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

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4 1 **Balancing measures or a balanced accounting of improvement impact. A qualitative**
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6 2 **analysis of individual and focus group interviews with improvement experts in**
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8 3 **Scotland**
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10
11 4 **ABSTRACT**
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13
14 6 **Background**

15 7 As quality improvement (QI) programmes have become progressively larger-scale, the risks of
16 8 implementation having unintended consequences is increasingly recognised. More routine use of
17 9 balancing measures to monitor unintended consequences has been proposed to evaluate overall
18 10 effectiveness, but in practice published improvement interventions hardly ever report identification
19 11 or measurement of consequences other than intended goals of improvement.
20 12

21 13 **Methods**

22 14 We conducted 15 semi-structured interviews and two focus groups with 24 improvement experts to
23 15 explore the current understanding of balancing measures in QI and inform a more balanced
24 16 accounting of the overall impact of improvement interventions. Data were analysed iteratively using
25 17 the framework approach.
26 18

27
28 19 **Results**

29 20 Participants described the consequences of improvement in terms of desirability/undesirability and
30 21 the extent to which they were expected/unexpected when planning improvement. Four types of
31 22 consequences were defined: expected desirable consequences (*goals*); expected undesirable
32 23 consequences (*trade-offs*); unexpected undesirable consequences (*unpleasant surprises*) and
33 24 unexpected desirable consequences (*pleasant surprises*). Unexpected consequences were
34 25 considered important but rarely measured in existing programmes, and an improvement pause to
35 26 take stock after implementation would allow these to be more actively identified and managed. A
36 27 balanced accounting of all consequences of improvement interventions can facilitate staff
37 28 engagement and reduce resistance to change, but has to be offset against the cost of additional data
38 29 collection.
39 30

40 31 **Conclusion**

41 32 Improvement measurement is usually focused on measuring intended *goals*, with minimal use of
42 33 balancing measures which when used, typically monitor *trade-offs* expected before implementation.
43 34 This paper proposes that improvers and leaders should seek a balanced accounting of all
44 35 consequences of improvement across the life of an improvement programme, including deliberately
45 36 pausing after implementation to identify and quantitatively or qualitatively evaluate any *pleasant* or
46 37 *unpleasant surprises*.
47 38

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50 39 **Keywords**

51
52 40 Quality improvement; Measurement of quality; Balancing measures; Unintended consequences;
53 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,¹⁻³ and so are an important
47 potential problem in quality improvement (QI).⁴⁻⁶ 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.⁷⁻¹⁰ 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).^{7,8} 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.¹¹⁻¹³

57 Despite calls for a more systematic accounting of all side effects of improvement interventions,^{14,15} 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,¹⁶
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*”.¹⁷ 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,¹⁸ and
65 another where only one of 121 studies of interventions to reduce patient falls and catheter-
66 associated infections measured any unintended consequences.¹⁹ Several other studies in the latter
67 review provided anecdotal evidence of “*unexpected occurrences*”,¹⁹ but robust evaluation of such
68 claims is rare in improvement programmes more generally.²⁰ There is additionally little evidence that
69 improvers routinely consider the potential for unexpected consequences post-implementation,²¹
70 and the amount of missing data about outcomes other than goals is often significant.^{22,23} 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 programmes²⁴, 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 approach²⁵ by developing codes and categories from the transcripts

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2
3 106 and grouping them into a preliminary coding matrix. The Diffusion of Innovation literature²⁶⁻³⁰ was
4 107 used to reinterpret the initial matrix and generate a more structured framework reflecting
5
6 108 participants' conceptualisation of balancing measures. The researcher who conducted the interviews
7
8 109 (MT) coded all transcripts with a selection of transcripts and the emerging framework reviewed by a
9
10 110 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).

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3 133 **Phase 1-Semi-structured interviews**

4
5 134 ***Identifying key themes and concepts***

6
7 135 When asked about their overall understanding of balancing measures, participants initially
8
9 136 emphasised negative consequences of improvement in other parts of the healthcare system,
10
11 137 paralleling the IHI definition.

12
13 138 *“My understanding is that a balancing measure is essentially something that you put in place*
14
15 139 *because you recognise that often you can go in with the best of intent to improve an issue,*
16
17 140 *you can deliver the improvement but you just end up creating more problems somewhere*
18
19 141 *else”* (Improvement advisor)

20
21 142 Specific examples were again typically framed negatively, often as “adverse” or “knock-on” effects.
22
23 143 Some of these were described as predictable from the outset, and measured routinely in the local
24
25 144 improvement context.

26
27 145 *“The mental health safety programme has balancing measures around recovery, about being*
28
29 146 *very clear that one way of improving safety could lead to less positive risk-taking, which*
30
31 147 *would be a very negative unintended consequence. We always use the Scottish recovery*
32
33 148 *indicator, making sure that we promote recovery-oriented practices and we're not clamping*
34
35 149 *down on folk.”* (Mental health care provider)

36
37 150 Other negative consequences were described as only emerging as a potential problem after initial
38
39 151 implementation, requiring improvers to be sensitive to the possibility of harm, and to be ready to
40
41 152 ask themselves “right, what are we going to put in place to measure these adverse effects and see
42
43 153 whether the improvement is actually causing any harm?” (Academic and public health specialist), in
44
45 154 order to inform further investigation or action.

46
47 155 *“Work to increase rates of early discharge and reduce length of stay led to patients being*
48
49 156 *discharged into inappropriate conditions which in turn caused an increase in costs and*
50
51 157 *readmission rates (...) That should be a wee bit of a red flag for you to think ‘why is*
52
53 158 *everybody coming back? Are they coming back in because of surgical site infections or*
54
55 159 *because you didn’t get their medicines reconciliation right on discharge?’ (...)”* (Improvement
56
57 160 advisor)

58
59 161 Less commonly, participants described unanticipated positive or beneficial consequences. Although
60
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.

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2
3 165 *“A QI initiative aimed at improving writing and reading skills in secondary schools led to a*
4 166 *reduction in absence rates as a result of better students’ engagement with different activities*
5
6 167 *across the school (...) It was actually quite surprising and certainly a delightful outcome that*
7
8 168 *we can now flip into a new piece of work to support children to become more engaged across*
9
10 169 *their whole learning journey.”* (Provider of social care services)

11
12 170 However, in practice, the use of balancing measures was perceived to be rare in large-scale
13
14 171 healthcare improvement programmes.

15
16 172 *“Most safety programmes haven't paid much attention to balancing measures. From forty-*
17 173 *nine pages of measures [in a safety improvement programme], there's probably only two or*
18
19 174 *three balancing measures like readmission rates, average length of stay or reintubation rates*
20
21 175 *when reducing the time patients spend on a ventilator after surgery (...)”* (Policy maker
22 176 health and social care)

23 24 177 **Formulating the framework**

25
26 178 In summary, when first asked about balancing measures, participants typically started from the
27
28 179 position that measures should be implemented to assess undesirable unintended consequences of
29
30 180 improvement work. However, their subsequent description of balancing measures also included
31
32 181 unanticipated desirable consequences, and considerable discussion of the extent to which all
33
34 182 consequences were predictable from the outset. Drawing on the Diffusion of Innovation literature,²⁶⁻
35
36 183 ³⁰ we developed an initial framework that describes the range of consequences that improvement
37
38 184 could have, in terms of their desirability and the extent to which they were anticipated when
39
40 185 planning improvement.

41
42 186 Four types of consequence were defined at this stage and described as *goals, trade-offs, classic*
43
44 187 *negative unintended consequences and serendipities.* (Figure 1, sent to phase 2 participants before
45
46 188 the focus groups)

47 189 **Phase 2-Focus group interviews**

48 190 **Mapping key themes and concepts**

49
50 191 Similar to the individual interviews, focus group participants initially described balancing measures in
51
52 192 terms of trade-offs, i.e. negative unintended consequences of QI that were expected from the
53
54 193 outset.

55
56 194 *“A lot of potential consequences are known at the start. ‘Oh, we need to actually count that,*
57
58 195 *it will be an interesting balancing measure’. In a recent project focused on improving growth*
59
60 196 *by early enteral feeding and maximise use of parenteral nutrition, the rates of necrotising*

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2
3 197 *enterocolitis and community-acquired bloodstream infections had reasonable potential for a*
4 198 *balancing measure.” (Provider of neonatology services)*

6
7 199 However, as in the individual interviews, participants discussed several examples when undesirable
8 200 consequences only became apparent after implementation, with examples from the same area of
9 201 care targeted by improvement, as well as other parts of the wider system.

12 202 *“Inducing pregnant women at 40 weeks aimed to decrease the risk of stillbirth and newborn*
13 203 *death but led to the use of extra interventions such as continuous fetal monitoring (...) which*
14 204 *in turn increased costs and decreased overall patient satisfaction. Also woman who had a*
15 205 *serious medical need for an induction could not get on the schedule because all of the*
16 206 *hospital beds were occupied by women being electively induced.” (Provider of maternal and*
17 207 *infant healthcare)*

22 208 Participants also mentioned desirable unintended consequences referring to *“serendipitous side*
23 209 *effects or bonuses which are not planned as original programme outcomes”* (academic and primary
24 210 care provider), which they said were important to consider in order to obtain a balanced view of the
25 211 overall impact of improvement interventions.

29 212 *“The Book Bug sessions were established to strengthen attachment between parents and*
30 213 *children by encouraging them to share and enjoy books together. One of the measures,*
31 214 *which wasn't a balancing measure in the first instance but turned into one, was an increased*
32 215 *interest from parents to improve their own literacy, bearing in mind that they had a young*
33 216 *child that would need supported through school.” (Public health specialist)*

38 217 However, even when unintended consequences were clearly identified, concerns were raised about
39 218 the difficulty of creating or implementing a fully balanced set of measures, since data was not
40 219 usually available from the outset unless routinely accessible from an existing source.

44 220 *“I think we struggle with balancing measures. We always know we should think about them*
45 221 *beforehand, but don't know how to deal with what comes up during the project (...) I think in*
46 222 *safety we probably talk more about negative expected consequences, and the unexpected*
47 223 *ones are the tip of the iceberg stuff (...) I don't think we become aware of them very often*
48 224 *and we tend to then think ‘oh it would have been nice to have data on that at the beginning’.*
49 225 *(...) they almost feel like a missed opportunity.” (Academic capacity building)*

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3 226 **Barriers and facilitators to using balancing measures**

4 227 In terms of measure design, the majority of interviewees found the distinction between ‘process’,
5
6 228 ‘outcome’ and ‘balancing’ measures in some of the improvement literature confusing, since
7
8 229 balancing measures could relate to processes and outcomes depending on the context.

9
10 230 *“We tend to be quite prescriptive about the family of measures and putting things into*
11
12 231 *baskets of process and outcome and balancing measures is not always helpful. I don’t think*
13
14 232 *we pay enough attention to balancing measures and I’m not sure whether they’re the right*
15
16 233 *ones either (...) Readmission rates and average length of stay are balancing measures, but*
17
18 234 *they could also be outcomes or processes that we might measure.” (Academic and palliative*
19
20 235 *care provider)*

21 236 Participants broadly perceived balancing measures to be important and relatively underused but
22
23 237 reflected on the increasing burden of data collection in already resource-constrained systems.

24 238 *“The time that we spend collecting or looking for data is time we don’t spend delivering*
25
26 239 *patient care, so there’s a cost to this. Having balancing measures could be disproportionately*
27
28 240 *expensive (...) just one of those things when measures are added on and on and nothing’s*
29
30 241 *changing. You’re just collecting for the sake of collecting. You need to consider these*
31
32 242 *measures very carefully or it’s a waste of peoples’ time.” (Provider of geriatric healthcare)*

33 243 However, there was a general agreement that engaging those involved in delivering care in the
34
35 244 choice and design of measures from the outset would likely lead to better understanding of the
36
37 245 rationale for measuring and could help minimise the burden of data collection.

38 246 *“If the work is owned by the frontline staff, if it’s their piece of improvement and if they’ve*
39
40 247 *developed their own balancing measures then they’re not going to think that measurement*
41
42 248 *is too onerous in the same way as other would if they don’t understand why they’re*
43
44 249 *measuring.” (Policy maker education and early years)*

45 250 More importantly, the overall process of considering unintended consequences and implementing
46
47 251 balancing measures was perceived to have value in its own right in terms of improving staff
48
49 252 engagement with improvement and overcoming resistance to change.

50
51 253 *“You find a lot of latent resistance because people are genuinely worried about an*
52
53 254 *unintended consequence and they don’t engage in the work. You can introduce your checklist*
54
55 255 *and it is fantastic, but it really annoys the staff because “this is just going to take up a huge*
56
57 256 *amount of time’ (...) Using a balancing measure can convince your communities that*
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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^{7 8} 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

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3 290 change. Balancing measures were seen as a necessary and integral part of evaluating the impact of
4
5 291 an improvement programme, as well as a pragmatic way of engaging sceptics constructively by
6
7 292 understanding their legitimate concerns around implementation. However, the value of designing
8
9 293 and implementing balancing measures has to be offset against their cost in the context of overall
10
11 294 measurement burden.

12 295 **Strengths and limitations of the study**

13 296 A strength of the study is that it drew on both empirical data from a purposively wide range of
14
15 297 stakeholders and existing literature on unintended consequences. A limitation is that the sample
16
17 298 was largely recruited from Scotland which may limit generalisability. However, NHS Scotland has a
18
19 299 history of centrally led, and broadly successful efforts to introduce system-wide improvement
20
21 300 interventions, most commonly based on the IHI Model for Improvement including training and
22
23 301 implementation of national safety programmes in acute hospitals, mental health care and primary
24
25 302 care.²⁴ Participants therefore had experience of a number of improvement programmes to draw on,
26
27 303 although limited implementation of electronic medical records in hospitals means that perceptions
28
29 304 of the burden of data collection will at least partly reflect that data used in national improvement
30
31 305 programmes currently almost entirely consists of bespoke data collected by clinical staff. Findings
32
33 306 were consistent across the diverse range of stakeholders (including those outside in Scotland), and
34
35 307 we believe that the measurement issues faced by improvement programmes in Scotland are likely to
36
37 308 be relevant in other countries and systems worldwide.

38 309 **Comparison with existing literature**

39 310 The existing improvement literature on measurement design emphasises the importance of
40
41 311 developing a balanced set of measures during the planning of an improvement programme,^{7-10 31-33}
42
43 312 often distinguishing between process and outcome measures for goals, and balancing measures for
44
45 313 expected undesirable consequences (*trade-offs*) which are easily predictable from the outset (Box
46
47 314 1). However, participants in this study found this framing too narrow because they were concerned
48
49 315 about unexpected undesirable consequences (*unpleasant surprises*) and valued unexpected
50
51 316 desirable consequences (*pleasant surprises*), neither of which could be defined prior to intervention
52
53 317 implementation.

54 318 Although there are some studies of *trade-offs*,³⁴⁻³⁶ and *pleasant*³⁷ and *unpleasant*^{38 39} *surprises* (Table
55
56 319 2), published improvement interventions rarely report data relating to unintended consequences.¹⁵⁻
57
58 320 ^{19 40} This may partly reflect publication bias, since authors are known to emphasise positive results
59
60 321 and “*tuck away*”⁴¹ negative contextual features and failures.²³ However, it also likely reflects more
61
62 322 general lack of consideration or measurement of unintended consequences, consistent with an

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2
3 323 observed preoccupation with measuring pre-specified local processes and outcomes (*goals*).⁴²⁻⁴⁴ The
4 324 implementation of PDSA cycles in healthcare for example has been criticised for often involving an
5 325 over-simplified “*Do, Do, Do*” approach¹⁵ focused on little and often measurement and delivery of
6 326 *goals* at the expense of thinking ahead and looking to the future (for *trade-offs*) and reflecting on
7 327 potential hazards during implementation (for *surprises*).^{45 46}

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,^{7 8} but they are sometimes poorly specified and do not appear to be
331 commonly implemented in practice.^{15-19 40} 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,^{14 40 47} and having a planned improvement pause after implementation to
339 deliberately step back from *goal* delivery to take stock and reflect on potential *surprises*.^{46 48} 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.⁴⁹

348 ⁵⁰

349 **Implications for reporting quality improvement projects**

350 Few improvement reports mention unintended consequences, despite the Standards for Quality
351 Improvement Reporting Excellence (SQUIRE) guidance¹⁴ 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 standard⁵¹ 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

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3 357 *should* report any measured or qualitatively assessed unintended consequences, or report that these
4 358 were not assessed, would be helpful to contextualise any evidence presented about the
5
6 359 achievement of improvement goals.
7

8 9 360 **CONCLUSION**

10 361 This study is largely based on analysis of data from interviews carried out in Scotland which has an
11 362 integrated single-payer healthcare system and relatively well-developed quality improvement
12 363 infrastructure.⁵² However, improvement interventions in complex systems will often result in
13 364 unintended consequences irrespective of context, so we believe that the conclusions apply more
14 365 widely, although the ability of improvers to evaluate or measure unintended consequences will vary,
15 366 being lower in more fragmented healthcare systems. Overall, the evidence is that improvement
16 367 programme measurement is usually focused on evaluating intended *goals*, with minimal use of
17 368 balancing measures which are typically monitoring *trade-offs* expected before implementation. We
18 369 conclude that a more balanced accounting of the effects of improvement should consider *goals* and
19 370 predictable *trade-offs* early in the design of an improvement programme, and also pause to take
20 371 stock of *pleasant and unpleasant surprises* after a period of implementation.
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3 372 **List of abbreviations**
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6
7 374 **QI:** Quality improvement

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9 375 **IHI:** Institute of Healthcare Improvement

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11 376 **NHS:** The National Health Service

12
13 377 **EMR:** Electronic Medical Record

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15 378 **PDSA:** Plan Do Study Act

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17 379 **SQUIRE:** Standards for Quality Improvement Reporting Excellence

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20
21 381 **DECLARATIONS**

22
23 382

24
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29 386 create the "*balanced accounting*" framework. We also acknowledge Julie Anderson and Anita Lee,
30 387 who provided invaluable feedback on the revised versions of this paper.

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33
34 388 **Ethics approval and consent to participate**

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36 389 The University of Dundee Research Ethics Committee waived ethical approval for this study (UREC
37 390 15069). Informed consent to participate in the study was obtained from all participants.

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39
40 391 **Consent for publication**

41
42 392 Not applicable

43
44 393 **Availability of data and material**

45
46 394 The data used and/or analysed during the current study are available from the corresponding author
47 395 on reasonable request.

48
49
50 396 **Competing interests**

51
52 397 The authors declare that they have no completing interests.

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1
2
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11
12 404 data and in writing the manuscript

13 405

14
15 406 **Authors' contributions**

16
17 407 MT and BG were responsible for planning the study and led the data collection and analysis. TD, NG
18
19 408 and DC contributed to data analysis. MT drafted and led the writing of the manuscript. BG, TD, NG
20
21 409 and DC participated in critically appraising and revising the intellectual content of the manuscript. All
22
23 410 authors read and approved the final manuscript.

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56 560 **Box 1: Institute of Healthcare Improvement recommended types of measures**^{7 8}
78
9 “Use a balanced set of measures for all improvement efforts: outcomes measures, process
10 measures, and balancing measures.
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- 12 1.
- Outcome Measures:**
- How does the system impact the values of patients, their health and
-
- 13 wellbeing? What are impacts on other stakeholders such as payers, employees, or the
-
- 14 community?
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- 16 2.
- Process Measures:**
- Are the parts/steps in the system performing as planned? Are we on
-
- 17 track in our efforts to improve the system?
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- 19 3.
- Balancing Measures**
- (looking at a system from different directions/dimensions): Are
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- 20 changes designed to improve one part of the system causing new problems in other parts
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- 21 of the system?”
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27 561 * Adapted from IHI (text is verbatim quote but examples are omitted and text is renumbered)
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562 **Table 1: Characteristics of participants in both phases of the study**

Participants' primary roles and responsibilities	Setting	Phase 1: Semi-structured interviews N=15*	Phase 2: Focus group interviews N=24**
Improvement advisors 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 academic base and perspective , 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
Providers of healthcare services 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
Providers of social care services 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
Policy-makers and commissioners involved in monitoring performance and setting the general direction of quality improvement	Health care, social care, Education and early years	3	2
Patient representatives 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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566

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 ³⁵	To improve the timeliness of management of vaso-occlusive pain events in children with sickle cell disease in paediatric emergency departments	Expected undesirable consequences (trade-offs)	<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, episodes of <i>respiratory depression</i> and inpatient <i>length of stay</i> .
Dewan 2017 ³⁶	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 (trade-offs)	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 ³⁷	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 (pleasant surprises)	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 ³⁸	To reduce the pre-operative use of antimicrobials associated with <i>Clostridium difficile</i> infection	Unexpected undesirable consequences (unpleasant surprises)	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 ³⁹	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 (unpleasant surprises)	Unexpected <i>delays in indicated anticoagulant and/or antimicrobial treatment initiation</i> were deemed sufficiently serious to warrant discontinuation of the improvement intervention.

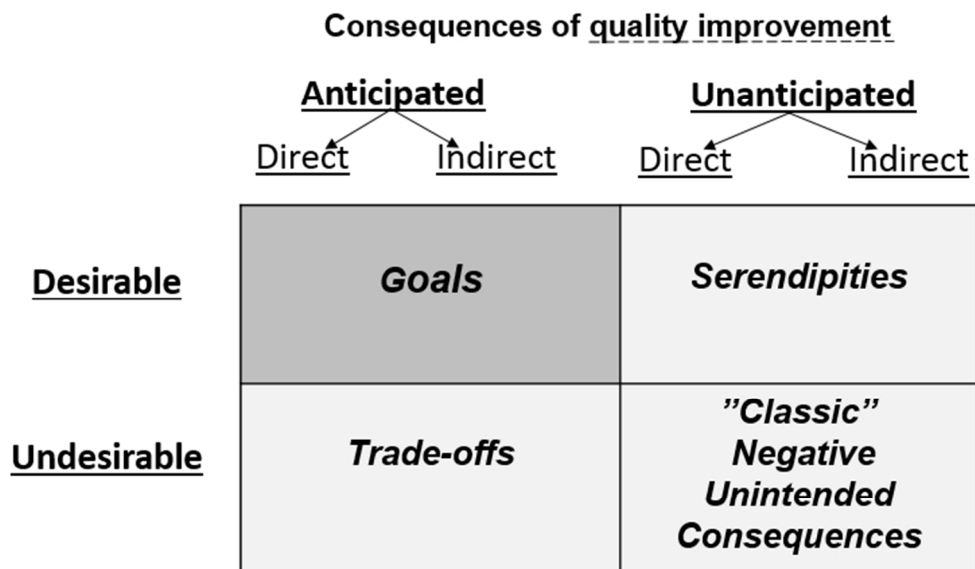
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569 **Figures/illustrations**

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)

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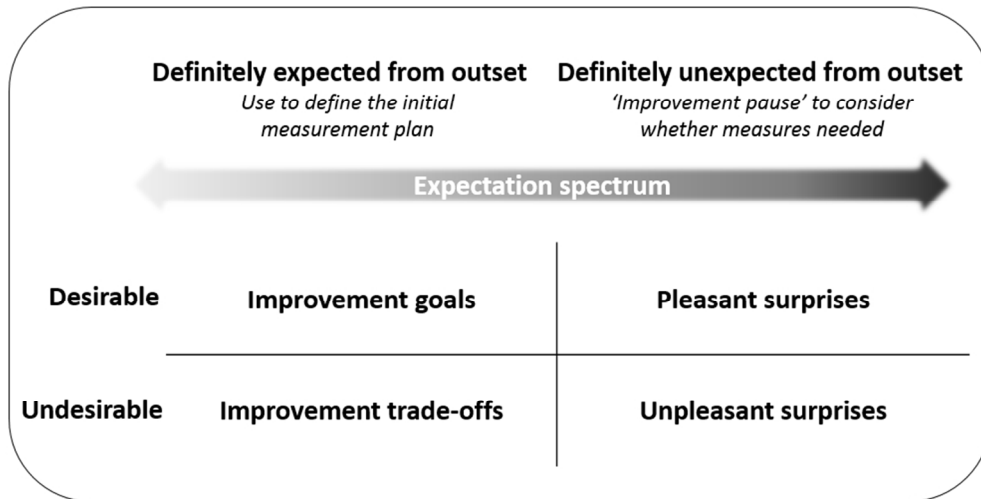


All four consequences can be:

- *Direct* (an *outcome*) or
- *Indirect* (a *process* believed to be linked to an outcome)

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

Review Only



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

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

For Review Only