

Patients' evaluations of patient safety in English general practices: a cross-sectional study

Ricci-Cabello I ¹, Marsden KS ², Avery AJ ², Bell B ², Kadam U ^{3,4}, Reeves D ⁵, Slight SP ^{6,7}, Perryman K ⁵, Barnett J ⁸, Litchfield I ⁹, Thomas S ¹⁰, Campbell SM ^{5,11}, Doos L ⁹, Esmail A, ⁵, Valderas JM ¹².

1. Nuffield Department of Primary Care Health Sciences, OX2 6GG, University of Oxford, Oxford, UK,
2. School of Medicine, Division of Primary Care, NG7 2UH, University of Nottingham, Nottingham, UK
3. Arthritis Primary Care Research Centre, Institute for Primary Care and Health Sciences, ST5 5BG, University of Keele, Keele, UK.
4. Health Services Research Unit, Institute for Science and Technology in Medicine, ST5 5BG, University of Keele, Keele, UK.
5. NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre, M13 9PL. University of Manchester, Manchester, UK
6. Division of Pharmacy, School of Medicine, Pharmacy and Health, Durham University DH1, Stockton on Tees, UK
7. Centre for Patient Safety Research and Practice, Division of General Internal Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston MA, 02120, US
8. Academic Unit of Primary Care and Population Sciences, SO17 1BJ. University of Southampton, Southampton, UK
9. Institute of Applied Health Research, Faculty of Medical and Dental Sciences B15 2TT, University of Birmingham, Birmingham, UK
10. NIHR Clinical Research Network LS2 9PH, West Midlands, UK
11. Centre for Research and Action in Public Health (CeRAPH) , Building 22, Floor B, University of Canberra, University Drive, Bruce, ACT 2617, Australia
12. Health Services & Policy Research Group, Patient Centred Care, University of Exeter Collaboration for Academic Primary Care (APEX), University of Exeter Medical School EX1 2LU, University of Exeter, Exeter, UK.

Corresponding author: Ignacio Ricci-Cabello. Nuffield Department of Primary Care Health Sciences, University of Oxford. Radcliffe Observatory Quarter, Woodstock Road, Oxford. OX2 6GG, UK.

ignacio.riccicabello@phc.ox.ac.uk. Tel: 0044 01865 289300

ABSTRACT

Background: The frequency and nature of safety problems and harm in general practices has previously relied on information supplied by health professionals, and scarce attention has been paid to experiences of patients.

Aim: To examine patient-reported experiences and outcomes of patient safety in Primary Care in England.

Design and Setting: Cross-sectional study in 45 general practices.

Method: A postal version of the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire was sent to a random sample of 6,736 patients. Main outcome measures included “practice activation” (what does the practice do to create a safe environment); “patient activation” (how pro-active are patients in ensuring safe healthcare delivery); “experiences of safety events” (safety errors); “outcomes of safety” (harm); and “overall perception of safety” (how safe do patients rate their practice).

Results: 1,244 patients (18.4%) returned completed questionnaires. Scores were high for “practice activation” (mean (standard error) = 80.4 out of 100 (2.0)) and low for “patient activation” (26.3 out of 100 (2.6)). A substantial proportion of patients (45%) reported having experienced at least one safety problem in the previous 12 months, mostly related to appointments (33%), diagnosis (17%), patient-provider communication (15%), and coordination between providers (14%). 221 patients (23%) reported some degree of harm in the previous 12 months. The overall assessment of the level of safety of their practices was generally high (86.0 out of 100 (16.8)).

Conclusion: Priority areas for patient safety improvement in general practices in England include appointments, diagnosis, communication, coordination and patient activation.

Keywords: Patient Safety; Primary Care; Patient-Centered Care; Health Care Evaluation Mechanisms; Health Care Surveys

How this fits in:

- Most of the research on patient safety has been conducted in the hospital setting, and less is known about safety in general practices, which is where the great majority of NHS consultations take place.
- Most of the previous studies have examined patient safety in general practices based on information supplied by health professionals, and scarce attention has been paid to patients themselves.
- In this large scale cross-sectional study we used a validated questionnaire to examine patients' perceptions and experiences of patient safety in English general practices.
- Our study showed that patient-reported experiences of safety problems and harm are frequent and preventable, but practices may be unable to detect an important proportion of them if exclusively relying on information provided by professionals.
- In order to achieve safer primary care special attention should be paid to areas related to appointments, diagnosis, communication and coordination between healthcare professionals and settings, as well as engaging patients as vigilant partners through patient activation.

INTRODUCTION

The growing interest in primary care patient safety worldwide ^{1,2} is perhaps best exemplified by the Safer Primary Care initiative established by the World Health Organisation in 2012 for advancing understanding and knowledge about the risks to patients, the magnitude and nature of the preventable harm due to unsafe practices, and safe mechanisms to protect patients^{3,4}. A recent systematic review including studies from 21 different countries estimated that 2-3 patient safety incidents occur per 100 primary care consultations.⁵ Available evidence suggests that between 45% and 76% of them can be prevented.⁶ Despite increasing awareness of its potential impact on population health, major gaps in understanding remain and there is scarce evidence on how safety might be improved in primary care.⁷

One of the barriers hindering progress in this area is that most research has relied on information supplied by healthcare providers, with limited attention paid to patients' perspectives.^{8,9} As highlighted by World Health Organization in a recent report,¹⁰ the person using health care services is the only consistent factor throughout the care pathway. They hold key information vital for process, systems and policy improvement. Tapping into such a rich resource could contribute significantly to improving safety in primary care.¹⁰⁻¹³

Previous studies used patient reported information to evaluate safety of healthcare.¹⁴⁻¹⁸ However, most of them followed a hospital orientated approach to patient safety research, being mostly focused on medication safety and technical aspects of healthcare. As observed by a number of recent qualitative studies,¹⁹⁻²³ these issues do not fully account for patients' priorities and perspectives of safety in primary care, for which issues around trust, patient-provider relationships, continuity, or access to healthcare play a more important role. In order to contribute to addressing this gap, we recently developed a patient-centred tool to measure patient safety in general practices – the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC).²⁴ This validated instrument enables the comprehensive measurement of patient perceptions, experiences and outcomes of patient safety in primary care.

The aim of this study was to use the PREOS-PC questionnaire to examine patients' perceptions and experiences of safety problems and harm in general practices in England.

METHODS

Study design and participants

We conducted a cross-sectional study. In June 2014 the PREOS-PC questionnaire was sent to 6,736 adult (18 years old or older) patients from 45 general practices distributed across five regions in the North, Centre and South of England. Practices were selected through purposefully sampling to ensure variation in terms of list size and deprivation.

Each practice sent the questionnaire with a covering letter and a pre-paid return envelope to a computer generated random sample of 150 adult patients who had at least one interaction with their primary healthcare providers in the last 12 months. A reminder was sent after an interval of approximately two weeks to patients in ten practices rather than to the whole sample of practices due to limited resources. Ethical approval was granted by Nottingham Research Ethics Committee.

Conceptualization and measurement of patient safety in primary care

Details of the conceptual framework used in this study and the development process, validation and psychometric properties of the PREOS-PC survey are available elsewhere.²⁴ In short, we conceptualized patient safety as a “property of healthcare systems and services associated with the occurrence, prevention and amelioration of patient safety events”. An event was defined as “harm or potential harm to one or more patients due to an interaction with the healthcare system that fails to adhere to accepted standards of care, or due to the intrinsic risks of healthcare”.

We used the survey to measure patient-reported patient safety as conceptualized above. Respondents reported on their perceptions, experiences and outcomes in relation to the safety of the healthcare received from their GP practice over the previous 12 months. The version used in this study contained 71 items distributed in five main domains: practice activation (what does the practice do to create a safe environment and to ensure safety); patient activation (how pro-active are patients in ensuring safe healthcare delivery); experiences of patient safety events (safety errors); outcomes of patient safety (harm); and patients’ overall perception of safety (how safe do patients rate their practice).

Statistical analyses

All analyses were conducted at the patient level and were based on individual items and on scales. Item-based analyses consisted of the calculation of the number and percentage of patients answering

each of the response categories in each item. Scale scores were calculated as the percentage of the maximum score achievable on all items, with scores ranging from 0 to 100. For all the scales higher scores suggested higher levels of patient safety. For multi-item scales, where responses were missing for more than 50% of the items the whole scale was scored as missing; otherwise a score was derived using the available items without any imputation. Scale-based analyses were restricted to the scales showing the best psychometric properties in each of the five PREOS-PC domains (Online Appendix 1), consisting of the calculation of weighted scores' mean and standard error (SE).

Inverse probability weights, related to likelihood of response, were applied in analysis to produce results more representative of the full practice populations, not just the patients who participated. For each participating practice we extracted data on the sex and age distributions of the patients registered. Subsequently we computed separate gender and age probability weights for each practice. For example if we received data from 30 male patients from a practice with 3000 male registered patients the weight was calculated as $3000/30=100$ (so each male in the sample would represent 100 males at that practice). The gender and age weights were then multiplied and rescaled in order for the weighted samples to match the practice list sizes.

Tables report both unweighted and weighted (in square brackets) results for questionnaire items and scales; results in the main text are weighted. In general weighted results did not substantially differ from unweighted results.

All data manipulation and analysis were carried out in STATA 12.1.

RESULTS

Description of participating practices

In comparison to the overall characteristics of all English practices, participating practices were larger on average (mean list size 8,744 v 7,041) and had a slightly higher proportion of non-White ethnicity patients (18.8% v 15.9%), but were very similar with respect to gender balance, proportion of older patients, and deprivation (Table 1).

[Table 1 about here]

Response rate

The overall response rate was 18.4% (1,244/6,736). Compared to the overall characteristics of all eligible patients registered in the 45 participating practices, respondents were more likely to be female (59% versus 51%), aged ≥ 65 (39% versus 20%) and of ‘‘white’’ ethnicity (91% versus 82%) (Table 2).

[Table 2 about here]

Practice activation

In general patients perceived that their providers took adequate measures to ensure safe healthcare delivery, with more than two thirds of the patients reporting the most positive options (always/often) for the eleven Likert-scale items measuring ‘‘Practice activation’’ (Table 3). The only exception was the response to the item ‘‘The general practitioner told you about what side effects of your treatments to watch for’’, for which only 63% (after weighting) of the patients provided positive answers. The great majority (90%) of the patients agreed that delivering safe healthcare was a top priority for their providers. The mean (SE) score of the ‘‘Practice activation’’ scale was 80.4/100 (2.0) points.

[Table 3 about here]

Patient activation

In general patients reported low levels of activation: 62% reported that they “never” or “rarely” raised a concern when they thought something was wrong with their healthcare, and 71% reported that they “never” or “rarely” made a suggestion to their healthcare providers when they thought that something could be done to improve the services provided. The mean (SE) score of the “Patient activation” scale was 26.3/100 (2.6) points.

Experiences of safety problems

A total of 479 patients (45%) reported at least one safety problem with the healthcare received in their practice in the last 12 months. The most frequently reported problem was not having access to appointments when needed (33%, n=353) (Table 4). Other frequently reported problems were related to diagnosis (17%), patient-provider communication (15%), co-ordination between professionals in the practice (14%), and co-ordination between professionals from different settings (11%). Only 29 patients (4%) reported a medication related safety problem. The mean (SE) score of the “Experiences of safety problems” scale was 90.2/100 (3.0) points.

[Table 4 about here]

Out of the 479 patients that reported a safety problem, the great majority (95%) perceived that the problem could have been prevented. In terms of responsibility for the safety problem, 76% perceived that professionals of their practices had at least some responsibility in it, while only 22% perceived that they themselves had some responsibility. A majority (59%) did not take any action in response of the safety problem experienced (e.g. such as reporting it to a healthcare professional, asking for an explanation about the problem, or asking for measures to prevent it occurring again). 48% reported that the safety problem was acknowledged by the practice (although only 29% thought it had been taken seriously), and 38% rated the response of the practice to the safety problem as ‘poor’ or ‘fair’.

Experiences of harm

221 patients (23%) reported having experienced harm as a result of the healthcare provided by their practice during the last 12 months (Table 5). Most frequent types of harm were related to mental

health (including anxiety or stress) problems (18.5%, n=147), limitations in social activities (14%), and pain (11%). Sixty-three patients reported that the harm experienced led to a permanent health problem (Online Appendix 2). The mean (SE) score of the “Experiences of harm” scale was 92.1/100 (2.8) points.

[Table 5 about here]

Overall perception of patient safety

Overall patients showed a positive perception of the safety of the healthcare provided in their practice, with 91% (n=1,072) of them agreeing that their providers were trustworthy. The overall assessment of the level of safety of their practices was positive, with a mean (SE) score of 84.6/100 (1.8) points.

DISCUSSION

Summary

In this study we observed that patients had a positive perception of the levels of safety in their practices. However almost half of them reported experiencing one or more safety problems and a quarter reported experiencing some degree of harm as a result of the healthcare received in the previous 12 months.

Strengths and limitations

This is the first large-scale quantitative study examining the safety of the healthcare provided in general practices in England as perceived by the patients. It included 45 practices from a large geographic area, urban and rural settings, and with different levels of deprivation. Patients' perceptions and experiences were measured using a valid and reliable patient-centred instrument, which supports the validity of our findings.

A number of limitations must be acknowledged. The overall response rate in our study was modest (18.4%). Non-response may introduce bias if non-respondents differ from respondents on the key measures of interest. Patients who experienced safety problems or harm may have been more likely to complete the survey than those who did not; which would have resulted in an overestimation of the frequency and severity of these problems. We only used an English version of the questionnaire which may also have increased response bias. Future work on this area should include the development of additional language versions of the questionnaire. Although we cannot estimate the magnitude of such bias in our sample, previous meta-analyses suggest that its effect can be reduced by using the rigorous probability sampling processes that we used in this study.²⁵ In addition response probability weights were applied in analysis to minimize bias from under-represented groups of patients (younger and male). We did not weight for ethnicity as some practices had very few non-White respondents resulting in unstable weight estimates; in addition, low percentages of non-White patients means that any adjustment would have had only a very small effect on the results.

Comparison with existing literature

One of the main findings in this study is the substantial proportion of patients reporting experiences of safety problems, which is higher than in previous studies (15.6% reported by Kistler et al²⁶ and 5.5% by Solberg et al²⁷). The measures used in previous studies focused on clinical and technical aspects of safe healthcare, whereas in this study we used a patient-centred instrument that expanded the number of potential problems. The high rate of safety problems observed was mainly driven by access related problems, which typically consisted of difficulties in obtaining appointments when needed. It is worth

noting that this study was conducted during a period of economic austerity in England. The financial cuts imposed in healthcare provision may have affected access more severely than other areas of safety. This hypothesis is supported by data from the GP Patient Survey (a survey measuring patient experiences in general practices in England, mailed each year to 2.7 million patients),²⁸ which revealed an increase over the last four years in the percentage of patients that had to wait more than one week for an appointment (from 13% in 2012 to 18% in 2015).²⁹ Although this is a valid patient safety issue from the patients' perspective,^{19,23} it also raises a number of issues regarding appropriate access and potential direct and indirect harm caused by too much access.

The second most frequent problem was related to diagnosis (reported by 17% of the participants), which is similar to the 13% rate observed by Kistler et al in the US.²⁶ Patients perceived a diagnostic safety problem when they experienced a delay in being diagnosed (which in some instances led to an exacerbation of their condition), or when they received a different diagnosis after seeking a second opinion. A considerable proportion of the research conducted so far on the area of patient safety in primary care has focused on medication related safety problems.¹⁴⁻¹⁸ However, we observed that medication related problems were relatively infrequent when compared with other issues examined. This finding resonates with previous research, which suggested that patients are more likely to identify safety problems related to access and relational issues rather than technical issues such as improper medical treatment.³⁰

The proportion of patients reporting harm (23%) was higher than the one reported in a previous study in the US.²⁶ Patients were more likely to report being harmed psychologically and emotionally, suggesting that the current focus of patient safety efforts on adverse drug events and surgical mishaps could overlook other patient priorities. As pointed out in a recent systematic review,¹⁸ in contrast to the expansive literature regarding clinician distress associated with adverse events, the physical, financial and psychological harms to patients are understudied.^{19,23} Notably, in this study, harm leading to permanent health deterioration was reported by 63 patients (23% of all patients reporting harm). This may be an over-estimation due to response bias. It could also be attributable to how patients conceptualize safety and harm.²¹ This figure is however consistent with results from a national telephone survey carried out in the US on behalf of the National Patient Safety Foundation, which showed that 32% of the patients reporting harm to physical health regarded it as permanent; as did the 22% that reported harm to emotional health.³¹ As they stand, our results appear to challenge the traditional view of harm being a source of concern in hospital but not in primary care settings.³²

Implications for practice

This is the first large-scale study evaluating patient reported experiences and outcomes of the safety of general practices in England. A number of priority areas for improving patient safety in practices in England have emerged: appointments, diagnosis, communication and coordination.

Moreover, we observed low levels of patient activation, with most of the patients showing reluctance to raise concerns when they perceived something was wrong with their care. Potential for patients to contribute to their safety by speaking up about their concerns depends heavily on the quality of patient–professional interactions and relationships,³³ and therefore interventions focused in improving patient-provider interactions are worth exploring.

Our study showed that patient reported safety problems are frequent and preventable, but less than half of them are acknowledged by practices. This may suggest that practices are not able to detect them, which could be partially due to a significant mismatch between what practice staff and patients perceive as safety issues. To achieve safer primary care is crucial for practices to better understand patients’ experiences and perspectives about the safety of the healthcare they receive.²³ For that purpose the routine use of standardized and validated patient centred instruments, such as the PREOS-PC questionnaire, might prove a valuable resource.

Finally, the significant proportion of patients rating their practices’ reactions after noticing a safety event as “poor” or “fair” might suggest the need for practices to develop and follow standardized procedures to ensure safety events are adequately and satisfactorily tackled when identified.

FOOTNOTES

Funding: This research is part-funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). Jose M Valderas was supported by a National Institute of Health Research (NIHR) Clinician Scientist Award (NIHR/CS/010/024). The views expressed are those of the authors and not necessarily those of the NIHR, the NHS or the Department of Health.

Ethical approval: Ethical approval was granted by Nottingham Research Ethics Committee (13/EM/0258).

Competing interests: The authors have declared no competing interests.

REFERENCES

- 1 Spencer R, Campbell SM. Tools for primary care patient safety: a narrative review. *BMC Fam Pract* 2014;**15**:166.
- 2 Ricci-Cabello I, Goncalves DC, Rojas-Garcia A, Valderas JM. Measuring experiences and outcomes of patient safety in primary care: a systematic review of available instruments. *Fam Pract* 2015; **32**:106-119.
- 3 World Health Organization. A Global Challenge. Summary of Inaugural Meeting of Safer Primary Care Expert Working Group. Available from: http://www.who.int/patientsafety/summary_report_of_primary_care_consultation.pdf?ua=1. Accessed on 7 November 2016.
- 4 World Health Organization. Patient Safety. Safer Primary Care. Available from http://www.who.int/patientsafety/safer_primary_care/en/. Accessed on 7 November 2016.
- 5 Panesar SS, deSilva D, Carson-Stevens A, et al. How safe is primary care? A systematic review. *BMJ Qual Saf* 2015; **25**(7):544-53.
- 6 Elder NC, Vonder Meulen M, Cassidy A. The identification of medical errors by family physicians during outpatient visits. *Ann Fam Med* 2004;**2**(2):125-9.
- 7 Lorincz CY, Drazen E, Sokol PE, et al. Research in Ambulatory Patient Safety 2000–2010: A 10-Year Review. Chicago IL: 2011. https://c.ymcdn.com/sites/npsf.site-ym.com/resource/resmgr/PDF/Research-in-Amb-Pat-Saf_AMAr.pdf, 7 November 2016.
- 8 Hor S-y, Godbold N, Collier A, Iedema R. Finding the patient in patient safety. *Health (London)* 2013;**17**:567-83.
- 9 Vincent CA, Coulter A. Patient safety: what about the patient? *Qual Saf Health Care* 2002;**11**(1):76-80.
- 10 World Health Organization. Safer primary care: Patient engagement. Technical Series on Safer Primary Care. In Press (2016).
- 11 Donaldson LJ. The wisdom of patients and families: ignore it at our peril. *BMJ Qual Saf* 2015; **24**:603-4.
- 12 Reader TW, Gillespie A, Roberts J. Patient complaints in healthcare systems: a systematic review and coding taxonomy. *BMJ Qual Saf* 2014; **23**:678-89.
- 13 Weingart SN, Pagovich O, Sands DZ, et al. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med* 2005;**20**:830-6.
- 14 Barber N, Parsons J, Clifford S, Darracott R, Horne R. Patients' problems with new medication for chronic conditions. *Qual Saf Health Care* 2004;**13**:172-5.
- 15 Borriild NJ. Patients' experiences of antihypertensive drugs in routine use: results of a Danish general practice survey. *Blood Press Suppl* 1997;**1**:23-5.

- 16 Crichton B, Green M. GP and patient perspectives on treatment with non-steroidal anti-inflammatory drugs for the treatment of pain in osteoarthritis. *Curr Med Res Opin* 2002;**18**:92-6.
- 17 Gandhi TK, Burstin HR, Cook EF, et al. Drug complications in outpatients. *J Gen Intern Med* 2000;**15**:149-54.
- 18 Harrison R, Walton M, Manias E, et al. The missing evidence: a systematic review of patients' experiences of adverse events in health care. *Int J Qual Health Care* 2015; **27**:423-41.
- 19 Burgess C, Cowie L, Gulliford M. Patients' perceptions of error in long-term illness care: qualitative study. *J Health Serv Res Policy* 2012;**17**:181-7.
- 20 Hernan AL, Giles SJ, Fuller J, Johnson JK, Walker C, Dunbar JA. Patient and carer identified factors which contribute to safety incidents in primary care: a qualitative study. *BMJ Qual Saf* 2015;**24**:583-93
- 21 Rhodes P, Campbell S, Sanders C. Trust, temporality and systems: how do patients understand patient safety in primary care? A qualitative study. *Health Expect* 2016; 19:253-63.
- 22 Rhodes P, McDonald R, Campbell S, Daker-White G, Sanders C. Sensemaking and the co-production of safety: a qualitative study of primary medical care patients. *Sociol Health Illn* 2016; **38**:270-85.
- 23 Ricci-Cabello I, Pons-Vigués M, Berenguera A, Pujol-Ribera E, Slight SP, Valderas JM. Patients' perceptions and experiences of patient safety in primary care in England. *Fam Pract* 2016; **33**:535-542.
- 24 Ricci-Cabello I, Avery AJ, Reeves D, Kadam U, Valderas JM. Measuring Patient Safety in Primary Care: The development and validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC). *Ann Fam Med* 2016;**14**:253-61.
- 25 Groves RM. Nonresponse Rates and Nonresponse Bias in Household Surveys. *Public Opin Q* 2006;**70**:646-75.
- 26 Kistler CE, Walter LC, Mitchell M, Sloane PD. Patient Perceptions of Mistakes in Ambulatory Care. *Arch Intern Med* 2010;**170**:1480-7.
- 27 Solberg LI, Asche SE, Averbek BM, et al. Can patient safety be measured by surveys of patient experiences? *Jt Comm J Qual Patient Saf* 2008;**34**:266-74.
- 28 Campbell J, Smith P, Nissen S, Bower P, Elliott M, Roland M. The GP Patient Survey for use in primary care in the National Health Service in the UK--development and psychometric characteristics. *BMC Fam Pract* 2009;**10**:57.
- 29 NHS England. GP Patient Survey Analysis Tool - Trend analysis 2015. Available from: <http://results.gp-patient.co.uk/report/Trend.aspx>. Accessed on 7 November 2016.
- 30 Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient Reports of Preventable Problems and Harms in Primary Health Care. *Ann Fam Med* 2004;**2**:333-40.

- 31 Louis Harris & Associates. Public Opinion of Patient Safety Issues. Research Findings. National Patient Safety Foundation at the AMA. 1997. Available from: https://c.ymcdn.com/sites/www.npsf.org/resource/collection/ABAB3CA8-4E0A-41C5-A480-6DE8B793536C/Public_Opinion_of_Patient_Safety_Issues.pdf. Accessed on 8 August 2016.
- 32 Wynia MK, Classen DC. Improving ambulatory patient safety: Learning from the last decade, moving ahead in the next. *JAMA* 2011;**306**:2504-5.
- 33 Entwistle VA, McCaughan D, Watt IS, et al. Speaking up about safety concerns: multi-setting qualitative study of patients' views and experiences. *Qual Saf Health Care* 2010;**19**:1-7.

Table 1. Characteristics of the participating practices

Practice characteristics	Participating practices		All English practices	
	Mean (SD)	Range	Mean (SD)	Range
Registered patients (n)	8,744 (6,288)	1,827; 37,474	7,041 (4,307)	17; 46,126
Female patients (%)	50.6 (6.0)	30.4; 59.7	49.1 (6.4)	0; 73.0
Non-white ethnicity patients (%)	18.8 (25.3)	0; 94.3	15.9 (21.7)	0; 100
Patients aged >65 (%)	16.5 (6.0)	0.6; 29.9	15.3 (6.3)	0; 97.0
Deprivation*	25.5 (12.8)	6; 58.1	24.0 (12.3)	2.9; 68.5
QOF score¶	975.6 (30.8)	823.6; 1000	962.8 (53.4)	244.8; 1000

* Measured using the Index of Multiple Deprivation

¶Quality and outcomes framework overall score achieved in the financial year 2012/2013

Table 2. Demographic and clinical characteristics of the participants

	N (%)
Sex ¹	
Male	497 (41.1%)
Female	712 (58.9%)
Age ²	
18-34	140 (12.0%)
35-64	570 (49.0%)
≥65	454 (39.0%)
Ethnicity ³	
White	1082 (91.2%)
Other ethnic group	105 (8.9%)
Educational level	
Degree, degree equivalent and above	411 (35.2%)
Other qualifications	532 (45.5%)
No qualifications	226 (19.3%)
Health status	
Very good/ Good	892 (73.5%)
Fair /Bad /Very bad	321 (26.5%)
Number of long term conditions	
0	330 (28.0%)
1	329 (27.9%)
2-3	366 (31.0%)
>3	154 (13.1%)
Number of medications taken	
0	344 (30.1%)
1-2	311 (27.2%)
3-4	222 (19.4%)
>4	266 (23.3%)

¹Mean (SD) proportion of female registered in the 45 practices that participated in the study: 0.51 (0.05).

²Mean (SD) proportion of eligible patients aged >65 registered in the 45 practices that participated in the study: 0.20 (0.01).

³Mean (SD) proportion of patients from white ethnicity registered in the 45 practices that participated in the study: 0.82 (0.04)

Table 3. Patients' evaluation of practice activation*

Practice Activation	Always/Often	Sometimes	Rarely/ Never	Total N
GP available when needed	888 (77.8%) [69.7%]	187 (16.4%) [23.1%]	66 (5.8%) [7.2%]	1141
GP gave the patient enough time to say and ask questions	1037 (90.7%) [90.1%]	87 (7.6%) [8.2%]	20 (1.8%) [1.7%]	1144
GP encouraged the patient to talk about healthcare concerns	834 (74.9%) [69.7%]	182 (16.3%) [16.5%]	98 (8.8%) [13.9%]	1114
GP took patient's concerns seriously	966 (86.3%) [81.2%]	115 (10.3%) [15.0%]	38 (3.4%) [3.8%]	1119
GP explained tests/treatments to the patient	961 (86.9%) [88.5%]	106 (9.6%) [8.1%]	39 (3.5%) [3.4%]	1106
GP told the patient about side effects	655 (64.9%) [63.0%]	178 (17.6%) [15.1%]	176 (17.4%) [21.9%]	1009
GP helped to arrange/organise right type of care	803 (85.4%) [80.2%]	93 (9.9%) [14.4%]	44 (4.7%) [5.4%]	940
GP had access to information	940 (86.8%) [85.1%]	101 (9.3%) [9.8%]	42 (3.9%) [5.1%]	1083
GP was aware of the recommendations from other professionals	686 (78.0%) [70.4%]	135 (15.4%) [23.0%]	58 (6.6%) [6.6%]	879
GP worked well with others	886 (89.1%) [81.9%]	79 (8.0%) [13.8%]	29 (2.9%) [4.3%]	994
	Strongly agree/ Agree	Neither agree nor disagree	Disagree/ Strongly disagree	Total N
Delivering safe care was a top priority for the practice	1017 (90.6%) [90.4%]	85 (7.6%) [6.9%]	20 (1.8%) [2.7%]	1122

* Figures in square brackets represent weighted percentages. GP, general practitioner.

Table 4. Experiences of safety problems in the previous 12 months*

Safety problems	No	Yes		Total N
		Once	Multiple times	
Appointments	783 (68.9%) [66.5%]	129 (11.4%) [11.5%]	224 (19.7%) [21.9%]	1136
Diagnosis	980 (90.2%) [83.0%]	81 (7.5%) [9.4%]	25 (2.3%) [7.5%]	1086
Patient-provider communication	1015 (91.4%) [85.1%]	54 (4.9%) [5.0%]	41 (3.7%) [9.9%]	1110
Communication/co-ordination between primary care providers	972 (92.5%) [86.3%]	44 (4.2%) [4.5%]	35 (3.3%) [9.2%]	1051
Communication/co-ordination between settings	987 (91.1%) [89.2%]	66 (6.1%) [6.8%]	31 (2.9%) [3.9%]	1084
Health record	1018 (96.0%) [95.8%]	28 (2.6%) [2.9%]	14 (1.3%) [1.3%]	1060
Medication	1097 (97.4%) [95.8%]	23 (2.0%) [3.1%]	6 (0.5%) [1.1%]	1126
Diagnosis and monitoring procedures	1044 (96.4%) [96.9%]	28 (2.6%) [1.8%]	11 (1.0%) [1.3%]	1083
Blood tests	1069 (96.2%) [97.0%]	25 (2.3%) [1.9%]	17 (1.5%) [1.3%]	1111
Other (non pharmacological) treatments	1040 (97.3%) [97.2%]	17 (1.6%) [1.8%]	12 (1.1%) [0.9%]	1069
Vaccines	1093 (99.3%) [99.1%]	8 (0.7%) [0.8%]	0 (0%) [0%]	1101

* Figures in square brackets represent weighted percentages.

Table 5. Experiences of harm*

Type of harm	Not at all	Hardly any /Yes, somewhat	Yes, a lot/ Yes, extreme	Total N
Mental health/ Anxiety or stress	919 (86.2%) [81.5%]	124 (11.6%) [10.5%]	23 (2.2%) [7.9%]	1066
Pain	951 (90.0%) [89.5%]	75 (7.1%) [7.8%]	31 (2.9%) [2.7%]	1057
Limitations doing usual activities	962 (91.4%) [86.0%]	65 (6.2%) [6.2%]	26 (2.5%) [7.8%]	1053
Physical health	967 (93.0%) [87.3%]	49 (4.7%) [9.0%]	24 (2.31%) [3.6%]	1040
Healthcare needs	977 (93.9%) [88.2%]	41 (3.9%) [7.9%]	22 (2.1%) [3.9%]	1040
Financial needs	1000 (95.8%) [89.8%]	32 (3.1%) [9.0%]	12 (1.2%) [1.2%]	1044
Personal care needs	997 (95.6%) [89.9%]	34 (3.3%) [3.0%]	12 (1.2%) [7.1%]	1043

* Figures in square brackets represent weighted percentages.

Online Appendix 1. Main outcomes measures

Practice activation (Cronbach's $\alpha = 0.89$)

Thinking about the healthcare you have received in your GP surgery in the last 12 months, in general how often did you feel that your GP(s)... (Always; Often; Sometimes; Rarely; Never; Not applicable)

- Was (were) available when you needed to see or talk to them?
- Gave you enough time to say what you wanted to say and to ask questions?
- Encouraged you to talk about any concerns about your healthcare?
- Explained your tests and treatments in a way you could understand?
- Told you about what side effects of your treatments to watch for?
- Took your concerns seriously?
- Helped you to arrange/organise the right type of care (referrals, follow-up, etc.)?
- Had access to relevant information when needed (medical history, test results, etc.)?
- Seemed to be aware of the recommendations for care from other professionals treating you?
- Seemed to work well together with the other professionals in the practice?
- Thinking about the healthcare you have received in your GP surgery in the last 12 months, to what extent would you agree that delivering safe care was a top priority for your GPs, nurses and other staff in your GP surgery? [Strongly agree; Agree; Neither agree nor disagree; Disagree; Strongly disagree; I don't know]

Patient activation (Cronbach's $\alpha = 0.80$)

Thinking about the healthcare you have received in your GP surgery in the last 12 months, how often did you ... (Always; Often; Sometimes; Rarely; Never; Not applicable)

- Raise a concern to your GPs, nurses or other staff in your GP surgery when you thought something was wrong with your healthcare?
- Make a suggestion to your GPs, nurses or other staff in your GP surgery when you thought something could be done to improve the service provided?

Experiences of safety problems (Cronbach's $\alpha = 0.75$)

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 ... (No; Only once; More than once)

- Diagnosis of your problems? (e.g. wrong diagnosis)
- The medication prescribed or given to you at your GP surgery? (e.g. receiving a medication that was meant for a different patient)
- Other treatments prescribed or administered at your GP surgery? (such as minor surgery, or acupuncture)
- Vaccines prescribed or administered at your GP surgery? (e.g. receiving a vaccine that you already knew you were allergic to)
- Blood tests and other laboratory tests ordered or performed at your GP surgery? (e.g. the test results being misplaced)
- 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)
- 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)
- 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)
- 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)
- Your appointments? (e.g. not getting an appointment when you needed one)
- Your health records? (e.g. your health records not being available when needed)

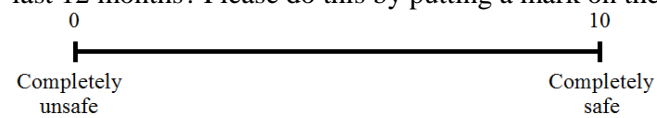
Experiences of harm (Cronbach's $\alpha = 0.96$)

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? (Not at all; Hardly any; Yes, somewhat; Yes, a lot; Yes, extreme)

- Pain
- Harm to your physical health
- Harm to your mental health
- Increased limitations in doing your usual social activities
- Increased health care needs
- Increased personal care needs
- Increased financial needs

Overall rating of patient safety

On a scale of 0-10, how safe do you think the healthcare you received in your GP surgery was in the last 12 months? Please do this by putting a mark on the line below like this: _____



Online Appendix 2. Time to recover from harm*

Time to recover from	Less than a week	More than a week but less than a month	More than a month, but I eventually recovered	I have a permanent problem	Total
Pain	20 (21.7%) [47.9%]	16 (17.4%) [21.5%]	14 (15.2%) [9.1%]	42 (45.7%) [21.5%]	92
Physical health	9 (12.9%) [5.9%]	9 (12.7%) [47.7%]	19 (26.8%) [22.0%]	34 (47.9%) [24.4%]	71
Mental health	22 (29.0%) [22.7%]	16 (21.1%) [50.7%]	16 (21.1%) [12.3%]	22 (29.0%) [14.3%]	76
Limitations doing usual activities	8 (10.4%) [7.6%]	10 (13.0%) [44.5%]	17 (22.1%) [21.0%]	42 (54.6%) [26.9%]	77
Overall harm	45 (27.8%) [20.2%]	23 (14.2%) [46.3%]	31 (19.1%) [10.6%]	63 (38.9%) [22.9%]	162
	About the same	Slightly worse	Worse	Much worse	Total
How much worse was the overall health as a result of the harm experienced	91 (54.2%) [38.1%]	39 (23.2%) [46.2%]	25 (14.9%) [8.5%]	13 (7.7%) [7.2%]	168

* Figures in square brackets represent weighted percentages.