Prospective Multicenter Multifaceted Before-After Implementation Study of ICU Delirium Guidelines: a Process Evaluation

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ABSTRACT

Background

Implementation of delirium guidelines at ICUs is suboptimal, although their adoption may improve patient outcomes and is endorsed by international guidelines. Within a prospective implementation study, we aimed to explore: the exposure of health care workers to the implementation program; effects on guideline adherence at ICU-level; impact on knowledge and barriers, and experiences with the implementation program.

Methods

This was a mixed method process evaluation of a prospective multicenter implementation study, including data for 4,449 adult ICU patients (21,015 patient days). A tailored implementation program was executed in six ICUs. Adherence to delirium guideline recommendations at ICU-level was determined before, and after implementation of delirium screening, after subsequent implementation of delirium guidelines, and finally, six months after implementation (to assess sustainability). Knowledge of professionals and perceived barriers were measured during phase 1 and 3. Finally, interviews were done at all sites to explore experiences with the implementation.

Results

Five of six ICUs were exposed to all implementation strategies as planned. More than 85% followed the required e-learnings; 92% of the nurses attended the clinical classroom lessons; 5 ICUs used all available implementation strategies and perceived to have implemented all guideline recommendations (> 90%). Adherence to predefined performance indicators at ICU level was only above the preset target (>85%) for delirium screening. For all other performance indicators, the inter-ICU variability was between 34 and 72% indicating variable adoption of guideline recommendations among the ICUs. The implementation of delirium guidelines was feasible and proved successful in resolving the majority of barriers found before the implementation, mainly by improving knowledge about delirium (from 61 to 65%). The improvement was generally well sustained six months after full guideline implementation. Local implementation teams experienced the implementation program as very successful in changing ICU professionals' recognition of delirium as an indicator of "brain failure".

Conclusions

Multifaceted implementation interventions can improve and sustain adherence to delirium guidelines. implementation programs are feasible using local champions and can largely be performed as planned. However, variability in delirium guideline adherence at individual ICUs remains a challenge, indicating the need for more tailoring at center-level.

BACKGROUND

Delirium is strongly associated with Intensive Care Unit (ICU) length of stay, mortality and long term cognitive and functional impairments [1-4]. Previous studies have indicated that delirium can be reduced by using less sedation and avoiding use of benzodiazepines, early weaning from mechanical ventilation, and early physical therapy and mobilization [3,5,6]. Those evidence-based interventions are summarized in the 2013 Pain, Agitation and Delirium (PAD) guidelines [7] and more recently in the updated PADIS (Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption) guidelines of the Society of Critical Care Medicine [8]. Implementation of PAD guidelines in the ICU setting was mostly done in previous studies with high levels of resources, and with dedicated research personnel using the "Awakening and Breathing Coordination, Choice of drugs, Delirium monitoring and management, Early mobility, and Family engagement" (ABCDEF) bundle [9-13].

Recently, we published the results of a multicenter implementation study aimed to implement delirium-oriented recommendations derived from the Dutch ICU Delirium Guidelines [14] and the 2013 PAD guidelines [15]. In this study named the 'ICU DElirium in Clinical PracTice Implementation Evaluation' (iDECePTIvE) study, a multifaceted implementation program based on pre-implementation assessment of barriers was developed and evaluated [16-18]. The overall results showed an improved adherence to delirium guidelines and recommendations. Further, the improved adherence resulted in decreased levels of brain dysfunction, meaning reduced delirium duration and a lower number of coma days [18]. However, variable guideline adoption among different sites is a well-known phenomenon [19], which may also provide insights on factors that enhance effective implementation and guideline adoption versus factors that do not. Therefore, this process evaluation study aimed to further zoom in into the implementation interventions to get insight into the determinants and indicators of success or failure of the implementation program and to provide more detailed background information on the entire implementation process.

We explore the following four issues: 1) actual exposure to the implementation program at the individual ICU level; 2) effects of the implementation program on guideline adherence at the individual ICU level and its sustainability after six-months; 3) impact of the implementation program on implementation barriers and knowledge among ICU professionals over time; and finally, 4) the experiences of the site-specific implementation teams with the implementation program.

METHODS

Design, Setting and Participants

This was a mixed method process evaluation of a multicenter prospective pre-post implementation study (iDECePTIvE). This report adhered to the Standards for Reporting Implementation Studies (StaRI) Statement [20]. The Implementation Model of Change of Grol and Wensing was used to structure the guideline implementation [21]. The details of the study design and methods have been reported previously [16,18]. Briefly, data for performance indicators (PIs) on adherence to guideline recommendations from the PAD guidelines related to delirium were collected in four phases, defined as follows: first phase (T1, baseline period); before implementation, usual care was evaluated, second phase (T2); after implementation of delirium screening tools, third phase (T3): after implementation of delirium treatment and prevention guidelines, and fourth phase (T4); six months after completion of the implementation in the third phase, to assess the sustainability of the implementation. Whereas the findings of the iDECePTIvE study were based on the comprehensive data of all ICUs combined [18], this process evaluation is a sub-analysis of data and expands on the findings at the individual site (ICU) level and the addition of results on short term-sustainability of guideline adoption. Several methods were used. Qualitative components involved semi-structured interviews with professionals. Quantitative components were surveys and data on seven performance indicators (PIs) to measure guideline adherence. Definitions of these performance indicators were previously defined [18].

The major implementation strategies of the implementation program were education, audit and feedback, and reminders, as previously described [18]. In brief, education was provided in the form of web-based e-learning. Education was provided first in phase II during implementation of screening for delirium and thereafter in phase III, where it focused on the contents of delirium prevention and management guidelines. In addition to e-learning, classroom educational sessions for nurses were held, aimed to discuss the questions raised about delirium screening and protocols, and to provide more information about the implementation and practical application of the protocols. The physicians were not required to be present at the clinical classroom lessons. During study phase II educational spot-checks of delirium screening (target was four spot check moments per nurses versus local experts) were performed. Audit and feedback were applied in two ways during phase II and III: 1) using posters with delirium screening adherence and prevalence of delirium of the individual ICU (phase II), which were presented to the ICU staff of the separate ICU every quarter [16]; and 2) using a so-called Implementation Readiness Test (IRT, phase three; explained in next paragraph). During phase II, posters on delirium screening were presented to the ICU staff of the separate ICUs every quarter. These posters presented the actual adherence rates of the individual

ICU and the mean of all centers to delirium screening for comparison and visualized the predefined adherence level-aim of 85% [16]. To further facilitate the use of the guidelines in daily practice and to sustain the implementation, an ICU Delirium App was developed as an implementation facilitator (link: http://icudelierapp.nl). The App was focused on the health care professional who received advice on additional management regarding delirium in a certain patient using a step-wise evaluation of the current status of the patient and current management. The App was released in January 2015. Reminders were used as the standard notifications and flowcharts for delirium screening and management in the electronic patient files system. An information leaflet and a poster for family members of ICU patients were used to inform them about the identification, prevention and treatment of delirium in an attempt to further enhance and stimulate structural attention for delirium by next-of-kin and stimulate discussions with care providers.

Data collection

1. Actual exposure to implementation program

To be able to follow the implementation progress at different sites and to provide the sites with implementation feedback, we drafted an implementation process check tool, which we named the "Implementation Readiness Test" (IRT)**.** The IRT was applied three times in eight months during the audit visits in Phase III to evaluate the current status and progress of implementation as perceived by the local implementation team. The IRT consisted of two parts: 1) assessment of application of the number of implementation strategies by the local study team; and 2) the local study team's perception of the extent to which the guideline recommendations were actually implemented into clinical practice. This enabled us to generate feedback for the local implementation teams. Based on the IRT, an action plan at site level including the priorities for each site, was made. Follow-up IRTs were done twice approximately every three months. The study team also used IRTs to monitor the progress of implementation at all sites, by giving each item one point for each site if a particular item was implemented. As such these scores were used to monitor and semi-quantitatively assess implementation progress. Of note, the IRT is not a validated tool and meant to monitor and stimulate the implementation progress in a pragmatic and face-valid manner.

2. Effect of the implementation program on guideline adherence at ICU level

All consecutive adult ICU patients were included. Adherence rates to the guideline recommendations at site-level were assessed with seven performance indicators (PI) [18]. In addition to the previous paper [18], we now added the data on the sustainability of the adherence changes 6 months after implementation phase III.

3. Impact of implementation program on knowledge and implementation barriers
Beliefs, attitudes, practices, knowledge, guideline implementation barriers and facilitators for nurses and physicians of the ICUs were assessed twice, both before T1, and after the guideline implementation (T3). Details of the questionnaire were previously published [17].

4. Experiences with the implementation program
In order to explore the experiences of local implementation teams, we organized interviews at each site after completion of phase III. The interviews were semi-structured with predefined questions about the experiences with the implementation program and its components **(Additional file 1)**. We also asked the members of local implementation teams to provide the study implementation management team with feedback and to give their opinions on the success of implementation, barriers perceived during execution of the implementation program and the satisfaction with the program. All interviews were audio-recorded and conducted by the same moderator (ZT).

Data analysis

Quantitative data
Data regarding the actual exposure to the individual elements of the implementation strategies were presented as percentages or absolute numbers. The questionnaires were distributed before phase I and after implementation. For the questions about 'attitude and perceptions' and the 'current practices' we used the questions with dichotomous answer options yes / no or agree / disagree (from the 5-point Likert scale statements where options: 1= strongly disagree; 2= disagree; 3= neutral; were marked as disagree and options 4= agree; 5= strongly agree) where marked as agree. Barriers for this dichotomous questions were considered to be present if <50 % of the respondents gave an answer implicating support for the issue pertaining to that statement. Barriers for delirium guideline and guidelines in general adherence were assessed with 6-point Likert-scales (no agreement = 0, and maximum agreement = 5). Mean scores of ≥ 3 were considered to indicate agreement with statements and was considered as a barrier [17]. A delirium knowledge score was calculated per respondent, defined as the percentage of correct answers. A mean delirium knowledge score below 70% was considered as a barrier regarding knowledge at the group level (e.g. ICU, nurses, physicians). Student t-test (for two groups) and one-way ANOVA (for three groups) was used to test the differences per ICU before versus after implementation. Frequencies and proportions were used to describe the adherence to the seven PIs and were described at ICU level and stratified by the four periods. The relative change in adherence difference between the baseline (T1) and the follow-up (T4) for each ICU and each guideline recommendation was given as ΔT4-T1 and the crude adherence numbers for T1 and T4 were reported.

Qualitative data

Associations between guideline adherence and exposure to implementation strategies was explored qualitatively by visual inspection. The interviews were transcribed verbatim and summaries of the interviews were sent to the participants to check for accuracy and validity of transcriptions. The moderator of the interviews (ZT) had also analyzed the data through reading and rereading interviews in order to obtain the essence of the whole. Thematic content analysis approach was used in searching themes [22]. Next, themes were labeled, coded and defined as: factors of implementation success, experience in collaboration with study implementation team (EI, MvdJ and ZT), and lessons learned for future implementations. Reliability checks were done by a second researcher (EI), and discussed and resolved in case of any unclarities.

RESULTS

All available staff working at the ICUs, 81 physicians (range within ICUs: 5 to 31) and 409 nurses (range: 35 to 125 per ICU), was targeted to participate in the implementation program. Depending on the number of ICU beds, the local implementation expert teams consisted of 2 to 11 ICU professionals. All ICUs were visited by the study management team at least seven times. One site (ICU4) was visited ten times due to challenges in the implementation caused by changes in RNs involved.

1. Actual exposure to implementation program

The average self-recorded time spent on both e-learnings was about 45 minutes per person per e-learning. Classical clinical lessons for delirium screening and PAD recommendations were repeated several times (about 45 minutes for each lesson). The majority of nurses (n = 375; 92%) attended the clinical classroom lessons. During study phase II educational spot-checks of delirium screening (nurses versus local experts) were performed as intended (four spot check moments per nurse).

Table 1 shows an overview of three completed IRT forms (filled in approximately three months apart), just before the T3 data collection period. Total score just before the start of T3 data collection was for both parts of IRT between 90 and 100% and had overall improved compared to the first assessment 6 months earlier. Five ICUs used all implementation strategies and implemented all guidelines recommendations, as estimated by the local intensivist or RN involved in the study. Only ICU 4 lagged behind and used 81% of the available implementation strategies and implemented only 67% of the advised protocol recommendations in daily practice.

Table 1: Implementation Readiness Test (Exposure in number of ICUs)

Part 1: Execution of Implementation Strategies				
Implementation strategy	Norm / requirements	IRT[1] 1	IRT 2	IRT 3
Education: Learning Part 1 screening	≥75% of nurses have completed the e-learning?	6[2]	6	6
Education: eLearning Part 1 screening	≥75% of physicians have completed the e-learning?	4	5	6
Education: e-learning Part 2 - treatment and preventive protocol	≥75% of nurses have completed the e-learning?	2	2	6
Education: e-learning Part 2 - treatment and preventive protocol	≥75% of physicians have completed the e-learning?	2	3	6
Clinical lessons screening	New employees are trained around delirium management?	3	4	4[3]
Educational outreach				
Spot-checks screening	There are at least 4 spot checks done by a nurse?	5	5	5
Quality control screening	This is scored by the experts? (Interobserver variation)?	3	4	5
Local implementation teams				
	Local implementation team is multidisciplinary (at least: intensivist, IC nurse, and possibly: psychiatrist / neurologist / geriatrician / physical therapist)?	6	6	6
	There were at least 2 consultations between local implementation team members (since beginning of the study) and there are agreements on implementation?	4	5	6
	It was agreed (preferably also recorded) who is responsible for which part of the implementation.	6	6	6
Local opinion leaders	It is clear who the implementation team members are and who is a contact for delirium in general and the study in particular?	5	5	6
Audit and feedback				
Indicators poster screening and incidence	1) Are the posters visible? 2) Are those discussed in the management team?	5 2	6 5	6 6
Decision support				
Laminated pocket cards screening CAM-ICU or ICDSC	Are pocket cards present for nurses and physicians?	5	6	6
	Pocket cards are used in practice?	3	4	5[4]
Reminders	There are reminders regarding screening and management of delirium (if available, popups PDMS for screening)	6	5	6
Focus groups / barrier analysis	Bottlenecks are discussed in local multidisciplinary meetings at the ICU level and is the implementation aimed to address them?	2	3	5

Table 1: Implementation Readiness Test (Exposure in number of ICUs) (continued)

TOTAL (of max 99)		**69 (70%)**	**80 (81%)**	**96 (97%)**
Part 2: Implementation of Protocol				
PDMS (patient demographic management system)	Is PDMS modified and helpful for delirium screening?	5	5	5[5]
Treatment delirium	Are the 4HS 4TS used in practice regularly if delirium screening result is a positive one (new delirium) ?	0	3	5
	Is it clear what the drug treatment for delirium (according to protocol) is?	4	6	5
	Is medication sometimes modified following the screening?	5	6	6
	Are the non-pharmacological measures optimized before starting medication?	2	3	5
Prevention of delirium: Physical therapy and early mobilization	Physical therapy: there are structural arrangements with physical therapist and there is agreement about how to provide early physical therapy and mobilization?	2	3	6
	Mobilisation of patients Is basically addressed daily patient rounds and this is implemented in the daily rounds?	4	5	6
	Its department policy in such a way that seeks to mobilize ventilated patients next of bed if possible?	3	4	5
Prevention: sleep hygiene	Is there a protocol regarding sleep promotion?	3	6	6
	Used this protocol and regularly followed in practice?	0	5	5
	Sleep protocol contains at least the next recommendations: lights off or muted overnight, strive for sleep (no standard rounds running if not necessary), and use of earplugs?	5	5	6
Prevention: psycho hygiene (among other, reducing sensory deprivation)	Is there a structural focus on using eyeglasses / hearing aid if the patient used normally in all patients / days?	4	5	6
Evaluation of pain-sedation-delirium	Daily delirium screening is implemented and "going well"?	3	4	6
	The coordination of delirium, sedation and pain management is implemented in any way in the daily rounds (eg. visit form)?	4	5	6
	Daily rounds checklist is implemented and used?	3	4	5
Sedation	Sedation with midazolam (or other benzodiazepines) by continuous infusion is avoided, and alternative sedation (analgo-sedation with opiate and possibly clonidine / dexmedetomidine / propofol targeting addressable patient comfortable?) is used?	4	5	6
Family engagement	Is there a leaflet about delirium for family?	4	4	6

Table 1: Implementation Readiness Test (Exposure in number of ICUs) (continued)

	Family of the ICU patient is getting the opportunity to contribute in identifying and / or treatment of delirium (eg. To help with washing, etc.)?	3	5	6
	Poster about family engagement by delirium is presented in the family room?	1	2	5
TOTAL (of max 113)		**59 (52%)**	**84 (74%)**	**106 (94%)**

[1] IRT = Implementation Readiness Test, drafted to measure the actual exposure to implementation strategies as perceived by the local study team. All three IRT overviews were made in Phase III during the implementation of guideline (total time = 10 months). The last one IRT overview was made just before the start of third data collection period (T3).
[2] The numbers indicates the number of sites which has implemented the item in daily practice.
[3] Not Applicable for two ICUs because there were no new employees at previous period.
[4] Not Applicable for one ICU because the information as given on Pocket cards was integrated in PDMS
[5] Not applicable for one ICU because no PDMS system was available.

2. Effect of the implementation program on guideline adherence at the level of participating ICUs and sustainability

The fourth data collection period served to assess sustainability of the implementation, and included an additional 519 patients (2727 days) next to the 3930 patients from the previous three phases. Only the percentage of mechanically ventilated patients was higher (51%) than in the preceding three phases (resp. 42%; 39%; 50%) as previously published [18]. See **Additional file 2** for patient demographics in phase T4.

Figure 1 displays the changes on adherence to the performance indicators in the different ICUs over time. Absolute numbers for all four measurement periods are given in **Additional file 3**. Adherence to the seven performance indicators improved overall and this improvement was sustained 6 months after active implementation support by the study management team had been terminated. Four PIs improved by more than 10%. The adherence to Delirium Screening (ΔT4-T1) improved most significantly with +57%, followed by avoiding benzodiazepines sedation (+18%); performing PT (+17%); and performing mobilization (+13%). Sedation assessments were improved during implementation, but the improvement of +8% was not sustained after implementation and dropped to the initial adherence level of 86%. Performing physical therapy initially improved by 27%, but dropped to 17% in T4. Light Sedation improved slightly by 7%.

Despite the overall improvement on process indicators, not all ICUs succeeded in adherence improvement for all performance indicators. In contrast and remarkably, decreases in adherence of more than 10% were measured on four performance indicators between baseline and follow up (**See Additional file 3** for ΔT4-T1). These were: Sedation Assessments (ICU 3 = -15%; and ICU 6 = -20%); Light sedation (ICU 1 = -13%); Avoiding Benzodiazepines Sedation (ICU 4 = -13%); and Performing Physical Therapy (ICU 1 = -26%; and ICU 4 = -35%).

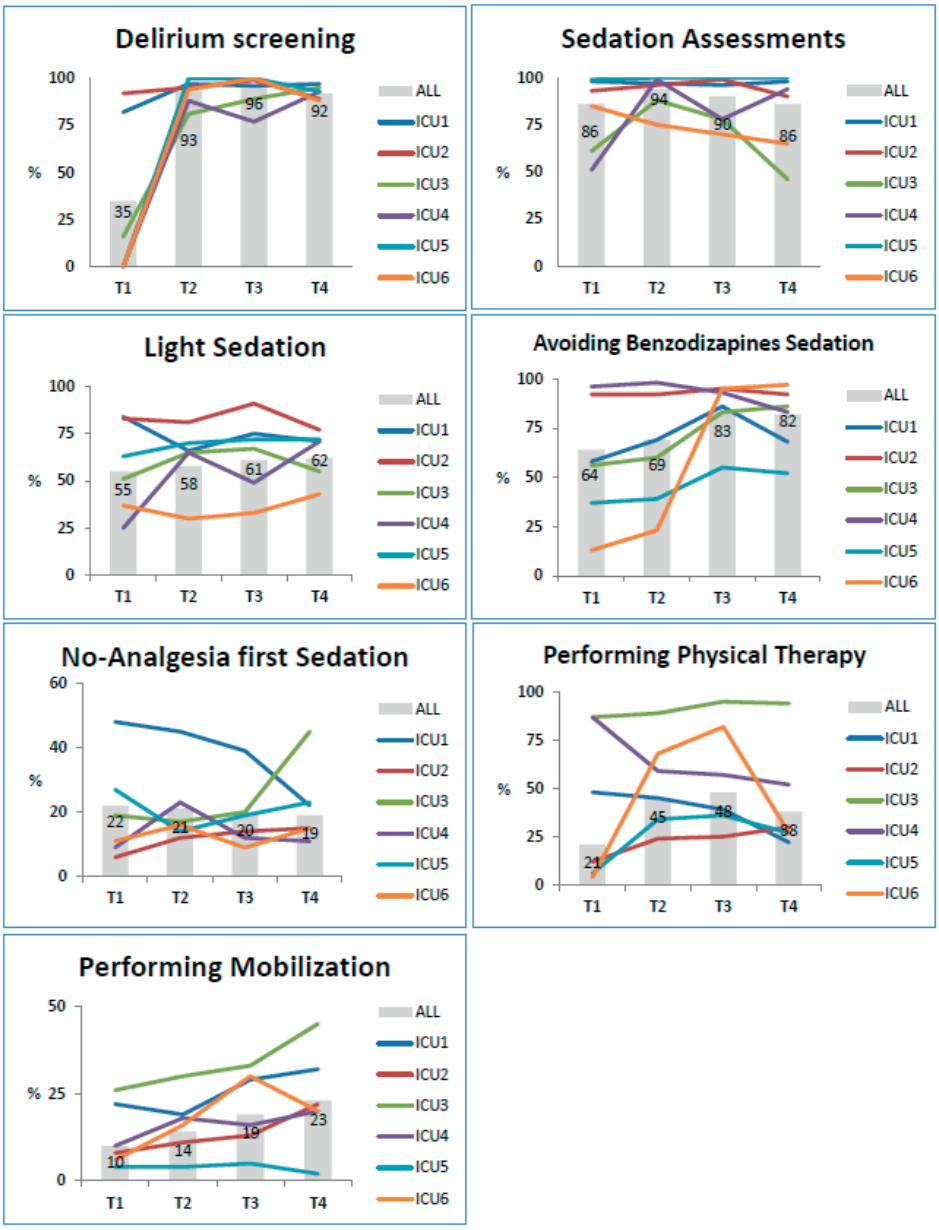

Figure 1: Adherence to Process Indicators over the study periods

There was no clear relationship between center specific adherence changes and clinical outcomes changes per ICU, similar to the overall results. **Additional file 4** shows the changes of clinical outcomes per ICU per study phase.

3. Impact of the implementation program on knowledge and implementation barriers

In total, 360 (69%) and 264 (50%) healthcare professionals completed the survey at T1 and T3 respectively. There were no differences between the participants at T1 and T3 in years of experience, work assignment, and age **(See Additional file 5)**. Delirium knowledge test scores improved from 62.9 (SD = 13.3) before to 65.1 (SD = 13.1) after the implementation (p = 0.037). However, significant differences were established by only three of the ICUs (ICU 1: from 65 to 67 %; ICU 2: from 62 to 64 %; and ICU 6: from 60 to 66 %) that succeeded in obtaining improved knowledge scores, while we found no differences in exposure to education for this three ICUs.

From all barriers identified through the survey before the implementation a quarter was not resolved by the implementation program. The perception that "delirium is not preventable" was not resolved. This may have affected, for example, the use of earplugs for the night. Also, the perception that "routinely addressing delirium in daily rounds can still be improved after the implementation" was not resolved, and finally, the satisfaction of nurses about delirium treatment did not improve **(Table 2)**.

4. Experiences with the implementation program

Overall, the members of the local implementation teams experienced the implementation program as very successful. The most important themes were the encouragement of the local implementation team by the implementation management team, change of culture with regard to the attitude of professionals towards delirium as a form of brain failure, and the improvement in collaboration with other (not ICU) disciplines due to the implementation. Despite the believe that a positive change in practice around delirium management had been made, the application of delirium preventive interventions still deserved more attention. A more detailed report of the semi-structured interview findings about experiences with the implementation program is given in **Additional file 6.**

DISCUSSION

In this process evaluation of a multicenter delirium guidelines implementation program, we found that all ICUs, except for one, were exposed to more than 90% of the implementation strategies. The implementation of the delirium guideline using the tailored implementation program was feasible and successful in resolving the majority of barriers found before the implementation. It resulted in improved knowledge about delirium, and it improved the daily process of care at six ICU sites as defined by seven performance indicators (PIs), which generally proved sustainable when measured after 6 months. However, the results on the PIs showed a considerable variation in guideline adoption across the six ICUs. Experiences with the implementation support from the

Table 2: Comparison of barriers found by first survey versus the results of second survey

	BEFORE	AFTER
(a) Attitudes and perceptions	**%**[a]	
Delirium occurrence and importance		
Delirium is preventable	21	15
Screening	%[a]	
Is a nurse capable to identify delirium with a validated delirium screening instrument?	34	80
Collaboration	%[a]	
When I as nurse suspect a patient to be delirious, I am satisfied with delirium treatment	47	40
When I as physician suspect a patient to be delirious, the nurse is satisfied with delirium treatment	42	11
Collaboration between doctors and nurses with regard to delirium at the ICU can be improved by better screening.	65	30
Collaboration between doctors and nurses with regard to delirium at the ICU can be improved by routinely addressing delirium in daily rounds.	74	78
(b) Current practices		
Delirium Screening	%[a]	
In the ICU unit where I work the following delirium screening scale is in use:		
CAM-ICU (Before: n=210; in only two hospitals / After: n=119)	58	45
ICDSC (Before: n=3 / After: n=104)	<1	39
Delirium Prevention		
Earplugs for the night	8	24
Family visits as much as possible	50	61
(c) Guideline adherence (n=136)		
If I follow the guideline recommendations, it is likely that my patients would not receive optimal care [b]	3.1 (1.0)	1.9(1.1)
I do not wish to change my delirium care practices, regardless of what delirium guideline recommends [b]	3.7 (1.0)	1.4(1.0)
I don't have time to use this Guideline [b]	3.5 (0.9)	1.7(1.0)
This guideline is cumbersome and inconvenient [b]	3.0 (1.1)	2.0(1.1)
(d) Guideline adherence in general (n=128)		
Generally, guidelines are cumbersome and inconvenient [b]	3.0 (0.9)	2.2(0.9)
Guidelines are difficult to apply and adopt to my specific practice [b]	3.1 (0.9)	2.0(0.9)
Guidelines interfere with my professional autonomy [b]	3.3 (0.9)	1.7(0.9)
Generally, I would prefer to continue my routines and habits rather than to change [b] based on practice guidelines [b]	3.3 (1.0)	1.9(0.9)
I am not really expected to use guidelines in my practice setting [b]	3.7 (0.9)	1.4(1.0)

[a] = % agreement (= %YES answers or % or the sum of agree and strongly agree answers (from the 5-point Likert scale statements)). Barriers depends on the question formulation. For positive formulated the barrier is ≤50% and negative formulated the barrier is ≥50%.[b] = mean and standard deviation based on the 6 point Likert-scale. Mean score of ≥3 was considered to indicate agreement with statement = Barrier

research coordinators were favorable, but continued support and coaching was deemed necessary to support the implementation interventions throughout the study.

Despite the general improvements in process of care outcomes, our data do not allow for conclusions regarding an association of individual implementation strategies and adherence changes because all sites largely executed the implementation as intended. Different entry levels of adherence and variation in time also make it difficult to compare the changes in time. However, the wide variation in guideline adoption, may be an argument that there is still room for more center-level tailoring.

We have identified relevant differences in the "dose" of implementation for individual PIs. Only for delirium screening the norm (goal ≥ 85%) was set before the implementation and repeated feedback about performance on this PI was given during the implementation phase. In daily practice there was more focus and education on this topic (separate e-learning and classical lessons, and spot-checks), and there were specific Patient Data Management System (PDMS) adjustments and delirium screening quality checks. This difference between the efforts made for the Performance Indicator for delirium screening and the rest of the Performance Indicators concerning other guideline recommendations from the PAD guidelines, resulted in the highest adherence (changes) on delirium screening PI during the implementation. Setting a clear adherence-level goal in combination with using audit and feedback for all PIs may have resulted in an increased level of adherence. Positive effects of audit and feedback on professionals intentions to improve practice have been empirically evaluated [23]. In our study the feedback data were collected and given only for delirium assessment and incidence of delirium. We suggest this was a facilitator in improving adherence in combination with electronic reminders to create continued awareness for delirium assessment and presence of delirium. However, we did not use the same feedback for the other PIs which may have hampered adoption of other guidelines than the screening for delirium. Otherwise, we could have intervened on time through providing feedback to those sites with deteriorating adherence on four PIs as described above.

Even though all sites were exposed to the same implementation program there were differences in the adherence changes across the sites. Based on the results of this process evaluation we cannot easily explain the variability within and between the sites. One of the possible explanations in the variability in adherence to the implementation program is the fact that there were other implementation projects, and organizational changes going on at the different sites which diverted the attention of the physicians, nurses and managers. During the study, two ICUs underwent organizational changes such as opening a medium care unit at the ICU, and separating medium care and ICU care patients at different units (ICU 1 and ICU 6). Such changes could be the reason behind the increased number of mechanically ventilated patients over the four study periods (baseline 42% to 51% in follow-up). But more importantly, we did not assess culture, organizational

aspects, and other context related factors before implementation across multiple sites which may have shed light on the variable adoption. Retrospectively, the Consolidated Framework For Implementation Research (CFIR) [24] could have been a helpful implementation model: in contrast to the implementation model of change of Grol and Wensing [21], the CFIR model operationalized the organizational context by two dedicated domains: "inner setting" (local culture, leadership engagement, implementation climate, etc.), and 'outer setting' (patients' needs and resources, cosmopolitanism, peer pressure and external polices and incentives). Readiness for implementation with the self-designed IRT was only one construct of 'inner setting' we used to get an overview of implementation progress across the sites. Local implementation teams experienced the implementation program as very successful in changing the culture of ICU professionals about delirium as indicator of brain failure and a problem that needs to be actively addressed, but that was not directly related to the degree of local implementation success.

One of the problems when comparing the degree of adherence with other guidelines implementation studies relates to the definitions of different PI measures [11] and the measurement of total or partial compliance in relation to hospital survival [13]. The question remains: when are we satisfied with the degree of adherence? We defined a target level for the PI for delirium screening only, and did not define this for other PIs or overall implementation success in advance. The definition of targeted adherence-level in advance is not a common practice in implementation studies, but we suggest that this may provide more clarity on the goals of implementation, which may facilitate adherence and, ultimately, quality of care [25].

Limitations of the study particularly relate to lacking assessment of the implementation context e.g. ICU culture and context of organization in advance, which impedes obtaining general insights from the implementation at large. Second, assessment of exposures of the ICUs to the implementation program partly depended on self-reported assessments, which may not have been entirely accurate. For example, when we assumed that the e-learning was executed as intended because the self-evaluation forms were filled in correctly, we cannot guarantee that knowledge indeed was conveyed optimally to every health care professional, because this depends on how serious the education was done. Third, predefined knowledge level of >70% was a choice and may not have represented sufficient knowledge. Apart from this predefined knowledge level, the survey was, although based on previously published studies, not a validated questionnaire and may not have had the most optimal validity to test knowledge. Fourth, our design was not appropriate for measuring the association between the individual implementation strategies and adherence changes. Finally, experience with implementation was measured only among the local implementation team members, and not among all involved health care professionals at the participating units. Also, the managers were not involved during the implementation whereas previous studies have shown that

healthcare managers may play an important role in facilitating implementation [26] and buy-in from medical staff seems essential. More inclusive assessment of experiences of both healthcare professionals and managers with the implementation could have provided more information about the "why" of non- (or suboptimal) adherence.

CONCLUSIONS

Multifaceted implementation interventions such as performed in this study can improve delirium guideline adherence in the ICU, moreover the improvements of these implementation interventions can be sustainable on the short term. Delivering multifaceted implementation interventions is feasible within the ICU setting, where these interventions can largely be performed as planned. Indicators of success or failure of the implementation remains very challenging to identify in an observational study as ours, because implementation success may be variably defined or perceived and because of the multitude of factors influencing both guideline adherence and clinical outcomes, including ICU culture which we did not formally assess. In spite of a general level of tailoring, variability in delirium guideline adherence at individual ICUs remained in this study. For future quality improvement, this could possibly be resolved with investing in a higher degree of tailoring implementation interventions to ICUs' local inner and outer context.

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ADDITIONAL FILES

Additional file 1: Semi structured interview for the assessment of experiences of local implementation teams with the implementation

1. Do you think that the implementation of delirium directive (generally) was successful?
- If not, why it was not successful?

2. Which components of the implementation were successful?
- If yes, which:
- If not, which:

3. Are the barriers identified at the beginning of the study for your center / ICU sufficiently resolved with the chosen implementation interventions?

4. Which individual components of the strategies have been effective and which ones (i.e. why the implementation was less successful (open question thus, and own opinion about this, will also provide additional information)?

5. Did you have a local project team / delirium expert team,
- Who was involved?
- How were the roles / responsibilities distribution inside the local team?
- Had we had to tackle different things (study team and ICs) differently?

6. Describe Part 1: implementation of screening and

7. Describe Part 2: Implementation of prevention and treatment.

8. Is the guideline delirium sufficiently guaranteed, and what does this prove?

9. What are the thoughts about Feedback on delirium incidence and delirium screening?

10. Control for screening of delirium: Are you going through this and how?

11. Nursing - doctor cooperation?

12. Is the delirium App applicable in practice?

Question about project organization:

1. Were the objectives of the coordination team (study team / we) clearly / concretely formulated?

2. What do you think of time investment (e.g. to implement screening)?

3. Sufficient support from coordinating team to achieve goals?

4. What did this project teach you for future implementation projects (such as protocols, guidelines)?

- Organization,
- Material,
- Communication,
- Staff,
- time

What combinations of strategies have been essential to your practice (what has been the key to success?)
Process
Finally, complete the completed IRT table of the relevant hospital and complete it at the end the interview.
Also check for any structural changes to the IC have been made. E.g.
1.

Additional file 2: Patient Demographics and Baseline Clinical Characteristics in T4

Characteristic	***Data-collection period[c] T4 / Sustaining***
No. of patients, n	519
No. of ICU[a] days, n	2727
Gender, n (%)	
Male	300 (58)
Female	219 (42)
Age (years), median (IQR[a])	66 (55, 76)
Admission status, n (%)[b]	
Elective surgery	135 (26)
Emergency surgery	55 (11)
Medical	271 (52)
APACHE-II[a], median (IQR)	16 (12, 22)
Mechanically Ventilated patients, n (%)	261 (51)
Hospital, n (%)	
1	73 (14)
2	117 (23)
3	103 (20)
4	37 (7)
5	124 (24)
6	65 (13)

[a]Acute Physiology and Chronic Health Evaluation II range is 0-71, IQR: Interquartile range; ICU: intensive care unit

[b] Admission status missing's for Sustaining period = 1

[c] Data about previous three phases were published previously[1]

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Additional file 3: Changes in Pain Agitation Delirium (PAD) Guidelines Performance Indicators at ICUs level across study

Performance Indicator (PI)[1]	ICU	T1[2] baseline	T2	T3	T4 follow-up	Δ T1 - T4% (T4% - T1%)
Delirium Screening (Total No. of days with at least one CAM-ICU or ICDSC assessment recorded / Total No. of patient-days at ICU)	1	82	97	96	97	+15 (97 - 82)
	2	92	95	99	89	-3 (89 - 92)
	3	16	81	89	95	+79 (95 - 16)
	4	0	88	77	93	+93 (93 - 0)
	5	0	100	100	93	+93 (93 - 0)
	6	0	94	100	88	+88 (88 - 0)
	ALL	35	93	96	92	+57 (92 - 35)
Sedation Assessments (Total No. of days with at least one sedation assessment recorded / Total No. of ICU days in ventilated patients receiving sedation and /or opioids)	1	98	97	96	98	0 (98 - 98)
	2	93	96	99	90	-3 (90 - 93)
	3	61	88	78	46	-15 (46 - 61)
	4	51	99	78	94	+43 (94 - 51)
	5	99	100	100	100	+1 (100 - 99)
	6	85	75	70	65	-20 (65 - 85)
	ALL	86	94	90	86	0 (86 - 86)
Light Sedation (No. of light sedation days[3] / Total No. of ICU days in ventilated patients receiving sedation and /or opioids)	1	84	66	75	71	-13 (71 - 84)
	2	83	81	91	77	-6 (77 - 83)
	3	51	65	67	55	+4 (55 -51)
	4	25	65	49	71	+46 (71 - 25)
	5	63	70	72	72	+9 (72 - 63)
	6	37	30	33	43	+6 (43 - 37)
	ALL	55	58	61	62	+7 (55 - 62)
Avoiding Benzodiazepines Sedation (No. of benzodiazepines[4] sedation days / Total no. of ICU days in mechanically ventilated patients during at least one ICU-day AND having received sedation and/or opioids)	1	58	69	86	68	+10 (68 - 58)
	2	92	92	95	92	0 (92 - 92)
	3	56	60	83	86	+30 (86 - 56)
	4	96	98	93	83	-13 (83 - 96)
	5	37	39	55	52	+15 (52 - 37)
	6	13	23	95	97	+84 (97 - 13)
	ALL	64	69	83	82	+18 (82 - 64)
No-Analgesia first sedation (No. of patient without-analgesia-while-sedated days / Total number of patient sedation days)	1	48	45	39	22	-26 (22 - 48)
	2	6	12	14	15	+9 (15 - 6)
	3	19	17	20	45	+26 (45 - 19)
	4	9	23	12	11	+2 (11 - 9)
	5	27	14	19	23	-4 (23 - 27)
	6	11	16	9	15	+4 (15 - 11)
	ALL	22	21	20	19	-3 (19 – 22)

Additional file 3: Changes in Pain Agitation Delirium (PAD) Guidelines Performance Indicators at ICUs level across study (continued)

Performance Indicator (PI)[1]	ICU	T1[2] baseline	T2	T3	T4 follow-up	Δ T1 - T4% (T4% - T1%)
Performing Physical Therapy (No. of patient-days with PT / Total No. of patient ICU days; included with LOS > 2 days)	1	48	45	39	22	-26 (22-48)
	2	12	24	25	30	+18 (30 - 12)
	3	87	89	95	94	+7 (94 - 87)
	4	87	59	57	52	-35 (52 - 87)
	5	6	34	36	27	+21 (27 - 6)
	6	4	68	82	27	+23 (27 - 4)
	ALL	21	45	48	38	+17 (38 - 21)
Performing Mobilization (No. of patient-days with mobilization / Total No. of patient ICU days included with LOS > 2 days)	1	22	19	29	32	+10 (32 - 22)
	2	8	11	13	22	+14 (22 -8)
	3	26	30	33	45	+26 (45 - 26)
	4	10	18	16	20	+10 (20 - 10)
	5	4	4	5	2	-2 (2 - 4)
	6	6	16	30	20	+14 (20 - 6)
	ALL	10	14	19	23	+13 (23 - 10)

[1] Predefined Performance Indicator(s) were used to assess the Pain Agitation Delirium (PAD) guidelines recommendations. For performance Indicators metrics see In and defined.

[2] T1= Baseline measurement (Before the start of implementation); T2= After delirium screening implementation; T3= After PAD guidelines implementation; T4= follow-up 6 months after implementation.

[3] Definition of Light sedation: Richmond Agitation and Sedation Scale (RASS) >- 3 or Critically Ill Assessment Scale (CIA) >6 or Ramsay Sedation Scale <5, see manuscript text for references.

[4] Benzodiazepines = midazolam and / or lorazepam as continuous intravenous sedative.

Additional file 4: Clinical Outcomes at ICUs level across the study

Outcomes		*Crude analysis*											
	ICU	**T1**		**T2**			**T3**			**T4**			
		Patients, n		*Patients, n*		*p-value (T1 versus T2)*[a]	*Patients, n*		*p-value (T1 versus T3)*[a]	*Patients (n)*		*p-value (T3 versus T4)*[a]	*p-value ALL*[b]
Delirium duration (days), median (IQR)	1	59	3 (2, 6)	38	1.5 (1 - 5.3)	*0.03*	44	3 (1 - 4)	*0.11*	24	4 (2 - 6.5)	*0.19*	*0.08*
	2	71	3 (2, 10)	83	2 (1 - 5)	*0.006*	99	3 (1 - 6)	*0.036*	36	4.5 (2 - 11)	*0.007*	*0.002*
	3	44	2 (1, 3)	60	2 (1 - 3)	*0.35*	54	2 (1 - 3)	*0.49*	23	2 (1 - 4)	*0.63*	*0.78*
	4	29	2 (1, 3)	30	2 (1 - 4)	*0.68*	15	2 (1 - 4)	*0.68*	7	2 (1 - 6)	*0.82*	*0.85*
	5	39	4 (2, 6)	38	1.5 (1 - 2)	*<0.001*	59	1 (1 - 3)	*<0.001*	27	1 (1 - 2)	*0.53*	*<0.001*
	6	32	3 (1, 4.8)	51	1 (1 - 2)	*0.001*	48	1 (1 - 2)	*<0.000*	18	2 (1 - 3)	*0.28*	*0.001*
	ALL	274	3 (2, 5)	300	2 (1 - 3)	*<0.001*	319	2 (1 - 3)	*<0.001*	135	2 (1 - 5)	*0.92*	*<0.001*
Patients with delirium during ICU admission, n (%)	1	145	59 (41%)	151	38 (25%)	*0.004*	188	44 (23%)	*0.001*	72	24 (33%)	*0.10*	*0.003*
	2	247	71 (29%)	242	83 (34%)	*0.19*	240	99 (41%)	*0.004*	108	36 (33%)	*0.16*	*0.036*
	3	231	44 (19%)	223	60 (27%)	*0.046*	240	54 (23%)	*0.36*	102	23 (23%)	*0.99*	*0.26*
	4	158	29 (18%)	150	30 (20%)	*0.71*	73	15 (21%)	*0.69*	36	7 (19%)	*0.89*	*0.98*
	5	251	39 (16%)	271	38 (14%)	*0.63*	216	59 (27%)	*0.002*	121	27 (22%)	*0.31*	*0.001*
	6	305	32 (11%)	297	51 (17%)	*0.017*	216	48 (22%)	*<0.001*	62	18 (29%)	*0.27*	*<0.001*
	ALL	1337	274 (21%)	1334	300 (21%)	*0.21*	1173	319 (27%)	*<0.001*	501	135 (27%)	*0.92*	*<0.001*
Duration of mechanical ventilation (days), median (IQR)	1	47	2 (1 – 3.6)	75	3 (2 – 6)	*0.005*	84	3 (2 – 5)	*0.020*	34	3 (2 – 9)	*0.40*	*0.023*
	2	193	1 (1 – 3)	176	2 (1 – 5)	*0.006*	192	2 (1 – 5)	*<0.001*	96	3 (1.5 – 8)	*0.048*	*0.003*
	3	57	1 (1 – 3)	76	2 (1 – 3.5)	*0.10*	58	2 (1 – 3)	*0.28*	23	3 (2 – 5.5)	*0.06*	*0.06*
	4	50	1 (1 - 2.5)	38	2 (2 – 6)	*0.002*	41	3 (2 – 8)	*<0.001*	12	4 (1 – 5)	*0.56*	*<0.001*
	5	120	2.6 (1 – 6.7)	103	3 (2 - 6)	*0.12*	118	3 (1 - 6)	*0.62*	59	3 (1.5 – 5)	*0.72*	*0.42*
	6	93	2.2 (1 – 6.4)	73	3 (2 – 7)	*0.15*	100	2 (1 - 4)	*0.31*	37	2 (2 – 4)	*0.39*	*0.08*
	ALL	560	1.5 (1 – 4.6)	541	2 (1 - 6)	*<0.001*	593	2 (1 - 5)	*<0.001*	261	3 (2 – 6)	*0.042*	*<0.001*

ICU LOS (days), median (IQR)	1	145	3 (2 – 6)	155	3 (2 - 5)	*0.033*	195	3 (2 – 5)	*0.04*	73	4 (2 – 6)	*0.01*	*0.004*
	2	247	3 (2 – 6)	248	3 (2 - 6)	*0.94*	242	3 (2 – 7)	*0.65*	117	3 (2 – 8)	*0.45*	*0.98*
	3	231	2 (2 - 3)	251	2 (2 – 4)	*0.84*	249	2 (2 – 4)	*0.12*	103	2 (2 – 3)	*0.49*	*0.43*
	4	158	2 (2 – 4)	166	2 (2 – 3)	*0.003*	76	3.5 (3 – 6.5)	*<0.001*	37	3 (2 – 5)	*0.05*	*<0.001*
	5	251	3 (2 – 6)	271	3 (2 – 4)	*0.028*	216	3 (2 – 5.5)	*0.98*	124	3 (2 - 4)	*0.07*	*0.038*
	6	305	2 (2 – 4)	308	2 (2 – 3)	*0.40*	216	3 (2 – 4)	*0.020*	65	4 (3 – 6)	*<0.001*	*<0.001*
	ALL	1337	3 (2 - 5)	1399	2(2 – 4)	*<0.001*	1194	3 (2 - 5)	*0.003*	519	3 (2 -5)	*0.21*	*<0.001*
ICU Mortality, n (%)	1	145	14 (9.7%)	155	15 (9.7%)	*0.99*	195	18 (9.2%)	*0.90*	73	9 (12.3%)	*0.45*	*0.90*
	2	247	51 (20.6%)	248	42 (16.9%)	*0.29*	241	41 (17%)	*0.31*	117	14 (12%)	*0.21*	*0.23*
	3	231	9 (3.9%)	251	26 (10.4%)	*0.006*	249	18 (7.2%)	*0.11*	103	8 (7.8%)	*0.86*	*0.06*
	4	158	10 (6.3%)	166	11 (6.6%)	*0.91*	75	8 (10.7%)	*0.25*	37	5 (13.5%)	*0.66*	*0.34*
	5	251	24 (9.6%)	271	23 (8.5%)	*0.67*	216	28 (13%)	*0.24*	124	21 (16.9%)	*0.32*	*0.06*
	6	305	27 (8.9%)	307	23 (7.5%)	*0.54*	216	13 (6.0%)	*0.23*	65	7 (10.8%)	*0.19*	*0.52*
	ALL	1337	135 (10.1%)	1398	140 (10%)	*0.94*	1192	126 (10.6%)	*0.70*	519	64 (12,3%)	*0.29*	*0.49*
Hospital Mortality, n (%)	1	145	32 (22.1%)	155	25 (16.1%)	*0.19*	195	27 (13.8%)	*0.048*	69	9 (13%)	*0.88*	*0.18*
	2	247	59 (23.9%)	248	49 (19.8%)	*0.27*	242	55 (22.7%)	*0.76*	85	15 (17.6%)	*0.33*	*0.53*
	3	231	17 (7.4%)	251	45 (17.9%)	*0.001*	249	30 (12%)	*0.08*	101	11 (10.9%)	*0.76*	*0.005*
	4	158	21 (13.3%)	166	20 (12%)	*0.74*	76	14 (18.4%)	*0.30*	26	6 (23.1%)	*0.61*	*0.32*
	5	251	45 (17.9%)	271	50 (18.5%)	*0.88*	216	46 (21.3%)	*0.36*	120	33 (20.3%)	*0.20*	*0.14*
	6	305	42 (13.8%)	308	37 (12%)	*0.51*	216	22 (10.2%)	*0.22*	63	10 (15.9%)	*0.21*	*0.53*
	ALL	1337	216 (16.2)	1399	226 (16.2)	*0.99*	1194	194 (16.2)	*0.95*	464	84 (18.1%)	*0.36*	*0.77*

[a] P-values are calculated as difference between two independent groups with Mann-Whitney Test for continue outcomes and Pearson Chi-Square Test was used for bivariate outcomes.

[b] P-values are calculated as difference between four independent groups (marked as ALL) with Kruskal-Wallis Test for continue outcomes and Pearson Chi-Square Test was used for bivariate outcomes.

Additional file 5: Demographics of survey respondents

Survey	**BEFORE n (%)**	**AFTER n (%)**
Type of healthcare professional		
ICU-physicians	53 (14)	53 (20)
· Intensivists (including fellows)	37 (10)	38 (14)
· Residents	16 (4)	15 (16)
ICU Nurses	283 (79)	201 (76)
Delirium experts (psychiatrists, geriatricians and specialized psychiatric nurses)	24 (7)	10 (4)
Years of work experience [a]		
< 1	47 (13)	22 (8)
1 to 4	64 (18)	50 (19)
5 to 9	72 (20)	63 (24)
≥10	177 (49)	129 (49)
Working assignment [b]		
<35%	7 (2)	3 (1)
35-55%	28 (8)	19 (7)
55-75%	46 (13)	49 (19)
75-90%	93 (26)	76 (29)
90-100%	186 (52)	117 (44)
Age (years) [c]		
<25	16 (4)	2 (1)
25-34	109 (30)	87 (33)
35-44	87 (24)	63 (24)
45-54	99 (28)	72 (37)
>55	42 (12)	33 (13)
missing	6 (2)	7 (3)

Differences between 6 participating ICUs in first survey (before): [a] p=0.67, [b] p=0.79, [c] p=0.15
Differences between 6 participating ICUs in second survey (after): [a] p=0.26, [b] p=0.29, [c] p=0.0

Additional file 6: Experiences with the implementation program

Overall, the members of the local implementation teams experienced the implementation program as very successful. More in detail, this was mainly due to constant attention given to the different parts of the guideline by the implementation teams. The implementation management team was able to encourage local implementation teams to stay focused on implementation at their ICUs. Initially, attention from the implementation management team was sometimes perceived as intrusive, but this feeling waned over time. The feeling that delirium is a form of *"vital organ failure"* was an important message which was embraced by the ICU professionals. Gradually, delirium was seen as a problem that needs as much attention as other forms of organ failure in critically ill patients, such as renal failure, respiratory (lung) failure, etc. This was perceived as a '*change of culture*'. Two ICUs had tried to implement delirium screening in the past. However, the local team members stated that "*this round was much more successful,*" (than previous attempt and relating this mainly to the analysis of barriers for screening being done before the implementation program). Further, bedside-teaching (practical training of delirium screening), creating a firm basis for acceptance and support, optimizing ICT facilities for screening and treatment, developing a comprehensive protocol and acceptance into daily rounds of the ICU were regarded facilitators for the implementation in some centers that succeeded in these items. The lack of ICT facilities and Research Nurses turnover were regarded crucial factors that limited the implementation at ICU 4. The respondents indicated that the implementation process sometimes faltered in their organization. For these local implementation leaders, the Implementation Readiness Test (IRT) was a very useful tool and worked for them as an "*implementation thermometer*" to accelerate the process. In addition, although the implementation took considerable time investment from the local teams, it had obviously translated into a concrete change of practice. At times, it was felt the local teams could have been addressed more actively by the implementation management team, referring to more directive and clearer clues on what to do and when. On the other hand, the project in different ICUs also had spin-off effects like optimizing collaboration with other disciplines. The implementation of other guideline recommendations can be picked up in the future because of the experience with this implementation (e.g. use of champions, opinion leaders (formally appointed an intensivist and research nurse at each site) and the use of IRT. Most people interviewed believed that delirium screening and drug treatment had been guaranteed in their ICU but that non-pharmacological interventions (such as earplugs) and other preventive measures still required attention for the future.