

The secondary use of data

Addressing the elephant in the room

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Chair ESC Regulatory Affairs Committee



- MEP Heart Group “EHDS & Registries: Restoring the EU’s primacy in research”
26 April 2023



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The elephant in the room



- The phrase “the elephant in the room,” generally refers to a problem that is glaringly obvious but willfully ignored.

THE INQUISITIVE MAN.

“GOOD day, dear friend ; where do you come from ?”
 “From the Museum, where I have spent three hours. I saw everything they have there, and examined it carefully. So much have I seen to astonish me, that, if you will believe me, I am neither strong enough nor clever enough to give you a full description of it. Upon my word it is a palace of wonders. How rich Nature is in invention ! What birds and beasts haven’t I seen there ! What flies, butterflies, cockroaches, little bits of beetles !—some like emeralds, others like coral. And what tiny cochineal insects ! Why, really, some of them are smaller than a pin’s head.”

“But did you see the elephant ? What did you think it looked like ? I’ll be bound you felt as if you were looking at a mountain.”

“Are you quite sure it’s there ?”

“Quite sure.”

“Well, brother, you mustn’t be too hard upon me ; but, to tell the truth, I didn’t remark the elephant.”

Ivan Andreevich Krylov’s
1814 fable, “The Inquisitive Man.”

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The elephant in the room – GDPR



- GDPR contains a large number of provisions that either permit or require Member States to make their own rules, so substantial national variations remain.
- The majority of Member States impose additional conditions regarding processing of personal data in the context of scientific research purposes or statistical purposes. The nature of these conditions varies substantially from one MS to the next.



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Elephant in the room – laissez faire policy



- There is not a single common EHR system operating across all EU Member States. Instead, some countries have it and some do not; and those which do often have different EHRs implemented at regional, municipal, hospital levels.



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A case of vendors - Cardiac Implantable Electronic Devices (CIED)



- CIED information can be retrieved by in-office interrogation or telemonitoring
- However, all CIED data CANNOT be viewed in a single place and
- Discrete data (battery; pacing sensing values; ...) CANNOT be retrieved, due to different file formats; inhomogeneous adherence to the format standard, differences between vendors, ...

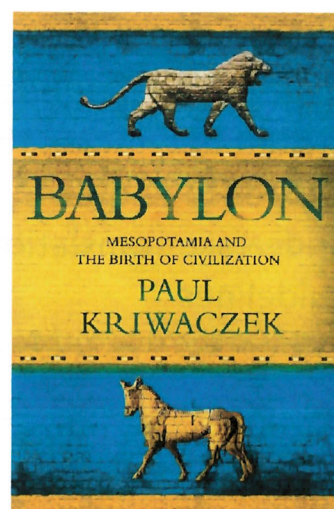


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A case of Mesopotamia



If history, as by most definitions, begins with writing, then the birth, rise and fall of ancient Mesopotamia occupies fully half of all history....



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Lessons to be learned from the past



- Throughout [its 2,500 years] **Mesopotamia preserved a single civilization, using one unique system of writing, cuneiform, from beginning to end; and with a single, continuously evolving literary, artistic, iconographic, mathematical, scientific, and religious tradition.**



• Paul Kriwaczek

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A case of ESC - Clinical Practice Guidelines




- National Cardiac Societies are invited to endorse the guidelines and, once endorsed, are free to undertake translations of the guidelines
- Guidelines are based on clinical evidence - science, clinical trials and registries




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Science tells us
what we can do...



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Randomized controlled trials tell us
what we should do...



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Real world data/registries tell us
what we are actually doing...

John Mandrola, Medscape

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The secondary use of data
Addressing the elephant in the room



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Health data reuse: the real game-changer



EDIDEMIOLOGY AND PREVENTION



INEQUALITIES IN ACCESS TO CARE



IDENTIFICATION AND MANAGEMENT OF RISK FACTORS



ARTIFFICIAL INTELLIGENCE

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Health data reuse: the real game-changer



EDIDEMIOLOGY AND PREVENTION



IDENTIFICATION AND MANAGEMENT OF RISK FACTORS

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Epidemiology and prevention



- Data reuse is critical for epidemiology and prevention as it generates insights about disease patterns, risk factors, and interventions, enabling to develop effective strategies to prevent and treat diseases, ultimately improving public health
- Data reuse has played a critical role in the epidemiology and prevention of COVID-19

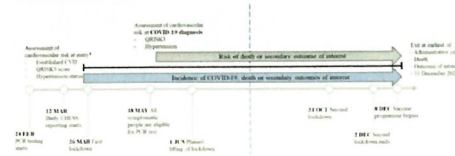
Severe COVID-19 outcomes by cardiovascular risk profile in England in 2020: a population-based cohort study

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³Institute of Health Informatics, University College London, London, UK

Summary
Background While cardiovascular disease (CVD) is a risk factor for severe COVID-19, the association between predicted cardiovascular risk and severe COVID-19 among people without diagnosed CVD is unclear.

Methods We carried out historical, population-based cohort studies among adults aged 40–84 years in England using linked data from the Clinical Practice Research Datalink. Individuals were categorized into existing CVD, raised cardiovascular risk (defined using QRISK3 score $\geq 10\%$) and low risk (QRISK3 score $< 10\%$) at 12/03/2020. We described incidence and severe outcomes of COVID-19 (death, intensive care unit [ICU] admissions, hospitalisations, major adverse cardiovascular events [MACE]) for each group. Among those with a COVID-19 record to 31/12/2020, we reclassified cardiovascular risk at infection and assessed the risk of severe outcomes using multivariable Cox regression with complete case analysis. We repeated analyses using hyperestimation to define raised cardiovascular risk.



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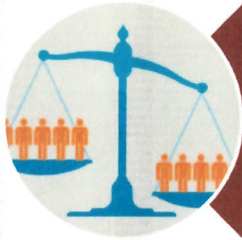
Data pseudonymization



- The use of pseudonymised data is key to enable data linkage for longitudinal studies, allowing researchers to track changes over time and draw meaningful conclusions from the data.
- According to the EHDS proposal, *“where the purpose of the data user’s processing cannot be achieved with anonymized data the health data access bodies shall provide access to electronic health data in pseudonymised format”*.
- **This provision should be maintained**, while providing adequate measures to safeguard patients’ privacy and avoid re-identification, including access through a secure processing environment.

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Health data reuse: the real game-changer

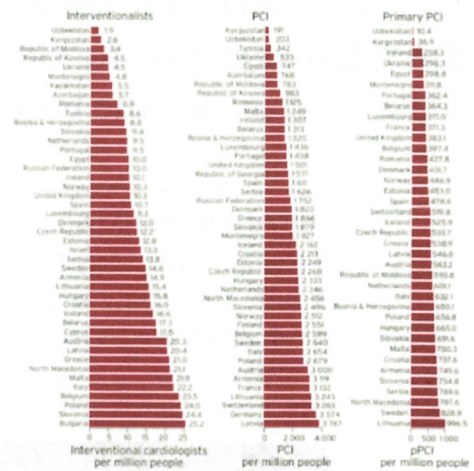


ADDRESSING INEQUALITIES
IN ACCESS TO CARE

Inequalities in access to care



ESC •
Cardiovascular
Realities 2022
An Illustrated Atlas of Key European Statistics



Addressing inequalities in access to care



- The EHDS has the potential to address inequalities in access to care and improve health outcomes for all populations in the European Union.
- Evidence-based policies tailored to the needs of specific populations.



An urgent need to ensure interoperability



Interoperability and standardization are a precondition for the EHDS to overcome the current fragmentation across Member States and unlock the potential of health data in the EU.

Structured data based on clinical characteristics key to ensure interoperability and allow for analyses across large datasets



Need to predefine disease-specific harmonized templates for structured data elements

Leveraging existing health data infrastructures, including registries in the cardiovascular disease field, to define common minimal datasets of clinical data and their characteristics.

Health data reuse: the real game-changer



ARTIFICIAL
INTELLIGENCE

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Definition of stupidity

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Definition of stupidity



- “Stupidity is using a rule where adding more data doesn’t improve your chances of getting [a problem] right. In fact, it makes it more likely you’ll get it wrong”

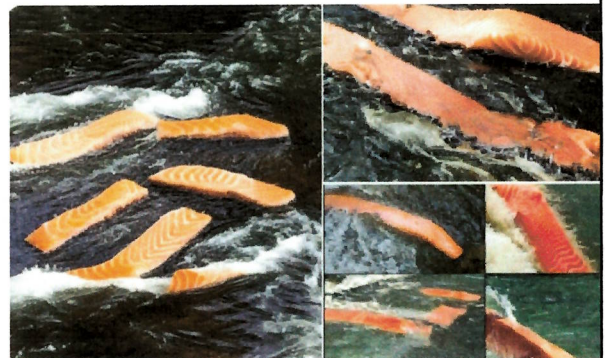
David Krakauer, Santa Fe Institute

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AI artwork



- Produced by the prompt „salmon swimming in the river”

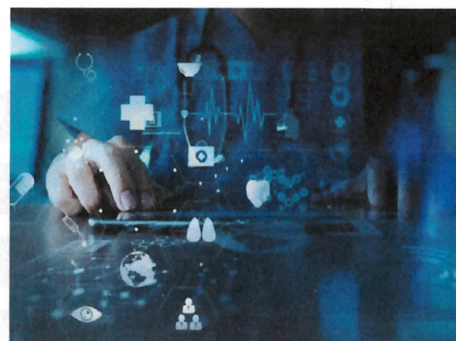


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Enhancing data quality



- The EHDS has the potential to enhance data quality by creating standards for data collection, analysis, and sharing, improving the development of new treatments, technologies and interventions.



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Opt-out: a balanced solution



- The success of the EHDS and the benefits of secondary use for public health are strongly dependent on the quality of the data collected.
- An opt-in/consent model for secondary use would be a barrier, as research and decision-making would be based on incomplete/not representative data, leading to biased findings and ultimately affecting patients' safety.
- On the other hand - although the Commission proposal already includes safeguards to protect patients' privacy - an opt-out approach could represent a balanced solution to strengthen privacy further while preserving data completeness.



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The role of medical societies



Healthcare professionals will be the key users and enablers of the EHDS. Medical societies can play a key role in the *implementation* of the new framework and contribute substantially to *harmonization*, especially for secondary use. To this end, the following recommendations are suggested:

-  Early consultation of medical societies in the definition of implementing and delegated acts
-  Leveraging the expertise with registries in CVD to define EHDS standards and minimal datasets
-  Support to non-profit organizations in collecting and sharing high-quality data
-  Involvement in the EHDS governance through participation in the EHDS Board
-  Access to electronic health data to perform activities contributing to public health

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Conclusions



- Electronic health data is a crucial resource for decision-making, health system management and improvement, and research, with potential substantial benefits to public health and society.
- Data quality and completeness are a precondition for the EHDS to achieve its objectives, while preserving patients' privacy. **Opt-out for secondary use appears as a balanced solution.**
- **Disease-specific harmonized templates for structured data elements must be predefined** to ensure interoperability, leveraging on existing health data infrastructures.
- When needed and conditional on safeguards to patients' privacy, **data pseudo-anonymization should be allowed.**
- **Medical societies** can play a key role in the implementation of the new framework and contribute substantially to harmonization. They **should be regularly consulted and involved in the governance of the new system.**

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