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Identifying factors leading to harm in English General Practices: a mixed-methods study based on patient experiences integrating structural equation modelling and qualitative content analysis

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24 **ABSTRACT**

25 **Objective:** To identify the main factors leading to harm in Primary Care based on the
26 experiences reported by patients.

27 **Methods:** We conducted a mixed-methods, cross-sectional study in 45 primary care centres in
28 England. A random sample of 6,736 patients was invited to complete the Patient Reported
29 Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire. We fitted
30 structural equation modelling on the quantitative data (n=1,244 respondents) to identify
31 contributory factors and primary incidents leading to harm. We conducted content analyses of
32 responses to seven open-ended questions (n=386) to obtain deeper insight into patient
33 perceptions of the causes of harm experienced. Results from quantitative and qualitative
34 analyses were triangulated.

35 **Results:** Patients reported harm related to physical health (13%), pain (11%), and mental
36 health (19%), and harm that increased limitations in social activities (14%). Physical harm was
37 associated with incidents affecting diagnosis ($\beta=0.43$; delayed and wrong), and treatment
38 (0.12; delayed, wrong treatment or dose), which were in turn associated with incidents with
39 patient-provider communication, coordination between providers, appointments, and
40 laboratory tests. Pain was associated with laboratory tests (0.21; caused when collecting blood
41 or tissue samples) and with problems booking an appointment when needed (0.13; delaying
42 treatment for pain). Harm to mental health was associated with incidents related to: diagnosis
43 (0.28), patient-provider communication (0.18), appointments (0.17), coordination between
44 different providers (0.14) and laboratory tests (0.12). Harm increasing limitations in social
45 activities was associated with incidents related to diagnosis (0.42) and diagnostic and
46 monitoring procedures (0.20).

47 **Conclusions:** Our findings suggest the need for patient-centred strategies to reduce harm in
48 primary care focusing on the improvement of the quality of diagnosis and patient-provider
49 communication.

50 **Keywords:** Patient Safety; Primary Health Care; Observational Study; Qualitative Research;
51 Latent Class Analysis

52 **Abbreviations:** PREOS-PC, Patient Reported Experiences and Outcomes of Safety in Primary
53 Care; SEM, structural equation model; RMSEA, Root Mean Squared Error of Approximation;
54 SRMR, Standardized Root Mean Squared Residual; SD, standard deviation; WHO, World Health
55 Organization.

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58

59 Introduction

60 Patient safety, defined by the World Health Organization (WHO) as “the prevention of errors
61 and adverse effects to patients associated with health care”,¹ has become an important
62 priority for health systems worldwide.^{2,3} A recent multi-setting systematic review estimated
63 that around one in 20 patients are exposed to preventable harm in medical care.⁴ Efforts for
64 safer healthcare previously concentrated in hospital settings⁵ due to the use of more invasive
65 procedures and therefore higher potential for harm. However there is an increasing
66 recognition of the huge importance of primary care and ambulatory settings.⁶ The vast
67 majority (more than 90%) of medical consultations occur in primary care settings and unsafe
68 primary care, even if uncommon, could potentially affect a much larger proportion of the
69 population and be an important threat to public health.⁷ A recent report by the OECD⁸ showed
70 that around 20%-25% of the population experience harm in primary and ambulatory care
71 settings, and that the direct costs of harm (additional tests, treatments and health care) are
72 around 2.5% of total health expenditure.⁸

73 Notwithstanding the significant increase in research on primary care patient safety in
74 recent years, this area of research is still in its infancy, and there is little evidence about how to
75 reduce harm in primary care patients.⁹ Previous studies investigating harms, safety events, and
76 contributory factors have done so by addressing each element in isolation from each other.
77 Understanding the main causes and contributory factors that lead to the most serious types of
78 harm is crucial to inform the design of effective interventions to prevent harm in primary
79 care.¹⁰

80 An important factor hindering progress in this area is a lack of interest on the patients’
81 perspectives.¹¹ Information on patient safety related processes and outcomes has traditionally
82 been supplied mostly by health care providers - largely ignoring patients’ own perspectives and
83 experiences. Patients are able to recognize a range of problems in healthcare delivery,¹² many

84 of which are not identified by traditional systems of healthcare monitoring.^{13,14} Patient
85 reported information could significantly contribute to achieving safer primary healthcare
86 provision,¹⁵ as evidence shows that they frequently perceive potentially harmful preventable
87 problems and can make useful suggestions for their prevention.^{16,17} Although previous studies
88 used questionnaires to examine patient perceptions of patient safety in primary care,^{18,19} they
89 were limited by a lack of validated instruments to capture patient safety incidents and harm.²⁰
90 To address this gap, the Patient Reported Experiences and Outcomes of Safety in Primary Care
91 (PREOS-PC) questionnaire has been developed.²¹ PREOS-PC was used in a large-scale survey
92 study of patient perceptions and experiences of patient safety in English general practices,
93 observing a 12 month prevalence of patient-reported harm of 23%²² and identifying patient
94 and practice characteristics associated with patients safety problems and harm.²³ PREOS-PC
95 offers patients the opportunity to elaborate on their responses with free text, which provide
96 rich and useful information.²⁴

97 In this study we aimed to identify the main factors leading to harm based on the
98 experiences reported by patients registered in English Primary Care centres.

99

100 **Methods**

101 *Study design and participants*

102 This cross-sectional study included patients registered with 45 practices distributed across five
103 regions in the North, Central and South of England. These practices were selected purposively
104 to ensure variation in terms of list size and levels of deprivation.²¹⁻²³

105

106 *Data collection*

107 Data on patient reported experiences of patient safety problems and harm were collected
108 using the PREOS-PC questionnaire, as detailed elsewhere.²¹ The instrument measures the
109 patient safety focussed domains of patient activation, practice activation, experience of safety
110 problems, harm and overall evaluation of patient safety using a both fixed response and open
111 ended items. Harm is conceptualized in terms of a negative impact on health (including its
112 physical, mental and social dimensions according to the WHO definition)²⁵ as a consequence of
113 an interaction with the health care system. Evidence of its reliability and validity has been
114 published elsewhere.²¹

115 The PREOS-PC questionnaire was posted in June 2014 to a computer-generated
116 random sample of 150 patients (≥18 years) registered with participating practices with a
117 covering letter and a pre-paid return envelope. A total of 1,244 patients completed and
118 returned the questionnaire (response rate =18.4%).^{21,26} Ethical approval was granted by
119 Nottingham Research Ethics Committee (Reference 13/EM/0258; July 2013).

120

121 *Data Management*

122 Quantitative data were obtained from patient responses to all the 19 PREOS-PC fixed-response
123 items (see Box 1) capturing patient experiences of patient safety problems and harm. To
124 reduce the number of items in order to facilitate convergence of statistical models (detailed
125 below) and the interpretation of results, we created the following composite variables:
126 problems related to treatment (based on items 1.2, 1.3, and 1.4), diagnostic or monitoring
127 procedures (items 1.5 and 1.6), communication and coordination between providers (items 1.8
128 and 1.9), and harm to mental and emotional health (items 2.3 and 2.4).

129 Qualitative data were obtained from responses to seven free text items capturing
130 information about experiences of safety problems and harm in the last 12 months (Box 1).
131 Qualitative data were cleaned by removing free text responses that contained no relevant
132 information e.g. “N/A” or “No comments”.

133 [Box 1 around here]

134 *Analyses*

135 We analysed the data following a mixed methods approach that involved three stages:

136 *Stage 1: Initial exploration of quantitative and qualitative data*

137 Quantitative analyses consisted in a structural equation model (SEM) ²⁷ to identify associations
138 between the safety problems and harms. The model, exploratory in nature, considered a large
139 number of potential associations. Under the assumption that all safety problems could
140 constitute primary incidents leading to harm, the model tested direct associations between all
141 types of safety problems and of harm considered in the questionnaire. Based on the
142 “Recursive Model of Incident Analysis”,²⁸ the model also considered that some safety
143 problems could act as contributory factors of other safety problems (primary incidents) leading
144 to harm. As a result, it included a number of selected direct associations between different
145 types of safety problems (see Figure 1). The model was evaluated using a hybrid SEM

146 combining path analysis and confirmatory factor analysis. A latent variable was constructed to
147 measure harm severity based on confirmatory factor analysis including three measures of
148 consequences of harm (items 3.1, 3.2, and 3.3). Standardized regression coefficients (β) were
149 estimated using the maximum likelihood estimator.

150 Qualitative analyses were based on content analysis²⁹ of patients' (n=386) responses to the
151 seven open-ended questions above detailed. The data were initially coded deductively. A
152 categorization matrix (see Online Appendix 1) was developed based on the "Recursive Model
153 of Incident Analysis". The categories of harm and safety incidents initially included in the
154 matrix were based on the taxonomy used in the PREOS-PC questionnaire. All qualitative data
155 were then read and reread, and coded by content according to the pre-specified categories,
156 using the patient as a unit of analysis. As part of this process we observed that the data were
157 detailed enough to allow a better understanding of patients' experiences beyond the main
158 categories initially proposed. Therefore, following established guidelines,²⁹ we started an
159 inductive approach in parallel that resulted in the identification of new subcategories of harm,
160 safety problems and contributory factors. Initial data coding was conducted by one researcher
161 (IRC), and reviewed by a second researcher (JG). Subsequently both researchers reviewed the
162 categories and subcategories following an iterative approach which resulted in grouping and
163 splitting categories, and recoding data accordingly. The final data coding was reviewed by the
164 rest of the team, and subsequently used to develop a model of the sources of harm in primary
165 care.

166 *Stage two: Triangulation of results for the development of an integrative model*

167 Results from exploratory quantitative and qualitative analyses were compared for
168 triangulation purposes. An integrative model based on the results of both types of analyses
169 was developed. For this integrative model we retained those paths to harm that: 1) either a)
170 had emerged in the qualitative analyses or b) were significant in the quantitative analyses

171 (standardized regression coefficient >0.10 AND $p<0.05$), or 2) had been confirmed in both
172 analyses.

173 *Stage three: Evaluation of the integrative model*

174 The integrative model was evaluated using a hybrid SEM following the same statistical
175 methods detailed in Stage 1. In a sensitivity analysis we also evaluated a more parsimonious
176 model retaining only paths to harm supported by both quantitative and qualitative data. In
177 both models we examined goodness of fit using assessment of Chi-squared, Standardized Root
178 Mean Squared Residual (SRMR), Comparative Fit Index, Root Mean Squared Error of
179 Approximation (RMSEA), and equation-level goodness of fit.

180 Statistical analyses were carried out in Stata v12.1. Qualitative analyses were carried
181 out using NVivo 11.

182

183 **Results**

184 *Findings from exploratory quantitative analysis*

185 221 out of the 1,244 respondents (23%) reported having experienced harm as a result of the
186 healthcare provided by their practice during the last 12 months. Patients reported harm
187 related to physical health (13%), pain (11%), and mental health (19%), and harm that increased
188 limitations in social activities (14%). Results from the SEM exploring the associations between
189 safety events, contributory factors and harm are shown in Online Appendix 2. We report
190 standardized regression coefficients (β), which can be interpreted as standard regression
191 coefficients that allow for direct comparison (e.g., a 1 SD increase in “problems with diagnosis”
192 is associated with a 0.39 SD increase in “harm to physical health,” but with a smaller 0.24 SD
193 increase in “harm to mental health”).

194

195 *Findings from exploratory qualitative analysis*

196 Narratives of harm experiences were identified from 117 out of the 386 patients that
197 answered to any of the free text items. Three different types of harm emerged: harm to
198 mental health, pain, and physical harm. More detailed results, including a model of sources of
199 harm based on this exploratory analysis is available in Online Appendix 3.

200

201 *Triangulation of the findings from qualitative and quantitative analyses.*

202 We observed a substantial level of agreement between qualitative and quantitative findings
203 (Online Appendix 4). Out of the 43 potential associations initially explored, 13 were confirmed
204 and 15 were rejected by both qualitative and quantitative analyses; eight were supported only
205 by quantitative analyses, and seven only by qualitative analyses.

206

207 *Types and causes of harm in primary care as reported by patients*

208 The resulting integrative model, retaining only those paths to harm empirically supported by
209 either qualitative or quantitative data or both, is presented in Figure 1. It describes the paths
210 to the four different types of harm.

211

212 [Figure 1 about here]

213

214 **Harm to physical health.** Harm to physical health was significantly associated with a negative
215 impact on wellbeing (0.36). Primary incidents leading to harm to physical health were related
216 to:

217 • Diagnosis (0.43): frequently reported as a result of an exacerbation of a pre-existing
218 condition, two types of diagnosis incidents emerged: delayed diagnosis (attributed to
219 administrative errors, such as problems with referral letters, or delayed tests or test
220 results) and; wrong diagnosis (attributed to providers not listening to them or not
221 taking their symptoms seriously, or failing to arrange tests). Similar findings revealed
222 our quantitative analysis, with diagnosis incidents being associated with problems
223 related to patient-provider and provider-provider communication problems (0.28 and
224 0.18 respectively).

225 *“Admin delay in finding a referral for a suspected trapped nerve in wrist, approx 2 years*
226 *ago. Lead to delay in investigation and subsequent surgery” (male, 65 years old)*

227 • Treatment (0.12): Treatment problems were associated with diagnosis problems (0.16)
228 and incidents with diagnosis and monitoring procedures (0.20). Three different types

229 of treatment incidents emerged from our qualitative data: delayed treatment, wrong
230 treatment or dose, and adverse drug reactions. Delayed treatment was mainly caused
231 by delayed diagnosis (see causes of delayed diagnosis above), but also by not being
232 able to book an appointment when needed (which extended or exacerbated patients'
233 condition because they were not able to receive adequate treatment), and by
234 provider-provider coordination problems (such as lost referral letters needed to obtain
235 an appointment with a consultant to initiate treatment). Wrong treatment (referenced
236 in terms wrong drug or wrong dose) was also identified as a cause of harm to physical
237 health. Some patients perceived it could have been prevented or ameliorated by closer
238 treatment monitoring. In some occasions patients had a sense of hidden agenda.

239 *"I saw a (...) doctor about a gum infection. She prescribed an antibiotic that I had a bad*
240 *reaction to. I returned and asked her to check if it was listed on my record as something*
241 *I was allergic to. It was. Despite this, the doctor still tried to brow-beat me into trying it*
242 *again. I refused. She finally agreed to prescribe an antibiotic that wasn't on the list of*
243 *allergies. I had no side effects to the second one. I can't help wondering if this was*
244 *down to the cost?"* (male; 64 years old)

245 Finally a number of patients reported adverse drug reactions as a source of harm to
246 physical health. They were not perceived as medical errors but rather as a result of the
247 intrinsic risk of taking medication.

248 • Laboratory tests or other diagnostic procedures were directly associated with harm to
249 physical health in our quantitative analyses (0.12), but no further information emerged
250 from our qualitative data.

251

252 **Pain.** Experiencing pain was significantly associated with a negative impact on wellbeing (0.33).

253 Primary incidents leading to pain were related to:

254 • Laboratory tests and other diagnostic procedures (0.21): failure to adequately deliver a
255 diagnostic or monitoring procedure, such as unnecessarily repeating blood tests, or
256 poorly performed diagnostic procedures.

257 *“I have received internal damage of soreness and bleeding after a smear test carried*
258 *out by a heavy handed practice nurse 3 years ago.”* (female, 62 years old)

259 • Treatment (only supported by qualitative data): delayed treatment (frequently as a
260 result of delayed appointments but also of delayed tests due to administrative errors)
261 and adverse drug reactions

262 *“Extended pain as appointment not available.”* (female, 31 years old)

263 • Diagnosis (0.43): a strong association was observed between diagnosis problems and
264 pain, which was however not observed in the qualitative analysis.

265

266 **Harm to mental health.** Harm to mental health was mostly referenced in terms of anxiety and
267 stress, and was perceived as less severe compared with the other types of harm identified.

268 Primary incidents leading to harm to mental health were related to:

269 • Appointments and referrals ($\beta=0.17$): not being able to book an appointment with
270 their providers when patients felt it was necessary.

271 *“Anxiety of needing to see doctor and being told to wait 4 weeks - not know if problem*
272 *serious or not.”* (female, 44 years old).

273 • Laboratory tests (0.12): failures in recording the tests results (which in occasions
274 prompted healthcare providers to arrange urgent appointments, causing distress to
275 the patient), or in communicating the results to patients (results not proactively
276 followed up by providers).

277 • Patient-provider communication (0.18): providers perceived as not having time to deal
278 with the patient’s problems, not taking them seriously, not believing them, and, on
279 occasion, verbally abusing them.

280 *“GP made private referral to consultant without 1. telling me. 2. asking if I wanted to*
281 *go privately (i did not)”* (female, 55 years old)

282 • Provider-provider coordination (0.14): problems with information transfer between
283 the surgery and hospital or private provider.

284 In addition, diagnosis problems were strongly associated with harm to mental health
285 (0.28), although our qualitative data did not reveal further information. According to our
286 qualitative data treatment related incidents were also an important source of harm to mental
287 health. It included delayed treatment initiation (due to errors in sending the test results back
288 to GP) and problems in receiving ongoing medication (with patients feeling anxious about the
289 prospect of medication being stopped abruptly due to administrative mistakes or lack of
290 coordination between providers).

291

292 **Increased limitations in social activities.** Harm in terms of increased limitation in social
293 activities was only identified from quantitative analyses. It was strongly associated with a
294 negative impact on wellbeing (0.45). The primary incidents associated with increased
295 limitation in social activities were incidents related to diagnosis (0.42) and with diagnostic and
296 monitoring procedures (0.20).

297

298 The results from our sensitivity analysis based on a more parsimonious model including only
299 paths to harm supported by both quantitative and qualitative data generally supported the

300 findings from our main analysis both in terms of the observed associations and of goodness of
301 fit (Online Appendix 5).

302 **Discussion**

303 In this study we used a mixed-methods approach to identify the main factors leading to harm
304 in primary care based on the patient-reported experiences. We identified three main types of
305 harm: harm to mental health, pain, and physical harm. Harm to mental health (mostly referred
306 in terms of anxiety and stress) was caused by incidents related to appointments, patient-
307 provider communication and coordination between different providers and settings. Factors
308 leading to pain included problems booking an appointment (delaying treatment for pre-
309 existing pain), and problems with blood or tissue extractions (causing incipient pain). Factors
310 leading to physical harm included incidents with diagnosis (delayed and wrong) and treatment
311 (delayed, wrong treatment or dose), which in turn were associated with incidents with patient-
312 provider communication, coordination between providers, appointments, and laboratory
313 tests.

314

315 *Strengths and limitations*

316 As far as we know this is the first study using patient-reported information to examine types
317 and sources of harm in primary care. The data were collected using a valid and reliable
318 instrument.²¹ We used a mixed-methods approach combining robust quantitative and
319 qualitative methods, which allowed us to confirm and complement our findings and
320 interpretations.

321 Our study had some limitations. First, its cross-sectional design limits assumptions
322 about causality. However, this limitation only affects our quantitative analysis, and qualitative
323 data allowed us to partially overcome this limitation by providing patients' narratives of the
324 incidents that preceded and contributed to the experienced harm. Second, the response rate
325 to the questionnaire was low. Although this could limit estimations of frequency of events, it is

326 less likely to have affected the identification of the causes of harm. Third, it may be argued
327 that the types of harm and safety events identified in our study are result of the specific
328 questions and categories of harm included in the questionnaire (i.e., result of a pre-imposed
329 framework). It might also be argued that some of the types of harm considered (e.g., pain)
330 were substantially subjective. However the questionnaire was designed with strong input from
331 patients (content informed by a meta-synthesis³⁰ and focus groups with patients),³¹ and
332 therefore the applied framework is consistent with patient's own perspectives and
333 experiences of patient safety in primary care. Also, is worth noting that this study did not aim
334 to objectively measure harm and associated factors, but rather to understand patients own
335 experiences and perceptions of harm and - which are subjective in nature. Finally, our study
336 was exploratory in nature, and, although our findings are useful for hypothesis generation,
337 future studies with a confirmatory approach are needed to accumulate evidence on this area.

338

339 *Comparison with previous literature*

340 Previous research examined patients' perceptions of different aspects of patient safety in
341 primary care, including the ways in which patients make sense of 'safety' in the context of
342 primary medical care;³² their perceptions of errors in long-term illness care;^{16,33,34} the effect
343 of workplace conditions on errors;³⁵ what they believe may be done to reduce errors;³⁶⁻³⁸ and
344 how safety problems may impact on their subsequent interactions with the health care
345 system.^{39,40} However, main factors leading to harm in Primary Care based on the experiences
346 reported by patients has seldom been examined by previous research. As far as we know, the
347 only exception is a study in Belgium in which poor patient-provider communication was
348 identified the main cause of wrong diagnoses or treatments and of adverse drug events.⁴¹ This
349 is consistent with the findings in our study, where patient communication emerged as a key
350 factor leading to harm associated with diagnosis and treatment related incidents. Our results

351 are also similar to those observed by studies based on data supplied by health care providers:
352 a recent study examining 40,000 provider-recorded safety incidents in UK general practices²⁸
353 identified four main contributory themes underpinning harm: i) communication errors in the
354 referral and discharge of patients; ii) physician decision-making; iii) unfamiliar symptom
355 presentation and inadequate administration delaying cancer diagnoses; and iv) delayed
356 management or mismanagement following failures to recognise signs of clinical deterioration.
357 In a similar study in older patients⁴² the main sources of harm were related to medication;
358 communication; and clinical decision-making. In a study in Spain involving 48 primary care
359 centres,⁴³ the authors observed that most severe harm was usually related to medication
360 related events (adverse drug reactions and medication errors), most of them caused by
361 problems in communication and management. A study in the US⁴⁴ estimated that 75,000
362 hospitalisations per year are due to preventable adverse events that occur in the ambulatory
363 setting - most of which are associated with preventable events related to diagnostics, surgical
364 and medical procedures, medication, and incorrect or delayed treatments. A study in Scotland
365 using a trigger tool to review 2251 primary care consultations⁴⁵ concluded that most of the
366 observed harm was associated with medication and medication-related activities such as
367 prescribing, administrative issues (including coding errors and errors resulting from
368 correspondence with secondary care), and delayed diagnosis and referral. Deficits in the
369 discharge process have also identified as an important source of harm.⁴⁶

370 The main difference between the results from our study based on patient reported
371 information and the results from these studies based on information supplied by healthcare
372 professionals is that our study identified diagnosis errors and delays associated with patient-
373 provider communication problems as a chief factor contributing to harm; whereas in the
374 available studies based on information supplied by healthcare professionals diagnosis
375 problems caused by communication problems do not emerge as the one of the most
376 important factors associated with harm.

377

378 *Implications*

379 By identifying the main primary types of incidents and contributory factors leading to harm,
380 our study reveals a number of potential targets for the design of interventions aimed at
381 reducing harm in primary care. An important finding in our study is that diagnosis, rather than
382 treatment, was a key type of primary incident leading to the four types of harm considered.
383 The prominent role of diagnosis in the pathway to all types of harm observed in our study
384 suggests that interventions aimed at improving the technical quality of diagnosis may play an
385 important role in preventing harm.

386 Similarly, the association between communication problems and problems with
387 diagnosis and significantly their direct link to mental health related harm suggests that
388 improving patient-centred communication may be particularly important. Practice
389 organisational aspects related to appointments and laboratory tests also seemed to have
390 direct links to mental health harm. Optimization of these systems to ensure responsiveness to
391 patient expectations would appear to have, in associations with improved patient-provider
392 communications, potential for reducing mental health related harm. Creating systems to allow
393 closer treatment monitoring when new prescriptions are issued may be a useful strategy to
394 avoid an important proportion of medication-produced harm.⁴⁷ Despite the lack of solid
395 evidence about effective interventions to improve patient safety in the primary care setting, a
396 number of strategies have already been proposed. The recently published monographs by the
397 World Health Organization offer a number of resources including online toolkits and manuals
398 to provide practical suggestions for countries and organizations committed to improving the
399 safety of primary care.⁴⁸ Each monograph contain specific strategies for different types of
400 safety events (e.g. diagnostic⁴⁹ or medication errors⁵⁰), as well as strategies to tackle areas

401 particularly challenging in the primary care setting, such as transitions of care⁵¹ or
402 multimorbidity.⁵²

403 Until effective interventions targeting these areas become available, embracing the
404 values and principles of the 1978 Alma-Ata Declaration 40 years ago,⁵³ by designing health
405 systems around and for people, and supporting citizens to play an active role to ensure they
406 receive safe healthcare is key for reducing harm.⁵⁴ Systematic actions are needed to create a
407 safety culture in which patients are seen as equal partners in the promotion of high-quality
408 and safe care.⁵⁵ The use of structured patient feedback to practices using validated
409 instruments such as the PREOS-PC may constitute a valuable resource to help practices
410 identify opportunities for safer primary care provision.^{14,15,56} Efforts to evaluate the use of
411 PREOS-PC to inform safety improvements in routine primary care practice are currently
412 underway in England⁵⁷ and Spain.⁵⁸

413 *Conclusions*

414 Although there is a complex network of primary incidents and contributory factors leading to
415 harm, this study highlight a number of factors potentially leading to harm in primary care
416 according to patient perspectives and experiences. Given the exploratory nature of our study,
417 and the early stage of this area of research, additional studies are needed to confirm our
418 findings and tackle these factors as priorities.

419

420 **Conflict of interest:** IRC and JMV co-developed the PREOS-PC questionnaire, which is now
421 being licensed by Oxford Innovation Ltd. The rest of the authors report no conflict of interest.

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Box 1. Items from the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire used as a source of quantitative and qualitative data.

Quantitative data

1. Experiences of safety problems

Thinking about the healthcare you have received in your GP surgery in the last 12 months, do you believe you had any problem related to ... [Response options: No; Only once; More than once]

- 1.1. Diagnosis of your problems? (e.g. wrong diagnosis)
- 1.2. The medication prescribed or given to you at your GP surgery? (e.g. receiving a medication that was meant for a different patient)
- 1.3. Other treatments prescribed or administered at your GP surgery? (such as minor surgery, or acupuncture)
- 1.4. Vaccines prescribed or administered at your GP surgery? (e.g. receiving a vaccine that you already knew you were allergic to)
- 1.5. Blood tests and other laboratory tests ordered or performed at your GP surgery? (e.g. the test results being misplaced)
- 1.6. Diagnostic and monitoring procedures other than blood and laboratory tests (such as an ear examination, or biopsy, etc.) ordered or performed at your GP surgery? (e.g. not receiving a procedure when needed)
- 1.7. Communication between you and the healthcare professionals in your GP surgery? (e.g. not receiving the information you needed about your health problems or healthcare)
- 1.8. Communication and co-ordination between the healthcare professionals in your GP surgery? (e.g. important information about your healthcare not being passed between the healthcare professionals)
- 1.9. Communication and co-ordination between professionals in your GP surgery and other professionals outside of the GP surgery? (e.g. a letter being missing from a hospital consultant)
- 1.10. Your appointments? (e.g. not getting an appointment when you needed one)
- 1.11. Your health records? (e.g. your health records not being available when needed)

2. Harm.

Do you think you have experienced any of the following types of harm as a result of the healthcare provided in your GP surgery in the last 12 months? [Response options: Not at all; Hardly any; Yes, somewhat; Yes, a lot; Yes, extreme]

- 2.1. Pain
- 2.2. Harm to your physical health
- 2.3. Harm to your mental health
- 2.4. Harm to your emotional health
- 2.5. Increased limitations in doing your usual social activities

3. Impact of harm on wellbeing

Do you think you have experienced any of the following types of harm as a result of the healthcare provided in your GP surgery in the last 12 months? [Response options: Not at all; Hardly any; Yes, somewhat; Yes, a lot; Yes, extreme]

- 3.1. Harm that led to increased healthcare needs (such as needed medications or tests)
- 3.2. Harm that led to increased personal needs (such as needing help preparing meals or cleaning)
- 3.3. Harm that led to increased financial needs

Qualitative data

- Please feel free to describe here in more detail the most recent problem that happened to you
- Please feel free to describe here your experience of being harmed (i.e., how your health/wellbeing was affected as a result of a problem with your health care)
- Were your family /friends affected by the problem? If so, please feel free to describe here how they were affected
- Do you think you have experienced any type of problem or harm as a result of the health care provided by your GP surgery before the last 12 months? If so, please describe your experience below (including the approximate date of when the problem happened). Otherwise, please leave it blank and go to the next question
- If you have experienced any type of problem or harm as a result of the health care provided by your GP surgery either in the last 12 months or before this time, have you learnt anything as a result of that? If so, what have you learnt?
- What things, if any, does your GP surgery do well to make sure that health care is provided safely?
- What changes, if any, would you suggest to your GP surgery to make sure that health care is provided safely?

Figure 1 (title):

Structural equation model of the causes harm (model based on evidence from qualitative and quantitative analyses)

Figure 1 (legend):

Colour code: green, supported by BOTH qualitative and quantitative ($p < 0.05$; standardized regression coefficient ≥ 0.1) analyses; orange (short dash), only supported by quantitative analyses; orange (long dash), only supported by qualitative analyses; black, loadings from confirmatory factor analysis.

*, Not statistically significant

The model explained a 54% of the observed variability (coefficient of determination for the whole model = 0.544). The chi-squared test indicated that the model performed significantly poorer than the saturated model (Prob > Chi2 = 0.000). Comparative fit index (0.66), with a value below the recommended 0.9, also suggested inadequate fit. This was also supported by RMSEA (0.231), below the recommended 0.8.