**A cluster randomised trial of staff education, regular sedation-analgesia quality feedback, and a sedation monitoring technology for improving sedation-analgesia quality for critically ill mechanically ventilated patients (DESIST trial).**

**SUPPLEMENTARY MATERIAL**

|  |  |  |
| --- | --- | --- |
| **ITEM** |  | **Page** |
| **Approaches to sedation management prior to the trial** | Table S1: Summary of the sedation and pain assessment tools used by each ICU, and their approach to using sedation holds and/or reducing sedation prior to starting the trial | 2 |
| **Admission diagnoses** | Table S2: Admission diagnostic categories for patients enrolled in the study at each ICU during the baseline and intervention periods | 3-4 |
| **Screening and exclusions** | Table S3: Summary of the screening and inclusion processes for each ICU in the baseline and intervention periods | 5-7 |
| **Results for each ICU** | Figure S1: Estimates of joint effects of interventions in each ICU on sedation-analgesia quality measures at DESIST care period level from modelling, prior to pooled analysis | 8 |
| **Primary outcome data** | Table S4: Numbers of patients and care periods with data available on primary outcome (optimum sedation), and number of care periods with optimum sedation by intervention group and study period | 9 |
| **Intraclass correlation coefficients (ICC)** | Table S5: ICCs for all the two-level outcomes | 10 |
| **Sensitivity analyses** | Table S6 (a-c): Results from the sensitivity analyses using data restricted to patients enrolled in last 30 weeks of the intervention period | 11-13 |
| **Changes to analysis** | Description of changes from original analysis plan | 14 |
| **Process evaluation** | Description of the process evaluation  Tables S7 and S8: Tabular summaries of the findings from inductive thematic analysis of focus groups and field work observations | 15-17  18-19 |
| **Process control feedback** | Example of a sedation-analgesia quality process feedback report | 20-30 |

Table S1: Summary of the sedation and pain assessment tools used by each of the ICUs, and their approach to using sedation holds and/or reducing sedation prior to starting the trial.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Education** | | **Education + Process Feedback** | | **Education + Responsiveness Monitoring** | | **Education + Process Feedback + Responsiveness Monitoring** | |
|  | **ICU1** | **ICU2** | **ICU3** | **ICU4** | **ICU5** | **ICU6** | **ICU7** | **ICU8** |
| **Sedation assessment tool** | RASS | RAMSAY | RASS | RASS | RASS | SAS | RASS | RASS |
| **Delirium monitoring** | CAM-ICU twice daily | NO | CAM-ICU twice daily | CAM-ICU twice daily | NO | No consistency | CAM-ICU | CAM-ICU |
| **Pain assessment tool for mechanically ventilated patients** | NO | NO | NO | Used in epidurals | NO | NO | NO | Visual Analogue Scale |
| **Sedation hold strategy** | No consistency in sedation hold practice. Sedation hold performed as part of VAP bundle. Gradual reduction of sedation. Not protocolized. | Done at 8am daily as part of VAP bundle. | No consistency in sedation hold practice. Individualised approach. Sedation hold performed as part of VAP bundle. | Individualised approach to sedation hold. Not protocolized. Sedation hold performed as part of VAP bundle. | Individualised approach to sedation hold. Not protocolized. Sedation hold performed as part of VAP bundle. | Individualised approach to sedation hold. Not protocolized. Sedation hold performed as part of VAP bundle. | Individualised approach to sedation hold. Sedation hold protocol available. | Individualised approach to sedation hold. Not protocolized. Sedation hold performed as part of VAP bundle. |

Table S2: Detailed breakdown of the diagnostic categories of the patients enrolled in the study at each ICU during each study period. All values are N (%).

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Education** | | **Education + Process Feedback** | | **Education + Responsiveness Monitoring** | | **Education + Process Feedback + Responsiveness Monitoring** | |
| **Diagnostic Category** | **Study Period** | **ICU1** | **ICU2** | **ICU3** | **ICU4** | **ICU5** | **ICU6** | **ICU7** | **ICU8** |
| Cardiovascular | Baseline | 38 (32·2%) | 29 (29·6%) | 83 (35·2%) | 34 (33·3%) | 30 (28·0%) | 15 (24·6%) | 18 (20·7%) | 12 (16·7%) |
| Intervention | 20 (30·8%) | 16 (27·6%) | 60 (35·7%) | 25 (46·3%) | 9 (14·5%) | 7 (25·0%) | 18 (16·4%) | 8 (18·6%) |
| Respiratory | Baseline | 34 (28·8%) | 39 (39·8%) | 46 (19·5%) | 32 (31·4%) | 32 (29·9%) | 26 (42·6%) | 25 (28·7%) | 32 (44·4%) |
| Intervention | 16 (24·6%) | 12 (20·7%) | 31 (18·5%) | 8 (14·8%) | 24 (38·7%) | 15 (53·6%) | 36 (32·7%) | 16 (37·2%) |
| Gastrointestinal | Baseline | 17 (14·4%) | 15 (15·3%) | 73 (30·9%) | 11 (10·8%) | 26 (24·3%) | 11 (18·0%) | 24 (27·6%) | 14 (19·4%) |
| Intervention | 15 (23·1%) | 13 (22·4%) | 54 (32·1%) | 10 (18·5%) | 20 (32·3%) | 5 (17·9%) | 24 (21·8%) | 11 (25·6%) |
| Trauma | Baseline | 6 (5·1%) | 0 (0·0%) | 4 (1·7%) | 12 (11·8%) | 4 (3·7%) | 0 (0·0%) | 4 (4·6%) | 2 (2·8%) |
| Intervention | 2 (3·1%) | 0 (0·0%) | 10 (6·0%) | 4 (7·4%) | 1 (1·6%) | 0 (0·0%) | 8 (7·3%) | 1 (2·3%) |
| Neurological | Baseline | 10 (8·5%) | 6 (6·1%) | 12 (5·1%) | 7 (6·9%) | 7 (6·5%) | 1 (1·6%) | 10 (11·5%) | 4 (5·6%) |
| Intervention | 3 (4·6%) | 6 (10·3%) | 4 (2·4%) | 4 (7·4%) | 1 (1·6%) | 0 (0·0%) | 11 (10·0%) | 3 (7·0%) |
| Obstetrics | Baseline | 0 (0·0%) | 1 (1·0%) | 0 (0·0%) | 0 (0·0%) | 0 (0·0%) | 0 (0·0%) | 1 (1·1%) | 0 (0·0%) |
| Intervention | 0 (0·0%) | 0 (0·0%) | 1 (0·6%) | 0 (0·0%) | 0 (0·0%) | 0 (0·0%) | 1 (0·9%) | 0 (0·0%) |
| Self-Inflicted Overdose | Baseline | 4 (3·4%) | 2 (2·0%) | 8 (3·4%) | 2 (2·0%) | 3 (2·8%) | 6 (9·8%) | 1 (1·1%) | 2 (2·8%) |
| Intervention | 4 (6·2%) | 3 (5·2%) | 4 (2·4%) | 2 (3·7%) | 2 (3·2%) | 1 (3·6%) | 2 (1·8%) | 1 (2·3%) |
| Miscellaneous Diagnoses | Baseline | 7 (5·9%) | 4 (4·1%) | 8 (3·4%) | 4 (3·9%) | 5 (4·7%) | 1 (1·6%) | 4 (4·6%) | 2 (2·8%) |
| Intervention | 3 (4·6%) | 5 (8·6%) | 4 (2·4%) | 1 (1·9%) | 1 (1·6%) | 0 (0·0%) | 7 (6·4%) | 2 (4·7%) |
| Renal Diagnosis | Baseline | 2 (1·7%) | 2 (2·0%) | 2 (0·8%) | 0 (0·0%) | 0 (0·0%) | 1 (1·6%) | 0 (0·0%) | 4 (5·6%) |
| Intervention | 2 (3·1%) | 3 (5·2%) | 0 (0·0%) | 0 (0·0%) | 4 (6·5%) | 0 (0·0%) | 3 (2·7%) | 1 (2·3%) |

Table S3: Detailed summary of the numbers of patients in screening and inclusion processes for each ICU during the baseline and intervention periods.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Education** | | **Education + Process Feedback** | | **Education + Responsiveness Monitoring** | | **Education + Process Feedback + Responsiveness Monitoring** | |
| **ICU 1** | **ICU2** | **ICU3** | **ICU4** | **ICU5** | **ICU6** | **ICU7** | **ICU8** |
| **BASELINE PERIOD (45 WEEKS)** | SCREENED (N) | 1225 | 483 | 1015 | 408 | 374 | 282 | 722 | 315 |
| EXCLUDED | 1019 | 293 | 562 | 134 | 239 | 141 | 499 | 209 |
| Died | 17 | 23 | 30 | 10 | 8 | 16 | 3 | 5 |
| Age <16 years | 13 | 3 | 5 | 8 | 11 | 2 | 4 | 0 |
| For palliative care | 8 | 1 | 1 | 1 | 0 | 1 | 2 | 1 |
| No mechanical ventilation | 894 | 162 | 272 | 27 | 153 | 55 | 343 | 54 |
| Mechanical ventilation discontinued at time of screening | 49 | 67 | 139 | 33 | 31 | 36 | 109 | 33 |
| Extubation anticipated within 4 hours of screening | 19 | 28 | 73 | 34 | 26 | 22 | 25 | 84 |
| Decision made to withdraw treatment | 14 | 1 | 15 | 18 | 10 | 6 | 9 | 31 |
| Already enrolled in the study during current hospital admission | 5 | 8 | 27 | 3 | 0 | 3 | 4 | 1 |
| ELIGIBLE | 206 | 190 | 453 | 274 | 135 | 141 | 223 | 106 |
| CONSENTED (% of eligible patients) | 120 (58) | 98 (52) | 236 (52) | 103 (38) | 108 (80) | 61 (43) | 92 (41) | 74 (70) |
| Reason not consented |  |  |  |  |  |  |  |  |
| No one available to provide consent | 17 | 31 | 34 | 24 | 3 | 6 | 48 | 10 |
| Lack of research staff | 3 | 0 | 32 | 47 | 0 | 5 | 1 | 0 |
| Not approached | 21 | 1 | 37 | 19 | 10 | 23 | 24 | 6 |
| Clinician refusal | 2 | 24 | 18 | 8 | 0 | 2 | 9 | 6 |
| Consent not obtained within 48 hours of admission | 32 | 22 | 79 | 44 | 4 | 27 | 35 | 6 |
| Other | 11 | 14 | 17 | 29 | 10 | 17 | 14 | 4 |
| EXCLUDED FROM ALL ANALYSES (status epilepticus) | 2 | 0 | 0 | 1 | 1 | 0 | 5 | 2 |
| PRIMARY OUTCOME DATA AVAILABLE | 113 | 91 | 232 | 101 | 104 | 61 | 78 | 67 |
| Reason for no primary outcome data |  |  |  |  |  |  |  |  |
| Mechanical ventilation for <48 hours | 3 | 5 | 4 | 0 | 3 | 0 | 7 | 4 |
| Receiving neuromuscular paralysis | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| No SQATs completed | 0 | 1 | 0 | 1 | 0 | 0 | 2 | 0 |
|  |  | **Education** | | **Education + Process Feedback** | | **Education + Responsiveness Monitoring** | | **Education + Process Feedback + Responsiveness Monitoring** | |
| **ICU 1** | **ICU2** | **ICU3** | **ICU4** | **ICU5** | **ICU6** | **ICU7** | **ICU8** |
| **INTERVENTION PERIOD (45 WEEKS)** | SCREENED (N) | 1105 | 369 | 944 | 345 | 244 | 191 | 394 | 209 |
| EXCLUDED | 987 | 249 | 638 | 182 | 154 | 110 | 193 | 146 |
| Died | 27 | 23 | 18 | 23 | 3 | 17 | 4 | 0 |
| Age <16 years | 8 | 3 | 2 | 2 | 4 | 0 | 2 | 0 |
| For palliative care | 6 | 0 | 1 | 0 | 0 | 0 | 2 | 0 |
| No mechanical ventilation | 866 | 123 | 302 | 33 | 102 | 28 | 84 | 48 |
| Mechanical ventilation discontinued at time of screening | 37 | 54 | 178 | 74 | 33 | 42 | 55 | 50 |
| Extubation anticipated within 4 hours of screening | 42 | 29 | 112 | 31 | 11 | 21 | 33 | 30 |
| Decision made to withdraw treatment | 0 | 13 | 22 | 15 | 1 | 2 | 10 | 11 |
| Already enrolled in the study during current hospital admission | 1 | 4 | 3 | 4 | 0 | 0 | 3 | 7 |
| ELIGIBLE | 118 | 120 | 306 | 163 | 90 | 81 | 201 | 63 |
| CONSENTED (% of eligible patients) | 65 (55) | 58 (48) | 170 (56) | 55 (34) | 62 (69) | 28 (35) | 116 (58) | 44 (70) |
| Reason not consented |  |  |  |  |  |  |  |  |
| No one available to provide consent | 6 | 11 | 25 | 8 | 2 | 11 | 10 | 2 |
| Lack of research staff | 4 | 6 | 6 | 17 | 0 | 0 | 4 | 0 |
| Not approached | 2 | 9 | 13 | 46 | 3 | 4 | 8 | 1 |
| Clinician refusal | 0 | 17 | 10 | 3 | 0 | 1 | 1 | 0 |
| Consent not obtained within 48 hours of admission | 23 | 5 | 25 | 5 | 1 | 31 | 26 | 0 |
| Other | 18 | 14 | 57 | 29 | 22 | 6 | 36 | 16 |
| EXCLUDED FROM ALL ANALYSES (status epilepticus) | 0 | 0 | 2 | 1 | 0 | 0 | 4 | 0 |
| PRIMARY OUTCOME DATA AVAILABLE | 64 | 56 | 167 | 52 | 61 | 28 | 107 | 42 |
| Reason for no primary outcome data |  |  |  |  |  |  |  |  |
| Mechanical ventilation for <48 hours | 1 | 1 | 1 | 1 | 1 | 0 | 4 | 0 |
| Receiving neuromuscular paralysis | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 |
| No SQATs completed | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 |

Note: SQAT, sedation quality assessment tool.

Figure S1: Estimates of joint effects of interventions, odds ratios (OR) and 95% confidence intervals, in each ICU on sedation-analgesia quality measures at DESIST care period level from modelling, prior to pooled analysis. An OR >1 indicates an increase in outcome with the intervention(s) (improvement).





Note: Results are from a generalised linear model with logit link. Adjusted for age, sex and APACHE II score.

Table S4: Number of patients and number of care periods with data available on primary outcome (optimum sedation-analgesia), and number of care periods with optimum sedation-analgesia by intervention group and study period. All data presented are raw data before modelling.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline period** | | | **Intervention period** | | |
| **Intervention** | Patients (N) | Care periods (N) | Care periods with optimum sedation (N (%)) | Patients (N) | Care periods (N) | Care periods with optimum sedation (N (%)) |
| **Education** | 847 | 9187 | 5150 (56·1) | 577 | 6947 | 3940 (56·7) |
| **Process Feedback**  **Implemented**  **Not Implemented** | 478  369 | 5383  3804 | 2930 (54·4)  2220 (58·4) | 368  209 | 4725  2222 | 2526 (53·5)  1414 (63·6) |
| **Responsiveness Monitoring**  **Implemented**  **Not Implemented** | 310  537 | 2902  6285 | 1486 (51·2)  3664 (58·3) | 238  339 | 2858  4089 | 1663 (58·2)  2277 (55·7) |

Note: There were 42 and 15 patients from the baseline and intervention periods respectively for whom the APACHE II score was imputed. Only 1 and 3 patients from the baseline and intervention periods respectively were excluded from statistical modelling due to missing covariate(s).

Table S5: Intraclass correlation coefficients (ICCs) for the primary outcome and the two-level secondary outcomes.

|  |  |
| --- | --- |
| **Outcome** | **ICC** |
| **Sedation-Analgesia Quality Measures at Care Period Level** | |
| **Primary Outcome** | |
| Optimum Sedation | 0·25 |
| **Components of Primary Outcome** | |
| Free from Excessive Sedation | 0·34 |
| Free from Agitation | 0·40 |
| Free from Poor Relaxation | 0·29 |
| Free from Poor Synchronisation | 0·27 |
| **Sedation-Related Adverse Events** | |
| Day on which a Sedation-Related Adverse Event (SRAE) occurred | 0·21 |
| **Sedative and Analgesic Drug Use** | |
| Day on which ≥4000mg Propofol (or equivalents) administered | 0·60 |

Table S6: Sensitivity analyses exploring effects of each intervention based on those patients enrolled during final 30 weeks of the intervention period.

Table S6(a): Estimates of effects on sedation-analgesia quality measures at DESIST care period level. An odds ratio (OR) >1 indicates an increase in the outcome with the intervention (improvement).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Education** | **Process Feedback** | **Responsiveness Monitoring** |
| **Primary Outcome** | | | | |
| Optimum Sedation | OR (95% CI) | 1·14 (0·83-1·57) | **0·66 (0·46-0·94)** | **1·51 (1·06-2·16)** |
| **Components of Primary Outcome** | | | | |
| Free from Excessive Sedation | OR (95% CI) | 1·12 (0·75-1·65) | **0·57 (0·36-0·89)** | **1·55 (1·00-2·38)** |
| Free from Agitation | OR (95% CI) | 1·27 (0·71-2·26) | 1·01 (0·53-1·94) | 0·83 (0·46-1·50) |
| Free from Poor Relaxation | OR (95% CI) | 0·77 (0·52-1·13) | 0·96 (0·63-1·46) | 1·35 (0·89-2·05) |
| Free from Poor Synchronisation | OR (95% CI) | 1·23 (0·83-1·83) | 0·78 (0·49-1·24) | **1·84 (1·19-2·85)** |

Note: Outcomes with statistically significant intervention effects (95% confidence intervals (CIs) do not overlap 1) are highlighted in bold. Results are from multilevel generalised linear model with logit link. Adjusted for age, sex and APACHE II score.

Table S6(b): Estimates of effects on sedation-analgesia quality measures at patient level. A rate ratio (RR) >1 indicates an increase in the outcome with the intervention (improvement).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Education** | **Process Feedback** | **Responsiveness Monitoring** |
| Optimum Sedation | RR (95% CI) | 1·03 (0·92-1·15) | **0·86 (0·75-0·98)** | **1·17 (1·02-1·35)** |
| Free from Excessive Sedation | RR (95% CI) | 1·02 (0·95-1·10) | **0·88 (0·81-0·96)** | 1·07 (0·98-1·16) |
| Free from Agitation | RR (95% CI) | 1·02 (0·96-1·09) | 1·02 (0·94-1·10) | 0·97 (0·90-1·05) |
| Free from Poor Relaxation | RR (95% CI) | 0·97 (0·91-1·04) | 0·97 (0·89-1·05) | 1·05 (0·96-1·14) |
| Free from Poor Synchronisation | RR (95% CI) | 1·02 (0·95-1·09) | 0·98 (0·90-1·06) | 1·05 (0·97-1·14) |

Note: Outcomes with statistically significant intervention effects (95% confidence intervals (CIs) do not overlap 1) are highlighted in bold. Results are from generalised linear model with log link and negative binomial error distribution for number of DESIST care periods with an outcomes present for each patient, using the total number of DESIST care periods with valid data for that outcome for each patient as an offset. Adjusted for age, sex and APACHE II score.

Table S6(c): Estimates of effects on sedation related adverse event (SRAE) outcomes. An odds ratio (OR) <1 indicates a decrease in the outcome with intervention (improvement).

|  | | **Education** | **Process Feedback** | **Responsiveness Monitoring** |
| --- | --- | --- | --- | --- |
| Day on which a SRAE Occurred | OR (95% CI) | 0·61 (0·33-1·13) | 0·85 (0·42-1·72) | **2·23 (1·09-4·57)** |
| Patient Experienced a SRAE | OR (95% CI) | 0·55 (0·30-1·04) | 1·04 (0·52-2·08) | **2·54 (1·25-5·15)** |

Note: Outcomes with statistically significant intervention effects (95% confidence intervals (CIs) do not overlap 1) are highlighted in bold. Results are from multilevel generalised linear model with logit link for SRAE at day level and a generalised linear model with logit link for SRAE at patient level. Adjusted for age, sex and APACHE II score.

**CHANGES TO ORIGINAL ANALYSIS PLAN**

In analysing the four components (excessive sedation; agitation; poor relaxation; poor ventilator synchronisation) of optimum sedation-analgesia we inverted these to model at care period level those which were free from excessive sedation, free from agitation, free from poor relaxation and free from poor ventilator synchronisation, and at patient level the number of care periods free from excessive sedation, free from agitation, free from poor relaxation and free from poor ventilator synchronisation. This clarified the presentation of the analysis by ensuring that an odds ratio or rate ratio >1 represented a favourable effect for both optimum sedation and each of the four components. [Figure 2, Tables 2A, S6(a), S6(b)]

For the analysis of optimum sedation and its components at patient level, we used a generalised linear model with log link but a negative binomial rather than the Poisson error distribution that was originally planned. This accounted appropriately for the unexpected over-dispersion observed in these outcomes. [Tables 2A, S6(b)]

**PROCESS EVALUATION**

**Aim**

A key goal of the process evaluation was to understand whether the interventions were implemented as planned, the barriers to implementation, and factors that worked well/less well. We planned a priori to compare effects between ICUs in which successful engagement and implementation appeared to occur versus those with less successful engagement and implementation. The cluster randomised design of DESIST allowed this comparison. The analysis strategy was a mixed methods approach in which qualitative data were used to provide context and explanation of the quantitative findings.

**Education intervention**

A total of 538 nurses completed the training. The eight ICUs achieved 74%, 80%, 80%, 96%, 96%, 98%, 100%, and 100% training completion of eligible nursing staff. The mean pre-training core knowledge test score (range 0-10) was 6.4 (SD 1.8). In total 394 nurses (73%) completed the re-test a median 32 weeks (1st-3rd quartile 28-39 weeks) after first test. The mean change in scores, adjusted for pre-test score, showed an increase of 0.82 (95% CI: 0.65-0.98; P<0.0001).

**Responsiveness monitoring**

In the four ICUs a total of 206 patients received RI monitoring (82% enrolled patients; range 76% to 95% between ICUs). The median (1st, 3rd quartile) time between intubation and starting monitoring was 21 hours (11, 34) and median duration of monitoring was 66 hours (27, 139). The first RI recorded was: red 59% (range 50-66% across ICUs), amber 12% (range 4-17%), and green 28% (range 25-38%). Among patients whose first RI was red 16% never had a green RI of whom 68% were ICU non-survivors. The median time to first recording a green RI when this occurred was 9 hours (4, 23). Among all patients the RI value was red for a median 35% of monitored time (range 23-48% across ICUs); the median longest recorded time with continuous red RI values within each patient was 7 hours (3, 14). Together these data suggested significant periods of low RI values despite the instruction to adjust sedation to achieve a higher RI value in the amber or green range.

**Qualitative evaluation**

Qualitative data were collected both during the baseline, during the implementation phase, and during the intervention periods of the study. We conducted multi-professional focus groups in each ICU prior to the implementation phase to understand the current culture of sedation practice. During the implementation period and intervention phase action research involving participant observation took place at each ICU at three distinct times to understand the uptake of the interventions and changes in practice: the end of implementation phase, midway during the intervention period, and at the end of the intervention period. We conducted multi-professional focus groups in the final month of the intervention period, in which participants reflected on the uptake of the intervention(s) and the changes to sedation practice. Data from field notes from participant observation and focus groups transcripts were verbatim transcribed and then checked for accuracy of transcription by the qualitative researcher (KK). Data were entered in NVivo 10 for windows software for qualitative analysis (QSR International, Ltd).

Data were organised by ICU setting for coding. An inductive thematic analysis was conducted without a pre-defined theoretical framework to allow the in-depth exploration and understanding of the impact of interventions on sedation management. Constant comparison ensured that the thematic analysis represented all perspectives and negative cases were sought. Validity checking of the coding included recoding of data from 4 ICUs, representative of each intervention group, by an independent researcher (GH). Discordant coding and agreement was resolved by discussion within the wider research team.

Data were extracted in relation to the characteristics of the interventions, its compatibility with the clinicians, its visibility in the clinical environment, any compelling attributes and the timing the intervention was introduced. Data related to the dissemination and the adoption of the intervention(s) included the adopters’ intra-individual factors such as their expectations of the intervention(s), the meaning of the intervention to them, their learning style and their tolerance of ambiguity about the intervention. Elements of the clinicians’ communication channels, availability of linkage agents, their clinical routines and existing cultures (such as documentation processes, daily housekeeping processes), elements of the ICU environment (size, facilities), geography of the setting (floor plan, types of admissions due to the geographical area) informed the adoption of the interventions. Clinicians’ initial expectations of the interventions as well as their knowledge of the intervention, including awareness knowledge (that the innovation exists), procedural knowledge (how to use the intervention) and principles knowledge (how the intervention works) were considered. Although some strategies to implement the interventions were suggested, we recorded how clinicians adjusted these strategies to facilitate implementation of interventions. We recorded the barriers and facilitators to implementation and adoption, and the role of staff involvement, including leadership roles, teamwork elements, and communication channels. In this supplement we present the clinicians’ perceived feedback on the use of the three interventions and the response of each ICU to the implementation of the interventions including any changes observed in their sedation-analgesia practice (Tables S7 and S8).

Table S7: Clinicians’ feedback on each intervention.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Education** | | **Process Feedback** | | **Responsiveness Monitoring** | |
| **Positive comments** | **Negative comments** | **Positive comments** | **Negative comments** | **Positive comments** | **Negative comments** |
| Informative and useful, in particular for junior staff. For senior nurses was a good reminder.  Met educational needs of staff.  Had a good summative assessment.  Staff were familiar with the online platform used (LearnPro). | Time consuming.  Overwhelming for some junior staff.  Some technical problems with access to the module delayed implementation (3 ICUs).  Debatable format (e-form vs hard copies).  Nurses needed feedback on the online assessments of knowledge. | Stimulated discussion about suboptimum sedation.  Used existing QI methodology and presentation familiar to the staff. | Disbelief in how the process measures were derived. Nurses felt SQAT tool questions, from which the process measures were derived, were not relevant to some patient cases and did not reflect current practice. (i.e. felt agitation was more prevalent to excessive sedation).  Process measures were not meaningful to nurses. Lack of understanding of the charts by the nurses.  The process measures were not disseminated timely; they needed to be presented weekly to drive change.  No consistent presentation.  The style of presentation needed improvement. | Monitor was easy to use and was a good prompt tool for some patient cases.  Families found it useful.  Used mainly as a research tool. | Lack of understanding of the role of the monitor. Some nurses felt it was useless.  There was no correlation of the monitor with the clinical picture in certain patients. Created disbelief.  There was time lag between monitor recording and physical presentation of the patient.  Non adhesive stickers - increased gaps in recording.  Skin excoriation because of the stickers.  Big size was a problem for small ICUs.  Some faulty parts of the monitor.  Families found it invasive. |

Table S8: Perceived changes in sedation-analgesia practice due to each intervention.

|  |  |  |
| --- | --- | --- |
| **Education** | **Process Feedback** | **Responsiveness Monitoring** |
| Raised awareness of sedation-analgesia management, sleep promotion, drug properties, delirium and agitation, psychosis. Able to differentiate between sedation and analgesia management.  Nurses felt more confident in their decision-making.  Introduced sleep promotion initiatives.  Re-enforced the use of sedation breaks and reviewing their timing.  Introduced new tools for assessment of pain (CPOT), delirium (CAM-ICU), and sedation, where not available.  Introduced/ updated protocols for management of sedation, agitation, delirium and pain.  Considered introducing agents for managing psychosis and delirium. | Recognised the need for improvement of sedation-analgesia practice.  Recognised the need for a standardised manner in managing sedation-analgesia.  Raised awareness of suboptimum sedation practice.  Introduced/ updated daily review of sedation-analgesia management and documentation where not available or not consistently performed.  Introduced checklists (e.g. ICU pause) in ward round meetings or safety briefs as an aide-memoir tool to highlight sedation-analgesia issues regularly.  Introduced audits on use of assessment tools, sleep quality, and pain. | Used as a prompt tool to identify excessive sedation and detect sleep. Able to differentiate between sleep and sedation.  Informed decisions about excessive sedation.  Reviewed the use of sedation boluses as a management method for agitation, observing their effect on the monitor recording and the physical appearance of the patient.  Identified the need to introduce a sleep promotion protocol. |

**Example of a full set of process feedback for one of the ICUs randomised to receive process feedback during the study**

**SEDATION RELATED QUALITY MEASURES REPORT – 21st DECEMBER 2014**

**Background**

The DESIST study is evaluating different approaches to improving the quality of sedation of intensive care patients. One of the approaches is to provide feedback on a range of quality indicators. This report provides you with information about the prevalence of excessive sedation, agitation, discomfort and sedation-related adverse events in your ICU. It also provides an overall measure of optimum sedation among patients.

The information used to generate these reports was recorded by nursing staff using the Sedation Quality Assessment Tool (SQAT) forms for each nursing shift, and information collected by research staff for the DESIST study.

**How to use these reports**

The information included in this report is intended to help improve sedation management in your ICU by providing you with feedback on current sedation quality. We suggest that information is shared with all staff groups through a range of media such as e-mail, posters, quality briefs, and meetings. We suggest that reports are reviewed at medical and nursing staff meetings, quality improvement teams, M&M meetings, and/or other local meetings in your ICU. We also encourage you to disseminate the findings in daily practice, for example at handovers or ward rounds. We hope you will use the information to review current sedation management, and initiate interventions and changes that will improve all aspects of sedation management. These charts will help you to monitor the effect of your interventions and changes.

The reports have been designed to illustrate changes over time, especially improvements or deterioration in performance for each quality measure. Reports will be circulated every 2 months, using recently collected data from the DESIST study. In this way the impact of local initiatives to improve management can be seen. We hope you will supplement these with local data collected more frequently; we have provided you with “toolkits” to do this.

**Summary Points**

**This is the final process measures report for the intervention period of DESIST. The report includes data from all patient cases entered to the database during the intervention period with resolved queries. It presents the last 2 months of recruitment.**

**In October to November 2014**:

|  |  |  |
| --- | --- | --- |
| **Proportion during**  **October – November 2014** | **Proportion during August – September 2014** | **Effect on sedation quality** |
| Excessive sedation was present for **26%** of care periods | **16%** | 10% **HIGHER** rate of excessive sedation  ☹ |
| Agitation was present for **7%** of care periods | **11%** | 4% **LOWER** rate of agitation  ☺ |
| Poor relaxation (a measure of pain and discomfort) was present for **12%** of care periods | **19.5%** | 7.5% **LOWER** rate of poor relaxation  ☺ |
| Poor ventilator synchronisation was present for **5%** of care periods | **8.5%** | 3.5% **LOWER** rate of poor ventilator synchronisation  ☺ |
| **4** sedation-related adverse events occurred during this period | **9** | **FEWER** sedation-related adverse events  ☺ |
| **Overall, optimum sedation was present for 62% of care periods** | **61%** | 1% **HIGHER** rate of optimum sedation  ☺ |

**Understanding the charts**

This report includes a series of *process control* charts, each under a separate section. Each chart includes:

1. A summary of how the quality indicator has been calculated from your data.
2. A **baseline proportion**. Depending on the type of chart, this is the average value for the quality indicator during your baseline “pre-intervention” period (the data collected during the first 11 months of the DESIST study, from October 2012 to August 2013).
3. **Process “warning” and “control” limits**. These upper and lower limits are calculated to assess whether the rate of the quality indicator has changed significantly in your ICU. If a warning limit is exceeded it means the quality indicator is in danger of moving “out of control” compared to the baseline rate. This could be good or bad depending on the direction of change. If a control limit is crossed, this probably means there has been a “real” change in the measure compared to the baseline rate. This might indicate a significant improvement or deterioration in the measure according to the direction of change.
4. **Data points**. A data point is included for every 2 months throughout the pre-intervention (baseline) and post-intervention periods for most charts. Each data point uses the available data from patients enrolled in the DESIST study for that period.

**Charts**

The following charts are included in this report:

**P charts:** these charts show the proportion of nursing shifts (12 hour periods) for which the quality indicator was reported.

* Proportion of periods with excessive sedation
* Proportion of periods with agitation
* Proportion of periods for which patient poorly relaxed
* Proportion of periods with poor ventilator synchronisation
* Proportion of periods with optimum sedation

**G charts:** these charts show the number of patients managed between the quality indicator events occurring.

* Number of patients treated without a sedation-related adverse event

**Sedation-related adverse events**

* Frequency table of all sedation related adverse events recorded during this period

**“Proportion of periods with excessive sedation”**

*How was this chart made?*

The data recorded by nurses on the SQAT form at the end of each shift was used to count the number of periods for which deep sedation was present. Information included on the SQAT form was used to exclude periods where deep sedation may have been appropriate, for example advanced ventilation, therapeutic hypothermia, or brain injury. The remaining periods were considered excessive sedation, because evidence would suggest these patients benefit from “lighter” sedation. Each data point has used 2 months of ICU admissions participating in the DESIST study.

*What does this chart mean?*

The **proportion** is the average rate of this quality measure that occurred in your ICU during the intervention period October to November 2014 in the DESIST study. **This means that for 26% of care periods in the ICU excessive sedation was present using the DESIST definition.**

The **observed proportion** is the rate of excessive sedation over 2 months of observations in the ICU. If the proportion moves closer to the **upper warning or control limit**, the occurrence of excessive sedation is *increasing*. If it crosses the **upper control limit** this represents a significant increase in excessive sedation in your ICU. If the proportion moves closer to the **lower warning or control limit**, the occurrence of excessive sedation is *decreasing*. If it crosses the **lower control limit** this represents a significant decrease in excessive sedation in your ICU.

**This chart suggests there has been INCREASE in excessive sedation during the period October to November 2014.**

To learn more about the importance of excessive sedation and how to avoid it, access the DESIST LearnPro education package, modules 1 (*Why is it important to get sedation right?)* and 4 (*avoiding excessive sedation*).

**“Proportion of periods with agitation”**

*How was this chart made?*

The data recorded by nurses on the SQAT form at the end of each shift was used to count the number of periods for which agitation was present. Each data point has used 2 months of ICU admissions participating in the DESIST study.

*What does this chart mean?*

The **proportion** is the average rate of this quality measure that occurred in the ICU during the intervention period October to November 2014 in the DESIST study. **This means that for 7% of care periods in the ICU agitation was present using the DESIST definition.**

The **observed proportion** is the rate of agitation over 2 months of observations in the ICU. If the proportion moves closer to the **upper warning or control limit**, the occurrence of agitation is increasing. If it crosses the **upper control limit** this represents a significant increase in agitation in your ICU. If the proportion moves closer to the **lower warning or control limit**, the occurrence of agitation is decreasing. If it crosses the **lower control limit** this represents a significant decrease in agitation in your ICU.

**This chart suggests there has been DECREASE in agitation during the period October to November 2014.**

Agitation has several causes, including pain, poor ventilator synchronisation, delirium, anxiety, drug withdrawal syndromes, or other causes of discomfort such as bowel discomfort (eg. constipation/distension).

To learn more about managing agitation, access the DESIST LearnPro education package, modules 6 (*managing agitation*), 7 (*managing delirium*), and 8 (*drug withdrawal*).

**“Proportion of periods during which patient poorly relaxed”**

*How was this chart made?*

The data recorded by nurses on the SQAT form at the end of each shift was used to count the number of periods for which patients were poorly relaxed based on ease of movement. Each data point has used 2 months of ICU admissions participating in the DESIST study.

*What does this chart mean?*

Poor relaxation is probably the best way of assessing pain and discomfort in patients unable to communicate verbally during critical illness.

The **proportion** is the average rate of this quality measure that occurred in the ICU during the intervention period October to November 2014 in the DESIST study. **This means that for 12% of care periods in the ICU poor relaxation was present using the DESIST definition.**

The **observed proportion** is the rate of poor relaxation over 2 months of observations in the ICU. If the proportion moves closer to the **upper warning or control limit**, the occurrence of poor relaxation is increasing. If it crosses the **upper control limit** this represents a significant increase in poor relaxation in your ICU. If the proportion moves closer to the **lower warning or control limit**, the occurrence of poor relaxation is decreasing. If it crosses the **lower control limit** this represents a significant decrease in poor relaxation in your ICU.

**This chart suggests that there has been DECREASE in poor relaxation (pain/discomfort) during the period October to November 2014.**

To learn more about managing pain access the DESIST LearnPro education package, module 5 (*assessing pain and discomfort in ICU*).

**“Proportion of periods with poor ventilator synchronisation”**

*How was this chart made?*

The data recorded by nurses on the SQAT form at the end of each shift was used to count the number of periods for which patients had poor ventilator synchronisation (coughing or gagging frequently or unable to control ventilation despite adjustments). Each data point has used 2 months of ICU admissions participating in the DESIST study.

*What does this chart mean?*

The **proportion** is the average rate of this quality measure that occurred in the the ICU during the intervention period October to November 2014 in the DESIST study. **This means that for 5% of care periods in the ICU poor ventilator synchronisation was present using the DESIST definition.**

The **observed proportion** is the rate of poor ventilator synchronisation over 2 months of observations in the the ICU. If the proportion moves closer to the **upper warning or control limit**, the occurrence of poor ventilator synchronisation is increasing. If it crosses the **upper control limit** this represents a significant increase in poor ventilator synchronisation in your ICU. If the proportion moves closer to the **lower warning or control limit**, the occurrence of poor ventilator synchronisation is decreasing. If it crosses the **lower control limit** this represents a significant decrease in poor ventilator synchronisation in your ICU.

**This chart suggests there has been DECREASE in poor ventilator synchronisation during the period October to November 2014.**

Poor ventilator synchronisation is a common cause of agitation. To learn more access the DESIST LearnPro education package module 6 (*managing agitation*).

**“Proportion of periods with optimum sedation”**

*How was this chart made?*

The data recorded by nurses on the SQAT form at the end of each shift was used to generate a measure of overall optimum sedation.

*Optimum sedation is defined as a care period (12 hour nursing shift) for which there was no excessive sedation or agitation or poorly relaxed patient or poor ventilator synchronisation.* These patients should be awake or rousable, non-agitated, and comfortable on the ventilator, unless there is a clinical reason for keeping them deeply sedated.

*What does this chart mean?*

The **proportion** is the average rate of this quality measure that occurred in the the ICU during the intervention period October to November 2014 in the DESIST study. **This means that for 62% of care periods in the ICU optimum sedation was present, using the DESIST definition.**

The **observed proportion** is the rate of optimum sedation over 2 months of observations in the the ICU. If the proportion moves closer to the **upper warning or control limit**, the occurrence of optimum sedation is increasing. If it crosses the **upper control limit** this represents a significant increase in optimum sedation in your ICU. If the proportion moves closer to the **lower warning or control limit**, the occurrence of optimum sedation is decreasing. If it crosses the **lower control limit** this represents a significant decrease in optimum sedation in your ICU.

**This chart suggests there has been INCREASE in optimum sedation during the period October to November 2014. This is largely due to DECREASE in agitation rate.**

To learn more about the importance of optimum sedation access the DESIST LearnPro education package module 1 (*Why is it important to get sedation right*?).

**“Number of patients treated without a sedation-related adverse event”**

*How was this chart made?*

In the DESIST study data concerning sedation-related adverse events are collected and recorded on a daily basis. For all sequential patients admitted to your ICU and enrolled in the DESIST study these daily data have been used to create this chart. If an adverse event was recorded during an admission this patient was counted as a patient with a “sedation-related adverse event”. We have counted all the sequential patients enrolled in the DESIST study in your ICU between each patient in whom a sedation-related adverse event was recorded. The number of patients is recorded on the Y-axis, and the actual dates on which patients admitted experienced an adverse event on the X-axis.

*What does this chart mean?*

If the rate of sedation-related adverse events is decreasing, there should be more “higher spikes” in the chart, because this means more patients were treated without an adverse event occurring.

The **average** is the average rate of this quality measure that occurred in the the ICU during the intervention period October to November 2014 in the DESIST study. On average, a **sedation-related adverse event occurred for every 3rd patient during that period.**

If the data points move closer to the **upper control or warning limit**, the rate of sedation-related adverse events is *decreasing*. If it crosses the **upper control limit** this represents a significant decrease compared to the baseline data, which probably means the rate of sedation-related adverse events has significantly decreased in your ICU.

**Sedation-related adverse events**

The number of several pre-defined sedation-related adverse events was recorded on a daily basis for patients participating in the DESIST study. An awareness of the events occurring in your ICU may allow you to plan changes and interventions to reduce adverse event rates. For example, you may review these in real time at local quality improvement or “M&M meetings” to explore why they are occurring. For the period October to November 2014, there were 4 sedation-related adverse events in the ICU.

*Total adverse events occurring during last two months period (October-November 2014)*

|  |  |
| --- | --- |
| **Type of Sedation-Related Adverse Events** | **Number** |
| Unplanned NG removal | 2 |
| Unplanned line removal (central) | 1 |
| Unplanned extubation | 1 |
| **Total** | **4** |