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**Editorial: Bioethics Issues around the Globe**

This first issue of volume 23 includes a series of papers on health care ethics from around the globe, exploring some of the similarities faced by patients, doctors, and citizens in countries such as Australia, Brazil, Iran, Japan, Mexico and Nigeria. One of the basic questions of bioethics is about decision making. Cerdán et al., conducted a survey in Mexico of who decides? The role of the family in the informed decision in Mexican cancer patients. Oluwasen Adeola Adenugba from Nigeria discusses the Epistemological Importance of Informed Consent in Clinical Research, and the rationale can be applied to any country and community. The case presented could also be seen in many countries of Asia-Pacific, and every other continent.

Atsushi Asai and Kenji Miki present a case study concerning privacy in the care of patients with HIV in Japan. Breach of privacy of patients is a form of malpractice and should be sanctioned. Medical malpractice: analysis of professional ethical processes in Paraíba, Brazil by Maria de Fátima Oliveira dos Santos et al. reports on the way that such breaches of good practice are regulated in Brazil. Nader Ghotbi describes ambiguity in the fatwahs that people follow in Iran, and affects the ethics of reproductive medicine in the Islamic Republic of Iran. Having many different sources of authority provides flexibility to patients with different decisions, but some would claim it is difficult to regulate. How far should we allow the exercise of informed decision making in societies so that people can have a child?

The premise of education also hopes that learners will be in a good state to learn. Susannah Tye, Wilhelmina van Rooy and Irina Pollard surveyed students in Australia and in their paper “Drug and Alcohol Use, Sexual Intimacy and Associated Health Status of Senior High School Students: Implications for Learning and Schooling” they find that a number of students may not be in a good state to study, nor make good decisions even if they had learnt the basics of decision making.

Annaswamy Nalini from India emphasizes the importance of humanism in medicine, and considers this as the main premise for rethinking medical ethics education. Medical education is important for health care workers to be able to relate properly to patients and provide informed consent.

We hope that scholars and policy makers from around the world will join the 14th Asian Bioethics Conference: Ethics in Emerging Technologies to Make Lives Better Together. It will be held during 19-23 November 2013 in Chennai, India, and for those who have not been to Southern India before, there are also plenty of smaller towns and countryside that can be visited before or after the conference. The 14th Asian Bioethics Conference 2013 will be hosted by the All India Association of Bioethics (AIBA) in collaboration with Loyola Institute of Frontier Energy (LIFE), Loyola College and Loyola-ICAM College of Engineering and Technology (LICET), Loyola Campus.

Please renew your Asian Bioethics Association subscriptions for 2013! New articles are welcome from around the world.

— Darryl Macer
Who decides? The role of the family in the informed decision in Mexican cancer patients

- Alonso Cerdán, MPA, Alejandro González, MBA.
- Instituto Nacional de Cancerología, Mexico**
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Abstract

Introduction: Worldwide, obtaining valid informed consent prior to carrying out medical, therapeutic, and diagnostic procedures has long been recognized as an elementary step in fulfilling the physician’s obligations towards the patient. Obtaining this consent is essential in building a successful physician-patient relationship and increases patient satisfaction and compliance with treatment. However, in Mexico, as relatives become the main decision-makers, often influenced by the family’s economic situation; the real and effective application of concepts such as informed consent and patient autonomy is questionable.

Methods: To gain insight concerning the type of patient seen at this cancer hospital, we studied the socioeconomic characteristics of 399 randomly selected patients seen during 2007 contained in each individual electronic chart. Confidentiality of the information was guaranteed by limited access to the charts. This initial information provided us with some insight for designing a semi-structured questionnaire to be applied in focus groups and interviews.

Patients invited to the focus groups were randomly selected in advance by the Institution’s social workers. Group conformation was unsystematic and included eight patients who were waiting for consultation and/or outpatient chemotherapy/radiotherapy the day the focus group was planned to take place. Selection of family members was managed likewise. Most of the times, these were not related to the patients participating in the same focus group. Four groups of eight patients each and two groups of eight relatives were made up. After explaining the purpose of the research and the procedures to be employed, we obtained verbal permission to tape the interviews. Questions with regards to the information provided on the patient’s disease, treatments, prognosis and disease stage, the name of the physician, the definition of “informed consent”, etc., were posed, and each patient or relative was encouraged to participate. A final comment was allowed.

Results: The information obtained from the initial chart evaluation showed that 20% of the patients were illiterate, and 50% had six or fewer years of education. The daily family income of over 50% of the patients seen at the Hospital was $2.00 U.S. dollars (USD) or less.

Focus group interviews showed that the patient’s need for information changed along with the disease. However, poor understanding of their disease and treatment was evident. At all times, patients were grateful to their physicians and mentioned that they had signed informed consent. The main concerns of the relatives were financially related which in turn influenced their decision making regarding treatment.

Discussion: This study shows that the cornerstone of patient autonomy in terms of the patient’s right to self-determination in the West may be different from Mexican family-based decision-making. During interviews it was clear that the patients’ sole concern was “the disease” in terms of physical pain and life expectancy. None played an active role in treatment decisions, financial arrangements, or the long-term socioeconomic consequences for themselves or their families. Most of the decisions were influenced by family members. Poor health literacy should be acknowledged by physicians, and proper measures should be implemented to improve physician-patient communication. At present, the validity of informed consent is questionable.

Key Words: Informed consent, Family decision-making, Autonomy, Cancer, Mexico

Introduction

The internationalization of bioethics has been dominated by the central concepts and the intellectual tools developed in the Anglo-American applied ethics movement, mainly represented by Tom L. Beauchamp and James F. Childress. Some bioethicists contend that there are fundamental ethical principles that should be applied transculturally and nationally. However, the emphasis on patient autonomy and informed consent as the cornerstone of this principle may be foreign to many non-U.S. cultures.

According to the American Medical Association (AMA), informed consent is a process of communication between a patient and physician that results in the patient’s authorization of or agreement to undergo a specific medical intervention. A patient will be competent to consent if he or she is capable of understanding what is involved in the medical treatment described, including the procedure, its consequences, and the consequences of non-treatment. The Western principle of autonomy demanding self-determination assumes a subjective conception of the good, and promotes the value of individual independence.

Many studies have suggested that because cultures vary, Western values that promote the principle of patient autonomy may not be universally applicable. In several non-Western countries, the principle of autonomy requires family-determination. These cultures place a higher value on autonomy-related beneficence and non-maleficence and frequently possess a long tradition of family-centered healthcare decisions. In this collective decision-making process, relatives receive information on the patient’s diagnosis and prognosis and make treatment choices, often without the patient’s input. According to some authors, ethnicity is the primary factor that influences attitudes toward patient decision-making.

In Mexico, healthcare provision is a constitutional right, and informed consent comprises both an ethical obligation and a legal requirement that are spelled out in the Mexican Legislation. Nevertheless, in Mexico’s fragmented healthcare system; one half of the country’s most impoverished population is uninsured, and access to healthcare is uncertain.
The Instituto Nacional de Cancerología (INCan), is one of the Ministry of Health’s (MOH) institutes, and provides specialized healthcare to the low-income, poorly educated, and uninsured population with cancer. The institution is funded by the State, and some services are inexpensive. However, out-of-pocket expenses for the majority of cancer drugs and other expenses could in turn become a direct cause of impoverishment.\textsuperscript{12}

In this setting, patients rarely ask about their disease and treatment options, and responses given by the healthcare team may be difficult to understand. Dissonance between the patients’ culture and that of the physicians is likely. Even if patient and physician share a common ethnic culture, medicine is itself a culture and socializes its members to think and act in particular ways.\textsuperscript{13, 14}

To be informed about and consenting prior to receiving a treatment is requested by the Mexican Law. Unfortunately, the limited health literacy of certain patients seen at the INCan, and failures in the physician-patient communications procedures may contribute to the lack of the patients’ ability to comprehend the nature of their disease and the treatment options required. Deficient understanding of the disease poses important ethical implications, and may have significant consequences in treatment compliance and an economic impact. In Mexico, little attention has been paid to these issues; therefore, at the present time, informed consent may be applied incorrectly.

The purpose of this work is to describe the patients’ perception concerning information provided by the healthcare team at the INCan, and their ability to make an autonomous informed consent-involved decision with this information. Another important factor to evaluate are the failures in the mechanisms of communication between patients and their physicians.

The results obtained may contribute to the understanding of the social, economic and cultural characteristics of the population seen at the INCan, and contribute in designing a proposal to improve the physician-patient-family-patient understanding of the nature of the disease and its treatments, in order to implement a new institutional policy concerning the informed consent procedure.

Patients and Methods

Initial interviews with INCan hospital authorities, physicians and social workers were conducted to learn about some of the administrative and medical requirements for patients admitted to the institution. According to these results, we developed the survey instrument and the focus group’s interview guide, and the protocol was submitted to and approved by the Hospital’s Institutional Review Board (IRB).

To gain insight on the main epidemiological and socioeconomic characteristics of patients seen at INCan and to design a representative focus-group composition\textsuperscript{15},\textsuperscript{16}, a random sample of the 3,735 patients admitted during 2007 was obtained. Three hundred thirty nine electronic charts of these patients were analyzed (calculated confidence interval was 95%, with a 5% margin of error). The variables recorded included diagnosis, age, gender, marital status, place of residence, level of education, occupation, monthly household income, type of housing, and income distribution (food, rent, utilities, etc.). The information obtained from the charts made up part of the socioeconomic evaluations performed by the INCan Department of Social Work for assigning a level to each patient (seven socioeconomic levels are assigned [1–7]). The consultation fee for a patient assigned to socioeconomic level (SEL) 1 is the equivalent of $1.00 USD/day (corresponding to 30% of the population seen at the INCan); SEL 2, implies a $3.00 USD/day income (50% of the population seen at the INCan), while SEL 3 corresponds to an income of $7.00 USD/day and those with a SEL 7 with an income of $30.00 USD/day (1% of patients admitted are exempt from fees because of living in extreme poverty).\textsuperscript{16}

Specific aspects of medically related and administrative information provided to patients were explored during focus-group interviews by means of a semi-structured questionnaire (Table 1). The questionnaire was initially designed to learn about the patients’ perception of information provided on their disease, and their ability to use this information to make an informed decision about their treatments. Focus groups interviews were selected for questionnaire application.

Patients invited to the focus groups were randomly selected in advance by INCan social workers. Focus-group composition was unsystematic and included eight patients each who were waiting for consultation and or out-patient chemotherapy/radiotherapy on the day that the focus group was scheduled. An initial approach to the patients was made by the social worker, who invited patients to participate in the focus groups, and the social worker gave a brief explanation of the purpose of the interviews.

Patients who accepted to participate were requested to gather in a small conference room. Sessions were informal; interviews began with the introduction of the coordinator and an explanation of the purpose of the research. After ensuring the voluntary character of the patients’ participation and the confidentiality and anonymity of the information, we requested permission to tape the interviews. Verbal consent was required by the IRB, and information and individual consents were also taped.

We allowed accompanying family members to be present in the back of the interview room. After the first interview, the group was approached by the relatives present, who expressed their opinion about the questions asked of the patients; therefore, we decided that separate focus-group interviews with family members was needed, and decided to organize two separate interviews with the patient’s relatives. The invitation to the family members present in the different hospital waiting rooms was also not conducted systematically- some focus-group participants were related to the patients interviewed, but the majority of these were not. Thirty two patients (four groups of eight patients each) and 16 relatives (two groups of eight relatives each) participated.

The facilitator introduced the topic to participants of the focus-group discussion and afterward asked patients their age, place of residence, and diagnosis. Subsequently, the facilitator posed non-leading questions to highlight the issue under discussion. Comments were recorded and simultaneous notes were taken. Both were immediately transcribed and authenticated by the
authors. Discussions were focused on the information-provided of the informed consent process and the roles played by the various key participants. Each exercise lasted for at least 2½ hours.

The transcribed material was analyzed by means of content analysis,\(^1\) to identify the different responses from each group, and were later grouped accordingly in the result.

No payment was provided to focus-group participants; however, we were permitted to provide participants with some refreshments during the interviews, in addition to a small gift (a pen, a notebook, and a plastic case to store their documents).

Results
Medical Characteristics
The chart review included patients with different tumors types: breast cancer and gynecological neoplasia represented 35% of cases, while gastrointestinal tumors corresponded to 17%, hematologic neoplasm (adults) 17%, prostate 8%, and skin cancer, 7%. Other types of neoplasms were less frequently present in the sample analyzed (head and neck cancer, lung, testicle, etc.). In accordance with the hospital authorities, the sample was representative of the incidence of the neoplasm in patients seen at the institution (Table 2).

Demography
Three hundred thirty-nine electronic charts of patients seen during 2007 were analyzed, representing 9% of patients admitted annually to the institution. The INCan provides care for adult patients with cancer; therefore, only a few patients (5/339 in this sample) were 18 years of age. The majority of patients seen (54%) were aged between the fourth and sixth decades of their lives (Table 2).

The female-male ratio of patients seen at the INCan is nearly 2:1. The high incidence of cervical cancer and the increased numbers of patients with breast cancer may contribute to these figures.

As expected, patients seen at the INCan (located in Mexico City) reside in Mexico City and in the nearby State of Mexico. Mexico has a Cancer Center Network that provides cancer treatment to uninsured patients from the 32 Mexican states; however, as described in Table 2, an important percentage (38%) of patients came to the INCan from cities located far from Mexico City.

The majority of patients seen at the institution live in urban households. The definition of urban household according to the Social Work Service relates to the place where the householder has a house or has non-remunerated employment (Table 3).

Education
Literacy levels were low: 20% of patients in this sample were illiterate, the majority of patients had 6 or less years of schooling (45%), and only 6% of patients seen at the institution had a university or comparable education (Table 3).

Occupation
As mentioned previously, the INCan, as part of the MOH, provides medical care for the uninsured population. The results obtained reflect the following issue: the majority of patients (74%) were unemployed or had non-remunerated work, while only 3% of these patients had well-remunerated employment (Table 3).

Monthly Family Income
Monthly family income reported in the charts reviewed is summarized in Table 3. Over one half of the patients (62%) had a monthly family income of <$300.00 USD. Notably, 7% of these patients had a family income of <$100.00 USD per day. According to information obtained, distribution of this income was used on food rent, and other utilities, including transportation (Table 3). None of these had considered healthcare- or education-related expenses.

Table 1: Focus-group interview questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>What were your main concerns during initial appointments in the institution?</td>
<td></td>
</tr>
<tr>
<td>What type of information did you want to receive?</td>
<td></td>
</tr>
<tr>
<td>How long did it take you to understand your diagnosis and the type of treatment you were going to receive?</td>
<td></td>
</tr>
<tr>
<td>Do you think there were specific factors that made you understand the information you received?</td>
<td></td>
</tr>
<tr>
<td>After having been at the Institute for some time now, do you consider that there would have been a better way to give you the information you received?</td>
<td></td>
</tr>
<tr>
<td>Are you familiar with the term “informed consent”?</td>
<td></td>
</tr>
<tr>
<td>Do you have an additional comment?</td>
<td></td>
</tr>
</tbody>
</table>

Specific aspects of medical-related and administrative information provided to patients were explored during Focus-group interviews by applying a semi-structured questionnaire.

Electronic chart review of 339 patients; sociodemographic characteristics are shown in Table 2. The female-male ratio of patients seen at the institution is nearly 2:1; the high incidence of cervical cancer and the increased numbers of patients with breast cancer may contribute to this figure. The majority of patients lived in Mexico City and nearby states; however, an important percentage of patients lived far from Mexico City. More than one half of patients' living conditions were poor (rural and semi-rural).

Table 2: Demographic characteristics

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>339</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean Range 48, 17–91</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 37.5%, Female 62.5%</td>
</tr>
<tr>
<td>Residence site</td>
<td>Mexico City and the State of Mexico 62%, Rest of the country 38%</td>
</tr>
<tr>
<td>Residence area type</td>
<td>Urban 47%, Semi-rural 34%, Rural 19%</td>
</tr>
<tr>
<td>Tumor type</td>
<td>Female cancers (breast, cervix, ovary) 36%, Gastrointestinal tumors 17%, Skin (not melanoma) 9%, Prostate cancer 8%, Leukemia and lymphoma 7%, Head and neck cancer (pharynx, oral cavity) 7%, Other types 16%</td>
</tr>
</tbody>
</table>
Table 3: Socioeconomic characteristics of patients seen at the INCan

<table>
<thead>
<tr>
<th>Years of education</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illiterate</td>
<td>20</td>
</tr>
<tr>
<td>1–6 years</td>
<td>45</td>
</tr>
<tr>
<td>6–9 years</td>
<td>21</td>
</tr>
<tr>
<td>9–12 years</td>
<td>8</td>
</tr>
<tr>
<td>12 years or more</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occupation</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unemployed or engaged in non-remunerated work*</td>
<td>74</td>
</tr>
<tr>
<td>Unskilled work</td>
<td>23</td>
</tr>
<tr>
<td>Skilled work</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monthly family income</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$1000 M.N. **</td>
<td>7</td>
</tr>
<tr>
<td>$1000–3000 M.N.</td>
<td>55</td>
</tr>
<tr>
<td>$3000–6000 M.N.</td>
<td>28</td>
</tr>
<tr>
<td>&gt;$6000 M.N.</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Expenditure on food (monthly)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$3000 M.N.</td>
<td>86</td>
</tr>
<tr>
<td>$3000–5000 M.N.</td>
<td>12</td>
</tr>
<tr>
<td>&gt;$5000 M.N.</td>
<td>2</td>
</tr>
</tbody>
</table>

* Included homemakers. Cultural aspects often force women to stop working when they get married.

**The exchange rate fluctuated between $10 $12 Mexican pesos (M.N.) per $1 U.S. dollar (USD).

Table 4: Representative responses from Focus-group interviews

<table>
<thead>
<tr>
<th>Questions</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main concerns during initial appointments at the Institution?</td>
<td>[Disease stage and chances of being cured, Possibilities of being admitted to the hospital] [Disease stage, Cost and length of treatment, Administrative aspects]</td>
</tr>
<tr>
<td>What type of information did you want to receive?</td>
<td>[Information on the disease, Administrative requirements] [Information on patient care at home, Treatment types and costs given simultaneously] [Need to be informed on the disease without the patient being present “to avoid additional concerns for the patient”] [To receive information in a language they could understand, without medical terms] [To receive an explanation on disease diagnosis procedures]</td>
</tr>
<tr>
<td>How long did it take for you to understand your diagnosis and type of treatment you were going to receive?</td>
<td>[Different answers, none of these reflecting an understanding of the disease, Possibilities of being cured] [Need for information on the disease and laboratory results] [A continuous process that requires the family to ask different questions at the different disease stages]</td>
</tr>
</tbody>
</table>

Do you think that there were specific factors that made you understand the information you received better?

- The information provided by physicians and information given by other patients
- Mainly information provided by other relatives in the waiting room
- Physician information

After having been at the Institution for some time, do you consider that there would have been a better way to provide you with the information you received?

- Clear and direct information on your disease given by the physician
- Written information or posters
- The cost of the hospitalization during surgery
- Written information
- A 24-h telephone hotline
- Specific information on patient care, drug reactions, adverse events, and disease prognosis
- Means of obtaining financial support

Are you familiar with the term “informed consent”?

- All patients had signed informed consent
- A requirement for admittance to the hospital
- Part of the administrative procedures

Do you have any additional comments?

- Grateful to the hospital and physicians
- A feeling of security
- When some one in the family has cancer, all the family suffers

Figure 1: Information requirements of the patients and their relatives

The upper panel boxes illustrate the different periods at the hospital: prior to patient admittance; during the initial hospital visits, and diagnostic procedures. Different diagnostic procedures: E1 (laboratory); E2 (x-rays), and En (Other). The last box represents the period of treatment and the additional diagnostic tests. In the right panel information requirements are divided as follows: Information about the disease; information about administrative procedures, and information about cost of treatments.

The arrows represent the patients’ (blue) and their relatives’ (yellow) information needs. Arrow thickness represents emphasis of the concern (Thick = ”very” ++++, narrow+ “not very concern”). Patients are always concerned with the “disease”. When they are told the type of treatment, they begin to become interested in administrative procedures (dates of appointments), and financial questions comprise the least important issue for them. In contrast, family members are concerned about:
Focus-Group Interviews

Patients

All patients were very interested in participating, and were eager to share their experiences. We found three main areas of concern to the first question (Table 4): 1) to learn about the disease stage and the chances of being cured; 2) the possibility of being admitted to the hospital, and 3) cost of the treatment. Representative responses to this question are described below:

"...My main concern was to know how advanced my disease was, because when you hear the word cancer, your life stops..." - Patient aged 56 years with breast cancer

"... I was very afraid of not being admitted to the hospital. Once I was admitted, I was calm and sure that I would be cured..." - Patient with melanoma aged 67 years

The information required for patients was shaped by disease type (patients with breast cancer were eager to receive information), time spent at the hospital (patients in treatment for several years required more accurate information), gender (male patients were concerned about their work), and age (older patients were concerned about chances of being cured).

Patients’ Relatives

We had an important participation of patients’ relatives, whose sessions tended to be longer. All patients’ relatives were concerned about disease diagnosis and stage; however, treatment costs and the means to pay for these were even more important issues to them (Table 4) (Figure 1).

There was no a unified type of response as to how long it took patients to understand their diagnosis and treatment options. All patient responses were related with the possibility of being cured.

"...I had the entire test done, but I don’t know anything, I have not been informed about anything. They told me I had a malignant tumor, but I would really like to know if I am sick or what’s wrong with me..." - 63-year-old patient with larynx cancer

"...I don’t understand anything. After 2 years of being a patient I am desperate, because I have faced many problems...I don’t know what will happen next, because they give some information now, and in few days they change the information..." - Patient aged 60 years with cervical cancer

Responses to the question on “factors that improve patient understanding of the disease” were different from the previously noted responses. The majority of patients said they had a clear picture of their disease, and that the physician had “clearly” explained the disease’s nature, prognosis, and treatment, in addition to mentioning that the information received by other patients was very useful (Table 4).

"...Yes, I am aware of my disease. The doctor explained to me that I have advanced cancer. What is going to happen or for how long I will be alive, I don’t know, because as my doctor mentioned, we are not gods, and only God knows how this will end..." - 45-year-old patient with cervical cancer

The majority of patients thought that written information or videos would make things easier to understand.

Regardless of their opinion concerning knowledge on their disease and treatment options, none of the 32 patients could accurately explain: cancer type, stage, treatment options, or their chances of being cured. The disease was described by patients as an “obsession” and was the only thing important to them at the time.

According to these results, all patients described that they had signed the informed consent document; however, very few patients knew the purpose of the document. The majority of patients declared that the document was a requirement for admittance to the hospital (Table 4).

"...We don’t care what it is for, they ask you to sign, and that’s enough for us to sign..."

Opinion of a group of patients

It is interesting enough, that none of the patients complained about their physicians (however, they complained about the information provided to them by the physicians). The patients were grateful for having been admitted to the hospital; they believed that the quality of the services provided by the hospital and the physicians were the best.

"...I am thankful for having been a patient at the INCan; "...I am grateful for the attention they provided to me", said a 60-year-old male patient while crying.

Patients’ Relatives

We had an important participation of patients’ relatives, whose sessions tended to be longer. All patients’ relatives were concerned about disease diagnosis and stage; however, treatment costs and the means to pay for these were even more important issues to them (Table 4) (Figure 1).

According to family members, the information provided at the hospital was confusing, and lack of information about different issues was mentioned. As described in Table 4, the majority of the patient’s relatives agreed that they needed information on the patient care at home, to have an explanation about diagnosis and procedures, and the types and costs of treatments available during the disease.

Some relatives mentioned that the information was often overwhelming, because it frequently included explanations about the disease, treatments, and the administrative procedures simultaneously. Finally, all relatives noted the need to be informed on the disease without the patient being present "to avoid additional concerns for the patients (themselves)". The following statement illustrates some of these concerns:

"...We had to wait for several hours before the doctor saw your patient. He asked a lot of questions, and reviewed the papers that we had. Then he asked my father why he had waited for so long before seeing a doctor? You have cancer, and you are very ill, do you
understand me? Later, the nurse told us about the payments, appointments, studies to be done. We were in shock, and after the doctor told my father that he had cancer, neither my father nor I could understand anything…” - Daughter of a 75-year-old patient with lung cancer

The majority of participants believed that the wording and language used by the physicians was difficult to understand such as: palliative treatment, cardiotoxicity, analgesic, adjuvant chemotherapy, neoadjuvant chemotherapy, disseminated disease, and non-curable disease.

The majority of relatives expressed that it takes some time to really understand the type of disease. According to these relatives, continuous conversations with physicians and patients’ relatives are important to learn about cancer and its treatment.

As Table 4 shows, the need for written information was mentioned. Nearly all relatives were concerned about issues related with what to expect during treatments. The information required included the need for guidelines for living with a cancer patient.

“…When my son was receiving chemotherapy for his testicular cancer, I made him eat hot chicken soup. I felt very guilty later on, because nobody told me that he had ulcerations in his esophagus, I made him suffer…..” - 40-year-old mother of a patient aged 19

All relatives mentioned that although their patients had signed some “consent” papers, the patients themselves did not decide on the treatment.

“… I don’t think my wife decided about her treatment. The doctor told her you have breast cancer, we are going to give you some medicines for 3 months to make the tumor smaller, and after that treatment, they will remove your breast…”

To some relatives, the concept of chronic disease was not clear, and money-related issues increased over time. The request for loans from and cooperation among all relatives is frequent. The family’s duty to care for the sick family member was frequently mentioned.

Relatives believed that the patients required family support during the disease; they questioned the physicians about their treatment decisions, prognoses, and treatment responses. While the patients’ only concern is to be cured, money-related issues played an important role in the relatives’ anxieties.

“…with each new appointment, you have to be ready to receive bad news and the request for a new treatment, and each time, the medicines become more expensive….” declared all the relatives participating in one of the interviews.

Discussion

According to the World Bank, Mexico has achieved substantial poverty reduction in recent years. However, with an aging population, facing an epidemiological transition, having more than one half of the total health expenditure out-of-pocket, particularly in poorer households, improvement of healthcare services is mandatory.

Currently, the economic burden on uninsured patients with chronic diseases often becomes the major concern, sideling the current norm in medical practice that entails shared decision-making between physician and patient.

The results of this work describe a clear picture of the Mexican population seen at the public hospitals. Some of the findings may appear confusing: for example, all patients affirmed that they had signed informed consent after being fully informed about their disease and treatment options; however, 20% of patients admitted to the hospital are illiterate (therefore raising questions about the validity of the form), and some patients, after several months/years of treatment declared that no diagnosis was ever mentioned to them.

These and other findings mentioned previously should question the manner in which the physicians explain diagnosis, prognosis, and treatment options to their patients, despite that a diagnosis of cancer is stressful and may influence the perception of the information provided. The inability of patients to describe some important aspects about having cancer, the chronic nature of the disease, and the requirement of different types of treatment at different stages of the disease require further studies and major changes in the information process in terms of patients.

Furthermore, it was surprising to learn that at all times, the majority of patients were grateful to their physicians and to the hospital. They were all certain that they were well informed about their disease, treatment options, and their prognoses.

We are aware of the limitation of the methodology selected (Focus group), because personal views about the diagnosis of cancer and individual knowledge of their disease can sometimes make it difficult to have group discussions with some patients.

Role of the Family in Decision-making

As mentioned above, the majority of patients (74%) are unemployed or engaged in non-remunerated work. Therefore, they are highly dependent on their family’s income. Consequently, relatives become the principal decision-makers, frequently influenced by the economic situation of the family, but attempting at the same time to procure the best medical care for their family members. In Mexican culture, affection, solidarity, and providing care constitute an everyday family interaction.

When a family member falls ill, it is common to observe several family members accompanying the patient to the physician’s office, and the same occurs when a patient is admitted for treatment. Sometimes there is no difference between the patient as an individual and his family. In Mexican society, as in other Eastern cultures, the physician first confronts the family members with the diagnosis prior to approaching the patient, and often, a joint strategy between the physician and the family is undertaken prior to approaching the patient.

The patient receiving a diagnosis of cancer experiences a process of readjustment, of grieving, of fragility, a lack of self-identity, and consequentially, of autonomy. Under these circumstances, and unlike what the rule is in Western countries stipulate, where the patient takes centre stage by both tradition and law, Mexican patients are more likely to possess a family-centred medical decision-making model.

Relatives are often those who question the decisions made by the physician, complain about the limited information provided to them, carry out the information to other family members, and take care of patient-related financial aspects (Figure 1). During the interviews, it was
clear that relatives were concerned about their patients’ health, but their main concerns were financially related.

Who Decides?
During the interviews, it was clear that the patients’ only concern was “the disease” in terms of physical pain and life expectancy. None said that they had an active role in treatment decisions, financial arrangements, or long-term socioeconomic consequences either for themselves or their families.

Therefore, the right to self-determination as a cornerstone of the patient’s autonomy in the West should be adapted to the Mexican family-based decision-making. Physicians at the INCan should be aware that valid informed consent requires three essential components: disclosure; capacity; and voluntariness. Consequently, it is important for the medical team to acknowledge that the demographic characteristics of patients seen at the institution (poor educations, and poverty) impact their understanding on health-related issues. As a result, there is a lack of compliance with one of the essential components for valid informed consent: disclosure.

The capacity to understand the information provided may be hampered in many of these individuals due to their rudimentary or absent reading skills; in this situation, they do not understand what they are told by the clinicians, nor can they read handouts or other written information provided to them by the physicians. Few clinicians recognize the prevalence of limited health literacy among their patients, and may not be aware that patients recall only a fraction of the information they receive from clinicians.

Improving health literacy involves more than the sole transmission of health information. It promotes greater independence and empowerment among individuals for making voluntary, informed, and ethical decisions concerning their treatments.

The provision of healthcare cannot be structurally disengaged from cultural and sociopolitical processes. Therefore, the family-centered model of medical decision-making should be acknowledged.

Conclusions
Although cancer management is becoming more structured by means of guidelines and clinical pathways, many decisions remain complex. There is no notion of a “best” option for everyone. Decisions are defined as being of higher quality when these are informed with the latest scientific evidence, and when they are associated with option outcomes based on patients’ informed values. Notwithstanding, clinicians are not good judges of patients’ values, and patients frequently possess inadequate knowledge, unrealistic expectations, and decisional conflict that interfere with their involvement in decision-making. The sophistication of these procedures burdens patients with the added task of processing scientific nomenclature, data, and technological concepts, a special challenge for patients with literacy, numeracy, or language barriers. Furthermore, as shown in this work, informed choice comprises a marginal concern eclipsed by the greater priority of gaining access to care.

The “autonomy paradigm” that has achieved dominance over the “social framework paradigm” in the U.S., may not be the best approach in our Mexican society. We believe that INCan authorities should be aware of the limited health literacy of patients and implement proper mechanisms to improve the physician-patient communication, and that family-based decision-making should be further studied.

References
3. An adult patient is presumed to be competent unless there is a good reason to doubt it: mentally ill; mentally disabled; affected by external factors such as drugs, alcohol, extreme pain, panic, or shock. In such cases, the patient will only be competent to consent if he or she is capable of ‘comprehending and retaining information’, believing and weighing it in the balance to arrive at choice”. http://www.cpsa.ab.ca/publicationsresources/attachments_policies/Competency%20Assessment%20and%20Surrogate%20Decision%20Making.pdf
16. INCanNET http://www.incan.edu.mx/

**Competing Interest Section.**

No competing interests for the purpose of this work are declared by any of the authors. This work was supported by the World Bank Award for Inventive Projects, granted to Alonso Cerdán in Mexico City. Full expenditure reports of the Grant Award (USD20,000) have been provided periodically to the World Bank. None of the authors received any salary or compensation from grant funds. The Institutional Review Board (IRB) of the Instituto Nacional de Cancerología did not allow payment to any of the study participants; however, refreshments and some food was provided during interviews, and at the end of these, a symbolic gift (with a value of ~$10 USD) was given to each Focus-group participant.

The Instituto Nacional de Cancerología, after study approval by the IRB, facilitated access to electronic charts, provided a place for interviews, and facilitated invitations for patients and their relatives. No written informed consent was required. Patients gave verbal consent in order to participate, allowed taping of the interviews, and transcription of the results.

Part of this work was accepted for presentation at the Latin America Forum of the 9th World Congress of Bioethics, September 3–9, 2008, in Rijeka, Croatia.

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**Medical malpractice: analysis of professional ethical processes in Paraiba, Brazil**

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**Abstract**

**Background:** In recent decades, there has been an increase in discussion about medical error that caused a major ethical and legal debate on the subject. In order to

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understand this issue much more, the objective was to investigate indicators for malpractice, from Ethical Professional Processes in violation of the First Article of the Code of Medical Ethics

**Methods:** This documentary research, retrospective, analyzed 169 ethical processes relating to ethical research on medical error involving 284 professionals, conducted in the period from 1999 to 2009 by the Regional Council of Medicine of Paraíba, Brazil. Data collection was performed by researchers using a structured instrument that included the variables of the study. The data were analyzed from descriptive statistics through simple calculations and relative frequencies. The level of significance in the analysis was 5%.

**Results:** The results show a significant difference between the reported male and female (76.9 X 23.1), as well as among those who had more than 21 years of practice and more of graduation (52.9%). As regards professional qualifications, 54.6% had residency, and in relation to qualification, it is most relevant, consecutively, of gynecology / obstetrics (59.7%), general surgery (46.2%) and pediatrics (40.0%).

**Conclusion:** The most significant infraction was the of Article 1 of the Code of Medical Ethics.

**Keywords:** Medical errors, Medical ethics, Medical legislation, Legal liability.

**Introduction**

Medicine has evolved rapidly, with the goal of finding cures for diseases and to improve the quality of life, which is expressed through scientific research. However, there is another reality, more and more advertised in the media: medical error. The situations arising from medical error have been the target of media attention, with major repercussions both in the medical profession and in society in general that sometimes takes an attitude of distrust regarding the qualification and competence of the professional (1).

The medical error results from an improper professional conduct, capable of producing damage to life or harm to patient health through incompetence, recklessness or negligence, as elucidated in Article 1 of the Code of Ethics Medical (2). The malpractice (doing harm) is the lack of compliance with technical standards for practical unpreparedness or lack of knowledge. The recklessness (doing too much) occurs when the doctor takes risks for the patient without scientific backing for their procedure. Already neglect (make fewer) is the lack of attention or care for the patient, when the Doctor fails to fulfill his professional duties (3). Categorize themselves, even as ethical issues arising from the physician's professional practice: issues in the doctor-patient advertising material unevenly; omission of aid; reports, surveys and certificates that do not match reality, sexual harassment, and disagreements unfair competition among peers, among other issues.

Regarding the determinants of malpractice, it is emphasized, among others, the poor doctor-patient relationship, which is responsible for most of the complaints made to the Regional Councils of Medicine (4). Thus, issues related to medical errors are a troubling trend for society, especially when it involves the integrity or patient survival. The error caused by a physician becomes more serious by the fact that professional constantly deal with the health and life of individuals, most often in fragile biopsychosocial states.

It is noteworthy that the malpractice also brings negative effects to the professional. Historical analysis regarding the judgments and penalties imposed severe penalties for doctors shows that today can be considered as inhuman, as they were determined by the Code of Hammurabi, which provided penalties as amputation of the hands of surgeons who were not successful in their procedures (5).

Currently, medical error can be examined under legal responsibility, in which the doctor has criminal and civil responsibility for their actions, and under moral responsibility, which is the jurisdiction of the Medical Councils, through ethical and disciplinary processes (6,7). The liability is equal to the need to compensate those who were harmed by others by mistake. This repair in modern law has pecuniary nature (7).

Despite the relevance of the issue now exposed, there are gaps regarding studies, particularly in our environment, enabling clarify on the different elements involved in medical errors and the characteristics of the professionals involved in this conduct, demanding, thus the development of research elucidating such aspects. For this, the analysis of ethical and professional tool is essential. Given this assertion was limited for this study the following objective: to investigate indicators for malpractice, from Ethical Professional Processes (PEPs) in violation of the First Article of the Code of Medical Ethics, which were processed in the period from 1999 to 2009, the Regional Council of Medicine in the state of Paraíba, Brazil.

**Methods**

This is a documentary research, retrospective, with a quantitative approach, in which a review was made of all PEPs of the Regional Council of Medicine of Paraíba (PB-CRM) in the years 1999 to 2009, in order to investigate indicators for the malpractice. The analyzed documents were 169 PEPs, involving 284 physicians. To compile the data, we designed a structured questionnaire in order to apprehend the following information: number of cases; reported data (sex, age, time since graduation, post-graduation - residence and / or medical specialty).

The data collection was conducted by researchers at the headquarters of the CRM-PB. Subsequently, the information collected was grouped, coded and scanned, resulting in a database, which was analyzed statistically with the aid of a statistical package SPSS (Statistical Package for Social Science) version 18, from descriptive statistics (frequency, percentage, mean, standard deviation and tests), adopting the usual measures of central tendency and dispersion calculations of absolute and relative frequencies. The level of significance in the analysis was 5%.

This study was approved by the Ethics in Research of the State Health Department of Paraíba, with Protocol N° 2912/10, respecting, so on, what advocates the Resolution 196/96 of the National Health Council, regarding the research people

**Results**

In findings obtained by analyzing the information in the 169 PEPs, involving 284 physicians, was found that the number of cases fluctuated in the years evaluated, and
the highest amount was recorded in 2007, with 22 (13%) cases, and the lowest quantity, in 2008, only eight (4.7%) cases. The articles of the Code of Medical Ethics cited most frequently by the investigator in the completion of the investigation were: Section 1 (28.5%), Article 57 (21.8%), Article 17 (12.3%) and Article 30 (8.1%).

Regarding the prevalence of medical error, endorsed in the Code of Medical Ethics, according to the opinion of the investigator, it was verified that the First Article had an incidence of 28.5%, which corresponds to the practice of harmful professional acts to the patient, which may be characterized as malpractice, recklessness or negligence. In analyzing the source of complaints, it was found that, in most cases, were performed by legal entities (55.6%). The remaining, 44.4%, by individuals.

Regarding the characteristics of denounced physicians described in Table 1, it was found that, by applying the Pearson chi-square test, a statistically significant association of the violation of the First Article with the age group of 40-49 years old (38%). It is noteworthy that a significant difference was found between males and females (76.9 X 23.1), as well as among those who had 21 or more years since graduation (53%). Regarding qualifications, the results showed that 55% had residency. Considering the specialties of doctors appointed on complaints regarding the violation of the First Article (data not shown in Table under review), there was greater relevance consecutively specialties of obstetrics / gynecology (60%), general surgery (46%) and pediatrics (40%).

Table 1 - Profile of physicians reported according to the infraction of the Article 1st. João Pessoa, PB, 2010.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Article 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Group</td>
<td>104</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Until 39 years old</td>
<td>24</td>
</tr>
<tr>
<td>40 a 49 years old</td>
<td>39</td>
</tr>
<tr>
<td>50 a 59 years old</td>
<td>25</td>
</tr>
<tr>
<td>60 years old (or older</td>
<td>16</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>80</td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
</tr>
<tr>
<td>Medical Residence</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>61</td>
</tr>
<tr>
<td>Not</td>
<td>43</td>
</tr>
<tr>
<td>Time of Graduation</td>
<td></td>
</tr>
<tr>
<td>Until 10 years old</td>
<td>12</td>
</tr>
<tr>
<td>11 until 20 years old</td>
<td>37</td>
</tr>
<tr>
<td>21 years old or older</td>
<td>55</td>
</tr>
</tbody>
</table>

The results of this study also reveal that time formed more than 21 years (55.6%) prevailed, which reinforces the maxim that the law enables, but does not qualify. Thus, with the passage of time, the doctor who does not seek improvement in order to improve their technical preparation, especially the acquisition of technologies of care called light, as it prioritizes the relationship between the provider and receiver of care, more likely to commit faults. This professional must be constantly informed, to
get hold of new technologies. For this, continuous improvement is necessary because it provides increased hit rate (9).

The denunciation for medical errors and ethical and professional violations are rising in Brazil and generate a main concern of our daily lives. The Regional Medical Council of the State of Paraíba recorded 769 complaints against doctors between 1999 and 2009. This significant increase in the number of investigations involving doctors for malpractice, due to a sum of elements, which are: disability education Institutions forming, insufficient number of openings for medical residency; poor remuneration of professionals; accumulation of jobs; lack of adequate conditions of service to the population; discontinuity and update technical skills and lack of ethical commitment to the profession and patient (10).

Excluding this scenario, the company began charging the public authorities of the minimum right to health, and how public health institutions are not adequately prepared to meet the population satisfactorily, complaints about poor service, in general, are sent to doctors or other professionals who are involved in the functioning of these institutions (11). Complaints began to turn into accusations, which have become increasingly publicized by the media, emerging thus varied cases of medical errors and ethical processes instituted in Brazil and worldwide.

The Article 1st of the EMC, which sets the malpractice, discusses that in order to allocate the proof of guilt or establish a causal link between the medical and damages should be based on at least one of the following pillars: incompetence, recklessness or negligence. It is noteworthy that, in the context of health care in our country, there is an impersonal relationship between professionals and services, especially in public, where the patient has to belong to the institutions. It grew gradually, the distance between him and the doctor and ran for a doctor-patient relationship weakened, based on the pillars of distance, dissatisfaction and mistrust (12).

Despite that, currently, patients have clearer awareness of their rights and should be supported to claim them. Experience shows that many of the complaints, public or veiled by patients are due to inadequate physician-patient relationship, leading to complaints with official lettering situation mistaken malpractice (13).

Another aspect that considers mentioning is the fact that 56% of investigated complaints against doctors have been formalized by legal entities, which signals that society has learned to distrust the medical and health system, so much more formalized charges against this professional. This corroborates a reality of the fact that becomes from them to evidence ethically inappropriate behaviors and unacceptable (14). To face this situation, these professionals seek to justify their unethical professional behavior with the financial situation, the lack of adequate working conditions, poor training and technical humanistic, among other reasons. Moreover, profound changes are occurring in medical science, many of them stemming from scientific and technological advances, in whose midst have implications for practice. With this, each day, new dilemmas and new ethical discussions come.

Given this scenario, it is necessary to differentiate between an error that results from something unpredictable, in which the physician, aware of their duties, acted with due precautions, acting reasonably under the circumstances, what can be called honest mistake and error that comes with the guilt that results in injury to the rights of the patient, which could have been avoided with a competent professional attitude, without acts of recklessness, negligence or malpractice (5).

In contemporary times, has been giving the doctor a variety of errors relevant professionals, such as superficial examination of the patient, performing unnecessary operations, failure of treatment, delay in transfer to another specialist, carelessness in performing blood transfusions or anesthesia, mistaken prescriptions, patient abandonment, neglect postoperatively, omission of necessary instruction to patients, between others (6). Extending this analysis, it is noted that, not always, therapeutic failure is linked to the conduct of the doctor. Therefore, one must seek the causal link between events and identify possible causes associated (anatomical, physiological, pathological, psychological or social actors) (15).

Considering this, medical professionals need to take a more systemic approach, a broader view of the situation or set of failures. Moreover, the use of appropriate technology and the creation and maintenance of mechanisms for recognition and repair of errors may generate situations that make the practice of medicine safer for patients and professionals. It is understood that technology does not replace the professional involved in patient care, but organizes and enables the information to identify link between them (10,16). Therefore, the use of technology strategy is a potentiator of work, a mechanism to be used to facilitate the activities of the physician.

Conclusion

The results presented here reveal the characteristics of ethical infractions committed by doctors of Paraíba (Brazil), indicated in the complaints sent to the CRM of the State. Under the influence of these aspects and the relevant literature, decides to make some reflections on the theme researched in order to subsidize other reflections exceedingly relevant for addressing medical errors, and not, by presenting systematic conclusions on the subject.

Malpractice is a major public health problem that needs more attention from those who are involved directly or indirectly with the phenomenon. It is noteworthy that the doctor-patient relationship was marked throughout the history of medicine, the power of decision on the health of the first second and consequently disregard for the will of this process in decision making about their own health. However, this reality has begun to be modified after the promulgation of the 1988 Federal Constitution and the Code of Consumer Protection in 1990. These legal instruments have contributed to the strengthening of citizenship and individual rights.

Besides the above, it is understood that the medical activities involve interaction, preferably equality between people. Good medical practice is characterized by the balance between scientific knowledge, available technology and the relationship between doctor and patient. However, sometimes, therapeutic failure is linked to the conduct of the doctor, which is why we must seek the causal link between events and identify possible causes associated (anatomical, physiological,
pathological, psychological or social actors), preferably, by region, because each site presents characteristics and health policies themselves. Considering these aspects, it can be stated that the Regional Council of Medicine of Paraíba has addressed the problem of medical error effectively and efficiently, in spite of the imperfections in the management of the database, which limits the qualitative analyzes of the issue. We recognize that the importance to know the risk factors for medical errors is critical to formulate measures in order to avoid malpractice. For this, it is undeniable that the role of medical education in the training of future physicians is extremely important to develop skills and technical skills, and ethical and moral values. This fact has been highlighted since the dawn of Medicine.

References

Case study concerning privacy in the care of patients with HIV

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1 Introduction
The right to privacy is one of a patient’s essential rights and the maintenance of confidentiality in the patient-physician relationship is a physician’s primary obligation. Respect for the privacy and dignity of a patient engenders trust that facilitates the provision of health care, and distrust would certainly ensued without it (1). A patient wants to control access to sensitive personal information and expects physicians to maintain that confidentiality (2). Today, however, the principle of confidentiality has rarely been regarded as an absolute requirement in several nations, and exceptions may arise when the health of others and public interests are jeopardized in a serious way (1-7). Accordingly, a physician is sometimes expected to act simultaneously in the interests of both the individual patient and other persons whom require care. The balance between preventing harm to innocent third parties and respecting the right of an individual patient can lead to difficult ethical and legal disputes because of a conflict between the two parties.

In this paper, we will describe the case concerning this type of conflict of interest and consider the decisions made and their rationale. A hypothetical scenario based on the actual case that happened in Japan will be described and discussed. By doing so, we define when a duty of confidentiality may be ethically overridden, what reasons can justify a physician’s breach of this fundamental ethical principle, and what constitutes confidential health information. Furthermore, we will discuss problems concerning the confidentiality of HIV-infected patients in the context of the overall medical care system in Japan.

2 Case for discussion (hypothetical scenario based on the actual case that happened in Japan)
A medical student, Q, now in his 20s, learned while he was a student at X University School of Medicine that he was HIV antibody positive. At that time, he consulted a physician, Dr. A, at the outpatient internal medicine clinic of X University Medical Hospital, who confirmed that he was infected with HIV. Thereafter, his HIV infection was managed at the same outpatient clinic.

At X University Medical Hospital, the HIV infection care team had been organized by three members, including Dr. A. One member of the team was Professor B, who was the head of the clinical laboratory of X University Hospital. During his first visit to this clinic, following the advice of Dr. A, Q consulted the HIV care team, including
Professor B, about their therapeutic policies. Dr. A was mainly in charge of the student's subsequent case management and continued to report on Q's condition and present his data to the HIV care team.

After a definite diagnosis of HIV infection was made, Q voluntarily disclosed this fact to the Dean of the Medical School, Dr. C, adding that he wanted to continue studying medicine. He had also told some other Medical School professors about his condition. Later, a meeting was held between Professor D (the chairman of the Education Committee and the Infection Countermeasures Commission of the Medical School) and the student, to discuss their future plans. Professor B attended the meeting and explained the student's condition. The Medical School organized an ad hoc committee consisting three professors including Professor D and tried to support Q's school life.

One year later, the student's condition had not changed markedly. In the meantime, X University School of Medicine members had initiated discussions as to whether, as a general rule, HIV-infected individuals should be allowed to become a physician after completing their education and training at a medical school. Following these discussions, the student received a notice from the university that there might be some limitations placed on him when he began his clinical training. Later, he appeared on a television program entitled, "Coming out! A choice of an AIDS-infected medical student." During the program, he acknowledged that he was gay and HIV-infected, and argued that it was unreasonable and unfair that he might not be able to compete his clinical training.

One week later, Professor D telephoned Professor B and asked him about Q's condition and health related data. Without Q's prior consent, Professor B disclosed the student's test results and other information on the student's medical records to Professor D. Professor B had not been directly involved in the student's care up to that time. The telephone call placed by Professor D to Professor B was intended to collect information for determining the university's policy concerning Q's clinical training. Information disclosed included Q's symptoms such as general fatigue and intermittent fever, laboratory data such as blood sugar level, white blood cell count, lymphocyte count, CD4 and CD8 count, and any change in clinical course. Two month later, Q had found that Professor B had revealed his health information to Professor D without his consent.

First, those who agree with the claim that a breach of confidentiality in this case was permissive would argue that a need-to-know obviously existed. Professor D, who was the chairman of the Education Committee and the Infection Countermeasures Commission of the Medical School undoubtedly needed to know Q's medical conditions in order to determine whether or not the student could participate in clinical training and to support the student in general. Professor D organized an ad hoc committee to support Q's school life, and asked Professor B about Q's current medical condition solely on behalf of the student. Here, Professor D had good intentions.

Second, it is alleged that Professor B could have reasonably expected that a disclosure of Q's medical information to Professor D would not lead to a leakage of Q's personal information outside X University School of Medicine. Professor B could place his trust in Professor D and that all information disclosed would be used exclusively for the interests of student Q. Thus, the disclosure of Q's medical information happened only inside the boundary in which confidential information could safely be shared (i.e. the X University School of Medicine), and Professor D was an appropriate person to reveal Q's medical secret. In addition, Professor B was also a suitable person to access Q's medical information despite the fact that Professor B had not been directly involved in the student's care up until that time. This is because he had been one of the members of Q's medical team in the past and was also a leading expert in the field of HIV care in the X prefecture.

Third, the disclosure did not bring any harm to Q. That is Professor D had already known Q's HIV status and there was no possibility that the information disclosed would disadvantage Q; i.e., misunderstanding or prejudice on Professor D's behalf. Also, the information between Professor D and B did not include either new facts about Q's physical condition or significant changes in laboratory data. After all, at that moment Professor D had already known that Q was HIV positive, had suffered from Diabetes Mellitus, and had mild general symptoms. Accordingly, nothing went against the student's interests.

Fourth, those who support the disclosure in this case may think that Q's medical information was no longer a secret. Student Q had voluntarily disclosed his HIV status to several professors of the Medical School when his HIV infection was definitely diagnosed. At the same time, it was common knowledge that Q was HIV positive not only inside the University, but also outside because he had appeared on a television program and acknowledged that he was gay and HIV-infected.

Finally, it can be argued that the medical information revealed to Professor D by Professor B was not information that Q would have prevented Professor B from disclosing to Professor D. Nothing might be regarded as better evidence of Q's acceptance of this than the fact that he did not complain of the actions that Professor B had taken a year prior. Professor B attended a meeting including Professor D and student Q where he explained to Professor D and two other professors about the student's condition. At that time, B telephoned the clinic where Dr. A cared for Q and obtained information on Q's medical condition. However, at that time, Q did not complain about this.

3 Case for breaching confidentiality

It is generally and firmly thought that a physician must not release a patient's health information without legitimate reasons. This principle has commonly been interpreted to mean in some countries including Japan that disclosure of a patient's medical information to a close relative such as a parent, a spouse, or a child should not necessarily be considered a breach of confidentiality. Exceptions occur when the disclosure to relatives cause disadvantages to the patient and when the patient has expressed his or her wish not to do so (8). The point at issue in this case is, therefore, whether or not there were legitimate reasons to override confidentiality. In the following, we will summarize the arguments that a breach of confidentiality in this case was ethically justified.

3.1 Legitimate reasons to override confidentiality

Accordingly, nothing went against the student's interests.

3.2 Exceptions to confidentiality

In addit...
In summary, those who think that a breach of confidentiality in this case was ethically justifiable would claim that the disclosure of Q’s HIV-related health information was legitimate because the release of information was done in good intention, with a significant need-to-know, within the boundary in which the secret could be kept, without any consequent harm, and that which was disclosed was information that Q probably did not want to keep secret.

4 The case against disclosure

We now turn to the arguments against disclosure in this case. Criteria to justify an overriding of confidentiality have been well established in medical ethics. When considering the disclosure of a patient’s private information to protect the public interest or the safety of third parties, a physician in charge must ask questions such as: Does the possibility of seriously harming the public or a third party exist and is the likelihood of that harm high? Can disclosure prevent harm to persons at risk? Are there alternative means to prevent harm? One ought also to question if the need for disclosure is urgent, if the person can be persuaded to disclose voluntarily, or if there is a preceding effort to seek the patient’s consent. These questions would help clarify if it is necessary to disclose the patient’s medical information without his or her consent. It should be asked whether the benefits of disclosure are comparable to the harms associated with breaching patient confidentiality (1, 2).

The proponent of disclosure in this case would claim that Professor D probably needed to know student Q’s clinical conditions in order to determine the university’s policy concerning his clinical training. We agree that this aim was legitimate and not malicious in any sense. The disclosure was made to benefit both student Q and X University. However, it seems that new and potential harm to third parties or to patients were irrelevant when Professor B disclosed Q’s information to Professor D. All faculty members and students at X University School of Medicine knew that Q was infected with HIV. The information revealed in this case such as lymphocyte count and blood sugar level has nothing to do with infectivity of HIV to others and the newly revealed information would make no impact on the University’s decision about whether or to what extent Q could join clinical training involving patients. Furthermore, Q did not begin his clinical training at that moment and he had no chance to directly contact with any patient. Accordingly, potential harm to the patients or to third parties was irrelevant in this very case, and the arguments based on need-to-know to protect others, do not sufficiently justify an overriding of confidentiality.

While disclosure was intended to serve the best interests of student Q, this benevolent intention cannot justify the means employed. This is because easy alternatives existed and there was no hurry to reveal the information. Both professors should have, in our opinion, asked student Q what his preferences were regarding disclosure. It was unlikely that Q would refuse such a request and disclosure was not necessarily urgent in this case. Thus, even if there were a good reason to reveal Q’s information to X University School of Medicine, it does not justify disclosure without Q’s explicit consent. We cannot help feeling that a half-hearted sense of duty of confidentiality and inconsiderate paternalism existed in the minds of the two professors.

The proponent would suggest that the disclosure of Q’s medical information was justified because it was unlikely that information would leak beyond the confines of the university. However, we argue that a patient’s secret should be kept strictly within a patient-physician relationship, and the claim that the medical school could be regarded as a boundary in which patient information is kept confidential is not acceptable. A patient who tells his or her personal information to a physician will assume that no other physicians and health care workers at that institution have access to one’s medical records without therapeutic necessity. One could argue that Professor D was a member of the ad hoc committee to support Q’s school life and he should be included in the patient-physician relationship, but it is Q who should be able to decide who can know his personal information. This holds true also for Professor B. Although Professor B was a member of the HIV medical team at X University School of Medicine, he was not one of Q’s primary physicians. Therefore, the claim that he could freely access Q’s medical information is not valid. The fact that Professor B is a leading specialist in the field of HIV infection in X prefecture is irrelevant as a justification for a breach of confidentiality between patient and physician.

One of the arguments posed by those who are in favour of overriding confidentiality in the case was that the disclosure did not bring about any harm to Q and that nothing was against the student’s interests. This claim would be valid if we focused on only visible or physical harm. It might also be true that the information revealed included nothing new and did not lead to an increase in the number of persons who were aware of Q’s HIV infection or exacerbation of discrimination. Nevertheless we should never forget potential psychological harm. We argue that an individual can be harmed by knowing that someone has access to his or her personal medical information. We claim that disclosure was harmful to the student because he lost his trust in X University Hospital and felt compelled to leave the university regardless of the existence of actual threats or pressures.

One might argue that Q’s prior voluntary disclosure to several professors at X University School of Medicine and the fact that he did not complain about Professor B’s similar actions in the past indicate that there was nothing wrong in the disclosure in question and the disclosure was justified. However, this argument overlooks two ethically relevant distinctions. First, there is a difference between voluntary and involuntary disclosure. When we voluntarily reveal a secret, we can choose which information should be disclosed, to whom the information is released, and when it is to be disclosed. On the other hand, we would lose control over these actions if disclosure were made behind our backs. In other words, voluntary disclosure is an autonomous act and involuntary divulgence is a violation against it. Second, it should be noted that an interpersonal relationship can change dramatically within a year, and the emotion and trust involved in a prior relationship can disappear and be replaced with dislike and distrust. Even the same action can be interpreted differently within the context of separate interpersonal relationships. One example is physical contact. In affectionate relationships, physical contact may be desired, but this is not the case after one
breaks up with one’s lover. Similarly, the fact that two individuals had an intimate relationship once cannot justify coercive physical contact in the future. Likewise, Q’s past acceptance of Professor B’s access to his secret information does not justify the latter’s access to the student’s secret without his permission.

Finally, we argue that there were no objective criteria to determine what information should remain confidential. Although there are general and broad agreements about what kind of information is sensitive, and therefore, should be considered strictly confidential, different people may have different attitudes toward the secrecy of their own medical information. Some might consider that one’s suffering from diabetes mellitus is confidential and others may not; some regard their body weight as confidential and others may not, and a patient may consider his or her CD4 count and clinical condition as confidential while another patient might not. Thus, unilateral decision about what is secret and what is open for disclosure cannot override individual preferences.

In conclusion, a boundary of confidentiality may not be stable or static. The existing boundaries should be considered issue-specific and recognized as being influenced by the relationships between concerned parties. We would argue that claims for supporting the two professors’ actions are governed by an insensitive and inconsiderate paternalism because no one could unilaterally determined the boundary within which private medical information could freely be exchanged beyond basic patient-physician relationship and what is sensitive secret for an individual. This is also because the two professors could ask Q directly for his consent without significant burdens and with plenty of time, and benefits and harms for a particular person could be highly subjective. Furthermore the claim for supporting the two professors’ actions fails to appreciate the fact that interpersonal relationship could change suddenly and dramatically in a short period of time. Again, benevolent intention cannot justify the means employed in this case.

It is claimed that one should have the freedom to share his or her own private information with those whom one chooses, and when one wants, even against the wishes of his or her own family (9). In light of the above considerations, we conclude that the disclosure in this case is ethically unsound.

5 HIV infection and the medical care system in Japan

In the final section of this paper, we consider the issues of privacy and confidentiality of HIV-infected patients in the context of Japan’s medical care system. Since the 1990s, in response to the rising number of the HIV/AIDS-infected patients, HIV/AIDS related medical facilities in Japan have increased to include a total of 369 local centers in 47 prefectures. These local centers report to 14 large regional district centers which, in turn, report to the National AIDS Center in Tokyo. All local centers and large regional district centers have been established within existing public or university hospitals (10).

While this system appears to be well organized, the realities at the level of local AIDS centers in non-metropolitan areas present considerable potential ethical problems. While it is true that the case of student N involved several unique and specific aspects, it did occur at a local AIDS center. Indeed, there may be general, widespread conditions at smaller local centers that are likely to cause more severe ethical problems according to the following study.

Some aspects of these adverse conditions at local AIDS centers were revealed in a nationwide study conducted between 1998-2000. A group of people were trained to pose as HIV-infected patients and then sent to 40 small local AIDS center hospitals, presenting themselves as HIV-infected patients seeking a medical checkup and appropriate medication. Results of this research point out a number of behavior patterns likely to lead to a breach of personal privacy and confidentiality – patient interviews used to collect sensitive personal information by non-medical personnel, physician-patient interviews carried out in HIV/AIDS counseling “rooms” located in the midst of a busy and noisy open office, and patient information displayed on a computer monitor visible to persons nearby (11). Not only do these behavioral patterns indicate an obvious lack of privacy and security that are not conducive to maintaining confidentiality, but they are also likely to discourage existing or potential HIV-infected patients from seeking medical care.

What circumstances account for a lack of attention to patient privacy at local centers? Geographic distribution of patients is relevant to this issue. A survey conducted in November of 2006 found that the total number of registered HIV-infected patients in Japan is 12,020, including 3,949 AIDS patients. 68% of these patients live in the Tokyo district, 13% in the Osaka district, and 9% in the Nagoya district. A total of 90% of all patients are concentrated in metropolitan areas (12). This is not simply a reflection of the overall demographics of metropolitan areas.

There are some specific reasons for HIV-infected patients to choose to move to and live in metropolitan centers. First, there is a higher quality of medical care available. Second, the anonymity of large metropolitan areas may be able to preserve privacy better than in a small community – certainly, HIV-infected patients are concerned about their privacy. In an interview with a supervisor of a regional AIDS center, we learned that many patients living in Osaka travel to Tokyo, and vice versa, for their regular checkups rather than having them done locally, in an effort to better preserve their privacy from their employer.

The tendency for HIV-infected patients to cluster in large metropolitan areas results in a very limited number of patients presenting themselves to smaller local centers. For example, among Japan’s 47 prefectures, in 2003, 14 prefectures reported no new HIV cases and 13 prefectures each reported only one new case. Similarly, regarding AIDS cases, 23 prefectures reported no new cases and ten prefectures each reported only one new case (13). As a result, in terms of the number and experience of hospital staff, there exists a gap between metropolitan regional AIDS centers and smaller, local AIDS centers. The Osaka regional center, for instance, has eight full-time doctors including two residents, two coordinator nurses, two pharmacists, two counselors (MSW), and two information officers serving 1,000 patients. The staff is accustomed to responding to a large number of patients every day, is familiar with the needs of patients and is sensitive to a patient’s personal privacy rights. Local centers, by contrast, have few patients; several staff members are part-time. For the
staff, medical practice at the local center is a new duty added to their own primary, very busy daily medical work. So their handing with private information of HIV/AIDS patients tends to be careless and training opportunities are limited. Under these circumstances, it is understandable that staff at local centers are likely to lack the training and experience necessary to adequately preserve the privacy of HIV-infected patients. Regular and effective training regarding the ethical aspects of maintaining such confidentiality is needed.

Every year, numerous articles relating to HIV infection appear in the mass media. A peak was seen in 1996 as a result of a court decision on HIV transmission by a tainted blood product. But the number of articles dealing with HIV infection and issues surrounding a breach of privacy are relatively sparse, averaging two or three per year even in national newspapers (14). This is surprising, given the relatively lax and potentially detrimental procedures common at local AIDS centers. This suggests that this human rights issue rarely comes to light in a society where prejudice and discrimination against HIV is still dominant.

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The ethics of reproductive medicine in the Islamic Republic of Iran

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Abstract
Reproductive medicine services have been provided at a fairly advanced stage in the Islamic Republic of Iran, and there are currently more than 75 infertility clinics which provide some of the latest technology in the field. From the ethical and religious point of view, Iran has provided a very flexible environment that is quite unique in the Middle East as well as the Muslim nations in general. This flexibility is mainly related to the role of *ijtihad* in *Shi’a* Islam where new rulings can be extracted by *Shi’a* jurists to facilitate the use of technologies that may be banned by traditional Islamic rulings. The possibility of temporary marriage in *Shi’a* has also helped legitimize the third party donation of gametes for treatment of infertility. The Supreme Leader in Iran has issued a series of *fatwas* that played a big role in legitimization of assisted reproductive technologies (ART) and the use of third party donated gametes for infertile couples in Iran. The problem is that infertility clinics have gained a large control over the ethical aspects of these services while their major focus is on a higher success rate. Also by keeping the donor and recipient information “anonymous” or “confidential” in order to avoid troublesome frictions, the identity of children may not be well protected as in original Islamic teachings. The infertile couples on the other hand are mainly concerned with the continuity and “purity” of their lineage and do not receive proper consultation to make ethically sound decisions. There is also a large potential of misconduct and misuse of technology over financial pay-offs, and therefore the lack of an ethical and legal system to protect the rights of concerned parties is quite worrisome. With the recent trend of the government away from population control and towards higher fertility rates, there is little hope that ethical and legal limits may be devised to regulate the activity of infertility clinics in the near future.

Keywords: Assisted reproductive technologies (ART), In vitro fertilization (IVF), Iran, Medical ethics, Reproductive medicine, *Shi’a* Islam

Introduction
This paper presents the second part of the research investigation into the three layer structure of bioethical decision-making in the Islamic Republic of Iran, and is based on an analytical review of the religious and ethical system of beliefs as well as the laws and practice of medical care in contemporary Iran (1980–now). The so-called “three layer structure” refers to the basic ethical concepts, including ethical theories and religious beliefs, as the 3rd level; the bioethical principles and laws, as the 2nd level; and the decisions made on bioethical issues in medicine, as the 1st level.
The area under investigation here is reproductive medicine, and thus we shall discuss the bioethical issues of reproductive medicine in Iran. The first report, as of last year (2011) provided the background information including the basic religious and ethical beliefs and theories (3rd level) of Shi'a in the Islamic Republic of Iran; however, issues related to reproductive medicine provide an opportunity to revisit the 3rd level for a better understanding of its policy implications. Therefore we shall consider the 3rd level again but mainly in the perspective of its impact on reproductive medicine, before explaining the 2nd level and the 1st level of bioethical decision structure in the area of reproductive medicine.

The 3rd level (basic ethical concepts, ethical theories and religious beliefs):

The fundamental question at the 3rd level is about the underlying ethical philosophy. The ethical thinking of Shi’a Islam in Iran is based on prima facie obligations similar to the views of the British philosopher W.D. Ross (1877-1971). Thus, the underlying ethical theory is not purely deontological and actions are not simply divided into right and wrong; each person at any moment may have a number of obligations some of which are more important than others. A Muslim may decide to perform various actions he is obliged to and to refrain from others that are to be avoided, based on a proper ranking of those obligations. Most obligations may be overridden by a more important obligation, which is basically the concept of a prima facie obligation.

Most of the moral obligations are not absolute, as opposed to the Kantian ethics, and exceptions are allowed depending on the circumstances. What a Muslim should do depends on the circumstances and the relative importance of various obligations on him. Actions may be judged ethical/unethical based on the circumstances surrounding them, and sometimes the consequences of actions may also receive considerable attention.

With prima facie way of thinking, there are situations where one may need to take a “moral risk”, just as Ross mentioned in his ethical theory. Shi’a Muslims are strongly encouraged to make decisions by “following” the decree of a clergy (faqih) who has completed years of studying and training to attain “ijtihad”. A decree in Shi’a comes from a “mujahed”, a Shi’a clergy who has studied extensively the Islamic law of “shari’a” and knows how to make the best decision after ranking the various obligations under the circumstances and specifics of a situation.

Under the theocratic system of Shi’a in Iran, during the occultation of the 12th Imam the Supreme Leader may rule over the nation and can rightfully interpret the Islamic law (shari’a). Therefore almost all religious, ethical, political and other decisions in the Islamic Republic of Iran ultimately depend on the interpretations of the Supreme Leader from Islam. The decrees made by the Supreme Leader over all affairs are considered as a legitimate source for decision-making by all authorities in the Islamic Republic of Iran.

On the positive side, because actions may be judged as ethical or unethical based on the circumstances surrounding them, there is some form of “flexibility”, meaning that religious decrees need not be very rigid and can take the new situation resulting from new technologies into consideration to form new rulings compatible with modern needs, including those used in reproductive medicine. However, on the negative side, when this flexibility extends to the extremes, it may seem to merge with ethical relativism. Many high level clerics are complaining that some basic rules supported by the Quran and Islamic traditions have been broken. An example that was brought up in the previous report was the winning of cash through “predicting” horse racing results in the Islamic Republic of Iran. Although Shari’a has banned gambling and Quran has described gambling as evil and unclean, new decrees in Iran have permitted many race-goers to “legally” bet on the horses as long as they are “predicting” through official channels. The Equestrian Federation of Iran sought permission from senior clerics and received the permission to provide betting on horses under certain conditions whereby jockeys authorize the horse-racing committee to place bets for other people on their behalf.

In the exploration of reproductive medicine practices in the Islamic Republic of Iran, many cases have been discovered where “flexible” decrees were used in contradiction to traditional Islamic rulings. Many infertility clinics in Iran go farther by providing their desperate patients with a working remedy without a thoughtful examination of the potential ethical problems, while other patients may search for “more flexible” clergies who would approve of what they needed to do to overcome infertility. I have used the analogy of red and green traffic lights in Japan where a green light prevails over the red light. The flexible rulings by a mujtahid provide the green light that allows a Shi’a Muslim to move against the basic ban, the red light, over the conduct (Figure 1).

![Figure 1: At this intersection, movement in all directions specified in green is allowed; flexible permissions obtained from mujtahids serve as a green light that prevails over the basic red signal.](image-url)

The 2nd level (biomedical principles and laws in Islam and Shi’a Iran):

Here we need to first examine the basic Islamic principles that are well recognized by the majority of Islamic thinkers, and then examine the modifications made to them in Shi’a Iran based on its use of “dynamic” and “flexible” ruling through ijtihad. This is not to say that all sources of ijtihad in Iran would agree with these modifications; however as noted before the more flexible rulings may still save Shi’a Muslims from the moral risk of making their own independent decision.

The most basic law underlying the ethics of reproductive medicine in Islam is the preservation of proper lineage (nasab). As such, shari’a requires that a
child be able to relate to his/her biological parents. In Islam, it is a child’s basic right to acquire his/her own untainted identity through a legitimate relationship between parents. Therefore generally in Islam, assisted reproductive technologies (ART) that are used within marriage and ensure the legitimate lineage of a child may be acceptable, and others may not. For example, if any of the female or male gametes used in IVF do not come from a married partner, the child’s rightful lineage cannot be assured and the practice may not be acceptable. If a gamete comes from an unknown donor, again the child’s lineage is lost and this cannot be accepted.

In Islam, children should be protected against a tainted lineage through an unmarried biological parent because it may be considered adulterous. A child born out of wedlock may be exposed to social stigma as well as the loss of dignity and respect, and the inheritance of estate and property. In Islam, adopted children should keep the lineage of their true biological parents, and not their adoptive parents. Therefore, adopting a child is a form of guardianship and a custodial role, but not true parenthood. This however, is not the case in some uses of ART in Shi’a Iran, as we shall explain.

In Islam, artificial insemination with husband’s sperm (AIH) is allowed by most jurists while artificial insemination with donor sperm (AID) is very problematic. One important principle in Islam is to guard the private parts (hizf furuq). Some Muslim jurists believe that the main prohibition is against having a sexual act performed between a sperm donor and a woman outside marriage but implanting the sperm without performing the sexual act may be permissible: this is the current practice in Shi’a Iran, while the mainstream judicial authorities in Sunni nations still do not allow the use of donor sperm because it has the potential of leading to incest among the next generation, and also does not protect the womb and the legitimacy of procurement. Ultimately, a legitimate parenthood depends on marriage and as long as the sperm belongs to the husband and the egg to the wife, it may be acceptable.

Therefore, it cannot simply be said that all IVF is acceptable in Islam or not; it may be acceptable as long as sinful acts are not done in its complex process. For example, the act of masturbation to produce sperm is morally questionable in Islam. Also the access of a male physician to the private parts of the woman undergoing IVF is questionable. Another potential problem is the fate of frozen embryos that won’t be needed after a successful pregnancy. Some Sunni jurists say that the sanctity of life doesn’t apply to embryos outside the womb, but other jurists may disagree. Another problem may arise if a widow wants to use a frozen embryo to get pregnant with the sperm of a deceased husband because legally the death of her husband means that the marriage contract has become void.

As such, an important Islamic ethical rule to be guarded for decision-making on IVF is protection from distress and impairment (al-usr wa al-hara). If the use of a technology such as IVF causes distress onto the family relationships of a married couple and/or the sanctity of the womb, then it should not be attempted. In fact, one way to avoid the many potential pitfalls in IVF would be to trust in God and submit to his wisdom which is the traditional Islamic guidance on the issue of fertility. However, infertility is a significant social stigma in Iran and its cure has been given priority over many of the afore-mentioned aspects that the mainstream Sunni jurists refer to. The Iranian parliament has even approved legislation to take fertility treatments under health insurance coverage because they consider infertility as more of a “disability”, and its treatment is not looked upon as enhancement.

Generally in Islam, surrogate motherhood is possible through the polygamy provisions of Islam. As long as the first wife agrees to a second marriage by her husband in order to provide a legitimate surrogate mother, this can be done. However, to “rent” the womb of another woman would be unacceptable. This has been made much less of a problem in Shi’a Iran because Shi’a allows temporary marriage (sighe) whereby a man, single or married, can make a direct contract of marriage to another woman that may last from an hour to 99 years. Nevertheless, it may be difficult to decide whether the child is related to the donor of the egg or the gestational mother. Many Muslim jurists would say that in principle a child belongs to the father (husband). As for the mother, some jurists say the genetic mother could be the rightful mother and others say that both of the women are mothers to the child because each has contributed to the child’s birth. This latter view is consistent with the fatwa of the Supreme Leader in Iran, but in practice a detailed documentation of the parents is hardly done and usually the parents are those who get to “own” the child by paying for the donated gamete or surrogate services.

There are major differences in the practice of ART between the mainly Sunni nations of the Middle East and the Shia Iran. One major difference is their different approach to the use of donated gametes. While the Sunni nations have banned all forms of third party donation of gametes because of its impact on lineage (nasab) and the possibility that it might lead to incest or adultery, Shi’a Iran has allowed it based on the fatwa by the Supreme Leader, Khamenei who issued a series of fatwas in the late 1990’s that allowed the use of third party donated gametes with the only condition being: “IVF is not in and of itself legally forbidden as long as no haram acts such as gaze or touch take place.” The series of fatwas has led to the legitimization of third-party gamete donation in Iran, although many other senior Shia clerics in Iran do not agree with such the interpretation by Khamenei.

Another major difference between the mainly Sunni nations and the mainly Shi’a Iran is the legality of “temporary marriage”, called sighe in Iran. For fertility treatments in Iran, a temporary marriage of 1 day can be made between the man and the egg donor. Khamenei decreed that there would be no difference between a temporary and a permanent wife in the matters of egg donation, and the decree turned into the solution for egg donation in fertility clinics. The basic concept is that the husband of an infertile woman nominally marries a female donor for one day so that her donated egg can be used for IVF.

However, temporary marriages are not properly documented in Iran, and many clinics especially private ones do not insist on verifying them. There are reports that many infertile women have had their sister donate an egg while technically a woman’s sister could not be temporarily wed to her husband, based on the Islamic law and tradition of mahram and non-mahram, which
basically means that some kinship relations are banned from marriage to one another. This well known tradition is based on clear Quranic verses (4:23, and 24:31).

Quran (4:23): Prohibited to you [for marriage] are your mothers, your daughters, your sisters, your father's sisters, your mother's sisters, your brother's daughters, your sister's daughters, your [milk] mothers who nursed you, your sisters through nursing, your wives' mothers, and your step-daughters under your guardianship [born] of your wives unto whom you have gone in. But if you have not gone in unto them, there is no sin upon you. And [also prohibited are] the wives of your sons who are from your [own] loins, and that you take [in marriage] two sisters simultaneously, except for what has already occurred. Indeed, Allah is ever forgiving and merciful.

However, in Iran the availability of a sister's egg and its genetic similarity to the infertile woman, plus the fact that no actual marriage between the sister and husband happens, make this a convenient choice for many infertile women. Sometimes even the brother of a man has donated sperm, though to use the sperm of a husband's brother would be considered adultery under Islamic law. This is because the technical remedy for an infertile woman to get donated sperm from a temporary marriage would be a lot more complicated than getting a donated egg: she must first divorce her husband and wait for about three months (called ʿiddah waiting period) until she can temporarily marry another person, and later divorce him to remarry the first husband. As we shall see in the next section (on the 1st level), desperate patients under the care of the infertility clinics have an open hand to provide donated gametes from almost any source they have access.

In the case of sperm donation, a fatwa by Khamenei has allowed that the child take the name of the social father rather than the sperm donor. Although Khamenei's fatwa still calls that the child must inherit from his biological father too, such rulings might not be followed in practice. In fact, the recent policy of the private and public clinics is to provide for “anonymous” and “confidential” gamete donors, respectively. This is obviously in contradiction to the basic Islamic principle over a child’s right to his/her lineage but apparently has helped the clinics avoid some of the frictions and socio-legal complications associated with non-anonymous infertility treatments.

An alternative solution for sperm donation would be to acquire a whole embryo from another married couple, and thus avoid the complex divorce and re-marriage procedures required to get donated sperm. Therefore in 2003, some leading clinics helped with the presentation of a bill for embryo donation to the parliament, and with the favorable verdicts of the clergies it was approved. As with all laws in Iran, the bill was sent to the Guardian Council (shorayeh negahban) for scrutiny and became law after their final approval. This law resolved the legal status of embryo donation that a fatwa alone could not achieve. The law specifies that with a court’s permission, clinics may treat infertile couples by transferring an embryo which has been fertilized outside the womb, to the infertile couple. The only conditions set are that the infertile couples must be in good health but infertile, be of sound mind, and healthy, must not have any incurable diseases or addictions, and must be nationals of Iran. It specifies that only people of the same religion can donate to each other, but it is unclear whether Sunnis can donate to Shi’a or vice versa. Nevertheless, many infertile couples still proceed with gamete donation from close relatives, without breaching the fundamental religious rule specified in Khamenei’s fatwa regarding touch and gaze.

Surrogacy has also been practiced in Iran since 2002. It was initially limited in scope due to a shortage of surrogate mothers because only relatives might have accepted to act as surrogate mothers. It would be a social stigma to explain how someone got pregnant as a “surrogate” to some infertile couple. However, now an increasing number of women agree to serve as a commercial surrogate mother. So far, no separate law has been passed on surrogacy and the courts use the same law of embryo donation as their point of reference. As such, there is some worry on the part of the infertile couple on what they could do if the surrogate mother would not return the baby to them after birth. The average payment to a surrogate mother is around $ 3000 (Termayne, 2009).

Contraception: Birth control as a form of family planning has long been permitted in Islam because it may improve the living conditions of poor Muslim communities. However, most Muslim jurists believe that a woman needs her husband’s permission to prevent from a pregnancy and some jurists believe that a husband also needs his wife’s permission before attempting to prevent from a pregnancy, including by penis withdrawal. Nevertheless, Islamic tradition would not allow permanent methods of prevention from conception, even with a husband’s permission. The reason is that this may be against the obligation to protect the lineage (nāš). Such limitations were disregarded in shi’a Iran as the so-called “family regulation” (tanzim-e khanevade) programs helped lower population growth from 3.8% in 1986 to 1.5% in 1996. Tubal ligation and vasectomy were provided for almost free in many public clinics with the only condition being that the couple had at least 2 children. However, it appears that the government is now attempting to reverse its long held policy towards population control, with many subsidies for fertility control being cut and a bill being sent to the parliament with the purpose of helping increase population growth.

Abortion and sex Selection: The legality of abortion in cases of adultery and rape has been confirmed in a number of Islamic studies. However, to terminate a pregnancy within a marriage is a completely different matter. Isn’t it a sin to abort unwanted embryos?

The answer to the question of early abortions heavily depends on the determination of when an embryo becomes a person. Quran does not specify a distinction between an embryo and a fetus. Most of the Muslim jurists believe that the soul or spirit (ruh) enters a human body some time after conception, based on the following verses from Quran:

Quran 32:7–9: God perfected everything which He created and began the creation of man from clay. Then He made his posterity out of the extract of a liquid disdained. Then He proportioned him and breathed into him from His soul and made for you hearing and vision and hearts; little are you grateful.

Sunni jurists have relied on a description of human development in the womb to conclude that “personhood” forms after the first trimester of pregnancy.
Quran 23:12–14: And certainly did we create man from an extract of clay. Then we placed him as a sperm-drop in a clinging clot. Then we made the sperm-drop into a clot, and we made the clot into a lump [of flesh], and we made from the lump, bones, and we covered the bones with flesh; then we developed him into another creation. So blessed is Allah, the best of creators.

There is also some hadith attributed to the Prophet which appears to define the time that a soul enters the body at about 40 to 45 days after conception. Some jurists have extended this period to the end of a period which is approximately the end of the first trimester, at 120 days after conception. However, hadith attributed to Shi’a Imams implies that personhood may start at the time of implantation. The significance of this timing is that abortion would not be allowed after the soul enters the body (ensoulment). As such, an intentional abortion of an embryo or a fetus is not allowed in Islam, and the starting point in time for this prohibition may well be the time of implantation in the womb:

Quran 6:98: And it is He who produced you from one soul and [gave you] a place of dwelling and of storage. We have detailed the signs for people who understand.

Nevertheless, because a fetus depends on the mother’s body for its life, it has only a “relative” right to live but the closer it gets to the time of the birth, this right becomes stronger. Some Muslims do not forbid abortion if the mother’s life is in danger because of the pregnancy. Abortion before the 40th day of a pregnancy should also have a very good reason like when a potential life is at stake. The acceptable cases include a certain threat to the mother’s life, and rape or incest.

When it comes to manipulating or selecting genetic traits, a more important Islamic principle is the obligation to save life. So basically there is no blanket permission in Islam to abort a defective fetus.

Quran 17:31: And do not kill your children for fear of poverty. We provide for them and for you. Indeed, their killing is ever a great sin.

The following verses from the Quran demonstrate that Islam considers sex selection and selective abortion as morally wrong:

Quran 16:58–59: And when one of them is informed of [the birth of] a female, his face becomes dark, and he suppresses grief. He hides himself from the people because of the ill of which he has been informed. Should he keep it in humiliation or bury it in the ground? Unquestionably, evil is what they decide.

Also the principle of public good (maslahah) in Islam requires that the formation of human life should not be manipulated for the sake of enhancement; thus positive eugenics practices are rejected in Islam. However, abortion may be allowed if there is a predominance of significant benefits (isticlah) in the form of preventing some major illness; thus negative eugenics is allowed in severe cases of fetal malformation.

The Islamic Juridical Council approved the clinical abortion of embryos that suffer from major genetic malformations such as the Down’s syndrome. The Islamic Jurisprudence Council of the World Islamic League (Organization of Islamic Countries) agreed in February, 1990 in Mecca to allow for the option of abortion under certain specific conditions; an abortion could be done if a committee of specialized, competent physicians determined that the fetus was grossly malformed and its life would cause severe suffering for both the family and itself. The malformation must be untreatable, unmanageable and very serious. The period of time to have such an abortion was limited to 120 days and it appears that a fetus before this time is not still a person in a legal-moral sense.

In Iran, stem cell research and PGD sex selection have been allowed through fatwa, though there is little supervision over “how” it is being performed (Saniee, 2012). Sex selection is offered by some fertility clinics in Iran through PGD in the context of the confidentiality of doctor-patient agreement, and the lack of bioethical consideration by the practicing doctors.

A final issue is the legality of donating fetal tissue for medical research, for example through harvesting of the stem cells. Islamic law allows this because fetal tissue may be treated as any other tissue that belongs to the woman and is discarded. Spare embryos in an IVF procedure may also be treated as pre-implantation tissue which can be used for medical purposes such as their stem cells because they were never implanted into the womb. Stem cell research is taking place in highly advanced research institutes in Iran.

The 1st level (the practice of reproductive medicine in contemporary Iran):

Infertility has been a significant problem in most Muslim families including those in Iran. Some infertile men do almost anything to hide their infertility from their relatives and community, or blatantly deny and ascribe it to their wife. A man may decide to revoke the marriage contract based on the infertility of his wife, and get a divorce or attempt to have a second marriage. Traditionally, infertile women would seek the help of a saint for fertility by visiting holy shrines. Some infertile couples who solved their problem through infertility clinics have later covered up the use of a third party donated gamete and told their relatives that some holy miracle helped them out. This shows the socio-cultural aspect of infertility problems and the stigma associated with it especially in smaller cities and towns in Iran.

Assisted reproductive technologies (ART) have certainly provided for a modern discourse and the possibilities they offer are certainly tempting to many desperate couples. On the other hand, in Iran the public is hardly notified about the decisions made at a fertility clinic and the medical practitioners are quite authoritarian; they may offer little information to the couples regarding the details of the procedure while they may require the couple’s full and unconditional consent before they “treat” the infertility problem.

Soraya Tremayne has done extensive research on the activity of infertility clinics in Iran and the ethical perspectives of their interactions with the policy-makers on one hand and their patients on the other (see Reference 21). She has updated that study with the latest developments as of 2012 (see Reference 23; Tremayne, 2012). Her comprehensive studies on the practice of infertility clinics in Iran, is a major source of information for this part of the paper. Infertility treatment centers have flourished in the major cities of Iran in the last couple of decades.

There are currently over 75 infertility centers in Iran, in the form of fully private clinics, semi-sponsored clinics, and governmental or public clinics that offer services with
a generous insurance coverage. They offer almost all forms of infertility treatment that includes third party donation of sperm and egg, as well as embryo, and also surrogacy. Some of the clinics offer PGD sex selection and there is one involved in stem cell research.

The medical doctors working in these clinics, especially those in the private clinics, have almost full control of the treatment process and increasingly keep the identity of the donors of gametes anonymous so that they can prevent from any possible sources of legal or social issues in the future. However, the clinics’ increasing tendency towards anonymous donation is in fact against the basic Islamic rules for gamete donation, which require that donation be accepted only within a marital union. Nevertheless, the study by Termayne shows that the major leading infertility clinics in Iran are now moving forward complete anonymity of the donors. The main preoccupation of most of these infertility clinics remains a higher success rate rather than ethical issues, and the control over the ethical and legal aspects of treatment is left to the clinics, with no law-enforcing body inspecting the procedures.

Temporary marriages may no longer be taking place or documented. For many of the infertility clinics, these are more of a formality, and more of the infertile couple’s problem. So they are advised to solve such issues outside the clinic, and just between the couple and the donor. Many infertile men have used donor sperm secretly, and have not even informed their wives about it, as they did not want to be known in the family as infertile.

The priority for infertile couples appears to be mostly in the continuity of their lineage and their choice of the donors that commonly would include their close relatives, whenever possible. By receiving donated gametes from their close relatives, they feel ensured about the ‘purity’ of their lineage, and can also avoid any possible legal claims by “outsiders” in the future.

Demand for the embryos is so high that it has already created undesirable and illegal practices which revolve around the financial potential. For example, there are reports (Termayne, 2009) of a woman who set up an agency for embryo donation and started charging large sums of money from the recipients. However, the embryos sold by the agency did not belong to married couples, as the law requires. Instead, the eggs had come from prostitutes and fertilized by strangers’ sperm. This is while an embryo that is the result of the union between a prostitute and a stranger’s sperm is effectively an illegitimate child.

As for surrogacy, the numbers are still quite limited for two reasons. One is that for infertile couples, the absence of a law to protect them from a breach of contract is worrying. They may have few options, other than making large payments, if a surrogate mother decides not to return the baby. The average cost of surrogate services is around US$ 3,000 which may be a significant amount for many couples. Even so, the cultural problem of having to explain a pregnancy by a non-married woman who accepts to be a surrogate mother is still quite significant in many cities in Iran. Nevertheless, the financial incentive may be strong enough for many women living in the largest cities, such as Tehran.

Discussion

The unique position of Iran as compared with other Islamic nations in its wide usage of assisted reproductive technologies (ART) and the use of third party donated gametes is associated with the dynamic nature of shi’a jurisprudence where jihat has become the source of new laws that may seem to contradict Islamic tradition. This flexibility has helped solve the agony of many infertile couples in Iran and flourish the use of modern technologies at an increasing number of infertility treatment clinics. The main key to this solution was a fatwa issued by the Supreme Leader which allowed the use of IVF as well as third party donated gametes through a nominal temporary marriage with the bare requirement of banning touch and gaze; such a ban may apply to any medical procedure in general and does not deal with the specific issues of infertility treatment. Therefore, the lack of a comprehensive legal structure on one hand and the weakness of bioethical consideration and review of practices at the infertility clinics on the other, have created a worrisome situation.

The identity of the children born to the use of third party donated gametes is at stake, which is quite a significant issue from an Islamic point of view. The prima facie system of ethics may be used to justify the “more important” obligation to help infertile couples get pregnant, but this does not reduce the obligation of the parents, the clinics and their practicing physicians, and a potential public system to supervise the process, from making efforts to assure that the best possible choices are being made. It is very important not to rush into the use of any emerging technology at such a wide scale before a public debate over the bioethical aspects and the social impact of that technology has been started.

The fact that many infertile couples do not receive proper consultation over the bioethical ramifications of their decisions, and the clinics mainly focus on the success of the treatment as an end and have neglect over the used biological material viewing them as the means, raises serious concerns for the future of a part of Iranian society. The large financial profits that can be made through surrogacy and the donation of embryo, egg and sperm, and the potential abuse of individuals, who may get involved in this complex process, together expand the width of possible social damages. It is therefore hoped that the bioethical aspects of infertility treatment for all potentially affected parties will be seriously considered, sufficient information especially on the bioethical aspects will be made available to these parties, and also appropriate checkpoints will be designed into the system.

Having said that, it cannot be denied that the flexible attitude of the Iranian government towards the use of new assisted reproductive technologies may have provided an atmosphere of freedom over the reproductive choices of people who based their decisions on their individual as well as the social values of the communities they belonged to. They may have largely benefited from the solution to their infertility problem, and they may be able to find ways to deal with potential problems of their children in the future; however we cannot deny that they might have made better decisions if they were better informed. The experience of Iran with infertility treatment so far may be interesting to other Islamic nations, whether Sunni or Shi’a, because of the
many religious, social and cultural customs and norms that are shared.

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References


Drug and Alcohol Use, Sexual Intimacy and Associated Health Status of Senior High School Students: Implications for Learning and Schooling

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Abstract
Objectives: To better recognize key maturation processes that drive adolescent socio-sexual activity and to explore the context in which this occurs. Since schools are one place where health choices should be debated in a supportive learning and teaching environment, the present study focuses on lifestyle choices and attitudes to health of Australian adolescents and identifies characteristics which link drug and alcohol use, health and resilience, sexual intimacy and/or sexual experience.

Methods & Results: Students (n=440) from diverse ethnicity, aged 15-17 at a range of New South Wales secondary schools were surveyed to ascertain their drug and alcohol use and their self-perceived physical and mental health condition. Six focus areas emerged from analysis of the data – drug use, diet and drug use, drug use and health/wellbeing ratings, drug use versus health/wellbeing by ethnicity, frequency of drug use, intimacy and sexual activity and awareness of contraception.

Conclusion and Schooling Implications: The strongest motive for drug consumption was enjoyment and peer pressure. Many respondents reported their wide experience with sexual partners before age 17 with the use of contraception, notably the condom and acknowledgment of the responsibility of both partners in the relationship. Significant gender associations between drug use and sexual behavior and low health/happiness ratings were found in girls but not in boys. Students commented on the lack of meaningful information and
discussion about their physical and mental health, their choice of lifestyle and the impact of these on their future provided by teachers and schools.

**Key words:** Adolescence; Human growth and development; Drug use; Drug addiction; Sexuality and sexual experience; Sex education at schools; Happiness ratings; Stress; Ethics; Bioethics; Bioscience ethics.

**Introduction**

Lifestyles and attitudes of young people is, increasingly, a significant component of current research when studying ways that genetic and epigenetic (that is, all the environmental variables which modulate gene activity) influence personal development, behavioural habits and social outlook. Social learning, where members of a particular group learn constructive ways to think and behave from others play a key role in safeguarding general health and wellbeing. Formal schooling as a social construct for learning is one such example. For many young people, their social interactions with parents, teachers and peers, and now via online social networking sites, shape and mediate their beliefs, views and attitudes towards all facets of their health and wellbeing.

Good health, far from being a natural state or universal right, is a matter of achievement, a consequence of privilege or good luck even. It is for this reason that health is defined in the Constitution of the World Health Organization (WHO) as being a state of ‘complete physical, mental and social wellbeing, not merely the absence of disease or infirmity’. This definition emphasizes succinctly the positive aspects of a fully realized genetic potential where good health can be seen as the result of a positive environment supported by socioeconomic advantage. Adolescents are particularly vulnerable to socio-environmental influences during their critical phases of accelerated growth and intellectual development and are, therefore, physiologically and behaviorally more susceptible to changing demands with potential health consequences. It is well acknowledged that risky lifestyle choices and habits in adolescence may adversely influence coping abilities that ameliorate anxiety, depression, social isolation, sexual intimacy and prevalence of drug and alcohol consumption. Schools, as places of social capital, play a key role in educating students about these matters in a positive, supportive and informed learning environment. They are well placed to engage students in meta-cognition about learning, health and wellbeing.

Early adverse social environments such as abuse and neglect have been associated with a wide range of negative outcomes, including increased risk of a variety of mental disorders, substance abuse and tobacco dependence. Importantly, lifestyle choices and patterns of psychological processing interact to influence a young person’s quality of overall health with diet, exercise, substance use, teenage pregnancies, optimism and problem solving ability all being good predictors of overall physical and mental health. Accordingly, the aim of this study was to focus our attention on lifestyle choices currently being made by senior high school students living in the inner city and surrounding suburbs of Sydney, Australia. By means of a structured questionnaire we identified key findings connecting drug and alcohol use, health and resilience by gender and country of birth, frequency of drug and alcohol use associated with intimacy and/or sexual experience, and the use of contraception. By targeting these interrelated behavioural patterns, we aim to advance senior high school educational delivery and youth accountability in important matters relating to lifestyle, health and general wellbeing.

**Methods**

**Participants and Descriptives of Student Questionnaire**

The participants recruited were a sectional sample of senior high school students aged 15-17 years of age (16.4±0.81 SE) living in the inner city and surrounding metropolitan areas in Sydney, Australia. A multimodal questionnaire (text, diagrams, tables and cartoons) was administered to 440 students from seven schools. This form of questionnaire was chosen as opposed to a text only questionnaire because of the academic and ethnic diversity of the student group. Doing so ensured that questions were accessible to most students and reliable answers to questions could be obtained. Student response to the questions was optional. Prior to implementation of the questionnaire, feedback was obtained from several experienced high school science and literacy teachers and students.

Students in this age cohort (Year 11) were in their 12th year of schooling and other than English and Mathematics, had studied two compulsory subjects until the end of Year 10, namely, science (all four disciplines) and personal development, health and physical education (PDHPE). Both subjects were no longer compulsory in the final two years of high school (Year 11 – 12). In previous years students had undertaken science studies in human physiology including reproduction and in health studies including psychological and emotional health.

**Statistical Analysis**

Data from all questionnaires was analyzed by means of a combination of statistical methods. All analyses were performed using SPSS version 16.0. Because each student gave multiple listings of variable questioned, a single value for analysis was established. The number of different effects was counted and this score was used for each of the following descriptive analyses. Friedman's test two-way analyses of variance by ranks and Bonferroni corrections were initially carried out to determine if the number of responses by students was consistent across all variables. Pearson’s Chi-square univariate analyses were undertaken to examine relationships between categorical outcome and independent study variables. Furthermore, the non-parametric Wilcoxon pair-wise comparisons test was performed to determine univariate associations between continuous and categorical variables and was used to assess two variables at a time; for example student’s own health, wellbeing and stress ratings on 1-10 scales. Non-parametric tests, including standard correlations, were more appropriate in the current study because the gathered data was not normally distributed. Multivariate regression analyses and elimination procedure variables to p<0.05 were also carried out.

**Results**
Six focus areas were identified from the questionnaire data.

**Focus 1: Drug Use**

Table 1 presents the overall incidence of drug use for tobacco, alcohol and illegal drugs. As can be seen 68% of respondents have never tried tobacco while, 10% smoked daily. 23% of respondents have never tried alcohol, 19% were drinking weekly, 22% monthly, 3% daily. 76% of respondents have never tried marijuana, 8% were using it weekly or daily. 91% of respondents have never tried ecstasy but 5% were using regularly on a monthly, weekly or daily basis. 90% of respondents have never tried amphetamine while 5% were using regularly on a monthly, weekly or daily basis. A significantly (p<0.001) higher use of ecstasy and amphetamine on monthly, weekly or daily bases was noted from students who identified themselves as coming from Middle Eastern backgrounds. This disturbing observation, however, is in serious doubt on account of the relatively small sample size and the statistical significance of the results requires confirmation. It would seem that students were aware of the dangers of drug use both in the short and the long term.

![Figure 1: Reasons for drug use among senior high school students 15-17 years old (n=307)](image)

**Table 1: Frequency of drug use among senior high school students 15-17 years old**

<table>
<thead>
<tr>
<th>Variable</th>
<th>% Incidence</th>
<th>Number Respondents / group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>68</td>
<td>311</td>
</tr>
<tr>
<td>Rarely</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>23</td>
<td>313</td>
</tr>
<tr>
<td>Rarely</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>76</td>
<td>313</td>
</tr>
<tr>
<td>Rarely</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Ecstasy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>91</td>
<td>310</td>
</tr>
<tr>
<td>Rarely</td>
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</tr>
<tr>
<td>Monthly</td>
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</tr>
<tr>
<td>Weekly</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
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<td></td>
</tr>
<tr>
<td>Amphetamines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>90</td>
<td>288</td>
</tr>
<tr>
<td>Rarely</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>2</td>
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</tr>
<tr>
<td>Weekly</td>
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</tr>
<tr>
<td>Daily</td>
<td>1</td>
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</tr>
</tbody>
</table>

**Focus 2: Diet and Drug Use**

Overall in females there is a significant inverse relationship between alcohol, amphetamine, ecstasy, tobacco, but not marijuana, use and poor diet scores (see below). It is not possible to ascertain whether the drug use resulted in poor diet or whether both co-exist. Of the 152 girls who responded, analysis showed an inverse relationship between drug use scores and a poor diet – tobacco use (p<0.03), alcohol (p<0.02), ecstasy (p<0.03) and amphetamine (p<0.02).

No significant relationship between diet score and drug consumption in males was found, although p-values of 0.1 and 0.2 suggest a possible non-significant trend in this direction. It is possible that males are partially protected from adverse diet effects owing to their higher exercise levels compared to girls.

Essential physiological relationships also exist between obesity and poor exercise levels. The traditional view that overweight and obesity is exclusively the result of over-indulgence in energy-dense, nutrient-poor foods with high levels of sugar and saturated fats is widespread. This is not necessarily the case promoting an urgent need to raise awareness about the multidisciplinary origins of this condition.

**Focus 3: Drug Use and Health/Wellbeing Ratings**

Overall there is a highly significant correlation (p<0.001) among low self-assessed health/happiness scores, high stress levels and drug use for both male and female students. Specifically, feelings of low health/wellbeing and drug use are highly significant for alcohol, marijuana and tobacco in both males and females. Happiness did not score but there is a correlation between ecstasy (male), marijuana and tobacco (female) and stress. It is not possible to unearth the order of appearance; whether drug use causes low self-assessed health/happiness or vice versa. Disturbingly, however, 16-17 year-olds seem to have access to a thorough range of legal and illegal drugs. Consumption is widespread despite precautionary information freely available online from reputable government and NGO sites along with blogs, Tweets and Facebook.

Relationships between drug use and self-assessed health/happiness and stress scores (number of respondents/group) are identified below:

- **Health:** Significantly poorer health ratings were found with increased drug use for tobacco (males p<0.001 – 156; females p<0.001 – 151), alcohol (male p<0.05 – 155; female p<0.004 – 152), and marijuana (male p<0.001 – 155; female p<0.02 – 152). Low p-values for amphetamine and ecstasy (p<0.1; p<0.3) suggest a similar, but non-significant trend for these drugs for both genders.

- **Happiness:** Increased marijuana use occurred in more “unhappy” males (p<0.05 – 155), and increased smoking occurred in more “unhappy” females (p<0.10 – 151). No relationship between happiness and marijuana use in females or happiness and smoking in males was found.

- **Stress:** High ratings of general everyday stress levels and drug use were significant for marijuana and ecstasy use in males (p<0.03 – 155; p<0.05 – 151) respectively; and greater tobacco use (p<0.02 – 151) in stressed females. A non-significant trend was observed between high ratings of general everyday stress levels and drug use for marijuana use in females (p = 0.067) and remaining drugs (p = 0.105-0.249).
Focus 4: Drug Use vs. Health/Wellbeing by Country of Birth

Overall low ratings of health and wellbeing/happiness were significantly correlated with drug consumption behaviour regardless of country of birth (as indicated by participants).

Health: Australia and New Zealand - tobacco (p<0.001), alcohol (p<0.02), marijuana (p<0.001), ecstasy (p<0.003) and amphetamine (p<0.02); Americas (US/Canada/S America) - tobacco (p<0.01), marijuana (p<0.01); Micronesia/Malaysia - tobacco (p<0.03).

Happiness: Australia and New Zealand - tobacco (p<0.004), alcohol (p<0.02), marijuana (p<0.005) and ecstasy (p<0.003); Americas (US/Canada/S America) - tobacco (p<0.01), alcohol (p<0.01), marijuana (p<0.01), ecstasy (p<0.01); and amphetamine (p<0.01); Europe – tobacco (p = 0.461), alcohol (p<0.01), marijuana (p<0.05); Africa - tobacco (p<0.01).

Stress: Australia and New Zealand - tobacco (p<0.02), marijuana (p<0.02), and ecstasy (p<0.05); Americas (US/Canada/S America) - tobacco (p<0.01); marijuana (p<0.01); Micronesia - alcohol (p<0.001).

Strong negative correlations between drug use and low health ratings was also indicated for other countries but these categories, having fewer than 20 respondents per cohort, are not listed. On the whole, however, cultural variation was found to be low.

The majority of students were aware that amphetamine (p<0.03 – 111), ecstasy (p<0.07 – 111) and marijuana (p<0.04 – 111) use have both short- and long-term negative health effects but consumed regardless. Interestingly, the drug that students responded with the lowest number of short-term health effects was nicotine but they did catalog long-term negative health effects highest for both nicotine and alcohol – even acknowledging that smoking significantly (p<0.05 – 149) accentuated the short-term effects of all other drugs consumed. Consequently, it is apparent that a majority of students are well aware that drug-consuming behaviours significantly reduce their health and wellbeing but choose to disregard this knowledge.

Figure 2: Frequency of alcohol use and intimacy amongst male senior high school 15-17 years old

Focus 5: Frequency of Drug Use, Intimacy and Sexual Activity

A significantly (p<0.001) greater frequency of alcohol use was seen in both male and female participants who had been intimate with or without sexual activity (Figures 2 & 3). This relationship is also present in those who have had just sex excluding intimacy. Likewise, there was a significantly greater frequency of marijuana use in males and females who have been intimate (p<0.005 males, p<0.004 females). There was also a significantly greater frequency of marijuana use and sexual activity excluding intimacy in males and females (p<0.002 males, p<0.001 females) as was the frequency of tobacco use in males and females who have been intimate (p<0.004 males, p<0.01 females) and who have had sex (p<0.01 males and p<0.001 females).

Figure 3: Frequency of alcohol use and intimacy amongst female senior high school students 15-17 years old

There was no significant relationship between amphetamine use and intimacy in either male or females, but was significant for sexual activity (p<0.04 for males and p<0.03 for females). As far as ecstasy was concerned, no significant relationship was observed in males and females with intimacy or sexual activity in either males or females.

Drug taking did not correlate with the number of sexual partners in males or females. What was of consequence, however, was the significantly lower happiness (p<0.002) and satisfaction (p<0.03) ratings reported in girls who had sexual intercourse compared with those who had not. There was also a non-significant (p=0.167) trend towards higher stress ratings in girls with sexual experience. No such correlations were found in boys.

Figure 4: Intimacy and sexual experience by region of birth (n=319)

It seems that students are well acquainted with sexuality and have wide experience on the whole with several partners before age 17 as disclosed in the data.
Of interest is that sexual experience and drug use is correlated i.e. sex and drugs are linked in the lifestyle of senior high school students aged 15-17 years. However, no significant correlation was found between students' awareness of what they may do to maximize their mental health and wellbeing and the number of sexual partners.

Focus 6: General Awareness of Contraception – whose responsibility is safe-sex precautions?

Overwhelmingly the condom (30% for boys, 28% for girls) and the condom combined with the oral contraceptive pill (22% for boys, 19% for girls) were considered the most effective contraception method by gender and region of birth. The contraceptive pill was not considered as effective as the condom or its combination with a condom (2% for both boys and girls). Abstinence and the female diaphragm were considered by less than 1% of all students to be effective.

Most male and female respondents were of the opinion that the responsibility for ensuring safe-sex precautions lay with both partners (42% for boys, 43% for girls), themselves alone (8% for boys, 4% for girls); their partner (1% for both boys and girls) and for neither (less than 1% for boys and girls) – all independent of region of birth.

Discussion

Structured questionnaire data provided by senior high school students 15-17 years of age living in the inner city and surrounding suburbs of Sydney (Australia), was examined from the perspectives of lifestyle choices, health/wellbeing ratings and sexual experience. Male and female respondents have ready access to tobacco, alcohol and a variety of illegal drugs. The strongest motives for drug consumption were enjoyment and peer pressure, although addiction, anxiety, depression and a desire to “forget problems” were also given as reasons for their drug use. There were no gender differences in type of drug chosen and frequency of consumption; although, a significant inverse relationship between tobacco, alcohol and illegal drug use and poor diet scores in female students was identified. No such relationship existed between diet score and drug consumption in male students. Notably, the data also revealed a highly significant correlation between low self-assessed health/happiness scores, high stress levels and alcohol, tobacco and marijuana use for both boys and girls. The strong inverse correlation between health/wellbeing, stress, happiness ratings and tobacco, alcohol and illegal drug use held regardless of country of birth. Concurrently, the majority of students were well aware of the short- and long-term negative health effects of their drug-consuming behaviour but indulged despite the consequences.

Our questionnaires also established that many Australian students would seem to be well acquainted with sexuality and have, on the whole, wide experience with several partners before age 17. A significant correlation between adolescent sexual experience and augmented drug use was found in both male and female respondents; however, the self-assessed happiness/satisfaction ratings in girls who had sexual intercourse was significantly lower compared with those who had not. No such correlation was found in boys; thus, in point of fact, paralleling the inverse relationship between drug taking behaviour and low health ratings in female students. Encouragingly, however, was that an overwhelming majority of respondents considered that the condom and the condom combined with the oral contraceptive pill to be the most effective contraception method. Equally the students were also of the opinion that the responsibility for ensuring safe-sex precautions lies with both partners. These findings held true for gender and region of birth.

Issues of drug use and sexual experience as they adversely relate to health and wellbeing in the young are major public health concerns and, disturbingly, 15-17 year-old Australian youth have ready access to a whole range of legal and illegal drugs. The issue that adolescent sexual experience and heightened substance use are significantly interrelated is not surprising and is supported by similar reports from; for example, Canada and the United Kingdom. However, the present study identifies important gender associations between drug and sex behaviours and low health/happiness ratings in adolescent girls but not in adolescent boys. These observations are critical and require more in-depth investigation.

Poulin et al reported a series of complex interacting factors among gender, substance use and age that can increase the risk of depressive symptoms in the general adolescent school population. Among males, depression risk was not related to age; among females, depression risk was related to age in a non-linear manner peaking at 15-16 years of age. Further, age and associated depression risk was significantly related to the pattern of drug use where younger female adolescents are at greater risk compared with older adolescents. There is mounting evidence supporting the forewarning signs that, on average, girls are maturing years earlier when compared with the 1950s to 1970s, predominantly, it is thought, due to improvements in nutrition. Understandably, the younger the girls experiencing puberty the more immediate the risk of becoming isolated and perhaps depressed, stimulating the decision to start smoking, become sexually active or become interested in other drugs carrying serious health consequences. However, the order of appearance is not possible to ascertain; whether drug use causes low self-assessed health/happiness ratings or low rating encourages drug seeking behaviour. In the final analysis, health and ill-health are dependent on the conditions under which we live and the ways in which we behave. Of particular concern is that addiction and depression may well impair a young person’s competence to make informed rational choices such as whether to partake, or not, of certain recreational drugs or whether to enter the adult world of sexuality.

The links between adolescence, drug intake and sexual experience can be described in a variety of ways but they are, essentially, biological in nature. Puberty is a gradual and complex period in an individual’s life during which adolescents reach sexual maturity and full reproductive potential. The onset of puberty in a girl occurs around ten years of age when her previously-dormant hypothalamic-pituitary-gonadal (HPG) axis is activated stimulating accelerated growth and development of the secondary sexual characteristics. The period of adolescence, as the individual passes through differing stages of development, is experienced as a changing kaleidoscope
of physical, cognitive, emotional and social capacities. In essence, adolescence is the period of life that takes on special characteristics where each and every aspect of being is impacted, where habits formed may promote or hinder ongoing personal development. Indeed, for many individuals, puberty ushers in profound changes in patterns of risk taking relating to health. It is a time when many individuals will first experiment with substances such as alcohol, cigarettes and marijuana.\(^2\)

As indicated above, varying statistics from differing sources have shown that the age at which girls reach puberty and undergo menarche (first menstruation) has decreased significantly\(^9,10\) and that precocious puberty in girls appears to be 5 times more likely compared to boys\(^11\). The early onset of secondary sexual characteristics such as breast buds and pubic hair is fuelling a growing fear that early maturity, lack of experience of drug use and its effects, and increased engagement in teenage sexual intercourse may generate the beginning of long-term ill-health. Precocious puberty is defined as “the appearance of secondary sexual characteristics in girls under 8 years and in boys under 9 years of age, the presence of menarche for girls under 9 years of age indicates sexual precocity”.\(^12\) Early engagement in sexual activity as a result of early puberty has both biological and psychosocial grounding. Biologically, rises in hormones such as DHEA (dehydroepiandrosterone), testosterone and estradiol; which are all released at high levels during puberty, are involved in establishing feelings of sexual attraction.\(^13,14\) Additionally the physical changes of the body, such as the development of the breasts and fat deposition on the hips make these young girls more attractive to males, and consequently a sexually mature female appearance results in attraction from more sexually mature males. The age at which precocious puberty occurs varies with heredity and ethnicity\(^16\) but it is an increasingly worldwide phenomenon regardless of heredity and ethnicity. Australian teenagers form a transnational, multi-ethnic group with differing backgrounds; thus, the mixing of genetic factors and ethnicity may in future become a major indicator of precocious puberty among Australian girls.

For the meantime, parents globally are expressing their concern whether the combination of early development in girls’ physical appearance combined with teenager sex being freely portrayed through the media, may push the faster maturing girls to embrace risk taking behaviour in alcohol/drug consumption with sexual intercourse before they are cognitively and psychologically ready.\(^12,15\) For example, the popular Hollywood movie ‘American Pie’\(^2\) was received favourably by young viewers worldwide. Images and signs across all media platforms provide mixed messages to girls about the right way to pursue ones sexuality or more generally, what is considered normal. It has been reported that girls who matured earlier showed greater interest, compared to later maturing girls, in seeing sexual content in movies, television, and magazines, and in listening to sexual content in music, regardless of chronological age or ethnicity.\(^16\) Exposure to sexualized media would no doubt influence a young girl’s view of herself, her surroundings and give her education about lifestyle choices that can be made at a stage when emotional and cognitive capabilities to make serious, informed decisions are not fully developed.

Another confirming survey study by Skinner et al.\(^17\) showed that Australian adolescents who are physically and emotionally ‘ready’ to engage in sexual intercourse are more likely to postpone the experience until they are comfortable with the partner and their relationship. Personal control is reported as one of the reasons for delaying intercourse. The survey also noted that peer pressure, specific coercion from sexual partners, and being intoxicated were the main reasons for premature and unwanted sexual intercourse.\(^17\) Therefore, greater physiological and psychological insights linking early onset of puberty to sexual intercourse and substance abuse is essential within a more holistic context of social and/or environmental factors that may contribute to a sub-group of adolescents running higher lifestyle risks compared with their peers. It has been reported that girls who have gone through puberty early are twice as likely to have been pregnant or aborted a pregnancy at the age of eighteen, compared with their peers.\(^18\)

Substance use and abuse is influenced through the brain’s dopamine reward pathway. Sexual activity also influences the dopamine reward pathway and both can lead to addictive and promiscuous behaviour.\(^19\) Dopamine is a neurotransmitter of the brain that generates the subjective feeling of pleasure or happiness and for this reason has been dubbed the ‘courier of addiction’. All drugs that are addictive activate the dopamine cells of the ventral tegmental area to enhance the amount of dopamine that is released in the nucleus accumbens; for example, alcohol stimulates the nucleus accumbens increasing amiability and attractiveness in social settings, and ecstasy stimulates euphoric feelings as its earthy term ‘the love drug’ implies. More recent research has established that dopamine is also the messenger that appears to operate in excess during adolescence\(^20\). By the strategic use of functional magnetic resonance imaging (fMRI) in conjunction with reward paradigms, it is now possible to substantiate the hypothesis that the dopamine system is hyper-responsive during adolescence, establishing that adolescence is the developmental period characterized by increased reward-seeking behaviour.\(^20\) Heightened stress such as occurs in individuals experiencing precocious puberty, may carry other significant consequences relating to reward-seeking behaviours. Increased concentration of the stress hormone cortisol speed up the responsiveness of the dopamine reward system\(^18\); thus, further enhancing the cycle of reward-seeking behaviour.

The causes of precocious puberty have been fiercely debated, with the most accepted grounds for such early development linked to diet components and obesity, genetic growth disorders related to hormones, chemical pollution in the food chain and hormonally-active chemical contaminates present in the environment.\(^3,21,22\) Other theories suggest exposure to unrelated male pheromones and father absenteeism, constant societal demands, and sexualized image bombardment could possibly be triggering changes in the brain’s chemistry accelerating developmental change toward sexual maturity.\(^16\) All of the above theories carry existing evidence, but differing levels of definitive proof. As a

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\(^2\) The film concentrates on four boys who make a pact to lose their virginity before their high school graduation.
relatively new phenomenon, a low percentage of infants who were conceived by assisted reproductive technology (ART) are also showing signs of precocious puberty possibly due to their prenatal exposure to exogenous sex steroids; thus, increasing awareness that an artificially altered intrauterine environment may impact on developmental stages in children conceived by ART. Long-term data and a safe threshold for estrogen use are yet to be determined.

Controversy as to which theory best fits atypical maturation aside; the evidence for its existence is solid, as is the heightened emotional-behavioural problems experienced by early maturing adolescents and young adults. Therefore, the question could possibly be asked ‘Is it time for our perceptions of normality to change?’ Currently, young girls experiencing precocious puberty at an awkward age face difficulties to define their place in their immediate surroundings. A more pragmatic acknowledgement of the science by parents and teachers alike may help to ameliorate the worst negative consequences. It is worth highlighting at this point that student respondents participating in our questionnaire commented on the lack of sex and drug education provided by their parents and by means of the education system. Biomedical issues such as described here are challenging as they involve the status quo, ethics, empowerment and justice across the generations – all matters of societal concern and responsibility. Bioscience ethics, by facilitating free and accurate information transfer from applied science to applied bioethics, may overcome some extant difficulties when communicating matters of socio-political significance. It is here that schooling can play a significant role by providing students with informed, supportive and positive learning environments. The availability and use of digital technologies in schools through blogs and wikis set up by teachers now facilitate student engagement in discussion of personal, sensitive topics in a non-identifiable online environment.

Conclusion and Schooling Implication

Lifestyle choices and attitudes to health and wellbeing are a consequence of both genetic and epigenetic variables. Schools are one place where such choices and attitudes can be debated in an informed, positive and supportive learning and teaching environment. However, across many Australian schools education regarding safe sex practices is often not taught in the classroom until students reach high school and for early maturing girls this may not be in time before their first sexual experience. Even lessons on reproductive biology, minus sexuality, are generally not taught until the late primary school years when students are 10-12 years old. To overcome predictable problems, education is an obvious, if not perfect, solution. Girls and boys should be educated about puberty at an appropriate age that correlates with their biological rather than with their chronological age in a learning context that minimizes embarrassment. They should be informed about the physiological changes that go on in their bodies, the emotional and psychological changes they will encounter and, importantly, corresponding changes in the other gender. Sex education with emphasis on safe sexual practices should also be introduced earlier coinciding with their learning about the physiology of reproduction. There should also be education platforms created that explains the risks of drug use and its effects on health including reproductive health and responsibility.

The phenomenon of addiction can be seen as the perfect integration of biological and behavioural factors where experiences that switch genes on and off have biochemical impacts; for example, in at-risk cases drinking and smoking habits may, in turn, increase the risk of major depression in those with a genetic predisposition to depression. Additionally, severe drug addiction is not readily treatable; thus, it becomes critical that targeted counseling should also be available to help young people deal with problems that they may encounter during this period of rapid change. Importantly, prevention rests on early drug awareness education so that potential teachers and parents can make socially responsible choices that help to protect the health of those in their care. Informational programs on their own are frequently ineffective as they may change individual knowledge but not necessarily behaviour. More encouraging outcomes could be found in programs that combine some kind of social competence training with a community wide involvement aimed not only at adolescents but also at their peers, parents and teachers. Such multifaceted efforts, especially if the programs begin when youngsters are preadolescent, ought to be effective in adaptively transforming the learning environment through personal and interpersonal skills development.

In the final analysis; therefore, all the above can be ethically managed with sensitivity and care on the part of parents and teachers. Today’s adolescents must not be ignored and need to be informed about self-respect, love and health, and the consequences of risk taking behaviour. In order to reach adaptive and responsible socio-ethical decision making, accurate biological information must be intelligible and communally accessible. It is in this context that we invite the reader to access the web portal at http://www.bioscience-bioethics.org/ which provides free admittance to educational material in the area of stress physiology, reproduction, developmental toxicology and other useful links for those interested in bioscience ethics and bioethics. Within this context, it is time that sex and related issues be advanced in educational institutions and in the family setting. Without widespread discussion in the classroom and the home, there can be little support between peers battling the same emotions and feelings as they transit into adulthood.

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References

Humanism in medicine as the main premise for rethinking medical ethics education

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“The goal of medical education is to produce the physician we would like to see if we are sick” - Melinkoff

The great humane physician William Osler remarked “The education of the heart- the moral side of man- must keep pace with the education of the head. Our fellow creatures can not be dealt with as man deals in corn and coal.” The most important premise for medical ethics education is the view of medicine as a humane enterprise. The medical profession enjoys the privileges of autonomy in practice and self-regulation in society. In return the society expects two fundamental attributes from the physicians- expertise in the scientific aspects of medicine and humanistic care. Unfortunately it is commonly observed now that the ‘human touch’ is not there in the practice of medicine. Samuel Le Baron remarked “W(w)e have lost a healthy and necessary balance in the learning and professing of medicine between knowledge(science) and wisdom(humanism). The word humanism has many connotations. In the context of medical practice it is used in the sense of “an attitude towards other people vaguely described as ‘love of man’”. The word is derived from the Latin ‘humanitas’. According to Pellegrino, humanism includes cognitive and affective components, the cognitive aspect pertaining to the physician as a human and the affective component referring to the physician’s feelings towards the patient as a person. Presently it is the affective component that is implied when the word humanism is employed- perceiving the patient as a whole human being situated in his/her psychological and social context. Humanism in medicine is defined as “the physician’s attitudes and actions that demonstrate interest in and respect for the patient and that address the patient’s concerns and values.”

The concept of humanism in medical practice has a long history, since the beginning of the Hippocratic tradition. In ancient India, the Caraka Samhita and Susruta Samhita laid down the codes of conduct for the physicians, students of medicine and their educators. “Thou shalt behave and act without arrogance and with undistracted mind, humility and constant reflection, thou shalt pray for the welfare of all creatures”- Caraka Samhita.

It cannot be disputed that the responsibility of educators of medical professionals lies in producing future physicians who exhibit the quality of humility and...
The Epistemological Importance of Informed Consent in Clinical Research

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Abstract
This paper attempts to establish the epistemological import and limits of informed consent in clinical research. It points out that informed consent is a necessary requirement in clinical research because it ensures adequate participation of care receivers in issues relating to their health. Besides ensuring that care receivers have knowledge of whatever medical intervention they are consenting to, informed consent, as an ideal, provides assurance that care receivers and others are neither coerced nor deceived. While the question of the value of disposition to honour the dignity of their colleagues and patients as fellow human beings. Patients who approach the medical professionals have two kinds of needs: clinical needs and interpersonal needs. Interpersonal needs can be fulfilled only by humanistic physicians who possess the qualities of integrity, honesty, respect for persons, empathy, compassion and altruism.

In the past, the technical aspects of health care diagnosis, therapy and prognosis were not so advanced as they are today and “often the physician had only a good bedside manner to offer”. But now that there is knowledge explosion and technological developments by leaps and bounds the tendency is for the ‘science’ of medicine to dominate over the ‘art’ of medicine. The focus of ethics teaching is presently on problem solving or “dilemma ethics”. The educators of medical students must focus on the affective component of clinical ethics.

Professional organisations all over the world have drawn attention to the need for emphasis on the this aspect of the profession.

It is true that humanism cannot be taught as a subject. Formal curricula may not be totally effective in inculcating humanistic behaviour in the medical students. Humanism should be imbied by the students and expressed in day to day experiences of the students in their encounters with their patients and colleagues. Positive role modelling by the teaching faculty and other members of the health care team can effectively shape the attitudes and behaviour of students. It is essential that the students themselves are treated with respect, care and compassion by their superiors to create an atmosphere conducive to assimilation of humanistic values. A pragmatic teaching method is presented by Branch and colleagues which includes taking advantage of seminal events, role modelling and using active learning skills.

Medical students, when they enter the medical school, are idealistic and they have the desire to become competent, caring and compassionate professionals. They are empathic, ready to listen to the patients in order to find out the perspectives of the patients. In the fast-paced clinical settings they lose sight of their idealism in order to fit into the system. Efforts are required on the part of the educators to enable the students “to keep alive the core values, validate their importance and learn to incorporate these into professional work.” Opportunities must be created for students to identify the patients’ perspectives, time allowed for reflection and focused mentoring provided by senior professionals because unguided reflection may prove to be counterproductive.

If the educators of medical professionals can motivate the young students to realise the essence of what the famous physician William Osler said more than hundred years ago that it is more important to know the patient who has the illness than to know the illness the patient has, they will succeed in making humane future doctors. The idea is not to demean the value of knowledge and skills in medical profession, but it is to emphasise the significance of attitudes, because physicians are much more than technical experts from the perspective of the patients.

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The Epistemological Importance of Informed Consent in Clinical Research

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Abstract
This paper attempts to establish the epistemological import and limits of informed consent in clinical research. It points out that informed consent is a necessary requirement in clinical research because it ensures adequate participation of care receivers in issues relating to their health. Besides ensuring that care receivers have knowledge of whatever medical intervention they are consenting to, informed consent, as an ideal, provides assurance that care receivers and others are neither coerced nor deceived. While the question of the value of patient compliance, the perspective of the patient is crucial.
informed consent in health care delivery is not so much controverted, in contest is the question of whether or not complete and wholly specifically informed consent can indeed be realized in medical intervention. Two orientations are identified in this debate. One insists that an individual will be able to make an informed decision and make reasonable choices amongst alternatives when fully informed. The other orientation sees as an epistemic illusion, achieving full informed consent, and rather opts for informed request. This paper examines this debate by clarifying the notion of informed consent, its components and its nexus with knowledge. The position of the paper is that informed consent is not only an ethical ideal in clinical research and health care; it is also an epistemic virtue that must be continuously strived towards. This paper establishes that health care receivers can only have an epistemic claim of their medical situation if all requirements of informed consent in health care delivery such as provision of adequate information, the risk and benefits of treatment, avoidance of vague/ambiguous statements, voluntariness, etc. are met.

**Keywords:** informed consent, epistemology, autonomy, health care, clinical research

**Introduction**

Epistemology and ethics are interrelated areas of philosophy. In the area of philosophy of medicine, this nexus plays out as well, though unusually recognized. In this paper, our intent is to critically discuss the epistemological import of informed consent in health care delivery. In doing this, the paper shall delve into the meaning and features of informed consent in relation to health care. In exploring the epistemological implications and limits of informed consent, conceptual analysis of knowledge and its conditions is provided. Consequently, the paper examines the connection between informed consent and knowing with some concluding critical notes.

**Informed Consent: Some Clarifications**

Aderogba, a 58 year barrister had received treatment for prostate cancer. At the time of diagnosis, investigations revealed local spread of the disease but there was then no evidence of systemic spread. 
Following initial treatment, he remained well for one year when the picture changed radically. The cancer had spread to several bones and, in particular, his spine. He was told of his diagnosis which he accepted in due faith. Because of his situation, he viewed life has a great mystery. Few months after, his physician told him about the area of philosophy of medicine, this was a positive one. Aderogba ignorantly consented and signed the informed consent form given him by the physician.

The above clearly shows the case of a research participant who consented to research procedure without information and knowledge. What then is informed consent?

Informed consent is very much prominent in modern bioethical discussions. It is a concept that recognizes the importance of the patient in health care system. Ideally, a patient who visits a physician is meant to divulge certain medical history about himself to the physician and the physician is equally meant to carefully digest the information given to him by the patient. This information is meant to assist the physician in the process of diagnosis. This is also applicable to research in health care delivery where prior information given to the patient is important in decision making. As an ethically acceptable medical practice especially when taking actions that concern others, informed consent can either be on medical treatment or on research on human subject. For the purpose of this paper, informed consent is used and understood in the latter sense.

Voluntary request and informed consent of human subjects have been the central focus of non-therapeutic research on human experimentation. There is a serious concern in research as a whole especially in relation to the involvement of research participants who are unable to consent to intervention. Research on human subject is a worrisome practice and this accounts for why there remains no satisfactory ethical justification for the inclusion of incompetent adults and children without any immediate intended benefits in the clinical research outcome. These set of individuals are seen as belonging to a vulnerable group. The inclusion of children has been extensively discussed in bioethics debates, and to this effect, it has been addressed in legislation and recommendation.¹

We cannot dispute the fact that research on humans are vital because of the obvious and challenging problems faced in health care system on daily basis. These problems require urgent attention especially in the wake of high number of avoidable death recorded on a daily basis on health deficiency ground. Some of these problems are not new while some are recent medical problems. Medical research have led to proffering cure to all sort of diseases such as cancer, leukemia, dementia, HIV etc. This has no doubt promoted the public good hence the need for research.

On the above premise, informed consent is important and necessary in medical practices specifically in clinical research; though there are some basic difficulties confronting it. We cannot give informed consent when we are very young or very ill, mentally impaired, demented or unconscious, or merely frail or confused. Often people cannot give informed consent to emergency treatment.² Besides these problems, even in cases of adult with maturity of minds, we must also note that the way in which persons comprehend information differs. One may probe further the cogency of informed consent by asking whether or not a competent care receiver whose consent has been sought with full information disclosed and discussed is disposable to responding more positively to care and treatment than a care receiver without informed consent.

This is a very important question to be considered. There are two sides to addressing this vital question. On one hand, a patient who has adequate information of his health in general and who is well informed of the research procedure he wants to engage in may respond positively to treatment. Some patients respond better when they are informed and know of the intended intervention. Such patients consciously decide to care less about the painful medical procedure in such research with the sole intention of achieving a positive
end. For such patients, knowing is a contributing factor to their health.

On the other hand, some patients may have a different outlook of life after knowing. In fact, they make a very radical decision by not even wanting it to work. Such patients may consciously decide not to cooperate in any way with the care giver considering the fact that the cooperation of the care receiver matter a lot in care delivery. Dealing with difficult patient in the process of care can be quiet frustrating and the objective of intervention may be a mirage. However, whether knowing yield a positive result for some and yield otherwise for the other does not make knowing and information giving not worth pursuing. Informed consent in research is a medical necessity that must be pursued giving all due recognition.

Components of Informed Consent

Having understood what informed consent is there is a need to point out the vital features of informed consent. Informed consent consists of two major components. One is the physician’s disclosure of all necessary information to the patient. This information must include diagnosis, prognosis, available and alternative treatment, and the risk, benefits, and consequences of having or refusing treatment. The second component is the consent of the patient who decides whether to accept or refuse treatment on the basis of the information provided.

Informed consent in clinical research has highlighted in Ad protocol, 2005 Art.13 should include the purpose of study, study design, risk and benefits, alternative to participation, duration of study, voluntariness and confidentiality of personal data. We may therefore ask if all these requirements are met before enrollment of research participants and if yes, can we be sure that participant fully get the information right.

The Nuremberg Code is a response to notorious abuses in researches in the past. This code establishes voluntary and informed consent of the human subject as the grounding principle for the ethical conduct of research. Voluntary consent according to the Nuremberg Code is defined in terms of the following: “This means that the person involved must have legal capacity to give consent should be so situated as to be able to exercise power of choice without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and should have sufficient knowledge and comprehension of the elements of the subject matter involved to enable him to make an understanding and enlightened decision” (Nuremberg Code).

Despite the cogency of this code, we cannot pretend as if it does not have its limitations. Deducing from the above quotation, this code says that person involved must have legal capacity to consent. But what about a situation where the concerned person is not legally competent to consent? The inadequacies in Nuremberg Code was addressed and recognized by the World Medical Association’s Declaration of Helsinki. The declaration states that in case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation.

Informed consent goes beyond informing and consenting. There are situations where consent is given as a result of coercion or manipulation. This cannot be considered as a genuine consent even if the patient is fully informed and fully understands. Coercion sounds very cruel and is something to be discouraged in health care delivery. This is the same to paternalism in doctor patient relationship where the physician believes s/he always knows better than the patient. However, it is not all unlikely that information might be provided to the patient in a way which will lead to the patient choosing as the practitioner would wish.

The above mentioned requirements of informed consent need to be further explained. In research, it is expected that the participant be given adequate information in comprehensible form. This is necessary in order to avoid participation in the absence of knowing. This is what is referred to as informed consent form. The informed consent form states very clearly all that the research is all about. These requirements are highlighted and briefly explained thus:

**The Purpose of research:** The informed consent form should state the purpose of the research. Why the research? What objective does it hope to attain? What are the contributions of the research to human life and existence? How can the research help develop the area of medicine and knowledge acquisition. All these need to be fully explained in the informed consent form

**The protocol purpose:** Research protocol is also given to research ethics committee before the approval of the research. Research ethics committee and research review board can either approve or deny the protocol as long as they are not satisfied with the content of the research protocol. This is done in order to ensure the protected of individual right and dignity.

**The study design:** The study design is included in the informed consent form so that patient can know and understand the pattern the research is going to take.

**Risk and benefits:** There is no research without its risk and benefit; therefore, the researchers should endeavor to provide the participant the likely risk in participating and also with the things to be benefited in participation. We cannot dispute the fact that there can be unexpected risk but information on the expected one should be made available in order to help in decision making in either to participate or not.

**Alternative to participation:** This like any other requirement of informed consent is also very important. The patient needs to know the alternative to participation. As a patient, if I am not participating, what do I lose? What other treatment is available for those who have chosen not to participate? This must be told with all sense of sincerity. The researcher does not need to present terrible situation to the patient so that he feels the best decision is to participate.

**Duration of study:** The patient need to know how long the research is taking. When the research is starting and when is ending. This will ensure proper planning and enable patient to have an already made mind set.

**Voluntariness.** In an ideal situation, it is expected or assumed that a person have the right to voluntarily accept or reject any offer. Acceptance of any proposal should be strictly voluntary and not through coercion. Equally, the patient should be allowed to exercise his or her right to refuse or to withdraw from intervention when he feels uncomfortable at any stage or phase.
Confidentiality of personal data: Certain information is needed before a person can be enrolled in research. Ideally, some research has age range. This is a convenient way of searching for those that truly qualify to participate in research. This information is meant to be kept strictly confidential and not be made available for public consumption.

It is worth noting that if any of the components is missing then, informed consent has not been met. It takes only a patient who has an in-depth understanding to either refuse or accept any intervention. However, a combination of these components is necessary but may be difficult to attain. These components can only be attained when we spell out the necessary requirements needed for a patient to be capable of consenting. Here comes in the issue of competency. Competency in decision making is a major problem with informed consent. How can we define competency and when is a person said to be capable of consenting? Who determines a competent patient? What happens in case of incompetency?

Having discussed the meaning and components of informed consent, there is a need to do a conceptual clarification of epistemology i.e. knowledge in a bit to bring out the epistemological import of informed consent.

What is Knowledge?
The concept of knowledge is the central concern of the field of epistemology. In Philosophy, there is no way we can possibly discuss knowledge without situating it in epistemology.

In the literary sense, there are two usages of knowing. The two senses are ‘knowing that’ and ‘knowing how’. To ‘know that’ could mean to have a fact and information about something, while ‘knowing how’ means the ability, proficiency and skill to do something. With this explanation, it is clear that there is a difference between ‘knowing that’ and ‘knowing how’. It is possible to know that something is the case and may not be able to know how. For example, if I can swim, I can as well make a categorical statement that I can swim and may not be able to explain how I do it. This is not the case in Philosophy; when you claim to have a knowledge claim of something you should be able to justify further that the claim is true.

Epistemology is a branch of Philosophy that is concerned with the nature and scope of knowledge. The Latin word episteme means knowledge or knowing. Thus epistemology is knowledge or the study of knowing. Epistemology addresses questions such as what is knowledge? How is knowledge acquired? What do we know? How do we know that we know what we claim to know? How certain is our knowledge claim? While these questions can be slightly confusing for common man, philosophers ponder on these questions in an attempt at coming up with plausible answers.

Like Philosophy, there is no universal acceptable definition of knowledge because there are divergent definitions provided. Not until 1960 when Edmund Gettier wrote a provocative essay to debunk these existing criteria of knowledge, for a very long time, the traditional definition of knowledge as justified, truth, belief was greatly embraced by scholars and considered a sufficient definition of knowledge. The traditional definition of knowledge as justified, truth and belief states that ‘S’ knows that ‘P’ if and only if ‘P’ is true, ‘S’ believes that ‘P’ and ‘S’ is justified in believing that ‘P’. This definition of knowledge goes in line with Ayer and Chilsom’s definition of knowledge. Gettier argument’s is that the traditionally held notion of knowledge cannot be considered an adequate definition of knowledge because it is possible for a person to be justified in believing a proposition that is in fact false. Knowledge is more than mere belief. When you claim to know something; you must also understand what you claim to know. Epistemology also states the difference between believing something and knowing something. You can believe something but that does not need to be right or wrong. In other words, you can believe in something and it could be right or wrong. On the other hand, if you know something, it cannot be wrong, as knowledge is absolute while belief is not. You continue to believe in things only when you are not sure of them. The moment you are sure of something, in other words, the moment you are certain about something, you stop believing it, as you know it.

It is important at this juncture to establish the connection between informed consent and knowing this would assist a great deal to bring out the epistemological import of informed consent in clinical research.

Informed Consent and Knowing
Informed consent is closely linked to knowing. Information gives the opportunity to know and knowing guarantees and secures consent. The patient needs to know or have knowledge of what h/she is consenting to. Knowledge opens up a wide range of understanding without which one cannot make an informed choice or decision.

Some lessons can be deduced from the citation of Isaiah Berlin. He writes:

I wish my life and decisions to depend on myself, not on external force of whatever kind. I wish to be the instrument of my own, not of other men's acts of will. I wish to be a subject, not an object to be moved by reason, by conscious purposes, which are my own, not by cause which affects me, as it were, from outside. I wish to be somebody, not nobody; a doer- deciding, not being decided for, self-directed and not acted upon by external nature or by other men as if I were a thing, or an animal or a slave...I wish, above all to be conscious of myself as a thinking, willing, active being, bearing responsibility for my choices and able to explain them by references to my own ideas and purposes.

The above quotation points to important thing that cannot be undermined. It shows very clearly the importance of autonomy, individual decision making capacity, and rejection of paternalism whether in clinical research or health care. In clinical research, if all the stipulated guidelines and conditions are fully explored, the potential participant cannot in any way claim ignorant during the research process because he would have been made to understand the risk/benefit of participating. Besides this, the avenue for exercising competence and autonomy would have been guaranteed. In all these, informed consent is intrinsically linked to knowledge because information produces knowledge and having the knowledge of something shows one has been informed.

Let us briefly examine the case of Mr. Aderogba. From the analysis of his case, it is clear that he consented...
without having the information that will enable him makes an informed decision. This can simply be termed consent void of information. The researcher in his case had failed to respect his autonomy, respect him as a person and respect his desires. This point can further be strengthened when will look closely at the components of informed consent earlier explained in this paper. We may need to ask if the purpose of research was adequately explained in the inform consent form. Does the participant understand the risk and benefit of the research? Did he give a voluntary consent? Can we say that Mr. Aderogba was duly informed prior to the carrying out of the research on him? How can we assess the competency of Mr. Aderogba in his decision? These and many more are the envisaged problems of informed consent and research in human subject. The issue here is not limited to whether the research exposes a subject to harm, but the moral wrong of using a person as a means to an end and only a means to an end.  

It is crystal clear from the case given above that Mr. Aderogba did not give an informed consent in the research he was made to participate in. He consented without information. This is because to give an informed consent to something, you must have a detailed and elaborate knowledge of that very thing and you must truly know the danger and likely benefit of what you are consenting to. In knowing, you must also understand what you claim to know. If understanding is lacking then it cannot be referred to as an informed consent.  

Conclusion  
Having thoroughly discussed the content, meaning and requirements of informed consent in research, it is deductible that informed consent is a key requirement for the ethical conduct of human subjects’ research. Informed consent no doubt guarantees participants actual participation in decision making of their health without any form of coercion medical paternalism. It is quiet unfortunate today that in many ways, care receivers are vulnerable to many medical interventions specifically in research. They are vulnerable because they do not know and cannot claim to have an epistemic claim of what they have consented to. We cannot at the same time claim ignorant that many researchers may want to use this avenue to exploit participant because research is highly important and vital to human continuous existence.  

On the whole, clinical research is often the most efficient and valid method to generate valuable knowledge that improves patient care. Without it, medical knowledge becomes static and health care delivery becomes handicap. This statement poses a very serious worry. There is problem with contradictory interest; should we sacrifice the interest of the majority at the expense of protecting and ensuring the individual's interest or vice versa? If this holds, then utilitarianism as an ethical theory should be embraced. This goes to show that informed consent is not only an ethical ideal in clinical research and health care; it is also an epistemic virtue that must be continuously strived towards. It is the position of this paper that informed consent is necessary only that all requirements of informed consent should be worked towards being met in order to protect the integrity of the research and ensure the dignified interest of the research participants.  

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Conferences  
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UNU-University of Kumamoto Bioethics Roundtable.; 6-8 December 2013, Kumamoto, Japan.
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