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Deadline for the September 2007 issue is **30 August, 2007**.

**Editorial: Bioethics Education and Discourse**

- Darryl Macer, Ph.D.
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This issue starts with a call for inclusion of spiritual dimensions into bioethics education, adding detail to some elements included in the *Joint Plan of Action for Regional Networking in Bioethics Education – Towards Better Bioethics Education* adopted at the UNESCO Asia-Pacific Conference on Bioethics Education held in Seoul (26-28 July, 2006). Sister Daphne outlines an approach for experience and deliberation to aid the cultivation of moral values. The question of when we can teach which kind of moral values is a central research question in bioethics education. At UNESCO Bangkok I am working with several museums to develop teacher training, youth leader training, and student training with a mixture of lectures, group work, moral games, and museum displays. From December 2007 there will be a display on bioethics and biotechnology at the Science Centre for Education in Bangkok which will run for a year, and visitors to Bangkok are invited (the display and interactive resource materials will be in Thai and English). We are also working with several partners in other countries to develop materials that can be used as traveling road shows of bioethics, all combined with evaluation methodology and feedback forms that we hope will answer some of these residual questions.

The other papers in this issue discuss principles for public health ethics, the adoption of palliative care in India, and how to respect vulnerable persons which explores experience in Thai prisons. There are two papers on pharmacology, one reports the way that risk assessment information was presented in informed consent forms, and the other is philosophical examining enhancement. The papers in the issue provide a mix of descriptive data along with philosophical analysis. *EJAIB* is open to authors from outside Asia, and the key component of the papers is that they offer something to the international and cross-cultural dialogues on bioethics. There is a lot of food for thought in this issue, and I invite commentators to send there comments for publication. In this way discourse, that is critical for our education in bioethics, is developed.

# **Towards a philosophical framework for Bioethics Education in India -** The role of religion and spirituality

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**Abstract**

There is a growing interest in bioethics education in Asia today. The UNESCO Asia-Pacific conference held in Seoul, (26-28 July, 2006) adopted a *Joint Plan of Action for Regional Networking in Bioethics Education – Towards Better Bioethics Education,* Paragraph 2 of which reads: *"Societies will progress along a more just, equitable and sustainable basis if the cultural, ethical and spiritual values of those societies are central determinants in shaping technology and science."*

I would like to reflect on how India can respond to this call, considering two contexts. The first is the multicultural, multi-religious, secular democracy that India is. The second relates to the strictly secular nature of the present-day bioethical discourse. In a secular world, what framework would best enable the contribution of cultural, ethical and, especially, *religious and spiritual values* in bioethics education?

This paper is situated in two moments – the first, an epistemological moment, defining the context, and the formative role of religion and spirituality in attitudes and values that students bring to the table. The second, a pedagogical moment, which evaluates bioethics education today, and describes the role of religion and spirituality in formation of the components of moral experience, viz. moral perception, moral justification and moral motivation.

A philosophical framework of capacity building in the process of "Deliberation" is proposed, which starts with the moral experience of the student and guides it towards the expertise required of participants in the moral discourse. The importance of inter-cultural and inter-religious dialogue in the bioethics education process is discussed.

## 1. Introduction

There is a growing interest in bioethics education in the continent of Asia today. The UNESCO Asia-Pacific conference on the topic of Bioethics Education held in Seoul, Republic of Korea, last year, 26-28 July, 2006, adopted a *Joint Plan of Action for Regional Networking in Bioethics Education Towards Better Bioethics Education* (Seoul 2006)

The **Rationale for bioethics education** in this document highlights the need for capacity building in bioethics at every level of society and community in order to enable participants to express and discuss their values coherently in the bioethical discourse and to enable the public to participate in making wise decisions about their own, and their children's, future. The document outlines goals, challenges and recommendations and allows free and full scope for interpretation and implementation at the local level in "culturally appropriate" ways. It encourages educators and researchers to network in the preparation of educational resources, and calls on parent institutions and governments to support the enterprise at every level.

One directive, however, immediately focuses the attention, given the secular trends today. It reads thus: *Societies and communities will progress in a more just, equitable and sustainable direction if the cultural, ethical, and spiritual values of these societies are central determinants in shaping technology and science*, given that these are developing rapidly today. The call to make cultural, ethical and spiritual values the central determinants in shaping technology and science is certainly a challenge to educators. A framework is needed within which this call can be realised in the educational setting, especially in the secular India of today.

## 2. The Context

### 2.1. India: a secular democracy, land of many faiths and cultures

India is a land of many religious faiths. Besides being the birthplace of Hinduism, Buddhism, Jainism, and Sikhism, India has also been open to religions from other lands – Christianity, Judaism, Islam, Zoroastrianism and, more recently, the Baha'i faith. Truly, it can be said that India is home to many religious traditions and that religion and spirituality are woven into the very fabric of daily life. Children from their earliest years are steeped in the tradition of the elders through myths retold and rituals re-enacted. The festivals of all religions, rich with symbolism and mystery, are celebrated on a national scale and festivals of the greatest significance to each religion are declared as public holidays.

India is also a land of many cultures. Culture refers to the total, complex, expression of the spirit of a people and is a community's way and view of life. It includes the group's relation to nature, the way they work and earn their living, the mode and organisation of production, the mobilisation of the community, their laws, traditions, festivals, language, arts, artefacts, tools, ornaments. Beneath all these there is a self-understanding of the group, an interpretation of life, a worldview and certain values and priorities which get expressed in popular sayings, stories, myths, and celebrations, in interpretations of birth, death and suffering. Cultures entail spirituality in the sense that they are people's responses to the reality of human needs, possibilities, historical events as well to their implications and promises. Culture is then the historically developed expression of insights, values and needs, which characterises the life of a community. Education is the process of critical/innovative transmission and reception of culture (Ryan, 2007).

Cultural pluralism refers to distinct cultures or sub-cultures with distinctive individual and collective identities with an over-arching civilisation unity. The basis of pluralism is well-established in the orthodoxy of ancient Indian tradition – Jaina non-violence, Buddhist compassion, Upanishadic universalism and Sufi-Bhakti mysticism. In Asia, plurality is so deeply and intricately woven into society that any attempt to homogenise it would be suicidal. The way of coping with it ranges from indifference and non-engagement all the way to affirmation and celebration (Heredia, 2007).

At the political level, the preamble to the Constitution of India reads: "We the PEOPLE OF INDIA have solemnly resolved to constitute India into a Sovereign, Socialist, Secular, Democratic Republic". The word *secular* was not in the original document, but was introduced as the 49$^{th}$ amendment in the context of inter-religion conflicts. Legislation-wise, religion is one of India's *fundamental freedoms* and the subject is taught, in the secular educational context, as a study of *Comparative Religions*. This approach favours education about religions as distinct from religious education – an extremely important distinction, since the former re-enforces universalism while the latter strengthens particularism (K.N. Panikkar, 2007). The approach tends to favour an analytical, intellectual understanding of other religions, rather than an intuitive appreciation from the heart.

### 2.2. Bioethics, as it began … and the bioethical discourse today

Bioethics, as a subject, was first introduced into U.S. medical schools during the 60s and early 70s in the aftermath

of the following four events – the abortion debate, the shift from civil rights to medical rights with consequent legal implications, the emergence of *scandals* regarding the treatment of human subjects, (the *Tuskegee* experiments and the Nuremberg code) and, finally, the biotechnological revolution which resulted in the Karen Quinlan case and the Seattle dialysis lottery. Today, bioethics education courses have been designed in several countries not only for medical schools, but for students at high school and university levels as well. Teacher-training programmes have a ripple effect which results in networking and easily available web-based programmes. (Encyclopaedia of Bioethics, 1st, 2nd, 3rd editions, 1978, 1995, 2004)

Initially, the subject was taught as *Medical Ethics* within a theological framework since it was hoped that this would have a humanising influence on medical education. Over the years, however, because of the specialisation that accompanies modernisation, religion slowly became relegated to the realm of the soul while science and politics were left to deal with that of the body (Marty, 1992). Thus, philosophy gradually exiled theology in the bioethical discourse, leading to the present-day secular trends, so that Engelhardt (1999), reflecting on Bioethics in the third millennium, stressed that "bioethics of the future must learn how to live with robust moral diversity" and that "bioethicists establish themselves as the equivalent of secular priests for our culture". His view is based upon the conviction that no particular moral vision can provide the ground for a moral consensus. In fact, the world in which we live today is so multicultural that most institutional if not interpersonal interactions are governed by an ethics of "moral strangers" (Engelhardt, 1996).

This type of secular bioethics, referred to as "moral pluralism" or "melting pot" bioethics, is driven by normative and descriptive ethics characterised by appeals to universalised principles and morally thin sets of procedural guidelines rather than by notions of teleology or the dignity of the human person. Since the participants come from morally neutral backgrounds, they meet as "moral strangers", remaining in a safely protected, yet totally separated, moral universe. The result is a neutralising effect on the content of moral conversation, as such, so that bioethics becomes merely a regulatory task diluting the distinction between the legal and the moral. Normative ethics (criteria) results from consensual agreement in relation to the *rightness* of the action prescribed, but the *goodness* of the ends implicitly pursued by these actions, the kind of moral personalities and moral societies they yield remain beyond the scope of ethics (Dell'Oro, 2007).

As a result of secularisation, not only is culture seen as secular and multicultural, but those who hold religious beliefs often voluntarily relegate religion to the private sphere, and tend to understand their own beliefs according to these assumptions as well. Furthermore, although they may have distinctive views, these views don't noticeably manifest themselves in distinctive or significant "difference-making" ways. Thus, their voices remain, effectively, unheard in the moral discourse. But, for the one who believes, religion can make all the difference – at least at the level of interpretation if not always at the level of action – and the contribution of these voices needs to be acknowledged (Hanson, 1998).

## 3. Religion and Spirituality … source of inner dynamism for the believer

While a simple definition of the word *religion* would be based on its derivation from the Latin *re-ligare,* which means *to bind together*, a more helpful description of models of religion and religious doctrine developed by the theologian, George Lindbeck (1984), is summarised here. The first model emphasises the cognitive aspects of religious doctrines. Here, religion is understood primarily as a collection of beliefs, rites and rituals, which a person chooses to adhere to or not. A second model focuses on the "experiential-expressive" dimension of religion. Here religious teachings are interpreted as "non-informative and non-discursive symbols of inner feelings, attitudes or existential orientations".

Still another approach is the "cultural-linguistic" alternative in which "a religion is viewed as a kind of cultural and/or linguistic framework or medium that shapes the entirety of life and thought. It is not *primarily* an array of beliefs about the true and the good (though it may involve these), or a symbolism expressive of basic attitudes, feelings, or sentiments (though these will be generated). Rather, it is similar to an idiom that makes possible the description of realities, the formulation of beliefs and the experiencing of inner attitudes, feelings and sentiments."

Although this model accommodates the cognitive aspects, religious doctrines are not merely a set of teachings to be believed. Rather, they are a medium and set of skills by which one learns to live one's life. Furthermore, there is a dialectical relation between religious doctrine and experience. Religious narratives combine with religious experience to provide a structure for an entire way of life for religious believers and the community. Religion is viewed as both a source of meaning for beliefs and experiences as well as an embodiment of ways of living that testify to religious truth.

The uniqueness of religion, however, lies in its link to the Transcendent – referred to in the Indian tradition as *The One Beyond All Name and Form* – the Absolute, the principle on which everything depends, the cause of which the whole world is merely an effect, the essence of which existence is merely a phenomenon. Since the *Absolute* is both transcendent and immanent, there is no way to express this adequately in human language and so this "something else" is frequently designated in the *Upanishads* by the simple pronoun *tad* (That).

Religion, understood in terms of the last model described above, comes very close to an understanding of spirituality, which is derived from the Latin word *spiritualitas,* meaning *breath,* and is generally considered to be a broader concept than religion.

Tanyi (2002), after analysing 76 articles and 19 books, defined spirituality in the following manner. "Spirituality is a personal search for meaning and purpose in life, which may or may not be related to religion. It entails connection to self-chosen and/or religious beliefs, values and practices that give meaning to life, thereby inspiring and motivating individuals to achieve their optimal being. This connection brings faith, hope, peace and empowerment. The results are joy, forgiveness of oneself and others, awareness and acceptance of hardship and mortality, a heightened sense of physical and emotional well-being and the ability to transcend beyond the infirmities of existence."

Sulmasy (2006) refers to the quality of transcendental relationship in his definition… "One's spirituality may be defined simply as the characteristics and qualities of one's relationship with the transcendent", while Martsolf and Mickley (1998) include a sense of "becoming" or an unfolding of life that calls for reflection and experience, including a sense of who one "is" and how one knows.

### 3.1. Religion and Spirituality: source of moral attitudes and values

When religion and spirituality are truly lived experiences, the participants in a moral discourse can be expected to bring to the table attitudes and values born of their experience, awareness and appreciation of a "transcendent dimension" to life beyond self. Chief among these will be an increased awareness of connectedness with oneself, others, God/Spirit/Divinity and nature/Nature. The ability to derive purpose and meaning from life will result in an intuitive approach to situations as being morally relevant or not.

Experience and capacity for reflection will make for a listening heart and wisdom in dialogue and decision-making.

The *attitudes* (virtues in the Aristotelian sense) of attentiveness, truthfulness, respect, and responsibility on personal, shared and social levels are experienced and developed as a result of fundamental life-options. So, too, are the feelings of empathy, compassion and concern for the other. Stemming from personal spirituality, they belong to the inner core of the person and enable one to choose and do the right thing. Attitudes are formed from an early age because of the influence of religion, culture and tradition and are the driving power of the bioethical reflection.

*Values*, likewise, are learned from the earliest years. They represent the importance, or significance, which a person attaches to a choice (or action) as good, worthwhile or desirable. Determined by the prevailing social and cultural norms, they can be fundamental or personal. Values include, among others, justice, trust, confidentiality, support, and, for some groups, community and autonomy. Together with attitudes and virtues, values represent the initial moral experience from which individuals can draw and, also, on which they can build.

Attitudes spring from religion and personal spirituality and can be considered to form the "spiritual" pillar on which the bioethical discourse rests; values are the result of interaction within a family, community or social group and form the "hermeneutical" pillar of the discourse. Each participant comes with a personal richness of experience, attitudes, values and emotions. Each voice needs to be heard so that the final decision may be wise and for the good of the whole.

In India, the multi-religious traditions constitute a rich field for dialectical dialogue and for the retrieval of bioethical principles and values. Thus, in Hinduism, the concept of *eikinata* (one-centredness – a distinct way of seeing and orienting oneself to the world) creates space for educating to ethical values of human dignity, equality, solidarity, sharing. The use of "one-centredness" in orientating oneself to the world engenders a drive towards unity, the unity of seeing the multiplicity of being as arising from a single Source, being sustained and interrelated through that source and seeking that source as the ultimate goal (Lipner, 2007).

Some other basic attitudes towards life, like *dharma* (the right way of living), *sarvam dhukham* (the all-pervasiveness of pain and evil), *maanaha* (respect for all forms of life), *karma* (cause and effect of one's actions), the cycle of life and death and *moksha* (liberation) form part of the most elementary religious instruction and one is aware of them from a very young age.

When participants at the table are able to draw from both the spiritual and the hermeneutical dimensions of their particular experiences and traditions, the richness of the discourse is enhanced, especially if their contributions are received in an open spirit of dialogue (Liégeois, 2006). The interaction leads to a more comprehensive understanding of the moral problem from several different points of view and a plan of action with a more holistic outcome.

### 3.2. **The initial moral experience of the student is fine-tuned through education**

To enable fruitful and wholesome participation in the discourse, education in several areas is needed. Of prime importance are the cognitive goals of theoretical and conceptual knowledge, analytical abilities to recognise and manage ethical issues, and the skills of ethical reasoning. Other cognitive goals are increased sensitivity and awareness of values, and critical reflection on already-held personal values. Practical areas include helping to bridge the gap between ethical theory and principles and actual ethical reasoning in practice. At the level of attitudes, promoting a humanistic attitude and emotional qualities through a personal reflection on one's own behaviour and an increased capacity for tolerance and acceptance of diversity (Myser, 1998).

The bioethics educational process is geared to fine-tuning the skills of students in ethical analysis and self-reflection. An increased awareness and appreciation of one's own personal attitudes, values and emotions, and the sources from which they spring, leads to a deeper appreciation of the attitudes, values and emotions of others. It also helps to develop openness and receptivity of heart in a non-threatening atmosphere where dialogue and healthy challenge are possible.

The observation that learning happens through doing has particular import for moral development and education. What we learn through behaviour influences later behavioural choices that, in their turn, will have an impact upon learning once again. The recursive process of human understanding continuously turns back upon itself to construct a truly human reality in which the agent is both participant and observer (Selling, 1999).

## 4. Bioethics Education

### 4.1. Lessons from four decades of experience

A brief review of the medical ethics education scenario over the last four decades can provide useful lessons for our own journey. Though the ongoing quest has been for relevance in terms of objectives, methodology, assessment and evaluation, and efforts have been made to develop the human side of students through encouraging the use of narratives and role models among the staff (Cattorini, 1994; Gross, 2001; Wellbery, 2006), the humanising influence on medical education, which was the main reason for starting bioethics courses, does not seem to have been achieved (Cooper, 2005). Students seem unable to translate their knowledge into action, and the introspection required for true behavioural change does not appear to have been fostered (Bertolami, 2006). I would like to dwell on three points that I feel are important.

The first refers to an ever-present danger that students tend to pick up ethical jargon just like they learn science and feel they know the subject because they can apply moral vocabulary more or less appropriately to cases. This needs to be counteracted by using familiar ethical concepts of ordinary language starting from the student's personal moral experience (Cowley, 2005).

A second is that bioethics education must be characterised by an open pluralism if it is to be effective. This means a commitment to explore, understand, and hear the voices of every moral community constituting a respective culture. "Open" pluralism is not to be confused with the "melting-pot" pluralism referred to earlier. On the contrary, "open" pluralism acknowledges that all parties involved in the conversation find themselves living within one or more particular moral traditions and would be open to what they have to say to each other (Kinghorn, 2007).

The third and most important lesson, however, is that bioethics education leads to an overemphasis on rationality while what is needed for true bioethical maturity is an intuitive *intelligence of the heart* (Coulehan, 2005). This implies that bioethics education does not seem to help in developing moral sensitivity; students lack empathy and moral perception and are unable to respond to morally demanding situations with compassion and understanding.

If this is true, then (whatever be the reasons) the main objectives of bioethics education, which are the ability to recognise ethical issues, an increased sensitivity and awareness of values, a critical reflection on already-held personal values and openness to the values of others – remains unfulfilled.

**4.2. Perception - ability to "*see*" the moral landscape – is the first step**

Though several remedies for the apparent lack of success of bioethics education programmes have been suggested over the years, I would like to dwell on a point made by James Rest (1982, 1999) who notes that moral behaviour involves more than thinking about conflicts: one must first recognize that a conflict exists. Vision, or moral perception, is, thus, an important aspect of moral development. It refers to an increasing ability to see the moral landscape clearly … an ability which involves the emotions, particularly the feeling of empathy. In fact, moral growth, development and functioning are the result of a complex web of cognitive, behavioural and affective forces that can be represented by the following four component processes:

1. Moral sensitivity or perception (ability to see that a moral problem exists)
2. Moral judgment (ability to judge what action would be justifiable in a moral sense)
3. Moral motivation (commitment; taking personal responsibility for moral outcomes)
4. Moral character (persistence in a moral task; courage, ability to overcome fatigue).

Failure to behave morally can result from deficiencies in any of the four components. For example, if a person is insensitive or if a situation is too ambiguous, the person may fail to act morally (deficiency in Component I). Or a person may be deficient in formulating a moral course of action or may employ simplistic and inadequate moral reasoning (Component II). Or moral values may be compromised or pre-empted by other values (Component III). Or it may be that a person has decided upon a moral course of action, but loses sight of the goal, is distracted, or just wears out (Component IV). While it is not possible to discuss these components in detail here, they remain important as a backdrop in bioethics education.

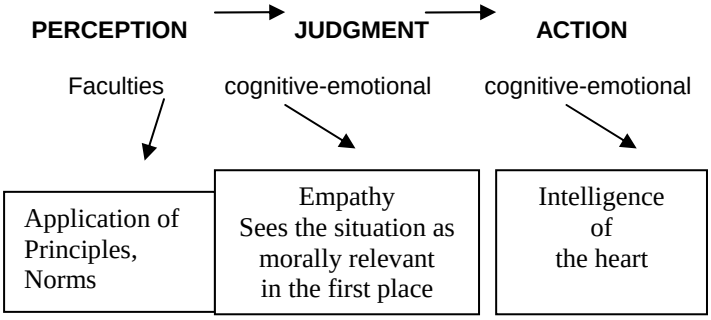
My personal experience is that when early moral development has been awakened and sustained in basic faith communities, and is not mere lip service, students are more sensitive to situations. The moral judgments they make are based more often on universal principles of justice and fairness rather than merely on personal interests or on satisfying norms. They are better able to renew their initial motivation after a setback and take personal responsibility for the decisions they make. They also have greater persistence and an internal dynamism, which helps to overcome fatigue. Education plays an important role in this process since educators must concentrate on those components that need formation, so that ethical maturity can be achieved.

Evaluating bioethics courses or student progress through the traditional methods of exams, papers and classroom performances also lacks validity, though awareness of the complexity and overlap between the four components is an initial step towards improvement. More interaction with psychologists is suggested to overcome some of these difficulties. So far the collaboration has been mainly between ethics instructors and philosophers; however, when the disciplines of philosophy and psychology have worked together, both theory and practice have benefited (Bebeau, 2002).

**4.3. Empathy – an emotion, basic to moral performance**

In his treatise, *Perception, Empathy and Judgment – An inquiry into the preconditions of moral performance,* philosopher Arne Johan Vetlesen (1994) argues for a re-instatement of the emotional faculties, especially that of empathy, into the realm of moral judgment and moral performance. His view is that the cognitive dimension has been overstressed in moral theory (i.e. actions done out of duty being considered "truly moral", as distinct from actions springing from inclination) whereas, in fact, it is the emotions that are the first element in perception.

Schematically, Vetlesen represents moral performance as spanning three levels, thus:




The sequence of moral performance is set in motion by an act of moral perception that provides and shapes the setting for moral judgment and moral action. The cognitive, (or rationality) element determines the principles and norms for judgment and action and how "best" to weigh and apply them in a particular situation. But intellectual knowledge is useless if one is not sensitive to "see" the situation as morally relevant, i.e. one calling for moral judgment and moral action, in the first place.

In order to truly be anchored to the *weal and woe* of others, *here and now,* the emotions – or more accurately, the faculty of empathy – are indispensable in providing first access to the domain of the moral, understood (in a wide sense) to include every "other" who is an object of respect and concern. Emotions, it must be remembered, are not irrational forces or morally neutral entities. As Nussbaum (2001) reminds us, people reveal what and who they are by the things that move them. Emotions, thus, always reflect a specific cultural context in which particular things are viewed as valuable or good. Emotions imply an object, are intentional by nature, embody certain beliefs about the object and are concerned with values.

**4.4. Education for Empathy**

"Moral perception", emphasises Vetlesen, "does not start from scratch." It is guided, channelled and developed through participation in morally sensitive communities and depends primarily on the socialisation experiences of love and concern in early childhood. Most children, except the severely emotionally deprived, have a natural ability to sense and feel the weal and woe of others.

Religion and spirituality are powerful motivating factors in the development of the emotion of empathy. Relationship with the Transcendent Absolute sensitises a person to the transitory nature of life and the pain inherent in the human situation. It deepens one's realisation of the unity of all creation and opens the mind and heart to feel the anxiety and distress of "the other" as one's own. Religion and spirituality also help in reflection, which is crucial to moral vision. This consists partly in seeing "into" oneself, paying attention to nagging doubts, articulating feelings; it requires time and quiet (Andre, 1992).

Enabling the quality of "intelligence of the heart" is a difficult, but not impossible, task for educators. Recognising and fostering the natural ability where it already exists is one way of helping students grow in empathy. Others include techniques like role-playing, sustained practice in imagining, portfolio keeping, the use of stories and developing a sense of wonder (Spiro 1992; Cole-Kelly 2006; Leget 2007). Success in educating for empathy lies in patient and continuing efforts at using differing learning environments, and education through example – i.e. teachers becoming role models.

However, the capacity for empathy is exceedingly vulnerable to societal manipulation and can easily be blocked by predetermined ideologies, technologies or bureaucracy. Re-kindling the emotional fire of empathy in these cases will be the first Herculean task for bioethics educators, since the basic

requirement for perceiving a situation as morally relevant is missing.

Finally, we must remember that empathy, considered as an art that encompasses both internal and external emotion management, cannot be achieved simply through explicit teaching (Larson, 2005). Rather, it requires a slow educational immersion process that can be likened to the maturing of a fine wine and its unfolding involves a response to changing targets and situations (Pence 1983). Enabling emotional maturity is one of the greatest challenges for bioethics educators.

Ultimately, the real test of bioethics education lies in the manner in which students approach moral situations they encounter in daily life, their ability to recognise the inherent moral problems, to empathise, make wise and appropriate moral judgments, and act with courage and persistence.

**5. Deliberation: a philosophical framework for bioethics education**

Van Tongeren (1988) reminds us that, as a branch of philosophy, ethics proceeds from empirical knowledge, namely, a person's moral experience. The moral dimension of the world is first and foremost experienced; moral experience is humanity's way of understanding itself in moral terms. Bioethics is thus the interpretation and explanation of this primordial understanding and relates to the hermeneutics of moral experience. "Before acting morally we must already know, at least to some extent, what is morally desirable or right. Otherwise, we would not recognise what is appealing in a moral sense. On the other hand, what we recognise in our experience is typically unclear and in need of further elucidation and interpretation" (Henk ten Have, 2005).

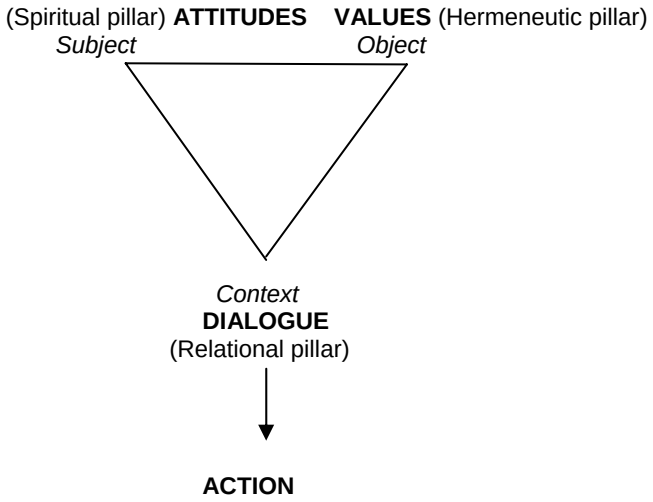
In this final section, I would like to explore a framework for bioethics education which starts with the moral experience of the student. Many methodologies have been proposed over the years to manage and resolve ethical problems, some of them based on decision-making theory and others based on philosophical traditions like principlism, casuistry, narrativism, hermeneutics, and pragmatism. Gracia (2003) defends the view that deliberation is the cornerstone of any adequate methodology. This is because moral decisions must take into account not only principles and ideas, but also emotions, values and beliefs.

*Deliberation* is defined as a process in which every person concerned by the decision is considered a valid moral agent, obliged to give reasons for their own points of view and to listen to the reasons of others. The premise is that a right answer does not exist in advance, that bioethical analysis consists in searching together for this answer. Deliberation attempts to analyse problems in all their complexity, weighing up the principles and values involved as well as the circumstances and consequences of each case so that all, or at least most, of the possible courses of action can be determined.

"Our moral decisions cannot be completely rational, due to the fact that they are influenced by feelings, values, beliefs, etc. but they must be reasonable, that is, wise and prudent. Deliberation is the main procedure to reach this goal. It obliges us to take others into account, respecting their different beliefs and values and prompting them to give reasons for their own points of view."

Deliberation, therefore, requires, among several other procedural steps, careful listening in a spirit of open pluralism which acknowledges that all participants in the discourse come from moral traditions that have a contribution to make; that all are open to what the others have to say so that the best and wisest course of action results under the circumstances. Of course, the outcome is always open to fresh input and may be changed in future if necessary.

The process of shared decision-making can be illustrated schematically as follows (Liégeois, 2006):




As we have seen earlier, *Attitudes* and *Values* refer to the personal attributes, which participants bring to the moral discourse, and they constitute two of the pillars (spiritual and hermeneutic) on which the particular context under deliberation rests.

*Dialogue* is the third and most important pillar of the deliberation process. It is the relational pillar requiring attentiveness, listening, openness, and the ability to express intuitions and evaluate responses in a non-threatening manner. The dialogic aspect of deliberation requires understanding of bioethical principles and theories as well as skills in both the methods of bioethical analysis and in communication. It is refined through the educational process and is best learned, experienced and practised in a relational environment.

For philosopher-theologian, Raimundo Pannikar (1983), dialogue is a way of being – a *most fundamental condition of existence.* "Dialectics", he says, "is the optimism of reason, while Dialogue is the optimism of the heart". Possible at the four levels of life, action, religious experience and theological exchange, dialogue is an art that must be learned, as it is essential to the process of deliberation. While the fourth level is where specialists seek to deepen their understanding of their respective religious heritages, students can certainly be taught to dialogue at the first three levels of life, action and religious experience; at this third level, rooted in their own religious traditions, they share of their spiritual riches.

Faced with moral questions in a bioethics discourse, students must be encouraged to listen attentively to all participants at the table and be allowed to respond from their personal religious and cultural experiences. They need to share their moral insights, feelings, attitudes and values, and the sources from which these are derived. They must also be taught to reflect on their own responses and those of others and to give and receive feedback in a spirit of openness. This will help to develop the skills required for dialogue and make the process of bioethical deliberation more natural.

Formal bioethics education must, of course, include a central place for developing the capacity for moral argumentation, for analysing the quality of arguments, for pointing out inferential mistakes, inconsistencies and illegitimate generalisations, while not omitting conceptual analysis (Cowley, 2005). However, educators need to be aware of their primary task, which is to develop in students an "intelligence of the heart."

Thus, bioethics education involves formation of participants in the moral discourse in certain basic methodologies so that they are capable of perceiving and understanding the

complexity of the moral problems involved; persons who can ask the right questions and provide wise and reflective responses; finally, persons with a sense of responsibility for their part in the deliberative process. The approach has to be holistic involving persons in their totality, in their physical, cognitive, affective and spiritual dimensions and, also, in relationship with their own inner self, with others (both as individuals and in the larger society) and with the transcendent. This holistic approach will respect the dynamic by which students arrive at moral decisions, while providing guidance and support through timely and appropriate interventions.

**Discussion**

This paper set out to reflect on the specific role of religion and spirituality in bioethics education in India today, in the context of the UNESCO *Joint Plan of Action for Regional Networking in Bioethics Education - Towards Better Bioethics Education,* asking what specifically these values could bring to the table of moral discourse in a multi-cultural, multi-religious, secular democracy like India.

Although India is secular in its constitution, and religion and spirituality are not normative, the religious and spiritual influence of the home and family are foundational experiences. Attitudes and values are formed from an early age because of the influence of religion, culture and tradition. Since they form two basic pillars (religious and hermeneutical) of the bioethics deliberation process, religion and spirituality have an important role in bioethics education.

Another important function of religion and spirituality is in the development of the emotions, especially the affective faculty of empathy, which is the basic faculty by which a situation is intuited as being morally relevant. Where the experiences and influences are positive, the possibility of forming morally sensitive persons, capable of thinking with the heart, is increased. However, these capacities are extremely sensitive to manipulation and can be stunted or blocked, even when the initial experiences are positive. Hence, a caring educational environment is important.

Dialogue is the third, and most important, relational pillar of the deliberative process. Besides knowledge and skills, it requires connectedness to oneself, to others and with the Transcendent. Continued practice and role models help to sustain motivation.

**Conclusion**

India is at the threshold of making her experience in the area of bioethics education. Two medical schools – St. John's Catholic Medical College in Bangalore (Ravindran et al, 1996) and Christian Medical College, Vellore, (Selvakumar et al, 2004) have organised medical ethics programmes for graduates and residents. But ethical values are presently taught in schools, integrated with different subjects (Bhardwaj & Macer, 1999).

We have the advantage of being able to learn from the experience of others. Does this mean that the process will be more successful? We can only try. If our starting point, at least in education, is values and attitudes, rather than norms and laws; teleological, rather than deontological; dialogue and relation-based, rather than principles-based; students will learn how to bring their viewpoints to the table of moral discourse in an atmosphere of *tolerance* in the deepest sense of that word. The education process will also forestall entry into the bioethical discourse from a point of neutrality and help participants in the moral discourse not to meet as complete *moral strangers.*

However, our milieu is multi-cultural, multi-religious and multi-dimensional at the educational level so the task is indeed challenging. In India, religion and spirituality are the stuff of life and the ethical dimension can be seen in the definition of *Bioethics is love of life* (Macer, 1998) which is a very coherent attitude.

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# Principles for Public Health Ethics – A Transcultural Approach

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**1. Introduction**

The last century has brought about a renaissance of medical ethics, transformed to bioethics due to a wider range of ethical challenges in medicine transcending the traditional physician-patient relationship. Ethical discussions of issues related to health – from the status of the embryo to access to the health care system up to questions of physician-assisted suicide – have since mainly been framed under the heading of "bioethics". But hardly any ethical discussions concerning the public's health have been led. In continental Europe, for example, little effort is being made to establish an explicit ethics framework for public health – although systematic ethical approaches for public health are needed as the immanent conflicts between the social good and individual rights are and become more and more obvious e.g. in the context of a threatening influenza pandemic caused by a new human influenza virus subtype.

This paper underlines the need for a public health ethics framework. I will argue that such a framework has to be normatively set apart from bioethics. Yet, to work with a concise set of mid-level principles and to utilize the well established methods of applied ethics – such as balancing and specification – will also prove well in public health ethics. This is what we can learn from the experiences in bioethics.

**2. From Influenza to HTA – Ethical challenges in public health**

Infectious diseases count among the major global health threats. Although vast ethical challenges are associated with these diseases, bioethics has neglected to deal with ethical aspects of infectious diseases and population health. Selgelid observes a "10/90 divide" which means that only 10% of all bioethics work deals with what constitutes 90% of all health burden – namely infectious diseases.[1]

Nowadays we are facing a possible influenza pandemic caused by a new human influenza virus subtype. Thus there is need for ethical debates on infectious disease control to inform policy making processes in this field. The bioterrorist threats, especially after September 11th 2001, and the SARS outbreak in Toronto in 2003 have stimulated a systematic discussion of a need for public health ethics and infectious disease control. Ethical aspects like finding the balance between protecting the public and restricting individual liberties are issues in these discussions. Especially the lessons from Toronto show that it is necessary to deal with ethical aspects of pandemic influenza preparedness as early as possible. Ethically sound and morally acceptable approaches for influenza preparedness plans should be founded in these discussions. In order to develop and to maintain public trust and cooperation, transparent and ethically justified regulations have to be discussed prior to a dilemma situation as part of preparedness planning.[2]

Other ethical challenges appear in public health. Among them are questions of how to conduct good epidemiological research (e.g. with vulnerable populations), which health inequalities are justified and which are morally devastating, whether to implement compulsory health programs (such as measles vaccination or screenings for some diseases), whether manipulative health education might be permissible, whether smoking should be banned from public places, how to balance the conflict between an anticipated health benefit of a public health campaign that might stigmatize some subpopulations (e.g. campaigns against high infant mortality among migrants) etc.[3] Also Health Technology Assessment (HTA), a procedure applied in public health to anticipate the impact of innovative tools and approaches in health, considers ethical aspects and implications. But a lack of systematic ethical approaches for HTA can be observed.

How can we approach these challenges? Normative theories in ethics and applied ethics are supposed to tell us how to act – or at least to give us criteria with which we can judge the moral implications of a motive or act. To arrive at norms in the context of these health challenges, we might first turn to the Hippocratic ethic to see if this traditional medical code with its norms can be a valid normative source for public health as well.

**3. Do medical ethics and bioethics know the answers?**

In medicine the Hippocratic Oath was an influential document that told the doctor to do good to his patient and to avoid harm. But the oath left the decision of what was good or harm to the judgement of the doctor – not the patient. Thus it is no surprise, says Veatch, that with progress in medicine and biotechnology that gave more leeway with regard to treatments (or with refraining from those) the Hippocratic ethic had to be overthrown: "The Hippocratic ethic will be relegated to the ash

[1] Selgelid MJ (2006) *Ethics and Infectious Disease*. Selgelid MJ, Battin MP, Smith CB (Ed.) *Ethics and Infectious Disease*. Malden: Blackwell Publishing: 3-19.
[2] Childress J (2005) Just Care: Rationing in a Public Health Crisis. *Update* 20: 1-7.
[3] See for a number of case studies Coughlin StS, Soskolne CL, Goodman KW (Ed.) (1997) *Case Studies in Public Health Ethics.* Washington: American Public Health Association.

heap of history – a benevolently paternalistic morality that may have worked for a culture in which patients were patient – when they were (as the word *patient* implies) passive, long-suffering, ignorant, and believed to be incapable of making choices."[4] As a consequence, bioethics entered the scene – most famously comprised in the four-principles-approach by Tom Beauchamp and Jim Childress.[5] They added the benchmark "respect for autonomy" to the Hippocratic principles "do good" (beneficence) and "avoid harm" (non-maleficence) that provides the core of their personal ethics principles for the patient-physician encounter. Yet, with technological progress and necessary decisions in situations of scarcity that appeared (e.g. doctors had more patients that needed dialysis than they could bring to this renal substitution therapy), the perspective had to be widened. Bioethics had to find answers to social challenges of biomedical progress and scarcity. Thus Beauchamp and Childress added the core principle of social ethics, i.e. justice, and gave some criteria for the good and right distribution of scarce resources.

Does the bioethics paradigm with its basic focus on personal ethics provide a sufficient framework for public health ethics? Probably not – as bioethics focused on individual good and autonomy and hardly ever thought about population health.[6] As such it is no wonder that bioethics has seldom dealt with infectious diseases and possible population health implications. At least in continental Europe and especially the German speaking realm, there are seldom public health scientists engaged in ethical discourse. Some papers mapping the terrain of public health issues actually only impose bioethics principles and methods on public health, calling this public health ethics.[7] But the focus on normative concepts of public health ethics is different from bioethics as the moral enterprise of public health is different from that of biomedicine. They both belong to different scientific and practical paradigms and scientific communities with different goals. These paradigms are neither incompatible nor incommensurable. Yet they are complementary and have different moral foundations and tasks; and they need different normative orientation.

Accordingly, there is a conceptual flaw to use bioethics for a primary ethical orientation of a population perspective in public health ethics and it is consequently inappropriate to focus on bioethics principles. Public health ethics has to emancipate from bioethics – theoretically – to sharpen its focus, taking into account the goals, approaches and competences of public health, and – practically – to enter discourses and communities of public health sciences and public health policy makers. Yet, an account to public health ethics based on principles seems a fruitful practical approach, as the practicability of the bioethics principles to the practitioners of biomedicine has proven well in the last 30 years and thus serves as an analogous example of good practice in applied ethics.

## 4. A concise set of ethical principles for public health practice

### *4.1 Why a concise set of principles?*

The Public Health Leadership Society (PHLS) has provided a set of twelve rules under the heading "Principles of the Ethical Practice of Public Health "[8]. They appear as rules, rather than principles as they themselves have called them because they express principles like respect for autonomy, social utility and so on but already in a specified form. "Specified" means that these principles are already branched out by considering each other. Take for example the second rule: "Public health should achieve community health in a way that respects the rights of individuals in the community." To achieve community health means to achieve "good" for the group which is close to the principle of social utility. The phrase "respect the rights of individuals" mirrors what can be expressed in short with "respect for autonomy" (or one could argue "justice" as they talk of "individuals" in the plural).

The twelve rules of the PHLS do have a good value; they provide a very detailed and lengthy instrument. But these twelve rules are no principles as we would understand principles in applied ethics. The set of their rules is detailed and not so much generalized and comprehensive as the four principles are in the context of bioethics. Yet, that it is this concise set of four bioethical principles that became so famous and proved well in the context of bioethics is more than a pragmatic reason to use prima facie mid-level principles to build an ethical corridor or framework for public health as well. I believe that it is still true what the Belmont Report (for which Tom Beauchamp was staff writer) demanded for a practical approach: Rules of codes of professional conduct are often "inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted."[9] Against this quote, the "Principles of the Ethical Practice of Public Health" of the Public Health Leadership Society appear like a code that consists of rules.

A concise set of broad ethical mid-level principles that are formulated and theorized by ethicists (maybe embedded in interdisciplinary working groups) seem to be useful tools for practitioners to use. A concise set of prima facie principles and a manual of ethical methods how to use them is like a baton passed on from ethical theorists to practitioners.

### *4.2 Benchmarks to consider – An "ethical toolbox" for public health researchers and practitioners*

Thus, in this paper, a concise set of broad central norms – analogue to the four bioethics principles – shall be offered as a public health ethics framework for discussion. The principles that are – in my opinion – adequate to serve as generalized norms as a public health ethics framework are social utility, respect for human dignity, social justice, efficiency and proportionality (see table 1). With five principles this is still a concise set. Passed on as an "ethical toolbox" from the toolmakers (the ethicists) to the public health practitioners and scientists, they are benchmarks for good and right public health research and practice. They are norms public health practitioners and researchers should follow by bringing them in a balance and/ or specifying them to more concrete moral rules and judgments to apply in particular contexts.

*Social Utility*: "Social utility" is for public health what "Beneficence" is for (bio-)medical practice. Both enterprises – public health and (bio-)medicine – try to generate the good, in this case health. Whereas "beneficence" is traditionally the principle of personal ethics to describe a moral duty of the physician, "social utility" is a principle of social ethics. The net-

[4] Veatch, R. (2000): Doctor Does Not Know Best: Why in the New Century Physicians Must Stop Trying to Benefit Patients, *J. Medicine and Philosophy* 25, 701-721. p. 702.

[5] Beauchamp TL, Childress JF (2001) *Principles of biomedical ethics*, 5. edition. Oxford University Press, New York.

[6] Callahan, Daniel; Jennings, Bruce (2002): Ethics and Public Health: Forging a Strong Relationship. *AJPH* 92: 169-176.

[7] Schröder P (2007) Public-Health-Ethik in Abgrenzung zur Medizinethik. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz* 50: 103-111.

[8] Public Health Leadership Society (2002) *Principles of the Ethical Practice of Public Health*. Version 2.2.[www.phls.org].

[9] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC.

benefit of "social utility" is to be sought in the whole of the population or group that is at stake. Some people in public health, such as Mackenbach[10], believe that "social utility" is at the heart of public health and many public health practitioners are virtuous persons that came into public health to bring about as much health as possible. Others, such as Miettinen[11], even insist that there cannot be any other moral norm than social utility to guide the practice of public health, which is a position I challenge.

| | Moral Aim: Maximizing good consequences (consequentalistic / teleological) | Moral Aim: Respecting rights (deontological) |
|---|---|---|
| Individual Level | | • **Respect for Human Dignity** |
| | • **Proportionality** | |
| Social Level | • **Social Utility**<br>• **Efficiency** | • **Social Justice** |

**Table 1**: Principles for public health ethics assigned to ethical categories.
Source: Self-study drawing on a scheme developed by Robert Veatch[12]

*Respect for Human Dignity*: If we only focused on "social utility" as a moral norm to abide by in public health practice and research, this might have devastating consequences. It would then be allowed to instrumentalize or sacrifice individuals (or whole groups) if only this provided a greater net-benefit. Although in extreme cases it might be ethically permissible to restrict individual liberty – e.g. when a contagious person with a deadly disease who resists to voluntarily going into isolation is forced into isolation or is not allowed to use an airplane – "respect for human dignity" reminds us of our duty not to sacrifice or instrumentalize individuals and to respect their free wills. Although "human dignity" is difficult to define[13], it has become a transcultural value and should prima facie be considered to be a "side constraint"[14] to "social utility".

*Social Justice*: "Social Justice" is another side constraint to social utility. It not only matters to better the net-benefit. It also matters how the benefits and burdens are distributed.[15] At the heart of public health research there are questions of health inequalities. Yet, it is not *a priori* clear what inequalities are justified and which are morally unacceptable. In other words: "Under conditions in which various socially situated groups interact with one another under conditions of inequality, what inequalities matter the most?"[16] An account of justice that grounds on sound criteria can help to identify what has to be done that all persons can live decent lives.

Social justice is the norm that tries to keep public health from discrimination, stigmatization and exclusion, it promotes fair treatment for those who have less chances for health and less chances to lead a full and flourishing life[17] – no matter if the overall net-benefit significantly rises or not while supporting this population.

*Efficiency:* When distributing goods – to either raise the net-benefit and bringing health to all or when supporting the most disadvantaged – "efficiency" becomes an essential principle that needs to be included in the concise set of mid-level principles for public health ethics. Although it seems to only support social utility or social justice by guiding these to spend resources responsibly, it has to be a principle at the forefront of public health practice. (It would be "effectiveness" that was more identical with "social utility" and "efficacy" that was closer to "beneficence" – hence, "efficiency" is complementary to "social utility").

Literally all public health systems worldwide lack resources. Thus to use the scarce resources efficiently is a moral duty because in this way more good to more people – including disadvantaged persons – can be achieved. The principle "efficiency" would thus demand in public health, e.g., to use evidence-based public health measures and to implement cost-benefit-analysis. It should be included in the concise set of ethical principles to always and prominently reassure public health practitioners and researchers that it is also a moral duty to be efficient.

*Proportionality*: The fifth ethical principle demands that when weighing and balancing individual freedoms against the social good this shall be done under the principle of proportionality. In the words of Childress et al. proportionality "is essential to show that the probable public health benefits outweigh the infringed general moral considerations […]. For instance, the policy may breach autonomy or privacy and have undesirable consequences. All of the positive features and benefits must be balanced against the negative features and effects."[18] But proportionality is also a principle that comes to the forefront of public health ethics principles by casuistic reasoning: Experiences of the SARS outbreak, which has revived public health ethics enterprises, draw the attention to this principle. If these experiences were not made in the case of the SARS outbreak in Toronto, it would probably not be a priori clear to focus on proportionality. Singer et al. report: *"In the initial stages of the outbreak, authorities named the woman who carried SARS to Canada from China, and her son, with the family's consent, because they believed it would provide additional public health benefit. Although public health officials took great pains to avoid linking ethnicity and illness, the linking of SARS with someone who had travelled from China, combined with the public's limited understanding of transmission, resulted in many people unnecessarily avoiding Chinese businesses. Proportionality requires that private information be released only if there are no less intrusive*

[10] Mackenbach J (2005) Kos, Dresden, Utopia … A Journey through idealism past and present in public health. *European Journal of Epidemiology* 20: 817-826.
[11] Miettinen OS (2005) Idealism and ethics of public-health practitioners. *European Journal of Epidemiology* 20, 805-807
[12] Veatch R (2000) *Theory of Action (Principles Summarizing Obligations and Rights.)* Washington: (Handout).
[13] Geier M, Schröder P (2002) The Concept of Human Dignity in Biomedical Law. In: Sándor J, den Exter, AP (Ed.): *Frontiers of the European Health Care Law: A Multidisciplinary Approach.* Erasmus University Press, Rotterdam, 146-182.
[14] Nozick R (1974) *Anarchy, State, and Utopia*. Basic Books, New York.
[15] Powers M, Faden R (2006) *Social Justice: The Moral Foundations of Public Health and Health Policy*. Oxford University Press, Oxford.
[16] ibid p. ix.
[17] Gostin LO, Powers M (2006) What does social justice require fort he public's health? Public health ethics and policy imperatives. *Health Affairs* 25: 1053-1059. Schröder P (2004) *Gendiagnostische Gerechtigkeit.* Lit, Münster.
[18] Childress JF, Faden RR, Gaare RD et al. (2002) Public Health Ethics: Mapping the Terrain. *Journal of Law, Medicine & Ethics* 30: 170-178. p. 173.

*means to protect the public health. For example, naming an individual or releasing a photograph could be justified if that person violates a quarantine order."*[19]

Hence, to consider proportionality as an explicit public health ethics principle seems very central to equip public health practitioners also in cases of pandemics and emergencies which belong to the field of public health.[20]

*4.3 Benchmarks not to consider – also for conciseness' sake*

Some readers might miss norms in this ethical toolbox. So let me first repeat that conciseness is a duty for a public health ethics framework. As such I focused on only five mid-level prima facie principles that seem to me by far the most comprehensive and essential benchmarks for good and right public health practice and research.

As mentioned before, *"beneficence"* is a principle of personal ethics with a rich history in medical ethics; so it rather belongs in the toolbox for medical or biomedical ethics. *"Non-maleficence"* demands not to harm individuals in the medical context. Yet, if taken to the public health ethics framework (as a norm that forbids to harm groups or individuals for the public good) it does not add anything new that would not be covered by the other principles – especially as non-maleficence forbids harming single patients in treatments, to harm them on their demand or to take too much risk in therapies. These cases – although prevailing in medical practice and research – are not as the forefront of public health that is, compared to a physician-patient relationship in which the physician might prescribe pharmaceuticals or do surgical interventions, non-interventionalist. Yet, in cases where persons have to be immunized or mandatorily screened there might be a conflict for the physician and his or her medical ethics and the public good. Whereas the physician should be bound to (bio-)medical ethics, the public health practitioners have to follow public health ethical norms. Concrete moral conflicts might have to be solved for those situations – e.g. by narrowing down the leeway for physicians.

Sometimes *"precaution"* is discussed as a principle for policy ethics and as such might be a candidate for the ethics of public health and / or public health. But precaution "is all about taking early anticipatory preventive action" [21] and as such reflects a value that is already at the core of public health. Weed and McKeown consider it also to be a specification of the more general principle beneficence[22] (or, as I would say, "social utility" or "social beneficence" rather than "beneficence").

Some might expect *"solidarity"* as a central benchmark for public health ethics. I omitted this for two reasons. First, solidarity is often an expression of mutuality or reciprocity. And as such only indirectly a moral norm – rather it is prudential. But if one has in mind that solidarity tells us what we owe to each other, I would rather say that "solidarity" adds nothing new to the debate that "social justice" would not cover. In other words: from an ethical point of view, duties of solidarity must be justified as duties of "social justice".

Values and norms such as "truth telling" and "avoiding killing" also belong to personal rather than social ethics and are to a great extent covered by the principles of "social justice" or "respect for human dignity". The same applies to "public trust". "Public trust" is an essential value in public health and especially in times of a public health crisis. In this case it would further the state to act more effectively and as such further "social utility" if people trust and thus act compliantly. Furthermore, "respect for human dignity" demands to tell people the truth[23] and "social justice" means to act on persons' behalf. As such, following these principles would mean to further transparency which leads to public trust[24] – and to "social utility" as a consequence.

**5. Methodology – What we should learn from Beauchamp and Childress**

To repeat, conciseness is a virtue of an approach of applied ethics – such as bioethics or public health ethics. A set of generalized norms – namely principles – that represent central moral benchmarks to follow in the conduct of biomedicine or public health respectively is most helpful to non-ethicist practitioners and researchers. This we can learn from The Belmont report and the Beauchamp and Childress approach – and the worldwide applications of their approaches.[25]

We can further learn that it is fruitful to conceptualize principles for applied ethics as universal prima facie principles that can be balanced and specified.[26] What does this mean more concretely?

The principles are universal because they reflect moral convictions all people share worldwide. This is the thesis of a "common morality" that grounds Beauchamp's and Childress' approach.[27] Defenders of a transcultural "common morality" believe, in the words of Veatch, "that there are common 'pre-theoretical' insights – moral laws, rules, feelings, intuitions, or perceptions of maxims – that are shared by peoples throughout the world. Evidence for this claim is gleaned from commonly shared judgments that certain behaviors such as killing, harming, and lying, are morally wrong. Others cite universally agreed upon rights that are 'self-evident' or otherwise known to all (giving rise to a world-wide acceptance of a Universal

[19] Singer, Peter A., Benatar, Solomon R; Bernstein, Mark et al. (2003) Ethics and SARS: lessons from Toronto. *British Medical Journal* 327: 1342-1344. p. 1342f.

[20] Thompson AK, Faith K, Gibson, Jennifer L.; Upshur, Ross EG (2006) Pandemic Influenza Preparedness: an ethical framework to guide decision making. *BMC Medical Ethics* 7: 12. Siehe auch: Singer, Peter A., Benatar, Solomon R; Bernstein, Mark et al. (2003) Ethics and SARS: lessons from Toronto. *British Medical Journal* 327: 1342-1344.

[21] Weed, Douglas (2004) Precaution, Prevention, and Public Health Ethics. *Journal of Medicine and Philosophy* 29(3): 313-332. p. 317.

[22] Weed, DL; McKeown, RE (2001): Ethics in Epidemiology and Public Health I. Technial Terms. *Journal for Epidemiology and Community Health* 55: 855-857. p. 856.

[23] Following Immanuel Kant – the great philosopher of human dignity in continental European philosophy – to respect human dignity would mean to never lie, without any exceptions. Kant was even of the opinion that one must not lie to a murderer that comes knocking at your door and wants to kill one's friend that hides in the back of the house. But this appears implausible to me and as such the principles proposed here are only "prima facie" principles.

[24] Childress, James F.; Gaare Bernheim, Ruth (2003) Beyond the liberal and communitarian impasse: a framework and vision for public health. *Florida Law Review* 55(5): 1191-1219. p. 1206.

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[27] Beauchamp, Tom (2003) A Defense of the Common Morality. Kennedy Institute of Ethics Journal 13 (3), 259-274. Beauchamp, Tom L. (2001) Internal and External Standards for Medical Morality. *Journal of Medicine and Philosophy* 26: 601-619.

Declaration of Human Rights)."[28] Beauchamp talks of "raw data for moral thinking"[29] that everybody in the world shares and might look like imperatives like "don't kill", "don't cause pain or suffering to others", "don't steal" or "treat all persons with equal moral considerations".[30] This "common morality" thesis of applied ethics finds more empirical evidence from the work of Harvard psychologist Marc Hauser[31] and was recently also discussed in this journal.[32]

We perhaps all believe that mid-level principles (i.e. generalized norms formulated in the context of certain applications – like the four bioethics principles or the five public health ethics principles) are agreeable on a quite superficial level. Yes, of course doctors should benefit the patient and public health practitioners should find just public health arrangements. These principles are "prima facie" which means that they should be valid as long as they come into conflict. But what if two norms come into conflict – this would then be the touchstone of the truth or at least the applicability of the respective ethics approach. With Beauchamp and Childress, I would suggest the established methods of *balancing* (especially in particular situations) and *specification* (especially when issuing policies and rules) to resolve moral conflicts.[33] I want to use a case study to argue for this methods:

Mr. R is infected with the airborne communicable disease D. He knows this – as his wife, a doctor who specialized on infectious diseases, has diagnosed him – and he knows that he is contagious with this disease. Yet, he is about to go on vacation for three weeks. It is a vacation to Hawaii he has been dreaming of for years and he does not care if he is a risk to others but wants to check in for his plane. His wife was first in a quandary about what to do but then in the meantime, while Mr. R was on the way to the airport, had informed the public health authorities. When checking in at the airport, Mr. R is identified and captured. Mrs. H is the responsible public health official to make decisions at the airport. She had recently taken classes in public health ethics when she was at a course for continuous education. She notices that there is now a conflict between "social utility" (because a whole plane is at immediate risk to contract D) and "respect for human dignity" that asks to exercise the liberty of individual's to decide for themselves. Yet she *balances* these principles and comes to the conclusion that the risk for the social utility is great enough to balance out the claims of own decision making of Mr. R. Thus, Mr. R. is not permitted to enter the plane and the health authorities of the district take over the case.

Mrs. H notices that future ethical challenges might arise – also when she is not in office but her deputies are. Thus she *specifies* the following norm reflecting the principles of social utility, respect for human dignity, social justice and proportionality: "Whenever a person is known to have a serious infectious disease that is highly contagious over the air so that it is likely that other passengers might get infected, he or she is – even against his or her will – not permitted to enter the plane but has to be held in isolation and handed over to the district's public health authorities. Yet, to make sure, this does not apply to infectious diseases like a simple cold (here to go against persons' will would be disproportionate as a cold is not a serious disease and people are likely to catch a cold once in a while anyway) or HIV which is a serious infection but cannot easily be transmitted. To prohibit persons that are HIV positive to enter planes would not only be totally disproportionate but also discriminatory against HIV positive persons." This rule be an example of a specification in which one spells out "where, when, why, how, by what means, to whom or by whom the action is to be done or avoided"[34]. It is like branching out the principles by considering each other as side constraints and "zooming into" concrete situations.

This case study is probably trivial because the case seems obvious – which would then also support the argument that you – the reader – and I seem to share a common morality, because if we both think it is obvious and plausible we seem to have the same underlying moral values. This case study should demonstrate how prima facie mid-level principles can be utilized to make decisions morally plausible and to find justifications for actions. The methods of specification and balancing are good tools in applying mid-level principles to practice.

**6. Conclusion**

The four-principles-approach of Tom Beauchamp and Jim Childress has been very influential and has proven well in bioethics in the last decades. It has helped practitioners, researchers and policy makers for almost three decades now to identify moral challenges, to show them moral beacons for orientation and to come to better argued for ethical decisions that improved the moral acceptability of their actions. I argued that the applicability of this approach for ethical challenges in the biomedical setting should stimulate a principled approach for ethical challenges of public health as well. Such an approach can utilize the method from Beauchamp and Childress. Principles for public health ethics, as presented in a concise set by the author, however, must be different in scope and content to meet the ethical challenges of public health. But then these principles can be applied with the help of balancing and specifications which are methods used and developed in bioethics contexts.

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# Risk Information Assessment in Pharmacological Projects

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**Abstract**
Good Clinical Practices should guarantee the rights to the participants' safety, protection and well-being. Risk assessment is a continuous challenge for the Research Ethics Committees (RECs) and a requirement established in Regulatory Process. The purpose of this study is to verify, as an incident case study, the risks of adverse events (AE) expected in pharmaceutical industry sponsored research projects, by analyzing the Informed Consent Form (ICF), the researcher brochure and the Research Protocol. Considering 61 protocols, 8543 AE risk references were identified. Only 708 (8%) were informed, with theoretical basis, to both participant and researcher. The other 1716 (20%) risk references were presented only in the ICF without theoretical basis, and 6119 (72%) to the researcher, with theoretical basis, in the protocol or brochure. Our data shows the importance of a careful reading of the documentation submitted to the RECs evaluation, whose purpose is the participant's active protection.
Key words: Adverse events, Research Ethics Committee, clinical research.
The study was performed in the Research and Post-Graduation Group of Hospital de Clínicas de Porto Alegre, where all the authors also work (Rua Ramiro Barcellos, 2350 - 90035-903 - Porto Alegre, Brazil).
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**1. Introduction**

Studies involving human subjects should describe the possible adverse events/expected risks, either in the protocol or in the researcher brochure or in the Informed Consent Form, and should be specified in the project, approved by the Research Ethics Committee, in order to comply with the requirements of the Informed Consent Form.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected (ICH, 1996).

The International Ethical Guidelines for Biomedical Research Involving Human Subjects were published in 1983 by the Council for International Organizations of Medicinal Sciences (CIOMS), in cooperation with the World Health Organization (WHO). These guidelines were later revised in 1993 and in 2002 (CIOMS 1993). In 1996, the Brazilian National Health Council (CNS) locally established that the Research Ethics Committee should be informed of all adverse events involving the research projects (Conselho Nacional de Saúde, 1996).

An adverse event (AE) may be any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. It can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (ICH, 1996).

A serious adverse event (SAE) is any untoward medical occurrence, that at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect (ICH, 1996).

Performing scientific studies with new drugs is a very important issue, which requires special care, mainly regarding the severity of risks of adverse events, to maintain an ethically adequate standard.

One of the main factors linked with the ethical adequacy of research projects is the risk associated with such studies. Many times, the risk is unknown due to insufficient supporting data or as not being properly described, which may affect the study development.

According to *Bioethics Thesaurus*, risk is the probability that an unfavorable event will occur, comprising a variety of probability measures based on statistic data or subjective judgment (Kennedy Institute of Ethics, 1995). Risk, according to Brazilian Research Guidelines, is the possibility of damages to physical, psychic, moral, intellectual, social, cultural and spiritual dimensions of the human being, in any stage of a study or resulting from it (Conselho Nacional de Saúde, 1996).

Giddens (2002) classifies risks according to their origin: natural or constructed risks. Research-related adverse events would be classified as constructed risks, as the subjects are exposed to them only due to their participation in the project. This author defines high-consequence risks as those in which the more disastrous the involved damages, the smaller experience we will have about what we put at risk. Then, serious adverse events would be considered as high-consequence constructed risks.

The adverse events are classified by the pharmaceutical companies supporting the study or by the researchers regarding their cause-effect relation, as: related; possibly related; the relation cannot be discarded; possibly unrelated or unrelated. Related adverse events imply that there is a known reaction standard to the studied drug. It is confirmed with the improved situation after the drug interruption and recurrent manifestations when using the drug again, and cannot be explained by known characteristics of the patient's disease. For possibly related adverse events, there is a reaction that follows a reasonable temporal sequence after the drug utilization, with a known reaction standard. It is confirmed with the drug interruption, without re-exposure. For 'the relation cannot be discarded', there is a reaction after a reasonable temporal sequence, but it may or may not follow a known reaction standard. Concerning possibly unrelated events, they present higher probability of being linked with factors other than those involving the suspected drug (Naranjo and Busto, 1991).

An adverse event can also be classified as being predictable or unpredictable, or expected or unexpected. When considered as expected, it can be classified regarding its occurrence probability as: very common (over 10%); common (1% to 10%); uncommon (0.1% to 1%); rare (0.01% to 0.1%) and very rare (under 0.01%) (CIOMS,1995).

An unexpected adverse event is a reaction to the drug that has not been described yet, and then, it has not been

included in a research protocol, researcher brochure, Informed Consent Form, or in the drug circular, for those already approved (ICH, 1996).

When combining the cause-effect and expected-unexpected criteria, the adverse events can be sorted into three different fields: risk, uncertainty and unknown reactions. Related and expected events present a quantifiable risk, which should be described in all study-related documents. Unrelated, but expected, events are in the uncertainty field category, as only subjective probabilities can be established regarding their occurrence. Unexpected events, whether related to the study intervention or not, are unknown by definition at the project elaboration moment. All these situations generate new information, which may indicate the need for project alterations, changes and updates in the information provided to participants, or even its interruption for security reasons.

The risk assessment is a systematic process through which damage possibility, exposure and risk are identified and quantified. This assessment process is intended to prevent health damages caused by exposures to the drug. The risk assessment objectives include the risk-benefit ratio analysis, the definition of risk levels and the help provided to define priority monitoring and vigilance activities (Oga and Siqueira, 2003).

The elevated risk is directly associated with a higher probability of health-related adverse event occurrences. According to the adverse event severity and its occurrence probability, it is possible to determine whether an estimated risk is negligible, tolerable or intolerable. Then, the risk characterization represents an important connection between scientific data from different studies and decision-making issues, from risk monitoring to communication (Oga and Siqueira, 2003).

Unknown risk, associated with scientific studies, generates a clear feeling of ambiguity. If the risk is fully unknown, the reaction may present a feeling of attraction due to a desired or repulsive known reaction, if we consider the knowledge as forbidden. Uncertainty is associated with the chance of a certain event to occur and is expressed as a ratio. The risk, when expected and known, indicates the occurrence probability.

The assumption that participating in a study is a risk situation is based on the Precautionary Principle, which is the guarantee that protection measures exist against potential risks that, according to the current knowledge, cannot be identified yet. This principle states that the existence of a risk causing a serious or irreversible damage requires the implementation of measures that can prevent such damage.

The Precautionary Principle should not be seen as an obstacle to clinical, and mainly, research activities. It is a way to protect the legitimate interests of each person in particular, and of the society as a whole. Recognizing the existence of damage occurrence possibility and the need for its assessment based on available knowledge is the great challenge to the world scientific community.

The execution of scientific studies with new drugs is necessary, but they should be supervised in all their stages by researchers, sponsors, institutions where the study is being conducted, research ethics committees and regulatory agencies, with the purpose of actively protecting the subjects involved in the study.

An Informed Consent Form, freely provided, should be obtained from each research subject before his/her participation in the clinical study, investigating the possibilities of risks/adverse events adequately. It is important to explain the risk associated with the research procedures, verifying the understanding and comprehension of the information provided to the research participants.

The purpose of this study is to verify the risk of adverse events (AEs) expected in pharmaceutical industry research projects by analyzing the Informed Consent Form (ICF), the researcher brochure and the protocol.

**2. Method**

This is a study of incident cases, with an observation reference to adverse events. For this reason, a study was performed in 61 pharmacological research projects sponsored by pharmaceutical industries, submitted to and approved by the Research Ethics Committee (REC) of Hospital de Clínicas de Porto Alegre (HCPA).

The study consisted of verifying the risks expected in the ICF comparing to those presented in the protocol or researcher brochure. A careful reading of the researcher project (protocol) was done, verifying the expected risks described and whether they presented the occurrence probabilities for adverse events, followed by the ICF reading, which considered the same aspects. Concomitantly, all adverse events were checked in the researcher brochure that occurred in other preliminary studies and in previous clinical phases (Phases I, II, III) performed in the country of origin and other countries, including Brazil, where they are being conducted. Previously conducted studies allowed calculation of risk occurrence probabilities regarding the studied drug and that those risks should be properly described in the security section of the researcher/sponsor brochure. After performing the study and comparisons involving the ICF, the protocol and the researcher brochure, the collected information was stored in a risk management system database of the Research and Post-Graduation Division of HCPA.

The obtained and calculated data was analyzed by descriptive and inferential statistics. Data assessment was performed with the help of SPSS program, version 14.

Figure 1: Expected adverse event risks described in pharmacological research protocols, in the Informed Consent Form and in the researcher brochure.

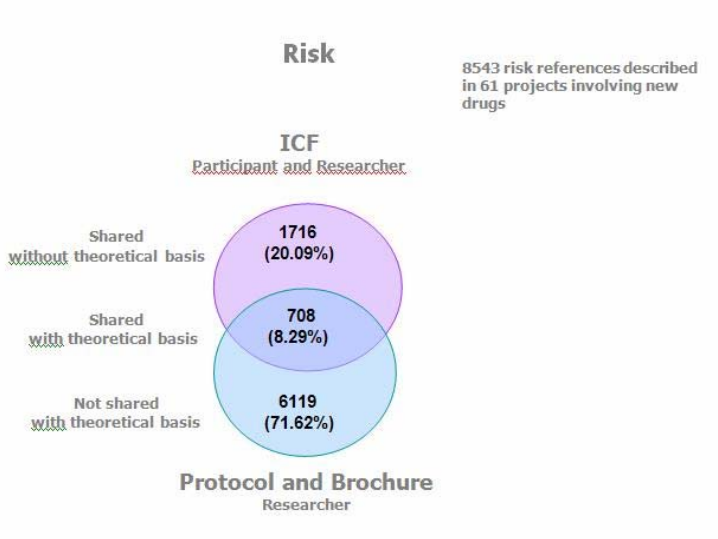
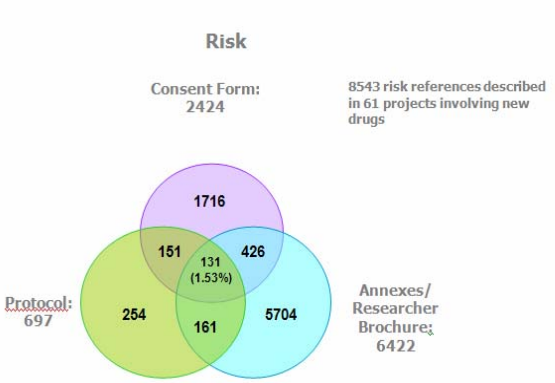


Figure 2: Expected adverse event risks described in the Informed Consent Form/ICF (participant and researcher) and in documents of access restricted to the researcher (protocol and brochure).




**3. Results**

Based on the total 61 analyzed projects, 8543 references were identified for expected risks of adverse events (AEs). The researcher brochure described 6422 references to risks; the Informed Consent Form (ICF) presented 2424 and the research protocol presented 697 references. Many times, the risks were not adequately informed in all three documents. Concerning the report on expected risks, 5704 (66.77%) of the risk references were described only in the researcher brochure, 1716 (20%) were described in the ICF and 254 (3%) were mentioned only in the protocol. Both ICF and researcher brochure mentioned simultaneously 426 (5%) of the risk references. Both protocol and brochure presented the description of 161 (1.9%) risk references, just as in ICF and the protocol: 151 (1.8%) references. Only 131 risk references (1.5%) out of the total 8543 reported references were simultaneously informed in all three documents (ICF/Protocol/Brochure), as illustrated in Figure 1.

Only 708 risk references (8%) were informed, with theoretical basis, to both participant and researcher. The other 1716 (20%) risk references were presented only in the ICF without theoretical basis and 6119 (72%) were informed only to the researcher, with theoretical basis, in the protocol or brochure. Considering the 2424 risk references described in the ICF, 71% (1716 risk references) were mentioned only in the ICF and in no other document. Considering the 6827 risk references informed in the protocol or Research Brochure (see Figure 2), 6119 (90%) of them were mentioned only in researcher's documents (protocol and brochure), i.e., non-shared information.

Most of quantified risks were presented only in the researcher brochure. The ICF described part of the risks, but not in quantified form.

**4. Discussion**

The evaluation of risks in pharmacological research projects is a continuous challenge for Research Ethics Committees (RECs), since it is a systematic process through which damage possibility, exposure and risk are identified and quantified. The risk, when expected, indicates the occurrence probability of adverse events. The protocol, the researcher brochure and the Informed Consent Form (ICF) should present, properly described, the AEs informed in previous studies involving the studied drug, providing the participants with knowledge to decide about the research participation. Based on the results obtained, it was possible to verify that most risks of AEs were described and quantified only in the researcher brochure. The ICF and the researcher protocol did not present information on part of such risks. Most of the ICFs were presented in clear language, enabling the research participant's understanding, but did not present all described risks, nor the occurrence probability, which may influence the decision factor regarding the study participation. Only 131 (1.5%) out of the total 8543 risk references of AEs were simultaneously informed in all three documents (ICF/Protocol/Brochure) and only 708 (8%) risk references were adequately shared, with theoretical basis, to participant and researcher. It is possible to observe a great discrepancy in the reporting of event risks that should be mentioned with theoretical basis, in the ICF and in the protocol or in the researcher's brochure (Figures 1 and 2).

The researcher has the access to the ICF, protocol and brochure. The participant has the access to the ICF only. Only the information contained in the consent term is externally published.

**5. Final Considerations**

The study refers to risk as those resulting from the research intervention, and not those naturally present in the participants' lives. An adequate investigation performed by the Research Ethics Committee (REC) should include the monitoring of all AEs, especially if the number of occurred events exceeds the expected risk.

The analyzed projects do not present homogeneity and standardization to properly express risks that have already occurred in previous studies. It shows the importance of a careful reading of all documentation submitted to the RECs evaluation, whose purpose is the participants' active protection.

The presented results indicate that the institutions should be committed to investigating systematically and in details the research projects involving subjects that are performed in their facilities. The information should be sent to the Research Ethics Committee for its assessment, and if required, the REC should promote changes in previously approved projects.

After these considerations, we can think of the consequences of performing a certain study, and whether it should be conducted or not. Opting for not performing some studies, or preventing certain subjects from participating, implies the protection against risks, especially in potential cases. Opting for allowing studies with expected risks, and informed serious adverse events, may result in exposure to risks, but with adequate control of the study and new forms of information to the participants (ICF); and greater damages might be previously perceived and prevented. In addition, once established that the risk is higher than the benefit, there is a possibility of thinking it over and interrupting the process, aiming at the health security.

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# Palliative Care in India: Ethical Issues Underlying Paradigmatic Shifts

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**Abstract**

The concept of palliative care represents a major paradigmatic shift in biomedicine. Understanding the socio-political factors which propelled the introduction of this paradigm in affluent countries of the West, may help developing countries to locate its relevance in their own local context. The paper identifies these factors, and in their backdrop examines the problems involved in creating specialist palliative care centers in India. It argues that a large number of ethical complexities may arise in a health care system which is already constrained by scanty resources and shortage of health workers. This suggests that mere adoption of western paradigms in end - of- life care may not help a country unless it has the infrastructural and organizational set up to implement new paradigms.

In many countries, efforts have been made to organize various stakeholder groups to develop a strong advocacy for quality end-of-life care, incorporating palliative care (PC) programs. Palliative care is primarily directed at providing relief to a terminally-ill person through alleviation of symptoms and pain management. The goal is not to cure or hold death in abeyance, but to provide comfort and maintain the highest possible quality of life for as long as life remains. Well-rounded palliative care programs also address mental health and spiritual needs of the terminally ill, and provide compassionate specialized care. Palliative care is well-suited to an interdisciplinary team model (involving social workers, psychologists, and alternative therapists) that provides support for the whole person and family members who are sharing the person's last journey in life.

This change of emphasis in the care of the terminally ill, seeded by the Hospice movement, constitutes a major paradigm shift in biomedicine. Palliative care is now an important concept in end- of -life care in the West, especially for cancer patients. Many countries have integrated it within a system of health care planning involving institutional care, hospices and home care and have evolved an efficient identification, referral and assessment system for the terminally ill. Insurance coverage has also been broadened, to include health support provided by skilled nursing facilities, homes and hospices, and to cater to the needs of people requiring long term care.

How far can the concept of palliative care, as it is developed in the West, be generalized and advocated in India? If palliative care is defined as care-- the goal of which is the achievement of maximum comfort and function of the total patient, then it can and should always be an integral part of the entire spectrum of patient care, irrespective of the level of health care of the country. In fact, it need not be confined only to the care for the patient who has been diagnosed with an irreversibly deteriorating or terminal condition, and for whom curative treatment is no longer possible. As an approach, it can be followed by all. But if specialist palliative care centers are to be run in a developing country like India where even primary care is lacking, a fine balancing has to be done between the needs of a vast majority of population whose lives could be improved through minimal treatment, and the terminally ill's right to a dignified death. This is not merely a question of ethical choice in the face of scanty health resources, but also a matter of judicious assessment of a country's infrastructural and organizational capacity to implement new concepts and approaches. In other words, one needs to implement concepts and approaches recommended by WHO with due consideration of their relevance in local conditions. In the absence of relevant structural and organizational inputs, any innovation, however ingenuous it is, may create serious contradictions. The dangers are especially real when we try to emulate models of care from societies which have made significant strides in improving health care to bring in other refined quality dimensions like compassion for those who are dying.

To initiate a system of healing in India based on symptomatic relief, caring, home care and spiritual comfort, is to re-emphasize an earlier model of healing when biomedicine had not yet attained its present triumphal success as a science. We may recall how WHO had to make serious efforts to change the health behavior of people in developing countries from a primarily home-based approach to an institutional one, incorporating biomedicine as the only scientific system of healing--even to the neglect of highly developed indigenous medicine. The latter was holistic, non-invasive, personalized and integrated with spiritual healing.

In developed countries, a de-technological model might redress the imbalances (at least in end- of- life care) created by an excessively scientific mode of health care. But in many developing countries, like India where the full potential of a technology oriented medicine has not been fully realized as yet, the introduction of palliative care may create several contradictions not foreseen by the West.

In fact, if we were to ask: Why did palliative care evolve the way it has and at this crucial juncture of medicine's glorious success, we find that at least four cluster of factors, at the level of macro-level planning, may have prompted a paradigm shift in Western countries. An understanding of these may uncover complex changes in biomedicine on one hand, and the political-economic context on the other. This, in turn might help developing countries to locate palliative care in their own context, and accordingly design strategies for effective end- of-life care.

**Factors Propelling Paradigm shift in the West**

1. The late 20$^{th}$ century has witnessed an acute crisis in the health care sector created by a long life span of population and, an epidemiological pattern of most people dying of diseases with long deteriorative terminal courses. High-tech bio-medical establishments that deal with such complexities have become extraordinarily expensive with formidable bureaucracies and increasing need for specialists. Many American hospitals, for instance, are closing doors, unable to survive in a competitive economic environment characterized by increasingly scarce resources and fragmentation in the medical market, and are being forced to adopt a major restructuring of the entire health delivery scheme (Russell 1979). So acute is the crises that scholars predict that the

venerable hospital may soon become an endangered species (cf. Risse 1993).

Within the structure of the existing system it has also become difficult to ensure personal care and nurses were the first to recognize this malaise. A rapidly falling average length of stay at the hospital has made it difficult for the nurses to develop high degree of mutuality and professional intimacy necessary for good caring. They made efforts to redeem their status within the professional hierarchy and also carve out a niche for themselves by developing a separate nursing zone.

2. There is also an acute shortage of health workers. According to the World Bank, there are currently 57 countries with critical shortage of health workers equivalent to a global deficit of 2.4 million doctors, nurses and midwives. Among the health workers, the shortage of nurses is particularly acute (The World Health Report 2006).

3.To make matters worse, there are growing disparities in health care delivery systems due to poor representation of ethnic and racial minorities (Baldwin 2003).Provider bias is becoming significantly important with the growing allegation of White domination inherent in, and perpetuated by medicine's research, clinical, and educational practices (Byrne, 2000; Feagin & Vera, 1995).

4. In addition to the above, in recent times, biomedicine has also been subjected to enormous criticism for its deep materialistic and reductionist stance (Kleinman 1995), inability to fathom pain and suffering (Illich 1976, Casell 1995, Good et al. 1994)) and failure to accommodate within its fold alternative paradigms of care. There has been a deep reaction to excessive medicalisation of disease and death, technologisation and bureaucratization of medical care, and impersonal, de- humanizing treatment regimes. palliative care seems to be redressing these problems in biomedicine

It is primarily in response to the above factors that the concept of palliative care emerged to emphasize care over cure. To cope with the crisis of health workers, solve the problem of disparities in health care delivery and increase patient satisfaction, perhaps the most practical step was to shift the locus of attention from institutional settings to non - institutional ones--home, community health centers and outpatient clinics, often blurring the distinction between social and medical care, in some respect. The concept of home care and hospice care need to be understood in the sense also (Struthers 2003). Putting care options in the hands of the families themselves, centers the ill person within his or her own social context, thereby avoiding the politics of different interest groups. The slant towards a caring approach requires a team approach and palliative care seems to address this issue also through a multidisciplinary model.

**Palliative care in India: Ethical Complexities**

Many of the structural factors which have served as propelling forces for introduction of palliative care in the west are differently located in the Indian context. Some are in fact, non-existent, and others though existing cannot be overcome with the same strategies as adopted by the west. We cannot overlook the fact that the concept has been introduced in India's health care system which is extremely poor. India's health spending is among the lowest in the world--USD4 a person, per year, less than one per cent of its gross domestic product, according to the United Nations Development Program. In such a scenario, how does a system geared towards enhancing quality end- of- life care perform; what are the major constraints, and what modifications are necessary to improve the system?

Many NGOs have started working in this area since 1980's with help from international donors and individual agencies. Although it is still too early to predict outcomes, it is simplistic to assume that palliative cares would help India achieve the same quality of care for its patients as afforded through similar structures in developed countries. As Rajagopal--one of the founders of the palliative care movement-- himself admits, there are many states which do not have any palliative care services, oral morphine (used for pain relief) reaches less than 1% of the needy and "the medical and nursing profession at large, have not accepted palliative care as an essential part of health care" (Rajagopal 1996).

If we examine the reasons we find that unlike western countries, India has not evolved an efficient system of health care as yet. End- of- life care is part of health care in general, and improvement in the former precedes improvement in the latter. Quality palliative care services require an integrated health care planning involving institutional care, palliative care, Hospices and home care--a feature lacking in India. In the absence of a continuum, or even a strong hospital- hospice/ palliative linkage, palliative care centers remain isolated experiments in healing. To establish a continuum, we need a proper identification, referral and assessment system. This would be possible only when we have strengthened our existing health services especially primary health centers and also the central role of the General Practitioner at each level. All this requires structural changes--changes in medical education, relevant guidelines to medical practitioners to make a transition from cure to care, with corresponding education and awareness among both patients and families about the importance of palliative care. Unless these structural inputs are present, palliative cares would remain isolated experiments.

Second, India is facing an acute shortage of trained force. While the west (which also faces similar problems), out sources personnel, especially nurses from developing countries, we cannot adopt similar methods to mitigate our crisis. India, Bangladesh and Indonesia top the list of South and South East Asian countries which have the greatest shortfall of health professionals. Although the number of registered doctors in India has increased from 61,800 in 1951 to about 645,825 in 2005, but that still means only 0.60 doctors for 1000 people. India has 1 nurse to 2,198 people. As compared to this, in Europe and North America, the figure is much greater than tenfold. An Escorts Heart Institute and Research Centre document prepared in 2005 stated that India would need at least one million more qualified nurses and 500,000 more doctors by 2012 (Down to Earth 2006). This, combined with mismanagement of existing facilities and manpower makes the situation worse. Researchers from MIT and Princeton working in 100 villages in Rajasthan found a no-show rate of 44% among medical personnel, rampant absenteeism among government doctors and nurses. In other words, even a dedicated workforce is not available at present to run palliative care programs.

One way of tackling the problem of workforce in the west has been to shift the locale of treatment from institutional setting to home, or at least provide people with the option of home as the locale of dying. At present, in India some home care services are managed by NGOS, others are linked to inpatient units. Preliminary field observations show that constrained by shortage of workforce, home visits are few and sporadic, the team is not always constituted with a doctor, and large distances are involved in covering each enlisted family, so that eventually only a few benefit at the end of the day . Moreover, in case of emergencies at odd hours, there is no way of locating team members. The link with a GP or the primary health centre is poor, and in any case constitute unreliable source of support. A sound territory –wise referral and treatment centre is necessary to obviate the crisis. It also needs to be borne in mind that enabling people to die at home is a complicated task which needs to devise ways of empowering families, provide public education balanced with continuing effort to improve home based models of care, early and

continuous risk assessment and training for palliative care not just for specialists but also for primary care professionals (Gomes and Higginson 2006).

We may also note that many patients in India, due to sub-optimal conditions at home, would be better cared at hospital. A sense of abandonment results in them when discharged from institutional settings. Home death, in many cases, results from limited resources and lack of alternatives rather than preferences. More research is necessary to investigate patient's preferences and factors which could indicate directionality or cause for such preferences --- factors related to illness, individual characteristics or health care input, for instance.

Home care raises serious ethical implications even in rich countries. As Garrard (1996) points out, a reasonable choice has to be made between alleviating one person's distressing symptom and actually saving another person's life. In resource poor countries, these ethical complexities become even more complex. Attributing moral propriety to quality rather than quantity is well nigh difficult. Unlike western countries, home care service providers receive limited assistance from public and private sources and have few trained community nurses.

A quality palliative care program involves liberal funding. It may be mentioned here that India is a low income country with 26% population living below the poverty line and 35% illiterate population with skewed health risks. But, insurance is available to only a small number covering 10% of the total population. Health insurance not only needs to reform coverage but also regulatory policy to broaden range and coverage of the program.

Finally, while we speak of palliative care's enormous potential to provide holistic treatment, it needs to be borne in mind that under the monopolistic onslaught of biomedicine, indigenous medicine in India has received a major set back. There is, at present, no relevant system to organize and integrate the diverse findings of indigenous medicine with biomedical practice. Incentives for patients to pursue indigenous medicine are also poor since it falls outside the purview of the existing insurance schemes. Moreover, indigenous medicine and spirituality in India are intertwined in ways difficult to decipher in the west. Promoting the former also helps inculcate spiritual values.

But the precise meaning of spirituality in modern life and within the modern health system remains fuzzy and unclear. Spiritual healing involves engaging the dying person's consciousness. But how do we achieve this? Do the meanings attributed to illness by the spiritualists on the one hand, and the doctor on the other, create contradictions in meanings for the patient? Can the patient in the grip of pain really draw solace from the discourses which are meta- body in nature?

There is not much empirical research on spirituality to substantiate all this. We also don't know the nature, mechanism and delivery of spiritual care. . The efficacy of spirituality in nursing practices, as Peberdy (2000) has rightly pointed, depends on structural and organizational factors, too. Spiritual matters are not only matters of relationships between individuals; the ethos of the institution and morale of the carers are equally important. This draws attention to the need to improve the employment conditions of nurses and caregivers and the amount of support and recognition to informal caregivers as well.

Can spiritual care be delivered from within the structure of professional care or outside it? How do we integrate a spiritual care plan with medical care? Do we deliver it independently or with the nursing and medical care plan? Its integration in some cultures, may juxtapose the almost fatalistic doctrine of life and death (as in Buddhism) with the awesome optimism of western medicine to cure all diseases. This may also contradict indigenous systems of medicine (like Ayurveda) which clearly admit the limitations of physicians in healing complex diseases. Then, spiritual care means different things to different hospices and palliative centers. A particular hospice for instance considers a quiet companioning presence, just listening, an expression of love and companionship, a humor or friendly chat and prayers as constituting spirituality. Others lay primacy on excellent interpersonal skills and communication (Buckman 2000).The variations in meanings can be immense. But, these measures may not still be adequate in providing the best solace to a dying individual.

**Research for Capacity Strengthening**

A careful assessment needs to be made about palliative care's relevance and effectiveness in the Indian situation. There has been no systematic audit on service outcomes and main QOL domains remain untested. Moreover, there are different models of palliative care and we do not really know how effectively these models respond to pain and suffering of the patients and their families, and the competence of different caregivers, both paid and unpaid to respond to eventual fatal chronic illness.

Moreover, it needs to be borne in mind that as a distinct approach to care for terminal patients, palliative care in the West has been mainly restricted to cancer patients and does provide many benefits. Not much is known about translating practices developed mainly in relation to cancer into feasible practices for the old, dying from a much more diverse multi-system pathology (see Wisam et al. 2006, George and Sykes 1997). But under Indian conditions it is debatable whether we should focus on cancer patients alone and scanty data exists with respect to workable options in other diseases.

There is another ethical dilemma --what aspects of palliative care should receive the greatest funding? Should the aim be to provide the best possible services for a limited number of patients,or should there be an excellent pain and symptom control for everyone, even if this means that there are insufficient resources to deal with all the fears and anxieties which patients may be experiencing?

**Conclusion**

To conclude the paper has looked at the implications of adopting palliative care centers in India. It suggests that mere adoption of new paradigms may not serve their purpose unless organizational and infrastructural facilities exist for their implementation. In India, a large number of contradictions may be expected when these centers operate within a larger system, which is so constrained as to be unable to support people with even primary health care. Moreover, the objectives of palliative care can hardly be achieved unless these centers are sufficiently funded, properly coordinated, manned by sufficient numbers of trained professionals, and incorporate new medical training programs and research in pain management.

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# A Sikh Perspective on Human Genetic Advances

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In this paper some recent advances and applications of human genetics are discussed from the context of Sikhism. Being born as a human being in the Sikh (disciple) tenet of faith, as in Hinduism in general, is a culmination of the journey of the soul through 8.4 m transmigrations /reincarnations (SGGS, p.50---*Through 8.4 million incarnations you have wandered, to obtain this rare and precious human life*). It is written thus in the holy Sikh scripture, Sri Guru Granth Sahib (SGGS- the embodiment of the Sikhs Guru's (teacher's) teachings; SGGS,p.326--*The mobile and immobile creatures, insects and moths - in numerous lifetimes, I have passed through those many forms. I lived in many such homes, O Lord, before I came into the womb this time. I was a Yogi, a celibate, a penitent, and a Brahmchaaree, with strict self-discipline. Sometimes I was a king, sitting on the throne, and sometimes I was a beggar*; also see SGGS,p.176). Actually, the present life is a gift from the Almighty because only in the human form can salvation from the *karmic* cycle of life be achieved through meditation and prayers (SGGS, p.12-*This human body has been given to you. This is your chance to meet the Lord of the Universe;* SGGS, p.28-This opportunity shall not come again. In the end, they depart, regretting and repenting), and by leading a godly way of life (SGGS, p.326--- *Says Kabeer, O God, have mercy on me. I am so tired; now, please bless me with Your perfection*) and serving humanity selflessly without adopting an attitude for gaining returns/retributions.

Further to this context is the observation that for the believer of the faith, whatever occurs in one's life is for the good and probably for the betterment/improvement of the individual in terms of an after-life and that whatever occurs in one's life should be accepted with a calmness and/or a gladness of heart neither to be tampered with or altered by prayers nor queried into the grand plan of things (rather in His grand plan) because its alteration or endeavours to alter it will cause an imbalance of the law of nature as identifiable with the *karmic* law. A Sikh should be in *status quo*, i.e. neither happy when in joy nor sad when in distress-meaning keeping a steady state of mind as that of calm acceptance. The clothing of the soul as a human being also does not requisite becoming a recluse in order to pray/meditate for achieving salvation but by being a householder (SGGS,p.281--- *In the midst of your household, remain balanced and unattached*) and earning one's life through hard work and thereby fulfilling one's obligations to the family. For the society and humanity, it mandates that one serves with humility; protection of the weak, looking after the destitute and standing-up for righteousness are parameters of the Sikh way of life (SGGS, p.26--- *In the midst of this world, do seva (service), and you shall be given a place of honor in the Court of the Lord*). A tolerance of others' religions without entertaining/ accepting fanaticism has been another attribute exemplified/practiced by all the ten Sikh Gurus (teachers). However, everything occurs because it has been ordained/ predestined and even praying and meditating by a person is possible if only it is as per the Almighty's wishes (SGGS, p.636--- *We come into the world, and we depart, with our destiny written and pre-ordained, O Beloved; realize the Command of the Commander*). And then there is also free will (SGGS,p.787--- *That alone is a good deed, O Nanak, which is done by one's own free will*).

**Basics of Sikhism**

Hence according to a Sikh inculcated into the way of life as per Sri Guru Granth Sahib, everything occurs as ordained by the Almighty and happens for the best for there is meaning to all things and purposes (SGGS, p.328--- *So many pregnancies end in miscarriage - why was this one spared?*). For the believers, the happenings in one's life are lessons that can assist in one's spiritual growth or for an after life-leading to salvation (SGGS, p.751--*But those who are attuned to the True Lord, are not reincarnated again*), or for an increment in one's spiritual growth. Extended to advances in Human Genetics, especially in Medical Genetics, a practicing Sikh to all intents and purposes will accept all the illnesses and diseases that affect him (SGGS,p.1326 --*My mind and body are calm and tranquil; the disease has been cured, and now I sleep in peace*). Of course, any treatments available would be undertaken by him, given that he has been suitably informed as to their nature. However, medical treatment which could have/ has been obtained from another person's life or has put another life at stake is to be categorically abstained from. This goes along with the tenet of keeping life sacred. The Gurus, as exemplified by their lives and conduct of life, upheld the rights of the oppressed, gender equality, equality of class, creed and religion, standing-up for righteous living, fighting tyranny and avoiding harm even to animal and other life forms.

This cuts across the overuse of the casual attitude towards abortion, since its widespread misuse following introduction of ultrasonography to assist obstetricians or for genetic diagnosis. Becoming legalised as a means of family planning and family spacing, abortion led to its further misuse for female foeticide. This did decrease female infanticide but led to further drastically skewed sex-ratios. What of the Sikh tenets? They have been swept away by the acclaimed

goodness of western medicine/advances and science. The system of Allopathic medicine has been adopted without cynosure with a naïve belief that it is the best and only remedial action available. As mentioned by Singh (2006), many of those guilty of these crimes (female foeticide) against humanity are Sikhs, although not the only ones, yet neither social nor economic desperation nor cultural constraints drive them to it. According to Coward (1993), though abortion is accepted by Hindus and Sikhs if essential to preserve the life of the mother, yet the religious prohibition of abortion is sometimes at odds with the cultural preference for sons (Coward and Sidhu, 2000). An article with views of different religions on abortion (The Orange County Register,1998) mentioned that in the Sikh faith, abortion, as all killings counters God's love for creation. The ages' old philosophy and the thinking and reflective nature have given way to easy acceptance of all scientific advances without assessing their effects and consequences. The spawning of fertility clinics and associated acceptance of procreation have also become a part of the acceptable system. Cloning, therapeutic and/or reproductive, prenatal, preimplantation and pre-symptomatic diagnoses/screening are all avenues which do not hold inhibition for the society. The concept about the soul and the *karmic* way of life, an after life and/or salvation are glossed over among the quagmire of rituals and easy means of getting one's demands met; not by calm acceptance of the divine command through meditation and prayers but by the calm acceptance of solutions offered by western science and medicine. Where congenital defects/genetic disorders/incurable diseases in the family were thought of as lessons for learning at a higher plane, now these are constraints to a modern and smart way of life, a burden too hard and difficult to carry, a yoke very difficult to bear, stigma and all. The general view goes along with the opportunistic way and manner of life style by taking a condescending way out of life's stresses. Sikhism, on the other hand, postulates that all problems and solutions lie within the purview/ throes of prayers (SGGS, p.1219--*Meditating, meditating in remembrance on my Lord and Master, I became cool and calm; my pains, sorrows and doubts are gone*) and in accepting Almighty's *Hukam* (SGGS, p.209---*Whatever God does, accept that with pleasure; in comfort and in suffering, meditate on Him*). The concept of *Hukam* has been best described as a combination of God's will, order or system (Rao et al., 2005).

With advances in Science and Technology have the issues of Prenatal Diagnosis, abortion, contraception vis-à-vis family planning and family spacing, sex selection, preimplantation diagnosis, Assisted Reproductive Technologies, Gene therapy, Reproductive and therapeutic cloning, Stem Cell biology, Euthanasia and assisted suicide, Organ donation and transplantation, *inter alia* surfaced. The advances (especially those pertaining to Medical /Human Genetics) from what is there in scriptures can only be viewed in the context of not going against God's will and that in the grand scheme of things, what is ordained will come to pass for it is in accordance with one's *karma* and deeds performed in (an) earlier lives (life). These are fruits as such and the present human life offers opportunity towards spiritual evolution and salvation (SGGS, p.706---*As one plants, so does he harvest; the body is the field of actions. The ungrateful wretches forget the Lord, and wander in reincarnation*; SGGS, p. 300---*Taking to the Sanctuary of the Supreme Lord God, his comings and goings in reincarnation are ended*).

**Prenatal Diagnosis, Abortion, Sex selection, Family Planning and Spacing**

The acceptance of all these techniques and procedures hinge and pivot on the questions of 'when life begins?' The scripture specifies that life begins at the time of fertilization (SGGS, p.706---*From egg and sperm, you were conceived, and placed in the fire of the womb*; SGGS, p.706--- *Creating the soul, the Lord places this creation in the womb of the mother*). Therefore the concepts of 'life' and 'death' need to be revisited in the present scenario.

**Sex Ratios**

The Census of India (2001) data reveal a drastic offset in the female-to-male (F:M) ratio in the 0-6 yr. group and this has shown a steady deterioration parallel to the introduction and widespread use of ultrasonography in the Indian sub-continent. Amniocentesis was first introduced in India in 1974 at All India Institute of Medical Sciences, New Delhi to detect foetal abnormalities. By 1975, it was being used for conducting selective abortions but was stopped in 1979, when the Govt. of India banned the misuse of medical technology for sex determination in all Govt. institutions (Singh and Arora, 2006).

The two-child family norm policy of the government (The National Population Policy, 2000) probably invited the misuse of this technology for sex determination/selection and family spacing coupled with the legalization of abortion as a population monitoring and control method (The 1972 Medical Termination of Pregnancy Act in India legalized abortion in order to reduce the incidence of illegal abortions c.f. Pande and Gupta,1979). The Dowry Prohibition Act of 1961 and the Hindu Succession (Amendment) Act 2005 (of The Hindu Property Act of 1956) further fuelled this. The ban on dowry invites harassment of the daughters by in-laws while daughters as stakeholders in parental property conflict with patrilineal culture. The fate of the female foetus was hence sealed. The second Guru, Guru Angad Dev ji also condemned the practice of dowry (SGGS, p. 435---*You have lost your self-discipline, you fool, and you have accepted an offering under false pretenses. The daughter of the alms-giver is just like your own; by accepting this payment for performing the wedding ceremony, you have cursed your own life*).

The medical fraternity also played a role in heavily promoting sex selection through ultrasound examination. By the time the ramifications were understood the damage had already been done. Female foeticide substituted for female infanticide (the age-old practice common to this part of the world). The government finally rose to the occasion by giving The Prenatal Diagnostic Act, 1994. This was later amended (2001) to include the Preimplantation techniques. However, there has been lassitude in its implementation and sex ratios have further fallen. The affluent Punjabis in the wake to appear modern, civilized and highly socially adaptable have adopted these advances in technology and science very eagerly. The underlying concept pertaining to 'life' and its 'values' has all been corroded and the collective wisdom/higher consciousness gained through the scriptures and over the *Yugas* (epochs) has been compromised. The Sikh Gurus always revered women and a special mention to this effect is present in the Sri Guru Granth Sahib (SGGS, p.473---*From the woman is our birth, in the woman's womb are we shaped; To the woman we are engaged, to the woman we are wedded; The woman is our friend and from woman is the family; Through the woman are the bonds of the world; Why call woman evil who gives birth to the leaders of the World? From the woman is the woman, without woman there is none*).

The continuous, contrary and unresolved debate by the scientists and most religious bodies on "when life begins?" has done nothing to resolve the issue. The thinking and debating interludes by the last generation (which supposedly is wiser and more religiously inclined) have not been utilized; the present generation has no time to contemplate-it accepts everything for its selfish motives. The modern Sikh/Punjabi has hence calmly and over-eagerly accepted these technologies amidst peer and social pressures. The Sikh scriptures specify the status of the embryo and foetus as embodied with life, having

consciousness, and that too with a high statute and degree of spirituality. Even in an upside down position in the womb for nine months, the foetus performs ablution by praying and is in-tune with the Almighty (SGGS, p.1013--*Through the union of mother and father are given the egg and semen (which) form(s) the body. In the uterus the fetus develops with head down in tranquility where God arranges every type of food*; SGGS, p.337---*You were upside-down, living in the womb; you generated the intense meditative heat of tapas (meditation)*). This harmony with Almighty however gets eroded gradually after birth as the infant progresses from infancy to adulthood (SGGS, p.337--- *He leaves the womb, and comes into the world; as soon as the air touches him, he forgets his Lord and Master*). This casual attitude has also inundated the "abortion" scenario leading to the skewed sex ratio-actually a case for doubly aggrieving-a female and then a female abortion. However, the tussle is amongst the God-fearing who believe in the sanctity of conception, believing it to be a life-force and not aborting it even in cases of an abnormality/disorder – taking it as a '*hukam*' (directive) and bearing it with forbearance and gratitude (SGGS, p.57---*Those who see pain and pleasure as one and the same find peace; they are pierced through by the Shabad (prayers/Psalm), taking it as a boon to appease sins of past lives or as a pay-off of karmic debts* (SGGS,p.695---*Pain and pleasure are the result of your own actions*). Presently, very few believe in such a philosophy. Non-conformation to or with the newer innovations or technologies is considered old-fashioned. Discussions on such issues are ignored and considered self-righteous. Opportunism is the *forte*.

**Embryonic Stem Cell Research**

The issue of Stem Cell Research (SCR) is not well understood by the lay person. Chahal (2004) has observed that the scriptures do not condemn research and benefits ensuing from SCR and that if a treatment option or medication is available, it should be used for the concerned ailment. This adage does not delve into probing into the etiology or source or base of the medication/ treatment option. Rather substantial evidence from medical research is considered a good enough reason to use it. A thought-provoking and inflammable debate could arise if clarified that embryonic stem cells (ESC) are derived from cells destined to be embryos with a full potential of growing into adults. It is believed that the earthly *karmic* cycle of life begins at conception (the entry point for a soul which has also spiritual and past *karmas;* SGGS, p.922--- *The Lord placed the soul to the cave of the body, and blew the breath of life into the musical instrument of the body*). With left-over embryos from assisted reproductive technologies forming a stock-pile for embryonic stem cells to provide treatments for several debilitating conditions, does this or does this not amount to treatment at the expense of a life? And since the embryo develops into the foetus, its abortion or preferential abortion if a female, does this not also comprise the same overture in terms of life and personhood? The scripture states '*You murder living beings and worship lifeless things; at your very last moment, you shall suffer in terrible pain*' (SGGS, p.332).

The availability of Assisted Reproductive Technology (ART) in mushrooming fertility clinics and no set procedures or clear-cut guidelines along with an overtly casual approach towards sperm donation/acceptance/ ova donation/ acceptance, surrogacy and the like, opens up a plethora of issues but only for those who want to delve into the intricacies of life-forms as portrayed in the scriptures. The religious philosophy of calm and gratuitous acceptance of life happenings is glossed over in the wake of casual and ready acceptance of medical advances. There is a negative tendency of not-to-make an in depth analysis of any advancement rooted in the theory that any task performed in ignorance is neither rated a sin nor a crime and metes a pardon in the Almighty's court.

The SCR issue offers two avenues for contemplation- the use of cells for somatic therapy/organ formation, and reproductive cloning. Again the 'bone-of-contention' is based on the aspect that reproductive cloning (where partners are not required) goes against that given in the scripture which specifies that the sperm is donated by the male and the female contributes the egg (SGGS, p.1022---*From the mother's egg and the flow of semen of father, the Infinite God has created a beautiful body. The energy and all types of food have been provided by You, the Creator, who pervades everywhere*) and also that conception is the moment or time of the entry of the soul (SGGS, p.77---*In the first watch of the night, O my merchant friend, the Lord placed your soul in the womb. In the tenth month, you were made into a human being, O my merchant friend, and you were given your allotted time to perform good deeds. You were given this time to perform good deeds, according to your pre-ordained destiny*). This offers contemplative reflections because in reproductive cloning where conception or fusion of the gametes is lacking, how /when/if can then there be entry of the soul?

**Assisted Suicide/ Euthanasia**

The taking of a person's life is considered a crime and sin in all religions and beliefs; no one has a right to give or take life. It is generally accepted that birth and death are the mercy of the Creator (SGGS, p.151---*By the Hukam of His Command we come, and by the Hukam of His Command we go*) and this again throws to the wind the issues of abortion and ESC research. In the Sikh belief, death is the ultimate truth of life and is accepted as inevitable (SGGS, p.36---*This world is an illusion; people pass their life-nights sleeping*; SGGS,p.15---*Life and death come to all who are born. Everything here gets devoured by Death*).

The concept of suicide is also considered against the Sikh tenets. If life cannot be created then how can death be controlled? (SGGS,p.1329---*No one can hold anyone back from coming; how could anyone hold anyone back from going? He alone thoroughly understands this, from whom all beings come; all are merged and immersed in Him*). Rather, suicide is frowned upon and it is believed that the taking of one's life is not the end of one's woes but further creates negative *karmas* and one will have to re-live this life in the next one. Bhatia (1985) has observed that Sikhism propagates `Suicide in the. face of misery and misfortune implies lack of faith in the goodness and righteousness of God'. Against this backdrop, the issue of assisted suicide also raises the same premise. Euthanasia as an extension is also considered an interference in God's plan (Mansukhani, 1977). Since life is a present from God (SGGS, p.575--- *Blessed is human life, which is obtained by virtuous actions. Human life is obtained only by the most virtuous actions; this body is radiant and golden*), there is a duty to live life in a responsible way and to respect it. Efforts have to be made to get well and this includes getting medical treatment (Rao et al., 2005). Rather appropriate distinctions have to be made between ending life and not artificially prolonging a terminal state (www.bbc.co.uk/religion/ethics/euthanasia/sikh.shtml). Further where people contemplate euthanasia, the Sikh reaction is to provide such good care that euthanasia becomes an unattractive option. The given life should be preserved and lived as per the Guru's tenets so that one is no longer trapped in the cycle of rebirths (SGGS, p.1096). The care of the wounded in the battlefield was initiated in the times of the tenth Guru, Guru Gobind Singh ji. In 1705, Bhai Kanhaiya was advised by him to care for the wounded soldiers, irrespective of friend or foe (Singh, 1992-99). Red Cross only started this about 150 years later. Hospice care for the destitute, the

mentally challenged and the handicapped, irrespective of caste, creed or religion, is an integral part of the Sikh way of life to serve humanity. Bhagat Puran Singh's efforts in 1947 initiated from the care of a single leper. Singh (2000) christened him as the 'Bearded Mother Teresa of Punjab'.

Recombinant DNA technology (genetic engineering) used for genetically modified (GM) organisms, is another moot point in the Sikh way of life. Every being created by the Almighty is unique (SGGS,p.1056---*My True Lord God has staged a play. He has created no one like anyone else .He made them different, and he gazes upon them with pleasure; he placed all the flavors in the body*). Besides the uniqueness, each being has the element of wholeness to it (SGGS, p.1412---*All that the Perfect Lord does is perfect; there is not too little, or too much*). Since each being is both unique and complete, there is no scope for altering or modifying it. Let nature be unadulterated, neither altered by miracles nor by science. There is a resonance of this cautionary principle (SGGS, p.1375---*Kabeer, the earth belongs to the Holy, but it is being occupied by thieves*). Further to this, the Almighty resides in everything (SGGS, p.922---*This whole world which you see is the image of the Lord; only the image of the Lord is seen. By Guru's Grace, I understand, and I see only the One Lord; there is no one except the Lord*). Accordingly, the Almighty can be seen in His creation and nature commands love; it is also to be revered since it has been created by the Almighty (SGGS, p.150---*The Lord, by the Hukam of His Command, has created the entire creation*). Changing (harming) any part of it is hence contrary. No thought of harm should be there if one has love for it because the Almighty is immanent in the creation (SGGS, p.1349---The Creation is in the Creator, and the Creator is in the Creation, totally pervading and permeating all places). And with this love for the Creator and creation comes self realization- which is spiritual progress. Chahal (2005) has posed some interesting queries: genetic engineering may effect a cure for a disease and so the person will not suffer from the associated physical *karmic* effects of earlier deeds However if there happen to be detrimental effects of such a therapy, can then these negative effects again be considered as new *karmic* effects? Does it mean that genetic engineering can alter *karma*? Berry (c.f. Chahal,2005) too states that the acceptance of the will of God means the acceptance of every condition as created and willed by God. In this context, a child with an abnormality or disease is the result of the child's and the parents' previous *karmas*. Genetic engineering may well provide options but it is faith or belief which can aid in resolving these conflicts.

**Sikh Clergy and Bioethics**

The Sikh religious authorities have generally remained silent on science-related issues except for female foeticide (and infanticide), *sati* (wife's self-immolation on husband's pyre to be with him in the next world) and genital mutilation (Chahal, 2004). The Sikh scripture mentions that the wife performing *sati* falls into the cycle of rebirths (SGSS, p.185---*Imitating what she sees, with her stubborn mind-set, she goes into the fire, She does not obtain the Company of her Beloved Lord, and she wanders through countless incarnations*; SGGS, p.328---*Without Truth, how can the woman be a true satee - a widow who burns herself on her husband's funeral pyre?*). The Sikh Gurus opposed *sati* during the 16th century - the third Guru, Guru Amar Das ji specifically stopped the practice of *sati* and also advocated widow marriages; in Punjab, this practice was banned in 1829 (c.f. Chahal,2004).

Circumcision is banned and the scriptures mention that principles of self discipline should be one's circumcision; purifying the mind and keeping the body complete without circumcision should be the code of conduct (SGGS, p.1084---*Let your meditation beads be the subjugation of the ten senses. Let good conduct and self-restraint be your circumcision*; SGGS, p.477---*Because of the love of woman, circumcision is done; I don't believe in it, O Siblings of Destiny. If God wished me to be a Muslim, it would be cut off by itself. If circumcision makes one a Muslim, then what about a woman?*).

The Sikh way of life further extols that each act should be evaluated. It should be pursued only if good for a person's life or for humanity (SGGS, p.1410---*O my mind, do not waver or walk on the crooked path; take the straight and true path*). Sikh clergy have now intensified efforts on a large scale to curb the practice of female foeticide in the region. The Hindu clergy in Banares in 2005 and the Sikh Clergy for the first time passed an edict condemning female foeticide (Vedanti calls for drive against female foeticide, 2003). In April 2006, the Sikh religious authority, the SGPC (Shiromani Gurdwara Prabandhak Committee, Amritsar)-SHRG (Sikh Human Rights' Group, UK)-UNESCO after deliberations in a seminar on "Female Foeticide" have risen to the occasion and have mobilized funds to initiate the Sikh clergy, NGOs and academicia to educate the rural and urban Punjabis for curbing the practice of female foeticide. The lax attitude for implementation of the Prenatal Diagnostic Act was also condemned. In UK, the leaders of the Sikh and other faiths, had written an open letter (Clerics' cloning plea to Lords, 2001) to the Lords urging them not to permit the creation of embryonic clones. It mentioned that the 'Sikh faith does not specifically ban embryo research. But respect for life is central and Sikh leaders feel parliament must be given more time to examine the scientists' motives'.

It is a turning point for the clerics in all set-ups to critically examine the current and future medical genetic advances given the wider ramifications of bioethics in cross-cultural settings and in order to safe guard the beliefs of various communities. It is indeed high time also for the Sikh religious authorities, after appropriate deliberations and debates with various strata of society and in keeping with the Sikh code of conduct as given in the SGGS and in the Sikh Reht Maryada (1945;1994), to formulate guidelines and directives on use and research applications arising from embryonic stem cell research, therapeutic cloning, ART, organ farming, designer babies, genetically modified (GM) organisms, keeping in view that these advances encroach onto what has been created by nature and as ordained and watched over by the Almighty (SGGS,p.1185---The Lord Himself plays, and He Himself watches; the Lord Himself created the creation; You alone know Your Creative Power, O Lord; no one else knows it. He alone realizes You, O my Beloved, unto whom You show Your Mercy). Brar (1998) had pointed out that the current Rehit Maryada does not contain answers to any of these and other quandaries besetting the Sikhs in the 21st century. The answers reside in the Living Guru, Sri Guru Granth Sahib but since every Sikh has personal interpretations and views on these topics, an updated Rehit Maryada is required in order to avoid such a plurality and to foster uniformity as per the Sikh doctrine.

The creator who created the world, He takes thought of it as well (SGGS, p.466).Harmony with the eternal implies a life of harmony with all existence. All life is interconnected; look at all existence as one and undifferentiated; the same light permeates/penetrates all existence (SGGS, p.599---As Gurmukh, look upon all with the single eye of equality; in each and every heart, the Divine Light is contained.). In Sikh belief, all creation has the same origin and ending. The humans must have consciousness to guide themselves through life with love, compassion and justice (Posey, 2002; SGGS,p.1384---If thou wouldst seek God, demolish and distort not the heart of any individual). The Sikhs have awareness (Sikh Faith Statement, 2003) and believe that a sacred relationship between humans and the environment is necessary for the health of our planet, and for our survival. A new "environmental ethic" dedicated to conservation and wise use of the resources provided by a

bountiful nature can only arise from an honest understanding and dedicated application of our old, tried and true spiritual heritage. Sikhism is foundationally ecosophical (Lourdunathan, 2002). The term eco-sophism (the wisdom of the universe) is appropriate as Sikhs believe that such wisdom is required for the promotion of sustainable and peaceful ecology-more so since the purpose of human beings is to achieve a blissful state and be in harmony with the earth and all creation (SGGS, p.1035). Sikh prayers also centre on the unity of mankind, and the inseparable links of humans to nature (Rajwant Singh). Furthermore, the acceptance of *Hukam* can provide solutions to the problems besetting an individual and the world.

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*Sri Guru Granth Sahib* (SGGS) Shiromani Gurdwara Parbandhak Committee, Amritsar, India. SGGS, p.176---Gauree Gwaarayree, Fifth Mehl:

In so many incarnations, you were a worm and an insect;
in so many incarnations, you were an elephant, a fish and a deer.In so many incarnations, you were a bird and a snake.In so many incarnations, you were yoked as an ox and a horse. ||1||Meet the Lord of the Universe - now is the time to meet Him.After so very long, this human body was fashioned for you. ||1||Pause||In so many incarnations, you were rocks and mountains;in so many incarnations, you were aborted in the womb;in so many incarnations, you developed branches and leaves;you wandered through 8.4 million incarnations. ||2||Through the Saadh Sangat, the Company of the Holy, you obtained this human life.Do seva - selfless service; follow the Guru's Teachings, and vibrate the Lord's Name, Har, Har.Abandon pride, falsehood and arrogance.Remain dead while yet alive, and you shall be welcomed in the Court of the Lord. ||3||Whatever has been, and whatever shall be, comes from You, Lord.
No one else can do anything at all.
We are united with You, when You unite us with Yourself.Says Nanak, sing the Glorious Praises of the Lord, Har, Har. ||4||3||72||.

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# Psychopharmacological Enhancement: Self-determination or self-manipulation?

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## 1. Introduction

The term psychopharmacological enhancement refers to the current trend of self-optimising one's cognitive abilities and psychic well-being via psychotropic drugs without the presence of a medical indication. The so called cognitive enhancement and mood enhancement mark two paradigmatic types of psychopharmacological enhancement. Methylphenidate is a substance frequently used for cognitive enhancement purposes, which stimulates the central nervous system. This chemical agent is often referred to as Ritalin and was primarily used in the treatment of ADHD (Attention-Deficit-Hyperactivity-Disorder). The chemical agent Fluoxetin is an anti-depressant that belongs to the class of serotonin-reuptake-inhibitors (SSRI's) and is frequently used for mood enhancement. In Germany Fluoxetin is known by its brand name Fluctin, in the USA it is mostly referred to as Prozac. Fluoxetin was primarily used for the treatment of depression.

In the following cognitive enhancement and mood enhancement will be assessed in respect to their ability of ensuring the self-determination of individuals. It will be scrutinised whether psychopharmacological enhancement via Prozac, resp. Ritalin is founded on an autonomous decision of the individual, whether it is a means for self-determined or self-manipulated self-creation and whether its outcome strengthens or erodes the individual's autonomy. For these considerations it is crucial to understand two differing concepts of authenticity – one of which is closely linked to the concept of autonomy and one of which almost contradicts it.

## 2. Disambiguation

The term "self-determination" derives from the Greek term "autonomy". With its components 'autós', 'self', and 'nómos', 'law', it means 'the right of self legislation', or more general: 'the right to live in accordance to one's own law' (Von Ungern-Sternberg, 1990:9). This political concept of autonomy*, decisively restricted to autonomy of act, is broadened to an ethical dimension that differentiates between autonomy of act and autonomy of person, as a result from questioning the person, who shall live according to its own law, and from questioning how this is workable. Self-determination becomes a moral ideal grounding on the ability or will of individuals to self-determination that gets manifest in decisions and acts (Quante, 2002:174). The ability to self-determination is constituted by internal factors such as self-awareness, rationality, reflecting power, self-knowledge, absence of inner forces, and external factors such as an autonomy encouraging socialisation, absence of external forces, etc. The internal prerequisites for self-determination, especially the constitutive moment of self-knowledge, are based on the idea of an authentic personality, a true self. For the desire, the will, the act, finally the life of an individual to be self-determined firstly the individual must possess the ability to reflect her own desires, volitions, acts and her own life critically in order to identify itself with them (Frankfurt, Dworkin and Quante in Quante, 2002:174-196). Thus an individual can develop an evaluative self-conception (Quante, 2002:177) which enables her to self-determine her desires and check the authenticity of her own wants. Desires and wants of an individual can only be authentic if they have emerged without manipulative influence and in absence of self-deception (Quante, 2002:180).

In the understanding of autonomy of act the external factors are sufficient for the self-determination of an individual. To be a self-determined individual according to the concept of autonomy of person however, external as well as internal conditions must be met. Furthermore a "biographic dimension" (Quante, 2002:179-181) is required to rule out an over-directed or self-manipulative origin, resp. motivation of the desires and wants of the individual. Whether the internal factors are ensured can be judged directly by the individual concerned but also indirectly, on the grounds of specific indicators, by other people. The coherence of a personality throughout time, the individual's background of socialisation, her articulated relation to herself or even neuro-scientific findings about the individual's brain can provide information about the individual's ability of self-determination. If the personality and the way of life of an individual do not appear to be coherent, if her socialisation* has not been shaped by the promotion of autonomy, but by the manipulation of her self in favour of over-directed purposes, if the individual has a disturbed self-relation, then this might indicate the individual's disability of self-determination. If relevant brain areas show lesions this might also be an indication for restrictive self-determination abilities.

Autonomy and authenticity are closely linked concepts. Authenticity means to discover and tread one's own path through life in a coherent manner and is therefore a form of existence of autonomy. A reflexive and a pre-reflexive kind of authenticity can be identified (Quante, 2002:192-196). Both, reflexive and pre-reflexive authenticity is immanent to be constitutive for an evaluative self-relation that means constitutive for personality (Quante, 2002:193). Pre-reflexive authenticity refers to a primordial, yet unreflecting connection resulting from external factors such as socialisation as well as internal, psychological factors; a coherence begetting concord with one's own self. Because pre-reflexive authenticity founds the self of a person reflexive authenticity refers to it as the condition sine qua non for the possibility of self-determination. Reflexive authenticity and autonomy are congruent: An individual is authentic if and only if she has 'adopted' all her desires and convictions as her own by identifying with them (Quante, 2002:193). As pre-reflexive authenticity already entails the moment of the evaluative self-relation and as it were fosters identity-establishing, reflexive authenticity, which itself makes personality a subject of discussion and critically reflects its convictions, thus must be existent as ability, but it need not be continually materialised to generate personal autonomy (Quante, 2002:192-195). The present study takes the interpretation of self-determination as just referred to as a basis.

## 3. Representation of arguments

In the controversial debate on Ritalin and Prozac as common means of cosmetic psychopharmacology – the former aiming at cognitive enhancement, the latter aiming at mood enhancement – the authors Peter Kramer and Carl Elliott adopt

* In the following the term "autonomy" and "self-determination" are used synonymously.

* The function of socialisation in relation to an individual's self-determination is problematic: On the one hand socialisation is of constitutive function for autonomy, on the other hand it may contain autonomy-endangering forces. However in general, one can distinguish between an autonomy fostering socialisation and an up-bringing that leads to independence, critical reflexion, etc. and an autonomy undermining socialisation. See also Quante and Stier.

opposing positions. Both critically examine the phenomenon of so called life-style-drugs and both have shaped the debate with a lasting effect. Particularly on the grounds of a differing concept of authenticity, Kramer and Elliott elaborate distinct attitudes towards the use of psychotropic drugs for psychopharmacological enhancement. Referring to a rather traditional interpretation of the concept of authenticity as his starting point, Elliott develops a critical stand towards psychopharmacological enhancement, whereas Kramer, on the basis of a rather post-modern and liberalist interpretation of authenticity, tends to support the use of psychotropic drugs for enhancement purposes. As set forth earlier, the concepts of authenticity and self-determination are intertwined and mutually dependent ideas. The following analysis intends to investigate both concepts of authenticity underlying the arguments for and against psychopharmacological enhancement. On three levels, motivation, means and result, the arguments shall be outlined thus extrapolating conclusions from the concepts of authenticity to the concepts of self-determination.

*A. Self-determination via the up-to-date interpretation of authenticity*

According to Kramer and other contemporary authors there is no authentic self one could act appropriately to or one could be true to. In accordance with this view the traditional ideal of an authentic self implies the "misleading image of the self as "given", static, or something there to be discovered" (DeGrazia, 2004:36). Instead Kramer and like-minded people intend to replace this metaphysical anchoring of the authentic self with a more comprehensible and liberalising understanding of authenticity. For them every individual creates her own narrative and can rewrite her life story at any time, because the individual herself is the director as well as the actor of her own life project. In contrast to self-fulfilment, self-creation (DeGrazia, 2004:33-41) is an authentic process. The assumption that personality traits were fixed components of the individual is rejected. Whether certain characteristics are definite and intrinsic of someone rather depends on the individual and her identification with them. Personality traits can only be authentic if the individual concerned autonomously identifies herself with them (DeGrazia, according to DRZE-Sachstandbericht, 2002:69). One is free to change one's sense for one's own identity at any time and one can always assess independently how much one values one's present personality (Gesang, 2006:10) or to what degree one wants to alter it. The view that individuals do not possess a substantial identity, but perform identity appropriately to different social roles, relates to the shift of the postmodern age.

"With this shift has come a far more positive take on the healthiness and morality of self-transformation. Not only can we change our identities, it is suggested, we do it all the time. And we ought to be glad, because this kind of plasticity is healthier, more honest, more apt to bring us happiness" (Elliott, 2003:47).

If identity is rather relative and malleable, the individual is relieved of the metaphysical pressure which imposes on her an ideal of being accordingly to her authentic self. This should imply that the individual is no longer damned to endless self-reflection and does no longer have to participate in an infinite regress of self-analysis. According to the up-to-date interpretation of authenticity the individual may just be happy without being compelled to justify her happiness referring back to her authentic self.

In modern society healthiness is one of the most strived for goods and as happiness results from psychological well-being it is considered to be healthy. Melancholy and alienation on the other hand are rooted in psychological indisposition. If they are ascribed intrinsic normative value this is due to a social construction whose valuing stems from an arbitrary connection made between melancholy and creativity or insightfulness. The identification of melancholy with profundity and happiness with superficiality is, according to Kramer, arbitrary and bases on an unwarranted "aesthetic valuation of melancholy" (Kramer, 2004:49). The topical definition of authenticity no longer focuses on the discovery of the self, but emphasises the process of self-designing. Resulting from this premise is an understanding of self-determination that solely addresses the notion of freedom of action, namely the absence of exterior forces limiting the process of self-creation, as important. From this point of view psychopharmacological enhancement, authenticity and self-determination build a symbiotic alliance: freed from metaphysical burden and constraints of a static self, the human being is not forced to enhance herself but can freely choose to do so (Gesang, 2006:10) via psychopharmacological enhancement thus self-determiningly creating an authentic self and producing psychological well-being and happiness.

*B. Self-manipulation via adulteration of the concept of authenticity*

Authenticity is a traditional concept on which numerous religiously or politically motivated approaches to self-fulfilment are based. Therewith self-fulfilment does not become a relative or hollow phrase there must be an authentic self that can be fulfilled. Especially the individualism burgeoning in the 18th century emphasises the uniqueness of every human being and bestows upon everyone the mission to live a life of self-fulfilment. Self-fulfilment unfolds a normative character and authenticity becomes a moral ideal: "To thine own self be true!" This "articulates perfectly the notion of authenticity as a moral ideal: the idea that we each have a way of living that is uniquely our own, and that we are each called to live in our own way rather than that of someone else" (Taylor according to Elliott, 2003:29).

Also today authenticity counts to be constitutive for self-fulfilment and a successful life. For many people authenticity is an important maxim for action because only an authentic life leads to a fully lived and happy life everyone strives for. "An ethic of authenticity says that in order to answer the question, "How should I live?" I will have to look inward, because there is no single universal way of living a meaningful life" (Elliott, 1998:181). Elliott registers a strong wish for authentic self-fulfilment in many of his patients. Oftentimes his patients refer to the concept of authenticity when they intend to unfold their true self with the aid of psychotropic drugs which for them are "tools of self-discovery and self-fulfilment" (Elliott, 2003:30). Many people explain their use of mood enhancement with their existential desire to be authentic, to be themselves. Before considering to take psychotropic drugs they say that it feels as if their true "I" was covered or suppressed by unrequested attitudes such as sadness, shyness or anxiety. Likewise users of cognitive enhancement justify their decisions with their will to (mostly job-related) self-fulfilment. In both cases the intention is to set the true self free by means of psychopharmacological enhancement but the aim is decisively not to betray oneself or others. However, the personality change induced by psychotropic drugs seems to "defy an ethic of authenticity" (Elliott, 1998:182) and it appears to be paradox to base these kinds of personality transformations on the moral ideal of authenticity. But patients insist on their account that they suffer from their melancholic or alienated character and want to separate from it as they are actually different. They seek to reveal their actual self via psychopharmacological enhancement. People who validate their efficiency to be insufficient for accomplishing their authentic self-fulfilment opt for psychopharmacological enhancement as well. Either group employs the word authenticity as "a way to describe self-change without betraying a complex moral ideal" (Almodovar according to Elliott, 2003:30).

Although Elliott estimates the desire of his patients for authentic self-fulfilment to be urgent and appreciates the "extraordinary amount of effort, pain, and risk that go into these self-transformations" (Elliott, 2003:39) he still considers the autonomy of his patients to be endangered. Elliott does not reject the use of psychoactive drugs for the purpose of self-fulfilment eo ipso but judges it very sceptically in our culture that simultaneously imposes the ideal of an authentic self and the ideal of a "flexible, adaptable identity" (Elliott, 2000:8).

From Elliott's point of view for our society only certain traits, in concrete those being connected with psychological well-being and professional success, are of normative value. Thus people are always endangered to be induced to a unilateral definition of self-fulfilment by the force of external authorities (Taylor, 1999:126). Happiness, extraversion, spontaneity and similar traits of personality are considered to be precious and worthwhile in western society, as they are likely to lead to social as well as professional success – the modern equivalent for a fulfilled life. Sadness, melancholy, shyness or alienation on the other hand are unfeasible if not debilitating traits in our society as they are unlikely to promote social and job-related success. The decision towards psychopharmacological enhancement thus originates in the conclusion of people who think that if I am "alienated, depressed, or anxious, I can't be completely fulfilled" (Elliott, 2003:300). This attitude produces the adulterated concept of authenticity and self-fulfilment that equates 'being authentic' with 'being happy and successful'. "Substitute self-fulfilment for happiness and you get something of the ethic that motivates the desire for enhancement technologies" (Elliott, 2003:303). The identification of authenticity with happiness is fatal for Elliott because it undermines the quintessence of the concept of authenticity. From Elliott's point of view it is wrong as such to equate the authentic self with the happy self. The moral status of authenticity as an ideal, as a desirable form of life is not constituted by a principle of happiness through cheerfulness but by a principle of felicitousness through self-awareness. Therefore it is "not simply the sense that an authentic life is a happier life; it is the sense that an authentic life is a *higher* life. Higher because it is a life of fulfilment, a life in which you know who you are and live your sense of yourself" (Elliott, 2003:39). An authentic reaction for instance, is a for a certain situation adequate reaction. "Some situations call for depression or alienation or anxiety. Some things call for fear and trembling" (Elliott, 2003:157). Does one witness the death of a loved one the feeling of sorrow, grief and loss can be authentic and precious. Also less existential experiences in everyday life can cause sadness or melancholy, such as an argument or a report on concussive fates in the world news. Moreover the feeling of personal, cultural or existential alienation can be an adequate and authentic response to the present living conditions: "Some external circumstances call for alienation" (Elliott, 2000:8).

The alleged agents of self-fulfilment who wish to actualise their authentic self while having recourse to psychotropic drugs, are impelled by the *tyranny of happiness* where "happiness is not just your right, it's your duty" (Elliott, 1998:187). Within the tyranny of happiness optimisation is defined unilaterally – better can only mean happier and more successful. At this the moral ideal of authenticity is falling by the wayside. Individuals are no longer called to live in accord with their true self, but to live in accord with the claims of society and adopt the traits that society values. The moral and qualitative virtue of authentic demeanour has given way to an economical and quantitative valuation.

Due to the one-sided definition of optimisation, enhancement measures oftentimes do not optimise – in the traditional sense of the word – moods or cognitive skills but transfer one normal trait into another normal, but dissimilar trait (Elliott, 2003:51). Thus psychotropic drugs do not just augment the psychological level of efficiency but alter personality traits. Prozac is considered to produce "the most extensive transformations of personality" (Edwards, 2004:36), rendering a shy person outgoing and extraverted or changing a rather inflexible and serious person into a spontaneous and easy-going one. Are these examples of authentic self-fulfilment? The alteration of character traits represents a significant intervention into one's own self, one's own identity. According to Elliott these interventions of external forces are hardly able to lead to an authentic, hence self-determined self-creation, as they ground in a distorted concept of authenticity. On the one hand this kind of self-creation does postulate an authentic essence within the human that ought to be actualised but on the other hand it renders its very essence senseless as it defines ex ante what the outcome of an authentic self-creation must be like - to wit happy and successful. The desire of people to authentically create themselves is exploited by lobbies and transformed into a scurrile mixture. "The commercial appeal of revealing the true self depends not only on the idea that you have a true self that can be revealed by a drug, but also that you will be happier and better off revealing it" (Elliott, 2003:76). In other words it is no longer the authentic self that is revealed via authentic self-creation but it is a happy self with a successful carrier. Self-creation in this sense leads to a self that is over-directed and fix from the first and does not cause a self-determined authentic self pursuant to the nature of the individual. As the idea of an identification of an authentic and good life with a happy and successful life manifests itself, people are decreasingly aware of the commercial misuse of the traditional concept of authenticity. What constitutes the traditional idea of authenticity is the existence of a unique self that can be realised and created. Reflective introspection is a necessary condition to self-determiningly and authentically realise and shape the unique self. The moral ideal of authenticity bases on the method of introspection, of looking inward to discover who you really are for the sake of avoiding manipulation of the self by external forces. Today, however, the answer to the question who one really is and how one can live authentically according to ones individual self is not given from the inside of the individual but from the outside. Authenticity is not self-determined but external-determined. Instead of listening to ones inner voice in order to understand who one is and wants to be, one looks outside to receive the uniform instruction to remain or become happy and successful. The result is a, to the prevailing trends of society, complying authenticity that contravenes the essential idea of authenticity. Happiness and success may arise from an authentic self-creation; they do not have to arise from it however. Being happy or successful are possible states of an authentic self. The ideal consequence of an authentic life is felicitousness which may contain happiness as well as sadness. The ideal consequence of an authentic life is wholeness and not restriction towards one mood or one status of career. To be momentarily happy does not necessarily require authentic self-creation, to be blissfully happy, however, does. "True happiness cannot be attained without fulfilment, and fulfilment requires being true to that inner voice" (Elliott, 2003:33), felicitousness necessitates authenticity. In our society felicitousness as the ultimate goal of human existence is superseded by professional success actualised in happiness. The good life is defined by a twofold criterion that combines happiness and profession. If, and only if you enjoy it, "to succeed at work is to succeed at life" (Elliott, 2003:153). For the realisation of felicitousness introspection and reflection are most likely the adequate means. For the actualisation of professional success and happiness the means are rather "Ritalin to improve our attention and concentration" (Elliott, 2003:153) and Prozac to facilitate blithe cheerfulness. Although the means and the interpretation of the ends are different, both approaches claim to aim for the authentically fulfilled, the good

life. For the latter concept the use of psychoactive drugs might be highly recommendable to induce a meaningful and authentic life but in order to realise the moral ideal of authenticity and a state of eudaimonia the use of psychoactive drugs appears to be at most the ultima ratio.

The use of psychoactive drugs might have its raison d'être if it only ceased to anchor its motivation in the traditional concept of authenticity. If users of psychoactive drugs explained their enhancement with the desire to be happy and successful at work instead of justifying it in reference to the realisation of their authentic self, this would be more honest and more authentic. Still it would not be self-determining to use Ritalin and Prozac for the sake of accomplishing fulfilment, as the principle of autonomy is closely linked to the principle of authenticity. Merely a theoretical dimension of self-determination may be adjudicated to those who voluntarily and consciously, hence autonomously decide to restrain their self-determination in order to function according to the normative dictate of society. However, many patients seem to delude themselves and others when referring to their desire of authentic self-creation that can only be realised under the chemical influence of their neurotransmitters. Kramer's patient Tess asserts she only is herself while taking Prozac. But Tess is a grown person – who was she all her life if not herself? (Kramer, 1997:19). Rather than Tess having found her authentic self it seems that she finally found a way to live in comfort. Likewise adults in certain positions – for instance a pressuring profession – consuming Ritalin seem to be motivated to enhance themselves by the desire to fulfil their social function rather than by the desire to authentically self-create.

**4. Conclusion**

Under the condition of self-reflexion, introspection, critical assessment and a further integration within the realm of a therapeutic approach or the like, an individual may be able to amend its project of authentic self-creation, resp. of self-determined self-fulfilment, with the use of psychoactive drugs.

However, even if there is the possibility of Ritalin or Prozac to ameliorate the condition of individuals it ultimately exponentiates the causale that led to the circumstance of a decimated well-being which again leads to the use of psychotropic drugs.

Psychopharmacological enhancement technologies "may relieve individual suffering, but in so doing they make the social problem even worse" (Elliott, 2003:190). This phenomenon that undermines the autonomy of individuals further than strengthening it is referred to as "cultural complicity" (Little in Elliott, 2003:190). The desire of healthy individuals for psychopharmacological enhancement results from "social values and attitudes that ought to be changed. Yet not only do enhancement technologies nothing to improve those attitudes, they may also make them worse" (Elliott, 2003:190). Due to the use of psychopharmacological enhancement the problematic values of society and the constrained concept of authenticity get affirmed. The more individuals concede the social pressure and accommodate themselves to the ideals imposed upon them by society, whom they can only do justice to with the aid of psychotropic drugs, the more they reinforce a "cultural frame that allows for narrower and narrower conceptions of authentic selves and life projects" (Parens, 2004:32). If individuals judge their sadness or shyness to be a deficiency that they have to respond to with the employment of psychoactive drugs, they only interfere with the biochemical balance of their brain but leave the reason why sadness and shyness are judged to be deficient untouched and do not question the normative valuation. Equally is the matter with individuals judging their productive capacity to be insufficient. Instead of lowering demands and accommodate them to the individuals, individuals accommodate and increase their efficiency via psychotropic drugs. In a society exclusively oriented at prospective economic expansion there is no limit of performance self-determined by individuals. At first the performance level of psychopharmacologically enhanced individuals may exceed the performance standard but over time this upper limit again becomes the status quo that is regarded as imperative to surpass. Exemplary, today's consume of caffeine barely leads to an increase in the performance level but is rather necessary to keep the performance standard.

In our society the motivation for psychopharmacological enhancement rather originates in a gentle force of the living conditions than in the self-determination of individuals. However, freedom of action is granted in terms of the decision making whether to accomplish cognitive or mood enhancement, the existence of freedom of will, resp. personal freedom is not only not ensured, but also severely threatened. There are no external forces that constrain actions directly, yet there is a strong manipulation of will that should not be underestimated.[*] Basic requirements for a self-determined, personal autonomy safeguarding use of psychopharmacological enhancement could be an equitable consideration of alternative treatment options, the embedding of enhancement in an integrated approach etc., but first and foremost a moral ideal of authenticity needs to be socially established which does not foster a partial pressure of normalisation. Suffering from alienation, a typical motivation for mood enhancement, and suffering from pressure to perform, a typical motivation for cognitive enhancement, are exemplary phenomena of our society in which authenticity has become a hollow phrase. A biased concept of authenticity that only values people's striving for cheerfulness and professional success fails to do justice to the central idea of authenticity namely that every individual is unique and should live according to her very own self. A striving for felicitousness can implicate the striving for happiness (amongst others) as well as a striving for the good life can implicate the striving for professional success (amongst others). The traditional moral ideal of authenticity leaves room for a self-determined interpretation and creation of the self and its life, whereas the stinted concept of authenticity reduces human striving to happiness and professional success. A self-creation that intends solely psychological well-being but completely neglects well-being of the soul can, neither via psychopharmacological enhancement, lead to a self-determined fulfilment of human life.

Psychopharmacological enhancement as a means intervening in the bio-chemical balance of the brain is rather unapt to empower an individual to self-determined self-creation. On the one hand it is neutral as a bio-chemical means and draws its normative value from its implementation in the actual society. On the other hand due to its bio-chemical bias it after all does not treat the person as a whole but only concentrates on its brain function thus failing to support the self-determination of persons. The argument that psychopharmacological enhancement could be used self-determiningly and if it was not it would not be due to the nature of the means but due to the nature of the particular society incompetent to use it accordingly, however is not supportive of the use of psychopharmacological enhancement within our society. To a greater degree it postulates the modification of our society. *Soma, Brave New World's* ultimate lifestyle-drug, is as a bio-chemical substance also neutral yet it constitutes the foundation of the well known dystopia. To warrant an autonomous use of psychopharmacological enhancement,

[*] Here it can only be pointed at the bondage of public discourse, or the internalisation of demands from lobbies, such as psychiatrists, health insurances and the pharmacological industry via direct-to-consumer-advertising in journals, television commercials, on the internet or radio.

inevitably the necessary societal parameters must be established first.

Since a modification of overall-societal conditions command a long process and the healthy yet suffering individuals should not per se be denied access to psychopharmacological enhancement, elucidation-practices such as the - so called "cognitive psychotherapy"[*] - represent a first step towards a self-determined comportment with psychopharmacological enhancement.

As long as psychopharmacological enhancement is motivated by gentle forces of society it is rather external-determined than self-determined. It is actually fear-determined by the worry to become redlined from society and to fail with the realisation of a valuable life, namely a happy carrier.

**(Further) Readings**


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[*] During a cognitive psychotherapy an individual is offered the relevant information concerning enhancement technologies, fathoms where her desire for enhancement stems from, is enabled to evaluate the coherence of her life-plans from an inner and outer perspective at the same time, learns to reflect her desires. Finally the individual should know whether she can autonomously identify herself with her desire, whether her desire belongs to her authentic and self-determined self or whether it should be rejected. See Brandt in Gesang, 12.

# Respecting Vulnerable Persons

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Regulatory and ethical guidelines for human research emphasize protection of research subjects. The Nuremberg Code, Helsinki Accord, and CIOMS guidelines consistently insist that each person enrolled as a subject in research give informed consent. Based on a free and informed choice to participate, the consent document describes the clinical trial in detail. Principal investigators make efforts to disclose all risks and benefits, and ethical oversight committees seek to ensure that subjects have access to all relevant information. Using principles of autonomy, beneficence, and justice, ethical oversight members work in corporation with clinical trial personnel to ensure that the subjects enrolled in the research are respected as moral agents who freely choose to participate.

The autonomy principle applied in the consent process and validated by the informed consent document assumes that the individual subjects are fully competent to assess the value and validity of the research; that they understand the risks and benefits, and all persons in the geographical location of the trial have fair and equal access to participation. By contrast, persons without the attributes necessary to satisfy ethical norms are considered vulnerable and due extra protection. Prisoners, because of their limited freedom, as well as persons with limited capacity, are examples of vulnerable persons. Protecting subjects becomes all the more imperative when their capacities are limited or compromised. Such protection requires a degree of paternalism that is unavoidable in human research ethics while respect for persons emphasizes autonomy.

In the doctor-patient relationship, the physician has skill and knowledge needed by the patient making the relationship inherently unequal. The doctor offers treatment options and the patient agrees to the recommendation or rejects it. Accepting or rejecting the recommendation is an exercise of autonomy by the patient whether or not it is in the best interest of the patient. If a child needed medical care and parents refused to allow the child treatment, legal recourse is an option. In clinical research, researchers function as physician and scientist. The best interest of the patient can putatively be at odds with the research goals. Research ethics review boards are charged with protecting human subjects from unnecessary risk while allowing some freedom and autonomy of the individual subject in the process of informed consent. Necessarily then research ethical oversight functions in adialectic of autonomy and paternalism.

**Autonomy vs. Paternalism**

Freedom and competent reasoning provide the foundation for autonomy. A moral agent chooses an action consistent with his/her normative values in a process of self-governance. Autonomy implies and expects reason to empower individual choice, to define life goals and to give priority to values, without specifying to what extent the context and circumstances of an individual situation may affect a person's exercise of moral choice. Respect for Persons posits that moral law (autonomy of the will) requires freedom. What a moral agent determines to do according to reason is autonomy of the will, which equates with the dignity of persons (1). Kant asserts that moral agents are subject to the moral law, which can be discovered by pure reason (2). Kant's "Categorical Imperative" posited: "Act only on that maxim which you can at the same time will to be a universal law" (2). Maxims are rules the moral agent crafts by way of a thought experiment, testing alternatives to discover whether one can act in a way that would seem prudent for any other person, without defeating one's own intention. The goal, end, objective and intention of the act proposed by the moral agent are important because the moral agent has a duty to self and others.

The presumption is that people should be free to do what they desire, to choose relationships, and to act as they determine morally right and best. Nevertheless, we regulate liberty when a person chooses to act in ways harmful to self and or others. Legal statutes prohibit injurious acts e.g. unwarranted violence, or to prevent harm, e.g. seat belt laws. A person's freedom can be limited for the individual and communal good. In extreme cases, such as attempted suicide the individual's freedom takes second place to protective actions. Paternalism in this sense is protective and for the intent of prevention of harm. If a persons' freedom is limited in a protective sense, it is what Joel Feinberg calls "soft paternalism" where the limitation of freedom is necessary because the individual's decision-making ability is impaired, or nonautonomous (3). In contrast, "hard paternalism" limits freedom of autonomous persons to protect them "against their will from harmful consequences even of their fully voluntary choices and undertakings" (3).

Circumstances may well limit the autonomous choice of a person. In cancer patients, a clinical trial may seem like the hidden therapeutic cure, in which the potential subject suffers from "therapeutic misconception." Because of a strong desire to live and failure to achieve help through standard therapies, a cancer patient may seek out a clinical trial as a last hope. Such patients enter phase I clinical trials where there is no "therapeutic benefit" and the consent document clearly states that "you will not benefit from this study" and yet patients assert that their hope is to benefit (4).

Accepting the justification that such patients intend to advance the research toward a more effective therapy is fairly common for ethical review boards. Interviewing individual patients in the consenting process is not one of the routine practices of the ethical review board members. A bystander, free of cancer or any other serious disease, might well question if the patients are cognitively impaired by the cancer, fear of dying, or other social and familial concerns. Minimally, individuals with terminal disease may suffer distortions of judgment in exercising autonomy.

**Research Interests**

Oversight committee members rely on the validation of autonomy by the process of informed consent. Trusting that subjects are exercising autonomy in research trials with substantial risks respects autonomy. The review board also weighs beneficence in assessing the risks in the protocol and the benefits to the individual subject as well as for general increase in knowledge anticipated by the study.

The basic values inherent in national and international guidelines for research with human subjects began with the Nuremberg Code requiring that the scientific merit of the study be likely to benefit humanity and that each and every subject give informed consent to participate. Within a decade it became obvious that research was done without obtaining informed consent (5) and as a correction, the Declaration of Helsinki of 1964 required independent ethical review of all research enrolling human subjects. The Belmont Report, grounded ethical review in the principles of autonomy, beneficence and justice (6). Codified in law, "the Common Rule" set a legal framework around the ethical review of research with human subjects. By adhering to the "Rule" and evaluating the research proposal with respect to the guiding principles, the review members accepted a necessary degree of paternalism. Absent

any paternalism, the risk limit would be set only by what the "volunteer" was willing to accept.

All clinical research is designed to answer scientific questions that have predictable value but unknown answers. Any subject in clinical research is at some degree of risk, hopefully counterbalanced by some benefit to the individual or community. Benefit to the individual may lie in the desire to see the trial through and to be part of some larger project that advances medicine. Volunteers in HIV/AIDS vaccine trials face the possibility that the vaccine will not be protective. No such vaccine is known at present (7). Vaccine testing of human volunteers in populations with high prevalence of HIV infection is required in order to evaluate the protective effect of a vaccine. If absolute protection were mandated to the extent that no subject in the study could become infected post-vaccination, the study would have no scientific merit. Thus, placebo controls although risky, are one way to determine efficacy of an experimental product. It would be unconscionable to put persons at risk of HIV infection without educating them about protective and preventative strategies. Thus the balance is delicate: education for preventing infection balanced against the need to evaluate the protective nature of the vaccine.

In international trials collaboration requires adherence to the guidelines of ethical oversight of human subject research and requires sensitive, active listening to review board members in the host country along side their counterparts from the sponsor. There are moral and rational reasons for conducting clinical trials in regions of the world with the highest prevalence of disease, HIV, malaria, so that efficacy can be determined. Critics have called attention to ethical challenges in this type of research, e.g. whether placebo controlled studies can be justified. Rather than impose sponsoring country rules or standards in international contexts, there is merit in a consideration of respecting the host's ethical reviews in their own context.

The U.S. Department of Health and Human Services (DHHS) commissioned a Working Group to examine how to implement 45 CFR 46.302 (8). The DHHS study was clear in the message to other countries that U.S. regulators are willing to compromise with respect to how, but not if, research participants are protected. Such evolving policies need to express sensitivity to multinational collaborative research.

**Prisoners, a case in point**

Generally, researchers often exclude prisoners as subjects because such persons are believed to lack sufficient freedom to satisfy the autonomy principle of informed consent. Regulations within 45CFR46 subpart C allows research with prisoners under tight controls, designed to protect their vulnerability. If interpreted too strictly, prisoners risk being denied the opportunity to participate and any putative benefits inherent in the research.

Imagine that a large clinical trial with an AIDS vaccine enrolled thousands of people. After completing the vaccination phase of the trial, and during the follow-up phase, individuals became prisoners. On the basis of the assumption that prisoners cannot be subjects, such individuals would be withdrawn from the study. Indeed ethical review might require such an action. In a recent international trial being conducted in Thailand this situation occurred and the Thailand Ethics Review Committee along with U.S. collaborators faced the decision to require withdrawal of persons while incarcerated or to allow individuals the freedom to choose to remain in the trial with a process of re-consent.

I served on the review team that visited two Thai prisons as part of the process of evaluation that is required to reach context sensitive decisions. As we drove into the parking lot near the first prison, we noted clean grounds; well-tended gardens of tropical plants surrounded the entrance, and construction that was modern and well maintained. The entry process included surrender of cell phones, cameras, and any sharp instruments. The guards were sharply dressed in uniforms, had pleasant demeanors, and carried no weapons. No guns were seen anywhere in the prison. Inside the grounds, the prisoners were employed at various jobs, some tended the plants lining the walks, others prepared food for the noon meal, others studied in classrooms, while others worked at metal or wood crafts. Prisoners were not sitting idle in cells but were actively engaged in activities useful for the prison community and simultaneously were acquiring useful skills for their future re-entry into society. The sleeping facilities were dorm style with clean showers and toilets, open to the tropical air, enclosed by gated bared doors. These conditions could not be staged for the benefit of outside visitors.

The clinic was well stocked with medicine, equipment and staffed with competent professionals. The interactions between prisoners and guards were polite, respectful and courteous. The impression was more like a college campus than a prison. Speaking with the warden, our questions revealed an impressive reform system. The recidivism rate had dropped to less than10% with the current emphasis on human dignity and a commitment to help each prisoner return as a productive member of society.

Respect for persons should allow individuals to exercise autonomy even while vulnerable. Study officials asserted that the prisoners already enrolled in the protocol prior to incarceration have a right to remain in the study. It was evident that being a prisoner in the two prisons we visited was a vastly different context than the conditions associated with being in prison in many other places. Given the communitarian ethos of Thai society, individuals in these prisons are not deprived of human interaction, not restricted to endless hours of boredom but have a communal role within the prison community. Nevertheless, they were in prison.

Recognizing that such research volunteers are vulnerable while incarcerated, their willingness to continue in the research would need additional safeguards, to protect their rights, safety, and welfare. Privacy and confidentiality issues were addressed by limiting knowledge of who was in the study to the prison physician and warden. Records for the research protocol were kept by the study team at a separate location from the prison medical records. At one site, research personnel made visits in the same way and at the same place as family members. At the other site, study participant visits followed the same procedures as for prisoners visiting the clinic for other reasons. Research visits were conducted in a private room. Further, each volunteer was given the opportunity to re-consent with each follow-up visit during incarceration and to withdraw if they desire.

**Respecting vulnerable persons**

Universally, autonomy is the principle underscoring informed consent. Plurality of interpretation in different contexts respects autonomy of human diversity. Gerald Dworkin noted that autonomy means, "liberty (positive or negative), dignity, integrity, individuality, independence, responsibility and self-knowledge … self assertion … critical reflection … freedom from obligation … absence of external causation … and knowledge of one's own interests." (9, 10) This partial list reveals how far contemporary conceptions of autonomy are from their Kantian origins. Rather than aligning autonomy with respect of persons as Kant did, current practice within the process of obtaining informed consent come closer to a form of individual independence. Given the more individualistic freedom model of autonomy, it is understandable why concern and policy would proscribe withdrawing any research subject during incarceration. From the view inside the Thai prison we visited, the greater praxis of respect for prisoners as persons, autonomy takes on a more Kantian connotation.

Research ethics committees have a responsibility to protect subjects from violations of their rights and welfare. It is clear that doing so means getting inside the context of the situation in view of the regulatory requirements. The process requires avoiding any stereotypic understanding of a persons' status be they prisoner or free. The experience reported here exposes how diverse the context and circumstances can be for "prisoners." Norms such as autonomy in clinical trial research are expected to transcend cultural differences. For a principle or moral standard to hold universal appeal and relevance, the particular context of the individual and group must be taken into account. Rules, principles, and research ethics guidelines are foundations from which we weigh particular situations using reason, interpretation and judgment (9).

Informed Consent is a process, not merely a document. Knowing prisoners are vulnerable subjects should not lead to an absolute application of exclusion; rather such knowledge should lead us to learn more about their specific circumstances. In situations where the prisoner has the other protections afforded human subjects, it is possible that sufficient autonomy is present to warrant their continued participation in a clinical trial for follow-up purposes. To deny that "right" simply by application of a protective rule could add unjustified burdens. Rather than ruling out such subjects, site visits and investigation into the circumstances of the trial participants offers the opportunity to determine how best to protect and simultaneously respect enrolled subjects. Soft paternalism may lead research review board members to assume that risk of harm to enrolled subjects while incarcerated justify removal of such persons from the study, but it is also possible that sensitivity and awareness of context would lead to a decision to allow subjects to remain in the study. We should not assume that subjects are incapable of protecting their own interests. We should strive to enable subjects to make autonomous decisions rather than rely on regulations to protect them.

Communitarian cultures such as that in Thailand remind us that one does not live alone, that persons are social beings, that an individual needs interaction with others, and that our values and goals are influenced by our society and friends. One person takes from the social construct what is good and refines his/her values according to reason. This process is the complex matrix in which a person is autonomous. Allowing a person to use their reason and act according to their values is a dynamic process.

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