined with patient characteristics and outcomes from the EHR. All research data will be analyzed and noted in digital databases of SPSS and Excel. The data will be noted in these databases in such a way that the data cannot be traced back to the participants or the patients that were admitted on the ICU. These databases will be saved on the internal server of the principal investigator within the Catharina Hospital Eindhoven. All data on paper will be scanned and digitalized, so that all digital data will be stored for at least ten years after the investigation on an internal sever in the hospital.

An account on the website http://attrakdiff.de will be used to generate and receive the results of the Attrakdiff esurvey. These results will be stored on the internal server of the principal investigator within the Catharina Hospital Eindhoven. The research hospital account of SurveyMonkey will be used send the TAM-2 based questionnaire to the participants and generate the outcomes. These outcomes will be stored on the internal server of the principal investigator within the Catharina Hospital Eindhoven.

10.2 Reporting amendments to the Ethics Committee

Amendments will be communicated to the relevant Ethics Committee, which will communicate with the principal investigator.

10.3 Reporting the progress of the investigation to the Research Ethics Committee

The principal investigator will inform the responsible local Research Ethics Committee, if required, after completing the study within eight weeks. If the investigation is terminated prematurely, the principal investigator shall inform the local REC about the termination.

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12. Attachments

Appendix 1: Content on which TraceBooks' dynamic digital checklist is based for the ICU ward round (for intensivists and residents) with an image as example.

1A. The currently used paper checklist (local standard of care).

The paper checklist.

Add Patient sticker

Department IC – Checklist IC rounds

Date: _____/_____/_____

F Enteral feeding possible?
Calories sufficient?
Recent defecation?
A Suitable pain relief?
Can / Should dose be adjusted? (VAS)
S Sedatives and / or antipsychotics prescribed?
Adjust dose? (RASS or CAM-ICU)
D Pressure Ulcer present? Prophylaxis / treatment needed?
T Indication for therapeutic anticoagulant?
Reason for bridging?
Adequate thrombosis prophylaxis?
H Headboard is at least 30 degrees up?
Indication for protective ventilation?
U Ulcer prophylaxis?
G Glucose protocol?
S SDD protocol? (selective intestinal decontamination)

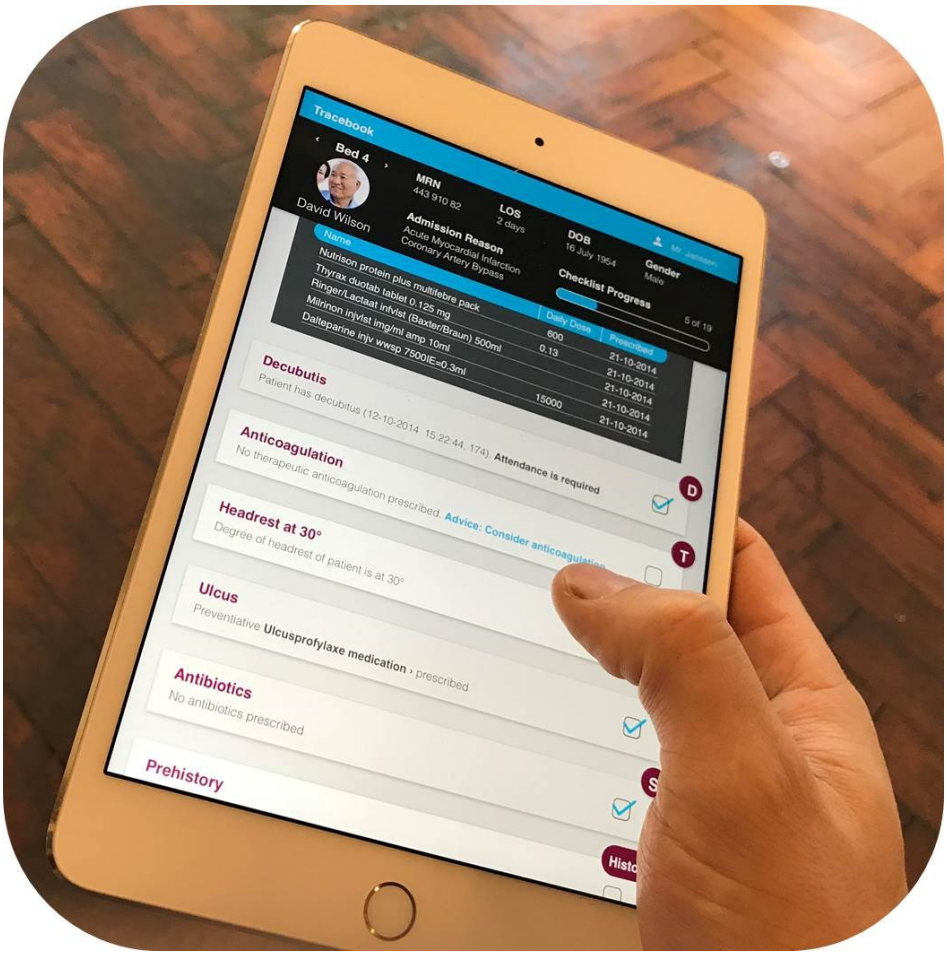
Lines
Place?
Since?
Antibiotics
Since?
Reason? (Cultivate?)
Levels?
Stop date?
Prior history
Does the prior history give reasons to deviate from the normal procedures?
Physical examination
Are there new aspects leading from the physical examination that require policy change?
Laboratory examination
Are there laboratory results that require a change of policy?
Radiological examination
Requires the radiological examination results a change of policy or intervention (position tube, pneumatic, etc.)?
Conclusion
Working diagnosis?
Goal formulated?
Communicated with all involved parties (nurses, consultants, family)?
Complications
Scored in EHR?
NICE data completed?

1B. The currently applied clinical rules (local standard of care).

Clinical rule:	
1.	The system checks if Methotrexate, with folic acid is administered; If so, it will provide a checkable item to check if dosage is correct and if folic acid is administered.
2.	The system checks if nephrotoxic medication is administered in case of kidney dysfunction; If so, it will provide a checkable item to check if nephrotoxic medication is needed or if the dosage can be changed.
3.	The system checks if laxatives are started simultaneously with the administered opiates; If not, it will provide a checkable item to start laxatives when there are no contraindications
4.	The system checks if aminoglycosides are administered; If so, it will provide a checkable item to check if aminoglycosides levels are monitored and if dosage is correct.
5.	The system checks if there is a hyper- or hypokalium and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check potassium levels and medication.
6.	The system checks if there is a hyper- or hyponatrium and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check natrium levels and medication.
7.	The system checks if there is a hyper- or hypocalcemia and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check calcium levels and medication.
8.	The system checks if stress ulcer prophylaxis is started and checks if NSAIDs are started. If not so, it will provide a checkable item to start stress ulcer prophylaxis and to check if NSAID is necessary.
9.	The system checks if the patient with heart failure gets medication that is contraindicated in heart failure. If so, it will provide a checkable item to check if this medication is necessary and to evaluate if it can be stopped.
10.	The system checks if the INR is >6. If so, it will it will provide a checkable item to suggest to start Vitamin K.
11.	The system checks if Lithium is prescribed for the patient and if blood levels of Lithium are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of lithium or if the dosage of Lithium needs to be modified.
12.	The system checks if Digoxin is prescribed for the patient and if blood levels of Digoxin are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of Digoxin or if the dosage of Digoxin needs to be modified.
13.	The system checks if Clozapine is prescribed for the patient and if blood levels of Clozapine are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of Clozapine or if the dosage of Clozapine needs to be modified.
14.	The system checks if Phenytoin is prescribed for the patient and if blood levels of Phenytoin are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of Phenytoin or if the dosage of Phenytoin needs to be modified.
15.	The system checks if enteral feeding and levothyroxine are given at the same time. If so, it will provide a checkable item to suggest skip one bolus of enteral feeding or pause enteral feeding for half an hour if given continuously.
16.	The system checks if dalteparin dosage >5000IE/day if the patient is >80kg. If not so, it will provide a checkable item to start daltaparin 5000IE/day.
17.	The system checks if the patient gets Daltaparin and whether the INR is two consecutive times > 2.2 If so, it will provide a checkable item to suggest pausing the Dalteparin.
18.	The system checks if the patient gets Amiodaron 1200mg/24hr >3 days If so, it will provide a checkable item to suggest to correct the dosage to 600mg/24hr or start oral

	Amiodaron.
19.	The system checks if Vancomycin is prescribed for the patient and if blood levels of Vancomycin are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of Vancomycin or if the dosage of Vancomycin needs to be modified.
20.	The system checks if Amikacin is prescribed for the patient and if blood levels of Amikacin are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of Amikacin or if the dosage of Amikacin needs to be modified.
21.	The system checks if selective oral decontamination is prescribed for patient admitted on the IC >48 hours. If not so, it will provide a checkable item to suggest starting selective oral decontamination.
22.	The system checks if the patient has an enteral tube and if the prescribed medication is eligible to be given through the enteral tube. If not so, it will provide a checkable item to suggest to change the ineligible medication to medication that can be given intravenously of with the enteral tube.
23.	The system checks if a venous or arterial line is in situ >7 days. If so, it will provide a checkable item to consider change the line or evaluate if the line is still needed.

1C. Image as example of TraceBooks' dynamic digital checklist for the ICU ward round.



Appendix 2: Content on which TraceBooks' dynamic digital checklist for the nurses' shift and handover checklists are based with images as example.

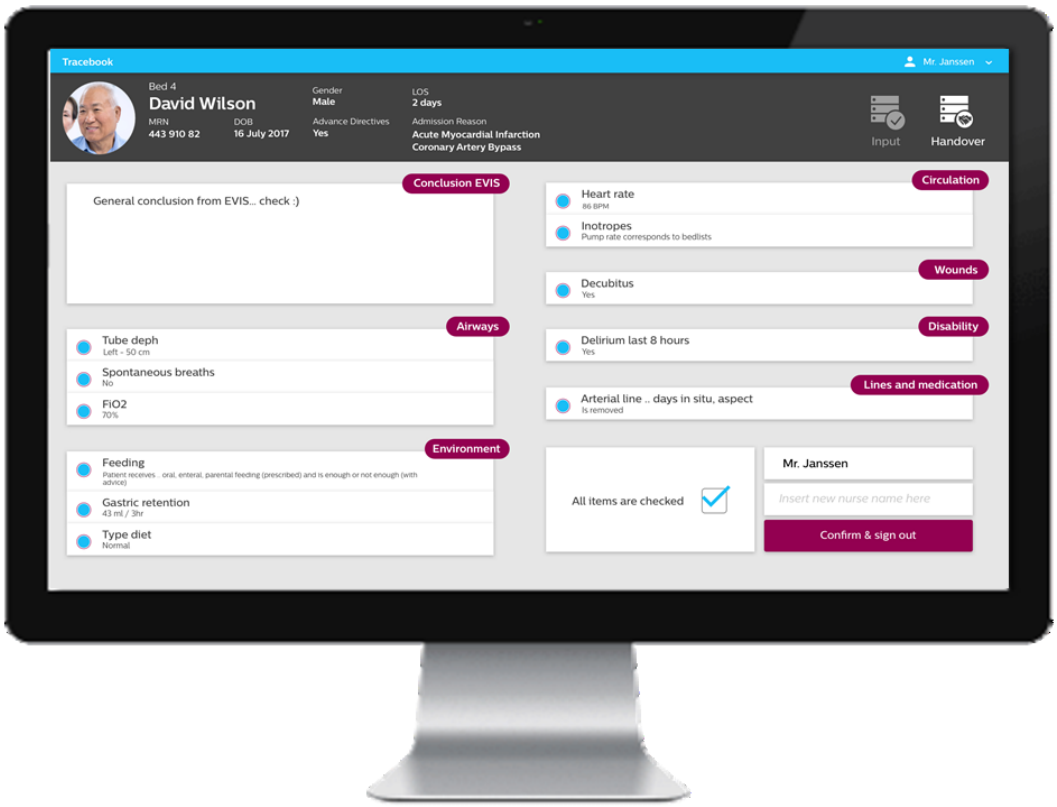
2A. Content current paper nursing handover checklist.

Date ../../….	15.00	23.00	07.30
Ventilator settings on bed list correspond to the ventilator?			
Humidifier is on?			
Respiration (VUE link) is secured?			
Medication Pump rates correspond to rates on bed list?			
Shelf lives of all medication syringes in pumps are sufficient?			
Are any medication syringes in pumps empty <2hours.			
All medication is checked			
All supposed interventions are double checked on the bedside list.			
Name nurse			

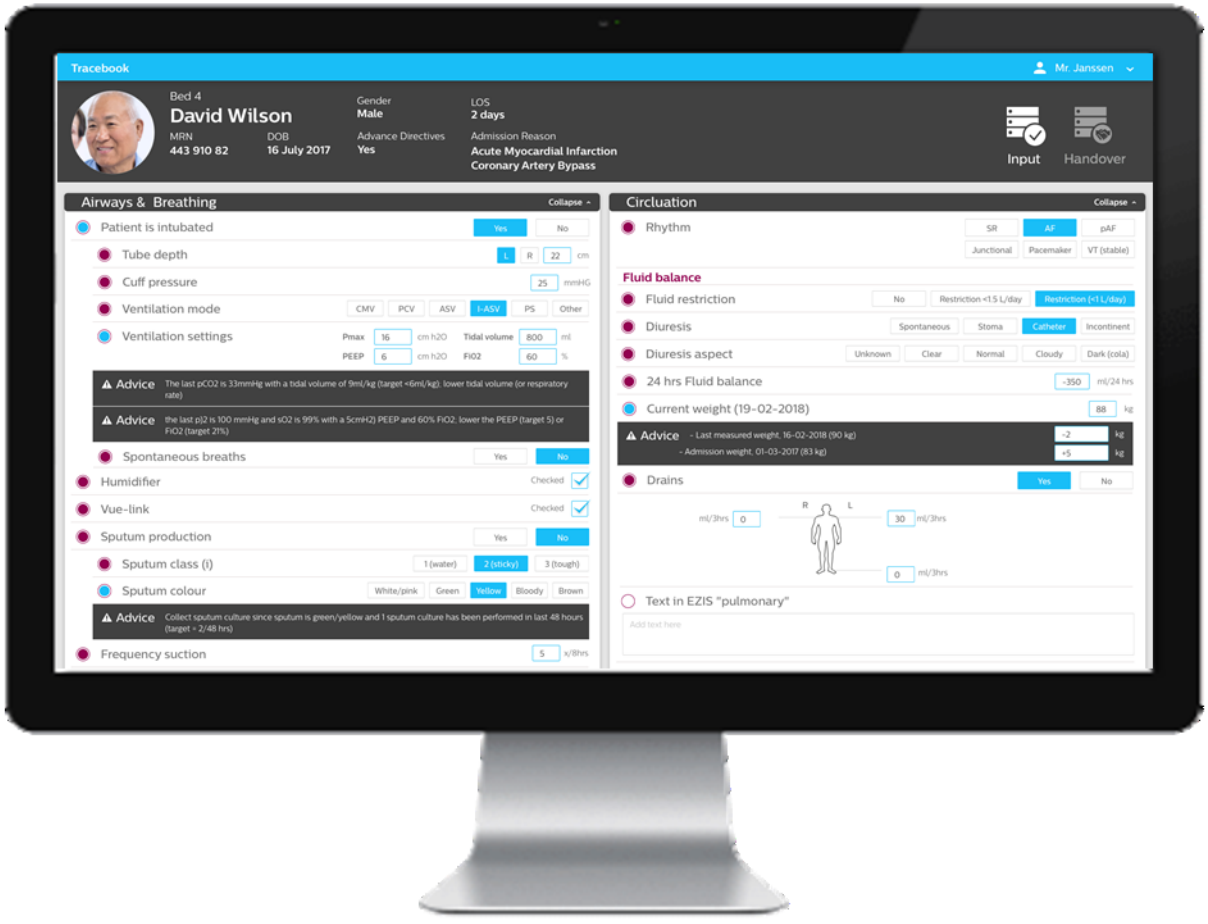
2B. Content current digital nursing shift checklist (current administration in EHR).

General	Open text field
Hemodynamics	Open text field
Pulmonary	Open text field
Tube position	Left / Right / middle
Tube depth	…cm
Renal	Open text field
Fluid balance	… ml
Diuresis	…ml/24hrs
Gastro-intestinal	Open text field
Required amount of calories	Open text field
Freq. defecation	…x
Wounds/drains	Open text field
Cerebral	Open text field
Delirium	Yes / No / possible (if yes CAM-ICU)
RASS	Score -5 to 4.
Pain	Open text field
VAS	1-10
Social	Open text field
Skin	Open text field
Weight	…kg
Weight deviation from admission weight	…kg
Extra information	Open text field

2C. Image as example of TraceBooks' dynamic digital checklist for nursing handover.



2D. Image as example of TraceBooks' dynamic digital checklist for nursing shift.



Appendix 3: Attrakdiff esurvey.

https://esurvey.uid.com/survey/#!wizard/uid-test-attrakdiff-03/0

Age?
Sex?
Profession?
Job experience on ICU?

human	o	o	o	o	o	o	o	technical
isolating	o	o	o	o	o	o	o	connective
pleasant	o	o	o	o	o	o	o	unpleasant
inventive	o	o	o	o	o	o	o	conventional
simple	o	o	o	o	o	o	o	complicated
professional	o	o	o	o	o	o	o	unprofessional
ugly	o	o	o	o	o	o	o	attractive
practical	o	o	o	o	o	o	o	impractical
likeable	o	o	o	o	o	o	o	disagreeable
cumbersome	o	o	o	o	o	o	o	straightforward
stylish	o	o	o	o	o	o	o	tacky
predictable	o	o	o	o	o	o	o	unpredictable
cheap	o	o	o	o	o	o	o	premium
alienating	o	o	o	o	o	o	o	integrating
brings me closer to people	o	o	o	o	o	o	o	separates me from people
unpresentable	o	o	o	o	o	o	o	presentable
rejecting	o	o	o	o	o	o	o	inviting
unimaginative	o	o	o	o	o	o	o	creative
good	o	o	o	o	o	o	o	bad
confusing	o	o	o	o	o	o	o	clearly structured
repelling	o	o	o	o	o	o	o	appealing
bold	o	o	o	o	o	o	o	cautious
innovative	o	o	o	o	o	o	o	conservative
dull	o	o	o	o	o	o	o	captivating
undemanding	o	o	o	o	o	o	o	challenging
motivating	o	o	o	o	o	o	o	discouraging
novel	o	o	o	o	o	o	o	ordinary
unruly	o	o	o	o	o	o	o	manageable

Appendix 4: TAM-2 based questionnaire.

https://nl.surveymonkey.com/r/TAM2surveyICU

Q1. Ik werk als: IC verpleegkundige of IC A(N)IOS/PA-er of Intensivist.
Q2. Mijn ervaring op de IC is: … jaar.
Q3. Mijn geslacht: man/vrouw
Q4. Leeftijd: … jaar.

	Vraag/score	1 Volledig oneens	2 Oneens	3 Neutraal	4 Eens	5 Volledig eens
	Training & Support:					
T1	De mail over het gebruik van TraceBook was duidelijk.	1	2	3	4	5
T2	De voordracht over TraceBook was duidelijk	1	2	3	4	5
T3	Na de uitleg over TraceBook had ik onvoldoende vertrouwen om TraceBook te gebruiken	5	4	3	2	1
T4	Collega's die ik waardeer vinden dat ik TraceBook moet gebruiken.	1	2	3	4	5
T5	Superieuren vinden dat ik TraceBook moet gebruiken.	1	2	3	4	5
T6	Vanuit mijn persoonlijke waarden vind ik dat ik TraceBook moet gebruiken.	1	2	3	4	5
T7	Management vindt dat ik TraceBook moet gebruiken.	1	2	3	4	5
T8	Er was iemand bereikbaar om me te assisteren als ik problemen had met TraceBook.	1	2	3	4	5
	De bruikbaarheid (usefulness)					
U1	TraceBook is goed bruikbaar voor mijn werk	1	2	3	4	5
U2	TraceBook zorgt er voor dat de behandeling meer gebaseerd is op wetenschappelijk bewijs.	1	2	3	4	5
U3	Met TraceBook kon ik mijn taken en de visite/overdracht niet effectief voltooien.	5	4	3	2	1
U4	Met TraceBook was ik in staat om mijn taken en de visite/overdracht snel te voltooien.	1	2	3	4	5
U5	Ik denk dat TraceBook de kwaliteit van zorg kan verbeteren.	1	2	3	4	5
U6	TraceBook verbetert de medicatie veiligheid van de patiënt.	1	2	3	4	5
U7	TraceBook verbetert de kwaliteit van mijn geleverde werk bij visites/overdrachten.	1	2	3	4	5
U8	Met TraceBook was ik in staat om mijn taken en de visite/overdracht efficiënt te voltooien.	1	2	3	4	5
U9	Als informatie niet dubbel genoteerd hoeft te worden, dan maakt TraceBook mijn administratie makkelijker.	1	2	3	4	5
U10	De informatie bolletjes met richtlijnen zijn een aanvulling op de te checken items.	1	2	3	4	5
U11	Ik denk dat het gebruik van TraceBook complicaties niet kan voorkomen.	5	4	3	2	1
U12	TraceBook maakt mijn werk makkelijker uitvoerbaar.	1	2	3	4	5
U13	TraceBook verbetert de dagelijkse behandeling en management van de patiënt.	1	2	3	4	5
U14	TraceBook is een goede geheugensteun.	1	2	3	4	5
U15	TraceBook sluit goed aan op mijn dagelijkse werk.	1	2	3	4	5

	Vraag/score	1 Volledig oneens	2 Oneens	3 Neutraal	4 Eens	5 Volledig eens
	Gebruiksvriendelijkheid (ease of use)					
EU1	Het gebruik van TraceBook is eenvoudig.	1	2	3	4	5
EU2	De adviezen afgegeven door de checklist waren duidelijk.	1	2	3	4	5
EU3	De gebruikersinterface van TraceBook is prettig.	1	2	3	4	5
EU4	Het was eenvoudig om de informatie te vinden die ik nodig had in TraceBook.	1	2	3	4	5
EU5	De lay-out van TraceBook is onoverzichtelijk.	5	4	3	2	1
EU6	Het zou handiger zijn als de gebruiker de adviezen van TraceBook met één klik kan overnemen in het elektronisch patiëntdossier.	1	2	3	4	5
EU7	Het gebruik van TraceBook kon ik snel onder de knie krijgen.	1	2	3	4	5
EU8	Het gebruik van TraceBook koste mij weinig moeite.	1	2	3	4	5
EU9	Als ik een fout maakte in TraceBook dan kon ik dit moeilijk oplossen.	5	4	3	2	1
EU10	Het was eenvoudig om relevante patiënt-gerelateerde informatie te vinden in TraceBook.	1	2	3	4	5
EU11	TraceBook heeft het vermogen om de administratie te verminderen.	1	2	3	4	5
EU12	TraceBook zou beter werken op een telefoon of tablet.	5	4	3	2	1
EU13	TraceBook was makkelijk toegankelijk.	1	2	3	4	5
	Invloed op gedrag					
Us1	Ik wil TraceBook gebruiken omdat het mij helpt	1	2	3	4	5
Us2	Zonder de TraceBook heb ik het gevoel dat ik belangrijke zaken vergeet.	1	2	3	4	5
Us3	Ik heb het gevoel dat ik door TraceBook de patiënt beter behandel.	1	2	3	4	5
Us4	Het gebruik van TraceBook is een goed idee	1	2	3	4	5
Us5	Werken met TraceBook is niet leuk	5	4	3	2	1
Us6	Door TraceBook zie ik mezelf als een betere zorgverlener.	1	2	3	4	5
Us7	Werken met TraceBook is omslachtig	5	4	3	2	1
Us8	Ik durf niet meer zonder TraceBook te werken	1	2	3	4	5
Us9	Door TraceBook voel ik me dommer worden	5	4	3	2	1
Us10	Ook al was er niemand in de buurt dan kon ik nog TraceBook goed gebruiken	1	2	3	4	5
	Algemeen en gebruikerstevredenheid:					
G1	De checklisten in TraceBook beschikken niet over te veel checks.	1	2	3	4	5
G2	Ik zou willen dat TraceBook ook buiten deze studie om beschikbaar zou blijven.	1	2	3	4	5
G3	TraceBook is een aanvulling op het huidige elektronische patiëntdossier.	1	2	3	4	5
G4	Ik vind het prettig dat TraceBook automatisch checks kan afvinken.	1	2	3	4	5
G5	De checklists in TraceBook genereren correcte relevante checks voor de patiënten.	1	2	3	4	5
G7	Over het geheel ben ik tevreden over TraceBook.	1	2	3	4	5
G8	Ik geef de TraceBook een: (1-5)					