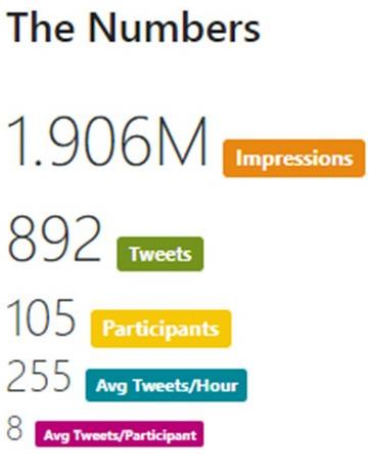
#WhyWeDoResearch

"Consent for Research During COVID-19"

This #WhyWeDoResearch tweetchat was dedicated to Sir John Pattison (former head of Research & Development in the Department of Health, UK). Sir Pattison pushed for patients to be more involved in research and for research to be more open and transparent.



The second #WhyWeDoResearch tweetchat, held on Tuesday 31st March 2020, explored 'Consent for Research During COVID-19'. Overall, 105 participants (across England, Wales, Scotland, Ireland & Australia) sent 892 #WhyWeDoResearch tweets. These tweets were seen (impressions) by over 1.9 million Twitter accounts. The key positive impact of the #WhyWeDoResearch tweetchat was that people said that they didn't feel alone (same problems/ issues were being tweeted about by other people), there was the 'space to discuss' initiatives and learn from each other. Below is a summary of everyone's tweets merged under different sub-headings. Please note that the representative examples may vary depending on the location and the experiences of individuals. The transcript of the #WhyWeDoResearch tweetchat (held on 31.03.2020) is available: click here.

Health & Wellbeing

We start each #WhyWeDoResearch tweetchat asking everyone how they are feeling in these difficult and challenging times. People spoke about being personally well but overworked and under pressure. Others said that they were anxious that the consent received for COVID-19 studies was valid and informed.

Infection Protection Control

Infection control/ avoiding cross-contamination when receiving paper consent was one of the biggest issues of the #WhyWeDoResearch tweetchat. People tweeted how their hospital was approaching documenting a patient's consent for COVID-19 studies:

- Research Nurse, wears basic PPE (apron, gloves, surgical mask), is in the room and witnesses the Principal Investigator (PI) consenting the patient. But need to get all clinical teams involved as they can then do the witnessing (especially for out-of-hours)
- Once consent is received, staff are wearing PPE (Personal Protective Equipment), then hold the signed consent form up to the glass of the isolation room. The 'clean' staff member takes a photograph of the consent. The consent form is then destroyed and the prosopography becomes the original.
- Once consent is received staff in the clinical area put the consent form in a resealable bag. After three days the research team take copies of the consent form.
- Once consent is received it is sealed in an envelope for five days and the details of the randomisation are written on the cover of the envelope.
- Some areas were not sure what device could be used to take the photograph and how that is then decontaminated. Plus downloading photographs onto hospital computers can be challenging.
- Exploring if a tablet to digitise a consent form/add a signature is possible. But the hardware would need to be able to be disinfected
- Others were using mobile phones (fit into sealable blood bags or freezer bags). The person with the mobile phone then emails (to their work email) the photograph, the photograph of the signed consent form is then saved to a suitable folder (with name, study number, participant no & date) and then the photograph is deleted from the mobile phone.
- Must ensure if using personal phone that the hospital has approved it's use for professional reasons and that all 'cloud' auto uploads are switched off.

Receiving consent

If unable to receive consent from a patient, and family members are not available (for whatever reason), doctors can act as 'Professional Legal Representative' (this means the

doctor is responsible for the medical treatment of the patient but independent of the study) who can give consent on behalf of the patient.

The questions being asked was how impartial can the doctor be and would they know the patient at all (have any idea of the patient's wishes)? There is a hierarchy of positions in hospitals. The Principal Investigator (PI) could be the senior consultant and the doctor acting as a Professional Legal Representative may not be a consultant or, as a consultant, could be under the authority of the PI. Questions asked included if a Professional Legal Representative ever refused to sign a consent form on a patient's behalf or, once the patient is accessed as meeting the inclusion criteria, they are enrolled as the consent form is signed on their behalf as just a means of meeting regulatory requirements?

Another concern is would patients, who are approached for consent be able to differentiate between consent for procedure/treatment versus research particularly in situations where it's the same staff or all staff are wearing PPE (and as you can't see their face hard to remember who is who).

Supporting Colleagues

Due to re-deployment most research teams had minimal staff. Also, as recruitment to COVID-19 studies is 24/7 seven days a week tweets discussed their concerns about being able to support their colleagues. People spoke about trying to ensure that training, and support, was available for research naive clinical colleagues. Some spoke of needing a supportive network, for all hospitals, to access. This would allow areas that are new to research access resources and guidance from colleagues more familiar with research.

The work load of colleagues versus infection control was also mentioned. Areas differed between research staff supporting consent being taken (but not in person to avoid cross contamination) and others where research staff were present when consent was taken.

Public Patient Involvement

Frustration about the lack of Public Patient Involvement (PPI) was clear. Some patients (who had seen information sheets for clinical trials) felt that they were too technical and not very

patient friendly. If the information leaflets are in a language that patients don't understand how can consent (whether that is to join or not) be informed? Others spoke of surveys that were poorly designed and it seemed evident that there was no PPI in the design or delivery of the study. Patients also spoke about missing the opportunities to provide guidance and support to strengthen research studies.

Public awareness

Many thought that now is the ideal time for a public campaign to raise the awareness on, and need for, research. That with so much attention on COVID-19 it presents an opportunity to increase basic research literacy, understanding evidence, randomisation etc. The benefits of increasing public awareness of research extends beyond COVID-19 and allows it to be become part of the conversation when discussing healthcare.

Let the public know about the COVID-19 research opportunities, give them the opportunity (while they are well and at home) to learn more about the research that they may be offered if admitted to hospital due to COVID-19. As some patients may be seriously ill when in hospital being approached to take part in a research study might be a bit too overwhelming for them. If they have the chance to be informed prior to potential becoming a candidate for the study they are better informed to say 'yes' or 'no'. It would also mean that their family would already be aware of the study too and this links with the next point.

Being aware of your family member's, friend's, partner's research wishes

Do we know our families wishes about participating in research?

People tweeted that consent in critical care environments can be difficult, especially as most units (currently) do not allow family or friends to visit. When the patient, due to COVID-19, is not in a position to make an informed choice about participating in a research study family members (when possible) are contacted. There was a concern that some family members may have therapeutic misconception about the study and/or be unaware of their loved one's wishes.

Tweets, linked with the comments made about public awareness, suggested how the public awareness campaigns should encourage the public to speak to their family members about their research wishes. This would mean that should a patient be admitted to hospital and due to their illness are unable to give their consent that their family members would already know their wishes.

Resources Shared

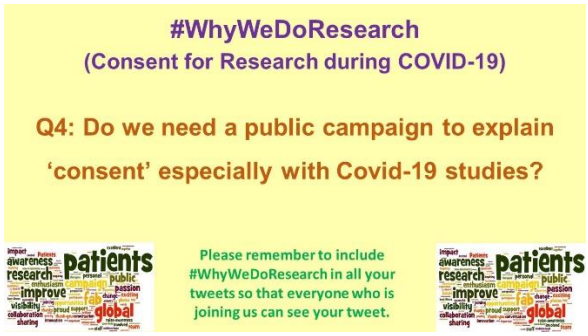
People tweeted about wanting to learn from COVID-19 (for research delivery and management). What can we learn, what worked well during COVID-19 and what works well after COVID-19.

During the #WhyWeDoResearch tweetchat some resources were shared and they are listed below:

- Gobat, NH et al (2015) Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness *Trials* **16**:591
- European Medicines Agency's "Human regulatory: COVID-19"

Questions Asked


#WhyWeDoResearch
(Consent for Research during COVID-19)
Q3: How did you find approaching relatives/ patients for consent to COVID-19 studies?
How would you feel about being a patient who is approached to be part COVID-19 trial/study?
Please remember to include #WhyWeDoResearch in all your tweets so that everyone who is joining us can see your tweet.


#WhyWeDoResearch
(Consent for Research during COVID-19)
Q4: Do we need a public campaign to explain 'consent' especially with Covid-19 studies?
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