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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ABSTRACT

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

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

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

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

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

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

Introduction

Patient safety, defined by the World Health Organization (WHO) as "the prevention of errors and adverse effects to patients associated with health care",[1] has become an important priority for health systems worldwide.[2,3] A recent multi-setting systematic review estimated that around one in 20 patients are exposed to preventable harm in medical care.[4] Efforts for safer healthcare previously concentrated in hospital settings[5] due to the use of more invasive procedures and therefore higher potential for harm. However there is an increasing recognition of the huge importance of primary care and ambulatory settings.[6] The vast majority (more than 90%) of medical consultations occur in primary care settings and unsafe primary care, even if uncommon, could potentially affect a much larger proportion of the population and be an important threat to public health.[7] A recent report by the OECD [8] showed that around 20%-25% of the population experience harm in primary and ambulatory care settings, and that the direct costs of harm (additional tests, treatments and health care) are around 2.5% of total health expenditure.[8]

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

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

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

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

Methods

Study design and participants

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

Data collection

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

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

Data Management

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

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

[Box 1 around here]

Analyses

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

Stage 1: Initial exploration of quantitative and qualitative data

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

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

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

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

Results from exploratory quantitative and qualitative analyses were compared for triangulation purposes. An integrative model based on the results of both types of analyses was developed. For this integrative model we retained those paths to harm that: 1) either a) 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

Results

Findings from exploratory quantitative analysis

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

Findings from exploratory qualitative analysis

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

Triangulation of the findings from qualitative and quantitative analyses.

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

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

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

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

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

Pain. Experiencing pain was significantly associated with a negative impact on wellbeing (0.33). Primary incidents leading to pain were related to:

- Laboratory tests and other diagnostic procedures (0.21): failure to adequately deliver a diagnostic or monitoring procedure, such us unnecessarily repeating blood tests, or poorly performed diagnostic procedures.

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

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

  "*Extended pain as appointment not available*." (female, 31 years old)

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

Harm to mental health. Harm to mental health was mostly referenced in terms of anxiety and stress, and was perceived as less severe compared with the other types of harm identified. Primary incidents leading to harm to mental health were related to:

- Appointments and referrals (β=0.17): not being able to book an appointment with their providers when patients felt it was necessary.

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

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

- Patient-provider communication (0.18): providers perceived as not having time to deal with the patient's problems, not taking them seriously, not believing them, and, on occasion, verbally abusing them.
  "*GP made private referral to consultant without 1. telling me. 2. asking if I wanted to go privately (i did not)*" (female, 55 years old)
- Provider-provider coordination (0.14): problems with information transfer between the surgery and hospital or private provider.

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

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

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

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

Discussion

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

Strengths and limitations

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

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

less likely to have affected the identification of the causes of harm. Third, it may be argued that the types of harm and safety events identified in our study are result of the specific questions and categories of harm included in the questionnaire (i.e., result of a pre-imposed framework). It might also be argued that some of the types of harm considered (e.g., pain) were substantially subjective. However the questionnaire was designed with strong input from patients (content informed by a meta-synthesis[30] and focus groups with patients),[31] and therefore the applied framework is consistent with patient's own perspectives and experiences of patient safety in primary care. Also, is worth noting that this study did not aim to objectively measure harm and associated factors, but rather to understand patients own experiences and perceptions of harm and - which are subjective in nature. Finally, our study was exploratory in nature, and, although our findings are useful for hypothesis generation, future studies with a confirmatory approach are needed to accumulate evidence on this area.

Comparison with previous literature

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

are also similar to those observed by studies based on data supplied by health care providers: a recent study examining 40,000 provider-recorded safety incidents in UK general practices [28] identified four main contributory themes underpinning harm: i) communication errors in the referral and discharge of patients; ii) physician decision-making; iii) unfamiliar symptom presentation and inadequate administration delaying cancer diagnoses; and iv) delayed management or mismanagement following failures to recognise signs of clinical deterioration. In a similar study in older patients[42] the main sources of harm were related to medication; communication; and clinical decision-making. In a study in Spain involving 48 primary care centres,[43] the authors observed that most severe harm was usually related to medication related events (adverse drug reactions and medication errors), most of them caused by problems in communication and management. A study in the US[44] estimated that 75,000 hospitalisations per year are due to preventable adverse events that occur in the ambulatory setting - most of which are associated with preventable events related to diagnostics, surgical and medical procedures, medication, and incorrect or delayed treatments. A study in Scotland using a trigger tool to review 2251 primary care consultations[45] concluded that most of the observed harm was associated with medication and medication-related activities such as prescribing, administrative issues (including coding errors and errors resulting from correspondence with secondary care), and delayed diagnosis and referral. Deficits in the discharge process have also identified as an important source of harm.[46]

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

Implications

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

Similarly, the association between communication problems and problems with diagnosis and significantly their direct link to mental health related harm suggests that improving patient-centred communication may be particularly important. Practice organisational aspects related to appointments and laboratory tests also seemed to have direct links to mental health harm. Optimization of these systems to ensure responsiveness to patient expectations would appear to have, in associations with improved patient-provider communications, potential for reducing mental health related harm. Creating systems to allow closer treatment monitoring when new prescriptions are issued may be a useful strategy to avoid an important proportion of medication-produced harm.[47] Despite the lack of solid evidence about effective interventions to improve patient safety in the primary care setting, a number of strategies have already been proposed. The recently published monographs by the World Health Organization offer a number of resources including online toolkits and manuals to provide practical suggestions for countries and organizations committed to improving the safety of primary care.[48] Each monograph contain specific strategies for different types of safety events (e.g. diagnostic [49] or medication errors[50]), as well as strategies to tackle areas

particularly challenging in the primary care setting, such as transitions of care[51] or multimorbidity.[52]

Until effective interventions targeting these areas become available, embracing the values and principles of the 1978 Alma-Ata Declaration 40 years ago,[53] by designing health systems around and for people, and supporting citizens to play an active role to ensure they receive safe healthcare is key for reducing harm.[54] Systematic actions are needed to create a safety culture in which patients are seen as equal partners in the promotion of high-quality and safe care.[55] The use of structured patient feedback to practices using validated instruments such as the PREOS-PC may constitute a valuable resource to help practices identify opportunities for safer primary care provision.[14,15,56] Efforts to evaluate the use of PREOS-PC to inform safety improvements in routine primary care practice are currently underway in England[57] and Spain.[58]

Conclusions

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

Conflict of interest: IRC and JMV co-developed the PREOS-PC questionnaire, which is now 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.