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Frailsafe: from conception to national breakthrough collaborative.

## **Introduction**

The number of people aged over 60 years worldwide is projected to rise from 605 million in 2000 to almost 2 billion by 2050, while those over 80 years will quadruple to 395 million<sup>1</sup>. Two-thirds of UK acute hospital admissions are over 65<sup>2</sup>, the highest consultation rate in general practice is in those aged 85–89<sup>3</sup> and the average age of elective surgical patients is increasing<sup>4</sup>. Adjusting medical systems to meet the demographic imperative has been recognised by the World Health Organisation to be the next global healthcare priority<sup>5</sup> and is a key feature of discussions on policy<sup>6</sup>, health services structures<sup>7</sup>, workforce reconfiguration<sup>8</sup> and frontline care delivery<sup>9</sup>.

While older people generally are more likely to access acute healthcare than a younger population, those who live with frailty are of most concern. Frailty has been defined as “a clinically recognizable state of increased vulnerability resulting from ageing associated decline in reserve and function across multiple physiologic systems such that the ability to cope with every-day or acute stressors is compromised”<sup>10</sup>. Frailty should be considered as a syndrome with multiple components<sup>11</sup>. The effects of the frailty syndrome can easily be seen in any medical admissions unit, where it often goes unrecognised thus increasing risks of iatrogenic harm to the patient<sup>12</sup>.

Faced with such a grand narrative and the expectation that ‘something must be done’, it could be easy for individual healthcare practitioners to feel impotent. National and international policy documents are, however, constructed with the ultimate ambition of changing frontline patient care and, at this level, individual teams at the coalface have the opportunity to drive service improvement.

Frailsafe presents a systematic approach to identifying a cohort of frail patients and promoting evidence-based management with the aim of reducing patient harm. We present here the rationale behind its development and the quality improvement process underpinning its evolution to date.

## **The Challenge – harm in hospitals**

Around 1.8 million patient safety incidents (PSIs) were reported in the National Health Service in England and Wales between October 2014 and September 2015; 1.2 million of these incidents were in the acute care setting of general hospitals<sup>13</sup>. In previous years it has been shown that the oldest old are disproportionately affected by PSIs involving harm. In 2011-2012, the NHS National Reporting and Learning System reported that despite accounting for approximately 8.3% of all admissions to the acute setting, patients aged over 85 were involved in 21% of PSIs involving severe harm or death. More precise data on the mechanisms of harm are hard to obtain from a single source, although some insight has been generated by recent innovations such as the National Audit of Inpatient Falls<sup>14</sup> and the NHS Safety Thermometer<sup>15</sup>.

For many of these categories of harm, there is little dispute about what represents gold standard care. The National Institute of Health and Care Excellence (NICE) has produced

specific guidelines on the primary and secondary prevention of falls<sup>16</sup>, pressure ulcers<sup>17</sup> and delirium<sup>18</sup>, and on optimisation of medication during visits to hospital<sup>19</sup>. Cannulas and catheters are invasive devices and should be removed as soon as they are no longer necessary. Yet nationally derived data where it is available, for example through the National Audit of Inpatient Falls and the NHS Safety Thermometer, has demonstrated wide-variability in current practice and examples of substantial deviation from gold-standard care as specified in national guidelines. The issue, in many of these instances, is not that we do not know what to do, the issue is that we do not do it – this has been described elsewhere as the “know-do” gap<sup>20</sup>.

### **The Challenge – dealing with complexity**

The complexity of healthcare has increased dramatically in the past forty years; the current version of ICD-10 includes codes for more than 14,000 diseases, and more than six thousand drugs and four thousand medical and surgical procedures are in existence. Medical knowledge is expanding at an ever-increasing rate. In 1950 the doubling time of medical knowledge was approximately 50 years; by 2020 it is predicted to be just 0.2 years, or 73 days<sup>21</sup>. The traditional response to the challenge of delivering increasingly complex healthcare has involved introducing greater degrees of specialisation, sub-specialisation and super-specialisation. There is an obvious rationale underpinning this direction of travel, in that mastery learning requires a manageable corpus of knowledge. However, there is an increasing recognition, through recent documents including the Francis report<sup>22</sup> and RCP Future Hospital Commission<sup>8</sup> that the increasing prevalence of multimorbidity and non-specific presentations driven by frailty demands an ability to view and co-ordinate care holistically. Thus, it has been asserted, we need an increased focus on generalism, acknowledging the importance of being able to consider the person as a whole, rather than as a collection of systems and organs. This is the best way to care for older people living with frailty, and those with complex healthcare problems<sup>23</sup>. Developing a consistent and systematic approach in the context of complexity during busy clinical practice is, however, acknowledged to be a considerable challenge.

### **Can a checklist be the solution?**

Checklists have been used successfully for many years in safety-critical industries to manage complexity and ensure reliability; they can be a tool to help close the know-do gap. In aviation, the tale of the B17 Flying Fortress, grounded after an early flight demonstration went catastrophically wrong, is often used to demonstrate the power of the ‘simple checklist’. Devised to manage the complexity of operating the aircraft, the B17 checklist is often credited with the aircraft’s exemplary safety record that followed its introduction. In other industries, use of the safety checklist is commonplace. Nuclear power and the construction industry provide examples of how checklists can deliver reliable performance when the stakes are high. The adaptation of checklists for use in healthcare has been a relatively recent development, and the how to implement checklists in this setting is not well understood. For many the notion that a checklist can be used to solve a complex patient safety problem is seen as an over-simplification of the underlying issues to be addressed<sup>24</sup>.

An example of successful implementation of a checklist in a healthcare setting comes from the work of Pronovost and colleagues. They took a five-point checklist for central line

insertion originally developed at Johns Hopkins Hospital in Baltimore and applied it in intensive care units across the state of Michigan. Median rates of catheter-related bloodstream infection dropped from 2.7 to 0 per 1000 catheter-hours within the first 0-3 months of the collaborative cohort study<sup>25</sup>. These findings were sustained during the 18-month follow-up period. Key learning from this initiative focussed attention not on the checklist itself, but on the people completing the checklist and their interaction with each other. The checklist is more than a piece of paper with boxes to tick, it prompts a 'check and challenge' process involving the person performing the procedure (operator) and an assistant. Analogous to a co-pilot and pilot completing a pre-flight checklist, the assistant works through each point on the list, raising a challenge to the operator each time to check that it has been done. This approach promotes flattening of hierarchy, brings a collective focus on safety, and over time can lead to a change in culture<sup>25,26</sup>.

Using the same check and challenge principles, Gawande and colleagues' Surgical Safety Checklist is another example of how theory can be successfully translated into healthcare practice on a global scale<sup>27</sup>. An international pilot study of 8 hospitals demonstrated significant benefit from the use of a checklist in operating theatres, including a reduction in death and complication rates of over a third. Further studies have supported the initial positive findings and reported wider benefits including cost savings, better communication and improved safety culture.

### **The development of Frailsafe**

The key question underlying Frailsafe is 'can check and challenge principles be used to minimise variability in acute medical care to patients with frailty, and thus reduce the incidence of patient harm?'

Frailsafe is a checklist designed to improve the safety and reliability of care for frail older people admitted urgently to hospital<sup>28</sup>. The idea behind the checklist is that it is used to ensure that a small set of evidence-based interventions have been completed as soon as possible after admission.

The design of Frailsafe has been iterative and collaborative. The initial phase involved a small group of geriatricians meeting to decide on the basic principles and triggers for use of the tool, and subsequently developing the first checklist. Very small scale testing within the units the group worked in was used in order to refine content, format and ways of delivering Frailsafe. Regular teleconferencing and discussion of findings from each trial allowed further versions of the checklist to be developed and tested on slightly larger numbers of patients. Three screening questions were developed to help identify hospital in-patients that may be frail and therefore benefit. A positive response to any of the screening questions prompts completion of the full checklist. This comprises seven areas where there is accepted gold-standard practice which, where adopted early, may help to reduce episodes of patient harm. The seven domains concern:

- assessment of dementia and delirium
- assessment of usual and current mobility

- risk of falls
- risk of pressure ulcers
- consideration of resuscitation status and escalation of care
- use of equipment (catheter, cannula, bed-rails)
- review of medication.

When selecting these domains, through a combination of iterative design process and advice from national and international experts in geriatric medicine, we acknowledged that other important areas where harm can occur would have to be omitted. This is not to say that issues such as continence and nutrition are not of great importance to older inpatients at risk of frailty but it was vital that the checklist remained manageable in length and usable in the acute care setting.

The award of a 'Closing the Gap in Patient Safety' grant funded a 12-month improvement collaborative with the aim of learning how to effectively implement Frailsafe across 12 acute NHS hospitals in the United Kingdom (figure I). We wanted to focus on establishing ownership of the idea within the teams using Frailsafe, and equipping those teams with improvement science skills to implement and test the checklist successfully in their local context. The secondary benefit of such a rigorous approach to implementation should be the achievement of a deeper understanding of the factors that may be important in achieving success when attempting to apply the Frailsafe checklist in any healthcare setting.

A key feature in the set-up for the collaborative was the employment of a design researcher with experience in design for healthcare. This professional input into the structure and format of the checklist transformed version 8 of Frailsafe into a user-friendly, testable tool with an active patient voice, and it was this version that was taken forward for larger scale testing by the collaborative. An evaluation team with experience in the area of healthcare checklist implementation was recruited to work alongside the project team throughout the course of the collaborative, with the task of conducting a quantitative and qualitative evaluation of Frailsafe.

### **The Collaborative**

Quality improvement collaboratives offer a structured, often multi-organisational approach to improving the quality of health services in a set topic area. The Frailsafe Collaborative has used the IHI Breakthrough Series model<sup>29</sup> (figure II); a short term learning system that brings together a number of hospital teams to seek improvement in a focussed topic area. This model uses rapid tests of change to refine ideas, and face-to-face learning sessions to facilitate collaborative learning at intervals. The process is supported and facilitated by a faculty with expertise in both improvement science and the subject under scrutiny. The Breakthrough Series model enabled a heavy focus on implementation of the Frailsafe checklist with importance placed on context throughout the collaborative. It was acknowledged from the start that there was no single defined method to implement Frailsafe, and individual teams would need to discover the optimal way to proceed within their unique clinical environment.

Using British Geriatric Society networks, expressions of interest were requested from acute NHS hospitals throughout the United Kingdom to participate in the Frailsafe Collaborative. From over seventy applicants, twelve sites were selected with the aim of being representative of hospitals in the UK. Trusts were selected according to geographical location, size, whether predominantly rural or urban and to provide a mixture of DGHs and teaching hospitals. A contract was signed by a board representative and the participating team at each of the successful sites to ensure consent to ongoing participation.

The Frailsafe Collaborative commenced in Autumn 2014, with improvement teams from the twelve sites meeting for the first time at a 3-day learning session the following month (figure III). Each site contributed four or five members of the multi-disciplinary team responsible for delivering acute care to older people within their organisation, and was asked to nominate a team leader who would take overall responsibility for the Frailsafe initiative at that location. Learning Session 1 introduced the concept of Frailsafe and challenged each group to consider the idea of using quality improvement methodology to learn how to implement Frailsafe in their local context. The Frailsafe design team, from Sheffield Hallam University, introduced the concept of user-centred healthcare design<sup>30</sup> and engaged the teams in activities to explore ways of thinking differently about the problems they needed to solve in order to improve. The learning session was delivered by a faculty that included geriatricians and those with expertise in quality improvement, collaborative methodology, and design for health. At the end of the three days, improvement teams were supported to develop their own plan for how they were going to start their improvement work locally. This plan provided them with a framework to use when they were back in the 'real world', and faced with restrictions on time and resource.

Subsequent learning sessions were structured in a similar way to the first learning session and focussed on getting teams to unpack and reflect upon the knowledge, skills and competencies that they were developing as they tested their improvement ideas. Teams from all twelve sites travelled to Sheffield for these learning sessions, which were held over two days each. Teams were encouraged to start by implementing Frailsafe in a small number of cases but, as learning increased, to think about scaling up of their successes to increase the impact of the work. The content within the sessions became more interactive as the collaborative progressed, with teams from individual hospitals playing a greater part over time as they came to meeting with learning and reflections to share. The face-to-face events helped foster this reflective process by ensuring time away from the pressures of frontline service delivery.

Monthly Action Period Calls took place throughout the collaborative, where the twelve improvement teams dialled in to a conference call to discuss progress and learn from each other. The Action Period Calls were scheduled to complement the face-to-face events, providing support and access to improvement expertise while encouraging progression of the improvement work at the required momentum and pace. Teleconferencing software with screen-sharing capability was used so that teams could deliver short presentations to one another. The calls followed a formal agenda, and over the course of the collaborative each site had at least one allocated session for them to discuss their work.

The final component in the collaborative model was access to a coaching resource. This was a relatively late addition, and came about as a response to emerging evidence in the area of

improvement collaboratives in healthcare which advocated the use of this method of support. Each team was introduced to a coach, supplied by Sheffield Teaching Hospitals NHS Foundation Trust Service Improvement Department. Teams were able to access their coach at any point during the course of the collaborative where they felt they were facing particular challenges with their work. The coaches all had quality improvement knowledge and expertise, along with first-hand experience of working with frontline teams to facilitate improvement in clinical services.

The Frailsafe Collaborative formally ended in September 2015 with a one-day celebration event. All twelve sites were represented, demonstrating the high level of engagement that was observed throughout the collaborative. Eleven of the twelve sites reported an interest in ongoing involvement with Frailsafe beyond the collaborative period.

### **The Evaluation**

The use of randomised control trial methodology in innovations in geriatric medicine can be challenging, and not give a full illustration of the effectiveness (or otherwise) of interventions. Alternative methodologies had to be sought to assess the Frailsafe checklist. This gave the possibility of answering important questions including can the use of Frailsafe change practice, and if so, how? Can a checklist such as this reduce variation in clinical practice?

Qualitative methods, including direct observation and annotated field-notes taken during collaborative meetings and site visits were used to develop thick descriptions of how teams and the organisations in which they work were structured, and the processes that they used to implement Frailsafe. As part of this case study model, quantitative evidence about completion rates of the Frailsafe tool were collected by local teams and uploaded to an online database which generated SPC charts enabling teams to monitor their own progress. The evaluation team were then able to use these to understand implementation. NHS Safety thermometer data was collected, where available, from all participating trusts to enable the impact of the tool on outcomes to be measured and presented back to the teams, again using SPC charts. These data demonstrated a much greater degree of variability between Trusts than the process data.

The evaluation team are working to compile and synthesise the qualitative and quantitative data describing structure, process and outcomes across the 12 pilot sites and these will be reported separately.

### **Summary and the future**

We have described the development of Frailsafe, a safety checklist for the care of frail older people in hospital, to ensure that issues which contribute to harm in this vulnerable patient group are properly and promptly addressed. The adaptation of checklists for the healthcare setting is an emerging area and we have used a Breakthrough Series Collaborative to learn

how to implement the checklist rather than adopting an approach that imposed the intervention on healthcare systems. The idea of Frailsafe has been tested by frontline teams from twelve different acute hospitals in the NHS to allow us to assess its effectiveness in sites ranging from small rural DGHs to large inner-city teaching hospitals. In the upcoming months we hope to be able to report outcomes from the Frailsafe Collaborative that will be relevant to people involved in the care of frail older people in hospital, and those who may be embarking on an intervention of this kind in any complex healthcare system in the future.

Development of Frailsafe will be an ongoing process, in keeping with quality improvement theories. However, in the near future the checklist will be available for people to use in their own departments and hospitals subject to participant trusts joining and sharing insights and experiences with the broader Frailsafe collaborative.

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On behalf of the Frailsafe Collaborative



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Figure I: the 12 Frailsafe sites

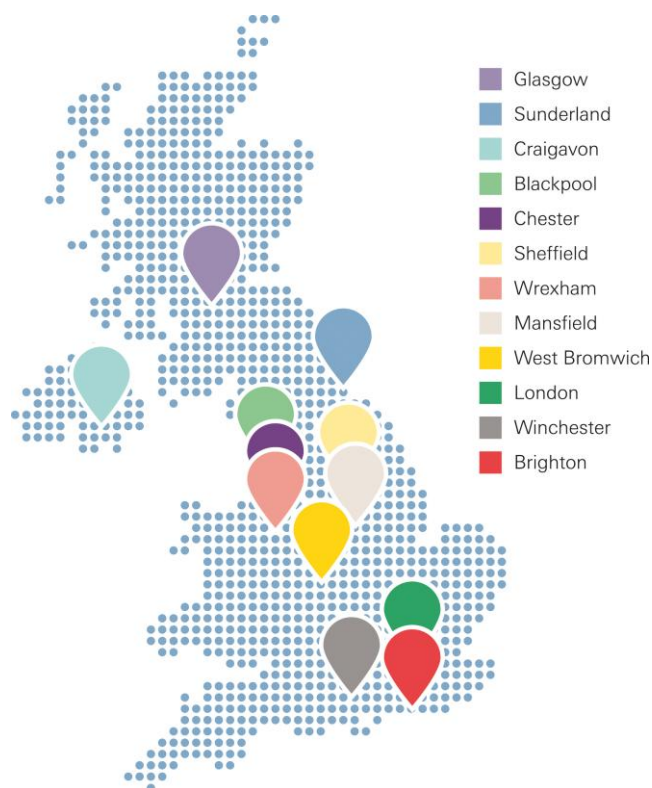


Figure II: the Frailsafe Collaborative

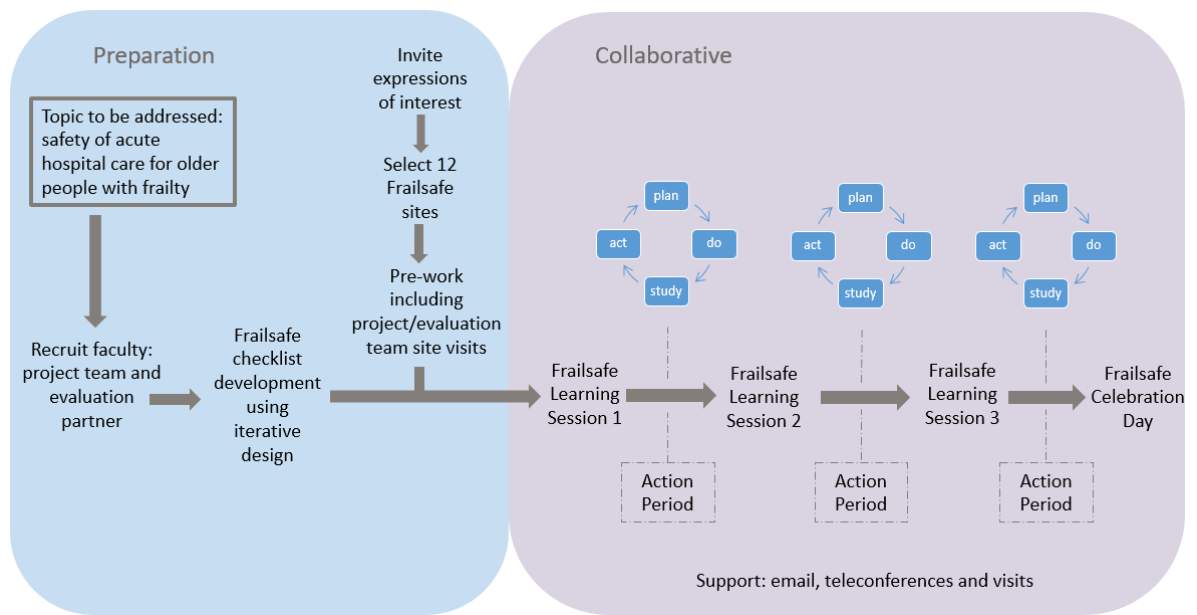


Figure III: Frailsafe timeline of events

