(THE MAIN) ETHICAL PROBLEMS IN ONCOLOGICAL PRACTICE

Giovanni Boniolo
Dipartimento di Scienze Biomediche e Chirurgico Specialistiche
Università di Ferrara, Italy
SUMMARY

- How to discuss ethical issues in research and clinical biomedicine
- Detection of cancer mutation
- Screening for cancer and false positive
- Early detection, overdiagnosis and overtreatment
- Breaking bad news
- Inclusion in clinical trials
- Right to try
- Planning treatment
- Cost of cancer care
- Alternative treatments
- End of life
- Oncofertility
- Understanding probability
- Understanding diversity
- Two reminders
Any proper ethical discussion in the oncological field should presuppose the acceptance of the following two points:

i) Concerning the object of the discussion:
   - Only the actions and the behaviours of the researchers and of the clinicians can and have to be discussed

ii) Concerning possible confusions:
   - The level of the medical description should not be confused with the level of the ethical valuation
   - The ethical problems should not be solved thanks to laws or religions
   - A good ethical discussion should not allow to introduce irrational believes
Methodological Claim I:

- Any solution of ethical problems concerning researchers and clinicians’ actions and behaviours has to be rationally justified
- Emotions play a relevant role only if they are positively governed
Methodological Claim II:

- Any solution of an ethical problem should be presented in two steps:
  1. The ethical problem has to be exposed
  2. The proposed solution has to be rationally justified
HOW TO DISCUSS ETHICAL ISSUES IN RESEARCH AND CLINICAL BIOMEDICINE – 1.4

Where

1. The exposition of the ethical problem is realized satisfying the following necessary five steps:
   - **First:** The scientific and clinical context has to be precisely and briefly described
   - **Second:** The ethical problem has to be precisely and concisely stated
   - **Third:** The relevant terms have to be disambiguated, if necessary
   - **Fourth:** The solutions alternative to the one we want to propose have to be critically analysed and debunked
   - **Fifth:** Our solution has to be precisely and concisely enunciated

2. The justification of the ethical solution proposed is made by presenting a rationally cogent argument

DETECTION OF A CANCER MUTATION – 2.1

Presymptomatic cancer testing and my decision concerning me!

Problem
If a patient asked me: “Do I have the right to do what I think best for me or should I also consider the effects of my actions on my relatives?”

Problem
If a patient asked me: “Is it ethically praiseworthy to make my decision public without considering the effects it could have on others, especially if I am a public person?”

“My mother fought cancer for almost a decade and died at 56. She held out long enough to meet the first of her grandchildren and to hold them in her arms. But my other children will never have the chance to know her and experience how loving and gracious she was.”

Angelina Jolie
New York Times, May 2003 on her medical choice

DETECTION OF A CANCER MUTATION – 2.2

Presymptomatic cancer testing and my decision concerning my lineage!

Problem
If a patient asked me: “Should I inform my relatives of a possible cancer mutation affecting them?”

Problem
If a patient asked me: “Should I charge them with the psychological burdens related with this information?”

Problem
If a patient asked me: “Should this kind of decision be linked with the treatability of the possible cancer?”

Problem
If a patient asked me: “When should I inform my children about a possible cancer mutation affecting them?”
Problem

Have I, the oncologist, correctly informed the candidate about what a false positive result is and about its possible bad effects?

Problem

Have I, the oncologist, understood why this is ethically relevant?

Problem

Have I, the oncologist, an adequate knowledge about the sensitivity and the specificity of a test and about what a positive predictive value is?

Problem

Do I, the oncologist, know how to communicate this issues?

Problem

Have I, the oncologist, fully understood my ethical responsibility on this kind of knowledge for me and for potential patients?
Problem

Have I, the oncologist, fully understood the possible bad consequences of an early detection for the potential patient?

Problem

If a patient asked me: “Have I well balanced the positive and negative consequences of a possible early detection for my life and for my relatives’ life?”

“Some Cancer Experts See ‘Overdiagnosis,’ Question Emphasis on Early Detection”

*The Wall Street Journal, Sept 14, 2014*
Problem
Do I, the oncologist, know all the possible barriers concerning the communication of bad news?

Problem
Do I, the oncologist, know the nocebo effects of a bad communication?

Chapter
Ethics and Governance of Biomedical Research
Volume 4 of the series Research Ethics Forum pp 47–55
Date: 10 May 2016

Nocebo Effects: The Dilemma of Disclosing Adverse Events

Luana Colloca

Problem

Are the non-disclosure of bad news or the lies really always detrimental to the patient’s autonomy?

Non-disclosure of cancer diagnosis: an examination of personal, medical, and psychosocial factors
Dégi CL


Commentary: Disclosure in oncology -- to whom does the truth belong?
Wood WA, McCabe MS, Goldberg RM.

Abstract
The term "therapeutic nondisclosure" refers to a clinician's decision to withhold diagnostic or prognostic information from a patient to protect him or her from perceived harm. We present a vignette in which the son of a 75-year-old Italian born immigrant asks her physician to withhold her new diagnosis of advanced myeloma. In the U.S., trends over the last 30 years have been toward more complete disclosure of cancer-related information. This can be attributed to the evolution of research subject protections, the "war on cancer," the civil rights and patient rights movements, and the rise of hospice and palliative care. In other parts of the world, however, therapeutic nondisclosure is still commonly practiced. Here, we deconstruct and call into question current arguments for nondisclosure. We provide practical recommendations to the practicing clinician in the U.S. who wishes to approach a request for nondisclosure, and disclosure itself, in a compassionate and respectful way.
Problem

Do I, the oncologist, know the ethical guidelines for clinical trials?

Problem

Have I, the oncologist, properly informed my patient?

Bernstein M. Curr Oncol 2006;13(2):55–60. Licenced under CC BY 2.0 https://creativecommons.org/licenses/by/2.0/uk/
Problem

Have I, the oncologist, given to my patient the proper information concerning the possibility of the RIGHT TO TRY, which up to now only exists in certain states of US?

About right to try

“Over 1 million Americans die from a terminal illness every year. These Americans aren’t just statistics, they’re our friends, loved ones and family members. Many spend years searching for a potential cure, or struggle in vain to get accepted into a clinical trial. Unfortunately, FDA red tape and government regulations restrict access to promising new treatments, and for those who do get access, it’s often too late. The FDA drug approval process can take up to 15 years. This is far too long for dying patients to wait. Terminal timelines are measured in months, weeks and days. Not decades. Many potentially life-saving treatments awaiting approval in the U.S. are already available overseas, and have been for years. Sadly, most Americans cannot afford to seek treatment abroad. Many are left without hope.

Right to Try legislation, already law in 30 states and under consideration in 18 more, gives terminally ill patients the right to try investigational medicines that have not yet received full FDA approval. Right to Try gives life-saving hope back to those who’ve lost it.”
Problem

Have I, the oncologist, planned the treatment with my patient, taking care of his/her autonomy and enforcing his/her empowerment?

Examples of Cancer Care Plans

Cancer care plans should have three parts

Treatment Care Plan – This plan should be discussed before you begin treatment and can help guide you as you talk with your doctor about what is important to you and any concerns you may have. It will help you talk about treatment options and possible side effects. The treatment plan can be shared with other doctors you might see for your cancer treatment or for any other health care needs.

Treatment Summary – The treatment summary should be provided once you transition off of active treatment and can be shared with other doctors and health care providers. It provides a list of medicines you are taking, describes any ongoing issues that need to be addressed, and describes the cancer care you received.

Follow-up Survivorship Care Plan – This plan will help map out your follow-up care when you have completed treatment. Cancer survivors need to be monitored for the rest of their lives and have different health care needs than before they were diagnosed. The Follow-Up Survivorship Care Plan helps to ensure that you and all of the members of your health care team know what follow-up is needed, when it is needed, and who you should see for that care

– National Coalition for Cancer Survivorship

Problem
Have I, the oncologist, informed my patient about his/her right to refuse treatments?

Problem
Do I, the patient, know the ethical consequences for my relatives of my refusing treatments?

NHS Choices (www.nhs.uk) was launched in 2007. It is the official website of the National Health Service in England.
Problem

Is it ethically praiseworthy to prescribe and implement treatments in the last phase of a lethal cancer even if I, the oncologist, know that they are of little value?

Problem

Should I, the oncologist, continue treating a patient only because his/her relatives ask for this even if I know it is of little value and extremely expensive?

by permission of Oxford University Press.
Projections of the Cost of Cancer Care in the United States: 2010–2020

Angela B. Mariotto, K. Robin Yabroff, Yongwu Shao, Eric J. Feuer, Martin L. Brown

Manuscript received January 14, 2010; revised November 4, 2010; accepted November 5, 2010.

Correspondence to: Angela B. Mariotto, Ph.D, Surveillance Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 6116 Executive Blvd, MSC 9244, Bethesda, MD 20892-9244 (e-mail: mariotto@mail.nih.gov).

Background

Current estimates of the costs of cancer care in the United States are based on data from 2003 and earlier. However, incidence, survival, and practice patterns have been changing for the majority of cancers.

Methods

Cancer prevalence was estimated and projected by phase of care (initial year following diagnosis, continuing, and last year of life) and tumor site for 13 cancers in men and 16 cancers in women through 2020. Cancer prevalence was calculated from cancer incidence and survival models estimated from Surveillance, Epidemiology, and End Results (SEER) Program data. Annualized net costs were estimated from recent SEER–Medicare linkage data, which included claims through 2006 among beneficiaries aged 65 years and older with a cancer diagnosis. Control subjects without cancer were identified from a 5% random sample of all Medicare beneficiaries residing in the SEER areas to adjust for expenditures not related to cancer. All cost estimates were adjusted to 2010 dollars. Different scenarios for assumptions about future trends in incidence, survival, and cost were assessed with sensitivity analysis.

Results

Assuming constant incidence, survival, and cost, we projected 13.8 and 18.1 million cancer survivors in 2010 and 2020, respectively, with associated costs of cancer care of 124.57 and 157.77 billion 2010 US dollars. This 27% increase in medical costs reflects US population changes only. The largest increases were in the continuing phase of care for prostate cancer (42%) and female breast cancer (32%). Projections of current trends in incidence (declining) and survival (increasing) had small effects on 2020 estimates. However, if costs of care increase annually by 2% in the initial and last year of life phases of care, the total cost in 2020 is projected to be $173 billion, which represents a 39% increase from 2010.

Conclusions

The national cost of cancer care is substantial and expected to increase because of population changes alone. Our findings have implications for policy makers in planning and allocation of resources.

J Natl Cancer Inst 2011;103:117–128


by permission of Oxford University Press.
Problem

Is it ethically praiseworthy that I, the oncologist, recommend my patient to avoid any alternative treatment, even if I know that there are no more possibilities with the standard ones?

**Viewpoint: what is the best and most ethical model for the relationship between mainstream and alternative medicine: opposition, integration, or pluralism?**

**Abstract**

"Despite radical improvements in medicine over the past 60 years, patients maintain multiple health care pathways that include high utilization of unconventional treatments. The authors examine three possible relationships between mainstream and alternative medicine: opposition, integration, and pluralism. Opposition, the traditional ethical position that the medical profession must eradicate unconventional medicine for the good of the patient, has withered away. Integration of mainstream and alternative medicine is increasingly advocated in tandem with hospital-based programs that amalgamate the use of conventional and alternative therapies. While advocates of integrative medicine often speak of “evidence-based” complementary and alternative medicine (CAM), integration fosters double standards for validating conventional and unconventional treatments. Integration also ignores unbridgeable epistemological beliefs and practices between mainstream and alternative medicine. Pluralism, which has been relatively ignored, calls for cooperation between the different medical systems rather than their integration. By recognizing the value of freedom of choice in medical options, pluralism is compatible with the principle of patient autonomy. Nonetheless, the pluralistic model does not amount to a relativistic stance according in which there would be no objective standards for comparing the therapeutic merit of conventional and CAM treatments. As an ethical model, pluralism realizes that physicians must be prepared to disagree with patient choices to pursue alternative therapies, and urge patients not to forgo medically indicated treatment. Pluralism encourages cooperation, research, and open communication and respect between practitioners despite the possible existence of honest disagreement, and preserves the integrity of each of the treatment systems involved."

Problem
Do I, the oncologist, know the possible positive placebo effects of an alternative treatment?

Problem
Is it ethically praiseworthy not to know the studies on cancer and placebo?
Problem
If a patient asked me: “Have I the right to ask for a public financial support of a non-scientifically tested treatment?”

Group rights vs. individual rights
Me, myself and them

From indigenous peoples to newly installed migrants, governments face awkward demands for collective exceptions and entitlements

The Economist May 12th, 2011

Problem

Is it ethically praiseworthy that I, the oncologist, do not provide as much as I can timely and comprehensive palliative care for my patients?

WHO, 2002

“Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment, and treatment of pain and other problems – physical, psychosocial and spiritual.”
Problem

Is it ethically praiseworthy that I, the oncologist, do not feel comfortable with starting palliative care treatments on the course of the disease management?

Integrating palliative care into the trajectory of cancer care

David Hui & Eduardo Bruera

Affiliations | Contributions | Corresponding author

Published online 24 November 2015
Problem

Is it ethically praiseworthy that I, the oncologist, insist with artificial nutrition and hydration on my patients because of my personal religious or philosophical beliefs?


Artificial nutrition and hydration: The evolution of ethics, evidence, and policy.
Brody H, Hermer LD, Scott LD, Grumbles LL, Kutac JE, McCammon SD.

ESPEN Guideline
ESPEN guideline on ethical aspects of artificial nutrition and hydration
Christian Druml a,*, Peter E. Ballmer b, Wilfred Druml c, Frank Oehmichen d, Alan Shenkin e, Pierre Singer f, Peter Soeters b, Arved Weimann h, Stephan C. Bischoff i

Reprinted from Clin Nutrit, 35 (3), Druml C, et al., ESPEN guideline on ethical aspects of artificial nutrition and hydration, 545–56. Copyright 2016, with permission from Elsevier
Problem
In case of adolescents who should make the decision: The parents? The adolescents themselves? At what age?

Problem
Should cancer patients with poor diagnosis be allowed or encouraged to begin or to continue fertility preservation?

Problem
What should be done with frozen gametes after the death of the cancer patient who decided for their cryopreservation?

ONCOFERTILITY – 12.2

Problem

If a patient asked me: “Is it ethically praiseworthy that I, a cancer patient with a poor diagnosis, ask for gametes cryopreservation?”
Problem
It is ethically praiseworthy that I, the oncologist, do not understand probability.

Problem
It is ethically praiseworthy that I, the oncologist, do not know how to communicate properly a probabilistic cancer outcome.

Do physicians understand cancer screening statistics?
A national survey of primary care physicians in the United States.

Problem
Is it ethically praiseworthy that I, the oncologist, may not be fully equipped to deal with patients' diversity?

Problem
Up to which point could I, the cancer patient, demand a particular treatment on the basis of my diversity?
John Stuart Mill, *On Liberty*, 1859

“In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign”

Formal freedom vs. substantive freedom
Problem
And if were I, the oncologist, a cancer patient?

Problem
In order to make more humane my complex work, should it not be better that, at least sometimes, I, the oncologist, did my work also considering the possibility to have the same cancer of the patient in front of me?
TO CONCLUDE
THANK YOU!