

EC17: ICS Core Curriculum (Free) Ethical Issues in Professional and Research Practice: An Intermediate Level Workshop

Workshop Chair: Nina Davis, United States 14 September 2016 10:30 - 12:00

Start	End	Торіс	Speakers
10:30	10:40	Welcome and Brief Review of Modern Medical Ethics	Elise De
10:40	11:10	Case #1 - Whose Responsibility Is It to Fund Treatment for	Ruwan Fernando, Suzy Elneil
		Female Pelvic Floor Conditions in Developing Nations?	
11:10	11:30	Case #2 – "Salami" and Other Problems in Medical Publishing	Ryuji Sakakibara
11:30	11:50	Case #3 – Treat the Patient, Not the Age!	Nina Davis
11:50	12:00	Questions	All

Aims of course/workshop

This workshop will be held in a half-round to allow maximum participation by all attendees. The intent is to foster lively discussion between presenters and participants. An initial brief review of medical and research ethics will serve as the foundation for the discussion of the clinical and research case studies outlined by the presenters. These case studies will be drawn from real-life occurrences in the areas of medical research, gynecologic practice, urologic practice and geriatrics. The presenters will help guide the discussion, highlighting important issues and working to build consensus in resolving the ethical dilemmas inherent in the case presentations.

Learning Objectives

After this workshop participants should be able to:

- 1. To gain greater understanding of modern health care ethics as it applies to clinical practice and research
- 2. To stimulate new ways of thinking about the topics covered in the workshop with the objective of raising controversy as well as fostering consensus
- 3. To enhance mutual understanding of the challenges in addressing ethical problems and identifying potential solutions

Learning Outcomes

After completion of the workshop, the participant will be able to:

- 1. Analyze complex ethical problems in clinical practice and medical research and recognize breaches in ethical standards
- 2. Using new knowledge, debate the ethical appropriateness of actions of clinicians and scientists
- 3. Appreciate the complexities of medical practice in developing nations

Target Audience

Members with an interest in difficult problems in modern health care ethics and motivated to engage in dialogue regarding the practical and cultural issues and potential solutions.

Advanced/Basic

Intermediate to Advanced

Conditions for learning

Restricted to 35 participants to allow for maximal audience participation.

Suggested Reading

- Steinbock B, London AJ, Arras JD. Ethical Issues in Modern Medicine, 8th ed. New York: McGraw Hill, 2012.
- Jonsen A, Siegler M, Winslade W. Clinical ethics: A Practical Approach to Ethical Decisions in Clinical Medicine, 7th Ed. New York: McGraw-Hill, 2010.
- Peters DH, Garg A, Bloom G et al. Poverty and access to health care in developing countries. Ann NY Acad Sci.2008;1136:161-171
- Petersen A. From bioethics to a sociology of bio-knowledge. Soc Sci Med. 2013; 98:264-270.
- Nosek BA. Alter G, Banks GC et al. Promoting an open research culture. Science 2015; 348 (6242):1422-1425.
- Wager E. Ethical publishing: the innocent author's guide to avoiding misconduct. Menopause Int. 2007; 13(3):98-102.
- Promoting research integrity: a new global effort. (no authors listed) Lancet 2012:380(9852); 1445.
- Robinson TN, Eiseman B, Wallace JI, et al. Redefining Geriatric Preoperative Assessment Using Frailty, Disability and Co-Morbidity. Ann Surg. 2009; 250(3):93-99.
- Rosin AJ and van Dijk. Subtle ethical dilemmas in geriatric management and clinical research. J Med Ethics 2005; 31:355-359.

Ruwan Fernando

Pelvic floor disorders in women in developing countries have significant socioeconomic impact. The majority of these problems are caused by poor management of labour and lack of facilities for provision of care. Fistulae caused by mismanaged childbirth are one of the most devastating gynaecologic conditions. UNFPA (2012) estimates that 2 to 3.5 million women are currently living with fistula worldwide with at least 50,000 to 100,000 new cases occurring every year. The true number of women with fistula may actually be even higher.

In a model outlined by Thaddeus and Maine (1994), delay in obtaining care was comprised of three phases. Phase I is a delay in deciding to seek care by an individual, family, or both, and includes factors associated with decision making, women's status, illness characteristics, distance from facilities, financial costs, previous health system experiences, and perceived quality of care. Phase II is delay in reaching an adequate care facility including facility distribution, travel time, availability and cost, and road conditions. Phase III comprises delay in receiving adequate care at a facility, including the adequacy of the referral system, and shortages of supplies, equipment, and trained personnel, as well as competence of the staff.

Barriers to effective management of obstetric fistulae include psychosocial, transportation infrastructure, cultural, facility shortages, awareness, quality of care, social, political and financial. Financial costs include care at home, transportation costs, and costs of ongoing care at facilities.

The ethics of financing prevention and treatment of obstetric fistulae center around the sources of funding, distributing the funds effectively and ensuring that the funds are apportioned equitably among deserving patients. Funding alone would not prevent the complication of obstetric fistulae. There needs to be a framework wherein all international and national organisations collectively address the barriers to prevention and effective management of obstetric fistulae.

Thaddeus, S. and D. Maine. 1994. Too far to walk: Maternal mortality in context. Social Science and Medicine 38(8): 1091–1110.

Ryuji Sakakibara

Research integrity in particular and publication ethics in general has garnered increasing attention of late because of the escalating frequency of retracted and fraudulent publications in recent years. Such examples of falsification of data or misrepresentation of results strike at the foundational principle of research – trust that the information being disseminated is based on valid and reproducible observations analysed using appropriate statistical methods and reported clearly and honestly. It is the most basic responsibility of the investigator to maintain the highest scientific standards in the conduct and publication of his/her research, ultimately for the good of mankind. When this solemn duty is breached, the harm can be far-reaching, from destruction of the researcher's reputation and career to placing patients at risk as in the case of translational research. The scourge of research misconduct has become a global problem, compelling government agencies, professional organizations dedicated to research ethics and journal editors to publish extensive guidelines and conduct educational symposia in an attempt to reverse this pernicious trend toward academic malpractice.

Some would maintain that "lesser" examples of professional dishonesty such as publishing the same or similar papers in multiple journals, lack of notification of conflict of interest or not publishing completed studies are not so much breaches of medical ethics, but rather lapses in honesty or lack of attention to detail that do no significant harm. This attitude is dangerous - not taking such misconduct seriously is a slippery slope that can result in erosion of the high ethical standards that should guide the conduct and reporting of scientific investigation.

Interestingly, there has been relatively little examination of the pressures placed on researchers that compel them to resort to unscrupulous methods to secure professional advancement. For this reason, numerous publications have come out urging complete transparency through the sharing of technology and data sets and the requirement for all studies to be entered into a central repository. Oversight is thereby facilitated. Responsibility for research integrity has also shifted to editors and reviewers who are tasked with ferreting out the compromised manuscript. When one cannot trust, one must verify.

In the final analysis, it is imperative that research integrity and maintenance of ethics in research be placed squarely back on the shoulders of those performing it. The current requirement for ethics training for all Ph.D. candidates and IRB oversight are good first steps. Perhaps the culture of "publish or perish" also needs to be examined and a system established for rewarding quality over quantity. Whatever the means, it is necessary to reverse the trend toward academic dishonesty, restore trust and ultimately serve the public good.

Nina Davis

It is well-established that the world population is ageing, According to the World Health Organization1, this phenomenon is due to a number of factors including a decline in fertility and concomitant 20-year increase in life expectancy over the last 50 years and the large numbers of children conceived during the 2 decades following WWII (the so-called "Baby Boomers"). The rising number of older adults will place an increasing burden on public health systems globally and significantly increase demand for medical and social services. Providing care for the elderly, therefore, will prove to be one of the greatest challenges for the WHO, governments and other large health care organizations in the future. In an effort to respond to these challenges, the WHO, as outlined in the above-referenced report, has provided comprehensive recommendations for broad changes in the approach toward the delivery of health care and services to older adults. These changes assume a significant paradigm shift, emphasizing "healthy ageing" and based on the optimization of "functional ability". The key features of the proposed policies are promoting healthy ageing, aligning health systems to the needs of older populations, providing integrated geriatric care (community-based multidisciplinary care and ancillary support services) and providing properly trained geriatric professionals to provide the necessary services to older adults. Such profound changes in health-care delivery to ageing populations require a parallel shift in the ethics governing decision-making for older adults.

Whereas, in the past, geriatric ethics largely focused on surrogate decision-making in palliative medicine and end-of-life care, the new perspective advocated by the WHO emphasizes the values of autonomy and dignity. This self-determination is to occur in the context of optimized mental and functional capacity as well as enhanced well-being through the optimization of therapeutic and technologic interventions. Ultimately, however, in order to assure elder-centric decision-making, it will be necessary to abolish age-based stereotypes and discrimination. Respect for ageing adults and attention to their needs and priorities is paramount. Being "old" is not defined by a specific number, but by a particular state. Helping adults avoid decline as they age should be the purpose of modern medicine. As Frank A Clark said, "We've put more effort into helping folks reach old age than into helping them enjoy it." Optimizing health, functionality and well-being is the best way to ensure that life at advanced age can still be enjoyed to its fullest

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September 14, 2016

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- Elise De, M.D. (USA)
- Ruwan Fernando, MBBS, MS, FRCOG (UK)
- Ryuji Sakakibara, M.D., Ph.D. (Japan)
- Special Guest Discussant Suzy Elneil, BSc, MBChB, MRCOG, PhD (UK)

Modern Bioethics

- The "Four Principles" approach postulated by Tom Beauchamp and James Childress in the textbook Principles of Biomedical Ethics
 - Respect for Autonomy the patient's right to accept or decline
 - Beneficence a practitioner should act in the best interest of the patient.
 - Non-maleficence "first, do no harm'
 - Justice concerns the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality).

• Other relevant values:

- Respect for persons: The patient (and the person treating the patient) have the right to be treated with dignity. Truthfulness and honesty the concept of informed consent

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- The circumstance of a public officeholder or professional whose personal interests might benefit from his or her official actions or
- her activities, interests, etc., can be advanced only at the expense of another of them.
- Research has shown that conflicts of interests are very common among both academic physicians and physicians in practice.
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Culture and Ethics

- Cultural relativism: the view that all beliefs, customs and ethics are relative to the individual within his own social context
- Cultural differences can create complex situations in medical ethics.
- Some cultures have spiritual or magical theories about the origins of disease, and reconciling these beliefs with Western medicine can be difficult.
- Euthanasia, access to care, life-extending technologies are approached differently by different countries sometimes due to religion or morality and sometimes due to situational influences (e.g. resources, political stability).

Research Ethics

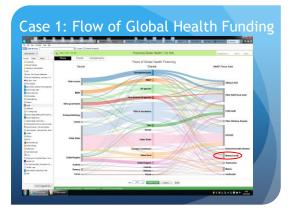
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- Based on trust in the conduct and reporting of research
- Ultimately ensures that research enhances public welfare

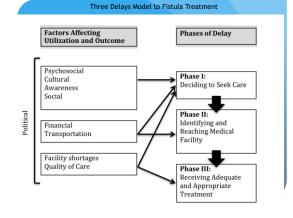
Case 1: Funding Gynaecologic **Care in Developing Nations**

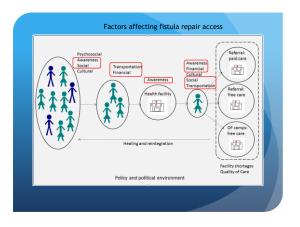
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Breaking the barriers in fistula treatment - Ethics of funding Who should fund? Countries themselves Developed countries Charitable organisations Professional organisations Industry

- 3.
- 4. 5.

How should fund?

- Funding for and by governments
 Direct funding to the patients
 Funding for prevention
 Funding for infrastructure
 Funding for research

Case 2 - "Salami" and Other Problems in Medical Publishing

- Physician researchers A, B, C, D and E publish a retrospective review of a single-center series of MUS surgeries, focusing on long-term dry rates.
- Physicians A and C provided the patients. Physician B collated and analyzed the data. Physician D (the fellow) wrote the paper and Physician E put his name on the paper because he is the department chair.
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- Questions
- In the U.S., when a study is broken up and published as multiple papers, these are called "LPUs" or "Least Publishable Units". This is usually frowned upon. WHY?
 - Is anyone hurt by this
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Case 2 - Types of "Publishing Malpractice"

- Self-plagiarism
- Textual recycling
- Ghost writing
- enese mining
- Duplicate publications
- Falsification of data
- Altering data
- Not publishing completed studies
- Selective reporting of outcomes

Publication Ethics (after Damaser

- Authorship and order of authorship should be determined based on contribution to the publication and not political or other factors
- Honesty in reporting methods & results (no fraud)

(no plagiarism)

- Declaration of all potential and perceived conflicts of interest
- Respect the peer-review process Intended to enable reproduction of the research Not intended to ferret out fraud
- Publish in ethical legitimate journals not predatory open-access journals

Gasparyan et al. JKMS, 2015 Wallace & Siersema, GI Endoscopy, 2015

Case #3: Treat the patient, not the age

- 95 yo female, living with her daughter, with Gr 4 anterior prolapse
- Hx of mild dementia, hypertension, hypothyroidism
- Extremely troubled by her symptoms
- Becoming progressively isolated
- Has tried conservative strategies including several pessaries, but unable to tolerate or retain
- Referred to Urogynecology for consideration for surgery

Case #3: Treat the patient, not the age

- It's not that easy...
- Over the last 6 months, turned down by two surgeons based on her age
- Minimum 3 month waitlist to see another surgeon
- Developed severe erosions on prolapsed mucosa leading to several ER visits for pain and bleeding
- Declining mobility due to inactivity, worsening proximal muscle strength
- Worsening mood feels depressed
- Increasingly dependent on daughter for assistance with care needs

Case #3: Treat the patient, not the age

- Would you consider operating on this patient?
- What other information would help guide your decision?
- What are your professional/ethical obligations to this patient?

TABLE 4. Post Hoc Clinical Pre	diction Rule for	Geriatric Preopera	tive Evaluation		
One point per clinical marker	Frailty		Cognition (Mini-Cog ≤3)		
				Albumin ≤3.3 g/dL	
				1 in past 6 mo)	
			Hematocrit <35%		
	Disability Co-morbidity		Dependence ≥ 1 ADLs Charlson index ≥ 3		
	Co-	-			
	No. Risk Factors				
	≥3	≥4	≥5	6	
6-month mortality					
Sensitivity	15/16 (94%)	13/16 (81%)	6/16 (38%)	5/16 (31%)	
Specificity	64/94 (68%)	81/94 (86%)	86/94 (91%)	90/94 (96%)	
Positive predictive value	15/45 (33%)	16/26 (62%)	6/14 (43%)	5/9 (56%)	
Negative predictive value	64/65 (98%)	81/84 (96%)	86/96 (90%)	90/101 (89%)	

Ethical principles

• Autonom

- Patient is capable in making her own medical decisions (dementia ≠ incapability)
- Wants surgical treatment
- Beneficence
- Surgery will not only fix her prolapse but also prevent other morbidity (isolation, worsening mobility/falls, depression, hospitalizations, etc.)
- Non-maleficence
- Justice

Ethical principles

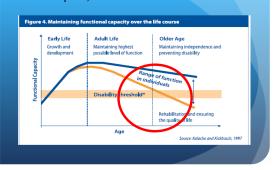
- Non-maleficence
- Surgery may cause harm (surgical complications, immobilization, post-operative delirium)
- Justice
 - Scarce resources (limited lifespan)- will more resources be used with or without surgery?
 - Beware ageism!

4-Box Approach	
<u>Medical Indications</u> -patient has failed conservative treatment and requires surgical intervention for repair of prolapse	Patient Preferences -patient has capacity to make health care decisions and wishes to have definitive treatment performed despite the risks
Quality of Life -increasing isolation, worsening mobility, hospital visits -daughter getting burned out -possible surgical complications also have potential to worsen quality of life	Contextual features -long waitlists to see surgeons -refusal due to age alone -scarcity of resources -impact of surgery vs. no surgery on the health care system

Heterogeneous Patient Population



All Shapes, Sizes and Abilities!



Summary

- Physical age ≠ biological age
- Holistic approach to geriatric patients consider medical indications, quality of life, patient preferences, contextual factors
- Changing our health care systems accessible geriatric pre-operative assessment, reassessing waitlists, tackling ageist attitudes



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Nina D. Davis, M.D., FACS

Affiliations to disclose[†]:

Medical Education Speakers Bureau (honoraria)

Funding for speaker to attend:

X Self-funded

Institution (non-industry) funded

Sponsored by:

Elise De, MD Albany Medical College

Affiliations to disclose⁺:

No Disclosures

Funding for speaker to attend:

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Ruwan Fernando, MBBS, MS, FRCOG



Affiliations to disclose[†]:

Laborie: Speaker, Honorarium, Fellowship, Travel grants
AMS: Speaker, Honorarium
Astellas: Speaker Honorarium, Trial participation, Fellowship, Travel grants
Pfizer: Speaker, Honorarium, Trial participation, Fellowship, Travel grants
* All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation
Funding for speaker to attend:

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Ryuji Sakakibara, M.D., Ph.D.

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Sohier (Suzy) Elneil, BSc, MBChB, MRCOG, Ph.D. 🖗 [😪

Affiliations to disclose⁺:

Bluewind Medical: Trial participation

Axonics: Trial participation

Astellas: Pharma Speaker honorarium

Medtronics: Speaker honorarium

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Research Ethics

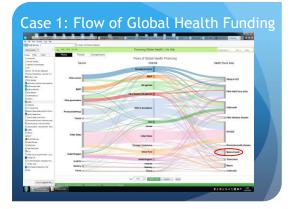
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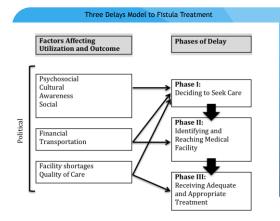
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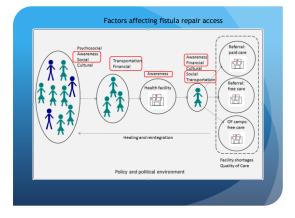
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 Industry

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 Funding for research

Urogenital Fistula Management Healthcare Delivery in LMICs: Morals and **Ethics**

Sohier Elneil Consultant in Urogynaecology and Uro-neurology

University College London Hospital and National Hospital for Neurology and Neuro-surgery

Incidence of Fistula

Main Aetiology is Obstetric Injury

Maternal Mortality Rates (in a lifetime)

Africa

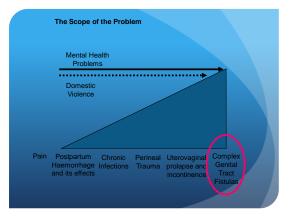
Scandinavia

1:12

1:300000

NB: No. of women who die annually in West Africa equals all those who died in Korean conflict in 1950s

For every woman that dies..... 20 will suffer crippling morbidity



A major health problem in low and middle income countries as a consequence of obstructed labour

In developed countries GTF are usually iatrogenic or following radiotherapy or foreign body injury

Quality of Life Impact

- Physica
- Losing bladder/ bowel contro
- Pain
- Dealing with chronic infections
- Social
- Embarrassment
- Affects lifestyle and avoidance of activities
- Impact on all relationships
- Increased dependence on caregivers
- Personal
- Mental Health secondary to divorce, etc
- Domestic Violence

What are the issues?

Who is doing the work?

- Single clinician
- Working in isolatior
- Access to other disciplines limited
- Certain cross-disciplines do not exist
 - But gradually,
 - Patient outcomes affected
- Patients expectations taken into account

What factors affect our decisions?

- Racial practices
- Religious practices
- Entrenched cultural practices
- Critically, financial needs and control





Where are we in the developing world?

- Need for investigative resources
- Need for increased trained manpower medical and paramedical
- Better operating facilities
- Integration of services
- Collaboration of clinicians across the continent, as in GTF
- Regular audit and publications

What are the pitfalls?

- Poor communication
- Consideration of political position of governments and NGO
- Financial contributions
- Corporate responsibility
- Recognition of individuals and institutions

The Morality of Funding in LMICs

- LMICs funding relationship to morality has to be debated
- It is often stated that funding in LMICs is with a view to ensuring the 'common good'
- However:
- The question of the 'common good' is slightly more specific than that of just morality
- The idea of a common good is usually associated with Utilitarianism, and as is always attractive with this school of thought, their definition is relatively straightforward.
- They would simply say that: 'the common good provides the greatest amount of good for the greatest amount of people'

But, who determines the 'common good'

- The patient
 - Do they have a choice?
 - The society
- _____
- Does it allow access?
- Is it free?
- The funder
- Whose interest does is serve?

e.g., Fistula

- The Patient
 No choice
- The elder of the village usually
- The Governmen
 - Not always free and access depends on service provision
- The Funders
 - Their interest: donors, 'funders agenda', direction of delivery

Conclusion 1

- Work in collaboration with donors, foundations, professional bodies and other partners, ensuring
 - Transparency
 - Effective community
- Trust
- Take ownership jointly on all projects
 - Accepting and taking risks together
 - Looking for and formulating new solutions together
 - Adapting science and technology to 'fit' in with defined needs
- Engage individuals, communities, NGOs, governments, the private sector

Conclusion 2

- The 'common good' agenda should be determined by LMICs, and funding should be a means to a designated end, not a primary determinant
- In order to support health research in LMICs that is both relevant and meaningful, the focus must be on developing health research that promotes equity and on developing local capacity in bioethics
- Only through such proactive measures can we address the emerging moral and ethical dilemmas and challenges that globalization and the genomics revolution will bring in their wake.



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- Duplicate publications
- Falsification of data
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Publication Ethics (after Dannaser)

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 - roubre te reboucuê o, methods auc
- Honesty in reporting methods & results (no fraud)

(no plagiarism)

- Declaration of all potential and perceived conflicts of interest
- Intended to enable reproduction of the research Not intended to ferret out fraud
- Publish in ethical legitimate journal not predatory open-access journals

Gasparyan et al. JKMS, 2015 Wallace & Siersema, GI Endoscopy, 2015

Case #3: Treat the patient, not the age

- 95 yo female, living with her daughter, with grade 4 anterior prolapse
- Hx of mild dementia, hypertension, hypothyroidism
- Extremely troubled by her prolapse symptoms
- Becoming progressively isolated
- Has tried conservative strategies including several pessaries, but unable to tolerate or retain
- Referred to Urogynecology for consideration for surgery

Case #3: Treat the patient, not the age

It's not that easy.

- Over the last 6 months, turned down by two surgeons based on her age
- Minimum 3 month waitlist to see another surgeon
- Developed severe erosions on prolapsed mucosa leading to several ER visits for pain and bleeding
- Declining mobility due to inactivity, worsening proximal muscle strength
- Worsening mood feels depressed
- Increasingly dependent on daughter for assistance with care needs

Case #3: Treat the patient, not the age

- Would you consider operating on this patient?
- What other information would help guide your decision?
- What are your professional/ethical obligations to this patient?

	Frailty Disability Co-mothidity		Cognition (Mini-Cog ≤ Albumin ≤3.3 g/dL Falls (≥1 in past 6 mo) Hematocrit <35% Dependence ≥1 ADLs Charlson index ≥3	
	No. Risk Factors			
2	±3	≥4	≥5	6
6-month mortality				
Sensitivity 15/16	(94%)	13/16 (81%)	6/16 (38%)	5/16 (319
Specificity 64/94	(68%)	81/94 (86%)	86/94 (91%)	90/94 (96
Positive predictive value 15/45	(33%)	16/26 (62%)	6/14 (43%)	5/9 (56%
Negative predictive value 64/65	(98%)	81/84 (96%)	86/96 (90%)	90/101 (895

Ethical principles

- Autonomy
- Patient is capable in making her own medical decisions (dementia ≠ incapability)
- Wants surgical treatment
- Beneficence
 - Surgery will not only fix her prolapse but also prevent other morbidity (isolation, worsening mobility/falls, depression, hospitalizations, etc.)
- Non-maleficence
- Justice

Ethical principles

- Non-maleficence
 - Surgery may cause harm (surgical complications, immobilization, post-operative delirium)
- Justice
 - Scarce resources (limited lifespan)- will more resources be used with or without surgery?
- Beware ageism!

4-Box Approach

<u>Medical Indications</u> -patient has failed conservative treatment and requires surgical intervention for repair of prolapse

Quality of Life

-increasing isolation, worsening mobility, hospital visits -daughter getting burned out -possible surgical complications also have potential to worsen quality of life

Patient Preferences -patient has capacity to make health

care decisions and wishes to have definitive treatment performed despite the risks

<u>Contextual features</u> -long waitlists to see surgeons

-refusal due to age alone -scarcity of resources -impact of surgery vs. no surgery on the health care system

Heterogeneous Patient Population







Summary

- Physical age ≠ biological age
- Holistic approach to geriatric patients consider medical indications, quality of life, patient preferences, contextual factors
- Changing our health care systems accessible geriatric pre-operative assessment, reassessing waitlists, tackling ageist attitudes

