

Recent Activities of the World Medical Association about Health Databases*¹

—Development of the Draft of the Policy Statement and Future Revision Process—

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I will talk about the activities of the World Medical Association (WMA) to develop its proposed declaration on ethical considerations regarding health databases and bio-banks.

The WMA agreed to support the Icelandic Medical Association in its fight against an Icelandic Government bill to establish a central health database for the entire population of Iceland in around 1998. The WMA General Assembly agreed to a request that the WMA Secretary General should assist the Icelandic Medical Association in seeking to clarify with the Icelandic Government the incalculable ethical consequences of the data collection Bill.

The WMA General Assembly in Ottawa in 1998 expressed its position to support Icelandic doctors' strong will to fight against the Bill. The second slide cites the words of Dr. Torben Pedersen, then President of the Danish Medical Association who is supportive of the Icelandic Medical Association's efforts (**Slides 1 and 2**).

Its Council Session in Santiago in 1999 also confirms its commitment to patient confidentiality which is one of the most important cores about this problem (**Slide 4**).

The WMA and WHO held a joint seminar in Geneva in May 2000 entitled "Ethical implications of centralized health databases." A joint seminar facilitates both the exchange of information and the future development of policy by the respective organizations (**Slide 5**).

The WMA Council Session in Divonne-les-

Bains, France in May 2000 decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians' representatives from across the world expressed their concern about the threat to privacy of patients' records. Dr. Anders Milton, the then Chair of WMA pointed that it is essential that to allay public concern about the growing development of these databases, internationally acceptable guidelines are drawn up to govern their use. And any guidelines must address the issues of privacy, consent, individual access and accountability (**Slides 6 and 7**).

The WMA General Assembly in Washington 2002 adopted a statement on ethical considerations regarding health databases. The first revision was discussed in the Council Session in Plague in 2012 with the Icelandic Medical Association as a rapporteur. This action was succeeded in Bangkok in the same year where a working group was established to develop a proposed revision of this document (**Slides 8 and 9**).

In 2013, the WMA General Assembly in Fortaleza, Dr. Snædal noted that there were several options for defining the scope of the WMA work in this area. The WG Chair made a motion requesting that the WG be instructed to continue its work on the broad concept of health databases. The motion was approved (**Slide 10**).

This year three doctors from the US, Korea and Iceland were invited by the Japan Medical Association to its conference on medical infor-

*1 This article is based on the lecture at the JMA Conference on Medical Information Technology held on February 8-9, 2014.

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mation technology on February 9 and delivered a presentation, “Big Data/Analytics and the US Healthcare System: Big Opportunity, Big Responsibility” by Dr. Robert Wah from the AMA, “ICT and Healthcare in Korea, Present and Perspectives” by Dr. Dong Chun Shin from Korea and “Centralized Health Databases Lessons from Iceland” by Dr. Jon Snædal from Iceland (**Slide 11**).

The WMA also held a WG meeting in Reykjavik in March 2014 to more closely discuss this topic (**Slide 12**).

These efforts will be succeeded to the WMA Council Session which will be held in Tokyo in April of this year. We will expect further development of the discussion there toward the adoption of this document in its general assembly in Durban in the coming October (**Slide 13**).

WORLD MEDICAL ASSOCIATION
Proposed Declaration on Ethical Considerations
Regarding Health Databases and Biobanks
—Development of the draft and future revision process—

Japan Medical Association Auditorium
February 8, 2014

Masami Ishii, MD
Vice-Chair of the World Medical Association
Secretary General of CMAAO

Slide 1

WMA General Assembly, Ottawa Oct. 1998
WMA to support Icelandic Doctors on Fight against Bill.

- The World Medical Association has agreed to support the Icelandic Medical Association in its fight against an Icelandic Government bill to establish a central health database for the entire population of Iceland.
- The General Assembly agreed to a request that the WMA Secretary General should assist the Icelandic Medical Association in seeking to clarify with the Icelandic Government the incalculable ethical consequences of the data collection Bill.

Slide 2

WMA General Assembly (Ottawa) Oct. 1998
WMA to support Icelandic Doctors on Fight against Bill

Dr. Torben Pedersen, President of the Danish Medical Association, told,

- The proposed data on patient information would be financed and organized by a private licensee, possibly a pharmaceutical company, in return for which the licensee would have a monopoly on the data for research purposes.
- The database would contain all accessible information on patients from the Icelandic health system over the past two or three decades.
- He said the ethical risks of this proposal included other researchers being denied access to the data, the possibility of carrying out a complete DNA registration of the entire Icelandic population and the risk of individual patient information being identifiable, thus stigmatizing families and isolated population groups.

Slide 3

WMA Council Session (Santiago) April, 1999
WMA Confirms Its Commitment To Patient Confidentiality

- Having heard representations from both the Icelandic Government and the Icelandic Medical Association about the creation of a national health database in Iceland, the World Medical Association has reaffirmed its commitment to patient confidentiality, the principle of informed consent and the freedom of scientific research.
- The WMA stands fully behind the position taken by the Icelandic Medical Association in opposing the Icelandic Healthcare Database legislation recently passed by the Icelandic Parliament.
- The WMA especially points to the need to protect the integrity of patient data and to have open access to all scientific data.
The WMA urges all national medical associations and governments to ensure that science is furthered by continued research that in no way breaches medical ethics and patient confidentiality.

Slide 4

Joint seminar of WMA and WHO May 2000

"Ethical Implications of Centralized Health Databases"

May 3, 2000
WHO Headquarters, Geneva, Switzerland

- This event has now been planned in conjunction with the World Health Organization.
- Other international organizations should be consulted to obtain their views on the ethical implications of Central Health Databases.
- A joint seminar should facilitate both the exchange of information and the future development of policy by the respective organizations.

Slide 5

WMA Council Session (Divonne Leis Van) May, 2000

WMA to Draw Up Health Database Guidelines

New international ethical guidelines for the development of centralized health databases are to be drawn up by the World Medical Association.

The association decided on the need for guidelines after holding a joint seminar in Geneva with the World Health Organization, where physicians' representatives from across the world expressed their concern about the threat to privacy of patients' records.

Slide 6

WMA Council Session (Divonne Leis Van) May, 2000

Dr. Anders Milton, Chair of the WMA

- It is essential that to allay public concern about the growing development of these databases, internationally acceptable guidelines are drawn up to govern their use.
- The public is rightly concerned about whether their right to privacy and confidentiality is threatened by these databases and whether information about them as individuals could be misused.
- Centralized health databases can make a tremendous contribution to the improvement of health.
- But the public's right to privacy and consent are essential to the trust and integrity of the patient/physician relationship and we must ensure that these rights are properly protected.
- Any guidelines must address the issues of privacy, consent, individual access and accountability.

Slide 7

WMA General Assembly (Washington), October 2002

Adoption of the WMA Statement on Ethical Considerations regarding Health Databases

- The privacy of a patient's personal health information is secured by the physician's duty of confidentiality.
- Confidentiality is at the heart of medical practice and is essential for maintaining trust and integrity in the patient-physician relationship.
- The primary purpose of collecting personal health information is the provision of care to the patient.
- Care must be taken to ensure that secondary uses of information do not inhibit patients from confiding information for their own health care needs, exploit their vulnerability or inappropriately borrow on the trust that patients invest in their physicians.
- Patients' consent is needed if the inclusion of their information on a database involves disclosure to a third party.
- National medical associations should co-operate with the relevant health authorities, ethical authorities and personal data authorities, at national and other appropriate administrative levels, to formulate health information policies based on the principles in this document.

Slide 8

WMA Council Session (Plaue), April 2012

WMA Statement on Ethical Considerations regarding Health Databases

- As a classification of 2002 policies, this document was considered during the 191st Council session in Prague, April 2012 to put this document on "major revision".
- The Icelandic Medical Association has been appointed as a Rapporteur.
- This document was circulated to NMAs for comment.

WMA General Assembly, Bangkok, 2012

Dr. J Snaedal presented the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments, and proposed that a working group be established to further discuss the document.

The Council set up a working group to look at the proposed Revision of the WMA Declaration on Ethical Considerations regarding Health Databases and Comments.

The constituent members of the WG: Iceland, Denmark, US, Israel, Australia and Germany.

Slide 9

WMA Bali Council Session on April 2013

WMA Statement on Ethical Considerations regarding Health Databases

- Dr. Snaedal, chair of the working group, reported on the activities of the working group.
- Dr. Snaedal indicated that the draft pape presented to the Committee was not the final proposal for consideration, but only for information, reflecting the advancement of the discussion.
- That the proposed WMA Declaration on ethical considerations regarding health databases be referred to the Medical Ethics Committee for further consideration.

WMA General Assembly in Fortaleza October 2013

Proposed WMA Statement on Ethical Considerations regarding Health Databases

- Oral report by Dr. Snaedal, Chair of the WG
- Dr. Snaedal noted that there were several options for defining the scope of the WMA work in this area.
- The WG Chair made a motion requesting that the WG be instructed to continue its work on the broad concept of health databases. The motion was approved.

Slide 10

JMA Conference on Medical Information Technology
 Feb. 9th, 2014
 JMA Auditorium
 International Session

- "Centralized Health Databases Lessons from Iceland"
 Jon Snaedal, Chair of Medical Ethics Committee of the Icelandic Medical Association
 Former President of the World Medical Association
- "ICT and Healthcare in Korea, Present and Perspectives"
 Dong Chun Shin, Professor, Dept. of Preventive Medicine Yonsei University College
 of Medicine Administrative,
 Director, Yonsei University Severance Hospital,
 Chair, Executive Committee of International Relations, Korean
 Medical Association
- "Big Data/Analytics and the US Healthcare System: Big Opportunity, Big
 Responsibility"
 Robert Wah, President-elect of the American Medical Association

Slide 11

WMA Work Group meeting on Health Databases and Biobanks
 Reykjavik 7. March 2014

Agenda – final draft

09:00 - 09:15 Opening of the morning session
 Jon Snaedal, Icelandic Medical Association (IcMA)

09:15 - 09:45 "IT technology in the Medical Service"
 Robert Wah, American Medical Association (AMA)

09:45 - 10:15 "Big data, research and ethics"
 Mads Koch Hansen, Danish Medical Association (DMA)

10:15 - 10:45 "Use of Health Data in a University Hospital"
 Maria Heimsdottir, IcMA

11:00 - 11:30 "Consent in health care and data protection law - Possible impacts of the EU's
 (Draft) Data Protection Regulation on consent in research"
 Annabel Seebom, WMA

11:30 - 12:00 "Biobanks, practical use in a divergent society"
 Ames Dhali, South African Medical Association (SAMA)

12:00 - 12:30 "Ethical aspects of Biobanks"
 Vilhjálmur Árnason, IcMA

Afternoon. Closed session of the WG.

Slide 12

WMA Council Session (Tokyo), April 2014
 24–26 April 2014
 Hotel Nikko Tokyo

- Thursday, 24 April
 Opening Plenary Session of the Council
 Medical Ethics Committee
 Finance and Planning Committee
- Friday, 25 April
 Finance and Planning Committee
 Socio-Medical Affairs Committee
- Saturday, 26 April
 Council Plenary Session
 Conclusion of Council Session

Slide 13