Appendix 1: Literature Review of Associated Frameworks in Healthcare

Table A.1 : List of established frameworks presently used in healthcare, their focus and the highlights that are applicable in developing metrics to comprise the PH Innovation Evaluation Framework.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Citation | Title | Focus | Highlights | Metrics used |
| 1 | Multiple Criteria Decision Analysis (MCDA) for evaluating new medicines in Health Technology Assessment and beyond: The Advance Value Framework | Innovation Value for stakeholders | - Disease targeted by Innovation - Intervention provided by Innovation - Safety considerations in using the Innovation - Ease of Use, Useability, Novelty of Innovation - Expected Impact of Innovation | - Burden of disease (severity, availability, prevalence) - Therapeutic - Safety (adverse events, tolerability, contraindications) - Innovation (clinical novelty, nature of treatment, ease of use and comfort) - Socioeconomic (public health, budget impact, social productivity) |
| 2 | IDEAL-D: a rational framework for evaluating and regulating the use of medical innovations | Evaluating Use | - Novelty of Innovation - Registration of Innovation (for discoverability) - Safety and Efficacy of Innovation - Evidence of Effectiveness of Innovation - Risk Assessment and Regulation of Innovation | - Evidence (safety, reliability, efficacy, randomised controlled trials)  - Innovation (Intellectual property, universal registration of product, do other similar devices exist?, comparative effectiveness)  - Risk assessments and regulation (Quality Assurance) |
| 3 | Using Mobile Technology for Cardiac Rehabilitation: A Review and Framework for Development and Evaluation | Evaluation metrics | - Disease Assessment, Patient Characteristics and Environment Assessment undertaken by the Innovation - Intervention of Innovation - Ease of Use, Personalisation of Innovation - Usability of Innovation - Expected Patient Impact of Innovation - Efficacy and Evidence of Innovation | - Core clinical components (patient assessment, patient‐centered outcomes) - Usability (tailored features) - Impact (improve patient‐centered outcomes)  - Cost - Evidence (efficacy, randomised controlled trials) |
| 4 | On the Definition and Evaluation of Telemedicine | Evaluation metrics | - Impact of the Innovation - Efficacy, Effectiveness, Safety, Accessibility, Quality, Cost - Claim of the Innovation - Accuracy, Reliability, Precision, Sensitivity/specificity - Evidence of Innovation - End-to-end Intervention of Innovation (Content of Care) - Impact on Patient Outcomes - Functional status, satisfaction, access to care, knowledge, attitude | - Evidence (efficacy, effectiveness, safety)  - Accessibility  - Quality  - Cost - Claim (performance, accuracy, reliability, precision, sensitivity/specificity)  - Perspectives of client, provider, and society Methodology of evaluation (clinical trials, surveys, controlled experiments)  - Content of care (diagnosis, treatment, prevention) - Effects on Clients (functional status, satisfaction, access to care, knowledge, attitude) |
| 5 | End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services | Evaluation Metrics | - Usability of Innovation - Efficacy and Evidence of Innovation | - Usability testing in health service context - Evidence of efficacy |
| 6 | CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions | Information Metrics | - Meta Data of Innovation (Developer, Sponsor, Version) - Usability and Evidence of Innovation - Usability and Evidence of Version of Innovation - Claim of Innovation - End-to-end Intervention of Innovation (Content of Care, Features, Use in Practice, Clinician Involvement) available online. - Safety, Privacy, Security of Innovation - Training and Support of Innovation | - Novelty (who developed and who owns it)  - Evidence (user testing of version)  - Quality assurance (accuracy of claims)  - Replicability  - Information management (online information about innovation) - Security (privacy considerations)  - Usability (components, features, how is intended to be used)  - Expected level of involvement from assistance (e.g. clinicians)  - Expected level of engagement  - Training/support |
| 7 | The eSana Framework: Mobile Services in eHealth using SOA | Service Architecture | - Security of Innovation - Privacy of Innovation - Interoperability and integrability of Innovation (particularly with legacy systems) - Implementation of Standards in Design and Development of Innovation - End-to-end Intervention of innovation (Features, Use in Practice) | - Process integrity (interoperability) - System integration - Security (privacy, investment) - Functionality (features, usability) - Efficacy of implementation |
| 8 | An Evaluation Framework for Adaptive Security for the IoT in eHealth | IoT Considerations | - Security of Innovation - Impact and Evidence of Innovation | - Security requirements - Quality of service |
| 9 | A framework for clinical evaluation of diagnostic technologies | Evaluations Considerations | - Claim, Efficacy and Evidence of Innovation - End-to-end Intervention of Innovation - Safety of Innovation (context of being used outside of original purpose) - Accuracy of Innovation - Impact of Innovation (on health services) - Intervention of Innovation (Clinical Impact) - Expected Patient Outcomes of Innovation | - Technical capability (perform within specifications) - Range of possible uses - Diagnostic accuracy - Impact on health care providers  - Therapeutic impact  - Patient outcome |
| 10 | Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario | Holistic considerations | - Expected Patient Outcomes of Innovation - Efficacy, Safety of Innovation - Condition Information, which Intervention of Innovation Targets - Integrability and integrability of Innovation - Novelty of Innovation - Impact of Innovation | - Clinical benefits (effectiveness, safety, burden of illness, need) - Consonance with social and ethical values (societal values regarding appropriate usage, ethical issues inherent in using or not using it) - Efficiency (value for money)  - Impact (ease of integration to healthcare, economic feasibility, organizational feasibility) |
| 11 | The Future of Precision Medicine: Potential Impacts for Health Technology Assessment | Holistic Considerations | - Intervention of Innovation - Evidence of Innovation - Targeted Users of Innovation - Continual Interaction and Engagement of Innovation | - Complexity of the problem being solved - Evidence - Equity considerations - Frequency of guidance updates |
| 12 | eHealth solutions in the context of Internet of Things | Architecture Considerations | - Data Collection of Innovation - Data Transactions of Innovation | - Flexibility regarding the functionalities  - Data collection (processing unit, data acquisition module)  - Data communication |

References

1. Angelis A, Kanavos P. Multiple Criteria Decision Analysis (MCDA) for evaluating new medicines in Health Technology Assessment and beyond: The Advance Value Framework. *Soc Sci Med*. 2017;188:137-156. doi:10.1016/j.socscimed.2017.06.024

2. Sedrakyan A, Campbell B, Merino JG, Kuntz R, Hirst A, McCulloch P. IDEAL-D: A rational framework for evaluating and regulating the use of medical devices. *BMJ*. 2016;353. doi:10.1136/bmj.i2372

3. Beatty AL, Fukuoka Y, Whooley MA. Using mobile technology for cardiac rehabilitation: a review and framework for development and evaluation. *J Am Heart Assoc*. 2013;2(6). doi:10.1161/JAHA.113.000568

4. Bashshur RL. On the definition and evaluation of telemedicine. *Telemed J*. 1995;1(1):19-30. doi:10.1089/tmj.1.1995.1.19

5. Gerdes M, Smaradottir B, Fensli R. End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services. In: *Scandinavian Conference on Health Informatics*. ; 2014:53.

6. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. *J Med Internet Res*. 2011;13(4). doi:10.2196/jmir.1923

7. Savini M, Ionas A, Meier A, Pop C, Stormer H. The eSana Framework: Mobile Services in eHealth using SOA. *2nd Eur Mob Gov Conf (Euro mGov 2006)*. 2006:191-200. doi:10.1.1.103.7496

8. Leister W, Hamdi M, Abie H, Poslad S, Torjusen A. An Evaluation Framework for Adaptive Security for the IoT in eHealth. *Int J Adv Secur*. 2014;7(3 and 4):93-109.

9. Guyatt GH, Tugwell PX, Feeny DH, Haynes RB, Drummond M. A framework for clinical evaluation of diagnostic technologies. *Can Med Assoc J*. 1986;134(6):587-594.

10. Johnson AP, Sikich NJ, Evans G, et al. Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario. *Int J Technol Assess Health Care*. 2009;25(2):141-150. doi:10.1017/S0266462309090199

11. Love-Koh J, Peel A, Rejon-Parrilla JC, et al. The Future of Precision Medicine: Potential Impacts for Health Technology Assessment. *Pharmacoeconomics*. 2018;36(12):1439-1451. doi:10.1007/s40273-018-0686-6

12. Sebestyen G, Hangan A, Oniga S, Gal Z. eHealth solutions in the context of internet of things. In: *Proceedings of 2014 IEEE International Conference on Automation, Quality and Testing, Robotics, AQTR 2014*. ; 2014. doi:10.1109/AQTR.2014.6857876