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Tel (33) 4 50 40 75 75
Fax (33) 4 50 40 59 37
E-mail: otmar.kloiber@wma.net

Website: http://www.wma.net

WMA Directory of National Member Medical Associations Officers and Council

Association and address/Officers

ANDORRA **S**
Col'legi Oficial de Metges
Edifici Plaza esc. B
Verge del Pilar 5,
4art. Despatx 11, Andorra La Vella
Tel: (376) 823 525/Fax: (376) 860 793
E-mail: coma@andorra.ad
Website: www.col-legidemetges.ad

ARGENTINA **S**
Confederación Médica Argentina
Av. Belgrano 1235
Buenos Aires 1093
Tel/Fax: (54-114) 383-8414/5511
E-mail: comra@sinectis.com.ar
Website: www.comra.health.org.ar

AUSTRALIA **E**
Australian Medical Association
P.O. Box 6090
Kingston, ACT 2604
Tel: (61-2) 6270-5460/Fax: -5499
Website: www.ama.com.au
E-mail: ama@ama.com.au

AUSTRIA **E**
Österreichische Ärztekammer
(Austrian Medical Chamber)
Weihburggasse 10-12 - P.O. Box 213
1010 Wien
Tel: (43-1) 51406-931
Fax: (43-1) 51406-933
E-mail: international@aek.or.at

REPUBLIC OF ARMENIA **E**
Armenian Medical Association
P.O. Box 143, Yerevan 375 010
Tel: (3741) 53 58-63
Fax: (3741) 53 48 79
E-mail:info@armeda.am
Website: www.armeda.am

AZERBAIJAN **E**
Azerbaijan Medical Association
5 Sona Velikham Str.
AZE 370001, Baku
Tel: (994 50) 328 1888
Fax: (994 12) 315 136
E-mail: Mahirs@lycos.com /
azerma@hotmail.com

BAHAMAS **E**
Medical Association of the Bahamas
Javon Medical Center
P.O. Box N999
Nassau
Tel: (1-242) 328 6802
Fax: (1-242) 323 2980
E-mail: mabnassau@yahoo.com

BANGLADESH **E**
Bangladesh Medical Association
B.M.A House
15/2 Topkhana Road,
Dhaka 1000
Tel: (880) 2-9568714/9562527
Fax: (880) 2-9566060/9568714
E-mail: bma@aitlbd.net

BELGIUM **F**
Association Belge des Syndicats
Médicaux
Chaussée de Boondael 6, bte 4
1050 Bruxelles
Tel: (32-2) 644-12 88/Fax: -1527
E-mail: absym.bras@euronet.be
Website: www.absym-bras.be

BOLIVIA **S**
Colegio Médico de Bolivia
Casilla 1088
Cochabamba
Tel/Fax: (591-04) 523658
E-mail: colmedbo_oru@hotmail.com
Website: www.colmedbo.org

BRAZIL **E**
Associaçao Médica Brasileira
R. Sao Carlos do Pinhal 324 – Bela Vista
Sao Paulo SP – CEP 01333-903
Tel: (55-11) 317868 00
Fax: (55-11) 317868 31
E-mail: presidente@amb.org.br
Website: www.amb.org.br

BULGARIA **E**
Bulgarian Medical Association
15, Acad. Ivan Geshov
1431 Sofia
Tel: (359-2) 954 -11 69/Fax:-1186
E-mail: usbls@inagency.com
Website: www.blsbg.com

CANADA **E**
Canadian Medical Association
P.O. Box 8650
1867 Alta Vista Drive
Ottawa, Ontario K1G 3Y6
Tel: (1-613) 731 9331/Fax: -1779
E-mail: monique.laframboise@cma.ca
Website: www.cma.ca

CHILE **S**
Colegio Médico de Chile
Esmeralda 678 - Casilla 639
Santiago
Tel: (56-2) 4277800
Fax: (56-2) 6330940 / 6336732
E-mail: sectecni@colegiomedico.c
Website: www.colegiomedico.cl

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CHINA **E**
Chinese Medical Association
42 Dongsi Xidajie
Beijing 100710
Tel: (86-10) 6524 9989
Fax: (86-10) 6512 3754
E-mail: suyumu@cma.org.cn
Website: www.chinamed.com.cn

COLOMBIA **S**
Federación Médica Colombiana
Calle 72 - N° 6-44, Piso 11
Santafé de Bogotá, D.E.
Tel: (57-1) 211 0208
Tel/Fax: (57-1) 212 6082
E-mail: federacionmedicacol@hotmail.com

DEMOCRATIC REP. OF CONGO **F**
Ordre des Médecins du Zaire
B.P. 4922
Kinshasa – Gombe
Tel: (242-12) 24589/
Fax (Présidente): (242) 8846574

COSTA RICA **S**
Unión Médica Nacional
Apartado 5920-1000
San José
Tel: (506) 290-5490
Fax: (506) 231 7373
E-mail: unmedica@sol.racsa.co.cr

CROATIA **E**
Croatian Medical Association
Subiceva 9
10000 Zagreb
Tel: (385-1) 46 93 300
Fax: (385-1) 46 55 066
E-mail: orlic@mamef.mef.hr

CZECH REPUBLIC **E**
Czech Medical Association
J.E. Purkyne
Sokolská 31 - P.O. Box 88
120 26 Prague 2
Tel: (420-2) 242 66 201/202/203/204
Fax: (420-2) 242 66 212 / 96 18 18 69
E-mail: czma@cls.cz
Website: www.cls.cz

UNITED STATES **S**
Colegio Médico Cubano Libre
P.O. Box 141016
717 Ponce de Leon Boulevard
Coral Gables, FL 33114-1016
Tel: (1-305) 446 9902/445 1429
Fax: (1-305) 4459310

DENMARK **E**
Danish Medical Association
9 Trondhjemsgade
2100 Copenhagen 0
Tel: (45) 35 44 -82 29/Fax:-8505
E-mail: er@dadl.dk
Website: www.laegeforeningen.dk

DOMINICAN REPUBLIC **S**
Asociación Médica Dominicana
Calle Paseo de los Medicos
Esquina Modesto Diaz Zona Universitaria
Santo Domingo
Tel: (1809) 533-4602/533-4686/533-8700
Fax: (1809) 535 7337
E-mail: asoc.medica@codetel.net.do

ECUADOR **S**
Federación Médica Ecuatoriana
V.M. Rendón 923 – 2 do.Piso Of. 201
P.O. Box 09-01-9848
Guayaquil
Tel/Fax: (593) 4 562569
E-mail: fdmedec@andinanet.net

EGYPT E
Egyptian Medical Association
„Dar El Hekmah“
42, Kasr El-Eini Street
Cairo
Tel: (20-2) 3543406

EL SALVADOR, C.A **S**
Colegio Médico de El Salvador
Final Pasaje N° 10
Colonia Miramonte
San Salvador
Tel: (503) 260-1111, 260-1112
Fax: -0324
E-mail: comcolmed@telesal.net
marnuca@hotmail.com

ESTONIA **E**
Estonian Medical Association (EsMA)
Pepleri 32
51010 Tartu
Tel/Fax (372) 7420429
E-mail: eal@arstideliit.ee
Website: www.arstideliit.ee

ETHIOPIA **E**
Ethiopian Medical Association
P.O. Box 2179
Addis Ababa
Tel: (251-1) 158174
Fax: (251-1) 533742
E-mail: ema.emj@telecom.net.et / ema@eth.healthnet.org

FIJI ISLANDS **E**
Fiji Medical Association
2nd Fl. Narsey's Bldg, Renwick Road
G.P.O. Box 1116
Suva
Tel: (679) 315388
Fax: (679) 387671
E-mail: fijimedassoc@connect.com.fj

FINLAND **E**
Finnish Medical Association
P.O. Box 49
00501 Helsinki
Tel: (358-9) 3930 826/Fax-794
Telex: 125336 sll sf
E-mail: fma@fimnet.fi
Website: www.medassoc.fi

FRANCE **F**
Association Médicale Française
180, Blvd. Haussmann
75389 Paris Cedex 08
Tel: (33) 1 53 89 32 41
Fax: (33) 1 53 89 33 44
E-mail: cnom-international@cn.medecin.fr

GEORGIA **E**
Georgian Medical Association
7 Asatiani Street
380077 Tbilisi
Tel: (995 32) 398686 / Fax: -398083
E-mail: Gma@posta.ge

GERMANY **E**
Bundesärztekammer
(German Medical Association)
Herbert-Lewin-Platz 1
10623 Berlin
Tel: (49-30) 400-456 363/Fax: -384
E-mail: renate.vonhoff-winter@baek.de
Website: www.bundesaerztekammer.de

GHANA **E**
Ghana Medical Association
P.O. Box 1596
Accra
Tel: (233-21) 670-510/Fax: -511
E-mail: gma@ghana.com

HAITI, W.I. **F**
Association Médicale Haitienne
1ère Av. du Travail #33 – Bois Verna
Port-au-Prince
Tel: (509) 245-2060
Fax: (509) 245-6323
E-mail: amh@amhhaiti.net
Website: www.amhhaiti.net

HONG KONG **E**
Hong Kong Medical Association, China
Duke of Windsor Building, 5th Floor
15 Hennessy Road
Tel: (852) 2527-8285
Fax: (852) 2865-0943
E-mail: hkma@hkma.org
Website: www.hkma.org

HUNGARY **E**
Association of Hungarian Medical Societies (MOTESZ)
Nádor u. 36
1443 Budapest, PO.Box 145
Tel: (36-1) 312 3807 – 311 6687
Fax: (36-1) 383-7918
E-mail: motesz@motesz.hu
Website: www.motesz.hu

ICELAND **E**
Icelandic Medical Association
Hlidasmari 8
200 Kópavogur
Tel: (354) 8640478
Fax: (354) 5644106
E-mail: icemed@icemed.is

INDIA **E**
Indian Medical Association
Indraprastha Marg
New Delhi 110 002
Tel: (91-11) 337009/3378819/3378680
Fax: (91-11) 3379178/3379470
E-mail: inmedici@vsnl.com / inmedici@ndb.vsnl.com

INDONESIA **E**
Indonesian Medical Association
Jalan Dr Sam Ratulangie N° 29
Jakarta 10350
Tel: (62-21) 3150679
Fax: (62-21) 390 0473/3154 091
E-mail: pbidi@idola.net.id

IRELAND **E**
Irish Medical Organisation
10 Fitzwilliam Place
Dublin 2
Tel: (353-1) 676-7273
Fax: (353-1) 6612758/6682168
Website: www.imo.ie

ISRAEL **E**
Israel Medical Association
2 Twin Towers, 35 Jabotinsky St.
P.O. Box 3566, Ramat-Gan 52136
Tel: (972-3) 6100444 / 424
Fax: (972-3) 5751616 / 5753303
E-mail: estish@ima.org.il
Website: www.ima.org.il

JAPAN **E**
Japan Medical Association
2-28-16 Honkomagome, Bunkyo-ku
Tokyo 113-8621
Tel: (81-3) 3946 2121/3942 6489
Fax: (81-3) 3946 6295
E-mail: jmaintl@po.med.or.jp

KAZAKHSTAN **F**

Association of Medical Doctors of Kazakhstan
117/1 Kazybek bi St.,
Almaty
Tel: (3272) 62 -43 01 / -92 92
Fax: -3606
E-mail: sadykova-aizhan@yahoo.com

REP. OF KOREA **E**
Korean Medical Association
302-75 Ichon 1-dong, Yongsan-gu
Seoul 140-721
Tel: (82-2) 794 2474
Fax: (82-2) 793 9190
E-mail: intl@kma.org
Website: www.kma.org

KUWAIT **E**
Kuwait Medical Association
P.O. Box 1202
Safat 13013
Tel: (965) 5333278, 5317971
Fax: (965) 5333276
E-mail: aks.shatti@kma.org.kw

LATVIA **E**
Latvian Physicians Association
Skolas Str. 3
Riga
1010 Latvia
Tel: (371-7) 22 06 61; 22 06 57
Fax: (371-7) 22 06 57
E-mail: lab@parks.lv

LIECHTENSTEIN **E**
Liechtensteinischer Ärztekammer
Postfach 52
9490 Vaduz
Tel: (423) 231-1690
Fax: (423) 231-1691
E-mail: office@aerztekammer.li
Website: www.aerzte-net.li

LITHUANIA **E**
Lithuanian Medical Association
Liubarto Str. 2
2004 Vilnius
Tel/Fax: (370-5) 2731400
E-mail: lgs@takas.lt

LUXEMBOURG **F**
Association des Médecins et Médecins Dentistes du Grand-Duché de Luxembourg
29, rue de Vianden
2680 Luxembourg
Tel: (352) 44 40 331
Fax: (352) 45 83 49
E-mail: secretariat@ammd.lu
Website: www.ammd.lu

MACEDONIA **E**
Macedonian Medical Association
Dame Gruev St. 3
P.O. Box 174
91000 Skopje
Tel/Fax: (389-91) 232577

MALAYSIA **E**
Malaysian Medical Association
4th Floor, MMA House
124 Jalan Pahang
53000 Kuala Lumpur
Tel: (60-3) 40418972/40411375
Fax: (60-3) 40418187/40434444
E-mail: mma@tm.net.my
Website: http://www.mma.org.my

MALTA **E**
Medical Association of Malta
The Professional Centre
Sliema Road, Gzira GZR 06
Tel: (356) 21312888
Fax: (356) 21331713
E-mail: mfpb@maltanet.net
Website: www.mam.org.mt

MEXICO **S**
Colegio Medico de Mexico
Fenacome
Hidalgo 1828 Pte. Cons. 410
Colonia Obispado C.P. 64060
Monterrey, Nuevo Léon
Tel/Fax: (52-8) 348-41-55
E-mail: fenacomemexico@usa.net
Website: www.fenacome.org

NEPAL **E**
Nepal Medical Association
Siddhi Sadan, Post Box 189
Exhibition Road
Katmandu
Tel: (977 1) 225860, 231825
Fax: (977 1) 225300
E-mail: nma@healthnet.org.np

NETHERLANDS **E**
Royal Dutch Medical Association
P.O. Box 20051
3502 LB Utrecht
Tel: (31-30) 28 23-267/Fax-318
E-mail: j.bouwman@fed.knmg.nl
Website: www.knmg.nl

NEW ZEALAND **E**
New Zealand Medical Association
P.O. Box 156
Wellington 1
Tel: (64-4) 472-4741
Fax: (64-4) 471 0838
E-mail: nzma@nzma.org.nz
Website: www.nzma.org.nz

NIGERIA **E**
Nigerian Medical Association
74, Adeniyi Jones Avenue Ikeja
P.O. Box 1108, Marina
Lagos
Tel: (234-1) 480 1569,
Fax: (234-1) 493 6854
E-mail: info@nigeriannma.org
Website: www.nigeriannma.org

NORWAY **E**
Norwegian Medical Association
P.O.Box 1152 sentrum
0107 Oslo
Tel: (47) 23 10 -90 00/Fax: -9010
E-mail: ellen.pettersen@
legeforeningen.no
Website: www.legeforeningen.no

PANAMA **S**
Asociación Médica Nacional
de la República de Panamá
Apartado Postal 2020
Panamá 1
Tel: (507) 263 7622 /263-7758
Fax: (507) 223 1462
Fax modem: (507) 223-5555
E-mail: amenalpa@sinfo.net

PERU **S**
Colegio Médico del Perú
Malecón Armendáriz N° 791
Miraflores
Lima
Tel: (51-1) 241 75 72
Fax: (51-1) 242 3917
E-mail: decano@colmedi.org.pe
Website: www.colmed.org.pe

PHILIPPINES **E**
Philippine Medical Association
PMA Bldg, North Avenue
Quezon City
Tel: (63-2) 929-63 66/Fax: -6951
E-mail: pmasec1@edsamail.com.ph

POLAND **E**
Polish Medical Association
Al. Ujazdowskie 24
00-478 Warszawa
Tel/Fax: (48-22) 628 86 99

PORTUGAL **E**
Ordem dos Médicos
Av. Almirante Gago Coutinho, 151
1749-084 Lisbon
Tel: (351-21) 842 71 00/842 71 11
Fax: (351-21) 842 71 99
E-mail: ordemmedicos@mail.telepac.pt
/ intl.omcne@omsul.com
Website: www.ordemdosmedicos.pt

ROMANIA **F**
Romanian Medical Association
Str. Progresului 10
Sect. 1, Bucarest, cod 70754
Tel: (40-1) 6141071
Fax: (40-1) 3121357
E-mail: amr@amr.sfos.ro
Website: www.cdi.pub.ro/CDI/
Parteneri/AMR_main.htm

RUSSIA **E**
Russian Medical Society
Udaltsova Street 85
121099 Moscow
Tel: (7-095)932-83-02
E-mail: rusmed@rusmed.rmt.ru
info@russmed.com

SLOVAK REPUBLIC **E**
Slovak Medical Association
Legionarska 4
81322 Bratislava
Tel: (421-2) 554 24 015
Fax: (421-2) 554 223 63
E-mail: secretarysma@ba.telecom.sk

SLOVENIA **E**
Slovenian Medical Association
Komenskega 4
61001 Ljubljana
Tel: (386-61) 323 469
Fax: (386-61) 301 955

SOUTH AFRICA **E**
The South African Medical Association
P.O. Box 74789, Lynnwood Rydge
0040 Pretoria
Tel: (27-12) 481 2036/7
Fax: (27-12) 481 2058
E-mail: liliang@samedical.org
Website: www.samedical.org

SPAIN **S**
Consejo General de Colegios Médicos
Plaza de las Cortes 11
Madrid 28014
Tel: (34-91) 431 7780
Fax: (34-91) 431 9620
E-mail: internacional1@cgcom.es

SWEDEN **E**
Swedish Medical Association
(Villagatan 5)
P.O. Box 5610
SE - 114 86 Stockholm
Tel: (46-8) 790 33 00
Fax: (46-8) 20 57 18
E-mail: info@slf.se
Website: www.lakarforbundet.se

SWITZERLAND **F**
Fédération des Médecins Suisses
Elfenstrasse 18 – POB 293
3000 Berne 16
Tel: (41-31) 359 –1111/Fax: -1112
E-mail: fmh@hin.ch
Website: www.fmh.ch

TAIWAN **E**
Medical Association
201, Shih-pai Rd., Sec. 2
P.O. Box 3043
Taipei 11217
Tel: (886-2) 2871-2121, ext 7358
Fax: (886-2) 28741097
E-mail: cma@vghtpe.gov.tw

THAILAND **E**
Medical Association of Thailand
2 Soi Soonvijai
New Petchburi Road
Bangkok 10320
Tel: (66-2) 314 4333/318-8170
Fax: (66-2) 314 6305
E-mail: math@loxinfo.co.th
Website: http://www.medassocthai.org/
index.htm.

TUNISIA **F**
Conseil National de l'Ordre
des Médecins de Tunisie
16, rue de Touraine
1082 Tunis Cité Jardins
Tel: (216-71) 792 736/799 041
Fax: (216-71) 788 729
E-mail: ordremed.na@planet.tn

TURKEY **E**
Turkish Medical Association
GMK Bulvary,.
Pehit Danip Tunalygil Sok. N° 2 Kat 4
Maltepe
Ankara
Tel: (90-312) 231 –3179/Fax: -1952
E-mail: Ttb@ttb.org.tr

UGANDA **E**
Uganda Medical Association
Plot 8, 41-43 circular rd.
P.O. Box 29874
Kampala
Tel: (256) 41 32 1795
Fax: (256) 41 34 5597
E-mail: myers28@hotmail.com

UNITED KINGDOM **E**
British Medical Association
BMA House, Tavistock Square
London WC1H 9JP
Tel: (44-207) 387-4499
Fax: (44- 207) 383-6710
E-mail: vivn@bma.org.uk
Website: www.bma.org.uk

UNITED STATES OF AMERICA **E**
American Medical Association
515 North State Street
Chicago, Illinois 60610
Tel: (1-312) 464 5040
Fax: (1-312) 464 5973
Website: http://www.ama-assn.org

URUGUAY **S**
Sindicato Médico del Uruguay
Bulevar Artigas 1515
CP 11200 Montevideo
Tel: (598-2) 401 47 01
Fax: (598-2) 409 16 03
E-mail: secretaria@smu.org.uy

VATICAN STATE **F**
Associazione Medica del Vaticano
Stato della Citta del Vaticano 00120
Tel: (39-06) 6983552
Fax: (39-06) 69885364
E-mail: servizi.sanitari@scv.va

VENEZUELA **S**
Federacion Médica Venezolana
Avenida Orinoco
Torre Federacion Médica Venezolana
Urbanizacion Las Mercedes
Caracas
Tel: (58-2) 9934547
Fax: (58-2) 9932890
Website: www.saludfmv.org
E-mail: info@saludgmv.org

VIETNAM **E**
Vietnam General Association
of Medicine and Pharmacy (VGAMP)
68A Ba Trieu-Street
Hoau Kiem district
Hanoi
Tel: (84) 4 943 9323
Fax: (84) 4 943 9323

ZIMBABWE **E**
Zimbabwe Medical Association
P.O. Box 3671
Harare
Tel: (263-4) 791/553
Fax: (263-4) 791561
E-mail: zima@healthnet.zw

OFFICIAL JOURNAL OF THE WORLD MEDICAL ASSOCIATION

Hon. Editor in Chief
Dr. Alan J. Rowe, OBE, FRCGP
Haughley Grange, Stowmarket
Suffolk IP14 3QT
UK

Executive Editor
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19 Wimblehurst Court
Ashleigh Road
Horsham
West Sussex RH12 2AQ
UK

Co-Editor
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Deutscher Ärzte-Verlag
Dieselstr. 2
D-50859 Köln
Germany

Business Managers
J. Führer, D. Weber
50859 Köln
Dieselstraße 2
Germany

Publisher
THE WORLD MEDICAL ASSOCIATION, INC.
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Editorial

Medical Professionalism

The problems facing the medical profession appear to be ever increasing. Some of the articles in the current issue of the World Medical Journal reflect this trend. The overview of bioethical and other aspects of medical technological advances presented in Tokyo during the scientific session of the WMA Assembly in Tokyo, analyse both the benefits and the problems related to technological advance *(see also Haddad's article in WMJ50(4)*.

It even possible to detect the relegation of clinical skills in some clinical protocols to a lower priority in the management of presenting disease ,which place the carrying out of technological tests before clinical examination in the list of priorities.

The concerns of the European Forum of Medical Associations and WHO about the Bologna Process, which proposes radical changes affecting the nature of basic medical training, at a time when there has already been general agreement about the reform of the basic medical curriculum, also express some feelings of serious disquiet. While welcoming some aspects of the proposals, there is grave concern at the suggestion that the fundamental proposals for Bachelor / Master degrees for recognising academic studies should be applied to medical basic studies. The apprehensions relate to the additional problems of recognition which these will raise in an increasingly globalised world, where the problems of recognition and increasing medical migration are significant problems already. It found no evidence that the proposed two cycle Bachelor / Master process will improve anything in the medical training process justifying the application of the Bologna proposals to medical studies which are a specific training for a profession. Finally it expressed deep concern, that such a move might undermine the positive integration of the theoretical and clinical parts of medical education and then be harmful for the quality of patient care."

Behind all of these problems is the increasing questioning of what constitutes professionalism in medicine. Dr. Mary Schramm ,President of the Fiji Medical Association, extracts of whose address appear in the NMA news section, reinforces the importance of some of the principles on which medical practice had been based for millenia. In the extracts from her speech which appear in the NMA News section ,and she calls for their reinforcement.

Faced with the number of problems which individual doctors in their ordinary daily practice have to address, it is essential that, in a time of changing values and expectations, the profession collectively also addresses the question of the professions' role in today's society and whether or not this has any implications for the fundamental principles on which the practice of medicine have been hitherto based.

Alan J. Rowe

Tracing The Aetiology Of Genetic Disorders In Children

At the Great Ormond Street Hospital for Children (GOSH) NHS Trust and the Institute of Child Health (ICH), the new Dean, Professor Andrew Copp[(i)], reports that research covers many aspects of child and developmental health, ranging from clinical genetics to mental health. The goal is to make discoveries that can improve clinical practice for the benefit of children locally, nationally and indeed internationally throughout the world. Research and teaching opportunities are provided for ever broader clinical questions in child health – evidence-based disgnosis and cures for many common childhood illnesses.

Editorial

The 'Jeans for Genes' Appeal

Following the complete sequences of the human genom, new ideas on genetic disorders, the relation between structure and function in the chromosomes, and the spontaneous occurrence of mutations, are being investigated. An innovative piece of equipment known as a pyrosequencer is at the heart of numerous collaborations between universities on the genes, development and disease theme. For example, Dr James Turton is researching the genetics of the forebrain and pituitary gland development, looking for mutations as transcription factor candidate genes in children with endocrine growth disorders. The DNA sequences in the genes will determine the function and developmental processes of each transcription factor, thus aiding disgnosis and treatment.

Pyrosequencing, using differential heat processes to 'melt' DNA chains, enables scientists to study genes much more quickly than was previously possible. Changes can thus be detected in the genes that might be relevant to disease causation. The system identifies genetic mutations or variations in a person's DNA sequence known as 'single nucleotide polymorphisms'. Such SNPs act like disease markers which identify people who may be prone to a certain disease.

The problem lies in identifying the genes that underlie childhood growth. Children come into GOSH with all kinds of growth problems, from relatively straightforward, easily measurable hormone deficiencies that can be treated by giving hormone replacement, right through to those who have life-threatening conditions in which their development is severely restricted or abnormal. Since the development of the pituitary gland is closely linked to that of the forebrain, some children may, for example, have very serious central nervous system problems such as blindness, autism and development delay. Severely affected children may never go on to develop normal brains, or in the case of Duchenne muscular dystrophy boys may become progressively weaker, resulting in death at a tragically young age.

The DNA pyrosequencer is used to screen candidate genes – those which have already been identified as playing a role in growth problems. The pituitary development group has identified many changes in both known and novel genes implicated in normal development of the pituitary and in control of human growth. The skill of the biochemist lies in being able to pick out genuine, disease-causing mutations from natural variations or polymorphisms found across the normal population. Nevertheless, even these variations may in time provide clues about transcription factors that modify growth, from DNA sequence to RNA (messenger, transfer and ribosomal) to functional proteins. Human growth hormone (HGH), via adenyl cyclase, can stimulate normal development and injections can be given to combat pituitary dwarfism. Local hormones, the cytokines, play their part in the growth and development of specialised tissues in terms of gene expression. Teams at GOSH are working on the genes involved in asthma connected with cystic fibrosis – where over 230 mutations have been found – juvenile arthritis disorders and various genetic dermatological diseases.

Gene therapy for cystic fibrosis

It is 17 years since scientists first discovered the gene responsible for cystic fibrosis, raising the prospect of a cure for a commonly inherited life-threatening disease.

In a recent breakthrough, Dr Adam Jaffe and his team at GOSH have discovered that, given the correct conditions, children can grow new and healthy lung tissue from stem cells. The first trials of gene therapy for patients with CF aimed to replace the abnormal gene with a healthy copy administered by a nasal spray. Despite initial optimism, and even a temporary cure in some patients who nevertheless reverted back to their original condition, treatment has proved to be elusive. This is partly because of the nature of CF: the disease causes the lungs' secretions to become thick and sticky. In the absence of treatment death can follow at an early age as these secretions clog up the lungs, making breathing difficult, causing recurrent infections and leading eventually to respiratory failure.

In order to replace the abnormal gene in CF sufferers, the healthy gene must be attached to a 'transfer agent' that will carry it into the target cell. Although this has been achieved using either a virus or a liposome (a fatty substance that sticks naturally to cell surfaces), the presence of so much mucus makes for great difficulty in penetrating the cell. An additional problem is uncertainly about exactly which cells within the airways should act as a focus for the vector.

It has long been known that bone marrow produces the cells that become blood cells. More recently, scientists have proved that bone marrow also produces stem cells with the property of 'plasticity' ? that is, they are capable of becoming other types of cell entirely. Indeed, stem cells in the blood could become lung cells, and so they could offer an effective means of replacing diseased lung cells affected by cystic fibrosis.

Dr Jaffe suggests that in the near future it might be possible to cure babies of CF in the womb. Treatment here may be less problematic because unborn babies have not yet developed their own independent immune systems, and would therefore put up less resistance to an incoming agent.

Gene therapy to tackle blindness

The eye represents a fruitful area for gene therapy according to Professor Robin Ali. Clinical trials are being set up for a rare inherited condition in the eye caused by a single defect that causes blindness in children, and age-related macular degeneration (AMD) in the over 65s, a relatively common cause of blindness in the elderly that has a complex mix of causes including diabetes. In both cases, a virus-derived vector would be used to insert a gene into the cells of the retina. For the inherited disorder, this would involve replacing the missing or defective gene. For AMD, genes would be employed to treat major symptoms of the condition, for example inhibiting the growth of destructive, invasive blood vessels into the retina.

Genetics, development and disease

According to Professor Peter Scambler, treating children with birth defects and inherited conditions constitutes a major part of medical practice in the West, America and Japan. Although individually rare (the commonest, CF, has a prevalence of carriers around 1 in every 25 people), the 4,000 or so known genetic disorders cause immense suffering for affected children and their families.

Clinical management and genetic counselling for these conditions depend on precise diagnoses, which are considerably helped by having sophisticated computer databases. The aim is to pick out the genes that have been mutated causing malformations and cancers, using the new techniques from biochemistry and molecular biology. Once a gene involved in a disease syndrome is identified, the function of the protein it encodes for is elucidated. In order to further our understanding of the fundamental mechanisms operating in embryology, it is important to establish an axis in the internal architecture of the cell. In the development of children's diseases, and in the expression of genetic mechanisms, rare disorders may present at the same time as common problems, for example in heart conditions, diabetes and mental illness.

At GOSH/ICH, in addition to studying single gene disorders, work is underway which attempts to unravel more complex gene and gene-environment interactions that may underlie common conditions such as deafness, cleft lip and palate, obesity and allergies in atopy. At the whole organ and cellular level, doctors are interested in disease processes and how they might be modelled effectively in the laboratory and on computer. For instance, significant progress has been made in understanding how malformed duplex kidneys occur, and in bringing back to life cells involved in ischaemic heart disease, the penumbra where they lack oxygen, and in spinal and neuronal injuries which can be treated with stem cells. Novel routes to treatment are being discovered which impact directly upon disease processes. Surgical treatments at the micro-level, such as heart valves delivered by catheter inside the heart, or relief of kidney and bladder malfunctions, are constantly being improved.

Making sense of Usher syndrome

Dr Maria Bitner-Glindzicz reports that Usher syndrome is a form of inherited deafness in which children also progressively lose their sight. Restricted vision or night blindness in Usher syndrome may first become apparent around the age of 7 years ? and this often progresses to severe visual impairment in the teens. During the year 2000, her medical team saw two very unusual families at GOSH and succeeded in identifying the gene responsible for their condition. Within these families, siblings or other relatives such as cousins had not only developed deafness, but they also had hyperinsulinaemia problems with blood glucose control, which had not been previously linked to Usher syndrome. It was established that the genes causing these conditions were located next to each other and that a stretch of DNA was missing from the tip of chromosome 11.

On-going research has revealed that abnormalities associated with at least 13 genes can underlie Usher syndrome. In most cases the normal role of the gene is to control the development of sensory hair cells of the inner ear. In relation to the eye, their function is less clear – young children with the condition develop normally until around 7–8 years of age. Visual problems controlled by these genes appear to be associated with maintaining photoreceptor cells required for sight.

The severity of Usher syndrome together with increasing knowledge of its genetic basis means that more sensitive detection and earlier treatment may become possible. The responsible genes identified to date are all recessive; hence a couple who are both carriers of the abnormal gene have a 1 in 4 chance of their child being affected. The condition is quite often diagnosed in a child before the couple have completed their family, and so this has very significant implications in terms of counselling. However, as we don't yet know all the genes that can cause Usher syndrome, and those that we do know are very large, accurate genetic testing during pregnacy is not yet possible.

To date there are three types of Usher syndrome which differ in severety and age at onset. The severest form, type 1, presents with profound deafness, balance problems, failure to develop speech and the need to learn sign language for communication unless there is a cochlear implant. Children with type 2 have moderate to severe deafness, normal balance, and they can learn to speak if they have a hearing aid. Type 3 is a recent category in which hearing is normal at birth but progressively deteriorates. All children suffering with Usher syndrome will ultimately develop severe visual problems.

The relative rarity of the syndrome, as with so many genetic diseases in children (1 in 1000 children are born deaf and about 5% of these are thought to have Usher syndrome), does not make it an obvious candidate for the development of genetic tests. Further knowledge about the genes involved in disease causation would not only allow pre-natal testing, but would also bring closer the possibility of gene therapy for the visual problems in affected children.

Genetic abnormalities underlying Bardet-Biedl syndrome

Infants with Bardet-Biedl syndrome (BBS) are often born with extra fingers or toes, have learning difficulties, and gradually develop progressive blindness and obesity. In some cases the latter can lead on to diabetes, heart disease or kidney failure, causing early death in about a third of those with BBS.

Dr Philip Beales, a Wellcome Trust Senior Research Fellow, explains that his interest in BBS started when he was working on diabetes in children, which involves many genes and gene interactions. When he saw his first case of BBS (1 in 70,000 children are affected), which has diabetes and obesity at its core, he realised that this condition might help doctors understand more common problems in the population.

With access to genetic information for about 500 families, much of Dr Beales' research focusses on the genetic abnormalities that

underlie BBS. The condition is unusual in that some of those affected have mutation not only in both copies of the same gene (one paternal, one maternal, the usual pattern in recessively inherited conditions), but they may also have a third mutation in another gene.

Eight genes involved in causing BBS have been found and, with colleagues from the USA and Canada, Dr Beales' group is investigating their function. Of particular interest is the role that some or all of these genes play in the motility of cilia. Ciliated cells with motile, flexible tails based on ATPase activity are widespread throughout the human body.

Much work has involved a Birmingham-based, Pakistani family in which all three sons (but not the one daugther) are severely affected by BBS. The protein encoded by the BBS-8 gene is missing in all three boys in this family. The researchers hope that these studies will reveal more about the link between ciliary and cellular function, and in turn further elucidate the developmental and cognitive patterns which occur in BBS.

Genes, sex, facial expression and autism

Two striking features in studying childhood to adult autism have been linked: the frequent problems of those affected in understanding the meaning of expressions on people's faces, and records which show that men are much more likely to have autism than women.

Professor David Skuse has reported progress in tracking these conditions. His team have looked at the sex chromosomes, XX for women and XY for men, and they found that one of the clearest risk factors for autism lies in possessing only one X chromosome. Women suffering from Turner's syndrome (one X instead of two) and men (XY) both have a much higher risk of autism than women with two X chromosomes. Indeed, women with a specific deletion of a particular section of the X chromosome cannot accurately process some facial expressions. They behave in this respect like autistic people.

This key section of the X chromosome is linked to the amygdala part of the brain involved in processing emotional expressions on people's faces. The data suggest that having two fully functioning X chromosomes definitely protects agains autism — and would account for the traditional, cooperative care so well developed amongst women as compared to the competitive, combative streak so often found in men.

Ivan M. Gillibrand

(i) *Reference*
Leading the way
Research Review 2003
Institute of Child Health and Great Ormond Street Hospital for Children NHS Trust

Medical Ethics and Human Rights

Unesco's proposed Declaration on Bioethics and human rights[1]

On January 28, 2005 the International Bioethics Committee (IBC) of UNESCO (United Nations Educational, Scientific and Cultural Organization) finalized its proposed *Universal Declaration on Bioethics and Human Rights*[2] According to the timetable approved in April 2004 by UNESCO's Executive Board, the Declaration will be presented to UNESCO's General Conference in October 2005 for adoption. Before going to the General Conference, the IBC final draft will be examined, and is likely to be amended, by a committee of government experts meeting in April and June 2005.

Despite two major consultations on earlier drafts of the Declaration and subsequent revisions, the IBC's final draft is seriously flawed. At a conference held on 25–26 February 2005 in Paris to review this draft, speaker after speaker pointed out ambiguities, inconsistencies and omissions and expressed major differences of opinion regarding the aims and contents of the document. Since no further consultation is scheduled, it will be up to the government experts and ultimately the government representatives to the UNESCO General Conference to determine the final form of the document and to decide whether it should be adopted.

Physicians and other health care professionals have good reason to be concerned about the deficiencies of the draft Declaration. Although it would not have the binding legal status of a Convention, it encourages nation states to "take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration[3]", and it contains provisions for monitoring and evaluating its implementation by states. It would be far better to correct the deficiencies of the document before it is adopted rather than having to deal with them afterwards.

Major Defects

Although the draft Declaration contains much that is worthy of support, its scope and aims are inappropriate and many of its principles present problems in their interpretation and application. In what follows, only the most important shortcomings of the Declaration will be discussed.

Scope – Contrary to the advice of the WMA Ethics Unit[4] and the World Health Organization (WHO)[5] among others, the Declaration defines 'bioethics' very broadly as "the systematic, pluralistic and interdisciplinary study and resolution of ethical

issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their application" (article 1). By including ethical issues in medicine in the scope of the document, UNESCO is clearly overstepping its mandate and encroaching on that of WHO. More seriously, many of the document's principles are inappropriately applied to clinical medical practice, as will be shown below.

Aims – Article 3 of the draft Declaration lists no less than seven aims. The first is the most problematic because it includes two incompatible proposals: (1) "to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics," and (2) "to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned." These statements demonstrate clearly the confusion of law and ethics that permeates the document. Given the definition of bioethics as "the study and resolution of ethical issues…," how can bioethics be incorporated into laws? There can be laws regulating the practice of medicine, medical research and the organization and delivery of medical care, but these should not be confused with bioethics. The second part of this article is appropriate for bioethics, insofar as it speaks of guidelines for individuals, groups and institutions. But these have a different status to that of laws. They speak to how people should act rather than how they must act.

Principles – The heart of the Declaration is a set of 12 principles that, according to article 2, "apply as appropriate and relevant: (i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and (ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States." Whether a principle is appropriate and relevant to a particular decision or practice will often be a matter of disagreement, particularly between the two main audiences to which the Declaration is addressed, namely, States and individuals/groups/institutions. Here again, the Document confuses law and ethics.

The following principles are particularly questionable for their application to medical practice:

Article 5 – Equality, Justice and Equity: "Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably." This principle fails to take into account the multiple, and incompatible, concepts of justice and equity in health care[6]. According to their codes of ethics, physicians are not being unjust when they give priority to their own patients over others, but a State could interpret this article in such a way as to require physicians to practise in public facilities open to all patients.

Article 7 – Respect for Cultural Diversity and Pluralism: "Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society." This is clearly impractical, if not impossible, in most clinical encounters between physicians and patients.

Article 10 – Informed Consent. This article is divided into three parts, the first dealing with research, the second with medical diagnosis and treatment, and the third with persons lacking the capacity to consent. Apart from the fact that it is clearly impossible to summarize the ethical principles relating to informed consent in five sentences, the article makes no provision for emergency treatment in situations where consent cannot be obtained. Moreover, although the Declaration is supposed to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, the principle for consent to medical diagnosis and treatment for incompetent patients in this article is simply that existing domestic law should be followed.

Article 11 – Privacy and Confidentiality: "Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than those for which it was collected." The second sentence of this article is considerably more restrictive than the WMA *Declaration on Ethical Considerations Regarding Health Databases*[7], as well as existing legislation in many countries. If adopted, it could seriously inhibit epidemiological research.

Article 12 – Solidarity and Cooperation: "Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end." Depending on how "due regard" is interpreted, this principle is inapplicable to patient-physician encounters.

Article 13 – Social Responsibility: "Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good." The comment on article 12 applies equally here.

Article 15 – Responsibility towards the Biosphere: "Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere." Here again, the Declaration is far removed from the realities of clinical medicine.

The next section of the Declaration is entitled, "Conditions for Implementation." The eight articles here are just as problematic as the above-mentioned principles. For example:

Article 16 – Decision-Making. This article requires that any decision or practice should "be made following full and free discussion and in accordance with fair procedures." This may be appropriate for law making but certainly cannot apply to emergency medical procedures.

Article 17 – Honesty and Integrity: "Any decision or practice should be made or carried out with: (i) professionalism, honesty and integrity; (ii) declaration of all conflicts of interest; and (iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society." Since the Declaration is

addressed to every individual, the requirements of professionalism and of a declaration of conflicts of interest are inappropriate. The "due regard" of the last sentence is open to multiple interpretations.

Conclusion

Despite its best efforts, the IBC was unable to produce an adequate Declaration on Bioethics and Human Rights in the nine months allotted to it by the UNESCO Executive Board. It is highly unlikely that the committee of government experts in two meetings will be able to succeed where the IBC failed. This is not at all surprising, given the nature of bioethics, its relatively recent rapprochement with human rights, and UNESCO's desire to respect cultural diversity and national sovereignty. The World Medical Association, which deals with similar challenges, took three years (1997-2000) to revise the *Declaration of Helsinki*. One reason for this delay that could be a lesson for the UNESCO project was the willingness of the WMA Council to recognize that the process followed during the first 18 months of the revision was not the right one and that a different approach was needed[8]. The new approach proved successful, despite many difficult challenges. We can only hope that the UNESCO Executive Board or General Assembly will likewise realise that the process followed to date to develop a Declaration on Bioethics and Human Rights has not been successful and will authorize a new approach, one that will include sufficient time for further consultation and consensus-building.

John R. Williams, Ph.D.

Director of Ethics

World Medical Association

1 The views expressed in this article are those of the author, not necessarily of the World Medical Association.

2 http://portal.unesco.org/shs/en/file_download.php/10d16a8d802caebf882673e4443950fd Preliminary_Draft_EN.pdf

3 Proposed Universal Declaration on Bioethics and Human Rights, paragraph 24

4 http://www.wma.net/e/ethicsunit/unesco_project_bioethics.htm

5 http://portal.unesco.org/shs/en/file_download.php/e9d8dfce8497c221c4e620d11952dde1Consultation_en.pdf

6 WMA Medical Ethics Manual (http://www.wma.net/e/ethicsunit/resources.htm), 72

7 http://www.wma.net/e/policy/d1.htm

8 Williams JR: The Promise and Limits of International Bioethics: Lessons from the Recent Revision of the Declaration of Helsinki. Journal international de bioéthique/International Journal of Bioethics 2004; 15: 36-37

Medical Information and Privacy in the Information Society

Norio Higuchi
Professor of Law
University of Tokyo, Japan

Presented at the WMA General Assembly in Tokyo 2004

It is truly a great honor and joy for me to be here, given a chance to talk about one of the most important and interesting topics which is medical information and privacy in contemporary society. I have been teaching comparative law and medicine for more than ten years at the University of Tokyo from the nnn in particular relating to the U.S. and Japan and now I am chairing a government committee for making guidelines on this subject.

I. Introduction: Two metaphors to deal with medical information

The importance of medical privacy in this era

1) As all of you are aware, from the ancient Hippocratic Oath to the present day, the most basic duty of physicians is that of confidentiality, or keeping the secrets of patients. Medical information and privacy issues are not new. No one, physicians, patients, or general public, need or should worry about it, since it has been a long established duty of physicians. Nevertheless, this particular issue is a major concern in most countries worldwide in this 21st century. Why? There should be some reason for it, and I believe there are at least three.

First, we have come to make more and more use of patients' information in a broader context. Medical information is originally acquired and accumulated for the care and cure of patients. It is nowadays, however, used in a much broader context. For instance, it is used for a variety of aims, such as the oversight of medical institutions, educational uses for young physicians, nurses, or paramedics. Also in some circumstances, physicians are legally obliged to disclose medical information to outside authorities. It is easy to imagine such situations in public health area and also child protection matters. At any rate, the more use there is of medical information, the more concern we should feel about it.

Second and related is the fact that we live in the so called "information society". This medical information is not in a paper form, but an electronic file. It could be transferred instantly to the opposite side of the world. Amazing it is, but it certainly increases fear among us. Imagine that someone we do not know at all or have never seen, knows about my illness, diagnosis, family medical history. it is really scary, isn't it?

Third, it has something to do with the increased distrust of physicians among the general public. It is well known that bioethics in the United States has grown from the big scandals about medical research in 1950s and 60s. Also informed consent doctrine and emphasis upon patient autonomy in that country is a sort of indication that we cannot rely upon paternalistic protection by physi-

cians any more, "in sum", we could not depent on medical professionals. In Japan, during the last ten years, we have seen many medical accidents in major hospitals,. Media report a lot and we see almost daily some reports of medical mishaps. Patient safety has become a major policy issue for the government, the Ministry of Health, Welfare and Labor, who are planning to accumulate and analyze the reports of medical accidents and incidents nationwide. Patient safety in this context means, as we should be aware, that patients should be safe from physicians!

2) Two metaphors to protect medical privacy in Japan: the metaphor of ownership

That is why we are now worrying about medical information issues. To deal with our concern, two metaphors are quite popular in Japan. I will show you what they are and, although they are popular and easy to understand or believe, they are wrong or useless. I wonder if the same type of metaphors is used in other countries. If it is, my discussion will apply as well.

The first metaphor is that of ownership of property or a thing. We see a number of publications, books and articles, which are titled "Who owns medical charts or medical records?" This metaphor of ownership of property is totally wrong.

In the first place, information is not a thing at all. For instance let us compare information with your paper material in your hand. The paper is certainly a thing, but information is not. Even though the paper includes information, information is distinguishable from the paper, which contains it. Information cannot be seen, or cannot be touched. It is intangible.

In the second place, the claim of ownership emphasizes monopolizing something. It means that this particular something is exclusively mine or yours or his or hers. Certainly, if you say this paper document is yours, then, when you read it, others cannot read it. Others can be completely excluded. Information is, however, difficult to monopolize. Rather, information can be shared at the same time. You can enjoy information without disturbing others' enjoying it. That is the peculiar characteristic of information.

In the third place and most importantly, it is hard to earmark so that this particular information is yours. With regard to the paper document in your hand, you can write your name on it to show your ownership. In the case of information, it is really hard to do so. Also, once information is disseminated out of your control, it is extremely difficult to recover and get back to the past. We should recognize that information is so special. It cannot be contained. It is not a thing.

You might say, however, that there is a legal device for the ownership of information. It is the scheme of intellectual property. Patents and copyrights are famous examples by which inventors or authors enjoy ownership over information they created, and the law recognizes it.

Professor Nobuhiro Nakayama, an authority of intellectual property law in Japan, says that if information can be successfully contained, then we could think of private property in it. There are two means for it. One is literally to contain information, or to keep it secret from any others. If you know something valuable, and also if you would like to take advantage of it in financial terms, then you can make it secret rigidly and share with only few of those who would pay for it. If you find someone who pays for it, the information is your property, which would bring money to you. However, this strategy has its own limitations. The more valuable the information is, then the more probable the information will be leaked. You cannot trace how it escapes and also it is hard to get back to the past.

That is how most society develops the intellectual property scheme. Through this device of legal imagination, the law grants a sort of ownership for a certain period to the inventors, authors of other creators of information. However, the important point is the fact that those inventors or authors could not keep it secret. Rather that the secrecy, the disclosure is encouraged under the intellectual property law. Well then, is there anything common between the intellectual property idea and our concern with medical information? Very little, if any, is my answer.

When we talk about medical privacy, we usually do not care about medical invention. What we do discuss is patients' concern about their privacy. After all, the legal system of intellectual property is a matter of money. It is an artifical legal device to encourage creative activities by giving financial incentives. Most patients, however, do not wish to keep their information protected for financial reasons. In other words, the metaphor of ownership and property fits very well with monetary interest, which has nothing to do with patients' concern.

3) The second metaphor: balance of interest

The second popular metaphor with regard to medical privacy is balancing of interests. Suppose there is a balance to judge what is just. On the one side, we put medical privacy and on the other, we put its uses for other values than privacy. Let me quote one example from what happened recently in Japan.

Our Parliament enacted the Individual Protection Act of 2003 which covers medical information, and will take effect from April 2005. The first section of this important act prescribes the main purpose of law, which is to protect the privacy rights of individuals while taking into consideration appropriate uses of information. In sum, this Act orders to make a good balance between protection and use of information about citizens.

But the problem is how to make good balance. To tell the truth, the act itself is of little help. Two points should be noted in particular.

First, in the process of enactement, a sort of interim report was published in 1999 by an advisory committee, which clearly emphasized the basic idea the coming Act should be the right to control one's own information. But, it is gone from the face of the Act. The idea of the right to control one's own information is close to the ownership metaphor. It is now gone and has moved to the balancing metaphor.

Second, Professor Yoshiharu Matsuura, a legal philosopher at Nagoya University, explains that the metaphor of balance works well only if there is already an established rule in a comparable situation. This is totally different from our situation, where we only say that both protection and use are important to medical information. We can see no related or established rule, and this

cannot make a good argument from the comparison and analysis from it.

4) The failure of two metaphors

To sum up so far, we love metaphors that are easy to understand and also to apply in appearance. The metaphor of ownership and balance are exactly those types. Yet, they give us only dreams or illusions. They do not help us much.

II Construction from the basis: why we should protect medical information

1) Search for a way of solution

When we find that popular metaphors fail, we need to get back to the starting point of discussion, as to why we should protect medical information.

The answers may appear so various that it may sound a waste of time. An example of balance metaphor comes from patient safety area in Japan. In April 2003, a government committee within the Ministry of Health, Welfare and Labour, issued a report to make hospitals and medicine safer. The core idea is that we should learn from mistakes. In order for us to do that, we need to collect accident and incident reports, and send back a proposal for deterrence and prevention to each medical institution. To realize and organize the scheme, the report argues for the establishement of a professional institution for patient safety.

Our interest in this report is that it tries to make uses of medical information of patient safety, while it emphasizes as well the importance of patient privacy. We can see the metaphor of balance.

For instance, when our Parliament enacted the Information Protection Act, in 2003, each House added a resolution requiring the government to consider within two years whether some additional special legislation should be enacted in three important evidences, to prove that our representatives regarded medical information protection as one of the highest policy issues.

But, if it is so crystal clear, we need not use the metaphor of balance from the beginning. We should protect patient information, and that is the end of discussion. The problem is, however, not so easy or not so simple. We need to return to the most basic question: why we should protect medical information.

Consider then an example from the credit and finance area, which includes sensitive, information in the medical field according to our Parliament. Suppose that you are a creditor and that you lend money to someone. Under Japanese law and maybe in other countries as well, you need not acquire consent from your debtor when you transfer your claim (chose in action against the debtor) to a third party. After completing the deal between you and the third party, the debtor will have to pay the debt, not to you, but to the third party. Under the Civil Code in Japan, you need not get consent from the debtor, but you have to give notice to the debtor. Otherwise, the debtor will be at a loss as to whom he or she should pay.

The Information Protection Act gave us an opportunity to reconsider this rule. Suppose that you want your claim cashed now, and decide that you would transfer or sell your claim to a third party. During the transaction, you would be required to explain about the debtor's financial situation. The potential assignee would ask: Is the debtor reliable? Does he have a stable job and position? Has he not made any defaults in the past deals? The information you would give to the third party is exactly credit information of the debtor. If the new Act protects credit and financial information and prescribes a consent rule to transfer it to the third party, you cannot enter a negotiation without consent from the debtor.

It is quite strange if you can transfer your claim without consent of the debtor under law, but you cannot negotiate with the third party without permission from the debtor. In monetary transactions, debt transfer is much more important than the information related to it. Still if the new act says, "you can do the principal part of transaction, but cannot do the incidental part and therefore cannot do the whole transaction," it is clearly a legal inconsistency. Also it would overthrow the credit transaction system altogether.

2) A couple of lessons from the example of credit area

Let us draw a few lessons from the example above mentioned.

First, the example reminds us that there are two parts of transaction, though they are closely related with each other, which should be definitely distinguished: transfer of debt, the principal part, and flow of Information, the incidental part. In the case of claim transfer, the new act could not have changed the fundamental rule of it. Even after the passage of Information Protection Act, therefore, any creditors could transfer their claim freely without taking consent from the debtor. It means that we should be cautious about interpreting the new Information Protection Act. While it appears to say that the transfer of information including credit status would always require consent some exception should apply to this case. One possibility is to look to a section in the Act that the information transfer to a third party is permissible without consent if the transfer has some legitimate basis under the law. Our Civil Code is exactly the law, one of the most basic laws in our country, and the Code allows the transfer of claims without consent, which transaction inevitably accompanies with information transfer. Thus, creditors could discuss with a potential buyer about debtor's credit status without his consent under the new law.

At any rate, the first lesson to learn from this credit example is this. We should keep in mind that we may be dealing with information matters side by side with the principle transaction, and the latter is more important than the former in most cases. In the medical context, the principal part of transaction between physician and patient is physicians' treatment of patients' body and mind. In this aspect, the ownership metaphor applies without question. Patients own their body and mind. It is not a metaphor, but a reality. The bodily integrity or the right to decide on one's own body and mind should be most highly respected. We should stricly apply the informed consent rule to this principle part of transaction, and that is for the better or best treatment for patients. We should, however, make a distinction with regard to information matters. Suppose, for instance, that a

physician hears that another physician has medical information about you, which is relevant and necessary for your treatment. Should he wait for your visit next time when he gets a consent from you authorizing the release of information from that physician? Should the same consent rule strictly apply? My answer is no. The rule would only delay your treatment, which is just a waste of time, since any of you would give your consent and the delay would not benefit you at all.

Also one more thing to note here is that the medical information is much more useful in a social context than credit information. It is easy to prove it. Let us compare a person who is bankrupt with another person who has an infectious disease. From the viewpoint of society as a whole, the latter information is much more important than the former. Thus, it is much harder for us to stick to the consent principle in the medical context.

A second lesson from the credit example is that the individual Information Protection Act has some significance, nevertheless. Let us suppose that the creditor tells a third party about the debtor in each of the following ways.

(A) The third party happens to be the employer of the debtor, and he decides to make use of credit information for the employment and promotion context. Or,

(B) The third party wants to know everything about the debtor, and the creditor informs the debtor's family matters, medical history, and the number of tickets he got from the police in the past. Or,

(C) The creditor makes mistakes and wrong information about the debtor's credit status is transferred to the third party, who makes a misjudgment on it.

These hypos vividly show that free information transfer should have its own limitations. We need some rules against these things happening for the protection of the debtor. And that is the very reason for the Information Protection Act.

In the medical context, these examples suggest that patients' concern about information transfer is natural and justified in the following cases.

(A) Information transferred may be used for discrimination.

(B) Information transferred may be more than necessary for the legitimate uses of information.

(C) The information transferred may be wrong and it may harm the patient's interest some way or other.

From the credit example, therefore, we could draw a couple of important lessons. The first one is that we should not believe in the consent principle too much in the information context. The second lesson is that can we still find legitimate concern of patients about information handling in medical context. Also that improvement of information protection would help not only patients but also society as a whole. We should think seriously about the strategy in that direction without relying only on the consent principle.

III A strategy for the better future

1) From the wishes of patients

In order to make a good strategy for future we need to get back to patients' wishes and ask what they want. They want at least the following:

(A) Patients wish to see their own medical record. Since medical information relates their health condition, their interest is natural. The rhetoric that they own the information is unnecessary, and what they need is "the right to know." Thus section 25 of the Information Protection Act prescribes the duty of disclosure on the part of hospitals.

(B) Patients want physicians and hospitals to take good care of their medical information. They fear that it may be leaked to others, and that they may receive some day those mail ads which clearly show that others know their illness.They fear discrimination by the reason of illness in the context of insurance, employment, or other social activities. Here as well, the rhetoric of metaphor of information ownership is not needed. What they need is the reight to monitor or check handling of information by medical experts. Under the Japanese law, it prohibits hospitals from making use of information for other purpose than the specific ones appropriately notified in advance. Also, disclosure of medical information to a third party requires consent by patients in principle.

(C) In some cases, patients' main concern may not be their information, but information about their health and medical treatment. That may be the precise reason for claiming the right to know access or medical records, by which they try to check the medical treatment itself. Also it may be true that those physicians, who manage medical information well treat patients well and take good care of them. In other words, patients wish to trust towards physicians.

Second, although patients' wish should be always important, I would repeat again and again that it is unnecessary and wrong for them to claim ownership of medical information. It is not logically correct, since information is not subject to ownership in most cases, but also it is not desirable for policy reasons. Patients should not monopolize their information. Of course, physicians should not monoplize it, either. It is easy to understand this, when you imagine a case in which a patient suffers from an infectious disease, and also when a physician finds a new method of treatment and tries to keep it secret. nnn The information should be reported and responded to, and in the case of new method of treatment, it should be shared. In a word, medical information is too precious and too valuable in social terms to be monopolized by anyone.

2) A strategy for protection and uses of medical information

We thus should seek for a new strategy to pursue two aims at the same time: best medical treatment for the individual patient and also best uses for the benefit of entire society. I have studied the so called "HIPAA privacy rule", which took effect in 2003 in the United States.

The most important characteristic of the HIPAA privacy rule is the fact that it seeks for two aims at the same time. It tried to speed up the standardization of medical information through electronic means and to reduce the health costs to society. Since stan-

European Forum of National Medical Associations

Statement on healthcare in prisons and other forms of detention

The European Forum of Medical Associations and WHO meeting in Oslo on 11 – 12 March 2005,

Notes that healthcare in prisons, detention centres and police institutions raises specific ethical and health issues;

Welcomes the activities and initiatives of national medical associations to provide support and education (such as the Norwegian Medical Association/WMA internet course) for doctors working in custodial care;

URGES national medical associations to address these issues, working to the following broad principles:

- Detained persons should receive a standard of medical care equal to that available within the general community.
- Healthcare in prisons should be structured to reflect the high level of mental health and substance abuse problems within the detained population, as well as its social, economic and educational makeup.
- While recognizing that physicians working in prison have dual loyalty, the healthcare and confidentiality of the patient should always be the doctor's primary concern.
- Healthcare policies should recognize the financial benefit of effectively treating health problems which, if left untreated, will result in significant overall additional cost to the community.
- Patients in prison should have the necessary access to secondary care services.
- Investment in after-care and support following release is essential.

dardizing in the form of electronic data increase the risk of privacy, they introduce a comprehensive nation-wide rule to protect medical information. Put another way, they found the accumulation of medical information in a standard form beneficial to society as a whole, and, in order to realize its benefit, found it necessary and indispensable to set up a legal system to protect medical privacy.

The same reasoning should apply to Japan as well. The first goal, then, is to set up a scheme to gather as much useful information as possible. The goal can be justified in two ways.

First, it is beneficial to patients. As we saw, the most basic and fundamental wish of patients was and has been the best medical treatment for them, and the best health care could be realized on the maximum of relevant information.

Second, accumulation of medical information is beneficial to the society as well. It can be used for variety of useful activities such as public health, medical research oversight of clinical practice etc.

Thus, we come to a conclusion that the first basic goal is to accumulate medical information. But the information to be gathered has a peculiar character, quite different from things or property we saw in the first part. Inaccurate information is useless and harmful. Even though it is accurate, if disseminated and used for bad purposes, then patients would be reluctant to share information, since it is extremely hard to recover the original status.

The specific character and importance of medical information requires us to be cautious with making up a legal strategy to protect medical privacy. The system should be equipped with three principles.

(1) Prevention principle to deter leakage of information.

(2) Discovery principle to find out violations as fast as possible.

(3) Sanction principle to punish intentional wrongdoings.

The first principle of prevention is realized by setting clear and concrete rules to be followed by both physicians and patients. The privacy rule should be clear cut in content and make no traps for those who deal with medical information. Also patients should understand, how their information is used, disclosed, and kept secret. Each hospital should publish a privacy statement or a privacy policy. It should include how the patients' "right to know" is respected and realized.

As to the second principle of discovery, there are a couple of means to make it easier to discover privacy violations. One is the patient's right to accounting, by which they can claim for tha actual use and disclosure of their inforamtion. More specifically, they have the right to know how has made access to their inforrmation has been used. Te American HIPAA privacy rule recognizes this right to accounting, but Japanes Act does not. We should consider seriously making use of monitoring incentives on the part of patients to discover privacy violations. It would help to deter violations. The other means for early discovery of violations is to give a privacy officer in medical institutions a high status and strong power. He or she should be responsible for compliance with the privacy rules. Under the Information Protection Act in Japan, every entity is required to have a privacy officer, but who it will be and what kind of expertise and power will be given remains to be seen.

The third principle of sanction is the most weak under Japanese law. The maximum sanction against privacy violations is six months imprisonment and 2,700 U.S. dollars fine. Let me contrast this with U.S. HIPAA privacy rules in which the maximum penalty is ten years imprisonment and a fine up to 250,000 dollars. Of course, criminal sanction is just a part of the whole scene.We should not forget that other sanctions could work well, but we should reconsider the comparatively lenient attitude even in the case of intentional wrongdoing when we think of the importance of medical privacy.

IV Conclusion

Medical information and its protection are important worldwide. The discussion about it, is however sometimes surrounded by misunderstandings or wrong metaphors. Medical information is not a thing anyone could or should own. Still, it may be critically important in some cases. Also it is beneficial not only to patients but also to society as a whole. We should seriously consider both the best uses and best protection of it. Discussion uses and protection in an adversarial way would lead in a wrong direction. Just to say that we should make good balance of uses and protection is useless or helpless.

We should set up a goal and make up a legal strategy to realize it. I know that Japan is just beginning to start in that direction. The World Medical Association would provide a good opportunity to discuss, compare, and improve the strategy each country should adapt. And through the support and efforts by the great Association, I hope that the wishes of patients to trust physicians come true.

WMA Secretary General

From the Secretary General's Desk

Some feel that Medical ethics nowadays is more important than ever. And indeed many ethical questions in medicine have had public attention during the last ten years: Questions concerning the beginning and end of life, research on embryos, cloning, euthanasia and assisted suicide, embryo transfer, substitute motherhood, together with subjects such as organ trade and doping, are just a few of those ethical questions which tend to be most visible in the public discussion. They all have been on the agenda of the World Medical Association and most likely they will return.

But the work of the WMA is much more than the high profile and much disputed questions with vibrant public attention: Patients' Rights – especially concerning children, research on humans, professional conduct – the questions of every day medical life are the ones that make the work of the WMA indispensable. Since World War II the WMA has been the voice of physicians on ethical and social questions in medicine worldwide.

In times of change this role is becoming more and more important. Our economical and political world has changed and so does our medical world. More and more people and governments see or deal with medicine as a commodity business. The work of physicians and other professionals in the field of health is under the threat of being turned into a plain commercial activity, ignoring the very special relationship between patients and their physicians.

And with that change both market and government influence on medicine grow in practices and in hospitals alike. Economic interventions in medicine driven by managed care organisations, insurers or governments threaten the professional autonomy of physicians. Our professional freedom – the freedom to provide care in the best interest of the patient is threatened in most, if not in all countries of this world regardless how different the health care systems are structured.

In a survey among the members of the World Medical Association during last summer, health reforms and their effects on medical practice got the highest attention. In all parts of the world questions of structure and reform move and affect physicians and patients alike. The WMA will tackle these questions. We will analyse and speak out on what health care reforms will do to the care for patients. Our commitment was and is to keep medicine as a free profession, dedicated to people, committed to health, demanding freedom from undue influence both from market and from inappropriate governmental influence.

Medicine is the unique combination of caring for people and the ethical application of science and art. The freedom it requires is no "divine right" and no permission for foolishness. It is rather a derivative of the patients' right to good and accessible health care and protection.

Higher cost and higher demands for medicine and rapidly changing demographics in many of our countries are only two of many reasons pressing for change. The rapid changes we are experiencing and their influence on our ethics and the care we provide would be an important, if not the most important global questions in medicine.

Whoever in this world uses scarce resources should be prudent and should handle those resources with regard to society at large, especially if those resources are not renewable, critical for life or in the public domain. Our work concerns all of these types of resources and most of us are aware of that. However, commercialisation or socialisation is no answer to the problem. Both limit the freedom necessary to provide choices, to allow confidentiality, to build trust. Both come with the inherent threat of rationing. The WMA gives us the platform to work together on answers to these questions.

As our governments work closely together on the international scene, exchange their views and discuss their tools, we have to do the same. Whoever believes that the international context is not important for medicine and health care will find him or herself in an isolated position very quickly.

The WMA consists of people with very different cultural backgrounds and traditions, with different economic situations, with different political views and different beliefs. And yet it is the ideal ground for the establishment and protection of common values and principles. The WMA is a membership organisation and the members are the heart and the brain of this organisation. It is their contribution and engagement that counts. It is the Secretary General's duty and service to make that work.

More than fifty years of very successful work of the WMA are a solid basis to work on, and to be a successor to the prominent persons, who have served in this position is an honour.

Otmar Kloiber

WMA

The WMA Medical Ethics Manual

On 18 January 2005 the WMA released its new Medical Ethics Manual. The Manual is a concise introduction to ethics for medical students and physicians worldwide. It deals with the basic ethical concepts in clinical medicine and research and related principles of human rights and medical professionalism, and it provides references to more detailed treatments of specific issues and other appropriate resources. It can be viewed and downloaded free of charge on the WMA web site (www.wma.net/e/ethicsunit/resources.htm) and a print version is available in limited quantities. A Japanese translation has been completed and French and Spanish ones are in progress. Other language versions will be produced as funds permit.

The manual is a product of the WMA Ethics Unit. It is an educational resource, not a WMA policy document (although it predominantly cites WMA policies).

Background

The WMA has a long-standing interest in medical ethics and medical education. In 1999 the WMA Assembly adopted the following *Resolution on the Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools World-Wide*:

1. Whereas Medical Ethics and Human Rights form an integral part of the work and culture of the medical profession, and
2. Whereas Medical Ethics and Human Rights form an integral part of the history, structure and objectives of the World Medical Association
3. It is hereby resolved that the WMA strongly recommend to Medical Schools world-wide that the teaching of Medical Ethics and Human Rights be included as an obligatory course in their curricula.

To assist in the implementation of this resolution, the WMA Council designated the development of an ethics manual as the principal activity of the WMA Ethics Unit, which was launched in 2003. It is also a primary objective in the WMA Strategic Plan 2003-2007.

A preliminary survey of medical ethics curriculum materials revealed that there are a large number of textbooks and monographs but these are generally written for a specific country and, moreover, are too expensive for most medical students in developing countries. The WMA Ethics Manual differs from these by being international in scope and available free of charge. Moreover, it relates medical ethics to both medical professionalism and human rights, three subjects that are usually treated separately.

Development

Work on the Manual began in the autumn of 2003 following my appointment as Director of the WMA Ethics Unit. I developed a prospectus for the Manual and circulated it to an international group of medical ethics teachers for comment. Following revision of the prospectus, I began writing the Manual early in 2004 and completed a first draft in June. That was sent to an expanded group of advisors, including a number of medical students. A second draft of the Manual that incorporated their comments and suggestions was completed by the end of September and that, too, was circulated to the advisors and to members of the WMA Council, along with a proposed design of the covers and layout. The final version of the text was completed in December and the PDF version of the Manual was prepared for its launch in January 2005.

Content

The Manual consists of an introduction, five principal chapters, a conclusion, and several appendices. Four of the five chapters begin with a paradigm case study that illustrates the issues dealt with in the chapter and end with suggestions for how the case should be resolved.

The *Introduction* states the goals and scope of the Manual and explains what medical ethics is, why it is important, and how it is related to medical professionalism, human rights and law.

Chapter One presents the principal features of medical ethics: its values of compassion, competence and autonomy; its pluralistic character; its gradual evolution over time; its differences and similarities from one country to another; and the role of the WMA. The chapter also provides a brief description of the different ways that individuals make ethical decisions.

Chapter Two, the longest in the Manual, deals with the patient-physician relationship. It discusses six topics that present challenges to physicians in their daily practice: respect and equal treatment; communication and consent; decision-making for incompetent patients; confidentiality; beginning-of-life issues; and end-of-life issues.

Chapter Three is concerned with the relationship of physicians and society, including those situations where there is an apparent or real conflict between the needs of patients and the demands of third parties (governments, employers, police, family members, etc.). The chapter also deals with the difficult matter of resource allocation or rationing and the role of physicians in public health and global health.

Chapter Four discusses the relationship of physicians and their colleagues in patient care, both other physicians and non-physicians. It describes what medical professionalism requires of physicians in their behaviour towards their physician colleagues, teachers and students, including reporting unsafe or unethical practices. It also stresses the need for cooperation with non-physician health professionals to provide optimal care for patients, and it suggests guidelines for dealing with conflicts about patient care.

Chapter Five focuses on the ethical requirements for medical research on human subjects, as set out in the WMA

Declaration of Helsinki. These include ethics review committee approval, scientific merit, social value, acceptable management of risks, informed consent, confidentiality, avoiding conflict of roles (physician vs. researcher), honest reporting of results, and dealing with unethical research.

The *Conclusion* calls attention to the fact that medical ethics should address the rights of physicians as well as their duties. It also deals with the responsibilities of physicians to themselves, and it concludes with some reflections on the future of medical ethics.

Five *Appendices* complete the Manual: a glossary; a list of resources that are available on the Internet; WMA and World Federation of Medical Education statements on medical ethics education; suggestions for strengthening ethics teaching in medical schools; and additional case studies.

Next Steps

An intensive communication program is underway to make the Manual known to teachers of medical ethics, medical students and practising physicians throughout the world.

The WMA Ethics Unit is developing a proposal to link teachers of medical ethics in a virtual network using the WMA website. The network could serve as a means of communication and exchange of experiences and suggestions for the teaching of ethics.

The Ethics Unit may also develop an online CME/CPD course based on the Manual.

John R. Williams, Ph.D.

Director of Ethics

Medical Science, Professional Practice and Education

Medical Implants For Higher Performance And Longer Life

Long-lifecycle MICS architecture ideal for pacemakers, defibrillators, remote telemonitors, orthopaedic devices, pump controllers, nerve stimulators and swallowable imaging systems

Cambridge UK and Boston MA, January 18, 2004 – Cambridge Consultants has designed a new 'control and communications' radio architecture for in-body medical diagnostic and therapeutic applications. Called SubQuore, it supports medical device manufacturers' drive for implantable devices which combine very low power requirements with robust wireless communications.

Cambridge Consultants' design combines exceptional power economy with great flexibility. In a typical pacemaker for example, SubQuore would deliver more than 10 years of activity from a lithium cell, but it is equally capable of meeting short term requirements for high volumes of data, in a swallowable video imaging device for example.

The implantable device market is currently growing at double digit rates: wireless communications have added a valuable new dimension to in-body therapeutic devices, and enabled a whole new generation of diagnostic aids. For device designers, the challenge is to exploit these new capacities within extreme size contraints, and with minimal power requirements. SubQuore is designed for implementation on system-on-chip (SoC) solutions, to provide a tiny control and communications platform suitable for devices using Medical Implant Communications Services (MICS) frequencies, the medical band now emerging as a global standard.

"Advances in electronics technology are enabling a host of new implantable applications, and this design draws on three of those trends: ultra low power consumption technology, more intelligent radio performance and extreme miniaturization" says Richard Traherne, head of Cambridge Consultants" wireless business unit. "Combined with the opportunities offered by the MICS frequency allocation — which is emerging as a worldwide standard endorsed by the FCC and ETSI — we see great demand for an optimized single-chip wireless platform that delivers the economy required for mass-volume medical applications".

The new implantable transceiver design leverages Cambridge Consultants' portfolio of field-proven intellectual property for ultra-low power radio, as well as the consultancy's lean RISC processor core, XAP. Extreme attention to power economy has been applied throughout the design, both to consumption in the transceiver architecture, as well as the power-saving algorithms that are employed to wake up and control the device. The architecture would consume an average current of less than 1µA, and less than 1.7mA peak, for a 0.05% duty-cycle, 400 kbits/second bi-directional communications application.

Although the range of implantable medical applications is expanding exponentially, each application is different and requires a particular mix of control, monitoring and communications facilites – and Cambridge Consultants expects to fine-tune the IC core for individual applications.

The SubQuore radio operates in the 402-405 MHz "MICS" frequency band – compatible with new FCC and ETSI standards – and offers a communications range of 6 feet/2 metres when implanted under the skin. The only other use of this band is for meteorological equipment, minimizing the potential for interference and providing an excellent platform for economy of scale through standardization.

Among the applications foreseen are for high-performance/long-lifecycle an MICS devices implantable pacemakers, defibrillators, remote telemonitors, orthopaedic devices, pump controllers, nerve stimulators and swallowable imaging and diagnostic systems.

Background In Freedonia report "Implantable Medical Devices" of October 2003, US demand for implantable medical devices is projected to increase nearly 11% annually to $24.4 billion by 2007.

Cambridge Consultants Inc., 451 D Street, Boston MA 02210, USA. Tel: +1 617 532 4700; Fax: +1 617 737 9889; www.cambridgeconsultants.com

Cambridge Consultants Ltd, Science Park, Milton Rod, Cambridge, CB4 0DW, UK. Tel: +44 (0) 1223 420024; Fax: +44 (0)1223 423373; www.cambridge-consultants.com

Advanced Medical Technology and Medical Ethics

Fumimaro Takaku, M.D., Ph.D.
President, Japanese Association of Medical Sciences

Presented at the WMA General Assembly in Tokyo 2004

Advanced medical technologies include organ transplants, reproductive medicine, genetic diagnosis, gene therapy and regenerative medicine. Among others, this presentation will primarily focus on genetic diagnosis and regenerative medicine and outline related bioethical issues.

First, in regard to genetic diagnosis, global collaborative research on human genome analysis (Human Genome Project) that started in 1990 advanced faster than was initially expected. The draft sequence of the human DNA base pairs was elucidated ten years later in June 2000, and further relate details were uncovered in February 2003. Many will remember that a variety of events celebrating this accomplishment together with the commemorative events celebrating the fiftieth anniversary of the discovery of the DNA helical structure by Dr. Watson and Dr. Crick, were held worldwide. It can be said that the elucidation of draft sequences of the human genome has finally led us to the age of new medical science and medical care that is identified as the "post-genome era"

It goes without saying that elucidating the draft sequence of human DNA itself has extremely great scientific significance. Furthermore, the global consensus is that the biggest goal of medical studies in the post-genome era is to elucidate the functions of each respective human genome for which the draft sequences were made clear as mentioned earlier, as well as to apply the results of such studies to medical science and medical care.

With regard to genetic disorders caused by a single abnormal gene, almost 1,000 kinds of abnormal genes, including notably less common genetic diseases, have already become clear, and the results of the studies concerning some of the genetic diseases have been widely used clinically for genetic diagnosis. In addition, with regard to acquired diseases, genetic diagnosis along with prognostic expectation etc., based on the results of such diagnosis, have been widely used clinically for many infectious diseases and some tumors. Moreover, in accordance with the recent elucidation of the complete base sequence of human DNA, further studies on the relationship between the results of DNA analyses and certain diseases have rapidly developed. Thus, it is expected that the studies will not only contribute to genetic diagnosis of congenital diseases, infectious diseases and specific tumors caused by a single abnormal gene, but also successively clarify the correlation between symptoms of a range of diseases that are classified as lifestyle-related diseases such as hypertension, diabetes, cancer, arteriosclerosis and Alzheimer's disease, which are considered to be caused by multiple gene-mutations. As a matter of fact, in Japan, studies on the correlation between mutations in genes including single nucleotide polymorphism (SNP) with regard to the five diseases; hypertension, diabetes, dementia, cancer and bronchial asthma, and clinical conditions of these diseases have been conducted with a unified national effort as the Millennium Genome Project since 2001. Development of these studies has every expectation of providing numerous benefits to all mankind through prevention of diseases, determination of diagnosis, choice of treatment method, prediction of sensitivity to specific medical agents and the emergence of side effects caused by medical agents for each individual patient – the individualized medical indication. On the other hand, there is also a big possibility that we must anticipate a large number of bioethical issues, which are presently being raised in connection with genetic diagnosis of congenital diseases, will be raised in a more magnified form in the future.

While genetic diagnosis has been conducted for a great number of congenital and acquired diseases, as mentioned earlier, the main characteristics of genetic diagnosis are summarized in the following three points: (1) More definitive diagnosis is possible compared to traditional diagnostic methods, (2) Diagnosis is possible with an extremely small amount of samples, and (3) Diagnosis before symptoms develop (presymptomatic diagnosis) is possible. Of these, the most controversial issue from the perspective of bioethics is (3), the possibility of presymptomatic diagnosis. This kind of problem does not exist in genetic diagnosis for congenital diseases, where abnormality is diagnosed by clinical symptoms and the results of laboratory examinations, or acquired diseases such as cancer and infectious diseases.

Presymptomatic diagnosis

However, it has been pointed out that a wide range of bioethical issues will arise due to genetic diagnosis for diseases, for which diagnosis can be determined using genetic diagnosis long before symptoms emerge. Patients suffer from serious conditions and no treatment exists for congenital diseases

such as familial amyloidosis, Huntington's disease, etc. For example, according to the research by the University of British Colombia in Canada announced in 1999, of 4,527 patients that were diagnosed with Huntington's disease, 44 people (0.97%) either committed suicide, attempted suicide or were hospitalized in a mental institution. Of these, half of those who had attempted suicide or were hospitalized in mental institutions were reported to have not at the time developed any symptoms. This suicide rate is more than times that of the average.

Another example of such problem as this is genetic diagnosis of breast cancer that clusters within a family. As it is confirmed that abnormal genes related to the development of breast cancer are identified as abnormalities of BRCA-1 and BRCA-2 genes, when a mother or sister was affected with breast cancer and abnormalities are found in BRCA-1 and BRCA-2 genes of the patient concerned, it is naturally understood that a healthy female in the family often desires to have the examination to check for the presence of abnormal BRCA-1 and BRCA-2 genes. Although the expensive cost of this examination of 2,000 US dollars or more is a problem, the psychological burden stemming from the test results is deemed to be a more serious problem. In other words, although there is no problem if the test result proves that genes are normal, there is no doubt that the person who took the test will suffer serious psychological damage if abnormal genes are found. The responses of healthy females with abnormal BRCA genes who have recovered from such psychological damage to some extent are assumed to be the following three:

(1) Cancer screening tests conducted by a doctor,
(2) Starting to take medicines that are recognized as preventing breast cancer development, including Tamoxifen, and
(3) Removing a normal breast in which an abnormality is not found in advance. It is reported that a considerable number of women choose to remove their normal breast and then undergo artificial breast reconstruction rather than being forever concerned with the fear of breast cancer developing in the future. However, since they have to go through much internal conflict before reaching such a conclusion, it is needless to say that counseling with specialists is regarded to be necessary during such a period. Since the frequency of breast cancer patients with an abnormal BRCA gene is 5% or less in Japan, (which is remarkably low compared to European countries and the U.S)., it rarely becomes subject of discussion at present, but similar issues are obviously expected to become a problem in the future.

Apart from the aforementioned issues, with respect to presymptomatic genetic diagnosis, it is questionable whether an individual needs to claim insurance for genetic diagnoses when the person is covered by health insurance and life insurance. Although, in Japan where all people are covered by public health insurance, this kind of situation is unlikely become a problem, genetic testing when taking out a life insurance plan has been studied for an extended period of time and a conclusion has not yet been reached. However, even in Japan, there is an undeniable possibility that an increased burden for the general public due to people with gene defects taking out insurance will come into question in the future.

Guidelines

Without posing the above mentioned examples, you are probably already aware that various bioethical issues arise in the research of human genes, and as a measure to cope with such problems, ethical guidelines concerning the study on human genome analysis and research were publicized as a common guideline by three ministries ,the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labor and Welfare; and the Ministry of Economy, Trade and Industry, in March 2001. While these guidelines are exclusively focused on basic studies on human genes, the ethical guidelines concerning genetic testing of clinical test samples were also publicized in April 2001. It was Japan Registered Clinical Laboratories Association that created these guidelines. In many instances, testing companies perform genetic tests as part of daily clinical examinations, based on the request from hospitals. This is the basic process in which the said guidelines were created by the association comprising these testing companies gathered together. Further, when conducting genetic tests in medical facilities, protection of privacy of patients who had had the test, counseling for patients and other issues will be an important issue to be addressed. To respond to these issues, ten societies including the Japan Society of Human Genetics, Japan Society of Obstetrics and Gynecology and Japan Society of Genetic Counseling prepared the guidelines concerning genetic testing in 2003. Furthermore, the subject of these guidelines is limited to genetic tests for mutations in genes of the generative cell system, and thus body cell gene analysis targeting cancer cells and such is not referred to.

Furthermore, in Japan, the Ministry of Health, Labor and Welfare publicized "Ethical Guidelines for Clinical Studies" in 2003. These are the guidelines dealing with clinical studies in general created basically in line with the "Helsinki Declaration," adopted at the World Medical Association in 1964, which has been modified and added to six times.

As presented above, regulations on genetic tests are distinctively placed in the format of guidelines. Despite differences in the detail of these guidelines according to the respective objectives and targets, the common points among them are as follows:

Protection of the rights of patients, their families and relatives,

Protection of personal information,

Legislation prohibiting genetic discrimination

Acquisition of written informed consent from search objectives,

Approval of facility chief after screening at Institutional Review Board (IRB), and

Preparation of mandatory genetic counseling system at testing facilities.

It is highly predictable that the research on the correlation between gene abnormality and diseases caused by multiple gene defects such as lifestyle-related diseases, which is competitively conducted on a global scale at present, will be developed, the correlation between the results of DNA analysis of each individual and the development of these dis-

eases will be manifested, and checking mutation in genes will enable the diagnosis of whether or not each individual is likely to be affected by these diseases. If such a situation is realized, it can easily be presumed that, in addition to the aforementioned issue of taking out insurance, a broad range of social issues including the possibility of genetic diagnoses in connection with finding employment, marriage and other daily issues; the issue of protecting confidentiality of personal data on genes etc. will be raised due to a great many more patients with lifestyle-related diseases being different from traditional cases of genetic diagnosis of congenital diseases. The pace of progress in bioscience is beyond our imagination and thus, we need to use this chance to discuss these issues, to a satisfactory extent, in preparation for the advent of such situations.

Diagnosis in the Fertilised Ovum

Further, diagnosis of fertilized ovum is what arouses concern in Japan as genetic tests related to reproductive medicine. Fertilized ovum diagnosis is among medical technologies for reproduction, in which "in vitro" fertilization is performed; one of the fertilized eggs is taken out for genetic testing when the division of the fertilized ovum proceeds and it is returned into uterus only when the results prove it is normal. In its bulletin, the Japan Society of Obstetrics and Gynecology approves fertilized ovum diagnosis only in the event of serious congenital diseases. However, the bulletin of the society has no legal force. On the other hand, there are some organizations that strongly oppose fertilized ovum diagnosis. Japanese law does not permit induced abortions on the grounds of genetic abnormalities. This is because of strong opposition insisting that approval of induced abortion of children with gene defects means discrimination towards disabled people, and I think opposition against fertilized ovum diagnosis stems from this same reason. However, in effect, it is estimated that induced abortions of fetuses with congenital diseases has been conducted for different reasons in Japan.

"Regenerative Medicine"

I would like to change the subject to bioethical issues related to "regenerative medicine" as in the case of genetic analysis. It was reported that Dolly, the sheep clone, was successfully generated by Dr. Wilmut of Roslin Institute in Britain in 1997 and became a worldwide topic of discussion.. It is not surprising that the mass media devoted much space to concerns over the possibility that the same technology may lead to human cloning. Later, there actually appeared doctors who attempted the creation of cloned human beings and there was some publicity given to those claiming to have been successful.

In Japan, "The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques" was enforced in June 2001 and the creation of humans utilizing cloning techniques has been prohibited by law. For your information, offenders of this law are to be fined up to 10 million yen or 100,000 US dollars and receive prison terms of up to ten years.

On the other hand with respect to human embryonic stem cells (ES cells) that are capable o being differentiated into a variety of cells, two American research groups reported the establishment of the ES cell line in 1998. ES cells can be differentiated into every kind of cell and consequently, it is natural that the application of this to medical transplantation is expected, especially for neurological disorders, severe cases of diabetes and critical hematological disorders that require bone marrow cell transplants. On the other hand, it is true that strong opposition is expressed, because creation of ES cells is accompanied by the destruction of blastocyte generated from human fertilized ovum. In Japan, the review at the Office for Bioethics and Biosafety, Lifescience Division of the Ministry of Education, Culture, Sports, Science and Technology led to the publication of "Guidelines for Derivation and Utilization of Human Embryonic Stem Cells". Consequently, both the production and use of human ES cells have become possible. However, when doing so, a dual screening system is employed in which the research plan submitted by the head of the institution after undergoing review by IRB of the respective facilities are to be reviewed again by the governmental review board. In Japan, the production of the human ES cell line as well as research using human ES cells has already been conducted at about ten research facilities.

When using the cell differentiated from human ES cells for medical transplantation, it is no wonder that the difference of HLA between the original ES cells and a patient will become an issue. It is because, needless to say, transplanted cells will be rejected despite the hard work of transplantation unless HLAs between ES cells and a patient match. The most effective method of solving this problem at the present stage is therapeutic cloning technology.This is to create cloned embryos by placing nuclei taken from a patient's somatic cells into donated ovum after denucleation and then creating ES cells from the cloned embryo. In addition, as for this technology, It has been recently proposed to use the term "nuclear transfer" since the term, cloning, is easily mixed up with reproductive cloning to create cloned human beings. The countries that admit the creation of ES cells created by using the patient's own nucleus, produced in the aforementioned manner, that is autochtonous ES cells, are the U.K., Belgium, Sweden, South Korea and China. South Korea attracted attention worldwide since Prof. Hwang, et al. in Seoul National University disclosed the successful creation of autochtonous ES cells on the on-line Science magazine in February 2004. After that, some people, centering on opponents of human cloned embryo, criticized the origin of donated ovum.

In Japan, the pros and cons of research on therapeutic cloning has been debated for over two and a half years by the Expert Committee on Bioethics of the Council for Science and Technology Policy in the Cabinet Office and it was finally decided in July 2004 to approve therapeutic cloning only in cases of basic research and to promote the preparation for a system for this. The reason behind the fact that it took a long time of two and a half years for the discussion to reach this conclusion was that diverse opinions concerning the pros and

cons of promoting the studies on therapeutic cloning among committee members of the said Expert Committee prevented a consensus from being reached.

I myself participated in the government-affiliated committee as a committee member with regard to bioethics to deal with the issues including reproductive medicine, gene therapy, human ES cells and studies on therapeutic cloning. The impression I got from the meeting was that the Japanese committee had only a few opportunities to hear patients' opinions. Actually, an open symposium concerning therapeutic cloning was the limited opportunity for me to directly listen to patients' opinions. In addition, I received the impression that media coverage was prone to bring up more negative opinions on the subject of the advanced medical technology mentioned above even if they were minority opinions. Furthermore, probably due to few opportunities to hear opinions from patients and their related parties at the hearings of the committee, I thought there were only a few situations when news reports raised patients' voices. On the other hand, partly because regulations on genetic diagnosis and regenerative medicine are executed as guidelines instead of laws, except for the Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques in Japan, it appears to be one of the characteristics in Japan that a big political impact has not been made to date. Medical care is certainly embarking on an age of globalization. The latest information on advanced medical technologies can easily be obtained via the Internet and it leads to the era when the most advanced medical care is available everywhere around the world as long as the expenses are not brought into question. Although the "Brain-Dead Transplant Bill" proposed in Japan does not permit the transplantation of organs from brain-dead children, families constantly go overseas to have their children undergo transplantation despite the substantial expenses. I also hear that many couples obtain fertilized ovum diagnosis overseas, which as I described can only rarely be conducted in Japan.. I suppose other countries probably have similar situations.

To overcome such conditions, I am looking forward to seeing the World Medical Association create universal ethical guidelines concerning advanced medical technologies. With admiration for the World Medical Association's formulation of the Helsinki Declaration that has been revised several times, I would venture to insist on the need to add universal ethical guidelines with regards to advanced medical technologies. As the perspectives concerning bioethics of advanced medical technologies vary widely depending on cultural and religious background of the respective countries, it is needless to say that difficulties generated when creating such universal guidelines could well be foreseen. However, advanced medical technologies have been developed and put into practical use not for the special benefit of us, medical experts, but for the benefit of patients whoreceive diagnosis and treatment utilizing such technologies. Given this fact, I regard it to be an important role that the World Medical Association should play to make an appeal so that people throughout the world may get equal benefit of all medical care including advanced medical technologies.

Modern Demands in Health Care

Haruo Uematsu, MD
President, Japan Medical Association

Presented at the WMA General Assembly in Tokyo 2004

In looking back on the past century, the 20th century is noteworthy for achieving scientific progress that is unprecedented in the history of mankind. In conjunction with developments attained in medical science, physics, chemistry, biology, and other fields, great strides have been made through interdisciplinary exchanges.

Especially noteworthy is the progress made in antibiotics, beginning with the discovery of penicillin, that has especially been very effective in controlling the foremost cause of mortality—the spread of infectious diseases. So effective was this control, that for a short period of time, many people were lulled into the belief that it was possible for infectious diseases to be completely controlled. However, the manifestation of drug-resistant strains of bacteria, the emergence and re-emergence of infectious diseases has shown that numerous problems will arise in tandem with future developments. In recent years, the focal point of the disease structure has shifted from infectious diseases to cancer, cerebrovascular diseases, diabetes, and other diseases that stem from lifestyle habits. This has led to a review of lifestyle habits and it has greatly affected the focus of medical care.

Another notable point is the progress that has been made in clinical imaging technology. The discovery of X-rays was a landmark discovery, but the development of the CT, MRI, PET in recent years has epitomized the fruits of interdisciplinary research, and the contributions to medical diagnosis made by these imaging techniques have been immeasurable. This has also been true for biochemical tests. Although progress in diagnostic technology that precedes medical treatment has incurred criticisms of excessiveness or the waste of financial resources earmarked for medical costs, progress in medical care is a foregone conclusion.

The twentieth century has been called the century of wars as attested to by the numerous wars that were fought in the last century. In the field of physics, fission phenomenon developed by nuclear science was not utilized for peaceful purposes, but to produce nuclear weapons; and tragically, there is a history of its actual use, which provides us with an unforgettable moral lesson about what occurs when the scientific achievements are mistakenly utilized to fulfill human or national greed.

Although with the passing years the growth of various industries led by scientific developments has made our lives much more convenient, it has also left us with a burdensome legacy of serious environmental pol-

lution and the destruction of the natural order of things. Moreover, it will require additional years and enormous effort to recover from these damages.

In Japan, the onset of the Minamata disease caused by seawater pollution is a tragic case example, as well as the large number of patients with respiratory disorders stemming from air pollution. The yin and yang results of scientific development often become apparent only after a fairly long period of time. Thus, the effort to acquire the wisdom to anticipate numerous phenomena that may occur over a wide spectrum of situations must not be neglected.

Since medical science and medical care are directly linked to life and death issues, its impact on the future must be constantly taken into consideration. In our review about medical care and its ideal form, an important point to consider is the relationship between medical science and medical care and recognition of their differences. The late Dr. Taro Takemi, former JMA president and the president of the WMA, defined medical care as "the social application of medical science". As to whether this is the best definition of medical care can be debated from a myriad of differing perspectives, but I believe that it is the most appropriate in explanations about medical care.

There is a relatively common perception about medical science that is shared among all countries. But, its social application is tempered by a panorama of factors that range from the natural environment, history, culture, politics, to the economy of each country. These exceedingly diverse conditions that surround medical science contribute to the complexity of medical care. Cold climate and tropical regions, mountainous and sea level regions, wet and dry regions the climactic and geographical differences lead to disparate diseases and the medical care that is needed to treat them also differs. A prime example is endemic diseases. Due to developments in transportation, infectious diseases that were once confined to a specific region have begun to spread rapidly and globally over a wide geographical area forcing each nation to be prepared to cope with these diseases. The most recent example of this phenomenon is SARS.

Diseases that are linked to the dietary habits in each country or region are effectively treated through lifestyle guidance measures rather than by medical care. In the northern, cold climate regions of Japan, studies have shown that there was a high incidence of hypertension due to a high dietary salt intake by the population, and lifestyle guidance measures have effectively helped to control salt intake levels.

However, medical care issues in countries that face political and economic hardships are the most difficult to resolve. Due to extremely poor public and environmental health conditions, many people are unable to receive needed medical care despite the high incidence of diseases. The WMA has a role to fulfill in such countries where the population is unable to receive proper medical care due to existing economic conditions.

Currently, organ transplants, genetic testing, gene therapy, reproductive medicine, regenerative medicine and other forms of advanced medical technology are being successively and practically applied. The advent of medical care that was once considered impossible or the development of minimally invasive treatment methods has raised the fervent expectations of many and has pushed advanced medical technology into the public limelight. Meanwhile, bioethical issues, professional ethical issues that confront physicians, and issues that question the very essence of medical care have come to the fore, as attested to by the ethical issues seen in reproductive medicine.

As a science, medicine has pursued progress in the treatment of diseases and it has sought to illuminate the phenomenon of life. The fruits of these endeavors have made advanced medical technology and medical care possible. Medicine as a science seeks to achieve the potential and to attain progress through cumulative research, but in order to apply the fruits of medical science in medical care, the impact of social factors mentioned earlier becomes crucial. Even the understanding of bioethical issues that are perceived as being analogous throughout the global community, will differ according to the history, culture, and religion of each country, as well as the ethos of the times.

In Japan, laws that govern brain death and organ transplants were not legislated for a long period of time. In truth, one of the underlying reasons for this delay was public distrust of medical care, as well as dissatisfaction with the traditional system of paternalism, an inadequate understanding of informed consent, compounded by Japan's own unique religious beliefs and perceptions about death. Thus, it took time to achieve public consensus. In view of the lessons that were learned from this experience, there must be adequate public disclosure of information and sufficient public dialogue with regard to highly advanced medical technology.

If there was even one physician who attempted to utilize advanced medical technology without the consensus of society for personal fame or to satisfy academic curiosity, public distrust of the entire medical field would be generated that would greatly damage progress and development. As professionals working in medical science and medical care, this is an issue that precedes ethics. However, advanced medical technology does contribute to human happiness and well being. It is essential that society recognizes that it is safe and there is an extremely high probability of success.

Therefore, ethics, IT, physician qualifications, professional autonomy, and other issues have been included in the program for the Scientific Session with the main theme of advanced medical technology. I will leave detailed discussions about these issues to the respective speakers who will be discussing them in the special lectures and symposium that have been planned.

In viewing the situation from a different perspective, advanced medical care has made it possible to provide treatments for diseases that were unavailable in the past. Simultaneously, it has forced physicians to specialize in order to provide this treatment. The curriculum in medical education has become excessively concentrated and segmented, and medical students are trained in the partial and individual treatment of dis-

eases. But this education does not adequately address issues such as patient QOL, does not consider what is truly beneficial for the well-being of the patient, and what measures should be taken to achieve this well-being from a broader perspective of medical care. In an increasingly aging society, these are issues that call for a reaffirmation of the importance of holistic medicine by all medical care providers. It is important to note that the perspectives about life and death that prevail in each country are also important contributing factors.

The greatest demand that is being made on medical care today, is to provide safe and high quality medical care that is accessible equally to all people. In Japan, as in other countries, Japanese society and its citizens have recently begun to stress the need for safe medical care due to the frequent occurrence of medical errors. Consequently, specific measures and results are being demanded of medical care providers.

The three causes of medical errors are people, equipment, and organization. Of these three causes, the foremost cause is people. In other words, measures must be taken to improve the professional qualifications of medical care personnel and to raise physician ethics. Although this is the responsibility of each individual physician, medical associations also have a major responsibility to fulfill as professional academic organizations for physicians. Likewise, society also has great expectations of medical associations in helping to address this issue. To meet these expectations, medical associations must actively pursue measures to raise the professional ethics of physicians and to promote CME programs for its members.

In the past, the physician was the focal target of responsibility for medical errors, but it is more important to clarify the cause of the error, to take measures to prevent its reoccurrence, to reeducate the responsible physician in lieu of punitive actions, and to pursue measures that allow physicians to provide a higher quality of medical care. Latent high-risk cases should not be simply compiled as potential medical error cases. This task should be actively carried out as a means of preventing medical errors. Although error-proof equipment, improved pharmaceutical packaging, improved usage, and other improvements have been targeted and implemented, ultimately, the responsibility returns full circle on shoulders of the physician-in-charge (the foremost cause of medical errors).

In the area of organization, there are a variety of issues that must be investigated such as the process of providing medical care and other factors; and many medical institutions have created review committees to address these issues. But, coordination between the different medical occupations within the medical institution becomes important and we return again to the foremost cause of people.

Presently, every nation is faced with the difficulties of securing financial resources to pay for medical care and with efforts to control medical costs. It is vital that each NMA actively stresses the importance of the need to inject funds to cover medical costs in order to secure safe medical care. It is also important for the WMA to publicly proclaim its viewpoint on this issue.

As of 1961, all residents in Japan have equal access to safe and high quality medical care at all times under the universal health insurance system. Consequently, according to a WHO report, Japan has the longest healthy life expectancy and the highest health record in the world. Moreover, national medical costs are ranked 17th in the world denoting the achievement of effective health care at low costs.

However, the universal insurance system in its current form was achieved after many trials and tribulations—nationwide strikes by medical personnel, mass resignations by health insurance physicians, political struggles against the government over health insurance measures, and many other activities. Medical payments are decided according to a nationwide, uniform point system for medical service fees. In Japan, all medical services that are provided, from consultation and examination fees, tests, treatment, surgery, injections, medication, to hospitalizations, are calculated and paid according to the medical fee schedule. This schedule is applied nationwide, and allows all residents to receive medical care at all times throughout the country under a uniform pricing structure. A breakdown of national medical cost coverage shows that 30 percent is funded by public expenditure, 50 percent by health insurance, and about 20 percent by individual patients. It is difficult to inject national taxes to pay for medical costs due to national economic conditions, and the government's recognition that medical care is part of social security also plays a great role. We are endeavoring to maintain this system amidst successive applications of costly, advanced medical technology within a rapidly aging society.

Each NMA is also undoubtedly striving to achieve a system that will provide equal, high quality medical care for all citizens, and it is hoped that Japan's universal health insurance system as well as the activities of the JMA will serve as an example.

Currently, the number of beds in proportion to the total population is high in Japan and the hospitalization period is lengthy. Consequently, hospitals have been criticized for allowing social hospitalizations or long hospital stays by patients who can be discharged. This has been toted as a prime example of wasteful medical costs. As a result, hospital beds have begun to be categorized as general hospital beds (for patients hospitalized for medical care) and convalescent beds (for convalescent patients with minimal medical care needs) and there is a move to reduce the number of hospital days.

The foremost problem with regard to outpatient services is the tendency of patients to go to large hospitals, which has contributed to extremely long waiting hours and reduced examination periods. This is a serious problem for many patients, that simultaneously places excessive demands on the physician. Thus, immediate countermeasures are needed. This is one of the inherent flaws of this universal insurance system since it allows patients to receive treatment at any medical institution with only a relatively low, initial co-payment fee.

To compensate for this flaw, to eliminate wasted medical resources, and to provide effective health care, a system of medical provision has been created. In order to provide medical care, including advanced medical technology, appropriately to those in need, the functions of medical institutions have been divided and coordinated. In addition, information about the functions of each medical institution are openly disclosed and measures to provide information that allow patients easy access have been pursued as an important means of improving the system.

In Japan, a community health and medical care plan has been created for communities with a population of about 300,000 that have been designated as medical zones with all required medical facilities. One of the focal aims of this plan is to allow community residents to live in security with regard to their medical care needs, which are mainly taken care of by a system of primary care physicians who are supported by a network of hospitals. The objective is to create a comprehensive community health and medical care system within a designated medical zone. This is not a system that simply provides medical care. The aim is to build communities where residents are able to live out their lives in relative security within a system that provides wide-ranging health insurance and medical care services. Medical association activities also include maternal and child health, school health, community health, industrial health insurance, health insurance for the elderly, as well as activities for health insurance for all ages, vaccinations, emergency medical care, and nursing care for the elderly. The perspective has shifted from medical care providers, who have traditionally been responsible for creating health services and providing medical care, to that of community residents, in order to establish active local communities and to carry out activities that will allow residents to live in security. It is a significant means of renewing public trust in medical care.

Long-term care or nursing care has become an important issue as Japanese society continues to age. In tandem with the national health insurance system, a long-term care insurance system was created. Initially, nursing care for the elderly was covered under the national health insurance scheme as social hospitalization. But, the focus of nursing care has begun to shift increasingly to in-home nursing care services. The idea is to support the independence and self-reliance of the elderly and to enable them to live at home in familiar surroundings. The amount of financial support that is provided for nursing care costs is divided into six levels, and a ceiling has been placed on the maximum amount of assistance that will be provided at each level.

Unlike the national health insurance, applicants must be certified as being in need of long-term nursing care in order to qualify for long-term care insurance. The applicant's primary physician must submit an accurate assessment of the applicant's need for nursing care and must follow-up on the patient to ascertain that proper care has been provided. Additionally, proper medical care must also be provided. Therefore, flaws in the system must be corrected and the physician's awareness must be reformed. In this respect, these measures can be included within the comprehensive community health and medical care system.

In thinking about societies that provide medical care, the political and economic conditions as well as the structure of the diseases that exist in each country differ. Thus, the issues that medical care faces are myriad. There are economically rich countries, countries beset by poverty, population growth, a declining birth rate, and there are countries that face problems that are completely contrary to these issues.

The major theme of advanced medical care that have been addressed at the Scientific Session of the WMA Tokyo General Assembly will discuss the fact that there are countries where ethical concepts and perceptions have been unable to keep up with the ever increasing pace of advanced medical technology and countries that desire to have access to advanced medical care, but cannot because of economic reasons, attesting to the complexity of the issues that are involved. It is difficult to come up with expedient proposals that address these issues and many must be addressed as political problems.

However, if medical care exists to further the well being and security of the human community, each nation is obligated to promote medical care with in the various conditions that exist despite the disparities between countries. It is important to continuously stress the fact that medical care is an investment in health and consequently, an investment in national strength to governments that try to control medical costs by defining medical care as simply consumption.

The medical care delivery system and the concept of a comprehensive community health and medical care system that is being promoted in Japan does not generate inordinate costs to implement, and they can be immediately adopted and implemented in countries that are economically burdened. Hopefully, this plan will also serve to assist such countries. I will be reporting periodically on how this system progresses in Japan and hope that the information may be of some assistance.

I have attempted to discuss the conditions that surround medical science and medical care, and the medical care issues that are being demanded by the public. In conclusion, what is being demanded today, is safe, progressive, and "quality" medical care that can be effectively and fairly accessed by all. Each physician and medical association must steadily strive to meet these demands supported by governments through national policies and financial measures.

Lastly, I would like to state that we, physicians who are entrusted with the task of protecting the health of humanity through daily medical care activities and the WMA, a major organization of medical associations, must take action and courageously voice their viewpoints on events that threaten human life, notably regional conflicts, starvation, and other hardships that accompany poverty.

Coordination of Progress in Information Technology with Health Care in the 21st Century

Shigekoto KAIHARA, MD
Vice President, International University of Health and Welfare

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1. Characteristics of Information Technology (IT) in the 21st Century

To summarize the advancement of information technology (IT) in the 21st century, we could say, "IT was utilized by health care providers at medical institutions in the 20th century. But with advancements in the IT world, IT has been disseminated not only to health care providers but also to patients in the 21st century, producing a great impact on health care." Today, I would like to speak about the harmonization of IT progress and health care, focusing on care provider and patient utilization of IT. The next speaker will discuss the great impact IT has had on medical research, so I will talk mainly about the impact of IT on medical practice.

First, let me summarize the characteristics of IT in the century. The advancement of IT in the century can be represented by 1) personal use of IT, 2) advanced communication, 3) multimedia, 4) large-scale database, and 5) robotics.

Personal use of IT means that IT is utilized by individuals. As of 2002, more than 70% of households in Japan had personal computers, and more than 80% of them are using the Internet. It has become easy for ordinary people to utilize information technology. Many people are using the Internet via cellular phones in Japan; 79% of cellular phones available in Japan are web-ready.

At home personal computers are connected to the Internet, and users can obtain a variety of information from around the world in no time. For example, national university hospitals can transmit high-resolution images using the satellite communication system, making it possible to exchange lectures such as live surgeries among universities. It is noteworthy that the broadband service fees in Japan are lower than in any other area in the world.

Multimedia technology has created new images such as the three-dimensional image and made it possible to accumulate and store high-resolution moving images for a long time.

In large-scale databases, life-long medical information of patients or the latest medical literatures can be compiled and stored. For example, it is widely known that the database of the National Library of Medicine in the U.S., on which some millions of literatures are compiled, is open to the world as a service called MEDLINE.

Robotics is also one of the characteristics of IT in the 21st century. How the humanoid robot technology will be applied is yet to be seen.

2. Impact of IT on Health Care

Each characteristic of IT is quite useful. We are witnessing the tremendous influence of modern science in our daily lives. But the latest advanced technology has disadvantages as well, even though the technology itself is wonderful. Although some technology is directly applied to human beings in health care, great technology does not simply result in good health care.

In fact, health care in the 21st century has been changing under the influence of IT. Human well-being could be enhanced if IT is utilized correctly, but may degenerate if IT is misused.

The changes in health care brought about by IT can be described in a number of ways, but I think the following four changes are symbolic of them in general: (1) scientification of health care, or dissemination of evidence based medicine, (2) decentralization of medical practice, (3) merger of public health, medical administration and clinical medicine, and (4) expansion of the active role of patients, or patient empowerment. I would like to talk about each of these symbolic changes in detail.

Scientification of health care

First, I will consider the scientification of health care, or dissemination of evidence based medicine. Various clinical trial methods have been established, and all clinical procedures are now required to be performed based on scientific evidence. Results of clinical trials are published as medical literature, compiled to establish clinical guidelines, and made available to physicians on the Internet. Physicians are expected to practice medicine following these guidelines. Results of such clinical practice are fed back to researchers, serving as cues for new research. In this cycle, the results of clinical studies are shared with clinicians in no time, and new medical knowledge is quickly disseminated all over the world. For example, reports on significant adverse drug reactions are made available to physicians in the world within a few days. Such speedy dissemination of important information would not have been possible without IT.

While this trend yields benefits for both physicians and patients, we should consider the availability of treatments recommended in clinical guidelines to patients in the world. There are numerous reasons for not being able to receive such treatments. No matter how advanced the information technology is, it takes time to disseminate information to each individual physician, and clinical guidelines are not necessarily put into practice immediately. There are more serious reasons for not being able to put guidelines into practice, however. One is not being able to obtain the medical resources necessary to provide recommended treatments for patients no matter how much such treatments are desired. For example, there may not be any physician who can perform the procedure, drugs may not be available in the area, or drugs may be available but cannot be obtained due to high costs. When talking about medicine on a global basis, it would not be exagerating to say that there are only a few countries where

medicine can be practiced by following clinical guidelines. As long as medicine is practical science, the constant presence of a gap between medical knowledge and medical practice is unavoidable.

Therefore, we should not criticize it as unscientific if medicine cannot be practiced by following clinical guidelines. Physicians should have more interest in bridging the gap between scientific medicine and actual health care. It is more difficult to close this gap compared with discovering new knowledge. In some cases, you may have to use alternative medicine (or traditional medicine) that has a long history. We should emphasize that the best medical practice is to do our best with whatever resources are available in the given environment.

Decentralization of medical practice

Secondly, IT has brought about decentralization of medical practice. Health care has been provided to patients who visit certain places where medical resources are centralized as much as possible. Since it is impossible for a physician to treat a lot of patients by visiting each of them with medical and testing devices, patients have to visit clinics, hospitals or health care centres to seek treatment. However, this may be undesirable for some patients. Needless to say, it is most desirable if they could receive the best treatment in the places where they live with their families.

In the advanced information-telecommunication society, even if decentralization of "tangible" medical resources cannot be achieved, the decentralization of medical "information" is now possible. With the advanced information-telecommunication system, information can be delivered anywhere in the world in no time. It is quite interesting that a large part of medical practice is receiving or providing information. Diagnosis, for the most part, means information processing by a physician, with information provided by a patient. The same can be said for determining a treatment strategy. In some treatment, physicians only provide information to patients who "act out" what they have learned. Moreover, in some cases what used to be done by physicians may be done by nurses instead. Taking into account these perspectives, medical practices, to a certain extent, could be given to patients at home by combining information exchange systems and a medical team of nurses.

Changes toward decentralization of medical practice can be seen in a variety of areas. In Japan, the value of home health care has been reconsidered. Advanced medicine can now be practiced on a ship in the Pacific Ocean or on a spaceship. Jacque Marescaux of IRCAD/EITS in Strasbourg, France, has successfully performed a heart operation through the intercontinental remote operation of a robot between Strasbourg and New York; it is called "Lindbergh operation" after the man who achieved the first trans-Atlantic flight. Such medical practice is called "distance medicine".

These are wonderful achievements in medicine brought about by IT. However, we should think about the disadvantages of the technology once again. First, we must never rely on information tools too much; humane health care must not be forgotten. No matter how the information technology advances, it is essential for physicians and patients to face each other as human beings. We should remember that information exchange through IT is one of complementary tools for medical practice.

Secondly, there is an issue of the cost of the systems. In other words, it is an issue of medical efficiency. Being efficient means being more economical. Patients have been required to visit medical institutions because health care can be provided more efficiently that way. In this sense, it is quite interesting to examine if distance medicine is more efficient than centralization of health care. The advanced countries are taking different approaches regarding this issue. In Canada and Australia where people live scattered across large land areas, depopulated areas in the U.S. and in the mountains in France, distance medicine is considered more efficient. The national or the state governments in such countries have already instituted policies promoting distance medicine. In densely-populated Japan, there is no consensus on whether health care can be provided more efficiently with distance medicine compared with the centralization of medical resources. When we think about harmonizing IT and medicine, we should consider the economical aspect of the harmonization.

Merger of clinical medicine and public health/medical administration

IT has also had an impact on public health and medical administration. Such an impact is associated with the construction of large-scale databases. Public health and medical administration services are provided for a large number of people in a certain area or in the whole country. It used to be impossible to handle data on hundreds of thousands of individuals; decisions on what services to provide and how to provide them were always made based on compiled data. In other words, clinical medicine and public health were totally different forms of health care.

However, to stretch the point, the technology for constructing these databases enabled us to build reservoirs with medical data on each individual. For example, the technology changed infection control measures. When there is an outbreak of a certain infection, the measures to control the infection are established based on the analysis of data on infected individuals compiled in the database. Medical institutions and administrative agencies work closely with each other, and analysis results are provided for physicians in the clinical sites in real time. Such information delivery was quite effective in the recent outbreak of severe acute respiratory syndrome (SARS), as well as the spread of E. coli O-157 infection in Japan several years ago.

Not only infection data but also the entire medical data in a certain area or a country could be retained, accumulated, and analyzed in a database if they are electronically stored. In countries where health care insurance is disseminated, data are usually digitized in the process of claiming medical fees. If these digitized data are compiled to build a database, the current situation of health care in that country can be completely grasped. Such databases are already available in some of the advanced Western countries. Although electronic data on the health care insurance has been promoted in Japan, a database does not

exist because such data have not been standardized. I am concerned that there may be a lack of data that could serve as a basis for the revision of medical fees.

Compilation of accurate medical data on the entire nation is quite useful for the efficient provision of health care. However, there are some issues to be considered. Two of the major issues are protection of privacy in the process of handling medical information and authorization to access the database. I will skip the privacy issue because Dr. Higuchi will talk about it in detail later. Here I would like to refer to authorization to access the database.

Analyzing medical data of individual persons in the database will reveal many facts; therefore, who will be authorized to access the database is a big issue. If the government has sole authority to analyze the data, the government gains tremendous power and may force a variety of policies on its people. Since this is surely undesirable, the medical database for analysis should be widely available to those who are interested in such analysis, while medical data containing personal information should be handled with caution. All nations should share their experiences in considering how to resolve these conflicting issues. The most important thing, I believe, is to establish rules for using the database, to make it public, and to authorize anybody who is willing to obey the rules. The present guideline for the medical database established by the World Medical Association puts emphasis on the privacy issue; however, I wish more consideration had been given to the access issue.

Patient empowerment

The most important impact of IT is that patients can now play a proactive role in health care. We can call it patient empowerment. Now that patients can easily obtain health care information on the Internet, they will be able to choose medical institutions according to the obtained information and discuss treatment options with physicians on equal terms. For example, patients can review their medical records kept at the hospital at home with their families via the Internet. Although the number is still small, some hospitals and clinics offer such services for their patients in Japan.

While this is a welcome change, we should keep in mind that much of the information available on the Internet could be wrong or exaggerated. The quality of information posted on the Internet may be questionable, and this is a common and serious problem, not limited to health care, in the modern, advanced IT world. It is almost impossible to totally eliminate bad quality information from the Internet. However, the influence of bad quality information can be minimized if medical professionals provide high quality information themselves. A group of physicians may evaluate the medical information on the Internet to set aside reliable information and give it an approval mark. It will be meaningful if voluntarily done by people with conscience in the private sector; it will be censorship and undesirable if done by the government. Physicians now should consider methods of quality assurance in providing information to their patients.

Contrary to reducing the trusting relationship between physicians and patients, patients' proactive role in health care should enhance such a relationship. Some say the number of medical lawsuits will increase if patients obtain health-related information; however, there is no evidence to support such a notion. In the 21st century, patients should proactively obtain information to enhance the trustful physician-patient relationship and improve the quality of health care.

Robotics

Lastly, I will talk about robotics. Robotics has only recently been put to practical use. Nursing robots and transportation robots are available now. There has been a growing interest in using robots to comfort people. One type of nursing robot will sense a slight movement of the hand of a paralyzed patient and put food into the patient's mouth with a spoon.

All the roles robots will have in health care is yet to be seen. There was a time when people considered using robots in health care to be totally inhumane and unacceptable. However, if we carefully choose where to apply robotics in health care, robots will be useful. I will stop here because I do not have enough data to further discuss this issue. We will have to observe the development and application of robotics in health care with interest as medical professionals.

3. Conclusion

I have spoken about the necessity of harmonizing IT and health care in the above-mentioned five areas. Needless to say, IT is a wonderful technology that will make great contributions to health care. In order to make such contributions worthwhile, it is important for all physicians to be interested in the technology and use it correctly. Health care will not improve just because IT is used; the quality of health care will improve only if IT is used correctly. Every physician should understand the technology and use it as his or her own tool in the 21st century.I hope we will all make efforts to enhance harmonization of IT and health care.

The Medical Liability System in Germany – An Accepted System

Dr. Suzanne Katelhön, Auslanddienst, Bundesärztekammer, Germany

Astronomical claims for damages and escalating premiums for medical professional liability insurance, a growing number of court cases against doctors - not least because of the high profits made by the lawyers and the possibility of aggressively soliciting suing patients - the snapshot presented by Dr. Palmisano in his article in the latest issue of the World Medical Journal (WMJ 50 (4)110 is alarming.

Worthy of note are the roughly 70% of medical liability cases that end up before a court and are closed without damages being paid.

The USA are not exceptional in this context. Comparable figures can also be found in Germany, the difference being, however, that the cost of litigation remains within reasonable limits, since many of these cases can be settled out of court.

The decisive factor behind this situation was the introduction of Expert Commissions and Arbitration Boards at the State Medical Chambers in 1975. They are independent bodies that examine differences of opinion between doctors and patients to objectively establish whether health-related complications are attributable to medical treatment giving rise to liability. The aim is to reach an out-of-court settlement between the doctor and the patient. The Expert Commission draws up a written expertise on the question of whether the doctor can be accused of medical malpractice, as a result of which the patient has suffered, or will suffer, damage to his health. The Expert Commissions are headed by a chairman qualified to hold judicial office, who is usually assisted by two members from the medical profession, at least one of whom is active in the same field as the doctor in question.

In agreement with the parties involved, meaning the patient, the doctor or hospital, and the liability insurer, the Arbitration Boards clarify the facts and circumstances of the case and then make a proposal for settlement of the dispute.

The members of the Arbitration Board are a doctor as chairman, a lawyer qualified to hold judicial office, and other members from the medical profession.

In this context, the statements of the Arbitration Boards globally judge compensation claims, while the Expert Commissions appraise the activity of the doctor as such. The decisions of the Expert Commissions and Arbitration Boards are determinations or recommendations. If the doctor or the patient disagrees with the decision, he can resort to the ordinary courts of law. According to an evaluation by the Expert Commission of the North Rhine Medical Chamber, only 13% of the petitioners in all appraisal procedures concluded in the year 2000 (133 out of a total of 1,032) decided to take such action. The fact that only 10% of petitioners (63 out of 637) resort to further litigation if medical malpractice cannot be established, is indicative of the high degree of acceptance of the expertises. Insofar as the proceedings had already been concluded, the court and the Expert Commission reached the same verdict in the vast majority of cases. Only on six occasions did the court decision differ from the result of the appraisal procedure.

There is no statistical recording of medical liability lawsuits in Germany. Consequently, there are likewise no data as regards the decline in the cost of litigation following the introduction of Arbitration Boards. Figures from the Arbitration Board of the Northern German Medical Chambers at least give an indication of the proportion of expensive litigation proceedings that it was possible to avoid: Of 4,000 petitions filed in 2004, only 70% (2,813) were accepted for a substantive decision at all. 1,208 petitions (30%) were not dealt with further, either because they had been withdrawn again by the petitioner (377 petitions), or because they were not pursued further for lack of jurisdiction (41 petitions). In 656 cases, no decision was reached because of a protest lodged by one of the parties involved. 92 cases were resolved simply by providing advice. The figures for the other Federal States are similar, making it clear that simple structures and relatively little effort are all it takes to avoid unnecessary litigation proceedings and thus save costs.

The advantage of the Arbitration Boards for the petitioner is also obvious: the arbitration procedure is free of charge for the patient. And with an average completion time of just 12 months, it is also much faster than recourse to the courts.

This, and the great acceptance of the decisions, has led to an increase in the number of petitions in the last 15 years. While, for example, the Arbitration Board of the Northern German Medical Chambers had to deal with some 1,500 petitions per year in 1990, the figure had already risen to over 4,000 in 2003. The Arbitration Boards of other State Medical Chambers also recorded an increase in the number of petitions received, but not to such a great extent as at the Northern German Medical Chambers. For instance, 1,023 petitions were filed with the North Rhine Medical Chamber in 1990, compared to a total of 1,656 recorded in 2001.

However, the results of the work of the Expert Commissions and Arbitration Boards do not remain confined to a regional level, but are collected and analysed centrally. The Standing Conference of Expert Commissions and Arbitration Boards was founded at the German Medical Association for this purpose. Its objective is to improve and standardise the individual procedural workflow. The results are not only used to compile national statistics. The information on medical malpractice is also used in the State Medical Chambers for the systematic analysis of the causes of mistakes and to pass on the findings to doctors in the framework of continuing education events. This helps to ensure continuous quality assurance.

Not only doctors, but also patients and the public at large, must accept that mistakes and damage can occur during any activity. Playing down medical malpractice, or even making a taboo of the subject, breeds doubt and suspicion. Mutual mistrust fosters compensation claims and liability suits. Comprehensible and exhaustive patient information that is documented in writing, evidence-based and transparent work, and an efficiently functioning system for managing faults are essential elements for regaining and promoting the confidence of patients both in the individual doctor and medicine in general. The medical community must learn to openly face up to its own mistakes and learn from them. Then, the patient will also understand that the access of the general public to medical care is worth more than the right of the individual to compensation.

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Human Evolution

Out Of Africa

According to Professor Fred Spoor of University College, London, man has evolved primarily through his capacity to run rather than climbing ability. Fossil evidence shows that man developed the art of walking around 4.5 million years ago, following ape evolution at 13 million years, and thence the ability to stride and run in order to escape his enemies and hunt in groups. In response to the changing environment of plate tectonics, man's legs have gradually become longer, relative to those of his nearest neighbour the chimpanzee, and his forearms have become shorter. The skeleton evolved directly as a reaction to the way *Homo sapiens* moved around, a classical form of evolution, over a 6 million year period. Efficacy in running emerged about 2 million years ago, being successfully better represented through surviving generations and men capable of raising large families. Thus man was enabled to migrate out of Africa and spread around the rest of the world. The question remains as to whether survival of the fittest is a product of random chance and deleterious mutations or are there specific feedback mechanisms operationg on the DNA template in evolution to fill environmental niches?

Evolution occurs when natural selection operates in a population containing many variations in their inheritable characteristics. The genetic heritage of a community tends to remain constant unless changed by external environmental influences.For example, a population living on an island will evolve much quicker than one allowing free mixing, as in the Galapagos Islands originally observed by Darwin, where each island has different varieties of finches and tortoises. Also, Madagascar represents an isolated island where there are no monkeys – lemurs have developed to fill this environmental niche. In tropical Australia there are many new species that have been free to develop in the absence of competition.

In terms of survival of the fittest, of malaria provides survival value in some native African populations when immunity to the parasite *Plasmodium* develops. Some mutations, perhaps as a result of adaptation to metabolic requirements, can be advantageous rather than damaging – and it is these genes which in the long run may come to be the norm within a population.

Ivan M. Gillibrand

WHO

WHO Supports Global Effort To Relieve Chronic Pain

Geneva – The World Health Organisation has co-sponsored the first Global Day Against Pain, which seeks to draw global attention to the urgent need for better pain relief for sufferers from diseases such as cancer and AIDS. The campaign, organised by the International Association on the Study of Pain (IASP) and the European Federation of the IASP Chapters (EFIC), asks for recognition that pain relief is integral to the right to the highest attainable level of physical and mental health.

WHO representatives joined global specialists in chronic pain management and relief at a conference in Geneva convened to highlight the Global Day Against Pain and to press for urgent action from governments across the world. The conference coincides with the release of the Council of Europe's newly formulated recommendations on palliative care including management of pain. The recommendations provide detailed guidance for setting up a national policy framework, and are available in 17 European languages.

"The majority of those suffering unrelieved pain are in low- and middle-income countries where there is an increasing burden of chronic conditions such as cancer and AIDS," said Dr Catherine Le Galès-Camus, WHO Assistant Director-General for Noncommunicable Diseases and Mental Health. "Limited health resources should not be allowed to deny sick people and their families the dignity of access to pain relief and palliative care, which are integral to the right to enjoy good health.We strongly support the Global Day Against Pain and the efforts of IASP and EFIC."

New statistics released by IASP and EFIC indicate that one in five people suffer from moderate to severe chronic pain, and that one in three are unable or less able to maintain an independent lifestyle due to their pain. Between one-half and two-thirds of people with chronic pain are less able or unable to exercise, enjoy normal sleep, perform household chores, attend social activities, drive a car, walk or have sexual relations. The effect of pain means that one in four reports that relationships with family and friends are strained or broken, according to the IASP/EFIC data.

The statistics also reveal that pain is second only to fever as the most common symptom in ambulatory persons with HIV/AIDS. Pain in HIV/AIDS usually involves several sources at once. The causes include tissue injury from inflammation (including autoimmune responses), infection (e.g. bacterial, syphilitic or tubercular) or neoplasia (lymphoma or sarcoma): so-called nociceptive pain. Nearly half of pain in HIV/AIDS is neuropathic, reflecting injury to the nervous system.

Oral morphine has proven to be a cost-effective pain medication for the treatment of moderate to severe pain when the underlying cause is cancer or HIV/AIDS. However, opioid analgesics are not adequately available, particularly in developing countries with limited resource set-

tings, due to ignorance of their medical use, restrictive regulations and pricing issues.

"Pain relief should be a human right, whether people are suffering from cancer, HIV/AIDS or any other painful condition," said Professor Sir Michael Bond MD, President of IASP. "Today's Global Day Against Pain marks an immense growth in the interest in this area and WHO co-sponsorship of our campaign shows that now is the time to take pain seriously."

"Chronic pain is one of the most underestimated health care problems in the world today, causing major consequences for the quality of life of the sufferer and a major burden on the health care systems of the Western world," said Professor Harald Breivik, President of EFIC. "We believe chronic pain is a disease in its own right. For people in developing countries, where pain relief is at its most minimal availability, the consequences of unrelieved pain are great." Professor Breivik said the decision to hold a Global Day resulted from the success of the European Week Against Pain, launched by EFIC four years ago under the leadership of its Past President Professor David Niv.

For further information please contact
WHO: Dr Cecilia Sepulveda, +41-22-791-3706, or David Porter +41-22-791-3774 (o), +41-79-477-1740 (m).
IASP: Prof Sir Michael Bond, President, Emeritus Prof of Psychiatry, University of Glasgow. UK, +44-141-330-3692. www.iasp-pain.org
EFIC: Prof Harald Breivik, President, Prof of Anaethesology, University of Oslo, Norway, +47-23073-691 www.efic.org

Clinical Obesity Pandemic

Fight Childhood Obesity To Help Prevent Diabetes, Say WHO & IDF

Geneva — Worldwide, it is estimated that more than 22 million children under five years old are obese or overweight, and more than 17 million of them are in developing countries. Each of these children is at increased risk of developing type 2 diabetes (which used to be known as mature onset diabetes), say the World Health Organization and the International Diabetes Federation (IDF).

"Tackling childhood obesity now is a highly effective way of preventing diabetes in the future," said Dr Catherine Le Galès-Camus, WHO Assistant Director-General for Noncommunicable Diseases and Mental Health.

Chronic diseases such as diabetes, heart disease, cancer and stroke are a barrier to economic development. While undernutrition continues to be a key concern, particularly in developing countries, governments are also facing up to the fact that many children in all regions of the world have poor eating habits and are not getting enough exercise.

Globally, an estimated 10% of school-aged children, between five and 17 years old, are overweight or obese, and the situation is getting worse. In the United States, for example, the rate of obesity and overweight among children and adolescents aged 6 to 18 years increased to more than 25% in the 1990s from 15% in the 1970s.

Such increases are not restricted to developed countries. In China, the rate of overweight and obesity observed in a study of urban schoolchildren increased from almost 8% in 1991 to more than 12% six years later. In Brazil, the rate of overweight and obesity among children and adolescents 6 to 18 years old more than tripled from 4% in the mid-1970s to over 13% in 1997.

The link between obesity and diabetes is well-established. Around 90% of people with diabetes have type 2 diabetes and of these the vast majority are overweight or obese. "Overweight and obesity increase the risk of many chronic diseases, including type 2 diabetes, heart disease, stroke and some cancers. Unless we address the underlying causes of the obesity epidemic it has the potential to overwhelm health systems throughout the world," said Dr Le Galès-Camus. "The direct health care costs of diabetes already account for between 2.5% and 15% of annual health care budgets."

WHO is working with its Member States throughout the world to implement the Global Strategy on Diet, Physical Activity and Health, which was adopted at the May 2004 World Health Assembly.

The strategy recommends a comprehensive range of changes at the individual, community, national and international levels which, if effectively implemented, have the potential to turn around the obesity epidemic. The strategy addresses changes needed in lifestyles that have been linked to the increase in overweight and obese children over the last twenty years.

Increased availability and promotion of foods high in fat and sugar mean that children no longer eat the way their parents did. Nor do they do the same amount of physical activity. In each country the situation is different, but the reasons why children are less active than a generation ago include increased urbanization and mechanisation, changes to transport systems and increased hours spent in front of TVs and computers.

Yet small changes can make a big difference. In Singapore, nutrition education in class, combined with a school environment offering healthy foods and drinks, and special attention for students who were already overweight or obese, resulted in a significant decline in the number of obese students. In the UK, limiting access to sweet, fizzy drinks at a group of primary schools resulted in slimmer children. Other studies have demonstrated success by increasing

physical activity in school, making changes to school lunches, limiting hours spent watching TV and providing health education.

Professor Pierre Levèbvre, President of IDF, underlined the need for urgent action. "Children and adolescents who are overweight tend to grow into overweight adults. Poor habits of nutrition and lack of physical activity are likely to endure, putting today's young people at risk of type 2 diabetes in the future. Even in childhood, overweight and obesity lead to higher levels of blood glucose (sugar), lipid (fat) and blood pressure. In many populations, doctors are seeing increasing numbers of adolescents with type 2 diabetes, a disease that in the past was not normally seen until middle or older age."

Diabetes is a chronic condition that occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. People who have type 1 diabetes produce very little or no insulin and require daily injections of insulin to survive. People with type 2 diabetes cannot use insulin effectively. They can sometimes manage their condition with lifestyle measures alone, but oral drugs are often required and, less frequently insulin, in order to achieve good metabolic control. Type 2 diabetes used to be known as non-insulin dependent diabetes or mature onset diabetes.

WHO and IDF are working together to raise awareness about diabetes worldwide. Their joint project, Diabetes Action Now, is supported by a World Diabetes Foundation grant to IDF and by WHO funds.

WHO Director-General Travels To Indonesia And Sri Lanka

Attends leaders' meeting, tours stricken areas

Jakarta/Geneva – The Director-General of the World Health Organization, Dr LEE Jong-wook, visited Jakarta for a five-day visit to Indonesia and Sri Lanka. During the visit, Dr Lee took part in the Special ASEAN Leaders' meeting on the Aftermath of the Tsunami.

Dr Lee, together with the Executive Director of UNICEF, Carol Bellamy, travelled to some of the worst hit areas around Banda Aceh in northern Sumatra to meet some of the victims of the tsunami and to assess the most urgent health needs. He also met and travelled with the European Commissioner for Development and Humanitarian Aid, Louis Michel.

After leaving Indonesia, Dr Lee travelled to Sri Lanka to review progress in the relief effort and to offer further support to the country and to the communities which have been most seriously affected by the tsunami.

Since the tsunami struck, WHO has been working together with a core group of countries helping to provide humanitarian support. WHO has mobilised teams of experts to work with countries to assess the most urgent health needs and to ensure that they are met as rapidly as possible.

The most urgent health need now is to prevent outbreaks of infectious disease, and particularly of water-borne diseases such as diarrhoeal, dysentery and typhoid. It is clear that providing clean water to as many as possible of the affected cmmunities is now the most pressing health priority.

Regional and NMA News

Fiji Medical Association

The following is based on, and extracted from the Presidential Address given to the Annual Scientific Conference of the Fiji Medical Association last year, entitled **"Profession, ethics and community in this Millenium" .**

Dr. Mary Schramm, referred to the principles of the Hippocratic Oath as follows "*Benefience* – your activity should be beneficial and never harmful
Respect for the patient, his home his family"
Honour – be worthy of the honour of trust given you by your patient
Spreading your art through learning and teaching –

But *Only to those who bind themselves to this very same code of ethical behaviour*"

She held in her hand a leaf from a tree grown from a seed which had itself grown from the tree under which Hippocrates taught his pupils two and a half millenia ago. It was passed from a pupil to his mentor, ultimately from another pupil and relative to Dr. Schramm herself. She valued the leaf as "a symbol of that continuity and trust which I had embraced to work out the core values of my profession in the marketplace of modern medicine".

While the values which she had embraced have survived, despite wars, the fall of empires, civil wars, ages of oppression and ages of enlightenment, "medicine has also changed". She continued by referring to Hippocratean practice as being that of its own time – mainly one-to-one medicine. But medicine has moved on Knowledge of, and incidence of disease has increased, and the technology for evaluating disease has progressed even faster. She commented that the comparatively cheap and simple procedure of an *exploratory operation* had been almost replaced by highly expensive technology. However she considered "that

the one-to-one relationship between physician and patient remains central to good medical care", which she considered to be only realised in the primary care setting where the patient had chosen the physician and joined himself with the physician in a health caring partnership.

"Modern acute medical care can only be given adequately by the team and the modern hospital and clinic is the setting in which it is done. Yet conversely it can be the setting for stress and frustration, if, or when we depend on the participation of people who do not share our (the *profession*'s) open-ended commitment to the patient, persons who were appointed perhaps to "common user" posts; whose primary commitment is to their own promotion, their own career path."

She continued "In this team setting, the core principles of ethics still stand, but the ways in which they are challenged and tested are subject to change". This challenge Dr Schramm observed, was to be the challenge which the meeting would discuss over the next three days. She elaborated this to be considering

- "Increasing understanding of how to focus our ethical commitment into day-to-day work:
- Examining systems of control and regulation of medical practice:
- Looking into who should blow the whistle – when why and how loud
- and who should respond, when, for whatever cause, people given the accolade of Registered Medical Practitioner, Doctor, are not practising up to defined ethical standards"

The bulk of the rest of Dr. Schramm's speech given in the presence of the Prime Minister and other guests, dealt with the call for legislative action to deal with needed changes needed in the registration and regulation of Medical Practitioners, and also the problems of emigrating medical manpower *(see WMJ (50) 1)* and movement from the government health service to private medical care.

Extracts by kind permission of the Editors, Fiji Medical Journal.

European Region

European NMAs meet in Oslo

Norwegian Telemedicine was demonstrated by a consultation between a patient and doctor in the north and the audience who were thousands of miles apart, during a presentation at the European Forum of Medical Associations and WHO annual meeting in Oslo, hosted by the Norwegian Medical Association and attended by 36 of the 51 NMAs in the European Region of WHO, and by 5 International organisations. The telemedicine network, which connects hospitals and many general practitioners throughout Norway, enables peripheral hospitals and practitioners to conduct virtual consultations with the patient and practitioner both present: it even permits practitioners to be trained in endoscopic techniques so that expert opinion thousands of miles away can be given on the endoscopy as it proceeds. This not only assists diagnosis and access to expert opinions in the more distant parts of the country, but also reduces the need for patients to travel great distances to hospitals and diagnostic centres. In addition to a presentation by the Norwegian Minister of Health on the Norwegian Health System and the report on WHO activity by Dr. Mila Garcia-Barbero from WHO EURO, the meeting appreciated a lively presentation by a previous Minister of Health on the success of the anti-tobacco action in Norway.

Excellent presentations and discussions also covered such diverse topics as Palliative Care, Liability without Fault, the Bologna Process and Medicine and Health Care in Prisons.

Following the lively discussions throughout the meeting three Statements were adopted. The first was on the Bologna Process and Medicine, in which the Forum found no evidence of any benefit for medicine in the two cycle Bachelor/Master process proposed for medical training and qualification in European Universities. It welcomed however its proposals concerning mobility, comparability and harmonisation in medical education in Europe.

The second statement on Tobacco control, reaffirmed NMAs commitment to tobacco control, urged NMAs to continue support for the Tobacco Convention, asked them also to campaign actively for effective "smoke free" laws in their countries and requested all NMA meetings and premises to be made no-smoking areas.

The third statement was on "Healthcare in prisons and other forms of detention", urging NMAs to address these issues in their countries (see Human Rights page 10) All statements were adopted by unanimous consensus in accordance with normal Forum procedure.

EFMA/WHO was founded in 1984 as a Forum for positive discussions between the National Medical Association of the whole European Region of 51' countries and WHO Europe. It holds an annual meeting hosted by one of the National Medical Associations and aims through dialogue between NMAs and WHO Europe:

- "to improve health and health care in Europe,
- to promote information exchange of information and ideas between NMAs and between NMAs & WHO,
- to integrate appropriate aspects of HFA policy into all basic, postgraduate and continuing medical education, and
- to formulate consensus policy statements on health issues".