A study into the prevalence of autistic spectrum conditions (ASC) in adults
Part of the National Study of Health and Wellbeing

STUDY PROTOCOL
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SCIENTIFIC SUMMARY

Background
The prevalence of Autistic Spectrum Conditions (ASC) has been established as part of the 2007 Adult Psychiatric Morbidity Survey (APMS). Adults with learning disability could not be included in this survey because: (a) a requirement of participation was ability to take part in a survey interview, and: (b) some live in communal care establishments.

Aims
- To estimate the prevalence of ASC in all adults in England
- To estimate the prevalence of ASC in adults with learning disability in England

Plan of Investigation
We plan to interview 500 adults with learning disability (or their carers/advocates) from three learning disability case registers in England. We will administer comparable diagnostic measures to those used in the APMS, 2007: the Autism Diagnostic Observation Schedule and in a random subset, the Diagnostic Interview for Social and Communication Disorders (DISCO). Consent will be obtained from participants (up to the limit of their capacity to consent) and their carers.

Impact
The results of the household survey are already cited in the Department of Health’s Autism Strategy following the passage of the Autism Act through parliament in 2009. The estimate from the learning disability population will help to inform the calculation of an overall prevalence estimate representative of all adults in England. This information will also inform future planning and projections of need of all people with ASC both with and without learning disability.
### Glossary of Terms

**Autistic Spectrum Condition (ASC)**  
A neurodevelopmental disorder, such as autism or Asperger syndrome, that impairs an individual’s ability to communicate and to socialise with others.

**Learning Impairment**  
Significant intellectual impairment with onset before adulthood, i.e. IQ<70 (approximately 1-3% of the population).

**Learning Disability**  
Significant intellectual impairment with onset before adulthood with significant deficits in adaptive functioning/need for support in daily functioning (approximately 0.4% of the population).

**Communal Care Establishment**  
Domestic group setting, such as a residential home or nursing home, that has an intrinsic care function.

**Adult Psychiatric Morbidity Survey (APMS)**  
A household survey of 7,400 adults in England.
LAY SUMMARY

Autistic spectrum conditions (ASC), including autism, are disorders of brain development that become apparent in early childhood. People with ASC often find it difficult to talk to and make friends with others.

The Government recently said that they would help to improve the lives of adults with ASC in England. However, to do this, they need to know how many adults have ASC. In 2007, we carried out a survey to see how many adults living in private households have ASC. The survey involved interviewing people in their own homes asking a list of questions to see if they have ASC. We estimated that 1 in 100 people had ASC. However, this survey only included people who live in their own homes, and did not include people who lived in special group accommodation, called “communal care establishments”, such as special hospitals or group homes. We think that people who live in these establishments might be more likely to have ASC than those in their own homes. In addition, we think that people who have learning disabilities might have found it difficult to take part in our first survey because they would not have been able to answer the questions.

So that we can find out how many people in the whole of England have ASC, we are going to interview 500 people with learning disabilities and their carers as they could not take part in the first survey. The person with learning disabilities will take part in a special assessment for ASC called “ADOS”. They will also be asked some questions about their health and lifestyle. Carers will be able to answer these questions if the person with learning disabilities finds this too difficult. Some carers will also be selected to take part in two other assessments, called DISCO and the ADI-R (where possible), which also help us to find out if the participant has ASC. These two assessments will be carried out on a different day. We will also find out the age, gender and, where possible, the ability level of people living in communal establishments and use what we find, to work out how many people living in communal care establishments have ASC.
1. BACKGROUND

Autistic spectrum conditions (ASC), including childhood autism and Asperger syndrome are neurodevelopmental disorders. Childhood autism and Asperger syndrome were first described in the 1940s\(^1\)\(^-\)\(^3\) and now fall within the concept of a broader spectrum of ASC\(^4\)\(^-\)\(^5\).

In February 2008, the Government announced work on a new national strategy for autism and guidance for the condition\(^6\), finally published in March 2010\(^7\). The aim of the strategy is to improve the quality of services provided to adults with autism in England and can only be achieved if the number of people with recognised and unrecognised ASC in the general population is quantified. Since the 1960s, there appears to have been a steady increase in the prevalence of ASC\(^8\)\(^-\)\(^12\), believed to be a result of improved diagnostic methods, widening of diagnostic criteria, less stigmatisation of the condition and increased awareness from health professionals\(^11\).

The most recent population-based Adult Psychiatric Morbidity Survey (APMS) set out to determine the prevalence of ASC in adults living in private households in England. The study was led by the principal investigator of the current study and used a household survey of 7,400 adults in England\(^13\). Over a one-year period, 650 adults were interviewed with up to four validated ASC questionnaires: the Autism-Spectrum Quotient, or AQ-20 (based on the AQ-50\(^14\)), the Autism Diagnostic Observation Schedule Module (ADOS-4)\(^15\), the Autism Diagnostic Interview Revised (ADI-R)\(^16\) and the Diagnostic Interview for Social and Communication Disorders (DISCO)\(^17\) together with a clinical consensus judgement procedure. The case definition of ASC was based on an ADOS Module 4 score of 10 or greater validated against 54 DISCO and ADI-R assessments and a consensus exercise involving six clinicians experienced in assessing adults with possible ASCs (to be reported separately) who assessed quantitative and descriptive information on 400 phase two respondents. Results from this APMS study revealed an overall prevalence of 1.0% (95% CI 0.3% to 1.7%) for ASC in adults\(^13\).

There were two limitations to the APMS. First, the APMS prevalence of 1% for ASC was based on adults who were living in private households. It is likely that ASC is more prevalent in some populations that were not sampled in the household survey. For example, people who live in communal care establishments, such as residential homes and nursing homes, and those in homeless accommodation and prisons are likely to
have a higher prevalence of ASC. Second, people with learning disabilities (defined by a significant intellectual impairment with onset before adulthood and deficits in skills needed for daily functioning, i.e. associated disabilities \(^{18}\)) often have significant problems that would have hindered their ability to participate in the APMS through not having decision-making capacity to consent to participate and so being excluded. Additionally, the APMS lay interviewers did not have the necessary training and methods required to assess the capacity of respondents who have significant communication problems. This group has an increased risk of ASC; current evidence suggests that the prevalence of ASC in adults with learning disabilities is between 7% and 20% \(^{19-20}\). Therefore the published APMS estimated prevalence of ASC which covered adults in private households is likely to be an underestimate for the total population, and also fails to highlight the high prevalence in the learning disabled population.

**Learning impairments and learning disabilities**

The population distribution of intelligence quotient (IQ) approximates to a normal distribution (although the greatest deviation from the norm is at the extreme ends of the distribution). Hence, about 2.27% would be expected to have an IQ less than two standard deviations from the mean i.e. IQ<70 points, or learning impairments. It is generally accepted that 1-3% of the population have learning impairments, with premature death reducing the rate in adulthood. Most people with learning impairments require support for learning in childhood, so by ICD-10, DSM-IV-TR, or Department of Health criteria, have learning disabilities. However, by adulthood, many with mild learning impairments will have gradually learned and acquired the necessary life skills to live independently, work, marry, raise families, and not consider themselves to be disabled, and nor do their family, friends and others consider them disabled. People with mild learning impairments participated in the APMS, and are not included in learning disabilities registers.

Learning impairments and learning disabilities are not synonymous terms, and the latter has lower population prevalence. Studies on adults with learning disabilities fairly consistently report the prevalence of moderate to profound learning disabilities to be 2 – 4 / 1000 \(^{21-26}\). Almost none of this group would have the ability to have participated in the APMS, in view of the linguistic complexity of the measures used, and more importantly, the requirement to have decision-making capacity to consent to participate resulted in them being excluded. Learning disability case registers also include people with mild learning disabilities. These individuals have mild learning impairments, and often have
significant comorbidities or problems with daily living, which require additional support from specialist learning disability service providers, and hence are notified to the registers. A proportion of these would not have been able to participate in the APMS because their decision-making capacity is impaired by their comorbidities.
2. STUDY AIMS AND OBJECTIVES

2.1. Aims

The aims of the current study are:

i. To estimate the prevalence of ASC in all adults in England

ii. To estimate the prevalence of ASC in adults with learning disabilities in England

2.2. Specific Objectives

The objectives of the current study are:

i. To identify a representative group of adults with learning disabilities in England (in terms of age, sex, and place of residence) who were either:
   (a) living in communal care establishments and thus not included in the APMS survey sample or: (b) living in the community in private households but unable to participate in the APMS survey due to learning disability. Adult Case registers in Leicester, Lambeth and Sheffield will be used for this purpose.

ii. To interview 250 adults with learning disabilities who live in communal care establishments with the validated clinical assessment ADOS, to determine the prevalence of ASC in this population.

iii. To interview 250 adults with learning disabilities who live in the community with the validated clinical assessment ADOS, to determine the prevalence of ASC in this population.

iv. To interview a sub-sample of 60 adults with learning disabilities (30 in communal care establishments and 30 in the community) with the clinical assessment DISCO, to calibrate ADOS.

v. To determine the characteristics of residents in communal care establishments identified in terms of age, sex and, where known, ability level (e.g. from the prison survey), so that the overall prevalence of ASC in communal care establishments can be estimated.

vi. To combine the acquired prevalence rates of ASC in adults with learning disabilities who live in private households and who live in communal care establishments with the prevalence of ASC in adults without learning disabilities living in private households (from the private household survey
in 2007) and communal care establishments (extrapolated) to derive an overall prevalence estimate for ASC in adults in England.

vii. To carry out a sensitivity analysis by extrapolating prevalence rates for adults with and without learning disability to those living in communal care establishments and prisons and to combine this prevalence estimate with the APMS estimate to determine how the combined estimate differs from objective (vi).
3. STUDY SETTING

Three learning disabilities registers located in Leicestershire, Lambeth and Sheffield, will be used as the sampling frame for this study. All were established via a multi-pronged approach to population ascertainment, and have similar rates, suggesting the approaches were robust. They have adult prevalence rates of learning disabilities within the expected range, 4.9 / 1000, 4.3 / 1000, and 5.4 / 1000 for the Leicestershire, Lambeth and Sheffield registers respectively \(^{27}\) and have been used extensively for research \(^{21,25-26}\). The Leicestershire learning disabilities register adult prevalence of specifically moderate to profound learning disabilities is 3.7 / 1000 population, which is also in keeping with published studies, suggesting that there has been robust ascertainment of the population. All adults (aged 18+ years) on the case registers will be eligible to be included in this survey.
4. STUDY DESIGN AND METHODS

4.1. Inclusion and Exclusion Criteria

**Inclusion Criteria**

(i) All adults (aged 18+ years) with learning disabilities who live in communal care establishments (e.g. residential homes, nursing homes, NHS accommodation)

(ii) All adults (aged 18+ years) who live in private households (e.g. independently, with family, in supported living accommodation) who would not have been able to participate in a survey interview due to communication difficulties/lack of capacity to decide whether to participate

**Exclusion Criteria**

The study involves using clinical assessments to determine ASC and severity of learning disability, which have only been validated in the English language. For this reason, participants who are able to be interviewed will be excluded if they do not speak English. Similarly, for informant interviews, participants will be excluded if their primary carer does not speak English.

4.2. Sampling Strategy

We aim to interview 500 people overall: 300 people from Leicestershire; 100 people from Lambeth; and 100 people from Sheffield. For Leicestershire, a response rate of 60% will be assumed. For Lambeth and Sheffield, a lower response rate of 50% (see section 4.3) will be assumed. However, it may also be necessary to study people in other areas of England.

In each area, 50% of the sample will be chosen from communal care establishments (e.g. residential homes, NHS accommodation, nursing homes) and 50% from the community (independent, family, supported living; each of which would come within a definition of a private household for the purposes of the APMS sampling method). This will maximise the potential for generating comparisons across the two groups, and ensures that the prevalence estimates for these two main groups are measured with
broadly equal precision. Based on the Leicestershire distribution, we believe this will not lead to an overall sample that is completely unrepresentative (around 39% of those eligible to be in the sample on the Leicestershire Learning Disability register live in communal care establishments).

**Sampling from Communal Care Establishments**

In order to keep interview costs down, the selection of participants from communal care establishments will be carried out in two stages: the first stage will involve randomly selecting around 122 communal care establishments with 4 or more residents; and the second stage will involve selecting participants from each of the chosen communal care establishments. The exact number will be confirmed once we have established the number and size distribution of the establishments for each of the registers.

The benefit of using this two-stage approach is that it reduces the number of establishment managers who need to be involved in this study. The clustering of the sample will increase standard errors to a degree, although it is difficult to estimate by how much in the planning stage. The establishment will be selected with probability proportional to the number of residents in each. Selection of residents within communal care establishments will be stratified by gender.

For practical and cost reasons, communal care establishments with fewer than 4 residents with learning disability will be excluded (as this avoids having to recruit establishments to the study for which very few assessments can be done). Approximately 18% of residents with learning disability will be excluded from this part of the study (i.e. will have zero probability of selection), which we consider to be a tolerably low exclusion rate.

**Leicestershire (Communal care establishments)**

To achieve a sample of 150 participants from communal care establishments in Leicestershire, we expect to need to sample 62 communal care establishments of which we expect around 45 to agree to take part. Within each of these, a stratified random sample of 4 residents will be asked to take part in the study (see table).

The sampling procedure for communal care establishments in Leicestershire involves listing communal care establishments and number of residents within each communal
care establishment, sorting by broad type of accommodation (to give stratification on this criterion), and then sorting by the number of residents (to give stratification by size). A total number of 62 communal care establishments will be selected from Leicestershire, with probability proportional to size. The number of residents within each communal care establishments will be sorted by sex and age and a random sample of 4 will be selected.

*Lambeth and Sheffield (Communal Care Establishments)*

For each of the two areas we will select around 25 communal care establishments of which we expect 17 to agree to take part. Within each of these, a stratified sample of 4 residents will be asked to take part in the study.

We assume that Lambeth and Sheffield will agree to provide ID number, age, sex and broad residential type (with a unique code for place of residence so that people living in the same residential home can be identified) to allow two-stage sampling to be carried out in-house.

The sampling procedure for communal care establishments involves listing communal care establishments, sorting by public/private status, and then sorting by the number of residents. A total of 25 communal care establishments will be selected from Lambeth and Sheffield, with probability proportional to size, in the same way as for Leicestershire.

*Sampling from the Community*

Adults from the community are eligible to take part in the study if they were not able to take part in the earlier APMS study. In the APMS study, the interviewer made this judgement when they visited the person and their carer in their own home. Communication is a two way process, and people are more likely to understand the purpose of research, and, what is being asked of them, if discussion and careful explanation is during a face-to-face meeting in a relaxed, familiar environment. We will use a two stage process in this study. Due to time restrictions, interviewers will be asked to make an initial judgement over the telephone, by talking to the potential participant (where possible). The interviewer will explain that the phone call is to see how many people the study is suitable for, and if the study is the right study to invite the person to take part in. She/he will discuss the information sheet and consent form. She/he will then ask a checklist of questions to check that the participant understands the research project, that it is voluntary and ask the participants what questions they have *(Appendix*
1.2). If the participant is clearly able to demonstrate that they understand the study, they will be thanked for their time, and it explained to them, in a positive manner that they were so good at answering the questions, that the rest of the study questions are the wrong ones for them. They will be excluded from the home visit and further assessments.

Any potential participant who did not fully manage to answer the questions will be visited at home (unless they or their carer indicate they do not wish to have further contact), and the assessment of whether they would have been able to take part in the APMS will be repeated. It is likely that some individuals will be more able in the familiar home setting, and with the non-verbal communications in the interview setting that were not seen or interpreted during the telephone conversation. These participants will also be excluded, again in a positive manner, and with explicit gratitude for their time given.

We consider it exceptionally unlikely that a person appears able to have taken part in the original APMS when assessed over the telephone, but does not during an interview in their own home, so this method will mirror the exclusion/inclusion criteria in the APMS, whilst reducing the resource required. We will keep clear records of the numbers excluded at each stage and the reasons why. Of the adults on the Leicestershire learning disability register who live in private households, 25% have mild learning disabilities; the majority of whom we anticipate will be excluded by this process as they would have been able to have taken part in the APMS survey.

**Leicestershire (Community)**

As we expect 25% of participants in the community to be ineligible to take part in this study, the target number of people screened will need to be increased by $1.33 = 25\%$ to 200 (i.e. $0.75n = 150$). The issued sample size will be 333 which allows for a 60% response rate (i.e. $0.6n = 200$).

All people on the Leicestershire Learning Disability Register who are living in the community will be sorted by living status (e.g. independent, family etc.), sex and age (to give stratification on these three factors), and a systematic random sample will be drawn from the sorted data. In Leicestershire there are approximately 2000 people living in the community, which will mean sampling every 7-8th person from the sorted data (with a random start).
**Lambeth and Sheffield (Community)**

To identify 50 eligible people with learning disability living in the community at each of the sites in Lambeth and Sheffield, we will need to sample 33% more participants. The target sample size for screening is thus 66.7 (i.e. 0.8n = 50). Assuming a response rate of 50% for both Lambeth and Sheffield, the issued sample size will be 133 per area (i.e. 0.5n = 62.5).

All people who are living in the community on the register will be selected and sorted by living status (e.g. independent, family etc.), sex and age, and a systematic random sample taken from the sorted data.

**Table: Summary of Sampling Strategy**

<table>
<thead>
<tr>
<th>Community Care Establishments</th>
<th>Target Individuals</th>
<th>Approach Establishments</th>
<th>Take part establishments</th>
<th>X4 individuals</th>
<th>Take part</th>
<th>Net response rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leicestershire</td>
<td>150</td>
<td>62</td>
<td>45 (73%)</td>
<td>180</td>
<td>150 (83%)</td>
<td>60.5%</td>
</tr>
<tr>
<td>Lambeth</td>
<td>50</td>
<td>25</td>
<td>17 (68%)</td>
<td>68</td>
<td>50 (74%)</td>
<td>50%</td>
</tr>
<tr>
<td>Sheffield</td>
<td>50</td>
<td>25</td>
<td>17 (68%)</td>
<td>68</td>
<td>50 (74%)</td>
<td>50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Community Sample</th>
<th>Target Individuals</th>
<th>Select</th>
<th>Ineligible</th>
<th>Eligible</th>
<th>Take part</th>
<th>Net response rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leicestershire</td>
<td>150</td>
<td>333</td>
<td>83 (25%)</td>
<td>250</td>
<td>150</td>
<td>60%</td>
</tr>
<tr>
<td>Lambeth</td>
<td>50</td>
<td>133</td>
<td>33 (25%)</td>
<td>100</td>
<td>50</td>
<td>50%</td>
</tr>
<tr>
<td>Sheffield</td>
<td>50</td>
<td>133</td>
<td>33 (25%)</td>
<td>100</td>
<td>50</td>
<td>50%</td>
</tr>
</tbody>
</table>

**4.3. Initial contact with participants**

**Community Settings**

Adults and their primary carers living in community settings will be obtained from the relevant case registers. For Leicestershire, ethical approval for this study has already been obtained. The ethics committee has approved an opt-out procedure, whereby the Medical Director will send a letter (Appendix 2.1), and information leaflet about the study (including an easy read version) (Appendix 3.1 and 3.2) to adults on the register and their primary carers if appropriate (identified on the Leicestershire Learning Disability Register). Participants will be asked to contact the research team if they do not wish to participate in the survey. Interviewers will then contact the participant to assess their eligibility (Appendix 1.1) and to organise a time that is convenient for them (the participant will have opportunity to opt out again at this stage).
For the Lambeth and Sheffield registers, an opt-in procedure will be adopted. Staff working on the relevant registers will send out a letter to adults on the register and their carers (Appendix 4.1), an invitation letter from the research team (Appendix 5) and information leaflet about the study (including an easy read version) (Appendix 6.1 and 6.2). Respondents will be asked to contact the research team if they would like to participate in the survey or need further information, whereby they will be assessed for eligibility (Appendix 7.1). Those that do not respond will be followed up by a telephone call by register staff at each site.

We do not anticipate that the differing procedures will result in differing characteristics of participants, as the decision to participate will largely be made by the carers. Hence, carer characteristics may conceivably differ, rather than that of the participants.

Communal Care Establishments
Adults in communal care establishments will be obtained from the relevant case registers. As previously mentioned, an opt-out procedure has been approved for Leicestershire. The Medical Director will send a letter (Appendix 2.2), and information leaflet about the study (including an easy read version) (Appendix 3.1 and 3.2) to Managers at the communal care establishments, naming the participants that have been selected to take part. Managers will be asked to contact the research team if they do not wish to participate in the survey. Interviewers will then contact the Manager by telephone and will identify the key workers who will participate in the interviews (Appendix 1.2), resending information leaflets where appropriate, and will organise a time to carry out interviews.

For the Lambeth and Sheffield registers, an opt-in procedure will be adopted. Staff working on the relevant registers will send out a letter to Managers of the communal care establishments (Appendix 4.2), an invitation letter from the research team (Appendix 5) and information leaflet about the study (including an easy read version) (Appendix 6.1 and 6.2). Managers will be asked to contact the research team if they would like to participate in the survey or need further information whereby contact details will be obtained (Appendix 7.2). Those that do not respond will be followed up by a telephone call by register staff at each site.
We do not anticipate that the differing procedures will result in differing characteristics of participants, as the decision to participate will largely be made by the carers. Hence, carer characteristics may conceivably differ, rather than that of the participants.

4.4. Interviews

Adults with learning disabilities and their primary carers (informal carers who look after the participant most of the time or paid carers who know the participant well) who have agreed to be interviewed will be contacted by the research team and a home interview will be arranged at a time that it convenient for them. The participant and carer have another opportunity to opt out at this stage. People with learning disabilities will be present throughout the interview and we find that the carer sometimes supports the selected participant to complete assessments.

Consent will be sought from both carer and from the participant up to the limits of his/her capacity to consent prior to conducting the interviews (Appendices 3.1, 3.2, 6.2, 6.3, 6.4). Participants and carers will have the opportunity to read through the information leaflets again and discuss the study with the interviewer, and it will be made clear that the participant/carer does not have to answer any questions that they do not want to. Specially designed easy-read information leaflets developed in conjunction with the “Brightlights” self-advocacy group in Leicester, will be available at the interview.

At interview, a maximum of two diagnostic tools for ASD (ADOS and DISCO Module 1 – see below) will be administered along with demographic details, key questions identified from the initial household survey relevant to this client group and the Vineland Adaptive Behaviour Scale survey form 28 to formally assess ability level. Participants will be asked if they would like their GP to be informed that they are in the study whereby a letter will be sent accordingly (Appendix 8.1 and 8.2). Interviews will last approximately 3-4 hours and 5 interviewers will be trained and employed for this specific purpose.

The interviews will take about 90 minutes. We aim to minimise respondent burden by taking regular breaks where needed and conducting the interview wherever is comfortable for the respondent. Where possible we aim to interview participants on the same day, but in some cases the interview may need to be completed on another day if the participant/carer becomes tired or distressed. Interviewers will be trained to identify when respondents are becoming tired or distressed, and to provide support for individuals where necessary after the interviews.
Screening Tools and Clinical Assessments

The success of this study relies on the same clinical assessments being used in the learning disability population as were used in the general household population reported in 2007. The clinical assessments used in the general household survey were:

i. **Autism-Spectrum Quotient (AQ-20)**
   The AQ-20, a shortened version of the AQ-50, is a screening tool and was used in the APMS household survey to identify potential underlying autistic traits. Those adults that scored ≥ 5 on the AQ-20 were interviewed with the additional instruments.

ii. **Autism Diagnostic Observation Schedule Module 1 and 4 (ADOS-1 and ADOS-4)**
   The ADOS is a semi-structured clinical assessment of whether the respondent demonstrates current behaviour consistent with a diagnosis of autistic disorder. The ADOS assessment consists of a series of rated tasks that evaluate communication, social functioning, creativity, imagination, stereotyped interests and restricted interests. Module 1 will be used as this is adapted for and has been used with respondents who are pre-verbal or who use single words only (i.e. non verbal). Our team have experience with training and use of Module 1 in adults. In some rare cases where participants have sufficient verbal ability, the ADOS-4 will be used.

iii. **Diagnostic Interview for Social and Communication Disorders (DISCO)**
   The DISCO is a semi-structured clinical assessment for informants and is designed to draw out a picture of the whole child or adult through the story of their development and behaviour from infancy onwards. However, the DISCO also includes an extensive assessment of current functioning that collects information required for diagnosing ASC. Thus it can generate ASC diagnoses in the absence of information on childhood development.

iv. **Autism Diagnostic Interview-Revised (ADI-R)**
   The ADI-R is a semi-structured clinical assessment for informants who know the person well. It focuses on quality of social interaction, communication and language and repetitive, restricted and stereotyped interests and behaviour. This information is gathered for when the individual was aged four to five and currently; therefore it can only be rated for early development where such information is available.
The present study will not include the screening stage with AQ-20 used in the APMS survey because many people with learning disabilities would be unable to complete the self-report questions. In the present study, therefore, adults will be assessed using the ADOS-1, and in very rare cases, ADOS-4. The recommended ADOS Module 1 threshold of 12 or more will be applied to indicate a case of ASC (Autism). A random sample of 30 individuals who score high in the ADOS and 30 who do not (n=60 in total) will also be interviewed via the appropriate carer with the DISCO (and also coded on the ADI-R if the information is available) to calibrate results from the ADOS-1. We will use these data to check that the recommended ADOS-1 threshold of 12 or more is equivalent to 10 or more threshold used in the APMS with Module 4.

**Other Measures**

1. **Basic demographic information**
   Basic anonymised demographic information (age, sex, place of residence and ethnicity) will be collected from the case registers (via their unique ID number) prior to contacting the individuals. If the participant agrees to participate in the study, this information will be linked to their responses at interview. Information on participants who do not respond or who refuse to take part in the study will be retained to assess whether characteristics of responders and non-responders differ.

2. **Questions from APMS survey**
   Where possible and appropriate, the same measures and definitions of personal characteristics will be collected as were used in the APMS household survey. These includes household details, socio-demographic details, personal characteristics, general health and well-being, activities of daily living, health conditions, service use and stressful life events. A few questions have been added for this client group (e.g. on the presence of chronic health and genetic conditions) – see Appendix 9.1 and 9.2. Where participants are not able to do so, carers will be asked questions about the participant.

3. **Vineland II Survey Interview/Caregiver rating form**
   The Vineland II caregiver rating form \(^{28}\) will be used to assess the severity of the participant’s learning disability. The scales of Vineland II are organised within a three domain structure: communication, daily living and socialisation, and an estimate of developmental age can be derived from scores achieved in the scales. The carer will be given the opportunity to complete the form before or during the interviews.

4.5. **Data Management**
The University of Leicester is registered with the Office of the Information Commissioner (Reg No: Z6551415), is fully aware of, and is compliant with, the obligations imposed on it by both the Data Protection Act, 1998, and the Freedom of Information Act, 2000.

Data entry
Questionnaires will be identified using a unique ID number only and will not contain any names or addresses. Information from the questionnaires will be entered onto a database at the Leicester Trials Support Unit. To increase accuracy, double data entry will be used. Data entry staff at the Trial Support Unit are already skilled in data entry procedures.

Data checking and cleaning
Internal consistency checks will be carried out on all data throughout the study. The initial data output will be tested for integrity to ensure that the database has the right number of cases and that each case has appropriate values for appropriate items, and the data will be scrutinised for face validity by running frequencies and key cross tabulations. Validation will be carried out by both the clinical trials unit and the statistician.

4.6. Consent

Consent Procedure

This study involves a vulnerable population. We have taken additional steps to determine the participant’s capacity to give informed consent and will adhere to English capacity legislation throughout. Informed consent involves providing people with sufficient information to make a reasoned decision about whether to take part in the survey. They must know what will be involved, what any consequences to them personally (either positive or negative) might be, and thus be in a position to decide whether or not to participate.

Our interviewers will be health professionals or graduates with relevant clinical experience who will be given additional training (over one month) for the study in learning disability psychiatric clinical settings. Under the Mental Capacity Act, they will be capable of making a judgement about the participant’s capacity to give consent. Senior clinically qualified members of the research team will be available to provide a second opinion in cases of doubt.
We aim to maximise response in order to ensure that the generalisability of the results will be valid. Our interviewers will undergo full training in Good Clinical Practice. Agreement to participate will be obtained based on a clear understanding of what will be involved so interviewers will be trained to provide such information and answer any questions or concerns. Even when initial agreement is given, respondents can (and do) refuse to answer certain questions or choose to terminate the interview before the end. These decisions will be respected.

Consent will be sought from both adult with learning disability up to the limit of her/his capacity to consent (e.g. the altruistic nature of research is a complex concept to comprehend, but the person might understand other aspects of the study), and their carer prior to conducting the interviews. Adults with full decision-making capacity to consent to participate are ineligible for the study, as outlined above. However, in many cases, participants will be able to give some indication of whether they would be willing to take part in the study (e.g. by giving a nod or shake of the head).

Where participants are unable to give any indication of whether they would like to take part in the study (for example, where they have profound learning disabilities), steps will be taken to identify a “personal consultee” or “nominated consultee” in accordance with the Mental Capacity Act (2005) and Department of Health guidance (2008).  

In private households, the vast majority of care is provided on an informal basis, usually by a family member. Where participants are unable to indicate whether they would like to take part in the study, the main informal carer, such as a parent or sibling, will be asked to act as “personal consultee” for this research. Their greater knowledge of the participant will enable them to advise the researcher about whether the person should take part in this research, having considered whether they would be happy to be assessed and whether the assessment might upset them. Where the identification of a “personal consultee” is not clear in a private household, such as for participants in supported living accommodation, the same steps will be taken to identify a personal or nominated consultee as for communal care establishments (see below).

In communal care establishments and where participants are unable to indicate whether they would like to take part in the study, the manager or key worker will be asked whether the person has any close relatives or other unpaid close person involved in their care and interested in their welfare. If so, we will consult with them and ask them to sign
to this effect (Appendix 6.4). In some cases there will not be an appropriate “personal consultee”, for example where there are no close relatives or family members have been out of contact with the participant for a number of years and the regular carers are care home staff. The key worker of the participant will then act as a “nominated consultee” on the basis that they have no connection with the project and are willing to be consulted about the participation of the person.

Information leaflets and specially designed easy read versions (developed in conjunction with specialist speech and language therapists in Leicestershire, representatives from MenCap, Leicester City self-advocacy group, “Brightlights”, and Leicestershire carer group) will be provided. The carer, personal or nominated consultee (where different), and adults with learning disabilities, if possible and appropriate, will be asked to tick a box and specify that they have read the leaflets, understand the study, and have been given the opportunity to ask questions.

Confidentiality and Data Protection
The University of Leicester is compliant with the Data Protection Act, 1998, and the Freedom of Information Act, 2000. During the study, seven interviewers will carry out the assessments in Leicestershire, Lambeth and Sheffield. It will not be feasible to return the completed consent forms to the research offices (Leicester General Hospital) on a daily basis. Thus all interviewers have been provided with a lockable metal box to hold A4 files. They will be asked to keep consent forms and questionnaires locked in this box in a secure place within their homes. Consent forms and questionnaires will be handed to the Project Manager (JS) at the research offices on a fortnightly basis.

Consent forms will be kept in a secure locked cupboard in a secure room within the research offices (Leicester General Hospital). Questionnaires will be identified by a unique ID number only and will be held at the Leicester Trials Support Unit in a separate location. All questionnaires will be scanned by the Leicester Trials Support Unit and archived.

Only interviewers and the selected members of the research team will know the identity of the participants, which will be held on a secure password-protected database, separate from the survey database. This study involves no interventions and results will be presented at a population level.
5. COSTS

5.1. Direct Costs

◆ Survey field work costs (5 research associates, clerical support)
◆ One part-time Statistician for 1 year (1 day per week)

5.2. Indirect Costs

◆ Professor Terry Brugha (0.1 FTE)
◆ Professor Howard Meltzer (0.08 FTE)
◆ Jane Smith (1.0 FTE)
◆ Freya Tyrer (0.4 FTE)
◆ Dr Fiona Scott (training in DISCO and ADI-R and advice on ASC)
◆ Professor Sally-Ann Cooper (consultancy advice on learning disability registers and ASC)
◆ Ms Sally McManus (general APMS advice and advice on sampling)
◆ Dr Susan Purdon (advice on sampling)
◆ Dr Reza Kiani (training in DISCO and ADI-R and advice on ASC)
◆ Mr Richard Mills (links with user and carer populations and advice on ASC in prisons)

5.3. Other Costs

Database
◆ Setting up of database and data entry (Leicester Trials Support Unit)

Consumables
◆ Interview materials

Other costs
◆ Travel costs for interviewers and accommodation
◆ Travel costs for meetings (NHS IC in London and Leeds, local co-ordination and management meetings)
◆ Entertainment + Hospitality
◆ Conference costs
6. STATISTICAL METHODS

6.1. Estimating overall ASC prevalence

The overall estimate of ASC prevalence will be derived as the weighted sum of four individual prevalence rates: the rate for adults in private households without learning disability (p1); the rate for adults in private households with learning disability (p2); the rate for adults in communal care establishments without learning disability (p3); and the rate for adults in communal establishments with learning disability (p4).

The weights per rate are the estimated population size per group (N1, N2, N3, and N4 respectively). That is:

\[
\text{Overall prevalence} = \frac{(N1 \times p1) + (N2 \times p2) + (N3 \times p3) + (N4 \times p4)}{(N1 + N2 + N3 + N4)}
\]

The source of the various statistics for this prevalence estimate are outlined below and then discussed in more detail.

N1 = count of private household population of adults without learning disability
(source: ONS population statistics for private households minus N2)
N2 = count of private household population of adults with learning disability
(source: estimated from case registers)
N3 = count of adults in communal care establishments without learning disability
(source: ONS population statistics for communal care establishments minus N4)
N4 = count of adults in communal care establishments with learning disability
(source: estimated from case registers)
P1 = proportion of adults in private households without learning disability with ASC
(source: APMS)
P2 = proportion of adults in private households with learning disability with ASC
(source: study findings)
P3 = proportion of adults in communal care establishments without learning disability with ASC
(source: estimated from APMS, assuming similar rates to those in private households after accounting for age-sex differences, but with sensitivity analyses bringing in other sources included)
P4 = proportion of adults in communal care establishments with learning disability with ASC
(source: study findings)
Estimating the communal care establishments population with and without learning disabilities (N3 and N4)

The overall size and age-sex structure of the population in communal care establishments will be estimated using ONS published statistics (based on the 2001 census). The national percentage of those with learning disability will be based on estimates of this percentage in Leicester, Lambeth and Sheffield.

Estimating the private household population with and without learning disabilities (N1 and N2)

ONS statistics will be used as the sources of an overall estimate of the private household population of England. The numbers within this population with learning disability will be estimated from the Leicestershire, Lambeth and Sheffield registers.

6.2. Precision of ASC prevalence estimate

Analyses will be carried out using SPSS 16.0 and Stata 11.0. In the private household sample, homogeneity of proportions by sex will be investigated using the chi-squared test.

In the sample from communal care establishments, the “svy” proportion statement in Stata 11.0 will be used to calculate estimates and confidence intervals, using Taylor linearization to adjust for the effects of clustering by communal care establishment and stratification by sex. Homogeneity of proportions by sex will be investigated using the chi-squared test corrected for survey design.

Combined prevalence estimates from the three surveyed populations (private household without learning disabilities, private household with learning disabilities and communal care establishment with learning disabilities) will be calculated by treating the surveys as strata from a single population and calculating post-stratification estimates in Stata 11.0. The likely precision of estimates that include the non-surveyed group (those in communal care establishments without learning disability) will be assessed via a sensitivity analysis (see below).

6.3. Sensitivity analysis
The main source of our estimate for the prevalence of ASC in the communal care establishment sample without learning disability will be the APMS (after allowing for age-sex differences in the two populations). As a means of testing the sensitivity of this estimate to our necessarily crude assumption (that prevalence rates do not differ across type of residence) additional information will be incorporated where possible. This will include data from the ONS Survey of Psychiatric Morbidity among Prisoners in England and Wales, 1997.

Similarly, we will test the sensitivity of the overall prevalence estimates to our assumptions about the percentages of people in the community and in communal care establishments with a learning disability.
KEY REFERENCES


30. **DH Scientific Development and Bioethics Division (2008)** Guidance on nominating a consultee for research involving adults who lack capacity to consent: issued by the Secretary of State and the Welsh Ministers in accordance with section 32(3) of the Mental Capacity Act 2005. *Department of Health, London*

31. **Statacorp (2009)** *Stata Statistical Software: Release 11.* College Station, TX: Statacorp, LP