# Electronic Supplementary Material (ESM) 1

TITLE: Factors Contributing to Best Practices for Patient Involvement in Pharmacovigilance in Europe: A Stakeholder Analysis

Authors: Monica van Hoof [1,2], Katherine Chinchilla[1], Linda Härmark[1], Cristiano Matos[3], Pedro Inácio[4,] Florence van Hunsel[1]

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Strategy for the literature review research (PUBMED®)

| Search number | Search details | Number of results obtained |
|---|---|---|
| #1 | **(((patient involvement) OR (patient participation)) AND (pharmacovigilance)) NOT (clinical trials) Filters: from 2010 - 2021** | 126 |
| #2 | **((((patient involvement) OR (patient participation)) OR (patient engagement)) AND (pharmacovigilance)) NOT (research)** Filters: **from 2009 - 2021** | 66 |
| #3 | **(((((patient involvement) OR (patient participation)) OR (patient engagement)) AND (pharmacovigilance)) NOT (research)) AND (2009:2021[pdat])) AND ((((patient involvement) OR (patient participation)) AND (pharmacovigilance)) NOT (clinical trials) AND (2010:2021[pdat]))))** | 54 |

# Electronic Supplementary Material (ESM) 2

## TITLE: Factors Contributing to Best Practices for Patient Involvement in Pharmacovigilance in Europe: A Stakeholder Analysis

Authors: Monica van Hoof [1,2], Katherine Chinchilla[1], Linda Härmark[1], Cristiano Matos[3], Pedro Inácio[4], Florence van Hunsel[1]

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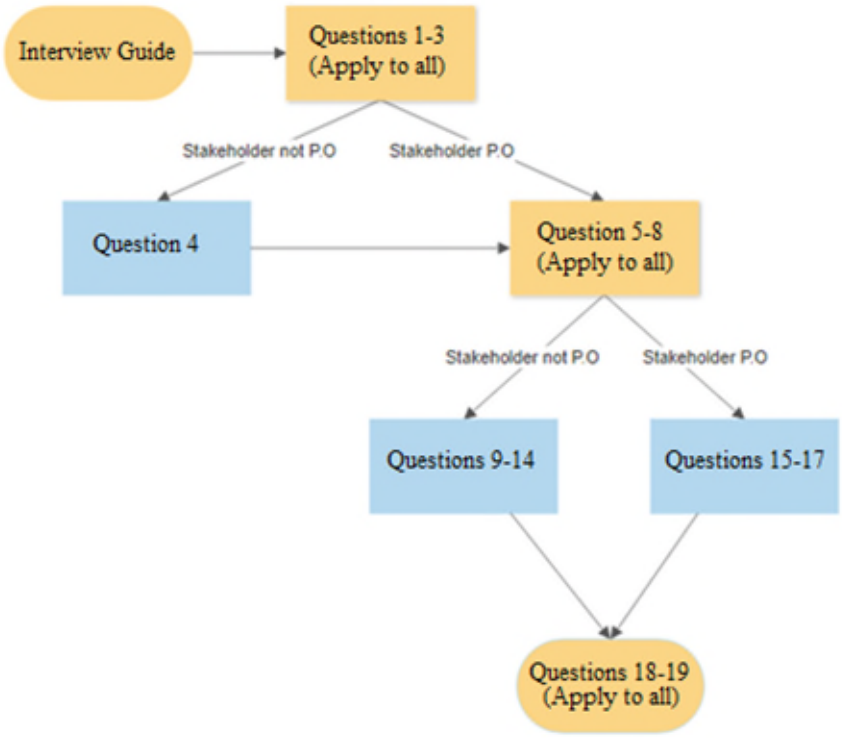
### Interview Questions

The interview starts with an introduction, that includes the name of the interviewer, the name of the organization supporting the research and a brief description of the objective and purpose of the study. The questionnaire contains 18 questions that are applied following the scheme below:



1) **Confirm name and position in the organization.**

   Help text: Also other personal information as age, time working in the position.

2) **How would you define patient involvement?**

   Help text: the idea is to find a definition

3) **Do you feel patient involvement is an important topic in pharmacovigilance? Why?**

4) **Can you mention the different areas where you involve patients in your organization and work?**

   Help text: This can include sits in the board, activities, the input of patients in different areas

5) **What type of patient involvement actions or activities do you consider to be ideal or most helpful and would like to do in the future?**

   Help text: For example public hearings, training sessions, podcasts, websites for sharing information, conferences, seminars, social media, newsletters.

6) **Could you elaborate in some projects or activities regarding patient involvement that your organization has developed or has been asked to participate in as a collaborator?**

7) **How has patient involvement affected your organization?**

   Help text:

8) **What are the benefits of involving patients in PV?**

   Help text: How does patient engagement impact the work that you do?

9) **While designing or organizing an activity in which patients are going to be involved do you seek for patients input?**

   If yes go to question 10 and 11, if no got to question 12

10) **In which stages of the designing do you seek for the input? Would you like to involve them earlier?**

11) **Do you think that patients are providing valuable input to those activities?**

12) **Would you consider involving patients in the design process of activities in the future?**

    Help text: Have there been any projects in the past that could have benefited from involving patients in the design process?

13) **How do you capture or receive feedback from patients on the activities and actions that seek to involve them?**

14) **How does this feedback from patients help improve activities in pharmacovigilance?**

15) **How does your organization feel about the activities that other stakeholders organize for your participation? Do you give any type of feedback about the activities that you are involved in?**

    Help text: Give examples of activities like public hearings, training sessions, podcasts, websites

for sharing information, conferences, seminars, social media, newsletters.

Do they feel heard and involved by them?

16) **What changes in the patient involvement activities and actions would you like to see in the future?**
17) **Which channels would be ideal for offering feedback in the future?**
18) **As part of this research we would like to include more people from the [regulatory/ MAH/ Patient Organization] area, we would appreciate if you could recommend us someone that you think would like to participate.**

# Electronic Supplementary Material (ESM) 3

## TITLE: Factors Contributing to Best Practices for Patient Involvement in Pharmacovigilance in Europe: A Stakeholder Analysis

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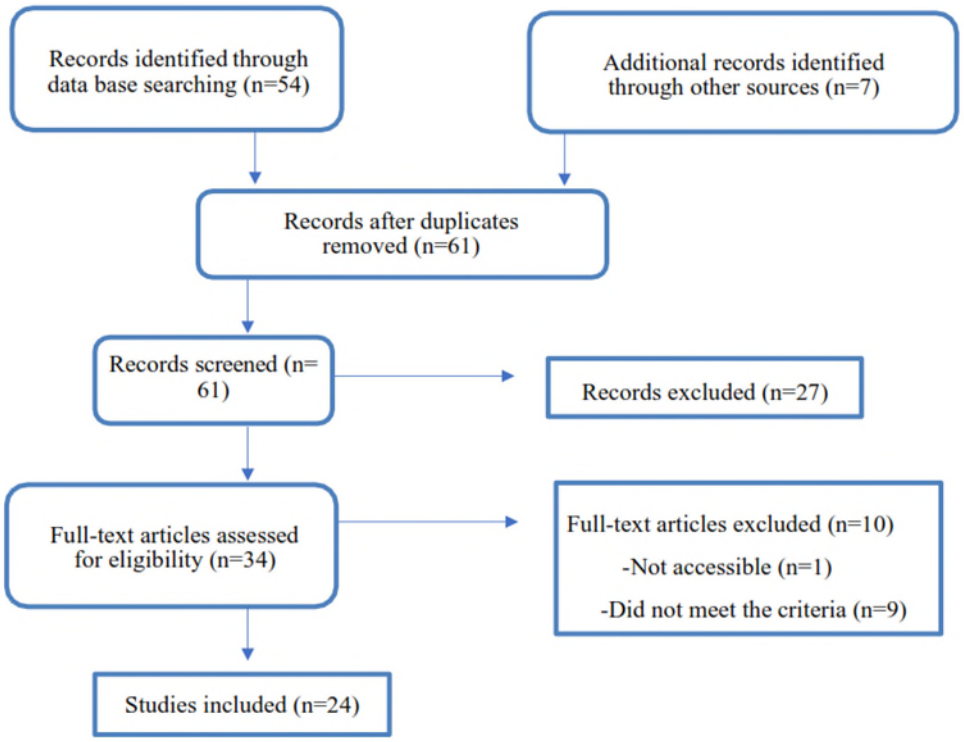


**Figure 1. Flowchart of included articles**

**Complete list of literature included in the literature review.**

Articles found through PubMed search


1. Adams SA. Using patient-reported experiences for pharmacovigilance? Stud Health Technol Inform. 2013;194:63-8.
2. Adisa R, Adeniyi OR, Fakeye TO. Knowledge, awareness, perception and reporting of experienced adverse drug reactions among outpatients in Nigeria. Int J Clin Pharm. 2019;41(4):1062-73.
3. Arlett P, Straus S, Rasi G. Pharmacovigilance 2030: Invited Commentary for the January 2020 "Futures" Edition of Clinical Pharmacology and Therapeutics. Clin Pharmacol Ther. 2020;107(1):89-91.
4. Benabdallah G, Benkirane R, Khattabi A, Edwards IR, Bencheikh RS. The involvement of Pharmacovigilance Centres in medication errors detection: a questionnaire-based analysis. Int J Risk Saf Med. 2011;23(1):17-29.
5. Borg JJ, Aislaitner G, Pirozynski M, Mifsud S. Strengthening and rationalizing pharmacovigilance in the EU: where is Europe heading to? A review of the new EU legislation on pharmacovigilance. Drug Saf. 2011;34(3):187-97.
6. Borg JJ, Tanti A, Kouvelas D, Lungu C, Pirozynski M, Serracino-Inglott A, et al. European Union pharmacovigilance capabilities: potential for the new legislation. Ther Adv Drug Saf. 2015;6(4):120-40.
7. Daban M, Lacroix C, Micallef J. Patients' organizations in rare diseases and involvement in drug information: Illustrations with LMC France, the French Association of Chronic Myeloid leukemia. Therapie. 2020;75(2):221-4.
8. Edwards IR, Graedon T. What do stakeholders think about pharmacovigilance? Drug Saf. 2010;33(8):619-21.
9. Esther Salgueiro M, Jimeno FJ, Aguirre C, García M, Ordóñez L, Manso G. [Direct reporting by patients of adverse drug reactions in Spain]. Farm Hosp. 2013;37(1):65-71.
10. Härmark L, van Hunsel F, Grundmark B. ADR Reporting by the General Public: Lessons Learnt from the Dutch and Swedish Systems. Drug Saf. 2015;38(4):337-47.
11. Matos C, Härmark L, van Hunsel F. Patient Reporting of Adverse Drug Reactions: An International Survey of National Competent Authorities' Views and Needs. Drug Saf. 2016;39(11):1105-16.
12. Matos C, Weits G, van Hunsel F. The Role of European Patient Organizations in Pharmacovigilance. Drug Saf. 2019;42(4):547-57.
13. Mavris M, Furia Helms A, Bere N. Engaging patients in medicines regulation: a tale of two agencies. Nat Rev Drug Discov. 2019;18(12):885-6.
14. Steurbaut S, Hanssens Y. Pharmacovigilance: empowering healthcare professionals and patients. Int J Clin Pharm. 2014;36(5):859-62.
15. Tejus A, Mathur AG, Vishnuprasad R, Singh A, Pradhan S. An observational study to assess the possibility of patient participation in implementing pharmacovigilance in a busy tertiary care hospital. Med J Armed Forces India. 2020;76(4):425-9.
16. van Hunsel F, de Waal S, Härmark L. The contribution of direct patient reported ADRs to drug safety signals in the Netherlands from 2010 to 2015. Pharmacoepidemiol Drug Saf. 2017;26(8):977-83.
17. van Hunsel F, Härmark L, Rolfes L. Fifteen years of patient reporting -what have we learned and where are we heading to? Expert Opin Drug Saf. 2019;18(6):477-84.


Record found through reference checks


1. European Medicines Agency. Summary EMA public hearing valproate pregnancy (2017).

2. Brown P, Bahri P. 'Engagement' of patients and healthcare professionals in regulatory pharmacovigilance: establishing a conceptual and methodological framework. Eur J Clin Pharmacol. 2019;75(9):1181-92.
3. Inacio P, Cavaco A, Allan E, Airaksinen M. Key pharmacovigilance stakeholders' experiences of direct patient reporting of adverse drug reactions and their prospects of future development in the European Union. Public Health. 2018;155:119-28.
4. Pal SN, Duncombe C, Falzon D, Olsson S. WHO strategy for collecting safety data in public health programmes: complementing spontaneous reporting systems. Drug Saf. 2013;36(2):75-81.
5. Smith MY, Benattia I. The Patient's Voice in Pharmacovigilance: Pragmatic Approaches to Building a Patient-Centric Drug Safety Organization. Drug Saf. 2016;39(9):779-85.
6. Watson S, Chandler RE, Taavola H, Harmark L, Grundmark B, Zekarias A, et al. Safety Concerns Reported by Patients Identified in a Collaborative Signal Detection Workshop using VigiBase: Results and Reflections from Lareb and Uppsala Monitoring Centre. Drug Saf. 2018;41(2):203-12.
7. Matos C, van Hunsel F, Tavares Ribeiro R, Nascimento do Ó D, Raposo JF. Diabetes patient’s pharmacovigilance knowledge and risk perception: the influence of being part of a patient organisation. Therapeutic Advances in Drug Safety. 2020;11:2042098620953935.