P-178

Evaluation of the introduction of a remote electronic consent process in the CO2 study

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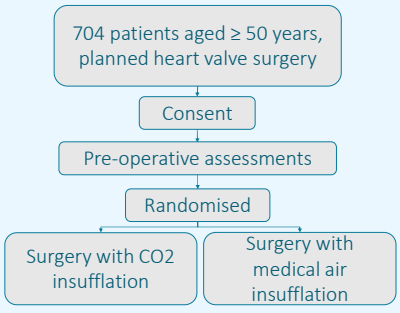
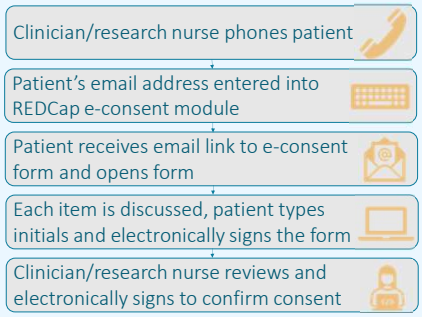
Introduction

- CO2 is a multicentre, placebo controlled, randomised controlled trial which aims to evaluate efficacy and safety of carbon dioxide insufflation as protection against brain injury during open heart valve surgery
- Remote electronic consent (e-consent), using a modified version of the REDCap e-consent module, was introduced to future proof against COVID-19, but uptake was lower than anticipated
- **This study aims to identify the features of a successful remote e-consent system**

CO2 schema



CO2 e-consent process



Methods

A questionnaire was designed in REDCap and emailed to all CO2 staff delegated to obtain consent

- 42 staff from 6 sites
  - 25 research nurses, 14 doctors/consultants, 3 research fellows/practitioners

Questionnaire

- Open to complete for 7 weeks
- 8-items with branching logic depending on experience

Topics:

Demographics	Experience with e-consent
Opinions of e-consent	Consent method preferences

Question types:

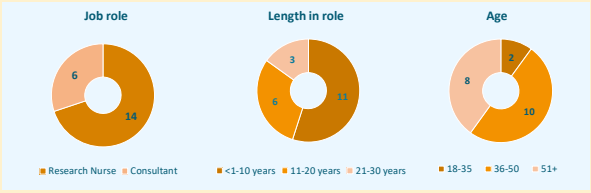
Free text | Likert scale | Multiple/single answers

There were additional questions for staff who had completed training on the CO2 e-consent module evaluating the training and usability of the module

Results

20/42 (48%) staff from six sites completed the questionnaire between 08/08/2022 and 26/09/2022.

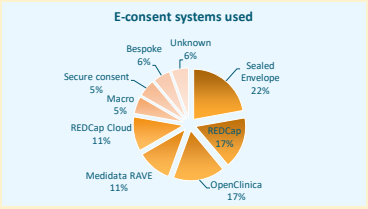
Demographics



Previous experience

5/20 (25%) had previous experience of using e-consent

- Those five respondents had used nine different systems



Thematic analysis of free text responses indicated:

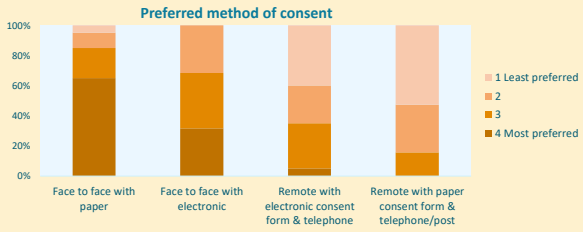
- Respondents liked e-consent because it was quick and easy to use and reduced participant burden

  "Quicker, real time consent. Easier to consent participants with busier lifestyles." (P1)

- Disadvantages of e-consent included technology challenges/equipment availability and a lack of face to face communication

Preferences

20 respondents ranked their preferred method of consent from least to most



- Respondents preferred a face to face approach as it facilitates better communication and enhances patient understanding

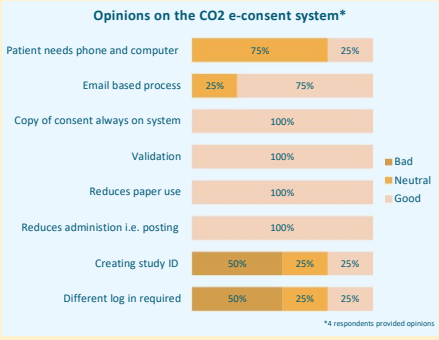
  "Face to face allows for better explanation of the study." (P5)

- Respondents were concerned that remote consent with a paper form and phone call was *"time consuming"* and *"unreliable"*

  "Signing a paper copy of the consent at home relies on patients remembering to send a copy of the form back. Time factor can also be an issue if surgery is taking place soon." (P6)

CO2 e-consent system

- 7/20 (35%) respondents had been trained to use the CO2 e-consent system
- The system had not been used to consent a patient as face to face methods were more practical in CO2
- Limited use of other systems meant it could not be compared



Discussion

- E-consent is viewed as quick and easy to use. However, few have experience and it has not been used in the CO2 study as patients are seen in person again
- Face to face consent methods are favoured by most. Remote methods are seen as time consuming and technology can be a barrier
- The CO2 system was deemed acceptable by those trained to use it. However, with many e-consent systems available, features may differ and create barriers

Conclusion

- E-consent remains feasible, but would be preferred as face to face rather than remote in CO2
- Feasibility of e-consent within the study setting and population should be considered before introduction
- Further work is required to determine features of an e-consent system which can be used remotely and in person

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