



# The BPSU Study Application Handbook

A guide to gaining approval for your study from the  
BPSU.

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# **BPSU Study Handbook: Part A – Applying to the BPSU**

## **Overview**

This document provides a step-by-step guide to getting approval for your study from the BPSU, Executive Committee (BPSU EC), the multi-centre research ethics committee (REC), the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB) and your local NHS Trust Research and Development (R&D) Department.

This guide includes a list of key contacts, abbreviations and a flowchart of the application process. Additional helpful documents which may be found on the BPSU website [www.bpsu.inopsu.com](http://www.bpsu.inopsu.com) are also referenced in this document.

## **Key contacts**

### *BPSU Office*

Mr Richard Lynn, Scientific Coordinator

Tel: (020) 7092 6173                      Email: [bpsu@rcpch.ac.uk](mailto:bpsu@rcpch.ac.uk)

Ms Helen Friend, Research Facilitator

Tel: (020) 7092 6174                      Email: [bpsu@rcpch.ac.uk](mailto:bpsu@rcpch.ac.uk)

### *BPSU Medical Advisers*

Dr Rachel Knowles, Medical Adviser (non-communicable disease)

Tel: (020) 7905 2278                      Email: [r.knowles@ich.ucl.ac.uk](mailto:r.knowles@ich.ucl.ac.uk)

Dr Colin Campbell, Medical Adviser (communicable disease)

Tel: (020) 8327 7199                      Email: [Colin.Campbell@hpa.org.uk](mailto:Colin.Campbell@hpa.org.uk)

### *BPSU Chair*

Professor Alan Emond, Chair of the BPSU Executive Committee

Email: [alan.emond@Bristol.ac.uk](mailto:alan.emond@Bristol.ac.uk)

The Scientific Co-ordinator and Research Facilitator are the first point of contact for general enquiries, including operational and process matters, meeting dates and press releases. Initial enquiries about undertaking a BPSU study should be directed to the BPSU Office.

For advice on development of an application, such as details of surveillance methodology, ethics or questionnaires, contact should be made with the relevant medical adviser (for communicable or non-communicable diseases). Contact details for medical advisers can be provided by the Scientific Co-ordinator or Research Facilitator. Medical advisers correspond with applicants and convey the views of the committee regarding research proposals.

The Chair of the BPSU Executive Committee (EC) may be contacted directly, however this would not usually be necessary during the course of a normal application procedure.

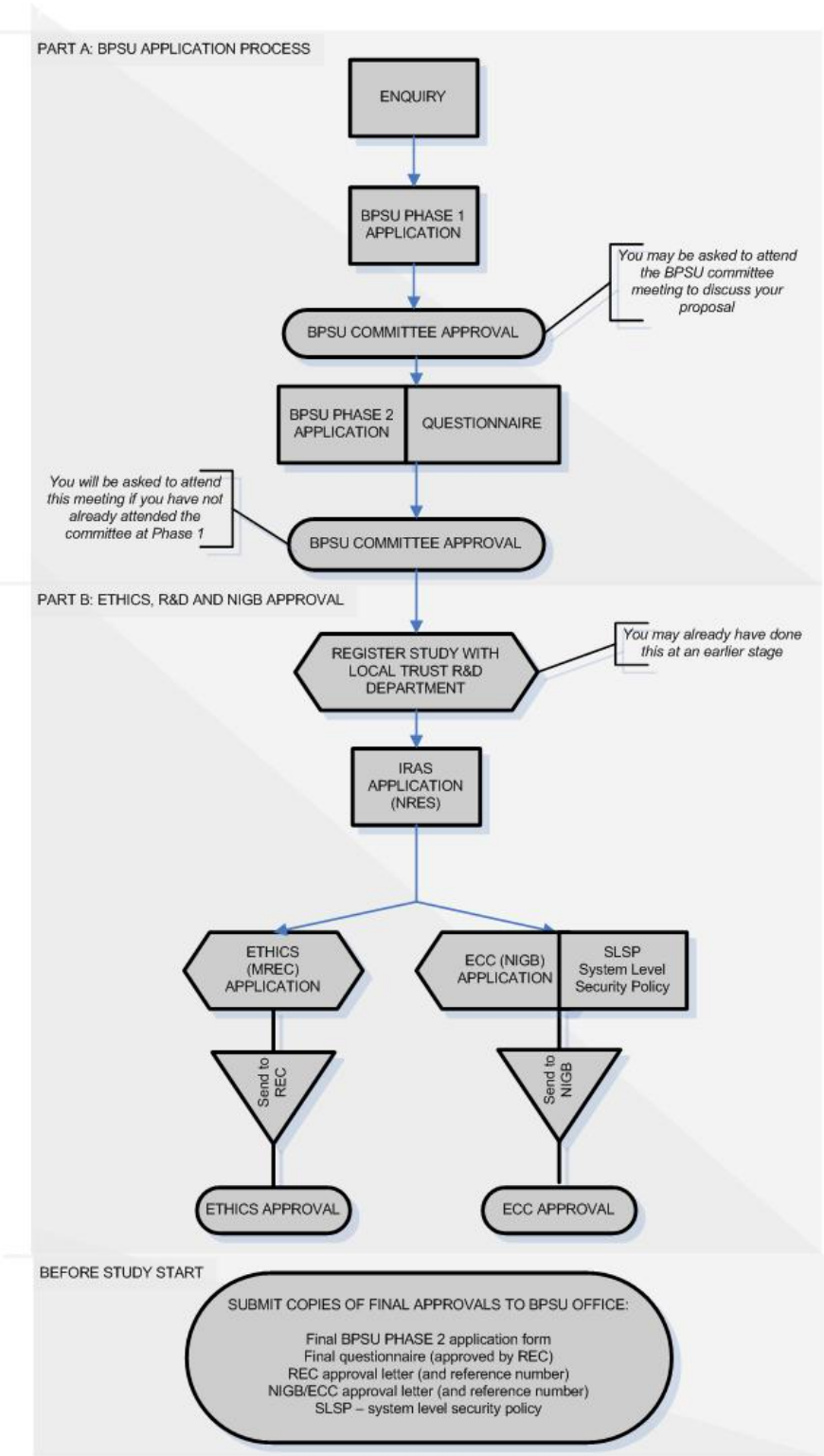
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### Abbreviations

<b>BPSU EC</b>	British Paediatric Surveillance Unit Executive Committee
<b>(M)REC</b>	(Multi-centre) Research Ethics Committee
<b>NRES</b>	National Research Ethics Service
<b>NPSA</b>	National Patient Safety Agency
<b>MRC</b>	Medical Research Council
<b>NIGB</b>	National Information Governance Board
<b>ECC</b>	Ethics and Confidentiality Committee (of the NIGB)
<b>PIAG</b>	Patient Information Advisory Board (now disbanded)
<b>Section 60</b>	Health and Social Care Act 2001 provision for unconsented data use
<b>Section 251</b>	NHS Act 2006 provision for unconsented data use (superseding Section 60)
<b>R&amp;D</b>	Research and Development (Department within NHS Trusts)
<b>NHS</b>	National Health Service
<b>IRAS</b>	Integrated Research Application System
<b>PAC</b>	Privacy Advisory Committee (Scotland only: advises ISD Scotland on data release) <i>PAC being established in Northern Ireland</i>

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## Flowchart of the Application Process



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## **Part A - Applying to the BPSU**

## **BPSU Study Handbook: Part A – Applying to the BPSU**

### **Section 1: Introduction - Making an enquiry to the BPSU**

#### **Introduction**

Applications for inclusion of a study on reporting cards are considered by the BPSU Executive Committee (BPSU EC), which meets every two months. As the success of the BPSU methodology relies entirely on willingness of consultant paediatricians to complete and return the monthly Orange Card and study questionnaires, it is essential that BPSU studies are scientifically robust, adequately resourced and contribute to clinical and public health practice without putting too great a burden on reporting doctors. The application process has been developed to reflect these responsibilities. However the BPSU is also committed to assisting potential investigators (especially those less experienced in research methodology) with advice from the medical advisers.

There is a two-stage application procedure. Phase 1 (P1) is an outline application to establish if the study meets the BPSU criteria. Applications should be submitted on the P1 application form. If the study is approved by the BPSU EC, a more detailed Phase 2 (P2) application will be invited. Sometimes, applicants are invited to attend a BPSU EC meeting to discuss a revised P1 application if a decision cannot be made on the basis of the P1 documentation.

For P2 applications there is a longer application form, which should be completed and accompanied by any letters and questionnaires that are to be used in the study. An applicant is invited to attend the BPSU EC meeting to discuss their proposal and any queries that have arisen.

Unfortunately some applications will be unsuccessful, however good the research idea may be. Applications are most often turned down because the BPSU EC considers that the study is not suited to BPSU surveillance methodology.

#### **Important considerations before applying**

- Make sure your study meets the BPSU eligibility criteria (see next section). Please discuss your application with a Medical Adviser or the Scientific Coordinator beforehand if these are unclear.
- Study aims must be appropriate for national surveillance methodology, for example studies to establish incidence of a rare disorder or investigate variations in management
- It takes several months to complete the application process as revisions to the methodology and questionnaires are often required. Please make an enquiry directly to the Scientific Coordinator if you consider your study should be considered more urgently.
- Applications should reach the BPSU office four weeks prior to the BPSU EC meeting to allow Medical Advisers to comment on the application and revisions to be made prior to committee papers being sent out. You may choose not to ask Medical Advisers to review the application but this may result in the need for resubmission of a revised Phase 1 application. Deadlines for forthcoming meetings are available from the BPSU Office or on the BPSU website.

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- The study surveillance period is usually 13 months though this can be extended if it is felt that additional case ascertainment is required to allow for meaningful analysis.
- There is an administrative charge for undertaking a study through the BPSU and applicants should have appropriate funding in place by the time the study commences. The charge is currently £300 per month. The initial 13 month payment of £3,900 is required advance plus the cost of the protocol card production (approximately £500). Further details of these costs can be obtained from the BPSU Office.

### **Enquiring about undertaking a BPSU study**

An enquiry about undertaking a study through the BPSU can be made by telephone, e-mail or in person to the BPSU office (Mr Richard Lynn, Scientific Coordinator, or Ms Helen Friend, Research Facilitator).

Any interest in a particular topic is recorded by the BPSU alongside the enquirer's name and contact details. The earliest enquiry about a specific topic is given precedence. If after 12 months, an enquiry has not been followed up by a Phase 1 application, then the BPSU Office would contact you to discuss removing your name from the enquiry list and to give you an opportunity to make a formal application before any action is taken.

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### **Section 2: The BPSU Phase 1 Application**

#### **Eligibility Criteria**

Studies considered eligible to be undertaken through the BPSU are those where:

- The condition is a relatively rare childhood disorder or a rare complication of a more common disease of such low incidence or prevalence as to require ascertainment of cases on a national scale in order to generate sufficient numbers for study. In practice, the condition studied should have an expected incidence in the UK of *no more than 300 cases per year*
- The majority of cases are seen by a general paediatrician
- Cases can be easily identified and defined using a clear case definition
- Study data is easily accessible from the normal clinical notes
- Ethics approval is sought
- Approval to collect unconsented identifiable data is sought from the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB).

Examples of studies which would not be eligible for study through the BPSU are those which:

- are interventional studies
- require controls
- intend to use the case cohort to establish a disease register
- require direct patient/parent consent
- can be undertaken through a regional study
- can be undertaken through a study involving specialist clinicians only
- do not intend to seek ethical approval
- require long term follow up (greater than 2 years)
- require retrospective reporting
- involve any additional clinical intervention for reported cases (other than the results of diagnostic tests on samples collected during routine clinical management).

#### **Outcomes from a Phase 1 application**

Following consideration of the P1 application you will be contacted by letter to inform you of the outcome. The following outcomes are possible.

- 1) The P1 may be accepted and a P2 sought with/without specific clarifications
- 2) Further details and a revised P1 application may be sought before a decision is made
- 3) You may be asked to attend and discuss your application with the BPSU EC before a final decision is made
- 4) The application may be rejected.

NB: Acceptance of the P1 does not imply that the P2 will be approved.

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### **Completing the Phase 1 Application Form**

Please read these details carefully before completing your P1 application. Failure to do so could lead to delay or even rejection of the application.

Prospective applicants are advised to submit their application at least twelve months before the proposed starting date.

Please check that you are using the current version of the P1 application form – the number and date of the current version is clearly stated on the BPSU website: <http://www.bpsu.inopsu.com/apply/phase1.html>.

### **Guidance on individual questions in the Phase 1 Application**

#### *1) Title of the study*

Please provide the full title of the study. If you consider the condition to be sensitive, you may wish to omit the condition name from the study title. If and when the study is finally accepted onto the orange card, please be aware that the title which appears on the orange card has a maximum length of 65 characters. You may also wish to provide an abbreviation or acronym in the title is long.

#### *2) Name of the investigators*

Please list all investigators involved in the study, their job title, affiliation, and contribution to this study. Please also indicate clearly the principal contact for correspondence on this application, giving a full contact address, e-mail address and telephone number. Please indicate also the individual who is the designated Principal Investigator – this person will be responsible for research governance. At least one of the study investigators should be a paediatrician receiving the Orange Card.

#### *3) Describe the study*

This should explain a) the condition to be studied, b) a review of the background to the study proposal, including current knowledge about incidence and prevalence, c) the public health and scientific importance of the study, d) the study methodology, and e) the expected benefits of the study. This explanation should be easily understood by a lay person as the BPSU EC includes lay and medical reviewers.

#### *4) Lay summary*

This should be a short, clear summary of the condition and study in terms that can be understood by a lay person. This will be the publicly available summary that is put on the BPSU website if the study is accepted. The lay summary should be no more than 250 words.

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### 5) *Research questions/surveillance objectives*

Give a clear statement of the specific research questions that will be investigated by this study. These usually fall into the categories of 1) estimating incidence/prevalence, 2) describing the clinical features at presentation, 3) describing management and short-term outcomes.

It must be possible to address these questions

- a) Without direct contact with patients
- b) Without seeking investigations that would normally not have been undertaken by the paediatrician
- c) Without a comparison (control) group.

There does not need to be a long list of objectives. Consider how you will ask suitable questions in the questionnaires to gather information to answer your research objectives. Consider if you will have a sufficiently large sample size to address your objectives, for example regional variations in incidence could not usually be addressed by a BPSU study as the sample size would be too small. Please note also that the BPSU surveillance methodology is not suitable for identifying causal relationships, as the frequency of 'risk' factors identified amongst notified cases cannot be compared with the frequency of these factors in unaffected 'control' children.

### 6) *Case definition*

Give a clear case definition for the condition of interest. The **surveillance case definition** is a case definition which may be wider than the analytic case definition in order to ensure cases are not missed. For example, the surveillance case definition will often include suspected cases where confirmation is awaited. The **analytic case definition** describes very carefully those children who will be included in the study, i.e. will become your 'confirmed cases' for further analysis. Examples of case definitions used in previous studies are provided in Appendix 2.

In most studies, the age range for cases will include ages from birth up to but not including 16 years. Please consider if children in the upper age range will be seen by paediatricians for this condition.

### 7) *Expected numbers*

Please supply an estimate of the number of cases expected each year, i.e. yearly incidence rate, indicate the sources that you have used to estimate this. More than 300 cases per year (or 30 per month) would normally be considered too high for the BPSU due to the monthly volume of notifications and the fact that regional studies may be sufficient. Please note that there are often duplicate reports so that the number of cases reported might be considerably higher than the number of true cases included in the analysis.

Indicate the source of denominator data for calculating incidence. This is often a routine data source, such as the Office for National Statistics mid-year population estimates or birth statistics ([www.statistics.gov.uk/](http://www.statistics.gov.uk/)). In Northern Ireland ([www.nisra.gov.uk/](http://www.nisra.gov.uk/)), the republic of Ireland ([www.cso.ie/](http://www.cso.ie/)) and Scotland ([www.isdscotland.org/](http://www.isdscotland.org/)), other bodies collate these statistics.

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### *8) Alternative sources of reporting*

Are there other clinicians besides paediatricians who are likely to see cases? If so, it is essential to consider whether to involve these clinical specialists in case reporting as this improves ascertainment and reduces bias. Please list any additional sources of case reporting that you are currently considering. Further details of these will be required in a P2 application.

### *9) Proposed level and nature of public involvement*

You will be expected to engage with public or patient organisations relevant to your study as early as possible. Please give this consideration and state which organisations you would be likely to approach and how you would plan to engage with them. You may also ask for advice from the BPSU Office or EC.

### *10) Proposed territorial coverage?*

The Orange Card is sent to paediatricians in England, Wales, Scotland, Northern Ireland and Ireland. If you wish to exclude any of these countries, then you must state this and provide justification for this. This will only be permitted in exceptional circumstances, for example when the Irish Paediatric Surveillance Unit is already conducting a similar study.

### *11) Funding, personnel and resource arrangements*

Please confirm that you are arranging funds to undertake the study, even if these are not yet confirmed. Please name any bodies to which a grant application has been submitted or for whom one is being prepared. If funding is already in place, please state whether this is from a commercial source or whether you are personally in receipt of funds to undertake the research. If funding is from a commercial source, you may be expected to demonstrate, for example through a contract with the funders, that this will not influence the reporting of results.

### *12) References*

A short list of any references relevant to the application should be included. If possible, attach copies of any papers which are not likely to be electronically available to the medical advisers.

### **Covering letter**

Please attach a signed covering letter from the main contact/principal investigator for the study.

### **Supporting letters**

Please attach any letters of support that you consider relevant for the committee to consider, for example award letters from funding bodies or letters confirming support by collaborating partners.

### **Signature**

An electronic version of the application can be submitted directly to the BPSU Office at [bpsu@rcpch.ac.uk](mailto:bpsu@rcpch.ac.uk) at least 2 weeks before the BPSU EC meeting. A signed paper copy must also be sent to the BPSU office.

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### **Section 3: The BPSU Phase 2 Application**

#### **The Phase 2 application**

This section gives detailed guidance on how to complete Phase 2 (P2) of the BPSU application process. The BPSU EC will give fair and impartial consideration to the applications. If appropriate, advice from independent referees may be sought. Please note that though your application has moved from a Phase 1, this in no way implies that the study is likely to be accepted at P2. Principal investigators are usually invited to attend a meeting of the BPSU EC to discuss their P2 proposal more fully.

When planning your application submission investigators are asked to take into account the following:

- The criteria for study application to the BPSU (Section 1).
- The process from submission of the P2 to acceptance may take several months. This process can be accelerated for conditions of public health importance which require immediate evaluation.
- Medical adviser must receive applications four weeks before the BPSU EC meeting date if you would like their comments on the application.
- The BPSU office must receive finalised applications which are ready for submission two weeks prior to the BPSU EC meeting, to allow time to circulate documents for review.
- The BPSU EC meets ever two months. Dates are available from the BPSU Office or on the website.
- Please read and follow the guidance for completing the application form as failure to do so can delay or even lead to rejection of the application.
- Timing of inclusion of new studies onto the BPSU card depends on the number and the nature of other studies being surveyed.

#### **Outcomes from a Phase 2 Application**

The BPSU EC meets five times per year to consider applications. The following outcomes are possible:

- 1) P2 may be accepted without revisions or clarifications
- 2) P2 accepted but with several minor points needing to be addressed or clarified
- 3) Further review, or specialist advice, may be sought before a final decision is made
- 4) P2 methodology approved but questionnaire needs amending
- 5) The study is rejected

Rejection of an application indicates simply that it is not a suitable application for the BPSU scheme. The BPSU Committee will give reasons for its decision and offer suggestions on how the study could be undertaken outside of the BPSU scheme.

Following acceptance of the study proposal and questionnaire at P2, ethics and NIGB approval will be required. Please refer to the flowchart of page 4 and to Sections 4-9 for details of these processes. If you have any further queries relating to the BPSU application procedure please do not hesitate to contact the Medical Advisers.

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### **Guidance on specific questions in the Phase 2 Application**

#### *1) Title of the study*

Please provide the full title of the study. If you consider the condition to be sensitive, you may wish to omit the condition name from the study title. If and when the study is finally accepted onto the orange card, please be aware that the title which appears on the orange card has a maximum length of 65 characters. You may also wish to provide an abbreviation or acronym in the title is long.

#### *2) Title to appear on Orange Card*

The character limit is 65 for the Orange Card study title.

#### *3) Name of the investigators*

Please list all investigators involved in the study, their job title, affiliation, and contribution to this study. Please also indicate clearly the principal contact for correspondence on this application, giving a full contact address, e-mail address and telephone number. Please indicate also the individual who is the designated Principal Investigator – this person will be responsible for research governance. At least one of the study investigators should be a paediatrician receiving the Orange Card.

You should have a named contact in Ireland who can support and promote the study, and advise on the suitability of your study methods and questionnaire for Irish paediatricians. The BPSU or Irish Paediatric Surveillance Unit can help you find a suitable contact that has a specialist interest in the condition that you are studying.

#### *4) Describe the study*

This should explain a) the condition to be studied, b) a review of the background to the study proposal, including current knowledge about incidence and prevalence, c) the public health and scientific importance of the study, d) the study methodology, and e) the expected benefits of the study. This explanation should be easily understood by a lay person as the BPSU EC includes lay and medical reviewers.

#### *5) Lay summary*

This should be a short, clear summary of the condition and study in terms that can be understood by a lay person. This will be the publicly available summary that is put on the BPSU website if the study is accepted. The lay summary should be no more than 250 words.

#### *6) Research questions/surveillance objectives*

Give a clear statement of the specific research questions that will be investigated by this study. These usually fall into the categories of 1) estimating incidence/prevalence, 2) describing the clinical features at presentation, 3) describing management and short-term outcomes.

It must be possible to address these questions

- a) Without direct contact with patients

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- b) Without seeking investigations that would normally not have been undertaken by the paediatrician
- c) Without a comparison (control) group.

There does not need to be a long list of objectives. Consider how you will ask suitable questions in the questionnaires to gather information to answer your research objectives. Consider if you will have a sufficiently large sample size to address your objectives, for example regional variations in incidence could not usually be addressed by a BPSU study as the sample size would be too small. Please note also that the BPSU surveillance methodology is not suitable for identifying causal relationships, as the frequency of 'risk' factors identified amongst notified cases cannot be compared with the frequency of these factors in unaffected 'control' children.

### 7) Case definition

Give a clear case definition for the condition of interest. The **surveillance case definition** is a case definition which may be wider than the analytic case definition in order to ensure cases are not missed. For example, the surveillance case definition will often include suspected cases where confirmation is awaited. The **analytic case definition** describes very carefully those children who will be included in the study, i.e. will become your 'confirmed cases' for further analysis.

In most studies, the age range for cases will include ages from birth up to but not including 16 years. Please consider if children in the upper age range will be seen by paediatricians for this condition.

Finally, you should have a set of **reporting instructions** telling clinicians which children should be reported to you. The reporting instructions will reflect your surveillance case definition but are likely to be a shortened or simplified version of these. Examples of case definitions used in previous studies are provided in Appendix 2.

### 8) Methods

Please provide clear details of the study methodology that you intend to employ to answer your research objectives. If you plan to request clinical specimens or vary your methods from conventional BPSU studies, then please provide details.

### 9) Expected numbers

Please supply an estimate of the number of cases expected each year, i.e. yearly incidence rate, indicate the sources that you have used to estimate this. More than 300 cases per year (or 30 per month) would normally be considered too high for the BPSU due to the monthly volume of notifications and the fact that regional studies may be sufficient. Please note that there are often duplicate reports so that the number of cases reported might be considerably higher than the number of true cases included in the analysis.

Indicate the source of denominator data for calculating incidence. This is often a routine data source, such as the Office for National Statistics mid-year population estimates or birth statistics

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([www.statistics.gov.uk/](http://www.statistics.gov.uk/)). In Northern Ireland ([www.nisra.gov.uk/](http://www.nisra.gov.uk/)), the republic of Ireland ([www.cso.ie/](http://www.cso.ie/)) and Scotland ([www.isdscotland.org/](http://www.isdscotland.org/)), other bodies collate these statistics.

### *10) Alternative sources of reporting*

Are there other clinicians besides paediatricians who are likely to see cases? If so, it is essential to consider whether to involve these clinical specialists in case reporting as this improves ascertainment and reduces bias. Please list any additional sources of case reporting that you intend to use (and provide letters of support as appropriate). Describe also the purpose of each additional source, how you will collect data and match between sources, and your proposed plan for analysis.

### *11) Proposed level and nature of public involvement*

You will be expected to engage with public or patient organisations relevant to your study. Please describe how you have involved, or intend to involve, the public in your study and whether this is consultation, collaboration or user-led (see below). Please then supply further details of this activity, including the organisations that you have approached and how they have been and will be involved in your study. Please attach any letters of support. For further information on public involvement in research visit [http://www.invo.org.uk/Key\\_Publications.asp](http://www.invo.org.uk/Key_Publications.asp)

Definitions for the terms you are being asked to assess are included here:

#### ***Consultation***

Researchers consult members of the public about the research e.g. through individual contacts, one-off meetings

#### ***Collaboration***

This includes active, on-going partnership between researchers and the members of the public e.g. involvement of members of the public on the project steering group, or as a research partners on a project.

#### ***User led / user controlled***

Members of the public lead the research and are in control of the research. This is often, through a community or voluntary organisation led by the service users.

It is recommended that researchers produce a public information leaflet including information about the condition and the study which can be distributed to relevant groups / organisations and posted on the BPSU website. Please state if you will do this and provide an example of any information leaflet or poster that you have produced for the study.

### *12) Questionnaires and letters to notifying paediatricians*

Copies of questionnaires and covering letters to respondents must be attached even if they are only in draft form. The BPSU EC will request final versions of your questionnaires and letters before final acceptance. It is essential to pilot your questionnaire with general paediatricians before submitting it to the BPSU for consideration. Please describe any pilots and changes made to questionnaires subsequent to this. It is advisable that you also consult any lay/public involvement representatives involved in the study about the questionnaire.

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Please note that the BPSU provides instructions for the design of questionnaires (see below and Appendix 3) within this guide. The BPSU has also devised a template questionnaire with additional guidance, which you are strongly advised to use. It is strongly advised that you liaise with the designated Medical Adviser before submitting your questionnaire as failure to do so may lead to delay in processing your application or its rejection.

### *13) Identifiers*

Provide details of the identifiable data that you will be collecting and justify why each identifier is required, e.g. for de-duplication or clinical data analysis.

### *14) Proposed Duration of Study*

Remember that the report card is sent to respondents at the end of each month, for cases seen in that month. The application and ethics approval process can take six to twelve months.

The BPSU recognises that two or more years of surveillance of a very rare condition may be required to provide adequate cases for the study. Applicants must therefore specify in their P2 application how long they wish to undertake surveillance and subsequent follow-up. Justification for the proposed study duration should be included in the supporting statement. Continuation of surveillance beyond one year is subject to receipt of a yearly progress report.

The follow-up period for further data collection should be no more than 2 years. Each investigator must also contribute a short report on their study each year to form part of the BPSU Annual Report. Please note that the BPSU EC has the option to limit initial surveillance duration to 13 months.

### *15) Funding arrangements*

Outline the funding arrangements for the project. BPSU costs are £3,900 + £500 for protocol card printing for a 13 month study. Inflationary costs for the contribution rates should be included if applying for more than one year's surveillance. Funding arrangements should not only cover BPSU costs but also administrative costs including research assistance/secretarial salaries.

Please name the body(ies) to which grant application(s) have been submitted or from whom funds will be available. Give the date by which arrangements are expected to be agreed. State whether funding is from a commercial source or whether you are personally in receipt of funds to undertake the research. If funding is from a commercial source, you may be expected to demonstrate, for example through a contract with the funders, that this will not influence the reporting of results, and you may wish to discuss this with the Medical Adviser. Where the study is funded by a third party (commercial or non-commercial source), it is unlikely to be acceptable for them to have access to identifiable data.

### *16) Organisational Arrangements*

Provide details for managing the project, such as administrative, scientific and computing support. Particular attention will be paid to whether the resources are sufficient to run a successful project, processing reports in a timely manner, information technology support etc.

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We strongly advise that a research administrator or officer is employed either part time or full time if the expected number of case reports is greater than 100 per year. You should be aware of the requirements for security and confidentiality in handling patient identifiable data described in Part B.

### *17) References*

A list of any references should be included. If possible, attach copies of any papers which are not likely to be electronically available to the medical advisers.

## **Additional documents**

### ***Covering letter***

Please attach a signed covering letter from the main contact/principal investigator for the study.

### ***Supporting letters***

Please attach any letters of support that you consider relevant for the committee to consider, for example award letters from funding bodies or letters confirming support by collaborating partners.

### ***Questionnaires and covering letters***

Please attach all questionnaires and letters that will be used within the study. Please provide a version number and date for each.

### ***Public information leaflet/poster***

Please attach any public information material, if appropriate.

### ***Supporting letters***

Please attach any letters or statements of support, if appropriate.

### ***Letter from funding body***

Please attach confirmation of funding, if appropriate.

### **Signature**

An electronic version of the application can be submitted directly to the BPSU Office at [bpsu@rcpch.ac.uk](mailto:bpsu@rcpch.ac.uk) at least 2 weeks before the BPSU EC meeting. A signed paper copy must also be sent to the BPSU office.

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### Questionnaire Design

A questionnaire template can be downloaded from the [BPSU website](#)

Listed below are some key issues to keep in mind when designing your questionnaire. A questionnaire template can be found on the BPSU website and general advice on questionnaire design is also provided in Appendix 3.

Investigators are welcome to discuss questionnaire design with the medical advisers and/or BPSU EC and copies of questionnaires used by existing studies are available on the BPSU website or on request from the BPSU Office.

A letter of introduction should be sent with the questionnaire and a thank you letter should be sent on return of the questionnaire (Appendix 4). This is vital in keeping the continued support of the clinicians.

#### *Key points*

- Questionnaires should be as brief and simple as possible, so as not to impose an excessive burden on the paediatrician. Two A4 pages are usually adequate for the questionnaire. Reasons for requiring a longer questionnaire must be outlined in the application. However, a well-laid out four-page questionnaire is preferable to one of two pages that is cramped and difficult to complete. As a guide, the questionnaire should take no longer than 15 minutes to complete.
- ‘The British Paediatric Surveillance unit of the Royal College of Paediatrics and Child Health’ should be included in the heading of questionnaires and covering letters
- Information sought should be easily accessible to the reporting clinician from medical case notes. Anonymised copies of discharge letters cannot be sought.
- A ‘tick box’ format should be used wherever possible, remember to include a ‘don’t know’ or ‘not tested’ box where appropriate.
- The cover page of the questionnaire should contain the hospital and minimal identifiable data; this can then be separated from the clinical details and stored separately to protect confidentiality. Names and addresses should not be sought although a unique identifier (e.g. NHS or CHI number) is usually essential. Minimal patient personal information to allow identification of duplicate reports and collection of follow-up data (e.g. initials, date of birth, sex, partial postcode or NHS number) is accepted by the BPSU, but you will also need to justify this to REC and ECC.
- You may wish to use a study title that does not state the condition if this is particularly sensitive, e.g. HIV.
- Specialist terms or abbreviations that may not be familiar to paediatricians should be explained in full.
- Standard accepted classifications should be used where possible. Ethnic group should be requested using the 2001 Census Classifications.

## **BPSU Study Handbook: Part A – Applying to the BPSU**

- Respondents should be asked to return the questionnaire even if they are unable to complete all items.
- A reply paid envelope for return of the data collection sheet is essential.



## **Part C - Appendices**

## BPSU Study Handbook: Part C - Appendices

### Appendix 1: Abbreviations and Useful Web Addresses

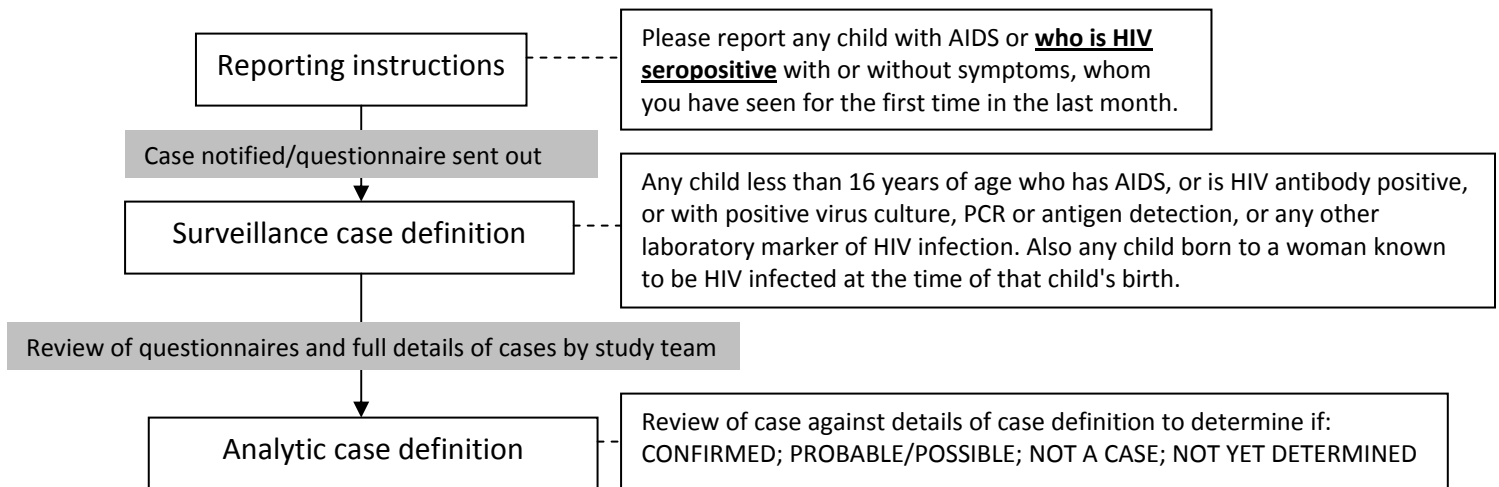
Abbreviation		Weblinks
<b>ECC</b>	Ethics and Confidentiality Committee (of the NIGB)	<a href="http://www.nigb.nhs.uk/ecc">www.nigb.nhs.uk/ecc</a>
<b>GROS</b>	General Register Office for Scotland	<a href="http://www.gro-scotland.gov.uk/statistics/">www.gro-scotland.gov.uk/statistics/</a>
<b>HES</b>	Hospital Episode Statistics	<a href="http://www.hesonline.nhs.uk/">www.hesonline.nhs.uk/</a>
<b>IC</b>	NHS Information Centre	<a href="http://www.ic.nhs.uk/services/medical-research-information-service">www.ic.nhs.uk/services/medical-research-information-service</a>
<b>IRAS</b>	Integrated Research Applications System	<a href="http://www.myresearchproject.org.uk/">www.myresearchproject.org.uk/</a>
<b>ISD</b>	Information and Statistics Division (Scotland's ONS)	<a href="http://www.isdscotland.org/">www.isdscotland.org/</a>
<b>MRIS</b>	Medical Research Information Service (NHS Information Centre )	<a href="http://www.ic.nhs.uk/services/medical-research-information-service">www.ic.nhs.uk/services/medical-research-information-service</a>
<b>NIGB</b>	National Information Governance Board	<a href="http://www.nigb.nhs.uk">www.nigb.nhs.uk</a>
<b>ONS</b>	Office for National Statistics	<a href="http://www.statistics.gov.uk/default.asp">www.statistics.gov.uk/default.asp</a>
<b>PAC</b>	Privacy Advisory Committee (Scotland and Northern Ireland only)	<a href="http://www.isdscotland.org/isd/3048.html">www.isdscotland.org/isd/3048.html</a>
<b>PIAG</b>	Patient Information Advisory Group (role taken over by ECC)	<a href="http://www.advisorybodies.doh.gov.uk/PIAG/Index.htm">www.advisorybodies.doh.gov.uk/PIAG/Index.htm</a>
<b>SLSP</b>	System Level Security Policy	<a href="http://www.nigb.nhs.uk/ecc/applications/SLSP.doc/view?searchterm=slsp">www.nigb.nhs.uk/ecc/applications/SLSP.doc/view?searchterm=slsp</a>
<b>UKCRC</b>	UK Clinical Research Collaboration	<a href="http://www.ukcrc.org/regulationgovernance.aspx">www.ukcrc.org/regulationgovernance.aspx</a>
<b>Other useful weblinks</b>		
	Research Database forms (and other example forms from IRAS)	<a href="http://www.myresearchproject.org.uk/Help/PdfFiles.aspx">www.myresearchproject.org.uk/Help/PdfFiles.aspx</a>
	NHS Information Governance Toolkit (from Connecting for Health)	<a href="http://www.igt.connectingforhealth.nhs.uk/">www.igt.connectingforhealth.nhs.uk/</a>
	MRC Data and Tissue Toolkit	<a href="http://www.dt-toolkit.ac.uk/home.cfm">www.dt-toolkit.ac.uk/home.cfm</a>
	MRC Personal Information for Medical Research Guidance	<a href="http://www.mrc.ac.uk/pdf-pimr.pdf">www.mrc.ac.uk/pdf-pimr.pdf</a>

## Appendix 2: Case Definition – Development and Examples

### Developing a case definition

If you are developing a case definition, consider which symptoms, signs and tests you use to make the diagnosis. Symptoms and signs, such as fatigue or fever, which are common to many conditions are unlikely to be useful elements of a case definition on their own, however they may be clearly diagnostic of a disorder when found in association with other specific symptoms or signs.

The **surveillance case definition** defines clinically the cases that investigators are aiming to identify. It should state the age range, clinical symptoms and signs and results of investigations which would indicate a child is definitely or is likely to be a case. The surveillance case definition may be broader (less specific) than the **analytic case definition** applied using information from the questionnaires. For example, the surveillance case definition may include suspected but unconfirmed cases, whilst the analytic case definition for incidence estimates should include confirmed cases only. The **reporting instructions** are based on the surveillance case definition and state simply which cases should be notified to the study by clinicians.



Examples of the reporting instructions and case definitions used in some current and previous BPSU studies are provided on the next page.

## BPSU Study Handbook: Part C - Appendices

### EXAMPLE REPORTING INSTRUCTIONS & CASE DEFINITIONS

#### 1. HIV infection & AIDS

**Case definition:** Any child less than 16 years of age who has AIDS, or is HIV antibody positive, or with positive virus culture, PCR or antigen detection, or any other laboratory marker of HIV infection. Also any child born to a woman known to be HIV infected at the time of that child's birth, regardless of the child's infection status.

**Reporting instructions:** Please report any child with AIDS or **who is HIV seropositive** with or without symptoms, whom you have seen for the first time.

#### 2. Progressive intellectual and neurological deterioration (PIND)

**Case definition:** Any child under 16 years of age at onset of symptoms who fulfils **all** of the following three criteria:

1. Progressive deterioration for more than three months with
2. Loss of already attained intellectual/developmental abilities and
3. Development of abnormal neurological signs.

**excluding :** Static intellectual loss e.g. after encephalitis, head injury or near drowning.

**including :**

- Children who meet the case definition even if specific neurological diagnoses have been made.
- Metabolic disorders leading to neurological deterioration.
- Seizure disorders if associated with **progressive** deterioration.
- Children that have been diagnosed as having neurodegenerative conditions but who have not yet developed symptoms

**Reporting restricted to:** Cases seen in the last month but including those whose conditions began earlier (i.e. including 'old cases' of children in follow-up if seen in that month).

**Reporting instructions:** Please report any child seen in the last month who meets the case definition, including those who have already been given a specific diagnosis.

## BPSU Study Handbook: Part C - Appendices

### 3. Neonatal Herpes Simplex Virus (HSV) Infection

#### Surveillance Case Definition

1. Any infant under one month
  - (a) with a diagnosis of HSV infection, based on virus detection by culture, PCR or IF, or serology – IgM and/or seroconversion, **or**
  - (b) treated with antiviral drugs for suspected HSV infection
2. Any stillborn infant in whom HSV infection is suspected

#### Analytic Case Definition

##### *Confirmed case of neonatal HSV:*

1. Virus detection by culture, PCR or IF, or serology – IgM and/or seroconversion, confirming HSV infection on a specimen taken within four weeks of birth, or
2. Typical clinical manifestations with maternal infection confirmed by either seroconversion during pregnancy or virus isolation around the time of delivery

##### *Suspected case of neonatal HSV:*

Typical clinical manifestations and treated with antiviral drugs for suspected HSV infection.

**Reporting Instructions:** Any live born or stillborn infant born since the beginning of 2004 in the UK or Ireland

**with** confirmed or suspected neonatal HSV infection, seen by you for the first time in the last month.

### 4. Medium Chain Acyl CoA Dehydrogenase Deficiency (MCADD)

The diagnosis of MCADD can be made following clinical presentation, investigation of a sudden unexpected death, diagnosis in an affected family member or through newborn screening. A child will be considered to have a diagnosis of MCADD if one or more of the following criteria are met:

- Elevated octanoyl carnitine in blood test using tandem mass spectrometry (or in other body fluids if a post-mortem diagnosis)
- Characteristic urine profile of organic acids with hexanoyl, suberyl and phenylpropionyl glycine
- Molecular genetic studies confirming presence of a mutation characteristic of MCADD
- Enzyme studies based on skin fibroblasts showing reduced activity of medium chain fat oxidation

**Reporting Instructions** Please report any newly diagnosed cases seen for the first time in the past month, which meet the surveillance case definition, including those where the child may have died. If the paediatrician is not certain or awaiting confirmation, the case should be reported anyway.

### 5. Early onset eating disorders in children less than 13 years

## BPSU Study Handbook: Part C - Appendices

**Case definition:** Any child aged under 13 years, newly diagnosed with early onset eating disorder which is defined as:

TWO OR MORE OF THE FOLLOWING

- weight loss or failure to gain weight during a period of expected growth, not due to any identifiable organic cause
- determined food avoidance
- fear of weight gain
- preoccupation with body weight or energy intake
- self induced vomiting
- excessive exercising<sup>1</sup>
- recurrent episodes of binge eating or abuse of laxatives

<sup>1</sup>*Exercise may be considered to be excessive when it significantly interferes with important activities, when it occurs at inappropriate times or in inappropriate settings, or when the individual continues to exercise despite injury or other medical complications." (American Psychiatric Association. DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, D.C.: American Psychiatric Association; 2004; pp. 590-591.)*

**Reporting Instructions:** Please report any **new** cases meeting the surveillance definition seen by you for the first time **even if** you believe the case may have been reported from elsewhere.

### 6. Methicillin-resistant Staphylococcus aureus (MRSA)

**Case definition:** Isolation of Methicillin-resistant Staphylococcus aureus (MRSA) from blood cultures of children less than 16 years of age.

**Reporting Instructions:** Please report any cases seen within the last month that meet the case definition. Please note that BPSU surveillance does not replace other forms of routine Staphylococcus aureus reporting to the Health Protection Agency (HPA).

### 7. Malaria In Children

**Case Definition:** Any child less than 16 years of age who is diagnosed with malaria through either microscopic examination of thick and thin blood smears or malaria antigen detection in the blood using commercially available assays.

**Reporting Instructions:** Please report any cases seen in the past month that meet the surveillance case definition. Please note that BPSU surveillance does not replace other ongoing reporting systems for malaria (e.g. enhanced surveillance through the Malaria Reference Laboratory mandatory notifications to the HPA).

## **BPSU Study Handbook: Part C - Appendices**

### **Appendix 3: Guidance on Developing A Questionnaire**

*(We are grateful to Helen Bedford for her help with this guidance).*

This is an introduction to some of the considerations involved in questionnaire design including practical suggestions.

#### **Self completion questionnaires – by clinicians**

The advantages of these are that they are:

- Less costly than interviews, requires less time and energy to administer
- Can include a national, geographically spread sample using a mailed questionnaire

The disadvantages are:

- Possible response bias, i.e. non-responders differ in some way from responders giving an unrepresentative picture.
- Questionnaire design is crucial; it must be absolutely clear as there is no opportunity to explain questions.
- Responses are final - no opportunity to probe.
- Responses are limited to what is available in clinical notes.
- No control over who actually completes questionnaire, this may be the intended consultant or a junior staff member.

#### **Questionnaire design**

You will require a well designed questionnaire. In practice designing a questionnaire is a skilled job and there are many pitfalls. Key points are:

- Avoid ambiguity, bias and confusion.
- Don't underestimate the time it will take to construct the finished product. The more intelligible it seems, the greater the expertise that has gone into it. Always seek views of intended audience during drafting, i.e. discuss with colleagues
- Using questionnaires or parts of questionnaires that have been previously tried and tested is acceptable and also provides you with the additional advantage of being able to compare your findings with that of others.
- Pilot questions or the whole questionnaire with a local sample of clinicians, preferably against real sets of case notes.

## **BPSU Study Handbook: Part C - Appendices**

### **Letters of introduction**

You need to introduce the study by letter. Letters should include:

- Aims of study and what you hope to get out of it e.g. 'we hope that the findings will help to improve services for children with disabilities in Brighton'.
- Assurance that information will be treated as confidential – it is best to state CONFIDENTIAL on the front sheet.
- Who you are, and your credentials
- Recognition of the effort required by the respondent
- Thanks
- Instructions re returning questionnaire
- Who to contact for more details
- Use plain English

### **The Questionnaire**

- Length – 2-3 sides of A4 is considered to be maximum
- Layout is important, it must look attractive and not too formidable, subjects must feel able to answer it.
- Using sections and boxes to separate different parts of the questionnaire can make it clearer and more inviting.
- Put instructions for completing at the top e.g. 'Tick the box next to the answer that applies to you'.
- If you are asking for more detail make sure there is enough space for people to write in.
- Skips are useful but must be clearly indicated e.g. ' GO TO QUESTION 3b'
- Language used is very important, should be appropriate to the sample e.g. language used for general public would differ from that used for health professionals.
- Don't be tempted to ask too many questions, stick to the minimum only, keep your research questions in mind all the time.
- It's occasionally useful to invite people to tell you anything else they want to at the end of the questionnaire but consider how this will be analysed
- Sensitive questions should be placed towards the end, then if the respondent does not wish to answer these, they may still have answered the others.

## BPSU Study Handbook: Part C - Appendices

### Types of question

**'Closed' or pre-coded questions**, e.g. *'Was the child born preterm (before 37 weeks gestation)?'*

- Yes
- No
- Don't know

#### Advantages

- This is useful if the range of answers to a question is limited and well established but always remember to include a 'don't know' option where relevant.
- Means people have to write very little, maybe useful for busy people.
- Makes analysis more straightforward.
- Make group comparisons easier
- Useful for testing specific hypotheses.

#### Disadvantages

- May be problem if all options are not included.
- Spontaneous response lost
- May be bias in answer categories, e.g. if respondents prefer to opt for 'socially acceptable', 'don't know' or 'middle' option.
- Can be too crude

### Open-ended questions

Allows respondent to answer in their own words, and highlight the particular issues that are important to them. e.g. *'How would you describe your relationship with your doctor?'*

#### Advantages

- Useful if you can't determine in advance what the main categories will be, useful in pilot surveys, means rich data is collected but dealing with the information in analysis is more difficult because if you have 50 responders you may get 50 completely different answers.
- Can place a burden as more time/thought required by respondents.
- More difficult to analyse against specific objectives.

**In practice most questionnaires use a combination of closed and open-ended questions e.g.**

*'Does the child have any problems with his/her eyesight?'*

- Yes
- No
- Don't know

*If YES, please describe .....*

It is often useful to begin with a closed 'yes/no' questions, then follow-up with an open-ended question that asks for detail.

### Summary of question types

**Open-ended:** These allow a respondent freedom to write detail and express opinions, e.g. please describe..., tell me about...

**Closed:** These require a selection from a fixed set of answers, e.g. yes/no/don't know or male/female. A rating scale may be used to offer a wider range of answers.

**Leading:** These suggest a 'correct' answer to the respondent and are poor questions, e.g. *Do you think seatbelts should be compulsory in cars?*

**Double-barrelled:** These have two different questions rolled into one so it is not clear which is being answered, e.g. *Do you agree or disagree with ...*, or *Was the child unwell or in a state of collapse at the time of diagnosis?*

**Hypothetical:** These cannot be confirmed so are about opinion only, e.g. *Would the patient have been better without treatment?*

### Measurement scales

These can be very useful for questions about health which tend to be on a continuum. Whether you choose a question or a scale depends on the nature of the variable you are measuring, e.g. whether it is categorical or continuous.

Examples of measurement scales:

**Likert scale:** used to indicate various degrees of strength of agreement or disagreement; commonly used to measure attitude, e.g.

*'I would like my child to have his/her vaccinations in one injection rather than two'*  
*strongly agree/ agree/ undecided/ disagree/ strongly disagree.*

There are usually five or seven points on the scale, as an odd number allows respondent to express a neutral response to the statement. Responses can be allocated a score.

**Guttman scale:** This is also used to measure attitude and consists of a set of items with which people are asked to agree or disagree. The number of items usually small and a number of statements relate to a single concept. One score is allocated to each of the statements with which the person agrees, and they are allowed to agree with one or more statement.

e.g. *Statements relating to social isolation:*

- 1. I feel lonely*
- 2. I'm finding it hard to make contact with people*
- 3. I feel there is nobody I am close to*
- 4. I feel I am a burden to people*

## BPSU Study Handbook: Part C - Appendices

**Semantic differential scales:** These are based on the importance of language reflecting a person's feelings. Respondents asked to make judgments about certain concepts and bipolar adjectives are stated at either end of a 7 point scale. These are only useful when responses to questions or statements can be categorised into conflicting adjectives.

e.g. *The session on questionnaire design was:-*

1.	<i>Unhelpful</i>	1	2	3	4	5	6	7	<i>Helpful</i>
2.	<i>Bad</i>	1	2	3	4	5	6	7	<i>Good</i>
3.	<i>Uninformative</i>	1	2	3	4	5	6	7	<i>Informative</i>

**Visual analogue scales:** These are frequently used in the clinical setting, e.g. measurement of pain

*No pain at all* *worst pain imaginable*

\_\_\_\_\_X\_\_\_\_\_

Traditionally the line is 100mm in length and subjects are asked to mark a point on the scale which represents the amount of sensation they are experiencing. The mark on the line can be measured and a score allocated between 0 and 100mm.

**Rating scales:** These are used to evaluate performance or for the prediction of risk, and are necessary when objective measures of some skills are not available or are too complicated for general use. The points on the scale are derived from expert ratings and the methods of rating may be complex or simple. Examples are the Glasgow coma scale and Edinburgh postnatal depression score. Assessors must be well practiced in the use of the scale to ensure high degree of inter-rater reliability.

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### Question construction

- Use plain English and the most simple language you can
- Avoid double barrelled questions, e.g. 'Do you agree or disagree with the following statement: Examinations are a poor method of assessing ability and should be banned'.
- Avoid ambiguity – e.g. as in this question taken from a survey questionnaire sent to all female staff irrespective of whether they were pregnant or not: 'Is your work made more difficult because you are expecting a baby?'
- Avoid leading questions, e.g. 'You don't think.....do you?'
- Be specific, e.g. if you want opinions on how an outpatients department organised their appointments system, it is no good asking 'Are you satisfied with the outpatients department at X hospital?'
- Avoid vague words like regularly, frequently, occasionally, which might be interpreted differently. Define things like 'collapse' or 'crisis', which may mean different things to different people.
- The wording of the question is crucial, for example when the General Household Survey was collecting information on chronic illness they asked 'Do you suffer from any disability?' and the response was far lower than they expected. Next time they asked 'Do you have any disability?' and got a more accurate response.

### Obtaining a good response rate with a mailed questionnaire

- Follow up non responders twice with reminders - can expect about 1/2 final response rate with first letter, another 1/3 with second and a few more with third.
- Need to be able to identify those who have not responded, so note consultant names/patient codes at the top of the questionnaire.
- Send reminders when replies stop coming back, usually after about 2-3 weeks with second class post. E-mail and telephone reminders are also acceptable.
- Always include another copy of the questionnaire in case it has been mislaid.
- FREEPOST or reply paid envelopes are essential.
- Printing questionnaire on coloured paper means it stands out from other correspondence.
- White envelopes differentiate from business mail.

### Assessing the quality and adequacy of a questionnaire

**Reliability** of a questionnaire is a main criterion – this is the extent to which a questionnaire produces similar results under the same conditions on all occasions.

**Validity** - many different types of validity exist but it broadly refers to the extent to which a questionnaire measures what it is supposed to measure. Establishing validity can be difficult but piloting is a very important exercise in achieving validity and reliability.

## **BPSU Study Handbook: Part C - Appendices**

### **Pilot Studies**

It is sensible to pilot your questionnaire, so difficulties can be ironed out before the main study starts. It is best to ask several clinicians to test the questionnaire against a set of real notes and provide feedback on questions which are difficult to understand or data which is hard to find in the notes.

### **Analysis**

Always think about your method of analysis when you are designing the questionnaire, as this may affect the design. For example, specific questions may relate to specific fields in an electronic database. Coding of responses, that is transforming them into numerical data to enable analysis, may be carried out during the planning stage of questionnaire design in which case you will need a coding frame either printed on the actual questionnaire or separately, or after the data is collected. The majority of closed questions can be pre-coded.

### **Examples of BPSU questionnaires**

Current questionnaires are available on the BPSU website.

## **BPSU Study Handbook: Part C - Appendices**

### **References and further reading**

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## BPSU Study Handbook: Part C - Appendices

### Appendix 4: Examples of Letters to Accompany Questionnaires

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health

#### EXAMPLE OF A LETTER TO THE REPORTING PAEDIATRICIAN

[Name]  
[Address]  
[Date]



Dear [Name],

#### **Re: Study**

Thank you for notifying a case(s) for this study, which is being undertaken by the Royal College of Paediatrics and Child Health Surveillance Unit.

We are writing to gather further information about this case on the enclosed questionnaire. We should be very grateful if you could complete it and return it in the enclosed reply paid envelope. **Please return the questionnaire, even if there are some sections you are unable to complete.**

We will not be contacting your patient or his/her family at any time. Some patient identifiable data are needed to avoid duplication and to allow an estimation of the completeness of reporting. These will be removed once the case has been confirmed to be a unique case and all information you provide will be treated in strict confidence.

The study is funded by the XXXX and has been approved by the XXXXXXXX Region MREC and by the Patient information Advisory Group.

Please do not hesitate to contact XXXXXX if you have any queries about the questionnaire, or any aspect of the study. If you need any clinical advice regarding the eligibility of a particular case for inclusion in the study please contact Dr XXXXX (contact details below).

We are very grateful to you for reporting to the BPSU and for taking the time to provide further information about your patient. It is our intention to send a short follow-up questionnaire in 12 months time to confirm outcome status.

Finally we will also ensure that you are sent a copy of the final report of the study.

With many thanks for your help,

Yours sincerely

## BPSU Study Handbook: Part C - Appendices

### EXAMPLE OF A THANK YOU LETTER FOLLOWING COMPLETION OF THE QUESTIONNAIRE

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health



[Name]  
[Address]

[Date]

Dear [Name],

**Re: Study**

Thank you for completing the questionnaire which we have just received and processed.

This questionnaire will help us to gain further information about XXXXXX in infants and children. **There is no intention to contact either the patient or their relatives and this data will not be converted into a registry.**

We will be contacting you in one year's time to see how the patient has fared.

We would like to thank you for your past and continuing assistance and please do not hesitate to contact us at the above address if there are any queries you would like to discuss further.

With many thanks for your help,

Yours sincerely

Phone:

Email:

## BPSU Study Handbook: Part C - Appendices

### EXAMPLE OF FOLLOW-UP LETTER TEMPLATES

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health

[Name]  
[Address]



[Date]

Dear [Name],

**Re: Study**

We would like to thank you for your notification of a case of XXXXXX to the British Paediatric Surveillance Unit (BPSU) and for completing the initial questionnaire we sent you. We are now contacting you to establish clinical outcomes at one year. We would be grateful if you would complete the enclosed questionnaire and return it in the prepaid envelope provided. Please try to complete the questionnaire, even if the child has died or has not been seen for some time.

If the child is no longer being cared for by you, we would be very grateful if you would let us have details of the child's new paediatrician or someone we could write to obtain this information.

Thank you for taking the time to be a part of this study. We will provide a report of the study to all notifying clinicians once it concludes. In the mean time, if you have any further questions regarding the study or the questionnaire, please do not hesitate to contact us by phone or e-mail.

Yours Sincerely,

Dr  
Principal Investigator

## BPSU Study Handbook: Part C - Appendices

Header and Address

### FOLLOW-UP LETTER REMINDER TEMPALTE

**On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health**

[Name]

[Address]

[Date]



Dear [Name],

**Re: Study**

Thank you for reporting a case of confirmed or suspected XXXXXX through the British Paediatric Surveillance Unit (BPSU) 'orange card' scheme and completing the initial questionnaire. We recently sent you a follow up questionnaire regarding this child, but have not yet received your reply. If this has been sent in the last week, please ignore this letter. If it has not, we would be most grateful if you would complete and return the questionnaire in the envelope provided. This information is important to us to understand clinical outcome and morbidity associated with this condition.

If the child is no longer being cared for by you, we would be very grateful if you would let us have details of the child's new paediatrician or someone we could write to obtain this information.

We will provide a report of the study to all notifying clinicians once it concludes. In the mean time, if you have any further questions regarding the study or the questionnaire, please do not hesitate to contact us by phone or e-mail.

Yours sincerely,

Dr  
Principal Investigator