



Panellist

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Professor Aishah is a Commission Member of the Companies Commission of Malaysia (CCM). She was a former Executive Council Member of International Centre for Law and Legal Studies (I-CeLL), Attorney General Chambers (AGC) of Malaysia and former Executive Council Member of Legal Aid Foundation of Malaysia (YBGK). She is also a Fellow and Council Member of Academy Sciences of Malaysia (ASM). Apart from being a law professor at UKM, she has been involved in various consultancy projects where she has advised various Government agencies in Malaysia relating to law reform and legal policies. Her experiences range from formulating new laws, revising legal and human rights strategies and policy development to programme implementation.

PRECISION MEDICINE INITIATIVE FOR MALAYSIA

Medical Law

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SCOPE

- Legal and regulatory governance
- Examples of human genetic database
- Data protection issues- patient data sharing
- IT issues – matters on privacy laws
- Insurance aspects
- Legal and Ethical values – human genome and human rights
- Cultural sensitivity
- Religious Issues
- Conclusion

Legal and Regulatory Governance

- Importance of legal and regulatory framework
- Ethical issues of human genetic database
- Consent – is the opt out model a morally acceptable solution – can individual give a blanket consent concerning the future use of their samples
- Confidentiality and access to the genetic databank – to what extent should databank be made secure enough to guarantee participants' privacy – should government / police / third parties have access? - responsibility to avoid discriminatory practices – health insurance , employment etc- should access to repositories / database be universal fro all researchers or should some researchers have privilege access? Should database and resulting research findings be commercially exploited
- Feedbacks to study participants – should participants be informed about the results of the genetic test performed on their data
- Benefit sharing – should benefit be shared and what is considered as a fair way sharing

Do we have sufficient laws to regulate precision medicine ?

- **Medical Act 1971 (Act 50) and related Medical regulations**
- **Human Tissue Act 1974**
- **DNA Identification Act 2009 (Act 699) and regulations**
- **Personal Data Protection Act 1970(Act 709)**
- **Insurance Act –repealed – Financial Services Act 2013 (Act 758)**
- **Biosafety Act 2007 (Act 678)**

Examples of genetic database – ethical problems and public debate

- Icelandic Health Sector Database – Health Sector Database Bill 1998, Biobank Acts (2000)-dealing with storage of human tissue
- UK National Biobank – UK Biobank /Database Human Tissue Act 2004,
- Estonian Gene Bank – Human Genes Research Act 2000
- Swiss Pediatric Oncology Group (SPOG) Tumor Bank

Data Protection issues / Intellectual property rights

- ▶ Common heritage mankind (CHM) argument
- ▶ Link between international law, human rights, health and development and notions of property – intellectual property
- ▶ IP laws – predominantly national in nature and are enforced within national boundaries
- ▶ But as IP protection become more important in international trade - demand of IPR at international level – across borders – TRIPS (Agreement on Trade Related Aspects of Intellectual Property)
- ▶ Internationalisation of IP rights
- ▶ Art 4 of 1997 UDHR- human genome in its natural state shall not give rise to financial gain
- ▶ Council of Europe 1999 European Convention on Human Rights and Biomedicine – human body and its part shall not as such give rise to financial gains
- ▶ Bermuda Rules – formed by policy makers and scientist involved in genomic research involve data sharing policies for communities use – whereby access to information relating to gene sequences can be quickly and freely obtained by interested users all around the world.
- ▶ International Bioethics Committee

Impact of Advancement of technology on human rights - IT Issues

- Artificial intelligence , big data and decision that affects human rights
- New technology can advance and restrict human rights- intersection
- **Human dignity**
- **Right to data privacy and personal autonomy**
- **Safety , security and the right to life**
- **Fairness and Right to non discrimination and equal treatment**
- Art 2 and 25 of ICCPR- new technologies relating to health can improve access to services and improve outcomes of socio economic indicators
- Article 17 – flow of data internationally and from private and state actors can make regulation of privacy more challenging (particularly in providing effective remedies)
- Art 15(1) of ICESCR - new technologies can improve enjoyment of human rights such as access to food , health and education

Insurance Aspects

- **Fear of “Genetic discrimination” - possibility of genetic information being used for nontherapeutic purposes which may discriminate against an individual or a segment of the population based on the genetic make up – preventing them from accessing important social goods such as insurance, employment or housing**
- **Protection for the participant – healthcare insurance**
- **Securing insurance before undergoing genetic testing**
- **Withholding information from insurers**
- **Formulating legal framework, policies and principles to address concern about genetics and personal insurance – example US Genetic Information Non Discrimination Act (GINA) , Code of Medical Ethics of the American Medical Association, Australian Insurance Act 1984, voluntary policies adopted by insurance companies - voluntary moratorium in UK not to use genetic information for insurance policies under a certain value- agreement sanctioned by the court**

Medical Ethics and Bioethics

- Nuremberg Code
- Governance of human genome
- Universal Declaration on the Human Genome and Human Rights Nov 1997 - first instrument on human genome(CHM)
- International Declaration on Human Genetic Data Oct 2003
- Universal Declaration on Bioethics and Human Rights Oct 2005
- Common Heritage Framework(CHM), right against self discrimination , right to health, right to informed consent - whether bioethics principle or human rights?
- CHM- Convention on Biological Diversity (1992)
- Allows exploitation of resource but used in an equitable manner (non –appropriation, international management and benefit sharing – mechanism of equitable exploitation)
- Right to health and right to development
- Right to health- Gewirth's rational human rights theory (Principle of Generic Consistency (PGC))
- Property rights and the economic of genomic research

Religious Issues

- Consultation with religious authorities
- Status of Fatwas
- Jawatankuasa Fatwa Majlis Kebangsaan bagi Hal Ehwal Ugama Islam Malaysia (MKI)
- Muzakarah Jawatankuasa Fatwa MKI
- Portal E- Fatwa JAKIM

Conclusion

- National Strategy and National Action Plan
- Legal and Regulatory Framework (Human Tissues Act ,data protection , privacy rights, genome testing , consent, non discrimination etc)
- Non genetic discrimination by Insurance companies – financing mechanism
- Ethical and social framework
- Code of Conduct
- Steering group and working group – multiple stakeholder (including religious authorities , human rights groups ,NGOs
- Capacity Building
- Awareness program