Interview

Interview with Dr. Jon Snaedal, Chair of the World Medical Association Workgroup for the Taipei Declaration; Representative of the Icelandic Medical Association: Health databases, biobank and fundamental human rights[1]

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(Thursday, October 20, 2016, during the WMA General Assembly, Grand Hyatt Taipei, Taiwan)

1. Background to the WMA Policy (From 1998 to 2002)

Interviewer　As the chair of WMA workgroup on the declaration on health databases and biobanks (Taipei Declaration)[*3] and as a member of Icelandic Medical Association, can you elaborate the background story of developing the WMA declaration and why this is important?

Snaedal　It started in March 1998 when the Icelandic Parliament introduced a bill allowing for collection of health information of every individual in the country into a single centralized database. The original intention was to collect information not only prospectively but also retrospectively from all sources - test, laboratory investigations, etc. The doctors in Iceland fiercely resisted the bill, because it was contrary to their commitment to the patients. The information they were receiving from their patients were to be handed over into a database governed by a private company and to be sold from there. The Icelandic Medical Association was at the forefront of this resistance. The Association took this issue first to the Nordic Medical Association and from there to the World Medical Association (WMA). WMA responded immediately by holding discussions with the Icelandic Medical Association as well as the health authorities and others that were proposing this bill. This resulted in an inside work in WMA led by Professor Jim Appleyard from the British Medical Association which after 2 years led to a policy on ethical considerations on health databases which was adopted at the WMA General Assembly in Washington, DC in 2002. After that, things became quiet for various reasons. In Iceland, although the bill was subsequently passed and contract given to a private company, they didn't have the financial capacity to realize it. Also, the

Dr. Jon Snaedal, during the interview.

[*3]　World Medical Association. WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks. Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016. Available from: https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

Dr. Jon Snaedal, during the interview.

data protection agency was adamant at increased security which proved to be a huge obstacle technically because data security in those days not as good as today. As a result, the centralized health database was never realized.

2. Subsequent revision of the WMA Policy

Snaedal   On the international front, the WMA Policy was not visible much as WMA did not engage much in dialog on the issue. However, in 2012, on the basis of a 10-year rule, a major revision was proposed because health database scenario had changed since 2002. Many health agencies, governments, and regions were in the process of producing various health databases. Almost every issue of prominent medical journals had research articles based on Big Data.

One of the goals of the policy revision was to make some pragmatic adjustments. Since biobanks are related to health database in many ways, it was also decided to include biobanks in the work on the policy. For example, every biobank creates database. Also, biobanks as well as databases are developed for long-term, and these repositories are used repeatedly to find new information and to ask new questions. Hence, biobanks and health databases are evolving. There are also new techniques available such as whole genome sequencing. With whole genome sequencing, the issue of anonymization becomes redundant, because every tissue can be used to identify the person based on whole genome sequences.

3. Internationalization and redrafting of the WMA Policy

Snaedal   When the drafting on databases and biobanks began, WMA felt the issue was important that agencies outside the WMA should be engaged in the process. So, in 2014, an external consultation process started. The response was overwhelming with almost 90 agencies - individuals, government agencies, universities, ethical boards – responding with their comments. Based on this response, a new draft was produced and meetings with external experts were held in different places like Copenhagen and Seoul to understand the development taking place in these parts of the world and to listen to their remarks. Finally, last spring (2015), a revision to the draft was produced and this was again sent out to the interested agencies. There were 39 responders, both internal and external, to the revised draft. This was followed by a whole-day meeting in Berlin and then a workgroup meeting in Taipei. The draft was then subsequently sent to the Ethics Committee.

Dr. Jon Snaedal, as a Chair of the Workgroup of the Taipei Declaration, explains about the final revision process of the Declaration, at the World Medical Association General Assembly, October 22, 2016.

4. Process of WMA Policy ratification

Snaedal　This Committee realized that the workgroup has worked hard on the draft policy and so this has been a substantial work with inputs from many special external advisors and consultants. Hence, the Ethics Committee approved the policy with no amendment and with very little discussion on the content. This was the biggest hurdle because the Ethics Committee is where policies are scrutinized meticulously and if stopped, it happens most often at this stage. However, to be sanctioned as a policy of WMA, the policy further needs to be approved by the General Assembly. Policies can also be stopped at the Council or at the General Assembly, but this is a rare occasion. Documents of ethical nature needs three-fourth majority to pass in the General Assembly. For example, the Declaration of Helsinki was not voted by 100%, but by about 90%, and there were oppositions to some issues in the declaration on every occasion. This is because it is so important to people that if there are issues they are not happy with, they try to do everything to oppose it.

5. Total anonymization and de-identification

Interviewer　Responding the public consultation of the Taipei Declaration, we submitted a comment concerning the issue of anonymization. How is the discussion on this point?

Snaedal　If you are discussing total anonymization of data, then it's outside the scope of WMA. Total anonymization means the data is not coded and totally de-identified. This is often done in hospitals for quality assurances where numbers of individuals are important and you do not have a clue as to the identification of these numbers.

Interviewer　We know that it would be diffi-

cult to reach to international consensus about the definitions and acceptable procedures of de-identification, which is linkable to biobank; or which is not linkable and completely de-identified.

Snaedal　This is a short document presenting the core ethical values. The issue of de-identification is one of the problems raised by many commentators who wanted us to be more consistent in many of these complicated things, but we were rather resistant to that. For example, we would only say that in a single biobank if it is totally de-identified with no code, then it does not apply. However, a total de-identification is not possible in tissues in biobanks when you have the technique to identify the individual by genetic means.

There are projects where identification is not required, for example, in many epidemiological studies. However, such projects have a beginning and an end. The problem we are facing in reality is that many project databases continue to be used after the project is over. You look again at the database to find new information on the individuals. Hence, you often have some kind of means to come back to the individuals. This was one of the main issues when we were discussing this 15 years ago. It had to be a continued process of collecting data and be linked to that person. Their claim that they were not identifiable was therefore not correct. There is also the technical question of how secure our coding is. Then you run into trouble if you are trying to convince that this is secure, but in reality you can do coding that is extremely difficult to break. You will never be able to show is completely unbreakable.

In case of, for example, rare diseases, hospitals may want to anonymize the individual, but on the basis of the data, theoretically, you can always identify that individual. Of course, not many would be able to do that. However, one issue we faced in this policy is transparency and openness. An indi-

vidual that is eager to help research may want to know how his/her data is used. He/She cannot know this today because there is little possibility as access is generally not possible for those outside the research group. However, we stress in the policy that this will be very valuable in the future.

For example, the chair of the Danish Medical Association will show today that in his country, when a patient is discharged from the hospital, 2 weeks later, he or she can have access to the medical record and can pinpoint errors. The patient is then able to send the record to the doctor for rectification. We would like to see the same happen with these databases so that you can make some amendments probably by sending to the governing body. Everyone collecting data knows that you need to have this process of looking at the data and cleaning it, but every time you have such correction, you have to go back and see if you have placed it correctly.

Interviewer　Apart from the discussion on technical issues, the Declaration seems to be based on universally agreed human rights derived from human dignity.

Snaedal　In some societies such as in Nordic countries and in United Kingdom (UK), there are national databases that have been established. In these countries, their own medical associations have been involved in structuring this database securing that person's integrity, dignity, and human rights are respected. We were faced with the problem that this WMA Policy would be incompatible with the laws which the respective associations have helped to create. Hence, we feared they would oppose this policy. So, during the last revision, we put in a new clause that is now found in paragraph 6 on this final draft. It basically says that when you have databases based on national laws produced through a democratic process acknowledging human rights aspects, you can produce other kinds

of methods like informed consent, like opt-out processes or other regulatory methods. They are content that this will comply with their countries' law. This is however sensitive, because people might think this is going to be misused, but we are not going to govern how others are doing with our policies.

Interviewer　The interesting points are benefit sharing and intellectual property issue, in the view of developing countries.

Snaedal　It is true that these issues are coming from developing countries like South Africa. For example, South Africa stressed that the issue of material transfer agreement (MTA) must be in place. This is because there are many examples where information and tissue is collected in the developing world and moved to a developed coun-

try for research with might not benefit the population that the data or tissue derived from. However, although the issue of MTA is included in this policy, we have not said how exactly such issues should be addressed because this is a technical. For example, when a child reaches adulthood, he/she should be asked about his/her decision on the informed consent which was earlier decided by his/her parents. We are saying you should have a process in place to make sure that this is possible.

Interviewer　Thank you so much for your valuable talk about the background story of the Declaration. We believe that your additional consideration would facilitate further and deep understanding of the Declaration and continuous, further international discussion on this important topic.
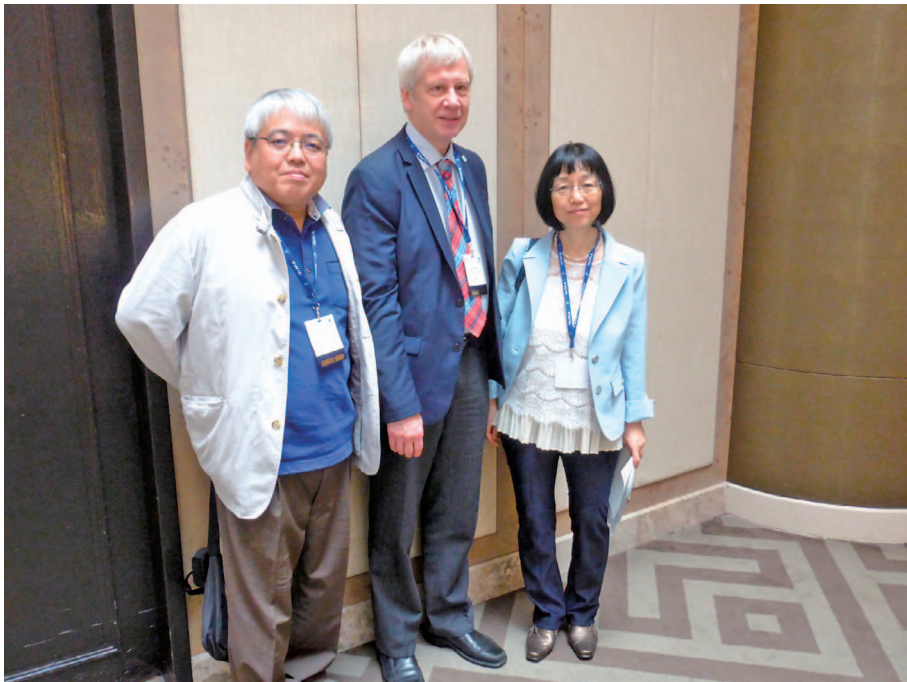
Dr. Jon Snaedal and interviewers.