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Peer Review

Review of: "Advancing Personal Health Data Spaces: Governance, Interoperability, and Real-World Evidence for Learning Healthcare Systems"

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This manuscript presents a timely, ambitious, and highly relevant commentary on the role of Personal Health Data Spaces in the future development of healthcare. I appreciate its patient-centred perspective and its recognition that personalised medicine cannot be achieved through isolated technological solutions, fragmented clinical information, or disconnected research initiatives.

The manuscript addresses a sensitive but fundamental problem: healthcare systems are still often organised in professional, institutional, and data-related silos. In practice, individual clinical units, specialists, and researchers may work with considerable expertise, but too often within separate perspectives and infrastructures. This can lead to duplication, incomplete understanding of the patient journey, inconsistent data use, and missed opportunities for collaboration.

From my own professional experience, I recognise this fragmentation. Major clinical and scientific questions are rarely solved by a single specialty, clinic, institution, or data source. The development of meaningful personalised treatment requires integration across clinical disciplines, longitudinal patient data, imaging, laboratory and genomic information, patient-reported outcomes, real-world evidence, and rigorous analytical methods.

A particular strength of the manuscript is its distinction between Personal Health Data Spaces and related concepts such as the European Health Data Space, federated data infrastructures, real-world evidence platforms, and learning healthcare systems. The

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proposed PHDS framework usefully positions the individual patient and the longitudinal healthcare journey at the centre, rather than treating data as an isolated institutional or technical asset.

I also welcome the manuscript's balanced discussion of governance, trust, privacy, cybersecurity, algorithmic bias, explainability, and consent. These aspects must be treated as core elements of implementation, not as secondary barriers to be addressed after technological deployment. Without transparent governance and genuine patient involvement, even technically advanced infrastructures may fail to gain the legitimacy necessary for long-term adoption.

The implementation roadmap is practical and valuable. In particular, its emphasis on interoperability standards, common data models, data-quality requirements, federated analytics, workforce capability, and phased implementation provides a realistic alternative to overly optimistic visions of immediate large-scale integration.

Overall, this is a thoughtful and valuable contribution. It provides a coherent conceptual framework for connecting personalised care, AI-enabled analytics, real-world evidence, and regulatory science within a trustworthy healthcare ecosystem. I recommend publication after minor revision, mainly to further clarify the operational model, the responsibilities of stakeholders, and the practical evidence needed to demonstrate impact on patient outcomes and healthcare delivery.

Recommendations

Clarify more explicitly how PHDS would operate in routine clinical workflows, including who is responsible for data curation, clinical validation, consent management, and decisions based on AI-supported outputs.

Add concrete use cases showing how PHDS can reduce fragmentation across primary care, specialist care, hospitals, research, and follow-up—oncology would be a particularly convincing example.

Define measurable success criteria, such as improved continuity of care, reduced duplicated testing, better treatment matching, improved representativeness of evidence, patient-reported outcomes, and more equitable access to innovation.

Discuss the risk that new PHDS infrastructures could themselves become another layer of fragmentation if standards, incentives, governance, and clinical ownership are not aligned. This point would reinforce the manuscript's central argument.

Strengthen the patient perspective by explaining how patients can participate not only through consent, but also in co-governance, priority-setting, access to their information, and decisions about secondary data use.

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Declarations

Potential competing interests: No potential competing interests to declare.