Presentations made during the Seventeenth (ordinary) Session of the International Bioethics Committee (IBC), held at UNESCO Headquarters in Paris on 26 and 27 October 2010

CONTENT

1. Principle of respect for human vulnerability and personal integrity: progress report on the IBC working group, by Mr Stefano Semplici, IBC

2. Traditional Medicine and Its Ethical Implications: the Natural Sciences Perspective, by Ms Serena Heckler, UNESCO Natural Sciences Sector


4. La médecine traditionnelle et ses implications éthiques Rapport d’étape (In French), by Mr Emilio La Rosa, IBC

5. Ethical Aspects of Traditional Medicine, by Mr Godfrey B. Tangwa, University of Yaounde, Cameroon.


The ideas and opinions expressed in these presentations are those of the authors and do not necessarily represent the views of UNESCO or its Members States
Principle of respect for human vulnerability and personal integrity:
progress report on the IBC working group

Stefano Semplici
Article 8

• Human vulnerability should be taken into account
• In applying and advancing scientific knowledge, medical practice and associated technologies
• Individuals and groups of special vulnerability should be protected
• And the personal integrity of such individuals respected
We have deliberately decided against attempting a general definition of vulnerability (and integrity or dignity). The method is rather “illustrative”. Despite of the philosophical difficulties involved in the concept, we easily recognize vulnerability when it arises. Therefore, we provide and discuss examples of vulnerability with regard to the three domains pointed out in Article 8.
A possible objection…

“Why is vulnerability a concern in bioethics? In order to answer this question, it is necessary to establish the criteria used to determine which individuals or groups are vulnerable, what counts as exploitation, and which efforts at protection may be paternalistic”.

(Ruth Macklin)
...and an explanation:

The general definition the working group decided not to work out in depth is the “philosophical” one, related to vulnerability as indeed general feature of the human condition. Fragility is an essential anthropological dimension. To take into account human vulnerability means to acknowledge that we are all in need for help and share a responsibility for others’ well-being. We are all confronted with disease, disability, environmental risks. At the same time, we over and over experience the possibility that harm and even death come from other human beings. We are all “committed” one to another.

Is it possible to give more attention in the Report to this aspect?
On the contrary, the “criteria” of “special” vulnerability are explicitly pointed out, on the premise that we are called upon is a shift from a rights-based to a duties-based orientation.

A. Special (temporary or permanent) conditions of human life (children, patients with diminished cognitive abilities, etc…).

B. Human and social determinants: culture, tradition, economy, power.

C. Nature and environment.

P. 2: the various factors can combine and strengthen each other.
Vulnerability in the clinical setting

A. The issue of self-determination and consent

B. The lack of access to proper health care
Vulnerability in human subject research

In this context, the additional safeguard of the physician’s primary focus being on restoring the patient to health is absent.

A. The issue of business.
B. Possible coercion arising from a number of sources, including the omission of relevant information about possible risks.
C. Deliberate exclusion of certain groups from participation in research.
Vulnerability in the development and application of biotechnology

Controversial developments such as stem cell research and therapy, therapeutic cloning and gene therapy may promise progress in healthcare capacities for the future, but they also pose special problems regarding current and future people whose social, personal and health status may be affected, rendering them socially and politically vulnerable.
Traditional Medicine and Its Ethical Implications: the Natural Sciences Perspective

Seventeenth Session of the International Bioethics Committee
Paris, 26 October 2010

Serena Heckler
PSD/SII
Summary

• Preliminary report
  – Definitions
  – Types of TM
  – The State of the Art
    • Regulation
    • The ethics of working with Indigenous communities

• Science Sector work
  – PSD/SII
  – EES: IPABS and IPR, Biocultural community protocol
  – BES: SIDS of Indian Ocean and Madagascar workshop

• Ethical Implications and Recommendations
Preliminary Report: Definitions

- The importance of TM for billions
- The increasing popularity of CAM
- They are not synonymous
Preliminary report: Definitions

• TM has developed in particular social, cultural and environmental contexts
• Is dynamic and syncretic
• To change it from outside may have wide ranging and unforeseen consequences
Preliminary report: definitions

Conceptual domains of medical systems

- Evaluation
- Biomedicine
- Traditional Medicine
Preliminary Report: Types of TM

• TMs are:
  – Generally empirical
  – But complex systems of testing and adjusting that are unknown from outside the tradition.
  – Accessed based on pragmatic and astute understandings of contingencies
  – Clinical legitimacy vs. scientific legitimacy

• Willis and White 2004
Preliminary Report: State of the Art

- Regulating TM: mixed results
  - Legal frameworks in 9 Latin American countries:
    - “Regulation of TM in … is not achieved through the application of a body of laws… This irregular process has become more of one of control than of regulation which depends upon the asymmetric power between those who control… and those who are controlled…”

  Nigenda et al. 2001: 38-9
Preliminary Report: State of the Art

• The impact of regulation and validation:
  – **Always** changes TM
  – Changes may be welcomed
    • e.g. Canadian CAM practitioners (Moss *et al.* 2007)
  – But may negatively affect access
    • E.g. biochemical testing of Korean TM (Kim 2009)
Preliminary Report: State of the Art

- The ethics of working with Indigenous communities, including health research
  - Health oversight bodies: E.g. Canadian Institute of Aboriginal People’s Health
  - Health research guidelines: Australian National Health and Medical Research Council
    - Strategic Framework for improving Aboriginal and Torres Strait Islander health through research (2002)
    - Values and Ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (2003)
• Division of Science Policy and Sustainable Development
  – Small Islands and Indigenous Knowledge Section
  • Ex: Pourchez, Laurence (in prep). Savoirs féminins liés à la nature, plantes médicinales et médecine traditionnelle dans les Mascareignes. UNESCO-LINKS
• Division of Ecological and Earth Sciences
  – International protocol on Access and Benefit Sharing (to be adopted this week?)
  – Biocultural community protocols:
    • Kruger to Canyons Biosphere Reserve
• Division of Basic and Engineering Sciences
  – Workshop on medicinal plants of the small islands developing states of the Indian Ocean and Madagascar in March/April 2011
Conclusions

• Ethical Implications
  – Article 4: Difference between theory and reality.
  – Protecting IPR and ABS (Articles 10, 15)
    • Article 5: Autonomy and individual responsibility
  – Article 17: Protection of biodiversity
Conclusions

• Recommendations
  – Learn from and take into account the experiences of other bodies that have attempted to regulate TM
  – Include TM practitioners on the working group
  – Include TM users into the process
  – Collaborative work at the local level may be most effective at ensuring ethical TM practice
Cultural Diversity Standards and Principles in light of the


Prepared jointly by the Policies for Culture and the Intangible Heritage Sections

Presented by Susanne Schnuttgen, Programme Specialist and Chief a.i.

Policies for Culture Section, Division for Cultural Policies and Intercultural Dialogue
UNESCO Culture Sector

UNESCO Headquarters, 26 October 2010
The protection and promotion of cultural diversity and its relation to the theme of the Bioethics Commission’s work on traditional medicine and its ethical implications

• What are the key concepts and principles that underlie the internationally agreed commitments for the protection and promotion of cultural diversity and how do they relate to the issue of traditional medicine and its ethical implications?

• How can we ensure that these international standards are respected and not limited in scope in current efforts to design an ethical framework for traditional medicine?
There is no programme on traditional medicine as such in the Culture Sector. However, traditional medicine emerges in several programmes, such as:

- Intangible heritage safeguarding
- Cultural approaches to HIV&AIDS prevention and care
- The indigenous peoples’ programme
- The intersectoral work on linkages between cultural and biological diversity.

UNESCO’s International Standards on Cultural Diversity and the place of traditional medicine in the UNESCO Culture Programmes
The UNESCO Universal Declaration on Cultural Diversity

• The equal dignity and value of all cultures is a key ethical principle

• commitment to human rights and fundamental freedoms; no one may invoke on cultural diversity to infringe upon human rights guaranteed by international law, nor to limit their scope

• A broad understanding of culture:

  Culture encompasses “in addition to art and literature, lifestyles, ways of living together, value systems, traditions and beliefs” (UNESCO, MONDIACULT, 1982 and UNESCO Universal Declaration on Cultural Diversity, 2001).
Traditional medicine is part and parcel of the world’s value systems, traditions and beliefs and thus an integral part of the world’s cultural diversity, which is considered the “common heritage of humanity and should be recognized and affirmed for the benefit of present and future generations” (Article 1, UNESCO Universal Declaration on Cultural Diversity).
The 2003 Convention for the Safeguarding of the Intangible Cultural Heritage

• Intangible or living heritage is understood as traditions, knowledge, practices, representations, expressions and skills.

The 2003 Convention:

– recognizes specific knowledge systems and values the existence of multiple knowledge systems and world views respecting their inherent logic
– is committed to free, prior, and informed consent
– promotes the idea that a deeper understanding of the value and rationale of knowledge systems and beliefs reveals itself “from within” and through a commitment to dialogue.
The UN Declaration on the Rights of Indigenous Peoples

Article 24:

Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services.
Traditional medicine often concerns biological resources and the knowledge of local and indigenous peoples and/or healers regarding their medicinal use. Thus, traditional medicine is interlinked with biodiversity conservation and with indigenous people's rights over their knowledge and resources.

Article 8(j) of this Convention calls on Parties to “respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities relevant for the conservation of biological diversity, to promote their wider applications with the approval of knowledge holders, and to encourage equitable sharing of benefits arising out of the use of biological diversity.”
Turning to the draft report

• What does “integration” mean from the equality of cultures perspective?

• there is no hierarchy of cultures

• Equal respect for different medical systems does not mean co-opting one into the other

These principles are above all, sustained by intercultural dialogue, since it encourages readiness to question well-established value-based certainties by bringing reason, emotion and creativity into play in order to find new shared understandings
Turning to the draft report

Consider for example the four WHO requirements cited in the closing recommendations of the draft report. An ethical approach fully grounded in the principles of the international human rights instruments mentioned earlier would require that ‘innocuousness, efficacy, quality and rational use’ be applied with full respect to different cultures’ own conceptions of each value.
International standards on protecting and promoting cultural diversity contribute to creating an enabling ethical framework for the protection and promotion of traditional medicine as part of larger strategies for sustainable development and human well-being.

Active dialogic participation of communities, groups or individuals from diverse cultural horizons and medical practices, with a willingness to ‘question well-established value-based certainties’ and address the critical issue of multiple verifications that different systems have in place in support of human rights.
La médecine traditionnelle et ses implications éthiques
Rapport d’étape

Emilio LA ROSA
Le Bureau du Comité international de bioéthique (CIB), lors de sa réunion de mars 2010, a décidé d’inscrire l’éthique et la médecine traditionnelle au programme de travail du CIB pour 2010-2011, considérant que la médecine traditionnelle avait été évoquée à plusieurs reprises lors des débats au sein du CIB en tant que thème particulièrement important pour les pays en développement et leurs comités nationaux de bioéthique.
LA COMPOSITION DU GROUPE DE TRAVAIL

- Dr. Emilio La Rosa, président du groupe
- Prof. Fouad Boustany
- Dr. Aïssatou Touré

Pour l’étude des cas
- Prof. Hu
- Prof. Boiro
- Prof. Massougbodji

Le groupe compte avec l’appui du
- Prof. Donald Evans, Président du CIB.
- Mme Dafna Feinholz
- Mme Sabina Colombo.
**SOMMAIRE**

1 INTRODUCTION
- 1.1 Objectifs du rapport
- 1.2 Contexte

2 CONSIDÉRATIONS GÉNÉRALES
- 2.1 Définitions
  - 2.1.1 Médecine traditionnelle
  - 2.1.2 Médecine complémentaire, parallèle, alternative, douce
- 2.2 Typologie de la médecine traditionnelle
- 2.3 État de la situation
- 2.4 Médecine traditionnelle et médecine conventionnelle : approches et perspectives
- 2.5 Médecine traditionnelle : bénéfices et risques
- 2.6 Médecine traditionnelle et système de santé

3 IMPLICATIONS ÉTHIQUES DE LA MéDECINE TRADITIONNELLE
- 3.1 Principes éthiques de la Déclaration universelle sur la bioéthique et les droits de l’homme
- 3.2 Pratique de la médecine traditionnelle : études de cas
  - 3.2.1 Afrique
  - 3.2.2 Région arabe
  - 3.2.3 Asie et Pacifique
  - 3.2.4 Amérique latine
- 3.3 Recherche en médecine traditionnelle
- 3.4 Formation, évaluation

4 CONCLUSIONS

2.6.1 Une médecine traditionnelle reconnue et intégrée aux systèmes de santé
2.6.2 Une médecine traditionnelle reconnue, mais non intégrées aux systèmes de santé
2.6.3 Une médecine traditionnelle tolérée
2.6.4 Une médecine traditionnelle ignorée
Selon l’Organisation mondiale de la santé (OMS), la médecine traditionnelle se définit comme « la somme totale des connaissances, compétences et pratiques qui reposent, rationnellement ou non, sur les théories, croyances et expériences propres à une culture et qui sont utilisées pour maintenir les êtres humains en santé ainsi que pour prévenir, diagnostiquer, traiter et guérir des maladies physiques et mentales ».
LE POURQUOI

- Le développement et l'importance sanitaire et économique de la médecine traditionnelle, ainsi que son ancrage dans l'histoire et les cultures des peuples,
- L’absence de normes éthiques relatives à la pratique traditionnelle dans bon nombre des pays
- L’OMS considère que la médecine traditionnelle doit être intégrée au système de santé en respectant un certain nombre d’exigences: innocuité, efficacité, qualité, usage rationnel.
La médecine traditionnelle dans les pays en développement

- En Afrique, 80% de la population utilise la médecine traditionnelle pour des raisons culturelles ou parce qu’il n’y a pas une autre alternative.

- En Chine,
  - 40% des soins de santé correspondent à la médecine traditionnelle,
  - 30 à 50% de la consommation totale de médicaments correspondent aux préparations à base de plantes,
  - 200 millions de personnes utilisent la médecine traditionnelle.

- La MT permet une facilité d’accès, une disponibilité et un bas coût
L’utilisation de la MT pour les soins de santé primaire
La médecine traditionnelle et alternative dans les pays industrialisés

Le pourcentage de personnes qui font appel à la médecine alternative augmente avec la croyance que tout ce qui est naturel n’a pas de danger et aussi parce que la médecine traditionnelle est un complément dans le cas de maladies chroniques.

Aux États Unis:
⇒ ⇒ 158 millions d’adultes ont utilisé, au cours de leur vie, un remède traditionnel, et
⇒ ⇒ en 2000, la population a dépensé plus de 17 milliards de dollars en remèdes traditionnels
Population ayant eu recours à la médecine alternative au moins une fois

Canada 70
France 49
Australie 48
USA 42
Belgique 31

Source : OMS
L’absence des normes

Source : OMS 2001

Réglementation des médicaments à base de plantes
La situation de la Médecine traditionnel vis-à-vis du système de santé des pays

La médecine traditionnelle vis-à-vis du système de santé:

- **Intégrée et reconnue**: Chine, République de Corée, République populaire démocratique de Corée et Vietnam
- **Reconnue** : mais pas intégrée au système de santé: Inde, Indonésie, Ghana, Nigeria, Mali, Canada,..
- **Tolérée** : la plupart des pays
Implications éthiques de la médecine traditionnelle

L’approche éthique de la médecine traditionnelle est faite à partir d’un certain nombre des principes énoncés dans la Déclaration universelle sur la bioéthique et les droits de l’homme
Articles pris en compte

- Article 3 - Dignité humaine
- Article 4 - Effets bénéfiques et nocifs
- Article 5 - Autonomie et responsabilité individuelle
- Articles 6 et 7 - Consentement et personnes incapables d’exprimer leur consentement
- Article 8 – Respect de la vulnérabilité humaine et de l’intégrité personnelle
Articles prise en compte

- Article 9 - Vie privée et confidentialité
- Article 12 - Respect de la diversité culturelle et du pluralisme
- Article 14 – Responsabilité sociale et santé
- Article 17 - Protection de l’environnement, de la biosphère et de la biodiversité
- Article 20 - Évaluation et gestion des risques
Articles pris en compte: quelques réflexions

- **Article 3 - Dignité humaine**
  - La dignité de la personne est mise à mal quand la médecine allopathique ne prend pas en compte les syndromes psychosomatique-culturels

- **Article 4 - Effets bénéfiques et nocifs**
  - Phytothérapie (plantes médicinales)
  - Thérapie spirituelle (syndromes psychosomatique-culturels)
  - Charlatanismes
Articles prise en compte
quelques réflexions

- Articles 6 - Consentement
- Article 9 - Vie privée et confidentialité
  - Syndromes psychosomatique-culturels : mauvais œil, « daño » (faire du mal), susto (peur).
Articles prise en compte
quelques réflexions

- Article 17 - Protection de
  l'environnement, de la biosphère et
de la biodiversité

- Biopiraterie: Les brevets déposés sur l'exploitation de
  végétaux et minéraux font l'objet d'une compétition
  acharnée entre multinationales. Conséquences : un
  paysan peut être, d'un point de vue légal, condamné à
devoir des royalties à une entreprise pour cultiver la
plante de ses ancêtres.
- Exploitation des plantes sauvages. Exemple, la
  « muña »
Pratique traditionnelle : études des cas

- **Les syndromes psychosomatiques-culturels:** La symptomatologie clinique peut cacher une maladie grave.
  - Exemple, les « susto » (peur): perte d’appétit, malaise, perte de poids, anémie, troubles nerveux, fièvre, nausées, vomissements, diarrhées,...

- **La phytothérapie:** Le manque de réglementation, contrôle et pharmaco-vigilance peut provoqué des dégâts sur la santé.
  - Exemple, l’éphédra, plante utilisé pour la congestion des voies respiratoire. Un usage excessive a provoque des troubles cardio-vasculaires (infarctus du myocarde, mort subite) et neurologiques (AVC).
Pratique traditionnelle : études des cas

- Les pathologies (visibles) : les diagnostics tardifs des maladies graves
  - Exemples, le cas d’un tumeur oculo-orbitaire (carcinome baso-cellulaire), la patiente avait été vu par deux tradipraticiens depuis le début de la maladie. Ceux-ci avaient estimé que l’affection était due à de mauvais sorts jetés au patient par un membre de sa famille. Pendant 9 mois, elle avait reçue des traitements sous forme de scarifications, mixtures et incantation.
ETHICAL ASPECTS OF TRADITIONAL MEDICINE

Godfrey B. Tangwa, PhD
Professor of Philosophy
University of Yaounde 1/Cameroon Bioethics Initiative (CAMBIN), Cameroon
CONCEPTUAL AND DEFINITIONAL PROBLEMS

- The term ‘traditional medicine’ is ambiguous.

- There is a sense in which every society/country has its traditional medicine which can be compared and contrasted with its modern medicine.

- Sometimes the term is used to refer to any medicine based on plants and other natural products in the environment.
Sometimes the term is used as a contrastive term to denote medical practice other than ‘Western scientific medicine’

Sometimes the following terms are used to designate traditional medicine: alternative medicine, parallel medicine, complementary medicine, soft medicine

And contrasted with Western medicine, designated as ‘conventional’, mainstream’, ‘dominant’, ‘orthodox’
WHO DEFINITION

“...the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses” [Fact sheet No. 134, December 2008]

This is a good working definition!
WHEREVER HUMAN BEINGS HAVE LIVED, THERE HAS BEEN THE NEED TO ADAPT THEMSELVES TO THE PECULIARITIES OF THEIR PHYSICAL ENVIRONMENT OR ECOLOGICAL NICHE

IN DOING THIS THEY DEVELOP COMMON WAYS OF FACING THE SAME PROBLEMS, SIMILAR WAYS OF DOING THE SAME THINGS, SIMILAR ATTITUDES AND EXPECTATIONS, AND EVENTUALLY SIMILAR IDEAS, BELIEFS, WAYS OF THINKING AND PRACTICES – THIS IS THEIR CULTURE

THE NEED TO MAINTAIN HEALTH, TO PREVENT DISEASE, TO GUESS THE CAUSE OF DISEASE AND TO TREAT IT, DEVELOPS NATURALLY ALONG WITH OTHER ASPECTS OF THEIR CULTURE – THIS IS THEIR TRADITIONAL MEDICINE, WITH STRONG LINKS TO THEIR ENVIRONMENT AND THEIR CULTURE
TOWARDS CONCEPTUAL CLARITY...(2)

- It is important that this medicine be ‘indigenous’; medical ideas coming from abroad remain foreign until they have been accepted, domesticated and indigenized

- Traditional medical knowledge cannot be limited to knowledge of the medicinal properties of herbs, animal products or minerals; it covers all that is necessary to maintain health, prevent disease and treat ailments, both physical, psychic and mental

- TM is necessarily holistic

- To the society/community in question, this is their ‘conventional’ ‘mainstream’, ‘orthodox’ medicine, while incoming new ideas and practices can be described as ‘unconventional’, ‘unorthodox’, etc.
WHY THERE SEEMS TO BE PROBLEM

- In little more than a century, Western TMs have rapidly evolved on the wings of science and technology, resulting in ‘Western scientific medicine’

- Western SM is essentially dualistic, having introduced a sharp distinction between body/mind and opted to concentrate on the former

- Western SM has contracted an indissoluble marriage with commerce or the market.

- Concomitantly, the Western world has overrun the rest of the globe, using conquest, enslavement, colonization, proselytization, education
WHY THERE SEEMS TO BE PROBLEM (CONT’D)

- Western culture, Western systems and practices, science and technology, have become dominant or domineering all over the globe.

- However, Western scientific medicine should accurately be described as such and not as ‘conventional’, ‘orthodox’ or ‘mainstream’ in non-Western cultures/contexts.

- Countries/cultures whose TM has evolved satisfactorily and is still strong and dominant today are those which have escaped Western colonization, proselytization, education and domination – China, Korea, Vietnam.
AFRICAN TM AND ETHICS

- The fundamental ethical principles that guide, have guided, and should guide African TM are no different from those that have been identified within Western SM and given the following catchy names:

  - **Autonomy** or respect for the otherness, individuality, distinctiveness and dignity of other human beings and even non-human beings (plant, animal and inanimate)
  
  - **Justice** or fairness and equity in dealing with and treating others, as conceived under autonomy above
  
  - **Beneficence** or doing good, at least in the intentional/motivational orders; ensuring that acts/actions are motivated by the intention of achieving noble ends/aims/objectives
  
  - **Non-maleficence** or the avoidance of doing harm knowingly, deliberately or willingly

- **Moral equality** is the overarching principle that binds together and renders operational the above four fundamental principles; where it is not recognized or seriously taken into consideration, none of the above can get off the ground
BACKGROUND FACTS/FACTORS

- Over 80% of the populations of sub-Saharan Africa use TM as a means of healthcare.

- Owing to rapid and intensive urbanization, slow-down or breakdown in traditional systems, African TM has been invaded by quacks, charlatans, con-wo(men), and all manner of livelihood seekers.

- Western SM exists side by side with African TM.

- Most practitioners of Western SM have contempt for, a superiority complex against and an exploitative/colonizing attitude towards African TM.

- Traditional medicine practitioners or healers should be called by their proper name; they are not ‘witchdoctors’, ‘necromancers’, sorcerers, etc.
BACKGROUND FACTS/FACTORS...(2)

- African TM is basically an art rather than a science
- It is coextensive with personal/family primary healthcare
- It is holistic, aimed at the well-being of the whole composite human person – body, mind and soul
- It has no particular or direct connection with commerce or the idea of earning a living; its benefits for the practitioner were indirect and voluntary
- It is easily accessible and affordable to the populations
- African TM, like any other cultural practice is modernizable
Some of its practitioners undergo several years of apprenticeship under a master.

Others simply exhibit mastery of the art (divine endowment?) without any prior training (like in the case of some painters, carvers, drummers, sculptors, etc.).

In African TM there is no formal ‘research’ or controlled experiments.

It is, nevertheless, evidence based in the sense that a bone-setter who sets no bones will not have any patients seeking him/her for bone-setting.

It depends on, respects and preserves biodiversity.
SUBSTANTIVE ETHICAL ISSUES

- As a professional group, practitioners of African TM were controlled and restricted by many ritual taboos – such as never administering or making available a poison to anybody, never ever helping to end a human life, be it that of a foetus or a terminally ill patient, etc.

- Violation of such taboos was sanctioned by mystical loss of knowledge and special endowments or by personal misfortune or by a bad death.

- In an age where belief in God and other living spirits, let alone fear of divine anger and retribution, are on the decline; where belief in physical causes for physical effects is on the rise, taboos become an increasingly ineffective method of behaviour control.
SUBSTANTIVE ETHICAL ISSUES...(2)

- Should ‘research’ and formal experimentation be introduced into African TM?
  - By all means, but by whom for what purpose?
  - If done by the practitioners of the art, this is one way of modernizing it
  - If done by non-practitioners, it is hard to see how the benefits of such research could be integrated into the art to affect it positively
SUBSTANTIVE ETHICAL ISSUES...(3)

- Should research be conducted on African TM?
- Why not, but by whom and for what purpose?
- If by practitioners, it is only normal and right
- If by non practitioners, their purposes and good intentions need first to be demonstrated
- The principle of reciprocity needs to apply.
Should African TM be incorporated and merged with Western SM?

Such a merger is likely to signal the disappearance of TM, given the dominance and domineering spirit, the acquisitive instincts, exploitative reputation and global historical track record of SM.

It would result in a mono-culture in the domain of health and healthcare – an anti-value to pluralism and cultural diversity [Art. 12, UDBHR]

But African TM and Western SM can co-exist quite compatibly in the same context and even be of use to each other.
CONCLUSION

- United Nations agencies, especially UNESCO and the WHO urgently need to reform the conceptual framework and vocabulary of their discourses on TM to rid it of derogatory and downgrading terms and assumptions.

- Accepting the moral equality of cultures, systems, countries is the pre-condition for evaluating them correctly and dealing with them fairly and equitably.
ETHICAL ASPECTS OF TRADITIONAL MEDICINE

Thank you

Merci

Beri ven feyi
HUMAN CLONING AND INTERNATIONAL GOVERNANCE: PROGRESS REPORT OF THE IBC WORKING GROUP

Toivo Maimets
IBC Co-chair and Chairman, IBC Working Group on Human Cloning and International Governance

International Bioethics Committee 17th Session, Paris 26-27 oct. 2010
BACKGROUND

-Aug. 2001 UN GA 56th Session
Permanent Missions of France and Germany: *International Convention against the Reproductive Cloning of Human Beings*

-March 2005, *UN Declaration on Human Cloning*
84 countries YES
34 countries AGAINST
37 countries ABSTAINING

ambivalent wording
linking issues of reproductive and non-reproductive cloning
- 2007 UNU Institute of Advanced Studies: *Is Human Cloning Inevitable: Future Options for UN Governance*
  Further development of international governance is needed. IBC?

- DG UNESCO expresses his wish that UNU-IAS Report will be discussed by IBC

- January 2008 IBC Bureau includes the issue into Work Programme 2008-2009 and establishes a Working Group
THE WORKING GROUP

Prof. (Mrs) Ephrat Levy-Lahad (Israel)
Prof. (Mr) Ching-Li Hu (China)
Prof. (Mr) Gamal Ibrahim Abou Serour (Egypt)
Prof. (Mr) Fernando Lolas Stepke (Chile)
Prof. (Mr) Toivo Maimets (Estonia), Chairperson

MANDATE OF THE WG:

“...to explore whether there is any scientific, social or political change that would justify a new initiative at the international level, rather than to initiate another ethical and scientific analysis of the issue of human cloning.”
ACITVITIES OF THE WG

-Meeting June 30- July 2, 2008, Paris HEARINGS

-HEARINGS on the 15th Session of IBC
October 28-29, Paris
ACITVITIES OF THE WG


- Joint Session of IGBC (36 Member States) and IBC, Paris Oct 30-31, 2008

- REPORT of IBC on Human Cloning and International Governance (9.06.09)
REPORT OF IBC
ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE

This Report has been drawn up by the International Bioethics Committee (IBC) on the basis of the reflection carried out in 2008 on the issue of human cloning and international governance: in particular, the deliberations of its working group on this issue and discussions held during the fifteenth session of IBC and the joint session of IBC and the Intergovernmental Bioethics Committee (IGBC) in October 2008.
ACITVITIES OF THE WG

- Intergovernmental Bioethics Committee 6th Session
  Paris 09.-10.07.09

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REPORT OF IBC ON
CLONING AND INTERNATIONAL GOVERNANCE

SHS/EST/CIB-16/09/CONF.503/2 Rev. 9. June 2009

I. BACKGROUND AND MANDATE
II. THE UNU-IAS REPORT
III. PRESENT SITUATION OF THE INTERNATIONAL
    GOVERNING OF HUMAN CLONING
IV. WORK CARRIED OUT BY IBC IN 2008-2009
V. NEW SCIENTIFIC, LEGAL AND SOCIAL DEVELOPMENTS:
   A PRELIMINARY ANALYSIS
VI. SUMMARY AND CONCLUSIONS

ANNEX
Study on National Legislation concerning Human Cloning
PRESENT SITUATION:

OF THE INTERNATIONAL GOVERNANCE OF HUMAN CLONING

- 3 UN declarations:
  
  Universal Declaration on the Human Genome and Human Rights (1997)
  Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).

PRESENT SITUATION:

AT THE REGIONAL LEVEL

- Oviedo Convention (1997), Council of Europe
- Pact of San Jose, Costa Rica (1969)
PRESENT SITUATION:

National Regulations are diverse and reflect different cultural, religious, social and political backgrounds (see ANNEX)
IBC CONCLUSIONS:

On the basis of reflection and debate held in 2008-2009, IBC has been able to identify the following:

- Changes have occurred in the last three years that may have an impact on future development of international governance of cloning:

  1. new scientific developments such as research on induced Pluripotent Stem (iPS) cells and its application; production of sperm cells from embryonic stem cells (=in vitro derived sperm) etc.

  2. increased international exchange (both legal and illegal) of embryos, eggs and stem cells;
IBC CONCLUSIONS:
Changes have occurred

3. increased public sensitivity and awareness
Together with the development of national regulations of governance of human cloning and embryo research in general.
IBC CONCLUSIONS:

- The terminology used in the bioethical debates is misleading and does not adequately describe the technical procedures used (or potentially to be used) today. An in-depth analysis aiming at re-defining this terminology according to the new developments in human embryo research would be highly beneficial.

- National regulations of governance of human cloning and embryo research in general adopted so far confirm the convergence of views on the refusal to adopt legislation or guidelines permitting reproductive cloning, while they still show variations on the legitimacy of human cloning carried out as part of research agendas.
IBC CONCLUSIONS:

- The dissemination, discussion and debate on cloning issues at the international level remain essential to foster public sensitivity and awareness-raising, so that all countries, including the developing and least developed countries, can participate and put forward their concerns regarding this new technology. These activities are very important and should be actively pursued in parallel with the other possible normative developments.
IBC CONCLUSIONS:
- Many countries, in particular developing ones, still lack specific regulations on human cloning. A clear and effective regulation of reproductive human cloning at the international level would greatly benefit the safeguarding of the interests of these nations and their peoples.

- While the technology required to give birth to a human being by cloning is not yet available, it could be developed in the near future and the existing International non-binding texts relevant to human cloning (i.e. the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997 and the UN Declaration on Human Cloning of 2005) are not sufficient to prevent human reproductive cloning.
IBC CONCLUSIONS:

- The issues surrounding the international governance of human cloning cannot be ignored and a focused international dialogue is crucially needed.

- UNESCO is in a privileged position to continue this reflection in a way that accommodates the multiplicity of views on the issue and explore the ethical aspects of new scientific developments and their impact on the present international normative framework.
IBC CONCLUSIONS:

- This should be developed together with other bodies of the UN, in particular WHO, and national scientific organizations, bioethics entities, the civil society and all other groups that could be concerned.

- Within this context, IBC is ready to continue to play its role in the international bioethics system and the debate on human cloning and its international regulation, together with the Intergovernmental Bioethics Committee (IGBC).
IBC CONCLUSIONS:

- Finally, IBC considers that UNESCO could develop specific strategies and materials to promote international discourse on this topic and more actively encourage and support national research organizations/academies and national bioethics committees in disseminating and debating cloning issues.
SIXTH SESSION OF THE INTERGOVERNMENTAL BIOETHICS COMMITTEE (IGBC)
Paris, 9 – 10 July 2009
10. Acknowledges and values the work carried out by IBC on human cloning and international governance, congratulates IBC for an inclusive and balanced report on the topic and invites the Secretariat to continue updating the annex to this document.

11. Concurs with IBC that an international dialogue on the international governance of human cloning is needed and should be pursued, and that the dissemination, discussion and debate on cloning issues at the international level remain essential to foster public sensitivity and awareness-raising, with a special attention to developing countries.

12. Supports the assessment of IBC that an in-depth analysis aiming at reviewing the terminology for human cloning according to the new developments in biomedical research would be highly beneficial.

13. Suggests that in pursuing its reflections on human cloning, IBC considers reviewing the terminology for human cloning as well as a wide range of related issues such as other possible options for its regulation and the vulnerability of women.
Bureau of IBC meeting, March 2010

to continue the work on human cloning and international governance in 2010-2011 by confirming and expanding the working group

Professor (Mr) Toivo Maimets, Chairperson of WG
Prof. (Mr) Abdallah Daar,
Prof. (Mr) Qingli Hu,
Prof. (Mr) Fernando Lolas Stepke,
Prof. (Mr) Takayuki Morisaki,
Prof. (Mr) Fawaz Saleh and
Prof. (Mrs) Jeanine-Anne Stiennon.
The Working Group received mandate to focus on three main areas:

- terminology and its ethical impact (including reviewing the Report on the use of embryonic stem cells in therapeutic research, Ref. BIO-7/00/GT-1/2 (Rev. 3) of 6 April 2001);

- different options for legal regulation of human reproductive cloning (including the possibility of a moratorium); and

- proposals for dissemination activities concerning the issue of human cloning and its governance.
Meeting of the Working Group, June 7th-8th 2010, Paris

First draft Aug. 2010
REPORT OF THE IBC WORKING GROUP
ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE

This report has been drawn up by the IBC working group established by the Bureau of the Committee within the framework of the work programme of IBC for 2010-2011

It does not pretend to be exhaustive nor prescriptive and does not necessarily represent the views of the Member States of UNESCO.
1. INTRODUCTION

2. NEW SCIENTIFIC DEVELOPMENTS UNDERLYING THE RE-EVALUATION OF EXISTING INTERNATIONAL GOVERNANCE OF HUMAN CLONING

3. THE ISSUE OF TERMINOLOGY

4. ANALYSIS OF ALTERNATIVE METHODS OF INTERNATIONAL GOVERNANCE OF HUMAN CLONING

5. DISSEMINATION

6. EXECUTIVE SUMMARY
The IBC Working Group has been able to identify the following findings concerning international governance of human cloning:

a. **New scientific developments**

New scientific developments in cloning technologies, such as the use of induced pluripotent stem cells and production of synthetic DNA create a new dimension of ethical debate and call for the re-evaluation of the existing international system for governance of human cloning.
b. Terminology

• Although the term “reproductive cloning,” indicating the production of identical human beings is scientifically incorrect, it should be retained since it is engrained in global discourse and already features in a number of national legislations and international guidelines. Instead, it would be advisable to formulate a universally acceptable definition for “reproductive cloning” and to conceptually delink it from other types of cloning.

• One possibility is to define today human “reproductive cloning” as using the linear DNA nucleotide sequence of an existing human being to create an embryo, which is implanted into womb with the purpose to produce human baby.

This definition underlines the importance of intent behind cloning technique in reproductive cloning.
The use of the terms “therapeutic” or “research” cloning to describe the process of obtaining pluripotent stem cells should be avoided.

Instead, a term that describes the process rather than the intention behind it, such as “derivation of pluripotent cells” (by somatic cell nuclear transfer; reprogramming (e.g. iPS) or any other existing or future technology) can be used. This terminology has an advantage of being descriptive, technically accurate, simple, easily understandable, and capable of incorporating any future scientific and technological developments. It also allows more nuanced and differentiated ethical analyses, depending on which technology is under scrutiny.
c. **Options for international governance**

The existing legal framework applicable to international governance of human cloning is based on national and regional legislation and guidelines that prohibit various practices related to human cloning, as well as on non-binding instruments adopted by international organizations, such as the Declarations of UNESCO. Any moratorium on cloning under international law will have to relate to the existing norms in this area.

The current non-binding regulations can not be considered as sufficient in addressing the challenges posed by the contemporary developments related to human cloning. Therefore, there is a clear need to advance processes towards a more robust mechanism, such as a moratorium or a convention on prohibition on human reproductive cloning.

As an international organization that has a solid track record in standard-setting and capacity-building in bioethics, UNESCO provides the best global platform to initiate the processes towards a moratorium or a prohibition on human reproductive cloning under international law. Today, due to the sufficient consensus amongst governments of Member States against human reproductive cloning, it is plausible for UNESCO to move towards a convention prohibiting human reproductive cloning.
d. Dissemination

In order to promote the dissemination of information and to raise public awareness of the issues related to human cloning and its regulation, UNESCO can pursue several actions, including:

• Creation of a database to serve as a clearinghouse of information and to monitor new developments that affect the ethical aspects of human cloning debate; and

• Organization of a major Conference under the auspices of UNESCO, dedicated to the theme of human cloning and international governance.
THANK YOU