Have you ever taken a medicine and felt something unexpected happen afterward, and wondered, was that just something that happens sometimes, or was it actually caused by my medication? Well, the answer matters more than you might think.

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SafePolyMed.eu

Improving Safety in Polymedication by Managing Drug-Drug-Gene Interactions

Safety in Polypharmacy training 2026

Session 5 - Video 1/2

Fundamental concepts in reporting treatment side effects

Understanding Adverse Events, Side Effects, and Adverse Drug Reactions

Tamika Lang, Olga Millán

LeukaNET Leukemia Advocates Network

Patvocates PATIENT ENGAGEMENT IS IN OUR DNA

Funded by the European Union

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Three Terms, Three Meanings



Adverse Event (AE)

Any unwanted sign, symptom, or occurrence that may or may not relate to treatment.



Side Effect

An unintended effect alongside a drug's desired effect. Not always negative.



Adverse Drug Reaction (ADR)

A noxious, unintended response. Harm tied directly to the medicine.

Example: Gabapentin. Approved for seizures and nerve pain but often prescribed off-label for restless leg syndrome or anxiety. Off-label side effects (e.g. drowsiness, addiction potential) are more easily overlooked and under-reported.

https://www.ema.europa.eu/en/glossary/adverse-event

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Why do ADRs Matter?

1 in 16

hospital admissions linked to ADRs

10–20%

of hospitalised patients affected by an ADR

+2%

of patients with an ADR die from it

Do not just assume that what you are experiencing is simply "what to expect" from a medication.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3950535/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9544666/

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Types of ADRs

According to predictability

Predictable: e.g. excessive drug effect, known secondary effect

Unpredictable: e.g. allergic or idiosyncratic reactions

According to the “Alphabetical” classification of ADRs



Type A — Augmented
Dose-related (e.g. insulin overdose → hypoglycaemia)



Type B — Bizarre
Non-dose-related (e.g. allergic / anaphylactic)



Type C — Chronic
Persist long-term (e.g. adrenal suppression)



Type D — Delayed
Appear after exposure (e.g. dyskinesia)



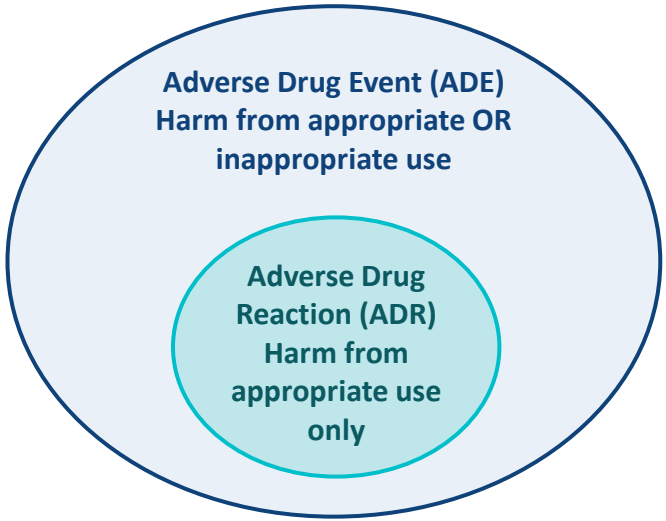
Type E — End of use
Withdrawal reactions (e.g. seizures)



Type F — Failure
Unexpected therapy failure (e.g. resistance)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6423864
https://pubmed.ncbi.nlm.nih.gov/11072960

Serious vs. Severe: A Critical Distinction



A "SERIOUS" reaction is one that:

- Results in death
- Life-threatening
- Requires hospitalisation
- Persistent / significant disability
- Birth defect

"Severe" is broader than "serious" and both must be reported.

https://www.ema.europa.eu/en/glossary/serious-adverse-reaction
https://slidetodoc.com/training-for-inactivated-poliovirus-vaccine-ipv-introduction-module-10

Why Reporting ADRs Matters

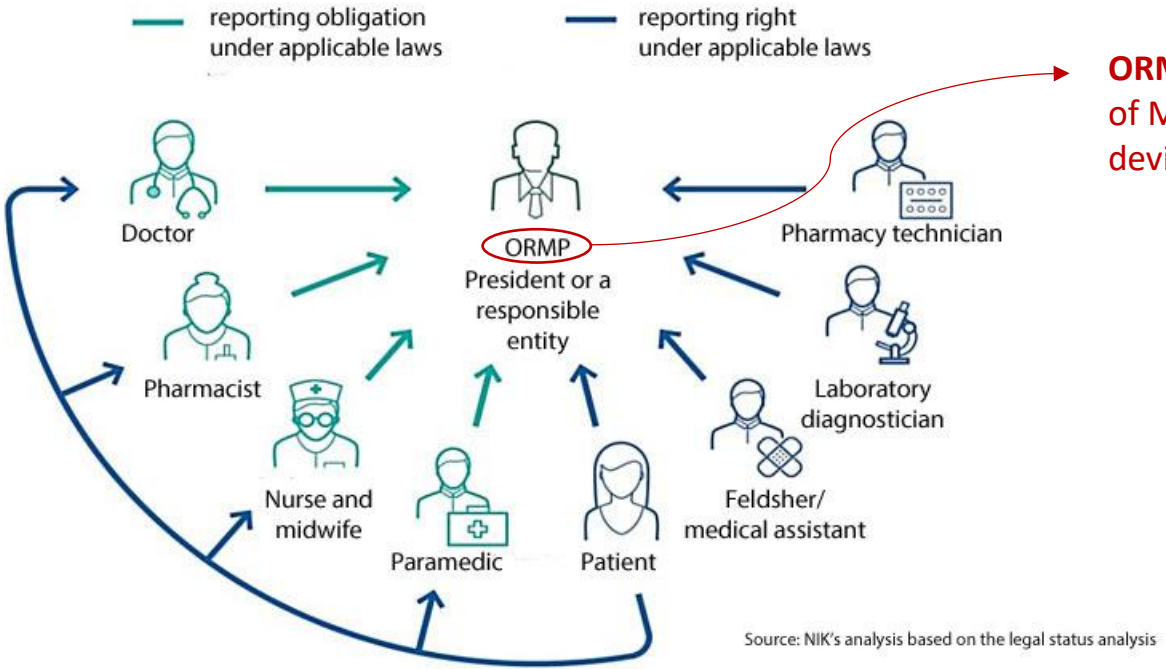


Reporting

- Drug development changes
- Market withdrawal
- New research directions
- Dose adjustments
- Label updates
- Restricted use

Patient reports often include more detail than clinician reports, and surface responses that might otherwise go unnoticed.

Who Reports ADRs, and How?



ORMP – Office for registration of Medicinal Products, Medical devices and Biocidal products.

Scheme for reporting adverse drug reactions (ADR): Supreme Audit Office of Poland (NIK), 2020. Explanatory annotation added.
NIK about the system of monitoring adverse drug reactions

Who Reports ADRs, and How?



Spontaneous Reports

Voluntary, unsolicited notifications from a patient, clinician, or anyone else alerting regulators to a possible reaction.



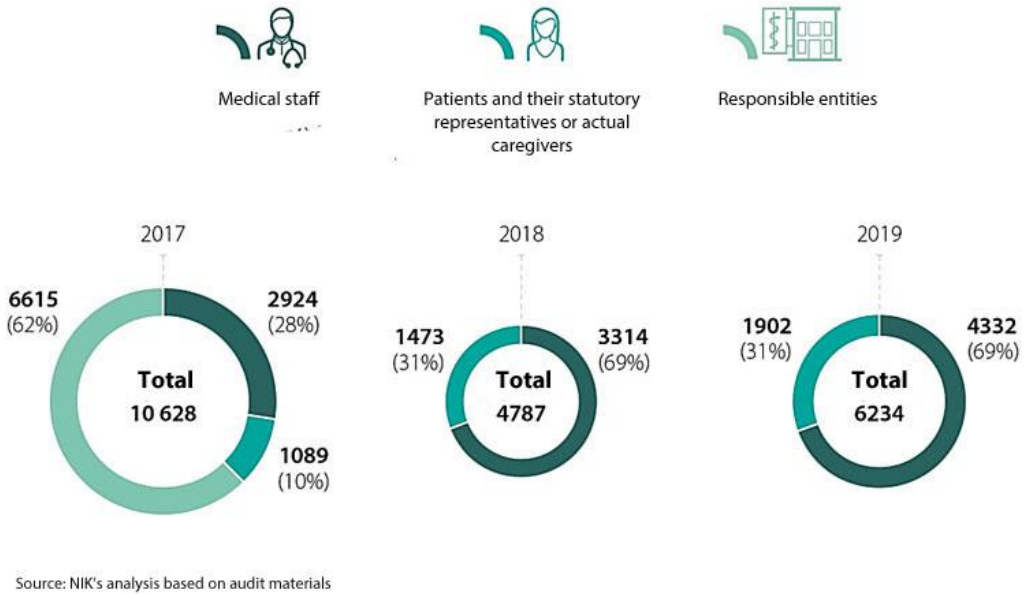
Solicited Reports

From organised systems like trials, registries, health institutions. A formal causality assessment precedes the report.

https://www.nik.gov.pl/en/news/nik-about-the-system-of-monitoring-adverse-drug-reactions.html

Who Reports ADRs, and How?

Real data, Poland. Number of ADR reports submitted to the ORMP (2017–2019): a gradual increase in reports coming directly from patients and their representatives, alongside pharmacies and healthcare institutions.



Number of ADR reports submitted to the ORMP in 2017–2019. Supreme Audit Office of Poland (NIK), 2020. NIK about the system of monitoring adverse drug reactions

ADRs in the Context of Polypharmacy

A 2020 meta-analysis by Chang and colleagues

31%

higher mortality risk with ≥5 prescribed drugs

14%

of hospital ADRs caused by drug-drug interactions (DDIs)

Risk of DDIs grows with every added drug

A common real-world case



Each drug may be safe alone but combined, they can cause kidney failure. Especially risky for elderly patients with underlying kidney issues.

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Grading Adverse Events: The CTCAE System

CTCAE: Common Terminology Criteria for Adverse Events

1	2	3	4	5
				
Mild	**Moderate**	**Severe**	**Life-threatening**	**Fatal**
Clinical/diagnostic observation only	Minimal, local, or non-invasive care	Medically significant, often hospitalisation	Urgent intervention	Adverse event resulted in death

https://www.ncbi.nlm.nih.gov/books/NBK599521/#:~:text=A%20score%20of%20%E2%89%A59,an%20ADR%20is%20in%20doubt. / https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf

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Grading Adverse Events: The CTCAE System

CTCAE: Common Terminology Criteria for Adverse Events

STRENGTHS

- ✓ **Internationally accepted**.
- ✓ **Organised by organ system** (e.g., ADRs that affect the cardiac system, GI system, etc.)
- ✓ It is **widely used for clinical trials**, cancer therapy (e.g. chemotherapy administration, etc).

WEAKNESSES

- ✓ May **underrepresent patients' perspectives on ADRs**.
- ✓ Many consider grade 3 or above to be more severe side effects.
- ✓ This **may not be widely accepted amongst the patient population**.

> *"This still affects my daily life"*
>
> *A Grade 2 side effect can meaningfully disrupt daily living, even though it isn't clinically "severe."*

https://www.uptodate.com/contents/common-terminology-criteria-for-adverse-events#H1157547

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Key Takeaways

- Know the difference: AE, side effect, and ADR are not interchangeable
- Understand how ADRs are classified and graded (CTCAE)
- Report even minor reactions. Patient reports fill in details clinicians might miss

Coming up next: **Video 2 — What Matters to Patients. Patient-Reported Outcomes & Preferences**

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Credits & Attributions

Authors

Tamika Lang | Olga Millán

AI disclosure

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Figures

- Scheme for reporting adverse drug reactions (ADR) & Number of ADR reports submitted to the ORMP in 2017–2019. Supreme Audit Office of Poland / Najwyższa Izba Kontroli (NIK), 2020. NIK about the system of monitoring adverse drug reactions. https://www.nik.gov.pl/en/news/nik-about-the-system-of-monitoring-adverse-drug-reactions.html. Explanatory annotation added to the reporting scheme.

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