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# Implementation of a complex intervention to improve care for patients whose situations are clinically uncertain in hospital settings: a multi-method study using normalisation process theory

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## 25 Abstract

26 Purpose: To examine the use of Normalisation Process Theory (NPT) to establish if, and in what  
27 ways, the AMBER care bundle can be successfully normalised into acute hospital practice, and to  
28 identify necessary modifications to optimise its implementation.

29 Method: Multi-method process evaluation embedded within a mixed-method feasibility cluster  
30 randomised controlled trial in two district general hospitals in England. Data were collected using (i)  
31 focus groups with health professionals (HPs), (ii) semi-structured interviews with patients and/or  
32 carers, (iii) non-participant observations of multi-disciplinary team meetings and (iv) patient clinical  
33 note review. Thematic analysis and descriptive statistics, with interpretation guided by NPT  
34 components (coherence; cognitive participation; collective action; reflexive monitoring). Data  
35 triangulated across sources.

36 Results: Two focus groups (26 HPs), nine non-participant observations, 12 interviews (two patients,  
37 10 relatives), 29 clinical note reviews were conducted. While coherence was evident, with HPs  
38 recognising the value of the AMBER care bundle, cognitive participation and collective action  
39 presented challenges. Specifically: (1) HPs were unable and unwilling to operationalise the concept  
40 of 'risk of dying' intervention eligibility criteria (2) integration relied on a 'champion' to drive  
41 participation and ensure sustainability; and (3) differing skills and confidence led to variable  
42 engagement with difficult conversations with patients and families about, for example, nearness to  
43 end of life. Opportunities for reflexive monitoring were not routinely embedded within the  
44 intervention. Reflections on the use of the AMBER care bundle from HPs and patients and families,  
45 including recommended modifications became evident through this NPT-driven analysis.

46 Conclusion: To be successfully normalised, new clinical practices, such as the AMBER care bundle,  
47 must be studied within the wider context in which they operate. NPT can be used to the aid  
48 identification of practical strategies to assist in normalisation of complex interventions where the  
49 focus of care is on clinical uncertainty in acute hospital settings.

## 51 Introduction

52 Poor hospital care has received growing attention, particularly among the frail elderly and those  
53 approaching end of life (1). There is increasing recognition of the challenges of caring for this growing  
54 population, many of whom face clinically uncertain outcomes in which they may improve or  
55 deteriorate further (2, 3). These patients often have complex clinical and psychosocial needs.  
56 However, they are often inadequately addressed due to poor identification of deterioration (4) and  
57 insufficient and delayed communication from health professionals (4-6). This has potential to  
58 negatively impact on patients and their families at a profoundly emotional level (1). It also affects  
59 health professionals and health systems. It has been argued their intolerance of clinical uncertainty  
60 includes sub-optimal decision-making and planning, poor communication, inappropriate levels of  
61 investigation, patient safety, and use of scarce healthcare resources (6) .

62

63 In response, a growing number of interventions, including the Serious Illness Conversation Guide (7,  
64 8), the Universal Form of Treatment Options (UFTO) (9), the Recommended Summary Plan for  
65 Emergency Care and Treatment (ReSPECT) (10), and the Psychosocial Assessment and Communication  
66 Evaluation (PACE) (11), among others, have emerged. These interventions have been designed  
67 specifically to assist health professionals identify patients whose situations are clinically uncertain and  
68 more effectively navigate decision-making (10, 12, 13), communication (5, 7, 8) and care for those  
69 approaching the end of life. Broadly, these interventions aim to provide a structured approach to  
70 managing complex needs and uncertainty by developing a clearly communicated and documented  
71 care and treatment plan, that incorporates escalation or de-escalation decisions (14). They also aim  
72 to ensure that patient preferences, in the context of clinical uncertainty, are taken into account,  
73 documented and understood across the wider clinical team (3).

74

75 However, these interventions are all inherently complex (15). They are often situated within  
76 complicated care settings, require the successful navigation of multiple interacting components, and

77 the involvement of health professionals, across specialties and roles, as well as patients who are  
78 acutely unwell and their families (2). In the context of clinical uncertainty and approaching end of life,  
79 this complexity may be exacerbated, with patients, many of whom are acutely unwell, relying on  
80 family to make decisions on their behalf (16). Further, negotiating critical decisions between health  
81 professionals, patients and their families, as well as across clinical specialities, can lead to interactional  
82 conflicts, often associated with differing vested interests and professional paradigms (16-18). If these  
83 dynamics are not sufficiently considered and understood, such interventions may be delivered  
84 inappropriately with potentially harmful consequences for patients, or not delivered at all (19) (20)  
85 (21).

86

87 The 'AMBER care bundle' (where AMBER refers to Assessment; Management; Best practice;  
88 Engagement; Recovery uncertain) is a notable example of these complex interventions. It was  
89 developed in 2010 to overcome issues of inadequate and discordant decision-making and  
90 communication in the acute hospital setting (3). It aims to improve care for patients who are  
91 deteriorating, clinically unstable with limited reversibility, and at risk of dying in the next one to two  
92 months (3). The latter criterion was subsequently amended to be at risk of dying during a patient's  
93 episode of hospital care, despite treatment (22). The AMBER care bundle is designed to make clinical  
94 decision-making explicit in situations of uncertainty by encouraging health professionals to work in  
95 concert with patients, who possess sufficient mental capacity, and their families, to develop and  
96 document a clear medical plan, including consideration of anticipated outcomes, cardiopulmonary  
97 resuscitation and escalation plans, while continuing to acknowledge their situation of uncertainty (12).  
98 The intervention encourages regular communication with the patient and family regarding treatment  
99 plans, preferences for care and any other concerns S1 Appendix (12) .

100

101 A growing body of literature has attempted to shed light on the processes and outcomes associated  
102 with the intervention, however, these have demonstrated mixed findings. A comparative

103 observational mixed-methods study of the AMBER care bundle identified increased frequency of  
104 discussions about prognosis between health professionals and patients, and higher awareness of  
105 prognosis by patients (23). However, despite instances of communication being greater, they were  
106 often associated with a lower quality of information being communicated (10). Interviews with health  
107 professionals in a qualitative study identified that the AMBER care bundle was often utilised as a tool  
108 to categorise patients, to change the focus of care delivery and indirectly served a symbolic purpose  
109 in influencing behaviours of individuals and teams (24). More recently, a feasibility cluster randomised  
110 controlled trial (cRCT) of the AMBER care bundle across four UK hospital sites revealed a highly varied  
111 experience of care and communication for patients supported by the intervention and their relatives  
112 (22, 25).

113  
114 Clinical and contextual equipoise therefore is still present. Concerns are amplified as this intervention  
115 has been identified by National Health Service (NHS) England as one of five key enablers to Transform  
116 End of Life Care in Acute Hospitals (26), highlighted as representing ‘good practice’ by both the Royal  
117 College of Physicians (27) and the National Institute for Health and Care Excellence (28). Additionally,  
118 it has been widely adopted across a network of approximately 40 UK District General Hospitals (29)  
119 and a growing number of hospitals in New South Wales, Australia (30).

120

## 121 **Choice of Normalisation Process Theory for process evaluation**

122 The development of this complex intervention was informed by a pragmatic clinical case note review  
123 with input from two specialties – palliative care and geriatric medicine (3). There is now increasing  
124 evidence that the successful development and implementation of complex interventions benefit  
125 from the contribution of theoretical frameworks (31) (32) (33). As part of the feasibility cRCT of the  
126 AMBER care bundle (22), we conducted a process evaluation to understand how the intervention  
127 was operationalised, and what modifications and refinements were needed to optimise its use in  
128 acute hospital settings. To achieve this, we made use of Normalisation Process Theory (NPT) (34), a

129 socio-behavioural theory. NPT was chosen as it focuses on the '*social organisation of the work*  
130 *(implementation), of making practices routine elements of everyday life (embedding) and of*  
131 *sustaining embedded practices in their social contexts (integration)*' (34)(p 538).

132

133 NPT provides a set of tools to identify and explain the social processes through which new or  
134 modified practices of thinking, enacting and organising work are operationalised in institutional  
135 settings: in this case, hospitals (21). Moreover, it sets out a three-stage model of implementation,  
136 embedding and integration and is organised around several important questions: (i) *What factors*  
137 *promote or inhibit the routine incorporation of the intervention in practice?* (ii) *What factors promote*  
138 *or inhibit the implementation, embedding and integration of the intervention?* (iii) *What factors*  
139 *promote or inhibit the mobilisation of structural and cognitive resources for the implementation of*  
140 *the intervention?* (35)

141

142 The theory identifies four essential determinants of embedding or 'normalising' complex  
143 interventions into common practice. These are (i) '*coherence*' – the extent to which an intervention  
144 is understood as being meaningful, achievable and valuable; (ii) '*cognitive participation*' – the  
145 engagement of individuals (in this case, health professionals) necessary to deliver the intervention;  
146 (iii) '*collective action*' – the work that brings the intervention into use; and (iv) '*reflexive monitoring*'  
147 – the on-going process of adjusting the intervention to keep it in place (22). These components are  
148 considered to be dynamic and interact within the wider context of the intervention, such as existing  
149 organisational structures and procedures (36). Importantly, they are in keeping with the UK's  
150 Medical Research Council (MRC) guidance on the development and evaluation of complex  
151 interventions (37) and the Methods of Researching End-of-life Care (MORECare) statement (15),  
152 which both stress the importance of theory in understanding what makes interventions effective.

153

## 154 **Aim and objectives**

155 In this paper, we examine the use of NPT to determine if, and in what ways, the AMBER care bundle  
156 can be successfully embedded or ‘normalised’ into acute hospital care practice to support patients  
157 whose situations are clinically uncertain, and their families. More specifically, the paper aimed to  
158 integrate our data across sources under NPT constructs to (i) understand individual and contextual  
159 facilitators and barriers surrounding the implementation of the AMBER care bundle and (ii) identify  
160 strategies to strengthen facilitators and mitigate barriers, informing the optimisation of the  
161 intervention and its future sustainability in acute hospital clinical care.

162

## 163 **Methods**

### 164 **Design**

165 We made use of a multi-method design (38) within the wider mixed-method feasibility cRCT trial  
166 (22). Data were collected in parallel and then analysed and integrated using NPT. The data collection  
167 approaches included (i) health professional focus groups, (ii) interviews with patients and/or  
168 relatives, and (iii) multi-disciplinary team meetings’ non-participant observations. The quantitative  
169 component involved a detailed examination of patients’ clinical notes. The study was registered in a  
170 freely accessible clinical trial registry (ISRCTN36040085).

171

### 172 **Study setting**

173 The feasibility cRCT took place across purposefully selected general medical wards located in clusters.  
174 For the purposes of this study, the clusters were represented by four district general hospital (DGHs)  
175 in England. Implementation of the AMBER care bundle were limited to two of the four DGHs. Selection  
176 of study wards at each site was informed by heat maps that provided contextual information at a ward  
177 level on the number of deaths during and up to 100 days after admission. Wards with the highest  
178 number of deaths per year were considered to be suitable for the study (22, 29). In this paper, we  
179 focus on the two intervention sites, where the AMBER care bundle was implemented and delivered

180 and who provided data for the process evaluation reported in this paper Table 1. Full details of how  
181 the sites were selected are reported elsewhere (22).

182

183 **Table 1. Description of study sites**

Site	Cluster	Specialty	Number of beds	End of life care plan	CQC rating
Site 1	1 general medical ward	<ul style="list-style-type: none"><li>▪ respiratory</li><li>▪ endocrinology</li></ul>	30	Individualised care plan for dying patients	Good
Site 2	2 general medical wards	<ul style="list-style-type: none"><li>▪ care of the elderly</li></ul>	36	End of life care plan	Requires improvement

184

## 185 Implementation of the AMBER Care Bundle

186 A nurse facilitator supported the implementation of the AMBER care bundle across the two  
187 intervention sites for a period of two months. This involved: familiarisation with the ward, introducing  
188 the intervention to health professionals and training them on its use, supporting them in the practice  
189 of using the intervention, and observing how they used it in practice. Full details of the  
190 implementation of the intervention across study sites is reported in detail elsewhere (22, 29).

191

## 192 Sampling

### 193 Recruitment of patient and family for interviews

194 Patient or family participants were identified by research nurses in conjunction with health  
195 professionals for the feasibility cRCT when patients met the following criteria: were over 18 years old,  
196 deteriorating, in a clinically uncertain situation with limited reversibility, at risk of dying during their  
197 current episode of care, despite treatment. Participants also needed to be able to provide written  
198 informed consent or assent through a personal consultee (consultee declaration) prior to the  
199 interview. We made the decision to pragmatically stop recruitment when we believed we had  
200 collected an adequate amount of data to address the research questions and where we could be  
201 confident from our on-going interviews and processes associated with our framework analysis



202 approach that new data would be considered to be redundant of data already collected (39-41). Each  
203 participant provided written informed consent prior to the interview.

204

### 205 **Recruitment for focus groups**

206 Ward staff from study wards were invited via research nurses and posters to participate in the focus  
207 groups. Of those who expressed interest, we aimed to recruit a range of health professionals with  
208 different levels of experience. Written informed consent was obtained from participating health  
209 professionals.

210

### 211 **Recruitment for non-participant multi-disciplinary observations**

212 For non-participant observations, the researcher (EY) organised with research nurses and clinical staff  
213 an appropriate schedule of attendance. Observations included multi-disciplinary team meetings  
214 including morning handovers and board rounds across study wards. Informed consent was obtained  
215 prior to these meetings.

216

### 217 **Data collection**

218 Questions asked during (i) focus groups with ward staff, (ii) semi-structured interviews with patients  
219 and/or relatives; (iii) issues noted during the non-participant observations of multi-disciplinary team  
220 meetings; and, (iv) the review of patient participants' clinical notes, were informed by our patient and  
221 public involvement (PPI) representatives, and were aligned to NPT.

222

#### 223 **(i) Qualitative interviews with patient and carers**

224 Interviews were semi-structured and topic guides explored key constructs of NPT including patients'  
225 and their relative's insights into the delivery of care S2 Appendix. Interviews were conducted by a  
226 research assistant (EY) and recorded on an encrypted digital voice recorder. During transcription, all  
227 potentially identifiable information was removed or anonymised.

228

229 **(ii) Focus groups with health professionals**

230 Health professionals' views on caring for patients whose situations are clinically uncertain and views  
231 about the intervention were explored during focus groups S3 Appendix. Focus groups were led by  
232 senior researchers (JK and CE) with experience in palliative care and qualitative research, and field  
233 notes were taken by EY and HJ. Focus groups were audio-recorded and transcribed verbatim and  
234 anonymised.

235

236 **(iii) Non-participant observations of multi-disciplinary team meetings**

237 Non-participant observations of multi-disciplinary team meetings took place at multiple time points  
238 on each of the wards. During these observations, the researcher (EY) noted who was present, the  
239 frequency and length of the meetings, and the type of conversations relating to patients identified as  
240 fulfilling the criteria to be supported by the AMBER care bundle. Notes were also made as to which  
241 professionals contributed to conversations, and the decision-making discussion and actions related to  
242 patient care. Observations were recorded as hand-written field notes throughout and immediately  
243 on leaving the meeting.

244

245 **(iv) Patient participant clinical case note review**

246 Following the implementation of the AMBER care bundle, we examined the clinical notes of patients  
247 who were in receipt of the intervention. Data were extracted by EY onto a designed-for-purpose form  
248 which captured details of admission, death or discharge, calculation of the length of stay, and  
249 documentation of the intervention components. All identifiable patient information was removed or  
250 anonymised before sharing with the rest of the research team.

251

252 **Analysis**

253 **Patient participant clinical case note review**

254 The numerical data in the case notes were analysed with SPSS (42) using descriptive statistics.

255 Interviews with patients and relatives, focus groups with health professionals,  
256 and non-participant observations of multi-disciplinary team meetings

257 Qualitative data were analysed using the Framework approach and thematic analysis (41) facilitated  
258 by NVIVO 10. Members of the research team who led on conducting the interviews, focus groups and  
259 observations (JK, EY and HJ) also led on the analysis. They familiarised themselves with the raw data  
260 and discussed their impressions of the dataset. The NPT constructs – ‘coherence’, ‘cognitive  
261 participation’, ‘collective action’ and ‘reflexive monitoring’ – provided a thematic framework Table 2.  
262 We took a robust approach to analysis: all interviews and focus groups were double coded in NVIVO  
263 10 by two researchers (EY and JK, EY and HJ, or JK and HJ) independently followed by comparing results  
264 and discussion within each researcher pair to ensure uniformity of coding. We also hosted ‘data  
265 workshops’ where the researchers coded a sample of transcripts together with our patient and public  
266 involvement (PPI) members to minimise bias in interpretation and the validity of findings. Once  
267 transcripts were coded, data was exported from NVIVO 10 and were charted and mapped using  
268 Excel®. Non-confirmatory data were also explored and consideration was made about their sources  
269 to avoid making unwarranted claims about patterns in the data (43).

270

271

**Table 2. NPT constructs relevant to the AMBER care bundle**

<b>Normalisation Process Theory (NPT) Constructs</b>	<b>NPT framework questions relevant to AMBER care bundle</b>
<p><b>NPT construct 1- ‘Coherence’</b> The work people engage individually and collectively when they are faced with the problem of operationalising a set of practices</p>	<ul style="list-style-type: none"> <li>• Is the AMBER care bundle easy to describe?</li> <li>• Is it distinct from other ward-based interventions? (i.e., meaning and sense-making by participants)</li> <li>• Does the AMBER care bundle have a clear purpose for all relevant participants i.e. ward staff?</li> <li>• Do ward staff have a shared sense of its purpose?</li> <li>• What benefits will the AMBER care bundle bring, and to whom?</li> <li>• It is AMBER care bundle expected to improve the performance and the clinical outcomes of patients and their families.</li> <li>• Are these benefits likely to be valued by potential participants?</li> <li>• Does the AMBER care bundle fit with the overall goals and activity of the organisation?</li> </ul>
<p><b>NPT construct 2- ‘Cognitive participation’</b> ‘Buy-in’ or relational work people do to build and sustain a community of practice around a complex intervention.</p>	<ul style="list-style-type: none"> <li>• Do ward staff consider the AMBER care bundle to be a good idea?</li> <li>• Will they see the point of the AMBER care bundle easily?</li> <li>• Will ward staff be prepared to invest time, energy and work in it?</li> </ul>
<p><b>NPT construct 3 - ‘Collective action’</b> The operational work that people do to enact a set of practices around a complex intervention.</p>	<ul style="list-style-type: none"> <li>• How will the AMBER care bundle affect the work of ward staff?</li> <li>• Will it promote or impede their work</li> <li>• Will ward staff require extensive training before they can use it?</li> </ul>
<p><b>NPT construct 4- ‘Reflexive monitoring’</b> The monitoring work that people do to understand and appraise the ways that a new set of practices affect them and others around them.</p>	<ul style="list-style-type: none"> <li>• How are ward staff likely to perceive the AMBER care bundle once it has been in use for a while?</li> <li>• Will the AMBER care bundle to be perceived as advantageous for patients or ward staff?</li> <li>• Will it be clear to them what the effects of the AMBER care bundle intervention have been?</li> <li>• Can users/staff contribute feedback about the AMBER care bundle once it is in use?</li> <li>• Can the AMBER care bundle intervention be adapted/improved based on experience?</li> </ul>

274 Data across all sources were then discussed further by the researchers and triangulated using the  
275 NPT constructs to understand the operation of the AMBER care bundle on each ward. At this stage,  
276 researchers identified areas of confirmation and contradictions across sources which were used to  
277 greater researchers understanding of the operation of the AMBER care bundle across health  
278 professionals, and the contributing facilitators and barriers involved in the sustainable use of the  
279 intervention.

280

## 281 **Research governance and ethical approval**

282 Ethical approval was obtained from the National Research Ethics Committee - Camden and King's  
283 Cross (20.12.2016, REC Reference: 16/LO/2010) and Health Research Authority (25.01.2017). Local  
284 research governance approvals were obtained from participating hospitals.

## 285 **Results**

286 We conducted two focus groups (26 health professionals), nine non-participant observations, 12  
287 interviews (two patients, 10 relatives) and 29 patient participant clinical note reviews. Demographics  
288 of those involved in focus groups, interviews, non-participant observations and clinical note reviews  
289 are provided in S1 – S4 Tables respectively. Using multi-methods, the implementation process across  
290 sites based on the four NPT constructs of coherence, cognitive participation, collective action and  
291 reflexive monitoring were examined. Within each construct, we present the barriers and facilitators  
292 to implementation and discuss strategies for optimising implementation of this complex intervention  
293 within the acute hospital setting.

294

295

296

297 **Coherence –making sense of, and finding meaning in, the AMBER care**  
298 **bundle**

299 Coherence represented the process through which ward staff shared a common and valid  
300 interpretation of the purpose and value of the AMBER care bundle. Overall, ward staff were observed  
301 as having a good practical understanding of the intervention and its constituent components. For  
302 example, during the non-participant observation of a morning handover at Site 1, a range of health  
303 professionals were noted as being confident and clearly explaining the intervention to a new  
304 consultant on the ward.

305

306 There was broad agreement from health professionals that the intervention represented a positive  
307 shift in the emphasis of care for a patient group who were previously overlooked in clinical practice.  
308 Ward staff recognised that the intervention prompted them to recognise and prioritise patients whose  
309 situations were clinically uncertain and further, engage in important discussions with them regarding  
310 preferences for care, escalation decisions and medical treatment. Many noted the value of this for  
311 ensuring that patient and family preferences were discussed, captured and communicated with those  
312 involved in the patients' care in a timely manner.

313

314 The AMBER care bundle was also perceived to be valuable in supporting some staff to provide care  
315 for this patient group. At Site 2, the ward manager highlighted the value of the intervention for junior  
316 staff. First, in increasing their understanding of clinical uncertainty, deterioration, and end of life and  
317 secondly, their increased confidence to engage with this patient population by using the intervention  
318 as a platform to broach such topics.

319

320 *... But now with the 'AMBER' I think they can talk, and they will feel more confident to talk with*  
321 *relatives. (Site2-014, female, Ward Manager)*

322

323 Whilst most health professionals suggested that the AMBER care bundle represented a fundamental  
324 change in care, a small number did not believe it differed noticeably from their existing practice. These  
325 individuals did, however, note that the intervention acted as a means to formalise their current  
326 practice, a view typified by the following junior doctor:

327

328 *Speaking for myself, if I have someone who I'm worried and has the potential of deteriorating,*  
329 *I would always within my best capacity to try and inform the family about their situation. I*  
330 *don't think it changed our practice. The only thing we're doing is just formally documenting it.*  
331 *We were doing everything we could, uhm yeah, even prior to AMBER bundle. (Site2-005,*  
332 *Female, Senior House Office)*

333

334 Despite health professionals holding a coherent view of the value of the AMBER care bundle, a lack  
335 of clarity surrounding the intervention's eligibility criteria resulted in a varied understanding of what  
336 patients were most appropriate for the AMBER care bundle. In practice, the clinical team were  
337 frequently observed making judgements on patients' suitability to be supported by the intervention,  
338 based on the patients' level of co-morbidity, frailty, disease progression, the likelihood of responding  
339 to treatment and medication, or their 'ceiling of care escalation', that represented proxies for 'clinical  
340 uncertainty'. They rarely referred to a patient's 'risk of dying' during the episode of care [the  
341 admission] to inform decisions. This was further exemplified by the responses received by health  
342 professionals during focus groups who when asked to describe the patients who were suitable to be  
343 supported by the intervention used descriptors such as 'those who are aged and frail', or 'those with  
344 an unpredictable recovery'.

345

346 One junior doctor on Site 2, explained that they had focused on identifying patients in clinically  
347 uncertain situations rather than those at risk of dying, due to the latter requiring them to

348 prognosticate, which they did not feel skilled or confident to do. This posed fundamental challenges  
349 and often made this aspect of the eligibility criteria impossible to operationalise coherently. Further,  
350 this reluctance to acknowledge a patient's 'risk of dying' was noted by patients and their family, who  
351 were often more aware of their own, or their loved one's likelihood of death.

352

353 *I remember having a conversation with the doctor and saying, "Do you really actually think*  
354 *he's going to be discharged out of here? Because he looks like he's a dying man to me." The*  
355 *doctor just said to me "You have to be optimistic", and I just said, "Optimistic or realistic?" you*  
356 *know? (Site1-017, Carer)*

357

## 358 Cognitive participation – commitment and engagement with the 359 AMBER care bundle

360 Cognitive participation represented the extent to which key stakeholders (health professionals) were  
361 adequately motivated to incorporate this complex intervention into their practice and how well it  
362 fitted in with existing approaches. All staff were expected to engage in the active identification of  
363 patients whose situations were clinically uncertain, discuss plans for treatment and care with patients  
364 and their family, and document these in patients' clinical notes.

365

366 Across sites, staff participating in the focus groups were unanimous that the role of the nurse  
367 facilitator was critical in successfully engaging with and operationalising the intervention. She  
368 encouraged them to appraise which patients might be suitable for the AMBER care bundle, as well as,  
369 importantly, prepare and reflect on conversations with patients and their families which were often  
370 difficult and emotionally demanding. Observations of multi-disciplinary team meetings supported  
371 these views. At numerous points, the nurse facilitator was observed encouraging health professionals  
372 to complete AMBER care bundle components, particularly in identifying instances of clinical



373 uncertainty, ensuring important discussions took place with patients and families and reminding staff  
374 of the requirement to document these circumstances.

375

376 *He's 'AMBER', so while writing the discharge letter, we should remember to note the things*  
377 *discussed and escalation decisions. (FIELD NOTE: Site2-011, Female, Nurse Facilitator:*  
378 *observed during Handover meeting)*

379

380 Importantly, because of their pressured workloads, ward staff did not believe they had additional  
381 capacity to 'champion' the intervention in the ward within their roles. During focus groups, they  
382 questioned their ability to engage in the delivery of the intervention without the continued dedicated  
383 support from the nurse facilitator. Specifically, they highlighted the challenges and time required to  
384 train new staff about the intervention, a situation amplified by increasing levels of staff turnover.

385

386 Staff were fearful of potential negative consequences which may come from the use of the  
387 intervention without a dedicated 'champion' to facilitate engagement. At the very least, there was  
388 concern that they would overlook patients who might benefit from the intervention and, more  
389 seriously, a wariness of engaging in potentially emotionally laborious conversations with patients and  
390 or their relatives.

391

392 *I think the nurse facilitator was excellent actually in helping us implement and 'do the*  
393 *AMBER'. Since she's gone, I think it dropped off a little bit. (Site1-022, Female, Ward*  
394 *Manager)*

395

396 **Collective action – work required to make the AMBER care bundle**  
397 **function**

398 Collective action represented the notion that ward staff performed actions or tasks based on  
399 principles outlined by the intervention. The data from across the different components of the study  
400 shed light on the resources and procedures associated with its integration into routine practice.  
401 Since the general principle of delivering patient-centred care was shared across staff, for some, the  
402 intervention was not perceived to represent a radical departure from their current way of delivering  
403 care for some individuals. This consequently meant that the work associated with the collective  
404 delivery of the intervention was generally well accepted into daily clinical practice.

405  
406 Nevertheless, formally operationalising the daily clinical activities associated with the intervention  
407 provided a welcomed opportunity for other ward staff to be involved in discussions about the  
408 decision-making process associated with the delivery of care for this patient group. Instances of  
409 teamwork and shared decision making were observed during the handover meetings. At Site 2, for  
410 instance, a range of health professionals contributed to discussions about patients' suitability for the  
411 AMBER care bundle. In one focus group, a consultant also highlighted that whilst it was doctors who  
412 were typically perceived as being pivotal in patients' care, the views of other professions increasingly  
413 began to contribute to patient-centred decisions and their medical plans. In this respect, the  
414 presence of the intervention enabled and empowered those who had previously not been called on  
415 for their views, to actively share them. A consultant on Site 1 emphasised the shift from clinical  
416 decisions being made independently to decisions made as an MDT, with health care assistants who  
417 often have more insight into the day-to-day care of the patient, and allied health professions now  
418 being involved in decision making.

419  
420 Perspectives from some patients and relatives substantiated health professionals' views, highlighting  
421 teamwork across professionals and specialties during their care, or the care of their family member:

422

423 *100% work together well. (Site2-009, Male, Patient)*

424

425 *The OTs especially have been brilliant there ... and yeah they seem to, they seem to all know*

426 *what's not and what's going on. (Site2-016, Female, Carer)*

427 The case note review of patient participant notes provided further insight into ward staffs'

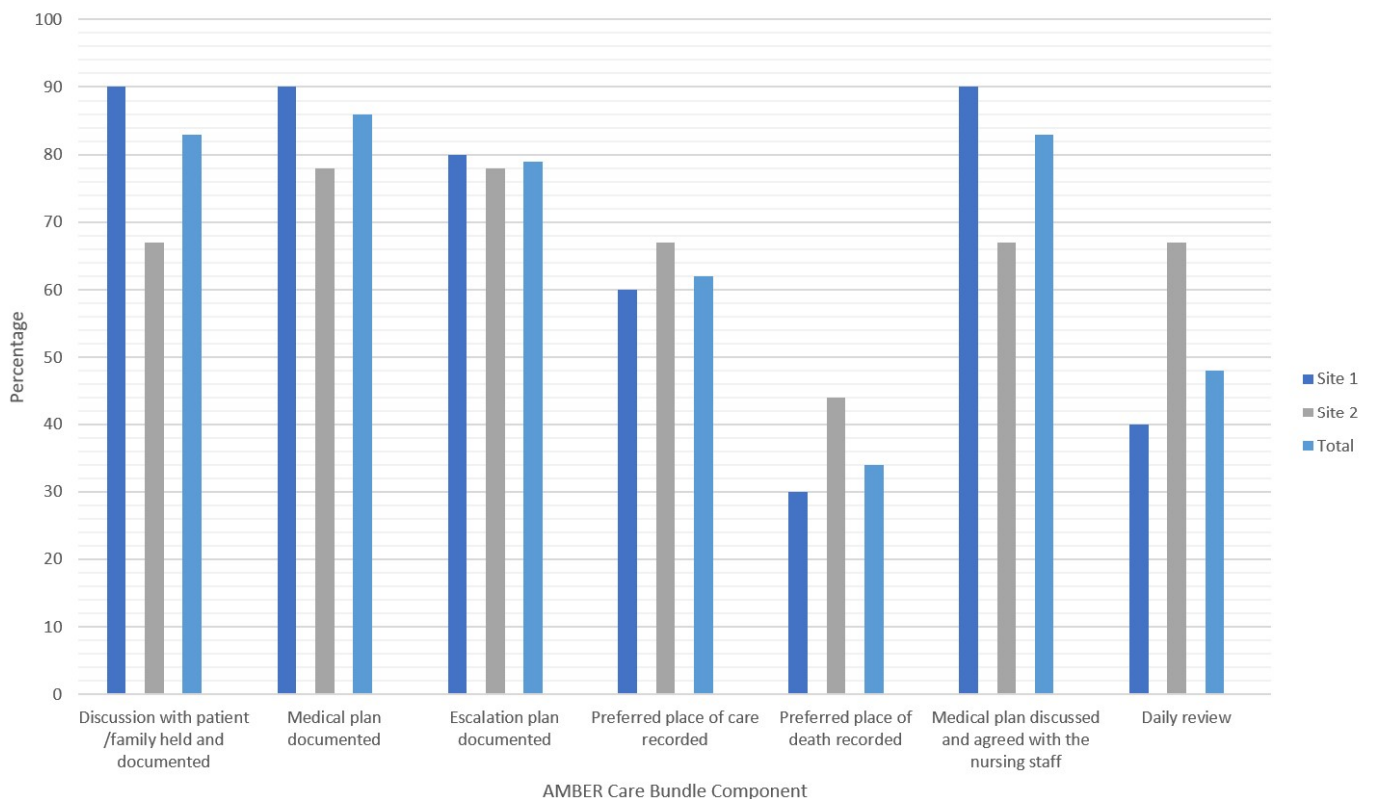
428 involvement in patient-centred decisions and medical plans Fig. 1. In Site 1, 90% of patient

429 participants' notes detailed discussion and agreement of patient medical plans with ward staff, and

430 in Site 2, this was noted in 67%, demonstrating documented involvement of other health

431 professionals.

432



433 **Fig 1. Documentation of AMBER Care Bundle components in patient participants' clinical notes**

434

435  
436 Further analysis of the patients' clinical notes provided additional insight into the collective action  
437 taken to complete the required documentation associated with the delivery of the intervention.  
438 Overall documentation of medical plans and escalation plans for patients across sites were high  
439 (medical plans 90% and 78% and escalation plans 80% and 78%, for Site 1 and 2 respectively).  
440 This high level of compliance may be due to health professionals perceiving the documentation  
441 required as part of the AMBER care bundle as valuable, simple, and easy to complete.

442  
443 Despite this, there were, however, collective action-related concerns with some of the intervention  
444 procedures, particularly those that relied on timely discussions between health professionals and  
445 patients and/or their relatives. The combined findings from the focus groups, interviews with patients  
446 and relatives, and review of clinical notes identified that the completion of initial conversations and  
447 follow-ups with patients or their family were often delayed. In focus groups, health professionals  
448 reflected that this was often because many of the patients suitable for the intervention were elderly,  
449 confused and lacked mental capacity. Consequently, engaging in conversations with these patients  
450 about their situation, and making treatment and care plans, necessitated the presence of family.

451  
452 Relatives, however, were not always available to have important discussions in a timely manner. For  
453 instance, some were unable to visit or were only able to visit on weekends or evenings, when health  
454 professionals most familiar with the patient's circumstances were not on the ward. Observations of  
455 multi-disciplinary team meetings further evidenced the challenges ward staff reported experiencing  
456 in accessing some family members. For instance, when talking about a patient on Site 1, a consultant  
457 at the multi-disciplinary team meeting was overheard suggesting a conversation was required with  
458 the patient's wife to discuss the possibility of a referral for a dementia assessment. However, an  
459 occupational therapist mentioned that the patient's wife was herself unwell and currently receiving  
460 chemotherapy, so any discussion soon would be unlikely.

461

462 A key component and goal of the AMBER care bundle is the requirement for staff to document  
463 patients' clinical situations and medical plans to ensure all staff, including weekend and out of hours  
464 staff, are familiar with a patients' situation. While patient participant clinical notes highlighted that  
465 this documentation was occurring in most cases, the detail in these notes often varied from patient  
466 to patient, translating to instances of inconsistency in care.

467

468 This is exemplified by a daughter of a patient on Site 1 who, when asked if she felt like she was getting  
469 consistent information from nurses and doctors, highlighted the importance of all staff being aware  
470 of a patient's clinical situation to ensure they are receiving consistent care.

471

472 *I think probably some of the nurses, I don't want to criticise them but I think probably some*  
473 *of the nurses who were maybe, bank nurses and things, who didn't know her [the patient] so*  
474 *well didn't quite realise about the delirium and thought it was the dementia. (Site 1-002,*  
475 *Carer)*

476

477 Similar experiences were shared by other relatives. Another daughter of a patient on Site 1,  
478 highlighted instances where her father had been in receipt of unnecessary tests from some health  
479 professionals who did not seem aware of the de-escalation for his clinical situation.

480

481 During engagements with patients and relatives, health professionals were encouraged, as part of the  
482 intervention, to discuss future plans, including preferred place of care and preferred place of death.  
483 Despite this, the clinical notes of patients demonstrated that these preferences were often  
484 inadequately recorded, particularly place of death. This was documented in only 30% and 44% of  
485 patient clinical notes for Site 1 and Site 2, respectively. Compliance with these components of the  
486 intervention appeared to be lower than other care plan elements, such as completion of escalation

487 plans and do not attempt resuscitation (DNAR) discussions. This corresponded with the views of  
488 patients and relatives who suggested that, while other areas of care were being discussed (such as  
489 treatment), preferred place of care and preferred place of death were often absent from these  
490 conversations.

491

492 *No, we didn't have any of those conversations in the hospital, and to be honest I haven't had*  
493 *any of those conversations since he's gone to the nursing home, which we need to have really*  
494 *to be honest. (Site 1-017, Carer)*

495

496 One consultant explained that discussions surrounding the preferred place of care or preferred place  
497 of death were difficult for health professionals, due to concerns they might not fulfil patients' or  
498 relatives' expectations if preferences could not be realised due to over-riding clinical reasons. One  
499 consultant explained that for some patients, while the preferred place of death is home in reality, it is  
500 unlikely that these patients would be able to be supported at home, due to the services they need and  
501 care they would require. There was therefore reluctance to engage in these conversations with  
502 patients in fear that they may be disappointed if preferred place of care or death could not be  
503 achieved.

504

505 Findings also highlighted that communication with patients and families was often variable due to  
506 workload pressures. During conversations, staff felt rushed and unable to provide adequate time to  
507 have these important discussions with patients and their relatives. This proved to be frustrating and  
508 health professionals believed that, whilst the intentions of the intervention were honourable, the  
509 fidelity of its delivery was often compromised. This was typified in the following comment from a  
510 registrar:

511

512 *Sometimes our communication is brief, just because of the time pressures we are in*  
513 *nowadays. Even when I have the conversation, I sometimes feel that if I spent 10 minutes*  
514 *more or 15 minutes more with a patient, I'd probably explain a lot better. (Site2-002, Male,*  
515 *Registrar)*

516

## 517 **Communication and Daily Review**

518 Engaging in difficult conversations was also heavily dependent on health professionals' skills and  
519 confidence. This varied considerably. While some consultants reported possessing well-honed skills  
520 and expertise in this area, other staff, particularly nurses, believed their skills were inadequate. One  
521 ward manager reflected that this was due to nurses having inadequate training in advanced  
522 communication, whereas doctors have more focus on this during their training.

523

524 Due to this perceived disparity in skills and confidence of ward staff, there were repercussions  
525 associated with the delivery of core collective activity in planning care and treatment in concert with  
526 patients and relatives. Since some ward staff were reticent to engage in these challenging  
527 conversations, this task was delegated by default to consultants, often leading to delays in these  
528 discussions occurring, due to consultants already pressured workloads. This finding was supported by  
529 the interviews with relatives who were frustrated by the lack of information provided by nurses, health  
530 care assistants and other front-line staff, particularly as they were told they would need to wait for  
531 the consultant or doctor to provide an update.

532

533 *The nurses never really actually talked about his, erm, terminal diagnosis ..., it was only the*  
534 *doctors, I'm sure the nurses were aware... his erm, condition would change, but the nurses*  
535 *didn't really talk about that. (Site 1-001, Carer)*

536

537 *Most of them were healthcare assistants but they were able to say functionally able to say*  
538 *how he was, but if you asked them anything medically, they wouldn't answer your questions.*  
539 *(Site 1-001, Carer)*

540

541 The emotive nature of discussions relating to clinical uncertainty and the impact of these on some  
542 health professionals, particularly junior doctors', also caused issues.

543

544 *I think as a med student, we didn't have to broach that with the family, so we just meet the*  
545 *patient and put them on 'AMBER care'. So, I'm meeting you for the first time and they may*  
546 *cry, and you know I found it quite hard, emotionally. (Site 2-023, M, Foundation Doctor Y 1)*

547

548 While the nurse facilitator provided some support in this respect, there was a strong desire to provide  
549 greater access to clinical supervision and protected time for staff to debrief after these disconcerting  
550 discussions.

551

552 The daily review component of the intervention also experienced low compliance; this intervention  
553 component was documented in only 40% and 67% of clinical notes at Site 1 and Site 2, respectively.

554 This component of the intervention required ward staff to take time each day to, first, review whether  
555 a patient's situation of clinical uncertainty remained and, second, to follow-up on any patient or family  
556 concerns and preferences identified during the initial discussion. Two issues were identified by health  
557 professionals to explain variance in the daily review. Firstly, some health professionals were of the  
558 view that appraising patients' clinically uncertain recovery status daily was unnecessary. This was  
559 exemplified by a consultant at Site 1 who preferred for his team to feel that there was always an  
560 element of uncertainty and to review patients less often, unless there is a drastic change in their  
561 situation of clinical situation. Secondly, others believed that frequent discussions with patients and



562 families about their situation of clinical uncertainty had the potential to cause additional and undue  
563 distress.

564

565 As part of the daily review, staff were also required to place a yellow sticker on patients' clinical notes  
566 each day that they were on the AMBER care bundle, alongside any relevant notes. In practice, the 'A'  
567 stickers were not perceived as adding value, were burdensome and therefore were quickly abandoned  
568 by staff.

569

570 However, in contrast to health professionals' concerns surrounding the daily review, relatives  
571 reported valuing the frequent updates from health professionals. Accepting the extensive workload  
572 and time pressures of health professionals, some suggested that they did not expect lengthy  
573 discussions, but brief updates would have been welcomed each time when they visited the ward.

574 *We wanted more communication. We were there every day, so there was no reason why they*  
575 *did not stop and spoken to us. (Site1-003, Carer)*

576

## 577 **Reflexive monitoring – opportunities to appraise the AMBER care** 578 **bundle**

579 Reflexive monitoring refers to the appraisal process which health professionals, formally and  
580 informally, undertook to assess and understand the ways that the AMBER care bundle affected  
581 themselves, patients and/or families and others around them. Opportunities for formal reflection  
582 and monitoring were not integrated into the intervention. However, we did identify, through  
583 observations and focus groups, attempts by health professionals to locally modify or reconstruct the  
584 AMBER care bundle and its delivery, to successfully enable implementation within their acute  
585 hospital setting. This included adapting the frequency of reviewing patients' situation of clinical  
586 uncertainty and removal of the requirement to place a yellow 'A' sticker in patients' notes Table 3.

587

588 **Table 3. Modifications to the AMBER care bundle component**

<b>Suggested Modification</b>	<b>Rationale for Modification</b>
<b>Remove prognostication from eligibility criteria</b>	Health professionals highlighted the difficulty of predicting whether patients were going to die during their current hospital admission. Consequently, many were reluctant to make decisions on patients' suitability for the AMBER care bundle based on their risk of death and instead focused on identifying situations of clinical uncertainty to inform their decisions. Additionally, health professionals suggested that simplification of the eligibility criteria to concentrate solely on 'clinical uncertainty' rather than 'deterioration' and 'risk of dying' would not only ensure that a wider group of patients would be identified and benefit from the AMBER care bundle, but it would mean that staff would not be required to use the ambiguity of prognostication as a decision-making tool.
<b>Removal of daily review stickers</b>	Health professionals saw little value in the requirement of placing a yellow 'A' sticker delineating 'AMBER' on patients' clinical notes to prompt staff to think about their situation. In practice, this task associated with the intervention was rarely completed. Health professionals therefore recommended that the sticker should be disposed with.
<b>Daily review of the patient's situation of clinical uncertainty</b>	Health professionals suggested that reviewing patients' clinical uncertainty within the clinical team was not required daily since patients' situations did not tend to change between recovery and deterioration that often. Further, some health professionals perceived that the requirement to revisit conversations on a daily basis were distressing for patients and family members. Staff therefore recommended that it would be more valuable and efficient to review patients' clinical situations only where there was evidence of a more profound change in their situation.
<b>Daily re-engagement with patients and/or family</b>	Paradoxically, patients and particularly relatives suggested that staff should provide a brief practical update to the patient and family each day regarding their general overall care. Aware of workload pressure of staff, patients and relatives suggested that these did not need to be lengthy discussions. Instead, they should be brief, covering any notable events that occurred throughout the previous day and provide a general update regarding their care. It was suggested that these brief updates could be undertaken by nurses and other ward staff who were present more often on the wards.

589

590 **Optimising implementation, integration and sustainability of the AMBER care**  
591 **bundle**

592 Figure 2 presents a model of the facilitators and barriers of the AMBER care bundle alongside  
593 modifications that must be considered to enable the normalisation of the intervention within the  
594 acute hospital setting. In response to these barriers, improvement strategies are identified that are  
595 likely to contribute to improving aspects of cognitive participation and collective action to sustain  
596 practices associated with the delivery of this complex intervention (44) (14).

597

598

599

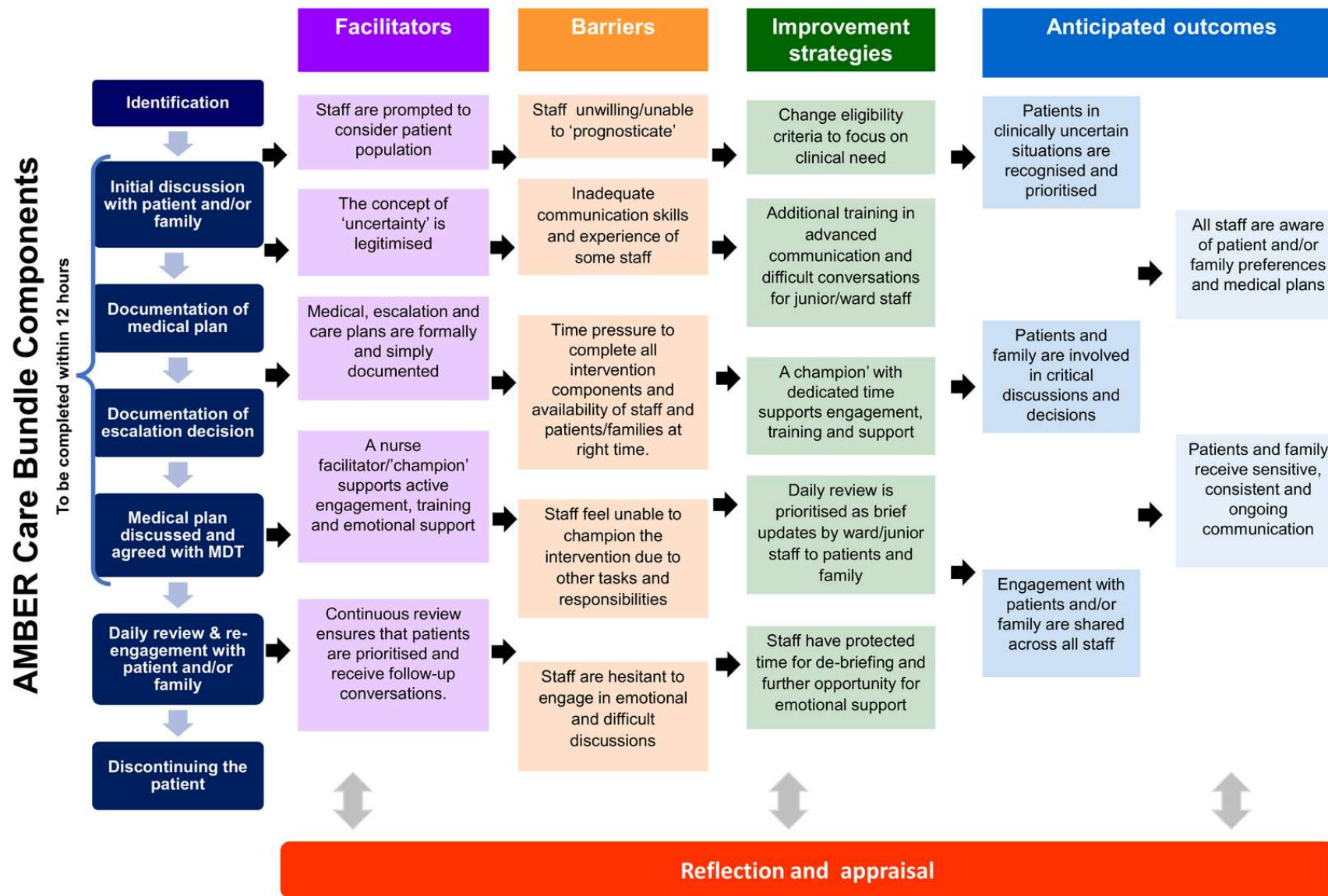
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601

602

603

604



605 Fig 2. Facilitators, barriers and strategies for normalisation of the AMBER care bundle in acute hospital settings

## 606 Discussion

607 Introducing new models of working in health care settings such as hospitals is often extremely  
608 challenging (45). This multi-method process evaluation study, residing within a wider cluster cRCT,  
609 has demonstrated a varied response to implementing the AMBER care bundle into routine practice to  
610 serve patients whose situations are clinically uncertain and their families. Whilst it is evident from our  
611 findings that the intervention was perceived as enhancing some aspects of care for this previously  
612 under-served patient group, we also identified barriers that block its successful integration and  
613 normalisation as it was intended and consequently its sustainability in routine practice. Below, we  
614 critically reflect on the findings to understand the intervention through an NPT lens, describing which  
615 aspects of the intervention work, which did not and importantly, why. We also outline what is vital to  
616 improve the intervention so it can be normalised and sustained in 'real-world' acute hospital ward  
617 settings and deliver favourable patient and family outcomes.

618

### 619 Aspects that aided normalisation of the AMBER care bundle

620 The intervention was used by health professionals to prompt them to actively consider the care and  
621 management of a patient group which were not previously prioritised in their clinical practice. The  
622 intervention itself acted as a platform to broach the issue of clinical uncertainty within the acute  
623 hospital setting, helping to shift the focus of care provided. This symbolic use of the AMBER care  
624 bundle is in line with previous qualitative explorations which identified health professionals use of  
625 interventions to prompt changing the focus of care (24) (46). For some health professionals, the  
626 AMBER care bundle was perceived to differ little from their current ways of working. Considering the  
627 growing number of end of life care-related support aids or tools, for example ReSPECT (10), a lack of  
628 differentiation may be present and problematic, with some staff resisting interventions they believe  
629 may replicate existing practices and reflect an unnecessary administrative burden (14). Yet most  
630 health professionals perceived little administrative burden associated with the AMBER care bundle,  
631 with the required documentation considered simple, clear and easy to complete. Further, while health

632 professionals recognised the value of the AMBER care bundle for improving their own processes  
633 (simple and clear documentation, the involvement of all staff in decision making), they were also clear  
634 on the value and benefit of the intervention for patients and their families, including empowering  
635 patients to share their preferences earlier, and involving patients and their family in critical decisions.  
636 This is a welcomed shift away from an overemphasis on processes to a greater focus on the ultimate  
637 goals of intervention delivery: improved care for patients and their families (46).

638  
639 Critical to initial and sustained engagement with the intervention was the provision of a ‘champion’  
640 (nurse facilitator) who ensured that health professionals were prompted to consider all components  
641 of the intervention and were supported throughout delivery. The importance of a ‘champion’ has  
642 been previously emphasised for the successful implementation of integrated end of life pathways  
643 within organisations (10, 47). For the AMBER care bundle, the ‘champion’ promoted active  
644 engagement, trained new staff members and provided emotional support to health professionals  
645 delivering the intervention.

646

## 647 **Aspects that were disadvantageous to the normalisation of the** 648 **AMBER care bundle**

649 Staff shared views on their concerns associated with identifying patients suitable for the AMBER care  
650 bundle which currently require staff to judge a patient’s ‘risk of dying during their episode of care’  
651 alongside their clinical uncertainty and deterioration. In practice, health professionals made decisions  
652 about who was suitable for the intervention based more broadly on their capacity to benefit from it,  
653 rather than specifically their ‘risk of dying’. This highlights health professionals unwillingness to make  
654 judgements based solely on prognostication and is in keeping with current evidence which notes the  
655 difficulty some health professionals have recognising impending death (48). Further, research  
656 suggests these judgements are highly subjective and are frequently inaccurate, which raises important  
657 issues for the operationalisation of the intervention (48). Solutions to this issue were present during

658 the development of ReSPECT (10). During the development phase of the intervention designers  
659 incorporated cognitive interviewing to understand exactly how terms were interpreted across  
660 different professional groups and levels of seniority in the field, prior to its wider-scale implementation  
661 (10). The results of this work contribute to ensuring intervention fidelity and also offer insights into  
662 where a more nuanced, flexible interpretation of the intervention eligibility criteria may be required.  
663 In its current form, we provide evidence that the eligibility criteria of the AMBER care bundle warrants  
664 serious consideration since it limits opportunities to potentially escalate care for those patients who  
665 might benefit from critical or high dependency care settings (49), as was originally intended by this  
666 intervention (3). This has potential implications for patient experience and outcomes.

667

668 Inadequate skills and confidence in communication also led to issues in the delivery of the  
669 intervention. Variation in staff skills meant that the delivery of difficult and daily follow up  
670 conversations with patients and their family were frequently allocated to specific health professionals  
671 to complete (those with greater experience and confidence in communicating), creating workload  
672 pressures and delays in delivery. Further, the emotive context surrounding difficult conversations  
673 relating to clinical uncertainty has the potential to impact on health professionals' well-being,  
674 particularly among some junior doctors (50). This is pertinent in light of the ongoing global COVID-19  
675 pandemic (51) where a growing number of relatively inexperienced junior doctors are being called  
676 upon to engage with profoundly unwell patients whose situations may be clinically uncertain, in  
677 addition to their very distressed families. Caring for patients in this situation is especially challenging,  
678 requiring additional skills, excellent communication, and importantly, systems of support for those  
679 delivering care (16, 52). The absence of such systems may contribute to health professionals  
680 experiencing what has been referred to as 'moral injury' (53), representing deviations or  
681 transgressions from health professionals' moral beliefs and expectations that are witnessed,  
682 perpetrated, or allowed by that individual. When not acknowledged and supported, this can lead to  
683 stress, depression, anxiety and post-traumatic distress.

684

685 Contextual issues, particularly workload pressures and time constraints were also cited as a significant  
686 barrier to the delivery of intervention components. Similar to previous studies exploring the  
687 implementation of complex interventions into clinical practice (47) (54) (55) frequent staff-turnover  
688 and competing priorities led to challenges and meant that health professionals felt unable to  
689 'champion' the intervention themselves, raising concerns about the sustainability of the intervention.

690

691 Notably, many of the patients who the health professionals believed suitable to be supported by the  
692 AMBER care bundle often lacked mental capacity. This was associated with additional time needed to  
693 contact the family to be involved in decision-making, creating further workload pressures, and often  
694 resulting in delays in important discussions. Having a clear understanding of the population the  
695 intervention intends to serve is critical to minimise harmful outcomes and is emphasised in the  
696 Medical Research Council and MORECare guidance (15, 37, 56).

697

## 698 **Supporting normalisation of the AMBER care bundle in acute hospital** 699 **settings**

700 To support the normalisation of the AMBER care bundle in acute hospital wards, important  
701 considerations regarding the skills, knowledge and attitudes of those delivering the intervention, and  
702 an understanding of the context in which it exists, is required. First, staff need to have a coherent view  
703 of who is suitable for the AMBER care bundle. It is therefore imperative that the AMBER care bundle  
704 eligibility criteria focus solely on a patient's 'clinical uncertainty' and their clinical needs. Criteria that  
705 avoid the need for prognostication may ensure patients who would benefit from being supported by  
706 the intervention can be quickly, and more efficiently, identified by health professionals (16).

707

708 Second, staff need to be equipped with adequate communication skills to engage clearly and  
709 compassionately with patients and their family and are allocated protected time to de-brief following



710 difficult encounters. Advanced communication training and integrated opportunities for emotional  
711 support therefore need to accompany the AMBER care bundle to ensure staff are skilled to deliver the  
712 intervention effectively. This is imperative for nursing and ward staff who are often more present on  
713 wards and therefore have potentially more opportunities to communicate with patients and their  
714 families. Additionally, previous research highlights the need to ensure this training is continually re-  
715 visited to further develop and strengthen staff knowledge and skills (50, 57, 58).

716

717 Last, while patients' clinical uncertainty may not change on a day-to-day basis, and the clinical team  
718 should adapt the frequency of reviewing this to their local needs, it is imperative that brief daily  
719 updates for patients and their family are still prioritised. These brief, but frequent updates should aim  
720 to provide patients and their family with an update on any medical and/or care changes and provide  
721 an opportunity for patients and family to discuss any changes in preferences.

722

## 723 **Implications for clinical practice**

724 The AMBER care bundle carries the potential to address a crucial gap in clinical practice and further  
725 refinements, as suggested above, would help ensure it is adequately normalised into practice. Patients  
726 and their families, who experience uncertainty in light of their conditions, appreciated communication  
727 from health professionals and found the opportunity to discuss issues that matter to them valuable.  
728 One advantage of the AMBER care bundle is the fact that it relies on the shared human experience of  
729 uncertainty. For health professionals, this uncertainty is about the prognosis and likelihood of  
730 imminent death or the possible outcomes of the active treatment. Clinical uncertainty can exist for  
731 many conditions and has been argued as being an inevitability (59). While emotive discussions, linked  
732 to expressing clinical uncertainty, have generally been seen as the job of designated health  
733 professionals, the recent COVID-19 global pandemic (60), has brought with it instances where more  
734 health professionals are required to do this work. Specifically, the COVID-19 pandemic has witnessed  
735 health professionals dealing with an extraordinary number of cases in acute hospital settings where

736 clinical uncertainty is omnipresent across multiple levels including within the health-system, among  
737 professionals, and the patients and their families, for which the course of disease deterioration and  
738 potential for recovery is still relatively unknown (51, 61, 62). As such, with considered modification,  
739 the AMBER care bundle has potential to offer health professionals with an approach to better serve  
740 patients affected by the COVID-19 and their families.

741

## 742 **Strengths and limitations**

743 Our approach used multiple data sources to inform our findings. This represented a practical and  
744 feasible way to explore NPT constructs associated with the implementation and operationalisation of  
745 the AMBER care bundle in acute hospital care settings, with qualitative components permitting us to  
746 explore salient contexts and mechanisms in more detail. Furthermore, the use of four data sources,  
747 and data being analysed iteratively by an inter-professional team, including input from our PPI  
748 members, should increase the dependability of the study findings and interpretations.

749

750 The use of the four NPT constructs as an analytic framework enabled us to provide an understanding  
751 of how the AMBER care bundle did, and in many instances could not become normalised within an  
752 acute hospital setting. Associated with this, we also identified barriers and facilitators to the future  
753 successful integration and implementation of the AMBER care bundle.

754

755 This study is also subject to limitations. It represents one component of a wider feasibility cRCT of the  
756 AMBER care bundle and was restricted to just two study sites.

757

758 Second, we are also mindful of the absence of nursing representation in one of the focus groups, who  
759 may have provided additional insights into the use of the intervention in practice from this  
760 professional group. Although, several nurses expressed interest, and confirmed their availability  
761 beforehand, on the day of the focus group no nurses were able to attend, due to urgent clinical

762 commitments. This highlights the issues faced while researching in a ‘real-world’ context and could be  
763 overcome in future studies by considering additional flexibility and resources in the study design to  
764 accommodate the unpredictable nature of clinical work. For example, holding two smaller health  
765 professional focus groups at each site, or following up individually with health professionals who were  
766 unable to join focus groups at the allocated time.

767

768 Third, we were not able to conduct direct observations of care due to ‘real-world’ resource and  
769 logistical constraints associated with the feasibility study. Direct observations of clinical practice would  
770 be possible if research ethical approval for the study included a provision for consent at the level of  
771 the unit/cluster level (63).

772

773 Last, whilst the model has been informed by NPT constructs, developed as a result of detailed  
774 discussions within the research team, the modifications suggested as a result of this study to the  
775 AMBER care bundle have yet to be tested in the field.

776

777 Future exploration of the AMBER care bundle across other care settings and professional groups will  
778 be valuable in providing further understanding of the normalisation of this intervention in practice.

779

## 780 Conclusions

781 Our findings support growing evidence that to be successfully implemented, scalable and to be of  
782 value, new clinical practices such as the AMBER care bundle must consider the social, organisational  
783 and environmental context in which they are required to operate (45). Whilst individual health  
784 professional change is necessary, the local context in which the intervention is intended to operate  
785 must also be supportive when implementing new, often highly complex, clinical interventions.  
786 Omitting this has potentially direct implications for patient and family experience and outcomes,  
787 patient safety and staff well-being, including issues raised by the *Independent Review of the Liverpool*

788 *Care Pathway* (64) that specifically stressed the importance of understanding interventions focused  
789 on clinical uncertainty and communication when caring for the dying.

790

791 The importance of in-depth examination of implementation processes should proceed with  
792 feasibility studies of complex interventions to identify and incorporate modifications required so  
793 that the intervention operates as intended. Our findings highlight both facilitators and barriers and  
794 offer practical strategies for normalising multiple inter-related components of a complex  
795 intervention where the focus of care is on clinical uncertainty and end of life care in acute hospital  
796 settings. This has particular resonance during a time when the global COVID-19 pandemic is  
797 challenging patient care, shared decision-making and planning, and exercising health professionals in  
798 an unprecedented manner (62).

799

800 It is central for the normalisation and successful sustainability of such interventions that the health  
801 professionals who deliver the intervention feel empowered, and supported, in contributing  
802 reflexively to making recommendations about the workability of intervention. As the AMBER care  
803 bundle is already being operated in some DGHs, key stakeholders involved in implementation  
804 development must be receptive to these findings and scrutiny. The costs of not doing so are now  
805 regrettably well known in palliative and end of life care.

806

807

## 808 **Competing interests**

809 None declared.

810

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817

## 818 Authors' contributions

819 **Conceptualisation:** JK, CE, FM, DY, GW & SB

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821 **Formal analysis:** HJ, EY, JK, SB, CE

822 **Funding acquisition:** JK, CE, FM, DY, GW & SB

823 **Investigation:** EY, JK, CE & HJ

824 **Methodology:** JK, CE, FM, DY, GW & SB

825 **Project administration:** JK, EY, CE, ES, JD, MF

826 **Validation:** HJ, JK, CE, EY

827 **Writing - original draft:** HJ & JK

828 **Writing– review & editing:** JK, HJ, CE, EY, FM, DY, GW, SB, ES, JD, MF

829

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## **Supporting Information**

S1 Appendix – The AMBER Care Bundle Tool

S2 Appendix – Topic guide for semi-structured interviews with patient and carers

S3 Appendix – Topic guide for focus groups with health professionals

S1 Table – Demographics of health professionals involved in focus groups at each site

S2 Table – Demographics of patients and carers involved in qualitative interviews at each site

S3 Table – Demographics of health professionals involved in non-participant observations at each site

S4 Table – Demographics of patient participants involved in clinical case note review

# S1 Appendix – The AMBER Care Bundle Tool



Date:

Time:

Patient Label

---

Consultant:

## Stage 1: Identification

**Is there clinical uncertainty of recovery?**

1. Is the patient deteriorating, clinically unstable with limited reversibility; and
2. Is the patient at risk of dying during this episode of care despite treatment?

**Stage 2: Day one interventions** Remember to apply the principles of the Mental Capacity Act 2005

Intervention Assess patient capacity for each decision and involve in line with the Mental Capacity Act 2005		Action / comments	Name Date Time
Complete within 12 hours at patient's pace.	Nursing responsibility to ensure intervention takes place	<b>Discussion with patient ± carer held and documented</b> May include: <ul style="list-style-type: none"> <li>• uncertain recovery &amp; treatment options</li> <li>• concerns, wishes &amp; preferences</li> <li>• preferred place of care</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Medical responsibility to ensure intervention takes place	<b>Medical plan documented in patient record</b> including: <ul style="list-style-type: none"> <li>• current key issues</li> <li>• anticipated outcomes</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Medical responsibility to ensure intervention takes place	<b>Escalation decision documented</b> <ul style="list-style-type: none"> <li>• <b>treatment plans</b></li> <li>• <b>resuscitation status</b></li> <li>• <b>level of intervention:</b>  <input type="checkbox"/> ward only <input type="checkbox"/> HDU only <input type="checkbox"/> ITU                             </li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Medical responsibility to ensure intervention takes place	<b>Medical plan discussed and agreed with nursing staff</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Record detail in the patient's record			

## Stage 3: ACT – Daily monitoring and review

**Review the patient daily using the principles of 'ACT'**

Assess patient capacity for each decision and involve in line with the Mental Capacity Act 2005

**A** Is the patient's care still suitable for support with the **AMBER** care bundle?

**C** Are there any medical **C**hanges?

**T** Have you **T**alked with the patient ± those important to them?  
**Have any preferences changed?**

## Stage 4: Discontinue the AMBER care bundle if

The patient's recovery is no longer uncertain and /or needs a different approach to care because:

- Patient has recovered from this acute episode
- Patient is likely to be dying and **an individual plan of care for the last days of life is developed**
- **Patient is transferred to a clinical area not familiar with its use**
- Patient is discharged

**Communicate patient preference for future care and treatment escalation plans on transfer or discharge.**

## **S2 Appendix – Draft topic guides for qualitative interview with patient and relative/friend participants**

### **PATIENT PARTICIPANT**

#### **Introductory questions**

I'd like to start this interview by asking if you would tell me the story, in any way you choose, about what happened to bring you to hospital.

#### **A - ILLNESS RELATED QUESTIONS**

I'd like you to tell me about your illness and how it has been bothering or troubling you whilst you have been in hospital. Probe by asking participant about symptoms and associated distress he or she has been experiencing

Tell me in your own words how you have been feeling in yourself

Tell me how the doctors and nurses caring for you have helped manage all these issues.

#### **B - INFORMATION AND COMMUNICATION ISSUES**

I'd like to ask you about other important aspects of care while you have been in hospital, for example what you have been told about your illness and treatment?

Did you completely understand what the doctors and nurses told you? What wasn't clear to you?

Did you feel that you were getting clear and consistent information from the nurses and doctors?

Were you encouraged by the doctors and nurses to ask questions about your situation? Ask for examples.

In your opinion to what extent do you feel the doctors and nurses have listened to your concerns? What more could they have done, and why?

#### **C - INVOLVEMENT IN DECISION MAKING**

I'd like to explore with you to what extent you and your family has felt involved in making important decisions about your care and treatment.

Can you give me example about issues where this has taken place?

How did you and your family feel about this? What more, if anything, would you have liked to talk about, and why?

Have the doctors and nurses caring for you talked about the future? What did they discuss? How did you and your family feel about this?

What more, if anything, would you have liked to talk about, and why?

#### D - CONFIDENCE IN CARE PROVIDED

In what ways do you feel confident about the care and treatment the doctors and nurse have given you? Probe for examples and areas where participant does not feel confident, and why.

Do you feel that the doctors, nurses and other health professionals (e.g. Physio, OT) worked well together? Give examples if possible.

#### E - CONCLUSION OF INTERVIEW

Is there anything else you would like to tell me about your illness or your time in hospital?

#### RELATIVE/FRIEND PARTICIPANT

##### INTRODUCTORY QUESTIONS

I'd like to start this interview by asking if you would tell me the story, in any way you choose, of what happened leading to your relative/friend's admission to hospital.

##### A- ILLNESS RELATED QUESTIONS

I'd like you to tell me what you understand about your relative/friend's illness and how it has been bothering or troubling them while he/she has been in hospital. *Probe by asking participant about symptoms and associated distress their relative/friend has been experiencing*

Tell me the main problem/s your relative/friend has been experiencing.

Tell me if you can how the doctors and nurses caring for your relative/friend have helped manage these problem/s.

##### B- INFORMATION AND COMMUNICATION ISSUES

I'd like to ask you about other important aspects of care while your relative/friend has been in hospital, for example what you have been told about your relative/friend's illness and treatment?

Did you completely understand what the doctors and nurses told you? If you did not tell me what was unclear?

Did you feel that you were getting consistent information from the nurses and doctors? Give examples. If not, in what ways was information different or unclear from one health care profession to the next, or at different times?

Were you encouraged by the doctors and nurses to ask questions about your relative/friend's situation? Ask for examples. If you were not would you have liked to? Why?

In your opinion to what extent do you feel they have listened to your concerns? Do you think they were taken seriously and then followed up? Give examples.

#### C- INVOLVEMENT IN DECISION MAKING

I'd like to explore with you to what extent you have felt involved in making important decisions together with your relative/friend's relating to care and treatment?

Can you give me example/s about issues where this took place?

How did you and your relative/friend feel about this? What more, if anything, would you have liked to talk about, and why?

Did the doctors and nurses caring for your relative/friend talk about the future? What did they discuss? How did you respond to this?

What more, if anything, would you have liked to talk about, and why?

#### D- CONFIDENCE IN CARE PROVIDED

In what ways do you feel confident about the care and treatment the doctors and nurse have given your relative/friend? *Probe for examples and areas where participant did not feel confident, and why*

Do you feel that the doctors, nurses and other health professionals (e.g. Physio, OT) worked well together? Give example/s if possible.

#### E- CONCLUSION OF INTERVIEW

Is there anything else you would like to tell me about your relative/friend's illness or their time in hospital?



## **S3 Appendix - Draft topic guide for focus groups with healthcare professional participants**

### **A. UNDERSTANDING AND VALUE OF THE INTERVENTION**

- **I would be grateful if you would tell me what you feel you and your colleagues feel about the AMBER care bundle.**
- **What do you consider to be the benefits from the AMBER care bundle?**
- **What do you consider to be the harms from the AMBER care bundle?**
- **In what ways do you think these conversations and plans that are then made produce the outcomes that are important to patient and their families?**
- **What aspects do you find difficult about caring for these patients? Can you give examples?**
  - **Probe: How do you recognize patients who are deteriorating and there is uncertainty as to their recovery or continued decline leading eventually to end of life.**
  - **Probe: How do you differentiate between this group and people who you consider are actively dying?**

### **B. ENGAGEMENT WITH THE INTERVENTION**

- **How well do you feel health care professionals work together in this sort of situation?**
  - **What is done well? What could be done better? Give examples where possible.**
- **Can you tell about what leadership there is or champions who can support you when you are managing the care of a patient whose clinical situation is uncertain?**
- **How does staff turnover on the ward influence how the team works together?**

### **C. DELIVERY OF THE INTERVENTION**

- **Can you explain to me how you and your colleagues talk to patients and their families about their situation? – What does this lead to?**
  - **Probe: How do you find this?**
  - **Probe: How are you supported with this? Prompt: Is there a system in place on the ward for providing emotional support to members of the healthcare team?**
- **How frequently and how long are conversations that take place with patients and their families?**

### **D. ACCEPTABILITY, AND POTENTIAL MODIFICATIONS**

- **To what extent do you think the AMBER care bundle needs to be refined or adapted to make it more acceptable/more relevant to the patients you are caring for and their families?**
- **I would like you to consider the different aspects of the AMBER care bundle - which bits do you think can remain the same and which need to change for the ward you are working on and why?**
- **Are you in any way unhappy with any aspect of the content or delivery of the AMBER care bundle? What specifically, and why?**
- **What are your views on the way in which the AMBER care bundle was implemented on this ward? What worked and why and what could have been done differently, and why?**
- **I would like you to consider to what extent is the right amount of the AMBER care bundle getting to the right recipients in the right way?**
- **Do you think those who are delivering/supporting patient with the AMBER care bundle on this ward adhere to how it was explained and according to the manual? If not, in what ways?**

**S1 Table. Demographics of health professionals involved in focus groups at each site**

<b>Site</b>	<b>Site 1 (N=11)</b>	<b>Site 2 (N=15)</b>
<b>Specialties in involved</b>	Geriatrics	Respiratory
<b>Professionals involved (Gender)</b>	Consultant Geriatrician-Ward X (F) Consultant Geriatrician-Ward Y (M) Ward Clerk-Ward Y (F) Ward sister-Ward Y (F) Ward manager (F) Ward manager assistant (F) Physician Associate-Ward X (F) Matron-Ward X (M) Nurse assistant (M) Research nurse (F) Research nurse (F)	Junior Ward Sister (F) Staff nurse (F) Registrar (F) Senior house office (F) F1 (F) Senior house office (F) Junior doctor (M) Matron (F) Palliative Care CNS (F) Research nurse (F) Ward manager (F) Junior doctor (M) Senior house office (F) Registrar (M) F1 (M)
<b>Duration</b>	50 minutes	49 minutes

**S2 Table. Demographics of patients and carers involved in qualitative interviews at each site**

	Site 1	Site 2
<b>Interviews</b>	8	4
<b>Interview participants</b>		
<b>Patient</b>	0	2
<b>Carer or relative</b>	8	2
<b>Interview participant ethnicity</b>		
<b>White British</b>	8	4
<b>Interview participant gender</b>		
<b>Female</b>	1	7
<b>Male</b>	2	2
<b>Relationship with the patient</b>		
<b>Wife</b>	1	1
<b>Husband</b>	1	1
<b>Daughter</b>	7	0
<b>Son</b>	1	0
<b>Patient disease group</b>		
<b>Cancer</b>	1	0
<b>Non-cancer</b>	7	4
<b>Patient age (years)</b>		
<b>50-64</b>	0	1
<b>65-79</b>	0	3
<b>80-94</b>	5	0
<b>95-109</b>	3	0
<b>Mean</b>	92	69
<b>Median</b>	92	69

<b>Range</b>	<b>85-100</b>	<b>63-74</b>
<b>Income</b>		
<b>Living comfortably with present income</b>	4	1
<b>Coping on present income</b>	1	2
<b>Difficult on present income</b>	1	1
<b>Prefer not to say</b>	2	0
<b>Pension</b>		
<b>State pension</b>	6	3
<b>Attendance allowance</b>	2	0
<b>Registered disabled</b>	0	1

**S3 Table. Demographics of health professionals involved in non-participant observations at each site**

<b>Site</b>	<b>Site 1</b>	<b>Site 2</b>
<b>Number of meetings observed</b>	6 ( <i>3 per ward</i> )	3
<b>Specialties in involved</b>	Geriatrics	Respiratory
<b>Type of meeting</b>	Morning handover	Board round/Morning handover
<b>Professionals involved</b>	Consultants Registrars SHOs F2s F1s GP trainee Ward managers Ward sisters Ward matron Occupational therapists Physiotherapists Physician associates and trainees	Consultants Registrars F1s Ward sisters Occupational therapists Physiotherapists Discharge coordinator Palliative Care CNS Research Nurse Staff nurse Respiratory nurse Nurse facilitator
<b>Number of participants per meeting (average)</b>	7	10
<b>Duration</b>	40 minutes	30-40 minutes

**S4 Table. Demographics of patient participants involved in clinical case note review n, (%)**

		<b>Site 1 (N=20)</b>	<b>Site 2 (N=9)</b>
<b>Gender</b>	Male	8 (40.0)	3 (33.3)
	Female	12 (60.0)	6 (66.7)
<b>Age</b>	50-64	0	1 (11.1)
	65-79	2 (10.0)	5 (55.6)
	80+	18 (90.0)	3 (33.3)
	Mean (SD)	89.0 (5.7)	77.1 (12.0)
<b>Education</b>	Did not go to school	0	0
	Secondary school (GCSE/O Level)	9 (45.0)	3 (33.3)
	Secondary school (A Level)	5 (25.0)	4 (44.4)
	Vocational qualification	1 (5.0)	1 (11.1)
	University	4 (20.0)	0
	Prefer not to say	0	1 (11.1)
	<i>Missing</i>	<i>1 (5.0)</i>	<i>0</i>
<b>Marital status</b>	Single	4 (20.0)	0
	Widowed	14 (70.0)	3 (33.3)
	Married/civil partnership/long-term relationship	2 (10.0)	6 (66.7)
<b>Ethnicity</b>	White British	19 (95.0)	9 (100.0)
	Other white	1 (5.0)	0
<b>Income</b>	Living comfortably at present	8 (40.0)	4 (44.4)
	Coping on present income	5 (25.0)	4 (44.4)
	Difficult on present income	4 (20.0)	1 (11.1)
	Very difficult on present income	0	0
	Prefer not to say	2 (10.0)	0
	Don't know	1 (5.0)	0