

Participant information in clinical research

– Focus on the patient

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Introduction

Informed consent is a cornerstone of clinical research, yet the way participant information is presented often lacks the depth and clarity needed to truly support autonomous decision-making. Standardized templates and checklist-based documents may meet formal ethical requirements but do not necessarily engage the cognitive processes required for genuine understanding. Combining that with results from the OECD's PIAAC study showing that one out of six Danes are poor readers, calls for changes on how we inform in research studies [131008-sfi-pjece-om-piaac.pdf].

A study from the Danish Blood Donor Study [Sundby 2019] illustrates the issue. 1,600 participants were asked whether they knew they were part of a biobank and a genetic research project. Only 27.6% and 9.6%, respectively, answered “yes”.

It calls for a pedagogical and reflective approach - one that draws on educational theory to rethink how such materials are designed and evaluated.

Bloom's Taxonomy offers a useful framework for understanding and enhancing cognitive engagement. Originally developed by Benjamin Bloom and colleagues in 1956 and later revised by Anderson and Krathwohl in 2001[Bloom 1956, Anderson 2001], the taxonomy categorizes cognitive skills into six hierarchical levels: remembering, understanding, applying, analyzing, evaluating, and creating. When

participant information to some extent is prepared to satisfy checklists from the Ethical Committee, it often remains at the lower levels of this taxonomy with low focus on how it will be received by the patient - [4. Krav til deltagerinformation – standard | De Videnskabetiske Komitéer]. However, ethically sound communication should aim for the higher levels, encouraging both creators and recipients of information to engage in analysis, evaluation, and even creative interpretation of the material.

This final project explores how Bloom's Taxonomy can be applied to the preparation of participant information sheets, with the goal of enhancing both the clarity and ethical integrity of research communication. By encouraging researchers to reflect critically on what is important to know for the participant in research.

Teaching Activity and Reflection

The teaching activity was designed to encourage higher-order thinking by involving participants in a critical and creative redesign of the “Cover-page” for participant information [[Forside til deltagerinformation.docx](#)]. Rather than simply reviewing it, students were asked to analyze the limitations of current practice think from a participant view on better ways, or prioritized order to present the information. This aligns with the upper levels of Bloom's Taxonomy - particularly analysis, evaluation, and creation [Anderson 2001].

The session began with an overview of the topic and clarification that the output would be presented to an ethics committee, where 1-3 students would be invited to join. This set a real-world context, which helped to increase student motivation and engagement. One participant immediately volunteered to attend the committee meeting, indicating early ownership of the task. I then introduced the issue at hand: while participant information is a familiar element of research practice, many professionals are unaware of the ethics committee's template for summarizing such information on a cover page. As expected, most participants had experience preparing participant information sheets, but none were familiar with the official summary format. This confirmed the relevance of the teaching activity.

Students were asked to work in pairs to develop their own version of the summary cover page. This activity required them to move beyond basic: they had to assess existing formats, consider the informational needs of potential participants, and make informed design decisions.

Initial clarifications were needed, but group discussions soon became lively and constructive. Visiting the groups allowed me to support their progress and ensure they remained on task.

The discussion phase further supported the development of critical thinking. All participants were encouraged to share their suggestions, and a particularly insightful debate emerged around the distinctions between terms such as “utility,” “benefit,” and “personal results.” This part of the session exemplified higher-order thinking, as students not only analyzed concepts but also questioned assumptions and proposed nuanced improvements. A member of the Central Denmark Region’s ethics committee contributed valuable insight and also offered to represent the group at the ethics committee meeting - an outcome that suggests the activity was both meaningful and impactful.

There was a minor technical challenge in locating the digital version of the ethics template, this obstacle served as a learning point in itself, emphasizing the inaccessibility of what I believe is a key resource. Overall, the session was successful in promoting reflective and creative engagement with the topic. The combination of practical relevance, active learning, and critical dialogue supported the intended learning outcomes.

Methodology

The design of the teaching activity was based on principles from reflective practice and constructive alignment. The objective was to create a learning environment where students could critically engage with a real-world problem - namely, how to communicate participant information more clearly. The activity was structured to align with higher levels of Bloom’s Taxonomy [Anderson & Krathwohl, 2001], particularly analyzing, evaluating, and creating.

Participants were asked to reflect on authentic examples of participant information sheets in advance of the session, encouraging

preparatory thinking. The actual session consisted of three phases: introduction and context-setting, group work, and a concluding discussion. The central task - developing a new version of the cover page for participant information - was designed as an open-ended, collaborative problem-solving activity. This format encouraged creativity and fostered deeper engagement than a purely theoretical or lecture-based approach would have.

Constructive alignment was achieved by ensuring that learning outcomes, teaching methods, and assessment criteria all emphasize critical reflection and innovation. The final output, which will be presented to an actual ethics committee in August, gave the activity a high degree of authenticity [Biggs 2011], further motivating participants to invest effort and apply their knowledge in a meaningful way.

Discussion

The teaching session demonstrated how educational theory can support ethical reflection and communication in research. The task of redesigning participant information was well-suited to encouraging transformative learning [Mezirow 19979], as participants were challenged to question familiar practices and consider the experience from the perspective of potential trial participants. In doing so, they moved from a compliance-oriented mindset toward a more user-centered approach.

Applying Bloom's Taxonomy proved particularly useful in highlighting the cognitive demands of the task. While lower-level activities might involve summarizing or recalling ethical guidelines, this activity required students to evaluate existing materials that were very familiar to them and create new formats. The rich group discussions - especially those concerning concepts like "utility" and "benefit" - showed that participants were operating at these higher cognitive levels.

The minor technical challenge encountered (finding the template online) unintentionally reinforced the main point: that tools and resources intended to guide ethical communication are not always intuitive or accessible. This moment served as an example of situated learning, where the learning context itself became part of the content. This key point will also be important when we meet with ethical committee to discuss format.

An important outcome was the real-world follow-up: two participants volunteered to attend the ethics committee meeting and were tasked with compiling the group's feedback. This not only ensured that the learning had a tangible impact beyond the classroom, but also placed responsibility and ownership in the hands of the learners - key features of adult learning theory (Knowles, 1984).

Conclusion

This teaching activity successfully demonstrated how Bloom's Taxonomy and reflective teaching methods can enhance the preparation of ethically sound participant information. By engaging learners in meaningful, real-world tasks and promoting higher-order thinking skills, the session helped shift the focus from regulatory compliance to ethical communication. The participants were not only able to reflect critically on existing practices but also to propose concrete improvements, grounded in empathy and ethical awareness.

In future sessions, more time could be allocated for group presentations, and scaffolding could be enhanced by introducing key terminology earlier in the process. Nonetheless, the activity's combination of structure, relevance, and participant engagement proved to be effective. Most importantly, it opened a space for critical reflection on how research communicates with its most important stakeholders: the participants themselves.

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