

**Charter of the International Network of Paediatric Surveillance Units (INoPSU)  
Established in June 2000 (Amsterdam-Ottawa)  
Charter revised September 2011 (Montreux)**

**Background and Rationale**

Rare diseases and infections are individually uncommon. Paradoxically, together they number thousands, and many rare diseases are characterised by chronicity and by high rates of disabling sequelae or death. Most pose a large financial and emotional burden for affected children, their families and health systems.

All such diseases are difficult to study as their low frequency often means that little may be known about their aetiology, clinical spectrum, sequelae, pathological features, diagnosis, treatment and management. This can result in delayed diagnosis, increasing the risk of preventable complications or death. It is also important to detect rare emerging infections as early as possible to enable timely responses to prevent their spread. In order to generate a sufficient number of cases to derive meaningful data, the study of rare diseases requires collaboration of many clinicians providing health care to large populations over large geographical areas.

The International Network of Paediatric Surveillance Units (INoPSU) was established in 2000 to address this issue. As of 2011, the Network consists of 13 national Paediatric Surveillance Units (PSUs) (Table 1).

**Table 1 – INoPSU Membership as of 2011**

<b>Member Units</b>	<b>Affiliate Members</b>
Australian Paediatric Surveillance Unit (APSU)*	British Ophthalmology Surveillance Unit
British Paediatric Surveillance Unit (BPSU)*	British Neurology Surveillance Unit (TBC)
Canadian Paediatric Surveillance Program (CPSP)*	UK Obstetrics Surveillance System (TBC)
Cyprus and Greece Surveillance Unit (CGPSU)	Belgium Paediatric Surveillance Unit (BePSU)
German Paediatric Surveillance Unit (ESPED)*	
Irish Paediatric Surveillance Unit (IPSU)	
Latvian Paediatric Surveillance Unit (LPSU)	
Netherlands Paediatric Surveillance Unit (NSCK)*	
New Zealand Paediatric Surveillance Unit (NZPSU)*	
Portugal Paediatric Surveillance Unit (PPSU)	
Swiss Paediatric Surveillance Unit (SPSU)*	
Welsh Paediatric Surveillance Unit (WPSU)	

\* Founding members

## **Principles and Term of References**

Individual paediatric surveillance units (PSUs) are usually related to the national body representing paediatricians as this has the most accurate database of paediatricians eligible to report on rare conditions in children. This also tends to maximise reporting as paediatricians have ownership of the system. The PSUs participating in INoPSU contribute and draw on other units for advice and information while remaining independent and responsive to individual national requirements for monitoring specific disorders.

INoPSU provides an efficient, effective framework for case-finding for investigators who wish to study rare conditions in children such as, infections, severe complications of infections, vaccine-preventable diseases, congenital and inherited (genetic) diseases, unusual injuries, rare adverse events of therapies and rare severe complications of common diseases. Enhanced surveillance and timely response to emerging public health issues is an added asset. Most PSUs encourage, facilitate or elicit studies but some lead and undertake research themselves.

INoPSU members regularly contact each other for results, sharing of protocols, putting researchers in touch with each other. INoPSU produces a regular report summarising the activities of all PSUs and each PSU includes a report on INoPSU in their national report.

### **Active surveillance**

Each national PSU accepts applications to conduct a study which are usually considered by an advisory committee having scientific, epidemiological and public health expertise, as well as paediatricians participating in the system. Other bodies concerned with child and public health are frequently represented on PSU committees. Investigators may pay a fee covering a proportion of central costs to conduct a study through the surveillance unit.

Accepted study protocols are then included on the report card. This report card listing conditions being studied is sent either electronically or via post every month from the PSU to all participating clinicians. Other specialists working in child health (e.g. paediatric/orthopaedic surgeons, urologists, neurologists, dermatologists or child psychiatrists) may also be included as participants who report on a monthly basis. The PSU mechanism relies on 'active' surveillance where the PSU actively seeks a response from each participant each month indicating whether or not they have seen a relevant case, rather than relying on participants to remember to report relevant cases without being prompted. The respondents are asked to indicate on the card the number of cases of the listed disorders seen in the previous month and to return the card to the PSU. It is important that the card is returned even if no cases have been seen, in order to monitor compliance with the scheme, and to maximise case ascertainment. This process is resource efficient and allows for simultaneous, prospective monthly collection of national data on up to 16 conditions. PSU surveillance serves to raise awareness, advance knowledge and inform public health prevention strategies. Surveillance is usually undertaken for between 1-3 years depending on the protocol, although some conditions of particular public health importance remain under long-term surveillance.

The precise structure of the mailing list for each surveillance unit varies to suit local circumstances. Mailing lists vary considerably in size but monthly response rates in many of the existing PSUs approach or exceed 90%. The method used to collect responses to the monthly cards varies among PSUs and may be either by return pre-paid post, telephone/fax, e-mail or via a secure website. When a case is reported, the reporting clinician is contacted to request de-identified clinical information. Some PSUs work with researchers to confirm the outcome status of a report (confirmed case, duplicate, not meeting the case definition etc.) and to calculate completion rates. External validation of case ascertainment can also be carried out for some studies.

Through active surveillance, INoPSU members aim to actualize the mission of the Network as described in the **Terms of Reference** (Appendix 1).

## Appendix 1

### Terms of Reference

#### 1. Agreement

To form an International Network of Paediatric Surveillance Units (INoPSU) to link the national paediatric surveillance units (PSUs).

#### 2. Mission

- 2.1. INoPSU supports international cooperation among national Paediatric Surveillance Units to advance epidemiological and clinical knowledge in the area of rare childhood conditions

#### 3. Aims of INoPSU and Benefits

- 3.1 To facilitate communication and co-operation between existing national PSUs, researchers and investigators and assist in the development of new and existing PSUs.
- 3.2 To facilitate collaboration for the study of rare childhood conditions among researchers from different nations and scientific disciplines, enable comparison of incidence, aetiology, management, efficacy of preventative strategies, outcomes and changing patterns of rare diseases over time.
- 3.3 To share information on current, past and anticipated projects, including protocols, case definitions and questionnaires in order to encourage development of surveillance projects for specific rare conditions in multiple countries.
- 3.4 To pool results, analyses and conclusions, and facilitate their dissemination via joint international publications, presentations and/or reports to national and international health authorities so as to raise awareness of rare childhood conditions to encourage early diagnosis and appropriate treatment and management and detect the emergence of new conditions.
- 3.5 To provide the means to support the development of international cohorts from identified cases this could potentially support future research.
- 3.6 To share and distribute information of educational benefit to newly forming PSUs notably on study and surveillance methodologies, statistical techniques and models and methods of evaluating the performance and effectiveness of national Units.
- 3.7 To encourage regular evaluation of PSUs participating in INoPSU
- 3.8 To provide a forum for discussion of areas of concern relating to surveillance data validation, ethics and confidentiality.
- 3.9 To identify rare disorders of mutual interest and public health importance for co-operative surveillance through each national unit.
- 3.10 To contribute to the development and clarification of internationally recognised diagnostic criteria for rare diseases, which will help standardise their identification.
- 3.11 To collaborate with and provide information to other groups interested in rare childhood diseases, such as parent support groups and policy-makers.
- 3.12 To respond promptly to international emergencies relating to rare childhood conditions where national and international studies can make a contribution to science or public health.
- 3.13 To vigorously encourage the promulgation of the benefits of surveillance to the whole community including the general public, patient groups, health care staff and decision makers.
- 3.14 To promote guidance to national units and others as to how surveillance can be carried out without prejudicing data protection, patient confidentiality and ethical standards and to discuss areas of concern relating to surveillance data validation.

**4. Principle and Membership**

- 4.1 National units participating in INoPSU will contribute to and draw on other units for advice and information while remaining independent and responsive to individual national requirements for monitoring specific rare conditions.
  - 4.1.1 The Network will consist of national PSUs and/or other specialty surveillance units, dedicated to collecting data in children.
  - 4.1.2 There will be full, introductory affiliate and individual/associate members (Table 2).
- 4.2 **Nomination**
  - 4.2.1 Applications for full and introductory affiliate membership will be received at any time but ratification will only take place at the INoPSU Business Meeting (BM) at which there is a quorum present (see 9). Candidates will be elected by a simple majority of current full members present.
  - 4.2.2 Applications for individual/associate membership must be supported by one current INoPSU member, full or affiliate. Ratification will follow the same process as described above.
  - 4.2.3 If a candidate is not accepted, the responsible administrative sections of the INoPSU are not obliged to make public their reasons.

**Table 2: Membership categories**

<b>Full members</b> will consist of:	<b>Introductory Affiliate members</b> will consist of:	<b>Individual/Associate members</b> will consist of:
<ul style="list-style-type: none"> <li>• The founding units*</li> <li>• Those meeting the following agreed criteria:                       “A national unit undertaking active, clinician-based paediatric surveillance, possessing a scientific committee and producing a regular report, preferably annually”.</li> </ul> <p>Other medical/surgical specialty (adult or paediatric) units using similar surveillance methodology and studying paediatric diseases.</p>	<ul style="list-style-type: none"> <li>• National Paediatric Associations/Societies preparing to set up surveillance and PSUs that are working towards meeting agreed criteria.</li> <li>• Other national specialty groups who are intending to set up paediatric surveillance and units that are working towards meeting agreed criteria.</li> </ul>	<ul style="list-style-type: none"> <li>• Individuals interested in understanding rare disease epidemiological surveillance</li> <li>• Individuals working in the area of rare disease either as researchers, clinicians, patients or caregivers</li> <li>• Patient support groups</li> <li>• Concerned not for profit organisations as agreed by current INoPSU full members.</li> <li>• International organisations working in the area of rare disease, such as the European Organisation for Rare Disease, North American Organisation for Rare Disease, EUROCAT, Orphanet etc., as agreed by the current INoPSU full members.</li> </ul>

<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• May submit abstracts for the INoPSU Scientific Meeting</li> <li>• May submit nominations for INoPSU membership</li> <li>• Have up to three representatives at the INoPSU business meeting, two of whom have one vote each</li> <li>• Are entitled to receive all the mailings of INoPSU newsletters and annual reports and have access and contribute to the shared research database.</li> <li>• Have opportunity for international collaboration and sharing of protocols and latest developments in surveillance methodology.</li> <li>• Have access to the INoPSU administration for supportive work</li> <li>• Have opportunity to lead and co-author joint international publications</li> </ul>	<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• May submit abstracts for the INoPSU Scientific Meeting</li> <li>• May submit nominations for INoPSU membership, provided that such nominations include a current INoPSU full member as either Proposer or Secunder.</li> <li>• Have two representatives at the INoPSU business meeting in a non voting capacity</li> <li>• Are entitled to receive all the mailings from INoPSU, newsletters and annual reports.</li> <li>• Have opportunity for international collaboration and sharing of protocols and latest developments in surveillance methodology.</li> <li>• Have access to the INoPSU administration for supportive work</li> <li>• Have opportunity for collaborative international comparative joint publications</li> </ul>	<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• May submit abstracts for the INoPSU Scientific Meeting.</li> <li>• Are entitled to receive the INoPSU newsletters.</li> <li>• May attend the INoPSU business meeting in a non voting capacity</li> <li>• Access to INoPSU links to aid in collaborative research</li> <li>• Receipt of the INOPSU newsletter</li> </ul>
<p><b>Obligations and conditions:</b></p> <ul style="list-style-type: none"> <li>• Must actively participate in INoPSU by communicating with the secretariat and by contributing to annual reports, newsletters and the shared research database</li> <li>• Must strive to present surveillance results at the INoPSU bi-annual conference and to contribute to joint INoPSU publications.</li> <li>• Must pay an annual subscription as set by the INoPSU Executive*, to cover postal and administrative expenses (this may depend on the size of the unit and their ability to generate income).</li> </ul> <p>* €1,000 for 2011-12</p>	<p><b>Obligations and conditions:</b></p> <ul style="list-style-type: none"> <li>• Must actively participate in INoPSU by communicating with the secretariat and by contributing to annual reports and newsletters.</li> <li>• Must strive to attend the INoPSU bi-annual conference and contribute to joint INoPSU publications, as appropriate.</li> <li>• May not hold office.</li> <li>• Must pay a reduced annual subscription as set by INoPSU Executive*, to cover postal and administrative expenses.</li> <li>• Must apply for full membership the year following their acceptance as affiliate member</li> </ul> <p>* €500 for 2011-12</p>	<p><b>Obligations and conditions:</b></p> <ul style="list-style-type: none"> <li>• May not hold office.</li> <li>• May not vote in the business affairs of the INoPSU.</li> <li>• Must pay a minimal annual subscription as set by INoPSU Executive*, to cover postal and administrative expenses.</li> </ul> <p>€50 2011-12</p>

## 5. Termination of membership

### 5.1 Membership will cease:

- 5.11 If a member gives written notice of his/her intention to leave to the INoPSU Executive three months before the end of the current INoPSU financial year (refer 7.1).
- 5.12 If the membership fee for the following year is not paid by end of November of the current INoPSU financial year, the INoPSU membership shall cease by January 1st. Members, who were excluded because of non-payment of fees, will be reinstated after payment without having to go through re-election.
- 5.13 By expulsion, if such a proposal is approved by at least three-quarters of the Members present (assuming there is a quorum) at the BM. Such a proposal shall only be made if a member is no longer able to fulfil the mission of INoPSU or has been in breach of the obligations and conditions set out in this document for more than 2 years or has seriously contravened the interests of INoPSU. The respective member must be informed by the INoPSU co-Chairs in writing of the intended expulsion before any action is taken.
- 5.14 Full members who do not comply with their obligations as stated above will be demoted to Affiliate membership. Once demoted, they may be reinstated to Full Membership only after they demonstrate that they are able to meet all obligations of membership.

## 6. Mechanism

- 6.1 All existing national Paediatric Surveillance Units will be members of INoPSU
- 6.2 National PSU members will communicate electronically with face to face meetings to occurring biennially.
- 6.2 Each PSU with full membership privileges will nominate 2 people as voting representatives to sit on the INoPSU Executive committee
- 6.3 The Executive committee will be convened biennially at the business meeting
- 6.4 A nominated Chair will lead the Executive committee. This post will be tenable for 2 years though this may be extended with the agreement of 51% of the voting membership.
- 6.5 A Deputy will support the Chair. This post is tenable for 2 years with the expectation that the Deputy will take over as chair at the end of the 2 years.
- 6.6 The chair and deputy will be accepted following a ballot of the Executive committee. Nominations will be called for by the INoPSU Business Coordinator no less than 3 months before the biennial business meeting.
- 6.7 There will be a nominated INoPSU Business Coordinator who will be one of the scientific coordinators from one of the member national units. Term of office shall be for 3 years renewable on approval of the full Executive committee at an INoPSU biennial meeting or via e-mail. The National Unit Director, to which the INoPSU Business Coordinator belongs, must agree for their unit to become the INoPSU coordinating unit and to the following:
  - To support the Business Coordinator to fulfil their functions on behalf of INoPSU
  - Provide support to host the INoPSU web-site which will provide resources and facilities as agreed by the Executive Committee.
  - To facilitate separate and transparent financial management of INoPSU funds
  - To facilitate annual financial reporting to the Executive (see 7)

6.8 The chair, deputy and Business Coordinator will make up the secretariat of the Executive which will be responsible for ensuring that INoPSU is active, meets its aims, and that its terms of reference are adhered to.

6.9 The Web-site will include:

- contact details of the Units,
- summary protocols (titles, research questions, case definitions and investigator contact details only) of current, and past and anticipated surveys
- a bulletin board for shared discussions.

## **7 Financial accountability**

7.1 The INoPSU financial year will run from September to August

7.2 A budget will be prepared each year for approval by the chair and deputy and circulated to the Executive.

7.3 An end of year set of accounts will be produced showing a detailed breakdown of income and expenditure and circulated to the Executive

7.4 Membership contributions will be requested no later than November of each year

7.5 Contributions will be held as a restricted budget line within the coordinating national unit's accounting system and will not be consolidated into the coordinating unit's general funds

7.6 INoPSU will not accept contributions from industry such as pharmaceutical companies, unless such funds are contributed for the purpose of an Educational fund or trust.

## **8 Notice**

Members shall be given not less than three months notice of a meeting

## **9 Quorum**

Quorum for a meeting shall be not less than half of the voting members

03-03-2012