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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?
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| 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)?
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| 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?
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| 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?
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| 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?
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| 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?
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| 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?
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| 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?
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| 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?
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| 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?
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