ETHICAL CONSIDERATIONS IN CLINICAL TRIALS IN THE ELDERLY

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Ethics does not treat of the world. Ethics is a condition of the world, like logic.

Ludwig Wittgenstein
Ethical considerations in oncology trials

- respect for the principle of *equipoise*

- *fairness and justice* in access to clinical trials to all patients, including women, elderly and minorities

- economic implications of human research (*costs* and *conflicts of interests*)

- role of *patients* and *advocates* in establishing *research priorities*
Ethical considerations in oncology trials

- respect for patients’ autonomous informed decisions regarding their participation and withdrawal

- quality assurance on informed consent procedures
  Joffe et al, Lancet 2001

- avoidance of therapeutic misconception
  Muggia, NEJM 2006

- patients’ information of preliminary results of ongoing clinical trials
  Partridge and Winer, Lancet 2005
Costs of clinical trials in the elderly

- Costs and charges are different

- Analysis of costs is not independent from perspectives

- Components of costs are:
  - Direct medical costs
  - Indirect medically-related costs
  - Indirect medically-unrelated (productivity)
  - Intangible costs (repercussions on care-givers)

Balducci L, Costs of cancer clinical trials in the elderly. CROH 2004
Elderly cancer patients: facts

- Over 60% of new ca. cases in patients > 65 yrs.
- Only 25% of ca. pts enrolled in clinical trials > 65 yrs.
- 35% of western ca. pts > 75 yrs.
- Only 10% of ca. pts > 75 yrs are enrolled in clinical trials.

- Elderly cancer patients are less likely
  - to be screened for cancer
  - to be considered for all range of curative therapies
  - to be offered participation in a clinical trials
  - to be provided appropriate and tailored palliation.
The illness trajectory of elderly cancer patients across cultures: SIOG position paper

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Elderly cancer patients: facts

- Compared with younger adults, the elderly are more likely
  - to have **concomitant illnesses**
  - to have **reduced opportunities** to be involved in society
  - to be **underserved**

- Elderly cancer population is at risk for **diminished quality of life** and increased psychological and physical stress.

- Elderly people tend to **adjust** and adapt to stressful events **better than** younger people by using age-specific passive and emotional-focused coping strategies.
Patients’ decisions about treatment, palliative and end-of-life care are based upon information, but also upon socioeconomic status, family and community support and cultural values and attitudes.

Culture influences understanding and expression of ethical norms in clinical practice.

Autonomy is traditionally perceived by elderly patients more as synonymous with isolation than with empowerment.

Elderly cancer patients: facts
Aging, SES and access to clinical trials

- **Poverty** is especially common in the elderly.

- Socioeconomic factors affect the elderly through the regulation of *sources of wealth* in adulthood and the scarcity of *social support*.

- For elderly cancer patients belonging to *ethnic minorities* in western countries, low SES has major negative influence on health status and access to care and research.
Ethical considerations 1

- **Assumption** that elderly neither want nor tolerate aggressive or new therapies has been proven wrong by empirical studies.

- It is a **misconception** to consider age as an independent factor for toxicity and efficacy.

- **Evidence** shows that many elderly patients can tolerate the same chemotherapy regimens offered to younger patients, with proper consideration of
  - physical and psychological co-morbidities
  - multiple drug interactions
  - social and ethical implications of clinical trials related to aging
  - cultural and contextual aspects of aging
Ethical considerations 2
factors affecting autonomy of elderly patients

- mental, physical, functional, cultural, social factors influence elderly patients’ dependency and autonomy

- socioeconomic factors
- loss of productivity and consequent life roles
- degrees of social integration or isolation
- degrees of physical and social independence
- availability and accessibility of community resources (transportation, companionship, home help)
- presence or absence of family support
Ethical considerations 3

Factors that may differ in elderly cancer patients

- Socioeconomic determinants of QOL in the elderly (safety, community resources)
- Communication needs, preferences and styles
- Sources of family and community support
Open questions in clinical trials for the elderly

- Is enrollment of elderly cost effective in terms of expected trial results? (lower life-expectancy, possible increased toxicity and reduced efficacy, indirect and intangible costs)

- Is care of elderly enrolled in clinical trials too complex and time-consuming? (CGA, HRQoL)

- Do we need to allocate limited health care resources to younger population? (world population is aging, cancer became WHO health priority)

Ethical considerations: conclusions

- There is **no scientific or ethical justification** for

  - **Not offering** clinical trials to elderly cancer patients.

  - **Not implementing** and **conducting** specific clinical trials in geriatric oncology.

  - **Not investing** sufficient resources to geriatric oncology.
Ethical considerations: future perspectives

- Study and apply specific tools for evaluation and grading of general health status and concomitant illnesses in the geriatric population.

- Revise inclusion criteria of existing clinical trials.

- Design innovative clinical studies tailored to the elderly population (ex: incremental steps.)

- Identify adequate outcome measures based on physical, mental, functional and social variables in elderly cancer patients.