ETHICS AND GERONTO PHARMACOLOGY

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INTRODUCTION

It is one of the main goals of researchers in medical sciences and health care professionals to heal sick individuals. Among the available means to reach this aim there is the usage of pharmaceuticals. Pharmaceuticals products (or drugs or medicines) are of great importance to providing consumers with a myriad of treatments and cures. It includes a wide range of prescriptions and non-prescription drugs, medicines and therapeutics, analgesics and anti-inflammatory drugs, cardiovascular products, advanced antibiotics, anti-viral and anti-cancer drugs, immune system products and anti-histamines, advanced cellular research products for preventative and therapeutic medicines, but also cosmetic products, such as, e.g., skin and hair care products.

Many issues are related to pharmaceuticals: where are the boundaries between pharmaceutical products exclusively useful for the beauty industry and such products really of importance for human medicine in terms of treating diseases? How can we decide and who decides that a product is essential? How a new drug is discovered and developed? What are the ethical criteria of the research on and with pharmaceuticals products? What happens with ‘orphan diseases’? What’s the purpose of patents? What is patentable? What is the aim of using a pharmaceutical product? (therapy? prevention, euphoria, wakefulness, appetite suppression, doping in sport, etc., pain relief?) Why there are huge inequities in the world in access to pharmaceuticals? What can be done to improving managing pharmaceuticals in international health?

These questions related to pharmacology concern all population but some of them are more acute in regard of the elderly people. As the number of elders is growing (especially in Western societies), so is the use of non prescription and prescription drugs or medicines among elders. Seniors are a burgeoning presence in the health care system, and these patients often seek emergency treatment for drug-related problems.

One of the success stories of the 20th century is the prolongation of life and the improvement of its quality (but not in all regions of the world). However inevitably linked to this success of the medicine is the permanent challenge of the society as a whole and particularly to health professionals to define the health care needs, to improve their accessibility and further enhance the well-being especially of elderly people as the main recipients of health care services.

The use of medications to treat the diseases and disabilities of elderly persons is substantial. Approximately 25% of all prescriptions are written for older patients. The average person over 65 years takes between 4 and 5 prescriptions at any one time (a survey in U.S.A indicates an average of 5-7 prescription medicines per elderly patient). Medications play an important if not

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solitary role in the treatment of many diseases, relieving symptoms and prolonging life. On the other hand, it also poses problems for the elderly: In general, elder people may respond differently to medicines compared with younger adults and face a greater likelihood of adverse drug reactions. Therefore the need of dose adjustment is obvious. Moreover, older people are often exposed to complex pharmacotherapies reflecting the simultaneous existence of various systemic diseases, but major clinical trials in geriatric pharmacology reflecting this complexity are still rare or even lacking. The genomic background of outcome and side effects in relation to aging is largely unknown. The increase in the variety and quantity of drugs, the knowledge of their benefits, and the widespread clinical use of medicines have far outdistanced our understanding of the problems associated with their use. “Inadequate knowledge about drug use is more preoccupied in relation to the elderly, because aged people become ill more often, suffer more from chronic conditions that are treatable with drugs, and are prescribed more medicines than are younger adults or children... And because of the sheer number of drugs prescribed the elderly often have difficulties taking their drugs as indicated, that is, a problem of drug compliance... The elderly who use prescription drugs, particularly those who are poor, face the additional problems of rising drug prices”\(^2\). We do not fully estimate the costs borne by the elderly, particularly those who are poor or struggling to have a decent life. Nor we do not fully appreciate the dangerous decisions many elderly make as a direct consequence of high prescription drug costs, as not taking life-saving drugs or redirecting limited financial resources to pay for drugs in lieu of other essentials, such as food and shelter.

In the years ahead, difficult decisions must be made regarding how to protect the elderly from rising drug costs while simultaneously improving the quality and economic of geriatric drug prescribing and use. In 1989, WHO made the statement that “one third of the world’s population was lacking effective access to quality assured essential medicines used rationally”. Today the proportion of those lacking access is lower in Asia and Latin America and higher in Africa, but there are probably about 2 billion people in this situation. Many people, especially the elderly, lack access to essential medicines because their countries are poor and because of inefficiencies in their health system. “Yet the 75% of the world’s population living in low and middle income countries consume barely 20% of the world’s medicines. And just 8% low and middle income countries consume over 60% of all the medicines available in the developing countries. Addressing these great inequalities is one of the major challenges in international health”\(^3\). And as Richard Laing affirms: “When poor people have limited resources and great needs, their lives depend on these scanty resources being spent as efficiently as possible. Managing pharmaceuticals in international health in a way which provides the greatest possible benefit for these in greatest need should be the goal of any public health practitioner or pharmacist working...”


\(^3\) ANDERSON, Stuart, (et alii), *Managing Pharmaceuticals in International Health*, Basel - Boston - Berlin: Birkhäuser Verlag, 2004, Preface, xi
in the world”.

These facts and situations raise serious ethical issues:
- age as criterion for allocating pharmaceuticals
- autonomy, competency and freedom of choice
- behavior control and goal of medicine
- access, distribution and justice
- age-entitlements, rights and duties
- social responsibility of actors: prescriber, manufacturer, consumer, pharmacist, society as a whole, etc.

What principles and guidelines may inspire our decisions and behaviors? It is the scope of this paper to look at some of the main ethical questions or dilemmas raised by the gerontopharmacology.

I- THE REALITY

Morality in rooted in reality. So it is very important to know facts and situations.

1.1. Practical considerations: age-related changes, pharmacokinetics and pharmacodynamics:

Age-related changes influence patterns of medication consumption and actions of medications in the body. These changes include alterations in the homeostasis, renal function, cardiac output, liver function, serum albumin level, body composition, and receptor sensitivity. The term pharmacokinetics refers to the movement of a drug in the body from the point of administration through absorption, distribution, metabolisme, and finally excretion. It is important for the gerontological health care practitioner to understand how pharmacokinetics may differ in older adult.

Absorption: no conclusive evidence that there is an appreciate change in the absorption process in older adults.

4 LAING, Richard, “Foreword”, in ANDERSON, Stuart ( et alii), Managing Pharmaceuticals in International Health, x

Distribution: once a drug is absorbed it must be distributed or transported to the receptor site on the target organ. Late life alterations in drug distribution are primarily related to changes in body composition, particularly decreases in lean body mass, increases in body fat, and decreases in total body water. Decrease in total body water and increase in total body fat affects volume of distribution. Decreased body water leads to higher serum levels of water-soluble drugs, such as digoxin, ethanol, and aminoglycosides.

Metabolism: process wherein in the chemical structure of the drug is converted to a metabolite that is more easily excreted. It is called biotransformation. The liver is the primary site of drug metabolism. Acetylation and conjugation do not change appreciably with age. With aging, the liver activity, mass, volume, and blood flow are diminished. These changes result in the potential for a decrease in the body’s ability to metabolize drugs. These changes result in a significant increase in the half-life of these drugs. For instance, the half-life of diazepam (valium) in a younger adult is about 37 hours but in an older adult this is extended to 82 hours. If the dose and timing are not adjusted for the older adult, the accumulation can have significant effects after the administration of a single dose.

Excretion and elimination: drugs and their metabolites are excreted in sweat, saliva, and other secretions but primarily through the kidneys. Since kidney function declines with aging, so does the ability to excrete or eliminate drugs in a timely manner. The significantly decreased glomerular filtration rate leads to prolongation of the half-life of drugs eliminated through the renal system, resulting in more opportunities for accumulation and potential toxicity or other adverse events. Serum creatinine is an unreliable marker although renal function cannot be estimated by the creatinine level, it can be approximated by the calculation of the creatinine clearance.

Pharmacodynamics: refers to the interaction between a medicine and the body (what the drug does to the body). The older the person gets, the more likely there will be an alteration or unreliable response of the body to the drug. Although it is not always possible to explain the alteration, several are known:

- some effects are increased. Alcohol causes increase in drowsiness and lateral sway in older persons that young one at same serum levels. Increased sensitivity to a number of medications, especially anticholinergics, benzodiazepines, narcotic analgesics, warfarin (Coumadin), etc.
- some effects are decreased. Older adults tend to have a decreased response to beta-adrenergic receptor stimulators and blockers.

1.2. Medication issues and older adults:

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This section is greatly inspired of EBERSOLE, HESS, TOUHY, JETT, *Gerontological Nursing & Healthy Aging*, Second Edition, p. 290-297; see also YEE, WILLIAMS, in BERNSTEIN LEWIS, Carole, *Aging*, p. 251-255; 262-265
- Prescription drugs: elderly accounts for 1/3 of prescription drug use while only 13% of population; ambulatory elderly fill between 9-13 prescriptions a year (new and refills); average of 5-7 prescriptions medicines per patient”.  

- Non-Prescription Drugs: Surveys indicate that elders take average of 2-4 non prescriptions drugs daily; laxatives used in about 1/3 - 1/2 of elders - many who are not constipated; non-steroidal anti-inflammatory medicines, sedating antihistamines, sedatives, and H2 blockers are all available without a prescription, and all may cause major side effects.  

- Polypharmacy: use of multiple medications at the same time. The “Prescribing Cascade”: common cause of polypharmacy in elderly people; Polypharmacy may be necessary if one had multiple chronic conditions or it may occur “accidentally” if and existing drug regimen is not considered when new prescriptions are given or any number of the thousands of OTC (out-of-the-counter) preparations and supplements are added to the prescribed medications. The 2 major concerns with polypharmacy are the increased risk for drug interactions and the increased risk for adverse events.  

- Drug Interactions: the more medications a person takes, the greater the possibility that one or more of them will interact with another one, a nutritional supplement, food or alcohol. When 2 or more medications or foods are given at the same time or closely together the drugs may potentiate one another or make one or both stronger; or antagonism may occur, with a drug or a food causes the other one or both to become ineffective. Possibility of a drug-related illness that may account for 15% to 23% of all hospital admissions. Possibility of altered pharmacokinetic activity or alteration in the absorption, distribution, metabolism or excretion. In pharmacodynamic interactions one drug alters the patient’s response to another drug without changing the pharmacokinetic properties. This can be especially dangerous for older adults when 2 or more drugs with same effect are additive, that is, together they are more potent than they are separately.  

- Adverse- Drug Reactions (ADR): it is an unwanted pharmacological effect, ranging from a minor annoyance to death, and includes allergic reactions. An estimated 40% of the elderly in the community have experienced ADR’s, 80% of which occurred with well-known drugs given at usual dosages. About 15% of hospitalization in the elderly are related to ADR. The risk for ADR is increased with the number of medications taken by most older adults. One the most troublesome ADR’s for the older adult is drug-induced delirium or confusion. Polypharmacy with several psychoactive drugs exerting anticholinergic action is perhaps the greatest precipitation of the adverse reaction of delirium. Drugs are a common cause of potentially reversible cognitive impairment. Demented patients are particularly prone to delirium from medicines. Drug may cause lethargy, phototoxicity and contribute to sexual dysfunction. Drug toxicity is the most life
threatening of the adverse effects. Toxicity or poisoning in the elderly may account for up to 25% of calls to poison control centers and 20-30% of hospitalizations.

- Misuse of drugs and non-compliance: The more drugs taken, the more likely misuse will occur. Forms of misuse include overuse, underuse, erratic use, and contraindicated use. Misuse may occur for any number of reasons from inadequate skills of the health care practitioner or the prescriber, to misunderstanding of prescriptions, to inadequate funds to purchase prescribed medications. In general, only scant evidence suggests that older age itself is a risk factor for non compliance. The use of 3 or more drugs a day places elderly people at particular risk for poor compliance. The complexity of regimen is also an important barrier to proper use. Compliance with one regimen does not mean that a patient will comply with another, and the prescribers cannot estimate compliance behavior on the basis of past drug-use histories. Underuse of drugs because of forgetting is common in older people and especially prevalent among those who are isolated or are cognitively impaired. Memory failures associated with non adherence to medication regimens are of 2 general types: forgetting the way to correctly take medication, and failure to remember to take medication at the correct times. These example are accidental. But the underuse of a prescribed may be deliberate. Some elderly patients may try to save money by lowering the dose or sharing medications. Others may save medications for future use by stopping a particular regimen early. Some may stop medications when symptoms diminish, believing that the condition has been cured; others may discontinue medication if symptoms persist, believing it is not working. For a variety of reasons, elderly persons often choose to self-medicate for some health conditions, such as arthritis, insomnia, or constipation. They often choose to self-medicate with OTC drugs rather than to visit a physician because of limited mobility or fixed incomes, unavailability of a family physician, greater exposure to drug use, increase in the number of OTC drugs on the market, etc. A problem of adherence may also occur because of limitation in vision which often make the older person unable to correctly follow instructions. The practice of giving rapid-fire directions is not effective in addressing the person with hearing impairments. Although the most common compliance problem seen in practice is the failure of the elderly to take enough medication, there may be an overuse. But deliberate overuse of prescribed drugs is relatively rare among the elderly. Finally the misuse of drugs may be expressed in the alteration of schedules and doses. Older patients may also change the dose or administration time of their medication to accommodate their own daily schedule. Many factors may contribute to non compliance in older patients: inadequate information regarding the necessity for pharmacotherapy, unclear prescribing direction, inadequate doctor-patient relationship. Drug non-compliance is a complex phenomenon. Adherence to instructions may vary according to individual personality, site of care, health beliefs, the drug prescribed, the disease being treated, and the side effects experienced. There are also mental disorders which adversely affect the ability of elderly patients to comply with prescribed treatment regimen. A rational drug prescription is more than ever essential, that means: careful evaluation before use begins and frequent monitoring thereafter; knowledge of age-related changes to provide a foundation for understanding the increased vulnerability of older persons to the side effects and adverse reactions to psychotropic drugs; surveillance for drug-induced illnesses; awareness of compliance behavior; and heightened attention to goals for older person’s overall functional
- Complementary or alternative therapies: “Homeopathy, herbal medicine, and folk remedies are viewed as non-traditional approaches to preventing and treating illness, despite the fact that these approaches have a long tradition in many non-Western cultures. Thousand of alternative healing products are widely available and being used increasingly by older adults. Even National Institute of Health have instituted an office of Alternative Medicine and have funded clinical trials of herbs, such as Ginkgo biloba and St-John’s wort. Health care practitioners need to be knowledgeable about a variety of therapies so that health care consumers can be advised about their use and effectiveness.”

Some drugs are inappropriate for elderly persons, and alternative therapies may be more efficient. But high-risk factors for medication safety among elderly patients is made even more complicated with the increased use of alternative and complementary medicines. For instance, non-stereoidal anti-inflammatory drugs (NSAID’s) may negate the usefulness of feverfew in treatment of migraine headaches. Echinacea could cause liver toxicity and should not be used with other hepatotoxic drugs such as anabolic steroids or methotrexate. We just begin to systemically study the drug-food-herb interactions, efficacy, and safety of herbal medicinals in treating various health conditions. Elder people and health care practitioners must be aware of the potential dangers of using herb medicinals with prescribed and OTC medications.

- Prescribing behavior of Physicians: Inappropriate medication use by elderly individuals may be explained by errors in medication prescribing. The most common types of medication errors include those related to knowledge and application and drug therapy knowledge; related to patient’s knowledge and patient characteristics that affect pharmacotherapy; due to incorrect calculations, decimal points, or unit and rate of expression; attributable to drug name, dosage form, or drug abbreviation. Golden and colleagues suggest that improvements in drug safety could be accomplished by focusing on organizational, technological, and risk management education and training efforts associated with prescribed errors. The prescribing behavior of physicians is influenced by personal characteristics such as age, medical school attended, attitudes concerning the value of medication in the management of acute and chronic disease, and outside pressures, such as pharmaceutical representatives, journals, advertising, etc. In fact, the pharmaceutical industry is estimated to spend billions of dollars a year, on advertising its products. Advertising encourages physicians to prescribe more drugs and consumers to take more medications. Mass media advertising provides the strongest influence on the drug-use behavior of health professionals and consumers.

- Costs: In many countries, especially poor countries, the health care system does not pay for prescription drugs for elderly people. In USA, average prescription drug cost for an older person


is $500/Year, but highly variable. In USA, drugs cost more than any other country. Non-prescription drugs and herbals can be quite expensive. New drugs cost more.

- **Inequities:** Millions of people worldwide still do not have access to essential medicines that are affordable and of good quality. In low and middle income countries, between 25 and 40% of health expenditures is on medicines, and that most of that expenditure is out of pocket. In contrast, high income countries spend only 8 to 15% of health expenditures in medicines, and this is mostly paid for by health insurance or social security funds. Global inequities in access to medicines exist between rich and poor countries because of market and government failures, as well as huge income differences. For millions of people, medicines remain unavailable, unaffordable, and unsafe, and even when available they are often used irrationally. “The enormous disparity in access to pharmaceuticals is best illustrated by a comparison between the percentage of the world’s population represented by a particular region, and the proportion of pharmaceuticals sales accounted for by that region. For instance, North America, with only 6% of the world’s population, accounts for over 50% of total world sales of pharmaceuticals. Asia, Oceania and Africa, which together account for 71% of the world’s population, are the recipient of only 8% of total world sales of pharmaceuticals. Even allowing for the very high price of pharmaceuticals in North America, together with a reliance on expensive medicines to treat the diseases of an affluent life-style, like those for obesity, depression and high blood pressure, these figures demonstrate a very high level of both inequality (lack of equivalence) and inequity (lack of fairness), if we believe that vital commodities such as pharmaceuticals should be provided according to the health needs of the population rather than ability to pay”\(^\text{10}\)

- **Medicines and patents:** International agreements on pharmaceuticals were consolidated following institution of the World Trade Organizatin (WTO) in 1994. An annexed agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) defined the patent life of a pharmaceutical product as 20 years from the date of registration. International guarantees of monopolies on medicines have been highly contested ever since, and are seen by many as a global reinforcement of inequity. Some question the wisdom of the research-based pharmaceutical industry which defends the existence of patents, arguing that it has to protect its investments and recoup the enormous costs of developing new medicines, as well as to promote innovation by providing incentives to invest in research and development. Dr Marcia Angell, who had worked 2 decades at the New England Journal of Medicine (looking at the pharmaceutical industry) exposes in her 2004 book\(^\text{11}\) the shocking truth of what the pharmaceutical industry has become and demonstrates how the claims that high drug prices are necessary for research and development are unfounded. According to her, the truth is that drug companies funnel the bulk of their resources into the marketing of products of dubious benefit. From a public health point of view, patent protection has the consequence of delaying affordable

\(^{10}\) ANDERSON, Stuart, et alii, *Managing Pharmaceuticals in International Health*, p.8

\(^{11}\) ANGELL, Marcia, *The truth about the drug companies: how they deceive us and what to do about it*, New York: Random House, c2004, 305p
generics. This is a major obstacle to medicine access and a reason why medicine research and development for developing countries and for diseases of the poor remain very limited, despite an ever-increasing need for safe, effective and affordable medicines for the treatment of the neglected diseases such as malaria, sleeping illness and tuberculosis.

2. ETHICAL ISSUES

Many ethical questions are related to gerontopharmacology: the question of autonomy and consent, the respect for aged people who have an important say in the way they will be treated, the question of access to the resources with the big issue of patenting, the duty to treat the most vulnerable ones, the pain management, especially in the final stage of a terminal illness, the participation of elderly persons in clinical research, the quality and sanctity of life, information on the educational efforts to be taken by the drug manufacturer to ensure that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits to ensure that they can make an adequate decision in clinical trials, etc. There are other issues such as behavior control, chemical dependency, etc. We won’t explore all ethical issues but reflect upon some specific issues which will help us to become aware of the complex and numerous ethical challenges linked to gerontopharmacology.

2.1. Ageism

In recent years ageism had joined racism and sexism in the list of attitudes which offend against current norms of human rights. Ageism is defined as disrespect and unjustified discrimination against elderly persons on the grounds of their age. Its manifestations range from laws and regulations about compulsory retirement through attitudes such as paternalism in medical and nursing care to extreme forms of physical and mental abuse. Old age or advanced age is often regarded as a debilitating disease which reduces elderly people to the status of small children or mental incompetents, incapable of making decisions about their health and welfare. To refuse treatment as CPR or dialysis for renal dysfunction to patients who have reached a certain age, is an example of ageism. To a considerable extent, ageism is intertwined with sexism, since a larger majority of elderly persons are women. They are often victims of great economic disadvantages as well as being the brunt of the other manifestations of ageism described above. Ageism is also expressed in the mistaken belief that clinically troublesome symptoms result for old age per se. It is almost never appropriate to consider a symptom in an older patient merely as “a result of the normal aging behavior”12. Chronological age per se is not an adequate explanation of or cause for dementia, mood disorders, fatigue, or a host of somatic symptoms such as incontinence or shortness of breath. The problem of ageism is particularly important in relation to the recognition of adverse drug events, which may present with symptoms readily mistaken by the unwary for ‘problems of normal aging’. The detection and the treatment of drug-induced illness - preferably by eliminating the offending drug rather than by

treatment the side effect with yet another medication can be among the most effective and rewarding interventions in all of geriatric practice. When an elderly patient or family member incorrectly attributes a treatable illness to aging is unfortunate; when this done by a physician, it is inexcusable. A clinically useful statement is a prerequisite and any new symptom in an older patient should be considered a possible drug side effect until proven otherwise. Most of all it is a question of respect for the inherent dignity of the elderly person who remains a person even when frail, diminished and dependent.

2.2. Competency and informed consent

Elderly people have the same ethical and legal right to make decisions about their health care as any other competent adults. They are, however, subject to medical problems which can impair their competency to make such decisions. Accordingly, the doctrine of informed consent requires a certain adaptation to the situation of the elderly. In cases of total and permanent incompetency, such as individuals suffering from advanced dementia or advanced stage of Alzheimer Disease, health care professionals must determine appropriate treatment according to the patient’s expressed wishes while competent, the best interests of the patient, and the instruction of “significant others” - family members, friends, etc.

Situation is more problematic with cases of doubtful or intermittent competency. Many elderly persons experience temporary confusion and loss of memory. The Royal College of Physicians and Surgeons of Canada, has advised its members to employ the following procedure in such cases: “If the patient’s competence is uncertain, the physician should attempt to minimize the uncertainty by seeking medical consultation before trying to secure informed consent. If the patient’s decisions or refusal to decide seem unreasonable and are likely to result in serious harm to them, the physician should consult with the families, colleagues, and hospitals authorities about the advisability of acting against, or in the absence of the patient’s expressed wishes, at least until their competence is no longer in doubt.” These guidelines should be used by other caregivers as well. They have also an obligation to respect the elderly person’s decision, no matter how unreasonable it appears, as long as it is most likely to cause serious harm. There are often considerable burdens involved in respecting patient autonomy, since many patients choose to do things that make life difficult for their caregivers. There is a strong temptation at these times to treat the person as incompetent, in order to solve such behavioural problems. Such an approach is generally unethical, and other solutions should be sought. Since competency is a prerequisite for the exercise of informed consent, it follows that health care practitioners should strive to preserve competence whenever it is threatened. In particular, they should avoid


administering medication that diminishes competency, unless absolutely necessary.

In many health care institutions, caregivers often employ chemical restraints such as sedative drugs to prevent elderly patients from acting in a way they (caregivers) consider to be a dangerous and bothersome fashion. In some cases, elderly persons may be incompetent to make their own decisions. In many others, the declaration of incompetency is clearly an excuse to impose the caregiver’s will on a powerless patient. Whether or not the patient is incompetent, the use of restraints requires strong justification. “Restraint use should be governed by the doctrine of informed consent. If patients are unable to consent proxy consent should be obtained. Only in cases of violent assault, or for the immediate protection of staff, is informed consent unnecessary”\textsuperscript{15}.

A ‘negotiated consent’:

How can we maintain this ideal of autonomy and freedom of choice while taking account of new historical and political conditions (population aging and advances in medical technologies) that oblige us to think about them in different ways? In lieu of an informed consent understood in the framework of adversary system of individual rights and individual autonomy, in lieu of a juridical model under which we operate in terms of rules and abstract concepts of right, instead of a rigid framework of age-based entitlements, Harry R. Moody\textsuperscript{16} proposes a more flexible and pragmatic version of liberalism that takes account of differences without recourse to the adversary style of the juridical approach. In practical terms, it means a civic model of communicative ethics (J. Habermas) and of virtue ethics (A. MacIntyre) with what he calls a ‘negotiated consent’ which achieves a compromise or negotiated settlement rather than a solution based on absolute rules and principles. This communicative ethics based on civic discourse both in small communities and in national politics represents a sustained effort to build up democracy and a political order that guides individual or collective judgment toward consultation and wisdom.

A ‘negotiated consent’ presents the following traits or features\textsuperscript{17}:

1. The clash and balancing of competing interests: there are multiple, legitimate views to consider - family, patient, institution - with promise as the typical result;
2. Shared or dispersed authority for decision making: no single party has the exclusive power of decision and attention must be given, for example, to the structure of team decision making, or conflict or consensus among family members;

\textsuperscript{15} MOSS, R.J., La PUMA, J., “The Ethics of Mechanical Restraints”, Hastings Center Report, 1991; 21/1: 22-25

\textsuperscript{16} Ethics in an Aging Society, Baltimore and London: The Johns Hopkins University Press, 1992

\textsuperscript{17} MOODY, Harry A. Ethics in an Aging Society, p. 174. 
3. A nonalgorithmic process: negotiation is not governed by strict deductive rules; it is heuristic in its cognitive style, implying less reliance on codes of ethics and more attention to opportunities for discussion and discovery;

4. Suboptimal outcomes: negotiation is appropriate for situations where the ideal outcome is not attainable and making the best of a bad situation in the most that can reasonably be expected;

5. A publicly justifiable rationale for the outcome: that is, negotiated decisions are not acts of arbitrary authority but must be discursively redeemed by producing reasons persuasive to parties to the negotiation.

In regard of patient consent, fair negotiation requires: 1. Active participation by the patient or the patient’s surrogate; 2. Wide consultation to ensure that all parties with an interest in the decision have their interests heard; 3. Knowledge of legal and ethical rights on the part of the weaker party (usually the patient); 4. Opportunity for scrutiny and enforcement of those rights through some outside, higher authority; and 5. Publicity about the negotiating process, which is itself subject to negotiation: in other words, publicity is neither forbidden nor obligatory for fair negotiation.

While it is imperative to extend the autonomy model, especially in guaranteeing the rights of the most vulnerable and improving their quality of life, we need a different ethical ideal, a communitarian one based on virtue in the face of tragic choices. The prevailing attitude toward old-age dependency - especially in North America - is one of shame and horror because we value individual freedom and independency. Against this cultural background it is understandable why ‘autonomy’, ‘dignity’ and ‘respect’ for persons should come to be almost interchangeable. An alternative view would see dignity and self-respect not in terms of individuality or rationality but rather in the web of human relationships that constitutes our social identity, in short, in community. “A communitarian approach will revive small-scale communities where the experience of old age can be meaningful. It will build on these ties to the community, and allowing elderly to do more for themselves and for each other. We should encourage interventions to enhance reciprocity and solidarity rather that the autonomy so prized by the advocates of individual rights”.

2.3. Treatment: the case of infection control

The definition of appropriate treatment for elderly patients is a matter of considerable debate. As Roy, Williams and Dickens wrote, “Some argue that, although the elderly person may have different requirements for medical treatment that other age groups, the principle of respect for them as persons means that their age should not be a decisive consideration in deciding whether or not to provide treatment. Like all other people, elderly people may decline any such treatment for whatever reasons they find compelling, but they should have access to all appropriate

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and needed medical services. Others believe that expensive, life-prolonging treatments are inappropriate for the elderly, and should not be available to them. As example let us look at the infection control treatment - the use of antibiotics to control infection. This treatment poses difficulties for elderly patients who are very susceptible to pneumonia and other infectious diseases. Today, antibiotics are administered routinely to combat infections, and patients are usually cured of that particular condition. Unfortunately, the quality of life that remains is often very low and the question arises whether it is in the elderly patient’s best interests to prevent death by such means. Physicians are reluctant to forego the use of antibiotics to combat life-threatening infections since they consider themselves obligated to use all ordinary means to preserve life. However, there are good reasons for considering antibiotics in the same class of medical treatments as CPR, when deciding with elderly persons with severe disabilities, especially those who are permanently unconscious or demented. “Respect for these patients requires that the 2 extreme positions be avoided: a) incompetent elderly patients should not be given antibiotics, because their lives are of very little value; and b) antibiotics must be given in every case where there is a chance of prolonging life”. Prolonging the dying process or letting the person to die with dignity is a big dilemma. Biological life is not an absolute, not the highest value. Comes a time when technological attempts to prolong biological life may interfere with higher personal values, and should give way to other forms of care. Palliative care was developed and brought a better management of pain relief, while maintaining patient consciousness. Physicians are not obligated to offer, and patients are not obliged to undergo treatments that are futile, i.e. that have no hope of success. This notion of futility is very complex. It is essential to distinguish, and even separate, two components in this concept of futility: the component of physiological effect and the component of benefit. Consideration of each individual patient in his / her body and biography, the holistic view of the person, is the key to the proper use of futility as a criterion for withholding or withdrawing life-prolonging treatments. “When the treatments that could prolong life cause a burden of suffering that exceeds the joys and opportunities for personal fulfillment that extended life could ever offer, when these treatments are disproportionate, therapeutically useless and not in the best interests of the patient, it is ethically justified to abandon these treatments. Life-prolonging treatments may be abandoned when other forms of treatment will allow a greater degree of caring and comfort, or when the prolongation of life will cause the patient intolerable and intractable pain and suffering”.

2.4. Allocation of resources

20 ROY, David J., WILLIAMS, John R., DICKENS, Bernard M., Bioethics in Canada, Scarborough, ON: Prentice Hall Canada Inc., 1994, p. 301

21 ROY, WILLIAMS, DICKENS, Bioethics in Canada, p. 304

22 ROY, WILLIAMS, DICKENS, Bioethics in Canada, p. 395
The allocation of health care resources is still today one of the most important bioethical issues. It affects the provision of care at all levels and poses big challenges to those work in the health care system as well to patients. It is a question of social justice.

Governments and countries need to define and implement health care priorities based on justice. The American bioethicist, Daniel Callahan\textsuperscript{23} puts forth a set of priorities for allocating health care resources. Some of his proposals, especially those concerning the elderly, have generated considerable controversy. If Callahan’s priorities were to be adopted, then health care practice and research would directed away from extending life for terminally ill patients and event healthy elderly persons, in favour of preventive health care, basic medical services and palliative care. Callahan’s view may be considered as an intermediate position between the rejection of old age as a criterion for treatment and the encouragement of suicide by elderly people before they require any expensive care. As Callahan stated: “I have tried to make plausible the claim that the appropriate good of medicine as it confronts aging is not the extension of life as such, but the achievement of a full and natural life-span. As it confronts aging, medicine should have as its specific goals averting premature death, understood as death before the fulfillment of a natural life span, and the relief of suffering. It should pursue those goals in order that the elderly can finish out their years with a conviction that their lives have meaning and significance, with as little suffering as possible, with as much vigor as possible in contributing to the welfare of the young and the community of which they are a part”\textsuperscript{24}. And further, “a goal of the extension of life combined with an insatiable desire for improvement in health - a longer and simultaneously better life for the elderly - is a recipe for monomania and bottomless spending. It fails to put health in its proper place, fails to accept aging and death as part of the human condition, and fails to present to younger generations a model of wise stewardship. A goal of aging that stresses the needs of the future generations, not only those of the old, and a goal of medicine that stresses the avoidance of premature death and the relief of suffering would together provide an alternative to our present situation”\textsuperscript{25} Callahan’s position has been widely criticized as being unfair to elderly people, since he would deny them access to medical treatments that are available to other younger patients \textsuperscript{26}. Callahan’s response to this charge is that the present allocation of health care resources to extending the lives of the


\textsuperscript{25} CALLAHAN, Setting Limits -Medical Goals in an Aging Society, p. 81

elderly is unfair to younger generations, who need these resources to provide such basic necessities as education, employment and preventive health care. Norman Daniels agrees with Callahan that social justice could require that scarce health care resources be rationed or deliberately withheld solely on grounds of chronological age. But he disagrees with Callahan’s argument that elderly are in competition with other age groups. For Daniels this argument is inaccurate and cannot help in resolving the debate about allocating resources among generations in a fair way. Daniels proposes the argument under which such limits are justified because savings that younger generations accumulate are generally not sufficient to pay for all possible medical interventions, where they reach old age.

While he agrees on the global principle - the social justice - for age-based allocation - and the regulative ideal of a natural life course as theoretical standard for allocating resources, Harry H. Moody does not endorse what Callahan purports as the means urged to achieve it (public national debate leading to a consensus and implementation of this policy consensus by cutting off treatment for people beyond a certain chronological age). According to Moody, a theoretical principle or standard is not the same thing as a pragmatic principle or a basis for political action.

As conclusion, we may say that age is an important element in the biography of a patient; it can and should be considered as one factor among others in the determination of appropriate treatment. This idea of age-based rationing is still debated. There is not yet a consensus but we cannot let the economic factor decide by itself. Ethical principles and reflection are essential and especially the virtue of prudence and practical wisdom. Claims about justice between generations need to be re-examined in a framework of free and open dialogue. “These competing claims cannot be resolved if we operate in the fashion of ‘interest’ group liberalism, which has been the basis of aging advocacy for the past generation. Especially in Western societies, we are faced with the dilemma of how to maintaining the integrity of public welfare programs for all age groups in a period when the temptation is for each group to seek its own advantages. Yet the legitimation for benefits for older people must be adapted to new demographic and economic circumstances. The exclusive framework of interest group liberalism and the political power of age-based entitlements fails to give any more basis for advancing the legitimate claims of other age groups such as poor children and the claims of future generations. We must think in terms of a fair negotiation of intergenerational claims in which all parties with a stake in the outcome can have their voices heard and then, perhaps, be more willing to bear burdens for the common good.”

In this regard, we need an ethics of caring and human relationship instead of an ethics of rights. Reciprocity, dignity, solidarity and justice are the key elements of a more communitarian approach.

As members of the great human family, we are interdependent and in need of each other.


29 *Ethics in an Aging Society*, p. 10
ideal of autonomy and ‘seniors independence’ is laudable to a certain extent but it should not become an absolute. It is perfectly normal to become more dependent as one enters old age, and this should not be regarded as a failure. Instead, the older adult should be encouraged to seek help from family members, health care institutions, community groups, government agencies and services when they need it. And society, in its turn, should encourage and facilitate efforts to anticipate these needs and develop programmes to meet them. There is no indignity to depend upon others.

2.5. International health and solidarity

We live in a world of enormous inequalities and terrible inequities marking the share of health care, treatment and medicines. How do we perceive these inequities? How do we judge these? Simply as facts, tragic indeed, but still as facts deriving from presumably unchangeable behavioural laws and based on national interests, that govern the relationship between nations, as facts deriving from unchangeable treaties or conventions as TRIPS which advantage the wealthy at the expenses of the poor and the vulnerable? Are we really capable of perceiving and judging these inequities as ethically intolerable? Are we capable of considering these inequities as totally incompatible with the relationships we, in the developed world, should have to people in developing countries? The number of medicines on the world market has increased immensely in the 20th century. But millions of people worldwide still do not have access to essential medicines that are affordable and of good quality. Access to medicines means access to treatment. In fact, drugs are not synonymous with health and medicinal products are not sufficient to provide adequate health. There are other factors: education, good nutrition, lodging, clean water, etc. But as WHO stresses, drugs are essential tools for health care and for the improvement of the quality of life. Improving access to quality treatment is currently the most important strategy to reduce death and disability from many diseases. More generally, ensuring access to effective treatment is a high priority issue for international public health. Constructive and multiple solutions are needed that can reduce the inequities in access to medicines (which means accessibility, availability, affordability, and acceptability), whilst at the same time protecting the incentives for research and development.

The survival of humankind is a global challenge, an imperative powerful enough to create a bond of global solidarity. But we have not yet grown up into a mature consciousness of global community and we remain doubtful about the extent of our moral imperative to work for the survival of others, and for assuring these standards of sustenance that are essential for human dignity. We desperately need a global ethic which requires a tremendous change in consciousness, a change that will lead to a preference for community over affluence, for solidarity and justice over individualism and interest. A new consciousness cannot arise within human persons only on the force of sermons and interpretations. It involves all actors: prescribers, manufacturers, family members, health care practitioners, governments, NGO, international agencies and organisations, who are ready to perform the actions and endeavors needed as the foundation of a new global ethics. Ethics is not ethics if there is no action, if there is no response to the other, especially when the other is frail, vulnerable and dependent.