Online E-consent event: UK collaboration

Interactive feedback discussion

UKTMN (NATALIE) JAN 27, 2022 10:16AM

Ethical considerations (1)

Inclusivity of participants
Access to equipment for informing or recording
Mixed methods preferable
Giving information and recording consent could use alternative methods

Are there any GDPR issues around contacting patients in the first instance via telephone? (i.e. patient might not like being telephoned, even by a nurse, outside of the clinical environment) — ANONYMOUS

We were advised by our Sponsor that eligible participants would have to be approached by a member of the clinical team and invited to take part. The participant would then contact the qualitative researcher directly to express their interest. — ANONYMOUS

Inclusivity = access to tech / capacity to use — MATTHEW SYDES

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Back up of modality, mix-and-match of information and consent (but offer electronic first to the "digital generation") — MATTHEW SYDES

Understand can be checked with quizzes - perhaps easier online — MATTHEW SYDES

Raise issues with HRA training (regional meetings) — MATTHEW SYDES

Access to translation services away from hospital — MATTHEW SYDES

Videos and editing - how to update without totally re-recording — MATTHEW SYDES

Holding of patients details for consent may support providing results at the end — MATTHEW SYDES

We've encountered the same problem, whereby the clinical team have to approach the patient first then it is up to the patient to contact the reserach team. — ANONYMOUS

Remote consent issues if participant lacks capacity and need to get permission from relative who can't get/isn't allowed into hospital — MATTHEW SYDES

A GDPR consideration that we worked on was what happens if you have collected an email address to send the consent form out but the participant doesnt go on to consent to take part in the study. We viewed this as needing to be removed as it was held under a legal basis of consent and not task in public interest like research data — ADAM BARRETT

Ethical considerations (2)

Identification of participants, verifying identity examples
Lack of guidance and inconsistency from R&D/NHS Trusts, varying approaches to one system
Need for solid guidance, less interpretation and pushback

What do people think the guidance would look like? Is another guidance document going to work? Case studies where eConsent has been succesfully implemented. Should it be something that people "sign up" too? — ELEANORMITCHELL

Maybe a guide on minimum requirements of eConsent (esp. remote consent), in order to achieve a 'valid' full consent? — ANONYMOUS

Programming/software (1)

Types of technology used
Redcap - similar tactics to solve issues but hard to share
Reinventing the wheel!

Being more collaborative eases the load — UKTMN (NATALIE)

Forums etc to connect with other CTUs — UKTMN (NATALIE)

Do units pay for a REDCAP licence? Is this budgeted on a unit level or trial by trial? — ANONYMOUS

REDCap community has a free license. Your costs come from hosting it and validating it — ADAM BARRETT

Could we develop a e-consent repository which CTUs would update regarding the system they have used for e-consent. For example, system used, functionality, validation certificate available or vendor assessment complete, context of use, mode of delivery, person to go to for more information etc (gleaned from a standard set of questions), plus also guidance on how to evaluate (standard set of questions perhaps, (e.g. resource required, upfront cost etc. flexibility etc.)... like SWAT repository, but tailed for e-consent platforms/issues? — ANONYMOUS

Programming/software (2)

Workflow in respect to staffing
CTUs using off the shelf speeds up delivery but increase in DM and IS in set-up
Mixed methods increases workload for set-up and validation
Extra programming for Redcap in inspection

Encrypted emails, participant and recruiters information kept separately - steps to make system more compliant (international inspection too) — UKTMN (NATALIE)

Re effort required for setup; We worked on our eConsent process for about a year before we applied it to a trial. The output of the years work was a REDCap template project and template specifications. Implementing a study using these templates now takes no more than a day for the enconsent forms to be setup. Additional time is required for testing and amendments
— ADAM BARRETT

Yes same - it took us about a year to design, set up and validate a sophisticated information sharing and eConsent system on Redcap before it was ready for use. This included a mix of free add on plug ins, and some bespoke 'modules' created by our programmer
— ANONYMOUS

Ditto — ANONYMOUS

Mixed methods

Giving the participant choice
Inclusivity theme
Paper accessible and technology accessible both important
Flexibility of providing PIS, depending on patient population
System flexibility but costs associated to be considered
Support for selecting vendors

Participant acceptability

Different patient groups, and also those lacking capacity
Try and implement, but don't make assumptions
Don't necessarily assume things about patient characteristics without testing the systems
Advisory panels approved of e-consent systems
Processes adapted to patient populations for accessibility to be applied to econsent
Learn from others
Generic system can be used

Quality assurance

E-consent easier, QA is considered earlier in the process
Monitoring and validation built in so less workload
Practical details needed

Anyone who has monitored this how did you carry it out. Can utilise QA to build the system but need QC (monitoring) ongoing
— ANONYMOUS

Most of what you monitor is incorporated in the econsent set up, for example, you cannot proceed to the next question without answering a question, the version is controlled centrally, you need to sign to leave the form, the delegation signature could be checked automatically. So there should probably be a check of the process but not of the individual data. — ANONYMOUS

Checking the process would be a QA activity? However how do you continue to ensure it is working as you could not carry out audit (QA) and MHRA always want to see QC activities — ANONYMOUS

Resourcing

Additional resources needed for mixed methods
Programming queries, how long does it take?
Updates to a standard module to make bespoke - what resource is needed, how long does it take?
Important to share experiences

This has been an issue that I've encountered, when wanting to establish how long it would take to send text messages through text messages — ANONYMOUS

Does anyone have any experience of switching from paper based consent to econsent during recruitment for a CTIMP? If so, how long did that process take? Did you pause recruitment whilst this was happening? — ANONYMOUS

Initial resource for first set up, but benefit reaped when repeating for other trials as set-up done and can be adapted
— UKTMN (NATALIE)

Regulatory acceptability

Gap between guidance and implementation
Real acceptable examples
Not much regulatory support in answering queries
Not many examples of inspection - hard to learn from

Any experiences of inspection of eConsent — ANONYMOUS