## **Supplemental materials for:**

Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, 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(3):253-261.

## Supplemental Appendix 1. Characteristics of the participating practices

	Participatin	g practices	All English practices		
	Mean (SD)	Mean (SD) Range		Range	
Registered patients (n)	8,744 (6,288)	1,827; 37,474	7,041 (4,307)	17; 46,126	
Female patients (%)	50.57 (5.95)	30.4; 59.7	49.07 (6.42)	0; 73.00	
Non-white ethnicity patients (%)	18.77 (25.31)	0; 94.3	15.85 (21.72)	0; 100	
Patients aged >65 (%)	16.48 (6.01)	0.6; 29.9	15.32 (6.32)	0; 97.00	
Deprivation*	25.47 (12.83)	6; 58.1	24.00 (12.26)	2.86; 68.47	
QOF achievement score¶	975.61 (30.83)	823.6; 1000	962,79 (53.43)	244.79; 1000	

<sup>\*.</sup> Measured using the Index of Multiple Deprivation (higher scores indicating higher levels of deprivation); ¶. Quality and outcomes framework overall score achieved in the financial year 2013/2014

**Supplemental Appendix 2**. Comparison of patient characteristics and scale scores between respondents to the first invitation vs the respondents to the reminders.

Table A. Multivariate logistic regression comparing the characteristics of the respondents to the first invitation vs the respondents to the reminders.\*

	Respondents to first mailing (n (%))	Respondents to reminder (n (%))	OR [95% CI]‡
Sex	\ //		
Male	82 (39%)	44 (33%)	1
Female	130 (61%)	90 (67%)	1.28 (0.75; 2.21 )
Age¶			
<35	20 (10%)	20 (15%)	1
35-54	58 (28%)	31 (24%)	0.43 (0.18; 1.02)
55-74	113 (55%)	58 (45%)	0.48 (0.21; 1.11)
>74	14 (7%)	21 (16%)	1.33 (0.40; 4.47)
Ethnicity			
White	194 (94%)	116 (88%)	1
Other ethnic group	13 (6%)	16 (12%)	2.05 (0.79; 5.27)
Educational level			
Degree, degree equivalent and above	87 (42%)	48 (37%)	1
Other qualifications	92 (45%)	52 (40%)	0.96 (0.54; 1.69)
No qualifications	27 (13%)	29 (22%)	1.99 (0.91; 4.35)
Health status			
Very good/ Good	170 (80%)	97 (73%)	1
Fair /Bad /Very bad	43 (20%)	36 (27%)	1.62 (0.73; 3.62)
Number of long term conditions			
0	73 (36%)	43 (33%)	1
1	50 (25%)	30 (23%)	1.25 (0.60; 2.60)
2-3	57 (28%)	43 (33%)	1.59 (0.71; 3.57)
4 or more	22 (11%)	13 (10%)	2.65 (0.74; 9.49)
Number of medications taken¶			,
0	71 (36%)	47 (38%)	1
1-2	61 (31%)	32 (26%)	0.66 (0.33; 1.32)
3-4	26 (13%)	26 (21%)	0.91 (0.36; 2.30)
>4	38 (19%)	18 (15%)	0.24 (0.07; 0.75)

<sup>\*</sup> Multilevel model, adjusted for all independent variables and for practice clustering effect; ‡ Odds Ratio, indicating the likelihood of respondent groups to reply to the reminder; ¶ Statistically significant differences according to post-estimation omnibus test.

Table B. Linear regression comparing scale scores between respondents to the first invitation vs the respondents to the reminders.\*

	Scores from respondents to first mailing (mean (sd))	Scores from respondents to first mailing (mean (sd))	β [95% CI]	Bootstrap SE
Practice Activation	86.24 (16.60)	84.28 (16.63)	-1.32 (-5.17;2.53)	1.97
Patient Activation	23.16 (29.74)	28.71 (32.19)	4.79 (-3.39; 12.98)	4.17
Experiences of safety problems	4.21 (8.06)	5.21 (9.04)	0.79 (-1.48; 3.05)	1.15
Health domain specific harm	4.04 (13.65)	5.47 (15.91)	1.07 (-2.54; 4.67)	1.89
Health and personal care, and financial needs	2.67 (11.75)	2.75 (11.73)	-0.10 (-2.94; 2.74)	1.45
Trustworthiness	88.96 (14.30)	87.93 (15.96)	-1.27 (-5.41; 2.87)	2.11
Overall rating of patient safety	86.62 (16.85)	84.40 (17.07)	-1.32 (-5.17; 2.53)	1.97

<sup>\*</sup> Multilevel model adjusting for practice clustering effect, and using bootstrap methods to account for skew score distributions.

sd, standard deviation;  $\beta$ , regression coefficient; CI, confidence interval; SE, standard error.

# **Supplemental appendix 3.** Confirmatory Factor Analysis for the evaluation of construct validity

	Coefficient	95%CI
Practice activation		
Available when needed	0.64	0.59; 0.69
Enough time to say and ask questions	0.76	0.73; 0.80
Encouraged to talk	0.75	0.71; 0.78
Explained tests/treatments	0.82	0.80; 0.85
Told about side effects	0.67	0.63; 0.71
Took concerns seriously	0.83	0.80; 0.85
Arranged right type of care	0.86	0.84; 0.88
Had access to information	0.80	0.78; 0.83
Was aware of others' recommendations	0.86	0.84; 0.88
Worked well with others	0.83	0.80; 0.85
Patient safety as a priority	0.70	0.65; 0.73
Experiences of safety problems		-
Experience of problem related to diagnosis	0.55	0.50; 0.61
Experience of problem related to medication	0.32	0.25; 0.39
Experience of problem related to other treatments	0.25	0.18; 0.32
Experience of problem related to vaccines	0.28	0.21; 0.35
Experience of problem related to blood tests	0.32	0.25; 0.38
Experience of problem related to other procedures	0.46	0.40; 0.52
Experience of problem related to communication patient-provider	0.71	0.67; 0.75
Experience of problem related to communication between providers	0.78	0.74; 0.81
Experience of problem related to communication between providers not GPs	0.62	0.57; 0.67
Experience of problem related to appointments	0.40	0.34; 0.47
Experience of problem related to health record	0.56	0.51; 0.62
Harm – Hhealth domain specific		
Pain	0.84	0.82; 0.86
Physical health	0.90	0.88; 0.91
Mental health	0.75	0.72; 0.78
Anxiety or stress	0.78	0.76; 0.81
Usual social activities	0.88	0.86; 0.90
Harm- Health and personal care, and financial needs		
Healthcare needs	0.94	0.92; 0.96
Personal care needs	0.84	0.81; 0.86
Financial needs	0.76	0.73; 0.79
Harm - Time to recover from harm (health domain specific)		-
Pain	0.71	0.61; 0.80
Physical health	0.91	0.85; 0.98
Mental health	0.43	0.28; 0.57
Usual social activities	0.83	0.76; 0.91

CI: confidence interval.

#### ¶ Goodness-of-fit:

Practice activation: p>chi2=0.000, SRMR=0.029, CFI=0.96; Experiences of safety problems: p>chi2=0.000, SRMR=0.055, CFI=0.83; Impact of harm on specific aspects of health: p>chi2=0.000, SRMR=0.040, CFI=0.94; Impact of harm on specific aspects of needs: p>chi2=0.000, SRMR=0.000, CFI=1.00; Time to recover from specific types of harm: p>chi2=0.000, SRMR=0.018, CFI=1.00

Please confirm the following details:
A. I am completing this survey:

☐ Based on my own experience as a patient

# PATIENT REPORTED EXPERIENCES AND OUTCOMES OF SAFETY IN PRIMARY CARE (PREOS-PC)

### Please carefully read the accompanying instructions before starting the survey

Your current GP surgery has sent you this questionnaire because they want to learn more about how to improve the quality of their services: please report freely to this questionnaire.

 $\square$  On behalf of someone else. Please tell us your relationship to them (mother/ carer, etc.): \_\_\_

<ul> <li>3. Have you seen or spoken to a GP, nurse or any other member of staff in your current GP surgery in the last 12 months?</li> <li>☐ Yes. → Please start the survey on question 1 under "Creating a safe environment for you".</li> <li>☐ No. → If you have not seen or spoken to a GP, nurse or any other member of staff in your GP surgery in the last 12 months, please start the survey in the section "Tell us more about how safe you feel at your practice", on question 26 on page 9.</li> </ul>								
CREATING A SA	FE ENVIR	ONMEN	T FOR YOU					
1. 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?								

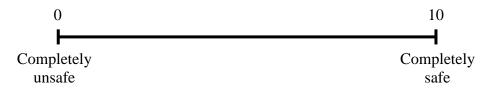
#### YOUR EXPERIENCES OF SAFETY PROBLEMS

Next we would like to ask you if you have experienced any safety problems. By "safety problems" we mean those problems that may happen when a patient receives healthcare that might cause harm to their health, or to their wellbeing. We do not mean issues just related to "health and safety", but rather problems such us not receiving an examination or treatment when needed, receiving a wrong diagnosis or the wrong medication. Question 5 on the next page contains a long list of other safety problems that may happen in GP surgeries that might help you to better understand what we mean by safety problems.

2. Thinking about the healthcare you have received in your GP surgery in the last 12 months, to what extent would you agree that...

	Strongly	Agree	Neither agree	Disagree	Strongly	I don't
	agree		nor disagree		disagree	know
Delivering safe care was a top priority for your GPs, nurses and other staff in your GP surgery?						
Overall the GPs, nurses and other staff in your GP surgery seemed to be trustworthy?						

3. 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:



4. 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?						

believe you had any problem related to ... Only More I don't No once than once know Diagnosis of your problems? (e.g. wrong diagnosis) П 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  $\Box$  $\Box$ 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) Other type of problem not listed above? Please describe here: П П • Thank you for completing this section. Now please read carefully the following instructions: If all your responses to question 5 were either "No" or "I don't know", please go to "Your experiences of harm", on page 7. Otherwise, please simply continue on to the next question.

5. Thinking about the healthcare you have received in your GP surgery in the last 12 months, do you

### YOUR MOST RECENT SAFETY PROBLEM

6. In case you	experienced more than one safety problem in the last 12 months, which of the following better
describes the	e most recent safety problem you experienced? Please select all the boxes that apply to you.
☐ Diagno	osis of your problems?
☐ Medic	ation prescribed or given to you at your GP surgery?
Other	treatments prescribed or administered at your GP surgery?
☐ Vaccir	nes prescribed or administered at your GP surgery?
☐ Blood	tests and other laboratory tests ordered or performed at your GP surgery?
_	ostic and monitoring procedures other than blood and laboratory tests ordered or performed at GP surgery?
□ Comm	unication between you and the healthcare professionals in your GP surgery?
☐ Comm	nunication and co-ordination between the healthcare professionals in your GP surgery?
☐ Comm	nunication and co-ordination between professionals in your GP surgery and other professionals
outside	e of the GP surgery?
☐ Your a	appointments?
☐ Your h	nealth records?
Other	type of problem not listed above?
7. Please feel fr	ree to describe here in more detail the most recent problem that happened to you:



ð.	VV II6	ere did this problem happen? Please select	11. How much responsibility do you think other			
	<u>all</u> t	he boxes that apply to you.	prof	fessionals outside your GP surgery (e.g.		
		In the consulting or treatment room of	pha	rmacist or hospital consultant) had for this		
		the GP surgery	prol	olem?		
		At the reception desk of the GP surgery		A great deal		
		In the waiting room of the GP surgery		Quite a lot		
		In a GP out of hours service		Some		
		Over the phone		Not very much		
		At home		None at all		
		In a care home		I don't know		
		Other, please specify:				
			12. Hov	w much responsibility do you think you		
		Not applicable (the problem did not	you	rself had for this problem?		
		happen in any specific location/s)		A great deal		
				Quite a lot		
9.	Whi	ich of the following professionals were		Some		
	invo	olved in this problem? Please select all the		Not very much		
	box	es that apply to you.		None at all		
		GP		I don't know		
		Nurse				
		Midwife	13. To v	what extent would you agree that this		
		Health visitor	prol	olem could have been prevented?		
		Receptionist		Strongly agree		
		Other. Please describe:		Agree		
				Disagree		
10.	Hov	w much responsibility do you think the		Strongly disagree		
	prof	Sessionals in your GP surgery had for this		I don't know		
	prob	olem?				
		A great deal				
		Quite a lot				
		Some				
		Not very much				
		None at all				
		I don't know				

14. Wh	at did you do about the problem, if	16. Did	the professionals in your GP surgery
any	thing? Please select <u>all</u> the boxes that	(ple	ase select <u>all</u> the boxes that apply to you)
app	ly to you.		Acknowledge the problem?
	I did not do anything about the problem		Take the problem seriously?
	I reported it		Give you clear and sufficient
	I asked for an explanation about the		information about the causes of the
	problem		problem?
	I asked to be involved in solving the		Give you clear and sufficient
	problem		information about the consequences of
	I asked for something to be done to		the problem?
	prevent it occurring again		Offer you a verbal apology?
	Other: Please explain		Offer you a written apology?
			Involve you in resolving the problem?
			Inform you that the problem was
15. Wh	o did you report the problem to? Please		recorded in your medical notes?
sele	ect all the boxes that apply to you.		Inform you that the GP surgery took
	Nobody		measures to prevent the problem
	My own GP		happening again?
	Another GP in my GP surgery		Other: Please explain
	Another healthcare professional, for		
	example a nurse, in my GP surgery		
	The manager of my GP surgery		
	A member of administrative staff in my		None of the above
	GP surgery		
	Hospital staff	17. Ove	rall, how would you rate your GP
	A lawyer	surg	gery's handling of the safety problem?
	Other. Please describe:		Excellent
			Very good
			Good
			Fair
			Poor



#### YOUR EXPERIENCES OF HARM

Next we would like to ask you whether you have been harmed as a result of the healthcare provided in your GP surgery. By "harm", we mean those situations in which healthcare actually causes a problem to patients' health or wellbeing.

Problems in healthcare can cause harm to patients. Sometimes this is because the healthcare is not as good as it might have been; but sometimes harm occurs even with high-quality healthcare. Please see the examples below.

- Example of harm caused by **inadequate** healthcare: A patient who is feeling unwell and who has symptoms of cancer that need further investigation according to current guidelines sees her GP. Her GP does not recognize the importance of the symptoms and takes no action. Months later the cancer is finally diagnosed, but at a stage that is more advanced than when the patient first visited the GP.
- Example of harm caused by **adequate** healthcare: A patient is given the right medication but develops an unexpected adverse reaction that makes him feel unwell.

Please complete this part of the survey even if you previously reported not having experienced any safety problem in the last 12 months.

18. 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	I don't know (yet)
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						

19. How long did it tak	te you to recover fi	rom your							
	Not applicable (I did not experience it)	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				
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									
O→ Please read carefu									
If <u>all</u> your responses to	-		•	_					
"Tell us more about ho	ow safe you feel at	your GP	practice", on the r	next page. Otherw	ise, please				
simply continue on to	the next question.								
20. Was the harm caused by the <b>most recent</b> problem you experienced and that you have previously reported in this survey (question 6, page 4)?  Yes, it was caused by the most recent problem I experienced.  No, it was not.									
21. 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 healthcare):  22. Were your family /friends affected by the problem? If so, please feel free to describe here									
how they were affecte	<u> </u>								



#### TELL US MORE ABOUT HOW SAFE YOU FEEL AT YOUR PRACTICE

23. Do you think you have experienced any	25. What things, if any, does your
type of problem or harm as a result of the	practice do well to ensure that care is
nealthcare provided by your GP surgery before	delivered safely?
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.	
	26. What changes, if any, would you
24. If you have experienced any type of	suggest to your GP surgery to ensure that
problem or harm as a result of the healthcare	care is delivered safely?
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?	
,	

Please return this survey in the reply paid envelope provided (no stamp is needed).

# Thank you for time and help

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