

# Do they really understand?

## Self-reported understanding as a tool for analyzing consent

### ■ Background

Understanding is a key issue in any analysis of informed consent. However, it is by no means clear what kind of understanding is required, which raises important questions in relation to longitudinal clinical research: what degree of understanding is sufficient, to what extent does understanding need to be maintained over time, and how should we measure it?

### ■ Methods

We analyzed and assessed self-reported understanding and factual knowledge within 7442 participant families involved in a longitudinal screening for Type 1 diabetes. Data was collected through the 5th year clinical questionnaire.

### ■ Results

Data revealed a considerable lack of knowledge even among those assessing their understanding as high (n=5763). We furthermore found that high self-reported understanding was significantly associated to level of actual knowledge, but also to having a positive attitude, being satisfied with information, being calm about research data and samples, having a stable psycho-social background, higher education, and a lower age (p<0.001).

### ■ Conclusion

Our results cast doubt on the method of using self-reported understanding as a good quality measure of what participants understand and know in a long-term perspective about the study they are involved in.

We suggest there is a need to develop methods of securing understanding and consent in longitudinal research. The identification of some basic background factors (age, education, satisfaction with information, general attitudes), as well as the identification of sub-groups within large-scale research, may provide valuable tools for consent strategies in such research.

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