The 1st Coordination Meeting of the
WHO BioDoseNet

MEETING REPORT

Hanover NH, USA - September 7, 2008
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List of Participants

Liz Ainsbury, HPA, UK
Joe Albanese, New Haven Center EPDR USA
Francesco Barquinero, UAB, Spain
Hilary Boulay Green, Defence Canada
Christina Beinke, Institute of Radiation Biology, Germany
William F. Blakely, AFRRI, USA
Zhanat Carr, WHO
Vadim Chumak, Ukraine
Firouz Darroudi, LUMC, Netherlands
Marina Di Giorgio, ARN, Argentina
Citlali Guerrero Carbajal, ININ, Mexico
Marco Espinoza, IPEN, Peru
Michael Fenech, CSIRO, Australia
Farrah Flegal, AECL, Canada
Valeria Hadjidekova, NCRRP, Bulgaria
Richard Hatchett, NIAID, USA
Michael Hopmeier, Unconventional Concepts Inc., USA
Andrew Huff, AFRRI, USA
Young-Woo Jin, RHRI, Korea
Chang-Mo Kang, KIRAMS, Republic of Korea
Patricia K. Lillis-Hearne, AFRRI, USA
Gordon Livingston, REAC/TS, USA
David Lloyd, HPA, UK
Wilner Martinez, IIBCE, Uruguay
Natalie Maznik, KIMR, Ukraine
Fabrizio Palitti, Univ of Tuscia, Italy
Narayani Ramakrishnan, NIAID, NIH
Alex Romanyukha, USUS, USA
Horst Romm, BfS, Germany
Laurence Roy, IRSN France /IAEA expert
Guenter Seitz, Germany
Natalia Slozina, NRCERM, Russia
James Smith, CDC rep, USA
Harold Swarz, Dartmouth School of Med USA
François Trompier, IRSN, France
Patricia Valdivia, CCHEN, Chile
Albert Wiley, REAC/TS, USA
Ruth Wilkins, HC, Canada
Mitsuaki Yoshida, NIRS, Japan

Apologies for absence received from:
Liu Jianxian, CDC, China
Igor Khvostunov, MRRC, Russia
Yoshiaki Kodama, RERF, Japan
Glev Kosovsky, IBP, Russia
Viktor Krivoshapov, URCRM, Russia
Carita Lindholm, STUK, Finland
Monica Stuck de Oliveira, Brasil
Pat Prasanna, AFRRI, USA
Harry Scherthan, Institute of Radiation Biology, Germany
Phillip Voisin, IRSN, France
Diana Wilkinson, Defence Canada
Documents circulated before the meeting:

- A provisional agenda
- A report of the start-up consultation meeting held in Geneva, December 2007.

Opening remarks

Zhanat Carr and Patricia Lillis-Hearne opened the meeting and particularly thanked Harold Swarz for hosting the meeting as a satellite of BioDose-2008 conference and US DoD and AFRRI for facilitating the event, notably David Jarrett and Patricia Lillis-Hearne, for providing financial support for the meeting.

Introductions

There followed a round-the-room introduction of everybody present. It was noted that the persons present constituted a good cross-section of the world scene in cytogenetic dosimetry and a useful spread of observers.

Zhanat Carr introduced David Lloyd as the chairman of the meeting.

Meeting Objectives

Zhanat Carr explained the origins of BioDoseNet and why WHO is particularly interested in setting up the network (see slides attached as Annex 1). There is a clear need for an integrated biodosimetric response to the threat of global mass-casualty radiological events and such a network is fully consistent with WHO’s mandate under the International Health Regulations (IHR 2005). The network will constitute part of the WHO’s GLaDNet; a Global Laboratory Directory and Network covering a broad range of laboratory issues to support IHR implementation.

The specific objectives for the meeting were:

1. To agree on policy issues and terms of reference (ToR) for BioDoseNet
2. To agree on structure and appoint a steering committee.
3. To identify tasks to refer to the steering committee and specific task groups
4. To develop a list of the activities and to agree on the time line of work
Existing networks

Some arrangements for national and international biodosimetry networking are already in place and these were reviewed, including IAEA’s Response Assistance Network (RANET) which includes few cytogenetic laboratories in IAEA Member States that have listed their capabilities to be used in emergency response under the Convention of Assistance. For more detailed information, see the slides attached in Annex 2.

Brief accounts of the existing regional and national networks’ structures, and activities were given by their members:

1. Marina Di Giorgio (PowerPoint slides annex 3): Latin America. A network initiated with IAEA funding comprising labs in Argentina, Brazil, Chile, Cuba, Mexico, Peru and Uruguay.

2. Ruth Wilkins (PowerPoint slides annex 4: Canada. Four reference labs in Ontario linked up with 18 others, mostly clinical cytogenetics labs, across the country. Plans to expand to include USA.


6. David Lloyd: European Union. A long-standing, tri-partite formal arrangement between France, Germany and UK with an informal link to Finland. An indication that EU funding may soon be available to expand the networking to cover all EU countries. Also within France a national network, similar to the Canadian / Connecticut etc models, centred on IRSN with links to five clinical labs.

7. Michael Fenech: Noted that the CBMN assay network (www.humn.org) comprises thirty countries using the micronucleus assay (and the whole cytome assay which includes anaphase bridges that derive from dicentrics).

It was made clear that BioDoseNet in no way seeks to compete with the existing international arrangements, rather complements them. In some instances biological dosimetry for a moderately large event would be handled by one of these networks, the laboratories involved quite likely being part of BioDoseNet anyway. Situations may arise in countries not covered by local networking or may be beyond the local resources. Then an appropriately scaled BioDoseNet response can be mounted following a request for assistance from the host nation.

Résumé of the Geneva consultation in December 2007

David Lloyd (PowerPoint slides attached as annex 4) gave an overview of the outcome of the consultation. Fuller details were available in the circulated meeting report and the Rad Res paper. A number of decisions were made at that meeting, which needed to be put to the wider community for ratification or further discussion and hence the present co-ordination meeting. In essence these were:

- The network will use just the dicentric assay in triage and full dose estimate modes.
• The structure of the network consists of a central steering committee backed up by a series of highly-qualified reference laboratories. These in turn may each have a number of associate laboratories. This is illustrated in Fig 3 of the Rad Res paper.

• Following on from the responses to a questionnaire sent out in 2007 a nucleus of potential reference labs has been identified. These are: Argentina, ARN; Canada, Health Canada; Finland, STUK; France, IRSN; Germany, BfS; Japan, NIRS; Russia, MRRC; UK, HPA and Ukraine KIMR. However this list is not complete and it needs to be supplemented, particularly from countries like India, Korea and China, to provide a better world-wide geographical spread.

• For any given event one of the reference laboratories will be chosen, based on criteria such as geography and pre-existing connections with the location / country of the event, to become the core laboratory. This lab will in effect co-ordinate the network’s response, drawing on outside assistance as necessary from the pool of associate and reference labs and the steering committee. The core lab will receive and collate all the biodosimetry data and act as the sole channel of communication between the network and the medical and scientific professionals dealing with the incident. The core lab only will also communicate with other interested persons such as the news media.

• ‘Quiet periods’ would be times when network inter-comparisons would be carried out conforming with the QA principles described in the ISO standard for the dicentric assay. The network would also audit the reference labs.

• Membership of BioDoseNet would be via a Memoranda of Understanding (MoU). The WHO has a generic format that will be adopted and used. WHO may also provide formal acknowledgement of membership, when requested.

• A BioDoseNet web site will be set up. This will be password protected. It will be the source of up-to-date contact information on all the members, a repository for the network’s documents including procedures developed by the task groups, instructions sheets, formats for results sheets and so on. Subject to copyright restrictions, members could also place copies of their relevant open literature publications on the site and documents such as the ISO standards. The web site would also provide a means of sharing lessons learned after a joint exercise or actual emergency.

Discussion of specific points

Arising from the presentations and the material in the Rad Res paper a number of specific points were raised in general discussion. These did not strictly conform to those listed in the provisional agenda because some areas were felt to be acceptable and required no further discussion or elaboration. The discussions, summarized below, helped define matters requiring detailed attention best referred to Task Groups.

1. Reference and associated laboratories. It was noted that some countries might require some encouragement to set up a laboratory. This could come from WHO which is working on the IHR requirements for member States’ needs. WHO of course can only advise, not force capabilities. Start-up funding is not forthcoming from WHO but it was noted that IAEA has
been responsible for funding new labs in some developing countries. It was hoped that this, together with training fellowships, will continue. Membership of the network can raise the national status of an existing lab and also provide some means for maintaining and improving the staff training. However it was stressed that the reference labs are seen as being already fully trained and functional labs that, in an emergency, can ‘drop everything’ and work on the immediate problem. Criteria, set at the Geneva meeting, were ratified that a lab should have a minimum capacity of 30 samples per week sustained for a month and after the initial triage time window (1-4 weeks), to be able to commit to follow-up with more suitable detailed analysis (i.e., scoring up to 500 metaphase spreads per case) for those cases that need further dose refinement to support clinical management; see full details in the Rad Res paper. Newly developed labs aspiring to this could join initially as an associate of a reference lab. For them the bi-lateral association could substantially assist in matters such as working up staff training. Likewise, smaller labs unable to meet the scoring capacity criteria of a reference lab or clinical labs, whose prime role might be surge assistance with ‘wet work’ sample processing, would be associates linked to the most appropriate reference lab. There was some concern that being a reference lab would be too much of a time commitment bearing in mind that each has its on-going business that can not be put aside for too long. It was made clear that the emergency commitment is really only for one month which should be manageable by most labs. Other activities such as participation in network inter-comparison exercises would facilitate what they should already be doing according to the ISO QA/QC criteria. Nevertheless these, together with their throughput capacity, have to be considered by each lab to decide if they meet the qualifications to join as a reference lab.

2. **Formal membership documentation.** It was envisaged that membership will be via a MoU. The WHO GlaDNet has experience of this already. However it was pointed out that labs in different countries have differing legal and administrative structures. Some are in governmental research institutes, others hospital-based and others within universities. Therefore a ‘one memo fits all’ document will not suffice. It was resolved that the Steering Committee will examine the existing MoU template and, in discussion with individual labs, attempt to modify it to suit the local administrations on a case-by-case basis. As a starting point, a copy of the existing MoU template would be sent for comments to everyone attending the meeting.

3. **How would the network be activated in an emergency?** At present for small events there has been many years experience of individual authorities organizing assistance from their own national biodosimetry resources or from another country. Sometimes this has been as part of the UN’s response through the formal channel for assistance from IAEA and WHO. The IHR when fully implemented will strengthen this mechanism. For larger events sufficient to require BioDoseNet activation, mechanisms need to be defined. This was referred to a specific Task Group (No. 1) to develop a Standard Operating Procedure (SOP) that is flexible enough to accommodate both the formal established route at governmental level to IAEA and also, for example, an individual biodosimetry laboratory being overwhelmed and requiring assistance by a direct approach to the BioDoseNet Steering Committee. The Task Group would concentrate on operational issues; not on cytogenetic technicalities.

4. **BioDoseNet Terms of Reference.** These were given in the Rad Res paper based on the outcome of the December 2007 Geneva meeting discussion. Three of the terms were queried. Two needed clarification; concerning a) how data were to be shared between members and b) the network’s role in additional activities such as exercises and auditing that support the
network’s proficiency and QA/QC. The third, concerning the network’s role in evaluating new methods, was deleted. Ruth Wilkins and David Lloyd undertook to rephrase the terms in the light of the discussion in time to make galley proof changes to the *Rad Res* paper. (Note: This was done promptly in Hanover immediately after the meeting and incorporated into the edits of the galleys of the manuscript).

Deletion from the ToR of any reference to new tools was discussed further and it was resolved that nevertheless all reference labs should be kept abreast of new diagnostic tools. The web site would be a suitable means for doing this. Should new tools be developed and validated experts in these can be invited to join the network and the ToR could be modified. It was noted that emerging technologies are a high priority, particularly in USA, and experts could be invited to discuss these at appropriate BioDoseNet meetings.

The WHO BioDoseNet Terms of Reference are as follows:

- In an emergency every participating laboratory commits to providing its services, if requested, to the network.
- The network laboratories perform emergency biodosimetry according to standard protocols approved by the steering committee and consistent with the relevant ISO standard.
- The network will perform peer-review evaluations of laboratories and reports are shared within the network.
- A consensus and common form of information sharing among the network will be set up. This will be a secure website providing an interactive resource centre for use in both quiet times and during emergency activation of the network.
- All laboratories are required to inform the network immediately about any changes in the laboratory’s contact information. This information (names, positions, phone and fax numbers and e-mail addresses) will be available on the secure web site.
- Raw data will not be shared among the network. Data will be aggregated for sharing and discussing within the network.
- Reporting of data, release of dose estimates and liaison with the medical and emergency response professionals will be done only through the reference laboratory that is designated as the network’s core laboratory for the particular radiological event.
- Any public release of information is to be channelled through the core laboratory. There will be no release by other network members. Requests for information are to be redirected to the steering committee and core laboratory.

5. **Patient selection.** To some extent this is driven by the early responding medical personnel who perform ‘traditional’ triage based on prodromal responses, location of casualty etc. It is recognized that these are not fail-proof and input from cytogenetics is valuable. Particularly as dicentric triage data begin to emerge, a system needs to be in place allowing re-prioritizing during the evolution of the event. It was resolved that a Task Group (No.2) should produce a practical algorithm for patient selection.
6. **Communications with news media.** It was generally agreed that a single channel for any BioDoseNet communications with the media is essential when an emergency response is under way. This should be one of the functions of the core reference lab and no other laboratory should provide information to the media without specific involvement of the IAEA /WHO. It follows therefore that a reference lab should be within an institution that has the means for press / public communications. The core lab of course can draw upon resources of the UN agencies and the steering committee in preparing material for release to the media.

7. **Surge capacity outside of core / reference labs.** This is the point when associate labs would tend to be mobilized. As well as those referred to above in existing networks Gordon Livingston reported that in USA there are a further 140, mostly clinical, cytogenetics labs that could be mobilized. A Task Group (No. 3) was set up to report on this topic. It would address appraising associates of the sample transport, coding, etc, (which is the remit of another Task Group No 4, below). Also it would consider a web-based portal for off-loading electronic images to share out scoring with other labs, along the lines of a REAC/TS project model.

8. **Sample collection, storage and transportation.** There are already instruction sheets covering these aspects developed by individual laboratories when dealing with small events. These are also discussed in the IAEA Manual. In addition, for international transport, there are UN guidelines for shipping diagnostic specimens such as blood, which have been adopted as required protocols by the International Air Transport Association (IATA). These would form the starting point for developing a network-wide document that can be disseminated, in translation, to healthcare workers in all countries. A Task Group (No 4) was set up to develop a network protocol.

9. **Ownership of information.** Following on from an emergency response, BioDoseNet would expect that its activities would lead to publication(s). It would fall to the core laboratory to take the lead in preparing material for peer-reviewed papers and/or UN agency reports. Publication should follow the normal rules of the international scientific community: Co-authorship and credit as appropriate to all persons and organizations that participated; Patient confidentiality and ethics approval consistent with the participating labs’ existing policies and of the requesting nation. It was noted that ethics and patient consent forms have already been addressed in international emergency situations and policies are in place that BioDoseNet can follow. WHO is well placed to cover this when the situations arise.

10. **Audit.** After a discussion on what an audit is, and who should see the results of an audit, a Task Group (No.5) was set up to define auditing procedures within BioDoseNet. It was stressed that audit should not be punitive but positive with constructive criticism if needed. Issues such as the QC/QA process and periodicity need to be formalized. The ISO cytogenetics standards will be a useful starting point for the Task Group. As auditing would be an on-going feature the Task Group would in reality be a Standing Sub-committee.

11. **Exercises and Inter-comparisons.** Again the ISO standards give some generic guidance. Also a recent scoring and dose estimation inter-comparison organized from ARN Argentina, primarily for the Latin America network, but in which many of the other labs present also participated, is a valuable model. Task Group 6 was set up to define issues such as periodicity magnitude and logistics of exercises and inter-comparisons.
12. **Communications.** This concerns communications within BioDoseNet during both ‘quiet’ and emergency periods. As discussed above a dedicated website will be the main means of communications. At the Geneva meeting Philippe Voisin had offered resources at IRSN to set this up. As he was absent from the Hanover meeting it was assumed that the offer still stood. (Note: this was later confirmed by Philippe Voisin). A Task Group (No. 7) was set up to develop a secure platform for network information sharing with good maintenance.
The composition of the Steering Committee (SC) and specific Task Groups (TG)

Below are listed alphabetically the SC and TG members, the TGs’ required outcomes as summarized at the end of the meeting and tentative deadlines. It was felt that each person’s willingness to serve on one or more of the groups should be marked by a confirmatory letter from WHO. In some instances this would be invaluable for passing on to their local directorate and administrations to strengthen the formal recognition of their involvement with the construction of BioDoseNet. (Note it was later pointed out that, in line with WHO practice, task groups should have two co-chairpersons identified to steer their work. Appointing co-chairs was overlooked at the Hanover meeting and therefore persons have been indicated later on the lists below).

**Steering committee:**

- William F. Blakely
- Zhanat Carr - WHO Secretariat
- Firrouz Darroudi
- Marina Di Giorgio
- Michael Hopmeier
- David Lloyd — Co-chair
- Natalie Maznik
- Horst Romm
- Phillip Voisin — Co-chair
- Ruth Wilkins
- Mitsauki Yoshida

**Task Group 1 - SOP Development:**

- Zhanat Carr — Co-chair
- Firouz Darroudi
- Richard Hatchett
- Michael Hopmeier — Co-chair

Output: SOP document (operational issues, not technical)
Deadline: 1st draft by end of Dec 08
Comments: end Feb 09
Finalized: end Mar 09

**Task Group 2 - Patient selection criteria for biodosimetry:**

- Joe Albanese/Nicholas Dainiak
- William F. Blakely — Co-chair
- Firouz Darroudi
- Marina Di Giorgio
- Michael Fenech
- J. Kaminski
- Horst Romm
- Albert Wiley — Co-chair

Output: an algorithm on sample collection, triage of victims, and prioritization of samples; a dynamic decision-support tool. To be circulated for comments to the BioDoseNet members.
Deadline: end March 09
Task Group 3 - Surge capacity for BioDoseNet:

Francesco Barquinero
Chang-Mo Kang
Patricia Lillis-Hearne
Gordon Livingston — Co-chair
Horst Romm — Co-chair
Laurence Roy
Ruth Wilkins
Mitsuaki Yoshida
Outcome: a web-based tool for training, consultation, scoring, available for ref labs, to use REAC/TS project model
Deadline: end 09

Task Group 4 - Sample collection, transport and storage:

Marco Espinoza
Michael Fenech — Co-chair
Fabrizio Palitti
Philippe Voisin
Diana Wilkinson — Co-chair
Outcome: A protocol to be provided to network members for comments and -when finalized - to be disseminated through WHO country offices to national health agencies dealing with medical response to radiation emergencies
Deadline: End March 09

Task Group 5 / Standing Sub-committee on audit and evaluation:

WHO- Secretariat
Firouz Darroudi
David Lloyd
Natalie Maznik — Co-chair
Philippe Voisin
Ruth Wilkins — Co-chair
Output: 1) To develop an audit form - evaluation protocol including evaluation criteria (accreditation, capability, trained personnel, etc.) This can utilize available info on WHO experience with other lab networks; 2) To define when and how evaluations will be done
Deadline: September 09

Task Group 6 - Exercises and inter-comparisons.

Liz Ainsbury
Francesco Barquinero
Marina Di Giorgio — Co-chair
Michael Fenech
Valeria Hajidekova
Laurence Roy — Co-chair
Natalia Slozina
Output: To define an inter-comparison study purpose, frequency, type, scope, parameters to be tested, etc. To plan, to coordinate, conduct, and evaluate inter-comparison exercises
Deadline: June, 2009
Task Group 7 - Communication within BioDoseNet:

Joe Albanese — Co-chair
J. Bader (suggested by Richard Hatchett)
Patricia Lillis-Hearne
Wilner Martinez
J. Smith
Philippe Voisin — Co-chair
Albert Wiley

Outputs: To develop a secure web-based platform for network maintenance, info sharing, knowledge management (English and Spanish)
Deadline: to be decided

Developments since the Hanover Meeting

1. Several members were impressed by the paper given at BioDos-08 by Dr Ying Chen of the Beijing Institute of Radiation Medicine. David Lloyd therefore suggested to her that her laboratory might wish to join BioDoseNet. Dr Chen agreed enthusiastically.

2. Paola Fattibene, Solomon Paul, Gabriel Pantelias and Rita Schneider have contacted Zhanat Carr, or have been suggested by members, for joining BioDoseNet or having observer status.

3. Nov 27-28 2008, the Radiation Emergency Preparedness and Response Center of NIRS (Chiba, Japan) held a regional workshop of the BioDoseNet with the support of the International Science and Technology Center (ISTC)¹ and in cooperation with WHO, where representatives of cytogenetic laboratories from Armenia, Belarus, China, India, Indonesia, Kazakhstan, Malaysia, Philippines, Russian Federation, Sri-Lanka, Thailand, and Vietnam have expressed their interest in joining the BioDoseNet. Further discussions between these laboratories and BioDoseNet Secretariat will follow.

Conclusions, summary

The 1st WHO BioDoseNet coordination meeting has resulted in the formal launch of the network, its terms of reference adopted by all members. The Steering Committee of the BioDoseNet has been appointed. The members of the network have jointly identified priority areas of work and set up respective topic-specific working groups. Concrete tasks with time line attached have been planned.

The group decided to hold the 2nd coordination meeting in 2010, if possible, in conjunction with the next BioDose conference, similar to how it was arranged for the 1st coordination meeting of BioDoseNet.

WHO Secretariat expressed its sincere appreciation for all participants who contributed to the work of the workshop and committed to joint work in future. WHO Secretariat will prepare the meeting report, which will be published electronically and placed on the BioDoseNet website.

List of Annexes

Annex 1. Introductory PowerPoint slides shown by Zhanat Carr summarizing the origin of BioDoseNet within UN structures and objectives of the Sept. 2008 Hanover meeting.

Annex 2. PowerPoint slides shown by Laurence Roy representing IAEA and describing the RANET arrangements and relevant activities of IAEA.

Annex 3. PowerPoint slides shown by Marina Di Giorgio describing work of the Argentina lab, the Latin America network and a recent inter-comparison exercise.

Annex 4. PowerPoint slides shown by Ruth Wilkins introducing the Canadian network

Annex 5. PowerPoint slides shown by David Lloyd summarizing points from the Geneva Dec. 2007 Meeting.