PARLIAMENT OF NEW SOUTH WALES

REPORT OF THE COMMITTEE ON THE HEALTH CARE COMPLAINTS COMMISSION

World Congress on Medical Law
and
Study of International Jurisdictions
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FUNCTIONS OF THE COMMITTEE

The Committee on the Health Care Complaints Commission was appointed in 1993. Its functions under Section 65 of the *Health Care Complaints Act 1993* are:

a. to monitor and to review the exercise by the Commission of the Commission's functions under this or any other Act;

b. to report to both Houses of Parliament, with such comments as it thinks fit, on any matter appertaining to the Commission or connected with the exercise of the Commission's functions to which, in the opinion of the Joint Committee, the attention of Parliament should be directed;

c. to examine each annual and other report made by the Commission, and presented to Parliament, under this or any other Act and to report to both Houses of Parliament on any matter appearing in, or arising out of, any such report;

d. to report to both Houses of Parliament any change that the Joint Committee considers desirable to the functions, structures and procedures of the Commission;

e. to inquire into any question in connection with the Joint Committee's functions which is referred to it by both Houses of Parliament, and to report to both Houses on that question.

The Committee is not authorised:

a. to re-investigate a particular complaint; or

b. to reconsider a decision to investigate, not to investigate or to discontinue investigation of a particular complaint; or

c. to reconsider the findings, recommendations, determinations or other decisions of the Commission, or of any other person, in relation to a particular investigation or complaint.

COMMITTEE MEMBERSHIP

Legislative Assembly

Mr Jeff Hunter MP - Chairman
Ms Marie Andrews MP – Vice-Chairman
Mr Wayne D Smith MP
Mr Peter W Webb MP

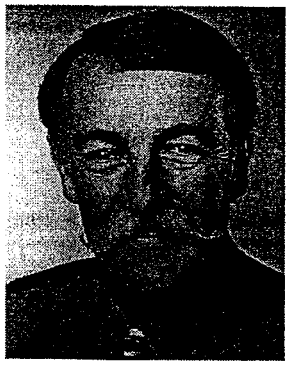
Mr Jeff Hunter MP
Chairman

Ms Marie Andrews MP
Vice-Chairman

Legislative Council

The Hon Dr Brian Pezzutti RFD, MLC
The Hon Henry Tsang OAM, MLC
The Hon Dr Peter Wong AM, MLC

Mr Wayne D Smith MP



Mr Peter W Webb MP

The Hon Dr Brian Pezzutti
RFD, MLC

The Hon Henry Tsang
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The Hon Dr Peter Wong
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Hon Dr Peter Wong AM, MLC
Ms Catherine Watson (Committee Manager)

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Singapore Medical Council
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Professor Lee Hin Peng, Council Member, Complaints Panel
Dr Bandara, Executive Secretary, Complaints Panel
Ms Tan Hui Cheng, Administrative Manager

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Mr Mab Kim Yong, MP, Deputy Chairperson
Mr A Palaniappan, Secretariat

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Mr Michael Wood, Deputy High Commissioner

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Mr Michael A Feafield, Chairman, Epsilon Systems Ltd

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Ms Soren Mattke

Australian Embassy
Ms Elizabeth Ambrose

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Dr Hon Law Chi-kwong, Member
Ms Cyd Ho Sau Lan, Member

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Dr Lee Kin Hung, Chairman
Dr David Fang
Dr Alexander Wong
Mr Raymond Chiu
Dr Robert Law
Dr Louis Shin

Hong Kong Department of Health
Dr Wong Man-ha, Monica, Principal Medical and Health Officer
Dr Constance Chan, Assistant Director
Dr Amy P Y Chiu

CHAIRMAN'S FOREWORD

This study trip was conducted to research particular aspects of investigations and prosecutions procedures in other jurisdictions, to inform the Committee's current Inquiry.

The World Congress on Medical Law provided the study delegation with a timely and concentrated opportunity to hear first-hand the work of top international researchers and practitioners on the latest advances in health care complaints systems; disclosure and privacy issues; transparency of processes; continuous improvement of health care complaints systems; the complex and necessary nexus between medicine and law in relation to prosecution processes; patient rights and responsibilities; and, analysis of reform processes in certain countries.

The study delegation also had the opportunity to examine work being undertaken in other international jurisdictions to improve safety for health care consumers and to advance the accountability and transparency of health care complaints processes and disciplinary actions against transgressing practitioners.

In the light of concerns about the need for procedural fairness, the study delegation was particularly pleased to examine the way in which legal training for medical and lay members of disciplinary committees in jurisdictions such as Singapore, Hong Kong and the United Kingdom.

The strategic use of medical expertise/advice by investigating bodies is another area of interest in the current Inquiry, which the delegation was able to look into.

In the United Kingdom, the motivation for reform of the General Medical Council and the lessons that organisation has learned and applied through the process proved to be of great benefit to the delegation. Analysis of the GMC reform process was also a topic of discussion at the World Congress on Medical Law.

The study delegation is confident that the outcomes of the trip can be successfully incorporated into case study examples and good practice for its forthcoming report on the Inquiry into Procedures Followed During Investigations and Prosecutions Undertaken by the Health Care Complaints Commission.

Jeff Hunter MP
Chairman

1 August 02:

Singapore Ministry of Health
Mr Ong Chun Kiat,
Assistant Director, Strategic Planning

The Ministry of Health regulates Singapore's health system. Its powers lie in control over hospitals and other medical establishments. These powers are contained in the *Private Hospitals and Medical Clinics Act* (PHMCA).

The Ministry of Health oversees the licensing, quality and appropriateness of services provided and the practices and procedures employed. It maintains a complaints system for these establishments.

Singapore's health system has dual components to its delivery.

The public system is managed by the government, providing 80% of the hospital care and 20% of the primary care through polyclinics, while the private system delivers 80% of the primary care through medical practitioners and 20% of the hospital sector.

Singaporeans are able to obtain treatment through either the private or public sectors. There are 11,798 hospital beds in 26 hospitals and specialty centres in Singapore. There are 5,154 doctors registered to practise in Singapore; 942 dentists (a ratio of 1 to 4,130) and 15, 947 nurses (a ratio of 1 to 244).

Healthcare in Singapore is financed through a combination of taxes, employee benefits and compulsory savings in the form of Medisave, insurance and out of pocket payment. In 2000, the government's recurrent health expenditure was $2.2 billion, or about 1.4% of GDP.

The financing philosophy of Singapore's health care system is based on individual responsibility and community support, ie patients sharing payment for their medical expenses with government subsidies helping to keep basic health care affordable, particularly for the poor.

Medisave was introduced in 1994 as a national medical savings scheme. Every individual sets aside 6-8 per cent of their monthly income into a personal Medisave account, from which they may withdraw to pay for hospitalisation expenses incurred by themselves or their family. It is a compulsory savings scheme.

Medifund is a low-cost catastrophic illness insurance scheme. It helps members meet the costs of prolonged or major illnesses, which their Medisave balance would not be sufficient to cover.

Singapore Medical Council

Professor Raj Manbair, Chairman, Complaints Panel
Professor Lee Hin Peng, Council Member, Complaints Panel
Dr Bandara, Executive Secretary, Complaints Panel
Ms Tan Hui Cheng, Administrative Manager

The Singapore Medical Council is responsible for the registration and conduct of practitioners under the *Medical Registration Act* (MRA).

The disciplinary procedures comprise two stages: a review by the Complaints Committee (CC); which may be followed by a formal inquiry by the Disciplinary Committee (DC).

A statutory declaration is required for complaints.

The Complaints Committee comprises: the Chairman of the Medical Council, a member of the Medical Council, one medical practitioner and a lay person. The Complaints Committee can only investigate the subject of the initial complaint.

If there is no formal inquiry necessary, the Committee may dismiss the complaint, provide a letter of advice or a letter of warning.

All hospitals have patient representatives.

The Disciplinary Committee includes three Medical Council members and a lay person. The standard of proof is 'proof beyond reasonable doubt'. Appeals are handled by the Supreme Court.

Appeals may be made only on a point of law.

The Training for Committee members involves regular sessions, prior to and after appointment. A legal assessor sits in on sessions to advise (similar to the Professional Services Review in Australia, but unlike to NSW Medical Board's PSCs).

The delegation discussed the concern that the Singapore health system has also been the victim of the insurance crisis that has struck Australia.

Many of the practitioners in the Singapore Health Scheme were insured with UMP at its Sydney office.

Following concerns raised about UMP during the first half of the year, the Singapore Medical Association initiated discussions with two insurance groups – the Medical Protection Society and NTUC Income Pty Ltd.

When NTUC was putting together an insurance package, it found that no re-insurer would provide cover for an 'occurrence-based' type of scheme. It provides only a 'claims made' insurance policy.

NTUC is providing an insurance policy for cover limited to $5m per year.

The Singapore Medical Association's June 2002 newsletter indicates that this is considered "good enough for Singapore, since claims beyond $1m have not yet been awarded".

UMP insured about 50% of Singapore's doctors.

2 August 02:

Singapore Parliament

Dr Lily Neo, MP, Chairperson, Parliamentary Health Committee
Mr Mab Kim Yong, MP, Deputy Chairperson
Mr A Palaniappan, Secretariat

The Singapore Parliament is modelled after the Westminster system, where Members of Parliament are voted in at regular General Elections.

There are nine doctors in the Singapore Parliament, out of a total of 85 Members of Parliament.

The Parliamentary Health Committee is briefed on health-related legislation before Parliament, and may speak to it. There are eight members on the Committee.

The delegation discussed the matter of the current insurance crisis for medical practitioners. The Singapore Parliament estimates that up to 50% of Singapore's doctors were insured with United Medical Protection. The government has offered no response to the situation – doctors are having to take on other insurance.

To date, only one other English insurer has been available, and is offering premiums which are approximately double what doctors were paying previously.

The Committee noted that it is anticipating forthcoming legislation relating to organ transplants, a program which the government wants to expand. They explained that in Singapore, individuals must opt out of organ donation rather than opting for it.

Dr Neo indicated that the Singapore Parliamentary Health Committee would like to maintain ongoing contact with the New South Wales Parliament Health Care Complaints Committee with the view for continual exchange of health-related information.

5 August 02:

General Medical Council, United Kingdom

Ms Isabel Nisbet, Director, Policy

The General Medical Council (GMC) is an organisation which was severely criticised in the Bristol Inquiry, for failing to take action when notified of concerns within that hospital. After extensive work by the GMC and others, a consultative paper was prepared and released by the Department of Health. Under the title of *Reform of the General Medical Council*, the 60 page paper has a deadline for submissions of 2 September 2002.

Ms Nisbet indicated that the main elements of the reforms will be:

1. The Council will be smaller. Currently there are 104 members, this will be reduced to 35, 14 of whom will be lay members and 21 doctors. The vast majority of Council members will be appointed. The GMC considers that the numbers of members on the Council is a compromise figure

2. Every five years, doctors must undergo revalidation to demonstrate their fitness to practice. Once the legislation is passed, the GMC will write to every doctor telling them what is required. Two years after that, the first reevaluation will occur. National Health Scheme appraisal will suffice, so doctors are happy with the scheme in general. The process will be broad, including feedback from an audit, peer or patient questionnaires and continuing professional education. It is a huge operational undertaking, as some 200,000 doctors are involved. The GMC is introducing a license to practice which must be revalidated, so that retired doctors can remain on the register but not necessarily achieve a license to practice. In the UK, only Universities can take away the title of 'Doctor', not the GMC.

3. The new Fitness to Practice system replaces the old process of bringing charges against doctors regarding their fitness to practice. Revalidation groups throughout the country will send recommendations to the GMC. If a problem is identified, the GMC would look at the doctor's fitness to practice. The whole issue of revalidation is being piloted exhaustively. There are now two stages, investigation and adjudication, instead of three. The new process has done away with screening, and preliminary committees – these are now combined into investigation.

The GMC looked at various models for this process. The European Human Rights Commission, for example, says that everyone has the right to a fair hearing in public, with an independent judiciary. Investigations will remain core to the GMC, but adjudication will be handled separately. No one from the Medical Investigation Council can serve on any investigatory panels. All adjudicators will be non-Medical Council members.

Reducing the size of the GMC means that many experienced ex-members will be available for this role.

the government is strongly committed to an inter-professional agenda – for example, there is a push for nurses to do some of the work undertaken now by doctors. A new Council, the Council for the Oversight of Health Care Regulators will be set up to oversee the regulations, encouraging consistency and good practice.

There is a perception of professional elitism on the part of doctors versus other health professionals.

The quorum on disciplinary panels will be reduced from five to three. There had previously been significant numbers of lay people appointed to panels, and these panel decisions had been the subject of appeals – particularly where there had been a lay majority on the panel.

Members of the panels go through relevant training, such as cultural awareness training. Cultural awareness training was introduced because the Policies Studies Institute conducted some research looking at why there was a disproportion of foreign doctors in the Fitness to Practice program. The numbers of complaints were roughly the same, but NHS employers accounted for about 40% of the overseas qualified. The GMC is also more likely to dismiss cases relating to local doctors. Cultural issues, such as apologising, are relevant. Local doctors seem to get off easier, even though foreign doctors are not unfairly treated.

Disciplinary panel members receive legal assessors' advice on the law. The British Medical Association pushed for legally qualified chairs for a while, but have backed of on this, recently. The GMC has suggested that legally qualified chairs would be useful in some circumstances, particularly where the case is very complicated.

There are around 20 overseas doctors and lay people on the Council at the moment. It is felt that overseas doctors have a strong lobby group.

The GMC is looking at the possibility of having a lower, PSC-type hearing, which can issue a warning, which will be disclosed to future employers and be included in future revalidation. It is often considered unfair to doctors that they appear before the GMC, as bigger NHS trusts would have dealt with the matter themselves. So complainant referrals to the GMC tend to come from smaller trusts and from the public. So it is considered to be the 'luck of the draw' really, as to whether a doctor ends up before the GMC.

Appeals have now been changed to be on any ground, and there are no leave requirements. Human rights requirements mean that appeals must be considered on merit. These are now going to the High Court, not the Privy Council.

The GMC notes that a 'draft orders' device is being used to amend the Medical Act. Summer 2003 is the target date for the establishment of the new Board, if the legislation goes through.

6 August 02:

National Patient Safety Agency, United Kingdom

Mr Julian Brooks, Head, Clinical Quality
Dr John Sharks, Director, Clinical Programs
Mr Kevin Hall, CEO
Ms Helen Glenister, Director of Modernisation

Following the adverse criticism from the Bristol Inquiry and others, the Department of Health issued a report *Building a Safer NHS for Patients.*

This report called for the establishment of definitions of adverse events and near misses for the purposes of logging and reporting them in a standard format, within the NHS. The establishment of the National Patient Safety Agency was central to this process.

The NPSA is a Special Health Authority, created in July 2001 to coordinate the efforts of the entire country to report, and more importantly, to learn from adverse events occurring in the NHS.

As well as making sure events are reported in the first place, the NPSA is trying to promote an open and fair culture in hospitals, encouraging doctors to report incidents without fear of personal reprimand.

It will then collect reports from throughout the country and initiate preventative measures, so the whole country can learn from each case, and patient safety thus improve.

The NPSA sees its role as promoting quality by focusing on the patient experience in the health system. It also works with NICE, the National Clinical Assessment Authority, CHAI, the National Care Standards Committee for individual nursing homes and professional bodies.

Following the establishment of the Agency, most of the staff have come on board in the last 6 months. The Agency has developed a focus on reporting and learning systems and solutions.

Training is a very big element of the Agency's role, and influencing undergraduate commitment is one part of this, in terms of promoting risk awareness.

The Agency has responded to 27,000 incidents from 28 NHS trusts in 7 months. It attributes the fact that it will deal with anonymous complaints for the significant reporting-rate.

The Agency is piloting solutions with a few other agencies. These include adverse events involving medical devices, and there has been dialogue with agencies within the NHS – Medical Devices Agency, Purchasing, Building and Supply, etc, as well as international learning opportunities.

The Agency has established external reference groups to be a test-bed for solutions. These include a 'Hand Hygiene Project'; a project on Infusion Pumps, which was started with the assistance of MDA, which has most of the information on incidents; a project on alternatives to latex; barcoding; and the standardisation of emergency numbers in hospitals.

The labelling of drugs is considered to be a real problem, as many labels appear similar, for example, there were deaths reported in Canada from Potassium Chloride overdose.

Following a June 2002 conference, action on the labelling of drugs has been fast-tracked. The target is to reduce by 80% the incidence of overdoses by June 2003.

This was an area already identified by the Chief Pharmacist – and some easy solutions had already been identified, such as labelling KCl with a big red "K' rather than leaving it to the manufacturers to label.

It was noted that the US has already addressed this problem.

The Emergency Care Research Institute, an international organisation for risk assessment, established in 1955, has been working with the Agency on this project. It proposed scrapping all paper-based forms, and collecting all data electronically.

National Clinical Assessment Authority, United Kingdom

Mr Alister Scotland

The National Clinical Assessment Authority is a Special Health Authority, set up as one of the central elements of the NHS' modernisation plans to ensure the high quality of health care.

The Authority's aim is to provide a support service to the NHS when concerns over the performance of an individual doctor are raised.

The NCAA will take referrals from doctors' employers – NHS Health Authorities, Hospital Trusts, Primary Care Groups and NHS Trusts.

The NCAA will not take over the role of an employer, nor will it function as a regulator. Rather, it will help the employer or health authority by carrying out an objective assessment.

Following such an assessment, it will advise the referring organisation on appropriate courses of action. This way, it is suggested, problems may be more effectively and speedily addressed.

The Commission for Health Improvement, the General Medical Council and the National Clinical Assessment Authority have agreed guidelines, setting out the roles and responsibilities of each body.

The CHI, GMC and NCAA have each signed a Memorandum of Understanding that sets out the position of each and the ways they expect to work together.

It does not place additional responsibilities on the organisations, or imply any transfer of responsibility from one to the other or sharing of statutory responsibilities.

The Memorandum makes clear:

- how the organisations will communicate while they are investigating a case that overlaps between their different remits
- how they will collaborate to develop new ways of working
- how they will regularly update each other on their progress.

7 August 02:

Health Services Commissioner, United Kingdom

Ms Hilary Scott, Deputy Commissioner

The Deputy Commissioner indicated that they have a 'posse' of full-time and part-time medical advisers working for the Health Services Commission. The Medical Director is Professor Seymour – he is the Director for Clinical Advice.

There is also a full-time clinical nurse, and specialists in Obstetrics and Gynaecology, Anaesthesia, etc. There are many specialists, working at least 3 days per week.

The HSC receives around 3,000 complaints per year. Most of these are out of their jurisdiction, as they must first go to the NHS under the terms of the legislation. Around 900 complaints are considered annually by the HSC, and around 25% of these are investigated.

There are around 50 investigators for England. When a case is investigated, the HSC always appoints external clinical assessors, matched for the discipline and practice. These assessors are always present for interviews.

The HSC considers that certain peer reviewers are just not good enough, and need to be weeded out.

'Screening' is largely done on paper and investigations are largely done face to face. At the beginning of each investigation, there is a case conference in which investigators come together to determine who they should interview. Medical experts usually attend this case conference.

The Commission believes this has 'captured' the confidence of the profession by having such medical input.

When appointing medical advisers, the Commission provides an outline of the case and all relevant notes.

The medical adviser is invited to the case conference. There are usually two assessors on each case. They are provided with a template as to how they should comment on the case, what they did, what they looked at, etc.

This helps them to logically structure their opinions, without guiding them.

The Commission notes that sometimes this does not work, as the expert goes 'off on their own hobby horse', but this is difficult to control.

The Commission is hoping to get the Royal College to accredit training for expert opinions.

On conciliation, the Commission believes that the NHS is getting better, however the Independent Review Panels could be improved.

The Commission meets with the professions once a year as a group. It publishes a lot of material. Reports of external assessors are published on the website. The Commission publishes the names of all clinical advisors and their qualifications in the annual report.

There are 18,000 peer reviewers on the list – or more particularly on the NHS list, which are eventually posted on the website.

The Commission does not send a draft report to the complainant, but will advise the complainant if it is considered a defamation issue.

The Commission believes it has a very different system from the HCCC, because they are not really dealing with the matter of doctors' registration.

Under the Public Service Scheme, the Commission cannot employ people beyond their 60th year, although this restriction will change. The NHS pension is a very good pension scheme, so it is highly prized.

However, it is hard to find doctors willing to be peer reviewers unless they are close to retirement. Peer reviewer nurses are not so difficult to obtain.

Currently, the list of external assessors is not broken down by gender or cultural information, but this will be available in the future.

Cultural awareness training is given to staff because of the realisation that due to cultural differences, you may mistake the intent of a response provided to you.

Scotland is about to introduce a 'Public Sector Ombudsman' – with responsibility for core service departments, including health and housing.

8 August 02:

Trade and Investment Office (New South Wales Government), London

Ms Leanne Grogan, Director, New South Wales Government Trade and Investment Office and
Mr Mark ϕberg-Brown, Fellow, Department of Paediatrics and Child Health, Royal Free and University College Medical School; Managing Director of Epsilon Systems
Mr Michael A Feafield, Chairman, Epsilon Systems Ltd

Epsilon is aiming to convert patient records for the College to electronic format by 2005.

While many other companies are working on systems, Epsilon has a system which encodes and encrypts data, which are then authenticated with a full audit.

It is designed to deliver on good practice and malpractice issues. Good audit control mechanisms are required, to ensure that data cannot be altered.

Epsilon has loaded up data from 35,000 children in North London.

The company is liaising with the Department of Health and the NHS Executive. It is working towards having this data base accepted as 'evidence at law', largely because of the rigid audit trail and the inability to alter records at all.

There are a lot of electronic patient record-keeping systems in existence, and there is a need to transfer all these records into a core database.

Epsilon is looking at distributed databases throughout the country, rather than one. The record will start at 8 weeks gestation, but can be applied to any system.

Epsilon uses a fingerprint to gain access to the system, so it cannot be accessed by doctors. Patients with significant conditions could allow their records to be accessed by, for example, paramedics.

The timetable for completion of a pilot is August 2002, then it is hoped to expand the use of the system to other Trusts.

9 August 02:

Organisation for Economic Cooperation and Development, Paris

Mr Jeremy Hurst, Principal Administrator and Ms Soren Mattke, OECD Health Policy Unit

The OECD emerged out of the Marshall Plan after World War 2. The OECD Health Policy Unit is examining the quality of clinical care in 30 industrialised nations. It is largely an advisory body. Australia is one of the OECD's most enthusiastic members.

That said, the OECD has not traditionally had a big interest in health issues. It has had more of a focus on economic trade and development. This has led to an interest in the welfare state as it underpins labour markets.

The focus on health issues by the OECD has begun in the last 5 years. Health care systems have been a large part of economies. So, while the World Health Organisation has had the primary role in the international field, the OECD is focusing on health data, statistics and economic aspects of health.

The Australian Institute of Health and Welfare puts out a very good comparative health statistics document which inspired the OECD's *Health at a Glance* document.

The Health Policy Unit representatives commented that it is one thing to measure performance, but queried how to change it for the better.

For this to occur, uniformity of measurement is needed. Hence, the Policy Unit is undertaking projects focusing on human resources in health care. They are examining how countries plan the right numbers of health care professionals for their system. To this end, the Unit is also looking at issues of staff motivation.

Another project, to take from 9 months to 2 years, is examining waiting lists and waiting times. It is investigating causes and is describing the evaluation of policies to tackle the problem.

New Zealand is leading the world in the management of waiting lists, where every patient is booked in within 6 months, or sent back to their GP, therefore promoting honesty in the process.

Spain has driven down waiting times by making hospitals more productive, and making better use of the greater numbers of doctors in Spain.

There are three components to the process: budget, productivity of resources; and a system designed in such a way that there is either a disincentive or an incentive to cut waiting lists.

The Unit is also looking at the use of health technology and private projects. It has just finalised one such project in South Korea (described on the OECD website).

France has a social health insurance, which is taken out of tax, and it has supplementary private health insurance to cover co-payments.

One project the Unit is undertaking is to develop a set of indicators to measure the quality of health care. At the moment, it is not possible to measure which countries are the most effective in terms of cost-effectiveness.

Life expectancy does not seem to be a good indicator – this merely goes up as the country gets richer. There is a need to focus upon the prognosis after major illnesses – that is, on outcomes after a major health problem diagnosis.

The Unit hopes to get the first set agreed upon and published in January 2003.

The second part of the project will involve clinical care quality monitoring and improvement, with a balance of professional regulation, government oversight and consumer advocacy.

This second stage will try to cover the realm of OECD countries.

There is an emerging vision on how health care systems should be run. Clearly micro-management should be left in the hands of the profession.

However, there should be a better framework in which doctors and other health professionals operate.

16 August 02:

Panel of Health Services, Legislative Council Health Committee, Hong Kong

Dr Hon Lo Wing-lok, Deputy Chairman
Dr Hon Law Chi-kwong, Member
Ms Cyd Ho Sau Lan, Member

The Hong Kong Legislative Council members noted that there has been only little progress on health reform. The members indicated that the Health Department would prefer to initiate an independent Commission.

However, the Government is not convinced that a complaints body should be independent. The medical system is complicated and there is a need for an agency that can assist the complainant as to where the complaint can be directed. However, the members indicated that the Government believed this should be undertaken by the Health Department, not by an independent commission.

The Government has the recommendation of the Health Committee under consideration (see Legislative Council Paper CB(2), March 02).

The Legislative Council members noted that neither the Ombudsman, Privacy Commissioner or Equal Opportunity Commissioner are, in their view, truly independent, as they are civil servants, so it is not promising that a health complaints body will be truly independent.

The professions are very concerned about an independent body. Only two universities in Hong Kong train doctors, so it is regarded as very much a close network.

Three of the eleven Hong Kong Ministers are doctors.

The Medical Council has also put in proposals for legislative change. The Professional Performance Committee is one of the new initiatives.

A Panel of Assessors is appointed to assess a doctor's performance if they are found to be lacking in performance, but not guilty of professional misconduct.

The Medical Council has 28 members, 14 of whom are elected and 14 appointed – 4 of these are lay people.

The Legislative Council members expressed concern about the extent of legal expertise on the Medical Panel, as decisions are often overturned on appeal in the courts. Currently, the Medical Council is considering ways to ensure better training for its members in relation to legal issues.

19 August 02:

Medical Council of Hong Kong

Dr Lee Kin Hung, Chairman
Dr David Fang
Dr Alexander Wong
Mr Raymond Chiu
Dr Robert Law
Dr Louis Shin

The Medical Council includes 24 medical practitioners, and 4 lay members, nominated by the major universities, the Hospital Authority, the Director of Health, the Hong Kong Academy of Medicine and the Hong Kong Medical Association. A further seven practitioners are elected to their positions by all medical practitioners.

The Medical Council has over 9,000 registered medical practitioners. While a medical council has been established for Chinese Medicine, there are as yet no formal links between the two. Informal linkages are in place.

The Mission of the Hong Kong Medical Council is to protect patients and guide doctors by:

- promoting good practical medicine
- keeping a current register of qualified doctors
- promoting high standards of medical education; and
- taking action where a complaint is made about a doctor's professional conduct or fitness to practise.

In hearings before the Medical Council there are lawyers on both sides who lead doctors. The Medical Council considers that this limits their ability to ask questions and get to the bottom of things. The Medical Council is also concerned about the status of judges for the tribunal, in that their role may not be seen as sufficiently important.

All preliminary investigations are overseen by the Preliminary Investigation Committee. Preliminary investigations are paper-based, but a full investigation is conducted face to face.

The Medical Council currently has a proposal that non-medical Board members will sit on a panel with a judge. The Panel will include 4 doctors and 3 lay persons, one of which will have a judicial background. Currently only one lay member must be present. In a new proposal, a doctor may appeal a decision from the Professional Performance Committee (the equivalent of a PSC) to the full Medical Council, and still have the matter heard in camera.

The Legislative Council Health Panel has asked for an independent Health Complaints Panel, but no one can say exactly what that means.

Hong Kong Department of Health

Dr Wong Man-ha, Monica, Principal Medical and Health Officer
Dr Constance Chan, Assistant Director
Dr Amy P Y Chiu

The Hong Kong Department of Health is the Government's adviser, and responsible for the execution of healthcare policy, statutory functions, licensing, inspection and food and drug safety. It delivers community health through a combination of promotional, preventative, curative and rehabilitation services. It also works with the private sector and teaching institutions to deliver primary health care to the community.

In the past decade, considerable efforts have been made to improve the delivery of health care to the citizens of Hong Kong. These were spearheaded by the 1997 Harvard Report in which a team of economists, physicians, epidemiologists and public health specialists was commissioned to undertake a comprehensive assessment of the health system and to propose alternative options for the financing and delivery of health care.

Recommendations designed to modernise health care delivery in Hong Kong have been part of an ongoing consultation process following the publication of the Harvard Report.

The Department of Health serves a population of 6.7 million people. There are some 28,000 beds in 42 public hospitals (administered by the Hong Kong Hospital Authority), and a further 3,000 beds in 12 private hospitals. There are also 18 nursing homes (accounting for 1200 beds) and a further 700 beds in correctional institutions.

A new Minister for Health has been appointed in Hong Kong, The Department is in the process of registering traditional Chinese medicine in line with the Chinese system.

In China, Western Medicine, TCM and certain other indigenous medicines (such at Tibetan) are registered.

Hong Kong is proposing to bring in a "grandfathering' system instantly recognising those practitioners who have worked in the field for more than 15 years as well as demanding the Chinese standard of education for newer practitioners, who will be required to sit an exam before registration.

Hong Kong is to set the correct standards for all herbal medicines. This is a difficult process and will not be completed until at least 2007.

There is now regular collaboration between the Hong Kong Health Department and Beijing. China is trying to attract private investors into the hospital system. Consumers will have to pay for these themselves, but China does not have a completely free to the public health system anyway.

14TH WORLD CONGRESS ON MEDICAL LAW, MAASTRICHT, THE NETHERLANDS 11-15 AUGUST 2002

The following summaries indicate sessions attended by the study delegation as the most relevant to their fields of inquiry:

Disclosing Medical Errors using a systems approach: a quality improvement Partnership of Physicians and Patients

This session was presented by Bryan A Liang, MD, PhD, JD, University of Houston School of Law, University of Texas School of Medicine, Health Law and Policy Institute, Houston, Texas

The session focused on the capacity of systems-based approaches (from similarly complex industries) to help reduce patient injury and improve health care quality.. Dr Liang argues that the potential of this capacity is reduced by the 'shame and blame' model of error that persists within medicine and law.

He suggests that an environment of 'disclosure for disclosure's sake' has worked against the empowerment of patients and the improvement of system outcomes..

Dr Liang identifies the need for education that a delivery system is the appropriate focus of quality improvement – emphasising the team effort in patient outcomes, hence the encouragement of cooperation and continuous improvement and a focus on systems improvement, not individual punishment.

Disclosure, accountability and corrective actions should arise from the system, rather than the individual, although the individuals does not abdicate their individual roles within.

Dr Liang argues that error disclosure literature often focuses on patient rights, but suggests that with these rights come responsibilities to be informed and understand what they can do to maintain a safe delivery system.

To engage patients, their role must be clear to them at the outset of their care – with the objective of having patients more involved in their care and in being active partners in safety as well as a direct impact on the outcome of care.

Dr Liang indicates that current efforts toward error disclosure are irregular and idiosyncratic and "a poor means to learn from errors".

He argues for formalisation of the system, with clear procedures for error detection, analysis and discussion. This should involve an error investigation team conducting analysis and a system error disclosure team communicating simultaneously with the patient and/or their family.

The disclosure system should be part of the quality enhancement process. The role of an apology is important, although Dr Liang stresses that this should be issued in terms of system accountability: "We are sorry that this event has occurred to you". Mediation is also regarded as important.

Dr Liang indicated legal situations where error disclosure should not occur, including situations of known family abuse, potential psychological harm and police or other formal investigations..

He argues, however, that there is no need in general to shy away from disclosure as there is some evidence that disclosure helps to lower damage settlements and suits.

Prevention of Patient Injuries

This session was led by Mr Martti Mikkonen, Research and Development Manager for the Finnish Patient Insurance Centre.

The Finnish patient insurance scheme compensates patients for bodily injuries received in connection with health care and medical treatment.

Compensation is paid regardless of fault or negligence on the part of medical personnel. While investigations are undertaken, there is not a culture of 'looking for a culprit'.

The Patient Insurance Centre is involved in injury prevention in some significant ways.

By not being involved in the medical treatment process or in the disciplinary process, the Centre can provide:

- impartial collection of information in the claims handling process
- processing of data through surveys, compilation of statistics and research projects
- distribution of information for policy holders, health care personnel, consumers and the media

The Centre has a database that includes survey information and data from all of the stakeholders.

A Comparison of Japanese and US Strategies for Medical Error Reduction: The Tension Between 'Cultures of Safety" and Public Accountability

This session was introduced by Mr Robert B Leflar, School of Law, University of Arkansas

The US hospital accreditation process now requires hospitals to undertake thorough 'root cause analyses' of serious preventable adverse events affecting patient safety.

However, medical providers fear that if these analyses fall into the hands of plaintiff lawyers, providers will be held more easily liable for patients' injuries and deaths.

There is a concern that the legal system may therefore foster secrecy and silence, thus defeating quality improvement efforts.

The issue now being pursued in Washington and Tokyo is the proper design and implementation of systems for reporting medical error, balancing goals of safety and accountability.

Issues include peer review and other evidentiary privileges of civil law, the nature of administrative reporting requirements and patterns of information sharing and secrecy.

The paper concludes that accountability is given greater weight in the US than in Japan, and offers explanations for that finding.

Liability in Relation to the Use of Professional Medical Guidelines

This session was introduced by Mr Albert Vermaas, University Medical School, Utrecht, The Netherlands

The author noted concern about the misuse of guidelines intended to promote quality of care, to bring cases against physicians and hospitals.

A case study is the Anti-Thrombosis case, in which anti thrombosis guidelines indicate that every patient receiving a particular type of surgery is to receive an anti-thrombosis injection.

One plaintiff who did not receive an injection, but suffered thrombosis, brought a case in which an initial ruling decided that the plaintiff would have to prove with a reasonable degree of certainty that if the injection had been given, thrombosis could have been prevented.

On appeal, a higher court overturned that decision, and put the burden of proof upon the surgeon and the hospital.

he surgeon's concern that the particular guideline was obsolete was not considered by the court.

A standard of care is a professional and a legal condition. Guidelines, however, which are developed by healthcare workers themselves, to help improve quality of care, are not legal regulations.

A question arises if a guideline is considered not to be a standard of care. The author considers that it is necessary for drafters of guidelines to be evidence-based (ie providing evidence of clinical benefit).

They should also be valid, applicable, clear and recognisable.

Art or Science? Understanding Medicine and the Common Law

This session was conducted by John A Harrington, Jean Monet Fellow, European University Institute, Florence, Italy and Lecturer in Law, University of Warwick, England.

In this presentation, the author examined the relationship between law and medicine from a philosophical perspective. He considers the manner in which an ideal of medicine has been constructed out of an opposition between the art and science models of practice.

The author advances a view that 'judicial tenderness' towards medical defendants is the result of an 'implicit contact' between the medical profession and the Labour government which 'ceded control of health care resources to doctors in return for their participation in the National Health Service (NHS) from 1948 on.

The author suggests that it is important to examine historical evidence about the relationship between medicine and law from the construct of what doctors and lawyers say about what they do. His studies indicate that this reveals a largely shared set of self-understandings around a distinction between art and science.

The idea of medicine and law as a science rested on a view of knowledge developing incrementally through vigorous conflicts of opinion. Pluralism and the tolerance of pluralism were integral to this view of science. The author also contends that by elaborating on their ideology of an art-science distinction, doctors and lawyers bolster professional monopolies and reinforce class structures within society.

Reforming Medical Regulation in the United Kingdom

This paper was presented by Dr Gerard Panting, United Kingdom

The author commented upon the changes to the General Medical Council, in particular the Fitness to Practise procedures, which are affected by new regulations introduced in July 2000. These include:

1. The establishment of an Interim Orders Committee with powers to suspend a doctor's name from the Medical Register or impose conditions on the doctor's registration, pending final determination of the case via one of the Fitness to Practise Committees

2. An increase in the minimum period of erasure from the Medical Register from 10 months to 5 years, and requiring doctors to demonstrate their fitness to practise before restoration to the Register

3. A new requirement on the GMC to notify any employer and other users of a doctor's services when complaints have been admitted for investigation and a new power enabling the GMC to require disclosure of documentation relevant to their investigation

4. Cooption of non-GMC members to serve on the Council's Fitness to Practice Committees.

Other proposals include the introduction of periodic revalidation (5 years) for doctors to demonstrate their fitness to practise, radical reform of the Constitution of the GMC, with greater lay involvement and the introduction of a lesser charge of professional misconduct as part of a major restructure of the fitness o practise procedures.

The author indicated that problems with the proposed scheme include some timing issues in relation to NHS obligations for annual appraisals; the proposed size of the new GMC (regarded as too small to provide members for the new Fitness to Practise Panels and other Committees); and, heavy reliance upon newly recruited Committee members, with an heavy training and administrative burden.

In addition to these changes, the UK Government is introducing a new Council for Regulation of Healthcare Professionals, to oversee the performance not just of the GMC, but all statutory health care regulators.

The Development of Health Law in Indonesia (Legislative Approaches in Health Care)

This session was introduced by Hermien H Koewadji and Herlien Megawe.

The development of health law/medical law in Indonesia began with the implementation of the national health system in the early 1980s, focusing on the dynamic nature of the system to tackle problem-solving.

This was enhanced by documentation regarding informed consent and medical records. The introduction of new elements into the health system, which challenge the features of community/government provision of not-for-profit services will introduce new complexities.

A particular issue for authorities includes meshing policy objectives with an understanding of societal values existing as living law in different cultures.

The role of informed, responsible patients making their own decisions is another critical medical/legal issue, resulting in the development of official guidelines for informed consent.

These guidelines reflect the unwritten rights of legally competent patients to grant or withhold consent. The authors note they also reflect the doctor's existing unwritten law, derived from the principle 'father knows best'.

On the Physician Credit

This paper was introduced by Ge Jianyi, China.

The author noted that 'credit' can also be termed 'honour' and 'trust', defined as a person's competence of doing something. Physician credit is the total of professional competence and professional character while fulfilling obligations.

The author notes that pursuing physician and hospital credit is essential in the market economy, confronted with greater competitiveness, in order to improve evaluation of methodologies, promote good practice, improve health standards and improve the standing of physicians in society.

The author outlined an evaluation process for physician credit, including compliance with legal and medical practice; patient outcomes; and satisfaction rates.

Controlling Medical Doctors in Belgium

This topic was introduced by Rita Schepers, Herman Nys, Panayota Mokos and Iris Van Bael.

The authors indicated that while the issue of self-regulation of the medical profession is high on the political agenda, there is very little actually known about the effectiveness of existing control measures.

The authors contend that the current system for controlling doctors is fragmented; there is resistance to control by external organisations; and there is a lack of transparency and reliability of data to control various aspects of the behaviour of doctors who might have transgressed.

The authors suggested that the norms and rules of the formal institutions involved are ill-defined and impractical.

Late Complications After Medical Treatment – Malpractice or Fate?

This session was introduced by Mario Darok, MD and Regina Gatternig, MD, Institute of Forensic Medicine, and Sebastian Mannweiler, MD, Institute of Pathology, University of Graz, Austria.

The presentation focused upon the changed public attitude towards medical malpractice over recent years.

The authors noted that if the lethal outcome occurs shortly after medical treatment, the possibility of medical malpractice must be considered, but there could also be late complications due to medical treatment, resulting in the death of the patient a long time afterwards.

Complications may result from foreign bodies left after surgery.

The authors noted that medico-legal autopsies were an important tool in the assessment of questioned malpractice – in determining whether the malpractice was due to negligence or fate.

The authors suggested that it should be standard practice to perform a post-mortem examination if a previous medical treatment precedes a death.

Complaints Alleging Serious Malpractice in Finland 1995-1999

This paper was presented by Viljami Laine and Jan Lassus, Department of Orthopaedics and Traumatology, Helsinki University Central Hospital and Aulikki Wallin, National Authority for Medicolegal Affairs, Helsinki, Finland

The authors analysed material concerning alleged serious malpractice cases sent to the national Authority for Medicolegal Affairs (TEO), as complaints by the bereaved 1995-1999.

TEO considers complaints involving death or serious injury to a patient. Other complaints are dealt with by state provincial offices.

TEO collects data (medical records, autopsy protocols, statements of health care professionals) and the evaluation of the case by members of TEO's expert panel. When a medical error is detected, a second hearing is provided to the health care professionals. TEO's conclusions are expressed in a final report, which is sent to the complainant.

As well as giving information and expressing a view about the case, TEO can admonish health care professionals as a supervisory action. TEO can also take disciplinary action or send the case to other authorities (police or public prosecutor).

The results of the study reveal that most of the complaints about serious malpractice in Finland are directed towards doctors in operative medicine, general practice or psychiatry.

Cases involving other health care professionals were rare. Malpractice could be proven in a small minority of cases. Improper communication and inadequate information were found in most cases.

Because the most severe cases of malpractice had already come to TEO's attention via police before a complaint was lodged, the sending of cases from TEO to other authorities was rare.

Civil Liability and Litigation for Medical Negligence

This paper was presented Zhang Yu and Dai Jinzeng, Tianjing Bureau of Public Health. Tianjin, PR China.

The authors addressed three questions:

- Civil liability for medical negligence is different from common civil liability for tort.

- Medical activities are one kind of special activity, needing accurate recognition and understanding.

- Medical activities are implemented by special practise.

Implementing the Patient's Rights Laws in Hospitals of Clalit Health Services

This presentation was made by Zipi Sadeh, Atty. Esther Ben-Haim and Navah Jelin, Israel

The authors noted that a Patient's Rights Law was enacted in Israel in 1996, mandating Clalit Health Services (as well as the other three Israeli health funds) to provide health care in accordance with the Law's precepts.

Clalit Health Services, with 3.7 million insured members, is the major health service in Israel and is regarded as a progressive health organisation.

Complaints reaching the Ombudsman's Office of Clalit revealed problems in implementing the Law. in areas relating to attitude, privacy, information and discrimination.

Studies showed that hospital staff had partial or no knowledge of the Law, or considered it to be irrelevant.

A customer-focused project involved accompanying hospitals through an intervention process over a one year period.

Training and provision of information about the Patient's Rights Laws and its implications were undertaken through multi-disciplinary teams.

The monitoring method chosen by the drivers of the project enabled hospital management to improve processes ensuring implementation of the Law, as well as contributing to shared learning between hospitals.

Patients Rights in the Slovak Republic

This paper was presented by Alexandra Brazinova, Slovak Republic

The author outlined a project which was aimed at evaluating public awareness of patients rights in the Slovak Republic. 2,600 copies of a questionnaire were distributed into 8 regional hospitals. From these, 1,874 questionnaires were evaluated.

The results were analysed, including the characteristics of respondents. The results indicated that the majority of citizens are aware that some patients' rights exist, but are not observed.

It was felt that people have sufficient knowledge about the choice of the physician and healthcare facility, but insufficient information about their right for information. It was suggested that health care professionals do not inform patients about their disease, diagnostics and treatment properly.

Citizens underestimate prevention and their responsibility for their own health. They also do not relate payment of health care insurance to the provision of health care.

The problem of patients' rights promotion in Ukraine and the readiness of the Ukrainian society

Dr Victor Glukhovsky presented this paper.

The author noted that a change of political and social priorities, as well as the unstable economy, has had an impact on the willingness of the Ukranian society to adopt modern principles to which health reform should have been oriented, ie social equity, human rights and ethical values.

Views on these principles have begun to be replaced with questions relating to the capacity or incapacity of the State to meet its guarantees in health care.

The author reported on a survey of 1800 people about patient rights legislation trends. The author noted that for most respondents, the concept of patient rights was a 'heard-for-the-first-time question'.

He expressed concern that the concept of patient rights might result in defensive positions on the part of physicians and patients.

He contended that Ukranian society needed some relevant terminology to better understand the concept of patient rights, and that this should extend to discussion of patient and physician rights and obligations.

The Maintenance of Rights of Patients

This session was introduced by Wu Chongqi, China Health Law Society, Beijing, PR China

The author noted that the concept of the maintenance of patients' rights is accepted across developing and developed countries today.

The author recommended that the ten rights of patients: right of life; right of human body; right of health; right of equal access to medical treatment; right of disease cognition; right of informed consent; right of privacy protection; right of exemption from specific social liabilities; right to sue; right to request compensation be embraced in national law in every country as they have been in China.

Rights of Patients: Informed Consent, Including the Right to Refuse Consent

This paper was given by Dr Arthur W Lewis, New Zealand

The author discussed the issues of informed consent, including the right to refuse consent, presenting two case studies to illustrate key points.

The author indicated that before making a choice or giving consent, every consumer should have the right to information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

The author noted that these rights are 'jealously guarded' under the Health and Disability Commissioner Act 1994, and in its Code in regard to all or any matters relating to the person's well being.

Is the Regulation of Clinical Ethical Decision-making Advisable?

This paper was presented by Katryn RY van Oudheusden, University Medical Center, Utrecht, The Netherlands

The author examined issues relating to euthanasia and assisted suicide, noting the confusion among jurists in the country about the expected capacity for medical ethical decision-making by medical professionals.

Possible methods of addressing these concerns include ethical education in Dutch Medical Schools, and regulation of clinical ethical decision-making.

The author concludes that education is desirable, and regulation necessary, but suggests that new laws and regulations need to build upon the foundation of a sound education system.

Opinions and relations about the concepts of bioethics and health professionals deonthology.

The authors of this paper were Professor Antonio Piga, Professor Teresa Alfonso and Professor Alejandro Reyes; Departmento de Cieces Sanitarias, Universidad de Alcala (Madrid), Spain, and Dr Manuel Cumplido, Asociacion Mundial de Derecho Medico, Argentina.

The authors reported on a semistructured questionnaire which they administered to different jurisdictions (universities, associations, hospitals and health care centers) to find out what professionals think about the concepts of bioethics and professional deonthology.

One of the objectives of their initiative has been to find out if behind the use of one or the other of those groups, there is a practical difference in the convictions, principles, methods and behaviours in the dialectic of the reports between individual professionals and their patients as well as among the professionals themselves in the health care team.

The Ethics Committee of the Soroka Medical Center: An overview of Activities

This paper was presented by Professor David A Frenkel, Department of Business Administration, School of Management, Ben-Gurion University of the Negev, Beer-Sheva, Israel.

The author has been the Chairman of the Ethics Committee of Soroka Medical Center in Beer-Sheva since its inception in 1998.

The Committee was appointed by the Israeli Ministry of Health in accordance with the Patients Rights Act of 1996.

This paper describes the work of the Committee and provides several cases for illustration.

Among the powers granted by law the Committee is empowered to approve performance of treatment against the patient's will, to approve withholding information from the patient when the information is likely to cause harm to the patient's mental or physical health, to approve disclosure of medical information when it is vital for the protection of the health of others or the public, and to examine the minutes, summations, conclusions and findings of Control and Quality Committees, upon the request of patients concerned.

The majority of cases involve petitions by the physicians who want to proceed with treatment against the will of patients when their lives are deemed to be in grave danger.

The Committee approves treatment, against the will of patients, only if the treatment is anticipated to significantly improve medical condition. However, the Committee found that in many cases, the patient refused treatment because of a lack of or bad communication. In most of these cases, patients gave their consent during the hearing by the Committee.

Other cases brought before the Committee were brought by doctors as well as by family members who requested that certain information be withheld from a patient. In all such cases, the Committee approved the applications when its members were convinced that providing the information was likely to result in severe harm to the patient's health.

As of the end of 2001, there was only one case in which the Committee approved the disclosure of medical information when it was vital for the protection of health of others.

Are Ethical Codes Ethical?

This paper was presented by Tom Meulenbergs, Belgium

The author noted that since the second half of the 20th century, ethical codes have constituted a substantial part of the set of ethics instruments that is at the disposal of health care workers. This, it was felt, had emanated from shock at the disclosures of physicians at the Nuremberg Trials.

A current question for the profession is whether or not there is a situation where documents have become pathology rather than cure.

The author contends that codes should act as an ethical compass, to signal the way in which the practice can assume its moral shape. There is a concern, however, that codification of ethics can lead to an impoverishment and simplification of ethics. There is also concern that ethics are becoming fragmented, with increasing specialisation of professional groups..

The author suggests it is important to 'bring ethical codes into the classroom'. By offering an initial formal education in ethics and subsequent clinical-ethical training, professionals will be able to assess real life situations.

The author further suggests that in this training, more attention needs to be given to the formation of the individual's character, so that they are not controlled by events as they unfold.

Medical Ethics and Health Law in China

This paper was presented by Yongfu Cao, Humane Medical Research Center, Shandong University, Jinan, China

The author expounded on the medical worker's morality, ethics and health law. He expressed the view that China's traditional medical virtue is the more important content of health law. He expressed the view that medical ethics is a foundation of health law.

He analysed medical ethics as an underpinning of Chinese health law, and expressed the view that medical workers have a good morality to help make medical ethics realise and help health law to be carried out.

Changing the Way of Patient Consent to Knowledge over Information

This paper was presented by Ken Berger, Faculty of Medicine, University of Toronto, Canada and Peter Allat, Clinical Ethicist, University of Toronto, Canada

The authors contend that there should be a fiduciary relationship between patient and physician. This should relate to all aspects of care, and needs to include effective communication, especially regarding treatment decisions.

The authors discussed the need to health care providers to occasionally act as filters of information into knowledge, especially where that might seem conflicting confusing or too complex for the patient.

They suggested that physicians and health care providers have a special knowledge to share, and that development of physicians and health care providers as educators is important in their abilities to transform information into knowledge.

They suggested that a meaningful partnership can exist between parties through the exchange of knowledge and understanding, and that this allegiance will be critical to face future challenges in the context of limited resources, the cost of advanced medical technologies and their fair allocation.

The Rights of Patients to Information: The French Situation

This paper was introduced by C Rouge-Maillart, N Jousset, and M Penneau, Consultation de medecine legale, Angers; and G Tournel and D Gosset, Institut de medecine legale, Lille, France

The authors discussed the rights of patients to information in the context of an historical obligation of the profession to provide information.

They noted that a signature on a form is insufficient to prove patient consent – there needs to be dialogue between the parties so it can be demonstrated that consent is informed.

Informed Consent in Finland: A Law Review

This paper was presented by Maritta Valimaki, Department of Nursing Science, University of Tampere; Helena Leino-Kilpi, Department of Nursing, University of Turku; Riita Suhonen, Forssa Health Care District, Finland

Health care in Finland is based on mutual understanding being reached between the patient and the carer. There are laws supporting patients' rights to take an active part in decisions concerning their own health and treatment.

Health care staff need to be aware of how informed consent works.

A study on informed consent indicated that the concept of informed consent is broad, and the meaning of it in laws is unclear. Although informed consent or its elements were mentioned in every law analysed, there was a variety between laws, and how patients' competence was defined.

The most often mentioned element was competence and disclosure. There was a lack of description regarding patients' understanding of how information could be evaluated, or how patients' voluntariness could be assured in practice.

The authors concluded that there is a need for a collaboration between health care professionals, lawyers and politicians in order for informed consent to be realised.

From Informed Consent to Informed Choice: Patient Access to Reliable Health Information on Medical Services and Medicinal Products in the Internet Age

The topic was introduced by Dr D Barth, Attorney, Health Care Administrator, Legal Department MSD Sharp and Dohme, GmbH, Munich

The authors noted that the concept of informed consent, with an intensive flow of reliable medical information prior to medical treatment has become common

sense. They suggest, however, that this health-related communication between health care providers and patients has been restricted by professional codes and legislation.

Today, they say, patients do not have enough access to reliable information on medical services and medicinal products to make an informed choice.

Both the right to inform as well as the right to get information about health services and products have to be considered fundamental human rights.

Furthermore, they suggest, an information society needs informed patients to let them play a more active role in the health care system.

The Internet has given a dramatic change in patient access to any kind of non-quality-reviewed health information.
Just recently, the European Commission and the Pharmaceutical industry have made several proposals for accurate, appropriate and comprehensive health information in the patient-provider communication process to ensure informed choices and improved partnerships.

Patients' Rights Legislation: Can Rights Exist Without Effective Remedies?

This paper was presented by Miles J Zaremski, USA

The author noted that he past decade has shown an increased awareness for patients' rights in terms of patient involvement in and responsibility for health choices. He indicates that many countries have responded by developing more balanced partnerships between health care providers and patients.

The author discusses the introduction of ERISA (Employee Retirement Income Security Act), which, in prescribing for quality of care, leaves the way open for patients to seek redress regarding a decision on medical treatment. or its timing.

He argues that there have been many cases in the US which have had to address the question of cause of action, but that these have been decided on an *ad hoc* basis. He therefore argues that a legislative clarification of ERISA is required.

Evaluation of Legislation: Dutch Experiences

This session was introduced by J Legemaate, The Netherlands

The author suggested that legislation is an important instrument for the realisation and promotion of the goals of health law.

In many countries, issues like patients' rights, organ donation, medical research, civil commitment, the quality of services provided and so on are dealt with in legislation.

In order to reach its goals, legislation must be effective and not be hindered by external circumstances. Factors concerning the structure or content of law might lead to a discrepancy between the intentions of law and actual practice. By evaluating legislation some time after it has come into force, these discrepancies can be discovered and remedied.

In The Netherlands, these evaluations are carried out by independent research institutes and monitored by a national committee. The outcome of the evaluations is debated in Parliament and may lead to amendments to the Act.

Patients' Rights in New Zealand: Complaint Resolution and Quality Improvement

The paper was presented by Ron Paterson, New Zealand Health and Disability Commissioner and Marie van Wyk, Legal Advisor to the Health and Disability Commissioner

The authors observed that a sea change occurred in New Zealand about patients' rights, after 1987, when it was revealed that a risky, poorly designed experiment to test the hypothesis that carcinoma in situ was not a precancerous condition led to conventional treatment being withheld from women without their knowledge or consent. Forty women subsequently developed invasive cancer.

The Health and Disability Commissioner Act proceeded from an inquiry into the above experiment.

The authors described the role and processes of the Health and Disability Commissioner, noting that the NZ complaints resolution process exists in a framework of a 'no fault' universal coverage health system.

In this context, medical malpractice litigation has been effectively barred from NZ. The Accident Compensation Corporation provides no-fault, state-funded rehabilitation and compensation for victims of medical misadventure, including medical error.

The authors noted, however, that a high threshold for awarding damages has not discouraged people from complaining about health care providers – this has been tied to the need for people to seek personal accountability.

The authors acknowledged that the current process is slow, result in too many investigations, and is stressful on all participants. The Commissioner must investigate every complaint alleging substandard health care or disability services provided after 1 July 1996.

However, it is expected that pending legislation will give a discretion to determine whether an independent investigation is necessary or appropriate.

The authors also believed that the intent of the system is to be rehabilitative rather than punitive, and that it was important to seek this balance in quality improvement in health care.

Promotion and Enforcement of Patients' Rights

This paper was presented by P Blaes, CEO Assistant, Lawyer, Belgian Federation Against Cancer

The author noted the international context of a growing interest in patients' rights, but observed that only nine European countries to date have adopted a specific law regarding patients' rights: France, Denmark, Finland, Iceland, Norway, Greece, Latvia, Lithuania and The Netherlands.

While not in this group, Belgium does accord recognition to patients' rights. It is seeking to ensure dialogue between patients, health professionals and healthcare institutions, based on mutual respect and hence the need to adopt measures at various levels to meet this end.

The Federation has recommended legislative changes along these lines to the government.

Challenges in Protecting Psychiatric Patient Rights: Advocacy in Ontario

This paper was introduced by Lora M Patton, Legal Counsel, Psychiatric Patient Advocate Office, Canada

The Psychiatric Patient Advocate Office has provided rights advice and advocacy services to the hospitalised seriously mentally ill since 1983.

The advocacy system is fully facility-based while the provincial mental healthcare system has changed significantly – services shifting from the hospital to the community.

The presenter illustrated the need for the PPAO to respond to new challenges to ensure the rights and entitlements of the seriously mentally ill are protected.

Attempts to Establish a System of Non-Fault Compensation for Medical Maltreatment in Austria

This paper was presented by Dr Gerhard Aigner and Dr Felix Wallner, Austria

The authors documented a process of discussion within the Austrian health system about how to establish a new no-fault compensation in the case of medical maltreatment.

They attributed interest in this area to the need for patients' confidence in the health system, interest in limited costrisks, and patient interest in receiving timely compensation.

Discussion occurred over several years until 2000, when the Austrian government commenced a minimal system covering only cases of maltreatment in publicly financed hospitals.

The scheme is financed through a levy on all public patients.

There is some concern about the implementation of the Federal Hospital Act in provincial areas.

The authors suggest that it should be a goal of the Austrian Government to extend the no-fault system to cover all types of hospitals, outpatient services and health professionals in private practice.

A Prospective Study of Error in Neurosurgery

This paper was presented by Mark Bernstein and Eric Massicote, Division of Neurosurgery; and Bernard Dickens, Joint Center for Bioethics, University of Toronto, Ontario, Canada.

The authors are conducting a study in medical errors in elective patients. One in 34 patients sustained a complication relating to major error, the majority of which were deemed preventable.

To improve the quality of health care, they suggest, it is important to identify mistakes in order to learn to prevent them. Placing errors in the context of education allows healthy and much needed discussion to take place.

The legal implications of recording and disclosing medical error may make physicians feel vulnerable, but they suggest, it is more likely to empower them, the profession and patients.

French Lessons on Wrongful Life

This paper was presented by PJ Lewis, King's College, London, UK

The author writes that a claim in wrongful life is a claim by a child born handicapped against medical staff or his (sic) parents, alleging that the defendants negligently allowed him (sic) to be born.

In November 2000, in Perruche, the French Cour de Cassation held that a claim by a child born severely physically and mentally handicapped as a result of his mother's exposure to rubella during pregnancy could recover damages against her doctor and a laboratory for negligently failing to diagnose rubella.

The mother had asserted at the time of the blood tests that she would terminate the pregnancy if the tests proved positive for rubella exposure.

The author notes that the case caused an outcry in France, and hastily drafted statutory provisions were proposed to ban recovery in such circumstances.

Despite ongoing public discussion, in July 2002, the Cour de Cassation confirmed its earlier decision. Three cases heard together maintain that wrongful life claims are justifiable in the French civil courts.

The author notes that questions to be examined as a result of this include: the role of the National Ethics Committee in influencing policy and legal change, and the impact of the wrongful life cases on the moves by the National Ethics Committee and some French legislators to decriminalise euthanasia.

New trends in obstetrical ultrasound malpractice litigation in Israel

The paper was presented by A Ticho and GA Kreisberg, Israel

The authors discuss the influence of the plaintiff's version in highly emotive cases (the case of a 'wrongful life' claim was outlined). They indicate that this can be done to the exclusion of certain key points, for example known family history or known risk factors.

They contend that the case they present demonstrates the court's apparent tendency to accept the comparatively new approach of placing the onus of responsibility on the medical profession, which has enabled the courts to rule more frequently in favour of the injured party.

Legal Status of Handicapped Newborn Child and Civil Liability

The paper was presented by Hajrija Mujovic-Zornic, PhD, Centre for Legal Research, Institute of Social Sciences and Yugoslav Association for Medical Law, Belgrade, Yugoslavia

The author suggests that in the discussion about the issue of medical liability for prenatal damages, there needs to be the inclusion of the view from the standpoint of the affected child.

He discusses the complexity, but also the justification of the liability concept from the point of view of the child's action. He indicates that this confirms the need for high standards of reproductive medicine care and genetic counselling. But it also confirms the rights of a child to sue for injury caused *in utero*.

He notes that for correct understanding of these claims, it is important to differentiate damages, that is to draw a distinction between child existence (life) and expenses caused by the handicap.

He suggests that this would remove any influence in the discussion about the sanctity of human life and promote dispassionate assessments of claims.

Pain: As Seen in the Portugese Labour, Civil and Penal Code

This paper was prepared by MJ Carneiro de Sousa, Alice Gouveia and J Pinto Da Costa, Biomedical Sciences Institute, 'Abel Salazar', Oporto University

The authors discuss the difficulty of defining and assessing pain, and suggest that its holistic meaning is required in order to understand pain, and the legal and comparative issues arising from that.

They note that an analysis of the Portugese legislation, its guidelines and points of view regarding pain, lead to a realisation that pain is linked to the cultural and personal observation of pain by self, and Law cannot lay strict rules in its evaluation, as everything in life, human being and sensitivity are not constant.

They suggest that to abide by strict rules of medical law and assessment of a human being suffering from pain at times leads to misjudgment.

Further, an assessment of a victim should take into account their personality, so that medical expertise complies with fairness in the diagnosis, assessment and quantification of pain, leading to a fair compensation, if relevant, in the legal sense.