



**University of Dundee**

## **Balancing measures or a balanced accounting of improvement impact**

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1 **Balancing measures or a balanced accounting of improvement impact. A qualitative**  
2 **analysis of individual and focus group interviews with improvement experts in**  
3 **Scotland**

4 **ABSTRACT**  
5

6 **Background**

7 As quality improvement (QI) programmes have become progressively larger-scale, the risks of  
8 implementation having unintended consequences is increasingly recognised. More routine use of  
9 balancing measures to monitor unintended consequences has been proposed to evaluate overall  
10 effectiveness, but in practice published improvement interventions hardly ever report identification  
11 or measurement of consequences other than intended goals of improvement.  
12

13 **Methods**

14 We conducted 15 semi-structured interviews and two focus groups with 24 improvement experts to  
15 explore the current understanding of balancing measures in QI and inform a more balanced  
16 accounting of the overall impact of improvement interventions. Data were analysed iteratively using  
17 the framework approach.  
18

19 **Results**

20 Participants described the consequences of improvement in terms of desirability/undesirability and  
21 the extent to which they were expected/unexpected when planning improvement. Four types of  
22 consequences were defined: expected desirable consequences (*goals*); expected undesirable  
23 consequences (*trade-offs*); unexpected undesirable consequences (*unpleasant surprises*) and  
24 unexpected desirable consequences (*pleasant surprises*). Unexpected consequences were  
25 considered important but rarely measured in existing programmes, and an improvement pause to  
26 take stock after implementation would allow these to be more actively identified and managed. A  
27 balanced accounting of all consequences of improvement interventions can facilitate staff  
28 engagement and reduce resistance to change, but has to be offset against the cost of additional data  
29 collection.  
30

31 **Conclusion**

32 Improvement measurement is usually focused on measuring intended *goals*, with minimal use of  
33 balancing measures which when used, typically monitor *trade-offs* expected before implementation.  
34 This paper proposes that improvers and leaders should seek a balanced accounting of all  
35 consequences of improvement across the life of an improvement programme, including deliberately  
36 pausing after implementation to identify and quantitatively or qualitatively evaluate any *pleasant* or  
37 *unpleasant surprises*.  
38

39 **Keywords**

40 Quality improvement; Measurement of quality; Balancing measures; Unintended consequences;  
41 Expected, unexpected, desirable and undesirable consequences

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## 44 BACKGROUND

45 Unintended consequences with negative or positive effects on care processes and outcomes can  
46 occur with any change in complex systems like healthcare organisations,<sup>1-3</sup> and so are an important  
47 potential problem in quality improvement (QI).<sup>4-6</sup> More routine use of balancing measures to  
48 account for and manage unintended consequences of improvement interventions is recommended  
49 by a number of organisations.<sup>7-10</sup> The Institute of Healthcare Improvement (IHI) for example  
50 describes measurement in improvement programmes in terms of process and outcome measures  
51 focused on delivering pre-defined intended benefits, and balancing measures in terms of negative  
52 unintended consequences in other parts of the healthcare system (Box 1).<sup>7,8</sup> Reflecting this  
53 perspective, hospital readmission rates are often used as a balancing measure for interventions  
54 aiming to reduce the length of hospital stay, since it is plausible that shortening length of stay could  
55 mean discharging patients who are then unable to manage at home.<sup>11-13</sup>

56

57 Despite calls for a more systematic accounting of all side effects of improvement interventions,<sup>14,15</sup> a  
58 number of systematic reviews have shown that balancing measures appear rarely used or reported  
59 in practice. A review of the application of Plan Do Study Act (PDSA) methods found that only six  
60 (6.4%) of 94 included studies reported any “*disconfirming observations*” about the intervention,<sup>16</sup>  
61 and only one of 100 included studies in a systematic review of perioperative care improvement  
62 interventions reported an “*unfavourable or unintended sign, symptom or event*”.<sup>17</sup> These findings  
63 are consistent with other reviews, including one of the application of improvement methodologies in  
64 surgery which found that none of 34 included studies reported on unintended consequences,<sup>18</sup> and  
65 another where only one of 121 studies of interventions to reduce patient falls and catheter-  
66 associated infections measured any unintended consequences.<sup>19</sup> Several other studies in the latter  
67 review provided anecdotal evidence of “*unexpected occurrences*”,<sup>19</sup> but robust evaluation of such  
68 claims is rare in improvement programmes more generally.<sup>20</sup> There is additionally little evidence that  
69 improvers routinely consider the potential for unexpected consequences post-implementation,<sup>21</sup>  
70 and the amount of missing data about outcomes other than goals is often significant.<sup>22,23</sup> The aim of  
71 this paper is to explore current understanding of balancing measures in healthcare improvement,  
72 including the range of consequences that could, or should be considered to inform a more balanced  
73 accounting of the overall impact of improvement interventions.

## 74 **METHODS**

### 75 **Design and participants**

76 The research was carried out in two phases, with semi-structured interviews used in the initial phase  
77 to formulate a draft conceptual framework for considering all consequences of improvement which  
78 was then explored using focus group interviews to refine and elaborate the framework, and to  
79 consider its wider applicability.

80 We used purposive sampling to include a broad spectrum of stakeholders with expertise in metrics  
81 and measure design in healthcare QI or relevant clinical and/or academic experience in  
82 improvement implementation. Participants in both phases of the study included improvement  
83 advisors, clinical academics, providers of health and social care services, policy-makers and patient  
84 representatives identified from relevant publication records and major conferences on QI, members  
85 of QI groups, on-line searches of open-access information and research teams' networks and  
86 contacts. Participants were largely based in Scotland, where comprehensive healthcare, which is free  
87 at the point of care, is provided to all residents by the taxpayer-funded National Health Service  
88 (NHS). Digital maturity of the system varies, with all primary care practices exclusively using  
89 electronic medical records (EMR) with widespread electronic data sharing (including for example,  
90 primary care sharing of data for hospital use in an emergency care summary, electronic transmission  
91 of letters and discharge summaries, and automated laboratory results transmission), but hospitals  
92 being at various stages of EMR implementation. NHS Scotland has invested significantly in staff  
93 training in improvement and introduced a number of centrally led national safety and quality  
94 improvement programmes<sup>24</sup>, largely (but not exclusively) based on the IHI Model for Improvement.  
95 Additional participants with particular expertise or known interest in measurement were purposively  
96 recruited from England and the United States. All participants were actively involved in service  
97 improvement across various settings including social care, mental health, public health, medicine for  
98 the elderly, maternity, neonatal and paediatric care.

### 99 **Data collection and analysis**

#### 100 ***Phase 1 -Semi-structured interviews to formulate the framework***

101 Twelve face to face semi-structured interviews and three telephone interviews each lasting for  
102 approximately one hour explored participants' understanding of balancing measures as part of a  
103 broader discussion about QI methods in health and social care. Individual interviews followed a topic  
104 guide based on the published literature and two pilot interviews. Data were analysed according to  
105 the principles of the Framework approach<sup>25</sup> by developing codes and categories from the transcripts

106 and grouping them into a preliminary coding matrix. The Diffusion of Innovation literature<sup>26-30</sup> was  
107 used to reinterpret the initial matrix and generate a more structured framework reflecting  
108 participants' conceptualisation of balancing measures. The researcher who conducted the interviews  
109 (MT) coded all transcripts with a selection of transcripts and the emerging framework reviewed by a  
110 second experienced researcher (BG) to refine the coding.

### 111 ***Phase 2 – Focus groups interviews to refine the framework***

112 Two focus groups were conducted to explore the current understanding of balancing measures in QI  
113 and to elaborate the framework generated in Phase 1. The draft framework was shared in a briefing  
114 paper prior to the focus group meeting and was used to inform initial discussions within the groups.  
115 Focus groups were facilitated by two experienced moderators (MT and BG), lasted about 75 minutes  
116 each, and took place on a single day. Interviews and focus groups were conducted in a non-directive  
117 manner, with participants encouraged to talk openly and with relative freedom to steer the  
118 discussion. The main researcher kept a journal with field notes reflecting on the research process,  
119 including prior assumptions that might have influenced the findings. Data were analysed using an  
120 iterative and step-wise process. The framework developed in phase one was used as a coding matrix  
121 in the analysis. Codes from focus groups transcripts were grouped into sub-themes, which were then  
122 allocated to one of the domains of the initial framework. One researcher (MT) coded all data and the  
123 wider team met regularly to reach consensus on the final framework structure, discuss additional  
124 categories, and resolve any disagreement.

125 All interviews and focus group data were audio-recorded, transcribed verbatim and analysed using  
126 NVivo11.

## 127 **FINDINGS**

### 128 **Participants' characteristics**

129 Semi-structured interviews with 15 participants and two focus groups with 24 participants (two of  
130 whom were also interviewed in phase 1) were completed. Participants had a wide range of roles in  
131 improvement and implementation science. 32 participants came from Scotland, four from England  
132 and one from the United States. (Table 1).

133 **Phase 1-Semi-structured interviews**

134 ***Identifying key themes and concepts***

135 When asked about their overall understanding of balancing measures, participants initially  
136 emphasised negative consequences of improvement in other parts of the healthcare system,  
137 paralleling the IHI definition.

138 *“My understanding is that a balancing measure is essentially something that you put in place*  
139 *because you recognise that often you can go in with the best of intent to improve an issue,*  
140 *you can deliver the improvement but you just end up creating more problems somewhere*  
141 *else” (Improvement advisor)*

142 Specific examples were again typically framed negatively, often as *“adverse”* or *“knock-on”* effects.  
143 Some of these were described as predictable from the outset, and measured routinely in the local  
144 improvement context.

145 *“The mental health safety programme has balancing measures around recovery, about being*  
146 *very clear that one way of improving safety could lead to less positive risk-taking, which*  
147 *would be a very negative unintended consequence. We always use the Scottish recovery*  
148 *indicator, making sure that we promote recovery-oriented practices and we're not clamping*  
149 *down on folk.” (Mental health care provider)*

150 Other negative consequences were described as only emerging as a potential problem after initial  
151 implementation, requiring improvers to be sensitive to the possibility of harm, and to be ready to  
152 ask themselves *“right, what are we going to put in place to measure these adverse effects and see*  
153 *whether the improvement is actually causing any harm?”* (Academic and public health specialist), in  
154 order to inform further investigation or action.

155 *“Work to increase rates of early discharge and reduce length of stay led to patients being*  
156 *discharged into inappropriate conditions which in turn caused an increase in costs and*  
157 *readmission rates (...) That should be a wee bit of a red flag for you to think ‘why is*  
158 *everybody coming back? Are they coming back in because of surgical site infections or*  
159 *because you didn’t get their medicines reconciliation right on discharge?’ (...)” (Improvement*  
160 *advisor)*

161 Less commonly, participants described unanticipated positive or beneficial consequences. Although  
162 they were often uncertain whether these could be considered ‘balancing measures’ since they did  
163 not balance the benefits of improvement, they were highly valued by those who had experience of  
164 them.

165           *“A QI initiative aimed at improving writing and reading skills in secondary schools led to a*  
166           *reduction in absence rates as a result of better students’ engagement with different activities*  
167           *across the school (...) It was actually quite surprising and certainly a delightful outcome that*  
168           *we can now flip into a new piece of work to support children to become more engaged across*  
169           *their whole learning journey.”* (Provider of social care services)

170       However, in practice, the use of balancing measures was perceived to be rare in large-scale  
171       healthcare improvement programmes.

172           *“Most safety programmes haven't paid much attention to balancing measures. From forty-*  
173           *nine pages of measures [in a safety improvement programme], there's probably only two or*  
174           *three balancing measures like readmission rates, average length of stay or reintubation rates*  
175           *when reducing the time patients spend on a ventilator after surgery (...)”* (Policy maker  
176           health and social care)

## 177       **Formulating the framework**

178       In summary, when first asked about balancing measures, participants typically started from the  
179       position that measures should be implemented to assess undesirable unintended consequences of  
180       improvement work. However, their subsequent description of balancing measures also included  
181       unanticipated desirable consequences, and considerable discussion of the extent to which all  
182       consequences were predictable from the outset. Drawing on the Diffusion of Innovation literature,<sup>26-</sup>  
183       <sup>30</sup> we developed an initial framework that describes the range of consequences that improvement  
184       could have, in terms of their desirability and the extent to which they were anticipated when  
185       planning improvement.

186       Four types of consequence were defined at this stage and described as *goals, trade-offs, classic*  
187       *negative unintended consequences and serendipities*. (Figure 1, sent to phase 2 participants before  
188       the focus groups)

## 189       **Phase 2-Focus group interviews**

### 190       **Mapping key themes and concepts**

191       Similar to the individual interviews, focus group participants initially described balancing measures in  
192       terms of trade-offs, i.e. negative unintended consequences of QI that were expected from the  
193       outset.

194           *“A lot of potential consequences are known at the start. ‘Oh, we need to actually count that,*  
195           *it will be an interesting balancing measure’. In a recent project focused on improving growth*  
196           *by early enteral feeding and maximise use of parenteral nutrition, the rates of necrotising*

197 *enterocolitis and community-acquired bloodstream infections had reasonable potential for a*  
198 *balancing measure.” (Provider of neonatology services)*

199 However, as in the individual interviews, participants discussed several examples when undesirable  
200 consequences only became apparent after implementation, with examples from the same area of  
201 care targeted by improvement, as well as other parts of the wider system.

202 *“Inducing pregnant women at 40 weeks aimed to decrease the risk of stillbirth and newborn*  
203 *death but led to the use of extra interventions such as continuous fetal monitoring (...) which*  
204 *in turn increased costs and decreased overall patient satisfaction. Also woman who had a*  
205 *serious medical need for an induction could not get on the schedule because all of the*  
206 *hospital beds were occupied by women being electively induced.” (Provider of maternal and*  
207 *infant healthcare)*

208 Participants also mentioned desirable unintended consequences referring to *“serendipitous side*  
209 *effects or bonuses which are not planned as original programme outcomes”* (academic and primary  
210 care provider), which they said were important to consider in order to obtain a balanced view of the  
211 overall impact of improvement interventions.

212 *“The Book Bug sessions were established to strengthen attachment between parents and*  
213 *children by encouraging them to share and enjoy books together. One of the measures,*  
214 *which wasn't a balancing measure in the first instance but turned into one, was an increased*  
215 *interest from parents to improve their own literacy, bearing in mind that they had a young*  
216 *child that would need supported through school.” (Public health specialist)*

217 However, even when unintended consequences were clearly identified, concerns were raised about  
218 the difficulty of creating or implementing a fully balanced set of measures, since data was not  
219 usually available from the outset unless routinely accessible from an existing source.

220 *“I think we struggle with balancing measures. We always know we should think about them*  
221 *beforehand, but don't know how to deal with what comes up during the project (...) I think in*  
222 *safety we probably talk more about negative expected consequences, and the unexpected*  
223 *ones are the tip of the iceberg stuff (...) I don't think we become aware of them very often*  
224 *and we tend to then think ‘oh it would have been nice to have data on that at the beginning’.*  
225 *(...) they almost feel like a missed opportunity.” (Academic capacity building)*

226 **Barriers and facilitators to using balancing measures**

227 In terms of measure design, the majority of interviewees found the distinction between ‘process’,  
228 ‘outcome’ and ‘balancing’ measures in some of the improvement literature confusing, since  
229 balancing measures could relate to processes and outcomes depending on the context.

230 *“We tend to be quite prescriptive about the family of measures and putting things into*  
231 *baskets of process and outcome and balancing measures is not always helpful. I don’t think*  
232 *we pay enough attention to balancing measures and I’m not sure whether they’re the right*  
233 *ones either (...) Readmission rates and average length of stay are balancing measures, but*  
234 *they could also be outcomes or processes that we might measure.” (Academic and palliative*  
235 *care provider)*

236 Participants broadly perceived balancing measures to be important and relatively underused but  
237 reflected on the increasing burden of data collection in already resource-constrained systems.

238 *“The time that we spend collecting or looking for data is time we don’t spend delivering*  
239 *patient care, so there’s a cost to this. Having balancing measures could be disproportionately*  
240 *expensive (...) just one of those things when measures are added on and on and nothing’s*  
241 *changing. You’re just collecting for the sake of collecting. You need to consider these*  
242 *measures very carefully or it’s a waste of peoples’ time.” (Provider of geriatric healthcare)*

243 However, there was a general agreement that engaging those involved in delivering care in the  
244 choice and design of measures from the outset would likely lead to better understanding of the  
245 rationale for measuring and could help minimise the burden of data collection.

246 *“If the work is owned by the frontline staff, if it’s their piece of improvement and if they’ve*  
247 *developed their own balancing measures then they’re not going to think that measurement*  
248 *is too onerous in the same way as other would if they don’t understand why they’re*  
249 *measuring.” (Policy maker education and early years)*

250 More importantly, the overall process of considering unintended consequences and implementing  
251 balancing measures was perceived to have value in its own right in terms of improving staff  
252 engagement with improvement and overcoming resistance to change.

253 *“You find a lot of latent resistance because people are genuinely worried about an*  
254 *unintended consequence and they don’t engage in the work. You can introduce your checklist*  
255 *and it is fantastic, but it really annoys the staff because “this is just going to take up a huge*  
256 *amount of time’ (...) Using a balancing measure can convince your communities that*

257 *improvement is needed and could be a goodwill builder if people know that you're*  
258 *monitoring and taking their concerns seriously.” (Academic community engagement)*

### 259 **Refining the framework**

260 Figure 2 shows a revised version of the framework that takes account of focus groups findings,  
261 including the language used (eg ‘expected’ rather than ‘anticipated’). Desirability was described as a  
262 clear dichotomy, but expectations were perceived as more of a spectrum. While an initial  
263 measurement plan can define consequences expected from the outset (*goals* and *trade-offs*),  
264 participants thought that improvement programmes might need to plan for a ‘pause’ after  
265 implementation to account for unexpected consequences, both desirable and undesirable. The  
266 language of ‘serendipities’ and ‘classic negative unintended consequences’ was disliked, and  
267 renamed. The four type of consequences in the revised framework (Figure 2) were therefore:

268 **Improvement goals:** the expected and desirable consequences of the improvement programme,  
269 defined by the initial measurement plan; **Improvement trade-offs:** the expected but undesirable  
270 consequences of the improvement programme, and implicitly believed to be smaller in magnitude  
271 than the goals (and so an acceptable compromise); **Pleasant surprises:** unexpected and desirable  
272 consequences emerging after implementation; **Unpleasant surprises:** unexpected and undesirable  
273 consequences emerging after implementation.

274 All four consequences can be measured using either process or outcome measures and can arise in  
275 the same area of care targeted by improvement, or elsewhere in the health and social care system.

## 276 **DISCUSSION**

### 277 **Summary of findings**

278 Participants started by discussing balancing measures in terms of undesirable consequences which  
279 were expected before or early in implementation (*trade-offs*) and which could offset some of the  
280 intended benefits of improvements (*goals*). Although a range of examples were discussed, most  
281 participants agreed that such measures were relatively rarely used. Participants additionally  
282 emphasised that many consequences only became apparent after implementation, and these  
283 unexpected consequences could be either desirable or undesirable (*pleasant* or *unpleasant*  
284 *surprises*) and could accrue in the same part of the system as the improvement work, or other parts.  
285 There was frequent confusion as to what a balancing measure should measure, since the implication  
286 of many existing framings<sup>7 8</sup> is that balancing measures are distinct in some way from process and  
287 outcome measures, rather than any type of consequence being measurable in terms of processes  
288 and outcomes. Involving front-line staff in identifying unintended consequences and balancing  
289 measure design was perceived to increase engagement with improvement and reduce resistance to

290 change. Balancing measures were seen as a necessary and integral part of evaluating the impact of  
291 an improvement programme, as well as a pragmatic way of engaging sceptics constructively by  
292 understanding their legitimate concerns around implementation. However, the value of designing  
293 and implementing balancing measures has to be offset against their cost in the context of overall  
294 measurement burden.

### 295 **Strengths and limitations of the study**

296 A strength of the study is that it drew on both empirical data from a purposively wide range of  
297 stakeholders and existing literature on unintended consequences. A limitation is that the sample  
298 was largely recruited from Scotland which may limit generalisability. However, NHS Scotland has a  
299 history of centrally led, and broadly successful efforts to introduce system-wide improvement  
300 interventions, most commonly based on the IHI Model for Improvement including training and  
301 implementation of national safety programmes in acute hospitals, mental health care and primary  
302 care.<sup>24</sup> Participants therefore had experience of a number of improvement programmes to draw on,  
303 although limited implementation of electronic medical records in hospitals means that perceptions  
304 of the burden of data collection will at least partly reflect that data used in national improvement  
305 programmes currently almost entirely consists of bespoke data collected by clinical staff. Findings  
306 were consistent across the diverse range of stakeholders (including those outside in Scotland), and  
307 we believe that the measurement issues faced by improvement programmes in Scotland are likely to  
308 be relevant in other countries and systems worldwide.

### 309 **Comparison with existing literature**

310 The existing improvement literature on measurement design emphasises the importance of  
311 developing a balanced set of measures during the planning of an improvement programme,<sup>7-10 31-33</sup>  
312 often distinguishing between process and outcome measures for goals, and balancing measures for  
313 expected undesirable consequences (*trade-offs*) which are easily predictable from the outset (Box  
314 1). However, participants in this study found this framing too narrow because they were concerned  
315 about unexpected undesirable consequences (*unpleasant surprises*) and valued unexpected  
316 desirable consequences (*pleasant surprises*), neither of which could be defined prior to intervention  
317 implementation.

318 Although there are some studies of *trade-offs*,<sup>34-36</sup> and *pleasant*<sup>37</sup> and *unpleasant*<sup>38 39</sup> *surprises* (Table  
319 2), published improvement interventions rarely report data relating to unintended consequences.<sup>15-</sup>  
320 <sup>19 40</sup> This may partly reflect publication bias, since authors are known to emphasise positive results  
321 and “*tuck away*”<sup>41</sup> negative contextual features and failures.<sup>23</sup> However, it also likely reflects more  
322 general lack of consideration or measurement of unintended consequences, consistent with an

323 observed preoccupation with measuring pre-specified local processes and outcomes (*goals*).<sup>42-44</sup> The  
324 implementation of PDSA cycles in healthcare for example has been criticised for often involving an  
325 over-simplified “*Do, Do, Do*” approach<sup>15</sup> focused on little and often measurement and delivery of  
326 *goals* at the expense of thinking ahead and looking to the future (for *trade-offs*) and reflecting on  
327 potential hazards during implementation (for *surprises*).<sup>45 46</sup>

### 328 **Implications for improvement programme design**

329 Balancing measures are an integral and core element of commonly used improvement models like  
330 the IHI Model for Improvement,<sup>7 8</sup> but they are sometimes poorly specified and do not appear to be  
331 commonly implemented in practice.<sup>15-19 40</sup> Based on the literature and the findings of this study, we  
332 believe that rather than focusing on balancing measures to implement at the start of improvement,  
333 improvers and leaders at all levels of management should consider how best to achieve a balanced  
334 accounting of the overall impact of improvement across the life of a programme. This requires  
335 consideration of all four types of consequence, any of which can be measured in terms of process  
336 and outcome. (Figure 2) Such a balanced accounting of impact can be achieved by articulating clear  
337 assumptions and formulating explicit predictions for both *goals* and *trade-offs* before  
338 implementation,<sup>14 40 47</sup> and having a planned improvement pause after implementation to  
339 deliberately step back from *goal* delivery to take stock and reflect on potential *surprises*.<sup>46 48</sup> In an  
340 ideal world, improvers would consult the available evidence base and seek external input from key  
341 stakeholders in order to identify potential *trade-offs*, speculate on and investigate potential  
342 *surprises*, and if necessary, to design relevant process and outcome measures to account for them.  
343 However, improvement takes place in resource-constrained environments, which will confine what  
344 is possible, including for example, the feasibility of measurement in other areas of a complex system.  
345 Focusing on a balanced accounting rather than balancing measures also emphasises that qualitative  
346 methods have much to offer both for the identification of *trade-offs* before implementation, and for  
347 understanding *surprises* after implementation where retrospective measurement may be difficult.<sup>49</sup>

348 <sup>50</sup>

### 349 **Implications for reporting quality improvement projects**

350 Few improvement reports mention unintended consequences, despite the Standards for Quality  
351 Improvement Reporting Excellence (SQUIRE) guidance<sup>14</sup> including a requirement that reporting  
352 should include “*unintended consequences, such as unexpected benefits, problems, failures or costs*  
353 *associated with the intervention*” (standard 13e). Of note though is that the SQUIRE explanation and  
354 elaboration for this standard<sup>51</sup> focuses more on exploring variation in implementation effectiveness  
355 and does not provide any examples of significant elaboration of unintended consequences. As the  
356 volume of publications in QI is growing, modification of SQUIRE to clarify that improvement reports

357 *should* report any measured or qualitatively assessed unintended consequences, or report that these  
358 were not assessed, would be helpful to contextualise any evidence presented about the  
359 achievement of improvement goals.

## 360 **CONCLUSION**

361 This study is largely based on analysis of data from interviews carried out in Scotland which has an  
362 integrated single-payer healthcare system and relatively well-developed quality improvement  
363 infrastructure.<sup>52</sup> However, improvement interventions in complex systems will often result in  
364 unintended consequences irrespective of context, so we believe that the conclusions apply more  
365 widely, although the ability of improvers to evaluate or measure unintended consequences will vary,  
366 being lower in more fragmented healthcare systems. Overall, the evidence is that improvement  
367 programme measurement is usually focused on evaluating intended *goals*, with minimal use of  
368 balancing measures which are typically monitoring *trade-offs* expected before implementation. We  
369 conclude that a more balanced accounting of the effects of improvement should consider *goals* and  
370 predictable *trade-offs* early in the design of an improvement programme, and also pause to take  
371 stock of *pleasant and unpleasant surprises* after a period of implementation.

372 **List of abbreviations**

373

374 **QI:** Quality improvement

375 **IHI:** Institute of Healthcare Improvement

376 **NHS:** The National Health Service

377 **EMR:** Electronic Medical Record

378 **PDSA:** Plan Do Study Act

379 **SQUIRE:** Standards for Quality Improvement Reporting Excellence

380

381 **DECLARATIONS**

382

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388 **Ethics approval and consent to participate**

389 The University of Dundee Research Ethics Committee waived ethical approval for this study (UREC  
390 15069). Informed consent to participate in the study was obtained from all participants.

391 **Consent for publication**

392 Not applicable

393 **Availability of data and material**

394 The data used and/or analysed during the current study are available from the corresponding author  
395 on reasonable request.

396 **Competing interests**

397 The authors declare that they have no competing interests.

398

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404 data and in writing the manuscript  
405

406 **Authors' contributions**

407 MT and BG were responsible for planning the study and led the data collection and analysis. TD, NG  
408 and DC contributed to data analysis. MT drafted and led the writing of the manuscript. BG, TD, NG  
409 and DC participated in critically appraising and revising the intellectual content of the manuscript. All  
410 authors read and approved the final manuscript.

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560 **Box 1: Institute of Healthcare Improvement recommended types of measures**<sup>78</sup>

“Use a balanced set of measures for all improvement efforts: outcomes measures, process measures, and balancing measures.

1. **Outcome Measures:** How does the system impact the values of patients, their health and wellbeing? What are impacts on other stakeholders such as payers, employees, or the community?
2. **Process Measures:** Are the parts/steps in the system performing as planned? Are we on track in our efforts to improve the system?
3. **Balancing Measures** (looking at a system from different directions/dimensions): Are changes designed to improve one part of the system causing new problems in other parts of the system?”

561 *\* Adapted from IHI (text is verbatim quote but examples are omitted and text is renumbered)*

562 **Table 1: Characteristics of participants in both phases of the study**

| Participants' primary roles and responsibilities   | Setting   | Phase 1:<br>Semi-structured interviews<br>N=15* | Phase 2:<br>Focus group interviews<br>N=24** |
|--|---|---|--|
| <b>Improvement advisors</b> with relevant clinical background and healthcare improvement expertise both locally and nationally, external to the local clinical and managerial teams  | Primary care, Maternity, neonatal and paediatrics, Mental health, Healthcare Associated Infections, High risk medicines   | 5   | 5  |
| People with a university or similar <b>academic base and perspective</b> , relevant clinical background and healthcare improvement expertise both locally and nationally   | Public health, Palliative care, Primary care, Community engagement, Health inequalities, Capacity and capability building | 3   | 9  |
| <b>Providers of healthcare services</b> including clinicians in leadership positions in quality and safety who retain a significant role within their routine clinical practice, being involved in delivering healthcare improvement both locally and nationally | Primary care, Mental health, Medicine for the elderly, Public health, Maternity, neonatal and paediatrics                 | 2   | 5  |
| <b>Providers of social care services</b> in leadership positions in quality and safety who are involved in facilitating improvements both locally and nationally across the integrated health and social care services   | Community health and social care partnerships   | 1   | 1  |
| <b>Policy-makers and commissioners</b> involved in monitoring performance and setting the general direction of quality improvement   | Health care, social care, Education and early years   | 3   | 2  |
| <b>Patient representatives</b> advising health boards on the most efficient ways of accounting for the views and experiences of the people who use the local services  | Cardiac care and rehabilitation, Dementia care, Maternity care  | 1   | 2  |

563 *\*All interviews were conducted face to face except two academics and one policy maker which were interviewed by telephone;*

564 *\*\*Two participants in the interviews (one improvement advisor and one academic) also attended the focus groups;*

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567 **Table 2: Published examples of trade-offs, pleasant and unpleasant surprises in the improvement literature**

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| Study                       | Improvement goals   | Other consequences  | Examples of balancing measures prior, during and post implementation   |
|-----------------------------|---|---|--|
| Kavanagh 2015 <sup>35</sup> | To improve the timeliness of management of vaso-occlusive pain events in children with sickle cell disease in paediatric emergency departments  | Expected undesirable consequences ( <b>trade-offs</b> )             | <i>Mean time from triage to the second intravenous opioid dose</i> was introduced as a balancing measure because of concern that the use of intranasal fentanyl as the first-line intervention might delay subsequent intravenous dosing. Other <i>trade-offs</i> measured included <i>readmission rates</i> within 24 hours of discharge, <i>episodes of respiratory depression</i> and <i>inpatient length of stay</i> . |
| Dewan 2017 <sup>36</sup>    | To decrease unnecessary routine complete blood count testing in a low risk cohort of postoperative patients in the paediatric intensive care units  | Expected undesirable consequences ( <b>trade-offs</b> )             | Balancing measures were implemented for <i>haemoglobin level below 8 g/dL</i> in patients for whom complete blood counts were actually sent and <i>blood transfusions up to 7 days postoperatively</i> for any patients in the cohort.   |
| Duvoisin 2014 <sup>37</sup> | To reduce the number of unnecessary diagnostic tests such as complete blood count and C-reactive protein in infants with risk factors for early-onset neonatal sepsis   | Unexpected desirable consequences ( <b>pleasant surprises</b> )     | There was pre-intervention concern that reduction in the use of diagnostic tests would <i>delay the initiation of antibiotic treatment</i> , but unexpectedly the intervention resulted in <i>earlier treatment of infection</i> on average.   |
| Bell 2014 <sup>38</sup>     | To reduce the pre-operative use of antimicrobials associated with Clostridium difficile infection   | Unexpected undesirable consequences ( <b>unpleasant surprises</b> ) | The new surgical prophylaxis regimen of four doses of flucloxacillin 1g plus single dose gentamicin 4mg/kg unexpectedly led to <i>increased rates of post-operative acute kidney injury</i> in orthopaedic patients, large enough to lead to the termination of the intervention through a change in the national antibiotic policy recommendation for orthopaedic surgical prophylaxis.                                   |
| Strom 2010 <sup>39</sup>    | To evaluate the effectiveness of a customized nearly hard stop alert in reducing concomitant orders for warfarin and trimethoprim- sulfamethoxazole compared with the standard practice of a pharmacist intervention program. | Unexpected undesirable consequences ( <b>unpleasant surprises</b> ) | Unexpected <i>delays in indicated anticoagulant and/or antimicrobial treatment initiation</i> were deemed sufficiently serious to warrant discontinuation of the improvement intervention.   |

569 **Figures/illustrations**

570 **Figure 1** – Draft framework of types of consequences of quality improvement projects (derived from  
571 phase 1 data and the literature, sent to phase 2 participants before the focus groups)

572 **Figure 2** – Refined framework of types of consequences of quality improvement projects (derived  
573 from phase 1 data and the literature, and refined after phase 2 focus groups)