



INGID NEWSLETTER

August 2006

This new INGID Newsletter contains a copy of the draft EU PID consensus statement that was agreed to by people who attended the EU conference in Frankfurt in June 2006. In addition do not forget the VII INGID Conference in Budapest, Hungary, which takes place from 4th. - 7th. October 2006 (further information can be found on the INGID website).

EU Consensus Conference

Earlier this year, a very important conference took place, in which members of ESID, INGID, IPOPI, and EFIS (European Federation of Immunology Societies) had the opportunity to put the case for the better diagnosis, treatment and care of people with Primary Immunodeficiencies (PIDs). The place where the conference was held was the Paul Ehrlich Institute in Langen, Frankfurt, Germany on the 19th. and 20th. of June, this year. Attendance at this conference was by invitation only, and hopefully it will have turned out to be a big step forward in the care of people with PIDs throughout Europe. A team of doctors, nurses, and patients from the 4 organisations mentioned above worked very hard to make sure that there were successful outcomes from this very important meeting. Representatives from the INGID Board who were invited to the conference were Dr. Ann Gardulf (Sweden), Amena Warner (UK), Dr. Peter Vickers (UK), and Nina Berger (Norway). In addition, Ann, Amena, and Peter were invited to give presentations examining the various issues around the theme of PIDs from the nurses' point of view. More information about these and other presentations can be found on the INGID website.

Before the consensus conference took place, a group had produced a draft consensus statement, and during the conference, all attendees were divided into 3 groups in order to discuss the statement and suggest changes to it.

There now follows a copy of the draft consensus statement that was agreed upon by the people who attended the EU consensus conference. The finalised document will be presented at the INGID/ESID/IPOPI meeting in Budapest in October of this year. As was stated in the IPOPI latest e-Update, the points made in the statement are not rocket science, rather they include simple, practical suggestions that are adaptable wherever you are in the world. If you want to know more about this statement, it will be available as a full report (on disc) at the Budapest meeting.



European Primary Immunodeficiencies Consensus Conference

19 – 20 June 2006
Paul-Ehrlich-Institut, Langen, Germany

DRAFT **EU PID CONSENSUS STATEMENT** **DRAFT**

Together, the attendees of this conference agreed on a Consensus Statement on PIDs with the intention of using this, as well as the conference's forthcoming recommendations and report, to:

- Communicate to EU governments the extent of the negative impact PIDs currently have on healthcare systems and undiagnosed patients.
- Demonstrate the disparities of care and treatment that exist for people with PIDs across the EU.
- Provide examples of immediate actions and initiatives that EU Member State governments can take to reduce the burden of PIDs.

The following Consensus Statement focuses on three key areas where priority action is needed:

1. Awareness and Education
2. Screening and Diagnosis
3. Treatment and Management

1. Awareness & Education - Consensus Statement

General public

- There is a lack of awareness of PIDs amongst the general public.
- There is misunderstanding of the impact of PIDs on schooling, work and social life of individual patients. This is especially important in terms of lack of avoidable loss of working days.
- The huge differences between PIDs and HIV/AIDS are not understood

- Lack of infectivity of PIDs is not appreciated and has to be presented at genetic even if multiple genes like diabetes.

Recommendations and tools needed - General Public

To increase awareness of PIDs, public health campaigns and educational programmes are needed; this is enabled by development, implementation and evaluation of:

- Updated, translated (for non-native speakers) and adjusted (for special groups) material used for the recognition of potential patients.
- Material suitable for primary school curricula, including books, leaflets, letters for parents and information for school nurses to distribute.
- Material suitable for public health campaigns world-wide; this might include:
 - a “Beat the bugs day for primary immune deficiencies” annually
 - hiring a public relations company to provide appropriate branding such as TV banner headlines for websites
 - standard advertisements (for ease of recognition) to be used (with translations) in all EU member states
- Inclusion of a PIDs story line in national TV soap-operas

Concentrating on:

- The difference between PIDs and HIV/AIDS
- Emphasising the lifelong nature of PIDs and their treatability.
- Infections: appreciation of the natural frequency of infections over a lifetime and how to recognise abnormal numbers / severity of infections
- Basic understanding of the mechanisms of immunisation, understanding the components involved and the implications of vaccine failure.

Strong patient groups can help to achieve this.

Healthcare professionals

- Due to a failure to include applied Immunology within professional training programmes, there is a lack of awareness of PIDs by:
- First line healthcare (family GPs, doctors, nurses, midwives) i.e. lack of awareness of symptoms

- Secondary healthcare (doctors in community and teaching hospitals) i.e. lack of understanding of availability and efficacy of treatments
- Allied professionals (physiotherapists, dieticians, genetics nurse specialists, pharmacists, psychologists, and dentists).

Recommendations and tools needed - Healthcare professionals

To increase awareness of PIDs, better education is needed; this is enabled by:

- Provision of standards for basic and applied immunology training in the core content for medical & nursing schools, with particular emphasis on PIDs,
- Coupling nurse education with protocols for vaccine failures and recognition of excessive numbers of infections,
- Integrating basic and applied immunology teaching, particularly alongside immunisation, into programmes for training fellows in general paediatric, internal medicine, rheumatology, respiratory medicine, and infectious disease,
- Distribute information used for education of all groups on accessible websites
- Enabling accrual of educational credits from shared material
- Reciprocation of information on PIDs, including guidelines and education, at professional meetings of related medical specialties.
- Including PIDs as a topic in continued professional development for related medical specialists in career posts, physiotherapists, nurses and midwives.

Healthcare policy makers and implementers

(These include:

**Healthcare policy makers and implementers at EU and national levels i.e. EU level: Institutions, Parliament, Member states, EMEA.*

**National level: regulators, legislators, national advisory bodies (such as NICE), Insurers.*

**World-wide level: WHO, pharmaceutical companies, vaccine manufacturers)*

- There is a lack of awareness of PIDs in healthcare policy makers, at national and EU level.
- There is a lack of information for immunisation campaigns for those individuals whom vaccine fail to protect
- There is a lack of awareness of PIDs in healthcare implementers i.e. managers, insurers and pharmaceutical companies (antibiotics, vaccines).

Recommendations and tools needed - Healthcare policy makers & implementers

To increase awareness of PIDs by:

- Studies on impact of diseases and therapy, coupled with epidemiology, public health impact and cost effectiveness studies to demonstrate savings and improvement in quality of life,
- Strong patient organisations in all EU countries, with identification of prominent patient advocates,
- Easily accessible information for health managers/insurers (e.g. leaflet)
- Regular publications from national registries

2. Screening & Diagnosis - Consensus Statement

PIDs are widely under diagnosed.

Early identification of PIDs will:

- Save lives,
- Improve health, quality of life, and lifespan in identified patients through adequate treatment,
- Enable genetic counselling and prenatal diagnosis within the family.

Tools for identification of PIDs are:

- Diagnostic guidelines for recognition of symptomatic patients,
- Appropriate immunologic and genetic laboratory tests,
- Screening tests for suitable diseases.

Recommendations and tools needed

I. Gathering information

Clinical protocols are needed to reliably identify PIDs; these can be created by development, implementation and evaluation of:

- Diagnostic guidelines on a scientific basis,
- Standardised diagnostic criteria for PIDs.

Assessment of the impact of PIDs on the community is needed; this is enabled by epidemiologic studies to assess:

- The prevalence and incidence of PIDs in the population,
- The impact of PIDs on public health,
- The impact of PIDs on health care costs.

International PID registries enable future diagnostic processes by identifying:

- The pattern of clinical presentation of these diseases,
- The natural history of the various PIDs (morbidity, mortality, complications),
- Relationships between clinical disease patterns and genetic backgrounds.

II. Appropriate diagnostic tools

Practical tools for efficient diagnosis of PIDs are needed in every country; this is enabled by availability of:

- Simple diagnostic tests at the local level,

- Immunologic tests in specialist diagnostic centres at the national level,
- Elaborate tests through networks of excellence across Europe.

Appropriate evaluation of diagnostic tools is needed; this is enabled by:

- Development of age-matched reference values for all diagnostic immunologic tests,
- Regular quality control of immunologic laboratories.

Research on the feasibility of screening programmes for PIDs is needed to prevent damage, including:

- Development of suitable tests,
- Assessment of costs and benefits,
- Evaluation of ethical aspects,
- Development of management guidelines for identified patients.

3. Treatment & Management - Consensus Statement

Effective therapies for PIDs exist.

Early treatment saves lives, prevents morbidity and improves quality of life.

Experts have reported that early treatment of PIDs is cost effective.

Treatment safety is a priority.

There is a significant disparity of care within and across EU Member States:

- There is a lack of specialised care in many countries,
- There are wide variations in the availability and funding of existing therapies,
- The availability of self treatment at home is inconsistent throughout the EU.

There are not enough trials for new therapeutic strategies.

Variation in methods in post marketing surveillance trials of products makes effective comparative analysis difficult.

Recommendations and tools needed

Develop and implement European guidelines that provide equal access to treatment within the EU, assuring a optimum standard and quality of patient care in the appropriate treatment setting.

Cross country initiatives should be developed to allow the exchange of expert experience and education in order to:

- Organise specialist nurse/midwife training courses in the EU,
- Fund medical & nurse specialists to visit other immunology centres,
- Educate related healthcare professionals.

EU treatment centre networks should be established to develop methods in order to determine disease outcomes through:

- Standardising clinical trials and post marketing surveillance,
- Using the online professional registry facility from ESID.

Adequate funding should be made available to provide:

- Optimum treatment and care in each EU Member State,
- Safe treatments,
- Support for the on-going development of the ESID registry.

Encourage and support the appropriate supply of treatment, specifically immunoglobulins, for PID patients requiring this life saving therapy.

The INGID Board/Peter Vickers (Editor)