

Inclusive clinical trials

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Moral obligation

Groups that are underrepresented in medical research should be provided appropriate access to participation in research

Scientific need

...may respond differently to an intervention due to differences in physiology or disease state. Only by studying the effects of an intervention in a range of groups can we be sure that the balance of [harm] and benefit is favourable...

Prevent harm

UK confidential inquiries into maternal deaths have repeatedly identified women who have died because medications have been stopped, or never started, in pregnancy as a result of unfounded safety concerns.

Why?

Survey

- ▶ Exploratory, online, cross-sectional
- ▶ Trialists
- ▶ Clinical trials funded by the NIHR HTA Programme 2022-2023
- ▶ Whether, why, and how pregnant women and people are included in or excluded from
- ▶ Summary statistics

Exclusion

Trial 57

“There are no adverse effects expected should a participant become pregnant whilst on the trial but because they cannot be insured, they must be withdrawn (even if they are on the standard care arm).”

Trial 5

“This is a pragmatic trial and I didn’t want the pregnancy exclusion. We were behind schedule at this point and arguing [with an external party] seemed a potentially fruitless task we didn’t have time for – and the gain in terms of likely number of pregnant recruits was minimal.”

Trial 13

"We are not specifically targeting requirement at pregnant people, and are expecting a very low number given that one of our inclusion criteria is 35+."

Trial 62

"The... trial is looking at the effects of [intervention] in children (aged 12-18 years)... Pregnancy is not an exclusion criteria but is very unlikely to occur"

It doesn't matter

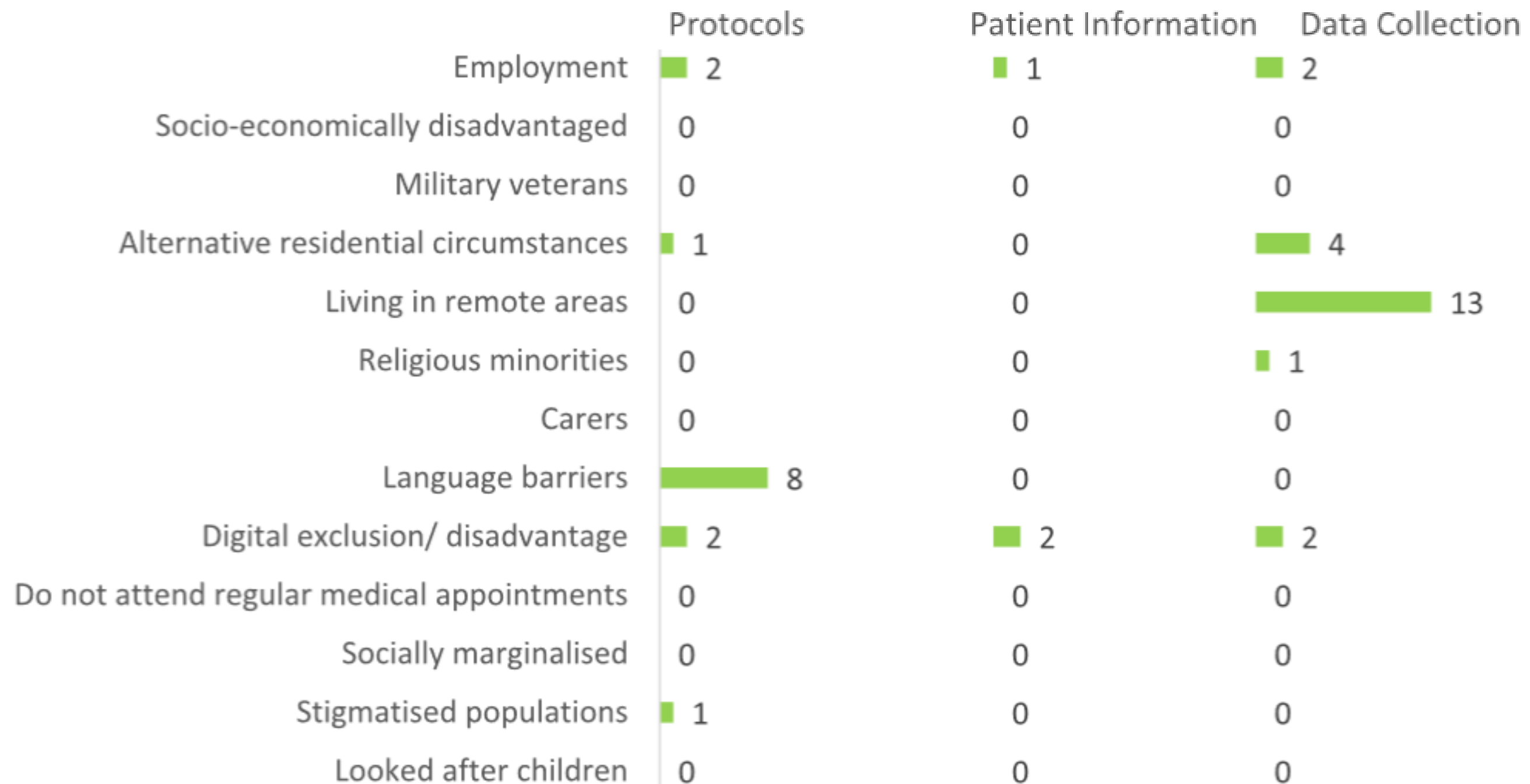
Trial 45

"[Type of intervention] would not be done on females"

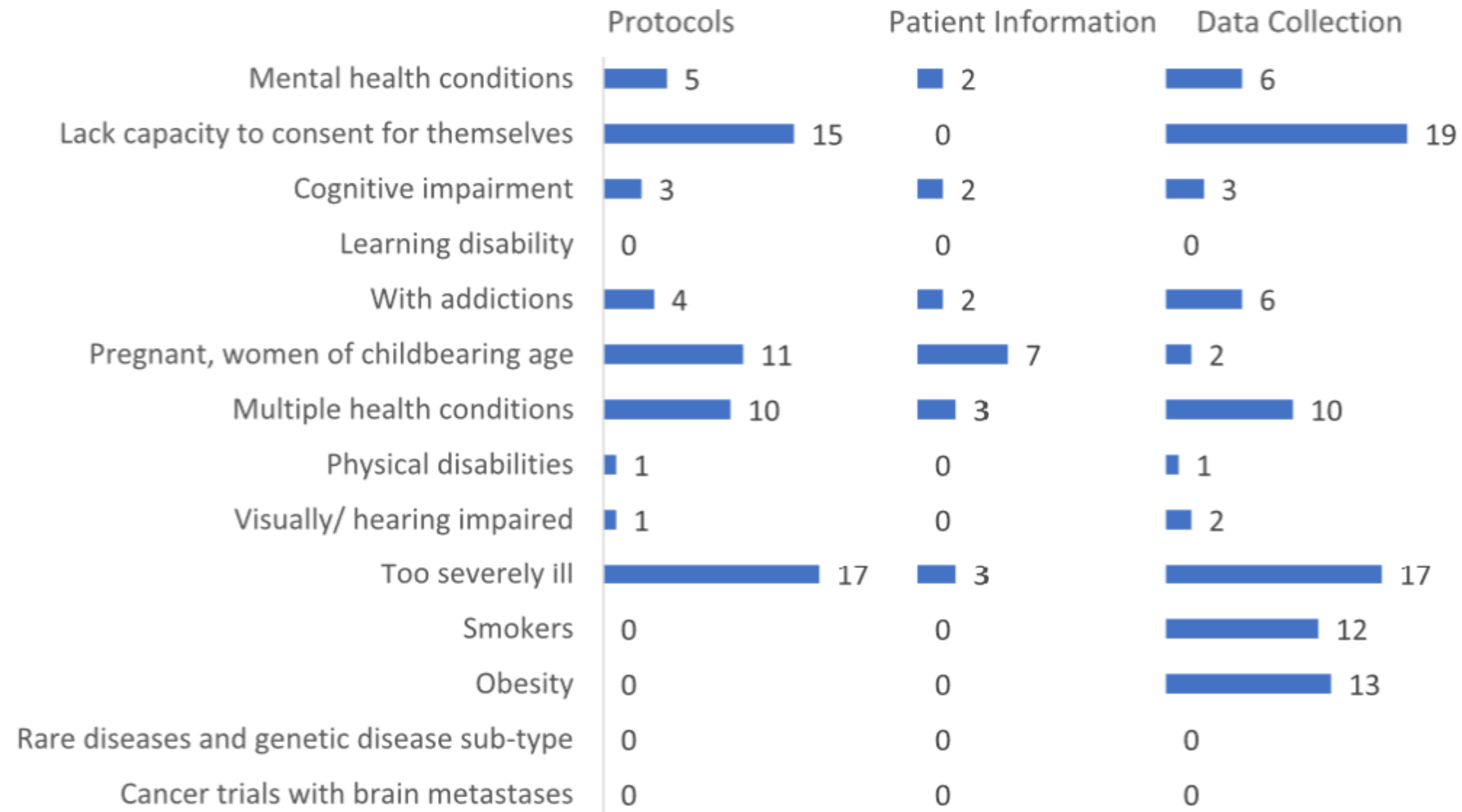
Audit

- ▶ Oxford Primary Care Clinical Trials Unit
- ▶ NIHR under-served groups and UK Equality Act 2010 protected characteristics (Patel *et al.*, 2024)
- ▶ Ethical approval between 2017 and 2023
- ▶ Protocols, patient-facing information and data collection tools
- ▶ explicit exclusions and data collection

Social and economic

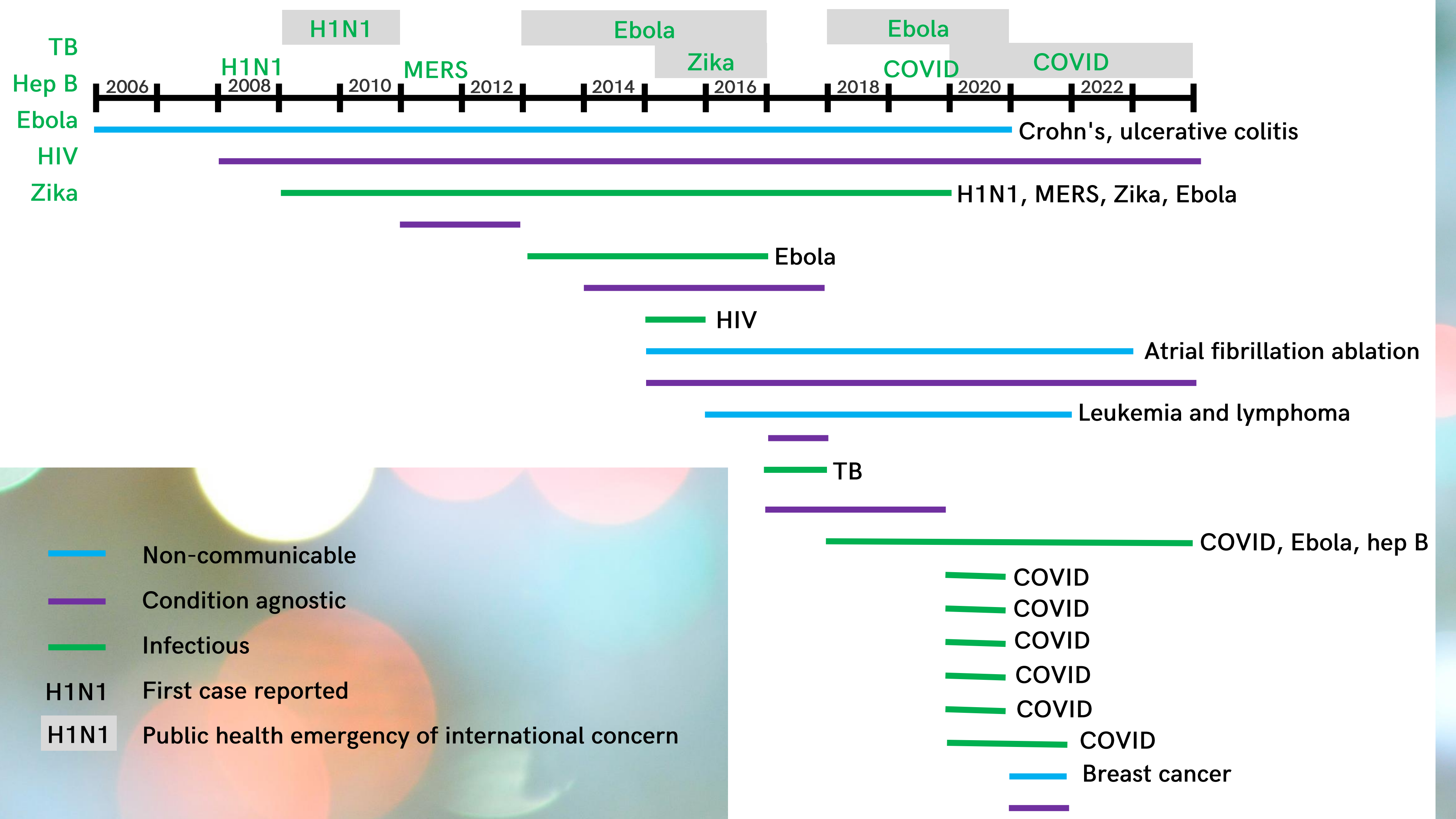


Health status



Review

- ▶ Rapid, scoping (Haby *et al.*, 2024)
- ▶ 2006-2025, English language
- ▶ Medline, Embase, CINAHL, Overton, Google Scholar, Google - NHS, EMA, FDA etc.
- ▶ Independent reviewers screening
- ▶ Data extraction and verification
- ▶ Basic descriptive analysis



Thank you!

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Survey



Audit



Review

