



World Association for Medical Law

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Editorial



Richard S. Wilbur, M.D., J.D.
WAML Chairman, Finance Committee

The World Association for Medical Law (WAML) has been a focal meeting place for physicians, attorneys, professors, both government and NGO executives, and all others concerned with the interface of law and medicine since its inception in 1967. As the WAML website states: "The purpose of the WAML is to encourage the study and discussion of problems concerning health law, legal medicine and ethics, and their possible solution in ways that are beneficial to humanity and advancement of human rights. The aim of the WAML is to promote the study of the consequences in jurisprudence, legislation and ethics of developments in medicine, health care and related sciences"

In support of these aims it has provided a forum for those of us concerned with the ethics and the regulation of health care to meet biannually at a World Congress of Medical Law. The 18th of these will meet Aug 8-12 in Zagreb, Croatia. This edition of the Bulletin has an invitation from the hosts of

this 18th Congress to all of those who wish to present their own views and their own work in the field to their colleagues from around the globe. These biennial Congresses have been a valuable place for the exchange of ideas during these past 43 years

This issue of the Bulletin also has a presentation by its organizer as to the reasons why the 13th Congress held in Helsinki, Finland in 2000 was such a well attended success. Paula Kokkonen, LL.M. Deputy Mayor of Helsinki and also a WAML Governor, has written a succinct guideline for hosting a winner.

WAML has also sponsored its International Journal "Medicine and Law" for the publication of more than 1500 articles by authors from more than 100 countries.

In the past, the Association has been relatively dormant between Congresses except for the Journal. Membership has consisted only of the attendees at the last previous Congress who were disproportionately from the host country and its surrounding neighbors. The next Congress, held in a different part of the world, had a different set of attendees and so WAML membership fluctuated widely in total numbers and in identity from Congress to Congress depending on where it was held and how successful each was at attracting a large attendance. The only real continuity came from the Board of Governors and Executive Committee.

However, the fields of health law, legal medicine, and ethics are expanding so rapidly in all parts of this Earth that there is a need for more than even such an achievement as the Helsinki Congress. Recently, the WAML leadership has begun to put together a more permanent structure. Instead of having a fluctuating membership dependent upon attendance at the immediately previous Congress, WAML now has a permanent cadre of members who join every year. It is from this membership that the WAML committees are being drawn which provide the opportunity for continuous participation by individual WAML members in the international interchange of ideas, concepts, and policies.

The Council of Presidents, begun over 10 years ago, was reconstituted during the 16th Congress in Toulouse, France in 2006 to provide a place for representatives from each country to meet and to exchange the views, positions and statements of their national organizations. In Secretary-General Beran's report in this issue of the Bulletin, he expresses it directly saying: "If you represent a regional medical law, legal medicine or bioethical organisation or institution then you should not seek only individual membership of the WAML, but also your organisation also should assume its place amongst like-minded associations and institutions. This can be achieved by your organisation seeking affiliate status with the WAML, Council of Presidents (CoP)"

Come to Zagreb this August and be a part of this new WAML! All persons concerned with these fields who can meet the qualifications to join WAML are eligible to attend the Annual Meeting and to be a part of the planning for an interactive, yearlong, permanent organization. One which can enable its members to better serve as leaders in health law and health

ethics within their own countries.

Concepts of ethics and patients' rights are not national, they are global. WAML is now becoming the organization which will enable its members to share their own experiences with leaders from other countries and to learn how people from different cultures have approached and solved the same problems in their own countries that you face in yours.

In addition to the Journal of Medicine and Law, WAML now has this Newsletter which carries shorter articles such as those in this copy from Adv Oren Asman and Associate Professor Mitsuyasu Kurosu Ph.D. The Bulletin, published quarterly, gives members yet another way in which to keep up on developments in other countries and to write about their own experiences and observations.

Let's talk about it in Zagreb.
See you there!

Richard S. Wilbur, M.D., J.D.
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Secretary-General's Report



Prof. Roy Beran,
WAML Secretary General

This is the first Newsletter for 2010 and coincides with the closing of receipt of abstracts for the World Congress of Medical Law (WCML), which will be held in Zagreb, in Croatia, in August this year. I do hope that we will have the opportunity to welcome many of you to the WCML. I am looking forward to coming to Europe and sharing ideas and learning from colleagues and friends.

The World Association for Medical Law (WAML), which for half a century has run on the good will and generosity of its executive, has taken on a new look. Through the offices of our Honorary Treasurer, Professor Thomas Noguchi, the WAML has established a professional secretariat. This is based in the USA, which is appropriate as the finances of the WAML are being run through the USA. As a result of local laws, the WAML has also approved becoming registered as an official organisation within the US. This was mandated to ensure that Professor Noguchi was not personally liable for the taxation ramifications that might flow from his generous commitment as Honorary Treasurer. This was not a simple decision and was closely examined by the Executive to ensure the

World Congress on Medical Law in Zagreb Croatia

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WAML did not lose its international global character. It was accepted by the executive that US registration was not necessarily the final place of registration. As the move was motivated by the dictate to protect our Treasurer from potential personal liability for taxation, it made obvious logical sense. As the home of the treasurer may/will move between nations, as the Honorary Treasurer changes, so it may become necessary to act likewise with registration within a different jurisdiction to protect future treasurers.

A similar need for change may arise, with change of domicile of the members of the executive, concerning the location of the secretariat, although this is not an absolute. With the ease of communication, the use of email and the era of e-technology it may be feasible to retain a US secretariat irrespective of the location of executive members.

This has also necessitated a change in ethos of the WAML. When Professor Raf Dierkens was the founder and Secretary General of the WAML, it was enshrined in the constitution (statutes) that the home of the WAML was to be the domicile of the Secretary General. Translating that into current status, this would mean that the home of the WAML is in Australia, the home of the current Secretary General, possibly with registration of the WAML, in Australia. Were that to be the case then it would fail to achieve the required protection of our Treasurer. It follows that the situation must remain fluid and adapt to the needs of the times and the circumstances that prevail at that time.

Currently the US is playing a dominant role in the WAML, not ignoring that the President lives in Israel, the Secretary General in Australia

and the Executive Vice President hails from New Zealand. With such an international executive, the risk of uni-national restriction of the WAML character is highly unlikely. We should not ignore that the constitution /statutes restrict Board of Governor membership to a single representative from each country. The Vice Presidents have been selected and elected to maintain the international flavour, with the aim being to have each Vice President representing a larger continent or major population base, such as China, which straddles a number of continents.

As I write this report the Board of Governors is conducting an on-line meeting. It is too early to offer any report from that meeting but I made an executive decision, as Secretary General, to try to actively motivate your Governors to exchange ideas and work for the betterment of the WAML. This requires closer communication as might be achieved with an on-line meeting.

With the changing nature of the organisation, there has also been an evolution in the process of becoming a financial member. For any of you who have not attended to the payment of your annual dues for 2010, I ask you to visit the website and pay your fees as soon as is possible. The membership seems to be growing, with barely a week going by without the credentialing committee reviewing a new applicant. Should you be reading this Newsletter and not yet have paid your dues for 2010 nor even yet be a member of the WAML, then now is the time to rectify that. You should act decisively to get your membership benefits, such as the journal and discounted registration for the WCML, which flow from financial affiliation.

If you represent a regional medical law, legal medicine or bioethical organisation or institution then you should not seek only individual membership of the WAML but your organisation also should assume its place amongst like-minded associations and institutions. This can be achieved by your organisation seeking affiliate status with the WAML, Council of Presidents (CoP). Jonathan Davies, the Chair of the Council, is constantly seeking new members to spread the word of the CoP, for without adequate membership organisations, the CoP would become a toothless tiger rather than a potential vehicle to further champion our cause of better understanding, education and advocacy.

As always, my Secretary-General's report is a call to arms. Please become more active, more committed and more enthusiastic. Only with such allegiance can we hope to realise our ambition to remain the premier body in health law, legal medicine and the standard for bioethical endeavour in a world rich in temptation.

I wish you all a successful 2010 and hope to meet you in Zagreb.

World Congress on Medical Law in Zagreb Croatia

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Current Educational Plan on Medical Law and Ethics in Medical Schools in Japan



Mitsuyasu Kurosu, Ph.D.

There has been a major revolutionary improvement in medical education during the last 10 years. However, we feel there is much more work ahead, especially in making sure that physicians keep up their clinical skills after graduation from medical school. Unfortunately, during the period, there has been frequent occurrence of bad publicity toward health care and physicians. The publicity causing such distrust was all related to the giving or withholding of cardiopulmonary resuscitation. These events have caused distrust toward the health care delivery system and medical doctors. As a result, medical law and ethics have become more important in the medical school curriculum. I would like to describe Japanese medical education, specifically on medical ethics and its trends, trends in bioethics education and training by future education on medical ethics by various organizations from government, medical associations, and specialty associations.

1. Current trends in Japanese medical education.

In recent years, in Japan, the long practiced system of medical teaching by giving lectures, assessing student knowledge based on memory, and then having the medical students learn how to treat patients by observing clinical teaching staff is being se-

rious debated. In 1999, the Japanese Department of Education (JDE) issued a report on the 21st Century challenges of medical education on the health care personnel. The report recommended improvement on medical education.

The following subjects were discussed, 1) revising the basic educational curriculum, 2) establishment of the core curriculum, and 3) national evaluation standards prior to medical students entering clinical curriculum. The main changes were to shift from traditional memory based education to problem solving education, and clinical training not based on observation, but on clinical participation. Following this report, the JDE funded a national survey and a study group on medical and dental education. In 2001, it proposed the model core curriculum, and agreed to have 2/3 of medical schools accept the new government plan, and the other 1/3 to rely on each university's choice of plan.

In order to improve public confidence in health care, it is necessary to have standardized curriculum and national standards. Starting in 2005, the written examination based on an objective computerized test (CBT) and assessment of Objective Skill Clinical Examination (OSCE) were begun. The teaching staffs of universities developed suitable examinations for the CBT.

2. Education on Bioethics and Current Activities

In 1983, the Minister of Health and Labor formed a high level study group, Life and Ethics to study the issues of surrogate pregnancy, brain death and organ transplantation. In 1985, the government officially reported the findings, and established terminal care committees. The Japanese Medical Association held a public meeting on bioethics matters. Every several years, the government has reported on selective birth practice of

preferring boys over girls, on the official report of death pronouncement being based on the cessation of brain function as proof of individual death, and reported on terminal care.

In 1988, the coordinating committee consisted with medically related schools, was established. The committee collected and disseminated information, but the government did not standardize or establish any policies based upon. Twice every year, the Government holds a symposium and in 2006 the topics were bioethics and education.

The Japanese Association of Medical Law was established in 1969. Its current membership is about 450, with 60% of members from the legal profession and 40% from the medical profession. This Association does not deal with education of medical law.

The Japan Society for Medical Education was established in 1969 and is supported by the university deans throughout Japan. The total membership is 2,150. Recently, the news reports of increased cases of medical errors have resulted in increased distrust of health care personnel as well as the health care system. The Society demanded improvement of doctors' images and improvement of medical education. Under this public pressure, in 2005, a workshop on ethics training, three times a year was set up. This workshop was designed to train ethic educators for graduate physicians after their basic medical education. In 2008, a clinical ethics training workshop was held for clinical ethicists. A two-day clinical discussion workshop based on the role-play model was developed. The Committee on medical ethics and the development of professionalism submitted the suggested curriculum and plans to hold workshop for teachers.

In 1982 the Japan Association of Philosophical Ethics was established by about 50 professors of philosophy, ethics and religion in the medical, dental, and pharmacy schools to teach how to effectively teach philosophy and medical ethics. Both keeping an eye on progressive medical research data, but not losing the traditional aim of maintaining health and overcoming illness, the discussion extended to life existence and happiness. There are now 420 members, who are from the fields of philosophy, ethics, medicine, nursing, sociology, law and religion.

The Japan Bioethics Association was founded in 1988. There are now 1,200 members whose various backgrounds include medicine, bioscience, philosophy, ethics, scientific ideology history, law, economics, religion, sociology, and cultural anthropology. Their presentations are on the education of bioethics, healthcare ethics, nursing ethics, and environmental ethics

3. The curriculum used in the Tokyo Medical University

Medical education has a six-year curriculum after high school. In the first year, the core curriculum includes bioethics, , at least 25 weekly 90 minute lectures.. The curriculum covers the subject of general ethics, medical ethics, and bioethics. Further expansion of bioethics covers four basic principles and the UNESCO Bioethics Declaration, informed consent, terminal care, death with dignity, euthanasia, brain death, organ transplant, abortion, surrogate pregnancy, genetic diagnosis and its proper usage, HIV and AIDS, clinical research, drug reactions, iatrogenic disease, medical informatics, and disaster preparedness. Our curriculum includes the actual testimony by a female victim of Thalidimide ®, the sedative medication which caused deformed fetuses. Another core lectures series

is related to medical law and the duties of physicians. The course is given over a half year totaling 10 separate lectures covering law and ethics, application of law and court, the patient's right to know, self-determination of health care, abortion, brain death, organ transplant, cancer and related law, euthanasia, and death with dignity.

Additionally, ten (10) half-day courses are offered for medical students, divided into small groups of six or seven students, who discuss the subject and then each students is required to submit a report. One of the topics is the highly debated subject of atrocities committed by the medical officers of the Japanese military, and issue of medical ethics. In the second year no ethic lecture is assigned, the students are learning anatomy, physiology, biochemistry, pathology, immunology, and foreign language.

In the third year, the core curriculum dealing with medical ethics has eight (8) intense lectures. These cover medical ethics and bioethics, ethical issues related to death and dying, the rights of the patients, medical doctors and judgment, informed consent, medical errors and complication, death of a human being, death with dignity and euthanasia.

In the fourth year level, one lecture each is given on laws related to the practice of medicine by personnel from the Departments of Legal Medicine and Public Health. In the clinical setting, a small number of hours are devoted to lectures on terminal care (ethics related to death), counseling for treatment ethics, ethics related to clinical oncology , patient dignity, and privacy of medical information., The above listed ethics and law courses, with the exception of the theme discussion in the first year level, are all lecture format.

In the fifth year level, there is no ethics course. Prof. Itai of Miyazaki University has scheduled the ethics

course after the medical students experience a clinical course at the sixth year level. This may be given in a small group discussion..

4. The role of teaching staff on ethics (bioethics and healthcare ethics) There is an increasing emphasis on ethics education and the teaching staff in charge of the course has increased. Furthermore, the review of proposals such as withdrawal or foregoing cardiopulmonary resuscitation has caused the more active participation of the teaching staff medical ethics. In Japan, in 2008, the Japanese Department of Health and Labor amended the directives on medical ethics. However, there are still only six out of the eighty medical schools in Japan that have a separate department of bioethics or healthcare ethics. Those schools are teaching the required curriculum by bringing various lecturers from outside the medical schools (Kodama's survey). I believe that the medical students and health care personnel must have continuous improvement of the curriculum on bioethics and health care ethics.

Mitsuyasu Kurosu, Ph.D.
Associate Professor,
Department of Bioethics
(Medical Ethics)



Tokyo Medical University

WAML Congress in Helsinki in 2000 Preparation of the Congress



Paula Kokkonen, LL.M.

1. Preparation started years in advance.

Preliminary discussions started with the President of the WAML, Professor Amnon Carmi. We discussed whether Finland was feasible as a Congress site or not. WAML had not had Congresses in Northern Europe. Finland was a safe country and also well organized. We were the first country in the world to have a Parliamentary law on Patient's Rights and we also had a no-fault compensation system for Patient injuries.

There seemed to be no major obstacles to Finland being a candidate. After having agreed upon this it was time to do some homework.

In Finland, I gathered representatives of organizations and individuals that had an interest in having a World Congress on Medical Law in Helsinki. The fact that I was at that time a member of the Finnish Parliament was helpful in contacting various actors.

Organizations that were approached were the Academy of Sciences of Finland, Ministry of Health and Social Affairs, Ministry of Justice, Ministry of Foreign Affairs, National Board of Medical Law, National Agency for Welfare and Health, Finnish Medi-

cal Association, Finnish Legal Association, Finnish Patient Insurance Association, several Parliamentary Committees, University of Helsinki, several Professors and Deans and the Finnish Association of Medical Law, the League of the Finnish Municipalities and the City of Helsinki. Also several eminent personalities, whom I knew were capable of mobilizing resources and organizing things, were approached.

After all of the above actors had been invited to a round table and they had promised money or other resources, I had the courage to make an official bid to WAML. The official bid consisted of several letters from the above actors, in which they committed themselves to participate in organizing the Congress and invited a WAML Congress to be held in Helsinki, Finland.

The President of WAML, Professor Carmi, was invited to Finland to meet with all of the actors mentioned above. He was told in a meeting chaired by me that they were committed to the common purpose and that they were ready to raise the resources needed.

The WAML Board of Governors voted on the venue for the 2000 WCML and selected Finland.

At some point President Carmi expressed a doubt about the readiness of people to come to Finland, which he thought had no major attractions. – It was then that I decided to show that we can mobilize people. The rest is history. It was a tremendous success—956 paid participants from 55 countries

2. Areas of particular concern. One problem was transferring the “threshold money” to WAML, an organization which was not incorporated anywhere in the world. Another

problem was a lack of continuity. The past experiences of organizing WAML congresses were not gathered in written form and I also didn't get a list of previous attendees and their contact information.

I think that a lot of money was wasted as the Board of Governors wanted to come to Helsinki to see the Congress Hotels. – On the other hand, that meeting probably made the Governors understand that we were capable of organizing the Congress as I brought the Board of Governors to meet the President of the Republic of Finland and the Speaker of the Finnish Parliament offered them a lunch at the Parliament.

3. Advice to future organizers Gather all those organizations that might have an interest in having a Congress on Medical Law or any Congress organized in your Country or City. Approach all your friends and colleagues and motivate them to participate in a common effort. And please do not forget to also involve your competitors!

Use a professional Congress Organizer.

University professors can easily mobilize volunteers as students have a possibility to learn at the Congress and get useful experience and beneficial contacts.

In order to broaden the participation, we in Finland collected young people from developing countries (through our embassies) and created a course in Medical Ethics for them in Helsinki University before they participated in the Congress. The Ministry of Foreign Affairs paid for this from the funds that are used for developing countries programs. Take care of your Family. You need them to get through it all, but they also need you!

More work is needed for a successful Congress than you can ever imagine.

Relationship with the WAML Administration:

With the communication technology available today, it is unnecessary to make on-site inspections except for social purposes. It is very costly and it may seem unfriendly to the host organizers.

Check lists are helpful. There are certain things that you have to check everywhere. In my mind the agreement with WAML is a checklist. Even with the agreement, there were still a lot of things to be checked before, during and after the Congress.

When giving advice to others we have to realize that cultures vary and people have different ways of working and approaching each other. Thus I can only state that what worked for me in Finland, which is a small nation (5.4 million inhabitants) where I knew personally all the important actors, might not work as a model elsewhere.

Paula Kokkonen, LL.M.
Deputy Mayor, Helsinki,
WAML 2000 Congress President



Night life in Zagreb Croatia

ON-LINE REGISTRATION FORM AND ABSTRACT SUBMISSION FORM AVAILABLE NOW

Dear Madam, Dear Sir,

Let us kindly inform you that the registration form and abstract submission form for 18th World Congress on Medical Law are available at the official congress website www.2010wcml.com

Using the same on-line registration form you will also be able to book accommodation in different Zagreb hotels, ranging from budget to luxury 5 star hotels, at special rates for Congress participants.

We would like to remind you about important dates and deadlines:

- Deadline for abstract submission is March 19, 2010
- Notification of abstract acceptance is until April 1, 2010
- Deadline for full paper for the accepted abstracts is **May 15, 2010**
- Full papers of the abstracts will be compiled into book proceeding
- Early registration **April 15, 2010**

Wide choice of Pre Congress and Post Congress tours as well as Accompanying person programme will be available SOON, we are already in December, at the official Congress web site.

For more information please visit our website www.2010wcml.com or contact us at info@2010wcml.com

**We are looking forward
to meet you in Zagreb!**

Kind regards,

**Congress team
of 18th World Congress on Medical Law**



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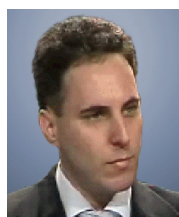
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Disclaimer

The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML

Editorial



Adv. Oren Asman
WAML Deputy Secretary
General

This sixth issue of the WAML newsletter illustrates both the multinational character of our association as well as its continuing development. We have received contributions from 4 continents and 6 different countries both in written form and, for the first time, in oral form!

This issue has an educational section, dealing both with a local Italian initiative to promote mental health and values among youngsters and with our a new WAML educational initiative- A radio program on Health, Ethics and Law, which aims to spread knowledge worldwide. Three special edition programs were made for this newsletter:

Prof. Ksenija Turkovic , chair of the scientific committee of the upcoming World Congress for Medical Law (WCML) is interviewed about the work done so far in constructing the scientific program for the 2010 WCML;

Prof. Wu Chong-qi, chair of the scientific committee for the 2008 WCML is interviewed about health law

in China and shares some insights from the last World Congress for Medical Law.

Prof. Michael Perlin from the New York Law School is interviewed about Mental Disability Law. As a prominent expert in that field, he gives a comprehensive introduction to Mental Disability Law, which is also the focus of this newsletter, the first "theme" issue newsletter so far.

A group of mental health professionals headed by Dr. Nathan Karny and Dr. Tal Bergman-Levy give an opportunity to learn about the work of a psychiatric hospital committee aiming to minimize violence, after several violent acts (some leading to legal action) moved the Israeli ministry of health to initiate such committees. Their work is closely related to the concept dealt with in another paper on interprofessional collaboration which provides a glimpse to an important project of the World Health Organization (WHO) which I was deputized by our Secretary General to represent WAML in. This WHO project also has a clear educational aim – educating for an interprofessional collaboration in the health care professions. WAML members are encouraged to join and contribute to this project.

Dr. Rosaria Nardello together with Dr. Adriano Compagno discusses the Italian legal viewpoint regarding criminal

responsibility of youngsters with various psychiatric disorders discussing both the clinical aspects and the legal aspects of this issue, and

Dr. Jacob Margolin and Prof. Eliezer Witztum give a short introduction to legal and ethical questions pertaining to compulsory psychiatric treatment in Israel.

Finally, our Secretary General, Prof. Roy Beran has provided a report on the last Board of Governors meeting and discusses many of the projects that WAML is already holding, calling for further involvement of our members with the already existing and perhaps with new initiatives of our Association.

This newsletter gives an idea as to the vast potential of our association which brings together prominent experts and professionals from all over the globe. It is my great honor to thank both Dr. Dick Wilbur and Prof. Roy Beran for their language and editorial remarks. Special thanks also to Prof. Noguchi and Mr. Vergara for their strenuous efforts to complete the layout for this special and first multimedia edition of our newsletter. With the help of such skillful professionals it has been a privilege to serve as the editor of this issue.

Adv. Oren Asman
WAML Deputy
Secretary General

The educational section

Adv. Oren Asman
WAML Radio

It is my pleasure to present to you with Health, Ethics And Law (HEAL).

A series of programs produced by the World Association for Medical Law (WAML), containing interviews with prominent experts from around the world, aiming to promote education and deliberation in matters pertaining to medical law, legal medicine and bioethics.

A central mission of WAML is to promote education for both communities of health workers and health consumers in order to examine and perhaps even produce and offer norms wherever this is feasible. As part of this educational mission, the Association has taken it upon itself to produce a radio program with an international perspective pertaining to Medical Law, Legal Medicine and Bioethics.

The interviews are usually held at important international congresses of WAML, or its collaborative organizations, and so a wide range of topics are covered and various states and countries are represented, in the true spirit of WAML.

The program is broadcast every other week beginning May 4th 2010. It is intended to enhance the involvement of WAML members and the general world-wide public in the important ethical and legal debate concerning health law and legal medicine. Each program remains available online and can be accessed at any time.

I wish to express my gratitude to Prof. Noguchi, our Treasurer, who also serves

as the scientific advisor for this program, for his ongoing support in this initiative; and as the interviewer I invite you, the members of WAML to take part in this program and be interviewed in the future.

Three interviews are attached to this newsletter.



[An interview with professor Ksenija Turkovic](http://www.wamlradio.org/turkovic), (<http://www.wamlradio.org/turkovic>) head of the scientific committee of the 18th world Congress of medical law



[An interview with professor Wu Chongqi](http://www.wamlradio.org/wu), (<http://www.wamlradio.org/wu>) WAML Vice president, chairman of the Chinese health law society and head of the scientific committee of the 17th world Congress on medical law.



[An interview with professor Michael Perlin](http://www.wamlradio.org/perlin) (<http://www.wamlradio.org/perlin>) from the New York Law School about mental disability law.

Adv. Oren Asman
WAML Deputy
Secretary General

Promoting mental health, ethical values and life quality among adolescents in Aosta Valley, Italy



An educational project headed by Dr. Miroslava Vasinova, head of the European

Center for Bioethics and Quality of Life and chair of the Italian unit of the UNESCO Chair for Bioethics has been conducted during the past 10 years with adolescents (ages 14-20).

This project aims to promote mental health, values and life style amongst the participants. It is a project based on the concept of preventive health, which strives to promote proper behavior and deal with societal problems that youngsters face nowadays.

The participants meet once or twice during the school year with the program leaders to discuss an actual and contemporary problem (for instance: alcohol use by youngsters, communication between adolescents, time and space etc.).

The organizers of the project realized over the years that creating working groups with an active participation and leadership by the adolescents is the best way to build that year's program. They get a chance to "speak their minds" and build the program and thus feel protagonists of this project and very much obligated to it and its success.

The yearly project is usually a creative initiative related to that year's topic (for instance: a theatrical piece, a song, a gymnastic project, producing a newspaper and so on).

At the end of the year, a big conference is held in a hotel in Aosta, where all the groups present their projects and attend meetings with professionals discussing that year's topic.

The meeting with the lecturers also takes into consideration the preferences and interests of the youngsters. For instance, when discussing Alcohol abuse, 6 Gold medal winners in the World Olympics came to talk to the children about the danger of alcohol abuse, while wearing their gold medal.

In another occasion, the young participants of the project were given the task to invent 10 non-alcoholic cocktails. These are to be presented to the program managers and later that year, students of the regional schools in the area of Aosta valley will gather at a special cocktail party and the students who invented the non-alcoholic cocktails will present and serve these drinks to their peers.

Perhaps such experiences are one of the reasons that some of the participants are happy to take part in this project the following year and apply again for participation as they view this as an empowering educational experience.

Adv. Oren Asman

Dr. Miroslava Vasinova

**World Congress
on Medical Law
in Zagreb Croatia**

August 8-12, 2010

Minimizing Violence in Mental Health Institutions

Several Insights from the Committee on the Prevention of Institutional Violence: The Importance of ‘Ward Cohesiveness’ and the ‘Visible Responsibility’



**Nathan
Karny, MD**



**Tal Bergman
Levy, MD**

**Jeanete
Grunspan
RN MA**



**Sigal Bakshi
MSW,CSW**

**Cyd Sherman
MSW,CSW**

Violence is physical, verbal or mental abuse towards someone, or threatening to hurt their feelings or property. This concept must be differentiated from the concept of aggression. Aggression is the urge that leads to thoughts or intentions of physically harming people or their property. Aggression is a universal phenomenon – a basic part of human nature. It is not anomalous or supernatural and it was originally, a basic survival mechanism. Donald Winnicott, A well known psychoanalyst during

the 1950's perceived aggression as a sign of life and vitality which triggers action. He claimed that when aggression is being owned and contained by the environment it is converted into a positive and energetic force, which can be directed towards creation and motivation. Failure to contain aggression however, can be devastating and lead to violence. Thus, Winnicott believed that the environment has a crucial role in containing aggression and controlling violence.

In 2007, after a series of violent assaults on physicians in several hospitals, the Israeli Ministry of Health recognized the need to understand and treat the root causes of patient violence. As a part of this campaign, the ministry also founded an interdisciplinary committee that discussed the ways to deal with violence in mental health institutes. This committee founded internal sub-committees in each and every mental health institute, tasked with studying the issue and suggesting methods for minimizing the phenomena.

The Beer-Yaacov, Ness- Ziona Mental Health Center currently provides inpatient as well as outpatient and community services for an urban catchment area of approximately 1,000,000 subjects. A committee for the prevention of institutional violence was appointed in the Center. It included representatives from different treatment sectors and was chaired by the Deputy Director of the Center.

The committee decided to address the problem using “field work” and met with many of the professional teams and staff members in the center. At each ward meeting there was a maxi-

mum representation of the various mental health professions. They were held in the form of open discussions, inviting the staff members to share their experiences and their thoughts regarding the issue. The committee was impressed by the highly motivated teams that were more than willing to accept necessary changes to deal with the phenomena. The staff members also accepted that they too share some responsibility for the incidents of patient violence in the center. The staff members raised many problems and difficulties that they perceived had provoked patient violence towards staff or other patients. Many of them asserted that there is a link between the emotional state of the caregiver and his ability to manage aggression. Problematic physical conditions at the institution were given much weight as causes or violence: Overcrowding, lack of staff, low ratios of caregivers per patient, a lack of special training for dealing with violence, were some of the issues stated as major influences on the ability of staff members to deal with and to manage problematic patients.

As we continued our initial analysis of the meetings with the teams, we noticed an important factor. We would like to term this factor: ‘Ward Cohesiveness’. Ward cohesiveness represents the ability of a ward to exist and act as a single and united entity, with full coordination and solidarity, presenting uniform attitude and policies towards its patients. The term addresses various functions in the ward, among them are coordination and cooperation in the ward's team work the ability to establish an empathic understanding between caregivers

to their different therapeutic agendas, developing empathy towards the needs of the ward and the priorities of the ward as a single entity. The authors believe that a ward lacking in its cohesiveness – will also lack in its ability to manage its most problematic patients and fail to prevent the transition of aggression into violence.

Many factors hinder the ability of the hospital wards to achieve proper ward cohesiveness. Most of the wards in Israeli public psychiatric services are built upon multi professional teams.. The various caregivers, many times having different backgrounds, treatment modalities and approaches towards patients, differ in their expectations and needs from the psychiatric system. These expectations and needs do not always coincide with the needs of the system as a system, and the needs of the ward as a ward.

Ward management has become extremely challenging in light of the sectorized organizational structure in the public mental health care system. The various professionals also answer to a head of their sector, who may not always put the interests of the wards at the top of his/her subordinates' priorities. Simultaneously answering to both the head of their sector and the head of the ward can create a sort of “functional confusion” and difficulty in determining who sets the tone in the ward. We believe that priority should be given first to the heads of wards, who are responsible for the clinical work, and only then to the heads of the various sectors – to reinforce the authority of the head of the ward as the main organizer and uniting factor in the ward.

In order to improve ward cohesiveness and improve the patient management ability of the wards, the committee recommended several initial steps which we termed 'visible responsibility'. An example of this is a reinstatement of the practice of having multi disciplinary rounds on a regular basis led by the head of the ward. This will familiarize the entire staff with all the patients and create an atmosphere of mutual responsibility.

It is important to clearly emphasize the role of the head of the ward in setting the tone in the ward – in both managerial as well as professional aspects.

In addition, full attendance of the entire ward staff during a violent event including of any non-urgent ward activity and a paying special attention to the violent event is of major importance. (For instance, a psychotherapist should not continue a therapeutic session during the occurrence of an adverse event in the ward). Another crucial element is a daily summary meeting with all the inpatients to address the irregular events of the day. Coping together as a ward with violent events in the suggested manner can increase the feeling of ward cohesiveness and solidarity and make the ward a supporting system that nourishes its workers and its patients.

There is no doubt that patient violence in a mental health system setting is a complex issue contributed by many factors. We are not presuming to have all the answers but merely want to share our observation and emphasize that lack of 'ward cohesiveness' is an important contributing factor to the phenom-

enon. Our work is still in a preliminary phase.

There is still work to be done in order to establish a research tool for a more quantitative evaluation, in order to base our field assumptions on the correlation between patient violence and the extent of 'ward cohesiveness'.

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Adolescent Deviance and criminal responsibility in the Italian Judicial System



Dr. Rosaria
Nardello



Dr. Adriano
Compagno

According to the Italian Judicial System, a child under 14 years of age is not criminally responsible. A minor, less than 18 but over 14 years old, can bear criminal responsibility only if competent.

This paper discusses some of the clinical aspects of establishing sanity/competency ('compos mentis') or insanity/incompetency ('non compos mentis') and the legal and clinical implications of declaring an adolescent offender insane – Can he/she be imprisoned? Hospitalized? Should he/she be treated any differently than a non minor under the same circumstances?

Sometimes, jurists refer to

the concept of maturity to answer this question, but they have not truly solved this dilemma. In fact, we could phrase the question like this: When can we consider an adolescent who committed an offence 'mature enough' to stand trial?

The question is still open and has many practical implications. Very often, in order to find an operational solution, the judges prefer to consider the more objective sociological and/or biological background. Namely, they evaluate if there is a problematic familial context, a low socio-cultural status, if the adolescent lives in a slum or hangs around with a bad company. In addition, they inquire into the cognitive, emotional and personality development of the adolescent. Therefore, some forensic psychiatrists and psychologists affirm the concept of 'social intelligence'. In simple words, we can define it as the cognitive, emotional, and behavioural skills that make the adolescent able to adapt to a social context.

The adolescent engaged in deviant behaviour often commits offences and consequently puts himself at risk of being prosecuted. In various cases this adolescent is affected by a conduct disorder.

According to the DSM-IV TR, this means that he or she can show: a) an aggressive conduct that causes or threatens physical harm to other people or animals, b) non-aggressive conduct that causes property loss or damage, c) deceitfulness or thefts, and d) serious violations of rules. Different aetiological mechanisms have been proposed, such as psychological (affective deprivation and ineffective caregiving in the first years of

life), organic/biological (hereditary or neurophysiological factors) and environmental ones (familial, social, and cultural). Psychiatrists and psychologists do not have an exhaustive idea about the relative importance of these possible aetiological mechanisms. The child psychiatrist or psychologist actively contributes to the evaluation of at least two of them (psychological and organic/biological factors) and takes part in the assessment of the third one together with the social worker. The child psychiatrist or psychologist needs to perform a clinical examination and some psychometric tests (i.e., cognitive tests, such as the Wechsler Scale of Intelligence for Children – Revised, WISC-R; affective and personality tests, like the Minnesota Multiphasic Personality Inventory – Adolescent, MMPI-A, or the Rorschach Inkblot Test), in order to evaluate if the adolescent is 'of sound mind' (compos mentis).

This is not easy to do. In fact, according to the DSM-IV, people having antisocial personality disorder very often suffered from a conduct disorder before the age of 15. As a consequence, an underlying condition of antisociality can be identified in the psychological functioning of adolescents affected by conduct disorder. Therefore, we can argue that an adolescent having antisocial personality traits could be totally or partially lacking that sense of "social intelligence" we have considered above. Consequently, we could ask: Do the deviant adolescents, so often committing offences, bear legal responsibility or not?

Pursuant to, and in accordance with, Article 88 of the Italian Penal Code, a person who committed an offence in

a condition of insanity shall not bear legal responsibility. This concerns both the adults and the minors between 14 and 18 years old. Italian jurists define insanity as mental or physical, organic or functional, acute or chronic, temporary or permanent, continuous or intermittent, congenital or acquired diseases, which totally or partially deprive the individual of his intellectual and decision-making faculty. (1)

Among these conditions, some psychiatric diseases such as personality disorders and psychopathy play a dominant role.

When, due to insanity, the defendant who committed great offences profits by an exoneration, he or she must be admitted to a special judicial psychiatric hospital for a period of at least two years (Italian Penal Code, Art. 222). This measure is applied also to the minor aged between 14 and 18, when a condition of insanity can be proved.

There has been long debate about this last question and some jurists criticize it openly. On the 14th of July 1998, the Italian Constitutional Court passed a judgment against the admission of the minor to the judicial psychiatric hospital. In fact, according to the Constitutional Court, this measure would be in conflict with the Italian Constitution (expressly with Articles 2 and 3), because it does not guarantee a proper treatment to very different subjects (the adult and the child). It also does not provide sufficient safeguard of the child, who is considered as a 'weak' growing individual. For the same reasons, the Italian Constitutional Court pointed out that the aforementioned part of Article 222 of the Italian Penal Code is in contradiction

with the "Declaration of the Rights of the Child" and with the "United Nations Minimum Standard Rules for the Administration of Juvenile Justice" (the so-called Beijing Rules"), whose principles have been acknowledged by the Italian legal system by means of the Article 10 of the Italian Constitution (according to which, the Italian legal system conforms to the generally recognized rules of international law).

The question is still debatable. Our remarks deal only with some of its numerous and controversial aspects, and we are aware that this brief essay could not be considered as a complete exploration of it. It directly involves the legal proficiency of jurists and the psychological expertise of child psychologists and psychiatrists trained in forensic psychology. It is mandatory to promote an exchange of opinions and opportunities to collaborate because, as we have tried to demonstrate, these theoretical issues have many practical implications.

(1) Puccini C. (2007). *Istituzioni di Medicina Legale, 6a Edizione. Milano: Casa Editrice Ambrosiana, 210.*

Dr. Rosaria Nardello

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Zagreb Croatia

Compulsory Psychiatric Treatment in the Israeli Legal System – A Short Introduction



Dr. Jacob Margolin

Prof. Eliezer Witztum

In Israel, like other countries, the comprehensive treatment of mentally ill people is accomplished according to a specific law ("Act for the Treatment of the Mentally Ill"). The first version of this law was enacted in 1955 and its second and current version was enacted in 1991. Two of the unique psychiatric organs in this Israeli Act are the District Psychiatrist and the District Psychiatric Committee.

Thus, the Israeli model of the District Psychiatrist (DP) was officially born in 1955 with the legislation of the "Act for the Treatment of the Mentally Ill." The role of the DP is deeply interwoven with the development of mental health services in Israel. The approach which led to the establishment of the DP's authority was derived from principles of charitable philosophy (e.g., "Parens Patriae" and "The Duty to Protect"), the practical experience of other nations, and local issues of public interest.

Continuation of public concern, shifting of social views, "landmark" court rulings and advancements in technologies of treatment, yielded the legislation of the 1991 ver-

sion of this law which is still in effect. This law broadened the scope and depth of the DP's authority. In spite of a clear situation of conflict of interests, the double role of the DP as a medical director of the local psychiatric hospital governed by the Ministry of Health continued for 40 years, until the end of the 20th century. On June 1, 1995, this unfavorable situation was put to an end. The new situation, backed by additional modern legislation, has enabled the DP to play a major role in the huge reforms that have characterized the mental health arena.

The DP is a Governmental psychiatrist who was appointed by the Minister of Health to be a DP according to the law. The DP is not a treating psychiatrist nor a manager of any mental health facility. He/She is legally authorized to issue orders for a forced psychiatric examination, for a forced commitment of a patient in a psychiatric ward or in a psychiatric hospital and for a forced psychiatric community (ambulatory) treatment in a community mental health center. The decisions of the District Psychiatrist in regard to forced hospitalization and community treatment, are time-limited, being for two weeks and six months respectively.

The DP's, decisions are subject to an appeal within a strict time limit before the District Psychiatric Committee. This quasi-legal authority is composed of three members: chairperson, who is a lawyer, with the credentials of being a magistrate court judge, and two psychiatrists, one working in the Governmental service and the other working in private practice or in a non-governmental agency. All of these members are ap-

pointed by the Minister of Health. Apart from hearing the appeals against the District Psychiatrist's decisions, the DP's Committee has the authority to prolong the time of enforced hospitalization or community-based psychiatric treatment.

Any decision of the District Psychiatric Committee is subject to an appeal within 45 days before a District Court of Law. This constitutes a system of checks and balances regarding decisions relating to involuntary treatment of the mentally ill, ensuring the right to refuse psychiatric treatment and guarding the civil liberties of people with mental disorders.

The Israeli Act for the Treatment of the Mentally Ill of 1991 also enables a DP to issue an order for compulsory psychiatric examination under certain conditions. The DP must receive apparent evidence that a certain person is a mental patient ("suffering from a mental illness"), that due to his mental illness he may cause imminent harm to himself or to others and that he/she refuses a psychiatric examination. Everyone can appeal to the District Psychiatrist. The DP has no obligation to personally examine the person in question, or even to see him/her and hear his/her position and a psychiatrist, legally authorized on his behalf, can conduct the examination. This is quite different from a judicial process, where the judge should personally see the person and hear his opinion, and the person should have a lawyer who legally represents him along the legal process.

The need for client/patient advocacy is an important issue that has only recently been recognized and addressed by

Israeli Law, at least with regard to legal representation of mentally ill patients before the Israeli District Psychiatric Committee. Since 2004, psychiatric patients have a legal right to be represented by a lawyer before the District Psychiatric Committee and these lawyers are paid by the State. Patients' advocacy requires well-trained representatives who are highly knowledgeable of the rights, entitlements and services available. There are some inherent questions regarding this advocacy. For example, what is the lawyer actually representing – the will of the patient, regardless of his mental state, his capacity to make a reasonable judgment or a reliable reality testing? Does he represent the medical and therapeutic interests of the patient, including the adequate facilities for their fulfillment? Or perhaps the legal representative has to see only the global interest of the patient/client, weighing his/her will, as well as the medical and therapeutic issues, and making a good balance of the patient's will and his personal security and necessities? These questions are constantly being asked by all parties involved: patients and their families, clinicians, and lawyers.

It seems to us that the last possibility, a legal representation that makes a good and honest balance between the different issues, should be preferred by the representatives of the mentally ill person appearing before the District Psychiatric Committee. Such a representation can lead to a better cooperation with the patient's therapists, avoiding unnecessary situations of mutual struggles before the Committee.

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Jacob Margolin, MD, MPA, was the District Psychiatrist of Tel Aviv Area, Israel, member of the District Psychiatric Committee of Tel Aviv Area, medical manager of the Jerusalem Mental Health Center, Jerusalem, Israel, and the secretary of the Israel Society for Forensic Psychiatry.

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18th World Congress
on Medical Law

Interprofessional Collaboration and Education in Health Care – An Ongoing Project Adv. Oren Asman

In recent years, health systems around the world have been dealing with a global health workforce crisis. The World Health Organization (WHO) is attempting to ensure the appropriate supply, mix and distribution of health workers, seeking new approaches to transform how health workers relate to one another and work within the community.

In its 2008 report on Primary Health Care [1], WHO includes the following message: "The health of people worldwide depends on health professionals working together across the boundaries of disciplines, professions and conventions to ensure the provision of equitable, patient-centred, fair, affordable, efficient and community-driven health services".

To promote this goal, a study group on Interprofessional Education and Collaborative Practice was established at the WHO. An initial document on Interprofessional Education & Collaborative Practice [2] has been produced and serves as a basic working paper in this regard.

In this context, the WHO has invited representatives from various World Organizations to take part in a Global consultation on "The contribution of health professions to primary health care and the global health agenda", which took place on June 25-26, 2009 in Geneva. Our Secretary General kindly deputized me to attend this meeting as a

World Association of Medical Law representative.

During this meeting, representatives from 45 different Organizations met and laid a foundation for an ongoing discussion. In order to follow up on this Global Consultation, a steering group for the Health Professionals Global Network (HPGN) was established. The steering group includes 16 members of various organizations, including our WAML.

After several conference calls we decided to initiate a time-bound virtual global discussion forum. This was held from 1st to 12th February 2010. The aim of the Forum was to re-energize the discussion on interprofessional collaboration and to continue the dialogue. More than a thousand participants from 100 different countries participated in this virtual global discussion forum (at www.hpgn.org).

I hereby present to you some of the ideas and thoughts that were raised so far in this initiative.

Primary Health Care

Primary Health Care was defined by WHO as “Essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-determination” [3].

In other words, Primary Health Care is inspired by the noble cause of “Health for all”.

The current worldwide shortage of health workers is esti-

mated at 4.3 million and this is defined as a health workforce crisis. Accordingly, the need to strengthen health systems based on the principles of primary health-care has become one of the most urgent health challenges around the world. [2] Interprofessional education was identified as an important component of primary health care since the coining of this term in 1978 [3].

Interprofessional Collaboration (IPC)

IPC may be of relevance whenever and wherever professions need help in responding together to complex needs beyond the capacity of any one of them alone. For example, failed communication and trust may contribute to undetected abuse of the helpless or to clinical errors. Its boundaries have extended accordingly, embracing all fields of health and social care, including patient safety and public health and recently also expanding to environmental issues.

IPC may be important in services for varied patients: The chronically ill, disabled and vulnerable adults and older people and also children, youngsters and their families.

Evidence continues to emerge that more positive patient outcomes are attained by collaborative inter-professional teams [4].

It is believed that working collaboratively with other health professionals, can help develop patient engagement, improve continuity of care and overcome fragmentation of healthcare systems. Continuity of care is an area where successful interprofessional collaboration can improve a patient’s wellbeing

and experience of healthcare whilst its lack may even lead to serious harm.

The range of relevant professions when talking about IPC widens beyond doctors, nurses, social workers and allied health professions since lawyers, police officers, probation officers and schoolteachers may also be of relevance and importance. A professional collaborating with others, learning with, from and about them may better serve both his/her own professional agenda and that of society as a whole.

Interprofessional Education (IPE)

“Interprofessional Education” describes learning interactions between health and social care professionals that are designed to improve both collaboration and the quality of care. The following definition has been adopted almost universally, and reads: “Occasions when two or more health professionals learn with, from and about each other, to improve collaboration and the quality of care” [5]

IPE that focuses on clinical problems presents students from many different professional backgrounds with an opportunity to learn about each other’s approaches to the management of those problems. [6]

Such educational projects are based on the belief, corroborated by a growing body of evidence, that well planned IPE can cultivate closer collaboration not only between professions and between organizations but also with service users and their carers; collaboration which, in turn, can improve care and quality of life for individuals, families and communities.

Since IPE projects and practices are emerging around the world, some observations are already suggested:

1. Interprofessional collaboration combined with Task shifting (Task Shifting: where a task normally performed by one health professional is transferred to another health professional with a different level of education and training, or to a person specifically trained to perform a limited task, without having a formal health education[7]) may also carry significant risks.

In this regard, The “World Medical Association (WMA) Resolution on Task Shifting from the Medical Profession”[7] states as follows:

“Although task shifting may be useful in certain situations, and may sometimes improve the level of patient care, it carries with it significant risks. First and foremost among these is the risk of decreased quality of patient care, particularly if medical judgment and decision making is transferred. In addition to the fact that the patient may be cared for by a lesser-trained health care worker, there are specific quality issues involved, including reduced patient-physician contact, fragmented and inefficient service, lack of proper follow up, incorrect diagnosis and treatment and inability to deal with complications. In addition, task shifting which deploys assistive personnel may actually increase the demand on physicians. Physicians will have increasing responsibilities as trainers and supervisors, diverting scarce time from their many other tasks such as direct patient care. They may also have increased professional and/or legal responsibility for the care given by health

care workers under their supervision.”

2. IPE and learning should be woven into the entire time-span of a student’s studies in order to be effective.

Experience has shown that, if this approach is started when students are at undergraduate level, success in collaborative attitudes between professions is far more secure than when interprofessional collaboration is introduced once ‘experienced’ practitioners have developed their own profession specific attitudes and biases.

3. For interprofessional learning to take place at primary health care levels, there is a need for an encouraging culture, suitable organizational structure, and a friendly work environment, in addition to external support of academic institutions, governments and regulatory bodies.

4. Patient Centered IPC requires asking the patients if he/she agrees to be involved in it. In the case where a him/her wishes to work with just one health professional, it is important to let him know that the dialogue and relationship between that professional and other supporting professionals is strong.

Interprofessional Collaboration raises important medico legal issues, about which our members are urged to share their opinions:

1. How can professional regulations support and endorse IPC/E standards ? What would be the legal status of such regulations?

2. What should be the legal and ethical standards and protocols for IPC/E ? To what extent should they be embedded in Health Laws?

3. Does IPC present a higher

standard of care? If so, what are the possible legal implications?

4. How can legal medicine positively impact on the process?

It is my hope that our members, who find the ideas and goals presented in this summary equally important, will add to the WAML contribution for the advancement of inter-professional collaborative practice, in the educational, clinical and legal spheres. You are welcome to join the Health Professionals Global Network (on www.hpgn.org) and contribute your input to the ongoing project.

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WAML Deputy
Secretary General

Secretary General’s Report



Prof. Roy Beran,
WAML Secretary General

This is the last newsletter before the World Congress on Medical Law (WCML) in Zagreb during the second week of August this year. I look forward to meeting and greeting you all in Croatia.

This issue of the newsletter is to be focus-specific, looking at mental health, which is a major topic in health law, legal medicine and bioethics. It should provide a valuable forum to examine topical issues as a precursor to the WCML, which also will explore human rights, which often are ignored when dealing with those who have problems with mental health.

It is also the first time I have had the opportunity to report to you following the one month long on-line Board of Governors (BoG) meeting. I do so before the minutes have been ratified, which will happen in Zagreb at the next BoG meeting, but I do so to show that the BoG has not been idle. Reports were supplied by the: President; Secretary General; Treasurer; Audit Committee; Chair of Council of Presidents (CoP); Chair of International People’s Rights’ Committee; Journal (Medicine and Law) Editor; and Chair of Proposed Financial Committee. There was a general call for members to become more actively involved and to herald the new initiative of the World Association for Medical Law (WAML) radio project, which may be accessed via www.wamlradio.org. The Audit Committee was complimentary regarding the better communications within the WAML membership. It also questioned the defined roles of the BoG and CoP. There was recognition as to the steady flow of new membership applications and a general desire to enhance the standing and attractiveness of the WAML to new membership.

In response to the report by the International People’s Rights Committee, there was a question raised as to what other areas should be addressed by the WAML. This newsletter offers each of you the opportunity to identify those areas that you believe should attract special attention by the WAML. Should you feel the WAML could contribute to the betterment of an area that is dear to your heart, please advise the BoG and the Executive Committee (EC). Please state clearly the

area to be addressed, the reason why you believe WAML should become involved and the specific aim of such involvement. With the face-to-face EC and BoG meetings in Zagreb, this is an ideal time to lobby for your area of interest and we will definitely discuss and explore each issue raised.

To further your involvement with the WAML, you should also explore how your local and national bodies can become more involved and to encourage them to become formally affiliated with the WAML and with the CoP. This is the perfect opportunity for your institution, college, association or society to play its role on the international stage. Zagreb offers a great opportunity for you, and your local organization, to meet world leaders who are likeminded, enhance contributions from all concerned and learn from interactions with colleagues, both at the conference in general and the CoP in particular.

Zagreb will also provide the WAML an opportunity to celebrate the 30th Anniversary of the establishment of our official journal, the Journal of Medicine and Law. This is a journal received by all financial members of the WAML, as well as others who subscribe, and provides a great vehicle for people involved in the disciplines of health, law and ethics to exchange results of research and to formulate ideas that may generate wider debate and understanding.

The activities of the WAML are not restricted to the second yearly World Congresses and, as recently as mid May this year, the WAML was well represented at the 1st Asia Pacific Conference of Health

Law held in Manado, Indonesia. It is so exciting to see, firsthand, the exponential growth of our discipline(s) within what was once called South East Asia. There were representatives from far afield as well as those from closer to the region, including China, Korea, India, Australia, Malaysia and of course a large contingent from Indonesia. It is extremely encouraging to see the enthusiasm and energy being generated and the growing groundswell of committed people, all of whom have something to offer to enhance our combined areas of study.

Collecting these data together bodes exceedingly well for our future in health, law and ethics and provides fuel to generate even greater commitment and development of our combined disciplines. The challenge is for each of you, reading this newsletter, to question how you can better contribute. To paraphrase JFK, "Ask not what WAML can do for you – ask what you can do for the WAML!"

Prof. Roy Beran,
WAML Secretary General



From the Production Team

The production team used a new four (4) columns format, per page in order to save space, so we can accommodate more articles.

We would very much like to have your feed back. The next Issue Editor will be Dr. Anne Marie Duguet of Toulouse, 2006 WCML Congress President. please contact her for contribution of your articles.
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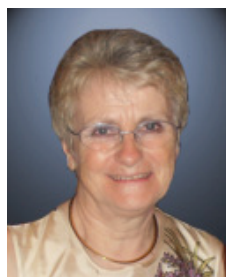
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this newsletter express the
views of the authors and
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of the WAML

Issue Editor



Anne Marie Duguet

Commercialisation of human body and body parts: A reality in some European countries

"Human body should not be used for commercial purposes... the human body is not an object and cannot be used as such, for instance blood and organs are not for sale" (opinion 21 of the French National Ethics Committee¹). Similarly, many international organizations, especially the World Health Organization² and the Council of Europe³, express disapproval of any trade transaction for the human body, organs and tissues. Despite these recommendations, in some countries, the compensation for organ donation and the commercialisation of tissues and organs, as well as the use of the human body, are becoming an acceptable reality in the general opinion.

The trade in organs and the trafficking

Because some countries

have no regulations, or a flexible legislation, allowing the donation between living persons under very wide conditions, donors and/or recipients move to these countries for the graft operation. The publication of some results of these activities encourages a veritable "transplant tourism" in several countries (Asia, India, Pakistan, Brazil, Philippines).

The report of Mrs. Vermot-Mangold⁴ for the Council of Europe (doc 9822 3 June 2003), shows that these practices have been conducted in Europe since 1980. She points out the shortage of organs and describes the conditions of organ traffic in Europe, especially the exploitation of poverty. The donors came from Moldova, Turkey, Ukraine, Bulgaria, Georgia, Russia, and Romania. Foremost among these practices, no medical monitoring is given to those donors whose health is deteriorating rapidly. Moreover, some former donors are promoting the trafficking.

In May 2010, the Sixty-third World Health Assembly (WHA63.22) condemned the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations. The assembly urged Member States to maximize donations from deceased donors and to protect the health and welfare of living donors with appropriate health-care

services and long-term follow up. Since 2004, a consensus statement (Amsterdam Forum), published by the Transplantation Society, on the care of the live kidney donor includes the obligation for the transplant center to facilitate the long term follow-up.

The utilisation of the body: the surrogate mothers

Some countries forbid surrogate motherhood in Europe (Germany, Austria, Italy, Switzerland, Spain, France), others tolerate this practice (Belgium, Denmark, The Netherlands), only the United Kingdom and Greece have a specific legislation. So a "tourism of procreation" started and surrogate motherhood, with compensation, became an internet business. For example "Surrogacy in Ukraine"⁵ says in its internet home page *"Ukraine is one of the few surrogacy friendly states in Europe. It does not limit surrogacy related payments and does not require legal procedure to obtain court order. No adoption of your own child is required. The recipient family creates embryo using their or donated gametes through IVF (In-vitro Fertilization) that are transferred to gestational surrogate mother. Ukrainian law allows to issue birth certificate to intend(ed) parent's names regardless of their genetic links to the child"*.

Nevertheless, when surrogate motherhood is allowed by the law, the ethical concerns are not solved so far, especially the attempt to preserve the dignity of the surrogate mother (instrumentalization of her body).

The commercial use of cadavers and body parts

Human bodies are used for medical research and training students. Post-mortem donation is based on altruistic living will. Unfortunately, corpses have become rare scientific material and an international trade supplies research centres and universities.

Annie Cheney⁶ describes the highly profitable business of buying and selling cadavers and body parts in America. The American Uniform Anatomical Gift Act of 1968 and 1987 prohibits buying and selling of dead bodies. However, the act allows recovering the cost of storage, transportation etc... The cadaver trade supplies bodies and body parts to scientists, surgical equipment corporations, tissue banks, pharmaceutical companies, medical schools and researchers

Publicly paid exhibitions of real human bodies have been presented in the World (15 million visitors says the advertising for "Bodies. The Exhibition"). This use of dead bodies, out of the context of education or science research, is an ethical and a legal issue. The respect for the human body remains after death in all the cultures. The origin of the bodies presented in the exhibition is another concern, they were supposed to come from China.

In France, when the exhibition arrived in Paris (after Marseilles and Lyon), two associations acting against the death penalty and for solidarity with China claimed in court

to close the exhibition. The judge followed their request on the basis of the article 16-1-1 of the Civil Code: the respect of the human body does not end with death, the remains of deceased persons, including the ashes, must be treated with respect, dignity and decency. The decision has been confirmed by the Court of Appeal (Paris 30 April 2009), which established that the organisers cannot provide documents on the origin of the bodies and the consent forms. Moreover, according to the French law, dead bodies can be used only in public institutions for medical or scientific purposes and not for private activities, such as commercial public exhibitions.

Conclusion

The exploitation of poverty is the main issue regarding the use of human body. All international institutions promote the principle of unpaid donation for the use of human material. This recommendation is not applicable when the legislation of the country agrees with the principle of compensation as some European countries do.

The living kidney donor without any long term follow-up should be considered as a victim, in the same way as a surrogate mother without any psychological support. The principle of autonomy and the informed consent constitute an insufficient protection of their rights, in countries where there is no regulation.

The respect and the limitation of commercial use of the body after death is not protected in some countries, it seems to be more an ethical or cultural reflection than a legal issue.

WAML members could pay a major role by giving assistance to the requests of these countries for proposals of regulations, or guidelines.

⁵ <http://www.ccne-ethique.fr/docs/en/avis021.pdf>

² http://www.who.int/ethics/topics/transplantation_guidelines_principles/en/index1.html

³ <http://conventions.coe.int/Treaty/EN/Treaties/Htm/186.htm>

⁴ doc 9822 3 June 2003 Trafficking in organs in Europe <http://assembly.coe.int/documents/workingDocs/>

⁵ <http://en.surrogacy-ukraine.com/programs.php>

⁶ Annie Cheney Body Brokers: inside Americans underground trade in human remains. Broadway Books Random House Inc: 2006 <http://www.issuesinmediaethics.org/151br40.html>

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Europe and international clinical research: Ethical requirements and regulatory actions



Annagrazia Altavilla

Clinical research is developing on an international scale. In 2009, the European Medicine Agency (EMA) published a report that analyzed Marketing Authorisation Applications (MAA) submitted to the EMA from January 2005 to December 2008. This report emphasized the phenomenon of the globalization of the research

and underlined that the number of patients, investigator sites and pivotal clinical trials conducted in Third countries (non EEA -European Economic Area countries) are increasing. The most favourite destinations for off-shoring of clinical trials are Middle/East Pacific Area (Russia, Ukraine), Africa, and South America (Brazil and Argentina).

Several reasons can be advanced to account for the general shift in many clinical trials away from the West and towards developing countries.

As far as the pharmaceutical industry is concerned: doing clinical trials in developing countries is 10-50% cheaper; regulatory constraints in developing countries are either less stringent or less actively policed; it is easier to find test subjects in developing countries, because participation in a trial is often the only treatment option, or because it offers the chance to make some money; test subjects in developing countries have less frequently already been exposed to similar medicines and this improves the reliability of the test results.; the governments of developing countries are also interested in the economic benefits of allowing clinical trials to be carried out in their countries. Finally, fewer and fewer people in Western countries appear to be prepared to take part in clinical trials, partly as the result of negative publicity related to unethical trial scandals.

This phenomenon raises important questions about the economical and ethical aspects of clinical research and the translation of trial results to clinical practice. Who benefits from the globalization of clinical trials? Which ethical standards are applied? What

is the potential for exploitation of research subjects? Are trials results accurate and valid and can they be extrapolated to other settings? Many reports have shown that the degree of transparency of clinical trials in developing countries is low.

In this context, to avoid unethical clinical trials and the exploitation of developing countries, Regulation (EC) n. EC/726/2004 states in recital 16 that “...with respect to clinical trials conducted outside the Community on medicinal products destined to be authorised within the Community, at the time of the evaluation of the application for authorisation, it should be verified that these trials were conducted in accordance with the principles of good clinical practice and the ethical requirements equivalent to the provisions of the Directive 2001/20/EC”. Furthermore, paragraph §8 of the Preamble – Introduction and General Principles of Annex 1 to Directive 2001/83/EC states: “...during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki.” Finally, the latest version of Directive 2001/83/EC requires to submit, in the application for Marketing Authorisation, a statement confirming that clinical trials carried out

outside the European Union meet the ethical requirements of Directive 2001/20/EC (article 8(3) (ib))

The EMA Work Programme for 2008 (http://www.ema.europa.eu/pdfs/general/direct/emeawp/EMA_Work_Programme_2008_full.pdf) set out a number of objectives relating to the acceptance, in MAAs submitted to the EMA, of clinical trials conducted in countries outside the European Economic Area (EEA) on medicinal products for human use. All such trials are required to meet internationally agreed ethical and data quality standards. These objectives need to be built into the process of clinical development. They need to be addressed before and during the conduct of the clinical trials and not only by assessment and inspection at the time of MAA by which point the trials have been completed, in some cases several years earlier.

In Dec 2008 the EMA published a strategy paper “Acceptance of clinical trials conducted in third countries for evaluation in Marketing Authorisation Applications” (<http://www.ema.europa.eu/Inspections/docs/22806708en.pdf>). In 2009, the EMA set up a Working Group on Third Country Clinical Trials in order to clarify ethical standards for clinical research conducted outside the EEA and included in MAAs. Practical steps to be undertaken during the provision of guidance and advice in the drug development and Marketing Authorization phases were established.

To this aim, a “Reflection paper on ethical and GCP (Good Clinical Practice) aspects of clinical trials of medicinal products for human use

conducted in third countries and submitted in marketing authorization applications to the EMA” was drafted. It integrates all the relevant ethical and legal sources recognized at European and international level, clarifies ethical standards to be taken into account and proposes some actions to be undertaken in the context of EMA activities, including Scientific Advice, Orphan Product Designation and Paediatric Investigation Plans through to the finalisation of the CHMP opinion on the MAA, and post-authorisation activities.

This document highlights and emphasizes that the best approach to achieve an ethical supervision of research across the world is to ensure that a robust framework exists for the oversight and conduct of clinical trials, no matter where in the world the clinical investigators’ sites are located and patients recruited.

The Reflection Paper highlights and emphasizes the need for cooperation between Regulatory Authorities involved in the supervision of clinical trials and the need to extend and link networks to support these activities. An international network of regulators from all countries involved, working together to share best practices, experiences and information and working to standards agreed and recognized by all, can provide an effective platform for such a robust framework.

To achieve these objectives and to guarantee a large participation of stakeholders, the EMA submitted the document for public consultation until the 30th of September 2010 and during the same period organised an international workshop with the

aim to discuss and provide feedback on this reflection paper. Comments on the paper could be provided using this template. The completed comments form should be sent to ctrefpaper@ema.europa.eu

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The importance of law for pandemic preparedness in Europe



Robyn Martin

Introduction

Although institutions such as the World Health Organization (WHO), the European Commission and ECDC, all play a role in disease prevention and control, final responsibility for disease surveillance and the management and control of disease outbreaks lies with individual states. In relation to a possible influenza pandemic, in particular H5N1, each state in Europe has a pandemic preparedness plan outlining

measures to be taken for prevention and control of pandemic disease. Such plans inevitably contain proposals for non-medical interventions such as compulsory screening, quarantine, detention, closure of facilities and, in some states, compulsory vaccination and medical treatment, to support medical disease control measures.

Law and pandemic preparedness

Pandemic preparedness plans are important but they are policy documents and in most states do not have the force of law. Many of the interventions proposed would, without legal authority, constitute criminal or tortious (delict) acts. Detention and quarantine without consent might well amount to false imprisonment for example, and compulsory screening or treatment without consent, to assault. It is essential that states proposing such interventions provide, alongside their preparedness plans, legislation authorising disease control measures.

Even where legislation authorises behaviors that might otherwise infringe individual autonomy, there will be constraints on the extent to which states can prioritise the public good over individual rights for the purposes of disease control. These constraints come from the need to exercise public health practice, within a framework of public health ethics, and from the abiding principles of human rights enshrined in documents such as the European Convention on Human Rights and Fundamental Freedoms. In the case of *Enhorn v Sweden*¹ the European Court of Human Rights confirmed that states must recognise human rights laws in

the exercise of public health powers. Hence, no state can afford to conduct its public health programmes without recourse to public health law to underpin public health measures and to constrain over-zealous exercise of public health interventions.

Pandemic influenza threatens to test societies to the extreme. Public health laws are likely to be critically important tools in supporting disease prevention and control and in regulating social and individual behaviour that threatens security during a crisis.

What is public health law?

Public health law is based on the state's responsibility to protect its citizens from foreseeable threats of harm. Powers and duties within the realm of public health law are framed in ways that address populations and govern the organised efforts of the state to provide services and interventions aimed at population health.² Public health operates within an ethical framework of communitarianism and utilitarianism, presupposing both that there are circumstances in which the greater good of the community justifies the overriding of autonomy of the individual and that the intervention which results in the greatest health benefits for the greatest number is the most appropriate.

The International Health Regulations (IHR)

The Constitution of WHO confers upon the World Health Assembly the authority to adopt regulations "designed to prevent the international spread of disease".³ These regulations enter into force for all WHO Member States

that do not affirmatively opt out of them. The revised IHRs 2005 impose disease reporting duties, duties in relation to the handling of epidemiological data and responsibilities on States to strengthen surveillance and response capacities. The WHO has powers to determine when a disease constitutes a public health emergency, to make recommendations and to respond to disease events. The IHR 2005 also recognise the constraints of human rights on public health interventions, requiring all public health measures to be evidence based and that health measures not be more restrictive or invasive than reasonably available alternative measures. The IHR 2005 prompted all signatory States to revisit their public health legislation, to enable them to act to control the spread of disease in a pandemic.

The PHLawFlu project

It was nevertheless unclear the extent to which States within Europe had at their disposal laws to support pandemic planning. One objective of the EU co-funded PHLawFlu project was to study laws underpinning human pandemic influenza preparedness across 27 member States plus Croatia, Turkey, Iceland, Liechtenstein and Norway. The methodology included a detailed questionnaire on state public health laws and workshops examining the cohesion between preparedness plans and disease control laws within States, as well as the cohesion between public health laws across States in Europe.

The project found a number of disconnects and differences of approach to pandemic planning and disease legislation across States. While

some States are reliant on 19th century laws updated for IHR compliance, others have new laws designed with pandemic disease in mind. Some States have general powers enabling any proportionate measure for a public health purpose. In only two of the States studied were all measures proposed in plans supported by specific legal authorisation.

Some States operate their public health laws at national level while in others, with devolved systems, regional laws are more important. Six Schengen States' plans consider a pandemic to constitute a serious enough threat to public policy or internal security to justify reintroduction of internal border controls. Ten States have laws that would authorise border closure in a pandemic. There was a range of interventions planned across the States including surveillance, compulsory treatment, medical examination, vaccination, quarantine and isolation. Some States proposed using emergency powers in a pandemic. In some States there was the potential for proposed interventions to infringe human rights.

One of the most important findings was that most States lack expertise in public health law. Participants in project workshops called for increased research and training in public health law in Europe.

Conclusion

Pandemic planning policies must be framed within laws that enshrine public health ethics and human rights. Previous disease outbreaks, in particular SARS, demonstrated that, across the world, public health laws are out of date and inappropriate.

ate to contemporary disease threats. The IHR 2005 have initiated global disease law reform but a paucity of teaching and research in public health law, particularly in Europe, has inhibited effective revision of disease laws. Law is a useful tool for public health but as yet there is little capacity to exploit it. We need to include teaching and research in public health law in both law and public health schools to build capacity in public health law expertise, to assist not only in pandemic preparedness but also in the control of other communicable and non-communicable diseases across Europe.

¹[2005]E.C.H.R. 56529/00

²See L.O.Gostin, *Public Health Law: power, duty and restraint*, Berkeley: University of California Press; 2000

³Articles 21(a) and 22

Robyn Martin,

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WAML Secretary General's Report



Prof. Roy Beran,
WAML Secretary General

I am delighted to provide this, the first Secretary General's report, following the 18th World Congress on Medical Law (WCML). It was an

extremely successful conference and the whole Croatian team MUST be congratulated on a great meeting. Its importance was highlighted by the fact that the President of Croatia, himself, opened the WCML and there was of the order of 400 delegates from around the world.

It was also a monumental meeting for the World Association for Medical Law (WAML) as Professor Amnon Carmi stepped down from the Presidency and from the Board of Governors after more than 20 years at its helm. To commemorate this event, the WAML created and presented the inaugural Amnon Carmi Award, created to perpetuate the name of a man who was, and is, the epitome of the WAML for so long. The recipient of the Award was Professor Bernard Dickens from Canada. Professor Dickens was unable to attend the WCML due to health problems but he too stepped down from the Board of Governors after many years of devoted service to the WAML.

On only the fourth occasion, in the half-century history of the WAML, the Raf Dierkens Medal, named after the founding father of the WAML, was awarded and the recipient was Professor Thomas Noguchi, who has attended the WCMLs since the very first meeting, all those years ago, in Ghent. Tom, as he is better known, was also elected as the next President of the WAML and presided over the Board of Governors meeting that immediately followed the General Assembly (GA) in Zagreb, Croatia.

The GA was a very lively meeting and the democratic way in which it was conducted bodes well for the future of the WAML. There

was healthy debate from the floor and the value of having established statutes, to map out our future, was reinforced. The GA elected new blood onto the Board of Governors, significantly lowering the average age, well below mine, which is a good thing and most encouraging for our future. Adv. Samuel Wolfman stepped down from the Audit Committee and the new Committee was ratified, including Dale Cowan (USA), Anne-Marie Duget (France) and the new member Itzhak Zaidese (Israel). The venue for the 2012 World Congress for Medical Law (WCML) was confirmed as Maceio, in Brazil, and that of the WCML in 2014 will be Bali, Indonesia. This reaffirms the global nature of the WAML.

At the Board of Governors meeting, following the GA, the executive was elected and consisted Tom Noguchi from USA (President), Roy Beran from Australia (Secretary General), Oren Asman from Israel (Treasurer) and David Collins from New Zealand (Executive Vice President). This maintained significant consistency on the Executive, with continuing members of the team, although half of them in different jobs. It reflects the confidence held by the Board of Governors that the Executive can provide a team necessary to ensure that the administration of the WAML will continue without too much upheaval following the monumental change of Presidents. It ensures that we can maintain the high standards necessary to fill those large shoes vacated by Professor Carmi. Personally, let me take this opportunity to thank all those who have supported me, as the Secretary General, and allow me to confirm my commitment

to ensure that the WAML will continue to grow and to go from strength to strength.

New blood was introduced into the ranks of the Vice Presidents and I can assure all those reading this newsletter that our future looks very bright with a new face Board of Governors and an enhanced level of enthusiasm and vitality from all those on the team.

During the 18th WCML there was a special celebration of the 30th Anniversary of our WAML journal 'Medicine and Law'. This was presided over by Dr Mohammed Wattad, who spoke about adopting Professor Carmi's "baby" and promising to be a good parent. Mohammed was married, just days before the meeting, and the whole of the WAML wishes him and his new bride, and now their adopted "baby", every happiness and success. We know the journal is in good hands and we are confident that it will also go from strength to strength

At the time of writing this report there has not yet been a week since my return from Zagreb and I cannot keep up with the flurry of email activity generated from our new President. Tom Noguchi, whom so many described to me as an 'old man', has the energy of a 20 year old and puts me to shame. He will drive us all into the ground with his boundless enthusiasm and absolute commitment. Denise McNally, the new Administrative Officer, was worth her weight in gold while in Zagreb and, since then, has not been allowed to surface to take breath. Oren Asman, who served me so faithfully as Deputy Secretary General and as an ex-officio member of the Executive, is now the new

Treasurer, to replace Tom Noguchi, and has promised to do both this task and continue to act as my Deputy. He has raised so many exciting new concepts, such as Facebook, U-tube and Twitter – terms new to an old soul like me but clearly evidence of a ‘time of change’ and a new season for the WAML.

At the Board of Governors meeting, preceding the GA, it was decided to canvass organizations interested in health, law and ethics around the world. Jonathan Davies, who was re-elected as Chair of the Council of Presidents (CoP), and I will write to as many as 1,000 organizations, to offer affiliate status with the CoP. There will be a two year moratorium on any charges to these bodies so as to ensure wider global representation for the WAML. Organizations seeking affiliation will still be encouraged to advocate individual memberships, which can be achieved over the WAML web-pages. Should anyone, reading this newsletter, be part of an appropriate organization or institution which could benefit from WAML affiliation, they are encouraged to contact our Administrative Officer, Denise McNally, to register the interest of that organization and we will make it our business to make contact.

Also in Zagreb, Dr Richard Wilbur, one of the most positive supporters of the WAML, over many years, was elected and accepted the role of Editor-in-Chief of the Newsletter, in conjunction with the issue specific editors. I truly look forward to the ongoing work with Dick. He is an inspiration and a real role model.

Amnon Carmi is not totally relinquishing his duties for the WAML and will direct an

‘Education Committee’ as one of a number of new committees to be formed. This will capitalise on his experience in the UNESCO Chair in Bioethics and his many years as an academic and teacher. Should any of our members want to serve on any of the newly formed committees or wish to nominate the formation of a new committee that they envisage would be to the future benefit of the WAML, they are encouraged to either contact me, as Secretary General or Tom Noguchi, as your President.

From the above, it can be seen that the changing of the guard at the top of the WAML really does offer a very positive opportunity for change, building on the very solid foundations provided by Prof Carmi. You, our members, can be confident in the future of your Association and the WAML is destined to achieve great things. As always, I conclude with a call to arms and I seek your continued and enhanced efforts to make this, your Association, the best it can be and for you to contribute in any way that you can.

Roy G Beran
Secretary General WAML

President's message



Thomas T. Noguchi
WAML President

As your newly elected President, I would like to convey a special message to you. First, I would like to urge you to encourage your colleagues

to become members of the WAML. The more members that we have will provide more resources and talents to engage in active educational projects, setting standards, and accreditation for educational efforts. We have the WAML membership brochures in pdf or hard copy for a membership drive.

I am open to any suggestions from the membership to improve the management and organization of the WAML and would like members to participate in future programs of the WAML.

Brazil will host the next World Congress. Congress President Eduardo Dantas spoke at the last World Congress in Zagreb, Croatia and pointed out that the 19th Congress will be the first Congress to be held by the WAML in Latin America. It is my great pleasure to invite you and your colleagues to attend the World Congress on Medical Law in Maceió, Brazil in August 9 - 13, 2012. Many of you may already have met Denise McNally during the Congress in Zagreb, Croatia. She has recently joined the WAML as Administrative Officer and Coordinator for membership services. Please do not hesitate to contact her for any suggestions or requests. Her E-mail address is mcnallyd@cvalley.net.



Following the successful meeting we had last month in Zagreb, I am happy to announce that we already

have started the preparation for the next Congress, to be held in Brazil, in the city of Maceió, in August 2012.

We are proud to host, on behalf of WAML, the first World Congress on Medical Law in Latin America. We believe this is the ideal opportunity to create bonds on both sides of the Atlantic, strengthening cooperation among researchers, associations and universities, thus encouraging the study and discussion of problems concerning health law, bioethics and legal medicine.

In the upcoming months, we will send information about deadlines, main themes, and registration at special rates for WAML members. Our website can be accessed at www.2012wcml.com, and there you will be able to contact the organizers, and find useful information for planning your trip.

More than that, we hope to have your active participation in this process, with your comments, suggestions and ideas. The commitment of each one of us is important to help the WAML grow stronger, reaching its goals, developing Medical Law, Legal Medicine and Bioethics and the advancement of human rights.

On behalf of the organizing committee, I'd like to welcome you all to Maceió, to Brazil, to Latin America.

Eduardo Dantas

Vice-President of WAML
2012 Congress President





World Association For Medical Law

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Disclaimer

The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML

Message From The Guest Editor



**Dr. Mohammed Saif-Alden
Wattad**

A few months ago I was invited to serve as the Guest Editor of the December 2010 WAML Newsletter; which invitation I have accepted with honour and respect.

On August 10th 2010, at 19:00, I declared the formal celebration of the 30th anniversary of the International Journal "Medicine & Law" (hereinafter: the Journal), in the inspiring lecture hall at the Faculty of Law in the University of Zagreb in Croatia. It was a very ceremonial event, held especially for this occasion as part of the World Congress on Medical Law of the World Association for Medical Law (hereinafter: the WAML). During

the celebrations, Prof. Amnon Carmi – the Founder of the Journal – announced his retirement from the Journal and appointed me as the new Editor-in-Chief. Shortly before announcing his resignation, for thirty minutes, one after the other, Prof. Roy Beran, Prof. Roberto Mester, Prof. Miriam Cotler, Prof. Christa van Wyk, Prof. Ken Berger, Prof. Michal Lupton, and Dr. Samuel Wolfman stood before one hundred well known international scholars in the field of medical law, sharing with each other their long collaboration with the Journal as well as with Prof. Carmi. The speakers honoured and thanked Prof. Carmi for a long-standing, very successful legacy in leading the Journal and wished me good luck in preserving this legacy. I view Prof. Carmi as a prophet whose decisiveness has enabled him to become so. He decided upon the subject matter of his prophecy by including the soci-

ety at which he aimed his efforts. He established an international society called "medical law" (hereinafter: the Society), thus appointing each of the Society's members as gods of his prophecy, empowered to draft their own holy book, namely, the International Journal "Medicine & Law".

On August 18th 2010 I celebrated my 30th birthday – eight days after the Journal had celebrated its 30th anniversary. I would like to take advantage of this opportunity to state the following: In a place where order, discipline and self-awareness are absent, success becomes only a matter of luck. However, luck is good enough in so far as a person gets the chance to be adopted by a man with order, discipline and self-awareness. Such a lucky person will know only success, thus making failure a matter of luck, or even bad luck. I am honoured to be part of the international society of "medical law".

I am honoured to be brought before this dignified and dignifying society by Prof. Carmi, and I am honoured to have been adopted by Prof. Carmi. To Prof. Carmi, I am grateful and indebted. I am not quite sure whether this has been luck that brought me to his attention or rather his wisdom and self-confidence. In one way or another, I feel honoured to serve in a position that has been occupied for 30 years – most successfully I should say – by a presence such as Prof. Carmi. At the same time, I feel a heavy responsibility has been laid on my shoulders; a responsibility that I shall attempt to fulfill with a great deal of passion and caution.

In the process of granting me the honour of serving as the Editor-in-Chief of the Journal, Prof. Carmi has submitted repeatedly that the Journal is his own baby. On August 1st 2010 I was married: therefore I still do not have a baby of my own. However, I am willing to make this oath before the international society of “medical law”; that I will devote myself to the care of the Journal as best as I can imagine treating a baby of my own in the future. The least I can offer Prof. Carmi – all the more so the “medical law” society

– is to dedicate this issue to the very extraordinary and unique contribution of Prof. Carmi as the Founder and the First Editor-in-Chief of the Journal.

Few days before the 30th anniversary ceremony was held, I attended a special presentation by a special figure. Dr. Abdallah A. Adlan, from King's College of the University of London, delivered a magnificent presentation on “The Tyranny of Informed Consent.” This was the kind of lecture that even if you do not agree with the presenter on his views, still you highly respect and value them. In editing this Issue of the WAML Newsletter, I could not think of a better academic contribution than that of Dr. Adlan, who was generous enough to accept my invitation promptly and without hesitation. I perceive Dr. Adlan as the keynote speaker of this Issue.

Besides thanking Dr. Adlan for his contribution, I would like to congratulate Dr. Thomas Noguchi for his new position as the President of the WAML and wish him a very successful term. It goes without saying that many thanks are due to all those who were kind enough to devote their very precious time in or-

der to contribute to this Issue and whose contributions are highly valuable to me and to the readers as well. Without further ado, I shall now let the readers enjoy the contributions presented in this Issue.

Dr. Mohammed Saif-Alden Wattad
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Message from the President



Thomas T. Noguchi
WAML President

With the end of the year approaching, I would like to wish all of you and your families, good health and a Happy New Year. We look forward to having another good year of activities.

We appreciate all the work done by the host organizing committees in putting together the Congress -. In the future, we will do more to - coordinate Congress management and work more closely with the local Congress Organizing Committees to ease their burden and standardize the programs. Denise McNally, WAML Administrative Officer, will be

working with the coming WCML Organizing Committee - to coordinate the preparation for the Congress.

The 2010–12 Board of Governors has new members: Adv. Oren Asman of Israel, Adv. Maria Escobar of Paraguay, Adv. Natalie Lojko of Poland, and Prof. Andre Pereira of Portugal. I am looking forward to working with them. We express our sincere appreciation to those who have served and completed their terms of office on the Board.

The Board granted two retired board members honorary status: Immediate Past President Professor Amnon Carmi and Vice President- Prof. Bernard Dickens.

For their long years of service, WAML bestowed the title of Honorary President to Prof. Amnon Carmi and Honorary Vice President to Prof. Bernard Dickens. Hopefully they will still remain active in the WAML and attend future World Congresses and WAML Board meetings.

We would like to continue maintaining our communication with members. If you have any suggestion or comment, please let us know. Denise McNally will be in touch with you regarding member-

ship services. Recently, we asked you for your feedback regarding the Congress and membership benefits and we are appreciative of your helpful responses -. We are looking forward to working with the Brazil WCML Organizing Committee and hope to see you there in 2012.

WAML Cross Fertilization Program. We feel that it is important for the WAML to have “cross fertilization” programs with national and international associations in our field. At the coming meeting of the International Association of Forensic Sciences (IAFS) in Madeira, Portugal in September 2011, WAML Governor, Professor Andre Pereira will be the Workshop Chair for the Program on Medical Law and Bioethics, specifically concerning the human body and tissues.

This year, a few WAML members have requested the WAML to provide program assistance or endorsement for their educational programs on medical law and bioethics. Adv. Radmyla Hrevtsova held a successful International Workshop on “Legal and Ethical Aspects of Informed Consent: Experience of Different Countries” which was conducted on Septem-

ber 22nd, 2010, in Kiev, Ukraine, by the Institute for Medical Law, Pharmaceutical Law and Bioethics at the Ukrainian Academy of Advocacy in collaboration with the WAML and the Ukrainian Medical and Legal Association.

In October, Prof. Roy Beran, the Secretary General, attended as an official WAML Representative at the opening ceremony of the International Research Institute of Health Law Sciences, at the Southern Medical University in Guangzhou, China. I, as President of the WAML, was appointed as the Honorary Dean of the Institute. I accepted this honor on behalf of the WAML. Our appreciation and respect go to Prof. Sun and Prof. Wu for their thoughtful consideration of the WAML in making this honorary appointment.

I, as President, went to Japan and discussed future collaboration with the Japanese Association for Medical Law. This Association was founded by Professor Koichi Bai, who is also a Founding Member and Governor of the WAML Board. The meeting was held with Prof. Katsunori Kai, Chairman of the Board of the Japanese Association of Medical Law in Tokyo and Prof.

M. Kurosu of Tokyo Medical University. I also attended the Annual Meeting of the Japan Medical Philosophy and Bioethics Association in Morioka, Northern Japan. We hope our Japanese colleagues will more actively participate in the WAML.

Starting with the December 2010 Newsletter, we will carry a list of the coming international meetings in medical law and bioethics, and meetings of the WAML Affiliated Associations. We encourage our members and affiliated association to send us the information of these coming meetings.

WAML Committees. We - invite members to participate in the WAML Business Committees as well as scientific committees. A few members of Committees have already been appointed. Those are the Audit, - Finance, - Communication and Website Committees. More appointments to committees will be forthcoming. I urge all governors and members to participate in the WAML administrative matters.

Registration of the WAML as a Not-for-Profit member organization is still in process. Upon completing the bylaws, the Board of Governors will be con-

tacted.

If you have any suggestion, please contact Denise McNally, mcnallyd@cvalley.net,

Happy Holidays

Thomas T. Noguchi
WAML President

Report From The Secretary General



Prof. Roy Beran,
WAML Secretary General

This is the last Newsletter for 2010 and there has been a great deal of activity in the last three months. Within weeks of the World Congress in Zagreb, quite a number of the Board of Governors, including Oren Asman from the Executive Committee and Eduardo Dantas, President of the next World Congress, represented the WAML at a conference on informed consent in the Ukraine.

I represented the WAML at the opening of the 1st International Research Institute of the Health Law Sciences in Guangzhou in China. I

was not the only invitee introduced by our Vice President, Professor Wu, as Sarah Barber represented the World Health Organization and our past President, Amnon Carmi, was there in his capacity as the holder of the UNESCO Chair in Bioethics. Our President, Professor Thomas Noguchi, was recognized as the Honorary Dean of the Institute with an obvious and significant mark of respect for the WAML. Professor Noguchi accepted the honour on behalf of the Executive Committee of the WAML but did not see this as a personal achievement, rather to be reflective of the high standing of the WAML in international circles. A number of WAML members were honoured with appointment to Visiting Professorial status within the Institute and, at this opening ceremony, I acknowledged that this could provide the blueprint for the establishment of other such initiatives around the world. The WAML is ready and willing to partner such international projects so long as there is no conflict of interest and the high moral and ethical standards of the WAML are enshrined in the ethos of any such development.

Professor Noguchi,

together with a number of other Governors, will also reflect the expertise of the WAML at an international Forensic Medicine meeting in Portugal. This again shows how the WAML is growing both in stature and capacity to offer world-class speakers for all manner of educational endeavours. For anyone who was worried about the change of leadership, once Professor Carmi stepped down from the Presidency in August this year, they can rest easy.

Professor Carmi also has not let the grass grow under his feet. He remains the world leader we have learnt to recognise him to be. He wore the cloak of the UNESCO Chair in Bioethics with pride and bearing. As if that were not enough, he also holds the position of Secretary General for an international Judges' Association. It is great to see Amnon so well, not skipping a beat in his activities on the world stage while maintaining his close ties to the WAML as an Honorary Board Member, having a perpetual WAML award named in his honour. He remains our dear and devoted friend of the WAML. He still has much to teach us and there is a great deal that we can learn from him.

It was my great pleasure to catch up with Amnon at the Southern University in China. I still have to take lessons from him, as he presented himself with a relaxed composure while I constantly fight the clock and Father Time. Amnon, I believe I will need your thoughtful mentoring and guidance long after the WAML realizes there are more capable people, within its ranks, than am I!

As 2010 draws to a close and 2011 bursts into life, I want to remind all of you to pay your membership dues. We need your membership to strengthen our ranks and to expand our sphere of influence. I hope you realize the wealth of benefits that attach to such membership and you will recommend that others of your colleagues and friends likewise join the WAML. The benefits go well beyond the recognition that you have been accepted amongst the elite in the Health Law, Legal Medicine and Bioethical International Community. As a member of the WAML, you receive this Newsletter, the Journal and discounts for WAML merchandise, events and courses. You also receive an established and most impressive network of leaders on the interna-

tional scene in Health Law, Legal Medicine and Bioethics. There is a growing dialogue regarding international exchange of students, access to regional and other meetings, possible supervision for post-graduate research and qualifications and a level of camaraderie that can only grow and empower our very specialised community.

My final duty for this Newsletter is to wish you all the very best for whatever festivals you might celebrate at the end of the year – be it Christmas, Hanukkah or an alternative festival that celebrates the betterment of humankind. May the light of peace shine upon us all and the fruits of tolerance and humanity grow to become an overwhelming force for good and prosperity. May there be equality among the genders, respect for the sanctity of life and an end to terrorism, inhumanity and abuse of those who dare to be different. Let education lead the way and love and caring follow.

Happy New Year to all of you – old and young; male and female; giver or receiver.

Roy G. Beran
Secretary General of
the World Association
for Medical Law

The Tyranny of Informed Consent



Dr. Abdallah A. Adlani

I would like to thank Dr. Mohammed S. Wattad, the Guest Editor of this Issue for inviting me to contribute my insights on the concept of “Informed Consent”, thus sharing them with the special “medical law” community.

This article is not meant to be a logical exercise where the points are embraced for the mere reason of the debate itself. On the contrary, it is an honest reflection based on very long experience in the field of applying informed consent. Assuming good intentions in ideal situations, informed consent can be defined as: “...an autonomous act by a patient or research subject to expressly permit a professional person to perform a medical action on the patient or to include a person in a research project...” (Beauchamp’s, as cited by Galpon (1987)). It is quite obvious that informed consent is ranked at the top of the bioethics

pyramid to insure neither deception nor coercion was inflicted. It is also perceived as the golden gate keeper of the principle of autonomy in the medical field. Nevertheless, it is pictured as a thin red line between committing a crime and performing an operation or recruiting for research. Such a high rank of perception can be attributed to several factors: (1) **It is tangible:** The fact that it is perceived as paper work eventually makes it the easiest among other principles to be maintained, screened and revisited without major contradictions. (2) **It is the less argued:** If an autonomous agent accepted the deal with no reportable coercion and after an adequate amount of contrived information, then it is legal to go ahead with anything. Hence we have the notion of two consenting adults. (3) **It is a legal protection:** This indeed has made informed consent a legal tool more than an ethical one. Informed consent is cooked up in lawyer’s kitchens and not by bioethicists, which subjects it to prioritization by organizations’ protections rather than patients’ protections.

Those facts and much more, have helped

giving informed consent its tyrannical power. This power is dominated by the legal industry. In other words, informed consent serves monetary interests, which are obviously not the patient’s interests in this context. At least up to this date, there is no reference to a hospital where a patient is required to attend with an attorney. Nevertheless, it is important to acknowledge that the main premise that gives informed consent such power, is the notion of autonomy, which is under the command of the forces of law.

Consideration of this begs the most important and most basic question about patient autonomy. “Can patients be autonomous?” If the word “yes” is in the horizon of answering this question, then visiting the following reasons is advised before embracing any answer: (1) **Patient Physician Vulnerability:** Physicians are usually looked-up-to as “the healers” among their patients. From that perspective, it is obvious that the patient accepts whatever comes from his/her healer. Such vulnerability can be tolerated to some extent; however it becomes unforgivable if the patient should act against his/

her will solely to please the “healing” physician. (2) **Patient Physician Trust:** In some cultures, physicians are highly trusted as the most knowledgeable agents. This goes to the extreme when some patients think that consulting another physician is an insult to the one providing treatment. (3) **The Hope and Desperation Factor:** It is usually the case that when patients are requested to consent, they act under mixed emotions such as hope, fear, hopelessness or desperation. The most dominant factors, I claim, are hope and desperation, for without those the patient is less likely to consent. This can be sensed in phrases such as “Are you sure it is safe? Or, “Am I going to be ok?” (4) **Physician Ego:** In some cases physicians give an assurance based on their experiences. Despite the odds or any miscalculation, they are over generous with assurances. This can be sensed in phrases like “What can go wrong? Or “Relax, we have done it hundreds of times”. (5) **Physician Paternity:** Some physicians are self-centered and above questioning. What they decide is the “best” for their patients. It turns more serious when pa-

tients are intimidated. The patient in this case would be under the impression that if he/she says “no”, he/she will lose the good relationship with the doctor. It may be perceived that this would lead to delay in follow-up appointments, less sensitive treatment or even transfer to a less experienced doctor.

These premises, and many more, make autonomy an over-romanticized idea. Thus, informed consent, in its current condition, is not the right measurement of ethics. This will leave us with the most important question of: what are the alternatives? To answer the latter question, it is unavoidable to differentiate between the two different practices where informed consent is widely used in clinical setups: Clinical intervention and non-clinical intervention.

Informed Consent in Clinical Practice:

According to the “Medical Council of New Zealand”:

A doctor is engaged in clinical practice, if he or she assesses, diagnoses, gives advice, treats or makes reports, whether face-to-face or otherwise, with a patient, or with a group of patients or a population.

This definition includes the activities of public health medicine and medical administration. Using this definition it can be concluded that clinical trials are part of it. However, it is more sensible to omit the clinical research in so far as informed consent is concerned. As it can be noticed, the main intention in this case is to help a patient him/herself and not to use him/her as a means for serving another purpose. If this is the case, more room for tolerance should be afforded the treating physician. However, the patient should not be totally ignorant of what is going on. The stronger alternative in that domain is informed choice not informed consent. This occurs when the patient is the one who makes the decision, not only consents to it. The difference between informed consent and informed choice might seem superficial but actually it is not. It goes deeper in so far as the informer’s intentions. Informed consent is the case when the decision is already made and the patient only consents to it with his signature after rushed, insufficient, ambiguous, or even deceiving information is given him/her. If the notion of unfair generalization is

suggested, an invitation is forwarded to consult the tens, or even hundreds, of incompetents assessing the quality of the practice of informed consent. Unless the patient is the one who is making the choice after having all the options objectively laid before him/her.

Informed Consent in Non Clinical Practice:

According to the “Medical Council of New Zealand”:

A doctor is practicing non-clinical medicine if he or she is not engaged in clinical practice as defined above, but is engaged in such activities as medical informatics, contributing to medical media, teaching to members of the profession and students (without direct patient contact), research not involving humans, medical advisory board or committee work (this list is not exhaustive) for which an annual practicing certificate is required.

It can be concluded that its encompassing activity (e.g. research using patient or patient data but not clinical research) is for scientific or educational gain and not of benefit to the individual patient. For the same reason, including clinical research

in this group would be more sensible with regards to informed consent. Despite the previous condemnation of the common practice of informed consent, the importance of informed process can never been stressed enough. Especially when health related research is the case. Given the seriousness of the research participant’s contribution, more detailed information should be assessed with rigor to check, recheck, monitor and quality control the whole process. Any conflicts of interest should be strongly acknowledged. This conflict of interests reveals its ugly face when the main interest of the researcher is to recruit for his/her research, regardless of patient welfare.

This should not give a green light for lawyers to start dominating the practice to the extent that it becomes normal to see informed consent agreements of about 30 pages. It strikes the other extreme of hiding information by giving too much of it and begs the question of where to draw the line between too little and too much consideration of this should be the call of the local human ethics committee.

Such issues will leave us with a grey region which includes databases, total quality reports (e.g. morbidity and mortality reports) and retrospective research. If the above mentioned definition is to be used, then reports are not meant to service an individual patient him/herself. Thus it can be rated as a kind of research. Despite the fact that these activities are rated as research, a strong voice suggests that the informed consent process be omitted in those cases.

The usual debates to wave informed consent use some fallacies such as: (1) It is not practical: In the case of reviewing hundreds, or even thousands, of cases, it is not practical to call all of the patients to allow them the choice of whether or not to participate. The answer to that is to think prospectively, starting at the earliest possible time to give all prospective patients the choice and try to catch up with those who are already registered patients. (2) There is no harm to just a chart a review: It is usually the case that such fallacies are widely used. The counter argument is that confidential information is protected by all the concerned laws.

The ownership of such belongs to the patient. This information at some time may be of financially harmful nature (when insurance companies are concerned) or socially harmful (when there is stigmatizing information). (3) There is no assurance that the patient will remain anonymous: It is almost impossible not to have at least one identifier such as the medical record number. This straight away breaks the claimed anonymity. (4) It is important to learn and improve quality. As it is said, doing it right is more important. Teaching the new generation using unethical means is a "crime" in itself.

As you may sense, it is primarily due to inaccuracies of ownership. Researchers, most of the time, think that they own the data because it is on the hospital premises. Even if they agree, that the data is owned by the patient, they tend to think that there is no need for patient approval because the patients are not going to feel it. To answer that claim, imagine a case where your electricity provider raised your bill by one cent more than was actually due. This one cent is virtually nothing to you but it means millions of

dollars to the company. How would you feel? Every one with fair reasoning would say it is not right, it is stealing! Now consider with me, why is it stealing when it comes to money but not when it is information? I think every one is entitled to choose, and not just consent, to whether or not he/she wants to participate.

In conclusion: (1) The process of informed consent must be further reviewed and continually assessed. (2) In current practice informed consent is a legal document more than an ethical one; this must be firmly reversed. (3) The request to wave the informed process of activities, in the border line between research practice and health related research, should be denied and informed process should be addressed accordingly. (4) The notion of informed choice is worth adopting as an alternative.

Dr. Abdallah A. Adlan
CBAS, King's Collage,
University of London

Educational Activities in Ukraine: A Focus On The Experience of Countries



Adv. Radmyla Hrevtsova, JD, PhD,

In September 2010 a number of medico-legal and bioethical events took place in Ukraine. Members of the WAML substantially contributed to them.

The series of events was opened by the **Fourth National Congress on Bioethics with international participation** organized by the Ministry of Health of Ukraine, the National Academy of Sciences of Ukraine and the Academy of Medical Sciences of Ukraine was held on September 20-23, 2010. The Congress program was largely focused on legal aspects of biomedical activities. **Prof. Yury Kundiev**, a member of the National Academy of Sciences and the Academy of Medical Sciences of Ukraine, outlined in his opening speech the issues which require better ethical and legislative solutions. They, among others, include:

abortions; the use of genetically modified organisms; and population immunization which faces serious problems in Ukraine because of an anti-vaccination media campaign, on one hand, and certain legislative drawbacks and violations of the existing legislative rules that are not rare, on the other hand. He pinpointed the necessity of bioethical education for members of ethics committees, doctors and other professionals dealing with health care issues.

Those issues were further discussed at the Congress Section "Bioethics and Law". **Dr. Mohammed Wattad, Adv.** (Israel), delivered his lecture on the topic "Bioethics – Teaching Ethics, Not Morals", which aroused profound interest in the audience. **Adv. Oren Asman** devoted his presentation to the topic "Ethics, Law and Religion: the Interplay in Israel". Illustrating his thoughts, he dwelled upon the Israeli approach to abortion and other issues that are debatable in Ukraine. **Dr. Eduardo Dantas** (Brazil) continued the topic focusing on informed consent, medical malpractice and a number of other issues showing the area of common concern of bioethics and law.

Local speakers also paid much attention to those topics, discussing foreign experiences and the possibilities of implementation of these practices in Ukraine. For example, Dr. Galina Mironova considered ways of introducing anticipatory directions and medical powers of attorney into Ukrainian legislation and practice. Dr. Olena Rohova devoted her lecture to the ethical and legal problems of organ transplantation, the proper resolution of which requires changing the relevant legislation that is currently very restrictive.

Importantly, such issues should be discussed not only among experts but presented for the attention of future professionals.

On September 22, 2010, **Dr. Mohammed Wattad, Adv.**, a senior lecturer at Zefat law school, a member of the Management Board of the International Centre for Health, Law and Ethics, delivered a public lecture at the Academy of Advocacy of Ukraine. While lecturing about burning issues in medical law, he drew the attention of the attendees to the necessity of a deep understanding of the essence of the medical profession. A focus was directed towards as-

sisted reproduction and informed consent. The latter is indeed one of the key concepts of contemporary medical law and bioethics. Dr. Wattad's lecture was an excellent introduction to the next event – an international workshop on informed consent that took place later on the same day.

The International Workshop "Legal and Ethical Aspects of Informed Consent: Experience of Different Countries" was conducted by the Institute of Medical Law, Pharmaceutical Law and Bioethics at the Ukrainian Academy of Advocacy in collaboration with the World Association for Medical Law and the Ukrainian Medical and Legal Association.

The Workshop was attended by representatives of the Ukrainian Ministry of Health, scientific institutions, higher educational establishments in the sphere of law and medicine, post-graduate institutions, practicing physicians and attorneys, as well as by law school graduates and LLM students.

The main contributors to the Workshop were: **Adv. Oren Asman** (Israel), member of the WAML Executive Committee and the Board of Governors, who initiated

the WAML endorsement of the event; **Dr. Eduardo Dantas** (Brazil), the WAML Vice-President; **Dr. Radmyla Hrevtsova** (Ukraine), a member of the WAML Council of Presidents, President of the Ukrainian Medical and Legal Association; **Prof. Anatoly Morozov** (Ukraine), deputy Director of the State Pharmacological Centre of the Ukrainian Ministry of Health; **Dr. Mohammed Wattad** (Israel), the WAML member, Chief Editor of the International Journal "Medicine and Law".

Adv. Oren Asman covered the general concept of informed consent and its role in protecting human rights in health care. Dr. Mohammed Wattad pointed out that improper supply of information to patients often turns informed consent into a fiction that violates patients' rights. Adv. Radmyla Hrevtsova outlined key issues related to informed consent thus initiating the discussion. Among others issues, the discussion included: the scope and character of information to be provided to a patient; the form of informed consent; fixation on the fact of supplying information to a patient and of the patient's consent provided on the basis of such information; and obtaining

informed consent in case of an extension of medical treatment. Dr. Eduardo Dantas and Adv. Oren Asman spoke about approaches to legal regulation of informed consent existing in Brazil, Israel and other countries. Prof. Anatoly Morozov shared his opinion as to how such approaches are viewed by clinicians. According to him, the value of informed consent for a patient and a doctor largely depends on the emotional maturity of the doctor and his or her ability to make information understandable to the patient.

The Workshop participants became involved in the discussion that appeared to be very lively and productive.

Informed consent, or to be more precise, the argument against the way it is often received and established, became the major topic of the two more public lectures of **Dr. Mohammed Wattad** –one organized by the National Medical University named after O.O.Bohomolets in collaboration with the Institute of Medical Law, Pharmaceutical Law and Bioethics at the Academy of Advocacy of Ukraine, and that delivered by him at the National University “Kyiv-Mohyla Law Academy”,

both on September 23, 2010. They were followed by questions and discussion in the course of which Dr. Eduardo Dantas and Adv. Oren Asman expressed their views on informed consent.

September 23, 2010, appeared to be full of medico-legal events. **Adv. Oren Asman** and **Dr. Mohammed Wattad** contributed to the **Round Table “Ethical and Legal Issues of the Use of Assisted Reproductive Technologies: Experience of Different Countries”** conducted by the Institute of Medical Law, Pharmaceutical Law and Bioethics at the Academy of Advocacy of Ukraine. The guest speaker there was **Prof. Fedir Dakhno** who is known as the doctor who provided medical assistance at the first birth a child of in vitro fertilization in Ukraine and received vast experience in that sphere. Naturally, his views on legal and ethical problems related to the use of reproductive technologies proved to be extremely interesting. The thoughts expressed in the speeches of advocates Oren Asman and Mohammed Wattad were no less interesting. Assisted reproduction in Israel is practiced on a very high level but some

technologies are not used for religious and ethical reasons. That allowed Israeli lawyers to raise a number of burning ethical issues. They were supported by **Dr. Zoryana Chernenko**, the Chairperson of the Board of the Ukrainian Medical and Legal Association, who shared the concerns that Ukrainian lawyers had in connection with some of the reproductive technologies.

In a continuation of the educational activities, on September 24, 2010, **Adv. Oren Asman**, lecturer at Haifa University and Zefat Law School and a member of the Management Board of the International Centre for Health, Law and Ethics, delivered a public lecture at the National Medical University named after O. Bohomolets. The lecture was devoted to ethical decision-making in health care. It was attended by medical school graduates, doctors, and academics who were greatly impressed by the presentation. The lecture was followed by a discussion. Dr. Eduardo Dantas was among its participants.

The public lecture of **Dr. Eduardo Dantas**, visiting professor of a number of universities, President of APEDIMES, was the next one in the series of lectures of for-

foreign experts on medical law. It took place on September 24, 2010, at the Academy of Advocacy of Ukraine. Dr. Dantas spoke about the interrelation between medical law and bioethics, providing interesting examples from his own legal practice, which attracted everybody's close attention. The lecture was followed by a discussion of cases in which Adv. Oren Asman and Dr. Radmyla Hrevtsova participated.

Ukrainian specialists and graduate students enjoyed a unique opportunity to listen to the leading foreign experts on medical law who came to Kyiv to participate in a number of events in which their contribution was greatly appreciated. Educational initiatives in that area are being continued in Ukraine with the active participation of international institutions and foreign experts.

Dr. Radmyla Hrevtsova
Adv. Radmyla Hrevtsova,
JD. PhD,
Director of the Institute of Medical Law, Pharmaceutical Law and Bioethics at the Academy of Advocacy of Ukraine, and President of the Ukrainian Medical and Legal Association

When Consent Is Not Enough: The Construction and Development of the Modern Concept of Autonomy



Eduardo Dantas
WAML Vice-President

Since the end of World War II, the bio-ethical concept of patient autonomy has gained importance, shifting the centuries-old balance in the paternalistic relationship between physicians and their patients. Case law stating the importance of consent can be found in Anglo-Saxon jurisprudence since the late years of the 18th Century but it was only after the Nuremberg trials, and moreover, the Tuskegee's experiments, that informed consent became one of the pillars of modern medicine, and almost the Holy Grail of medical ethics.

Very often, tough physicians and health care providers misunderstand the concept of the so-called *informed consent*. The right to be informed has nothing, or very little, to do with the true exercise of the patient's autonomy. The act of consenting

to some treatment, research, experiment or surgical procedure is just part of a bigger process, where the patient can exercise his/her autonomy. Someone can consent, based on trust in the doctor, based on indifference, fear, or even *because* he/she did not receive all the necessary information to really *choose* among different possible options.

We have been stressing the importance of consent – and consent forms – over the past years, forgetting that there are more important situations to be dealt with, arising from the relationship in question. Let us take as an example, article 5 of the European Convention on Human Rights and Biomedicine (the Oviedo Convention). All attention is drawn to the first part of the text, which says that “*an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it*”. The key to understanding the true spirit of the law lies in the second part of the article, which states that “*this person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks*”.

Appropriate infor-

mation seems to be the main element concerning a patient's autonomy rights. The information, to be “appropriate”, does NOT need to meet the doctor's assessment of the situation, but the patient's. All relevant data, alternatives (even those the physician thinks are not appropriate to the case, based on his/her experience) and risks must be disclosed to the patient, in an understandable way, in order to provide sufficient elements for a decision – a choice – to be made. This – and not the act of consenting – is the real exercise of autonomy. These exact same ideas are expounded in article 11 of the Interamerican Convention of Human Rights (1969).

In the U.S., the Patient *Self-determination Act* regulates the idea of the right to information as a basic requirement, the right to informed consent being just a part of the process, not its final goal. A consent form, signed by the patient, is not a safeguard from lawsuits. It is an important document but cannot be seen as the only thing that matters in defensive medicine. Examples of legal documents could go on and on from all over the world, showing that there is a new way of dealing with old dilemmas, and that health

care providers have to adapt their concepts to the new ideas. The world has evolved and that requires adaptation.

A patient does not need to consent to a proposed treatment. This may come as a shock to many doctors, as they are trained to “fight” diseases, and save lives, no matter what. What they are not taught in medical schools is the fact that their main obligation – apart from acting with the best of their techniques and skills – is that they must provide information to the patient. The patient will decide, based on his/her personal life, values, morals and beliefs, which is the best option. Only then can autonomy be respected and enforced.

Health care providers tend to think that the sanctity of life is the most important guarantee and the most important fundamental right in modern constitutions in the western world. It is *not*. Legislators – and philosophers – all over the world are beginning to understand *Human Dignity* as a fundamental principle. Dying with dignity – choosing not to undergo painful treatments to prolong life beyond cure; choosing to withdraw useless treatment, to leave the hospital and die at home, surrounded by family and

friends instead of doctors, nurses and beeping machines; and even refusing treatments that would intrude deeply against a patient's religious beliefs – is part of living with dignity. This is a fundamental right that must be enforced.

The physician's obligation is to help the patient to choose what is best for him/her, providing complete and adequate information. Is the doctor more prepared to understand the technical consequences of each choice? Undoubtedly, yes, but the patient has the final word, which cannot be compromised by the physician's personal opinions. Otherwise, we are back to Tuskegee and Nuremberg.

These words may sound to some as praise for suicide. They are not. They are a vivid defense of autonomy, of the right to choice; a defense of the idea that responsibility for one's own acts has to walk side by side with rights. Therefore, we need to stop discussing excessively about informed *consent* and start focusing on informed *choice*. We are accustomed to talking and reading about patients' rights and medical liability but it is time to start thinking about shared responsibilities, to start thinking about patients' duties, since they are

granted the power of actually choosing how their life and treatment must be conducted. With great power, comes great responsibility.

Eduardo Dantas
Lawyer, MPhil. in Medical Law by the University of Glasgow. Vice-President of the World Association for Medical Law.

2012 Congress Brief Report

Following our efforts to deliver a big event in 2012, and also, an opportunity to gather medical law researchers from all corners of the planet, the organizing committee is proud to announce that the 19th World Congress on Medical Law will have the support and active participation of our colleagues from the Latin American Medical Law Association.

With that, we expect to have a larger amount of countries represented during the conferences, adding their views and experiences to the knowledge exchange, contributing thus to a better and stronger scientific and academic development for bioethics, legal medicine and medical law.

During the first months of next semester, information on main themes, abstract submission, and pre-registration

prices will be available at the congress' website (www.2012wcml.com) and will also be sent to our registered mailing list. We would like to invite all WAML members to join us in the preparation for the congress. All suggestions, ideas and propositions are welcome.

Eduardo Dantas
Vice-President of WAML
2012 Congress President.

August
9-13
2012

WAML Brazil



FUTURE MEETINGS

A Focus On The Experience of Countries

3rd International Congress on Medical Law with a Special Focus on Patients' Rights

February 22 – 24, 2011

Kish Convention Center in Islamic Republic of Iran

Contacts: Mahmoud Abbasi, Ph.D.

Congress Director

Director of the Iranian Association of Medical Law

Chief of the Iranian Research Center for Ethics and Law in Medicine

Email: congress@iranmedicallaw.com

Website: www.iranmedicallaw.com

2011 ACLM Annual Meeting Medicine and Law for Health care Professionals

February 24 – 27, 2011

Planet Hollywood Resort & Casino, Las Vegas, Nevada

Contact: Sue O'Sullivan

Website: www.aclm.org

Vth All-Ukrainian (IVth International) Research and Practice Conference in Medical Law: "Medical Law of Ukraine: Legislative Provision in the Sphere of Health Care (Genesis, International Standards, Development and Improvement Trends)"

May 19 – 21, 2011 in Odessa, Ukraine

Contact: Iryna Senyuta prlawlab@ukr.net

Chairman of Organizing Committee, President ANO "Foundation of
Medical Law and Bioethic of Ukraine"

Website: www.medicallaw.org.ua

International Association of Forensic Sciences September 12 – 17, 2011

Madeira, Portugal

Contact: Duarte Nuno Vieira

Email: dnvieira@inml.mj.pt

Website: www.iafs2011.mj.pt

Health Care Rationing Conference

December 9 – 10, 2010

Rotterdam, The Netherlands

Contact: Roos van Bommel

Website: www.erasmusobservatoryonhealthlaw.nl

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