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An RCT to establish the effectiveness of EM vs. MRCP in patients with symptomatic gallbladder disease undergoing lap. chole at low or moderate risk of CBD stones

The Sunflower Study



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Sunflower
Study

IMPLEMENTING E-CONSENT

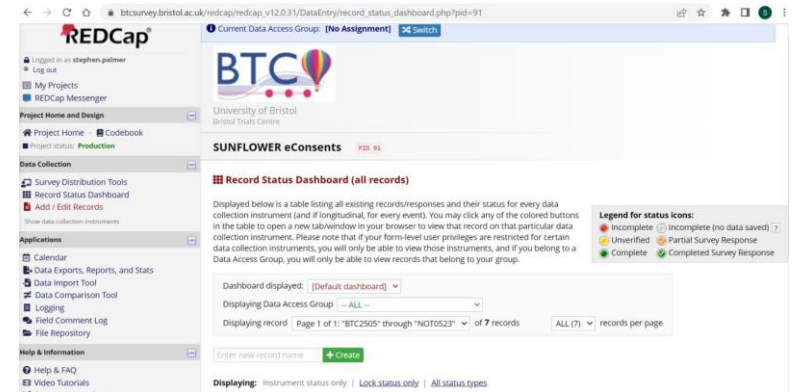
Stephen Palmer



eConsent – what and why?

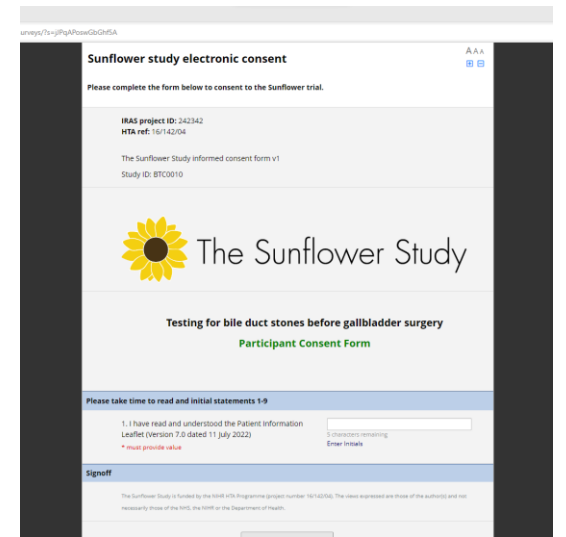
■ A new remote consent method:

- A system was developed using REDCap to allow sites to consent patients remotely, via an online consent form
- This was introduced in an amendment to the study in July 2022
- eConsent was intended to work alongside the face-to-face and other remote consent methods
- Why?
 - Difficulty contacting patients with less clinic visits after Covid-19
 - Postal delays and a lack of success with postal consenting
 - Saves time for staff and patients
 - Reduces errors
 - Study behind on recruitment & patients still out there



eConsent – how does it work?

- Site teams approach eligible patients and offer electronic option
- Set a suitable time where the patient will have access to a phone and to their emails
- PIL and consent form can be sent by email in advance – this helps when targeting patients from waiting lists
- During the eConsent phone call the patient gives their email address and receives a link to complete the consent form online, while the staff member remains on the phone to support
- The staff member stays on phone while reviewing the consent form
- The site team and the patient both receive a PDF of the completed consent
- The aim is to mirror a face-to-face appointment



eConsent – how did we implement it?

- We advertised the system to all sites and asked for teams to approach us for training
- So far, we have trained 32 sites in short 30min sessions
- Of those, 21 sites have used the system to successfully consent at least one patient
- Thoughts from site staff since implementing:
 - “I find electronic consent a more streamline and efficient way of gaining remote consent. With postal consent, we experienced delays in getting completed consent forms back, and sometimes there were mistakes on forms when we finally did receive them. This often led to repeated telephone calls, and on some occasions, it became too late to randomise the patient.”
 - “Patients also seem happy with the process as it keeps things simple, and most people nowadays are used to/prefer doing things online”.
 - “it has sped up the whole process and boosted our recruitment by enabling us to receive consent from patients with no face-to-face appointments with smaller window for recruitment, due to hot gallbladder surgery. From my experience, when asked, most participants prefer this method over postal consent”.

eConsent – PPI Comments

- Kerry Avery & Liz Booth initially conducted patient interviews in which eConsent was considered to be beneficial
- Conducted focus groups with members of the patient and public population. The group were shown the entire process from staff and patient-facing perspectives
- Comments from PPI members included:
 - eConsent process seems easy to complete
 - the process provided patients with adequate explanation and support throughout completion
 - Data protection arrangements were sufficient
 - They liked that patients would receive a digital copy of their consent
 - Some issues were raised; what about patients who work full-time – will they find room for appointments and will older patients find this too complicated

HOW IS IT GOING?

- First electronic consent on 8th September 2022
- 142 patients successfully consented electronically
- In this time period the study as a whole consented 1150
- 21 sites have successfully consented at least one patient electronically
 - At these sites 590 were consented overall
 - This equates to (142/590) **24%** of consents at active sites coming through electronic system



Sites Open

Birmingham	Milton Keynes	St. Georges
Bradford	Newcastle	Isle of Wight
Calderdale & Huddersfield	North Bristol Trust	Surrey & Sussex
Chester	Northampton General	University Hospitals Bristol
County Durham & Darlington	Northern Devon	Weston General
Derby	Nottingham	Whittington
Doncaster	Plymouth	William Harvey Hospital
Gloucester	Royal Bolton	Worcester
Guys & St. Thomas	Royal Free	Wrightington, Wigan & Leigh
Imperial	Southampton	York & Scarborough
Leeds	Southend	Forth Valley

Are you using the eConsent system?

Is everybody receiving consent signed up to REDCap?

If you are not open would you like to book training?