# Randolph Concordat

## Purpose of the concordat

The purpose of the Randolph Concordat is to document an agreed set of purposes and principles to facilitate co-operation and collaborative working across and between national Obstetric Survey Systems. These terms are set out in a constitution for the International Network of Obstetric Survey Systems (INOSS).

# INOSS constitution

## Background and rationale

Many serious disorders in pregnancy are individually uncommon, but together represent a considerable burden to the women they affect and the health systems that care for them. Rare conditions of pregnancy are difficult to study and as a consequence they are under-researched, our understanding of them is poor and any interventions used in current clinical practice are rarely based on robust evidence. Routine sources of information are limited or unreliable,[1,2] and comprehensive studies of uncommon obstetric conditions, such as the BEST survey of eclampsia in 1992,[3] require a large collaboration to identify relatively small numbers of women. Additionally, requests for information from multiple sources about different uncommon disorders can place an unacceptable burden on reporting clinicians. A single, routine, reporting system avoids all these problems and has the benefit of allowing the range of conditions under study to change over time.

Many rare disorders may also be classified as ‘near-miss’ events. A ‘near-miss’ may be defined as "a severe life-threatening obstetric complication necessitating an urgent medical intervention in order to prevent likely death of the mother.“ [4] Maternal deaths have been studied in-depth in many countries using Confidential Enquiry methodology. Publication of the results from confidential enquiries have been key to identifying and introducing changes in clinical practice and health care systems that have led to a reduction in the numbers of maternal deaths. It has been recognised in recent UK maternal death confidential enquiry reports that additional study of ‘near-miss’ events may be useful for several reasons.[5,6] The process involves more rapid reporting and the number of cases studied is larger than when deaths alone are considered, hence the analysis results in more robust conclusions. It also allows the comparison of maternal deaths with near-misses and examination of the quality of care.[7] Further advantages include the identification of additional risk factors amenable to change, and the provision of information to improve service planning.[8]

Following the establishment of the UK Obstetric Surveillance System (UKOSS) in 2005 to study rare disorders in pregnancy, including near-miss events, this model was adopted in other countries. By 2009, with several national and regional systems actively collecting data, it seemed an opportune time to establish an international body to bring together the various national and regional Obstetric Survey Systems and, in 2010, to formally set in place an agreement for co-operative and collaborative working.

## Name

The name of the organisation is the 'International Network of Obstetric Survey Systems' referred to herein as INOSS.

## Mission statement

The mission of INOSS is to improve the care given to women, their babies and their families, by advancing knowledge and contributing to the evidence base about serious, rare disorders in pregnancy including near-miss events, through international co-operation and collaborative working.

## Aims

The mission of INOSS will be achieved through working towards the following aims:

1. To promote co-operation and collaboration across and between existing population-based Obstetric Survey Systems.

2. To support the development of new population-based Obstetric Survey Systems.

3. To share information about on-going and completed surveys, including protocol details, case definitions, study methodologies, analytical approaches and outcomes.

4. To encourage the development of shared study protocols to enable the harmonisation of the case definitions used and the variables collected, and thus enable pooling of data, particularly for the rarest disorders in pregnancy. Thereby enabling cross-national comparisons of incidence, aetiology, management, prevention and outcomes.

5. To conduct contemporaneous collaborative studies across different Survey Systems.

6. Where requested, to support the evaluation of existing and proposed Survey Systems.

7. To discuss issues of common interest including case definitions, data validation, methodology, ethics, data protection, patient confidentiality and the publication of results involving small numbers.

8. To support continued enhancement and harmonisation of the performance of Obstetric Survey Systems.

9. To seek to provide evidence to enable prevention where possible, manage better, and improve outcomes and thereby contribute to improvements in patient safety and the quality of care provided to women with serious, rare disorders in pregnancy.

10. Through dissemination of findings, advocate for best care for mothers and for funding for research into serious, rare disorders in pregnancy.

11. To seek funding to support INOSS to ensure the long-term sustainability of INOSS.

## Principles and membership

1. National and regional Survey Systems will be members of INOSS whilst at the same time remaining independent and responsive to their own national survey requirements.

2. INOSS will consist of national and regional ‘Obstetric Survey System Members’ and ‘Other Members’.

Obstetric Survey System (OSS) Members will consist of:

a. Obstetric Survey Systems meeting the following criteria:
    i. A national or regional population-based Obstetric Survey System actively undertaking national or regional surveys of serious, rare disorders in pregnancy.
    ii. Overseen by an appropriate committee structure ensuring scientific excellence.
    iii. Producing regular reports, preferably on an annual basis.
b. Obstetric Survey Systems that cease active data collection will move to become Other Members.

Other Members will consist of:

a. Organisations preparing to, or in the early stages of setting up, national or regional population-based Obstetric Survey Systems that have yet to meet the criteria to become an OSS Member.
b. Organisations undertaking national or regional population-based studies of serious, rare obstetric disorders using an alternative framework to an Obstetric Survey System.
c. OSS Members whose survey system has become inactive but wish to remain involved in INOSS.
d. Other international organisations working in the area of rare obstetric disorders, or related rare conditions, eg. the European organisation for Rare Diseases, the North American Organisation for Rare Diseases.
e. Other medical specialties using similar survey systems.
f. Other relevant concerned bodies.

## Operational arrangements

INOSS will function primarily as a virtual network:

1. Six monthly teleconferences involving all INOSS members will be the primary means of conducting meetings. Additional *ad hoc* meetings will be held as required.

2. Annual face-to-face meetings will be held.

3. Between-meeting communications will be via a shared email list.

4. Each Survey System will nominate an INOSS link person whose details including email address will be included on the publically accessible part of the INOSS website.

5. An INOSS website will be established that will have public and private areas and will include:

    a. Contact details of all INOSS members (OSS and Other).
    b. Links to individual INOSS member Survey System websites and other key organisations.
    c. Protocols of collaborative studies.
    d. A private area for use by members for the inclusion of meeting minutes, protocols under development and other non-public documents.

6. There will be a 3-5 person Network Secretariat representing different INOSS members that will be responsible for ensuring that INOSS is active and meeting its aims. The Network Secretariat will consist of no more than four ‘OSS’ members and one ‘Other’ member. Secretariat members will be identified by self-nomination; voting will take place only in the event that there are more nominations than vacancies. Secretariat members will serve for no more than 5 years. A Chair will be elected from amongst the members of the secretariat to serve for no more than 3 years.

7. Application to become an ‘OSS’ Member or ‘Other’ Member will be by letter to the Chair of the Network Secretariat that should outline how the Survey System meets the criteria for membership. Applications for membership may also be by invitation. Applications will be discussed at the next INOSS teleconference following receipt.

8. Members of INOSS and the Secretariat will be self-funding until such time as funding to support INOSS is obtained.

## Founding members of INOSS present at the inaugural meeting at the Randolph Hotel, Oxford in July 2010

Australasian (Australia & New Zealand) Maternity Outcomes Surveillance System (AMOSS)
Austrian Obstetric Surveillance System (AuOSS)
ULB, Belgium
Inserm Unit 953, France
German Obstetric Surveillance System (GerOSS)
Nordic Obstetric Surveillance System (NOSS)
Portuguese Obstetric Surveillance System (POSS)
The Netherlands (LEMMoN study)
UK Obstetric Surveillance System (UKOSS)

## Review arrangements for the constitution

To ensure that the constitution remains fit for purpose it will be reviewed by members on a three yearly basis.

## Review date

July 2013

**8th July 2010,**
**Randolph Hotel,**
**Oxford**

## Acknowledgements

In drafting the INOSS constitution we were grateful for the experience of those who have gone before us; we drew on the documentation of the British Isles Network of Congenital Anomalies Registers (BINOCAR)[9], the European Surveillance of Congenital Anomalies (EUROCAT)[10] and the International Network of Paediatric Surveillance Units (INoPSU).[11]

## References

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[2] Ch'ng CL, Morgan M, Hainsworth I, Kingham J. Prospective study of liver dysfunction in pregnancy in Southwest Wales. Gut 2002; 51:876-80.

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[4] Filippi V, Ronsmans C, Gandaho T, Graham W, Alihonou E, Santos P. Women's reports of severe (near-miss) obstetric complications in Benin. Stud Fam Plann 2000; 31(4):309-24.

[5] Confidential Enquiry into Maternal Deaths. Why women die 1997-99. London: RCOG, 2001.

[6] Confidential Enquiry into Maternal and Child Health. Why women die 2000-2002. London: RCOG, 2004.

[7] Brace V, Penney G, Hall M. Quantifying severe maternal morbidity: a Scottish population study. BJOG 2004; 111(5):481-4.

[8] Pattinson RC, Hall M. Near misses: a useful adjunct to maternal death enquiries. Br Med Bull 2003; 67:231-43.

[9] British Isles Network of Congenital Anomalies Register (BINOCAR) at: http://www.binocar.org/

[10] European Surveillance of Congenital Anomalies (EUROCAT) at: http://www.eurocat-network.eu/

[11] International Network of Paediatric Surveillance Units (INoPSU). Amsterdam-Ottawa Note. Available at: http://www.inopsu.com/