



**First Global Consultative Meeting
for the BIG V&S Project
(Bologna Initiative for Global
Vigilance and Surveillance)**

5-6 July 2011, Geneva

Draft Report

Introductory Note from the Secretariat

This consultation was made possible thanks to the generous support of the Centro Nazionale Trapianti, CNT, the Italian National Transplantation Centre, to WHO's activities in the area of vigilance and surveillance for transplantation.

This publication reports on the deliberations and outcomes of the First Global Consultative Meeting for the Bologna Initiative for Global Vigilance and Surveillance (BIG V&S) Project, held in Geneva from 5 to 6 July 2011. This meeting initiated a consultative process to advise on WHO's work for vigilance and surveillance of cells, tissues and organs for transplantation according to the requirements of World Health Assembly Resolution WHA63.22 on Human Organ and Tissue Transplantation adopted in May 2010.

The consultation was prepared with the invaluable help of the CNT team in particular Deirdre Fehily, Daniela Minutoli and Stratos Chatzixiros, and with the effective contribution of Mike Strong.

This report represents the views of the participants, not necessarily those of WHO. All the participants in the consultation should be thanked for their active participation and their will to achieve consensus. The Secretariat owes special thanks to the Chairmen of the meeting, Alessandro Nanni-Costa followed by Rajesh Srivastava and to the two very efficient Rapporteurs, Marian Macsai and Bronwen Shaw.

The report was submitted to all participants for comment. We are grateful to them for their input. Any error or omissions are, of course, our responsibility, not theirs.

Luc Noël, Coordinator Clinical Procedures
HIS/HPW

Executive summary

This report summarises the discussion and outcomes of the first meeting of the Bologna Initiative for Global Vigilance and Surveillance (BIG V&S) in Geneva in July 2011. This initiative followed the highly successful project NOTIFY meeting in Bologna in February 2011.

The objectives of this meeting were to bring together a global group of experts in V&S from diverse backgrounds (including agencies, professional societies and individuals with specific skills or experience in the area) to further the aims of implementing the World Health Assembly Resolution WHA63.22, in relation to vigilance, and to finalise the outputs of the Bologna meeting.

There had been significant progress since Bologna, in particular in the development of a new public website (www.notifylibrary.org) documenting reactions and events, together with associated references, in a searchable database. It was recognised at the meeting that some work was required to complete this website before it goes live. In particular there is a need for harmonisation of the formatting of the current events/reactions in the database and for editing the text relating to alerting signals and confirmation of imputability. Other outputs included an update on the didactic documents from the Bologna working groups, which are shortly to be published. An area of discussion focussed on the production, by this group, of a booklet for clinicians raising awareness about their roles and responsibilities in V&S. The balance is to provide a resource that is easily accessible, multi-media and practical, but contains sufficient information to be of use. These discussions are ongoing.

Several resolutions were achieved by the close of the meeting. There was a fruitful discussion around the ongoing maintenance and governance structures for the NOTIFY library going forward. The group agreed in principle that several editorial working groups, covering all the tissue and cell types, would be created to curate and review the addition of new cases. A governance group would have broad representation and a remit to invite experts to do the editorial work according to defined criteria. The Italian National Transplant Centre will host the website and database on behalf of WHO through a collaborative agreement. The group felt strongly that the WHO should own this project as the global oversight and strengths of the WHO add enormous value and ensure the trust of the public and users in this resource.

Introduction

Participants were welcomed by Dr Luc Noel, Coordinator, Clinical Procedures, Essential Health Technologies, Health Systems and Services, World Health Organization.

Participants introduced themselves. There was broad global and professional and Health Authority representation. The full list of participants is shown at Annex 1.

The proposed Programme of Work was approved by the participants and is shown at Annex 2. Dr Alessandro Nanni Costa (CNT, Italy) was elected Chairman for day one and R.K. Srivastava (New Delhi, India) for day two. Dr Marian Macsai (EBAA, USA) and Dr Bronwen Shaw (WMDA, UK) were elected Rapporteurs.

The BIG V&S project: objectives of the first consultation

Luc Noel

Dr Noel welcomed all to the meeting and reminded participants that the meeting in Bologna had brought together an international group of individuals, agencies and professional societies who are interested in V&S, and in implementing the principles outlined in World Health Assembly Resolution WHA63.22.

He stressed the concepts of International Best Practices and the need for global collaboration in collecting, analysing and sharing knowledge about adverse events and reactions; the use of globally consistent coding systems; systems for traceability and the need for improving member states' (and the public's) access to appropriate information about adverse events and reactions.

V&S is a safeguard of transparency across the entire donation and transplantation process, protecting patients from what does go wrong as well as what can go wrong. Health authorities are in a position to preserve the system, however collaboration with all stakeholders is necessary to ensure safety and maintain public trust. Negative media attention about even a single transplant can influence the public's perception of safety.

In addition, V&S is about avoiding crisis, deserving trust and demonstrating community solidarity in order to meet patients' needs. V&S is the end result, as well as the process and serves as an ethical safeguard and a vector for progress.

A global community providing a V&S network supported by the WHO is desirable as identified during the Bologna meeting. This should involve all regions of WHO at all levels of development. The role of this network includes: information sharing, training, guidance for national organizations, structured collaborations between WHO and key institutions or organisations, and collaborations with other V&S schemes especially for Medical Products of Human Origin (MPOHO) Tools to support this network are being developed by this group and include: The NOTIFY Booklet, The NOTIFY website, The NOTIFY Library database and guidance documents, as well as an ongoing exchange of information and annual global consultations. These principles

are all in line with WHO reform and WHO Core Functions (11th General Programme of Work, 2006 to 2015).

Progress of the outcomes from Bologna

Dr Deirdre Fehily

Project NOTIFY began with the pre-Bologna Google website shared working space, continued at the Bologna meeting and is ongoing as BIG V&S.

The Google Site/Bologna meeting

This brought together 102 people from 25 countries, representing amongst others: Governmental organisations – both regulatory and non regulatory (WHO, European Commission, FDA, CDC, TGA, HTA, FHEA, AFSSAPS, ABM, CNT, ONT, PHAC, DMA, IMB, KFDA, PHA); Professional Societies (TTS, AABB, AATB, EATB, ESHRE, EEBA, EBAA, EBMT, WMDA, SICOT); National and international non-governmental organisations (NMDP, UNOS, Eurotransplant, Donor Action) and European projects (Efretos, SOHO V&S).

Working groups 1-5 gathered documented cases (with references) of adverse reactions and events associated with organ, tissue or cell application (Organs, Corneas, Other tissue, haematopoietic progenitor cells (HPC), Gametes and Embryos) in humans. They attempted to define the triggers that alerted clinicians to the event or reaction and the procedures followed to clarify imputability.

Working groups 6-10 used the references gathered by groups 1-5 and produced ‘master documents’ concerned with infection, malignancy, product characteristics/handling, clinical errors (which have since been merged), genetics and donor reactions. Together these groups gathered approximately 1500 references which have since been incorporated into an endnote library. Ultimately the Google site will be discontinued and will be replaced by a public website hosting the searchable database.

116 attendees from 36 countries attended the Bologna meeting where the content of the work on the Google site was discussed and appraised.

Outputs:

- A new public website with all of the reaction and event cases, together with associated references, in a searchable database
- 4 didactic documents from the working groups are in draft form (later divided into 5 documents with the separation of genetic transmissions from donor reactions)
- Frances Delaney (and support rapporteurs) have written a report of the Bologna meeting
- The meeting report and didactic documents will be available on the NOTIFY website and will be published as a special supplement to the journal Organs, Tissues and Cells in the Autumn.

Booklet for advocacy / awareness / guidance

Mike Strong

One of the key outputs recommended following the Bologna meeting was a booklet providing V&S guidance for clinicians (“Vigilance and surveillance of human cells, tissues and organs for transplantation: Your responsibility for your patients and the community”). Dr Michael Strong presented the progress on this front. He briefly outlined the structure and content of the booklet.

A. Introduction

B. Substances of Human Origin (SOHO)

1. Health products of an exceptional nature
2. Donation and ethics
3. Risks of Progenitor Cell, Tissue and Living Organ Donation
 - a) Haematopoietic Progenitor Cell Donation
 - 1) Recommendations
 - b) Autograft Tissue Donors
 - c) Living Organ Donor Reactions
 - 1) Recommendations
4. SOHOs and the risks for recipients
5. Traceability the absolute pre-requisite

C. Vigilance and Surveillance (V&S)

1. History of V&S for health products
2. International guidance
3. A safeguard, a damage limitation system
 - a) Early notification, timely reaction
4. A necessity for the public, a responsibility for authorities
5. An evolving understanding of V&S
 - a) Infection threat watch
 - b) Transmissible disease screening for donor suitability
 - c) Product Centered
 - d) Ethical breaches, fraudulent/illegal practices
 - e) Definitions
6. Organization for a comprehensive V&S
 - a) Quality Management
 - b) Post-marketing and Clinical practice surveillance
 - c) Integration
 - 1) For the various risks associated with a given product
 - 2) For SOHOs
7. Key Factors for an Effective National Vigilance and Surveillance Scheme

D. What has V&S taught us

- a) Per Allograft
- b) Per type
- c) The notify database as a reference for unusual donor suitability questions

E. The risk/benefit Calculation: Number, Denominators and transparency

F. Investigating reactions and events

1. Infections
 - a) The Graft Recipient and the Presentation of Allograft-Associated Infections
 - b) Recommendations
2. Malignancy
 - a) Donor malignancies known to be transmitted or known not to be

transmitted by cancer, organ and cell type

- 1) Diagnosis
- 2) Biological behaviour of the tumor
- 3) Tumor therapy performed/ current follow up
- b) Providing guidance on early detection and prevention of transmission
 - 1) Providing guidance on immediate steps to take for index recipient and other potentially affected recipients
 - a) Tracing, alerting and notification
 - b) Graft removal and cessation of immunosuppression
 - c) Immunotherapy
 - d) Conventional treatment strategies based upon cancer type if organ, tissue or cell cannot be removed
 - 2) Providing guidance on steps to investigate and confirm the imputability of disease transmission
 - a) Suspected transmission malignancy
 - b) Traceability from donor to recipients, alerting and assessing
 - c) Tumor histology in donor and recipients
 - d) Karotype of donor and recipient
 - e) Genetic testing of sample from cancer, eg HLA testing
3. Genetic Transmissions – HPC
 - a) Recommendations
4. Organs, tissues and Cells: characteristics, handling and clinical errors

G. Reporting

1. Governments
2. Professional Associations and Societies

H. Conclusion

Discussion:

- Length of booklet/Target audience: One challenge is to produce a booklet which contains all the critical information (is not “dangerous” due to lack of detail) but is short enough to be read by the target audience. The outputs of the Bologna meeting ran over 600 pages, which is difficult/impossible to reproduce in a booklet of 40 pages. Clinicians are very unlikely to read a long document. Countries with different levels of experience may have different requirements.
- Content: The target audience determines the content. Regulators may require only a ‘framework’ while clinicians will need detail. One of the benefits of this document is bringing together products which are not usually combined (providing commonality of approach). Outside of the ‘framework’ a living document is required, so as to prevent becoming out of date/unsafe. An example of a similar system is Up to Date (www.uptodate.com). Responsibility for ‘maintaining’ the living document needs to be determined. Some content on autologous donation is required.

- Method of dissemination: The booklet may need to be produced as more than one product. For example, for a national authority this booklet may be used for the development of a system, or as a training reference manual. This could then be customized to meet their needs. To reach the clinician (especially trainees) it should be available in multiple formats: a searchable website, PDA technology or other digitally based product. In these formats the booklet could be used as a source to link the reader to areas of more in depth analysis. Dissemination may occur through professional societies (websites) and/or training programs. An e-learning tool for CME could be developed. It should be easy to find (high on the Google search list, highlighted on relevant websites). Signposting both from and to the booklet is critical.

Progress of the Bologna outcomes 2: Didactic documents, publications and project

A more comprehensive summary is provided in the report from the Bologna meeting (link to Notify Report on WHO website).

6. Infections

Mike Ison

The document was produced by a group of experts, divided by pathogen type. There was very broad global representation. The goal was to provide a written discussion of findings detailed in the references and to cover all tissue types. Key focus areas are epidemiology & risk factors, testing & disease mitigation and an explanation of the limitation of existing data. Data analysis included: which tissue types were associated with transmissions, number of transmissions by category (proven, probable, possible, unlikely, intervention without documented transmission (IWDT), excluded, or not assessable), modulating factors (i.e. pathogen inactivation, immune suppression), time of onset relative to implantation, presentation of transmission (i.e. symptoms), diagnostic testing. The written document includes: key clinical features, donor screening, donors at increased risk of infectious transmission, presence of documented pre-procurement infection, assay window period and the logistics of donor laboratory testing.

Discussion:

- The scope of the document was discussed and it was noted that it would be informative if transmissions by blood were also covered although it is currently outside the scope of the Notify initiative.
- Situations that raise concerns (e.g. abnormalities of the cerebro-spinal fluid) should be discussed.
- Due to the rapid timescale of organ/donor acceptance screening is difficult, but perhaps the document should address those tests which can/should be done in a short time.
- If the infection is treatable in the patient the organ should not usually be turned down.

7. Malignancy

Rosario Marazuela

The objectives of this group were:

1. To list donor malignancies known to be transmitted or known not to be transmitted by tissue, organ and cell type
2. To provide guidance on early detection and prevention of transmission
3. To provide guidance on immediate steps to take for index recipient and other potentially affected recipients
4. To provide guidance on steps to investigate and confirm the attributability of disease transmission

Publications in English describing original reports of transmissions were included. The original author's clinical terminology was retained. The final worksheet included: risk transmission (estimates), donor & cause of death (if deceased), clinical & laboratory findings, time sequence, transmission, neoplasia (if known), other recipients, attributability, last follow up. Risk assessment included: Pre transplantation (from knowledge of the donors: a theoretical risk), post transplantation (donor malignancy discovered: cells have been transplanted but there is no disease yet in the recipient), post transplant (malignancy in the recipient: is it donor derived, donor transmitted or neither). Transmission risk, potential transmissions, donor transmitted and donor derived malignancies are defined. The importance of alerting of all teams and tracing the tissues from the donor, in order to notify all other recipients or to assess the risk of remaining (non-transplanted) products is discussed.

Discussion:

- The impact of ongoing immunosuppression in the recipient on donor derived/transmitted malignancies was highlighted.

8/9. Characteristics, handling and clinical errors Scott Brubaker /Axel Rahmel

Overall each cell, tissue or organ (HCTO) allograft intended for transplantation, implantation, infusion or transfer has specific quality attributes and characteristics determined by anatomy and usual function. Handling activities that support the maintenance of desired efficacy or utility of the organ, tissue or cells can affect clinical outcome. When a gap exists or a step or process fails, a serious adverse event (SAE) or a serious adverse reaction (SAR) can occur.

The systems require control at multiple steps (from consent through use) including consent/authorization; donor screening, donor/tissue testing, and test kits/methods; recovery, procurement or collection; preservation/processing (qualification of materials, reagents, equipment and facilities as well as maintenance, where applicable, and validation of processes that incorporate process controls and/or verification of steps); storage, transport and distribution; selection for use and allocation (where applicable); preparation for use (or other final disposition); qualified personnel with sufficient training who are deemed competent; and documentation and maintenance of records for all the above. Failures fall into three broad categories: equipment, process and human error. Specific examples of errors for each product type are given. Many aspects differ according to product type (e.g. no storage/banking for organs).

This document considered living and cadaveric donors as well as autologous donors. The document did not consider failures that resulted in transmission of disease. The importance of donor records was stressed, particularly as there may be a long time lapse between the event and the original error. The issue of who reports the failures

was addressed, but not easily defined. Lack of information/uniformity and education of Clinician remains a problem. The importance of root cause analysis was stressed. The importance of recognising incidents that might be an indicator for a systematic error / underlying pattern was stressed.

Discussion:

- Clinical side effects (e.g. graft versus host disease) should be removed from the document. It is the processing error (e.g. mislabelling) which should be reported and in this context the clinical consequence is irrelevant.
- Errors in testing due to hemodilution or other iatrogenic factors should be included within the calculated risk.
- Organs recovered but not used should be reported.

10. Genetics and Donor

Bronwen Shaw/Deirdre Fehily/Axel Rahmel

This document was prepared in three parts: HPC, living organ donors and ART.

HPC: the document was based on the literature review, existing reports through the global WMDA Serious (product) adverse events and reactions registry and personal communications. Recommendations are made for categorising SAE/R by time (early: initiation of donation to day 30 post donation and late: malignancy and auto-immune only) and donation type (peripheral blood stem cells versus bone marrow donation). The importance of a global minimum data set is stressed. Each event reaction type is described further by: frequency, seriousness, sentinel events, prevention, treatment, references. Since Bologna the WMDA has adopted the common terminology agreed at that meeting and formed of an expert group to review and assign imputability to all SAE/R. The need for similar structures in related donors is mentioned.

Living Organ Donors: The high impact on public confidence due to (unsubstantiated/unexplained) negative press reports was raised. There is limited knowledge on long term effects in living organ and HPC donors, due to a lack of structured reporting and more importantly a lack of structured (long-term) follow up of the donors. There is thus an urgent need for a registry, linked at supranational level and screened and evaluated by supranational panel of experts. Data collection (short and long term) should be mandatory (independent of recipient outcome). Links with Efretos are stressed.

ART: the two main categories are Ovarian Hyperstimulation Syndrome associated with oocyte collection and genetic transmissions by sperm donation. Fatal or life-threatening events should be reported. The transmission of genetic conditions by gamete donation should be reported, vigilance can be crucial in stopping the further distribution of implicated sperm. There is a need to educate the parents, the pediatrician and neonates, the donors (if later diagnosed with a condition) and genetic specialists about the potential that a pregnancy/child may have been born as a result of ART.

Discussion:

- The issue of collecting data on all donors in order to identify the long term issues affecting both health and other aspects of life (such as loss of work for

the surgery, loss of health insurance, other types of discrimination) e.g. chronic fatigue following renal donation, was discussed.

- The cost of following all donors is substantial and the funding streams need to be considered/identified.
- A 'registry of registries' model was discussed.
- Donor advocates are desirable, but there is no good data/evidence or registry to base advice on.
- Self reporting was highlighted particularly with regards to genetic transmissions. Parents may not divulge that the pregnancy/child is a product of ART especially as medical tourism is common.

Overall discussion/ issues raised (WG 6-10):

- It was noted that a varied approach was used by each of working groups 6-10 and therefore the resulting documents do not exactly resemble each other. Standardization is important.
- Definitions were not completely harmonised between documents (e.g. imputability for infections and malignancies).
- Working groups 6 and 7 focused predominantly on organs. Tissues and cells should be added.
- Document 10 contained quite different topics (HPC, ART, living organ donors) and should perhaps be separated.
- The scope of the project was discussed: is the intention to provide a global repository of adverse events and reactions or advice/guidelines on issues such as donor screening/ mandatory testing/ donor selection? It was confirmed that the aim to provide access to information regarding events and reactions, their detection and confirmation.
- The literature is not comprehensive and thus absolute risk cannot be estimated. In addition, publications take a long time and thus knowledge based only on published literature is always somewhat out of date.
- The denominator is frequently unknown (i.e. the level of risk of transmission is hard to calculate as often only positive transmissions are recorded, but not infections/malignancies which are not transmitted).
- A control group is missing (e.g. people who have been fully assessed as fit to donate but not gone ahead).
- The decision to accept or reject a tissue/organ is often made on a personal basis by the attending clinician based on personal experience, but often without (published) evidence based decisions or guidelines.
- Acceptable risk varies by product type. Donor eligibility is not standardised.
- Whether 'expected' events or reactions should be reported was discussed.
- The importance of linking to/combining with existing strategies or guidelines (e.g. Efretos/WMDA) is recognised.
- The question of quality indicator monitoring versus V&S was discussed.

The BIG V&S website**Deirdre Fehily/Daniela Minutoli/ Stratos Chatziros**

This will be a free website, for public access; it is currently restricted to participating collaborators while under development. It is intended as a resource/tool and not for guidance/regulatory purposes. It contains files (WHA resolutions and guiding documents), background documents (e.g. EUSTITE, EFRETOS) and the outputs of the Bologna meeting (didactic documents, booklet). There are ‘help’ tools such as a guide to searching the website, lists of V&S partners, a ‘contact us’ key and a ‘links’ section. The NOTIFY LIBRARY is the entry point to the bibliography and database which was prepared for Bologna. Going forward required strategies for adding new information either automated, manual or both with the intention to identify new types of events/reactions, new substances and new information about signals.

The references, gathered for the Bologna meeting, have been saved into an endnote library. The interpretive material contained on the worksheets is being tidied up. Several discrepancies between worksheets have been found and the free text used is very difficult to search. Common structures to make the database searchable and user friendly are required. Issues which need to be resolved include: terminology, content, duplication of records and categorization. The CNT office proposed search strategies and database organisation to achieve this.

Discussion/issues raised:

- Clarify about website organisation:
 - Should the website have (sponsoring) partners and how does an organization become a partner? Are all members listed and does this include email addresses?
 - Contact us - Who is being contacted, and what is the contact about – content of the website/links or background?
 - The Booklet should be linked to appropriate parts of the website to increase the readership
 - Signposting to all relevant partners is critical
 - A glossary of terms is useful
- Clarity about website content:
 - The website should add value over a simple Pubmed search – the expert opinions fulfil this (supported or unsupported by published literature), as does a simple (non prescriptive) search tool.
 - It was stressed that the website may contain three levels of information: 1. Peer reviewed, 2. “grey Literature” data from experts: e.g. The OARSS (online adverse event reporting system of the EBAA), Health authorities, MMWR and 3. ‘Noise’ or just anecdotal reports. Criteria to review and separate these reports are needed. The anecdotal reports should be restricted to a forums area of the site.
 - Strategies to clearly indicate what is peer-reviewed literature and what is unpublished reports from organisations and societies are needed
 - Standardization of the terminology will help with harmonization, such as “biologic failure” or HPC(A)
 - Free text should be avoided in the spreadsheets, as this is very difficult to search. More standardization will help. Key words are important.
 - Preconceived notions in the search terms should be avoided and techniques to enable broad searches should be added to allow flexibility

- There was recognition that often Serious Adverse Events don't get published (and for reactions there is often a significant lag time). This site would help to recognise and highlight these earlier and potentially allow corrective actions. There may be a quality control aspect to this and responsibility for this should be defined.
- Clarity about website function:
 - It was agreed that a guidance document is needed to explain processes such as: investigation of a transmission, strategy for entering new cases and how they are reviewed
 - One function of the site is to be a source to see if this SAR/E has happened before.
 - Disclaimers and commentary should be posted (ownership of the site, liability, function of the site)
- It was agreed that there was an absolute requirement for review and reorganization of the documents from groups 1-10 before the website goes live. The website should be absolutely ready to ensure that users are immediately impressed with its usefulness.

Round table discussions

a. Group 1: Library

The need to 'clean up' the existing spreadsheets in the notify library was recognised as each group prepared the documents in slightly different ways.

- The 9 groups need to identify one (or more) individual to review the references and revise according to the agreed criteria
- Each reaction/event should be categorised according to the following headings: reaction (patient has been harmed) or event (no patient is harmed), product type, incident type, signs and symptoms, latency, demonstration of imputability (include the definitions of imputability), references, comments
- Drop down boxes and limitations on free text may help to harmonise the spreadsheets

b. Group 2: Editorial Groups

There was a proposal for 5 editorial groups: infections, malignancy, process, genetic, and donor. The function of each group is to:

- Accept cases
 - Only cases of adverse outcomes or risk of adverse outcomes associated with transplantation, transfer or infusion of SOHO
 - Each group will define acceptance criteria
 - Reject cases with reason
- Analyze the incoming cases and categorise them according to substance type, reaction/event type etc., including information regarding latency, alerting signals etc.

Each group will define the criteria for SAE/SAR in their area, define the format for submission, screen for duplicate submissions, manage workflow (define literature search strategy, define data flow of unpublished data) and protect privacy.

Membership of the Editorial groups should include:

- Representation of tissue types (Organ, Tissue, HSCT, ART, Cornea, Other)
2 Co-Chairs (Chair elect, Chair, Past Chair)
5 Members (including chairs)
- The membership should reflect varied expertise (donation/processing, transplantor/end users, regulatory) and be global in representation

The communication structure will be via website space, recorded conversations, conference calls and face-to-face meetings.

c. Group 3: Governance

The Project Notify Library is a source of information on a website with editorial groups and a secretariat accountable to an annual WHO global consultation, with the following tasks and representation.

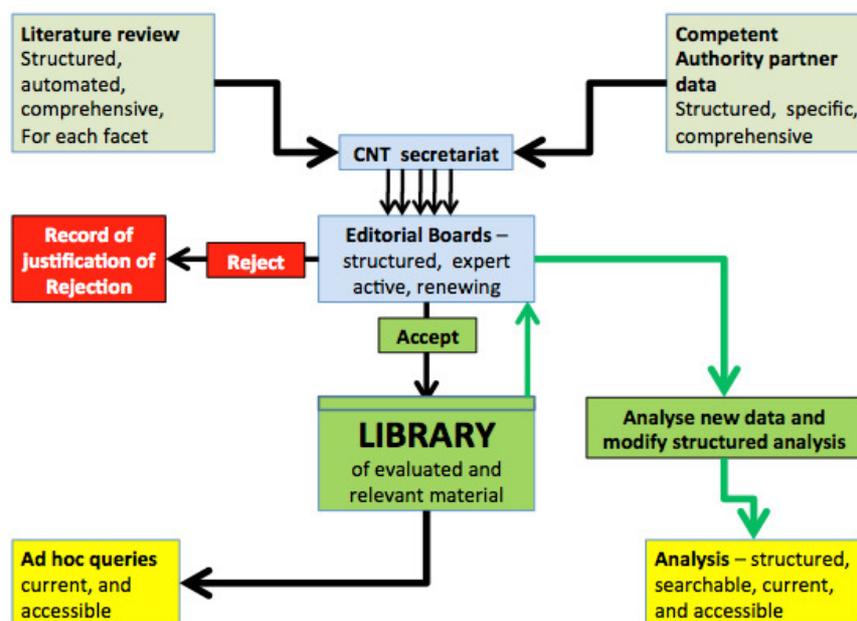
- Tasks: To ensure that the mission of the Notify Library is fulfilled
 - Develop policy, review and/or initiate protocols and procedures as appropriate
 - Approve the composition of the editorial groups in terms of principles (independence, geographical, composition, expertise)
 - Nominate the editorial group members
 - Determine criteria for ‘approval’ of partners for the submission of unpublished information to the site
 - Define who has access to the data
- Representation
 - Editorial working groups
 - Organizations providing information to the site will be invited to the annual consultation
 - Established sources of V&S information (e.g. Health Authorities)
 - Global or Regional scientific and professional societies with established databases of V&S information
 - The consultation will also ensure a representation of relevant national and international health authorities as well as individual experts from Member States from all regions of WHO

Discussion:

Issues were raised around the need for a leadership structure and an executive body (due to the size of the board).

Notify vision

Jeremy Chapman



Discussion:

- The Notify library is not intended to be a reporting system and should not replace reporting to regulatory authorities. It is a library of documented information
- It highlights the importance of data sharing and bringing people with diverse interests together
- A possibility that this system could be used to release urgent notifications to the relevant communities was rejected by the group, as outside the purview.

Summary: the NOTIFY LIBRARY

Luc Noel

- Participants confirmed that the work carried out in preparation of and during the Bologna meeting showed that a reviewed comprehensive source on reported types of adverse events and reactions (AE/R) should be a valuable tool for donation and transplantation activities and ART
- It should provide stakeholders with an unparalleled source of information on AE/R by bringing together as much as possible of the global experience and be a reference for V&S activities.
- As part of a collaboration with WHO on V&S the CNT is developing an appropriate database and is developing a dedicated website on behalf of the global community
- Publication in the scientific and medical literature on AE/R is one source of information. V&S Reports from National Health Authorities/Competent Authorities (NHA) and Global /Regional Scientific and Professional Societies (SPS) also contain relevant information.
- Adverse events are rarely published in the literature. Yet the reported types of AE can inspire preventive action and provide a reference for their

- management. The participation of NHA and SPS is essential.
- Source of information must be limited to collaborating partners and from all regions of WHO. A network of partner institutions in all regions will be constituted in parallel to the promotion of V&S by WHO regional offices with Member States.
 - An introductory statement on the NOTIFY website will explain objectives and methods and include a disclaimer
 - A BIG V&S editorial committee consolidates reports of a similar type, identifies new types and summarizes key aspects to facilitate access in an easy manner.
 - The NOTIFY Library will be submitted to the oversight of an annual WHO global consultation and will benefit from CNT secretariat services

Discussion:

The group has asked that the WHO manage this project with the advice of the regular global consultation, as the global oversight and strengths of the WHO adds value to this project, and ensures the trust of the public and users in this resource

Summary

The meeting concluded on a positive note, with broad overall agreement on the aims and scope of this group and the next steps to be undertaken.

Annex 1: list of participants



**World Health
Organization**



Centro Nazionale Trapianti

**First Global Consultative Meeting for the BIG V&S Project
(Bologna Initiative for Global Vigilance and Surveillance)**

5-6 July 2011, Geneva, Room M 105

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Annex 2: Programme of work



First Global Consultative Meeting for the BIG V&S Project (Bologna Initiative for Global Vigilance and Surveillance)

5-6 July 2011, Geneva, Room M 105

Draft Programme of Work 5 July

09:30	Welcome Luc Noel and Alessandro Nanni Costa	
09:40	Introduction of participants Election of Chair and Rapporteurs	
10:00	The BIG V&S project, objectives of the first consultation	Luc Noel
10:10	Progress of the Bologna outcomes Report of the meeting	Deirdre Fehily
10:25	Booklet for advocacy / awareness / guidance	Mike Strong
10:40	Discussion	
11:00	Coffee Break	
11:30	Progress of the Bologna outcomes 2 Didactic documents, publications and project	
11:30	Infections	Mike Ison
11:45 Marazuela	Malignancy	Rosario
12:00 /	Characteristics, handling and clinical practice	Scott Brubaker Axel Rahmel
12:15 Cozzi /	Genetic and Donor	Emanuele Deirdre Fehily
12:30	Discussion	

13:00	Lunch	
14:00	Progress of the Bologna outcomes 3	
14:00	The BIG V&S website	Deirdre Fehily
14:20	Discussion	
14:30	Preserving the NOTIFY database	Stratos Chatzixiros
14:45	Discussion	
15:00	Coffee Break	
15:30	The new NOTIFY Library, concepts , demonstration step by step and timeframe with discussion	CNT team
18:00	Close for the day	

Draft Programme of Work 6 July

9:00	Summary by Rapporteurs Round table discussion on BIG V&S website and NOTIFY Library Optimal use Access Data input	
10:00	Discussion: Consistency with V&S globally and with other health care areas	
10:30	Discussion Interface with regional V&S projects	
11:00	Coffee break	
11:20	V&S in countries according to the Global Observatory on Donation and Transplantation	Mar Carmona
11:35	Round table discussion: Promotion of V&S for CTO in all regions	
12:30	Lunch break	
13:30	General discussion: Salient points, recommendations, next steps and timeframe	
14:45	Coffee break	
15:15	Distribution of tasks for next steps including the drafting of proposals	
16:00	Close of meeting	