Studying complex interventions: Lessons from the Safer Patients Initiative

Jonathan Benn

NIHR Centre for Patient Safety and Service Quality
Imperial College London
Aim

Consider the implications of complex intervention programmes for researchers and evaluators, using the Safer Patients Initiative as an example.
The Safer Patients Initiative: a complex intervention
The Safer Patients Initiative (SPI) 2004

UK Health Foundation initiative in collaboration with US Institute for Healthcare Improvement (IHI) and 24 UK Trusts

Safer Patients Initiative trusts explain how they are making hospitals safer for patients

Now entering its second year, The Health Foundation’s £4.3 million Safer Patient Initiative (SPI) is currently running in four UK acute trusts in partnership with the Institute for Healthcare Improvement (IHI) in the US. The initiative is showing early, but significant, results in improving patient safety.

The four trusts are conducting an organisation-wide programme to radically improve patient safety within their hospitals. They aim to reduce adverse events by 50% by October 2006 and to become centres of excellence in the UK.

Chief Executives and other key participants in the Safer Patient Initiative presented two sessions at the National Patient Safety Agency’s 2006 Patient Safety Conference. They spoke about some of the challenges and some of the early
Longitudinal, phased programme structure

• SPI Phase 1:
  – 4 UK acute care organisations
  – 4 year programme 2004-2006

• SPI Phase 2:
  – 20 UK acute care organisations arranged in 10 couplets
  – 2 year programme until end of 2008

• SPI Phase 3: Safer Patients Network
  – 2009 ongoing
Multiple system level aims

- Mortality: 15% reduction
- Adverse Events: 30% reduction
- Ventilator Associated Pneumonia: 0 (or 300 days between)
- Central Line Bloodstream Infection: 0 (or 300 days between)
- Blood Sugars w/in Range (ITU/HDU): 80% or > w/in range
- MRSA Bloodstream Infection: 50% reduction
- Crash Calls: 30% reduction
- Harm from Anti-coagulation: 50% reduction in ADEs
- Surgical Site Infections: 50% reduction
IHI Breakthrough Series Collaborative model

Select Topic

Recruit Faculty

Develop Framework and Changes

Enroll Participants

Prework

LS1

AP1

LS2

AP2

LS3

AP3

Supports:

Email • Visits • Phone Conferences • Monthly Team Reports • Assessments

LS1: Learning Session
AP: Action Period
P-D-S-A: Plan-Do-Study-Act
Multiple programme elements

Programme model

Expert support

QI methodology

Change elements

Process measurement

Collaborative learning

Safer Patients Initiative
Participating hospital site

**Programme model**

- **Safer Patients Initiative**
- **Participating hospital site**

**Expert support**

- **QI methodology**

**Multiple programme elements**

- **Incremental spread**
- **Iterative development of local innovations**

**Change elements**

<table>
<thead>
<tr>
<th>Work Area</th>
<th>Change Package Element</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Care</td>
<td></td>
</tr>
<tr>
<td>General Ward</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td></td>
</tr>
<tr>
<td>Medicines</td>
<td></td>
</tr>
<tr>
<td>Perioperative</td>
<td></td>
</tr>
</tbody>
</table>

**Process measurement**

- **Annotated Run Charts**
- **Process analysis**

**Programme model**

- **Breakthrough Series Model**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**

**Multiple programme elements**

- **Breakthrough Series**
- **Model**

**Programme model**

- **Lesbian, Gay, Bisexual, Transgender (LGBT) Initiatives**
- **Patient Experience**
- **Performance Improvement**
- **Quality Improvement**

**Collaborative learning**

- **A**
- **B**

**Annotated Run Charts**

- **80 metrics**
- **(34 standard)**

**Process analysis**

- **Safer Patients Initiative**
- **Participating hospital site**

**QI methodology**

- **Iterative development of local innovations**
- **Make part of routine operations**
- **Spreading a change to other locations**
- **Testing a change**
- **Act**
- **Plan**
- **Do**
- **Incremental spread**
<table>
<thead>
<tr>
<th>Work Area</th>
<th>Change Package Element</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Care</td>
<td>Establish infrastructure&lt;br&gt;- Daily goal sheets&lt;br&gt;- Daily multi-disciplinary rounds</td>
</tr>
<tr>
<td></td>
<td><strong>Infection Prevention</strong>&lt;br&gt;- Ventilator bundle&lt;br&gt;- Central line bundle&lt;br&gt;- MRSA&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td>- Glucose control (ITU then to HDU)</td>
</tr>
<tr>
<td>General Ward</td>
<td><strong>Risk Identification and Response</strong>&lt;br&gt;- Rapid response (Outreach) teams&lt;br&gt;</td>
</tr>
<tr>
<td></td>
<td>- Early warning system</td>
</tr>
<tr>
<td></td>
<td><strong>Infection Prevention</strong>&lt;br&gt;- MRSA</td>
</tr>
<tr>
<td></td>
<td><strong>Communication and Teamwork</strong>&lt;br&gt;- Safety briefings&lt;br&gt;- Communication tools (e.g. SBAR)</td>
</tr>
<tr>
<td>Leadership</td>
<td><strong>Infrastructure to support safety</strong>&lt;br&gt;- Strategic placement&lt;br&gt;- WalkRounds</td>
</tr>
<tr>
<td>Medicines Management</td>
<td><strong>Reconciliation</strong>&lt;br&gt;- Anticoagulation&lt;br&gt;- Conduct an FMEA on a high risk medication process</td>
</tr>
<tr>
<td>Perioperative</td>
<td><strong>SSI bundle</strong>&lt;br&gt;- Culture of safety&lt;br&gt;- DVT Prophylaxis&lt;br&gt;- Beta Blocker (known BB patients first)</td>
</tr>
</tbody>
</table>
Rapid improvement cycles; iterative development and spread

- Iterative development of local innovations
- Make part of routine operations
- Spreading a change to other locations
- Implementing a change
- Testing a change
- Developing a change
- Theory and Prediction

Rapid improvement cycles
Iterative development
Sensitivity to local context
Incremental spread
### Characteristics of large-scale programmes that pose challenges for research

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Plurality in contexts</strong></td>
<td>• Interaction between local factors and programme model causes multiple local implementations</td>
</tr>
<tr>
<td><strong>2. Complex causality</strong></td>
<td>• Multiple components mean that effects are multivariate and mediated</td>
</tr>
<tr>
<td><strong>3. Socio-technical focus</strong></td>
<td>• Sociocultural, clinical, organisational, technological &amp; methodological factors implicated</td>
</tr>
<tr>
<td><strong>4. Poorly defined models</strong></td>
<td>• Under-specification of the mechanism of change leads to inability to reproduce or port the intervention (or build evidence)</td>
</tr>
<tr>
<td><strong>5. Longitudinal intervention</strong></td>
<td>• Programme evolves as a process. Intervention model isn’t stable. Serial/cumulative effects with no clear end point for evaluation</td>
</tr>
<tr>
<td><strong>6. Multilevel systems</strong></td>
<td>• Nested units &amp; hierarchical systems means that micro- and macro-level alignment is important</td>
</tr>
</tbody>
</table>
Consequences for the evidence base?

- **Evaluation of quality improvement programmes (Ovretveit & Gustafson, 2002):**
  - Little research evidence for the effectiveness or conditions for maximum effectiveness of complex interventions. Reliance upon anecdotal reports.
  - **Systematic review of evidence for the impact of quality improvement collaboratives (Schouten et al. 2008; Hulscher, 2009)**
    - Mixed/limited positive results
    - Heterogeneity of interventions at this level limits our ability to conclude they have an effect
    - Inability to separate “intervention” from continuous internal development/processes
    - Studies generally do not capture what happens in the “black box” – studies focus upon outcome rather than process data

- **Systematic reviews of the evidence for quality improvement models in health care (Boaden; Powell):**
  - Some evidence of positive effects for specific programmes but large overlap between programme models
  - The effects are context-specific (influenced by a range of implementation and contextual factors)
Discrete effect or “facilitated evolution”: Intervention as process

Safer Patients Initiative

Timeline

Organisational readiness
Pre-intervention

External interaction with SPI learning process & support

Sustainability & Spread
Post-intervention

Intervention as designed

Contextual variation between sites

Site X

Local patient safety capability

Intervention as implemented
Healthcare system: a nested, multilevel model

The effects of context
Selecting the right level of analysis

1. Programme level (Macro): Programme response across sites?

2. Organisational level: Hospital mortality/safety climate?

3. Microsystem level: HDU mortality/ICU Infection rates

4. Individual process level: Compliance with change package element
Complex causality

Interest in process & mechanism
Context-specific information
Case-based narratives
Micro-system analysis
Theory-building (inductive)
Subjective interpretation
Purpose is formative investigation
Scope potentially unbounded
Focus is sociotechnical processes

Outcome-oriented
Generalisable findings
Experimental designs
Macro level focus
Hypothesis testing (deductive)
Objective measurement
Purpose is summative evaluation
Scope bounded systematically
Focus is technical parameters

The research spectrum for evaluation of complex interventions

‘Soft’ unstructured enquiry
‘Hard’ structured evaluation
Research dimensions

- Outcome/Process
- Generalisability
- Sensitivity to context
- Level of analysis
- Inductive/Deductive
- Subjective/Objective
- Evaluative purpose
- Structured/open-ended
- Social/technical focus

Programme characteristics

1. Plurality in contexts
2. Complex causality
3. Socio-technical focus
4. Poorly defined models
5. Longitudinal interventions
6. Multilevel systems
‘Soft’ unstructured enquiry

Open ethnographic enquiry & action research
Inductive/grounded theory

Semi-structured qualitative designs
Interview studies & content analysis

Social sciences surveys

Quantitative exploratory designs

‘Hard’ structured evaluation

Single group time-series
Uncontrolled pre-post studies
Quasi-experimental designs

Controlled trials

Mixed methods evaluations; mixed methods case studies
Examples of research into “impact”
## Qualitative perspectives on the impact of SPI

| Cultural change | “But I think the cultural changes in the long run are probably more important than system changes...because I think that if you don’t change the culture, then the other things won’t be sustainable.” (Senior clinical manager) |
| Organisational strategy/leadership | “There is a perception, in this organisation, as in any other organisation, that the focus of the executives and the board is on finance and performance. This was different. This was coming along and saying, “we are interested in quality...” (Senior manager) |
| Multidisciplinary working | “...there’s also a lot of bridging between clinical groups, teams now... and I don’t think that kind of thing was happening before...” (Senior clinician) |
| Capability for QI | “...it’s not just about the patient safety programme, it’s about redesign, it’s about other quality improvement...and applying the same methodology...we learned this from SPI, we’re going to use it for a lot of other things...” (Patient safety coordinator) |
## SPI Impact Upon Human, Organisational & Clinical Care System Dimensions

### 1. Organisational Culture
- **1.1 Cultural change**
- **1.2 Awareness of care quality & safety issues**
- **1.3 Attitude to risk, harm & reliability**
- **1.4 Empowerment & involvement for quality improvement**

**Examples of programme impact:**
- Changes attitudes and values towards improvement work to ensure sustainability
- Raises personal awareness of quality and safety in care professionals’ routine practice
- Generates realisation that risk is present but harm is preventable by taking action
- Creates a sense of ownership for the improvement work amongst care professionals

### 2. Multi-professional Engagement in Improvement
- **2.1 Clinical engagement**
- **2.2 Multidisciplinary working**

**Examples of programme impact:**
- Provides a focus upon quality of care that engages clinical interest and support
- Increases multi-professional collaboration to resolve quality and safety-related issues

### 3. Organisational Capability for Continuous Improvement
- **3.1 Permanently embedding changes in org. systems**
- **3.2 Generalised use of improvement methods**
- **3.3 Learning from examples of best practice**
- **3.4 Capacity for measurement & reporting on reliability**
- **3.5 Integration with staff training & development**

**Examples of programme impact:**
- Transfers improvement capacity from motivated individuals to repeatable org. processes
- Provides a generic methodology for improving clinical work & organisational systems
- Promotes collaborative learning through sharing local innovations between organisations
- Makes cause and effect concerning intervention efforts visible to support improvement
- Promotes and supports quality and safety focus in staff induction and education

### 4. Strategic Priority for Safe & Reliable Care
- **4.1 High level quality & safety agenda**
- **4.2 Senior leadership for quality improvement**

**Examples of programme impact:**
- Raises the profile of quality and safety alongside other external and financial targets
- Provides processes and impetus for organisational leadership to support improvement work

### 5. Clinical Care Delivery
- **5.1 Standardisation of routine care provision**
- **5.2 Changes in clinical practice**
- **5.3 Impact upon quality & safety of care**
- **5.4 Impact upon costs & productivity**

**Examples of programme impact:**
- Shifts emphasis to reducing potentially harmful process variations and improved reliability
- Focuses attention upon implementing specific evidence-based best practices in care
- Improves measured parameters relating to care quality and safety within targeted areas
- Focus upon reliability reduces waste and improves efficiency
Principal components of “Impact”

1. Staff safety awareness and practice
   Staff awareness of quality and safety issues, compliance with safe practice, monitoring quality of care and communication on safety issues ($\alpha = .87$)

2. Care cost efficiency
   Timeliness of care delivery and financial performance ($\alpha = .66$)

3. Organisational context for safety
   Senior level support for improving care, organisational culture for safety and adequacy of systems and processes for improvement ($\alpha = .78$)

4. Safety and quality of delivered care
   Care safety, reliability, effectiveness and patient-focus ($\alpha = .83$)
A multi-dimensional approach to measuring impact

Time-point 2

Time-point 1

- Awareness and commitment to safe practices
- Senior management support and leadership
- Learning from failure and improving patient safety
- Monitoring, measurement and feedback
- Communication and teamwork for safety
Mean All Orgs (n=284)

-2.00  2.00
-1.50  1.50
-1.00  1.00
-0.50  0.50
  0.00
  1.00
  1.50
  2.00
2a.Staff_awareness
2b.Safety_training
2c.Taking_responsibility
2d.Openness_to_change
2e.Compliance_safe_prac
3a.S_Mgt_engagement
3b.S_Mgt_Availability
3c.Frontline_authority
3d.Execs_Support
3e.Leader_Commitment
3f.Mgt_safety_priority
4a.Multiprof_teamwork
4b.Multiprof_commitment
4c.Prof_groups_heard
4d.Effective_communication
4e.Freq_team_briefings
4f.Open_communication
5a.Routine_measurement
5b.Safety_reporting
5c.Data_used_evaluatively
5d.Staff_QS_feedback
5e.Risk_info_available
5f.Dissem_PS_activities
6a.Staff_engagement
6b.Resource_availability
6c.Org_learning
6d.No_blame_culture
6e.Incident_investigation
6f.Action_taken
Org 13 (n=22)

-2.00
-1.50
-1.00
-0.50
0.00
0.50
1.00
1.50
2.00

2a. Staff awareness
2b. Safety training
2c. Taking responsibility
2d. Openness to change
2e. Compliance safe prac
3a. S Mgt engagement
3b. S Mgt Availability
3c. Frontline authority
3d. Execs Support
3e. Leader Commitment
3f. Mgt safety priority
4a. Multiprof teamwork
4b. Multiprof commitment
4c. Prof groups heard
4d. Effective communication
4e. Freq team briefings
5a. Routine measurement
5b. Safety reporting
5c. Data used evaluatively
5d. Staff QS feedback
5e. Risk info available
5f. Dissem PS activities
6a. Staff engagement
6b. Resource availability
6c. Org learning
6d. No blame culture
6e. Incident investigation
6f. Action taken
6g. Changes effective

Mean t2
Mean t1
Org 12 (n=20)

- Staff awareness
- Safety training
- Taking responsibility
- Openness to change
- Compliance safe prac
- S_Mgt_engagement
- S_Mgt_Availability
- Frontline authority
- Execs Support
- Leader Commitment
- Mgt safety priority
- Multiprof teamwork
- Multiprof commitment
- Prof groups heard
- Effective communication
- Freq team briefings
- Open communication
- Staff engagement
- Resource availability
- Org learning
- No blame culture
- Incident investigation
- Dissem PS activities
- Risk info available
- Staff QS feedback
- Data used evaluatively
- Routine measurement
- Safety reporting
Factors predicting change in hospital safety climate and capability in a multi-site patient safety collaborative: a longitudinal survey study

Jonathan Benn, Susan Burnett, Anam Parand, Anna Pinto, Charles Vincent

ABSTRACT

Objective: The study had two specific objectives: (1) To analyse change in a survey measure of organisational patient safety climate and capability (SCC) resulting from participation in the UK Safer Patients Initiative and (2) To investigate the role of a range of programme and contextual factors in predicting change in SCC scores.

Design: Single group longitudinal design with repeated measurement at 12-month follow-up.

Setting: Multiple service areas within NHS hospital sites across England, Wales, Scotland and Northern Ireland.

Participants: Stratified sample of 284 respondents representing programme teams at 19 hospital sites.

Intratable problems for modern health service organisations. At the service level, the last 15 years have shown increasing use of large-scale, national programmes, drawing upon the quality improvement collaborative model, as a means of driving improvement on a broad scale. In the UK in 2004, the Health Foundation launched the Safer Patients Initiative which aimed to improve the safety and reliability of care within 24 participating hospitals, across four nations. The Safer Patients Initiative was structured...
Fitting statistical models according to causal and temporal priority

Diagram showing the flow of external influences, site programme timeline, research model, and programme outcomes with various determinants and processes.
Fitting statistical models according to causal and temporal priority

Programme implementation factors experienced during the active phase:

- Frontline staff support for the SPI programme
- Availability of early adopters to lead the testing of changes
- Staff understanding of SPI aims & methods
- Adequacy of clinical administrative systems to support data collection
- The compatibility of SPI objectives with other targets
- Senior management/executive support
- Support from consultants for the SPI programme
- Collaboration between different professional groups
- The time period over which process data was collected
Findings

• Modest but significant positive movement in safety climate and capability score was observed between the study time-points.

• Individual programme responsibility, availability of early adopters, multi-professional collaboration and extent of process measurement were significant predictors of change in safety climate and capability.

• Contextual factors: Hospital type and size, along with a range of programme preconditions, were found to be NOT significant.
Time series analysis
Key points: Studying complex interventions

• **Effects are multi-dimensional**
  – evaluative model must be correctly specified to account for observed variation

• **Focus upon process as well as end-point**
  – Describe mechanisms of effect and interactions as part of the intervention model

• **Account for variations in local context and implementation**
  – Intervention model is not singular, but specified in multiple instantiations

• **Utilise a broad spectrum of research methods:**
  – Qualitative and quantitative designs
  – Account for longitudinal trends and variation over time