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## **RESEARCH PAPER**

# Investigation of ward fidelity to a multicomponent delirium prevention intervention during a multicentre, pragmatic, cluster randomised, controlled feasibility trial

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## Abstract

**Background:** delirium is a frequent complication of hospital admission for older people and can be reduced by multicomponent interventions, but implementation and delivery of such interventions is challenging.

**Objective:** to investigate fidelity to the prevention of delirium system of care within a multicentre, pragmatic, cluster randomised, controlled feasibility trial.

Setting: five care of older people and three orthopaedic trauma wards in eight hospitals in England and Wales.

Data collection: research nurse observations of ward practice; case note reviews and examination of documentation.

**Assessment:** 10 health care professionals with experience in older people's care assessed the fidelity to 21 essential implementation components within four domains: intervention installation (five items; maximum score = 5); intervention delivery (12 items; maximum score = 48); intervention coverage (three items; maximum score = 16); and duration of delivery (one item; maximum score = 1).

**Results:** the mean score (range) for each domain was: installation 4.5 (3.5–5); delivery 32.6 (range 27.3–38.3); coverage 7.9 (range 4.2–10.1); and duration 0.38 (0–1). Of the 10 delirium risk factors, infection, nutrition, hypoxia and pain were the most and cognitive impairment, sensory impairment and multiple medications the least consistently addressed. Overall fidelity to the intervention was assessed as high ( $\geq$ 80%) in two wards, medium (51–79%) in five wards and low ( $\leq$ 50%) in one ward.

**Conclusion:** the trial was designed as a pragmatic evaluation, and the findings of medium intervention fidelity are likely to be generalisable to delirium prevention in routine care and provide an important context to interpret the trial outcomes.

Keywords: delirium prevention, older people, multi-component intervention, intervention fidelity

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#### **Key points**

- Delirium is a frequent complication of hospital admission for older people and can be reduced by multicomponent interventions,
- Implementation and delivery of such interventions is challenging.
- We investigated the fidelity to the prevention of delirium system of care within a multicentre feasibility trial.
- Fidelity to the intervention was assessed as high (≥80%) in two wards, medium (51–79%) five wards and low (≤50%) in one ward.
- These findings are likely to be generalisable to similar wards in the NHS.

#### Introduction

Multicomponent (complex) health care interventions require the delivery of several discrete aspects of care, often by different professionals. Orchestrating the implementation and subsequent ongoing delivery of such interventions can be challenging, especially if the intervention needs to be tailored to the needs of an individual. Delirium is a common and serious condition affecting about 20% of older people admitted to hospital [1] and is associated with adverse outcomes [2]. Multicomponent interventions for older people admitted to hospital are associated with a reduction of about a third in delirium incidence [3]. The National Institute for Health and Care Excellence (NICE) recommends that these interventions are offered to patients at risk of delirium presenting to hospitals in the National Health Service (NHS) in England and Wales [4].

We developed a multicomponent system of care to prevent delirium for use in the English and Welsh NHS [5,6]. The Prevention of Delirium (POD) programme is a manualised, multicomponent intervention and systematic implementation process designed to secure ward practice changes consistent with a reduction in delirium. It comprises actions centred on 10 clinical factors associated with the development of delirium in at-risk patients [4] and is based on the Hospital Elder Life Program [7,8] and NICE guidelines [4]. The implementation process is supported and reinforced through education of staff and, optionally, volunteers in delirium prevention and an action-planning cycle of observation and audit of current practice to establish what needs to be put in place to introduce and sustain the POD system of care. The principles underpinning POD are standardised and generalisable, but implementation is flexible according to pre-existing practice and local decision-making. Fidelity plays an important independent role in the effectiveness of multicomponent delirium prevention interventions with higher levels of fidelity resulting in lower rates of delirium incidence [9]. Previously, we investigated strategies to optimise intervention fidelity in a pilot study involving five wards in four sites [6]. This work suggested that the implementation of POD into routine ward practice would take about 6 months and was best achieved by prior verification of adequate ward staffing levels, through the formation of local implementation teams and by the provision of ringfenced time (one day per week) for a senior healthcare professional (the 'POD facilitator') to lead the implementation. In addition, we provided an implementation timetable that included a progress checklist within the POD manual.

To explore the potential effectiveness of the POD system of care, we conducted a multicentre, pragmatic, cluster randomised, controlled, feasibility trial in 16 older people's care and orthopaedic trauma wards in eight NHS hospitals in England and Wales [10]. Following a 6-month implementation period for the POD system of care, 714 study participants were recruited over a 6-month period with prospective follow-up for outcome assessment. The details and outcomes of this study are presented elsewhere [10,11]. To aid the interpretation of the feasibility findings of the trial, we report here on an assessment of intervention fidelity for the 343 patients recruited within the eight participating intervention wards.

#### Methods

We adopted the Conceptual Framework for Implementation approach [12] which has been previously used for the assessment of fidelity in complex health interventions [13,14]. In this framework, the core element of fidelity measurement is adherence, defined as 'the degree to which implementers adhere to the intervention as intended by the intervention designers'. Adherence encompasses: content (the 'active ingredients'); frequency of delivery to each patient; duration of implementation on the ward; and coverage (intervention recipients in relation to the target group).

After reviewing NICE guidance [4], the content of the POD system of care and checklists contained within the POD manual, we identified 21 tasks essential for the successful implementation and delivery of POD. We grouped the tasks into the Conceptual Framework for Implementation domains but added an additional domain (intervention installation), and combined the domains of content and frequency into a delivery domain (Table 1).

#### **Data collection**

#### Ward observations

We conducted non-participant observations on the eight intervention wards during the second half of the 6-month

#### Table I. Essential components of the intervention

| Mandatory tasks   | Number   | Requirement  | Score      |  |  |
|---|----------|--|------------|--|--|
| · · · · · · · · · · · · · · · · · · ·   |          |  |            |  |  |
| Domain 1: Intervention installation   |          |  | 0-1        |  |  |
| Staff education   | 1        | Educate ward staff by start of delivery phase  |            |  |  |
| Review of practice  | 2        | Complete all audits and observations by start of delivery phase  |            |  |  |
| Delirium risk factor assessment   | 3        | Develop/pilot/introduce in practice by start of delivery phase   |            |  |  |
| Delirium care plan and care record  | 4        | Develop/pilot/introduce in practice by start of delivery phase   | 0-1        |  |  |
| nformation leaflet  | 5        | Develop and introduce into practice by start of delivery phase   | 0-1        |  |  |
| Domain 2: Intervention delivery*<br>Address cognitive impairment and/or<br>lisorientation by: |          |  |            |  |  |
| Environment   | 1        | Providing appropriate lighting and clear signage; a clock (consider providing a 24-hour clock in critical care) and a calendar should also be easily visible to the  | 0–4        |  |  |
|   |          | person at risk   |            |  |  |
| Staff/patient communication   | 2        | Talking to the person to re-orientate them by explaining where they are, who they are and what your role is  |            |  |  |
| Cognitive stimulation   | 3        | Introducing cognitively stimulating activities (for example reminiscence)<br>Facilitating regular visits from family and friends   |            |  |  |
| Address dehydration and/or constipation by:   | 4        | Ensuring adequate fluid intake to prevent dehydration by encouraging the patient to drink  | 0–4        |  |  |
|   |          | Consider offering subcutaneous fluids if necessary<br>Taking advice if necessary when managing fluid balance for people with<br>co-morbidities (for example heart failure or chronic kidney disease)           |            |  |  |
| Hypoxia   | 5        | Assess for hypoxia and optimise oxygen saturation if necessary, as clinically appropriate.   |            |  |  |
| Address infection by:   | 6        | Looking for and treating infection   | 0-4        |  |  |
|   |          | Avoiding unnecessary catheterisation   |            |  |  |
|   |          | Implementing infection control procedures in line with 'Infection control' (NICE clinical guideline 2).  |            |  |  |
| Address immobility or limited mobility hrough the following actions:                          | 7        | Encourage people to: mobilise soon after surgery; walk (provide walking aids if needed—these should be accessible at all times)  | 0–4        |  |  |
| inough the following actions.   |          | Encourage all people, including those unable to walk, to carry out active  |            |  |  |
| Address pain by:  | 8        | range-of-motion exercises.<br>Assessing for pain   | 0-4        |  |  |
| raditess pain by.   | 0        | Looking for non-verbal signs of pain, particularly in those with communication difficulties (for example, people with learning difficulties or dementia, or people on a ventilator or who have a tracheostomy) | 0-1        |  |  |
|   |          | Starting and reviewing appropriate pain management in any person in whom pain is identified or suspected.  |            |  |  |
| Multiple medications  | 9        | Carry out a medication review for people taking multiple drugs, taking into accoun<br>both the type and number of medications.   |            |  |  |
| Address poor nutrition by:  | 10       | Following the advice given on nutrition in 'Nutrition support in adults' (NICE clinical guideline 32)  | 0–4        |  |  |
|   |          | If people have dentures, ensure they fit properly.   |            |  |  |
| Address sensory impairment by:  | 11       | Resolving any reversible cause of the impairment, such as impacted ear wax<br>Ensuring hearing hearing and visual aids are available to and used by people who   | 0–4        |  |  |
|   |          | need them and that they are in good working order.   |            |  |  |
| Promote good sleep patterns and sleep hygiene   | 12       | Avoiding nursing or medical procedures during sleeping hours, if possible  | 0–4        |  |  |
| y:  |          | Scheduling medication rounds to avoid disturbing sleep<br>Reducing noise to a minimum during sleep periods.  |            |  |  |
| <b>Domain 3: Intervention coverage</b>  |          |  |            |  |  |
| assessment for delirium risk  | 1a<br>1b | Carry out assessment of clinical risk factors that increase delirium risk<br>Use a bespoke delirium risk assessment document   | 0-4<br>0-4 |  |  |
| Consistent attention to ten clinical factors  | 2        | To deliver care to all at-risk patients  | 0-4<br>0-4 |  |  |
| Provision of information leaflet  | 3        | To ensure that an information leaflet is available to all at-risk patients and their relatives   | 0-4<br>0-4 |  |  |
| Domain 4: Intervention duration   |          |  |            |  |  |
| Six-month delivery period   | 1        | POD to be delivered for a minimum of 6 months  | 0-1        |  |  |

Total score ranges: Domain 1: 0–5; Domain 2: 0–48; Domain 3: 0–16; Domain 4: 0–1. Higher scores indicate greater fidelity. \*© NICE (2010) Delirium: prevention, diagnosis and management. Clinical Guidance. Available from www.nice.org.uk/guidance/cg103. All rights reserved. Subject to Notice of rights. NICE guidance is prepared for the NHS in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.

delivery period using the Person, Interactions and Environment method [15] as a framework to explore the delivery of care in relation to delirium prevention. The observations focused on the extent to which staff considered each patient as a person to personalise care (Person), the quality of staff interactions (Interaction) and the impact of the immediate modifiable physical environment or organisation of care (Environment). The observations were conducted on one occasion for each intervention ward by a research nurse experienced in care of older people for three periods, each of 2hour duration: early morning (including staff handover); late morning (including lunchtime); and afternoon (Appendix 1 Tables 1 and 2). To investigate factors that might contribute to variations in fidelity, we collected information on ward type and size, the age and cognitive impairment of the patients, and the number and type of nurses (registered nurse and health care assistants (HCAs)).

#### Case note reviews

We extracted standardised information from the medical and nursing records of up to 10 trial participants randomly selected by the Clinical Trials Research Unit from each of the eight intervention wards, half with an admission date during the first 3 months and half with an admission date during the second 3 months of the POD delivery period. The review used the relevant questions from the National Audit of Dementia Care [15] supplemented by additional questions relating to the fidelity framework domains (see Appendix 2).

#### Examination of POD documentation

We inspected the intervention installation checklists contained in the POD manual at the end of the 6-month setup period to ascertain the extent of completion of the key tasks. In preparation for delivering the POD Programme, intervention wards were advised to put systems in place for the routine assessment of each patient for delirium risk factors and the documentation of interventions carried out by staff and volunteers to address these. The case note review included a search for evidence that these POD-specific documentation systems were in use for the randomly selected patients.

#### Within-study communication

We carried out a content analysis of email correspondence and prospectively collected summaries of telephone and faceto-face communications between the research team and ward staff during the installation, delivery and post-delivery periods to provide additional evidence regarding intervention installation, coverage and duration.

#### **Fidelity assessment**

We used the data to populate four tables of evidence for each ward relating to the four fidelity domains and their associated content items. A scoring system was developed,

piloted and modified to quantify intervention fidelity and to facilitate consistency of assessor judgements. Domain score ranges were: Domain 1: installation (0-5); Domain 2: delivery (0-48); Domain 3: coverage (0-16); and Domain 4: duration (0-1), with higher scores indicating greater fidelity. Assessors were provided with a briefing document containing information about POD, guidance on completing the assessment, a pack for each ward containing background information about the ward (Appendix 3 Table 1) and the four tables of evidence (Appendix 3 Table 2). The assessors were asked to read the evidence presented for each ward and consider the extent to which each of the essential tasks had been accomplished and then enter the corresponding score. Once all four evidence tables had been completed, the assessors were asked to provide an overall fidelity score (low adherence <50%; medium adherence 51-79%; high adherence >80%) based on their judgement of the extent of completion of the essential tasks [16].

The study was approved by the UK National Research Ethics Service (reference 13/YH/0400). Study registration: ISRCTN01187372. Registered 13 March 2014.

### Results

Non-participant observations were conducted on all eight wards (average observational time = 6 hours (range 5.5–6). Case note reviews were conducted for 76 (22.2%) of the 343 patients recruited to the trial (average per site = 9.5; range 8 to 11). The fidelity evidence tables for each of the eight wards were assessed by 10 health professionals or researchers with experience in the healthcare of older people and/or delirium prevention and who had no previous involvement with the POD Programme.

#### Domain I: intervention installation

The mean score for intervention installation was 4.5 (range 3.5-5; maximum possible = 5) (Table 2). Only Hospital 2: Ward 4 was considered to have completed all essential tasks. The tasks most frequently judged not to be completed in the other wards were staff education and review of practice.

#### **Domain 2: intervention delivery**

The mean score for intervention delivery was 32.6 (range 27.3–38.3; maximum possible = 48) (Table 2). Hospital 5: Ward 9 was considered to have carried out 10 of the 12 essential tasks 'most of the time' (assessor grading of  $\geq$ 3), compared with only three of the 12 mandatory tasks for Hospital 2: Ward 3 and Hospital 6: Ward 12 (Table 3). Of the 10 delirium risk factors, infection, nutrition, hypoxia and pain were most consistently addressed by staff. Cognitive impairment (stimulation), sensory impairment and multiple medications were least consistently addressed (Table 3).

| Hospital:                              | 1            | 2            | 2            | 5            | 5            | 6            | 7            | 8            |       |
|--|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|-------|
| Ward:                                  | 1            | 3            | 4            | 9            | 10           | 12           | 13           | 16           |       |
| Ward type*                             | EC           | EC           | T/O          | EC           | T/O          | T/O          | EC           | EC           |       |
| Number of beds                         | 28           | 28           | 28           | 21           | 25           | 32           | 24           | 14           |       |
| Registered nurses on duty <sup>†</sup> | 4            | 4            | 5            | 3            | 4            | 3            | 3            | 3            |       |
| Ratio of registered nurses             | 1:7          | 1:7          | 1:6          | 1:7          | 1:6          | 1:11         | 1:8          | 1:5          |       |
| to patients                            |              |              |              |              |              |              |              |              |       |
| HCAs on duty <sup>†</sup>              | 3            | 3            | 3            | 4            | 3            | 4            | 4            | 2            |       |
| Ratio of HCAs to patients              | 1:9          | 1:9          | 1:9          | 1:5          | 1:8          | 1:8          | 1:6          | 1:7          |       |
| Mean (range) age of                    | 87 (83–94)   | 84 (73–94)   | 89 (80–94)   | ‡            | 86 (74–90)   | 84 (75–93)   | 87 (74–96)   | 87 (84–90)   |       |
| observed patients                      |              |              |              |              |              |              |              |              |       |
| Observed patients with                 | 50%          | 50%          | 62%          | ‡            | 55%          | 75%          | 66%          | 43%          |       |
| cognitive impairment (%)               |              |              |              |              |              |              |              |              |       |
| Domain:                                |              |              |              |              |              |              |              |              | Mean  |
| 1. Installation                        | 4.6 (4–5)    | 4.7 (4–5)    | 5.0 (5–5)    | 4.8 (4–5)    | 4.7 (4–5)    | 3.5 (1–5)    | 4.7 (4–5)    | 4.1 (3–5)    | 4.51  |
| 2. Delivery                            | 32.0 (21-39) | 27.3 (17–33) | 31.5 (21–38) | 38.3 (27-45) | 35.6 (25-40) | 27.7 (18–38) | 35.4 (26–42) | 32.9 (22–41) | 32.59 |
| 3. Coverage                            | 7.1 (4–10)   | 4.2 (3-6)    | 7.3 (5–9)    | 10.0 (8-13)  | 8.9 (8-11)   | 10.1 (5-12)  | 9.9 (8–11)   | 5.5 (4–7)    | 7.88  |
| 4. Duration                            | 0.1          | 0            | 0            | 1            | 0.4          | 0            | 0.9          | 0.6          | 0.38  |
| Overall fidelity <sup>§</sup>          | Medium       | Low          | Medium       | High         | Medium       | Medium       | High         | Medium       |       |

Table 2. Ward and patient characteristics and mean (range) scores for each assessed domain and overall fidelity

\*EC, elderly care; T/O, trauma and orthopaedics. <sup>†</sup>At time of ward observations. <sup>‡</sup>Not available at time of ward observation. <sup>§</sup>Low adherence:  $\leq$ 50%; medium adherence:  $\leq$ 1–79%; high adherence:  $\geq$ 80%.

**Table 3**. Mean (range) scores\* for the essential tasks within Domain 2 (intervention delivery) and Domain 3 (intervention coverage)

| Hospital:                            | 1         | 2         | 2         | 5         | 5                                     | 6         | 7         | 8         |      |
|--------------------------------------|-----------|-----------|-----------|-----------|---------------------------------------|-----------|-----------|-----------|------|
| Ward:                                | 1         | 3         | 4         | 9         | · · · · · · · · · · · · · · · · · · · | 12        | 13        | 16        |      |
| Component                            | -         | U         | -         | 2         |                                       |           | -0        |           | Mean |
| Domain 2: intervention delivery      |           |           |           |           |                                       |           |           |           |      |
| Cognitive impairment:                |           |           |           |           |                                       |           |           |           |      |
| Communication                        | 2.2 (2-3) | 2.1 (2-3) | 2.3 (2-3) | 3.2 (3-4) | 3.3 (2-4)                             | 2 (1-3)   | 3.1 (2-4) | 2.2 (1-3) | 2.55 |
| Stimulation                          | 2.3 (2-3) | 1.6 (1-2) | 1.8 (1.3) | 3.1 (3-4) | 1.8 (1-3)                             | 1.8 (1-2) | 1.8 (1-2) | 1.3 (1-2) | 1.94 |
| Environment                          | 2.6 (2-3) | 3 (3–3)   | 2.9 (2-3) | 3.7 (2-4) | 3.7 (2-4)                             | 2.3 (1-2) | 4 (4-4)   | 1.9 (1-4) | 3.01 |
| Dehydration                          | 2.7 (1-4) | 1.8 (1-2) | 2.6 (2-3) | 3.3 (2-4) | 2.7 (2-3)                             | 2.7 (2-3) | 3 (2-4)   | 2.4 (1-3) | 2.65 |
| Hypoxia                              | 3.6 (2-4) | 3.4 (1-4) | 3.5 (1-4) | 3.4 (1-4) | 3.4 (1-4)                             | 1.1 (0-4) | 3.4 (1-4) | 3.5 (1-4) | 3.16 |
| Immobility                           | 3.2 (2-4) | 2.3 (1-4) | 2.7 (2-4) | 3.7 (3-4) | 2.8 (2-3)                             | 3.6 (2-4) | 3 (2-4)   | 2.7 (2-3) | 3.00 |
| Infection                            | 3.6 (2-4) | 3.4 (1-4) | 3.5 (2-4) | 3.4 (1-4) | 3.4 (1-4)                             | 3.5 (1-4) | 3.6 (2-4) | 3.6 (2-4) | 3.50 |
| Multiple medication                  | 1.3 (1-2) | 1.1 (1-2) | 1.6 (1-2) | 2 (1–3)   | 2.7 (2-3)                             | 0.7 (0-4) | 1.2 (1-2) | 1.5 (1-2) | 1.51 |
| Pain                                 | 3 (2-4)   | 2.7 (1-4) | 3.2 (2-4) | 3.2 (2-4) | 3.3 (3-4)                             | 2.9 (2-4) | 2.8 (2-4) | 3.6 (3-4) | 3.09 |
| Poor nutrition                       | 3 (2-4)   | 2.7 (2-3) | 3 (2-4)   | 3.3 (3-4) | 3 (2-4)                               | 3.1 (2-4) | 3.5 (2-4) | 3.8 (3-4) | 3.18 |
| Sensory impairment                   | 2.1 (1-3) | 1.5 (1-2) | 1.5 (1-2) | 2.7 (2-3) | 2.8 (2-3)                             | 1.5 (1-2) | 2.9 (2-3) | 3 (2-4)   | 2.25 |
| Sleep                                | 2.4 (1-4) | 1.7 (1-3) | 2.9 (1-4) | 3.3 (2-4) | 2.7 (2-4)                             | 2.5 (1-4) | 3.1 (2-4) | 3.4 (2-4) | 2.75 |
| Domain 3: intervention coverage      |           |           |           |           |                                       |           |           |           |      |
| Assessment for delirium risk factors | 3.2 (3-4) | 2.6 (3-4) | 2.7 (2-4) | 3.3 (3-4) | 3.3 (3-4)                             | 2.8 (2-4) | 3 (3–3)   | 2.9 (3-4) | 2.98 |
| Use of risk assessment document      | 0.1 (0-1) | 0 (0–0)   | 0.6 (0-2) | 1 (1-1)   | 0 (0–0)                               | 2.2 (0-3) | 2 (2-2)   | 0.2 (01)  | 0.76 |
| Delivery of care to all patients     | 1.5 (0-3) | 1.6 (1-3) | 1.4 (1-2) | 1.8 (1-4) | 1.8 (1-3)                             | 1.7 (1-2) | 1.5 (0-3) | 2.3 (1-3) | 1.70 |
| Provision of information leaflet     | 2.3 (0-4) | 0.1(0-1)  | 2.6 (2-4) | 3.9 (3-4) | 3.8 (3-4)                             | 3.4 (0-4) | 3.4 (2-4) | 0.1(0-1)  | 2.45 |

\*0, never; 1, hardly ever; 2, some of the time; 3, most of the time; 4, always.

#### Domain 3: intervention coverage

The mean score for intervention coverage was 7.9 (range 4.2-10.1; maximum possible = 16) (Table 2). Scores for the component tasks are shown in Table 3. All wards were judged to have undertaken assessment for clinical factors that increase delirium risk at least some of the time, but the completion of the other three essential tasks (i.e. use of risk assessment

documents; delivery of care to all patients and provision of information leaflets) was more incomplete.

#### **Domain 4: duration of delivery**

The mean score for the duration of delivery was 0.38 (range 0-1; maximum possible = 1) (Table 2). Two wards were considered to have delivered the intervention for the stipulated

6 months, whereas four wards had not, and it was unclear for two wards.

#### **Overall fidelity**

Assessors concluded that the overall fidelity to the intervention was high in two wards (25.0%), medium in five wards (62.5%) and low in one ward (12.5%) (Table 2). In terms of factors that might have influenced fidelity to POD, there was no difference in adherence between the two types of ward (older people's care and orthopaedic) and the patients we observed were similar in terms of age across all wards (Table 2). The proportion of observed patients with cognitive impairment varied between 43 and 75%, but the ward with the lowest fidelity had 50% of patients with cognitive impairment, and one of the wards with the highest fidelity had 66% (missing data for the other high fidelity scoring ward). There were some differences in staffing across wards. One of the two wards which had markedly lower scores for the domain of delivery (Hospital 6: Ward 12) had a notably lower registered nurse to patient ratio on the day of observation (1:11) compared with the other wards (mean: 1:7; range: 1:5-1:8) (Table 2). However, registered nurse staffing levels on the other ward with a low score for the domain of delivery (Hospital 2: Ward 3) were similar to the higher scoring wards. On both the wards which achieved overall high adherence, there were more HCAs per patient than other wards (1:5 and 1:6) (Table 2). This may have had a positive impact on adherence as HCAs typically have more frequent and prolonged face-to-face contact with patients than do registered nurses.

## Discussion

Complex interventions such as the POD system of care are frequently implemented with lower fidelity than intended [17–19], and an understanding of the intervention fidelity is integral to the internal validity of evaluation studies in relation to study outcome interpretation [18]. However, the methods to assess fidelity are imperfectly developed in part because of continuing debate concerning the conceptualisation and measurement of implementation fidelity [20]. We examined the literature for appropriate frameworks to guide our fidelity assessment and identified the Conceptual Framework for Implementation as a potentially suitable approach [12]. This comprehensive framework includes the contribution of possible barriers to the implementation and the assessment of moderating factors including intervention complexity, facilitation strategy and participant responsiveness. However, our randomised trial was the final part of a programme of interlinked studies and we had examined moderating factors and facilitation during an earlier stage [6]. Our intent in the current study was to investigate the extent to which the POD system of care was implemented and delivered as intended. We therefore decided that we should focus on quantifying the delivery of the intervention

as described in the POD manual in the context of the feasibility trial.

We identified a set of 21 essential tasks as core components of the POD system of care. Accurate descriptive data are a key requirement when assessing fidelity to an intervention [21]. We used a range of methods including non-participant observations of care delivery, case note reviews and examination of staff-completed delirium risk assessments and care plans to obtain as complete a picture of intervention fidelity as possible. This information was then tabulated and evaluated and graded by 10 independent assessors using a standardised scoring process. Of the eight wards, two achieved an overall rating of high  $(\geq 80\%)$  adherence, five achieved an overall medium (51– 79%) adherence and one was rated as low ( $\leq$ 50%) adherence. Fidelity to the individual essential tasks was variable. Of the actions relating to the 10 risk factors for delirium [4], care related to infection, poor nutrition and pain was generally the most consistently delivered, whereas multiple medications, cognitive impairment and sensory impairment received less consistent attention. Moreover, the mean overall score for intervention coverage (the patients who received the intervention compared with the at-risk patients) was low (mean score 7.9 out of a maximum of 16), and four wards were considered by the assessors not to have continued the intervention for the whole of the prescribed 6 months.

As part of the POD implementation process, a senior healthcare professional (the POD facilitator) was appointed and given ring-fenced time to lead the implementation on each ward. It seems that the extent to which the POD facilitator was able to engage the nursing staff and other members of the ward team in POD may have had an impact on adherence. In the majority of wards, this role was undertaken by a senior nurse from the ward nursing team. However, in Hospital 2: Ward 3 (which achieved a low score for the domain of delivery and the lowest overall adherence score), initial facilitation of POD was carried out by a physiotherapist who encountered difficulty engaging the ward nursing team in implementing POD. In Hospital 6: Ward 12, which also achieved a low score for the domain of delivery, the ability of the POD facilitator (a senior staff nurse on the ward) to promote POD and involve the ward team in implementation tasks was limited due to ongoing staffing shortages.

The involvement of volunteers was an optional component of the POD intervention. Two wards (Hospital 2: Ward 3 and Hospital 2: Ward 4) elected not to involve volunteers. Of the remaining six wards, one (Hospital 1: Ward 1) had engaged POD volunteers (n = 10). In ward observations, these volunteers were observed to have an impact on implementation, particularly with regard to orientation and cognitive stimulation. However, this volunteer activity was focused on only one six-bedded bay which housed patients with cognitive impairment at risk of falls rather than across the whole ward. The remaining five hospitals intended to recruit, train and deploy POD volunteers. Although progress had been made towards this deployment, the volunteers were not in place by the start of POD delivery. The overall impact of volunteers on the delivery of the POD intervention was therefore minimal.

Robust fidelity assessment has not commonly been incorporated into evaluations of multicomponent delirium prevention interventions. Two studies reported fidelity rates comparable to those achieved by the lower scoring wards in our study [22,23]. In the first of these, a controlled clinical trial involving patients with hip fracture, fidelity to recommendations made by the inpatient geriatric consultation team was 56.8% [22]. In the second, a before and after study conducted on three older people's care wards in a single hospital site, the recorded fidelity to the several delirium risk factor modification protocols varied between 27 and 57% [23]. The latter study was similar to our own in that the intervention was designed to be delivered as routine practice to all patients admitted to the ward, rather than targeted at selected patients as in other studies [7,22,24].

Three studies reported overall fidelity rates similar to those achieved by our higher scoring wards [7,24,25]. In all these studies, the intervention was implemented in a single site compared with six hospitals in the present study. Consistent monitoring and support is probably easier to achieve in a single site and may result in increased fidelity to the intervention, and our study arguably provides a more realistic, 'real world' assessment of fidelity for the complex intervention of multicomponent delirium prevention. Additionally, in the study which achieved a notably high rate of fidelity [7], the core intervention was delivered by specially trained hospital volunteers as their sole remit rather than by ward staff who may have competing calls on their time.

#### Limitations

We used a multimethod approach to data collection to form as comprehensive view as possible of intervention fidelity. However, it is possible that the data we obtained may not have been an entirely accurate reflection of the care received by patients. For example, observed staff may have made greater effort to adhere to intervention protocols. Ideally, additional days of observation might have been helpful but would have needed greater research resources. Additionally, except for age and cognitive status, the researcher conducting the observations did not have access to clinical information about the patients. It is therefore possible that some of the observed variation in delirium prevention care between patients may have been due to differences in the presence of the clinical factors that contribute to delirium risk rather than the lack of fidelity to the intervention.

Obtaining accurate data from case notes and ward documentation relies on sufficiently comprehensive recording by staff. There is some evidence that nurses carry out more activities than they document [23,26] and that this is more evident as workload increases [26]. In our study, we frequently found gaps in the record of daily delirium prevention care for each patient. It is unclear whether this represented non-completion of the delirium prevention tasks or inconsistent documentation. In this respect, the case note reviews are likely to have presented a conservative assessment of intervention fidelity for the 22% sample of patients included in the process.

#### Conclusions

To our knowledge, this is the first multicentre, multicomponent delirium prevention study to report intervention fidelity. Overall fidelity to the POD Programme was medium (>50% but <80%) in the majority of wards, with only two of the eight wards achieving a high level of fidelity (>80%). This information provides an important context against which to interpret the outcomes of the pragmatic intervention feasibility study [11], within which the fidelity component was embedded. The reported adjusted odds ratio for delirium incidence for the patients randomised to the POD Programme compared with usual care was 0.68 (95% confidence interval 0.37-1.26) and is consistent with previous single centre studies of a more explanatory type [3-4,8,27]. This suggests that the implementation methods developed and used in the POD system of care are sufficiently robust for use in routine care.

**Supplementary data:** Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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