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The ethics of informed consent in novel treatment including a gender perspective

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Task 2.6
New strategies for increasing participation of patients from diverse cultural and religious backgrounds in clinical trials

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TASK TITLE:	New strategies for increasing participation of patients from diverse cultural and religious backgrounds in clinical trials
TASK DESCRIPTION:	Based on the findings of WP1, the task aims at identifying innovative strategies for an active engagement and participation of diverse ethnic and religious groups in clinical trials, taking into account also the characteristics and opportunities offered by new social media and ICT tools.
TYPE OF STUDY:	A design thinking workshop in Rome: 23rd January, 7th February, and 28th February 2019 (LUMSA, OPBG)
LEADING PARTNER:	LUMSA
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[1] **R** = Report, **DEM** = Demonstrator, prototype, **DEC** = Websites, press & media actions, videos, **OTHER** = Software, technical diagram, etc

[2] **PU** = Public, **CO** = Confidential, restricted under conditions set out in Model Grant Agreement

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GENERAL INFORMATION

Executive Summary

Background

Design Thinking is a user-centered model of thinking. It uses empathy, collaboration and experimentation to generate new approaches to complex healthcare problems. We aimed to look at a Clinical Trial Informed Consent document from another perspective, from that of diverse users (patients, cultural mediators, doctors, and researchers), and re-design our materials and processes to facilitate better understanding and inclusivity.

Methods

Multidisciplinary teams were compiled, provided with domain-specific knowledge, and guided by an empathetic mind-set and methods to generate a large number of ideas, which were then honed to develop prototypes. We worked with a team of cultural mediators, parents, doctors and researchers during three half-day practical sessions, spaced over a 2-month period. We worked iteratively: between the sessions, our research team worked to process the ideas that emerged from the previous session, and design the next session accordingly.

Results

Common concerns were raised by participants, regardless of cultural background. Issues that related directly to the child's health (vaccine side-effects and sexual health) garnered the most concern. Little concern was expressed in relation to data and privacy. By the end of the last session we had developed 4 prototypes; to create these participants revised the text content and format of informed consent.

Conclusion

Participants made modifications to text content and generated informed consent prototypes for different types of media. In addition to recommendations on specific points (as outlined in the results section), overarching recommendations were generated (as outlined in the recommendations section), the key points of which are as follows:

- Core human needs are the same for all informed consent users regardless of perceived differences that include gender, cultural background, and religion;
- To facilitate diversity, adaptations should be made, considering both individual-level and societal needs. We perceive that technology could better enable us to do this;
- The needs of potential research participants should be prioritised above the needs of others (e.g. reseachers);
- When designing informed consent in a specific context, we recommend using participatory, mixed research methods such as design thinking to gain insights from diverse users;
- The wider environment should be considered when determining whether a decision is autonomous; particularly in relation to the trust of individuals and organizations, deferral of the decision to others, and referral to external sources of information;
- We emphasise the importance of clear communication;
- We consider that the needs of potential participants will likely change as technology evolves and suggest regular future review of recommendations to ensure that they keep pace with technology.

Background

What is design thinking?

In recent years, the use of design thinking (DT) has become much more widespread (1). It fosters new approaches to complex healthcare problems (2) by using a user-centred (3,4) model of thinking based upon three main pillars - empathy, collaboration, and experimentation (3). Multidisciplinary teams are compiled, and then prompted to generate a large number of ideas. Team members are guided by an empathetic mind-set and methods, along with domain-specific knowledge. Through working as a team, ideas are honed to develop, and then test prototypes (4–6). DT prioritises a deep empathy for the end-users' desires, needs and challenges, which results in a better understanding of the problem in order to develop more comprehensive and effective solutions (7).

The design thinking mindset differs to that of traditional approaches used in public health. "Design *thinking* uses a "designer-ly" mindset—constructive, experiential and rooted in the needs and context of end-users of a product or service—to develop novel solutions (4). It can be seen as collectively revolving around several core concepts including empathy with users, a discipline of prototyping to gain insights, and tolerance for both ambiguity and failure (8) (9). The process is iterative, in contrast to the traditional scientific method which is linear[3] (10), and DT is tolerant to ambiguity, pivots, and rapid prototyping (9). The iterative process to understand the problem followed by cycles of idea generation, testing, and prototyping in DT reduces the timeframe for design and implementation; enabling solutions to complex challenges to be developed and tested rapidly (10).

While inherent tensions exist between the way research is undertaken in design versus in the health sector where hypothesis-driven research is the norm and where the evidence base (typically peer-reviewed literature) is used to generate concepts for study; using DT to address complex questions around health may prove valuable and complementary to existing approaches. Indeed, increasing pressure to improve health outcomes of populations using limited resources has prompted an emphasis on innovation (7), and a number of public health projects utilizing DT have emerged in recent years (9). DT has been used on a huge variety of complex healthcare problems in a wide range of fields including disease management related to serious or chronic illness, health systems and care management, infectious disease prevention or care, and primary prevention and health behavior/education (9); and it can be applied to intervention development to large-scale organizational and systems changes (11). One study in the USA aimed to use DT to redesign human research protections, for which informed consent was considered as one of many elements of interest. The results of this study in relation to informed consent are provided in Box 1 (12). While Bloss *et al.* used Design Thinking to generate general recommendations for consent, we aim to take the process a step further and after idea generation, develop a solution – a prototype for informed consent.

[3] hypotheses are generated and experiments conducted to generate results and form conclusions

Box 1. Redesigning the informed consent process. Results of a design thinking study by Bloss *et al.*(12)

"The ethical principle of respect for persons implies that individuals should be informed about and voluntarily consent to participate in research. How do we ensure that consent is actually informed? How do we ensure that research participants from diverse backgrounds truly understand research study risks and opportunities? In regard to the first question, one idea may be to establish mechanisms through which participants can provide real-time feedback about their experiences to researchers. These mechanisms could serve to collect empirical data regarding the clarity of consent forms and potential participants' perceptions of risks and benefits. These data could inform and drive potential revisions to the consent form and other aspects of the research protocol. Relatedly, it is often the case that investigators write their consent forms to adhere to institutional templates, which may prompt the inclusion of content that is not relevant to or appropriate for a study. Thus, accurate and understandable descriptions of research should be encouraged in consent forms and processes, and inappropriate adherence to templates should be discouraged.

In addition, to make the informed consent process more accessible, one idea may be to think of the Creative Commons licenses [22] as a model. Similarly to the "three layers of licenses" used by Creative Commons, research studies could create three consent forms: one that contains all the legalese and scientific exposition; one in plain English that presents the facts; and a third that is simplified even further and presents risks in bullet point format. To make the process of obtaining consent culturally appropriate for underserved and underrepresented populations, community leaders, such as a *Promotor/a* in a Latino community, could be asked to help design the consent form and facilitate its use in ways that address community-specific concerns that researchers might not anticipate. Researchers could work with the community leader to help communicate these risks in a way that resonates with the community."

Why use Design Thinking for informed consent?

In recent years, technology has advanced rapidly, but regulation has not kept pace. Informed consent, the process that enables a patient to voluntarily decide whether they would like to participate in clinical research, has remained relatively unchanged for decades. The information currently contained in informed consent documents is often not well communicated and often doesn't cater to the needs of different patients (for example by age, gender, or cultural background). This can lead to a) unbalanced participation in clinical trials which can jeopardize research quality or b) the unethical involvement of patients who may have otherwise chosen not to participate.

Aim

Through using design thinking, we aimed to generate creative ideas to look at informed consent from another perspective – that of diverse users; which we hope will enable us to redesign our materials and/or processes for informed consent in clinical studies to facilitate better understanding and inclusivity.

Methodology

Overview

An agenda, including a list of participants is provided in Appendix 1.

Participants were selected according to their role in clinical trials, and cultural background. The aim was to create a diverse group that would be able to offer a wide range of perspectives.

Session 1

January 23rd 2018. A half-day briefing session was held at LUMSA University (Appendix 2). It aimed to sensitize participants to the overall objectives, process, and the topics that would frame the design thinking exercise, and gain their consent for participation.

- An overview of the objectives and work of the iConsent consortium was given by Prof. Laura Palazzani (LUMSA University). In addition, all participants received an information leaflet about the work of the consortium.
- Mara Zampol gave a presentation on the design thinking workshop's objectives and the process that would be followed (Appendix 3). She emphasized that Design Thinking is a design methodology that provides a human-centric, solution-based approach to solving problems, explaining that the methodology emphasizes: the importance of teamwork; the importance of exposing ideas in a peer-to-peer way; and the importance of generating ideas from the ideas of others (this allows you to grow and expand your world).
- Dr. Elisabetta Pandolfi explained that the scenario that would be covered during the workshop was a girl thinking about enrolling in a vaccine trial for a new HPV vaccine. It was noted that this topic was chosen as it helps to focus on gender and minors. The HPV vaccine and disease were explained and Dr. Pandolfi responded to a series of clinical questions about the topic.

After participants were informed verbally, time was given to answer questions. Participants were were asked to give their consent for participation through reading a written information sheet and signing a consent form (Appendix 4).

Session 2

February 7th, 2018. A half-day session was held at LUMSA University (Appendix 5). It aimed to identify existing problems with the informed consent text and process, and enable participants to ideate and generate solutions.

- Defining the problem: Our facilitator encouraged empathy by describing a scenario where a teenage girl was invited to part in a hypothetical vaccine trial of a currently unlicensed human papillomavirus vaccine. A hypothetical letter, based on an OPBG introductory letter that is sent to potential participants, was provided to the group (Appendix 6). We had anticipated discussion about concerns in four domains so, in addition to the introduction letter, had prepared sections of a hypothetical informed consent document on vaccine receipt (pain, fear etc.) (Appendix 7), side-effects (Appendix 8), sexual health (Appendix 9), and data/privacy (Appendix 10). For each section, participants were asked to add post-it notes to a board, with statements about what they thought, felt, saw, and would do; plus any positive or negative sentiments they had. Different colored post-it notes were given to different types of participants so it was easier to see if people with different backgrounds had different perspectives (Appendix 5).

- Generating solutions: Ideas were organised. A facilitator then looked at the post-it note comments on the board, and talked through them, presenting a summary of what had been written by the group, particularly noting where the ideas converged and diverged. The group then discussed the points raised in order to develop a more cohesive vision of what they felt the main problems with the document were. They were also encouraged to develop and discuss ideas about potential solutions (Appendix 5).

Interim analysis

After session 1, the facilitator entered all of the post-it comments (comment; role of person making the comment; and position of the comment) into an excel spreadsheet, then the moderator conducted a qualitative thematic analysis, identifying and then coding the different comments. For each major comment group, potential modifications for the document were identified. The document was then rewritten by researchers to incorporate the changes that the participants had identified.

Session 3

28 February 2018. A half-day session was held at LUMSA University (Appendix 12). It aimed to hone the solution ideas that were generated in Session 2, to develop a prototype. A presentation was given to participants on the main findings from the analysis of Session 2 (Appendix 13). Participants were divided into 4 groups (for the 4 internal topics of the document) and asked to re-design the informed consent document. Each group was provided with both the old and the modified document text, craft materials, and an example prototype. This included modifying the text plus re-designing the format for its delivery (any media). After the prototypes were developed, each group presented it to the rest of the participants, and the modifications to the text and features of the prototype were discussed (Appendix 12).

Final analysis

After all of the sessions were complete, the moderator created a summary of all of the information gained throughout the design thinking process. This summary was reviewed and revised by all of the members of the team to ensure that the key points raised throughout the process were included, and the final messages accurately reflected the perspectives of the participants.

Results

Session 1

Participants agreed that the understanding of information in healthcare and in clinical trials is crucial, because the subject is making decisions about her/his body. Some key themes emerged from a brief discussion opened by participants on some aspects related to informed consent (Table 1).

Table 1. Key comments and major themes raised by participants in Session 1.

#	Theme	Comment
1	Autonomy	Participants noted that from an ethical and legal perspective, the decision to take part to clinical research should be autonomous.
2		A cultural mediator referred to the case of an Afghan woman who decided to sign informed consent only after looking to her husband/following his opinion. It was noted that even if legally we had the signature of the woman, this may not constitute voluntary participation.
3		It was suggested that i-CONSENT should work to improve the guidelines on promoting autonomy and increasing access to information in the consent process.
4	Trust	Participants noted the importance of trust for people regardless of differences in cultural and religious backgrounds.
5	Process	Having sufficient time to read the consent form and ask questions is necessary.
6	Environment and actors	The context (structure) where informed consent is obtained needs to be considered as different structures generate different levels of trust.
7		It was stressed that when the cultural mediator introduces into the doctor-patient relationship, he/she has a direct relationship with the patient (or research participant); and it was suggested that talking about the empathy of cultural mediators, rather than just the empathy of the doctor, could be more appropriate.
8		Participants also discussed the skills required for cultural mediation, noting how it differs from linguistic mediation and translation, including the need for knowledge specific to medical language.

Session 2

The number of comments made by participants when presented with the text of each topic are given in Table 2, split by sense (think, feel, see, do). After the general topic (introductory letter), most comments were on sexual health issues. There were relatively few comments on privacy. Most of the comments fell into the thought category as oppose to other emotions, followed by do and feel.

Table 2. Number of post-it note comments on each topic

		Topic					
		General - introductory letter	Side-effects	Vaccine administration	Data & privacy	Sexual health	Total
Sense	*Think*	22	15	18	11	17	83
	Feel	10	3	6	1	10	30
	See	4	3	1	1	3	12
	Do	15	3	6	2	9	35
	Negatives	5	4	5	1	4	19
	Positives	4	2	1	2	2	11
	Grand Total	**60**	**30**	**37**	**18**	**45**	**190**

Key topics expressed in the comments were:

- Poor comprehension (complexity of both the science and the language used).
- Fears, particularly safety issues (side effects of vaccines and unknown allergies).
- Trust: The motive of the study was questioned and it was stated that the parent would gain information from a variety of other sources, indicating a lack of trust. Participants wondered if their child had particularly been targeted for the study.
- The necessity of both contraception and the vaccine (questioned due to the child's age).
- The importance of the child's autonomy
- Difficulties in communication within the family unit because of the topic's sensitivity.

A summary of the main problems and needs identified through thematic analysis of the comments is given in Tables 3-7. The full thematic analysis is given in Appendix 11.

Table 3. Main problems identified in the informed consent document, and their associated needs

General information letter	
Problems	Need
Lack of comprehension - topic and language used are complex	Clear language, better explanation
Fear – vaccine side effects	Clear information about risks
Process unclear - focused on how they will be informed about the study and the role and autonomy of the child	Clear information about process for both the parent and child
Recruitment method unclear	Description of who the study is targeted at and how the individual was selected
Altruism noted as a driver for study participation	Clear, balanced information about who will benefit from the study so the individual can weigh it against personal risk (benefits should not be exaggerated as risk of coercion)
For many, the next step would be information seeking from other sources	Guidance to good sources of information

Table 4. Main problems identified in the sexual health information, and their associated needs

Sexual health	
Problems	Need
Age of child - too young to consider sexual activity	More information about why vaccination is conducted at this age
Lack of understanding about how a virus can cause cancer	More scientific information on disease progression
Questions about the need and appropriateness for contraception	More explanation of the conditions under which a girl would need to take contraceptives (if sexually active), inclusion of abstinence as an option
Difficult conversations to have in the family unit	Information about, and materials for communicating with a child on the topic; or communicating with other family members (e.g. husband)
Concerns about risks including fertility	Clearer information about risks
Will go to get more information from other sources	Direction to trustworthy information sources and/or development of new sources
Complex language	Simplification of language
Process unclear	More details about the process

Table 5. Main problems identified in the side-effects information, and their associated needs

Side effects	
Problems	**Need**
Purpose of the study – why doing it and why such a focus on sexuality	Better explanation of aim
Concerns about allergies, particularly unknown ones	More information about allergies – including how they would have presented previously
Concerns about risks – what exactly are the side effects, how long do they last	More information about side effects
Incentives for participation	Clearer information about the benefits and risks (including separation of individual and societal), so patients can better weigh up the pros and cons
Process – specifically who the researchers were and whether withdrawal from the study would have consequences	Information about researchers and the withdrawal process
Questions about the science, and comment that this was an opportunity to increase health literacy	More scientific information needed on specifics (reactions, blood production, age of vaccination)

Table 6. Main problems identified in the vaccine administration information, and their associated needs

Vaccine administration	
Problems	**Need**
Many comments asking about details of the process	Provide more information about the process – or present it in a different way?
Questions about safety	More details about what types of illness could occur as a result of information
Several questions about the purpose of the experiment, particularly in relation to the availability of the other vaccines	More explicit details about the other vaccines available
Complex language	Simplification of language
Need for more information from pediatrician	Training of/materials for the pediatrician?

Table 7. Main problems identified in the privacy information, and their associated needs

Privacy	
Problems	**Need**
Why is there so much attention to privacy?	To balance the sections of the informed consent form in line with the patients concerns (e.g. less privacy, more health risks)
Access to data	Details about when and how patients can access the data
How long data is kept	More information about how long the data will be used for this study, and explicit details about sharing with third parties
Anonymization	More details about if data can be linked back to participants

Session 3

Participants developed four prototypes; one for each of the main topics. Changes were made to text content for all topics. The original and modified versions are in Appendices 6-10.

One group felt like a website would be a good medium to convey information about side-effects; the privacy group opted for a mobile phone app; and the group working on vaccine administration suggested either paper or a mobile phone app. Only one group (working on sexual health) opted to leave the communication mechanism as plain text.

All of the groups suggested a structure that broke down each piece of text into sub-topics/pages – interestingly each group proposed splitting the text into 5 sub-sections. Participants phrased the subsection heading's a bit like a "how-to" guide – each section either posed a specific question or provided information about how to practically do something.

The group working on side effects suggested that adult and child-specific websites should be developed to cater adequately to their different communication needs. They also suggested that multiple languages be used to overcome linguistic barriers with adults, while animation/emoticons be used to enable communication to children from all backgrounds. One practical tool suggested by the vaccine administration group was a calendar, which aimed to improve the ability of participants in tracking the process.

An overview of the prototypes is given in Table 8. Photographs of the prototypes are given in Appendix 12.

Table 8. Overview of the prototypes developed

Topic	Interface	Overview of structure	Overview of content	Overview of media
Side effects	Website – main page links to either a child or an adult's site	Child. One page.	Basic child's site (one page) containing a video for download.	Animation with emoticon.
		Adult. Page split into 5 main (linked) sections with link to a sub-page detailing side effects.	General information/FAQ	Video (multilingual) - doctor providing information
			Risks and side effects of vaccination	Text description with LINK to photos; contact details of doctor (phone/e-mail).
			What to say to the doctor (allergies)	Text description and photos.
			What to do on the day of the vaccination	Text description
			Benefits of vaccination	Text description; LINK to "contact doctor"
Privacy	Mobile phone app	5 (linked) pages	Why is your consent important?	Text
			Who is holding my information?	Text and link to OPBG and vaccine society websites
			Are you free to withdraw from participating?	Link to details on how to withdraw
			Can I have access to my data?	Text and link to OPBG
			Check that everything is understood and consent	Checkbox
Vaccine administration	Paper or phone app	Text split into 5 sections, and calendar	Introduction explaining where the vaccine is being administered	Text
			When and how is the vaccine administered?	Text
			How will analyses be done?	Text
			Calendar	Calendar
			Next contact with researchers	Text
Sexual health	Paper	Text with 5 headings	What is HPV?	Text
			The vaccine	Text
			Who should be vaccinated?	Text
			Contraindications	Text
			To participate in the study	Text

Recommendations

I. Information should be communicated in a way that enables full comprehension[4], and therefore autonomous decision-making.
II. Individuals should not be generalised into groups, but viewed as individuals, each with specific needs; generalisation can be considered a form of discrimination.
III. The provision of information to potential participants should be prioritised according to their needs, as oppose to the needs of others[5].
IV. Needs for informed consent should be considered in two dimensions:
    i. Core human needs: the same for all informed consent users regardless of perceived differences that include gender, cultural and religious backgrounds.
    ii. Adaptations to facilitate diversity.
V. Core human needs: The minimum information requirements necessary to meet core human needs should be clearly defined by the iConsent group. From the Design Thinking sessions, some proposals for meeting basic needs include provision of clear information on the following:
    i. *Individual-level benefit and risk.* To ensure clarity, individual-level and population-level benefit/risk information should be presented separately.
    ii. *Voluntariness of participation and availability of alternatives.* It should be clearly stated that participation is not compulsory, and information about all available alternatives should be provided (including through research and public/private health systems).
    iii. *Recruitment strategy.* Potential participants should be informed about why they have been selected. This includes an explaination of the full sampling approach (i.e. who, when, where, why, how many).
    iv. *Details about what participation will involve* for each stage of the research process, and post-trial (e.g. data retention).
    v. *Complete rights of the participant* for example exiting the trial at any time, and rights to access to data or medication during/post-trial.
VI. Adaptations to facilitate diversity
    i. Meeting individual-level needs. Different types of technology and media can be used to personalise information to individuals[6].
    ii. Meeting societal needs. Local adaptations to informed consent should be made for differences between individuals that cluster according to characteristics including gender, cultural background, and religion. These adaptations should be made to improve access to, and comprehension of information. For example, materials should be adapted to meet different linguistic needs[7].
VII. We recommend that when designing informed consent, researchers use participatory, mixed research methods to gain insights relevant for their specific context. We suggest
    i. Conducting a design thinking workshop to rapidly gain practical information about how to adapt informed consent to different needs.
    ii. Involving people in a variety of research roles (for example patients, researchers, doctors, and cultural mediators).
VIII. When determining if a decision is autonomous, the wider environment should be considered, including:
    i. Trust between potential participants and the researcher (individual and organization).

[4] We gained several suggestions for improving the way that information was conveyed. These included using simple language at the level of comprehension (linguistic and scientific) of the individual; and splitting the currently bulky text into smaller units aligned with the key questions/concerns of the target population.
[5] As oppose to purely for the purposes of legal protection of the researcher for example
[6] For example, interactive multimedia can better enable individuals to navigate to the informed consent information that is relevant to their specific needs.
[7] For adults, it was proposed that information should be presented in multiple languages. For children, via animation and emoticons.

ii. Deferral of the decision to others (e.g. family members, family doctor): Information could be provided to facilitate discussion of sensitive topics within the family unit.
iii. Referral to external sources of information when making a decision. The risk of deferral to poor sources of information should be mitigated[8].

IX. As technology evolves, particularly in relation to privacy and data sharing, the needs of potential participants will likely change[9]. To ensure that recommendations keep pace with the evolution of technology, review by an expert group will be necessary in the future.

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[8] It was suggested that links to external websites with supporting information could be provided within the informed consent form
[9] We found that the privacy section of an informed consent form was outdated; and that the overall prioritisation of the document was not aligned with the concerns and priorities of potential participants.