

Appendix 38 Rationale for changes to the original prevalence survey protocol

The current protocol for the prevalence survey component of ClaSS contains certain changes from the protocol originally submitted to the HTA. These changes relate to methodological refinements to the original protocol. Modifications have been made in the light of experience with the initial practices surveyed in Bristol and Birmingham. In addition, interviews were conducted with a purposive sample of 11 patients from study practices aged 16 to 39 years. These patients (who had not been selected for ClaSS) were interviewed in their homes regarding their reaction to the study pack and the invitation to participate in ClaSS. These reactions were discussed and further modifications to study methodology were made. This process is described in more detail in the revised Social Research Study protocol.

Changes made relate to strategies to improve response rate and the ability to characterise the study population, some changes relate to ethical committee requirements. These changes, and their rationale, are described in the table below.

Prevalence Survey Protocol Changes

Subsection of current protocol document	Original Prevalence Protocol	Current Prevalence Protocol	Rationale
2.1.1	Total number of GP practices = 20 (10 in Bristol; 10 in Birmingham).	Total number of GP practices = 27 (11 in Bristol; 16 in Birmingham).	To increase generalisability through coverage of a greater diversity of practice populations and through the inclusion of smaller practices – including “single-handed” practices.
5.1	Initial patient contact Study pack.	Initial patient contact Advanced Introductory GP Letter containing Chlamydia Fact Sheet and ClaSS Information Leaflet sent prior to study pack.	To improve response rates and reduce the amount of written information in the study pack.
6.1	Main study pack Containing: introductory letter, consent form, short questionnaire, information leaflets, sample containers and prepaid return envelope.	Main study pack As before but now including reply form to allow expression of wish not to participate.	To meet ethical stipulations.

Subsection of current protocol document	Original Prevalence Protocol	Current Prevalence Protocol	Rationale
6.1	Main study pack As previous page.	Main study pack Letter now includes offer of £10 inconvenience fee for participation and entry into £1000 “prize draw”.	To improve response rate (pending ethical approval and confirmation of adequate funding).
6.1	Short prevalence questionnaire content Covering: socio-economic status, self-identified ethnic group, use of sexual health services, recent use of antibiotics, women – last period and regularity of period.	Short prevalence questionnaire content Covering: date of birth, self-identified ethnic group, ever had sexual intercourse, date of last menstrual period, date and time sample was taken, whether urine was first passed that day, which part of urine flow sample was taken.	Rationalisation of minimal information requirements to allow collection of data on single sided form. Additional information now gathered through the case-control questionnaire.

Subsection of current protocol document	Original Prevalence Protocol	Current Prevalence Protocol	Rationale
5.1.5	No reminder postcard	Reminder postcard (sent out 7 days after receipt of study pack).	To improve response rates.
N/A	Cervical samples for positive women	No cervical samples taken	Specimen requirements of the test evaluation studies have now changed – see new Laboratory Protocol.
N/A	Invitation for negative women to undergo cervical testing	No invitation for cervical testing	Specimen requirements of the test evaluation studies have now changed – see new Laboratory Protocol.
8.1.2	<p>Sample(s) returned with consent form missing/incomplete</p> <p>Sample(s) not tested.</p>	<p>Sample(s) returned with consent form missing/incomplete</p> <p>Sample frozen and consent form re-issued; sample tested on receipt of completed consent form.</p>	<p>To meet ethical requirements.</p> <p>Refinements of protocol in the light of experience</p>

Subsection of current protocol document	Original Prevalence Protocol	Current Prevalence Protocol	Rationale
8.1.2	<p>Incomplete samples with completed consent form</p> <p>Not covered in original protocol.</p>	<p>Incomplete samples with completed consent form</p> <p>No urine – reissue entire pack; no swab – no action.</p>	Refinements of protocol in the light of experience
5.1.6	<p>Delivery method</p> <p>Recorded delivery through Royal Mail.</p>	<p>Delivery method</p> <p>Dedicated courier.</p>	To improve ability to characterise denominator for prevalence estimates (i.e. integrity of sampling frame) following experience of difficulties in this area with use of recorded delivery.
7.1	<p>Non-responders</p> <p>Recorded delivery reminder after 3 weeks and telephone after a further 3 weeks if still non-responder.</p>	<p>Non-responders</p> <p>Non –responders protocols still undergoing evaluation see Section 7 of Detailed Prevalence Protocol.</p>	To improve response rates.
7.1.4	<p>“Ghost” Sub-sample visited, n=50</p>	<p>“Ghost” Sub-sample visited, n=25</p>	Issue of “ghosts” is now substantially addressed by the new delivery system.