Your health data can reveal far more than a diagnosis, it can reveal your genetic makeup, your family’s medical history, even predictions about your future health. That is exactly why the GDPR treats it differently from ordinary personal data.

SAFEPOLYMED

SafePolyMed.eu

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

Safety in Polypharmacy training 2026

Session 7 - Video 2/3

Data Safety, Privacy, and GDPR

GDPR in Health Research and Polypharmacy: From Consent to Everyday Care

Patricia Cervera de la Cruz, Dominique Hamerlijnck, Joan Jordan, Olga Millán

LeukaNET Leukemia Advocates Network

Patvocates PATIENT ENGAGEMENT IS IN OUR DNA

Funded by the European Union

AI Disclosure: *Avatars, voices, and some visual elements in this video were generated using HeyGen & Copilot. The educational content was created by humans and subsequently edited and summarised with AI assistance.*

Why Health Data Gets Special Protection

The GDPR recognises health data as a "special category" of data, with its own definition and dedicated safeguards.

General Personal Data

Standard safeguards apply.

Special Category: Health Data

Dedicated, stronger safeguards to protect a genuinely sensitive category of data.

Without that trust, patients and participants won't engage, and research and care would suffer.

Recommended video: https://youtu.be/uQeKVE05IgU

https://www.edps.europa.eu/data-protection/our-work/subjects/health_en
https://www.scconline.com/blog/post/2021/01/04/data-protection-all-you-need-to-know-about-gdpr-implementation-in-eu-countries/

Genetic Data: Sensitive in a Different Way

Genetic and genomic data, information about your unique genetic blueprint that can reveal health information, traits, ancestry, and even future medical conditions.



Deeply Personal

Reveals highly intimate information about you.

Potential for Misuse

Carries genuine privacy and discrimination risk.

Family Implications

Says something about your relatives too, not just you.

https://gdpr-info.eu/art-9-gdpr/

SAFEPOLYMED

How Does GDPR Protect Your Genomic Data?

Genomic data receives GDPR's strongest protections, built around four key guarantees:

Lawful Basis

Required before your genetic data can be processed

Right to Know

You can find out how your data is used, who has access to it, and why

Right to Withdraw

You can withdraw consent at any time

Extra Protection

Genetic data is a special category, with extra safeguards

Building trust by ensuring genomic data is handled and used ethically and securely.

https://gdpr-info.eu/art-9-gdpr/
https://guides.gdprinfo.eu/en-article-9

Legal Bases for Processing Health Data: Consent is not the Only Route

A common misconception: Many assume consent is the only legal basis for processing health data. But it is not, it is one of several.



Explicit consent



Employment / social law



Vital interests



Non-profit activities



Substantial public interest



Data made public



Legal claims



Healthcare & medicine



Research / archiving

https://gdpr-info.eu/art-6-gdpr/
https://gdpr-info.eu/art-9-gdpr/

Research Ethics Consent vs. GDPR Consent

Two related but distinct ideas: consent to participate in research, and consent under the GDPR.



Research Ethics Consent

Rooted in the Declaration of Helsinki. The ethical foundation for interventional biomedical studies. Generally treated as the primary basis for participation.





GDPR Consent

One of several legal bases under data protection law, more flexible than research ethics, which treats consent as central.

https://www.ga4gh.org/news_item/policy-brief-what-is-the-difference-between-research-ethics-consent-and-data-protection-consent/

What Makes Consent Truly “Informed”?

Freely given

A real choice, no pressure or power imbalance.

Specific

Every type of processing is spelled out clearly.

Informed

Genuinely valid information, whether written, oral, audio, or video.

Unambiguous

A clear, deliberate action, never implied.

Patients are sometimes required to sign two separate consent forms, one for research participation, and a separate one for data processing.

https://www.uu.nl/en/research/research-data-management/guides/legal-considerations/how-to-write-an-informed-consent-form

SAFEPOLYMED

Protecting Vulnerable Groups in Research

Ethical principles:

Autonomy

Respecting each person's right to make informed choices

Beneficence

Minimising risk, maximising benefit

Justice

Fair, equal treatment, no exploitation

Best practices for involving vulnerable patients:

Children

Age-appropriate language, visual aids, assent, guardian present

Elderly Patients

Accommodate impairments, simplify documents, check in regularly

Cognitive Impairment

Involve family/guardians, decision-aids, adapt to fluctuating capacity

https://www.privacy-regulation.eu/en/recital-43-GDPR.htm
https://pmc.ncbi.nlm.nih.gov/articles/PMC7923912/

GDPR and Polypharmacy

Data Protection in Everyday Care

If you’re managing multiple medications, chances are your health data doesn’t live in just one place. It’s with your GP, your pharmacist, maybe a specialist, and perhaps a medication-tracking app too. Who is making sure all that data stays protected as it moves between them?

Let’s connect GDPR directly to the everyday reality of polypharmacy, and what you, as a patient or caregiver, can do about it. And we start with the basics.

GDPR Concepts That Matter Most in Polypharmacy



Personal Data

Medical history, prescriptions, health records



Legal Basis

Always required for processing data



Right to Access

Understand your treatments, manage medication



Data Minimisation

Only what is necessary is collected



Data Security

Crucial, multiple providers, one patient

What Patients Should Be Told

- What data will be used for
- Exactly what data is being collected
- A data breach that has ever affected you
- How long the data will be stored
- Your right to be forgotten

Patients who move between countries or health systems often find a new provider has no history on them at all, especially critical for vulnerable groups.

https://www.scconline.com/blog/post/2021/01/04/data-protection-all-you-need-to-know-about-gdpr-implementation-in-eu-countries/

GDPR in Action: Three Everyday Examples



Sharing Between Providers

Data shared between doctors, pharmacists, and specialists must be secure, with patients informed who has access.



Digital Health Apps

Medication-tracking apps may only collect what's genuinely necessary for the app to function, nothing more.



Consent for Adjustments

Before adjusting or adding medications, providers must explain why data-sharing is necessary and obtain consent.

Practical Tips for Patients and Caregivers

Keep Records

Maintain an updated list of medications, dosages, and prescribing doctors

Ask Questions

Don't hesitate to ask how your data is protected and shared

Use Secure Channels

Make sure digital medication tools are genuinely GDPR-compliant

Report Concerns

If something feels wrong, report it to your provider or the DPA

SAFEPOLYMED

Key Takeaways

Health data carries real power to improve care, but only when handled with genuine respect for consent, context, and the people it belongs to.

- Health data gets special protection
- Consent isn't the only legal basis
- Informed consent has real requirements
- Vulnerable groups need tailored safeguards to be involved in research
- Practical tips you can take in everyday polypharmacy care

Coming up next: Video 3 — The European Health Data Space

SAFEPOLYMED

Credits & Attributions

Authors

Patricia Cervera de la Cruz | Dominique Hamerlijnck | Joan Jordan| Olga Millán

AI disclosure

Avatars, voices, and some visual elements in this video were generated using HeyGen & Copilot. The educational content was created by humans and subsequently edited and summarised with AI assistance.

Icons

- Selected icons adapted from Font Awesome Free by Fonticons, Inc. - fontawesome.com – licensed under CC BY 4.0. Colours modified.
- Selected icons by Icons8 - http://icons8.com/icons

Educational use only | Not medical advice | Non-commercial.