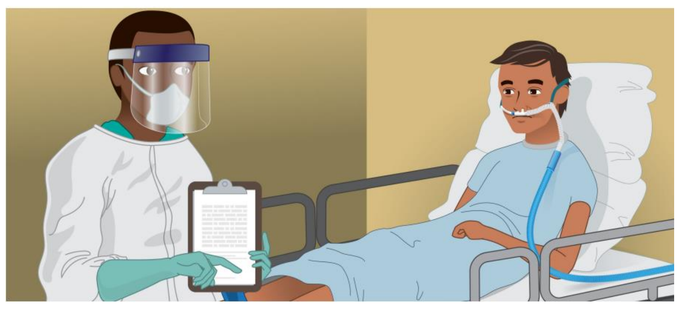
Success of consent and follow up in the Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma (PACKMaN) study - an analysis of how participants respond to communication approaches.

Owen Stanley[1], Elisha Miller[2], Dr Mike Smyth[3]
[1] West Midlands Ambulance Service [2] Yorkshire Ambulance Service [3] Warwick Medical School
owen.stanley@wmas.nhs.uk

1. Background

Recruitment into the PACKMaN study required verbal assent from patients unless their pain was too severe to respond appropriately. This was done in order to limit time to analgesia in a patient group that require urgent treatment.

Research paramedics would then provide further information about the study, allowing patients to make an informed decision about follow up - hospital data collection and two questionnaires. It is important to determine if either approach affects patient decisions on whether to continue participation.



2. Remote consent

Development of the PACKMaN study was interrupted by Covid-19 and redeployment of staff. On return, the world was a very different place and face-to-face interactions were massively reduced. Remote consent had not previously been commonplace in pre-hospital studies.

PACKMaN devised a multi-approach contact process, allowing greater flexibility and reduced risk of research paramedics transmitting disease between patients.

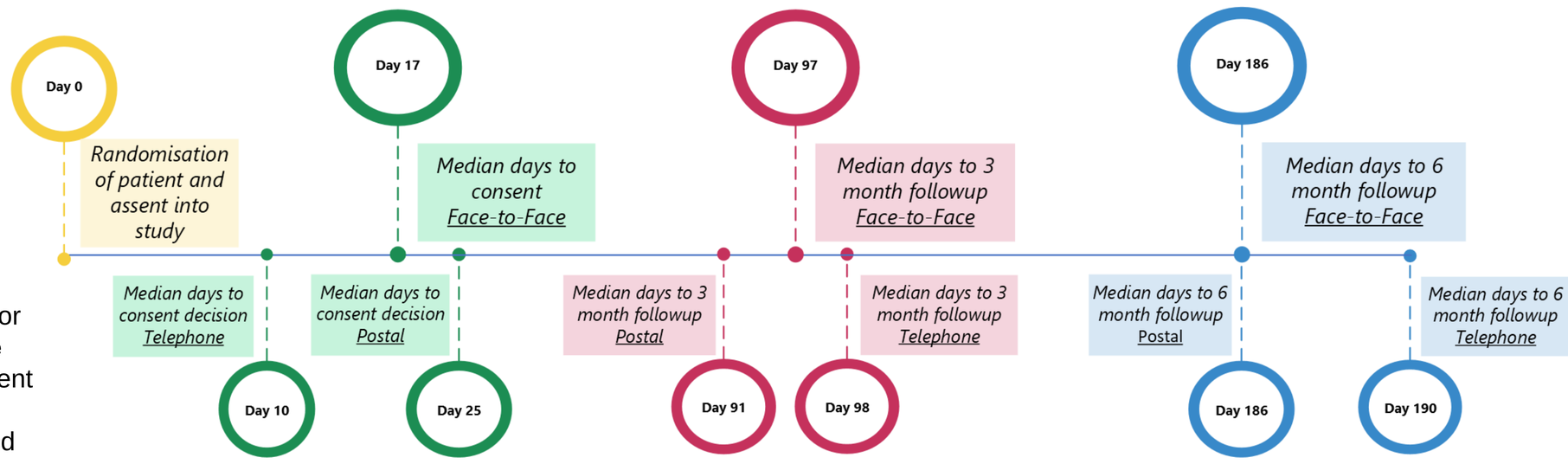
While there was no pre-determined contact preference, Trust A generally attempted to visit patients face-to-face (where clinically appropriate) and Trust B chose to focus on telephone calls.

3. Follow up

Follow up followed a similar mixed contact method approach. Trust A completed most follow up questionnaires by telephone, whereas Trust B solely posted follow up questionnaires to patients to fill and return.

By comparing consent method with completion of follow up questionnaires, it is possible to determine if a relationship exists. This can then guide future study development in order to maximise follow up.

Participant involvement in PACKMaN



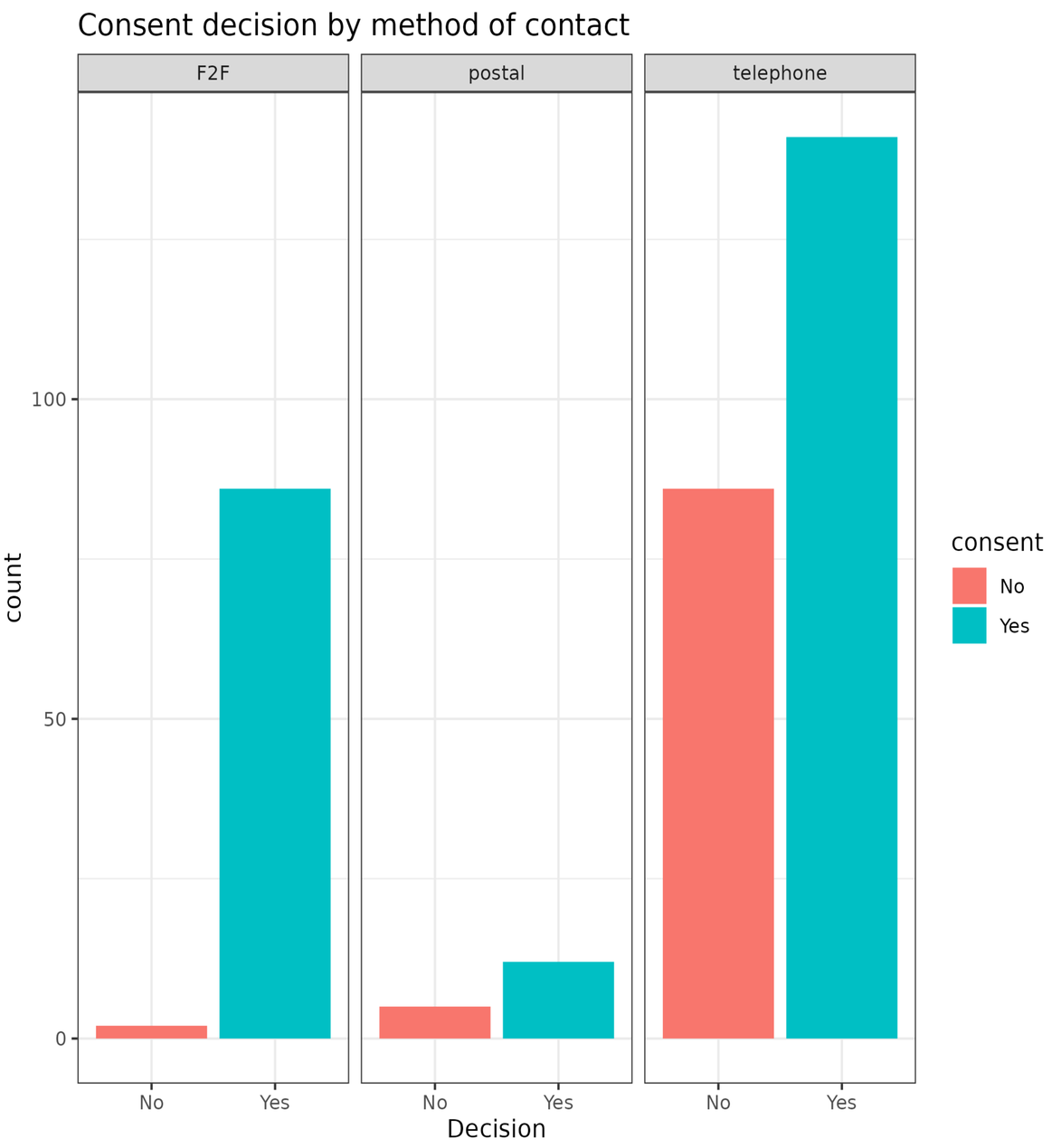
4. Results

Face-to-Face consent consisted of in hospital visits or were pre-arranged at a patient's home address. The Face-to-Face group was most likely to provide consent (97%), with postal and telephone yielding the same 68%, albeit postal was used for very few patients and was generally used where contact had been unsuccessful in person or by telephone.

Consent method	consented	3 month follow up	6 month follow up
Face-to-Face	97%	60%	40%
Telephone	68%	50%	25%
Postal	68%	57%	47%

As the study was ongoing at time of analysis, these rates reflect patients that had not yet reached the follow up timepoints but still show an emerging trend

Patients who provided consent via telephone were least likely to provide follow up data, although some of this difference may be due to the differing follow up approaches between Trusts. Trust B utilised the postal only follow-up represent a large proportion of the telephone based consents.



5. Conclusions

354 patients had been recruited at the time of analysis, of which 241(68%) provided consent to follow up. 67(19%) patients had not responded to research paramedics, most of whom had only been contacted by telephone.

Face-to-Face visits had much higher levels of consent to follow up than other methods but this did not equate to actual levels of questionnaire completion.

All staff receiving consent were up to date with Good Clinical Practice principles and ensured patients had ample opportunity to consider information and decline participation. However, whilst patients were more likely to agree to participate when approached face-to-face, they did not necessarily wish to follow up when the time came.

Further research may be required to ensure high levels of follow up, whilst working with limited ambulance service resources and ensuring participants do not feel any undue pressure to take part.

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