Algorithm?

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Background

- One of the fundamental tools used in precision medicine are algorithms, which are becoming more complex and particularly influenced by the wider use of Artificial intelligence (Love-Koh, et al. 2018; Faulkner, et al. 2020)
- Facing missing information on how or why something reproducibly works could make algorithms obscured even to their developers (Nicholson Price II, 2017)
- Although they can be of enormous aid in unfeasible activities for humans, algorithms can also result in errors typical for automated systems, leading to a new range of ethical and policy concerns (OECD, 2017; Watson et al. 2019)
- Following the ambiguity of what an algorithm represents in precision medicine and challenges surrounding their development, regulation, and future, we investigated these issues further

Method

- List of **13 questions** with potential sub-questions
- **30** semi-structured **interviews** with experts across Europe/US
- **Transcription** of the audio recordings
- Content **analysis**
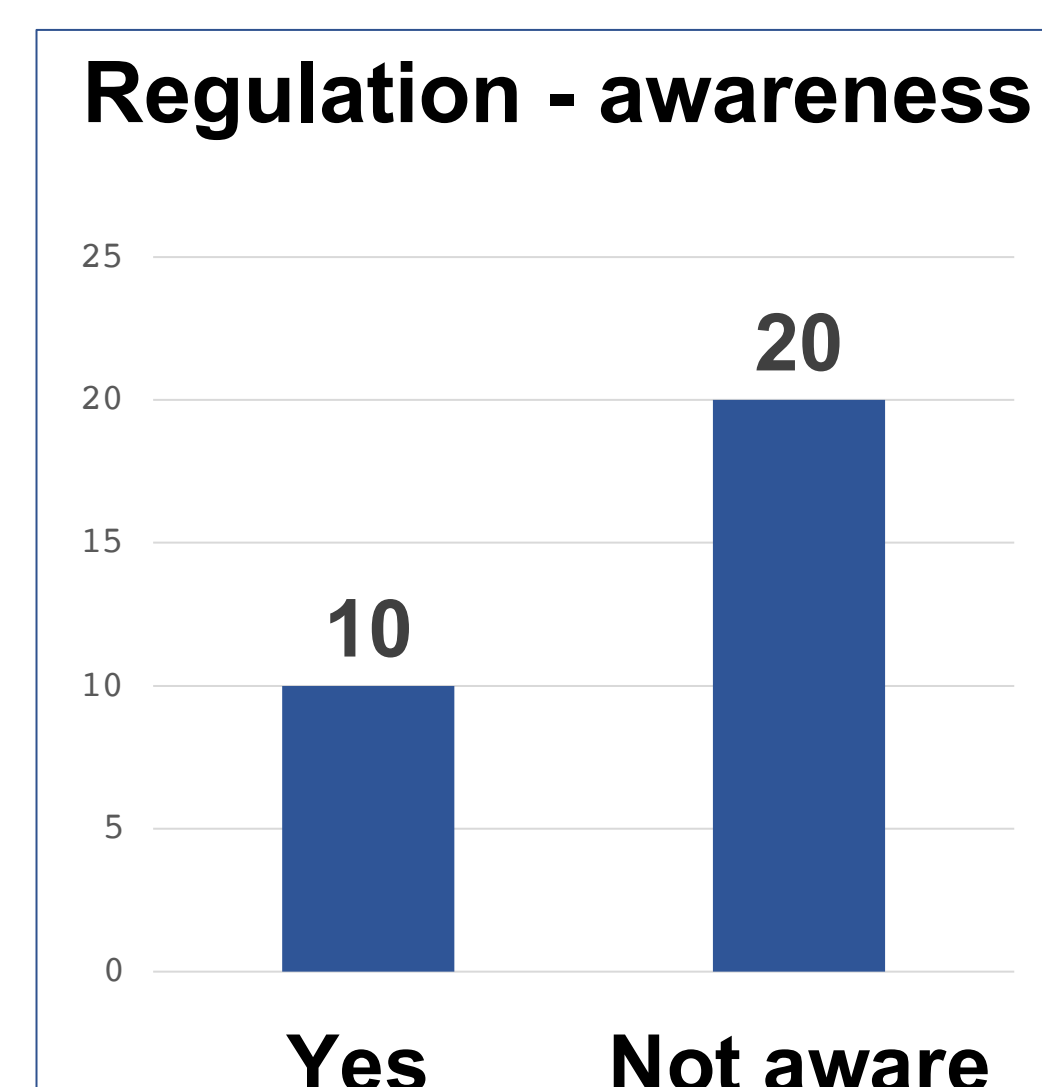- **Results**

Results

> When you say an algorithm, I mean sometimes it can be a computer program, but sometimes it is just a part of a clinical assessment, and it is kind of an algorithm that is in the clinician's head. (INT1)

- Multiple respondents stress the need for the right data in algorithm development, along with addressing the challenge of providing high-quality longitudinal data
- Providing evidence is seen as particularly demanding within rare diseases
- The relevance in use of genomic and genetic data should depend on the type of disease in question
- Lack of threshold indicating whether an algorithm is good enough for being used in practice is present

- Challenges in regulating algorithms reflect mainly in the feasibility of the regulation process and its overall length
- Identified need for enhanced risk communication among practitioners, developers and regulators

Regulation - awareness

	Yes	Not aware
	10	20

> Well, I don´t think that the regulatory bodies can regulate that anymore, by the time that you regulate the test, the test might have changed or improved, and essentially you need a new evaluation. It should be a collaborative regulation. (INT6)

Conclusions

Challenges identified in the study:

- Ambiguity in the understanding of what an algorithm represents in the context of precision medicine
- Advanced dynamic algorithms are further questioning the current methods used for evaluation
- Complexity and length of the regulation process are two main obstacles hindering wider use of algorithms in the clinical practice
- Extensive use of AI and self-learning algorithms will amplify all these challenges further

What can we do?

- We should aim for more data, research, improved regulation and infrastructure. Along with these, enhanced risk communication among stakeholders is seen as a necessity for the responsible use of algorithms within every-day precision medicine.

References

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