

REAL WORLD DATA AND EVIDENCE

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RESEARCH

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A framework for value-creating learning health systems



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Health Research Policy
And Systems, 2019

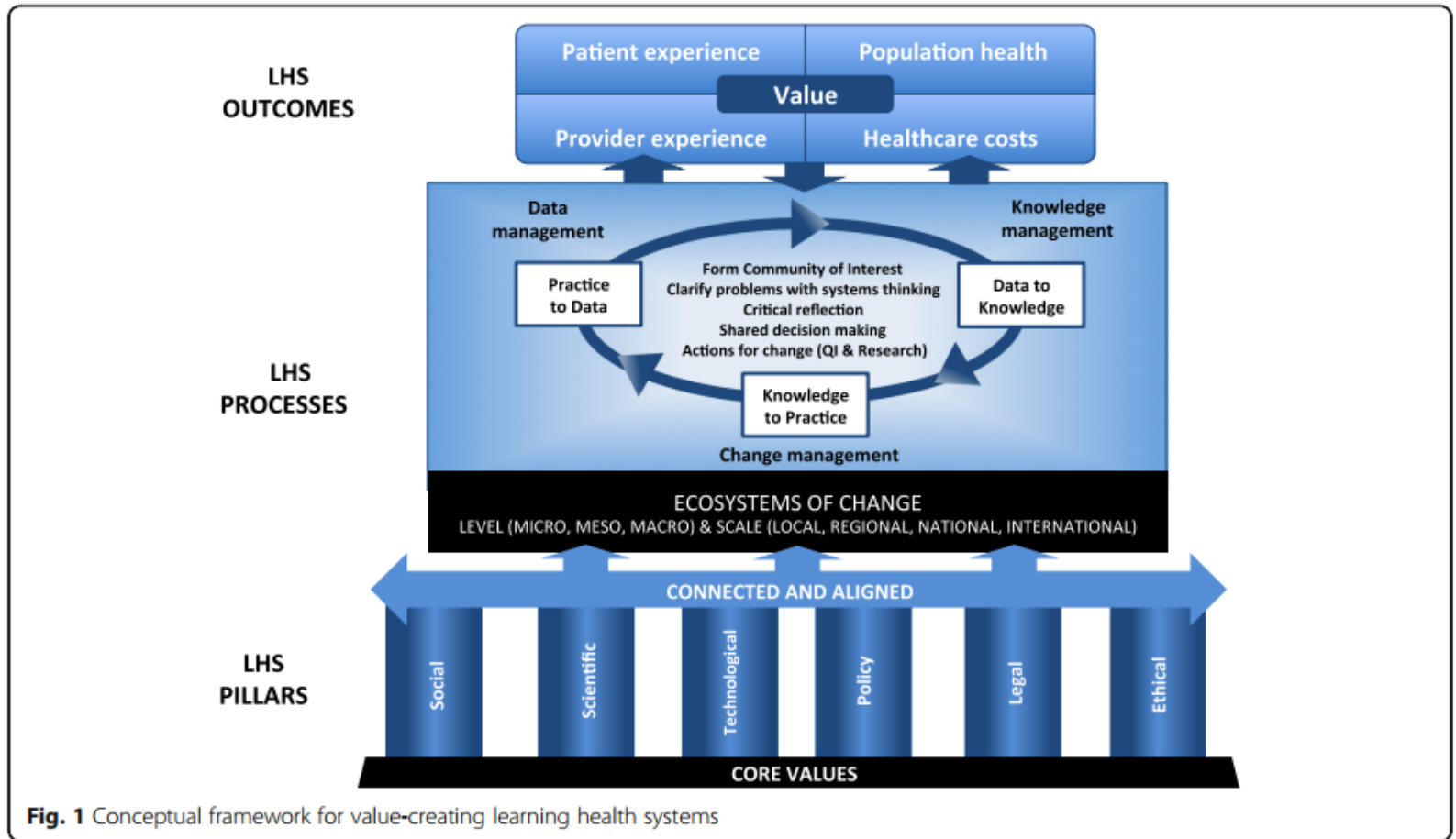


Fig. 1 Conceptual framework for value-creating learning health systems

European Commission - Press release



Commission and Germany's Presidency of the Council of the EU underline importance of the European Health Data Space

Brussels, 11 November 2020

Today at the virtual High-Level Conference "Digital Health 2020 - EU on the Move", the Commission and Germany's Presidency of the Council of the EU announced their intention to work closely together on a secure and patient-oriented use of health data for Europe, and EU-wide collaboration in this area, through a European Health Data Space for better healthcare, better research and better health policy making. The set-up of the European Health Data Space will be an integral part of building a European Health Union, a process launched by the Commission today with a first set of proposals to reinforce preparedness and response during health crisis. This is also a direct follow up of the Data strategy adopted by the Commission in February this year, where the Commission had already stressed the importance of creating European data spaces, including on health.

European Commission,
11 november 2020

- The Commission proposes a European Health Data Space in 2021;
- A Joint Action with 22 Member States to propose options on governance, infrastructure, data quality and data solidarity and empowering citizens with regards to secondary health data use in the EU;
- Investments to support the European Health Data Space under the EU4Health programme, as well as common data spaces and digital health related innovation under Horizon Europe and the Digital Europe programmes;
- Engagement with relevant actors to develop targeted Codes of Conduct for secondary health data use;
- A pilot project, to demonstrate the feasibility of cross border analysis for healthcare improvement, regulation and innovation;
- Other EU funding opportunities for digital transformation of health and care will be available for Member States as of 2021 under Recovery and Resilience Facility, European Regional Development Fund, European Social Fund+, InvestEU.



Brussels, 25.11.2020
COM(2020) 761 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

Pharmaceutical Strategy for Europe

{SWD(2020) 286 final}

European Commission,
25 november 2020


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Policy

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Real-world evidence to support Payer/HTA decisions about highly innovative technologies in the EU—actions for stakeholders

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Challenges	Policy Asks
<p>Fragmentation and duplication in RWE requests</p> <p>Regulator and payer/ HTA requests differ according to the question being asked, the level of risk and other considerations such as the ability to capture other data, availability of other treatments and unmet medical need</p>	<p>EU and National Policy Makers</p> <ul style="list-style-type: none"> • Develop a framework, for cross-country collaboration on studies underway across different jurisdictions to enable data amalgamation. • Funding to develop the infrastructure for cross organisational sharing of RWE generation plans and post-licensing evidence generation and information about RWD (HTA).
<p>Lack of methodological processes</p> <p>For trust in the quality of RWD in order to incorporate it into decision-making</p>	<p>EU and National and International Policy Makers</p> <ul style="list-style-type: none"> • Ensure the European Health Data Space facilitates data quality and accessibility. • Develop evidentiary standards for RWE that take account of the context and agree on common core data elements (in terms of accuracy, completeness and tracability) to ensure validity and consistency across sources. • Promote comprehensive and internationally aligned harmonized guidance across bodies (epidemiology society, EUnetHTA, ISPOR, EMA...). Guidance to include how to reconcile differences between RWE data sets, and how RWE can complement Randomised Clinical Trial (RCT) data.
<p>Legal uncertainty regarding interpretation of data protection legislation</p> <p>E.g. GDPR and data access</p>	<p>EU and National Policy Makers</p> <ul style="list-style-type: none"> • Provide a framework for data security and privacy for individuals, while offering a clear legal basis for interoperability of health records across different data sources e.g. pre-existing data sets, electronic medical records, health insurance claims databases.
<p>Lack of patient involvement to address their unmet needs</p>	<p>EU and National Policy Makers</p> <ul style="list-style-type: none"> • Ensure systematic patient involvement in RWD collection to capture “real-world” experience of patients. • Monitor level of impact of RWE on availability of highly innovative treatments across Europe (in terms of speed of access and quality of patient outcomes).
<p>Under-utilisation of digitalized data in healthcare and medical practice</p>	<p>EU and National Policy Makers</p> <ul style="list-style-type: none"> • Promote the use of digitalized data in healthcare and medical practice.

