International Society of Pharmacovigilance

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ISoP Mid-Year Symposium 2024

June 3-4, Barcelona (Spain)

The value of real-world data for ensuring patient safety

Speakers Abstracts Presentations

Day 1 - Monday 3 June
Session 2

Stefania Spila-Alegiani and Marco Massari
National Institute of Health (Italy)

#40 - Abstract Title: TheShinISS-Vax: post-marketing active surveillance of the safety of COVID-19 and influenza vaccines in Italy

Introduction:
The Istituto Superiore di Sanità (ISS-Italian National Institute of Health) and the Italian Medicines Agency coordinate TheShinISS-Vax, a nationwide post-marketing active surveillance of the safety of COVID-19 and influenza vaccines [1-3].

Objective:
The purpose of TheShinISS-Vax surveillance is to examine the association between vaccines and potential adverse events requiring hospital admission or emergency care.

Methods:
To process data routinely collected from regional healthcare registries, TheShinISS-Vax uses TheShinISS, an R-based open-source statistical tool developed by researchers from the ISS [4]. TheShinISS tool, once tailored to the objectives of the study, enables distributed analyses according to a study-specific Common Data Model strategy and ensures the reproducibility of the creation of local analytical datasets; the tool is currently maintained and customized by the "TheShinISS Network", which includes researchers from ISS and other Italian public and academic research groups. The ShinISS-Vax surveillance uses the Self-Controlled Case Series (SCCS) design, which is the appropriate methodology to evaluate the safety of vaccines [5,6]. This approach requires information only from individuals with the specific event, automatically making allowance for multiplicative time-invariant confounders, even when they remain unmeasured or unknown.

Results:
Over the last years, a number of safety studies have been conducted within the framework of TheShinISS-Vax, investigating the association between COVID-19 [1,2] and influenza vaccines [3] and various events of interest, such as myocarditis/pericarditis, Guillain-Barré syndrome.

Conclusion:
Continuous monitoring of suspected adverse events is a crucial element of any vaccination program. TheShinISS-Vax surveillance aims to support regulators, health professionals, and clinical guideline developers in the risk-benefit evaluations of vaccines.

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Judit Riera-Arnau
University Medical Center Utrecht (UMCU)(Netherlands)

#55-Abstract Title: A way towards reliable research: mapping data quality assessments in multi-database pharmacoepidemiologic studies

Introduction:
Real-world data studies have become increasingly important as they can provide valuable insights into medications' safety and effectiveness. However, data quality remains to be one of the biggest challenges. Several authors and networks have proposed a set of data quality assessments (DQA) to be made when carrying out multi-database studies[1,2,3,4].

Objectives:
Our aim was to 1) map existing DQA for multi-databases pharmacoepidemiologic studies (MDPES) and 2) to evaluate its reporting frequency in MDPES.

Methods:
We searched PubMed and grey literature for publications from September-2016 to July-2023, since this is when Kahn et al published one of the firsts DQA proposals[5]. The search string included terms like "medications", "pharmacoepidemiology", "multidatabase" or "healthcare records". Trials or primary data collection studies were excluded. Three review rounds were performed using the machine learning software ASReview using different learning models (naive Bayes, logistic regression and neural networks). Due to the huge amount of literature, a text-mining app (SysKey) was created and validated to detect MDPES including DQA information. We established the ≥80% PPV (positive predictive value) as a goal. We extracted information on 1) DQA dimensions and subdimensions which definitions and synonyms were previously mapped, 2) DQ frameworks, and 3) if a Common Data Model conversion was applied.

Results:

Out of 16087 identified papers, we found 543 MDPES. SysKey validation was achieved (87% PPV). Eleven main dimensions were encountered and mapped (see Table). Reliability and coherence were the most comprehensive dimensions by including I) precision, accuracy or correctness, assumption requirements of data, data provenance, concordance and plausibility subdimensions, and II) structure, format, semantic, relational, uniqueness or redundancy, and conformance subdimensions, respectively. Most reported DQA refer to verification (quality within a dataset) instead of validation (across datasets). Fit-for-purpose assessments are also scarce. Extensiveness is the most reported dimension in PDES, while computational-related assessments are well-defined in the reference frameworks and literature about specific database processes, but usually not reported in the MDPES publication. Temporal DQA assessment is rare for every dimension. The authors tend to use synonymous terms, but also homonyms, which creates difficulties when interpreting the DQA performed.

Conclusions:

Adherence to standard definitions for DQA dimensions and subdimensions with a uniform terminology are needed[6], as well as for their categorization. Also, uniform terminology is required to be more comprehensive. Finally, a consensus and guidance on DQA to be required and reported when performing MDPES, especially when such are used for drug safety decisions.

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Table: Data quality assessment (DQA) dimensions, their mapped synonym terms, and definitions

DQA DIMENSION	DEFINITION
Assessment of Extensiveness includes completeness and coverage	It relates to the amount of data available, how much data do we have, how sufficient the data are to represent our population. It includes completeness and coverage.
Assessment of Reliability: includes precision, accuracy/correctness, assumptions, concordance, plausibility and traceability/data lineage/transparency	How closely the data reflects what they are designed to measure, to what degree are data corresponding to reality, how trustworthy data are. It includes precision, accuracy and plausibility.

Assessment of Coherence/Consistency: includes format, semantic, structural/relational, uniqueness/redundancy and conformance	Expresses how different parts of an overall datasets are consistent in their representation and meaning. Is the format of values the same across the dataset, an ID is properly linked across parts of the dataset, are data analysable. It includes format coherence, structural/relational coherence, semantic coherence, uniqueness and conformance.
Assessment of Timeliness: includes currency and lateness	Availability of data at the right time for the study. How closely the data reflects the reality at the time it intends to measure. Considers the average time of updates in a database and the last update of a database. It includes currency and lateness.
Assessment of Relevance	Is defined to the extent to which a dataset presents data elements useful to answer a research question. Does the dataset present the kind of values that we need to address a specific question? How closely the data reflects the aspects of reality that we intend to measure. Relevance depends on the domain of study.
Assessment of Validity or Benchmarking	Is the reference model/population/system/setting specific to the dataset being assessed? It includes internal (intrinsic characteristics of the data per se) and external (objective/target/context of its appliance) validity, which strongly overlaps with some of the previous items. However, some studies may report it as an independent concept.
Assessment of usability/accessibility, maintainability or ease-of-use of data	Degree to which data can be accessed and used and the degree to which data can be updated, maintained, and managed.
Assessment of security and/or governance	Personal data is not corrupted, and access suitably controlled to ensure privacy and confidentiality. Set of practices for making decisions about data and for managing data throughout its lifecycle to optimize the organization's capability to use data to generate information that informs policy, strategy, and operational management. Rules and norms that shape roles and responsibilities, incentives and interactions in the health sector.
Other dimensions	• Assessment of flexibility, interoperability or adaptability of data • Assessment of interpretability or understandability of data • Assessment of data degradation or information loss, decay, corruptibility

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Session 3

Vaishali Patadia
AMGEN (USA)
#7- Abstract title: Using Real-World Data (RWD) for Rapid Safety Signal Assessment

Introduction:
Signal assessments in patient safety can benefit from real-world data (RWD) but conducting RWD analyses with fully-specified protocols can be time-consuming and resource-intensive, making it challenging to complete within the timeframes typically required by regulatory agencies. In 2022, the TransCelerate BioPharma Rapid Signal Assessment Using RWD (RSA-RWD) Initiative was formed to find ways to overcome these challenges. The team gathered current-state information through a literature review and a questionnaire to member companies, which showed the potential value of a well-defined framework to help enable the incorporation of rapid analyses of RWD into signal assessments.
Objective:
To develop a framework for using RWD to support the rapid analyses of safety signal assessments while maintaining quality, rigor, and robustness of evidence generation.
Methods:
A targeted literature review was conducted to identify opportunities to expedite RWD analyses and organize the process into steps. The team developed a three-stage framework for rapid use RWD for signal assessment that includes (1) problem formulation, planning, and design; (2) analysis execution; and (3) results interpretation and communication. The framework also provides a glossary, an alternative-to-full-protocol template and four use cases.
Results:
The RSA-RWD Framework is a practical resource for cross-functional safety teams who want to leverage rapid use of RWD as part of a safety signal assessment. The framework offers guidance on how to clearly formulate a research question, identify data sources, develop and approve a protocol or rapid data analysis plan, execute the analysis, interpret results, and communicate findings. The framework also highlights the opportunities to increase rapidity in each step, while maintaining quality, rigor, and robustness.
Conclusion:
The RSA-RWD Framework is a novel contribution to pharmacovigilance that provides an end-to-end process map for using RWD rapidly during safety signal assessments. The framework can help crossfunctional safety teams generate RWD evidence that is timely, relevant, and reliable for regulatory decision-making and patient safety.

María Sáinz Gil
Universidad de Valladolid (Spain)
#51-Abstract title : Antipsychotics and risk of relevant weight gain in naïve patients: a nested Case-Control study from the ICARO study

Introduction:
Antipsychotics are used for many different psychiatric and neurological disorders in all age groups. One of their adverse effects is weight gain, which contributes to cardiovascular risk, reduced quality of life and leads to non-adherence [1,2,3].
Objective:
To analyse the risks of different antipsychotic drugs on clinically relevant weight gain in ordinary conditions of treatment, as well as associated risk factors, including genetics.

Methods:
A nested case-control study in Spanish population was carried out. Inclusion criteria: age > 14 years, ≤ 1 month of first antipsychotic treatment. Patients with severe obesity were excluded. Interviews were performed at 0, 3 and 6 months; blood samples were taken for genotyping. Cases were patients who gained ≥ 7% of their baseline weight at 6 months. The remaining patients served as controls. Patients receiving antipsychotic treatment for at least 3 weeks were considered exposed. Potential confounders examined were age, baseline BMI, educational level, cardiovascular disease, and dementia indication.
Results. Of the 181 patients included, 30.4% were cases. The OR_{adj} (95%CI) obtained were: amisulpride, 9.41 (0.80-110.27); risperidone, 3.59 (1.36-9.51); olanzapine, 3.17 (1.18-8.52); aripiprazole, 2.45 (0.88-6.79) and paliperidone, 2.29 (0.61-8.62). Age would be a protective factor with an OR of 0.14 (0.03-0.73). Only 137 patients completed the genetic study. The presence of allele G (CG or GG) of rs7566605, INSIG2 gene shows an OR (95%CI) of 0.33 (0.11-0.96) and the C allele (CT or CC) of rs1049353, CNR1 gene shows an OR of 2.43 (1.07-5.53).
Conclusions:
Most patients starting antipsychotic treatment gain weight after 6 months. Three out of ten patients gained significant weight. The highest risk is observed for olanzapine and risperidone. A larger sample would be needed to establish a statistically significant risk for amisulpride, aripiprazole and paliperidone, which appear to be very high. Sex, living with others, employment status, metabolic disorders, tumours, relevant surgery, hospital admissions, dementia or family history of obesity do not seem to influence weight gain. Age is the most important confounding variable, inversely related to weight gain, and should be analysed as a modifier of this effect. The presence of allele G (CG or GG) of rs7566605, INSIG2 gene, seems to be associated with a lower risk of a relevant weight gain. The variant C allele (CT or CC) of rs1049353, CNR1 gene, seems to be associated with a higher risk.
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Session 4

Wed AlGhannam
Saudi Food and Drug Authority (Saudi Arabia)
#17- Abstract title: Integrating Risk Minimization Measures of Medications into Hospital Information Systems: Insights from three Hospitals in Saudi Arabia

Background:
Additional risk minimization measures (aRMMs) are required for certain medications. These measures often consist of educational materials, such as printed brochures or alert cards, that inform healthcare professionals and patients on the key risks associated with the medication and actions necessary to minimize them. In Saudi Arabia, these materials are distributed through various channels, including printed dissemination or through e-mail. Here, we present an exploration of a regulatory initiative aimed at integrating medications' aRMMs into the Hospital Information

System (HIS) in hospitals. The objective of this initiative is to enhance patient safety and improve the accessibility of aRMMs by directly incorporating them into Electronic Health Record (EHR) systems.

Objective:

To describe the collaborative initiative between the SFDA and three hospitals in Saudi Arabia to enhance awareness of risk minimization measures by integrating them into the HIS.

Methods:

We included all hospitals that participated in this regulatory initiative in Saudi Arabia and successfully integrated some or all of the approved additional risk minimization measures into their information systems.

Results:

Three hospitals have completed the incorporation of additional risk minimization measures into their internal HIS. In a tertiary care hospital in Riyadh, a dedicated portal has been developed to consolidate all aRMM information. This portal is seamlessly linked with the Electronic Healthcare Record (EHR) system, allowing prescribers to access aRMM details at the point of medication prescription. Upon prescribing a medication, an alert is generated and sent to the prescriber's email, notifying them that aRMM are applied to the prescribed medication. Simultaneously, a text message is sent to the patient, providing a direct link to educational material associated with the aRMM.

Furthermore, another tertiary care hospital in Riyadh incorporated aRMMs for Janus Kinase Inhibitors (Tofacitinib and Upadacitinib) into their EHR system. Instructions are displayed in the electronic system to the prescriber, along with the patients' materials. Additionally, a tertiary hospital located in Dhahran effectively integrated aRMMs by implementing prescribing alerts. Prescribers were required to acknowledge mandatory pop-up alerts when prescribing medications associated with aRMMs, ensuring their awareness and compliance with the risk minimization measures.

Conclusion:

The successful incorporation of aRMMs in the examined hospitals presents a promising framework that can be applied to other healthcare institutions, potentially yielding benefits in terms of patient safety and healthcare provider awareness. Nevertheless, the assessment of the impact of these digitalized measures on adverse reaction reduction and patient safety outcomes necessitates further research.

Margarida Perdigão
University of Evora (Portugal)

#25- Abstract title: Analysis of the teaching-learning process of pharmacovigilance in Portugal

Introduction:

Pharmacovigilance stands out for its importance in patient safety and should be recognized as a continuous line of study[1]. Professionals must have a differentiated training that allows them to perform their pharmacovigilant functions in the simplest, most intuitive, and rigorous way possible[2]. The under-reporting that persists can be filled through continuous professional development programs, reinforcing theoretical and practical knowledge in curricular plans of health courses[3].

Objective:

To describe and characterize the teaching-learning process of pharmacovigilance in Portugal, through the analysis of curricular content of university healthcare courses in order to identify contents related to pharmacovigilance, and the application of an online questionnaire to students and healthcare professionals.

Methods:

A mixed analysis method was used, composed by a direct analysis (spread of an online questionnaire on social media based on a non-probabilistic technique, referred to as snowball, and also via e-mail to several institutional contacts and student's nucleus); and by indirect analysis (through an explicit revision of the curricular plan in the health degrees by keywords searching in the course plans).

Results:

In total, 93 curricular unit forms of the 17 healthcare courses included were analyzed - only 3 refer to pharmacovigilance as mandatory and 39 do not address any keywords.

The questionnaire applied was answered by 650 participants - students (62%) and professionals (38%). Only 24.6% of the students and 17.8% of professionals refer the existence of a specific course contents dedicated to pharmacovigilance in their degrees. Of these, 81.9% of the students revealed having heard about pharmacovigilance, and 70.7% of the students, as well as 78.1% of the professionals fully agree that this subject should be part of their curricular plans. Most students and professionals showed interest on the integration of pharmacovigilance in the academic curriculum of the healthcare courses and in the on-going training plans of health professionals. The majority totally agreed that pharmacovigilance adds value to their practical application on a professional context and claims to feel more motivated to report suspected adverse reaction, if taught.

Conclusion:

In view of these results, since there are few institutions teaching programmatic contents regarding the pharmacovigilance in the different healthcare courses and given the questionnaire results, it's evident the need of a wider reflection regarding further training and constant update of practicing professionals as wells as in the diverse health institutions, investing in the creation of an academic curriculum that integrates pharmacovigilance in healthcare courses.

References/Further sources of information:

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Day 2- Tuesday 4 June
Session 7

Emiliano Cappello
University of Pisa (Italy)

#43- Abstract Title: Integrating spontaneous reporting with real world data for signal detection processing: the example of acquired haemophilia A and COVID-19 Vaccines

BACKGROUND:

Acquired hemophilia A (AHA) is a rare autoimmune blood disorder marked by spontaneous bleeding, occurring at an estimated rate of around 1.5 incident cases per million individuals annually[1]. In 2021, an unusual and unexpected number of AHA diagnoses temporally related to COVID-19 vaccination was reported (17 cases per million inhabitants/year in the province of Reggio Emilia in

Italy)[2,3].

OBJECTIVE:

To present a comprehensive signal detection analysis by combining quantitative and qualitative assessments of spontaneous reporting databases with an ecological study utilizing administrative health data from Tuscany, Italy.

METHODS:

First, we performed a disproportionality analysis on the World Health Organization spontaneous reporting database (VigiBase®) by calculating the information component (IC), examining all COVID-19 vaccines collectively and individually. Additionally, to assess clinical plausibility, we conducted a qualitative review of AHA reports associated with any COVID-19 vaccine in Vigibase®, alongside data from the FDA's Vaccine Adverse Events Reporting System (VAERS) and medical literature[4]. Subsequently, we conducted an ecological study utilizing population health data from Tuscany, sourced from the Agenzia Regionale di Sanità della Toscana, a regional administrative data repository. Patients were included for each year from 2017 to 2021. Temporal trends in the annual incidence of potential AHA cases and tested AHA patients were observed. Rates of potential AHA cases were computed for patients tested for AHA in 2021 and the period spanning 2017-2019, respectively[5].

RESULTS:

We identified 150 suspected cases of AHA linked to COVID-19 vaccines in Vigibase®. Disproportionality analysis indicated a significant confidence interval (CI) for the term "acquired hemophilia" concerning all COVID-19 vaccines (IC:1.3;IC025:1.1) and the BNT162b2 vaccine (IC:1.9;IC025:1.6). Of these cases, 96 underwent qualitative evaluation, with no alternative causes found besides immunization. In Tuscany during 2021, the standardized incidence rates for potential AHA cases (5.6/million subjects/year;95%CI=3.4–8.7) and tested AHA patients (60.7/1,000 subjects/year;95%CI=60.4–60.9) did not surpass those of previous years. The standardized rate of potential AHA cases per tested AHA patients was 9.2/100,000 (95%CI=5.6–14.3) in 2021 and 12.5/100,000 (95%CI=8.2–18.1) during the 2017–2019 period.

CONCLUSION:

The disproportionality analysis indicated a significant association between COVID-19 vaccines and AHA reporting, and several high-quality reports of AHAs with no other apparent causes related to COVID-19 immunization were found. However, the examination of administrative data from Tuscany did not support the hypothesis of an increase in AHA cases during the COVID-19 vaccination campaign. These findings highlight the importance of health databases in promptly confirming or refuting risk signals identified through spontaneous reporting data.

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Rana Jajou
The Netherlands Pharmacovigilance Lareb

#11- Abstract title: GP consultations for menstrual disorders after COVID-19 - a self-controlled cohort study based on routine healthcare data from the Netherlands

Introduction:
Several studies described that COVID-19 vaccinations can cause menstrual disorders [1,2]. However, it is not well known whether this also resulted in more General Practitioner (GP) consultations for menstrual disorders after COVID-19 vaccination.

Objective:
The primary aim of this study is to analyse whether there is an increase in GP consultations for menstrual disorders after COVID-19 vaccinations. Secondary aims are to determine risk factors and risk groups with increased GP consultations for menstrual disorders after COVID-19 vaccinations.

Methods:
A self-controlled cohort study was performed including vaccinated women aged 12-49 years from two large, representative GP databases in the Netherlands (Nivel Primary Care Database and PHARMO GP database). Women were excluded if they consulted the GP for a menstrual disorder in the six months before cohort-entry date (January 1, 2021), if no data was available in the six months before cohortentry, or if they had been diagnosed with postmenopausal bleeding. All included women were followed from cohort-entry date until the GP was consulted for a menstrual disorder in 2021, until deregistration at the GP practice in 2021, or until December 31, 2021 was reached, whichever cohort-exit date came first. The follow-up period is defined as the time between the cohort entry date and cohort-exit date. The exposed period was set at maximum six months after each COVID-19 vaccination and the nonexposed period was defined as the follow-up period minus the exposed period. Incidence rates and incidence rate ratio's (IRR) were calculated using Poisson regression, adjusting for SARS-CoV-2 infection. P-values < 0.05 were considered statistically significant.

Results:
The cohort included 631.802 women, of which 18.986 (3%) consulted the GP for a menstrual disorder.
Increased risks were observed among 12-14-year olds for amenorrhea/hypomenorrhea/oligomenorrhea
(IRR: 1.85, 95% CI: 1.30-2.65) and irregular/frequent menstruation (IRR: 1.33, 95% CI: 1.06-1.69) after COVID-19 vaccination in general, and after Pfizer/BioNTech vaccination (IRR: 1.87, 95% CI: 1.31-2.67 for amenorrhea/hypomenorrhea/oligomenorrhea and IRR: 1.35, 95% CI: 1.06-1.70 for irregular/frequent menstruation). No increased risks were observed for older age groups, other vaccine brands, and potential risk groups.

Conclusion:
For the majority of women, no increased risk of consulting the GP for menstrual disorders was found.
Solely for the youngest age group an increased risk of GP consultation for specific types of menstrual disorders was found. It is possible that older age groups perceive menstrual disorders as less serious and therefore did not actively seek medical help.

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ISoP Mid-Year Symposium 2024

June 3-4, Barcelona (Spain)

The value of real-world data for ensuring patient safety

List of Abstracts Presentations

Abstract No	Author(s)	Affiliation(s)	Title
#7	V. Patadia[1], N. Golchin[2], R. McDermott[3]	[1]Global Patient Safety, Amgen, Thousand Oaks, CA, USA, vpatadia@amgen.com [2]Epidemiology Strategy, Bristol Myers Squibb, Seattle WA, USA [3]Patient Safety, Shionogi B.V., London, UK	Using Real-World Data (RWD) for Rapid Safety Signal Assessment
#11	R. Jajou[1], T. Lieber[1], E. van Puijenbroek[1], E. Mulder[1], J. Overbeek[2], K. Hek[3], F. van Hunsel[1], A. Kant[1]	[1]Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands, r.jajou@lareb.nl [2]PHARMO Institute, Utrecht, The Netherlands [3]Nivel (Netherlands Institute for Health Services Research), Utrecht, The Netherlands	GP consultations for menstrual disorders after COVID-19 vaccination – a self-controlled cohort study based on routine healthcare data from the Netherlands
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#25	M. Perdigão[1,2], A. Afonso[3,4], S.Oliveira-Martins[2,5], M.J. Lopes[1,2,6] & A.M. Advinha[1,2,7]	[1]University of Évora, Pharmacovigilance Regional Unit of the Central and North Alentejo, Évora, Portugal, margarida.perdigao@uevora.pt [2]CHRC – Comprehensive Health Research Centre, Évora, Portugal [3]University of Évora, School of Sciences and Technology, Department of Mathematics, Évora, Portugal [4]Research Center for Mathematics and Applications – CIMA, Évora, Portugal [5]Faculty of Pharmacy of the University of Lisbon, Lisbon, Portugal [6]University of Évora, School of Nursing S. João de Deus, Department of Nursing, Évora, Portugal. [7]University of Évora, School of Health and Human Development, Department of Health and Medical Sciences, Évora, Portugal	Analysis of the teaching-learning process of pharmacovigilance in Portugal

#40	S. Spila-Alegiani,[1] & M. Massari,[1] C. Morciano,[1] M. Cutillo,[1] R. Da Cas,[1] G. Marano,[1] I. Ippoliti,[1] F. Mayer,[1] F. Menniti-Ippolito[1]	[1]National Centre for Drug Research and Evaluation, Istituto Superiore di Sanità (National Institute of Health), Rome, Italy, marco.massari@iss.it, stefania.spila@iss.it	TheShinISS-Vax: post-marketing active surveillance of the safety of COVID-19 and influenza vaccines in Italy
#43	E Cappello[1], I Convertino[1], Marco Bonaso[1], S Ferraro[1], M Franchini[2], U Moretti[3], D Focosi[4], G Roberto[5], O Paoletti[5], G Hyeraci[5], R Gini[5], M Tuccori[6].	[1]Unit of Pharmacology and Pharmacovigilance, Department of Clinical and Experimental Medicine, University of Pisa, Italy, emilianocappello@gmail.com [2]Division of Transfusion Medicine, Carlo Poma Hospital, Mantua, Italy [3]Section of Pharmacology, Department of Diagnostics and Public Health, University of Verona, Verona, Italy [4]North-Western Tuscany Blood Bank, Pisa University Hospital, Pisa, Italy [5]Epidemiology unit, Agenzia Regionale di Sanità della Toscana, Florence, Italy [6]Unit of Adverse Drug Reaction Monitoring – University Hospital of Pisa, Italy	Integrating spontaneous reporting with real world data for signal detection processing: the example of acquired haemophilia A and COVID-19 Vaccines
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#55	J. Riera-Arnau[1,2], C. Andaur Navarro[1], V. Hoxhaj[1], M. Sturkenboom[1], O. Klungel[3], S. Abtahi[3]	[1]Department of Datascience and Biostatistics, Julius Center for Health Sciences and Primary Health, University Medical Center Utrecht, Utrecht, Netherlands, j.rieraarnau@umcutrecht.nl [2]Clinical Pharmacology Department, Hospital Universitari de la Vall d'Hebron, Universitat Autònoma de Barcelona (UAB), Barcelona, Spain [3]Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University (UU), David de Wiedgebouw, Universiteitsweg 99, 3584 CG, Utrecht, The Netherlands	A way towards reliable research: mapping data quality assessments in multi-database pharmacoepidemiologic studies