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Item Type	Article
Authors	Hwi, Kim Kah;Chuan, Chin Kah;Goto, Munehiro
Publisher	Eubios Ethics Institute
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Download date	2026-07-05 10:18:11
Link to Item	http://hdl.handle.net/20.500.12424/170918

Eubios Journal of Asian and International Bioethics

EJAIB Vol 15 (3) May 2005 ISSN 1173-2571

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31 Colwyn Street, Christchurch 8005, New Zealand
c/o Darryl Macer, RUSHSAP, UNESCO Bangkok, 920 Sukhumvit Rd, Prakanong, Bangkok 10110, THAILAND

Eubios Ethics Institute World Wide Web: http://www.unescobkk.org/index.php?id=41
Official Journal of the Asian Bioethics Association (ABA) and the IUBS Bioethics Program

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Send papers to the editor in electronic form if possible. Please use reference style used in News section, do not use automatic footnotes or endnotes. Papers are peer reviewed.

Editorial address: Prof. Darryl Macer
RUSHSAP, UNESCO Bangkok,
920 Sukhumvit Rd, Prakanong,
Bangkok 10110, THAILAND
Fax: Int+66-2-664-3772
Email: asianbioethics@yahoo.co.nz
d.macer@unescobkk.org

Deadline for the July 2005 issue is **1 July, 2005**.

Editorial: New website

- Darryl Macer, Ph.D.
Director, Eubios Ethics Institute
Affiliated Professor, United Nations University

If you have looked at the Internet recently you should have noticed that the Eubios website is shifted to Bangkok, and no longer on the Tsukuba website. Please move your booklinks. Note that all the old files are available on the new site: **www2.unescobkk.org.org/eubios** but all end with htm no longer using html as a suffix.

***EJAIB* - Aims:**

1. *EJAIB* is the official journal of the **Asian Bioethics Association** (ABA) and the IUBS Bioethics Program.
2. To **review and update news and trends in bioethics** from around the world (about 1000 papers each issue). Bioethics is broadly defined as life ethics, including both medical and environmental ethics, and environmental, ethical, legal and social issues arising from biotechnology.
3. To pay particular attention to issues raised by genetic and reproductive technology, and other news for the International Association of Bioethics **Genetics Network**. To publish letters on such topics, promoting international debate.
4. To publish research papers, and relevant news, and letters, on topics within **Asian Bioethics**, promoting research in bioethics in the Asian region, and contributing to the interchange of ideas within and between Asia and global international bioethics. Asia is defined for the general purposes of this journal as the geographical area, including the Far East, China, South East Asia, Oceania, the Indian subcontinent, the Islamic world and Israel.
5. To promote **scientific responsibility**, in coordination with **MURS Japan** (Universal Movement for Scientific Responsibility); and the International Union of Biological Sciences (**IUBS**) **Bioethics Program.**

Declaring Death, Giving Life

David Cummiskey, Ph.D.
Bates College
Maine, USA
Email: dcummisk@bates.edu

Abstract

After many years of reflection and debate, there is a clear international trend, indeed a near consensus, to endorse as a matter of ethics and law the modern biomedical conception of brain death as an alternative to the traditional conception of death. Alireza Bagheri has surveyed the current state of the law governing organ donation in eight Asian countries. His research shows that for the purpose of facilitating organ donation, the following countries have adopted the biomedical standard of brain death: Turkey (1979), Saudi Arabia (1986), Singapore (1987/2004), Philippines (1991), India (1994), Japan (1997), Korea (1999), and Iran (2000).(1) In addition, there is an active and ongoing movement in China to also enact a brain death legal standard.(2) On the other hand, the new definition of brain death always has been controversial.(3) It is worthwhile to pause and survey the arguments for and the objections to the now popular conception of human death as brain-death. In light of the arguments over the definition of death and also of a survey of the different legal constraints on organ donation in different countries, the key elements of a model policy that incorporates the best of all of these different approaches will be defended. This model policy incorporates a pluralist standard of death, which allows individuals to choose a cardio-respiratory, whole brain, or higher brain conception of death. It also includes what I call a donor-recipient priority principle that gives priority to organ donors as recipient of organ transplants. Rather than requiring an organ donor card, a model policy should be based on a principle of presumed consent for organ transplant and a principle of surrogate consent. Finally, although a principle requiring family consent is too restrictive, family consultation in these important decisions should be encouraged by physicians and public policy.

The Definition of Death

There was a time when we thought of life and death to be as clear as the distinction between black and white. The light is ON or the light is OFF. A very dim light is still on; it may be barely on but it is still on until it is off. So too, a person may be barely alive until they are really "gone", beloved still, but "departed" nonetheless. Modern bio-medicine has shaken up this old conviction and it has made us confront more directly the grey area where the body may live on after the person is gone.

This is not to deny that issues of personal identity and of the relation of mind and body, the soul and its vessel, are as old as human self-reflection. What seemed clear, however, was that to be alive was to have a beating heart and the breath of life filling one's lungs. More precisely, the **Traditional Definition of Death**, now often called the **Cardio-Respiratory Standard**, maintained that *death is a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration and pulsation.* Some cultural and religious traditions put more emphasis on the breath of life while others emphasize the flow of bodily fluids, especially the circulation of blood. But these are so closely linked biologically that it makes little practical difference whether the flow of blood or the breath of life is thought to be primary. If we stop breathing our heart stops too and if our heart fails we shall stop breathing soon enough. It turns out, however, that the two are linked in a particularly interesting and salient way. If we force the lungs to "breathe" the heart will reflexively pump and maintain the circulation of blood. Respiratory function causes circulation and the "vital functions consequent thereon." As a result contemporary respirators can keep the body alive even when the brain is dead. Indeed, in principle, on a respirator with obvious additional interventions, a decapitated body could continue cardio-respiratory function. In such a state, whatever we say of the continued biological functioning of the body, the person is clearly gone and dead. Indeed, the very idea is an inhuman affront, sacrilegious, an indignity. This macabre concept does, however, typically lend some intuitive support for the otherwise unintuitive concept that, despite the pulsating and breathing body, when the brain dies the person is dead.

But why should we care about this theoretical and conceptual distinction? If it were not for organ transplantation, our interest in these modern biological possibilities would probably be confined to the philosophy departments – surely adding new fuel to disputes about the metaphysics of personal identity and the philosophy of mind, but of little interest to physicians and the writers of laws. Organ transplantation, however, has led to lively debates over refining our concept of death. The philosophical debate was perhaps formally started in1968, in the West with the Ad Hoc Harvard Committee studying the concept of Death,(4) and in the East Asia with the controversy in Japan over whether organ transplants involved illegal experimentation on human subjects.(5) It has also been significantly shaped by the US President's Commission report "Defining Death" in 1981.(6) Although these particular philosophical and political discussions are important the issue and problem is clearly really driven by the dual powers of modern medicine (1) to keep the body alive when in an important sense the person is dead and (2) to save the life of a vibrant living person when the body (or at least part of it) is dying.

The organ donor from death gives the gift of life. This is really an amazing and wonderful thing: A living body with a brain that has died gives new life to a person with a dying body. The promise and value of life, the compassion of giving one's own body to save life, these are values and virtues embraced by all traditions; all religions; and most people. Yet our understanding of what is death, of what it is that we value when we value life, and of how we respect the dead, are also implicated by redefining death (and by the transplantation of the dead person's organs to save another's life). This is heady stuff. Individual people, religious traditions, and societies may come to different conclusions about what is right with respect to these issues, but the underlying values and the competing principles at issue are actually quite clear. It is the goal of this paper to clarify these issues, so that we can make difficult decisions with the clearest possible sense of the issues that are at stake.

Although there has indeed formed a consensus around the Whole Brain Standard, it is actually unclear why this conception is preferable to either the Traditional Cardio-Pulmonary Standard,(7) or alternatively, to a Higher Brain Standard of death,(8) which focus on the biological basis of the capacity for consciousness. The simple idea supporting a Higher Brain Standard is that once we are motivated to switch to a brain based conception, which focuses on the death of the person, it is the irreversible loss of the capacity for consciousness itself that should be the focus of the concept of death; and not the death of the whole brain which even includes the brain stem. As so many Asian countries switch from a cardio-pulmonary to a brain death standard, and in the midst of China's discussion of a brain-death law, it is worth pausing and reflecting on the important objections to this recent trend.

It has been only 50 years since mechanical respiration has made possible the reality of patients with spontaneously beating hearts and no significant brain activity. It has been less than 40 years since the first "living wills" appeared. The first Hospice was established in London in 1967 and the same

year, in South Africa, Christian Barnard and in Japan, Dr. Juro Wada, successfully performed the first heart transplants from "brain dead" donors. In 1968, Harvard University formed an Ad Hoc Committee to explore criteria for brain death, with an explicit eye to the promise of organ transplantation. The process of reconsidering the definition of death culminated in the West in1981, when the President's Commission Defining Death in the United States proposed the following **Uniform Determination of Death Act:** *An individual who has sustained either (1) irreversible loss of circulatory and respiratory functions or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.* In Japan, in 1983, an ad hoc Committee on Brain Death was established by the Ministry of Health and Welfare, and it issued its report outlining the criteria for establishing brain-death in 1985. The concept of brain-death as human death remained controversial in East Asia and laws recognizing brain death were not enacted in Japan until 1997 and in Korea until 1999. The Chinese Ministry of Health, in 2002, released draft criteria for establishing brain-death but legislation has not yet been enacted. Despite controversy, in a short 50 years, the concept of brain-death has spread across the globe crossing and transcending countless initial cultural barriers. I will not here explore the cultural variations that exist in redefining death, instead we will look to the universal, transcended issues that all cultures must confront when addressing this complex question.

The Uniform Determination of Death Act conjoins a conception of irreversible loss of brain function with the traditional cardio-pulmonary standard. By including the traditional standard, it allows the determination of death to continue to occur in the vast majority of most cases in accordance with current medical standards, and yet by incorporating brain-death too, it recognizes that a person whose brain is dead and whose body is sustained exclusively by external artificial means has indeed died. On this definition, brain death is sufficient for death, even when circulation and respiration continue by artificial means. Since brain death always results from the irreversible loss of circulation and respiration, brain death is the primary standard of death under this new uniform definition. Yet under this dual standard for the determination of death, the criteria and the (sophisticated and expensive) medical tests to establish brain death are unnecessary for the *determination* of death in the vast majority of cases. The underlying standard of death is death of the brain and it is explicitly states that death requires the death, the irreversible loss of significant function, of the whole brain.

The Whole-Brain Standard *requires the irreversible cessation of the entire brain: the cerebrum and cortex, the cerebellum, and the brain stem composed of the midbrain, pons, and medulla oblongata.* Why then should we redefine death in this way?

There are two main reasons typically given in support of the standard of whole-brain death. First, the brain is the locus of death, it is argued, because it is the "primary organ" of distinctive human life, of our personhood, and our distinctive humanity. We will turn to this idea in a moment, but for now it should be clear that what is distinctive and special about human life (whatever it is one takes this to be) can be irreversibly lost prior to the death of the entire brain. If only the brain stem lives on, and all else is lost, the person is just as clearly dead in this case as the case of whole brain death. So why require the irreversible cessation of functioning of the entire brain?

Thus, second, rather than focusing on what is distinctive of our humanity, the standard of whole-brain death is based, it is argued, on the biologically distinctive role of the brain in maintaining and sustaining human life. The brain is essential to the integrated functioning of the body's other major organ systems. The brain including the lower brain and brain stem is the command center of the body. Indeed, bodies with only lower brain-function can breathe, metabolize, maintain temperature and blood pressure, and also sigh, yawn, track light, and react to pain or reflex stimulation. It is thus argued that a person with continued lower brain function is thus clearly still a living, human life. It is counterintuitive indeed to declare such a living body to be dead.

It has been argued that this second argument actually supports a Brain Stem Standard of death, since it is the brainstem that is responsible for the integrated biological functioning of a human being. The irreversible loss of brainstem function is biologically linked to the irreversible loss of the capacity for consciousness and of independent cardio-respiratory function, it is argued, and so it marks the death of an independently functioning human being. The standard of brainstem death received significant attention in the United Kingdom in the late 1970s, and it was adopted as the standard of death in India in 1994.(9) Nonetheless, whatever its distinctive merits, since the concept of whole brain death includes brainstem death, we shall set it aside as a distinctive position and focus, in this discussion, on the more common, indeed near universal, whole-brain standard.

There are, however, complexities and problems that are too often ignored by those defending the whole-brain standard of death. First, in practice "whole" brain death actually involves loss of "significant" functions because cellular level functions, nests of cells and super cellular-level functions remain long after the "brain" has irreversibly stopped functioning. The same, of course, is true of any part of the human body. There is insignificant biological and cellular functioning that continues long after the irreversible cessation of cardio-pulmonary function. Whatever the definition of death, we must acknowledge that the organs and cellular activity of the body dies off slowly after the person has died. When significant function is lost, the person is dead, despite the human biological "life" that continues during the slow process of cellular death, necrosis, and decay. In the case of brain death, when measuring to see if there is continued neural activity, small (2 microvolt) electrical potentials on an EEG are thus discounted by "whole-brain" determinations of death. A flat EEG is easily achieved by the choice of the sensitivity setting on the EEG machine.

It is worth pausing here and noting that these considerations are used as a rational for focusing on the brainstem in particular, rather than the whole brain. It is the loss of the integrated biological functioning of the brainstem and not other isolated functions that is significant, it is argued by defenders of the brainstem standard. If this is the case, the whole-brain and brainstem conceptions are equivalent in that the "significant" functions emphasized by the whole-brain defenders are instantiated by the brainstem. On the other hand, the whole-brain conception has the advantage of clearly including higher brain cognitive functions and the capacity for consciousness in its conception of what must be lost for death. If it were possible, as is clearly imaginable, to artificially replace all brainstem functions, so that the brain stem could "die" in a conscience perhaps lucid person, such a person would clearly still be a live. Of course is biological brainstem function is in fact necessary for consciousness, then this is not an empirical possibility. Nonetheless, the whole-brain standard makes more explicit that death requires cognitive death.

On the other hand, this raises the question: why not focus on what is truly the "significant" function of the "whole" brain, that is, the cognitive capacity for conscious awareness? Indeed, advocates of a Higher-Brain Standard, in criticizing the whole-brain standard, emphasize that the continued functional activity that occurs when only the brainstem still functions is essentially reflex activity that is on a par with reflexive spinal cord activity. Like the supercellular functions that remain after a declaration of "whole" brain death, this activity also simply is

not "significant" functioning. This activity includes breathing, metabolizing, maintaining bodily temperature and blood pressure, and the body may also sigh, yawn, track light, and react to stimulation. Although it is natural to have an emotional response to a subject displaying this type of spontaneous biological, these continued functions simply do not indicate any conscious awareness or any significant cognitive functioning. Of course, a brain dead body on a life support also reflexively continues functioning. Whole Brain advocates argue, however, that, since these are simply spinal cord reflexes, they do not indicate continued functioning of the brain. This, however, simply highlights the problem: If *spinal cord reflexes* can be ignored, as is maintained by whole-brain accounts, why not the *brain stem reflexes* as well? Indeed, the spinal cord is a continuation of the brain stem and so there really is no significant difference between the one and the other. When higher brain function is irreversibly lost, the being that remains is in limbo between life and death. Complex biological functions remain but all possibility for even the most minimal conscious awareness is forever lost.

The reason the uniform standard of death gives primacy to the brain is that its death marks the death of an individual with consciousness. The definition of death is important, of course, because we are concerned with protecting each individual person from premature declarations of death. It is the individual person who is the subject of our moral concern, and therefore the focus should be on the death of a person. To be a person, and not a mere thing, involves many cognitive and higher order mental capacities, but the most basic and essential capacity is that a person has the capacity for conscious awareness.

These considerations and the above objections to the whole brain standard suggest that we should adopt a "higher-brain" standard of death. According to **The Higher-Brain Standard**, t*he person dies when there is an irreversible cessation of the capacity for any from of consciousness, and consciousness is forever lost with the irreversible cessation of cerebral, higher-brain, functions.* If we are moved to modify the traditional cardio-pulmonary concept of death, it is the continued capacity for conscious life that should be our focus of concern. Although it has received little support from medical associations and public officials, the higher-brain standard is the philosophically favored standard of brain death.

So why is it neglected in favor of the philosophically weaker whole-brain standard? Some critics raise concerns over the criteria for measuring higher-brain death. The irreversible cessation of all brain activity can be measured and determined with reasonable certainty, but *irreversible* loss of consciousness is notoriously much harder to determine. Defenders of the higher-brain standard respond that first, there is sufficient accuracy in measuring persistent loss of all consciousness, and, second, that this is a clinical issue but not a challenge to the definition itself. The latter point is indeed important. We need to clearly distinguish what we are trying to determine, the death of the person, and the criteria we use to make this determination. In the case of the traditional definition of death, there have been many cases of mistaken declarations of death. But this does not undermine our confidence in the traditional standard of death itself. What we should conclude instead is that a level of conservativism is called for when making a determination of higher-brain death. Although on this *standard* we are indeed dead when the capacity for consciousness is forever lost, the *criteria* determining death could be based on the irreversible cessation of all significant neural activity of the cerebrum, cortex, and the cerebellum; essential all brain activity other than mere brain stem activity.

A related concern takes the form of a classic "slippery slope" argument: If consciousness is what matters for life, does this not also (unacceptably) imply that those with severe dementia, and thus marginal or significantly diminished consciousness, have also lost their personhood. If we are interested in the death of the person, why aren't they dead? This is an important objection. In response, we must draw a distinction between the irreversible loss of the person, as a subject with a continuous personality, from the death of the person. To take one all too common example, although in one sense we do lose our loved one, when they are suffering from advanced dementia, they are still clearly a conscious living person. These types of cases show that it is a mistake to focus on loss of personhood in the definition of human death, but they do not present a challenge to consciousness based conceptions of death. Quite simply diminished consciousness is still consciousness, and so, on the higher-brain standard, whenever there remains the possibility of any form of consciousness, the person is not yet dead. Without embracing dualism, we can all see a clear sense in which human life involves in an important sense the union of a conscious mind and a living body.

Nonetheless, however strong these philosophical arguments maybe, the higher brain standard is very counter-intuitive. Although it is a stretch, and somewhat of a contradiction, to think of a brain dead body on "life support" as already dead, it is even harder to think of a body whose higher-brain is dead but yet that is still naturally (reflexively) breathing as dead. This is the problem of the still breathing but dead patient. Some respond to this problem by arguing that we need to now distinguish the death of the person from the death of the biological organism. The person dies when the possibility of consciousness is forever lost. The living body that remains when all consciousness is forever lost is the person's "living remains." In many ways this language already captures how many people do think in this type of unusual and difficult cases. When a brain-dead patient on life-support dies we realize that it is for the best because our loved one was already gone. If a society ever moves to a higher-brain standard, it may also come to seem natural to distinguish the death of the person from the death of the rest of their body, but for now the mere fact that the persons body is only artificially sustained and that it dies too when life-support is removed keeps us from having to conceptualize the life that remains when a person is brain-dead. But does the mere fact that life is artificially sustained really make a different to the status of a body as living or dead? Is not the body just as a live when life is artificially sustained?

To be clear, this is not to deny the permissibility and indeed reasonableness of turning off all life support whenever brain-death, either whole-brain or higher-brain, has occurred, and letting the remaining body die. When a person has forever lost the capacity for consciousness, it is hard to see how (barring fantastical assumptions) we can benefit them in any way by keeping them alive. We here have an unusually clear case of medical futility. In the case of higher-brain death, the withdrawal of all life support, including intravenous nutrition and hydration, may be appropriate and reasonable (perhaps depending on the values and principles of the patient). The point is simply that we should not confuse the decision that it is reasonable to let a patient die with the quite different judgment that a patient has already died. Yet here again we face confusion when it is the fact of brain death that leads us to believe that it is reasonable, human and natural to end all forms of life-support.

To summarize:

- **The Traditional Cardio-Respiratory Standard** of death has the intuitive advantage of identifying life with the vital functions of pulsation and breathing that are the clear indicators of and a necessary condition of life. Indeed intuitively the lack of pulsation and respiration may also be a necessary condition of death. The problem is that these conditions do not seem to be sufficient for life when the whole brain (or the higher brain) is dead.

- **The Whole Brain Standard** has the clear advantage of identifying death with what seems to be the body's commanding vital organ and the seat of consciousness. The problem with the traditional standard is that the life of *the body* can survive beyond the point where it can sustain the life of *human being* as a possible subject of consciousness. A living body with no brain function is not the human life that is the subject of our moral concern. So the continued possibility of a functioning brain is a necessary condition for continued life. The problem is that, first, the higher-brain, not the whole-brain, is the necessary basis of continued consciousness. A body with only a living brain stem is biologically incapable of sustaining consciousness. We care about the brain because without it the person is forever gone, but the person is forever gone when all but the brain stem remains. The second problem is that the whole-brain standard arbitrarily draws a distinction between brain stem activity and spinal cord activity that survives the death of the brain stem, yet there is nor relevant difference between these activities. From a biological and functional point of view it is arbitrary to draw a line through the spinal cord at the base of the brain. This is a conceptual distinction with no significant biological basis.
- **The Higher Brain Standard** has the clear advantage of identifying death directly with the capacity for continued conscious life. A human body with only brain stem function is truly an automaton completely incapable of any form of conscious life. The brain must be able to sustain conscious human life if it is described as still having significant function. Just as super-cellular higher-brain activity and spinal cord reflexes are not "significant" function for whole brain advocates, so too, and for the same reasons, brain stem activity alone is not significant brain function for the purposes of declaring the death of a person. The problem with this seemingly philosophically sound distinction is that it is overwhelmingly counter-intuitive to declare dead an independently breathing, pulsating, and functioning human body. Although we (societies) may someday get use to the idea of a person's "living remains," common sense and thus public policy is still far from that day. This suggests, however, that an independently breathing body is sufficient for life. But what is the vital difference between a body living with the support of a respirator and one off life support? A conscious person is no less alive simply because they are dependent on life support. Both are equally alive – that's why it's called "life" support. Since it is hard to see why it should matter if cardio-respiratory activity is naturally or artificially sustained, some argue that only the traditional definition of death in fact captures our intuitive distinction between life and death. This suggestion, however, brings of full circle and back to the problems with the traditional standard of death.

Thus we see that the distinction between Life and Death is just not as clear-cut as we assume, and would like, it to be. The truth is that there is the death of the person, the death of a conscious life, the death of all but the brain stem, the death of the whole brain including the brain stem, the death of cardio-respiratory function, and the death of the persons' viable organs and ultimately of all cellular life. Declaring death is always contextual and specific. Furthermore, these competing standards of death reflect different individual principles and spiritual beliefs about the nature and essence of human life.

Giving Life

Things would be simpler if it were only the determination of death that was at stake, but the promise of giving life through organ donations has always added an urgency and direction to these debates. As the result of basic biology, living organs need continued cardio-respiratory activity. We thus maximize the success of organ transplantation by harvesting the living organs when the brain dead body is still on life-support. In many cases, this leads to the practice of establishing first that the accepted medical criteria of whole-brain death have been met, second, turning off life-support, so that traditional cardio-pulmonary death occurs, and declaring death, and, third, resuming life-support to maintain the organs during the transplantation operation. In this roundabout way, what has been called, the "dead donor rule" for transplantation is supposedly satisfied.

Some have suggested, Truog most explicitly,(7) that it would be preferable to return to the traditional cardio-respiratory standard of death, but abandon the dead donor rule for organ transplantation, or more accurately that we should just specify that a determination of brain-death is sufficient for organ transplantation. Defenders of the traditional definition have always focused on the continued moral standing of the living human biological organism. In support of this, they point out the near universal rejection of the use of brain dead bodies for blood banks or organ farms. Indeed we would never bury or cremate a brain-dead but still breathing body, they argue. The total unacceptability of these ideas, they argue, reflects our clear sense that the person, and not just a body, is still alive.

The rejection of such macabre ideas, however, may simply reflect our normal sense that we should respect a person's body, in this case the "living remains," even after death. In all cultures there are rituals and rules about how one respects the dead. The near universal aversion to turning a dead person's body into a blood bank may simply reflect the incompatibility of this idea with cultural rituals and rules, and need not reflect a clear judgment that the person is still alive. Indeed, a major conclusion that we can draw from these issues is that our "clear" traditional intuitions about death are simply *not prepared and attuned* to deal with the moral complexities of truly novel medical and technological possibilities like the giving of life by transplanting the living organs of a brain-dead body, which is itself maintained and sustained by modern medical technology.

Here is a proposal: First, we should follow the Japanese example and adopt a **Pluralist Standard of Death**.(10) The law in Japan allows an individual to choose either a brain based or a traditional cardio-respiratory standard of death. We would expand this to include all three standards of death. A pluralist standard acknowledges and recognizes that there is no biological fact of the matter that distinguishes *significant* human life from death, that there are *three clear positions* that one can take on this issue, that it is a *spiritual matter* or *value judgment* that determines one's view of this question, and thus that different individuals should be allowed to choose from among the three different standards of death. The individual's choice could easily be added to living will documents and/or organ donation cards. More generally, as a matter of public policy, organ donor status and preferred definition of death can easily be indicated on driver's licenses or identity cards. As a default standard, either the traditional standard as used in Japan, or the whole-brain standard, could be used. The whole-brain standard has the advantage of being the moderate position, and the most intuitive position (in that, unlike the higher-brain standard, it does not judge a body with independent biological functioning as dead, or claim that the person is not dead when there is no brain function and no possibility of independent cardio-respiratory function, as maintained by the cardio-respiratory standard). Nonetheless, the decision on the default standard, for an individual who has not expressed a preference, is really a matter of public policy. In respecting community and individual values, it clearly makes sense to choose the standard of death most widely accepted in the society, and not surprisingly in most societies the whole-brain standard of death for organ transplantation is accepted by about 70-80% of the population. A society might, however, opt for any of the three standards of death.

A Pluralistic Standard of Death does add complexity to a legal system, and Alexander Capron argues that it thus "sows confusion and invites litigation."(11) The problem here is that

a person may be declared dead under one standard but alive under another standard, and this can give rise to controversy and indeterminacy in the criminal and civil law. The obvious legal issues here include homicide, wrongful death, inheritance, life and health insurance benefits, and marital status.

Despite these initial concerns, however, it is not clear why "pluralism about death" raises any serious problems: First, inheritance law involves the personal transfer of property and so clearly fits with the individual or family's judgment about the nature of death. Second, life and health insurance is either a contractual or social entitlement and should thus be governed accordingly. Third, the issue of marital status raises its own special issues that will clearly depend on cultural norms in different societies. Fourth, in cases of the determination of homicide and wrongful death, the societies default standard is the obvious "neutral" legal standard for prosecution of crimes and adjudication of harms. Finally, although, it is likely that these particular social and legal issues can easily sort themselves out overtime, and that they need not give rise to confusion or unnecessary litigation, one obvious simpler solution is to have one standard of death, the default legal standard, serve as the State's Legal Standard for purposes of the criminal and civil law.

Alternatively, since the harm of death is clearly present in all cases in which a person suffers irreversible loss of the capacity for consciousness, the standard of higher-brain death may actually be the best legal standard of death for use in the criminal and civil law of homicide and wrongful death. It clearly seems appropriate to treat an action (or culpable omission) that causes an irreversible loss of the capacity for consciousness as equivalent to the harm of death for purposes of sanctions and civil damages. The problem here, however, is that the criteria for discerning higher brain death are more controversial and thus could lead to greater indeterminacy than either the whole brain standard or the cardio-respiratory standard. So we are left with a public policy decision of how a society decides to balance the need for determinacy in the law and the demands of retribution and rectification for serious harm. Societies can reasonably disagree on how to balance these values.

From the start in 1967, the primary social goal motivating the rethinking of the standard of death has clearly been the concern to facilitate the possibility of life-saving organ donation. By switching our focus, from the definition of death, directly to organ donation, we may more directly and effectively adopt policies that facilitate and encourage organ donation. Here we find some interesting and promising proposals that are already on the books in Asian countries and that when brought together offer a model for organ donation policies:

Donor-Recipient Priority Principle: In addition to standard policies for the allocation of organs like medical need, medical utility, and first come first serve, all countries should follow Singapore's lead and give recipient priority to declared organ donors over other persons who have not consented to be an organ donor (or where applicable who have signed an objection to donor status card). This is a simple matter of reciprocity (they who will not give shall be the last to receive), and also recognizes that conscientious objectors have no grounds for complaint when they must live (or die) by their own principles. Of course the fair implementation of such a policy will depend on the other policies in place that facilitate the identification of willing donors. Giving first priority to declared donors may serve to make individuals pause and reconsider the basis of their own refusal to offer the gift of life to others. I suspect more people will consent to organ donation when they consider the consequences of refusal. Although this may seem to be a harsh appeal to self interest, this policy simply asks that we do unto others as we would have others do unto us -- and this principle of moral refection is embraced by Confucian, Buddhist, and Christians alike. Indeed, it is also reflected in Kant's categorical imperative and in utilitarian principles of impartiality and concern for the good of all.

In addition, Singapore has adopted a **principle of presumed consent** for organ donation. The assumption is that a reasonable person would not object to donating their organs after death so as to save the lives of others. Rather than signing an organ donor card, one signs an organ objector or refusal card. This is analogous to the model of presumed consent that is common practice in medical emergencies. We assume that a person wants to be saved unless they have a DNR order, or perhaps a living will (or medical bracelet) stating that they are a Jehovah's Witness and conscientiously object to blood transfusions. The assumption is that a reasonable person would want to be saved and thus would consent if they could. Similarly, for organ donation we should assume that a reasonable person would want to help others in serious and mortal need, when they can do so at no cost or harm to themselves. If one has conscientious objection to saving others lives in this way then one has the individual responsibility of making this declaration.

Although I am sympathetic to the principle of presumed consent, its basis is less clear in the case of organ donation than emergency medicine. The assumption that one wants life-saving emergency medicine reflects a clear preference that people have for life. Obviously, people do not yet have such a clear preference supporting organ donation. So, the justification of a principle of presumed consent must be based on the assumption that a person would want to be saved by organ transplantation combined with the above moral principle of donor-recipient reciprocity. Since the assumption that people endorse organ transplantation is an empirical principle that may or may not be true, a principle of presumed consent is only justified in societies that have already formed a consensus in support of organ transplants. It follows that the principle of presumed consent typically should not be part of the first step in the implementation of organ transplantation policies, and that it is rather a principle to be added once a favorable consensus has established itself.

In the absence of a recognized principle of presumed consent, a **principle of surrogate consent** is all the more important. Surrogate consent to organ donation plays an important role in countries where a common, easy, and widely used system for determining organ donor individual preference is *not* in place. If every driver's license and every identification card included donor preference, surrogate consent would be less of an issue. As it is, however, whether consent is required or presumed, surrogates are an important means of determining the values and wishes of potential donors. It is indeed common practice, indeed near universal, to permit proxy consent for organ donation. Japan is quite distinctive in that it does not accept surrogate consent and in fact requires a written donor card co-signed also by a family member. This is sometimes called the family veto principle, and, as Bagheri has pointed out, it is puzzling and perhaps inconsistent to allow a family veto and disallow family surrogate consent.(12)

In point of fact, however, the policy in Japan actually is not really a family veto, which implies any family member can veto an individuals decision, but instead it a requirement to have one family member agree with one's decision and sign the donor card. The family co-consent is thus not as restrictive as it may at first seem. The requirement is simply to have one family member support one's decision. This family member concurrence in the decision could have the advantage of informing and including family members, and this in turn could minimize objections at the crucial moment when the donor is brain dead and the need to transplant is at hand. Encouraging prior **family consultation** is indeed a very good idea. In the United States, a suppose bastion of individual autonomy and self determination, it is a common occurrence that the donor's

expressed and explicit wishes are set aside because the family consent to the organ donation. For surely complex reasons, physicians routinely bow to the wishes of a living, grieving family member over those of the dead patient. We can be confident that this would be less common if family members were included and indeed had consented in advance to the donors decision. Without supporting a requirement for family co-consent, it clearly is advisable to include family members in one's decision making and to generally disclose one's donor status to one's family. This is best encouraged, however, in the context of a physician's office or through public information campaigns, rather than a restrictive requirement.

A final point, we need to consider the sensitive subject of organ donation from minors.(13) In Japan, children under 15 can not consent to be organ donors, and since Japan does not recognize surrogate consent, this is a significant obstacle to saving young children in need of a life-saving transplant. The age for donor consent varies significantly in other countries: the age for organ donation is 16 in Korea, it is 18 in India, the Philippines, Saudi Arabia, and Turkey, and it is 21 in Singapore for dissent (since they presume consent in Singapore). In these countries, however, parental and surrogate consent is recognized and so the effect of the age restriction is to leave the decision with parents or guardians. The range of ages for consent in these countries reflects the fact that it is simply not clear what the standard for competency should be for consent to organ donation. I would think that the appropriate standard is the common medical standard of informed consent, and that the typical 16 year old adolescent can sufficiently understand the issues at stake in organ donation. Alternatively, using the age standard for voting or enlisting in the military, often the age of 18 is more conservative and has the advantage of consistency in public policy on the age of consent. Whether it is 16 or 18, it would seem that even a twelve year old child can have some understanding of the issues involve in organ transplantation and brain death, and so perhaps a principle of co-consent of parents and the adolescent is to be preferred for the ages 12-16/18. The specifics of the age of consent, however, clearly reflect cultural differences that public policy should accommodate, but the principles guiding the policy choice are still clear enough: On the one hand, informed consent when appropriate and, on the other hand, the importance of respecting parental consent for children in the parent's care.

The restriction in Japan on parental consent for minors is puzzling; it is not clear why such sweeping restriction on organ donation from minors is necessary. First, just as we trust family members to look out for the interest of their children in parental consent to medical care, here too we should defer, other things equal, to parental consent in organ donation and in the definition of death. A child's death is a terrible devastating event, and the death of two children is twice the pain and devastation. A systematic policy prohibiting child organ donation makes no sense. Although some parents may oppose, for reasons of conscience, the standard of brain death, and although some parents may choose not to donate the organs of a lost child, we should not stop the people who are willing to give the gift of life to another from finding a small solace in their loss in the effort to save of the life of another child. If the concern is simply to protect children, some sort of judicial review may provide a middle ground. If however the restriction on child organ donations reflects a simple categorical presumption against organ donation, against the gift of life, we have seen that there is no philosophical basis for this seeming bias. This is not to say that the expressed view of minor children is to be simply dismissed. In the cases that involve adolescents between the ages of twelve and sixteen, the benefits of respecting the wishes of the individual, when they have been expressed an informed preference, typically should be considered equally with those of the parents.

Conclusion

In sum, a model policy for declaring death and facilitating the giving of life through organ donation will include the following five elements:

1. A pluralist standard of death
2. A donor-recipient priority principle
3. A principle of surrogate consent, and when appropriate a principle of presumed consent
4. A recommendation for family consultation
5. Surrogate parental consent for minors under 16 (or 18), co-consent, i.e., parental consent and prior consent honored, for ages 12-16 (or 18)

These elements both recognize reasonable disagreement on the standard of declaring death and, at the same time, they directly build a social context that facilitates the giving of life through the modern medical miracle of organ transplantation.

Notes

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2. Li Benfu (President, Chinese Medical Association), "Ethical Issues Implementing the Criteria of Brain Death in China," 7th World Congress of Bioethics, Sydney Australia, Nov. 12th 2004. For Chinese Ministry of Health's draft criteria for determining brain death, see the China Peoples Daily, Aug 29, 2002: http://english.people.com.cn/200208/29/eng20020829_102271.shtm; and see the American Embassy in China, newsletter Nov. 15, 2002: http://www.usembassy-china.org.cn/sandt/estnews111502.htm; for the first recorded brain death case in China, see the American Embassy in China, newsletter May 9, 2003: http://www.usembassy-china.org.cn/sandt/estnews050903.htm; For changing cultural attitudes on Organ Transplantation, see the Shanghai Star 07-08, 2004: http://app1.chinadaily.com.cn/star/2004/0708/fo6-1.html.
3. See, for example, Hans Jonas, "Against The Stream: Comments on the Definition and Redefinition of Death" from Philosophical Essays, 1974. Also see this journal, Paolo Becchi, "Are the Dead Truly Departed When We Remove Their Organs?" and Masahiro Morioka, Commentary on Becchi, both in Eubois: Journal of Asian and International Bioethics 15 (1), January 2005, pp. 25-29.
4. Harvard Medical School, "A Definition of Irreversible Coma" (Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death), in the *Journal of the American Medical Association* (JAMA) 205, 1968, pp. 337-340.
5. For the history of the debate in Japan see Mashario Morioka "Reconsidering Brain Death: A Lesson from Japan, Fifteen Years Experience," *Hastings Center Report* 31 (4), 2001, pp. 41-46.
6. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Defining Death: Medical, Legal, and Ethical Issues in the Definition of Death." US Government Printing Office, Washington DC, 1981
7. For an interesting critique of the use of the concept of brain death for organ transplantation, and an interesting argument that we should return to the traditional definition of death but abandon the "dead donor rule" for organ transplantation, see Robert D. Truog "Is it Time to Abandon Brain Death," *Hastings Center Report* 27 (1), 1997, pp. 29-37.
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9. For a defense of the brainstem standard, see Chris Pallis, "On the Brainstem Criterion of Death," in *The Definition of Death: Contemporary Controversies*, ed. Youngner et al., (Johns Hopkins University Press, 1999), pp.117-36.
10. Mashario Morioka "Reconsidering Brain Deatrh: A Lesson from Japan, Fifteen Years Experience," *Hastings Center Report* 31 (4), 2001, pp. 41-46. Robert M. Veatch argued for a similar idea in the form of "conscience clauses" that allowed individuals to choose their own conception of death as early as 1976, in *Death, Dying and the Biological Revolution* (Yale University Press, 1976), pp. 72-76. For a more recent statement of his position see, Veatch "The Conscience Clause" in *The Definition of Death: Contemporary Controversies*, ed. Youngner et al., (Johns Hopkins University Press, 1999), pp.136-60. In the United States, New

Jersey (in 1991) enacted a statute with a conscience clause for religious objectors in particular to reject brain death in favor of the traditional cardio respiratory standard. The New Jersey law, however, does not allow one to opt for a higher-brain standard or to object to brain death on secular grounds. On this issue see, Robert S Olick, "Brain Death, Religious Freedom, and Public Policy," *Kennedy Institute of Ethics Journal* 1 (4), 1991, pp. 275-288.

11. Alexander M. Capron, "The Bifurcated Legal Standard for Determining Death" in *The Definition of Death: Contemporary Controversies*, ed. Youngner et al., (Johns Hopkins University Press, 1999), pp.117-36; p.130.

12. Alireza Bagheri, "Criticism of 'Brain Death' Policy in Japan," *Kennedy Institute of Ethics Journal* 13 (4), 2003, pp. 359-372; especially p. 364.

13. On the issue of child consent, see Masahiro Morioka, "Current Debate on the Ethical Issues of Brain Death" -- *Proceedings of International Congress on Ethical Issues in Brain Death and Organ Transplantation*, University of Tsukuba, (2004):57-59. For criticism of Moriorka's view, see Bagheri, "Children Competency and donor's prior declaration," Eubios Journal of Asian and International Bioethics 11(6) pp: 195-6 (2001). For a clear and compelling defense of the principle permitting surrogate decision making for minors and the "principle of limited familial autonomy," see Veatch "The Conscience Clause" in *The Definition of Death: Contemporary Controversies*, ed. Youngner et al., (Johns Hopkins University Press, 1999), pp.136-60; especially pp 145-46.

Bioethics in Property Rights and Biosafety of Biotech-governance: Role of Behaviourome Mapping

Dipankar Saha [1] and Darryl Macer [2]

1. Agriculture Research Service Scientist, Indian Council of Agricultural Research, Central Research Institute for Jute and Allied Fibres, Barrackpore, Kolkata- 700 120, India.
2. Email: dipankar@ejobs.every1.net
3. Director, Eubios Ethics Institute, New Zealand and Japan and Regional Adviser for Social and Human Sciences, UNESCO Regional Office, Bangkok, 10110, Thailand
Email: d.macer@unescobkk.org

Abstract

In understanding the implicative resonance of biotech applications research and development, it is necessary to apply the intricate consonance of bioethics studies like behaviourome studies in the form of mental mapping in diverse groups of society for trying to resolve moral issues such as IPR or biosafety. Social perception analysis being the subjective domain of bioethics and related biotechnological issues are the functional epitome in ensuring benevolent biotechnological entrepreneurship development. In this pursuit studies of social genomics can ascertain the positive implications of functional genomics being one of the most important fragments of science of biotechnology. The development of guidelines should be culturally sensitive in the way ethical, social and legal aspects are considered. Having a map of human ideas will enable us to reflect more diversity of ideas into policy frameworks.

Introduction

The bioethics movement has been committed to serving the interests of individual and environment by promoting personal and professional morality. Bioethics is broad in its interests and embraces clinical, organizational, community and environmental levels of ethical issues. Many definitions of the clinical, agricultural and/or environmental side of bioethics have been favored. The idea of shared decision-making is now the standard of bioethics. Shared decision making involves all the stakeholders in a field of interested persons coming together to think through the burdens and benefits from the point of view of the technology and the persons and environment. Bioethics is a way of helping people and environment to understand their situation by helping them grapple with their own moral beliefs.

When the successful cloning of a lamb called Dolly was announced by Scottish researchers, it set off a spate of anxious questions. Many of them concerned the ethics of cloning, but another set asked about the unanticipated consequences. If we go down the cloning road, where will it lead? The answer is that we don't know. All of our technological roads twist and turn, and we can never see around the bend or through the fog.

We begin here with a look at some definitions, which shed light on the matter, and then consider the nature of change. This leads to a broadening of the definition of the word 'technology', and a look at what was one of our earliest examples of unanticipated consequences. We will then address the crucial question of why we usually have such consequences. Some additional examples follow, and we will then look at what society naturally does in the form of their perceptual development in the face of unanticipated consequences. The paper will also try to conclude with a discussion of some of the ethical implications of enactment when we know that there can be unanticipated consequences to our actions and also the possible ways to derive out the theories behind the ethical decision making and finding out the possible ways to map those.

Some Definitions

It is important here to distinguish between unanticipated and undesired consequences. The former are consequences, which are not foreseen and dealt with in advance of their appearance. Undesired consequences are those which are harmful, but which we are willing to accept, or accept the risk of occurring. Consequences may be:

Anticipated

- intended and desired
- not desired but common or probable
- not desired and improbable

Unanticipated

- desirable
- undesirable

Two brief points should be made before we proceed. The first is that change is always with us. Even without the intervention of human beings, nature changes constantly. Continents move, weather changes, species evolve, new worlds are born and old ones die. The second point is that all change seems to involve unanticipated consequences. Hence, the unanticipated is a part of life. There is no absolute security. Unanticipated consequences can be mitigated, largely through the gaining of additional information or knowledge, but not eliminated. That's the nature of our life, natural and human. Although we focus here on the term 'technology' as it is usually taken, it is worth pointing out that human beings do much that has unanticipated consequences, in all areas of life, certainly including, for example: medicine, business, law, politics, religion, education, and many more. Because of the parallels among these fields it is useful to think of a broader definition of technology, such as "...that which can be done, excluding only those capabilities that occur naturally in living systems." (Benziger, 1986). Postman, 1993, also dealt with this matter in some detail.

Unintended Consequences?

Dietrich Dorner (1996) has analyzed systems in a way that can help us to see why unintended consequences can be

so difficult to understand, and hence why consequences are unanticipated. Dorner has also identified four features of systems which make a full understanding of any real system impossible. These are:

- complexity
- dynamics
- intransparence
- ignorance and mistaken hypotheses

Lets look next at some other perspectives on this problem. Peter Bernstein, 1996 has addressed the matter from the viewpoint of probabilities and economics. He pointed out that economists have sometimes believed that deterministic forces drive our societies and their enterprises. Tenner (1996) raised an example, which is particularly interesting for two reasons. First, it is not clear which of a number of technologies is causing the unanticipated effects. Second, the issue is intensely political and interpersonal, partially because of the first reason. Now lets turn very briefly to an example of emerging technologies whose major unanticipated consequences we have yet to experience.

The technology which has stirred the public imagination in the waning years of this century is the cloning of animals, and the possibility that we may eventually be able to clone human beings. There has been no dearth of questions about the future raised by this subject. Here are just a few.

1. Will cloning of human beings change what it means to be human?
2. What good might come from the development of cloning?
3. Should we halt research on cloning animals because it might lead to human cloning?
4. If the government takes no action to control cloning could that decision be worse than a decision to take some specific action?
5. Is it possible to control cloning effectively?

Each of these questions speaks to the uncertainty inherent in the actions, which we might take in this field. We are trying here just an example, which make concrete the concerns, which we may have about the unintended and unanticipated consequences of our actions and our enterprises. We may ask what society as a whole does in the face of uncertainty. Here lies the implications of bioethics which obviously encompasses the biosafety and associated risk assessment, and we need to look into the biosafety by name that what it intended to reflect by its subjectivity and objective implications for benevolent biotechnology entrepreneurship development.

Biosafety and Biological Diversity

Biosafety, as discussed in the Convention of Biological Diversity (CBD), refers to environmental and human health safeguards concerning living modified organisms produced by modern biotechnology, especially biotechnology related to gene-transfer or transgenics whereas biological diversity is a global resource of tremendous value to all of humankind. The biotechnology industry is supposed to support the goals of conservation, sustainable use of biodiversity and equitable sharing of the benefits of biotechnology.

For example, in January 2000, the U.N. Convention on Biological Diversity, which grew out of the 1992 Earth Summit in Rio de Janiero, met in Montreal and announced the Biosafety Protocol (known as the Cartagena Protocol on Biosafety). The Protocol focuses on transboundary movement of any living modified organism (LMO) that could harm conservation and sustainable use of biological diversity. It allows a country to require prior notification through an advanced informed agreement (AIA) from countries exporting biotech seeds and living organisms intended for introduction into the environment. Further, it requires that shipments of products that may contain LMOs, such as bulk commodities for food, feed or pharmaceuticals, be labeled accordingly. The AIA provided by the exporter should include written notification of shipment accompanied by an extensive risk assessment. Within biosafety in general, there is a sub-set of questions that relate to the applications of the new biotechnologies to food and agriculture. In this connection, it should be recalled that the Conference of the Parties (COP) for the Convention on Biological Diversity (CBD), in its decision II/15, recognized "the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions". There is a series of instruments in the field of food and agriculture that deal directly or indirectly with biosafety related issues, which would be of relevance to the development and application of the protocol. In this context it will be good to find out the policy propositions between the biodiversity and the intellectual property rights.

Biodiversity and Intellectual Property Rights

The 1990s has been characterized by contentious debate about how to reconcile the protection of biodiversity and intellectual property rights. Two international treaties, the Convention on Biological Diversity (CBD), and the Trade Related Intellectual Property Rights (TRIPs) agreement of the World Trade Organisation (WTO) have significant implications for the intellectual property rights (IPRs), biodiversity and associated knowledge systems. The CBD required parties to safeguard biodiversity and the traditions and knowledge of those indigenous and other local communities associated with this biodiversity, and laid down the basic elements for access to biodiversity resources and associated knowledge systems. The TRIPs Agreement obliged party states to modify their national IPR regimes to meet much-enhanced international standards, which could have significant implications for biodiversity and the associated knowledge systems. In addition, the World Intellectual Property Organisation (WIPO) and other international institutions are becoming increasingly active on the subject. The singular advantage that the WTO process has for ensuring compliance arises from the fact that it can use the instrument of trade sanctions against an erring member, while the CBD has no enforcement mechanisms.

In response to the debate at the international level, there is considerable activity at the national level. Several countries like India has developed legislation, or other measures, which respond to the above treaties or in other ways address the relationship between IPRs and biodiversity. Nations in general are seeking to achieve the following objectives:

- Protection of indigenous knowledge (traditional and modern) from being "pirated" and used in IPR claims by industrial/commercial interests;
- Regulation of access to biological resources so that alleged historical "theft" of these resources by the more powerful sectors of the global society can be stopped, and communities/countries are able to gain control and benefits from their use.

IPRs, as the term suggests, accord legal protection to ideas and information that are used to develop new inventions or processes. These rights enable the holder to exclude imitators from marketing such inventions or processes for a specified time; in exchange, the holder is required to disclose the formula or idea behind the product/process. The stated purpose of IPRs is to stimulate innovation, by offering higher monetary returns than the market otherwise might provide.

While IPRs such as copyrights, patents, and trademarks are centuries old, the extension of IPRs to living entities and attendant knowledge/technologies occurred only relatively recently. In 1930, the US Plant Patent Act was passed, which accorded IPRs to asexually reproduced plant varieties. Several other countries subsequently extended some form of protection to plant varieties, until in 1961, an International Convention for the Protection of New Varieties of Plants was signed. Most signatories were industrialized countries, who had also formed a Union for the Protection of New Varieties of

Plants (UPOV). This treaty came into force in 1968. Plant varieties or breeders' rights (PVRs/PBRs) give the holder of the right limited regulatory powers over the marketing of 'their' varieties. Until recently, most countries allowed farmers and other breeders to be exempted from such rights, as long as they did not indulge in branded commercial transactions. However, a 1991 amendment to the UPOV has tightened the monopolistic nature of PVRs/PBRs, and some countries have virtually eliminated the exemptions for farmers and breeders.

Historically, plant varieties had been exempted from the international patent regime in deference to farmers' traditional practices of saving and exchanging seeds. Industrialised countries, however, have been debating the merits of PBRs as a form of monopoly that may encourage plant-breeding activity. This culminated in the International Convention for the Protection of New Varieties of Plants (UPOV Convention) in 1978, which as indicated above, was amended in 1991, further strengthening the monopolistic hold of plant breeders. Until recently, the UPOV Convention was primarily comprised of Organisation for Economic Co-operation and Development (OECD) countries. However, the TRIPs Agreement now extends the requirement to protect plant variety property rights to all WTO Member States. In addition, in many countries, patents with full monopolistic restrictions are now applicable to plant varieties, microorganisms, and genetically modified animals. To have an insight into the triad of biodiversity, IPR and trade flows being the basis of bio-economics, we can analyse its interrelationships.

Intellectual Property Rights and International Trade

Intellectual property rights (IPRs) affect international trade flows when knowledge-intensive goods move across national boundaries. The importance of IPRs for trade has gained more significance as the share of knowledge-intensive or high technology products in total world trade has doubled since 1980. At the international level, IPRs have traditionally been governed by several conventions – most prominently the Paris Convention for patents and trademarks and the Berne Convention for copyright – which are administered by the World Intellectual Property Organization (WIPO). In the1980s, mounting disputes over IPRs lead to the inclusion of trade-related IPRs on the agenda of the GATT/WTO Uruguay round and the resulting "Trade Related Intellectual Property Rights Agreement, including Trade in Counterfeit Goods" (TRIPs) of 1994 represents the most far-reaching multilateral agreement towards global harmonization of IPRs.

We will try here to find out the relationship between the IPRs and trade flows in brief due to the fact that in modern days the biological diversity resources are being considered as the commodity in the international trade flows. In general perspective, several studies have already been attempted to estimate the extent to which IPRs are trade-related. Maskus and Penubarti (1995) use an augmented version of the Helpman-Krugman model of monopolistic competition to estimate the effects of patent protection on international trade flows. Their results indicate that higher levels of protection have a positive impact on bilateral manufacturing imports into both small and large developing economies. These results are confirmed by Primo Braga and Fink (1997) where an estimation showed a similar model and found the same positive link between patent protection and trade flows.

The conventional economic rationale for the protection of IPRs in closed economies can be found in Arrow (1962). Since knowledge is non-rival in nature, it should be freely available (apart from the cost of transmitting knowledge). If this were the case, however, the market would underinvest in the production of new knowledge, because innovators would not be able to recover their costs. By granting innovators the exclusive rights to commercialize their intellectual assets over a certain period of time, IPRs offer an incentive for the production of knowledge. In short, IPRs introduce a static distortion (i.e., access to proprietary knowledge is sold above its marginal cost), which is rationalized as an effective way to foster the dynamic benefits associated with innovative activities.

From a **dynamic** point of view, the introduction of IPRs stimulates innovation in the source country and thus increase future trade flows. This will be beneficial for both trading economies assuming that social returns on these innovations exceed private returns. The international recognition of IPRs also can be seen as an adjustment mechanism which guarantees the functioning of dynamic competition between countries.

On average, it is not clear whether these dynamic benefits can compensate for the static losses in the countries strengthening their IPRs systems and whether tighter IPRs improve world economic welfare via their impact on trade flows. It is worth pointing out that these theoretical considerations may be moot in a world economy in which political economy considerations are clearly in favor of higher standards of protection.

More empirical research is needed to gain more insight regarding the IPRs-trade link, especially at industry and farm level. One alternative, for instance, would be to consider a country which at some point in the past significantly changed its system of IPRs and to test for structural change. A further important field of research is to examine the impact of tighter IPRs on FDI and their interplay with trade flows with special reference to biological resources.

Biotechnology, Biodiversity and Industries

Although they are often used synonymously, there is a strict difference between biotechnology and genetic engineering. The definition of biotechnology given in 1992 in the CBD states that it includes “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses” (Committee on Agriculture, 1999). Biotechnology covers all techniques that involve the isolation, amplification, modification, and recombination of DNA. Genetic engineering is only one of these techniques, but it is by far the most debated. It can be seen as a particular type of biotechnology that involves the modification of DNA and the transfer of gene components between species in order to encourage replication of certain specific traits (Altieri, 1998). Most of the debate on biotechnology, especially in agriculture, focuses on the use of genetic engineering to produce genetically modified organisms or transgenic products. These various terms will be used throughout the paper.

Biotechnology has been existed around for centuries. Products such as yogurt, cheese and beer have always been made in a process that is presently best referred to as traditional biotechnology (McHugen, 2000). To the same category belongs crossbreeding, which aims at combining positive traits of different varieties of the same species in order to create organisms with certain attractive properties. Since the process of crossbreeding combines whole strings of DNA it is limited to mixing varieties of the same species. A particular application of crossbreeding is in animal husbandry, where certain varieties of a species have been crossed so as to create a wide range of domesticated animals. Nowadays, virtually every type of foodstuff, with the exception of wild game and wild fruit, has been modified in some way, so as to make it more attractive or resourceful, or its production more efficient. This has been done using either traditional or modern biotechnology. Modern biotechnology is a relatively young technology. It can be classified into the genetic modification of plants, animals or micro organisms that are used either for agricultural, medicinal or industrial purposes. Recombinant-DNA techniques, which are at its basis, were first applied in the 1970’s. They allowed the cutting and slicing of genes of one organism and the insertion of them into another organism,

thus changing the latter's production of certain proteins so as to indirectly remove from it undesirable or add to it desirable features. The first genetically modified plants were produced in 1983 and the first modified whole food entered the market in 1994 (McHugen, 2000). The fundamental difference between traditional biotechnology and genetic engineering is that the latter allows the crossing of species' boundaries. Genetic engineering even allows the transfer of genes from animals to plants and vice versa. Although the modern biotech industry is young, it has experienced a tremendous growth over the past three decades. The total sales for the year 2010 are estimated to reach US$25 billion (James, 1999). There are also several public sector organizations involved in the biotechnological research and production process. Most public research focuses on seeking benefits involving small-scale farmers and improving production in tropical and subtropical environments (The Third World Academy of Sciences, 2000). However, current funding for international agricultural research centers is less than US$350 million while the support provided by the US government for agricultural research has dropped by about 30% in real terms since 1960 (Shah and Strong, 1999). The result is that unlike during the green revolution where public organizations played a mayor strategic roles, the main players in biotechnology development are private, profit seeking firms. Responses by consumers, NGOs and even countries already have had quite a lot of influence on the operations and marketing of the private biotech companies. Several large food companies have recently changed their strategies based on fear for their reputation and market share. This does not mean, however, that the production of genetically modified products is decreasing. The main change is that certain products that contain artificially modified proteins are not being sold to consumers at this moment. But a range of other products like butter, cookies, soups, bread and sauces with ingredients from GMOs are still available. Environmental NGOs claim that firms in the foodstuff industry pay little attention to the production methods of the ingredients of their products (Reijnders, 2000). In this sense biotechnology is no exception; standards for labor, environmental and biotechnological characteristics of products and production processes have been discussed at the international level for a long time now, notably in a GATT/WTO context. It is just a matter of time before such standards will be internationally agreed upon, including those relating to applications of modern biotechnology. In this context we need to oversee the integration of bioethics in biotechnology R&D at the industry level.

Biotechnology Industries and Bioethics

Several biotech companies have formed Ethics Advisory Boards in recent years, with more likely to join their ranks in the near future. The trend reflects a realization that biotech companies engage in research that raises difficult ethical issues. But are the advisory boards engaging in rigorous analyses of these issues, or just providing window dressing? Placebo-controlled brain surgery to implant neural cells in patients with Parkinson's disease, culturing human embryonic stem cells, and the birth of Dolly through nuclear transfer--these are not just highlights in the recent history of biotechnology. They are also flashpoints in the public's understanding of biotech, and fuel for the ongoing debate about the ethics of these and other new technologies. But does the biotech industry really care what the public thinks about its science?

Of late, biotechnology has generated a wealth of issues with few easy answers, ranging from privacy and genetic information, to informed consent, to who should be tested for genetic mutations, to the cultural problems of conducting clinical trials internationally among indigenous peoples. The industry has come to understand that it cannot afford to alienate the public--which includes investors and consumers--with its science, for it is with the public that its fate ultimately lies. "It's a growing phenomenon--everywhere that companies setting up boards, using consultants, and establishing internal bioethics programs. The list of companies using bioethics specialists includes Glaxo Wellcome, Genzyme, SmithKline Beecham, Millennium Pharmaceuticals, Myriad Genetics, Pfizer, and Affymetrix, and is growing as technologies raise new questions and controversies, which have no easy answers. The industry learns some hard lessons from the way bioengineered food and agricultural products were introduced in Europe and the UK, and how badly they have been received. Mishandling their introduction created what he called an "ab-reaction" to bioengineered food, which remains "a hotbed" of controversy and a "disaster" of public opposition stretching from the 1970s until now.

But it is clear that more and more companies consider bioethics an important new aspect of community relations--one that has the potential to offer a real exchange between companies and the public, and that may ultimately guide critical corporate decisions. If the "business of bioethics" remains linked to the business of biotechnology, companies will be loathe to stray too far from public opinion. Let us now have a fundamental insight into the structural analogy and functional implications of ethical decision-making.

Framework for Moral Decision Making

Dealing with these moral issues is often perplexing. How, exactly, should we think through an ethical issue? What questions should we ask? What factors should we consider? The first step in analyzing moral issues is obvious but not always easy: Get the facts. Some moral issues create controversies simply because we do not bother to check the facts. This first step, although obvious, is also among the most important and the most frequently overlooked. But having the facts is not enough. Facts by themselves only tell us what *is*; they do not tell us what *ought* to be. In addition to getting the facts, resolving an ethical issue also requires an appeal to values. Philosophers have developed five different approaches to values to deal with moral issues which are The Utilitarian Approach, The Rights Approach, The Fairness or Justice Approach, The Common-Good Approach, The Virtue Approach and the Ethical Problem Solving.

Semantics for Moral Terms?

Conceptual role semantics is no newcomer on the metaethical scene. Many cognitivists, like Frank Jackson, Philip Pettit, Peter Railton, and Michael Smith appeal to conceptual role semantics in their accounts of the meaning of thin moral terms. Taking David Lewis' approach to defining theoretical terms as their model (Lewis 1970), these authors suggest that the conceptual role we associate with a moral term provides the 'job description' which a property must fulfil if it is to count as the semantic value of that term. Expressivists like Simon Blackburn (1984, 1993) and Allan Gibbard (1990) can also be understood as embracing a conceptual role semantics for moral terms. They claim that the meaning of those terms is exhausted by their distinctive role in practical deliberation and the guidance of action. Ralph Wedgwood has recently proposed an ambitious and sophisticated alternative to these standard ways of using conceptual role semantics in metaethics. Like expressivists, Wedgwood thinks the open question argument suggests that the central element in the meaning of moral terms is their action-guiding role. Indeed, according to Wedgwood, grasping the action-guiding role of those terms is all there is to understanding their meaning. But Wedgwood embraces cognitivism: he thinks that the conceptual role of moral terms provides the resources to single out genuine properties as their semantic value. What's surprising about Wedgwood's account is that it promises so much for so little: the action-guiding role of moral terms, he suggests, suffices to determine which property they pick out. To find our very precisely the aspects of ethical biotechnology

we are supposed to correlate the domain of uncertainty and irreversibility along with its implicit functions with the public perception issues.

Uncertainty, irreversibility for ethical biotechnology and public perceptions issues

Most of the issues raised by the pressure groups concerning health and environmental issues involve trying to influence the public safety feeling, in other words, influencing the level of a publicly acceptable risk. As Miller (1998) describes, in the public's perception unfamiliar risks tends to be overestimated. People generally have very little knowledge and understanding of the history of traditional biotechnology and the achievements of its application, let alone the application of modern biotechnology and genetic engineering. In this case little information at the right time can shift the balance of opinions. This is undesirable, since often the information is partial or simply incorrect. An example of the difference in perception of risk between the public and the scientific community is the issue of health concerns. Furthermore, we found no strict distinction between the health and environment risk posed by plants modified through modern genetic engineering techniques and those modified by conventional breeding practices." (Adkinson, 2000). Nuffield Council on Bioethics (1999) makes similar statements.

Endogenous risk

One cannot assume that risks relating to GMO's are absolute or exogenous (Crocker and Shogren, 1999). For instance, in the present context a risk affecting strategy is to limit hybridization (Hails, 2000). This can be done, among others, with terminator technology, which allows the genetic control of sterility by preventing pollen development or seed germination. Such strategies may impact both the likelihood that something will happen and the impact of the outcome. Notably the health related effects, and their probabilities, of biotechnology can be adapted by ex ante and ex post actions. Ex ante, human responses to new products can be tested. Ex post, consumers can decide not to buy certain products, farmers to move away from certain areas, etc. Protection can also result from public intervention. All in all, this means that risks of using biotechnology should not be considered as objective and exogenous. Risk can be changed by management and endogenous responses to perceived or real risks. Moreover, some types of risks are insurable. Consequently, risk management in this area should take both natural and social-economic aspects into account, in order not to be (at best) inaccurate or (at worst) ineffective. The most serious risks, however, relate to ecological damages. Insurance against these is often impossible. The impact, such as evolutionary change or loss of ecosystem functions, is irreversible and cannot be compensated in financial terms. This brings us to the next consideration.

Irreversibility of lost opportunities

The problem of choosing for or against genetic modification of agricultural crops can be cast in a framework of opportunities and irreversible or even path-dependent development. These are themes that have been studied in evolutionary economics and economics of technology (Arthur, 1989) and economics of nature conservation (Fisher and Krutilla, 1985; Porter, 1982). The results of these studies indicate that the historical development of technology may be far from economically or socially optimal, since technologies get locked in due to increasing returns and network externalities. This has relevance for a number of problems studied nowadays, including climate change (Kolstadt, 1994) and biotechnology. Different biotechnology scenarios are associated with lost opportunities due to certain irreversible processes. Two extreme case scenarios are particularly relevant in this context. In a first scenario with large investments made in biotechnology, the irreversibility of the resulting quick progress in biotechnology applications has both economic and ecological-evolutionary elements. Economic irreversibility is due to an increased dependence of agriculture on GMOs. Ecological-evolutionary irreversibility involves changes in the genetic composition of species, both crops, wild relatives and ecologically related species.

Another scenario is the rejection of genetically modified products by some western consumers, which to some extent, is currently happening in most countries in Europe. This can eventually have a large negative impact on the biotech industry. This would result in potentially foregone future benefits for people now and in the future. Presently, the conditions set by donors of development aid and by financial institutions on the use of biotechnology already force many developing countries to restrain the import of both genetically modified crops and its technology (Paarlberg, 2000). The result is that while the discussion of genetically modified crops goes on in the west, the developing nations are unable to make their own choices. In finding out the very basic of moral decision making we need to recon ciliate idea biosynthesis within any individual or community and to do so we can utilize the concept of mental mapping which in turn can help us very precisely to look into the bioethical aspects and its related perceivable issues encompassing variable domain of biotechnological applications. Studies on network based behaviourome can be a comprehensive tool to understand the multivariate neural network within and overlaid social network beyond leading to the possible definition of the fuzzy contours of idea evolution and its enactment both at the individual and community level.

Behaviourome : an abstraction towards mental mapping in understanding public perception issues and idea evolution

Bioethics is a "unifying field of vision" with a varied range of subsets i.e.; medical ethics, environmental ethics, animal rights etc (Macer, 2002, Saha *et al*, 2000). Bioethics is a derivative of a process in perception of limitations in the struggle for human existence (Saha *et al* 2000). However all universal principles always do not have unifying expressiveness. They take their meanings from particular cultural framework. Away from the unique context that gives it a meaning, a principle may have no more than nominal significance. Consequently bioethicist ought to make a move towards understanding the meanings of principles within their natural ambience. Principle are made meaningful not by their being held in common but by their being understood in their unifying approach.

One of the most interesting questions before thinking being is whether we can comprehend the ideas and thoughts of other beings, and conversely whether they can also read our mind. Researchers have argued that they have already the means to embark upon a human mental map with the goal of describing the diversity of ideas a human being makes in any given situation or dilemma (Macer 2002). This is the behaviourome or human mental map. This is not a map of a physical structure but a map of ideas. The map can help us to understand ourselves, and whether the number of ideas is really finite. In 1994, based on the results of the International Bioethics Survey, which gathered opinions from 6000+ persons in 10 countries on 150 questions of bioethics dilemmas, Macer proposed that the number of human ideas is finite. Since then the evidence continues to suggest the number may be finite, and thus countable! We will only know after we map them to compare mental maps and idea diversity between persons and species. This will allow the development of descriptive bioethics into a common framework for comparative ethics to aid in policy making to make policy that respects the diversity of people in a culture, and globally. This would help develop bioethics for the people by the people. The

development of biotechnology and use of humans in clinical trials in many countries raises fundamental questions about whether the standards used should be universal or local. The development of guidelines should be culturally sensitive in the way ethical, social and legal aspects are considered. Having a map of human ideas will enable us to reflect more diversity of ideas into policy frameworks. We will have to pay attention to ensure it is used well, and not used to dictate majority views to minorities. If we can make individual mental maps, this would offer persons assistance when making moral decisions. This would give them a chance to consider all their ideas, and to make a more considered moral choices. This would also be useful in the testing and implementation of better bioethics education being the very base for every ethical decision and probably leading to an altruistic society wherein the development and application of biotechnology related gazettes will be rational and management of biosafety issues will be easier.

The current mental map is built with the intention to study all the ideas used when facing moral dilemmas, but there are other areas of the human mind that include ideas which will be explored for integrating into a mental map. One example of an idea that was given was the desire for food, which is a biological necessity. One of the points that was made in several discussions was that it is difficult to say that we can understand the idea of another being. This concern has already been incorporated into the mental map by the concept that the idea points would have spheres of uncertainty around them as we have already discussed in the first section of this paper.

The integrative reciprocity of the human mind with its biophysical and metaphysical entities will help in targeting capillaries of rationality that are embedded within emotional flux leading to the rational epitome of mind function. Understanding of the human mind acting behind any system modalities (both individual and biosystem as a whole) can be a tool in (1) perceiving , (2) analyzing , (3) interpreting and (4) implementing the accumulative bioethical insight. If we define an "idea " as the mental conceptualization of "something "including physical objects as an action or sensory experiences - then the number of objects in the universe of a living being is finite. It may be conceptualized as may be the fact that individuals in every spheres of life as well as organizations in many fields , by their values (the bioethical relativity) driven by "n" number of images based on every moment of mental interactions with the ambience and the sum of their actions as a resultant (idea) having usual impact in shaping up the world environment of the future, if we really could come out with nature of images and its processing within human mind (Saha et al, 2003).

In this context again, if we refer to the "stable continuance" for any social decisions making framework likely "constitutional dimension" the relationship (qualitative) implicit in the pattern between the importance of a specific issue and "dissensus", a more mathematically tractable inverse of agreement or consensus. But will it be so in the case of genesis of individuals' ideas (implicit domain) wherein any mathematically calcuable relationship (linear and/ or piece - wise linear) can be established through the result of integrative human idea mapping.

At this time when the tendency of limiting development to techno-economic fields like biotechnology per se has reduced humans to the status of disposable economic units, what is required is to search for human perceptions of the ambience and evolving attitudes towards it which is again an integral part of the long history of human interactions with the rest of the nature and its resources. The individual's perceptions (constant imaging and its superimposition within conscious and subconscious domain of idea generation) may be molded by tradition, personal observations, experiences, education and non formal information from a diversity of sources.

Without any doubt, like any technology, biotechnology has both positive and negative consequences. Particular attention need to be devoted to the way uncertainty can be addressed in evaluating potential social costs and benefits of biotechnology applications and the mind mapping will probably be the overlaid mosaic which entails the epitome of sustenance by injecting the dialogue and debates within the cognitive finite/infinite trajectory of human mind to anticipate for further evolution of ideas to come in framing up suitable regulatory mechanisms for its holistic enactment at every level of development and applications.

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Euthanasia: A 2005 New South Wales Supreme Court Decision

- Sarah E Hilmer
17/30 Cowper Street, Randwick 2031, NSW, AUSTRALIA
Email: sarahhilmer@web.de

Courts from different jurisdictions get more and more involved in the difficult decision making process of *parens patriae* jurisdiction, which gives rise to moral and ethical considerations and questions. Such a process expects the Court to act in the welfare of a person who is unable to care for himself or herself or make his or her own decision as to what is in his or her own best interest.

A recent 2005 decision of the NSW Supreme Court is the one of *Isaac Messiha (by his tutor Magdy Messiha) v South East Health*[1] by Howie J[2]. This case concerns the Plaintiff´s application for order restraining hospital from terminating current treatment of the patient Mr. Messiha. Since his admission to hospital on the 17 October 2004, he has been unconscious and in a deep coma. Dr. Jacques, the Director of the Intensive Care Unit, suggested the withdrawal of the patient's treatment. Based on medical evidence, this will have the effect of reducing the life expectancy from possible weeks to possibly days. However, the patient's family brought the matter before the Court and believed that signs of improvement occurred and within those Mr. Messiha`s condition. Thus, any alteration of the patient's treatment by the hospital staff, takes every opportunity of improvement away.

The Plaintiff submitted the application with the strong believe that the patient made improvements over the last days after admission to hospital, such as eye movements of the patient in response to words spoken to him.[3] Therefore, the current treatment should not be altered and the ventilator not removed. The Defendant indicated that the 75 years old patient was without oxygen for at least 25 minutes before he was admitted to hospital, and therefore he suffered severe brain damage. Further, Dr. Jacques determined from the patient`s age and the medical history: severe lung disease, a cardiac arrest, as well as cardiac surgery 10 years ago, that Mr. Messiha`s prognosis is very poor.[4] The family of Mr. Messiha obtained another medical expert opinion. However, this expert also confirmed Dr. Jacques prognosis that a meaningful recovery is rather impossible.[5] The conditions of the patient did not improve over the next days, thus, the Dr. put forward to change the nature of the treatment to "comfort care" by removing the ventilator.[6]

Judge Howie in the present case referred in his judgment to the case of *Northridge v Central Sydney Area Health Service*[7]. In *Northridge* O´Keefe J stated that such an application concerns the best interest of health and welfare of the patient and that the court is not bound to give effect to the medical opinion.[8] His Honor further indicated that

"There is undoubted jurisdiction in the Supreme Court of New South Wales to act to protect the right of an unconscious person to receive ordinary reasonable and appropriate (...) medical treatment. (...) What constitutes appropriate medical treatment in a given case is a medical matter in the first instance. However, where there is doubt or serious dispute in this regard the court has the power to act to protect the life and welfare of the unconscious person."[9]

However, Howie J explained that this court, unlike in *Northridge*, should not act against the medical experts appropriate treatment regime.[10] Moreover, Howie J pointed out that "*it is simply an acceptance of the fact that the treatment of the patient where, as here, the Court is satisfied that decision as to the appropriate treatment is being made in the welfare and interest of the patient, is principally a matter for the expertise of professional medical practitioners."*[11] The medical evidence in the present case is that there is no real prospect of significant recovery by the patient[12] and the fact that there is no support that any improvement of the patient has taken place, but rather his conditions deteriorated since his admission to hospital.[13]

Thus, the facts of the present case are different to *Northridge* as there is no medical evidence which suggests that there is any real prospect of improvement if the current treatment were to be continued for any significant period of time. Therefore, Judge Howie concluded that "*The withdrawal of treatment may put his life in jeopardy but only to the extent of bringing forward what I believe to be the inevitable in the short term. I am not satisfied that the withdrawal of his present treatment is not in the patient`s best interest and welfare."*[14] Based on these grounds Howie J dismissed the summons.

Howie`s J judgment again rises the question of how far court`s jurisdiction can go? Even if his Honor based his decision on the grounds of medical evidence provided to him, which is at least different to the case of *Northridge*, it still

[1] [2004] NSWSC 1061
[2] Hearing date: 1/11/2004; Judgment day: 11/11/2004
[3] Howie J at para 13
[4] Howie J at para 5
[5] Howie J at para 6, 12
[6] Howie J at para 7, 8, 11
[7] (2000) 50 NSWLR 549
[8] O`Keefe J at 25
[9] O'Keefe J at 24
[10] Howie J at para 25
[11] Howie J at para 25; also O`Keefe at 24 in *Northridge*
[12] Howie J at para 26, 6, 12, 19
[13] Howie J at para 14
[14] Howie J at para 28

serves an open field for discussion in terms of moral and ethical questions. Views of the general public confront the medical profession and among these two groups courts exercise its jurisdiction. Again, even if Judge Howie pointed out that *"the Court should exercise the jurisdiction only with caution"*[15], at the end of the day he has to make a decision, which was here to dismiss the summons submitted by the Plaintiff`s family, which means to remove Mr. Messiha from the ventilator.

The remaining questions are: Where are we heading regarding euthanasia? Who decides under which conditions life is worthwhile living? and Who sets the conditions?

This highly delicate topic of euthanasia remains a critical and sensitive one and needs to be closely looked at and followed up within the near future. Cases from different jurisdictions deal with this issue and the decisions vary, not only because of the different legislations in certain countries, but also because no guidelines exist. However, if such "guidelines" are established, again the question arise: Who sets these guidelines? Should it be called "comfort care" or rather "a right to die"?

Therefore, this sensitive area needs special consideration and attention, so that a broader interpretation of each case would be favorable in order to leave space for following cases which might be interpreted in a different way by considering the whole situation and not only the mere facts of a case.

Interpreting Helsinki in a Pluralistic World

- Ann Boyd and Denise Hise
Biology Dept., Hood College, 401 Rosemont Ave,
Frederick, Maryland 21701-8575, USA
Email: boyd@hermes.hood.edu
Email: liveandlearn@starpower.net

"We live today in a world densely populated by human beings living in close communication with one another all over the surface of the planet. Viewed from a certain distance it has the look of a single society, a community, the swarming of an intensely social species trying to figure ways to become successfully interdependent. We obviously need at this stage, to begin the construction of some sort of world civilization."

-- Lewis Thomas [1]

Environmental, cultural and individual influences have contributed in significant ways to the complexity of human societies and the shape of the modern world. [2] Global wealth and resources are unevenly distributed and the poor and marginalized segments of societies continue to bear the greatest burdens of disease as a result of the vast disparities in resources committed to disease control. Long chains of causation have led to this state of affairs and inequalities of access to care and outcome of disease increasingly characterize our world. The fundamental insights and social transformations required to rectify this profound global injustice will not come quickly, if at all, yet it is critical to bring the necessary resources to bear on the 'plagues of the poor' and to diminish worldwide disparities in health care. Given these disparities what does it mean to have clinical trials with human subjects conducted by developed country agents in developing countries? Two revisions in Helsinki 2000 deserve closer scrutiny: the articles dealing with standard of care and reasonable availability.

Plagues of the Poor

Collectively Malaria, Acquired Immune Deficiency Syndrome (AIDS) and Tuberculosis (TB) kill at least six million people a year, the majority in resource-poor countries, and constitute major public health challenges undermining development in these countries. [3] A brief review of the plight of persons in sub-Saharan Africa and South East Asia regarding these infectious pathogens reveals the severity of the situation.

- Two-thirds of the global population is at risk for malaria. Nearly 90% of deaths from malaria occur in sub-Saharan Africa where an estimated one million children die annually. [4] The incidence of malaria is increasing in part due to resistance of parasites and mosquitoes to drugs and insecticides, respectively. The absence of a reliable animal model for vaccine and prophylaxis testing, as well as treatment of active disease, means that human subjects are the only universally recognized way to design research aimed at preventing or treating malaria. [5] A small percentage of persons from the developing world are at risk for malaria due to travel or work in endemic regions.
- Nearly 40 million people live with HIV/AIDS worldwide, including 2.2 million children under the age of 15. HIV has entrenched itself amongst the world's poor and marginalized, predominantly in sub-Saharan Africa and South-East Asia, while incidence is declining in wealthy countries. Three million people die each year from AIDS, totaling 30 million since the beginning of the epidemic. [6] There is an urgent need to create and systematically evaluate more candidate vaccines and human clinical trials are ultimately required to define vaccine/drug effectiveness. No single regimen is likely, at least initially, to provide the optimal balance of efficacy, safety and cost for all regions of the world. [7]
- One-third of the global population is infected with Mycobacterium tuberculosis. Eight million people become sick with TB each year, 95% of them reside in the developing world and half of these cases occur in Bangladesh, China, India, Indonesia, Pakistan, the Philippines and Thailand. TB kills two million people each year, including over 100,000 children. TB is completely curable with short-course treatment. [8,9] However, multidrug-resistant TB strains have emerged making treatment much more difficult and expensive, essentially translating to a death sentence for the poor. In addition, 14 million people are co-infected with TB and HIV, and TB is the leading infectious cause of death in HIV-positive individuals. [10] Clearly TB, especially drug resistant strains, poses a threat to people everywhere, but the vast majority of cases occur in zones already compromised by poverty.

Lower socioeconomic status has been linked to poorer health throughout history, with impoverished individuals having the highest rates of morbidity and mortality within human populations of any culture. [11] Impoverished populations continue to bear the brunt of disease but lack the health care infrastructure to cope with the burden. They are therefore dependent on wealthy nations or global health initiatives to intervene on their behalf. In ethical terms then, these populations are vulnerable.

Many of the urgent health problems that remain to be solved in the world necessitate further research to find new ways to prevent and treat illness and develop more effective interventions with fewer side effects that can be more universally accessible. Conducting such research in developing countries introduces the risk of exploitation when access to regular health care is limited. The formal agreement between pharmaceutical industries and governments represents both the interest in development of new and improved treatments while simultaneously risking at the least, the perception of exploitation. Individuals in any culture may fail to achieve a clear distinction between research and clinical care. In conditions where access to care is limited, the clinical

[15] Howie J at para 24

trial becomes all the more attractive. Informed consent derived from the principle of autonomy deserves serious review when the choice is simply research trial or nothing. There are circumstances in pockets of poverty in wealthy nations where unequal access may lure a person to enter a research trial. It may not necessarily be wrong to respect the individual's choice where options are severely limited. Doing something is often preferable to doing nothing, but it is not justification for exploitation or doing harm.

Autonomy, beneficence and justice provide ethical norms for review of human subjects research but as western philosophical principles are subject to diverse pluralistic interpretation within the diverse local culture as well as the international community. Whether or not these three principles are the right choice for international research with human subjects is open to question. Minimally, autonomy does not stand alone as the icon of ethical approval but works best in tension with beneficence and justice. These principles however provide the lens through which Helsinki guidance in human subjects research regarding standard of care and fair benefits is subject to interpretation and application.

Helsinki 2000 Concerns

Standard of care refers to the optimal treatment for a given diagnosis, but the question is whether that treatment is the best anywhere in the world or locally defined. Defining the standard of care for clinical trial participants is at the heart of the debate as we continue to refine our approach to trans-cultural research. The debate centers in particular on two paragraphs of the 2000 revision of the World Medical Association Declaration of Helsinki, which provides guidance on the ethical conduct of medical research involving human subjects.

The Nuremberg Code created a universal expectation that all research involving human subjects be deemed scientifically worthy and all subjects voluntarily choose to participate. Ascent did not yield compliance [12] and thus, the Declaration of Helsinki added the normative step of independent ethical review for all clinical research involving human subjects. Experience and critique discovered cases in which the intent of both Nuremberg and Helsinki were inadequately applied. The latest and sixth revision of Helsinki Declaration (2000) challenges the concept and practical interpretation of the principle of beneficence in terms of risk-benefit, justice as fair access, and autonomy as informed consent.

The Helsinki Declaration version VI of 2000 contains two paragraphs of particular relevance to international clinical trials with prophylactic drugs. Paragraph 29 reads, "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment in those studies where no proven prophylactic, diagnostic or therapeutic method exists." Paragraph 30 reads: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." Several interpretations of the wording of these two guidelines deserve reflective consideration in regard to any international clinical research trial with human subjects.

Following prolific writing in response to Helsinki 2000, the WMA added a note of clarification to paragraph 29 in 2002: "The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
- where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk or serious or irreversible harm." [13]

Placebo controls and "Best current" method

Ethically, the debate continues on whether the standard of care ought to refer to a global context as anywhere in the world, or to the standard available in the host country, or to the standard of care in the sponsoring country and whether placebo-controlled trials in developing countries would be deemed unethical if an effective prophylactic treatment existed, even if it was not available in the prospective host country as a standard of care at the time of the pending trial. [14,15] The "best current" provision and the rejection of placebo controls may be unreasonable and unrealistic in the context of developing nations and an impediment to developing new therapies for medical conditions for which there is any existing proven therapeutic benefit. [16,17] The Helsinki Declaration itself risks losing "its moral authority" [18], if guidelines derived from it are too ambiguous. Alternatively if the Declaration is too directive and strident, the risk is that the norms will simply be ignored. Nevertheless, the effort to recognize the potential for exploitation and injustice requires elimination of the insidious double standard in medical research that rejects for the rich what is acceptable for the poor. In an ideal situation, the value of individual human beings would no longer be ignored in the pursuit of scientific knowledge and the standard of care would be the same for everyone. Lacking agreement about who will bear the expense of absolute equality leads to the stalemate of applying the Helsinki 2000 revisions. The pendulum swing is extreme in the demand for radical change that establishes a firm egalitarian equality by literal adherence to the revisions and the resistance that fears a collapse of medical progress in the inhibitions inferred for clinical trials. The fundamental tenant of Helsinki is however to offer guidance not to dictate protocol.

Change as process

Viewed from a certain distance this has the look of a society reacting to the introduction of a new idea. New ideas threaten the existing order and are generally met with resistance. Initiated as speculative suggestions, new interpretations to "standard of care" and "placebo-control designed trials" invite heated debate – the traditionalists citing all the harms of change and the proponents of greater equality cite harms of current practice. The suggested changes deserve debate, and ought to be seasoned by reflection and dialogue, allowing time for adaptation and application, even if in limited ways. [19] The pace of progress is slow. But, at times, seemingly impractical ideals can be a program for reform. The Helsinki Declaration describes an ideal, an ethical framework that we know ought to be imposed to eliminate the risks of exploitation of persons in the developing world, something to strive for in our dystopia. Every society tolerates certain blots, at that stage inevitable. [19] At this particular stage in our history, given the worldwide disparities in health care, our inability to implement a literal interpretation of this ideal appears to be our blot. Yet within this framework, many possibilities can be imagined to set us on the path toward gradually attaining this ultimate ideal, and in this way is not restrictive at all.

The Helsinki Declaration is offered for international guidance without the force of law or sanctions for noncompliance. However, if the language of the guidelines is taken literally, the risk may be that research in developing countries is eliminated from consideration. If guidelines are considered unreasonable or unrealistic, they may simply be

ignored or displaced by local or national legal alternatives. Retreating into regional or national regulations loses sight of the global community in which human health and flourishing are as integrated as are economic or environmental issues.

Rather than the provisions being taken literally and imposed as ultimatums, perhaps a progressive view of the standards as a goal for clinical research with human subjects could parallel the current practice of autonomy in informed consent. Autonomy is derived from the western philosophical notion of free rational choice, but autonomy in some cultures may mean adherence to the communal good rather than individual priority. To impose any one understanding of autonomy can hamper achieving the intent of informed consent as much as insisting that a document signed by the participant is all that autonomy means. Although it is natural to seek consensus or highly general principles underlying our codes of ethics, there is always more than one way to proceed and no regulative notion can be defined precisely enough to prescribe details of conduct for all circumstances. [19] Ambiguity can be a source of strength, providing avenues for negotiation and compromise. Flexible, alternative solutions that will allow research with the potential to benefit host communities without exploiting them can be found.

A few months ago, one of us (Boyd) was in Kenya reviewing the clinical trials sponsored there as a collaboration between the Kenyan Ministry of Health and the Walter Reed Army Institute of Research (WRAIR) in Washington D.C. The nurses in one clinic described the impact of the clinical center built in the community and the increased availability of routine medical care as well as the opportunity to participate in clinical trials as a transition from "despair to hope." Prior to the availability of testing for HIV status with subsequent delivery of antiviral drugs, very few people would consent to be tested. Once aware that if tested, and HIV positive, drugs would allow a person to live longer and return to work, a dramatic increase in surveillance and treatment occurred. Her elaborated meaning gave me a new sense of what it means to work toward equality in a culturally sensitive way. Does this example mean that once the clinical trials sponsored by WRAIR began, that all Kenyan nationals had access to testing or to antiviral therapy? Certainly not, but the improved participation, education, and economic impact of the work has encouraged the Kenyan government to invest in healthcare in a new way. If the modest improvement of infrastructure and availability of treatment options for some percentage of the population is acceptable to the leaders and citizens of Kenya in terms of Helsinki normative standards, I think respect of persons encourages us to accept their interpretation.

The Helsinki Declaration has been regularly revised, attempting to incorporate current thoughts and ideals. [20] Perhaps this time it is our turn to broaden our interpretative lens, to recognize that there is more than one ethically acceptable approach and imagine some effective alternatives that can be made available to communities with limited resources. Thus we begin a process so badly needed of addressing standing global inequalities in health care and work toward allaying the unnecessary suffering they cause. Poverty is a central fact of life in many areas of the globe and remains a primary cause of disease prevalence in those regions. The burden of disease has increased rapidly in severely affected countries and failure to intervene effectively could undermine past progress and threaten public health in general. [21] The formulation of appropriate policies and interventions is a matter of particular urgency; our fellow beings can ill-afford to wait for reality to catch up to our ideals. Our reaction will be a measure of what we judge to be worthwhile, our capacity for compassion and our commitment to social justice. Seeking common ground between the best standard being the best anywhere and the best being merely what is locally offered provides a way to respect the international guidance of Helsinki and promote ethical research with human subjects. [22]

Common Ground

Perhaps it would help to consider the standard of care and best-proven treatment concept in parallel with a culturally sensitive approach to obtaining informed consent. Both processes ought to mutually respect the collaboration between sponsor and host country participants (scientists, government authorities, ethicists, and community representatives from the proposed trial area). Developing culturally appropriate ways to meet the standard of voluntary informed consent includes culturally appropriate methods of disclosing information, seeking permission for research participation from a community representative or family member, and assessing participants' understanding of information relevant to the trial. These cultural sensitivity steps neither seek to assure that individuals are forced to comply with western ethical principles e.g. autonomy, justice and beneficence, nor are they necessarily exploited. The requirement of individual informed consent is not to be ignored or waived but amended in process and language to fit the situation.

Likewise, reaching an objective conclusion about what constitutes ethical international research between a sponsor and a developing nation requires an understanding of the context in which the research will be done. The challenge centers on the validity of applying ethical principles for medical research in diverse cultures and even whether such research is ethically justified in areas without adequate access to basic health care. If the reference point for the standard of care judgment is deemed to be anywhere in the world then, practically speaking, research in developing countries risks being eliminated from consideration. Alternatively, if the standard of care is determined on that available in the host country, then the risk of exploitation remains without corrective. The extreme poles of the interpretation delineate the ethical need to assess the situation regarding the local standard of care and seek to understand it within the social, economic, and cultural framework of the host country without neglecting awareness of what is globally most effective.

Fair Benefits

Standards of care often refer to specific products or interventions, ignoring larger interpretations of benefit that may include the overall care in a health system. [23] It would seem that the best way forward at this time would be to adopt a flexible, pragmatic approach that enlisted the full participation of the host country in finding an acceptable balance between the burdens and benefits of the ensuing research initiative, making provision for them to receive a fair level of benefits as determined by their standards.

The fair benefits framework relies on four foundational principles: a) that the research would have social value, b) that it will address a health problem in the developing country, c) that the location proposed for the research is chosen for valid scientific reasons, and d) the risk-benefit ratio is favorable. [24] An advantage to the conceptual phrase "fair benefit" is the interpretative flexibility. A population in a developing country could consider a diverse range of benefits from research appropriately "fair," for example, the construction of health care facilities, training of nationals, public health infrastructure improvement. Benefits could be directly associated with participation in the research, or to the population during the research, or to the participants and population after completion of the research. Capacity development or enhanced training in ethics review could thereby be considered community benefit, as could the acquisition and dissemination of generalizable knowledge that may improve health for others. [25]

The perspective of the putative host country on the merit of the proposed research is essential. [26, 27, 28] The local

government, community representatives and ethical review should determine the value of the trial benefits for its own people. Outsiders will likely not clearly understand the health care system or the cultural norms of a host population. Transparency in the negotiation of the trial is necessary in order to gain consensus within the host country and among concerned collaborators. [29] Respect for local opinion and appreciation of cultural values, social practices and traditions will promote mutual understanding and encourage the establishment of trusting, collaborative partnerships between host countries, industry, government, research, and ethical oversight that are necessary if effective preventive and therapeutic interventions are to impact the current devastating effects of disease. Each protocol should be subject to the judgment of all relevant parties in the research effort and ethical principles should be thoughtfully balanced against each other to determine what can to be done in a given situation. The relevant parties to address the risk-benefit ratio of the trial for the participants and the after-trial benefits to the host community should negotiate agreement. Thus, interpreting beneficence multiculturally ought to parallel a pluralistic interpretation of autonomy.

A flexible interpretation and cultural sensitivity to plurality of normative standards will allow the most practical and realistic approach to being faithful to the intent of the Helsinki Declaration so that scientists may continue the development of prophylactic and therapeutic drugs to treat diseases of the poor. If the leaders of the research enterprise in the United States take Helsinki seriously, universal health care within the nation will become a higher priority. Taking care of one's own house has a validity that a pronouncement of ideal values fails to accomplish. It is clear from the current lack of health care coverage in the United States that absolute equality as a norm of justice challenges our applied ethics universally.

Interdependence

Ethical guidelines for international research are important because values and beliefs differ between individuals and across cultures. Are the principles of autonomy, beneficence and justice the right norms for international, multicultural research using human subjects? While they remain the basis of research ethical assessment, we are right to set the standard high in order to propel us in the direction of global equity, and yet, it seems paramount that we retain a flexible interpretation that will allow us to work gradually toward a more fair distribution of resources for public health. Acknowledgment and acceptance of our diversity and interdependence may enable us to approach the ethical issues of our time with renewed clarity of vision and to choose paradigms that will accommodate our continued growth and evolution. We are dynamic beings, capable of changing our attitudes consciously and at will. We can exercise our judgment and call for certain measures because they are the best that can be done. We are not yet so morally bereft as to require our hand held while absolute instructions are read aloud. We can act on our own vision of the future and begin the construction of some sort of world civilization.

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Africa's AIDS crisis : A case study in international injustice

Mpho Selemogo (from Botswana)
4/37 Saunders Street, Coburg , Victoria, 3058, Australia
Email: mphogift@yahoo.com

Introduction

International injustice, characterized among other attributes by self enrichment of nations at the expense of others, is a well described phenomenon. Exposing unjust practices and persistently speaking up against them is perhaps one of the greatest lessons we learn from great

heroes like Nelson Mandela of how to combat any form of injustice.

This paper examines some aspects of the response of those with extra resources to the African AIDS crisis and concludes that the response could be best seen as an epitome of international injustice. More than just exposing the unjust practices, the importance of such a thesis is that it also represents part of the persistent voices that aim to keep reminding the economically affluent about the plight of the 5000 Africans dying daily of AIDS.

The global health fund

Africa, home to more than 10% of the world's population, lives on about 1% of the global economy. It is the world's poorest continent with half its 700 million people living on 65 US cents or less a day and the only continent that has actually grown poorer in the past 25 years.(1) The reasons for this dismal economic state are complex and beyond the scope of this manuscript.

This continent also bears 80% of the world's AIDS deaths, 95% of the world's AIDS orphans, 70% of new HIV infections and 90% of the world's children living with HIV/AIDS.(2) Because of HIV/AIDS, life expectancies in Africa have fallen by 20 years or even more in some countries. In my country Botswana for instance, the life expectancy has fallen from 67 years to 47 since the HIV pandemic. In many sub-Saharan countries (SSA), the chances that an adolescent will ultimately be killed by AIDS have been reported as greater than 50%.(3) Antenatal HIV prevalence has also been reported as greater than 10% and going up to 30% in some countries.(3) Needless to say, the scale of suffering and premature death represented by these numbers is harrowing. Also, the prospects of Africa being able to develop its economy in the face of such numbers are gloomy.

One would think that in our supposedly civilised world, these statistics would be devastating enough to provoke those with extra resources to spontaneous benevolent action. Writing in 2002, Cheru has noted however that "[t]he unprecedented scale of HIV/AIDS-related death in Africa and the resulting breakdown of family and social networks have yet to stir the international community to anything near the level of action required."(4) The 1990s have seen the commitments of many donors decline and become increasingly sporadic reducing to only a trickle.(5) Aid levels have dropped relative to the growth of HIV to the extent that now the lack of finance is said to be the primary constraint on progress against AIDS.(5)

The global health fund was set up by the UN in 2001 in response to the plummeting aid levels; its aim being that of raising $10 billion annually, from governments of the economically affluent countries and private donors, for the fight against HIV/AIDS, tuberculosis and malaria in the developing countries. In its first year of operation (ie. 2002), only one-tenth of the needed amount was received (6) which again showed a lack of commitment on the part of the 'donor community'. This is despite the fact that the $10 billion needed annually to produce a meaningful response against AIDS in the developing countries is only microscopic in relation to the incomes of the donor countries (the so called DAC countries which comprise of 22 wealthy counties). In fact based on a slightly lower target figure of $7.5 billion, Attaran *et. al* in 2001 point out that this amount would make up just 4 cents per every $100 of the national income of these countries.(5) To put things in context, the G7 countries (the group of the 7 richest DAC countries) hold about a fifth of the world's population yet produce and consume four-fifths of the world's goods and services, contrasted to the developing nations who with four-fifths of the world's population produce and consume just one fifth of the world's resources.(7)

As highlighted at the 2004 World AIDS Conference, this fund continues to fall short of meeting the $10 billion annual goal and is increasingly becoming just another missed opportunity at showing some respect for human life and dignity in Africa and the rest of the developing world. The response of those with extra resources to this fund may only validate the claim that the world operates in a system of 'global apartheid' in which access to human dignity is largely determined by race, class, gender and geography.(4)

'See no evil, hear no evil'

In a piece entitled 'Journalism is failing in its coverage of global AIDS' Russell laments of how " the worst global pandemic since the black death of the middle ages receives less attention than a world cup soccer match" which essentially makes the rest of the western world ignorant of the AIDS tragedy.(8) The chronic and slow moving nature of HIV rather than the acute and spectacular which journalists generally favour, is suggested by the paper to be the reason behind this incredible media failure. This proposition however does not seem to hold up when consideration is made of other such slow moving and non dramatic phenomena. The spread of the West Nile virus in the USA, for instance, managed an extensive media coverage despite causing 654 deaths in 6 years, and having a fatality rate of less than 0.15%.(9) The current western obesity epidemic would also be another non spectacular that is getting a huge media attention. Admittedly, the point of contention here may be on just what one regards as a spectacular event. For the author, 5000 daily AIDS deaths and a near 100% fatality rate, as seen in Africa should count as dramatic enough to get attention of the world's media. In contemplating why fatal diseases in Africa fail to get the front page in the West, a 2005 Lancet editorial rhetorically asks:

So why do diseases in African countries get so little attention from the west? Are horrific diseases just expected to take their toll in developing countries? Are they only big news when they start to kill the wealthy? (9)

Indeed as we have seen recently as the G8 met in Gleneagles, it now takes the world's biggest rock concert to focus the attention of the media on the plight of Africa's poor. Unfortunately, as others have correctly observed, the present Africa has been constructed as a place of perpetual catastrophe and of "unnatural" disasters.(10) It is this construct that seems to have framed a situation in which inferior rights and unacceptable conditions are considered appropriate for Africa and her people; a situation in which an African life is so dispensable as to stir up any useful media reaction in the west. Considering how a media coverage of the AIDS tragedy could potentially cause ordinary citizens in the affluent nations to feel the misery of the distant others and to hopefully 'speak out' thereby helping shape government policies which do remember and budgets for those in need, this silence by the western media amounts to another missed opportunity to upholding human rights and dignity in sub- Saharan Africa.

HIV/AIDS research

For researchers worldwide, Africa's soaring HIV/AIDS rates effectively turned it into a goldmine for HIV research; research that could produce remedies against

the HIV affliction. The first AIDS vaccine trial for example took place in Africa. Against a background of past cases of disregard for the rights of research participants in the developing countries by the affluent countries, the research quickly rekindled the debate on the ethics of conducting research in developing countries.(11)

Sadly, the results of this research now find their greatest application in the developed world and are sometimes even irrelevant to the African communities on whom the research risks were imposed.(12) Even more disappointing is the fact that at times the research done was unethical.(13) Parts of the important and critical clinical data such as published in 'Preventing sexual transmission of HIV- new ideas from sub-Saharan Africa'(14), for instance was derived from a controlled trial done on Ugandan people, with such problematic ethical issues that it could not have been performed in the USA.(12)

Other studies merely exposed what would have been avenues to saving lives; opportunities for saving lives which are unfortunately now wasted due to failure of benevolence by those with extra resources. One study for example investigated the effects of HIV load (changeable by antiretrovirals) on HIV transmission. In the absence of any commitment to improve access to antiretrovirals in Africa (reported as only 1 in 1000 in 2001 (15)), this sort of information would have had no immediate relevance to the African communities bearing the burden of the research.(12)

By the year 2000, Africa was reported to have the highest incidence of curable sexually transmitted diseases (STDs) in the world, at 284 cases per 1000 people aged 15-49.(16) A randomized community trial was done in Uganda investigating the control of these sexually transmitted diseases for AIDS prevention.(17) While a positive correlation would have sparked campaigns in the industrialized countries to eliminate such curable STDs, it probably would have done almost nothing to the communities who bore the risks of this research given their already stretched per capita expenditure on health of less than US$10.

In the studies just cited, those who bear the risks and their communities are arguably not benefiting from the results, though justice would require that they should. Supporting the global fund, at least for now, appears to be the only way of ensuring that the fruit of this research gives hope to where it is most needed. If the results of these studies do not benefit those most afflicted simply because of their absolute poverty situation, it is difficult for one not to see them as mere exploitative exercises.

The relentless medical brain drain

With millions of new infections every year, the African AIDS pandemic literally breeds thousands of new clients daily for the already strained, and in some places, collapsing health systems. All countries are in desperate need of doctors particularly sub-Saharan ones where a total of only 600 000 healthcare workers reportedly serve a multitude of 682 million people.(18) Eleven countries of this region also do not have even a single medical school while 24 out of the 47 have only one medical school.(19) Considering these statistics, it is easy to see how doctors are such an invaluable resource in the settings. With its feature of creating more disadvantage, AIDS is now thought to be taking away this precious resource, killing Africa's doctors almost at the same rate as it kills the general population.(20) Rates of about 30% mortality have, for instance, been suggested for a Ugandan cohort of doctors for a 20 year period.(20)

Despite this predicament, some of the developed nations (with doctor to patient ratios of over 100/100 000) continue to recruit or hire doctors from these devastated countries of SSA to serve in their already well off health systems. In 2003 for example, UK reportedly approved, for work permit, 5880 health and medical personnel from South Africa (a country with the highest number of HIV infected individuals), 2825 from Zimbabwe, 1510 from Nigeria, and 850 from Ghana.(19) In 2000, 600 South African doctors were registered to practice in New Zealand.(21) Noteworthy is the fact that most of these doctors migrating from SSA do not tend to return to practice in their own countries.(19) The UN conference on Trade and Development has estimated a value of US$184 000 loss to every doctor taken away (19) which is just too much to loose for countries being ravaged helplessly by HIV/AIDS. While the migration of doctors is a worldwide phenomenon, this particular pattern in which doctors are taken from very disadvantaged countries by rich countries, at no cost, has recently been brought to question.(21)

Seeing the morally dubious nature of their actions, some of the economically affluent countries claim that they do not target SSA countries for active recruitment. The numbers just quoted at the very least suggest that they have their doors widely open and the claim of passivity in the face of these shocking numbers of permits for just one year is simply unsustainable. One may still argue that some of these doctors are in fact driven away from Africa by such factors like civil unrest, security issues, under-funding, poor working conditions and that the affluent countries cannot be held accountable for their migration. These issues of shortcomings in the African countries need to be seen, as Benatar has often pointed out "in the context of powerful external disruptive forces acting over several centuries to impede progress in Africa."(22) While African countries cannot stop these doctors from migrating in pursuit of greener pastures, the more affluent countries can, as Bunbred *et al* has suggested, seek more innovative and ethically sound methods of meeting their own human resource needs without relying on graduates from poorer countries.(21) Otherwise their actions would only amount to giving with one hand while robbing African countries with the other by siphoning off their most precious resource of trained doctors and nurses.(18)

Conclusion

An old testament passage reads: "There were two men in a certain town, one rich and the other poor. The rich man had a very large number of sheep and cattle, but the poor man had nothing except one little ewe lamb he had bought. He raised it, and it grew up with him and his children. It shared his food, drank from his cup and even slept in his arms…Now a traveler came to the rich man, but the rich man refrained from taking one of his own sheep or cattle to prepare a meal for the traveler who had come to him. Instead, he took the ewe lamb that belonged to the poor man and prepared it for the one who had come to him." (23)

This paper has presented the response to the African AIDS crisis as an illustration of international injustice. Just as is the situation in the preceding story, the avenues for philanthropy have not been utilized usefully by those with extra resources, rather those of self enrichment. The challenge now for those on the side of the poor and those on the side of justice is to "speak out against th[is] moral hollowness of political inaction…[for] the only crime equal to willful inhumanity is the crime of indifference, of silence and forgetting."(24)

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Cloning of Little 'Nikky': What Next ?

- M.N.Jha, Ph. D.
HOD, Microbiology, Faculty of Basic Sciences & Humanities,
Rajendra Agricultural University, Pusa, Samastipur (Bihar), India -84812
Email: mani_raksha@yahoo.com

Darwins's natural selection is an obsolete concept. Nature is no more most powerful and highly skilled engineer. The believe that nature herself undertook a 'natural breeding selection and through the struggle for existence, selected the next suitable creatures, is at stake. The new concept of 21st century is "Biotechnocrat's selection" (sorry for calling biotechnocrat rather than biotechnologist). Their selection is based on self interest. They love to cherish illusions. They are not able to accept that their findings have been for the flattering to themselves. They may have been getting a tag smug about their knowledge and power over nature. Such complacency might have been due to development of technology for organ donation, organ hiring, organ allocation, organ transplantation, cloning of animals including human being to date. A fatherless mouse, a transgenic cow with human milk, an athlete mouse, multiple copies of many animals, cloned human being are some of their achievement. Recently they developed "little Nikky" to replace a recently died "Nikky' cat at the total cost of merely 70,000 dollars to satisfy the emotional desire of a lady who owned this cat. Is it a source of technological immorality? Is it a way for loved ones existence to be perpetuated in a new, cloned body? There may be a situation when a woman just for fantasy intends to mate gorillas or wants to have child as big as elephant and we will be in a position to fulfill the fantasy of such women. But, why do we want to do it? We want to do it to prove that scientific fiction and religious myth is a reality. Is it our next step? Before discussing next step, let us examine the ways of cloning and possible products.

Most fundamentally, cloning represents threat to the sanctity of human life. The possibility of producing multiple copies of a person infers that each individual is a replaceable unit, like the machine parts in the industrial system. I fear, in a world in which individuals are easily duplicated, life itself will become cheap.

In approaching reproductive cloning, it is helpful to make several important distinctions. One in cloning by blastomere separation (embryo splitting) and cloning by somatic cell nucleic transfer (SCNT) technology. The former involves the deliberate creations of multiple copies of a genome by separating or multiplying the individual cell of an embryo. The latter, involves the use of somatic cell, nucleus from an existing (or even a deceased) individual to replicate the genome of that individual. Embryo splitting makes possible the production of multiple identical genotypes. SCNT cloning raises the issue of reproducing the genome of living being. It can be used to mass produce identical genome by starting with multiple copies of a somatic cell.

The use of procreative SCNT by people who can not otherwise have a biologically related child seems to be justified. But this kind of procreative SCNT technology may be attractive to lesbians or gay. Some lesbian couples, for example are hesitant to employ donor insemination because they fear that the sperm donor may later assert parenting claims. But can we justify the feeling of such lesbian in relation to social health? Replicative reproductive cloning in contrast, deliberately aims at the duplication or multiplication of existing genomes. Thus, it can be used commercially in connection with the sale of celebrity genomes for reproductive purposes. Finally, governments or other organization might use it to produce many desired genotypes for military or other purposes.

The cloning of little Nikky opens a path for fulfilling the desire of human being to 'replace' a wife/son/daughter who died. Imagine a situation where a newly married couple after enjoying one year honeymoon period lost his/her partner. The surviving partner say husband decideds to get clone of his wife just before death by paying 70,000 dollars to biotechnocrat, like Nikky's owner. He nurtures the baby with a desire to marry once she attains the age of eighteen and finally he marries that girl. Can readers suggest me whether it is unethical or immoral or illegal or combination of any two or all three? Similarly, a female child cloned from her mother might develop a desire for relationships to her 'father' that after all is also her biological twin sister.

Fictional literature, films and religious myth are considered as highly imaginative but often offer scientifically dubious scenarios. But, I feel difficulty in calling these themes

as dubious ones on the basis of pace of development in cloning. Let use examine some of these themes.

The movie "Jurassic park" describes about a theme park populated by cloned dinosaurs and the disaster that results. The basic story is that DNA from dinosaur was cloned and then used to produce a dinosaur. Biotechnocrats claim that they will produce extinct species from their DNA within five years and get a breakthrough. So, don't call it fiction. The movies "Multiplicity" and "The Sixth Day" portrays existing individuals losing their individual identity or rights through the instant (and possibly unconsented and surreptitious) production of cloned copies of them. A related scenario of envision cloning being used by despots to mass produce obedient armies of "Super warrior" or Bin Laden" making an army of ten million identical robotic killers from his somatic cell. Previously, I also believe in scientific argument that genotype does not equal phenotype person character. Attitude, desire, approach etc depends on the environment. So, cloned counterpart may be identical in appearance with his/her mother but not in characters. But now, I am a bit confused with the claim of biotechnocrat for identifying gay gene, divorce gene, criminal gene, loving gene, thrill seekers gene and so on, number increasing day by day.

The mythical story of Vedic India in likely to be proved true these days. In *Srimadbhagavat,* it has been mentioned that when His Excellency Nimi was dead, the seers by process of *Mantha*, (perhaps, human cloning in modern idioms) created a new baby from his dead body. The baby was called *Janaka*, as it was out of *(mantha*) cloning of his father. It was called *Videha*, as it was born out of a non-sexual process. As the baby was born out of a process of *mantha* it was called *Mithila* and his kingdom was also named as *Mithila.*

The epic also narrate that she-deity "*Yoga Maya*' successfully transplanted the embryo found in the womb of *Devaki* in the womb of *Rohini*, another wife of *Vasudeva*, the father of *Krishna.* This is no more a myth as evident from the successful transplantation of the embryo of a daughter in the womb of her mother by a team of biotechnocrats in USA.

Another myth that Taksheela students had reanimated a lion out of its laying bones will be a reality in coming days. People will also see how Zygote of *Gandhari* (Mahabharata), after abortion, would have been metamorphosed into hundred embryos or hundred sons.

As narrated in *Vedas,* God converted men and demon into supermen and superdemon respectively by blessing with boons. *Hirankashyapu*, a superdemon was blessed by god that he will neither be killed by the men or animal, by the *Sastra or Astra* (weapon), neither on the earth nor in the sky, neither inside home nor outside home and neither in day nor in night. The superdemons started destroying the natural harmony and declared himself as God. With the passing of time, his atrocities crossed all limits and thus God metamorphosed himself into a hybrid of man and lion (*Narsingh*) and killed him during dawn period with his nail beneath the corridor of home. God is also known to have metamorphosed himself into hybrid of man and pig *(Barah)* man and fish *(Matsya*), man and tortoise *(kurma*) to protect earth from superdemons from time to time. Is it considered a God creation or biotechnocrat creation of those days, I am bit confused. It seems that time span between atrocities period and killing might have been utilized by biotechnocrat of those days to get remedy of their mistakes. Should we repeat such mistake in modern days and then search for remedies? will it be possible? If yes, then there would not be an era of *satyug, Treta, Dwapar* and *Kalyug.* It is said that we are in *Kalyug* era and all other era has completed its span or destroyed by the creation of superdemon or supermen.

Similarly, in Ramayana a superdemon *Ravana* had regenerating ability like many animals. He had ten heads and cutting of any head used to get regenerated. His brother *Khumbhakaran* had 31 feet height and 1000 year longevity. He had a fleet of army with different hybrid combination. Another character *Raktabeeja* had ability to produce multiple copies of clone if any drop of his blood falls on the earth. These characters considered as a myth , is really a myth. Now, we can get a multiple copies of any individual through SCNT. We have already made hybrid cells between a yeast and the blood cells of a chick, between the cells of a man and a mouse, between the cells of a man and monkey. We have transplanted human milk gene in the cow. Its a matter of time when we will transplant lizard regulating gene into human being and prove that character of *Ravana* was not a myth.

But, we don't forget the story of *Bhasmasur*, another superdemon. God or Biotechnocrat of those days blessed him that if he will put his hand on the head of any individual, he will be converted into ash. *Bhasmasur* desired to test this new acquired character over his mentor. The mentor had to run away for protecting himself. Another God 'Vishnu' came for his rescue. He metamorphosed himself into a beautiful dancer and started performing dance in front of *Bhamasur*. *Bhamasur* enjoying the moment, started copying activities of dancer. Dancer put her hand on head and *Bhamasur* did the same and thus was converted into ash. This is not story rather than reality of coming days. Such remedy may not click in many cases and in such situation existence of this era *kalyug* will also follow the path of its predecer *Satuyg, Treta and Dawaper*. Biotechnocrat have already laid the foundation stones to convert all these myth into reality.

The scientific fiction like possibility for human being to "See" with their ears, transmitting visible, invisible and even ionising rays, getting sixth sense for anticipating Tsunami, transforming into autotrophic mode of nutrition and fulfilling the oldest dream of mankind, the dream of eternal youth seems to be fulfilled in coming days. Such fulfillment merely requires the transplanting of respective gene(s) in human being. Such gene pool is already available in nature in abundance. Bat can find their way by hearing instead of sight and deep sea fish transmit visible, invisible and even ionizing rays due to presence of such gene. A plant have phototrophic gene and an *amoeba* have immortal gene. The sixth sense in animals may be responsible for getting wind of Tsunami disaster. From Khao Lak Elephant tracking centre in Thailand to Yala on the Sri Lankan coast, elephants were trumpeting long before the Tsumami waves crashed. Further, two pet dogs refused to go for the daily rums on the beach that morning. Bats were seen frantically flying away just before the Tsunami attack. The gene responsible for such sixth sense will be transplanted in human being and at last the transplanting of photosynthetic gene will free us from agriculture. But, I am scared that transplanting photosynthetic gene will not only relive us from food hunting but also relive us from all responsibility.

Besides converting myth, movie imagination and scientific fiction into reality, cloning will also open employment for even uneducated mass of society. There may be some discrimination on the basis of sex but weaker sex will be more in demand. Women can rent their wombs, and also sell their eggs for a lucrative price. But, the woman whose womb feeds the zygote and develops the fetus, does not feel well. The feeling due to cloning cell fetus and feeling of own genetically tied fetus can not be the same. In the first case the mother will feel herself a carrier of an outsider fetus, while in the later case the mother will feel a psychological bond with the moving baby. In the first case, we find a permanent feeling of otherness of a mother towards the fetus and also an inferiority complex of either not being the real mother or someone has hired her. So, this mechanical process is a heinous act, which produces a psychological alienation in mother towards the child. The feeling of the baby moving within the womb, the mother perceives the fetus as a part of herself than as a separate individual. Such psychological affinity in not possible with the hired womb. It will only enhance the hiring of women womb for developing the clone fetus. Naturally the poor

women will be the victim of the rich people. I think, this will lead towards the slavery period because the women who carriers the fetus has no right even to call the born child son or daughter. Just she will be paid and nothing else. Really, do we need such type of employment? Man will also enter in this business for selling their sperm. The "Noble Laureates' sperm bank is already established few years ago but unfortunately did little business.

Thus, in coming days, lot of relationships will emerge. Such relationship may be between organs and organism, between human beings and animals and between human beings and the higher self (if any). The path will lead to possessing a body even after death. All these developments will pose many question like: Should we encourage womb hirer and sperm donor ? should monetary value replace organ value ? should free riders hire free donors ? Should we arm with sixth sense, autotrophic, regenerating etc gene(s)? Should we develop a hybrid like *Narsingha, Barah, Matsya and Kurma*? Should we clone human as a commercial enterprise ? Just think of what future Christmas shopper might be able to buy - gifts of genes!what kind of practical joke might be played on us? Some not no funny, I think.

Converting the possibility of such next (already something achieved) into reality by Biotechnocrat of modern days will fulfill the desire, to overrule the nature rather than being the part. But such desire will never be fulfilled. Infact the greatest illusion of human being is that they are supreme commander of this planet earth. Some of them have forgotten mortal lesson that we are part of the nature and nature is not our part. Truly speaking, man is an imperfect being. It has no natural protection against the cold such as animals have in the form of fur and feathers and his physical strength is insignificant compared to other animals of the same size as himself. A medium sized dog has far better teeth than man , and he lacks any natural weapons such as claws, tusk, etc. An unarmed man is completely helpless when faced with a beast of prey, as he can neither fight nor flee with any hope of successes. He does not have sixth sense like animals of lower order in evolution for protecting from natural calamities like tsunami. Several animals are far superior to him in their sensory abilities to sound, temperature, touch, vibration and to electrostatic, chemical and magnetic changes in their environment. Had such a human being remained purely animal in nature, it would soon have disappeared from the earth because it was not equipped for the stern struggle for existence. But, time and time again nature shows that she is capable of giving a chance to her creations even under the most unfavorable condition, and this applies equally to human beings. This is the reason that resourceful nature has provided intelligence to human race in place of many animal characters. Man will have to prove to the nature that he is not only be knowledgeable but also wise. It can only be proved by distancing from the steps that lead to eradication of world 'fiction and 'myth' from dictionary.

Last night, I had a chat with nature in dream. She confessed that she can not compete with Biotechnocrat in velocity of cloning but biotechnocrat can not compete with me in accuracy of cloning . I can sustain the disaster. You human being can not sustain the disaster. So, Please advise Biotechnocrat, not to divert his/her intelligence towards human cloning. I don't want premature death of *Kalyug* or present era.

Expert System on Diagnosis, Treatment and Alleviation of Stress

- Kim Kah Hwi, Chin Kah Chuan and [1]Munehiro Goto.
Dept. of Physiology, Faculty of Medicine, Universiti Malaya, 50603 Kuala Lumpur
[1]Department of Electronic Engineering, Faculty of Engineering, Gifu University. Gifu-shi, Yanagido 1-1, Gifu 501-11, Japan.

Abstract

We conducted stress psychotherapy using an expert system via computer networks, telephones and facsimiles in Gifu City, Japan. Through the therapy, we have obtained some distinct knowledge about the source of stress, stress related disorders and illness.

This paper reports some of the results categorized as follows; adolescents, housewives, career women, geriatric persons, researchers, salarymen and managers. For example, the stresses of career women are due to sexual harassment in their working time and serving tea and coffee to clients. About half of them have felt a lack of personal satisfactions with friends, spouses, children and in-laws. They also expressed problems in time-management between family and office work and difficulty in accomplishing tasks impart due to distractions. When they feel lack of self esteem due to self-demand and self-blaming, they have a problem in expressing their own feelings and thus keep their problems and pressures to themselves. Emotional symptoms manifested by stress are developed personal sensitivity, and pre-menstrual tension. The career women pre-menstrual tensions are four times higher then for housewives. Psychological disorders caused by stress are hostility, anxiety and depression. Physiological disorders include tension headaches, migraine headaches and insomnia. A few of the career women experienced sacroiliac pain and duodenal ulcers. We believe that our expert system for the stress management is convenient and user friendly for stress diagnosis and to seek treatment to find ways to alleviate stress.

Introduction

About 75% of the patients treated by physicians in the United States have stress related disorders. They have been prevented, alleviated, or healed by reducing stress (Charlesworth & Nathan, 1984). The data collected in Japan have shown an increase of 'sudden death' due to cardiac diseases and cerebral hemorrhages. This is clearly related also to an increase of stress related problems due to the rising rate of cancer, cardiovascular diseases and epidemic on 'sudden deaths' (Chang Yvonne, 1991).

In Japan, the stress psychotherapy is carried out by physicians (psychiatrists) with the help of nurses and social workers. Problems arise from the difficulty of individuals to express their problems freely and in a relaxed manner, due to inferiority complexes, shyness, the feeling of shame and the lack of motivation. The patients usually have a difficulty trusting or understanding the physician, nurse or social worker and do not have a good relationship with them.

In this study we conducted a stress psychotherapy using an Expert System was set-up in Gifu University, Gifu, Japan. This system is available for individuals to conduct the stress consultation service freely through internet via their personal computers. Diagnosis is made referring to signs and symptoms elucidated with the alternative treatments to alleviate symptoms and to overcome the stress disorders, are suggested to the users.

The results obtained from the diagnosis for

adolescents, housewives, career women, geriatric person, researchers and managerial staffs, have clearly showed that this expert system is capable to diagnose or pinpoint the source of stress and make some suggestion treatments for the stress alleviation. We have planed to provide this system toward over the Japan in order to help individuals to understand and overcome the adverse effects of stress, as well as to encourage them to seek the treatments by psychiatrists.

Methods

The interview and the psychological tests to the patients are the main tools used by the psychiatrist in the stress therapy. Through these tools psychiatrists determine the mental states of the patient and elicit the cause or the history of present illness. The main stress therapy is to encourage the individuals to narrate their story, talk about their own stress and problems in their own words. The individuals need to express their own emotions in a relaxed manner and may even cry in order to release the conscious or unconscious accumulated stress. Significant emotional responses cannot be obtained unless the individual expresses his deepest feelings with trust and without tension and anxiety (Hodges & Felling 1970). To achieve this situation, we have tried to encourage the individual to do stress consultations, by using Expert System through internet via their personal computers.

The Expert System program was written in common LISP Language 3.0 version by Sun micro software system. The entire program consists of the same sections as presented in the Fig. 1. And its data flow chart is shown in Fig. 2. The program consists of five sections as follows:

1. Collection of Personal Data

This section includes the name, date of birth, age, sex, and details about parents, siblings, marital status, children, hobbies, educational level, qualifications, occupation and the present state of health of the patient.

Figure 1. Schematic database structure of Expert System on Stress.

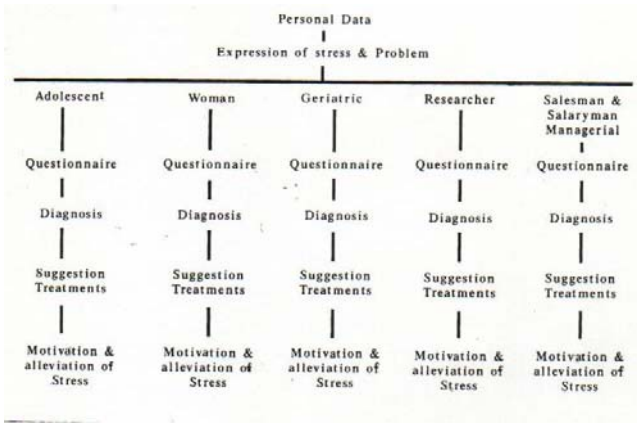

Figure 2. Schematic data flowchart structure of Expert System on Stress.

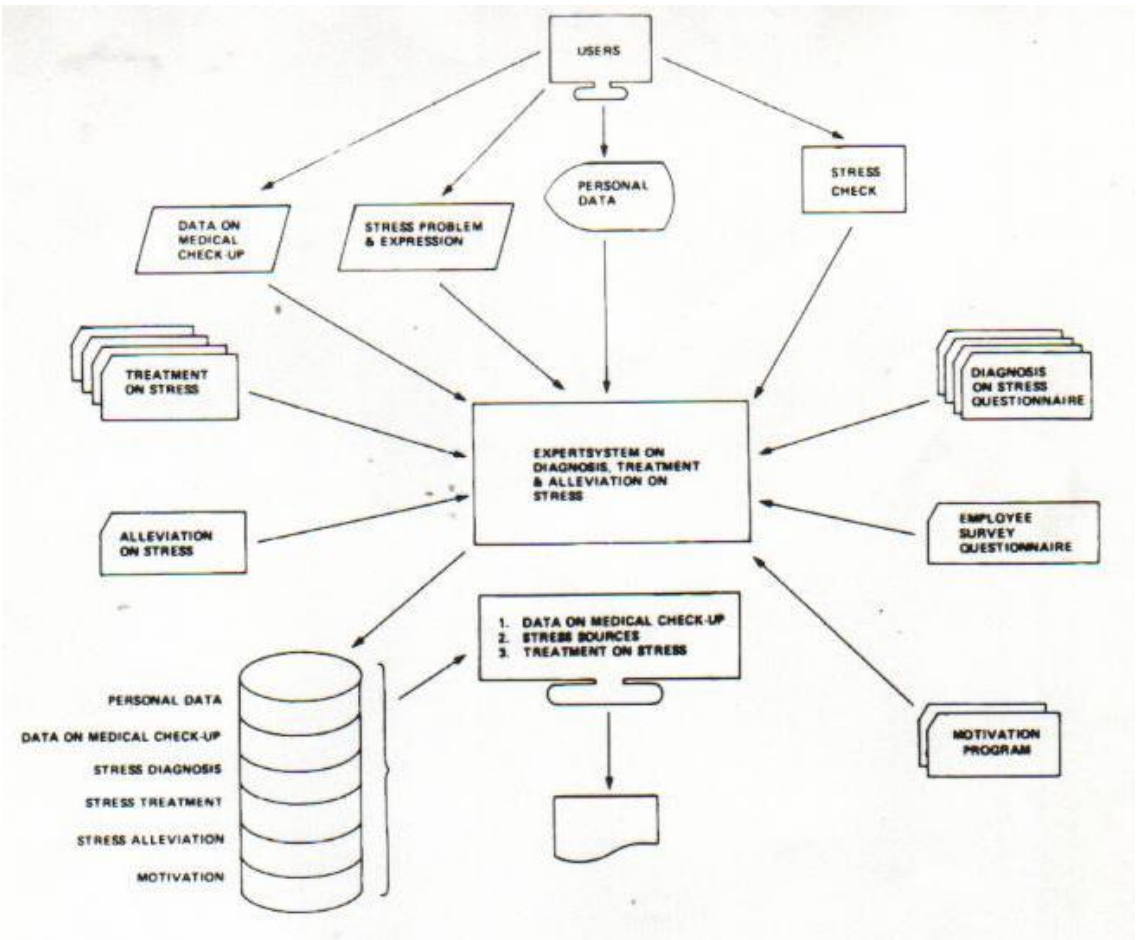

Table 1: Assessment of stress or Stress sources, Symptoms developed, Condition of moods, and Personal character of users (in %). A= Adolescence (n=450), W= Women (n=350), G= Geriatric (n=350), R= Researchers (n=120), SSM= Salesman, Salarymen & Managers (n=280).

1. ASSESSMENT OF STRESS.	A	W	G	R	SSM
1.1. WORK OR JOB.					
1. Working Environment.	5	15	3	38	18
2. Working Pressure.	66	70	2	80	15
3. Working Satisfaction.	11	14	5	90	88
1.2. LIFE-STRESS.					
1. Personal Change.	14	22	89	28	84
2. Personal Pressure.	73	24	41	46	20
3. Personal Satisfaction.	14	19	45	85	37
4..Personal Behavior.	12	18	18	32	49
1.3. COPING RESPONSE & LIABILITIES.					
1. Self-Care.	17	86	18	77	37
2. Direct Action.	21	18	16	37	11
3. Support Seeking.	85	16	13	86	19
4. Situation Mastery.	14	22	81	37	27
5. Adaptability.	12	24	18	36	66
6. Time Management.	88	12	22	72	58
7. Interpersonal Trust.	17	90	96	46	59
1.4. THOUGHTS & FEELING.					
1. Self- Esteem.	17	86	13	23	31
2. Positive Outlook.	19	9	9	71	63
3. Personal Power.	12	18	18	37	20
4. Connection.	17	1	19	35	16
5. Expression.	62	1	18	46	87
6. Compassion.	17	16	13	45	26
2. SYMPTOMS DEVELOPED					
1. BEHAVIORAL SYMPTOM.	85	16	13	70	22
2. EMOTIONAL SYMPTOM.	34	20	81	74	91
3. PHYSICAL SYMPTOM.	31	16	83	35	63
4. PRE-MENSTRUAL TENSION.	29	72	-	-	-
3. CONDITION OF MOODS.					
1. UNDER CONTROL.	16	24	8	20	14
2. OUT OF CONTROL.	34	30	22	30	16
3. CONFUSION.	21	18	38	20	9
4. CLARITY.	35	19	44	63	52
5. ACCEPTANCE.	12	24	13	30	49
6. REJECTION.	30	82	20	46	16
7. TYPICAL.	55	10	25	21	51
8. ATYPICAL.	37	19	21	26	13
9. CHANGE.	21	26	25	28	27
10. STABILITY.	32	13	14	28	65
4. PERSONAL CHARACTER.					
1. POSITIVE CHARATER.	54	48	44	71	87
2. NEGATIVE CHARACTER.	7	40	22	20	8

2. Expression of Stress and Problems

This section is one of the most important sections in stress therapy. Individuals are encouraged and guided to express themselves freely in their own words. The expression depends on their emotional state, stress level, feeling of distress, physical complaints, trouble and dissatisfaction in their life, suicidal thoughts or thought of self hurting, alcohol consumption, drug abuse and the possible history of past events that may have caused to develop the present disorder.

The stress therapy in this system is classified into the following groups: adolescents, women, geriatric persons, researchers and salesmen or salarymen or managers. Each group is followed up with the particular emphasized questionnaires on the diagnosis of stress to pinpoint the source of stress, then follow-up with the suggestion treatments and the motivation to alleviate their stress.

2.1. Adolescents

In Japan stress therapy for adolescents is usually carried out by teachers because adolescents seldom go to psychiatrists by themselves, unless suggested by the teachers. A good interview between a teacher and a student should be a relaxed conversation, where confidentiality is preserved and privacy is ensured. In all industrialized societies, adolescence is defined as the important period of life in which decisions which affect the social and occupational status attained in adulthood are made (Hurrrelmann, Engel, Holler, & Nordlohne, 1988). Thus the questionnaires for adolescents put more emphasis on the variables related to their school, parents, family members, teachers and peers.

450 healthy adolescents (250 female, 200 male) were chosen from various high schools and colleges in Gifu City to utilize this system.

2.2. Women.

The responses to the stress therapy of females were different from that of males, which is due to differences in the stress process and differences in their physiology (Barnett, Biener, & Baruch, 1987). In Japan, mothers play the most important roles in the family and are most influential in their children's development. The family is a universally important sociocultural institution. Therefore the family is the keystone of society and the key to understand human beings including their success or failure as one.

Questionnaires for women put emphasis on variables related to the status, roles and problems related to the family. For career women, a bigger emphasis is put on their work related questionnaire. In this study we were able to collect data from 350 housewives and 250 career women.

2.3. Geriatrics

Geriatrics is regarded as those who are 65 years old or above. These people are in the period of life where an inevitable and progressive functional impairment occurs in the individual's capacity to adapt, adjust and survive. A significant decline in physical, mental and functional capacity is measurable at this stage of life.

Aging persons should be aware that their stress disorders are mainly due to the loss of family, friends, social or economic roles, status, occupations, the change in sexual roles and decline in their physical and mental capacity together with attendant physical illness and the prospect of death (Goldfarb, 1967). Questionnaires for the geriatric group put emphasis on the variables related to reaction to the loss of occupation and status, economic loss, physical & physiological changes, isolation and loneliness. For the aging people involved in the Second World War, a special attention was paid and the questionnaire on the posttraumatic stress disorder was adopted from Wolf and Misaim 1990.

350 (200 female, 150 male) members of the aging population have participated in this system.

2.4. Researchers

The persons involved in research and development (R & D) in companies or research centers are greatly influenced by the stress due to their work, and can slowly change their personality. Some of them may reach to the stress disorders. In Japan, researchers are important contributors in creation and development of sophisticated and advanced technologies. The important factors for the future success of the researchers are the researcher's personal interest in the area concerned, the financial support and encouragement given to them.

Questionnaires for researchers put emphasis on the stress caused by the research and environment in which the research is carried out. The participants of this group included 120 researchers from the local research centers, software development centers and Gifu University.

2.5. Salesmen, Salarymen and Managers

This section is especially concerned with persons involved in business; either in sales and administration (clerks, salarymen) or managerial positions (managers, directors, presidents). The salesmen are always exposed to various situations when meeting customers to sell and promote their products. In Japan, a man who works in a company and receives a fix salary is called a "salaryman". He is usually overworked, and contributes largely to the success and development of the company.

Questionnaires for this group put emphasis on the variables related to interpersonal relationships with customers, colleagues, supervisors, managerial staffs, friends and the family. This study involved 250 salarymen, 120 Salesmen and 10 presidents of companies in Gifu City.

3. Questionnaires

The questionnaires are mainly divided into three categories of variables, i.e., stressors, stress reaction and personal characteristics. The posttraumatic stress disorder, however, is set only for the aging people involved in the Second World War. Questionnaires are rated on a zero to three point scale. The stress level is determined by the total score, which is divided into four stages: optimum, average, alarm and breakdown.

3.1 Stress questionnaires in this study include the terms related to the job or work, life stress, coping and appraisal:

3.1.1. Job or Work includes working environment, working pressure and working satisfaction. These are considered as the major life events and include positive as well the negative life events taken from "social readjustment rating scale" by Holmes & Rahe 1967; Dohrenwend, 1978.; Horowitz, 1977 and "life events questionnaire" by Marziali & Pilkonis, 1986.

3.1.2. Life stress includes personal change, personal pressure, personal satisfaction and personal behavior. Questionnaires are adopted from "hassles scale" (Kanner, Coyne, Svhaefer, Lazarus, 1981), "stress situations questionnaire" (Hodges & Felling, 1970.) and "fear survey schedule" (Wolpe & Lang, 1964.).

3.1.3. Coping response and liabilities contribute to self-care, self direct action, self support seeking, self situation mastery, self adaptability, time-management and interpersonal trust. The questionnaires related to these are modified from coping response and liabilities by Folkman & Lazarus, 1985; Folkman, Lazarus, Dunkkel-Schetter, DeLongis & Gruen, 1986.

3.1.4. Thoughts and feeling is related to self-esteem, positive outlook, personal power, self connection, self expression and self compassion. These questionnaires are from "relation behavior inventory" by Shorkey & Whiteman, 1977.

3.2. Stress reaction questionnaires are adopted from "behavioral and physiological responses" known as the personal health check. These include behavioral symptoms, emotional symptoms, physical symptoms, illness, disease and pre-menstrual tension.

The behavioral response is modified from "assertion inventory" by Grambril & Richey, 1975 and innumerable scales which assess the behavior such as alcohol usage, sexual behavior, smoking, eating habits, social skills and assertiveness described in Hersen & Bellack, 1981. Physiological response is modified from "Allen and Hyde symptoms checklist" by Allen & Hyde, 1980 and "stress symptoms & disease" by Ronald, Thomas, & Paul, 1989.

3.3. Personal characteristics are taken from the daily mood assessments by Hedges, Jandorf, & Stone, 1985 known as questionnaires on the mood check, which includes self control, confusion or clarity of mind, acceptance or rejection character, typical or atypical type of mood, change and stability of mood. Whereas, personal multidimensional questionnaires which are adopted from Karasu,1990 include positive affective and negative affective. Finally, the posttraumatic stress disorder questionnaires are modified from those by Wolf & Mosnaim 1990.

4. Diagnosis

Diagnosis for the stress is based on the data obtained from the questionnaires and problems expressed by the individuals. Diagnosis results are classified as follows:

4.1. Stress sources include stresses from work or job, life stress, coping response & liabilities and thought & feeling.

4.2. Symptoms developed by the stress are behavioral, emotional, physical or pre-menstrual tension etc.

4.3. Conditions of mood show the individuals are under self control, out of self control, confusion or clarity of mind, acceptance or rejection character, typical or atypical mood, change and stability of mood.

4.4. Personal character of individuals is either a positive character or a negative character.

4.5. Psychological disorders developed by the stress are anxiety, obsessive-compulsive, interpersonal sensitivity, depression, hostility, physical somatisation disorder, drug or substance abuse, pre- menstrual tension and posttraumatic stress disorder.
4.6 Physical disorders are developed by stresses on skeletal muscles, cardiovascular system, gastrointestinal system, respiratory system, autonomic nervous system and allergic reactions (Cohen, 1980; Mitchell & Drossman, 1987; Braunwald, 1987).

5. Suggestions for Treatments

Suggestions for treatments are for stress management to guide a person to overcome or reduce his / her stress level. These include five major sections:
5.1 Prevention, avoidance and how to keep your stress level down (Albrecht & Selye, 1979).
5.2. Physiological approaches: They are classified into relaxation therapies and the suggestion for living healthy life-styles.
5.2.1. Relaxation therapy: The therapies need training, self-control and a regular practice. One or several techniques are used to diffuse the negative physiological symptoms which the body displays under the stress. The goal of relaxation therapy is to enable the individual to voluntarily produce an alternative physiological response to the stress (Keable, 1985 a, b). Examples of relaxation therapies suggested in this study are the controlled breathing, deep relaxation techniques and a good sleep (Jeffrey & Myers, 1987). Controlled breathing guides a person how to voluntarily control their breathing. This includes four basic breathing exercises to overcome their breathing problems.

Relaxation techniques include "progressive relaxation", "Yoga exercise" (Jacobson, 1976), and "transcendental meditation" (Bloomfield, Cain, & Jaffe, 1976). Also note Benson's relaxation response and "autogenic training" (Norris & Fahrion, 1984), "biofeedback for EMG on reducing the muscle tension" (Basmajian, J. 1979), "biofeedback on EEG for increasing the alpha wave activity" (Shiga, 1989), momentary relaxation (Albrecht & Selye 1979.) and "visual imagery or day dreaming" (Jeffrey, 1987).

Getting good a sleep is essential for maintaining good health and one of the successful ways for managing individual stress. This section notes the side effects due to sleeplessness and the common factors that interrupt individual sleep and also fourteen principles for getting a good night's sleep.
5.2.2. Suggestion for healthy life-style behavior: This suggestion is able to reduce the intensity of physiological aspects of the stress reaction, as well as moderate the effects of stress (Kaplin, 1984). Those who wish to live a healthy life-style are advised to perform a regular exercise (Martin at al., 1984), maintain physical fitness (Roth & Holmes,1985; 1987) and a good posture. Further, they are guided the accurate ways to relieve of pain (Jeffrey, 1987), build up a happy family and have a happy and joyful sex life (Dore, 1990). Guidance's and advices are given also on the diet and good eating habits (Edward, 1987.). In some cases individuals are asked to quit smoking (Cotton, 1990) and moderate intake of alcohol (Farber, Khavari, & Douglas, 1980; Dore, 1990).
5.3. Behavior strategies: These are mainly to find out how the individual acts, what he should do, what will occur when he feel stress. The therapy watches behavior excesses: frequency, duration, intensity or quality. Behavior deficits are evident when the desirable type of behavior fails to occur with a sufficient frequency, for a proper duration, with adequate intensity, in an appropriate manner, or up to the social expectation. Deficits may occur in social skills, assertiveness, ability to manage time effectively or ability to use leisure time effectively. However, a positive behavior can contribute to reducing stress or moderating the stress responses (Cotton, 1990). Suggested treatments for these cases include self-management and time-management (Kanfer & Golstein, 1986), assertiveness training (Alberti & Emmons, 1982) and encouragement of the individuals to use leisure activities more meaningfully (Witt & Bishop, 1970).
5.4. Alleviation of stress: This includes the possible sports, social activities, physical fitness, traveling, hobbies and leisure activities to overcome stress.
5.5. Motivation:. Motivation can play an important role in encouraging the individuals to fully utilize suggested treatments. Besides, motivation itself may serve as a guide and simultaneously stimulate the individual's inner desire to overcome the adverse effects of stress. Motivation programs given are taken from the books "Positive principle today" (Peale, 1976), "Faith is the answer" (Peale & Blanton, 1978), and "Thick & growth rich" (Dutton, 1988).

Results and Discussion
1. Adolescence

Their stresses are mainly due to the school work pressure and long hour of schooling, which make them feel a lack of time to do other things. Besides they always feel the pressure that they have to perform well in their studies in order to respond to the expectations of parents and teachers and sometimes to defeat the mates in examinations. These stresses make them seek some kinds of support and feel difficult to express directly their feeling (Table 1).

Stress disorders or personality disorders found in the adolescent are hostility (83%), anxiety (81%) and obsessive-compulsive behavior (79%). Their symptoms manifested by the stress include avoidance behavior, sadistic, antisocial, schizoid, self-defeating, depressive, aggressive and disorganized behaviors. While physiological disorders such as tension headache are common (72%), and only 29% of them have dry mouth and loss of appetite.

The suggestion treatments given are the relaxation techniques (79%) which include yoga relaxation, a biofeedback on an EMG (muscle massage), and an EEG (by increasing alpha waves through listening to music). The adolescents are also advised to do a regular posture exercise (10 minutes in the morning and night) (86%) and daily sports (81%) to overcome the stress. Besides, 85% of them are guided how to manage their time more properly by self management and increase their self confidence to study more effectively.

The personal pressure for them to have to perform well always leads to anxiety for entering a better university and procuring a better job in the future. In Japan, the career opportunities offered to the candidates are based on their education level. The high school or college attended by the adolescent is also taken into consideration, which are similar trends to those reported by Hurrelmann, 1988. For example, the candidates from a prestigious university such as Tokyo University would easily obtain the better jobs. This makes parents put a great pressure on their children to achieve excellent results in the examinations. These circumstances cause the increase of the psychosocial stress for the adolescents, especially when there is a conflict with their parents on the school performance, educational aspirations and the emotional tension.

The anxiety over the studies has become a main cause in the development of stress-related disorders in adolescents. As a result, the drugs or substance abuse, and suicidal thoughts, due to examination failure and the family pressure, increase among adolescents in Japan.

2. Women (Working ladies & Housewives)

Japanese housewives have felt the stress due to an increase of work demands, pressure in housework, part-time jobs, difficulties in interpersonal relationships with in-laws and a temporary separation from their husbands who are

transferred to the other place to work.

The life stresses are mainly due to the self-care and the lack of self-esteem. The former is caused by the lack of exercise, worry about self appearance, and as a result, many of them are not able to relax. While, the latter is caused by self-demand and self respect. Only a few of housewife have a pre-menstrual tension (Table 1).

The stresses which the career women expressed are due to the sexual harassments in their working time and serving tea and coffee to clients. About half of them have felt the lack of personal satisfaction with a friends, spouse, children and in-laws. They also expressed problems in time-management between family and office work and difficulty in accomplishing the task and the distraction. When they feel lack of self esteem due to self-demand and self-blaming, they have problems in expressing their own feelings and keeping their problems and pressures to themselves.

Emotional symptoms manifested by stress are the developed personal sensitivity, rejection of mind and pre-menstrual tension. The career women's pre-menstrual tension symptoms found in working ladies were four time higher then housewives.

Psychological disorders caused by stress are hostility (79%), anxiety (44%), and depression (41%). The physiological disorders include tension headaches, migraine headache, and insomnia (87%). Only about 38% of the career women experienced sacroiliac pain and duodenal ulcers.

The suggestion treatment given for the women are relaxation techniques (92%) which include yoga relaxation, a progressive relaxation training and a biofeedback EMG (muscle group massage), an EEG (increasing the brain alpha wave output by listening to music, watching videotapes of the environment). These people are also advised to moderate alcohol intake (86%), fulfill their sex lives (73%), stay happily with their family (56 %), and 39% of them are asked to do physical fitness, have a regular exercise and maintain the ideal body weight.

To those who felt difficulty in managing time (76%), we advised how to manage the time more efficient by doing self management, doing assertive training and applying positive principles. Traveling and sports are recommended to alleviate stress (38%).

Generally speaking, the status of Japanese women in the companies, social, or political circles is low. Japanese women have been fighting for equal status with men. Unfortunately, their achievements have been far from expected, as compared to the other industrial countries like USA or European countries. This may be due to the influence of strongly held ancient beliefs, traditional thoughts and cultural influences on the role of women in the society.

3. Geriatrics

The aging people have expressed the stresses caused by changes in the personal life style due to retiring from their works, living at home, the lost of spouse and the divorce. They encounter problems of situation mastery which include frequent expressing of anger, difficulty in the problem-solving and feeling of helpless. They have also expressed the lack of interpersonal trust to other person even to their own spouses (Table 1).

Emotional symptoms manifested by stress include hostility, emotional drain, anxiety, developed interpersonal sensitivity, depression, difficulty in sleep, and forgetfulness. Physical symptoms developed by stress are back pain, joint pain, heart and chest pain, stomach upset, difficulty in breathing and hearing, cold or hot spell and frequent urination (Table 1).

Psychological disorders which equally found in older men and women include an obsessive-compulsive behavior (76%), interpersonal sensitivity (76%), hostility (53%), and 45% developed physical somatisation disorders, disorganization, and neurosis. Anxiety and depression are more commonly found in females (65%). On the other hand posttraumatic stress disorders are more commonly seen in males (70%), which is a persistence of disappointment, discouragement, hopelessness, depression and fear of the horror of war. Unfortunately the psychiatric consultation is not well accepted by the elderly people, and moreover the research on psychological changes in the elderly who were involved in the Second World War has not been so well carried out as that of America soldiers involved in the Vietnam War (Wolf & Mosnaim, 1990).

Illness in the aging people caused by the stress are essential hypertension (70%), chest pain (70%), angina pectoris (70%), headache (70%), hearing (61%), eye side problem (58%), gastric ulcers (48%) and ulcerative colitis (48%). A few of them (18%) are rheumatoid arthritis, neurodermatitis and insomnia.

Suggestion treatments given to geriatrics are advised on diet and eating habit (73%), getting a better sleep (67%), abstaining from alcohol, quitting smoking (41%), do massage and pain relive (39%), controlling breathing, biofeedback on EMG & EEG (36%). We have also recommended self-management, travel, leisure activities, and motivated them to live life more positively, and to encourage to be involved in social welfare activities.

The aging people are more sensitive to changes in the environment, e.g. weather, noise levels, situation at home, and personal change. The elderly are affected by the loss of control for different situations and the loss of interpersonal trust, emotional and physical symptoms, developed stress disorders, and posttraumatic stress disorders. They have usually difficulty in coping with or adapting to physical changes. Most of them still hold the top position in the companies or societies and some make important decisions for the company, after retiring the companies some people are still working as farmers, sweepers, building cleaners or security guards in order to fulfill their loneliness at home or the desire to work hard which they have got after the second world war.

The physical decline makes them seek medical treatments and a few need to undergo rehabilitation programs in hospital. Alcohol consumption is still high and can be considered as one of the main causes in the development of their diseases.

4. Research workers

Researcher's stresses are normally due to the lack of work satisfaction, working pressures and the feeling of personal pressure. The lack of work satisfaction is due to the lack of opportunity for advancement and growth, the lack of freedom of choosing his own research, difficulty coping with the boss and too long working hours. The working pressures are caused by poor facilities and the pressure by the demand from the boss. They have also the personal pressures due to financial problems, the conflict with spouse and children and difficulty having enough time for the family.

Life stress is due to the lack of support to their researches, time constrict, date line pressure, difficulty in accomplishing tasks and distractions. Most of them usually have a very positive character and clearly know what they are doing in their research and life. (Table 1).

Behavioral symptoms manifested by the stress are found as an increase in smoking and drinking behaviors, withdrawal from friends and feeling overwhelmed by work. Emotional symptoms developed by the stress include emotional drain, low sexual desire, and worrying or chewing about things.

Psychological disorders include depressed (76%), obsessive-compulsive behavior (70%), and anxiety (35%). On the other hand, physiological disorders are tension headache, lost of appetite, heartburn, and nervousness (65%).

Suggestion treatments given to the researchers

(85%) are advises on progressive relaxation, biofeedback on an EMG & an EEG, getting better sleep, good eating habits, living happily with family, moderating alcohol intake and having regular exercise. They are also suggested assertiveness training (71%), sports and traveling (39%) to alleviate on stress, and given motivation programs on positive thinking (91%) to overcome their problems and research.

Problems in the lack of support, motivation, and respect for others are usually caused by the director or the head of department who are the decisions maker, determines or approves the planning and the financial allowance. Usually research workers are not allowed to argue or go against their decisions. Situations become worse when they are not allowed to carry out the research in their own area of interest and forced to go home late.

Research workers are commonly faced with failure, obstacles, unexpected results or difficulties in carrying out experiments. To overcome these problems, research workers are encouraged to share, discuss or seek advises from others. Unfortunately in Japan, they seldom open enough to share their problem or obtain the advice. This situation becomes worse when they become narrow minded and have conflict with their families.

5. Salesmen, Salarymen and Managerial Staff

The stresses of the people in this group are due to the lack of personal satisfaction in work, feeling of personal change, problems of adaptability and the problem in time management. The lack of a good relationship with the supervisor, the lack of appreciation on completed tasks, and long working hours have caused them develops the lack of personal satisfaction. In Japan the staffs are frequently transferred to the other places to work, which leads them into difficulty in coping with and adapting to a new working condition. These have contributed stresses on feelings of personal change, problems of adaptability, tension build-up, difficulty in solving problems, the lack of interpersonal trust, and problems in time-management. Most of them however have the clarity of mind, positive character and have the desire for more power. (Table1).

Emotional symptoms manifested by the stress for them are anxiety, loss of sexual interest, hopeless and difficulty in concentrating. Physical symptoms manifested by stress for these people include back pain, tension headache, muscle stiffness, heartburn, dry mouth, cold and sweating hand, shortness of breath, and skin rash. Behavioral symptoms developed by the stress in them are lost of appetite, over criticizing, increase in smoking and drinking behavior (Table 1).

Psychological disorders such as anxiety (98%) and hostility (87%) are found in them. The developed physiological disorders include tension headache (63%), nervousness (63%), gastrointestinal related illness (diarrhea, gastric ulcers. lost of appetite and duodenal ulcers) (59%), and cardiovascular related illness (chest pain, essential hypertension and heartburn) (69%).

Suggestion treatments given to reduce stress are relaxation techniques (98%) on biofeedback on EMG and EEG, to moderate alcohol intake (96%), to quit smoking (92%), good eating habits (88%), and to do a regular exercise (87%). They are also suggested to have assertiveness training (92%), leisure activities (90%), how to do self-management (88%), and how to manage their time more effectively (75%). Besides, motivation programs taken from books “think and growth rich” (91%) and “positive principles today” (81%) are advises to help them become more successful in their career seeking.

Salarymen in Japan commonly face with the problems of having to rush to work in overcrowded trains, overloading of office work and problems in interpersonal relationships with colleagues or supervisors who often sit close by. Their working environment is noisy and not easy to keep a personal privacy. Moreover they have to accept the compulsive drinking after the work and compulsive company decisions including transfers to the other working places. Managerial staffs usually are experienced, respected and hold the senior positions in the company. They do make decisions and determine company regulations. They face with problems in managing their staff to achieve the sales targets and competing with their competitors.

The descriptions above are the knowledge which we have got from the system users. In conclusion, we have been able to assist individuals in Japan and diagnose their source of stress. Simultaneously, we advise them how to manage their stress and how to heal from stress related disorders and illness. In the future, we will continue to follow-up studies on those individuals who have got stress relief and healed from the illness by using this system.

Footnote

Part of the results obtained has been presented in the X International Congress of EMG and Clinical Neurophysiology. (OCT. 15-19 TH.1995) held in Kyoto. Japan. We thank Hitachi Scholarship Foundation for the fellowship.

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