**PREOS-PC – BIBLIOGRAFÍA RELACIONADA**

## Bibliografía de la adaptación española del PREOS-PC

1. **Cross-Cultural Adaptation, Validation and Piloting of the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) Questionnaire for Its Use in Spain.**

   Serrano-Ripoll MJ, Llobera J, Valderas JM, Olry de Labry Lima A, Fiol-deRoque MA, Ripoll J, Ricci-Cabello I. Journal of Patient Safety. Accepted 19 Sept 2020.

   OBJECTIVE: To cross-culturally adapt, validate and pilot the *Patient Reported Experiences and Outcomes of Safety in Primary Care* (PREOS-PC) questionnaire for its use in Spain.

   METHOD: After setting up an expert panel to determine its content validity, the questionnaire was translated and back translated, and subjected to cognitive testing. The questionnaire was piloted in a cross-sectional study in 10 Primary Healthcare (PHC) centres in Spain. 50 patients per centre completed the questionnaire while waiting for an appointment. We estimated: i) acceptability of the questionnaire (response rate); ii) scores distribution (floor and ceiling effects); iii) internal consistency (Cronbach's α) and, iv) construct validity (exploratory factor analyses and correlation between scales). To examine patients' evaluations of patient safety we followed a mixed methods approach: i) statistical analyses at scale and item level based on responses to standardized items, and ii) qualitative content analysis based on responses to open-ended questions.

   RESULTS: Complete data was collected from 493 patients (participation rate =77%). A ceiling effect was observed for three scales ("safety problems", "harm severity", "harm needs"). The internal consistency was adequate (α>0.7) for the majority of scales. Exploratory factor analysis and correlation between scales suggested appropriate construct validity. 226 (45.8%) respondents experienced at least one safety problem, and 109 (23.2%) reported harm in the previous 12 months.

   CONCLUSION: The multi-dimensional PHC patient safety instrument PREOS-PC is now available for its use in Spain. Initial testing demonstrates its potential for use in primary care. Future developments will further address its use in actual clinical practice.

2. **Traducción, adaptación y validación psicométrica del cuestionario "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC).**

   Ricci-Cabello I, Serrano-Ripoll MJ, Valderas JM. IV Jornada científica BiblioPro. 21 febrero 2019. Madrid. https://www.bibliopro.org/media/upload/arxius/Servicios/PROGRAMA-2019-ilovepdf-compressed.pdf

   INTRODUCCIÓN Y OBJETIVOS: El cuestionario PREOS-PC se desarrolló en Inglaterra con el objetivo de medir la seguridad del paciente en base a las percepciones, experiencias y resultados en salud reportados por pacientes de atención primaria. Consta de 5 dominios (27 ítems): activación de centros de salud; activación de pacientes; experiencias de problemas de seguridad; daño; evaluación global del nivel de seguridad percibido. A pesar del potencial de este tipo de herramientas para informar mejoras en la práctica clínica, en España no existen instrumentos para medir la seguridad del paciente en atención primaria basados en información proporcionada por pacientes. El objetivo de este estudio fue adaptar y traducir PREOS-PC para su uso en centros de salud de España, así como evaluar sus propiedades psicométricas.

MÉTODOS: Un Panel de Expertos (n=5) evaluó la validez del contenido de la versión original de PREOS-PC para su uso en España. El cuestionario fue traducido al castellano independientemente por dos traductores. Una tercera revisora armonizó ambas traducciones, y la versión resultante fue retrotraducida por otra revisora. La versión española se testó y refinó en un proceso iterativo informado por 10 entrevistas cognitivas. Tras un pilotaje con cuatro pacientes, el cuestionario fue administrado electrónicamente a 500 pacientes, que fueron invitados a autocompletar el cuestionario (mediante tablets) en 10 centros de salud de Mallorca. Se llevaron a cabo análisis psicométricos a nivel de ítem y escala para examinar: aceptabilidad del cuestionario (tasa de respuesta), efecto suelo/techo (distribución puntuaciones), consistencia interna (Cronbach α, correlación ítem-test), validez estructural (análisis factorial exploratorio), y validez de constructo (correlación entre escalas).

RESULTADOS: Tras la incorporación de cambios menores, el Panel de Expertos confirmó la validez de contenido. El nivel léxico, tras entrevistas cognitivas y pilotaje, resultó equivalente a una dificultad "normal" (fórmula Szigriszt = 64.9). El 77% (585/780) de los pacientes invitados completaron el cuestionario. Se observó un efecto techo en ítems y escalas de "experiencias de problemas de seguridad" y "daño". Las cinco escalas multi-ítem presentaron adecuada consistencia interna (α= 0.68 - 0.85). El análisis factorial exploratorio indicó adecuada validez estructural en todas las escalas (valores > 0.5). Las correlaciones entre escalas sugirieron adecuada validez de constructo.

CONCLUSIONES: Los resultados obtenidos (alta aceptabilidad por parte de pacientes, adecuada consistencia interna, y alta validez de contenido, y de constructo) indican que la versión española del PREOS-PC es una herramienta apropiada para evaluar la seguridad del paciente en los centros de salud de España.

## Bibliografía del desarrollo del cuestionario original

3. **Measuring Patient Safety in Primary Care: The Development and Validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC).**

Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, Valderas JM. Ann Fam Med. *2016* May;14(3):253-61. doi: 10.1370/afm.1935. PubMed PMID: 27184996. http://www.annfammed.org/content/14/3/253.long

*ABSTRACT:*

PURPOSE: We set out to develop and validate a patient-reported instrument for measuring experiences and outcomes related to patient safety in primary care.

METHOD: The instrument was developed in a multistage process supported by an international expert panel and informed by a systematic review of instruments, a meta-synthesis of qualitative studies, 4 patient focus groups, 18 cognitive interviews, and a pilot study. The trial version of Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) covered 5 domains and 11 scales: practice activation (1 scale); patient activation (1 scale); experiences of patient safety events (1 scale); harm (6 scales); and general perceptions of patient safety (2 scales). The questionnaire was posted to 6,736 patients in 45 practices across England. We used "gold standard" psychometric methods to evaluate its acceptability, reliability, structural and construct validity, and ability to discriminate among practices.

RESULTS: 1,244 completed questionnaires (18.5%) were returned. Median item-specific response rate was 91.3% (interquartile range 28.0%). No major ceiling or floor effects were observed. All 6 multi-item scales showed high internal consistency (Cronbach's α 0.75-0.96). Factor analysis, correlation between scales, and known group

analyses generally supported structural and construct validity. The scales demonstrated a heterogeneous ability to discriminate between practices. The final version of PREOS-PC consisted of 5 domains, 8 scales, and 58 items.

CONCLUSIONS: PREOS-PC is a new multi-dimensional patient safety instrument for primary care developed with experts and patients. Initial testing shows its potential for use in primary care, and future developments will further address its use in **actual** clinical practice.

4. **The development of an online patient safety questionnaire for Primary Care (PREOS-PC)**

Salema N, Marsden K, Lafond N, Gangannagaripalli J, Mounce L, Valderas JM, Avery T. SAPC ASM 2019 - Exeter.

https://sapc.ac.uk/conference/2019/abstract/development-of-online-patient-safety-questionnaire-primary-care-preos-pc_p1

*ABSTRACT:*

PROBLEM: The Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire was developed and piloted as part of the Patient Safety Toolkit for Primary Care developmental work. This was the first large-scale survey to evaluate the safety of general practices in England as experienced by the patients themselves. Suggestions for improving the questionnaire included making it shorter and developing an online version. This current study was undertaken to explore the feasibility of using two online, shortened, versions of PREOS-PC questionnaire (Short-Form and Compact questionnaires) in general practice.

APPROACH: After registering with the PREOS-PC database, 17 participating practices in the East Midlands sent emails containing a link to the questionnaire to a random sample of patients (18 years and over). Questionnaire responses were directly stored in the database and a downloadable report available to each practice in real-time. Patients also provided feedback on the process of completing the online questionnaire. Data were analysed using both quantitative and qualitative methods.

FINDINGS: A total of 699 Compact and 247 Short-Form questionnaires were completed. Overall, patients perceived their general practices to be safe. Results showed that practices were more proactive than patients at ensuring safer healthcare. Free text responses from patients highlighted areas where practices performed well in relation to patient safety and areas where improvements could be made.

CONSEQUENCES: This study successfully demonstrated that it is feasible to disseminate the PREOS-PC questionnaire online. Strategies and opportunities to engage the practice staff and patient participation groups in utilising results from the PREOS-PC questionnaire are needed.

5. **Development of two short patient-report questionnaires of patient safety in Primary Care**

Mounce L, Salema ND, Gangannagaripalli J, Ricci-Cabello I, Avery AJ, Kadam UT, Valderas JM. Development of two short patient-report questionnaires of patient safety in Primary Care. Journal of Patient Safety. Accepted Oct 2020.

*ABSTRACT:*

OBJECTIVES: The Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOSPC) is a valid and reliable instrument (61 items across 5 domains). Stakeholder feedback has supported shorter versions for

improving choice and facilitating uptake of routine patient-centred evaluation. We sought to develop two shorter versions of PREOS-PC: one including the shortest possible scales that met established measurement performance standards, and a screening version including a single item for each relevant domain.

METHODS: 1,244 patients from 45 General Practices across England completed PREOS-PC questionnaires. All scale items in PREOS-PC underwent Item Response Theory analysis, applying standard criteria for the item reduction. Cognitive debriefing from 10 patient interviews allowed assessment of the instruments readability. The instruments' psychometrics properties were reassessed in a validation sample of 1557 patients in 21 English General Practices.

RESULTS: 'PREOS-PC Compact' includes 25 items and 2 open-ended questions across the five domains. 'PREOS-PC Screen' consists of 6 items; the best performing single items for 2 domains, one item modified from original items for each of the remaining 3 domains, and one open-ended question. The evaluation of the instruments confirmed they were acceptable to patients and met standards for readability; construct, convergent and divergent validity; and reliability.

CONCLUSIONS: PREOS-PC Compact meets high performance standards whilst reducing patient burden for routine monitoring of patient safety in Primary Care. PREOS-PC Screen is a concise tool apt for incorporation into audits, and to target more in depth review as needed.


## Otra bibliografía relacionada con el cuestionario PREOS-PC

6. **Identifying patient-centred recommendations for improving patient safety in General Practices in England: a qualitative content analysis of free-text responses using the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire.**

*ABSTRACT:*

BACKGROUND: There is a growing interest in identifying strategies to achieve safer primary health-care provision. However, most of the research conducted so far in this area relies on information supplied by health-care providers, and limited attention has been paid to patients' perspectives.

OBJECTIVE: To explore patients' experiences and perceptions of patient safety in English general practices with the aim of eliciting patient-centred recommendations for improving patient safety.

METHODS: The Patient Reported Experiences and Outcomes of Safety in Primary Care questionnaire was sent to a random sample of 6736 primary care users registered in 45 English practices. We conducted a qualitative content analysis of responses to seven open-ended items addressing patients' experiences of safety problems, lessons learnt as a result of such experiences and recommendations for safer health care.

RESULTS: A total of 1244 (18.4%) participants returned completed questionnaires. Of those, 678 (54.5%) responded to at least one open-ended question. Two main themes emerged as follows: (i) experiences of safety problems and (ii) good practices and recommendations to improve patient safety in primary care. Most frequent experiences of safety problems were related to appointments, coordination between providers, tests, medication

and diagnosis. Patients' responses to these problems included increased patient activation (eg speaking up about concerns with their health care) and avoidance of unnecessary health care. Recommendations for safer health care included improvements in patient-centred communication, continuity of care, timely appointments, technical quality of care, active monitoring, teamwork, health records and practice environment.

CONCLUSION: This study identified a number of patient-centred recommendations for improving patient safety in English general practices.

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

https://bjgp.org/content/67/660/e474.long

*ABSTRACT:*

BACKGROUND: Description of safety problems and harm in general practices has previously relied on information from health professionals, with scarce attention paid to experiences of patients.

AIM: To examine patient-reported experiences and outcomes of patient safety in primary care.

DESIGN AND SETTING: Cross-sectional study in 45 general practices across five regions in the north, centre, and south of England.

METHOD: A version of the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire was sent to a random sample of 6736 patients. Main outcome measures included 'practice activation' (what a practice does to create a safe environment); 'patient activation' (how proactive are patients in ensuring safe healthcare delivery); 'experiences of safety events' (safety errors); 'outcomes of safety' (harm); and 'overall perception of safety' (how safe patients rate their practice).

RESULTS: Questionnaires were returned by 1244 patients (18.4%). 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]). Of the patients, 45% reported experiencing 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%). Twenty-three per cent of the responders reported some degree of harm in the previous 12 months. The overall assessment of level of safety of 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.

8. **Identifying patient and practice characteristics associated with patient-reported experiences of safety problems and harm: a cross-sectional study using a multilevel modelling approach.**

https://qualitysafety.bmj.com/content/26/11/899.long

*ABSTRACT:*

OBJECTIVE: To identify patient and family practice characteristics associated with patient-reported experiences of safety problems and harm.

DESIGN: Cross-sectional study combining data from the individual postal administration of the validated Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire to a random sample of patients in family practices (response rate=18.4%) and practice-level data for those practices obtained from NHS Digital. We built linear multilevel multivariate regression models to model the association between patient-level (clinical and sociodemographic) and practice-level (size and case-mix, human resources, indicators of quality and safety of care, and practice safety activation) characteristics, and outcome measures.

SETTING: Practices distributed across five regions in the North, Centre and South of England.

PARTICIPANTS: 1190 patients registered in 45 practices purposefully sampled (maximal variation in practice size and levels of deprivation).

MAIN OUTCOME MEASURES: Self-reported safety problems, harm and overall perception of safety.

RESULTS: Higher self-reported levels of safety problems were associated with younger age of patients (beta coefficient 0.15) and lower levels of practice safety activation (0.44). Higher self-reported levels of harm were associated with younger age (0.13) and worse self-reported health status (0.23). Lower self-reported healthcare safety was associated with lower levels of practice safety activation (0.40). The fully adjusted models explained 4.5% of the variance in experiences of safety problems, 8.6% of the variance in harm and 4.4% of the variance in perceptions of patient safety.

CONCLUSIONS: Practices' safety activation levels and patients' age and health status are associated with patient-reported safety outcomes in English family practices. The development of interventions aimed at improving patient safety outcomes would benefit from focusing on the identified groups.

9. **Development and evaluation of an intervention based on the provision of patient feedback to improve patient safety in Spanish primary healthcare centres: study protocol.**

*ABSTRACT:*

INTRODUCTION: Despite the enormous potential for adverse events in primary healthcare (PHC), the knowledge about how to improve patient safety in this context is still sparse. We describe the methods for the development and evaluation of an intervention targeted at PHC professionals to improve patient safety in Spanish PHC centres.

METHODS AND ANALYSIS: The intervention will consist in using the patient reported experiences and outcomes of safety in primary care (PREOS-PC) survey to gather patient-reported experiences and outcomes concerning the safety of the healthcare patients receive in their PHC centres, and feed that information back to the PHC professionals to help them identify opportunities for safer healthcare provision. The study will involve three stages. Stage 1 (developing the intervention) will involve: (i) qualitative study with 40 PHC providers to optimise the acceptability and perceived utility of the proposed intervention; (ii) Spanish translation, cross-cultural adaptation and validation of the PREOS-PC survey; (iii) developing the intervention components; and (iv) developing an online tool to electronically administrate PREOS-PC and automatically generate feedback reports to PHC centres. Stage 2 (piloting the intervention) will involve a 3-month feasibility (one group pre-post) study in

10 PHC centres (500 patients, 260 providers). Stage 3 (evaluating the intervention) will involve: (i) a 12-month, two-arm, two-level cluster randomised controlled trial (1248 PHC professionals within 48 PHC centres; with randomisation at the centre level in a 1:1 ratio) to evaluate the impact of the intervention on patient safety culture (primary outcome), patient-reported safety experiences and outcomes (using the PREOS-PC survey), and avoidable hospitalisations; (ii) qualitative study with 20 PHC providers to evaluate the acceptability and perceived utility of the intervention and identify implementation barriers.

ETHICS AND DISSEMINATION: The study was approved by the Ethics Committee of the Balearic Islands (CEI IB: 3686/18) with the 1964 Helsinki Declaration and its later amendments. The results will be disseminated in peer-reviewed publications and national and international conferences. TRIAL REGISTRATION NUMBER: NCT03837912; pre-results.

10. **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**

Ricci-Cabello I, Gangannagaripalli J, Mounce LTA, Valderas JM. *J Pat Safety.* **2020 Mar 13**; PMID: 32175959 DOI: 10.1097/PTS.0000000000000669. Online ahead of print.

https://journals.lww.com/journalpatientsafety/Abstract/9000/Identifying_Factors_Leading_to_Harm_in_English.99191.aspx

*ABSTRACT:*

OBJECTIVE: The aim of the study was 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 centers in England. A random sample of 6736 patients was invited to complete the Patient-Reported Experiences and Outcomes of Safety in Primary Care questionnaire. We fitted structural equation modeling on the quantitative data (n = 1244 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 ($\beta = 0.43$; 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 the following: 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-centered strategies to reduce harm in primary care focusing on the improvement of the quality of diagnosis and patient-provider communication.

11. **Patients' Perceptions of Safety in General Practice Captured Using an Online Patient Safety Questionnaire for Primary Care (PREOS-PC).**

Salema N., Gangannagaripalli J., Mounce L., Valderas J.M., Ricci-Cabello I., and Avery A. PRIMM (UK & Ireland)
31st Annual Scientific Meeting; 2020

*ABSTRACT:*

BACKGROUND: Patients are in a unique position to provide a perspective on patient safety through sharing their experiences of interacting with general practice. However, what has been lacking, especially in primary care, is comprehensive patient reported measures of patient safety.[1] In response to this, the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire was developed and piloted.[2] The latest developments include the design of two shortened, online versions of the questionnaire.

AIMS: To explore the feasibility and acceptability of using two online, shortened, versions of PREOS-PC questionnaire (Short-Form (6 items) and Compact (27 items) questionnaires) in general practice and to assess patients' views on their perception of safety within their general practices.

METHODS: Seventeen practices in the East Midlands and five in the South West of England registered with the PREOS-PC database and distributed questionnaires (Compact n=12 practices and Short-Form n=10 practices) to a random sample of their patients (18 years and over). A report summarising questionnaire responses was available to each practice to download in real-time. Study data were analysed using both quantitative and qualitative methods.

RESULTS: A total of 699 Compact and 900 Short-Form questionnaires were completed between January 2018 and May 2019. Questionnaire respondents were mainly white (96.3%) and 57.6% were female. High general perceptions of safety scores were recorded by patients completing both questionnaires. The results highlighted that patients were not as proactive as practices in instigating safety initiatives. The main areas of patient satisfaction noted included appointments, communication and staff attitudes/attributes. However, these issues were also highlighted as the main safety areas that could benefit from improvement by practices. Patients mentioned that some areas of safety identified as needing improvement were outside the control of individual practices and warranted policy changes to take place for safety at general practice to be realised.

CONCLUSION: The PREOS-PC questionnaire is an online tool that has been successfully used to give patients a platform to highlight areas of commendable safe practice but also suggest areas where improvements in safety could be considered by general practices. The potential contribution the PREOS-PC can make in the area of patient safety relies on practices engaging with the patient feedback to enact appropriate interventions for bringing about the necessary changes.