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DEVELOPMENT AND EVALUATION OF A MULTIMEDIA TOOL FOR OBTAINING INFORMED CONSENT IN THE GAMBIA: A MIXED METHOD STUDY

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Background Communicating crucial research information to low-literacy research participants in Africa is highly challenging in the context of several factors which make the participants vulnerable to poor comprehension of consent information. We

previously developed and validated a digitised audio comprehension questionnaire. Here, we report the development and evaluation of a multimedia consent tool amongst low-literacy participants in The Gambia.

Methods Adults eligible for inclusion in a malaria treatment trial (n=311) were randomised to receive information needed for informed consent using either a multimedia tool (intervention arm) or a standard procedure (control arm).

A computerised audio questionnaire was used to assess participants' comprehension of informed consent. This was done immediately after consent had been obtained (at day 0) and at subsequent follow-up visits (days 7, 14, 21 and 28). The acceptability and ease of use of the multimedia tool were assessed in focus groups.

Results On day 0, the median comprehension score in the intervention arm was 64% compared with 40% in the control arm ($p=0.042$). The difference remained significant at all follow-up visits. Poorer comprehension was independently associated with female sex (odds ratio, OR: 0.29; 95% CI: 0.12 – 0.70) and residing in Jahaly rather than Basse province (OR: 0.33; 95% CI: 0.13–0.82). There was no significant independent association with educational level. The risk that a participant's comprehension score would drop to half of the initial value was lower in the intervention arm (hazard ratio 0.22, 95% CI: 0.16–0.31). Overall, 70% (42/60) of focus group participants from the intervention arm found the multimedia tool clear and easy to understand.

Conclusions A customised multimedia tool significantly improved comprehension and retention of consent information by research participants with low levels of literacy in The Gambia. Further evaluation of the tool is warranted in similar settings.