

# SIGNET consent in the donation conversation

Dan Harvey, on behalf of SIGNET team in Clinical Trials Unit & OD Research Team

## Background

- SIGNET is a UK-wide randomised controlled trial, enrolling DBD organ donors in level 1 & 2 hospitals
- Donors are randomised to receive a single dose of simvastatin, a safe and commonly used drug, or standard donor care alone
- Specialist Nurses (SNs) take consent from the donor families
- Typically consent for research occurs at the end of the consent conversation, considering organs that cannot be transplanted, however the protocol and SOP empowers SNs to decide where to discuss SIGNET
- Feedback during the first year of SIGNET also suggested that there has been a shift in the number, location and frequency of donor family conversations around the time of diagnosis of death by neurological criteria. For example, fewer overall conversations, greater use of telephone conversations, single approach conversation more likely (no statistical data)
- As a result of this feedback, the team amended the protocol (approved by the research ethics committee) to allow consent for SIGNET to be taken earlier in the consent conversation if this is appropriate and to continue to be aligned with OD consent

## Methods

- SIGNET consent was discussed in team meetings and at national shared practice sessions
- This gave an opportunity to raise suggestions of where in the consent conversation SNs approach SIGNET and share examples of good practice
- Feedback was sought during study set-up, post go-live and one year following the start of recruitment

## Results

SN feedback helped shape how SIGNET is run and has contributed to the study's success. Through the feedback sessions the following suggestions were made for where approach for SIGNET consent could occur ;

- During MASH discussion
- When talking about donating the heart
- Discussing donor support / management on ICU
- Research – in a specialist hospital
- Other research – IONOR, QUOD
- Nonprescriptive approach triggered by family

## Discussion

- There are several different approach options available, and this gives SNs freedom to read the room and decide where the most appropriate place is to approach for SIGNET consent.
- More research is needed to understand the impact of different approach strategies, in particular do they influence family acceptance and understanding, consent rate, or reduce burdens of consent conversation for SNs and family
- An embedded qualitative study of family & SN experiences of research consent in the SIGNET study is in progress and will give more insight into these questions

## Conclusion

SNs are able to flexibly adjust approaches to seeking research consent during the organ donation consent conversation and develop personal practise. Research protocols can devolve decisions on approach safely and effectively to SNs during the organ donation process