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| **Phase** | **Theme** | **The PRECISE4Q Reflective Framework for Big Data Health Research** |
| Development | Purpose of the tool | * In what phase of stroke is the tool to be used (prevention, acute, rehabilitation or reintegration)? * What is the specific problem the tool aims to address? * Who is the primary user group? * Are there any secondary end-user groups? * What is the intended purpose of the tool in clinical practice? * How might the tool be used by clinicians and how may this shape their professional role perceptions? * Is there a risk of inappropriate use and how might this risk be mitigated? |
| Data quality and representativeness | * How has the data been obtained, and which ethical principles were considered in this process? * What do we know about the data quality and its representativeness for the target population? * What measures are in place to ensure data quality and representativeness (e.g., who might be under or overrepresented)? * What consequences may data characteristics have on the performance of the model for these population(s)? |
| Explainability | * What kind of information on the tool will be available to end-users? * Are models explainable and if so, is there an impact on predictive performance? * If available, are explanations tailored to the needs of end-users? * How may the information end-users have or lack impact their interaction with the tool? |
| Usability and user experience | * Have prospective end-users been involved in the development process and if so, how has their input shaped the tool? * If prospective end-users were not involved in the development, what consequences may this have on the tool and its adoption in clinical practice? * Have usability and user experience been assessed, and if so, how? |
| Clinical validation | * How is the tool validated? * What does clinical validation mean to developers, what does it mean to clinicians and patients? * What impact may clinical validation have on clinicians’ and patients’ trust? * What impact may clinical validation have on clinicians’ perceived responsibility and accountability? |
| Deployment | Disclosure of AI | * How much information can and should be disclosed to the patient? * How much do clinicians need to know about the tool and its application to fulfil their role? * What impact may predictive health information with disclosure of AI have on patient autonomy, trust, and the doctor-patient relationship (e.g., shared decision-making)? * What about the impact of disclosure on vulnerable populations (e.g., socially disadvantaged groups, stigmatized groups, groups with lower health literacy skills? |
| Responsibility | * How is responsibility/liability addressed? * Is there a risk of deskilling? * What is the developers’ responsibility? * What impact may incorrect decisions caused by the tool have on clinicians’ moral responsibility? |
| Empathy | * How may the tool impact clinicians’ empathy towards patients? * How can patient values, beliefs, and preferences be incorporated into the decision-making process? * Might the tool replace human contact in the clinical encounter and if so, what consequences may this have for patients and clinicians? |
| Privacy & Data Protection | * Given that stroke prevention takes place before any symptoms occur, how can health benefits and privacy be balanced? * Should there be different privacy standards for the different phases of stroke (prevention, acute, rehabilitation, reintegration)? * Which mechanisms would need to be in place to ensure patient privacy? * What might be the consequences of failing to ensure patient privacy? |
| Monitoring & Evaluation | * What should process and impact monitoring and evaluation look like along the patient journey and life cycle of the technology? * Who is responsible for conducting continuous monitoring and evaluation? * What might be the consequences of failing to conduct continuous monitoring and evaluation? |