Safety in Polypharmacy Training Course

Session 6

Safety Signal Reporting & Digital Health Tools

Written version of the video scripts

In this session

Video #1 — Pharmacovigilance, Risk Management, and How to Report a Side Effect

Video #2 — Digital Health Tools and the Future of Polypharmacy Safety

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VIDEO #1 — Pharmacovigilance, Risk Management, and How to Report a Side Effect

Estimated Duration: 11–14 minutes
Target Audience: Broad: patients, caregivers, and clinicians

1. Introduction

You report a side effect to your doctor. It disappears into the system somewhere. But what actually happens to it next? Who looks at it, what do they do with it, and could it ever help someone else?

In this video, we are pulling back the curtain on pharmacovigilance, the science of keeping medicines safe after they reach the market and showing you exactly how to report a side effect yourself.

2. Main content

What Is Pharmacovigilance?

Pharmacovigilance is the science and set of activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine- or vaccine-related problem, as defined by the World Health Organization. Good pharmacovigilance practices, or GVP, are the structured measures that make this possible across the European Union. They apply to marketing-authorisation holders, the European Medicines Agency, and national medicines regulators alike, covering both centrally and nationally authorised medicines.

The European Medicines Agency, or EMA, coordinates pharmacovigilance across the EU, gathering data from patients, healthcare professionals, clinical studies, and medical literature, and collaborating with regulators across member states. Their dedicated committee, the Pharmacovigilance Risk Assessment Committee, or PRAC, plays a central role in assessing and monitoring medicine safety, meeting monthly to review emerging concerns and, when needed, recommend swift action.

The Goals and Steps of Pharmacovigilance

Pharmacovigilance has four main goals: continuously monitoring the risk-benefit ratio of a medicine, detecting adverse drug reactions and interactions early, identifying the risk factors and mechanisms behind them, and distributing that information to the people who need it.

In practice, this follows a stepwise process: Data is collected and reported, then compiled into aggregate reports that can reveal patterns across large populations. Those patterns are assessed by bodies like PRAC, and depending on what is found, the response might be an updated risk management plan, a new warning, or in serious cases, even removing a drug from the market. This is not just theoretical, it is exactly what happened in the case mentioned in session 5, with fenfluramine-phentermine, the weight-loss drug combination being pulled from the market in the 1990s after safety signals revealed serious heart valve and lung risks.

Understanding Risk Management

We need to be clear here. No medicine is without risk!

Risk is the probability of harm occurring from using a treatment; while benefit is the positive outcome that treatment provides, like relief of symptoms, cure, or prevention. The two must always be weighed against each other, deliberately and systematically, never left to chance. Failing to manage that balance can lead to genuine crises with real consequences for patient safety and public health.

This risk management rests on three pillars. First, the safety profile: a compiled record of all identified and potential risks, along with a note of what safety information is still missing. Second, ongoing risk assessment through pharmacovigilance, both routine and additional activities to keep identifying, characterising, and assessing risk. And third, the Risk Management Plan, or RMP: the actual plan for minimising risk, combining routine and additional risk-minimisation activities. An RMP can be submitted or updated at any point in a medicine's life cycle, both before and after authorisation, because pharmacovigilance legislation, and our understanding of risk, is always evolving.

Medicines Under Additional Monitoring

Have you ever noticed a black, inverted triangle on some medicine packaging or leaflets? Do you know what it means?

Well, this symbol means the medicine is under additional monitoring, which usually applies for a five-year period. It is a signal to both patients and doctors to say: Please report any suspected side effects through your national reporting system, so new information can be analysed quickly and efficiently!

But other medicines can also be placed under additional monitoring at any time, based on a decision by the PRAC, in which patients are members.

So, this kind of reporting is essential and complements all other pharmacovigilance activities, helping build a whole picture of a medicine's real-world safety profile.

An example of a drug that was approved and had a new safety signal emerging through post marketing pharmacovigilance is Valproate, which is a generic drug used to treat primarily seizure and bipolar disorder. Later on in the drug cycle it was found that this drug caused birth defects when taken during pregnancy, so a black inverted triangle was added.

The Benefits of Risk Management

Let's be real. Risk management can be challenging and costly, but it is ultimately rewarding and reassuring. It enhances the benefit-risk balance in real-world use, and it is a cornerstone for keeping complex medicines, like advanced-therapy medicines, sustainably available on the market. Beyond that, it protects patients, helps avoid crises, deepens our knowledge of the products we use, and builds trust between companies, regulators, and the patients and providers who rely on their medicines.

How to Self-Report a Side Effect

So, the real question is, how do you report a side effect yourself?

Well, you should start with the information you will want to have ready: details about the person affected, like sex and age, a description of the side effect, the dose and name of the suspected medicine, including both the brand name and active ingredient, the batch number found on the packaging, any other medicines being taken at the same time, including non-prescription drugs, herbal remedies, and contraceptives, and any other relevant health conditions.

From there, check the package leaflet for guidance, or report through your doctor or local pharmacy. You can also report directly through your National Competent Authority, each EU

member state has its own online system, or through the EMA's dedicated EudraVigilance ADR Reports website, which shows side effects reported by both healthcare professionals and patients, and guides you through the process.

Let's just have a short look at the EudraVigilance site so you can get an idea on how it looks. This is the public page, and it is open to everyone, you don't need an account or any special access. From here you can report a suspected side effect yourself, without going through your doctor or pharmacist first. The site shows you key information, and it guides you step by step. The same page also lets you search the reports that have already been submitted for a given medicine, so you can see what others have experienced with suspected adverse drug reactions. Remember, you don't have to be certain that the medicine caused the problem, as a suspicion is enough, and it is always better to report than to stay silent.

Here is an honest note, though: This is not always as easy as it sounds. In one of our own course discussions, a participant tried navigating another country's reporting system just to see how accessible it would be for an average patient, and found it genuinely difficult, with dense information and no clear starting point. That is a real gap worth mentioning: Knowing a reporting system exists is very different from being able to use it. If you ever get stuck, do not hesitate to look for direct contact information, a phone number or email for your National Medicines Regulatory Agency, and simply ask.

Two Perspectives, One Fuller Picture: PROs vs. Clinicians' Reports

So now that we know how to do a report, let's connect this back to something we covered last session: Patient-reported outcomes.

PROs capture the subjective experience and preferences of the patient, centred on how they perceive their own health and quality of life, using patient-reported tools and questionnaires. Clinicians' reports, by contrast, offer an objective clinical evaluation, focused on clinical indicators and health status, relying on clinical tests, assessments, and criteria like CTCAE.

Neither is more "correct" than the other, they are complementary. PROs help improve patient-clinician communication by surfacing issues that might not show up in a clinical assessment alone. Clinicians' reports provide the standardized, objective data essential for diagnosis and treatment monitoring.

And combining both gives a genuinely comprehensive view of a patient's health, enabling truly holistic, personalised care. This combination is exactly what is meant by patient-centred research.

3. Key takeaways

So, here you learned about pharmacovigilance, and that it only works if people participate in it, including you. You learned the basics on risk management and additional monitoring, and some insights on how to report suspected ADRs.

The next time you experience a side effect, however small it seems, consider reporting it. It genuinely helps build the bigger picture that keeps medicines safe for everyone.

In our next video, we will look at how digital health tools are transforming the way patients and providers manage polypharmacy, and what trade-offs come with that transformation. See you in the next one!

VIDEO #2 — Digital Health Tools and the Future of Polypharmacy Safety

Estimated Duration: 10–13 minutes
Target Audience: Broad: patients, caregivers, and clinicians

1. Introduction

Your smartwatch tracks your heart rate. An app checks your medications for dangerous interactions. Your doctor reviews your symptoms without you ever leaving home. This is not the future; it is already happening!

In this video, we are exploring digital health: what it actually means, the real benefits it brings to polypharmacy safety, and the honest trade-offs that come along with it.

2. Main content

What Do We Mean by "Digital Health"?

The European Commission defines digital health and care as tools and services based on information and communication technologies that improve the prevention, diagnosis, treatment, monitoring, and management of health-related issues, and that help monitor and manage the lifestyle habits that impact health. The World Health Organization describes it more broadly still: an umbrella term encompassing e-health and emerging fields like big data, genomics, and artificial intelligence.

In practice, digital health includes mobile health apps, telehealth, health surveillance, health literature and education, and much more. All built on the cost-effective, secure use of digital technologies in support of health.

Why Digital Health Matters

But why is this important? Digital health is transforming three things at once: how medical professionals provide care, what patients do to receive it, and how entire healthcare systems operate. Whether it is providing more personalised care in person, expanding access through

mobile apps, or using neural networks to help diagnose disease; digital tools are reshaping healthcare delivery from the ground up, and this shift accelerated dramatically in the wake of COVID-19.

The Benefits of Digital Health

So, the upside or benefits of digital health are substantial: improved diagnoses through artificial intelligence, expanded access to care for historically marginalised communities, decreased healthcare costs for both patients and providers, better health outcomes through personalised treatment plans, and increased operational efficiency at healthcare facilities like hospitals.

The Trade-Offs of Digital Health

But digital health is not without real trade-offs. It requires people to actually have access to the technology in the first place, and digital literacy is essential, not everyone finds these tools intuitive. Cost is a genuine barrier too: Implementing large-scale digital systems is expensive. One health system's rollout of a single electronic medical record system, for example, can be very costly, an investment most healthcare systems simply cannot take lightly. There are also data protection concerns under regulations like GDPR, and something more personal: The impact on the patient-provider relationship itself. If patients are focused on constantly tracking data through wearable devices and apps, does that risk overwhelming them? Or subtly changing the dynamic between patient and provider? A participant in our live session described going to see her cardiologist and being asked about her smartwatch data before anything else, a small but telling sign of how digital tools are reshaping even routine care.

The Digital-health-enabled Patient Pathway

Let's walk through what a digital-health-enabled patient pathway can look like: It starts with symptom onset, moves to a doctor's appointment, potentially conducted via telehealth through diagnosis, intervention, and treatment, and then into ongoing monitoring, often supported by wearable devices or remote check-ins. At each stage, digital tools can streamline the process, reduce delays, and keep both patient and provider better informed.

A Vision for the Future: Home-Centred Geriatric Care

Now, looking ahead, researchers envision a future of home-centred geriatric care, where older adults managing polypharmacy are supported by connected devices, remote monitoring, and

digital tools that bring care to them, rather than requiring frequent trips to a clinic. This kind of model could be especially valuable for older patients managing multiple medications, where frequent monitoring matters but mobility and access can be real challenges.

Digital Tools in Practice: Checking Your Medications

So, digital tools can help patients and healthcare professionals better understand potential medication-related risks and interactions.

One example is the SafepolyMed's Medication Management Centre or MMC, a digital tool that brings together about a person's medicines with pharmacogenetic data and patient-reported health information. The aim is to give patients and healthcare professionals a more complete picture of potential medication-related risks and support safer, more personalised medication management.

Tools like this support discussions with the healthcare team and put a piece of pharmacovigilance directly into the hands of patients' and healthcare professionals, helping catch inappropriate combinations before they become a problem.

3. Key takeaways

Here our take aways for this session.

Digital health offers real promise for making polypharmacy safer, from AI-assisted diagnoses to medication-checking apps to remote monitoring that brings care home. But it works best when it is paired with digital literacy, thoughtful data protection, and a healthcare relationship that stays genuinely human at its core.

We went through what digital health is, what tools it includes, its real benefits but also its trade-offs. And how the patient pathway is changing to a more digital experience.

You have completed Session 6!

In our next and final session, we will look at data safety, privacy, and GDPR, the rules that govern how all this health data is protected in the first place.

See you in session 7!

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