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CRITICAL CARE

Intelligent checklists improve checklist compliance in the intensive care unit: a prospective before-and-after mixed-method study

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Abstract

Background: We examined whether a context and process-sensitive 'intelligent' checklist increases compliance with best practice compared with a paper checklist during intensive care ward rounds.
Methods: We conducted a single-centre prospective before-and-after mixed-method trial in a 35 bed medical and surgical ICU. Daily ICU ward rounds were observed during two periods of 8 weeks. We compared paper checklists (control) with a dynamic (digital) clinical checklist (DCC, intervention). The primary outcome was compliance with best clinical practice, measured as the percentages of checked items and unchecked critical items. Secondary outcomes included ICU stay and the usability of digital checklists. Data are presented as median (interquartile range).
Results: Clinical characteristics and severity of critical illness were similar during both control and intervention periods of study. A total of 36 clinicians visited 197 patients during 352 ward rounds using the paper checklist, compared with 211 patients during 366 ward rounds using the DCC. Per ICU round, a median of 100% of items (94.4–100.0) were completed by DCC, compared with 75.1% (66.7–86.4) by paper checklist (P=0.03). No critical items remained unchecked by the DCC, compared with 15.4% (8.3–27.3) by the paper checklist (P=0.01). The DCC was associated with reduced ICU stay (1 day [1–3]), compared with the paper checklist (2 days [1–4]; P=0.05). Usability of the DCC was judged by clinicians to require further improvement.
Conclusions: A digital checklist improved compliance with best clinical practice, compared with a paper checklist, during ward rounds on a mixed ICU.
Clinical trial registration: NCT 03599856.

Keywords: checklist; clinical decision support system; intensive care unit; medical errors; patient safety; technology acceptance

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Editor's key points

- Studies exploring the impact of clinical checklists on outcomes are inconsistent.
- Digital checklists may overcome these barriers by optimising compliance with using checklists.
- This single-centre prospective before-and-after mixed-method trial in ICU compared paper *vs* digital checklists.
- The digital intervention increased checklist compliance and this was associated with shorter ICU stays.
- A digital checklist during ICU ward rounds appears to improve compliance with best clinical practices.

Implementation of medical checklists in clinical practice may reduce adverse events and related deaths.[1–5] However, studies on the impact of checklists have been inconsistent,[5–9] which may be explained by a lack of compliance as a result of multiple socio-organisational barriers. Checklist design, accessibility, workflow integration, and perceived relevance of content by clinicians may also hinder the uptake and impact of checklists.[2,6,8]

Digital checklists may overcome these barriers and optimise compliance with checklists.[10–13] A clinical decision support system (CDSS) called TraceBook has been developed that uses dynamic clinical checklists (DCCs) in a process-oriented and context-aware manner.[14,15] This CDSS contains several innovations to support successful use of checklists in healthcare. First, the CDSS is able to gather and integrate information from different data sources within the hospital. Second, the rule engine within the CDSS prepares personalised digital checklists containing items relevant to the care of each individual patient.[11,12,15] Third, automated checks are feasible when healthcare professionals locally agree that a rule can be checked automatically. Finally, the CDSS provides better insight into workflow, displays guideline recommendations upon request, and highlights relevant data from the medical databases requiring extra attention such as laboratory results.[14,15]

The results of a simulation study in 2017 showed that implementing the DCC for ICU ward rounds was associated with markedly improved compliance to local guidelines compared with local standard of care with a paper checklist.[11] Participating physicians appreciated the DCCs with a high satisfaction score.[11] Although promising, these results shed no light on compliance and effectiveness of the DCCs in real clinical practice. Therefore, we conducted this before-and-after mixed-method trial to evaluate and provide context about the effect of DCCs on the compliance with best eligible practice during ICU ward rounds compared with the local standard of care using paper checklists.

Methods

Study design and setting

This prospective before-and-after mixed-method study was carried out from July 2018 until March 2019 in the ICU of Catharina Hospital Eindhoven, a tertiary hospital in the Netherlands. This department is a 35 bed mixed medical and surgical ICU, including cardiothoracic surgery (Supplementary Table S1). The study consisted of two periods: a control period of 8 weeks with local standard of care and an intervention period of 8 weeks (Supplementary Table S2). A mixed-methods design, including questionnaires and interviews, was used to provide context for the quantitative results. The study was approved by the Institutional Review Board (W18.046) and registered at clinicaltrials.gov (NCT03599856). We adhered to the guidelines for Strengthening the Reporting of Observational studies in Epidemiology (Supplementary material).[16]

Study population and eligibility criteria

Eligible participants of this study were intensivists, residents, and ICU physician assistants who were in the lead of the ICU daily ward round.[17] The intensivist carried the final responsibility during these rounds. All clinical ICU staff were informed about the study and all consented to participate. The full study protocol is available online.

Control: local standard of care—paper checklists

An ICU ward round is a scheduled visit of the ICU patients at the end of the morning in which residents or physician assistants review relevant clinical data and clinical decisions are made together with the responsible intensivist. A bedside paper checklist containing 17 items is available to be used at their convenience. This checklist is based on the FAST HUG mnemonic with extra items added based on local guidelines developed since its introduction in the ICU (Supplementary Table S2).[18,19] In addition, the hospital uses the CDSS Gaston® (Gaston Medical, Eindhoven, the Netherlands) to review prescribed medication on the ICU and alert pharmacists if one of the 23 predetermined pharmacological clinical rules for the ICU are violated.[20–22]

Intervention: dynamic clinical checklist

TraceBook's DCC generates on request dedicated checklists for each individual patient and is easily accessible on a tablet or computer (Fig. 1). To generate the DCC, the systems of TraceBook and GASTON both have a rule engine containing a model of transparent algorithms, comparable with a decision tree, with clinical rules and pharmacological rules. First, GASTON gathers the relevant medical data of a patient from various medical information systems, such as the electronic health record, the laboratory information system, the pharmaceutical prescription system, and others. Then, both systems run the rule engines and TraceBook determines which rules are relevant for an individual patient in a specific context. These items then become a checkable item for the DCC of that particular patient (Supplementary Fig. S1 provides a schematic overview of how a DCC is composed).[20,21,23] After considering an item, users can tab the corresponding box and make a note if desired until the DCC is completed. The whole system is designed to easily create or modify rules, even by caregivers themselves. The model for the ICU ward round DCC is comparable with the DCC used in the previous simulation-based trial.[14] Before starting the study, algorithms were updated by researcher ADB and checked by researcher AB to match currently applied local guidelines.[11] Rules were not modified during both periods.

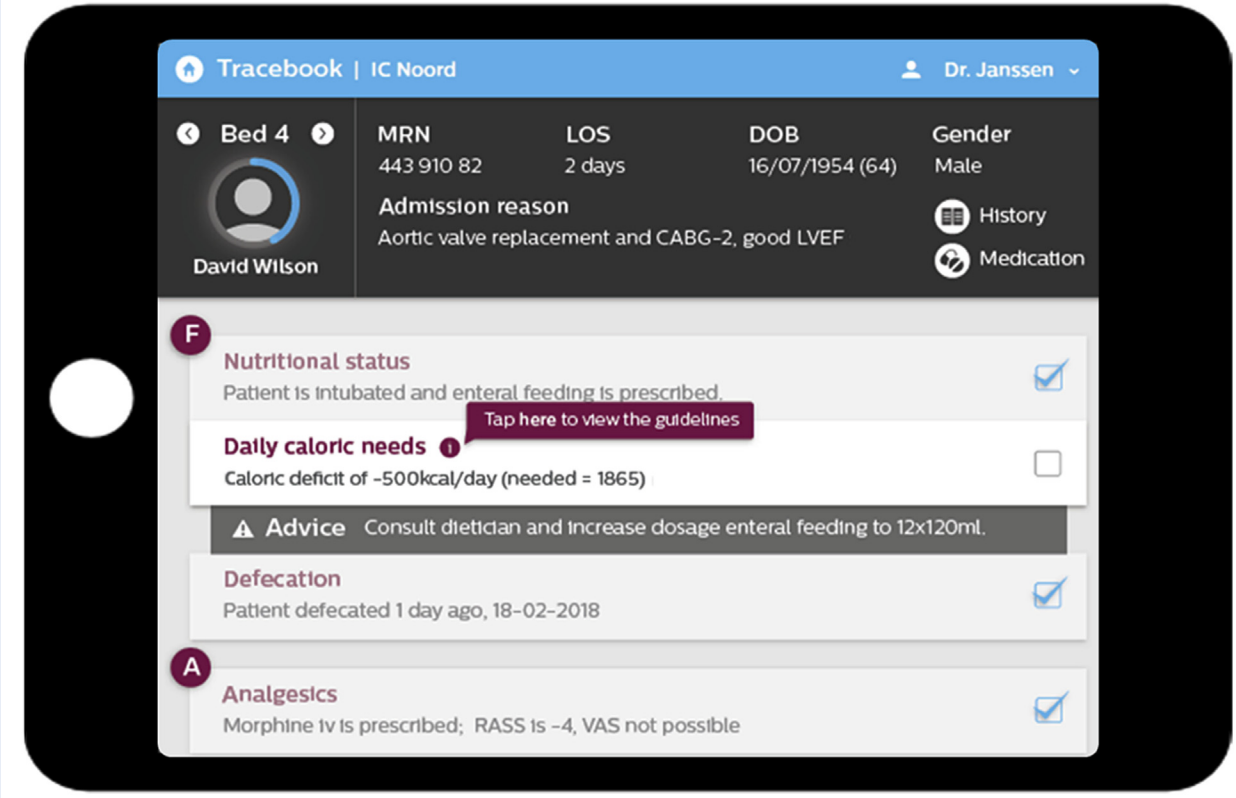


Fig 1. Screenshot of TraceBook's dynamic clinical checklists for the ICU ward round from a fictional person.

Data collection and endpoints

Two researchers (ADB and EM) observed the rounds. Both observers were former ICU residents and familiar with the local practice and guidelines. A ceiling-mounted camera and a microphone allowed the researchers to observe the rounds in another room out of the sight of the ICU staff (video was not recorded). Except for the weekends, all morning rounds were eligible to be observed if observers were available (Supplementary Fig. S2).

Primary outcome

The primary outcome was a composite of compliance with best clinical practice (assessed as the percentage of discussed checklist items) and the percentage of critical checklist items that were unaddressed per patient on each ward round. A critical item was defined as an item that required an intervention based on local protocol. A standardised paper list with 25 predefined items, based on the paper checklist and local guidelines (Supplementary Table S2), combined with the output of the DCC were used to judge which items needed to be discussed (e.g. the item 'radiological examination' was considered inapplicable if no examination was performed in the last 24 h).

Secondary outcomes

We also analysed the following secondary outcomes:

1. Patient-centred outcomes: length of ICU stay, mortality rate, and number of ventilator days.
2. Outcomes related to specific care processes: number of automatically checked items for violated pharmacological clinical rules and registered complications; prescribed regular use of analgesics, sedatives, and empiric antibiotics; pain scores (Critical Care Pain Observation Tool [CPOT; 0–6] and VAS [0–10])[23]; and the Richmond Agitation-Sedation Scale (RASS; −5 to 5).[24]

Assessment of end-user experience

We evaluated clinicians' experience of the digital intervention period using self-report questionnaires and semi-structured interviews at the end of each period. The AttrakDiff questionnaire was used to assess usability based on pragmatic and ease-of-use (hedonic) factors (Supplementary material).[25] User acceptance was assessed with a questionnaire based on the Technology Acceptance Model-2 (TAM-2; Supplementary material).[26] To better understand the quantitative insights on user acceptance with DCC, interviews were conducted. An independent researcher (LG) conducted semi-structured interviews in the 2 weeks after the intervention period. An interview topic guide based on the TAM-2 model was used to explore acceptance, perceived strengths and weaknesses of the DCC, expectations and experiences, and the perceived barriers to implementation (Supplementary material).

Table 1 Primary and secondary outcomes.

	Control period	Intervention period	χ^2- or z-score	P-value[¶]
	Paper checklist (*n*=352 in 196 patients)	Digital dynamic checklist (*n*=366 in 205 patients)		
Primary outcomes				
Percentage of checked items, %; median (IQR)	77.8 (66.7–86.4)	100.0 (94.4–100.0)	z=21.9	0.03
Percentage of unchecked critical items, %; median (IQR)	15.4 (8.3–27.3)	0.0 (0.0–0.0)	z=−17.7	0.02
Secondary outcomes				
Medication-related rules				
Number of alerts, median (range)	0 (0–32)	0 (0–14)	z=−1.52	0.30
Number of relevant alerts[*], median (range)	0 (0–6)	0 (0–3)	z=−0.15	0.98
Phone calls of pharmacist to ICU clinician, median (range)	0 (0–5)	0 (0–3)	z=−0.15	1.02
Number of intervention-based alerts, median (range)	0 (0–3)	0 (0–3)	z=−0.21	1.08
Prescribed medication: number of days per patient; Median (range)				
Opiates; prescribed as regular use each day	1.0 (0.0–24.0)	1.0 (0.0–14.0)	z=−2.00	0.17
Paracetamol; prescribed as regular use each day	2.0 (0.0–47.0)	1.0 (0.0–30.0)	z=−1.32	0.41
No PPI, while indicated	1.0 (0.0–37.0)	1.0 (0.0–30.0)	z=−0.30	1.16
I.V. sedatives[†]	0.0 (0.0–11.0)	1.0 (0.0–12.0)	z=−7.09	0.01
Antibiotics[‡]	0.0 (0.0–34.0)	0.0 (0.0–18.0)	z=−3.78	<0.01
Secondary outcomes				
Complications				
Registered complications, median (range)	0.0 (0.0–19.0)	1.0 (0.0–11.0)	z=−0.34	1.17
Gastrointestinal bleedings, *n* (%)	1 (0.5)	5 (2.4)	χ^2=1.88	0.47
Hospital-acquired pneumonia, *n* (%)	8 (4.1)	5 (2.4)	χ^2=0.48	0.82
CRBSI, *n* (%)	3 (1.5)	0 (0.0)	χ^2=3.24	0.21
Hypoglycaemia (<4 mmol L^{-1}), median (range)	0.0 (0.0–9.0)	1.0 (0.0–6.0)	z=−0.19	1.02
Hyperglycaemia (>15 mmol L^{-1}), median (range)	0.0 (0.0–9.0)	1.0 (0.0–5.0)	z=−1.85	0.19
Days without defecation for at least >48 h, median (range)	1.0 (0.0–7.0)	0.0 (0.0–5.0)	z=−1.61	0.28
VAS (1–10), *n*	*n*=1052	*n*=1266		
Median (IQR)	1.0 (0.0–3.0)	1.0 (0.0–3.0)	z=−0.91	0.65
Pain scores (1–10) >4; *n* (%)	177 (16.8)	207 (16.4)	χ^2=0.06	1.09
CPOT (0–6), *n*	*n*=453	*n*=404		
Median (IQR)	1.0 (0.0–2.0)	0.0 (0.0–1.8)	z=−4.98	<0.01
CPOT score (0–6) >2; *n* (%)	115 (25.4)	64 (15.8)	χ^2=11.20	<0.01
RASS (−5–5), *n*	*n*=1158	*n*=1270		
Median (IQR)	0.0 (−1.0–0.0)	0.0 (−1.0–0.0)	z=−1.22	0.44

CPOT, Critical Care Pain Observation Tool; CRBSI, central-venous-catheter-related bloodstream infections; IQR, inter-quartile range; PPI, proton pump inhibitor; RASS, Richmond Agitation-Sedation Scale.

[*] Determined by the hospital pharmacist on duty.

[†] Propofol or midazolam.

[‡] Days with only selective digestive decontamination excluded.

[¶] False discovery rate adjusted *P*-value.

Statistical analyses

Quantitative data analyses were performed with SPSS (version 22.0; IBM Corp, Armonk, NY, USA). Distribution of continuous variables was assessed with the Kolmogorov–Smirnov test and by analyses of the histograms. Non-normally distributed data were analysed with the Mann–Whitney *U*-test or the χ^2 test. A false discovery rate correction was used to correct for the multiple comparisons and calculate the false discovery rate adjusted *P*-values.[27] We report the z-score (also called a standard score), a measure of how many standard deviations below or above the population mean a raw score is. All the reported *P*-values are two-sided, all have been adjusted, and a *P*-value of 0.05 or lower was considered statistically significant.

A deductive approach was applied for the qualitative data analysis, with categories based on the TAM-2 with additional elements around the topic of routines and habits. Analyses started with annotations at the sentence, question, and topic level on the interview transcripts by two independent researchers (LG and KD) with Atlas.ti 7 (Atlas.ti, Scientific Software Development GmbH, Berlin, Germany, 2013). For each factor, variations in opinions within the factors were described (e.g. positive *vs* negative; pros *vs* cons).

Sample size estimation

A sample size calculation was performed with G*power (G*power team, version 3.1.9.2, Kiel, Germany). Based on findings of the pilot study {73.6% (inter-quartile range [IQR]:

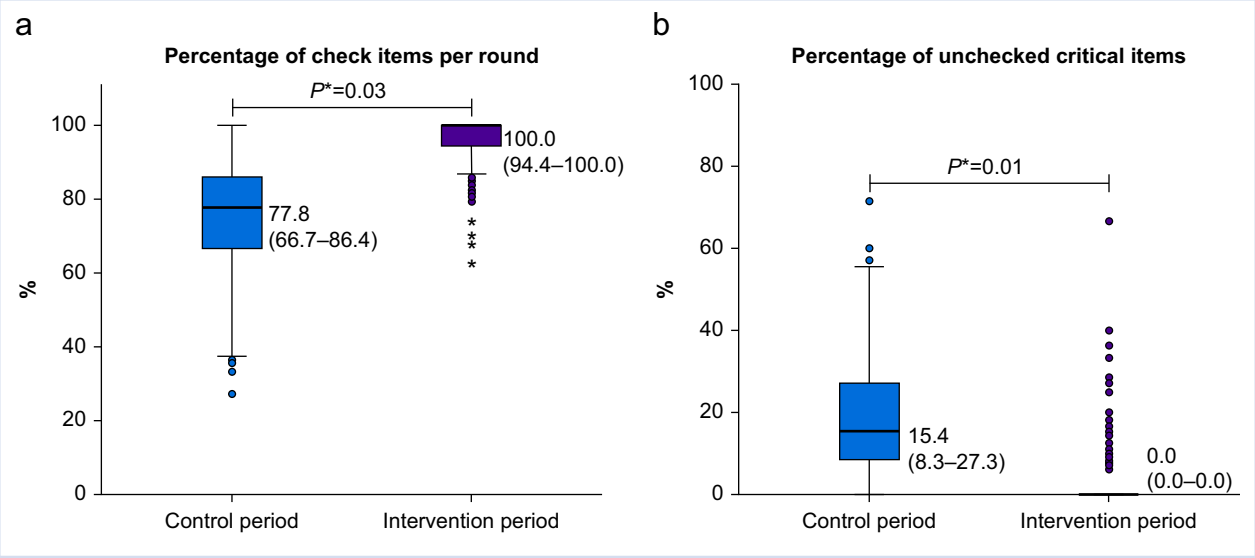


Fig 2. Boxplots of the median percentage checked items (a) and unchecked critical items (b) per ICU ward round. *Adjusted P-value.

64.5–79.3) *vs* 100% (IQR: 100.0–100.0)},[11] a sample of 50 observed patients during each period would provide 95% power to detect a difference of 26.4% of checked items with a type I error of 5% and corrected for dropouts. We aimed for 120 patients in each period, because in contrast to a simulation-based study the patient scenarios in real practice are not controlled by the researchers.

Results

Participants

Clinical characteristics, severity-of-disease classification score and comorbidities were similar between both periods (Supplementary Table S3). During both study periods, 14 intensivists, seven ICU physician assistants, and 15 doctors in training were observed during daily ICU rounds.

Study characteristics

A total of 196 patients were included during the control (paper checklist) period (July–August 2018). Participants performed four ICU rounds (range one to eight), with 14 items (range eight to 22) applicable per patient; 3764/5007 checklist items (75.2%) were discussed by clinicians during 352 rounds. In the DCC intervention period (September–November 2018), three rotating residents replaced eight residents who worked on the ICU during the control period. A total of 205 patients were included, with clinicians performing five ICU rounds (range three to eight) per day. During 366 rounds, 10 (range five to 18) checklist items were applicable per patient, with 5332/5476 items (97.4%) checked (Supplementary material provides more detailed descriptive information for both groups).

Primary outcome

We observed an increase of checked overall items from 77.8% (IQR=66.7–86.4) in the control period to 100% (IQR=94.4–100.0) when the DCC was used during the intervention period (P=0.03, z=−22.3; Table 1; Fig. 2). The percentage of unchecked critical items decreased from 15.4% (IQR=8.3–27.3) during the control (paper checklist) period, to zero during the DCC period

Table 2 Clinical outcomes of the patients in the control and the intervention period. IQR, inter-quartile range.

	Control period	Intervention period	χ^2- or z-score	P-value*
	Paper checklist (*n*=197)	Digital dynamic checklist (*n*=211)		
Mortality, *n* (%)				
ICU	12 (6.1)	14 (6.6)	χ^2=<0.01	1.01
30-day	17 (8.6)	20 (9.5)	χ^2=0.02	0.96
90-day	23 (11.7)	28 (13.3)	χ^2=0.11	1.06
Length of stay (days), median (IQR)				
ICU	2.0 (1.0–4.0)	1.0 (1.0–3.0)	z=−2.55	0.05
Hospital	9.0 (6.8–17.0)	8.0 (6.0–16.0)	z=−2.46	0.05
Invasive ventilation time (h), median (IQR)				
Overall group	7.0 (4.0–23.3)	7.0 (4.0–30.0)	z=−0.02	0.98
Patients >24 h of invasive ventilation	89.0 (42.0–117.0)	68.0 (42.8–173.0)	z=−0.20	1.05

*False discovery rate adjusted P-value.

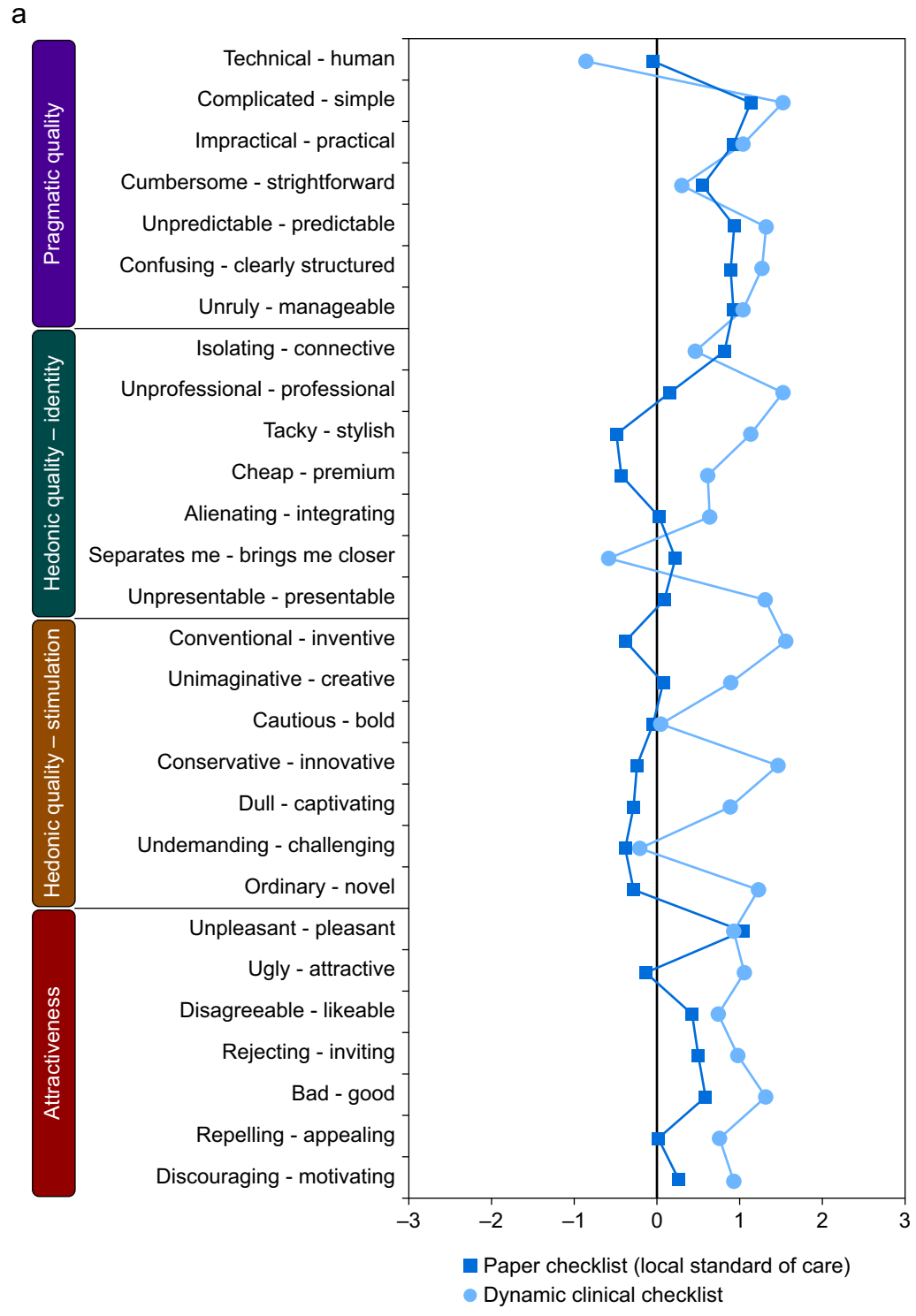
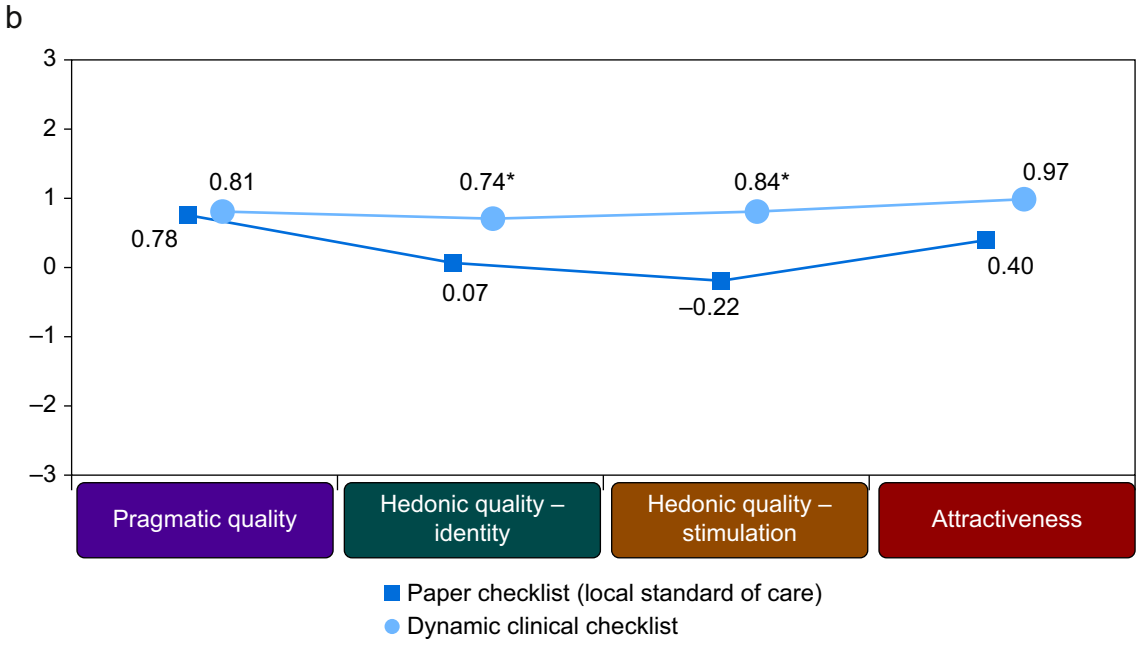


Fig 3. Results of the AttrakDiff questionnaire: (a) mean scores for each element of the questionnaire, (b) mean score for each domain, and (c) and the overall score of the ease-of-use (hedonic) and pragmatic qualities. ATT, attractiveness; HQ-I, hedonic quality-identity; HQ-S, hedonic quality-stimulation; PQ, pragmatic quality. *$p < 0.05$.



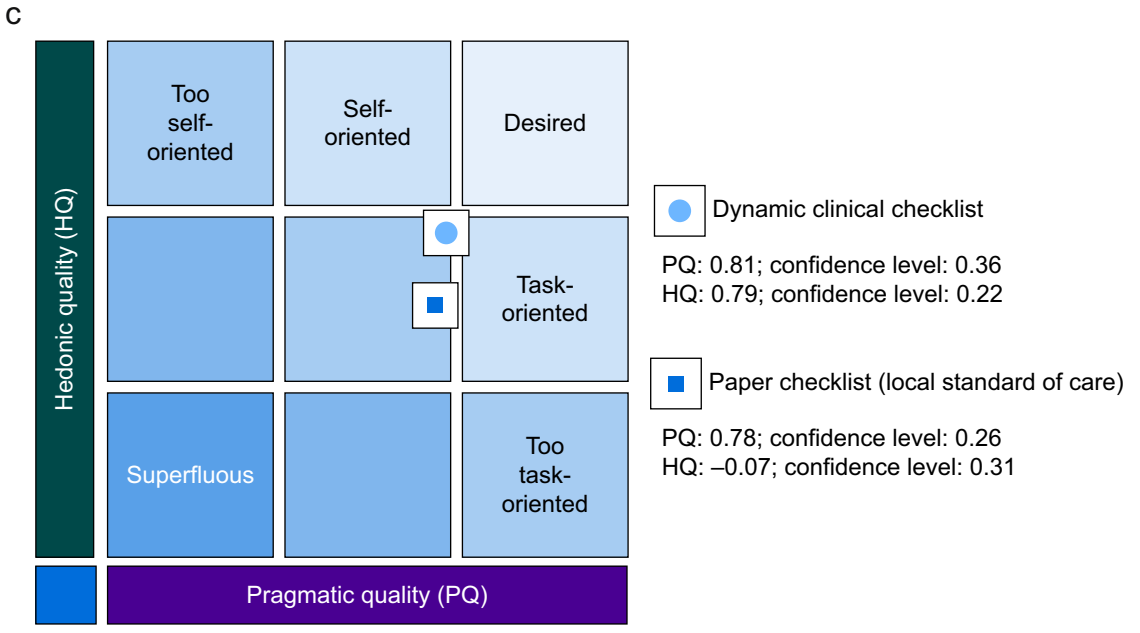


Fig 3. (*continued*).

(P=0.02, z=−16.2; Table 1). Correcting for false discovery rates did not alter these findings (Supplementary Table S4).

Secondary outcomes

Patient-centred outcomes

The length of stay in the ICU (z-score −2.5, P=0.05) and hospital (z-score −2.5, P=0.05) was shorter during the DCC period (Table 2), including after adjustment for false discovery rate correction (Supplementary Table S4). Mortality rates and invasive ventilation time were similar during both study periods (Table 2).

Outcomes related to specific care processes

The median CPOT score was lower during the DCC period compared with the control period, whereas the median number of days with i.v. sedatives prescribed was higher (Table 1). Opiates prescribed for regular use and empiric antibiotic prescriptions were reduced during the DCC period

Table 3 Quotes of interviewed participants after the intervention period. DCC, dynamic clinical checklists; TAM, Technology Acceptance Model.

TAM-2 categories	Quotes		Participant
Perceived ease of use	Q1	*'The layout is good. The DCC is very clear with that little round circle. I find that a positive thing. It is quick. It is not a very slow system. [...] I think those are the real benefits.'*	Female, intensivist, <5 yr of experience
	Q2	*' ... I found it annoying that it sometimes jumps out, logged out and that I have to log back in ... Or if I accidentally press on it, it switches off.'*	Male, intensivist, <5 yr of experience
Job relevance	Q3	*'I don't want to be dependent on such a machine when thinking about a patient. But I am a human being and I make mistakes. I slip up and then a safety net is welcome.'*	Female, intensivist, 5–10 yr of experience
	Q4	*'I think that the greatest added value is related to medication. That's where I found the extra information [from the DCC] always valuable.'*	Female, physician assistant, <5 yr of experience
Perceived usefulness	Q5	*'It's a sort of check for myself, if I am not missing anything, if I have thought about everything. It provides structure. Yes, it is an aid. I feel more reassured when using the checklist.'*	Female, physician assistant, <5 yr of experience
	Q6	*'To improve the health of patients is quite a stretch. I think it increases the odds of people following protocol. But if that improves the odds of patients improving? I don't know. Maybe sometimes yes, sometimes no. But protocols are there for a reason and it is important to follow them.'*	Male, physician assistant, 5–10 yr of experience
Beliefs and attitudes	Q7	*'The danger is if you only are trained with cognitive support tools and in the end, no one can really help you with that. Identifying the main topics and details, and being able to see the endpoint, that is where we need to focus.'*	Male, intensivist, <5 yr of experience
	Q8	*'Decision support is valuable. It is more valuable than checklists. The DCC is now too much of a checklist.'*	Male, intensivist, 5–10 yr of experience

(Table 1). Other secondary outcomes were similar between both periods of study. *Post hoc* analyses (correcting for false discovery rate) were similar, other than for opiate use (Supplementary Table S4).

Assessment of end-user experience

The DCC was rated as easier to use than the paper checklist, as assessed by the AttrakDiff questionnaire (n=21 participants after each period; Supplementary Table S5) and the TAM-2-based questionnaire (18 participants after the control period; 21 participants after the intervention period; Supplementary Table S6). Clinicians preferred the DCC to accomplish their goals during the rounds (Fig. 3; Supplementary material).

Semi-structured interviews

Most clinicians found the DCC intuitive and easy to use (Table 3), despite not receiving training on how to use it. Most clinicians agree that the content of the DCC was relevant for their work and believed it could prevent mistakes (Supplementary material). However, clinicians were not convinced that this would translate into improved patient outcomes because the DCC mainly covers protocolised care processes but not clinical decision-making for the treatment of the underlying life-threatening diseases. There were several suggestions as to how the usability of the DCC could be improved (Supplementary material).

Discussion

In this prospective before-and-after mixed-method study we observed that compliance with best practice improved after a DCC was implemented during ICU ward rounds. Use of the DCC was associated with a shorter ICU stay and fewer days with prescribed empiric antibiotics. In the intervention period, the increased number of days with i.v. continuous sedatives translated into less unacceptable levels of critical care pain scores. Overall, physicians valued the DCC as an attractive and innovative technology. Although in questionnaires the usability of the DCC was rated similar to the paper checklist, the majority of the physicians mentioned that the DCC was easily applied in daily practice and has more future potential compared with paper checklists.

The compliance rate of the paper checklist items in the control period was similar to other studies and the previous simulation pilot study.[9,11,28–30] As compared with the pilot study, similar high rates of checked items were found in this study, but now for an intervention period of 8 weeks in real practice.[11] These high rates provide reassurance that physicians considered the presented items and chose to follow or intentionally deviate from protocol in the interest of their individual patient. The observed improvement is in line with results of most other healthcare studies evaluating electronic checklists.[10,11,31] However, these studies compared electronic checklists with no checklist, or were simulation studies. Thus it remains difficult to determine if specific features of electronic checklists were responsible for the higher compliance rates besides the general impact of having a checklist as a memory aid.[10] Our present study suggests that the observed higher compliance rate is the result of the specific features of an electronic checklist with dynamic properties, because it compared the DCC with a paper checklist in real practice. The improved rate can partly be explained by the ability of the DCC to automatically check items. Approximately one-third of the checkable items were checked automatically resulting in shorter checklists with a more relevant content.

Our study showed that the use of the DCC was associated with a reduced length of stay in the ICU and several improved care processes. However, some care processes included in the DCC did not result in improvements. Nor could we reproduce the reduction of pharmacists' phone calls as a result of violated pharmacological clinical rules found in the previous simulation study.[11] This discrepancy might be explained by the different study designs. In the simulation study, some flaws were deliberately implemented and occurred therefore in every simulation. In real practice, however, there are more occasions over the day and night that the violation of a pharmacological clinical rules can be noticed and corrected. This might explain why fewer violations were found during the ward rounds and this sample size was probably too small to detect a significant difference, although the absolute number of violations tended to be smaller in the intervention period. The lack of improvement in the other care processes is in line with the findings of other quality improvement multifaceted approach studies on the ICU.[9,28,32–34] Similar to these type of studies, our findings need further study as several potential factors may be involved: (1) the before-and-after design of this study might have been influenced by secular trends,[35] (2) the inclusion of a broader patient population than the studies that found an effect of a specific care process, (3) even though some care processes are recommended by ICU guidelines, their effect on patient outcomes are still undetermined,[36,37](4) the study was not powered for particular secondary outcomes (e.g. a smaller number of violated pharmacological clinical rules were found in this real practice study compared with the previous simulation study),[11] and (5) both the period of intervention and follow-up time were too short to find measurable effects.[38]

The discrepancy of improved ease-of-use with no effect on usability, as observed with the questionnaires, was unexpected. Insufficient training and time for introduction, or a complicated user interface seem not to be causing this difference as most users perceived the DCC as intuitive except for some hitches. In addition, in the interviews users appreciated that the DCC provided useful suggestions and tried to prevent mistakes that they thought would have otherwise remained unnoticed. This opinion of a checklist's purpose is in line with a previous qualitative study evaluating a paper checklist for ICU ward rounds.[39] In the present study, users acknowledged errors could be prevented, especially for items of care processes that are based on complicated and frequently updated guidelines, such as the anticoagulation-related management guideline. On the contrary, users indicated that the DCC still functioned too much as a checklist for care processes instead of a cognitive aid supporting decision-making at the bedside. In their opinion the dynamic properties of this DCC have the potential to fulfil this expectation, although some also argued that clinicians should not become too dependent on technology.

Future development of the DCC and studies should focus on: (1) the capability of retrieving more data and trends from multiple sources as input for algorithms, including wearable devices, (2) implementing and validating multiple interacting DCCs for various clinicians within patients' clinical pathways, (3) the use of more sophisticated algorithms based on machine learning for which the DCC can also retrieve reliable relevant missing data, (4) DCC capability of improving the translation and application of the available or new medical knowledge and evidence into clinical practice, such as during emerging pandemics, and (5) improving user experience.

This study has several limitations. The single-centre nature of the study decreases its external validity. Most biases are inherent to both the before-and-after and mixed-method design of this study. Although the baseline characteristics seemed balanced, subtle differences might have introduced selection bias. Regression to the mean might have occurred since multiple rounds were observed in patients admitted for more than one day. We tried to reduce the Hawthorne effect through discrete observation of participant behaviour. Measurement bias could have occurred in the control period, since the output of the DCC was used to judge if items needed to be discussed. Participation in the questionnaires and interviews was voluntary and participants might have tried to please the investigators.

In summary, the introduction of a DCC in an ICU with high standard of care for ward rounds improved the compliance to best practice and was associated with a reduction in ICU length of stay, daily use of antibiotics, and pain observation scores. The DCC model needs further refinement to fulfil physicians' expectations of a patient-centred and user-specific cognitive aid.

Authors' contributions

The conception and design of the study: AJRDB, EM, WC, SN, JE, SVL, HVDP, FS, LX, AJGHB, RAB, HHMK
Acquisition of data, analysis and interpretation of data: AJRDB, EM, WC
Writing the manuscript: AJRDB, EM, WC, LG, KD, AJGHB, RAB, HHMK
Incorporated the rule engine TraceBook in the hospital server: SN, HVDP, LX
Checking the first draft and final manuscript: SN, JE, SVL, HVDP, FS, LX
Acquisition of data (semi-structured interviews): LG, KD
User experience design lead for improved TraceBook's user interface design: JE
Designing the study; managed the information technology, integration, and logistic parts of the study; improved TraceBooks's interface: SVL
Reviewed the TraceBook results in an early phase: FS, AJGH, RAB, HHMK
Aligned with business objectives and commissioned the User Experience design, interface, and code implementation for the TraceBook clinical validation study; presented preliminary results in an e/MTIC event: FS

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Pieter Van Gorp, Department of Industrial Engineering and Innovation Sciences, Eindhoven University of Technology, Eindhoven, the Netherlands: served as scientific advisor.
Lonneke Vermeulen, Department of Industrial Engineering and Innovation Sciences, Eindhoven University of Technology, Eindhoven, the Netherlands: served as scientific advisor.
Jelle Tuinhout, Department of Philips Design, Eindhoven, the Netherlands: created the user interface design of TraceBooks' DCC.
Alexander Heuts, Department of Software Concepts, Philips Research, Eindhoven, the Netherlands: improved the user-interface and implemented the new design of TraceBooks' DCC.

Gertjan Maas, Department of Software Concepts, Philips Research, Eindhoven, the Netherlands: improved the user-interface and implemented the new design of TraceBooks' DCC.
Jasper Stam, Department of Software Concepts, Philips Research, Eindhoven, the Netherlands: improved the user-interface and implemented the new design of TraceBooks' DCC.
Tim Brouwer, Healthcare Intelligence, Catharina Hospital Eindhoven, Eindhoven, the Netherlands: helped with acquiring data from the electronic health record.
Paul Kuijpers, Department of Intensive Care Unit, Catharina Hospital Eindhoven, Eindhoven, the Netherlands: Manager of the ICU and helped with logistic parts of the study.
Saskia Houterman, Department of education and research, Catharina Hospital Eindhoven, Eindhoven, the Netherlands: epidemiologist who helped with the statistics.
To compose the trials, we used the clinical decision support system Gaston®, which was already available in our hospital and free to use.

Declarations of interest

None of the authors have a financial interest or personal financial gain in TraceBook. RAB and HHMK have acted as clinical consultants for Philips Research in Eindhoven, the Netherlands, since January 2016. RAB received travel support from CSL Behring to visit NATA 2015. ADB, AJGHB, SN, and HHMK received travel funding for a lecture in China from a local research fund of the Catharina Hospital Eindhoven and the Brain Bridge project, a collaboration of Zhejiang University, Eindhoven University of Technology and Philips Research. The PhD research of SN to create TraceBook was funded by the Brain Bridge Project, and the PhD research of ADB to clinically evaluate TraceBook was funded by IMPULS-2. IMPULS-2 is a project that provides funding for PhD research in which engineers and physicians collaborate. The project is a collaboration of the Catharina Hospital in Eindhoven, Technical University of Eindhoven, and Philips Research of the Netherlands. LVG, KD, JE, SVL, FS are all employees of Philips Research and this study was conducted as part of their regular work. They declare that appropriate measures were undertaken to prevent bias and that this study was done for the purpose of generating scientific knowledge. EM, WC, HVDP, and XL declare that they have no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.09.044.

References

1. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009; **360**: 491–9
2. Bergs J, Lambrechts F, Simons P, et al. Barriers and facilitators related to the implementation of surgical safety checklists: a systematic review of the qualitative evidence. *BMJ Qual Saf* 2015; **24**: 776–86
3. de Vries EN, Prins HA, Crolla RM, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med* 2010; **363**: 1928–37
4. Haugen AS, Softeland E, Almeland SK, et al. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg* 2015; **261**: 821–8
5. Bergs J, Hellings J, Cleemput I, et al. Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. *Br J Surg* 2014; **101**: 150–8
6. Fourcade A, Blache JL, Grenier C, Bourgain JL, Minvielle E. Barriers to staff adoption of a surgical safety checklist. *BMJ Qual Saf* 2012; **21**: 191–7
7. van Klei WA, Hoff RG, van Aarnhem EE, et al. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. *Ann Surg* 2012; **255**: 44–9
8. Borchard A, Schwappach DL, Barbir A, Bezzola P. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012; **256**: 925–33
9. Cavalcanti AB, Bozza FA, Machado FR, et al. Effect of a quality improvement intervention with daily round checklists, goal setting, and clinician prompting on mortality of critically ill patients: a randomized clinical trial. *JAMA* 2016; **315**: 1480–90
10. Kramer HS, Drews FA. Checking the lists: a systematic review of electronic checklist use in health care. *J Biomed Inform* 2017; **71S**: S6–12
11. De Bie AJR, Nan S, Vermeulen LRE, et al. Intelligent dynamic clinical checklists improved checklist compliance in the intensive care unit. *Br J Anaesth* 2017; **119**: 231–8
12. Webster CS. Checklists, cognitive aids, and the future of patient safety. *Br J Anaesth* 2017; **119**: 178–81
13. Nan S, De Bie A, Zhang S, Korsten H, Lu X, Duan H. Identify facilitators and challenges in computerized checklist implementation. *Stud Health Technol Inform* 2019; **264**: 1737–8
14. Nan S, Van Gorp P, Lu X, et al. A meta-model for computer executable dynamic clinical safety checklists. *BMC Med Inform Decis Mak* 2017; **17**: 170
15. Nan S, Van Gorp P, Korsten H, et al. Tracebook: a dynamic checklist support system. *IEEE 27th Int Symp Computer-Based Med Syst* 2014: 48–51
16. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007; **370**: 1453–7
17. Kreeftenberg HG, Aarts JT, de Bie A, Bindels A, Roos AN, van der Voort PHJ. An alternative ICU staffing model: implementation of the non-physician provider. *Neth J Med* 2018; **76**: 176–83
18. Vincent JL. Give your patient a fast hug (at least) once a day. *Crit Care Med* 2005; **33**: 1225–9
19. Papadimos TJ, Hensley SJ, Duggan JM, et al. Implementation of the "FASTHUG" concept decreases the incidence of ventilator-associated pneumonia in a surgical intensive care unit. *Patient Saf Surg* 2008; **2**: 3
20. de Clercq PA, Hasman A, Blom JA, Korsten HH. Design and implementation of a framework to support the

development of clinical guidelines. *Int J Med Inform* 2001; **64**: 285–318
21. Scheepers-Hoeks AM, Neef C, Doppen AMJ, Korsten EHM. Preventive prescribing of laxatives for opioid-induced constipation using electronic clinical rule implementation by cinical pharmacists. *Adv Pharmacoepidemiol Drug Saf* 2014; **3**: 1–5
22. van der Linden CM, Jansen PA, van Marum RJ, Grouls RJ, Egberts TC, Korsten EH. An electronic system to document reasons for medication discontinuation and to flag unwanted represcriptions in geriatric patients. *Drugs Aging* 2012; **29**: 957–62
23. Barr J, Fraser GL, Puntillo K, et al. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit. *Crit Care Med* 2013; **41**: 263–306
24. Ely EW, Truman B, Shintani A, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). *JAMA* 2003; **289**: 298391
25. Hassenzahl M, Platz A, Burmester M, Lehner K. Hedonic and ergonomic quality aspect determine a software's appeal. In: *Proceedings of the CHI 2000 conference on human factors in computing systems, Extended abstracts, New York: ACM*; 2000. p. 1283–6
26. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: four longitudinal field studies. *Manag Sci* 2000; **46**: 186–204
27. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. *J R Stat Soc Ser B Methodol* 1995; **57**: 289–300
28. Carlos WG, Patel DG, Vannostrand KM, Gupta S, Cucci AR, Bosslet GT. Intensive care unit rounding checklist implementation. Effect of accountability measures on physician compliance. *Ann Am Thorac Soc* 2015; **12**: 533–8
29. de Vries EN, Prins HA, Bennink MC, et al. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. *BMJ Qual Saf* 2012; **21**: 503–8
30. Pucher PH, Aggarwal R, Almond MH, Darzi A. Surgical care checklists to optimize patient care following postoperative complications. *Am J Surg* 2015; **210**: 517–25
31. Sevilla-Berrios R, O'Horo JC, Schmickl CN, et al. Prompting with electronic checklist improves clinician performance in medical emergencies: a high-fidelity simulation study. *Int J Emerg Med* 2018; **11**: 26
32. Byrnes MC, Schuerer DJ, Schallom ME, et al. Implementation of a mandatory checklist of protocols and objectives improves compliance with a wide range of evidence-based intensive care unit practices. *Crit Care Med* 2009; **37**: 2775–81
33. Weiss CH, Moazed F, McEvoy CA, et al. Prompting physicians to address a daily checklist and process of care and clinical outcomes: a single-site study. *Am J Respir Crit Care Med* 2011; **184**: 680–6
34. Scales DC, Dainty K, Hales B, et al. A multifaceted intervention for quality improvement in a network of intensive care units: a cluster randomized trial. *JAMA* 2011; **305**: 363–72
35. Ko HC, Turner TJ, Finnigan MA. Systematic review of safety checklists for use by medical care teams in acute hospital settings – limited evidence of effectiveness. *BMC Health Serv Res* 2011; **11**: 211
36. Aitken LM, Bucknall T, Kent B, Mitchell M, Burmeister E, Keogh SJ. Protocol-directed sedation versus non-protocol-directed sedation in mechanically ventilated intensive care adults and children. *Cochrane Database Syst Rev* 2018; **11**: CD009771
37. Wang L, Li X, Yang Z, et al. Semi-recumbent position versus supine position for the prevention of ventilator-associated pneumonia in adults requiring mechanical ventilation. *Cochrane Database Syst Rev* 2016; **2016**: CD009946
38. van der Voort PHJ. Quality improvement in the ICU: treat first what kills first. *J Thorac Dis* 2017; **9**. E310–E2
39. Hallam BD, Kuza CC, Rak K, et al. Perceptions of rounding checklists in the intensive care unit: a qualitative study. *BMJ Qual Saf* 2018; **27**: 836–43

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