INFORMED CONSENT AND CULTURAL DIVERSITY

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INTRODUCTION

The key concept of informed consent was clearly defined in the 1947 Nuremberg Code, a document which sets out the meaning of *high quality* informed consent and identifies what constitutes this quality.

Of course, the Nuremberg Code is not the only document to address this issue, and one of the most recent to consider it has been Unesco's Universal Declaration on Bioethics and Human Rights (2005).

During recent years in Catalonia, health institutions and professionals have been concerned to disseminate good practice which involves informed consent.

Informed consent involves more than just signing a piece of paper. Rather, it entails a duty of good communication between doctor and patient (or between researcher and research subject) with the aim of informing patients and research subjects about their situation and advising them about the choices they have to make, so that they are in a position to reach a reasonable decision on the basis of an adequate understanding of the issues involved.

If this communication is already difficult in normal situations, then it is even more difficult when there is no shared language or when the same words have different meanings because they are used in different semantic contexts. Indeed, in my opinion this is the most difficult situation of all, because individuals believe they have understood each other when in fact they haven't.

These are the issues we will discuss with Anne Davis and Eusebio Macete, when they give their presentations, and which we will then explore with Estanislao Alonso, Mohammed Chaib, Francisco Collazos and Josefina Goberna as part of a round table discussion which will be open to contributions from the audience.

Margarita Boladeras
Chairperson

FIRST PAPER

VARIATIONS ON A VALUE: INFORMED CONSENT AND CULTURAL DIVERSITY

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Publications:

- Davis AJ, Aroskar M, *Ethical Dilemmas and Nursing Practice,* Appleton Century Crofts, 1978. Considered first modern nursing ethics book.
- Kalkman M. and Davis AJ, *Psychiatric Nursing,* (5th ed.) McGraw Hill, 1980.
- Davis AJ, Krueger J, *Patients, Nurses, Ethics,* American Nurses Association, 1981.

Variations on a value: informed consent and cultural diversity

Introduction

The outline of this presentation is Informed Consent: (a) selected historical and philosophical factors, (b) value assumptions, (c) and cultural diversity, and ends with (d) three case studies[1]. Informed consent is applied ethics so we need to understand something of the ethics we are applying.

Historical and Philosophical Factors

In the USA, informed consent is defined as an autonomous authorization by an individual for a medical intervention or for involvement in research. Autonomy means that individuals have the right to information and using it, the right to agree or refuse to participate in research or to undergo treatment proposed[2]. This individual is a competent adult capable of understanding information and of making decisions. Health professionals have an ethical obligation to help the individual patient understand the information being given and the consequences of decisions made. The family may be included but the patient's values, wishes, and decisions are expected to determine what happens in 99.9 % of treatment decision cases.

1. I am indebted to Marsha Fowler, RN, PhD, FAAN of Azusa Pacific University in Calif. for her generosity in allowing me to use these case studies. I have made some changes in them.

2. Davis A.J., Aroskar M.A., Liaschenko J., Drought T. (1997) *Ethical Dilemmas and Nursing Practice.* Stamford, Ct: Appleton & Lang, 105.

Non-competent adults and children are not expected to give informed consent but someone else acts in their best interest. The ethical principle shifts from autonomy to doing good /best interest.

Diego Gracia has distinguished between Mediterranean biomedical ethics and the Anglo-American kind by saying that Southern European patients were less concerned with informed consent than with trust in their physician. This is an ethics that focuses more on virtues than on rights. But he also observed that this is changing rapidly so informed consent and cultural pluralism is a timely topic[3]. Virtue ethics, focused on character traits, is also important in the relationship between health care professionals and patient/family. This ethics gives us the bases for describing the Good Physician and the Good Nurse.

Historically, the universal norm indicated that the patient was not informed and had no role in health care decisions. While this was a universal, since it was found in every culture, this was not viewed as an ethical problem or a cultural problem that over looked cultural differences. The paternalistic medical "culture" was universal and disregarded cultural differences among patients.

Informed consent has several foundational sources: (a) the Nuremberg trials revealing unethical experimentation in World War II concentration camps and unethical experimentations in other countries such as the USA[4], (b) civil rights movements in Africa, Ireland, USA, etc. and the international women's movement, (c) previous laws that could be extended to include patient's rights, (d) the western philosophical tradition's definition of the individual and autonomous self, (e) the rise and spread of Christianity requiring individual choice and the historical period, the Enlightenment, embellished these notions of self, individual rights, choice, and individual responsibility.

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3. Gracia D. (1993) The intellectual basis of bioethics in southern European countries. *Bioethics* 7:2/3, 100-101.

4. Reverby S. (ed) (2000) *Rethinking the Tuskegee Syphilis Study.* Chapel Hill, NC: University of North Carolina Press.

The current concept of informed consent, as a way to respect individuals and their autonomy, was developed over time in cultural and historical contexts; however, it is important to remember that Informed Consent, as we know it today, is a relatively new phenomenon. Informed consent, complex for many reasons, means consent for both treatment and for research. Treatment is usually for patient benefit while research may or may not be for the benefit of the particular patient involved. In clinical trials these two purposes can be difficult to separate. It seems reasonable to say that informed consent of the individual being asked to participate in research should always be obtained from the potential research subject therefore I limit my remarks to informed consent and treatment.

Some General Problems with Informed Consent

Even without taking into account cultural diversity, health professionals can face difficulties in obtaining informed consent. Informed consent makes several assumptions including: (a) All adults want information to participate in decisions about their treatment. (b) The patient, as a self to be respected, should be the person who is informed and who gives consent. (c) Patient autonomy can outweigh other ethical principles such as Do No Harm. (d) There are ethically acceptable ways to deal with non-standard patient situations.

Even when we do not take into account cultural diversity, informed consent can be problematic. This does not mean that we have less of an ethical obligation to inform and to obtain consent. It does imply that we need to think about this ethical obligation carefully and not let it become just another routine matter in our check list of things to do. Informed consent can become bureaucratize to such an extent that it loses its meaning and ethical import. If it becomes just a matter of the patient signing a consent form then this waste everyone's time and importantly, under these circumstances it does not meet the goals of this ethical cornerstone in modern health care found in many countries.

Adding the variable of cultural differences makes informed consent even more complex. We have a tendency to think in a number of ways. When we

believe that all adults want information and to make decisions we have a possible tension between two aspects of patient care in which more weight is placed on ethical universals than on cultural differences. Some call this ethical imperialism. When we believe that all adults in a specific cultural group want the same thing with regards to informed consent we create a possible tension between two aspects of patient care that puts more weight on cultural aspects than on individual differences. Some call this cultural imperialism.

Along with culture as a variable, the age of the adult patient can play a part in the informed consent process. It is sometimes assumed that family members should give consent for older, competent adult patients because they are old. Both health professionals and family members assume this without input from the elderly patient. But how old is old? This year I am 75 years old and I want to make my own decisions. My position is a cultural one and also an individual one. Not everyone thinks like I do even in my own culture. Given individual differences in a culture, is it possible to tailor make the informed consent process to fit individual, cultural, and demographic factors of a specific patient? Is it ethically a good idea to even try this? Is doing this practical?

Both of these approaches (a) every adult should do X, and (b) every adult in this culture should do Y, have problems because they tend to group people leaving no room for individual differences. This lends itself to stereotyping such as when the physician or nurse says: This patient is Chinese therefore culturally we do X because we do X for all Chinese patients. Research in Korea indicates that some older people want to be given information but they want to make decisions with their family involved[5]. The Korean norm is older people do not want to know and their family alone, without patient involvement, should be informed and make decisions. This research, conducted by a nurse, does not support this cul-

5. Chang Soo-Jung, et al. (2005) Ethical Dimensions of Information-Seeking by Older People and Their Desire to Participate in Health Care Decision-Making. Unpublished PhD dissertation, Seoul: Yonsei University.

tural/ ethical norm. Discovering individual patient's values and preferences takes time and may not be attempted or if attempted, not accomplished. This could be an important activity for nurses and a major function in the informed consent process.

More than 50 years ago I read in an anthropology book:

In some ways I am like all other people

In some ways I am like some other people

In some ways I am like no other people[6].

This refrain tells us that we are human, members of a culture, and unique individuals. I have raised questions about each of these statements regarding informed consent. Now I will discuss some specific ethical and cultural aspects of informed consent.

Informed Consent and Cultural Diversity

This discussion focuses on two different cultures: the Anglo-American and the Asian-American because I know them best with regards to their cultural values and norms. Both cultures have complexities and contradictions created by many socio-historical factors that I have no time to discuss. In addition, grouping people together such as Asian-Americans disregards differences found within Asia and among individuals in the same Asian culture.

The USA, a very young country greatly influenced by ideal from the Enlightenment, values the individual and individual's rights. These rights fall into two categories: 1. the right TO certain things such as free speech and the

6. Kluckholm C, Murray C (1950) Personality Formation: The Determinants. *In Personality in Nature, Culture and Society*. NYC: Alfred A. Knopf, 35-48.

right FROM certain things or the right to be left alone. Informed consent falls into the latter[7]. As a USA patient, I have the right to information and the right to decide, and if I refuse, the right to be left alone.

This is the ethical base line of informed consent. Recently I had surgery and was given a form entitled: "Your Right to Make Decisions About Medical Treatment". It's an interesting document and I brought it with me in case anyone wants to see it. On the front of this it says: "A federal law requires us to give you this information. We hope that this information will help increase your control over your medical treatment.[8]" We speak of THE law and everyone is obligated to obey the law but we do not speak of THE ethics and we do not expect everyone to have the same exact values and ethics because there are cultural differences. Maybe not everyone wants to *control* his or her medical treatment.

The USA is one of the most culturally pluralistic countries in the world. San Francisco, where I live, reports one-third of its population as Asian and there is a large community of Spanish speaking people from Mexico, Central and South America. Within the so-called white or Anglo community we have Russians, French, Irish, Italians and Scandinavians among others. Everyone is a Hyphenated- American such as Chinese-American, Russian-American, etc. I am an Anglo-American meaning my family originally came from the UK.

Health care ethics in the USA is cast in the cultural mold of Anglo-Americans, the majority population and in the power structure. Our values, definitions and assumptions are embedded in all ethical procedures such as informed consent. This works fine most of the time as long as the patient is like me. But not all patients are like me and not all non-Anglo-American patients have acculturated into the main stream of the American culture. There is also the English speaking Black culture whose members have been in the USA since slavery in the early day of the republic.

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7. Bandman E, Bandman B (1986) *Bioethics and Human Rights.* Lanham, MD: University Press of America.

8. California Department of Health Services (2000) *Your Right to Make Decisions About Medical Treatment.*

In the Anglo-American ethics model, usually the family is in second place to the competent adult patient. Bioethics indicates that the individual patient receives information and makes choices to have more control over medical treatment. Ideally, physicians and researchers do not, as a rule, go to the family first if the patient is a competent adult able to understand and make decisions.

Cultures can be thought of as individualistic or collective. They can also be described as high-context or low-context[9, 10]. Individualistic cultures have priority of personal goals: to establish individual identity, fulfill one's potential, assert one's strength, separate from others to enact these goals, respect one's physical and psychological needs.

People in collectivist cultures do not tend to make important decision on their own but consult with family or community members because group interests are more important than individual interests. Each person belongs to the community of shared values, beliefs, traditions. Children usually follow their parents' wishes and expectations more than their own. In collective cultures, individuals are deeply embedded in their group which is usually their family.

This collectivist, high-context cultures that value unity, harmony, and community maintain the extended social bonds. Japan and China are good examples of this cultural type. I select them because I know a bit more about these cultures than many others having worked in China part time over 23 years and having lived and worked in Japan for 6.5 years.

In examining these case studies, we cannot deny that different historical eras and cultures exhibit a variety of moral beliefs and practices. Both the role

9. Hall E (1976) *Beyond Culture*. NYC: Doubleday.

10. Griswold W (2004) *Cultures and Societies in a Changing World*. Thousand Oaks, Ca: Pine Forge Press.

of the individual in Asian bioethics and the role of the family in Anglo-American bioethics can be challenged. The main point here is to examine more than one model of informed consent, to move beyond rigidity that can become either cultural imperialism or ethical imperialism but not to return to medical paternalism as the international norm. Case studies help give clinical grounding to these ideas.

Case Study 1- Ideal Anglo-American model

Thomas, an Anglo-American 57 year old male patient, is diagnosed with late stage cancer. He receives this information from his physician while his wife is in the room. The physician leaves them alone to absorb this news. The patient has a good relationship with the nurse and asked her to help them think about his situation. The physician returns later when the three of them discuss the diagnosis, prognosis, medical alternatives and their possible outcomes based on what the physician knows from research and clinical experience. The choices are: (a) aggressive treatment even if results in little or no benefit to Thomas, (b) minimal treatment, (c) hospice comfort care. Thomas is fully aware of his terminal status and chooses hospice which he can have at home. The family is alerted and plans are made for everyone to come home to have some time with Thomas and each other.

Comment- This case would not present any ethical or cultural issues for the clinical staff or clinical ethics committee to discuss. The ethical obligations of informed consent and respect for the patient's rights to know and decide have been met.

Case Study 2- Japanese-American patient and unified family

Akiro, a Japanese-American 57 year old male patient is diagnosed with late stage cancer. The physician knows about the Japanese culture so goes to the patient's wife and adult daughter and they say not to inform Akiro of his terminal illness because this information will take away his hope and he will commit suicide. This is a culturally-based request based on cultural beliefs and expectations. So the family and physician, without input from Akiro, decide the alternative, minimal treatment. Some days later, Akiro says to his nurse,

"I am told that I am getting better but that does not seem to be true. I think I am very ill. What do you think? Am I seriously ill?" Does this nurse face an ethical problem? If so, why and if not, why not?

Comment- This is an example of a high-context culture that emphasizes mutual dependency over the individual and one in which communication usually relies on explicit coding of information[11]. In a high-context culture not being told the diagnosis is to be told that the information is bad news even tragic. The patient, believing himself to be seriously ill, breaks the norm of explicit messages by stating what he thinks of his health status and asking direct questions. In the Japanese culture is it very important to attend to what is not said and to non-verbal communication since many important messages are found here.

The physician has honored the East Asian principle of autonomy whereby the family makes decisions[12]. This custom allows families to choose treatment for patients on behalf of competent adult patients but the family may not refuse treatment on behalf of this patient[13]. Do you think informed consent has occurred in Akiro's case? Is this only medical paternalism updated? Should the family and physician re-think informed consent now that Akiro has asked his question? Should they honor the patient's desire to know at whatever level of knowledge he chooses?

Should they feel obligated to give answers to questions not asked? Akiro did not ask if he were dying, for example.

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11. Doi T (1985) *The Anatomy of Dependency: The Individual Versus Society*. Tokyo: Kodansha International.

12. Fan R (1997) Self-Determination vs. Family-Determination: Two Incommensurable Principles of Autonomy, *Bioethics* 11, 309-322.

13. Macklin R (1999) *Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine*. NYC: Oxford University Press.

Case Study 3- Chinese-American patient and disagreeing family members

Ju Ying is an unmarried 35 year old Chinese –American woman who has a malignant thalamic tumor that has not responded to conventional therapies.

She is on a ventilator but alert and able to communicate by writing, gesturing and nodding. She finally consented to a "last ditch" treatment which means the physicians have tried everything else and this attempt may be futile. Her decision was difficult because her father claimed his cultural authority over Ju Ying to make decisions for her and refused to have her fully informed of her medical status and prognosis. Her more "westernized", culturally assimilated older brother says his sister should make her own decisions. Before a solution was found, nursing staff and physicians are very uncomfortable caring for Ju Ying, feeling that they could not talk to her about her care. Her father and/or mother were usually in the room. Clinical staff members worried that they would begin avoiding Ju Ying because they felt so uncomfortable in her presence.

Chinese culture can be described as a high power distance culture in which there is a structured inequality in society; every person has a fixed, rightful place in society and in relationships. This derives from Confucius thought which remains very strong in Chinese culture even with generational differences. This is obviously a collectivist culture where people are born into extended families or clans that protect them in exchange for loyalty, decisional hierarch and belief in group decisions. Patient's role is to be the recipient of family care and concerns. The main question here is: How does the staff bridge the generational issues and give the appropriate respect to the father, while maintaining important-decision making conversations with the patient?

Some possible answers to this question are: (a) Ask Ju Ying about her wishes regarding decision making authority. (b) Construct a milieu of care where Ju Ying has freedom to inquire for more information. (c) Enhance the brother's ability to communicate with Ju Ying while still observing cul-

tural norms. The outcomes: (a) Ju Ying said she wants to make her own decisions but she does not want to show disrespect to her father, (b) clinical staff secured time in the room without family members to discuss care issues with Ju Ying, (c) She was in the ICU for an extended time and was finally able to be weaned from the ventilator support. Then Ju Ying went home in her parent's care. Shortly after, she died at home among her family members.

This might seem less than a good solution but it does deal with Ju Ying's wish to make her decisions and give informed consent while it does not show open disrespect to her father. It does deceive him in going around his decision making authority. Maybe you can think of a better solution.

In closing, I want to list the major ideas that I have used in this presentation. Each one needs more exploration than I have time for here so I leave that to you for later. The ideas are: (a) individual /family autonomy, (b) rights, (c) competent adult, (d) western philosophical tradition, (e)the self, (f) respect for the person, (g) cultural diversity, (h) stereotyping, (i) Hyphenated-Americans, (j) Individualistic/collective cultures, (k) high-context/ low-context cultures, (l) High-power-distance cultures, and (m) Mediterranean biomedical ethics.

I now look forward to your comments and questions. There are other ways to think about the issues in informed consent and also in cultural diversity. No culture is static without differences and changes within it. Culture is a major factor in the way each of us define ourselves. One reason I stayed in Japan for 6.5 years was that I often faced situation that threw my world view into question. While at times difficult, it was a remarkable learning experience in understanding myself better and in trying to develop a deeper tolerance for differences. I believe that among the most difficult and important ethical issues in life is the question of how to balance the general value of tolerance for cultural differences with the questioning or even condemning of cultural practices differing from one's own. This is central to any discussion of human rights and international health care ethics. To maintain ethical standards while at the same time developing tolerance for differences in ethical standards remains a life

time endeavor[14]. After all these years, I am still working on this balancing act but perhaps the important thing is to continue to seek even if the answers are not so easy or in final form. Our world gives us many variations on cultural values and not only in regards to informed consent.

14. Davis AJ (2003) International Nursing Ethics: Contexts and Concerns. In V. Tschudin (Ed) *Approaches to Ethics: Nursing Beyond Boundaries.* London: Butterworth Heinemann, 95-104.

SECOND PAPER

PROBLEMS IN APPLYING ETHICAL STANDARDS IN CLINICAL TRIALS IN DEVELOPING COUNTRIES

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Publications:

- Roca A, Sigauque B, Quinto L, Mandomando I, Valles X, Espasa M, Abacassamo F, Sacarlal J, **Macete E**, Nhacolo A, Levine M, Alonso P. Invasive pneumococcal disease in children <5 years of age in rural Mozambique. *Trop Med Int Health*. 2006 Sep;11(9):1422-31.
- Quinto L, Aponte JJ, Menendez C, Sacarlal J, Aide P, Espasa M, Mandomando I, Guinovart C, **Macete E**, Hirt R, Urassa H, Navia MM, Thompson R, Alonso PL. Relationship between haemoglobin and haematocrit in the definition of anaemia. *Trop Med Int Health*. 2006 Aug;11(8):1295-302.
- **Macete E**, Aide P, Aponte JJ, Sanz S, Mandomando I, Espasa M, Sigauque B, Dobano C, Mabunda S, Dgedge M, Alonso P, Menendez C. Intermittent preventive treatment for malaria control administered at the time of routine vaccinations in Mozambican infants: a randomized, placebo-controlled trial. *J Infect Dis*. 2006 Aug 1;194(3):276-85. Epub 2006 Jun 30.

Introduction

As is still the case in some European countries, in many African countries bioethics is a new discipline, and it will take some time before it is widely understood and is incorporated into the general health system. At present, the current level of development of health systems means it is mainly associated with research initiatives to identify solutions to specific health problems.

The application of bioethics involves complex multi-disciplinary applications. More complex still is the application of standards which have been created in very different contexts. This complexity may arise from economic or cultural differences or from problems in gaining access to information.

Research is a way of improving people's well-being, irrespective of their geographical location. However, conducting research and following research protocols in developing countries is far from easy when it comes to ethics. One of the main limitations is the fact that current international standards do not reflect the cultural differences which we find in places such as Africa[1].

Many developing countries have very high illiteracy rates: in Mozambique, for example, the rate is 60.5%[2].

In these countries, a large part of the resources to support the operation of the health system comes from international aid programmes. The research sector is still in its infancy and depends on funds from foreign institutions.

In Mozambique, the Manhiça Health Research Centre has for the last 5 years been conducting a variety of research initiatives, from clinical trials for the development of drugs and vaccinations to anthropological studies[3], and one

1. Kilama WL. The malaria burden and the need for research and capacity strengthening in Africa. *Am J Trop Med Hyg* 2001; 64(1-2 Suppl):iii.

2. Republica de Mozambique. *http://www.ine.gov.mz/censos_dir/recenseamento_geral/estudos_analise/eud/view?searchterm=analfabetismo%20taxa.* 2006. 14-9-2006. Ref Type: Electronic Citation

3. *www.manhica.org. http://www.manhica.org/pages/espanol/espanol.htm.* 2006. 11-9-0006. Ref. Type: Electronic Citation

aspect which has always presented a challenge is the application of western ethical standards in the African context.

One of the main problems is that, as Dr. Pablo Simon Lorda explains in his book *Problemas prácticos del consentimiento informado* [*Practical problems of informed consent*], for many years doctors have been the key source of information for understanding and treating problems which affect the normal operation of the patient's body. As a result, for a long time the relationship between doctor and patient has been one of submission by the latter to the former.

This was the case for many years in both Europe and the United States, and continues to be so in Asia, Latin America and Africa, all of which are weakened by a range of factors. There was a similar situation in Europe after the Second World War. In the developing world, we are often talking about countries which have recently emerged from civil war, drought and other socio-economic problems. These are just examples, and we might also cite factors such as the role of the Catholic Church and the activities of nuns and priests in providing primary health care during the colonial period, in which care for the individual as believer and as patient is combined.

This questioning of the doctor-patient relationship, with regard to the rights of patients to know about the treatments which are to be applied to their bodies, arises in large part in partnership with the advance of American civil rights[4], and the right to participate in the political and social decisions of the communities in which each citizen lives. Over time, this led people to question the right of others to intervene on their bodies, whatever their state of health. The medical world and its institutions were unprepared for such changes.

This gave rise to the establishment of informed consent. When we look at the impact of the theory of informed consent, for example in the United States, we observe a massive expansion of the legal system[4]. This is often a response to an increase in complaints by the public, and makes doctors and researchers increasingly defensive. By contrast, people in Africa are more peaceable and

4. Lorda PS, Barrio C, I. Historical framework for a new discipline: bioethics. *Med Clin* (Barc) 1995; 105(15):583-597. 26

less demanding, and often operate on the basis of trust in those who are close to them; and the closer the relationship the higher the level of trust. This concept of proximity may reflect a range of factors including cultural, family and ethnic relationships.

The ethical mechanisms or procedures are assumed to be universal, but in practice such universality does not exist. Rather, such universals are relative and only exist in the light of our interests, and the contexts and cultures in which we live. Does the universal exist only when people know about and are aware of it, or does it exist independently of human knowledge of it?

The borders which are easiest to globalize are those which have guards, the physical ones. By contrast, free borders – social and cultural ones – are more difficult to cross. Indeed, there are immigrants who cross the first kind of border but not the second, so that wherever they are they continue to live within their own culture. Ethics is only universal in so far as we are able to adapt it to the practical restraints of individual cultures.

When decisions such as whether to participate in a trial arise, this alters the whole context of the doctor-patient relationship. This is because people usually attend hospital because they are ill or concerned about their health, and do not expect to confront such decisions.

Informed consent

It is now clear that, in order to follow good practice in clinical research, we have to promote the use of informed consent, and to promote the need for medical care which meets minimum standards which are acceptable for the context, and to establish ethics committees to oversee ethical issues.

To start with, there are few committees which operate on a regular basis. African countries need and are gradually introducing a way of conducting clinical research in accordance with international standards but taking into account African cultural and legislative realities.

Secondly, the care to which subjects have access during trials in many northern hemisphere countries is harmonized and may even be defined by legislation.

There are many alternatives in medical care. If a European patient doesn't like the services provided by one hospital, he or she may transfer to another. For a range of reasons: because there are always trials in process, or for other reasons. In many African countries, particularly in the rural context, this option does not exist.

In places where health structures lack resources, there is a greater likelihood that participants will agree to join the trial as a way of receiving better care.

We have to ask to what degree participants are really free at the moment of giving informed consent[5] in small communities where health centres are the major providers of care and sometimes of employment. For example, before entering a clinical trial, all subjects should have had sufficient time to review the information and to decide whether or not they wish to participate. This means that they need time to understand the informed consent.

It is true that there are certain issues, for example mosquito control field studies, where it is not an individual but a community, and sometimes quite a large one, which participates in the trial[6]. In this case, individual power is compromised by a majority decision. In clinical trials, subjects are allowed to leave the trial while it is in progress, but this is not possible in large-scale fumigations, for example[6].

These are all reasons why from a practical perspective it is even more difficult to apply international standards in countries where resources are scarce. Even if this were not the case, the mere fact that when working with serious illnesses, such as malaria, meningitis or diarrhoea, investigators have to ask for the consent of a sick person or one of their relatives is already an obstacle to acting on the basis of freedom.

Thirdly, the compensation payable as a result of injury can be a further source of problems. In many countries, subjects are not given this information during clinical trials. Investigators often ask what would happen if people in

5. Obyerodhyambo O. Keeping medical research ethical. *Science* 2005; 309(5732):246.

6. Kilama WL. Ethical perspective on malaria research for Africa. *Acta Trop* 2005; 95(3):276-284.

situations of great poverty were to discover the full details of the compensation available to those in other countries in the same situation. What matters is how the message is communicated.

Finally, there is the issue of the power wielded by those in the patient's immediate circle. The group surrounding the person whose consent is specifically sought may include many individuals with an effective power of veto[6]. This is due to a range of factors, one of which is the trust which the subject places in his friends and family, due to his lack of knowledge of the outside world (illiteracy rate).

Some years ago, the guidelines stated that informed consent had to be obtained in writing and signed by the subject, but current versions now allow consent to be obtained orally (WMA, 2000; CIOMS, 2002; COE, 2004; NCOB, 2002).[7]

In many cultural contexts, the mere act of asking someone to sign a document before doing something signifies the acceptance of negative consequences. It is as if it is known that there will be a problem in the future and that the subject's signature involves him more deeply in the process.

Translation into local languages is another complication. In many African languages some scientific concepts contained in the informed consent information do not exist. Despite this, investigators have to seek ways of ensuring that the message is understood.

Political aspects

In all research projects, the existence of official structures means that government inevitably plays a key role, from accrediting and strengthening ethics committees, to demonstrating that these are genuinely independent and have the necessary technical expertise.

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7. Bota AA. [Contribution of the CIOMS 2002 standards to biotechnological development. The responsibility of the scientist]. *Biol Res* 2003; 36(2):148-154.

In most African countries, ethics committees are the only structures available to review and analyse the various research projects being conducted there.

One of the challenges for researchers and governments is how to guarantee the rights of participants. For example, the fact that malaria has the greatest impact on children aged below 5 years and on pregnant women, especially during the first and second pregnancy, means that these groups are constantly involved in trials. This increases the pressure on ethics committees, whose members also have other duties. Women and girls are even more vulnerable, primarily as a result of cultural factors. By contrast, there are other population groups which are always excluded from trials, such as consultants or foreign visitors on short visits to high risk countries, who are not included in malaria trials.

In the case of trials of new products in countries where HIV is a problem, we encounter questions such as who guarantees treatment, and for how long? What happens to participants who are HIV-positive or who become HIV-positive during the trial? Although the situation is gradually changing with the introduction of national treatment programmes with anti-retrovirals, this remains a delicate area.

Other issues include whether or not it is necessary for Phase I and II Clinical Trials to be conducted in the sponsor's country. According to CIOMS 1993 these phases should be conducted in the sponsor's country, but in the case of drugs or vaccines for malaria, where this is not transmitted in the sponsor's country, these phases have to be conducted in countries where the illness is endemic.

Upon completion of the trial, international bioethical standards mean that the sponsor has a duty to promote the benefits of the trial to the participants. But for some illnesses it is not the sponsor but the government through its national health system which is in a position to ensure this. In situations where the state does not have the capacity to do this, the participants are the ones who lose out. (World Medical Association WMA, 2000; Council for International Organization of Medical Sciences CIOMS, 2000.) So there is a contradiction with regard to who is responsible for guaranteeing the benefits at the end of the trial.

At the same time, in accordance with NCOB, 2005 paragraph 9.36, there is an emphasis on cooperation between the public and private sector to ensure that participants receive the benefits. Despite all these problems, we should also recognize that recent years have seen serious efforts being made to overcome these obstacles. African organizations such as AMANET are one example of this.

Practical experience

Our experience has been gained at the Manhiça Health Research Centre, in Mozambique, which celebrated its 10th anniversary in 2006. I will now try to give you a brief summary of our experience at Manhiça with regard to informed consent.

In 2001 of the results of a trial conducted in Tanzania on the efficacy of a new malaria control treatment, Intermittent Preventive Treatment in infants (IPTi)[8], administered through the expanded vaccination programme of the World Health Organization (WHO), were published. The interesting nature of the results led to the creation of a consortium to conduct more trials in different countries, with the aim of providing more data on both efficacy and safety, in order to evaluate whether this could be applied as a large-scale control measure[9].

In September 2002, we started a clinical trial in Manhiça to evaluate the efficacy and safety of IPTi, after obtaining approval from ethics bodies and the national authorities. The trial was conducted in the district of Manhiça (Mozambique), which has a population of around 134,000. The participants came from an area covering approximately 100 km^2 with 36,000 inhabitants, of whom 12% are below 5 years of age, and 23% are women of childbearing age (INE 1999). The majority of the active population are peasants engaged in the

8. Schellenberg D, Menendez C, Kahigwa E, Aponte J, Vidal J, Tanner M et al. Intermittent treatment for malaria and anaemia control at time of routine vaccinations in Tanzanian infants: a randomised, placebo-controlled trial. *Lancet* 2001; 357(9267):1471-1477.

9. Egan A, Crawley J, Schellenberg D. Intermittent preventive treatment for malaria control in infants: moving towards evidence-based policy and public health action. *Trop Med Int Health* 2005; 10(9):815-817.

cultivation of sugar cane, banana and rice. The district also has two sugar cane and rice processing factories. There are two major towns, but the majority of the population lives close to the national highway. More details about the area can be found in Loscertales et al[10] and Macete et al[11].

When we started the trial, the informed consent rate was around 80%, but after 2 or 3 months we began to experience recruitment problems, and the rate fell as low as 50%. We undertook an anthropological study to identify the reasons for the decline in recruitment, and it transpired that one of the main reasons was the inclusion in the trial of some procedures which mothers did not view as normal or usual.

These included the fact that height measurements were taken for the children, and this was interpreted by some mothers as being done so that we could make a coffin if the child died. Rumours quickly spread through the community. During the informed consent process, mothers had to wait for a while at the hospital, and the children were given biscuits and something to drink so they would not go hungry. The interpretation of this was that these products had been poisoned so that the children would die.

In response, a communication plan was drawn up to communicate with the community, and this was supported by the local authorities, traditional leaders, and the church. After a month of the communication campaign acceptance levels returned to their initial levels and remained there until the end of the trial. Another factor was the fact that mothers who had initially been afraid could see that nothing happened to the children who took part in the trial.

There are many examples we could mention to illustrate the difficulties of applying ethical standards developed in the northern hemisphere to Africa, as

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10. Loscertales MP, Roca A, Ventura PJ, Abacassamo F, Dos SF, Sitaube M et al. Epidemiology and clinical presentation of respiratory syncytial virus infection in a rural area of southern Mozambique. *Pediatr Infect Dis J* 2002; 21(2):148-155.

11. Macete E, Aide P, Aponte JJ, Sanz S, Mandomando I, Espasa M et al. Intermittent preventive treatment for malaria control administered at the time of routine vaccinations in mozambican infants: a randomized, placebo-controlled trial. *J Infect Dis* 2006; 194(3):276-285. 32

a result of cultural differences. The second case I will mention is one which was published in:

Trends Parasitol 2002; 18(5):231-234

"Mfutso-Bengu JM, Taylor TE. Ethical jurisdictions in biomedical research."[12]

This case occurred during a study of the clinical pathological correlation of fatal cerebral malaria. Autopsies were carried out on children who had died of cerebral malaria and on people who had died of other illnesses.

A dilemma arose between the local ethics committee and the committee in the country funding the study. There were a series of problems for the local community, starting with the fact that the autopsies took 3 to 4 hours while according to local tradition burial should be immediate. In addition to this, the families wanted nothing to do with the extraction of organs. Well, one of the trial procedures involved a thorough histological study of the eye, and this involved its removal. Everyone was aware of the importance of the trial. In accordance with international standards, the foreign committee proposed giving families comprehensive information about the procedure, including the eye examination, and offering to replace the eye with a prosthesis. However, the local committee decided that if this approach was taken to the consent, the trial would face difficulties, and that it was best not to inform relatives about the procedures to be performed with the eyes. This led to disagreement between the two committees and in the end the local committee's recommendations were followed[12].

These two experiences show us that while standards are necessary and there is a need for harmonization, in developing countries the greatest need is to protect subjects, and cultural differences must always be borne in mind.

12. Mfutso-Bengu JM, Taylor TE. Ethical jurisdictions in biomedical research. *Trends Parasitol* 2002; 18(5):231-234.

Acknowledgements

I would like to express my special gratitude to the Víctor Grífols i Lucas Foundation for giving me this opportunity and for allowing me to learn so much about this issue. I would also like to thank Dr Xavier Carné for all the support he has given to Mozambique and in particular to the ethics team there; my thanks are also due to Dr Caterina Guinovart Florensa for her friendship, companionship and help in writing this text; and finally, I would like to acknowledge the support provided by the management of the International Health Centre of the Hospital Clínic.

Contributions from specialists

Estanislao Alonso. Advisor to the Immigration Management Plan of the Department of Health of the Government of Catalonia

I will share with you my experience of adaptation in the health sector from a professional, management and institutional perspective in the form of the Immigration Management Plan. This plan has only recently sought to address ethical issues such as that of informed consent with regard to cultural diversity. While other sociological or anthropological issues, together with biological ones, have been the focus of greater attention, ethical issues have at most been implicit in many of our considerations, although initiatives such as this one have recently taught us a great deal.

In this regard, we should congratulate Professor Margarita Boladeras and the multiculturalism and diversity group which she leads within the Bioethics Committee of Catalonia, and one of its members, Dr Francisco Collazos, a leading expert in competency and transcultural psychiatry, whose contribution we will be able to listen to today. He has been and continues to be a great stimulus to the Immigration Management Plan team because he identifies new perspectives and issues to be addressed by institutions and health professionals.

This was the case, for example, when drawing up the *Guia per al respecte a la pluralitat religiosa a l'àmbit hospitalari* [Guide for respecting religious pluralism in hospitals]

http://www.gencat.net/salut/depsan/units/sanitat/pdf/guiaplurireli.pdf

In doing this, we had the opportunity of working with the General Section for Religious Affairs of the Presidency of the Government of Catalonia, which was responsible for drawing up the guide. This provides important information for professionals and also identifies further areas where professionals, institutions and the administration need to make changes in order to adapt to the diverse world in which we live. Sensitive issues such as diet, beliefs, general health and death mean that we must update our attitudes, skills and knowledge: what is sometimes referred to as our "cultural competency".

I would like to start by recalling the history of migration in our country, and in particular the wave of migration during the 1960s and 1970s from other regions of Spain to Catalonia, which also had health implications. Both the earlier and more recent waves have been studied by mental health experts. However, health professionals were the first to react to the new situations and challenges raised by foreign immigration, which initially involved relatively small numbers of people, and soon drew up protocols and tools to help respond to them. Recent migration policies have brought health into inter-departmental policies, giving rise to a number of institutional initiatives such as the Plan for Diversity of the Catalan Health Institute, followed by the Office for International Health Cooperation and Migrational Health or the more recent Immigration Management Plan in the health sphere. We have moved from spontaneous, practical, professional initiatives which were, however, isolated and disparate, towards more coherent planning, as expressed in this Management Plan. The task now is to develop our approaches to purchasing and providing services, training staff, welcoming patients, and to create tools to deal with new challenges. Fortunately, we have the advantage of being able to draw on the experience of health professionals who, despite working under conditions of isolation and dispersion, have developed practical ideas which ensure we will be able to face the future.

With specific reference to informed consent and how it is affected by cultural diversity, what is clear that it is the whole doctor-patient relationship which is at stake, which has been transformed and which must be transformed even further if it is to recognize the patient's autonomy as a citizen. In other words, the social model of rights and values provides the model of citizenship which responds to the phenomenon of cultural diversity. And if, in order to create a relationship model which respects and fosters patient autonomy, we must achieve communicational competency, because information and communication are essential, then cultural diversity demands a cultural competency which consists of attitudes, knowledge and skills.

Indeed, cultural competency has become one of the conditions for delivering quality, and we need to define the corresponding standards to identify whether or not this competency has been achieved. While health professionals are ideally best placed to ensure that they are understood in new situations, the

fact that such diversity is so new in the health context means that the mediation of other people who have been trained to perform this task may help to overcome communication barriers when these arise. We believe that the training of health professionals is fundamental, but that mediation can also help to make up for any temporary shortcomings, providing a valuable complement to existing resources. In fact, this is the main focus of the Immigration Management Plan to improve accessibility: reception, mediation and training plans.

We need to change and improve our attitudes towards tolerance and respect, rejecting paternalism and ethnocentrism, and taking instead an ethnorelativist approach. We believe that the existence of "sensitive" health professionals is a first step towards enabling the health profession, the health system and society as a whole to acquire cultural competency.

In order to deliver health care which responds to this diversity we do not require exhaustive knowledge of every culture, but instead we must remain open to the possibility of acquiring this knowledge, of integrating biological, psychological and social aspects. We must be attentive to the need to interpret codes and symbols, and phenomena which accompany migrations such as homesickness or the practice of traditional medicine, which we may need to demystify if it could present a threat to health, but which we must also respect.

As or more important than knowledge are the skills which enable health professionals to overcome any obstacles they may meet. These are primarily communication skills but also involve attitudes and the capacity to understand. These skills are acquired as a result of experience, and it is therefore those professionals with most experience of diversity who have the task of overcoming initial fear and confusion, of transmitting trust in the skills of those with an open, tolerant attitude, and to promote the principle of trusting patients.

We thus started to develop the Immigration Management Plan to bring together reception, mediation and training processes, and to plan measures to adapt our institutions to the challenge of diversity. So far the experience has been a positive one, and we have already carried out a lot of training initiatives which are helping to change attitudes, raise awareness, and improve knowledge

and skills, all of which are key components of cultural competency. At the same time, we have opened up a debate and provided the institutional framework to continue progressing towards our goals, so that we have the best possible conditions for addressing diversity in the health sector. But we sometimes have the feeling that the demands on us are so overwhelming that we are doing little more than dealing with the most pressing problems, and that this is a phenomenon which has made a recent but dramatic appearance in our country and will continue to represent a real challenge in the future, and in response to which we must develop new strategies. We believe that it is important to continue along these lines, working with the necessary resources, and taking into account social forces and ethical issues, together with health planning techniques.

I would also like to tell you about some of the tools which are already available, such as a Department of Health website to share information with health professionals: *www.gencat.net/salut/immigracio.htm* and to provide information to citizens, whether from abroad or not, with regard to diversity: *www.gencat.net/salut/immigrants.htm*. This will coincide with a reception website which is being developed in parallel by the Secretariat for Immigration and which will include, among others, reception support materials created in collaboration with a range of bodies and institutions, to enable a coordinated approach to the reception of recent arrivals, based on the same information.

Finally, I would like to mention our mediation plans which involve a range of individuals: translators, intercultural mediators, community health agents and overseas professionals; training and the local development of these plans through the Regional Health Authorities, working at a local level in areas such as community health. We believe that mutual adaptation is called for, and that this is the best way to adapt the health system in the face of diversity. This adaptation will facilitate both cultural and informational competency, enabling the new model of the relationship between health professional and citizen which represents genuine informed consent.

Mohammed Chaib. Chairman of the Ibn Batuta Socio-Cultural Association[1].

First of all, I would like to thank the Víctor Grífols Foundation and Dr Margarita Boladeras for being so kind as to invite me to take part in this workshop, and to discuss such an important issue as the current situation in Catalonia with regard to immigration and the cultural pluralism to which this gives rise in our daily lives. The number of foreigners resident in Catalonia is around one million, in other words 12% of the total population, and this number is growing constantly. As a result, the impact in the health sphere is considerable.

At the Ibn Batuta Socio-Cultural Association of which I am the Chairman, we have for a long time received requests for help and cooperation from hospitals when they have had a foreign patient, either North African or Muslim, requiring special attention as a result of a lack of knowledge of the language or the patient not having any relatives in Catalonia. And in fact we helped patients to take decisions regarding treatment or surgery, providing them with all the information they needed and explaining that the medical team needed their consent in order to protect their rights as a patient, rights which also involve cultural and religious aspects.

One example is when the patient is terminally ill and, in the opinion of the medical team, has only a few months left to live. In this case, you have to explain the reality of the situation very clearly not only to the patient but perhaps also to his family in his country of origin. The family has to receive information to help decide whether the patient is to remain in Catalonia to continue with treatment during the remaining months or days, or is to return to his country of origin, with all the difficulties he is likely to face with regard to continuing with the treatment, but with the opportunity of spending the final moments of his life with his family.

1. The Ibn Batuta Socio-Cultural Association is based at c/ Sant Pau, 82 Bajos 08001 Barcelona - Spain. Tels. / Fax +34 93 329 30 54 +34 93 329 35 40.

On other occasions, we have to intervene after the patient has already died and has to be repatriated, speak to his family, find out whether or not they are able to pay for repatriation, prepare all the documentation and paperwork, etc.

Sometimes after the patient has died nobody claims the body for a long time, and then suddenly the family appears and wants to sue the hospital for removing organs without the consent of the family, because in Muslim culture this is a very serious sin. So the hospital must be aware that the family of the deceased may appear at any time and ask whether the patient had consented to whatever has been done.

We also dealt with the case of a mixed marriage between a local Catalan woman married to a Muslim man. After a long illness, the husband died in hospital. The wife expressed a wish to have his body cremated, as that was what she had agreed verbally with the husband, but she didn't have any consent in writing. The Muslim family said they would never allow their son to be cremated because in Islam this is absolutely forbidden and the body can only be buried in the ground, in addition to which the family had travelled from Morocco to repatriate the body. The judge became involved and the man's body was finally buried in a Muslim cemetery in Catalonia, close to his wife and in accordance with Muslim rites. This case gives an idea of the complexity of responding adequately to the cultural pluralism of our country.

In providing health care to people who have come from other countries with different cultures, it is essential that health staff have the necessary resources to respond appropriately to this population. In Belgium, a country with a long tradition of receiving immigrants, a doctor had been attending to a Moroccan patient for a long time. Despite receiving treatment, the patient did not appear to be improving, and the doctor decided to talk to her. The patient explained that she believed her body was possessed by a kind of demon known as an Aicha Kandicha. Her real problem was cultural rather than therapeutic, and the treatment therefore also needed to be cultural.

Another important issue to be aware of is that of the patient's religion. In this regard, the Health Department and the Office of the President of the Government of Catalonia drew up a Guide for respecting religious pluralism in hospitals, which was a very interesting initiative. But who should provide

religious care? The imams? Are these the people whose consent we should ask for on some issues? In Catalonia the Islamic Cultural Council of Catalonia brings together the imams of this region, and performs a vital religious task of supporting the sick. They also help medical staff by explaining, for example, that according to Islam the month of fasting, Ramadan, is not obligatory for pregnant women, the elderly or those who are undergoing treatment. Even so, there are individuals who insist on fasting even though it is not obligatory. It is clear that there are issues where it would not be necessary to ask for the consent or support of the clergy, but where the patient or family should be asked directly.

The same occurs with intercultural mediators. In some cases they are very useful and at other times they aren't, because the patient has not fully explained what is really happening to him and would prefer to explain it directly to the health staff. This depends in large measure on the ability of the mediator to inspire the patient's trust.

Sometimes, Muslim women ask to consult their husbands before taking a decision about treatment or surgery. In such cases, I believe they should be allowed to consult whoever they want. Of course, the person who has to receive the information is the woman, so that she can take a decision about her illness. These clearly tend to be unusual situations, which are not typical, but people should be aware of them.

All in all, informed consent entails creating trust between the patient and the medical team so that a diagnosis can be made or treatment carried out. This trust is created when the patient can see that health staff are concerned with him as a whole person, that they understand him culturally, that they know what is really happening to him, that they know his situation, that they are concerned for his family and relatives, and that the doctor is not just asking the patient to submit to him. The patient must know what his rights are and must know that these will be guaranteed; he must be fully informed. All of this means that health staff must be properly trained and if there is a cultural difference must know the patient well, in order to be able to attend to him on the same basis as they would attend to any other citizen.

Francisco Collazos. Psychiatrist. Vall d'Hebron General Hospital.

In recent years medicine has undergone significant changes which have made a major impact on everyday clinical practice. Firstly, there is the impact of the gradual arrival of immigrants in our society. We have gone, in little more than a decade, from being a more or less homogenous society to living in a situation of genuine multiculturalism, where society is made up of people from all corners of the globe. Different cultural, ethnic and religious backgrounds and different languages come together, with a greater or lesser degree of harmony, in our towns and cities. This unstoppable flow of migrants is inevitably reflected in the consulting rooms and hospitals where health professionals have to deal with service users from different ethnic and cultural groups, with all that this implies. Secondly, there is the radical change in the doctor-patient relationship which has occurred in recent years. Until recently this relationship was a very unequal one (I decide and you comply). Now what prevails, beyond the principles of beneficence and non-maleficence, is the patient's autonomy. Informed consent is, in this sense, the paradigm of this progress towards a supposedly more equal relationship. We need to reflect carefully upon the combination of these two changes.

Informed consent is, in itself, entirely a construct of western culture in which the individual is paramount in the event of illness. This vision clashes with more collectivist approaches typical of what we might call more traditional cultures. The majority of the immigrants we receive here come from precisely this type of culture.

While it is true that the origin of informed consent goes back to medical excesses such as those practised by the Nazi regime or those which occurred in the USA with the Afro-American population, if today informed consent has become a standard part of care or research practice it is, in my opinion, the fear of being sued for negligence which leads the professional to ask for a signature which, in the event of potentially risky operations, could be used in his defence. This defensive attitude is legitimate in the face of the furious attack to which doctors are subjected in the performance of their "scientific" activities, often with little justification. If western society is unable to understand that not all "science" can be subjected to mathematical certainty, that there are very few

incontrovertible truths in the human sciences, and that most doctors, working on the basis of the best available knowledge, seek to make diagnoses and then apply the most appropriate treatments, following a rational procedure, that is, on the basis of knowledge accumulated as a result of years of development, scientific research and personal skill obtained from years of individual professional experience, then there is no other option but to defend oneself. And that is why health professionals turn to informed consent in their daily practice: when being attacked, one must defend oneself.

Of course this situation is not currently shared by all societies. And this is where cultural differences come in. In many societies the doctor-patient relationship remains much the same as the one which prevailed in the West only a few decades ago. Often the intellectual and social distance between the doctor and his patients is so great that this type of shared consultation involving both parties to reach a decision would be unthinkable. As a result it is difficult for people who belong to one of these cultures (the great majority of the migrant population which comes to the West) to understand the true spirit of consent. And when we come to applying informed consent, we get to the core of the problem. If we are to be faithful to the spirit of informed consent, then it has to be implemented in accordance with the law, and here there is no room for doubt. The person who gives the consent must have received the information in a comprehensible form. How many times does this happen? Usually, no translations of the documents are available (an official translation, which has been properly reviewed) and instead use has to be made of more or less well-qualified relatives or, in the best of circumstances, of a medical interpreter or intercultural mediator. And this is where a new ethical conflict arises: the question of to what degree this new participant in the medical encounter is in a position to fulfil the delicate mission of satisfactorily "informing" the patient. (Such participants are not officially recognized as health staff, they do not usually belong to the staff of the hospital or health centre where they are asked to act, and there is no official academic qualification which specifies their curriculum or their competencies, or the ethical code they should be bound by.) At present, we are giving extremely sensitive, health-related information to people who operate in this ethical and, I would say, legal vacuum. The consequences of this lack of clarity are easy to imagine.

Another issue which we should pay attention to is the format of the informed consent. For the reasons explained above, the informed consent used in conditions where there is real risk for patient and doctor is explicit, signed consent. This is the form of consent which has the greatest weight when it comes to mounting a defence. However, it clashes with an indisputable reality. If what is of prime importance is that the information should be as comprehensible and clear as possible, then we have to consider other formats, given that many "immigrants" may have little knowledge of reading. In the USA it has been concluded that the impact of information received (in a campaign about diabetes among the Hispanic population) was much greater when the information was given orally (provided on a CD which could be listened to as many times as necessary at home) than when carefully translated information leaflets were provided. In other words, it appears that it is not just a question of adapting the content but also the form.

So we are facing a new challenge, that of how to operate efficiently with all the users who turn to the health service, irrespective of their ethnic or cultural origin. Adapting how informed consent is implemented in a way which is culturally sensitive is an ethical commitment which will serve to preserve the essence of this concept, and will help us to rise successfully to the challenge of multiculturalism.

Josefina Goberna. Lecturer at the Department of Nursing and Public, Mental and Maternal and Children's Health. University School of Nursing. University of Barcelona.

CONSIDERATIONS ON INFORMED DECISION-MAKING AND CULTURAL DIVERSITY IN HEALTH CARE IN CHILDBIRTH

My contribution will focus on a series of considerations about the taking of informed decisions in maternity care, cultural diversity and some of the questions which are raised by health professionals.

Introduction

Maternity is part of the biological process of the life of the majority of women. Pregnancy and birth are not illnesses but health processes; however, maternity is a time when women are particularly vulnerable, and this is why childbirth and the period immediately following it have always been the focus of care and attention. The aim of obstetric care is to promote the health and well-being of mothers and children, and this is achieved by offering high-quality care, but this means seeking to ensure that this care is sensitive both to different individual and different cultural requirements.

In today's society these different requirements have become particularly clear. Throughout the 20th century the developed world has seen spectacular technological progress which has generally delivered better health and longer life expectancy, together with a significant decrease in infant mortality rates. Advances in knowledge and health technology have led to the appearance and development of technologically-dominated care, in obstetrics as elsewhere. Births take place in a hospital environment where the use of technology is a constant: heart monitors, anaesthesia and the stimulation of contractions are everyday practices in childbirth. This technological expansion has also been felt in pregnancy care, greatly increasing

the health service's capacity for the prenatal diagnosis of congenital defects[1].

The increasing role of technology in obstetric care has led to the appearance of deep differences in individual attitudes to models of obstetric care, and this makes clear the need for genuine informed consent obtained after an appropriate information process which enables the mother to make responsible, informed choices[2].

The technologisation of obstetric care: Individual differences in attitudes to care models.

Nowadays the processes of pregnancy and childbirth and the post-natal period are very safe. In western countries maternity has become a choice for women and their partners, who are able to decide when to have children and how many children to have.

We are also beginning to see the emergency of a critical attitude towards the excessive use of technology, and a call for a more human approach to care. In other words, technologisation and humanisation are the two extremes of the continuum of health care during pregnancy and childbirth.

I would like to illustrate this with a few examples:

- Alicia is pregnant and believes that birth is a unique experience which should be lived consciously and to the full; she asks to be accompanied by her partner throughout and wants the health staff attending to her to allow the birth to follow its physiological course; she states that only essential medical interventions should be performed, and does not want to have her waters artificially broken or to have an episiotomy unless this is strictly necessary.

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1. Carrera JM, Gallo M, López M. (2001): "Aspectos legales del diagnóstico prenatal. Diagnóstico prenatal de los defectos congénitos" in Fabre E. *Manual de asistencia al embarazo normal;* Zaragoza, Sociedad Española de Ginecología y Obstetricia, pp. 446-454.

2. Cooke P. (2005): "Helping women to make their own decisions" in Raynor M.D., Marshall J.E., Sullivan A. *Decision making in midwifery practice*; London, Elsevier, Churchill Livingstone, pp. 127-135.

- To ensure that her preferences are respected she looks for a hospital which has a care protocol for "normal, non-medicalised births", and has to attend a hospital over 70 km from her home to find such a care protocol.

Non-medicalised care in childbirth is care which, while still monitoring mother and foetus, involves minimum obstetric intervention[3]. There is a minority of the population who request this type of care. Some associations created to defend these interests have drawn up informed consent documents[4] where they clearly express their preference not to undergo any of the care measures which are not backed by scientific analysis of best available practice, such as systematic episiotomy, shaving of the vulva, enemas or the use of oxytocin with the sole aim of reducing the duration of labour.

But we will also find completely opposite cases, such as the following:

- Esther is also pregnant and believes that childbirth is a painful biological process; she wants to have access to all the available resources to make childbirth shorter; she would even like to be able to plan the birthdate of her child, and is also afraid that a vaginal birth could harm her and increase her risk of urinary incontinence in the future; as a result, she is considering requesting an elective Caesarean in order not to go through the process of dilation.
- Esther reaches 41 weeks of gestation, and her gynaecologist tells her that she should have an induction. She requests a Caesarean but is told that she should attempt a vaginal birth and not have a Caesarean unless indicated on medical grounds, after 12 hours of induction to no avail, she is given a Caesarean due to a failed induction.

For women who share the first point of view, that of Alicia, a medicalised hospital birth can be seen as a real attack, while according to the second point

3. Departament de Sanitat i Seguretat Social. Generalitat de Catalunya. (2003): *Protocol d'assistència al part i al puerperi i d'atenció al nadó,* Barcelona, Generalitat de Catalunya.

4. El parto es nuestro. (2006): *Consentimiento informado en obstetricia*; consulta 20/09/06. (Available at: *http://www.elpartoesnuestro.es/components/com_docman/documents/CI_Obstetricia.doc)*

of view, that of Esther, the discomfort and pain of a vaginal birth and the desire to control the process are of more importance than the "unlikely" possibility of complications for mother and foetus of a Caesarean birth.

We could give many more examples of care practices, including:

- The use of exercise balls and hot baths during the dilation process
- The use of epidural anaesthesia or other mechanisms to relieve pain
- The position of the mother during dilation and especially while the child is emerging
- Home birth
- Breastfeeding or bottle feeding

Drawing up a document setting out each woman's preferences, what is known as a "Birth plan",[3,5] can be a good way of documenting the informed choices of the woman in this regard.

However, this new attitude towards care raises new questions. Should health professionals always adapt to women's preferences? Does the training provided by university hospitals produce health professionals who feel confident of practising in a non-interventionist way with minimal use of technology? Can certain practices be refused if they are considered to be less effective or less safe? Is such a personalised approach to care compatible with a growing care load? Should the type of care be agreed between the health professional, the woman and her partner, or should each hospital define the care which it wishes or is able to provide according to the resources available? Even more controversial is the issue of elective Caesarean. The practice of Caesarean on demand, where not medically indicated and solely at the request of the patient, is currently a widely debated

5. Kohner N. (2001): "Deciding where to have your baby" in *The Pregnancy book*; London, Nacional Health Service, pp. 33-38.

issue and there are many arguments both for and against it in the literature.[6,7,8,9,10]

Cultural differences in care during childbirth. Caring for women from other ethnic groups or cultures

In addition to these very significant differences between women who belong to the same culture, our health system attends to a growing number of mothers from other cultural groups. Of more than 79,000 babies born in Catalonia in 2005,[11] almost 21% were born to mothers of foreign nationality.

Many women become pregnant soon after arriving, when their knowledge of the language is poor or even non-existent. Let us consider the different elements which constitute informed consent:[12] 1) the competence of the agent, 2) the explanation of the information, 3) the comprehension of the information, 4) the voluntary nature of the decision, and 5) the consent. Looking at these, it is clear that the information elements, which are essential if we are to respect personal autonomy, cannot be provided in these circumstances. It is impossible, or extremely difficult, to explain information, give health advice and ensure that both of these are understood if there is no basis for shared communication.

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6. Foradada C.M., (2006): Reflexiones sobre la cesárea; *Matronas profesión,* 7(1) pp. 5-13.
7. Paterson-Brown S. (1998): "Should doctors perfom an elective Caesarean section on request?" *BMJ*, 317, pp. 462-465.
8. Cotzias C.S., Paterson-Brown S., Fisk N.M. (2001): "Obstetricians say yes to maternal request for elective caesarean section: a survey of current opinion"; *European Journal of Obstetrics & Gynecology and Reproductive Biology* 97, pp. 15-16.
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10. National Institutes of Health State-of-the-Science (2006): "Cesarean Delivery on Maternal Request"; *Obstetrics & Ginecology,* 107(6), pp. 1386-1397.
11. Instituto Nacional de Estadística (2006): Movimiento Natural de la Población. Resultados provisonales 2005; consulted 20/09/06. (Available at: http://www.ine.es/ inebase/cgi/axi)
12. Beauchamp T.L., Childress J. F. (1999): *Principios de Ética Biomédica*; Barcelona, Masson, (Spanish version of the 4th edition. Original title: *Principles of Biomedical Ethics;* Spanish translation by García T., Júdez F.J., Feito L.), p. 137.

In a study which we conducted in 2002[13] to identify the difficulties faced by midwives caring for pregnant women from the Maghreb and sub-Saharan Africa, and in which we interviewed the midwives providing antenatal care in the province of Barcelona, 89% stated that not sharing a common language hindered communication, 35% felt that this difficulty was very important, 31% that it was important, and 24 % that it created a degree of difficulty; only 8% felt that the lack of a common language posed little difficulty for satisfactory performance of the health relationship. Pregnant women who did not know the language usually attended appointments in the company of some kind of mediator, generally the husband but it could also be another woman, a minor, generally a young child, or even a man who was not the husband; this made it much more difficult to address the sort of private issues which have to be considered during antenatal appointments. The intercultural mediator (incidentally, a highly controversial figure in pregnancy care) was only mentioned as the usual mediator by 4% of midwives.

But even where there is a shared language, as is the case for women from Central or South America, there are cultural differences: for example, in the age considered "usual" for having one's first child. What in our society might be considered a teenage pregnancy may be considered by other groups as something normal and usual.[13]

Some groups of women accessing the health system for the first time for pregnancy care have difficulty understanding the Western concept of prevention. The concept of health and of the health system which they bring from their home cultures means that they often delay the first contact for pregnancy care, or make use of hospital emergency services for pregnancy checks. How should we address these issues? How do we provide culturally competent and respectful care which is also compatible with heavy workloads?

13. Goberna Tricas J., Viñas Llebot A., Palacio Tauste A., Gali García M., Paulí Cabezas A., Gómez Moreno C. "Atención al embarazo a mujeres africanas inmigrantes. Percepción de las matronas de asistencia primaria". *Enfermería Clínica.* 2005; 15(2):88-94. 50

Providing care for women from other cultures and ethnic groups. Addressing preventive activities.

Health promotion and health education are key aspects of antenatal care. The new groups bring with them their own culture and lifestyles. How should we deal with practices and customs with which we are not familiar? Let us consider two very different examples.

1. Observance of Ramadan in Muslim women:

A study published in the *British Journal of Nutrition*[14] shows that a third of British Asian women in Birmingham observed Ramadan during pregnancy, despite the fact that the Koran allows women to postpone it until after they have given birth. Although I don't have any data about what happens in Catalonia, my impression is that the figures could be similar. How should we address this? The scientific evidence shows that there is no difference in the birthweight of babies whose mothers have observed Ramadan, but that there are metabolic changes in the mother, especially during the last days of fasting, and that in some cases these could be harmful. Should health professionals seek to persuade women not to follow this practice during pregnancy? Should they simply provide information about the possible effects of fasting? Or is it better to respect this behaviour as something which forms part of the women's beliefs and gives meaning to their lives?

2. Female genital mutilation:

Another very different example, due to the clear need to attempt to prevent and suppress this practice, is female genital mutilation. Female genital mutilation is an age-old practice which exists among many African peoples (although not exclusively) and has deep social and cultural roots[15].

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14. Malhotra A., Scott PH, Scott J, Gee H, Wharton BA. (1989): "Metabolic changes in Asian Muslim pregnant mothers observing the Ramadan fast in Britain". *British Journal of Nutrition;* 61, pp. 663-72.

15. Kaplan A., Martínez C., et al (2004): *Mutilación genital femenina: prevención y atención. Guía para profesionales;* Barcelona, Associació Catalana de Llevadores.

In Catalonia the form of mutilation we see most frequently is type I or circumcision; the most serious, type III or infibulation, is practised principally in some regions of the Sudan, Eritrea, Ethiopia, Somalia and part of Egypt, and there has been little immigration into Catalonia from these areas; however, when a case occurs it is a complex issue for health professionals to deal with; linguistic difficulties are compounded by the discomfort which health professionals tend to feel in the face of such practices. When dealing with a pregnant woman, it is important to choose the correct moment for disinfibulation before childbirth, and to raise the issue of informed consent with her and her partner, together with the legal prohibition on reinfibulating after the birth of the child. When attending to a woman with any type of mutilation, and particularly if she is to give birth to a girl, antenatal care offers a good opportunity to raise the issue of preventing the practice being applied to the daughter in the future.

This is a complex issue which requires training, sensitivity and respect, but at the same time calls for firmness and a commitment to raising awareness if we are to be committed to eradicating the practice.

Final considerations

Margarita Boladeras

The discussion which followed these contributions provided an opportunity to consider some of the core issues of informed consent in multicultural contexts, and to emphasise some of the ideas already expressed. I will not attempt to reproduce the discussion but will instead recapitulate some of the key points raised during the session as a whole.

The proper practice of informed consent is to be at the service of ensuring that patients are adequately informed, so that they can take decisions on the basis of proper knowledge, and to promote good communication which enables the patient to trust his or her carers. In her paper, Anne Davis gave the following definition: "In the USA, informed consent is defined as an autonomous authorization by an individual for a medical intervention or for involvement in research. Autonomy means that individuals have the right to information and using it, the right to agree or refuse to participate in research or to undergo treatment proposed. This individual is a competent adult capable of understanding information and of making decisions. Health professionals have an ethical obligation to help the individual patient understand the information being given and the consequences of decisions made." It also has other functions, such as defence of the doctor and the institution in the event of disputes. But when health professionals use informed consent solely as a means of defence and forget about the need for good communication with their patients, it becomes the opposite of what it should be.

In this regard, Francisco Collazos observed that some of these defensive attitudes are due to the unjustified attacks to which health professionals are sometimes subjected by individuals who do not understand that medicine is not an exact science; but he also warned against the absurdity of obtaining informed consent solely in order to defend doctors and not because of the needs of patients.

When it becomes a mere administrative formality instead of being an integral part of the medical interaction, the obligation of informed consent can

give rise to acts which lack any legal validity and are ethically reprehensible. There is an ethical duty to explain, to advise and to facilitate understanding which then provides a basis for rational decision-making; as a result, in addition to verbal exchanges, written explanations can help the patient to better understand the issues and formulate questions regarding to his situation. Both health staff and patients have rights and duties, and these can combine to form the basis of a good relationship which creates a positive dynamic and supports medical care.

Knowing how to relate to others and successfully achieving good communication is no easy task, particularly when dealing with people who may be ill and suffer from feelings of insecurity. It requires an ability to understand people and to interpret different situations; it calls for communicative skills; and, when implementing informed consent, it also requires the ability to assess the comprehension and decision-making capacities of patients suffering from physical or mental stress.

In multicultural contexts, this communication can be particularly difficult due to the lack of a shared language or because the two parties understand things differently. Francisco Collazos argued that dealing with people from other cultures is particularly challenging; in many cases, the patient has great difficulty understanding the meaning of informed consent and why the doctor is not taking the decisions. In this case, how can we achieve the basic requirement of ensuring that the procedure is accessible to the patient? Intercultural mediators or communicators can be of great help in facilitating communication between health staff and their patients. The role they perform goes beyond that of a translator, as they also facilitate understanding of the character of the person from the other culture. In Estanislao Alonso's opinion, the intercultural communicator should have a transitional role, as with the passage of time there should be a shared language between patients and doctors, and health staff should have adequate cultural competency. This position, of course, is the subject of debate. Francisco Collazos expressed concern at the position of the medical interpreter or intercultural communicator, as they "are not officially recognized as health staff, they do not usually belong to the staff of the hospital or health centre where they are asked to act, and there is no official academic qualification which specifies their curriculum or their competencies, or the

ethical code they should be bound by." Under these conditions, it is difficult to know whether, they are "in a position to fulfil the delicate mission of satisfactorily "informing" the patient. At present, we are giving extremely sensitive, health-related information to people who operate in this ethical and, I would say, legal vacuum. The consequences of this lack of clarity are easy to imagine."

Cultural competency assumes knowledge of different cultural concepts and sensitivities, the diversity of customs, and a critical attitude towards ethnocentrism. This knowledge makes it possible to understand the internal logic which underlies different lifestyles, to overcome ethnocentric prejudices, and to promote the respect which every individual deserves. Only by breaking down the barriers of incomprehension can we build trust.

Anne Davis stressed the importance of taking the patient's social and cultural context into account when addressing their problems. This has implications for the practice of informed consent. Decision-making is something which different cultures allocate to different members of the family or clan, and this gives rise to potentially complex situations, because different members of the family will have a different attitude to these traditions and to the way issues should be addressed. If we are to establish a good problem-solving dynamic it is important to go beyond stereotypes and to resolve conflicts in order to reach solutions which "preserve" the dignity of those involved. Western categories and standards cannot be applied unthinkingly to people who live in other cultures. Josefina Goberna also referred in the discussion to the ethnocentric prejudices which often accompany our assessment of unfamiliar customs, many of which are very similar to what occurred in Spain thirty or fifty years ago. Another issue is that "the increasing role of technology in obstetric care has led to the appearance of deep differences in individual attitudes to models of obstetric care, and this makes clear the need for genuine informed consent obtained after an appropriate information process which enables the mother to make responsible, informed choices". These differences multiply when we are caring for women from different cultures (of the more than 79,000 babies born in Catalonia in 2005, almost 21% were born to mothers of foreign nationality). Some of the problems which are characteristic of these groups relate to the lack of habits of prevention and continuous care for pregnant women, certain religious customs (for example, fasting during Ramadan)

and ignorance of the language. This last factor is particularly important, and Goberna offered the following statistics: "In a study which we conducted in 2002, to identify the difficulties faced by midwives caring for pregnant women from the Maghreb and sub-Saharan Africa, and in which we interviewed the midwives providing antenatal care in the province of Barcelona, 89% stated that not sharing a common language hindered communication, 35% felt that this difficult was very important, 31% that it was important, and 24 % that it created a degree of difficulty; only 8% felt that the lack of a common language posed little difficulty for satisfactory performance of the health relationship. Pregnant women who did not know the language usually attended appointments in the company of some kind of mediator, generally the husband but it could also be another woman, a minor, generally a young child, or even a man who was not the husband; this made it much more difficult to the sort of private issues which have to be considered during antenatal appointments. The intercultural mediator (incidentally, a highly controversial figure in pregnancy care) was only mentioned as the usual mediator by 4% of midwives."

Josefina Goberna also referred to the problem of female genital mutilation and the need to prevent and eliminate it. In the discussion, both Estanislao Alonso and Anne Davis returned to this issue, and Davis argued that often prevention is not carried out properly because they don't talk to the right person; for example, some international programmes do not address the male head of the family, who is usually the centre of the problem. To the question which came up during the discussion as to where the limit on respect for the customs of other cultures lies (if we do not wish to accept everything, for example, female genital mutilation), Josefina Goberna answered that we should distinguish between respecting people and accepting their practices. Everyone deserves to be treated with respect, but this does not imply accepting all of their practices and the consequences of these.

Mohammed Chaib explained in his contribution that, "according to Islam the month of fasting, Ramadan, is not obligatory for pregnant women, the elderly or those who are undergoing treatment"; what happens is that "there are individuals who insist on fasting even though it is not obligatory." In Catalonia there are Muslim groups which help the followers of this religion to understand its rules. The Ibn Batuta Socio-Cultural Association provides advice and

support to individuals and health centres who request it; it has provided help in cases of language difficulties, has given patients guidance on informed consent, terminal illness, dealing with death, etc. At the level of the health system, the Health Department and the Office of the President of the Government of Catalonia have drawn up a Guide for respecting religious pluralism in hospitals, an interesting initiative which needs to be followed up with more practical measures. The statistics give an indication of the scope of the issue: "The number of foreigners resident in Catalonia is around one million, in other words 12% of the total population, and this number is growing constantly."

The informed consent required for clinical trials is worthy of special mention, particularly when the trial is to be conducted in Africa or in places whose cultures and social contexts are very different to those found in economically developed countries. Eusebio Macete called our attention to the impossibility of simply transplanting western regulatory models; these have to be adapted and used flexibly if we are to take into account problems such as illiteracy, the struggle for survival, socioeconomic dependency, and age-old prejudices. The standards drawn up by international organisations do not take such situations into account and impose inappropriate procedures on some groups of people. The problem is very serious, because these research programmes are an irreplaceable source of economic support and are essential for poor countries; any obstacles to assessing the implementation of the trial can lead to the trial itself being suspended, and this is very harmful for the population. In his presentation, Macete used a range of examples to clearly illustrate the different sorts of difficulties which researchers encounter when working in African countries.

List of invited specialists

Speakers:

- **Anne Davis**, Emeritus Professor at the University of California, San Francisco and the Nagano College of Nursing in Japan.
- **Eusebio Macete**, Researcher at the Manhiça Health Research Centre (CISM), Manhiça, Mozambique.

Coordinator and chairperson:

- **Margarita Boladeras,** Professor of Moral and Political Philosophy at the University of Barcelona and director of the study group on Multiculturalism and Health created by the Advisory Committee on Bioethics of Catalonia.

Invited specialists:

- **Estanislao Alonso,** Advisor to the Immigration Management Plan of the Department of Health of the Government of Catalonia
- **Mohammed Chaib,** Chairman of the Ibn Batuta Socio-Cultural Association.
- **Francisco Collazos,** Psychiatrist. Vall d'Hebron General Hospital.
- **Josefina Goberna,** Lecturer at the Department of Nursing and Public, Mental and Maternal and Children's Health. University School of Nursing. University of Barcelona.

Publications

Bioethics Monographs:

15. *Informed consent and cultural diversity*
14. *The issue of patient competence*
13. *Health information and the active participation of users*
12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of The Goals of Medicine)
10. *Corresponsabilidad empresarial en el desarrollo sostenible* (Corporate responsibility in sustainable development)
9. *Ethics and sedation at the close of life*
8. *El uso racional de los medicamentos. Aspectos éticos* (The rational use of medication: ethical aspects)
7. *La gestión de los errores médicos* (The management of medical errors)
6. *Ethics of medical communication*
5. *Problemas prácticos del consentimiento informado* (Practical problems of informed consent)
4. *Predictive medicine and discrimination*
3. *The pharmaceutical industry and medical progress*
2. *Ethical and scientific standards in research*
1. *Freedom and health*

Reports of the Foundation:

4. *Las prestaciones privadas en las organizaciones sanitarias públicas* (Private services in public health organizations)
3. *Therapeutic Cloning: ethical, legal and scientific perspectives*
2. *An ethical framework for cooperation between companies and research centers*
1. *Social Perceptions of Biotechnology*

Ethical Qestions:

1. *¿Qué hacer con los agresores sexuales reincidentes?* (How to deal with repeat sexual offenders?)

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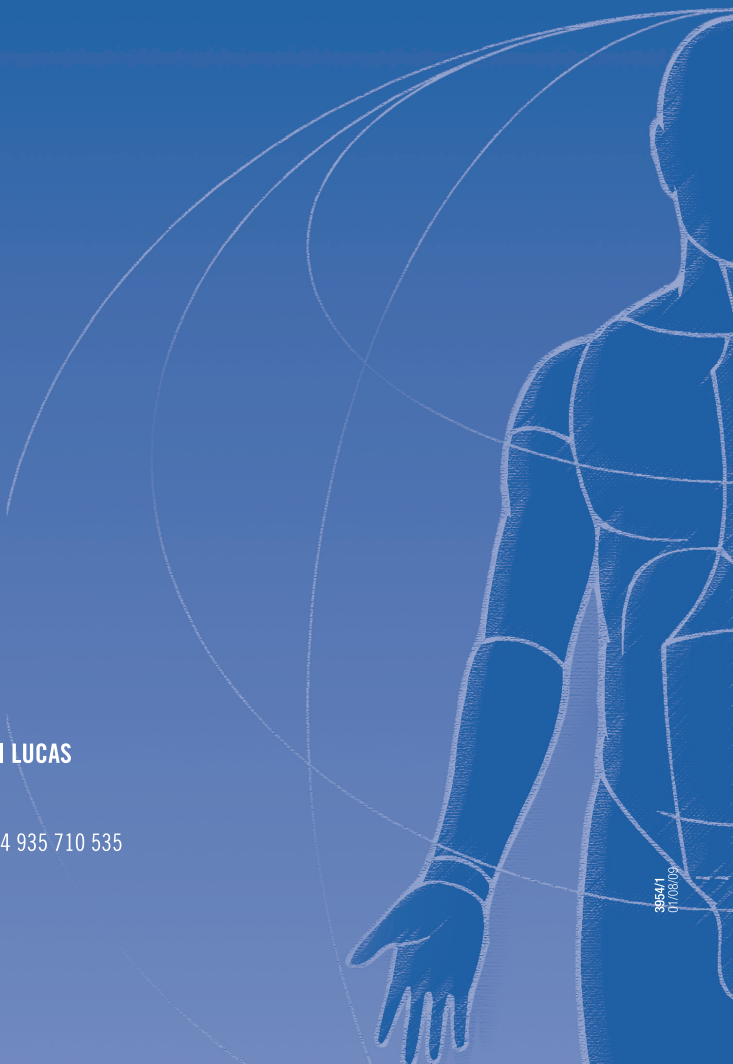

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