INTERNATIONAL

HealthTechScan

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Personalized Medicine Framework for the evaluation

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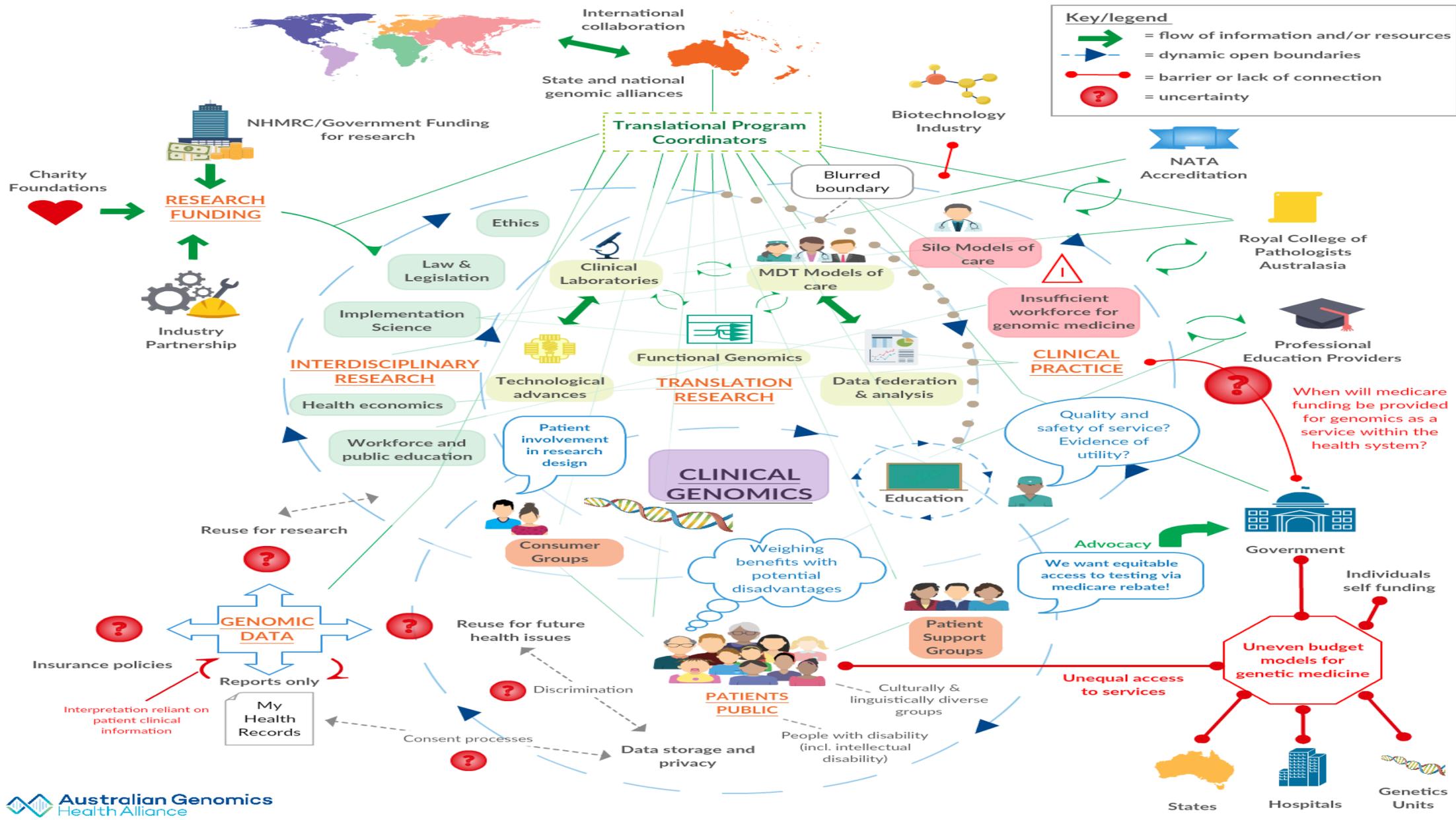I-HTS Scientific Director

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What is the personalized medicine?

Personalized medicine is an approach aimed at the prevention, diagnosing and treating disease based on an individual's specific profile.

A **holistic** approach to health systems is recommended to achieve the implementation of PM and omics.

Long, Janet C., et al. "A dynamic systems view of clinical genomics: a rich picture of the landscape in Australia using a complexity science lens." *BMC medical genomics* 14.1 (2021): 1-15

Are health systems ready?

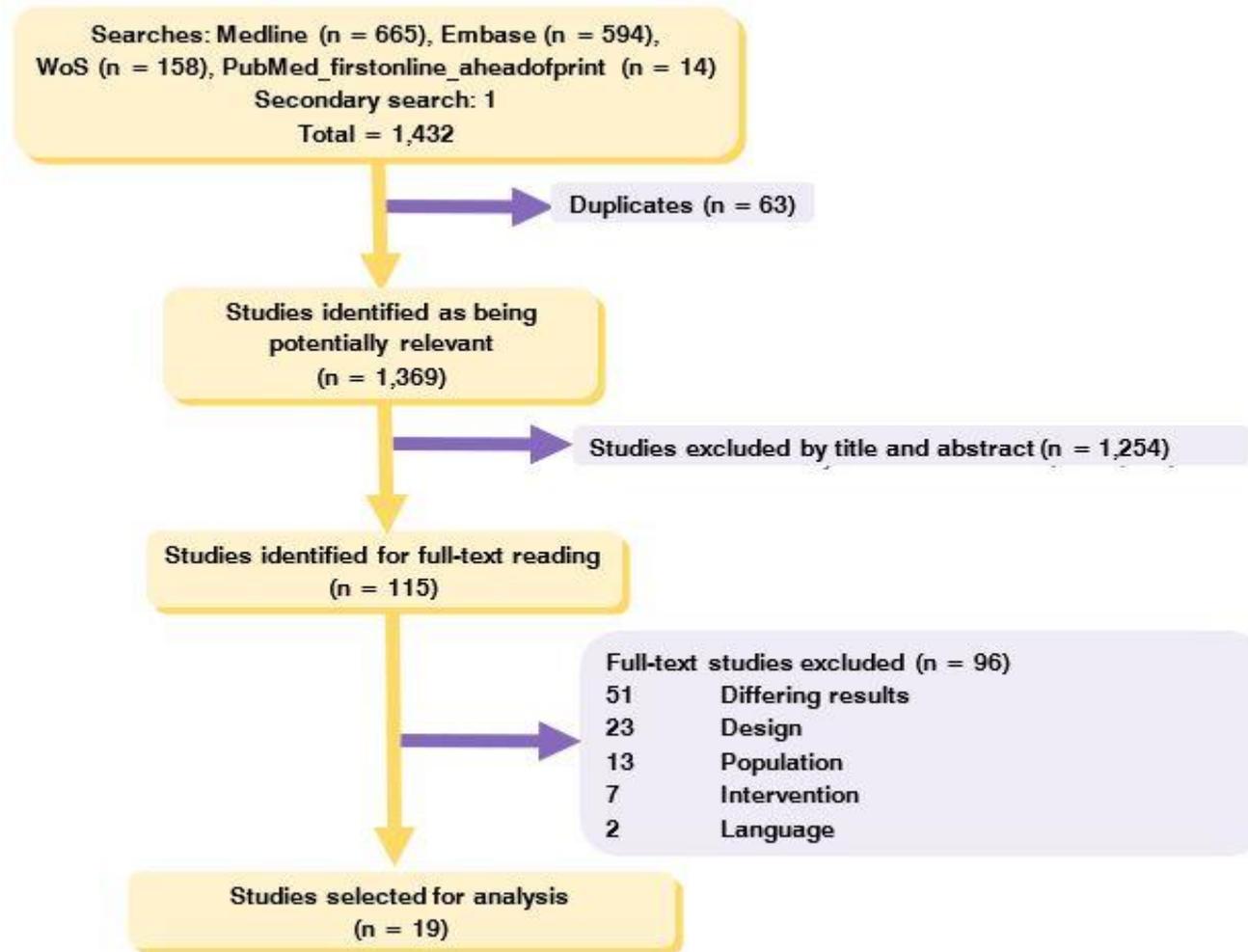Countries are developing PM implementation strategies and initiatives.

How to assess the readiness of health systems for PM?

What are the domains for determining the level of implementation of PM at the national level?

The protocol for this review was registered in the PROSPERO repository with ID no **CRD42022338611**.

How to assess the readiness of health systems for PM?

Searches: Medline (n = 665), Embase (n = 594),
WoS (n = 158), PubMed_firstonline_aheadofprint (n = 14)
Secondary search: 1
Total = 1,432

Duplicates (n = 63)

Studies identified as being potentially relevant (n = 1,369)

Studies excluded by title and abstract (n = 1,254)

Studies identified for full-text reading (n = 115)

Full-text studies excluded (n = 96)
51   Differing results
23   Design
13   Population
7   Intervention
2   Language

Studies selected for analysis (n = 19)

Results

Results

Framework for the qualitative and quantitative determination of personalized medicine implementation level.

The framework includes **11 domains** comprising **37 individually quantifiable elements.**

Scores:

- **Score 0:** a national implementation plan does not include this element or no information about it can be found.

- **Score 1:** a national implementation plan includes this element.

- **Score 2:** this element is already in the implementation phase.

A mathematical formula was applied to standardize the weight of the domains in the final assessment of the implementation. In such a way, those **domains with a higher number of assessable elements not to have a bigger weight in the implementation's final score.**

Framework for personalized medicine (I)

Health policies

- **Introduction project or initiative**
- **Legislation/Regulation**
- **Collaborative working groups among the different stakeholders**

Integration of PM in the health system

- **Portfolio of PM services**
- **Level of accessibility of PM in the health system**
- **Portfolio of purpose of care**

Basic research and translation

- **Plan for the promotion of basic research in PM and translation to clinical research**

Infrastructures and resources

- **Projects for gathering omics information at the population level**
- **Biobanks**
- **Electronic health record storage platforms**
- **Omics data storage platforms**
- **Omics data and big data analysis platforms**

Data management and availability

- **Harmonization, quality, and protection of electronic health records**
- **Harmonization, quality, and protection of omics data**
- **Incorporation of omics data into electronic health records**
- **Access to omics data of and interoperability among practitioners and entities**
- **Use of omics data in clinical decision-making**

Framework for personalized medicine (II)

Organizational areas
- **Interoperability among basic and translational research organizations and resources**
- **Introduction of areas specializing in PM**
- **Reinforcement of non-specialized areas involved in PM**
- **Development and adoption of procedural guidelines**
- **Organizational structure of omics testing**
- **Omic testing equipment**

Ethical, legal and social implications (ELSI)
- **Patient information care level**
- **Standardized informed consent forms**
- **Data protection mechanisms**

Educational needs
- **Education and training for healthcare staff specialized and non-specialized in PM**
- **Education of patients and relatives in PM**
- **Awareness-raising and outreach activities for the citizenry**

Assessment of health technologies
- **PM-specific health technology assessment plan**
- **Health technology assessment body**
- **PM-specific health technology assessment methodology**
- **HTA decision-making group**

Assessment of implementation
- **PM implementation evaluation plan**
- **Implementation evaluation body**
- **Implementation evaluation methodology**

Funding
- **PM implementation budget forecast**

Utilities of this framework

✓ Assess the situation of personalized medicine in different healthcare systems.

✓ Determine possible areas for improvement in personalized medicine implementation plans.

✓ Guide for the drafting of future personalized medicine implementation plans.

✓ Detect the best personalized medicine implementation plans that can serve as a model for future implementation plans.

Thank you for your attention!