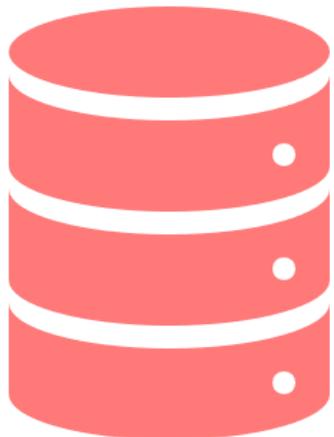


Pre-conference 2023 Dublin

A guideline to the European Health Data Space language based on health literacy principles



Wicklow Hall 1 | Wednesday 8 10 November 2023 | 09:00 to 12:30 h

Prof. Orkan Okan, Dr. phil.
Technical University of Munich
School of Medicine and Health
Department of Health and Sport Sciences
Health Literacy Unit
Munich, Bavaria, Germany
orkan.okan@tum.de

Dr. Nienke Schutte, PhD, Head of
Unit
EU Health Information System Unit
Sciensano
Brussels, Belgium
Nienke.Schutte@sciensano.be

Health literacy and human



Andrew Pleasant
1962 - 2022



Jürgen M. Pelikan
1940 - 2023



Objectives

EHDS



- To bring awareness to the changing environment and concepts due to digital transformation
- To discuss concepts and terminologies that are in the EHDS regulation
- To form a bridge between citizens and researchers
- To provide practical recommendations to professionals on how to improve the health literacy of citizens

Agenda

- 9:15-10:00 Two presentations by Kristine Sørensen and Nienke Schutte
- 10:00-11:30 Working groups to discuss EHDS concepts
- 10:30-11:00 Coffee and networking break
- 11:30-12:00 Presentations from the working groups
- 12:00-12:20 Presentation by Tina D. Purnat
- 12:20-12:30 Closing remarks
- 12:30-13:30 Networking lunch





European Commission

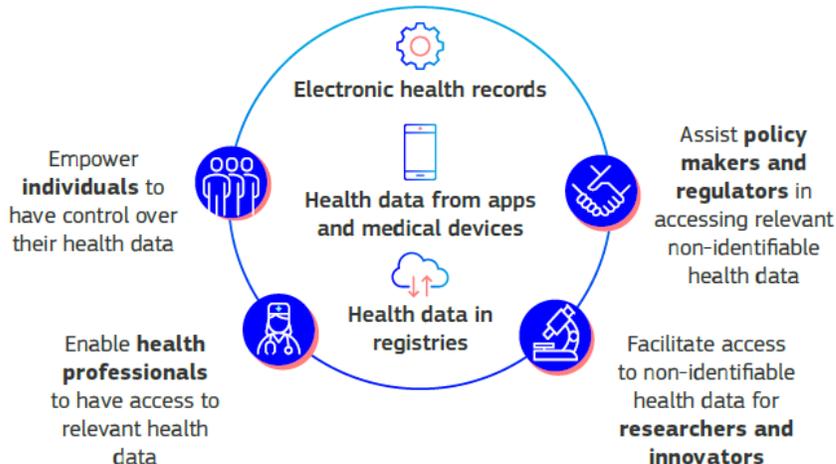
EUROPEAN HEALTH DATA SPACE

#EUDigitalHealth

OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency



Better health policy, greater opportunities for research and innovation

GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY



5.5 billion €

In savings for the EU over ten years from better access and exchange of health data in **healthcare**



20-30%

Additional growth of the digital health market



5.4 billion €

In savings for the EU over ten years from better use of health data **for research, innovation and policy making**



As a citizen

- **You will have control over health data:**
 - You will have **access** to your health data in electronic form immediately and without any cost.
 - You will be able to **share** your data with health professionals nationally or cross-border.
 - You will be able to **add** information, **rectify** errors, **restrict** access and obtain information on how your data are used.
 - You will have a right to health data, issued and accepted, in a common **European format**.
- **Your security and privacy will be ensured**
 - Researchers, industry or public institutions will have access to health data only for specific purposes that benefit individuals and society.
 - The researcher, industry or public institution may only access data that do **not reveal the identity** of the individual.
 - The data may only be accessed and processed in closed, **secure environments**.

As a health professional

- You will have **faster access** to patient's health records, including across borders.
- You will have easier access to health records from different systems, greatly **reducing the administrative burden**.



As a researcher

- You will have **access** to large amounts of health data, of higher quality, in order to carry out research.
- You will be able to know what data is available, where, and of what quality.
- You will be able to access the data **cheaper and more effectively**.



As regulators and policy-makers

- You will have easier, more transparent and less costly **access** to non-identifiable health data for the benefit of public health and the overall functioning of healthcare systems and to ensure patient safety.



As industry

- Thanks to standardization, you could more easily **enter into new markets** for electronic health records in other Member States.
- You will benefit from the greater availability of non-identifiable electronic health data, enabling the use of data for **innovation**.



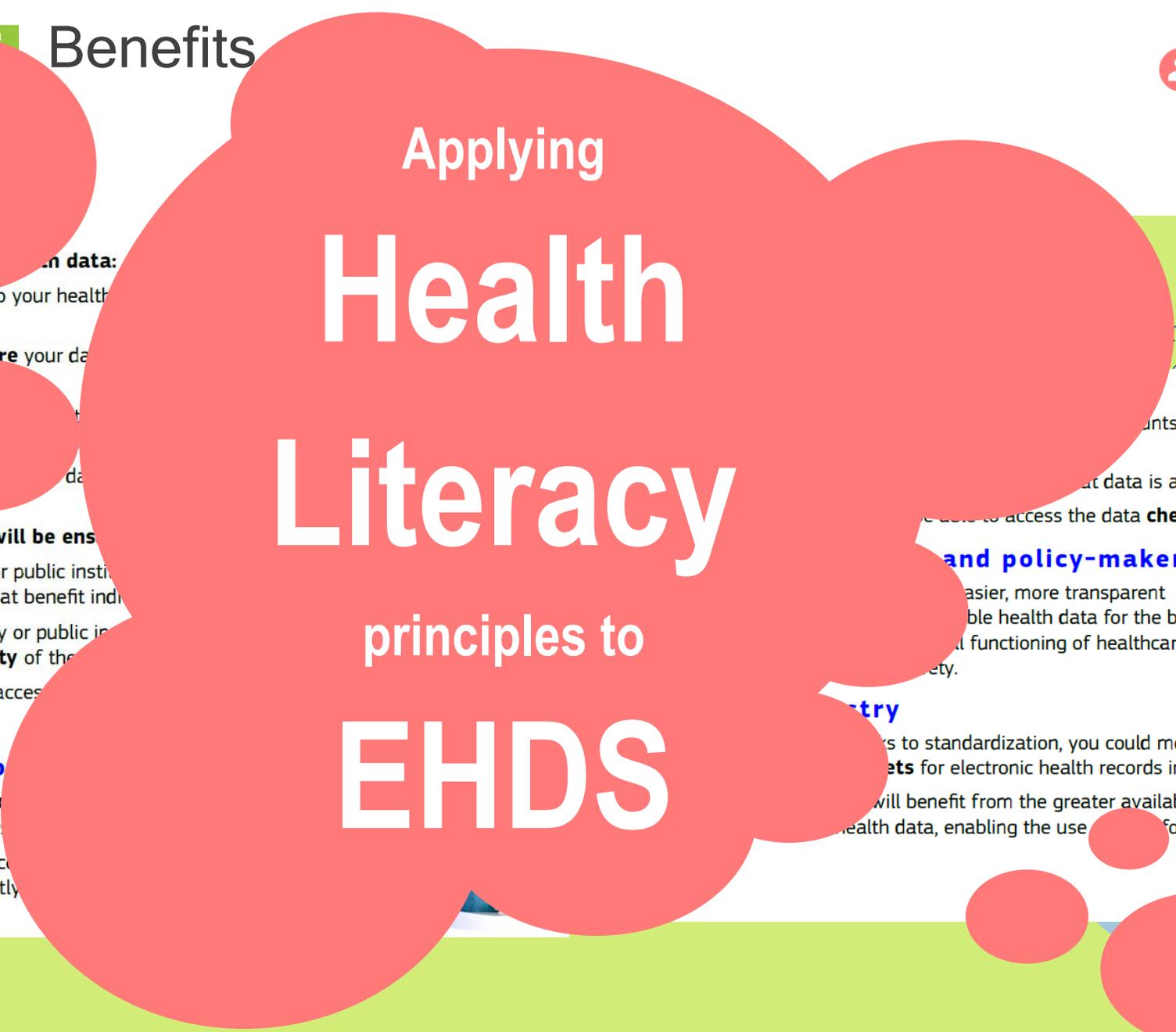


As a citizen

- **You will have access to your data:**
 - You will have **access** to your health data without any cost.
 - You will be able to **share** your data.
 - You will be able to **share** your data in a secure and informative way.
 - You will have **control** over your data in a **transparent format**.
- **Your security and privacy will be ensured:**
 - Researchers, industry or public institutions will have **access** to your data for specific purposes that benefit individuals.
 - The researcher, industry or public institution will **not reveal the identity** of the individual.
 - The data may only be accessed in **secure and safe environments**.

As a health professional

- You will have **faster access** to your data, including across borders.
- You will have easier access to different systems, greatly reducing the **burden**.



Applying
Health Literacy
principles to
EHDS

...ants of health data, of higher quality, in...
...at data is available, where, and of what quality.
...to access the data **cheaper and more effectively**.

and policy-makers

...asier, more transparent and less costly **access**
...able health data for the benefit of public health
... functioning of healthcare systems and to ensure
...ety.

entry

...s to standardization, you could more easily **enter into new**
...ets for electronic health records in other Member States.
...will benefit from the greater availability of non-identifiable electronic
...health data, enabling the use of data for **innovation**.

Join the Network

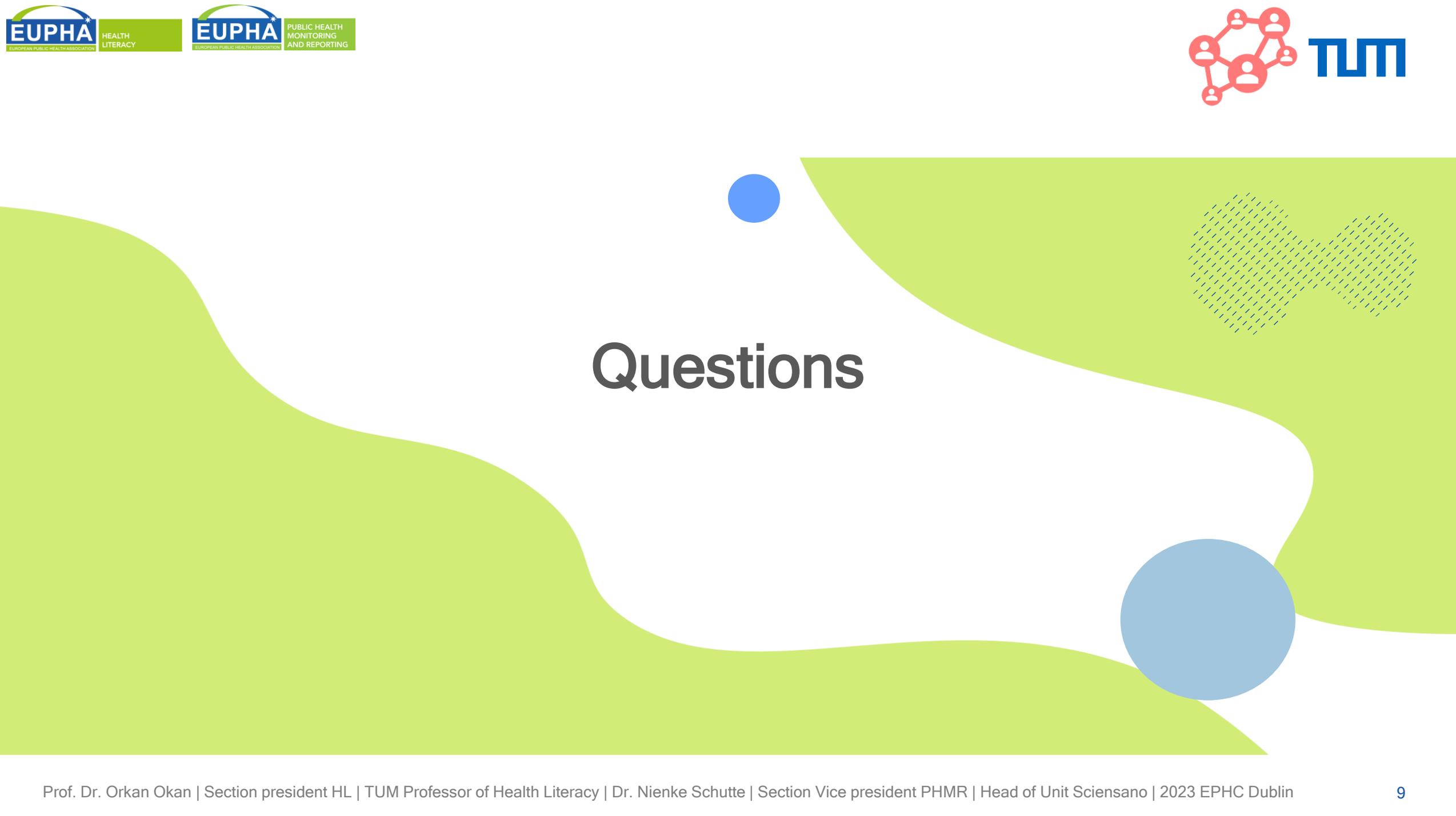


Fri 10th | 14:00-15:00
JTN21 - Health literacy initiative
Liffey Meeting Room 2



Fri 10th | 14:00-15:00
JTN22 - Public health monitoring and reporting -
Wicklow Hall 2A





Questions

BUILDING A EUROPEAN HEALTH DATA SPACE

Dr. Nienke Schutte
EU health information system unit Sciensano

Sciensano's EU Health Information System Unit

Aim: to facilitate the secondary use of health information for research and evidence-informed health policies



**Nienke
Schutte**



**Miriam
Saso**



**Shona
Cosgrove**



**Charles-Andrew
Vande Catsyne**



**Pascal
Derycke**



**Barthélémy Moreau
de Lizoreux**



**Iris Van
Dam**



**Sasha
Milbeck**



A European health data space (EHDS)

The collection, access, storage, use and re-use of health(care) data present specific challenges that require a regulatory framework that best serves individuals' interests and rights.

→ The creation of a **European Health Data Space**

OBJECTIVES

Timely and simplified *exchange of and access to health data*

SCOPE & EXPECTED IMPACT

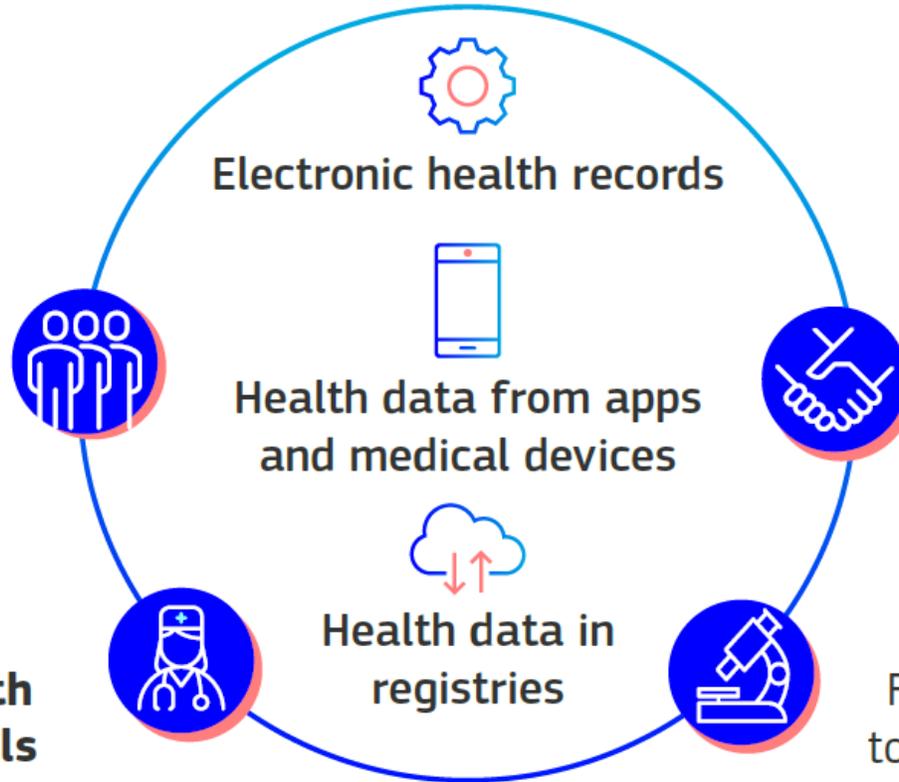


A European Health Data Space (EHDS)

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data



Assist **policy makers and regulators** in accessing relevant non-identifiable health data

Facilitate access to non-identifiable health data for **researchers and innovators**

Better health policy, greater opportunities for research and innovation

Provides rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

The EHDS proposal: chapters

1.I: General provisions

II: Primary use of electronic health data

III: EHR systems and wellness applications

IV: Secondary use of electronic health data

V: Additional actions

VI: European governance and coordination

VII: Delegation and Committee

VIII: Miscellaneous

IX: Deferred application and final provisions

EHDS1 and EHDS2

EHDS1 – Primary use

Processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of a person

Patient summaries, electronic prescriptions, electronic dispensations, medical images and image reports, laboratory results; discharge reports

MyHealth@EU: infrastructure to facilitate cross-border exchange of electronic health data

Access of natural persons to their health data

Self-certification scheme for EHR systems

EHDS2 – Secondary use

Processing of electronic health data for reasons of public interest, produce statistics, research, education, innovation activities

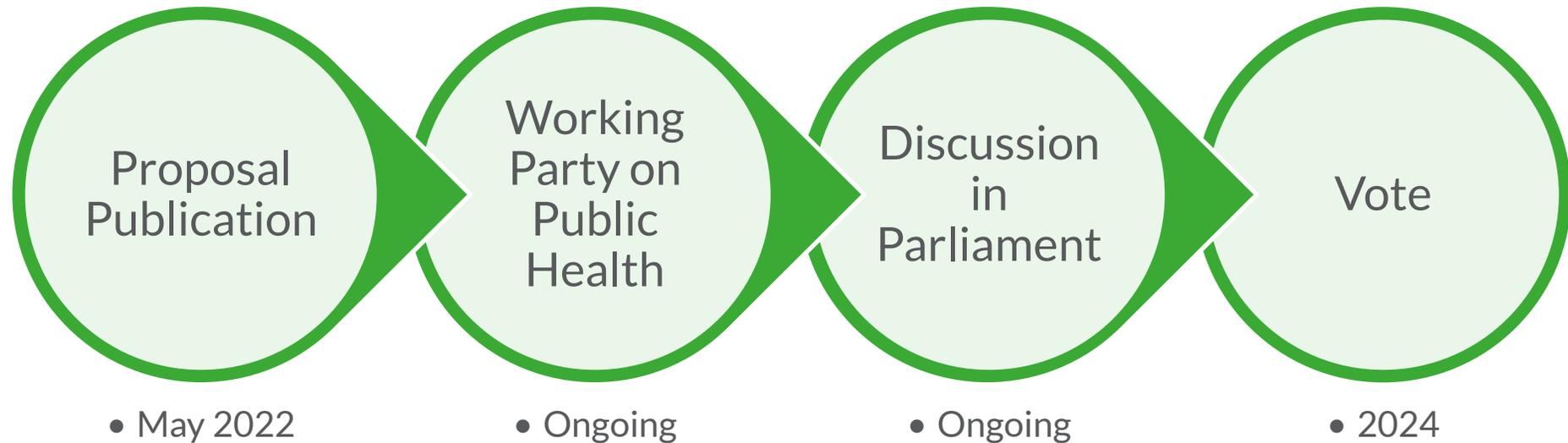
Health data from patients and healthcare professionals, other research data, all types of health data

HealthData@EU: infrastructure connecting national contact points for secondary use of electronic health data and the central platform;

Duties and obligations of the health data access body, the data holders and the data users

General provisions on transparency of fees calculation.

Timeline



The infrastructure for primary and secondary uses of health data should be operational earlier to enable the onboarding of all Member States before this Regulation becomes fully applicable.

Expectations from stakeholders

Results from health information system assessments in 12 countries
in Joint Action TEHDAS



- Political will to join the European Health Data Space
- Concerns with regards to capacity; more staff with technical/legal expertise
- Maturity level of (national) health data management systems differ: countries need different roadmaps for implementation
- Different interpretations of GDPR
- Currently specific national legislation for secondary use of health data
- Diverse, lengthy and sometimes nontransparent access procedures

Nienke Schutte • Nienke.Schutte@sciensano.be

Plain language is communication your audience understands the first time they read it or hear it.

Organize to serve the audience

- Know your audience and purpose before you begin.
- Put the most important message first.
- Present other information in order of importance to the audience.
- Break text into logical chunks and use headings.

Choose words carefully

- Write in the active voice.
- Choose words and numbers your audience knows
- Strive for an average of 20 words per sentence. Limit each sentence to 1 idea.
- Limit paragraphs to 1 topic and 5 sentences.
- Use “you” and other pronouns.

Make information easy to find

- Use headings and text boxes.
- Delete unnecessary words, sentences, and paragraphs.
- Create lists and tables, if appropriate.

Make information easy to understand

Make information easy to evaluate

Make information easy to use



Family Name	First Name	Group
Bartnicka	Joanna Julia	1
Macedo Silva	Anabelle	1
Goss	Hannah	1
Smith	Craig	1
Belfrage	Samantha	1
Prajapati	Nirmala	2
Bakker	Mark Matthijs	2
Tolonen	Hanna	2
SAWAYA	Melissa	2
Derycke	Pascal	3
Palantza	Christina	3
Bonigut	Matthias	3
Von Rueden	Ursula	3
Somekh	David	3
García Sanz	Patricia Julia	4
Aguilera-Cobos	Lorena	4
Guðmundsdóttir	Ingibjörg	4
Murray	Elaine	4
Mathieu-Mendes	Agnès	4
Hussey	Pamela	5
Purnat	Tina	5
Kirchhoff	Sandra	5
Schulenkorf	Tessa	5
Alexandra	Fretian	5



LESSONS FROM TRUSTBUILDING AHEAD OF EMERGENCIES FOR TRUSTBUILDING FOR EHDS

TINA PURNAT

EUPHA Annual Conference 2023





**Trust is reinforced
through experience, not
(just) communication**

Building trust and confidence requires timely and consistent words, actions and interventions.

LOW

access to **health services**
access to **health information**

trust in health system, health workers and recommended health behaviors

HIGH

experiencing practical, social and economic barriers to following health guidance

historically low levels of trust across all dimensions

sometimes follows health guidance that is practical and reasonable to follow

changing trust over time

follows health guidance

consistent trust

Effective social and behavior change in health includes two components

Social marketing for health

social norming = make it easy, sexy and fun

vaccine confidence visible with nurses wearing buttons that say they are vaccinated

HIV status visible on dating apps

promoting free soft drinks for designated drivers at a bar

offering condoms and sanitary products for free in bathrooms

making diaper tables standard in men's restrooms

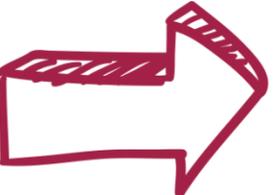
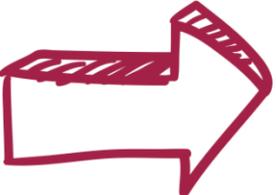
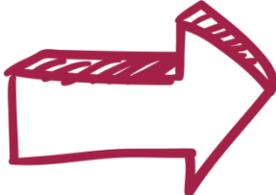


Environmental restructuring/ supportive policy

paid time off for vaccination, education on vaccine benefits, and easy access to vaccinations at or near the workplace

tax breaks or subsidies for bars that participate

building codes, and regulations require public buildings to include diaper-changing facilities; guidelines support implementation

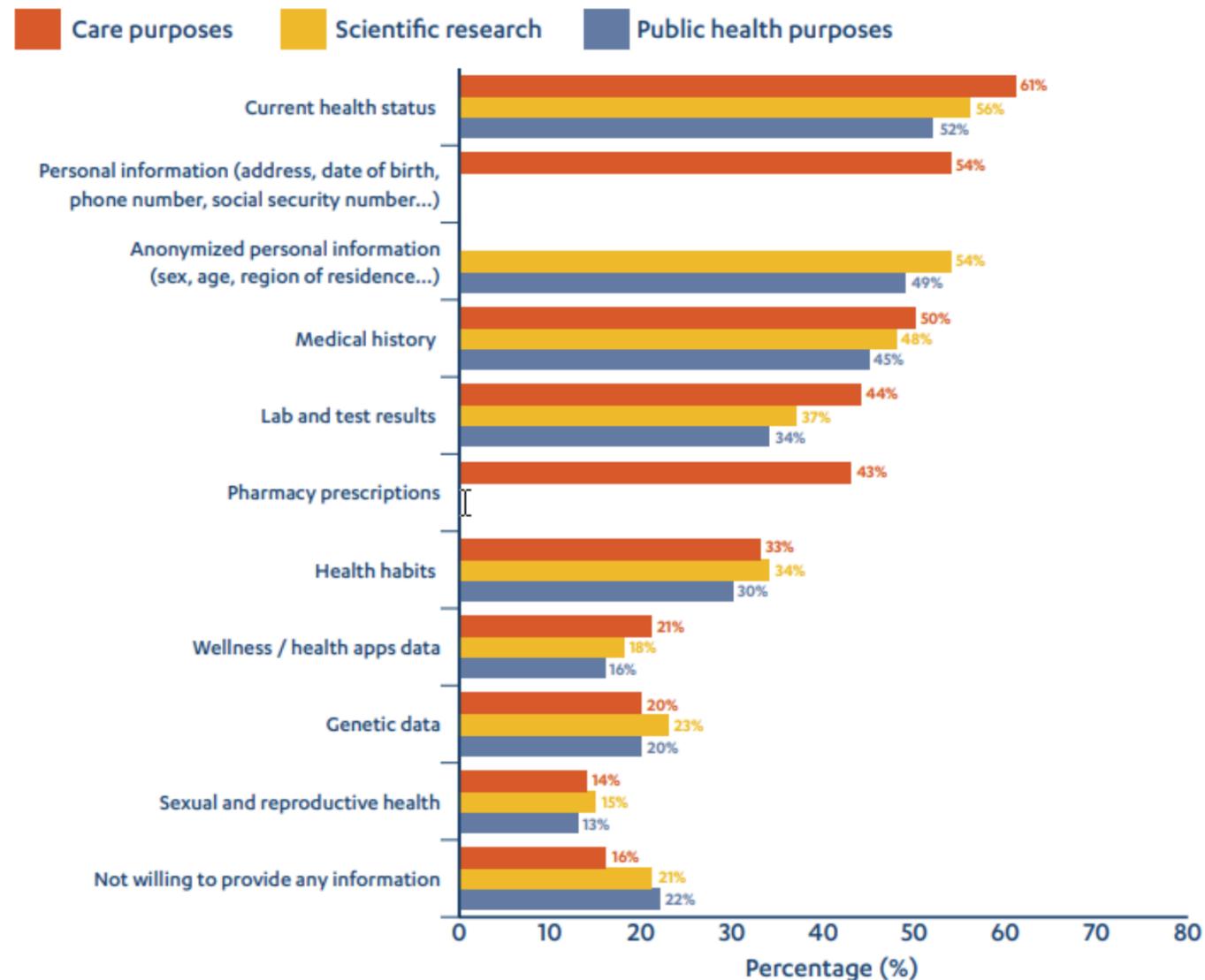


A man in a grey suit and yellow tie is shown from the chest up, holding a large crowd of blue human icons in his left hand and a network of business-related icons in his right hand. The icons include a doctor, a house with a cross, a calendar, a briefcase with a cross, a smartphone with a lock, a cloud with a lock, a laptop with a graph, a stack of money, a bar chart, and a person in a hard hat. The background is a soft, light blue gradient.

**What does this have to do with
EHDS?**

People are very selective about the health data they are willing to share

Which of the following types of personal information would you be willing to provide through an online healthcare platform for...?



for care purposes (61% are willing to share)

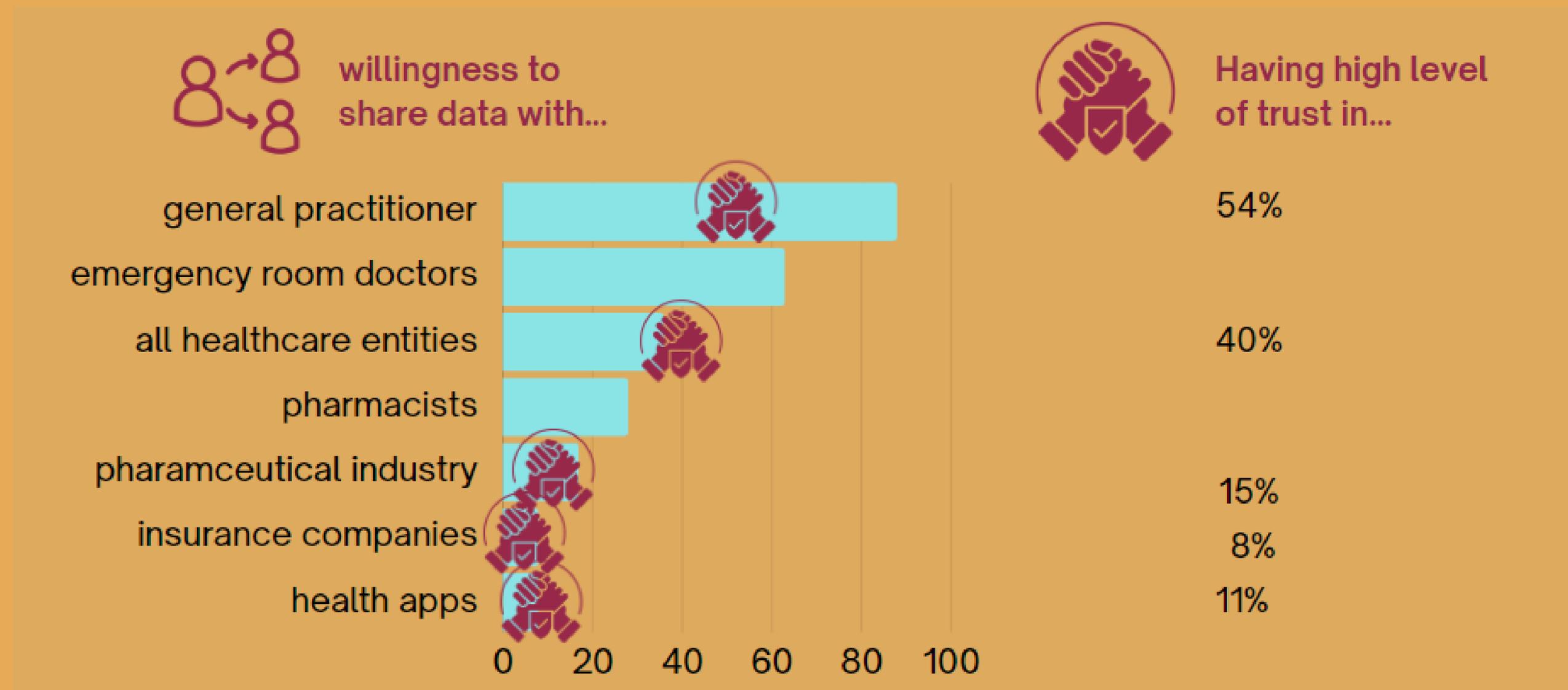


health habits (33% and 30% are willing to share)



genetic data (23% and 20% are willing to share)

Willingness to share data depends on level of trust placed in the receiving entity and how close that entity is to the direct provision of healthcare.



There's a gap between intent and action --- people want to choose what happens to their data, prefer to opt in to share their health data, but their privacy settings today do not reflect that.



81% prefer to choose which data, to whom and for what purpose

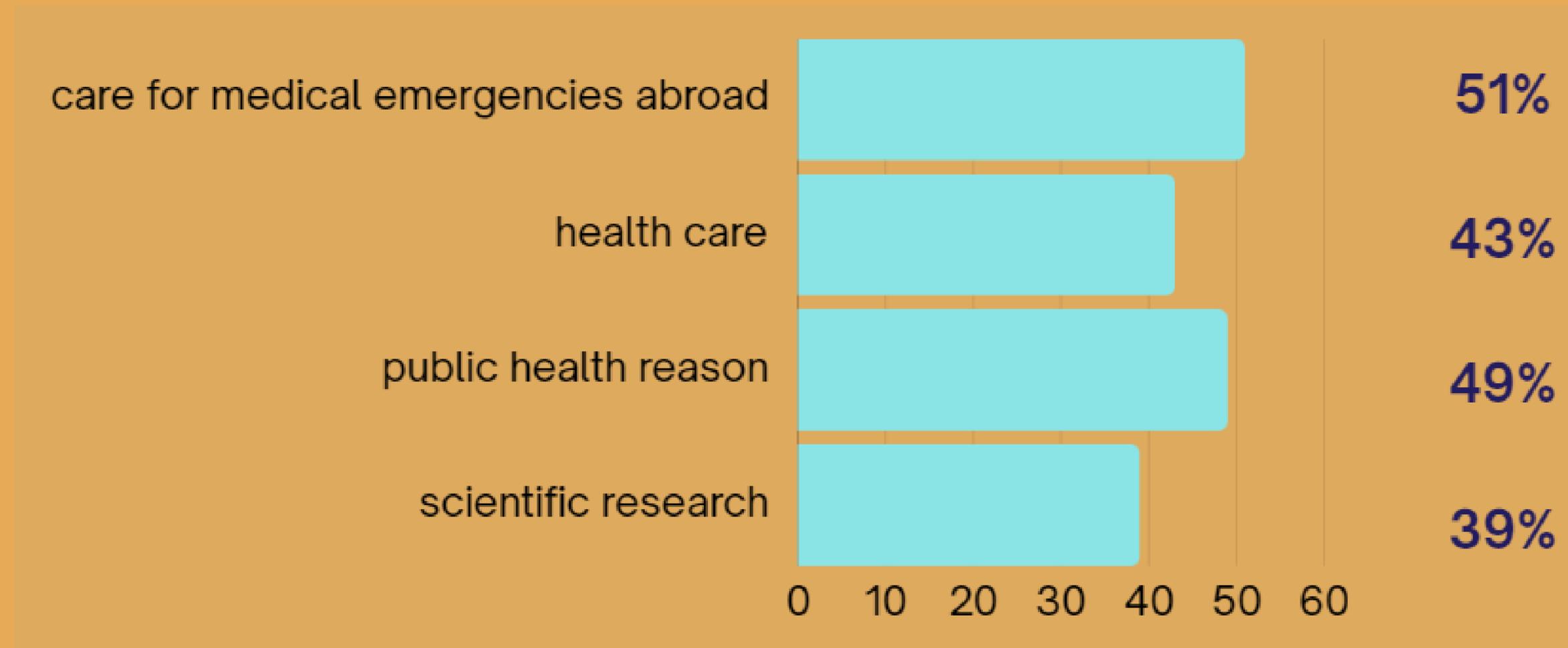


>50% want data accessible only after explicit consent is given



41% haven't taken any actions to limit privacy

Consumers are split about sharing their data across borders of the EU.



People can see benefits, but also have concerns when they share their health data electronically.



Benefits from sharing data

new or better diagnostic systems (39%)

treatment access across the EU (32%)

easier access to health records (32%)

better medical followup (30%)

no benefit (7%)



Concerns about sharing data

data theft (44%)

unauthorized access (40%)

unauthorized use (39%)

refusal to insure or higher insurance premiums (27%)

no concerns (3%)

EU health data space impossible without trust, Commissioner says

By Giedre Peseckyte | Euractiv.com ⌚ Est. 6min

📅 Nov 16, 2022 (updated: 📅 Nov 21, 2022)

No	Lead	Recommendation	Timeframe
1	MS, EU jointly	Engage all the stakeholders (citizens, professionals as well as policy makers) at all levels and throughout the process of implementation of the EHDS to ensure understanding and support to the secondary use of health data.	Short
2	MS	Develop strong and effective citizen communication around the secondary use of health data, including use cases demonstrating the added value for all stakeholder groups.	Short
3	EU	Support exchange of best practices regarding effective communication and awareness raising strategies that lead to increased understanding and acceptance.	Medium
4	MS	Prepare for measures and communication in situations where problems have occurred in the use of health data despite all safeguards and precautions.	Short
5	EU	Study the role and uses of social media, with the aim to reach all citizens, to visualise uses and benefits of sharing health data in the EHDS2.	Medium
6	EU, MS jointly	Implement stringent tools to safeguard the data collected and to prevent any misuse, and strengthen cyber security.	Short
7	MS	Provide individuals means to understand where and how their data is used and provide options for individuals to manage better their health data.	Long

accountability

transparency

crisis communication

social media campaigns,
awareness raising and effective
communication

Data altruism

Without voluntary data sharing by individuals, there will not be enough rich data available for research, innovation and decision-making.

Transparency, trust and citizen empowerment are crucial elements for public acceptance.



**Trust is reinforced
through experience, not
(just) communication**

Building trust and confidence starts with understanding and addressing concerns and trusted messengers...

- address questions and concerns through communication, actions and policies
- address concerns and narratives among populations feeling vulnerable from sharing data
- work with health workers to build and increase confidence in secondary health data sharing and use
- participatory methods in understanding confidence and barriers, building confidence and evaluating confidence

[Front Med \(Lausanne\)](#), 2023; 10: 1141685.

PMCID: PMC10098212

Published online 2023 Mar 30. doi: [10.3389/fmed.2023.1141685](https://doi.org/10.3389/fmed.2023.1141685)

PMID: [37064041](https://pubmed.ncbi.nlm.nih.gov/37064041/)

The application of data altruism in clinical research through empirical and legal analysis lenses

[Teodora Lalova-Spinks](#),^{1,2,*} [Janos Meszaros](#),^{1,2} and [Isabelle Huys](#)¹

► [Author information](#) ► [Article notes](#) ► [Copyright and License information](#) [PMC Disclaimer](#)

Results

Fourteen experts took part in the interviews, more than half of which were DPOs/legal experts. Interviewees were based in seven EU Member states and the United Kingdom. The majority of participants were critical towards the data altruism mechanism and pointed out challenges and risks associated with its application.

... but we will need to make health data sharing and secondary data use a social and workplace norm

Social marketing for health



Environmental restructuring/
supportive policy

social norming = make it easy, sexy and fun



- emphasize serving positive experiences of people with data linkage
- make data and secondary use projects as tangible to people as possible - “I see the linked data”, “I see purpose of public health and research”
- promoting digital, information and health literacy
- requiring researchers to look for existing data before more data collection
- develop strategies to promote workplace norms based on organizational psychology



**Thank you
very much!**

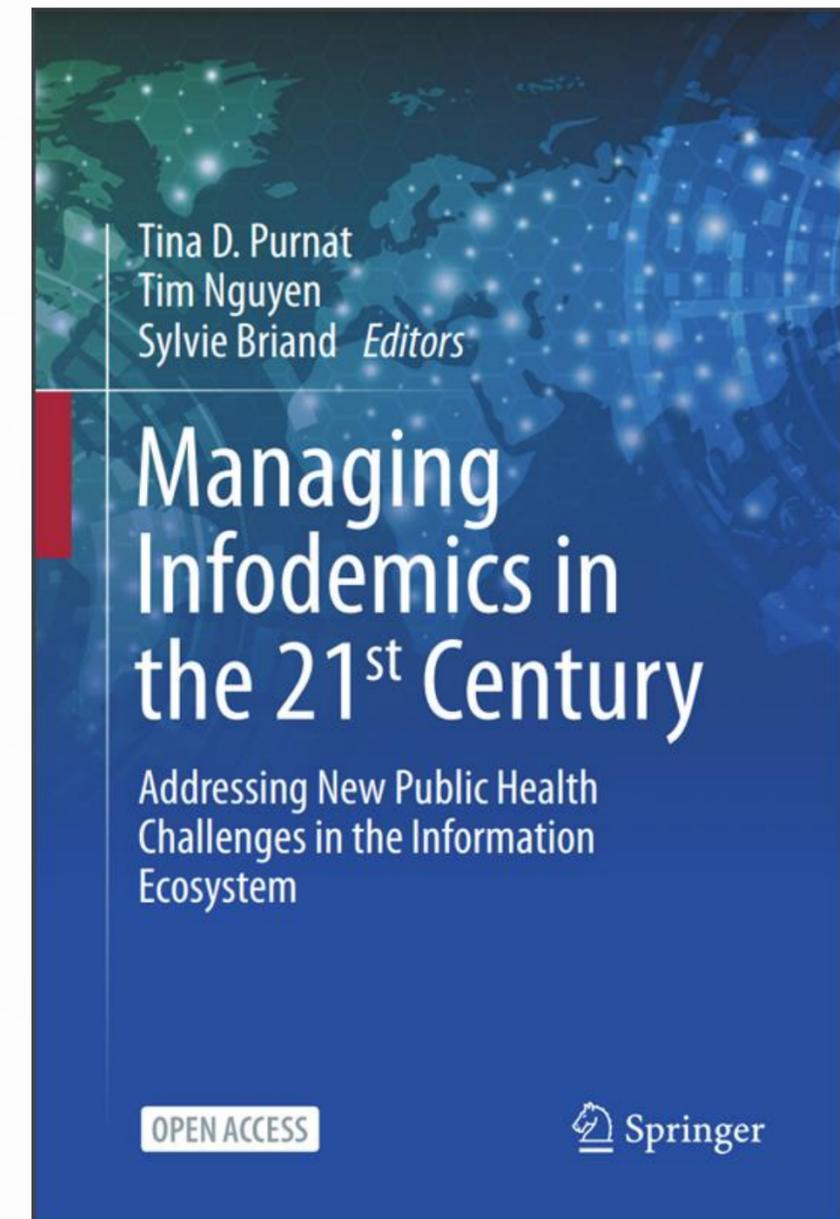


tinapurnat.com

Infodemic management

An **infodemic** is an overabundance of information, accurate or not, in the digital and physical space, accompanying an acute health event such as an outbreak or epidemic.

Infodemic management is the systematic use of risk- and evidence-based analysis and approaches to promote a healthier information environment and resilience against infodemic impacts on health behaviours during health emergencies.



Challenges in the information environment need to be identified and addressed.



deceptive marketing in health



hyperbolic press coverage

infodemic

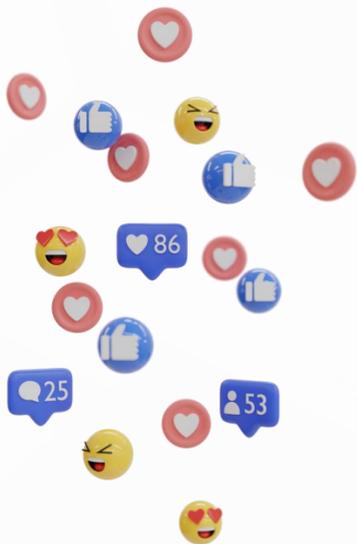
(unaddressed questions, concerns, information voids, misinformation and harmful narratives related to an acute health event)

health misinformation

publication of low quality scientific papers



subpar communication from health authorities



Information environment x trust



- **Trust in policies and governance** related to health care, supply, service delivery
- Asymmetries in demand for **care and prevention**
- Asymmetries in demand for **supplies and health technologies**



- Trust in health workers; **doxxing and harassment**
- **Health worker own confidence** in products and services, in own knowledge about guidance and information



- Risk perception of **disease**
- Trust in and acceptability of recommended **behaviors and public health and social measures**
- Trust in, safety and acceptability of **devices, diagnostics, treatments and vaccines**
- **Social cohesion**

Strategies for building trust in communities



**Listening to questions, concerns,
and circulating narratives**



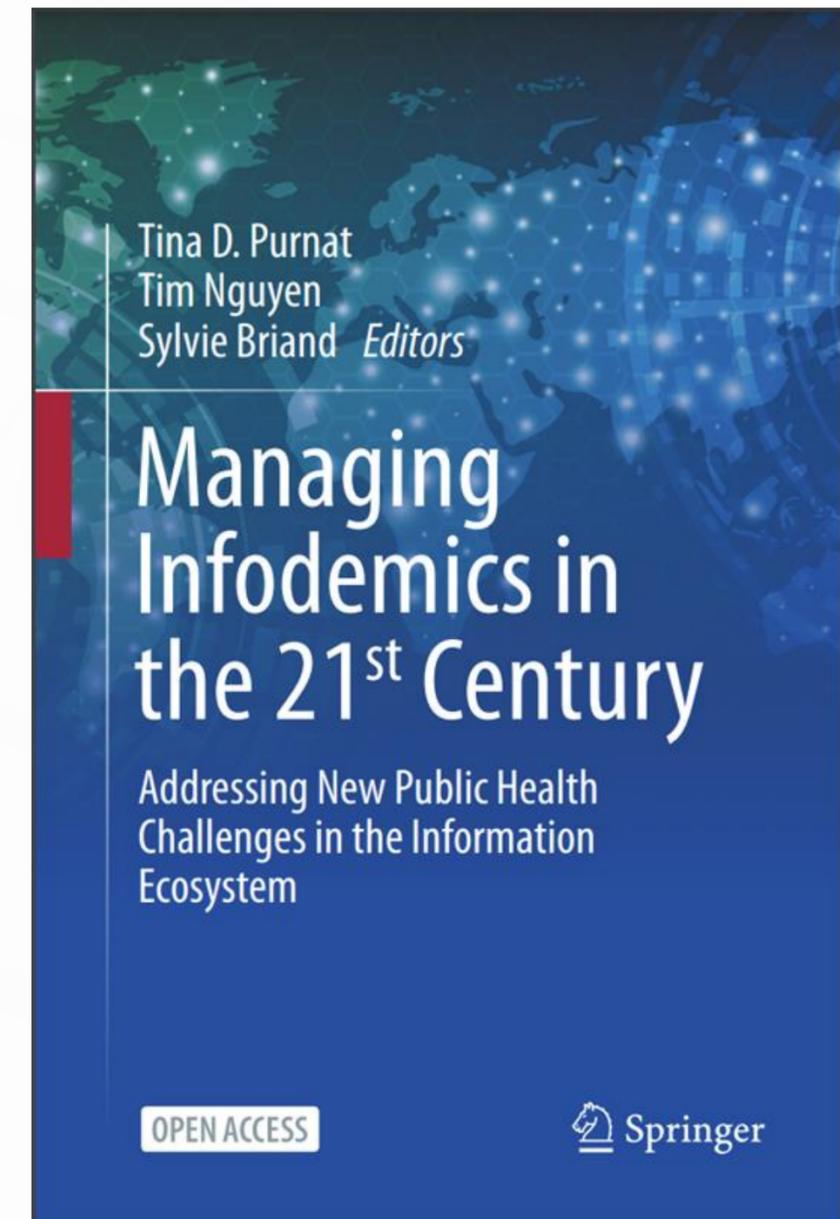
Communicating science



**Promoting resilience to infodemic/
confusion/ misinformation**



Empowering communities



Trustbuilding strategies



Increase linkage between health system and communities



Increase linkage between health workers and patients



promote confidence and uptake of recommended behaviors among health workers



promote health, digital, information, science and media literacy



listen to questions and concerns and address them through words, actions and interventions



involve communities in policymaking so they are reflected in policies and are partners in implementation