

International Medication Safety Update



International Medication Safety Update

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2022-2023 ISMP International Medication Safety Management Fellow
Supported by Novartis, Name Creation & Regulatory Strategy

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Topics

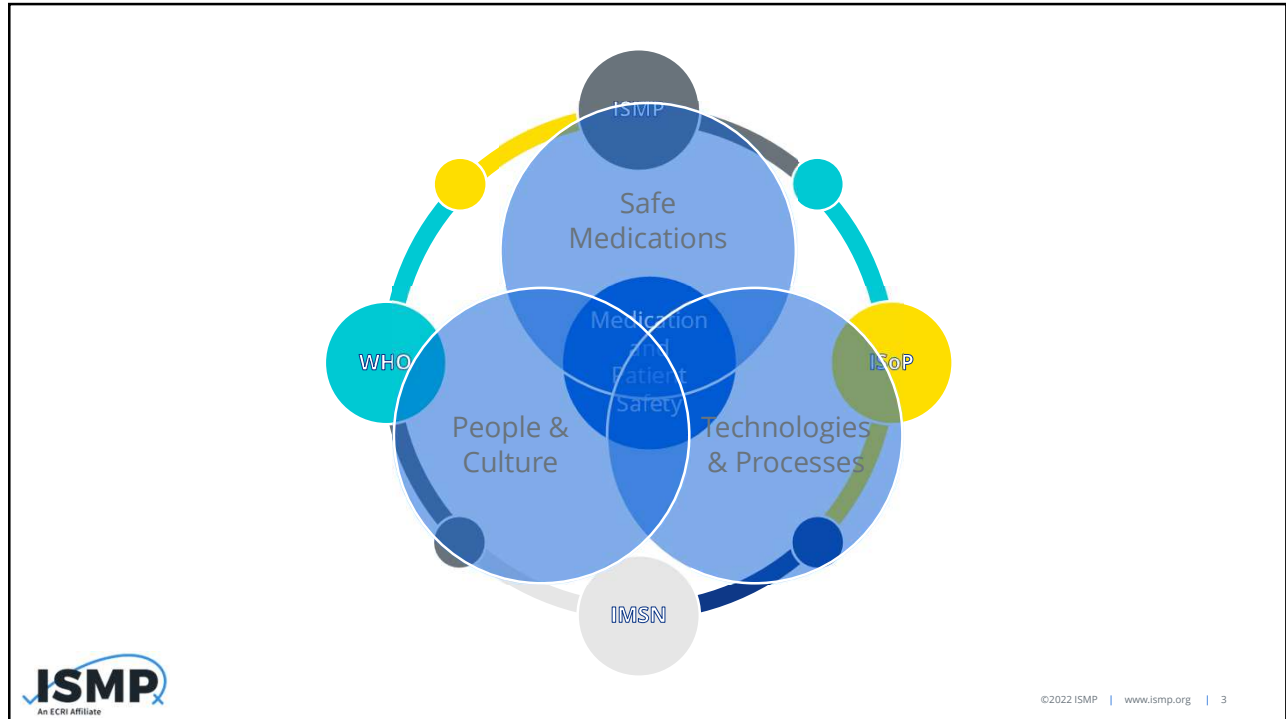
- International interactions
- International Medication Safety Network (IMSN)
- International Society of Pharmacovigilance (ISoP)
- World Health Organization (WHO)
 - Uppsala Monitoring Centre (UMC)
 - The Council for International Organizations of Medical Sciences (CIOMS)



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Core Concept

"Those that fail to learn from history are doomed to repeat it."

-Winston Churchill

- Errors are almost never unique to an individual practitioner, patient care unit, hospital, or country
- Only through open and just communication of medication errors can we learn from one-another, share best practices, and advance patient safety on a global scale



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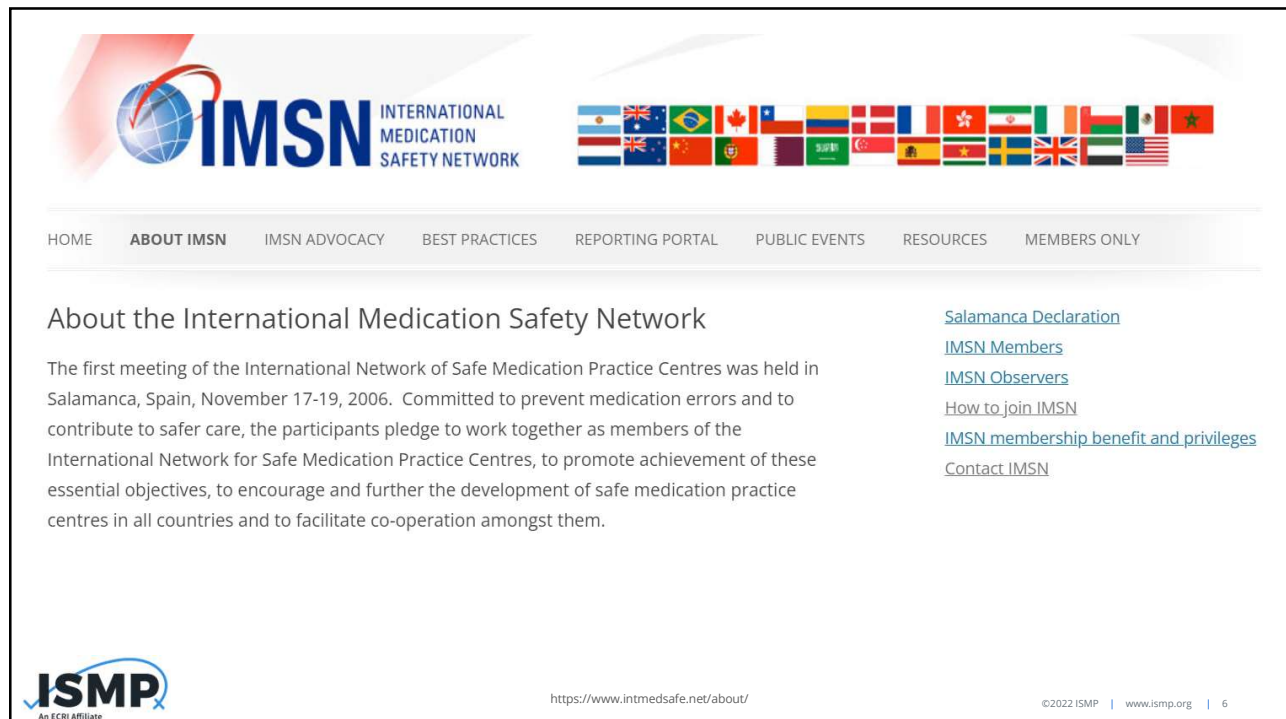
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Balancing recommendations with capabilities



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IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

HOME ABOUT IMSN IMSN ADVOCACY BEST PRACTICES REPORTING PORTAL PUBLIC EVENTS RESOURCES MEMBERS ONLY

About the International Medication Safety Network

The first meeting of the International Network of Safe Medication Practice Centres was held in Salamanca, Spain, November 17-19, 2006. Committed to prevent medication errors and to contribute to safer care, the participants pledge to work together as members of the International Network for Safe Medication Practice Centres, to promote achievement of these essential objectives, to encourage and further the development of safe medication practice centres in all countries and to facilitate co-operation amongst them.

[Salamanca Declaration](#)
[IMSN Members](#)
[IMSN Observers](#)
[How to join IMSN](#)
[IMSN membership benefit and privileges](#)
[Contact IMSN](#)

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<https://www.intmedsafe.net/about/>

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IMSN Membership and Partners

- Currently 25 member countries
 - Mixture of national regulatory agencies and non-profit safety organizations
- European Medicines Agency, US Food & Drug Administration
- Observers: UMC, WHO
- Industry Associates: Baxter, Novartis, Pfizer



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Global Targeted Medication Safety Best Practices

1. Remove potassium chloride concentrate injection from drug storage areas on all inpatient nursing units/wards
2. Prepare and dispense vinca alkaloids in a minibag, never in a syringe
3. Prevent inadvertent daily dosing of methotrexate for non-oncologic conditions
4. Prevent errors related to improper preparation of 2-component vaccines



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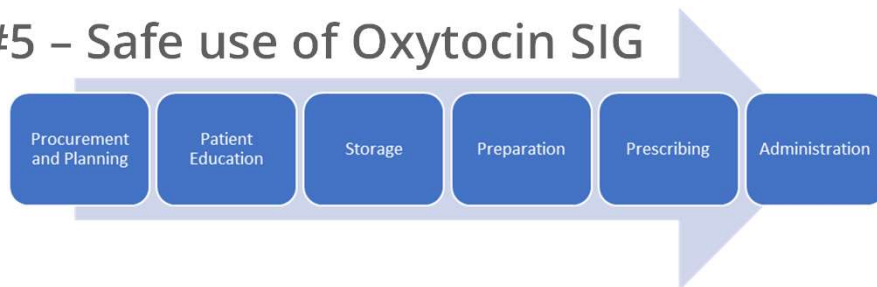
GTMSBP #5 – Safe use of Oxytocin SIG

- Working on compiling global safe practices surrounding the use of oxytocin during labor and delivery
- Working with representatives from around the world to identify common, and unique, issues surrounding the use of this high-risk medication.
 - Presentations provided by USA, Canada, UMC, France, Singapore, Saudi Arabia and (coming soon) NHS and Saudi Arabia part 2
- Identifying safety enhancements at every stage of the medication-use system, from prescribing to administration and including the patient as well.



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GTMSBP #5 – Safe use of Oxytocin SIG



- **Synto**cin or **Synto**metrine?
- Oxytocin or Ondansetron?
- Pharmacy v. Nursing preparation



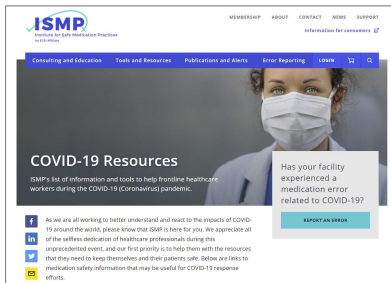
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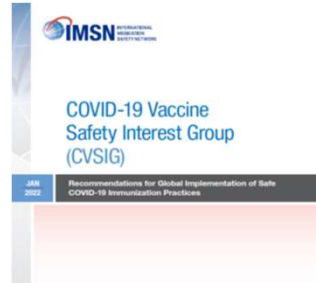
Global Safety Initiatives

ISMP in collaboration with the International Medication Safety Network (IMSN), with participation from members of ISO P

- **IMSN COVID-19 Vaccine Safety Interest Group Recommendations for Global Implementation of Safe COVID-19 Immunization Practices**



<https://www.ismp.org/covid-19-resources>



<https://www.intmedsafe.net/imsn-cvsig-issues-recommendations-for-global-implementation-of-safe-covid-19-immunization-practices/>

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IMSN Annual Meeting

- November 14th and 15th (Virtual)
- Updates from member countries
- Included presenters from SwissMedic, WHO, ISO P, UMC (Uppsala Monitoring Centre), Saudi FDA, and the United States FDA



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Noteworthy Notables

- Hong Kong
 - Improving warfarin safety
- New Zealand
 - Issues with lack of regulations enabling formalized medication error reporting
- ISMP Canada
 - Working on labelling improvements for mineral supplements
 - Emerging issues with compounding of commercially available products due to shortages
 - Pharmacy compounding safety and need for improved labelling of API



Noteworthy Notables

- ISMP Spain
 - Improved recommendations for medication reconciliation in primary care
 - Updating recommendations concerning high-alert medications
- Oman
 - Enhancing the role of medication safety officers
- Morocco
 - Discussed an error involving a patient who accidentally overdosed on acetaminoPHEN (not paracetamol) thinking it was ibuproFEN
- European Medicines Agency
 - Issues with COVID-19 vaccine labelling differences between first batches and final approved labelling



Noteworthy Notables

- French Network of Pharmacovigilance Centers
 - ADRs related to drug shortages
- Prescrire (France)
 - Tranexamic Acid mix-ups
- China
 - Errors involving thrombin lyophilized powder being given intravenously due to vial packaging



Noteworthy Notables

- Norway
 - Initiatives for reducing opioid related death
- Denmark
 - Methotrexate electronic prescribing warnings
- Brazil
 - Issues with receiving medication shortage relief shipments from other countries in different languages and in different concentrations



Ampules, Ampuls and Ampoules



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What's next?

- Searching for 2023 IMSN Project
 - Neuromuscular blocking agents
 - Pharmacy compounding safety
- Looking to expand membership in South America and Asia



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The International Society of Pharmacovigilance (ISoP) is a professional, independent, non-profit society, open to anyone with an interest in the safe and effective use of medicinal products.

International Society of Pharmacovigilance

- About ISoP
- A message from the President
- ISoP/ESOP History
- ISoP Board Elections
- Advisory Board 2019 - 2022
- Scientific Board
- Past Executive

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<https://isoponline.org/about-isop/>

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ISMP and ISoP: Great Minds Think Alike

- **1992:** European Society of Pharmacovigilance (ESoP), later becoming ISoP founded in Paris
 - Contributing to better knowledge and understanding of the safe and effective use of medicines, pre- and post-marketing.
- **1994:** ISMP founded in Pennsylvania, USA
 - Advancing patient safety worldwide by empowering the healthcare community to prevent medication errors.

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Pharmaco...

— Pharmacovigilance

- Signal detection → data collection/evaluation → risk/benefit
 - Rising use of artificial intelligence to tie together un-related sources/registries of real world data to further evaluate links
- Importance highlighted by COVID-19 vaccine roll-out
 - Identification of Vaccine Induced Thrombotic Thrombocytopenia (VITT) and myocarditis associated with some vaccines.

— Pharmacoepidemiology

— Phytopharmacovigilance

— “New” - Ecopharmacovigilance



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ISoP 21st Annual Meeting

— A new Era of Pharmacovigilance: Challenges and Opportunities

- Lessons learned from COVID-19
 - The importance of vaccine surveillance and pharmacovigilance
 - Communicating risk in crisis
- Innovative approaches to post marketing surveillance
 - Multi-Omics → working to identify biological markers for predicting adverse events
- Big Data → growing use of artificial intelligence
- Contributions of pharmacovigilance to healthy medical prescribing
- Advancing phytopharmaceutical education in pharmacy curricula
- What is the future:
 - 4Ps: **predictive, proactive, personalized, participatory**
 - Changes in how we approve and evaluate new medications → Big data + AI



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Novel Path for COVID-19 Vaccines

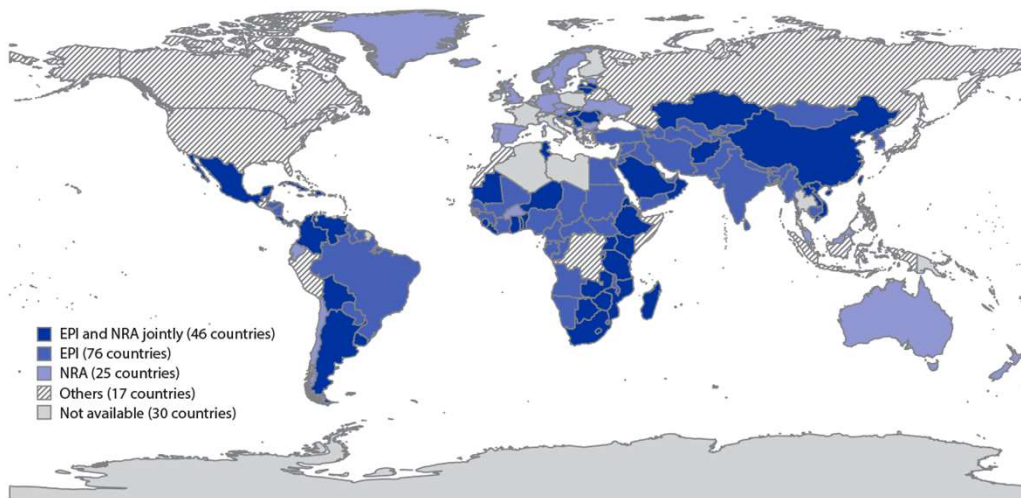
- Vaccine development typically took/takes 12 years
- The need for speed...
 - Overlapping of trial phases to shorten timelines
 - Diversify
- Vaccines from one part of the world being used to treat patients on the other side of the world
 - More need than ever to share outcomes/data
 - Need to standardize how we share that information



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2019

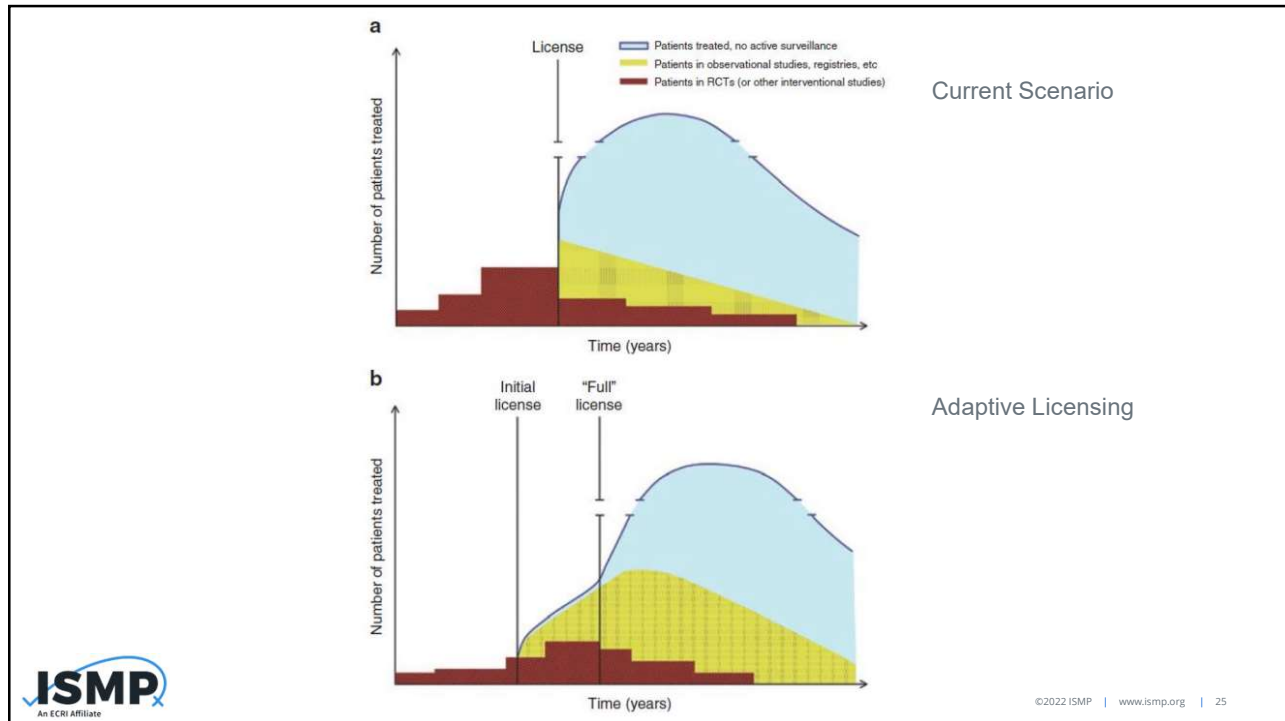


EPI = Expanded Programme on Immunization
NRA = National Regulatory Agency

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ISoP Medication Errors SIG

- Medication Safety Officer (MSO) Program
 - Aim with this project is to develop a training curriculum and a job profile for the role of MSO within the ISoP working principles.
- MeDRA Coding
 - Training on how to code appropriately
 - Abstract submitted concerning the coding issues of medication errors based on a sample for data relative to covid-19 vaccines.
- AM2P (American Program in Pharmacovigilance) program
- Collaboration with ISMP



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ISMP Targeted Medication Safety Best Practices for Hospitals 2022-2023

Goal:

To identify, inspire, and mobilize widespread adoption of consensus-based Best Practices for medication safety issues that continue to cause fatal and harmful errors



<https://www.ismp.org/guidelines/best-practices-hospitals>

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Balancing recommendations with capabilities



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Background

- Initiated in 2014
- Updated every 2 years
- 19 total
 - 4 in archived status
 - 1 (#12) was incorporated into another (#15)
- Targeted for hospital setting; but applicable to other healthcare settings
- Source:
 - ISMP's National Medication Errors Reporting Program (MERP)
 - ISMP's National Vaccine Errors Reporting Program (VERP)
 - Cases from literature, media reports, ECRI



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Best Practice #1

- Dispense vincristine and other vinca alkaloids in a minibag of a compatible solution and **not** a syringe
 - Often given together with intrathecal cytarabine, hydrocortisone or methotrexate
 - Inadvertent administration via IT instead of IV route can cause fatal neurological effects
 - >130 cases reported worldwide
 - In 2007, WHO issued alert about medication errors related to accidental IT injection of vinca alkaloids
 - In 2019, IMSN introduced this as the new global targeted medication safety best Practice 2
 - In 2021, US FDA changed prescribing information to call for dilution in a minibag only
 - In 2022, Australian TGA call for administering vinca alkaloids by IV infusion only



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Best Practice #7

- Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.
 - ISMP has received well over 100 reports concerning accidental administration of NMBs and has been discussing the hazards of these agents since 1996.
 - Most errors with the use of these agents have been the result of using or compounding a NMB in error instead of the intended drug.
 - Nurse removed and administered vecuronium instead of versed (midazolam) resulting in patient death.
 - Pharmacy prepared a patient infusion incorrectly using rocuronium instead of fosphenytoin.



Best Practice #10 (Archived)

- Eliminate all 1,000 mL bags of sterile water (labeled for “injection,” “irrigation,” or “inhalation”) from all areas outside of the pharmacy.
 - Administering large quantities of hypotonic sterile water IV has resulted in patient harm, including death, from hemolysis.
 - ISMP has received reports of mix-ups between the 1 liter bags of sterile water for injection, irrigation, and inhalation with 1 liter bags of dextrose 5% (D5W) and 0.9% sodium chloride (normal saline [NS]). These products look very similar in size, shape, and type of flexible plastic bag used for distribution.
 - What do these products look like in your practice?



Best Practice #14

- Seek out and use information about medication safety risks and errors that have occurred in other organizations outside of your facility and take action to prevent similar errors.
 - Appoint a single healthcare professional (preferably a MSO) to be responsible for oversight of this entire activity in the hospital.
 - Identify reputable resources to learn about risks and errors that have occurred externally.
 - Determine appropriate actions to minimize the risk of these types of errors occurring.
 - Share your results!



Future of the ISMP – ISoP Collaboration

- How can ISMP and ISoP continue to collaborate to advance safety on a global scale?
- What safety challenges are other countries facing that can potentially be shared at other facilities or in other countries?



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World Health Organization

Health Topics ▾ Countries ▾ Newsroom ▾ Emergencies ▾ Data ▾ About WHO ▾

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<https://www.who.int/news-room/events/detail/2022/09/17/default-calendar/world-patient-safety-day-2022>

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WHO Patient Safety Day 2022 (9/17/22)

- Theme: “Medication Safety: Medications Without Harm”
 - RAISE global awareness of the high burden of medication-related harm due to medication errors and unsafe practices, and ADVOCATE urgent action to improve medication safety.
 - ENGAGE key stakeholders and partners in the efforts to prevent medication errors and reduce medication-related harm.
 - EMPOWER patients and families to be actively involved in the safe use of medication.
 - SCALE UP implementation of the WHO Global Patient Safety Challenge: Medication Without Harm.
- WHO Global Patient Safety Challenge: Medications Without Harm (2017)
 - Healthcare Professionals
 - Medicines
 - Systems and Practices of Medications
 - Patients and the Public



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The Council for International Organizations of Medical Sciences (CIOMS)

- Established jointly by WHO and UNESCO in 1949
- CIOMS is an international, non-governmental, non-profit organization with the mission to advance public health through guidance on health research and policy including ethics, medical product development and pharmacovigilance.
- CIOMS represents a substantial proportion of the biomedical scientific community through its member organizations:
 - many of the biomedical disciplines
 - national academies of sciences
 - medical research councils.
- CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety.

UNESCO: United Nations Educational, Scientific and Cultural Organization

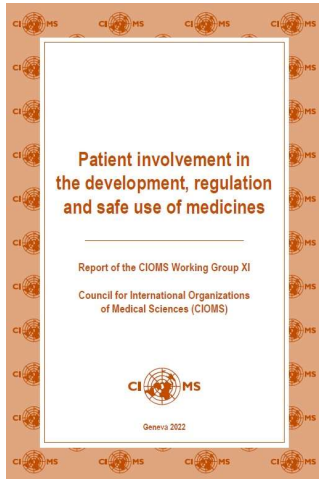


<https://cioms.ch/>

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Patient involvement in the development, regulation and safe use of medicines



- This report describes the importance of systematically involving patients throughout a medicine's life
 - From its early development
 - Through the regulatory process
 - To ongoing monitoring and safe use in everyday healthcare.
- It provides a comprehensive overview of
 - The current knowledge about the benefits of patient involvement and existing initiatives
 - Gives many examples and recommendations
 - Addresses the remaining challenges and practice gaps.
- The report will prompt readers to implement its best practice recommendations according to how well they fit in with their organizational and national needs.



<https://cioms.ch/publications/product/patient-involvement/>

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<https://who-umc.org/medsafetyweek/>

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Uppsala Monitoring Centre (UMC)

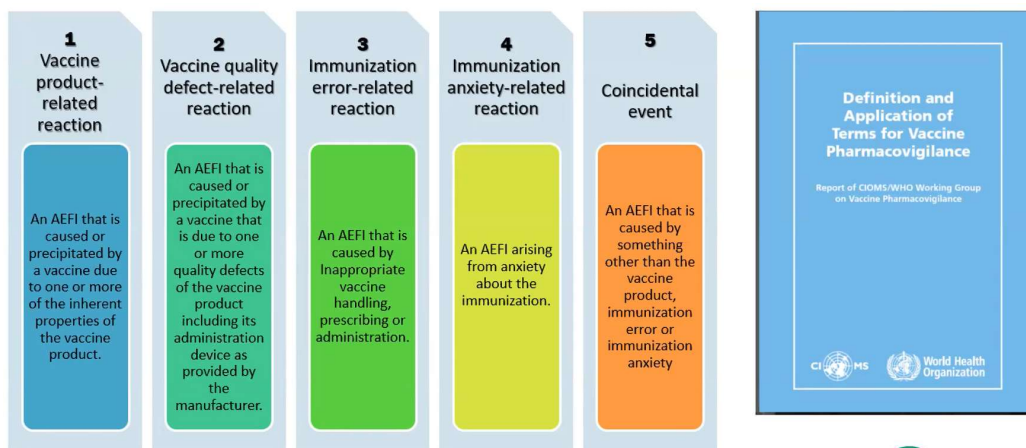
- Support for global data sharing and national level AESI/AEFI analysis
- WHODrug = dictionary of medicinal products
 - Reports come in from around the world with different names
 - WHODrug standardizes the name for harmonization in databases
- VigiFlow → VigiBase → VigiLyze → VigiAccess
 - AND NOW...VigiMobile

AESI = Adverse Event of Special Interest
AEFI = Adverse Event Following Immunization



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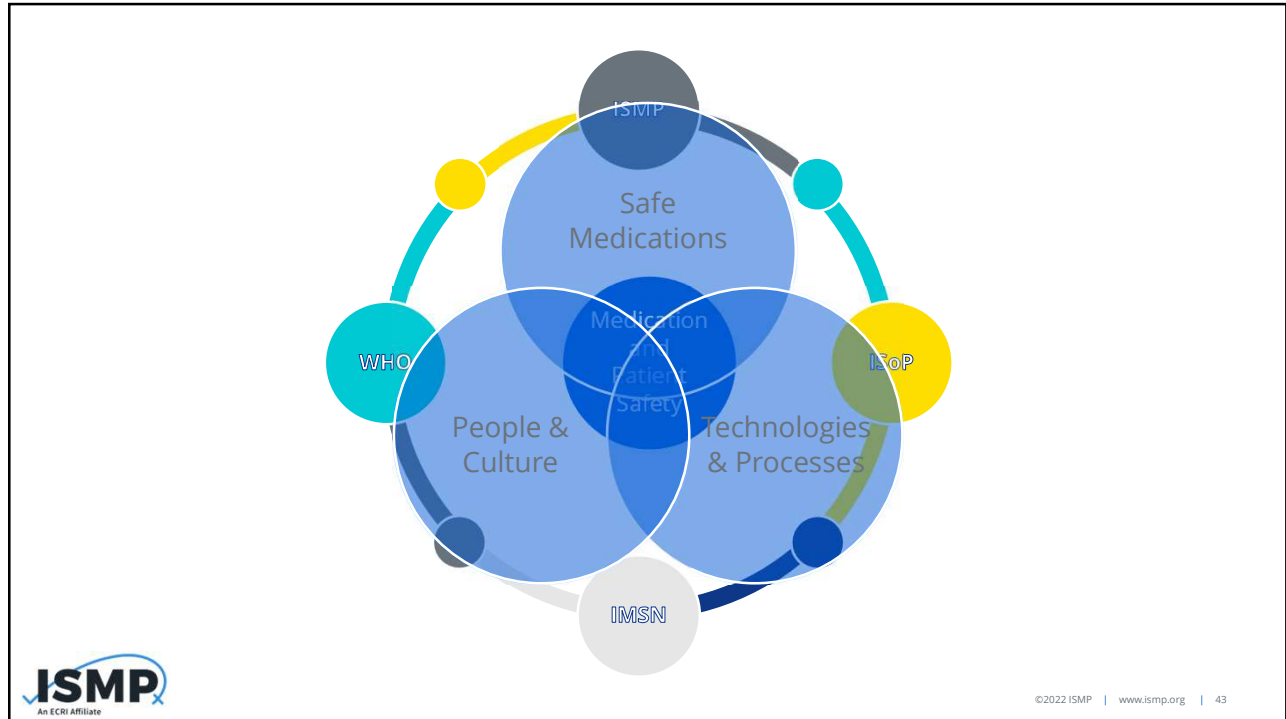
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Questions?

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