SECTION 5

Closing the loop: The relation between primary and secondary use

Challenges and enablers for implementation

While the focus of the roundtable series was on secondary use of health data, this could not be considered in isolation because its effectiveness will depend on the quality of data collection in the primary use setting. Healthcare professionals will therefore have a key role in implementing data standards and collection practices that must not just support them in delivering patient care, but also meet the needs of the research ecosystem. Ideally, primary data collection would be designed from the outset to allow reuse for secondary purposes, generating rich clinical profiles for research and reducing the need for additional processing steps to make data interoperable. The reality reported across most countries represented in the discussions, however, is that current workflows and data management in healthcare are not geared towards such structured data entry and professionals generally lack both the capacity and the incentive to record information beyond what they directly need to deliver care to patients. It is hoped that technology will resolve this conflict through new possibilities such as automated data collection and transfer, as well as integrated analytical features offering insights and decision-making support to clinicians within the data capture environment. In this area and in many others, secondary use of data will inevitably transform its primary use. New data-driven solutions will change established clinical care processes and require new patient pathways to be defined and standardised. They could also accelerate the shift from treatment of illness to prediction and prevention in the way healthcare is delivered—a shift that will need to be accompanied by an overhaul of European health

systems' current funding and reimbursement models. Healthcare professionals, patients and citizens should be included as active participants early on to keep their interests at the heart of the process and foster trust in the transformation. To ensure that the most valuable innovations reach all those who could benefit from them without delay, paths for the evaluation of data-driven innovation and its introduction into clinical pathways will need to be further developed and standardised across the EU. In this area, public-private partnerships could be instrumental to ensuring that novel solutions and services are designed from the start with a clearly defined unmet healthcare need in mind.

Solutions should aim to

▶ **Facilitate the flow of data from primary to secondary use settings**

▶ **Build trust in the outputs of secondary use of data**

▶ **Chart the paths to closing the loop between primary and secondary data**

At European level

Define which primary data needs to be collected for reuse and accelerate the adoption of international standards and coding for the relevant data categories.

Establish a standardised path for secondary users to comply with their obligation to report incidental findings. The finding should be reported in a timely manner, defining how, where and to whom the relevant information on patients must be provided.

At national and regional levels

Support technical-legal approaches and standard-setting to enable automatic transfer of EHR data from primary to secondary use systems and smooth integration with national health data access bodies.

Engage with healthcare professionals and involve them in data-sharing platforms early on to demonstrate tangible value and foster trust and active participation in the EHDS.

Develop standard methods for evaluating data-driven health technologies' reliability and fitness for clinical practice.

Establish step-by-step rules and processes to address ethical and other issues that arise from the use of AI in healthcare.

Develop educational resources for all stakeholder groups (citizens, healthcare professionals, health institutions, insurance providers, payers, public health, and political actors) to improve knowledge of the new technologies being developed and deployed in the health sector.

Develop structured paths to adoption and reimbursement of data-driven innovation by the healthcare systems, centred around defined patient or societal needs.

Specify the characteristics that data or insights from secondary use must have to be considered relevant and useful to share with healthcare providers.

Health data access bodies

Facilitate data traceability to foster trust in the new outputs and technologies to be fed back into healthcare.

Healthcare providers

Generate use cases to demonstrate to healthcare professionals the benefits and time savings that can be achieved for them through the digital transformation of healthcare and educate them on their role in entering high-quality data into health information systems.

Develop guidelines and standard protocols for data collection that support healthcare professionals and integrate easily into their workflows.

Specify the characteristics and type of data and/or analysis from secondary use that are relevant and useful to be provided to healthcare professionals.

▶ EXAMPLE

Italy's DARE Digital Lifelong Prevention programme is a four-year initiative financed by the national Ministry of Higher Education and Research, aiming to develop a distributed knowledge community that can foster the emergence of new models and solutions for health promotion, monitoring, and disease prevention for the general population and subgroups such as children, pregnant women, or chronic patients. A diverse network of partners including universities, research centres, local health authorities, foundations, and private companies work together to harness the potential of digital technologies to bridge social and geographic disparities in the delivery of integrated health and care services. Another valuable initiative in this area is the Data Value in Integrated Diagnostics educational programme carried out by EIT Health, Italy's IRCCS Synlab SDN and other partners, which aims to create "data friend" professionals capable of informing patients and encouraging data-sharing, and familiar with the principles of data analytics and correct procedures for data collection.

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