

**Charter of the International Network of Paediatric Surveillance Units (INoPSU)
Established in June 2000 (Amsterdam-Ottawa)
Charter revised August 2016 (Vancouver)**

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 2016, the Network consists of 11 national Paediatric Surveillance Units (PSUs) (Table 1).

Table 1 – INoPSU Membership as of 2011

Member Units	Affiliate Members
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 Paediatric Surveillance unit (CGPSU)	Belgium Paediatric Surveillance Unit (BePSU)
German Paediatric Surveillance Unit (ESPED)*	Scot PSU – need to contact them to see if they wish to affiliate
Irish Paediatric Surveillance Unit (IPSU)	
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 international framework for active case-finding for investigators who wish to study rare conditions in children if possible in more than one country such as, newly emerging 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 and surveillance themselves.

INoPSU members regularly contact each other for results, sharing of protocols, and putting researchers in touch with each other. Updated information of currently running and completed studies is posted on the INoPSU website.

Active surveillance

Each national PSU accepts applications to conduct surveillance studies 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. Some PSUs may charge investigators a fee covering a proportion of central costs to conduct a study through the surveillance unit.

Accepted study protocols are included on the report card after appropriate ethical approval is obtained where needed. This report card listing conditions being studied is sent every month from the PSU to all participating clinicians. Other specialists working in child health (e.g. paediatric/orthopaedic surgeons, 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 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 be 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. 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 and specific aims of the study, although some conditions of particular public health importance or conditions which are extremely rare may 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 case 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, where alternative sources of data exist.

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) by linking to 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 addressing issues such as differing disease awareness, diagnostic procedures, treatment policies a.o..
- 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 share and distribute information of educational benefit to newly forming PSUs notably on study and surveillance methodologies, statistical techniques, and publication.
- 3.6 To support and encourage evaluation of PSUs participating in INoPSU by developing and sharing models and methods of evaluating the performance and effectiveness of national PSUs.
- 3.7 To provide a forum for discussion of areas of concern relating to surveillance data validation, ethics and confidentiality.
- 3.8 To identify rare disorders of mutual interest and public health importance for co-operative surveillance through several PSUs.
- 3.9 To contribute to the development and clarification of internationally recognised diagnostic criteria for rare diseases, which will help standardise their identification.
- 3.10 To collaborate with and provide information to other groups interested in rare childhood diseases, such as parent support groups and policy-makers.
- 3.11 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.

4. Principle and Membership

- 4.1 National PSUs 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, affiliate and individual/associate members (Table 2).
- 4.2 **Nomination**
 - 4.2.1 Applications for full and affiliate membership will be received and assessed at any time by correspondence via email or a meeting whether face-to-face or via teleconference 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/affiliate membership is always possible, with ratification by the INoPSU chair/s in office.
 - 4.2.3 If a candidate member unit is not accepted, the responsible administrative sections of the INoPSU are not obliged to make public their reasons.

Table 2: Membership categories

<p>Full members will consist of:</p> <ul style="list-style-type: none"> • The founding units* • Those meeting the following agreed criteria: “A national unit undertaking active, clinician-based paediatric surveillance, possessing a scientific committee and contributing to the regular country activity report sent out by the secretariat. Other medical/surgical specialty (adult or paediatric) units using similar surveillance methodology and studying paediatric diseases. 	<p>Affiliate members will consist of:</p> <ul style="list-style-type: none"> • National Paediatric Associations/Societies or specialty groups that have a specific interest in rare diseases and INoPSU activities 	<p>Individual/Associate members will consist of:</p> <ul style="list-style-type: none"> • Individuals interested in understanding rare disease epidemiological surveillance • Individuals working in the area of rare disease either as researchers, clinicians, patients or caregivers • Patient support groups • Concerned not-for-profit organisations. • 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.
<p>Benefits:</p> <ul style="list-style-type: none"> • May submit abstracts for the INoPSU Scientific Meeting • May submit nominations for INoPSU membership • Have one representative at the INoPSU business meeting with the right to vote • Are entitled to receive all the 	<p>Benefits:</p> <ul style="list-style-type: none"> • May submit abstracts for the INoPSU Scientific Meeting • Are entitled to receive all the mailings from INoPSU, • Have opportunity for international collaboration and sharing of protocols and latest developments in 	<p>Benefits:</p> <ul style="list-style-type: none"> • May submit abstracts for the INoPSU Scientific Meeting. • Access to INoPSU links to aid in collaborative research

<p>mailings of INoPSU and have access and contribute to the shared research database.</p> <ul style="list-style-type: none"> • Have opportunity for international collaboration and sharing of protocols and latest developments in surveillance methodology. • Have access to the INoPSU administration for supportive work • Have opportunity to lead and co-author joint international publications 	<p>surveillance methodology.</p> <ul style="list-style-type: none"> • Have opportunity for collaborative international comparative joint publications 	
<p>Obligations and conditions:</p> <ul style="list-style-type: none"> • Must actively participate in INoPSU by communicating with the secretariat and by contributing to country activity reports, Website postings and the shared research database • Must participate at INoPSU business meetings and strive to present surveillance results at the INoPSU symposia and to contribute to joint INoPSU publications. • Must pay an annual subscription as set by the INoPSU Executive Committee <p>* €1,000 for 2016-18</p>	<p>Obligations and conditions:</p> <ul style="list-style-type: none"> • Must actively participate in INoPSU by communicating with the secretariat and by contributing to Website postings. • Must strive to attend the INoPSU conference and contribute to joint INoPSU publications, as appropriate. <ul style="list-style-type: none"> • May not hold office. • May not vote in the business affairs of the INoPSU. 	<p>Obligations and conditions:</p> <ul style="list-style-type: none"> • May not hold office. • May not vote in the business affairs of the INoPSU.

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 no later than 30th November of the current year
- 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 unless exceptional circumstances apply. 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 current Members at the Business Meeting. 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 or has seriously contravened the interests of INoPSU. The respective member must be informed by the INoPSU Chair in writing of the intended expulsion before any action is taken.

6. Mechanism

- 6.1 All existing national Paediatric Surveillance Units can be members of INoPSU
- 6.2 National PSU members will communicate electronically (email, teleconference, Skype etc) and in face to face meetings every 2 to 3 years.
- 6.2 Each PSU with full membership privileges will nominate a one person as voting representatives to sit on the INoPSU Executive committee
- 6.3 The Executive Committee will be convened every two to three years in conjunction with an international or national paediatric conference and hold its business meeting
- 6.4 A nominated Chair will lead the Executive Committee. This post will be tenable for 2 to 3 years. The term may be extended with the agreement of 51% of the voting members at a face-to-face business meeting or by e-mail, teleconference or other electronic means.
- 6.5 A Deputy will support the Chair. This post is tenable for a term in line with the chair i.e. 2 to 3 years with the expectation that the Deputy will take over as chair at the end of the term.
- 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 business meeting.
- 6.7 There will be a nominated INoPSU Business Coordinator who will be a member of the Executive board of a national unit. Term of office shall be for 2 to 3 years renewable on approval of the full Executive committee at an INoPSU business 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
 - 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 committee which will be responsible for ensuring that INoPSU is active, meets its aims, and that its terms of reference are adhered to.

7 Financial accountability

The INoPSU financial year will run from January 1st to December 31st.

- 7.2 A budget will be prepared each year for approval by the Chair and Deputy and circulated to the Executive committee by e-mail
- 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 committee by e-mail.
- 7.4 Membership contributions will be requested no later than February of each year, due April 31st.
- 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 Contributions will be used for the maintenance of the website and the fostering of the business meeting, or other activities or projects agreed by the Executive to be of direct benefit to the INoPSU.

- 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