

Supplementary file 1: Table of Adverse Events from Trial of APT

Person involved (ID if participant)	Date	Person reporting	Event and action taken	Severity (low, moderate, severe)	Further action	Implications for analysis
RBH100-01 and RBH 101-01	28.01.19	Laboratory provider	The laboratory provider sent results (including name, DOB, gender, and contact details) by post marked confidential to Hospital A, instead of by secure email to named individuals, as requested. Staff at the site were alerted and retrieved the envelopes from the post room.	Low	The laboratory provider set up secure email addresses for results and confirmed that this would be the only method of reporting. The print function was removed so hard copies could no longer be produced. Laboratory provider sent a full incident report for trial records.	Nil
TAC130-01 and TAC133-01	28.01.19	Laboratory provider	The laboratory provider sent results (including name, DOB, gender, and contact details) by post marked confidential to Hospital B, instead of by	Low	The laboratory provider set up secure email addresses for results and confirmed that this would be the only	Nil

			secure email to named individuals, as requested. Staff at the site were alerted and confirmed that the envelopes had been delivered to the clinic.		method of reporting. The print function was removed so hard copies could no longer be produced. Laboratory provider sent a full incident report for trial records.	
Sex partner of index patient (AKC145)	18.03.19	Research Health Adviser	Sex partner provided with antibiotics without assessment – error by nurse. Sex partner tested negative elsewhere and did not take medication.	Low	Local retraining	Nil
List of participants supplied by software provider	Separate report by software provider	Software provider	See attached report	Low	See attached report	Inclusion of affected vs non-affected variable in analysis
NGH283	15.08.19	Research Health Adviser	NGH283 took APT packs for two partners. She reported to research health adviser at 2-	Low	Information distributed to all healthcare professionals involved	Nil

			<p>week follow-up that Partner A found APT pack for Partner B, opened it, and found registration form with Partner B's full name & mobile number. Partner A called Partner B and 'had a go'.</p>		<p>in LUSTRUM (via newsletter) to remind them not to include any identifying information on APT packs</p>	
<p>Index patient received postal kit in error (PHC049)</p>	<p>18.10.19</p>	<p>Research Health Adviser</p>	<p>Event: As data cannot be edited in RELAY, healthcare professional at site re-entered data for PHC048 as PHC049. PHC048 had opted in to receive postal kit but PHC049 had opted out. Patient told nurse at repeat visit that she had received kit and was upset. RHA confirmed with site that nothing untoward happened (e.g., parents opening kit), nurse had apologised, and patient</p>	<p>Low</p>	<p>Continue double-checking duplicate entries until the end of the trial</p>	<p>Nil</p>

			<p>accepted apology.</p> <p>Action: All duplicate entries double-checked to ensure patients will not receive a postal kit if they opted out.</p>			
ID not traced	October 2019	Research Health Adviser	<p>Patient told healthcare professional they received a LUSTRUM SMS with negative results but said they had not done any tests; patient was not upset, just pointing out the error; team investigated but could not find record of patient in RELAY or at the laboratory provider.</p>	Low	Nil	Nil