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A resource for evidence-based breastfeeding intelligence

LactaHub Workshop: Explore Ethical Principles in Health and Breastfeeding Research

EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

26 April 2023

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Four experts will guide us through the workshop today

Ms. Caroline Kithinji
Scientific and Ethics Review Unit (SERU) at Kenya Medical Research Institute (KEMRI)

Prof. Violet Naanyu
Moi University School of Arts and Social Sciences

Dr. Stephen Ombok Muhudhia
Nairobi Hospital, Kenya & Trinity International University

Prof. Nikola Biller-Andorno
Institute of Biomedical Ethics and History of Medicine (University of Zurich), a WHO Collaborating Centre for Bioethics

They will share their scientific expertise with us – and will encourage you to share your personal experiences and views during the working sessions

08:15 – 08:35 **Introduction of participants and expectations**
Caroline Kithinji

08:35 – 09:35 **Ethical considerations in research and interventions related to breastmilk and breastfeeding – focusing on vulnerability of research and intervention participants**
Prof. Violet Naanyu

09:35 – 10:00 **Conflict of interest in research and interventions related to breastfeeding and breastmilk**
Dr. Stephen Ombok Muhudhia

10:00 – 10:25 **Coffee break**

10:30 – 11:15 **EFBRI – Ethical Framework Informing Breastfeeding Research and Interventions**
Prof. Nikola Biller-Andorno (via Zoom)

11:15 – 12:15 **Group work and case studies**

12:15 – 13:15 **Plenary presentations, discussion of group work and conclusions**

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Introduction to Research Ethics

Ms. Caroline Kithinji
Scientific and Ethics Review Unit (SERU),
Kenya Medical Research Institute (KEMRI)

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Introduction to Research Ethics

Research participants

Introduction to Research Ethics

Breastfeeding and mental health

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Nature and Dynamics of Vulnerability (Mechanic & Tanner, 2007)
Defined as "susceptibility to harm"

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What is Ethics?

The formal study of:

- What is right and wrong.
- The study of the basis or principles for deciding right and wrong.
- The analyses of the processes by which we decide what is right and wrong.

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Research Ethics

Research ethics is specifically interested in the analysis of ethical issues that are raised when people are involved as participants in research.

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History of the Ethical Research Movement

- Breaking and re-breaking of **bones** (to see how many times they could be broken before healing failed to occur) *Nazi war crimes*
- Patients **injected** with live cancer cells *(Jewish Chronic Disease Hospital, NY, 1963)*
- 400 men **left to suffer** with syphilis long after a cure (penicillin) was available. *(Tuskegee, Alabama, 1932-72)*
- Milgram's study sustained no physical harm, they **suffered shame** and embarrassment for having behaved inhumanely toward their fellow human beings.*(1963)*

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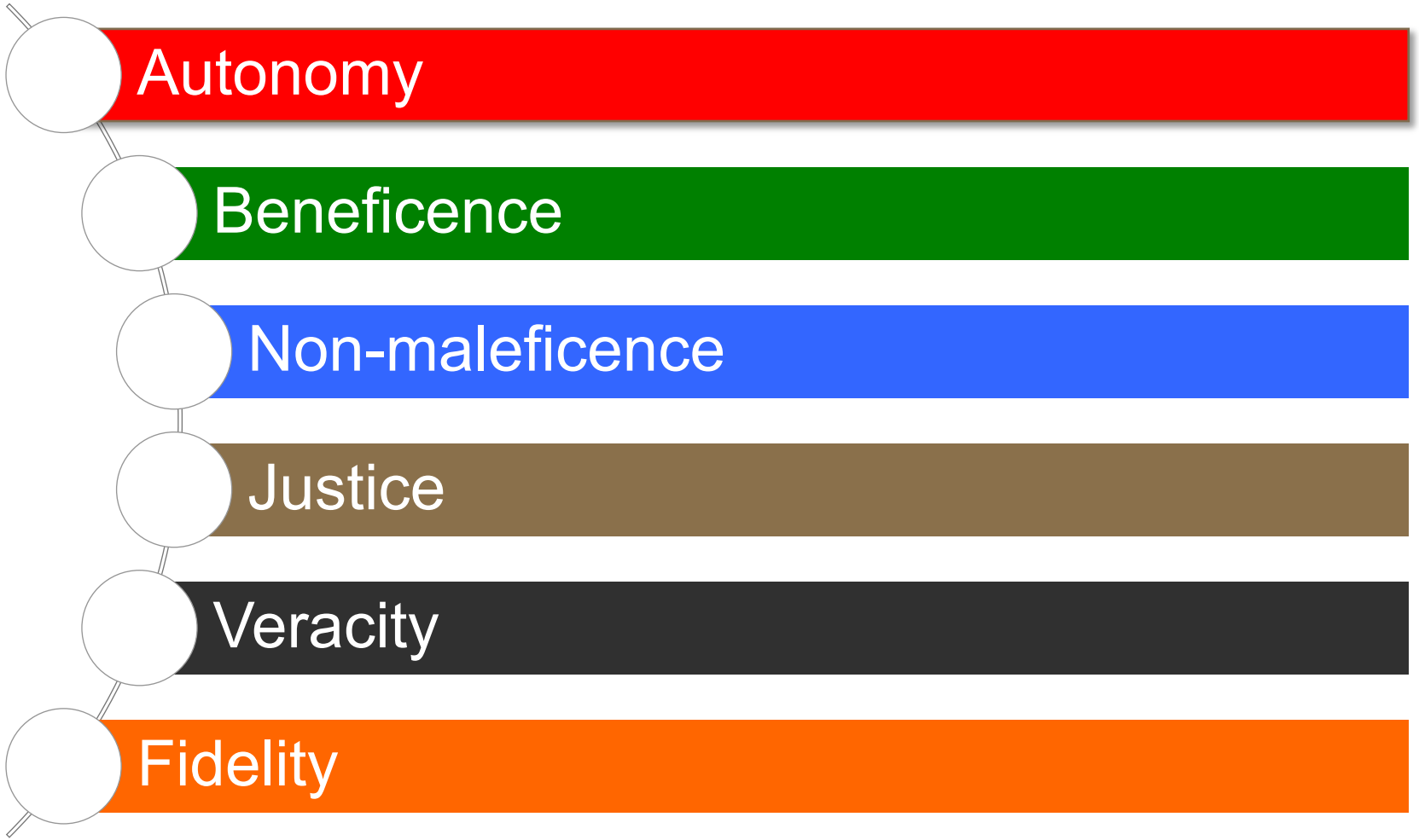
Research Ethics Principles



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Decision making in research Ethics

Deductive or principle-based reasoning

- Start with an ethical theory—
- Continue with a specific principle
- Develop rules
- Make judgments

Jeff Cooper
Albany Medical Center, Ethical Decision Making, 2001, p. 1

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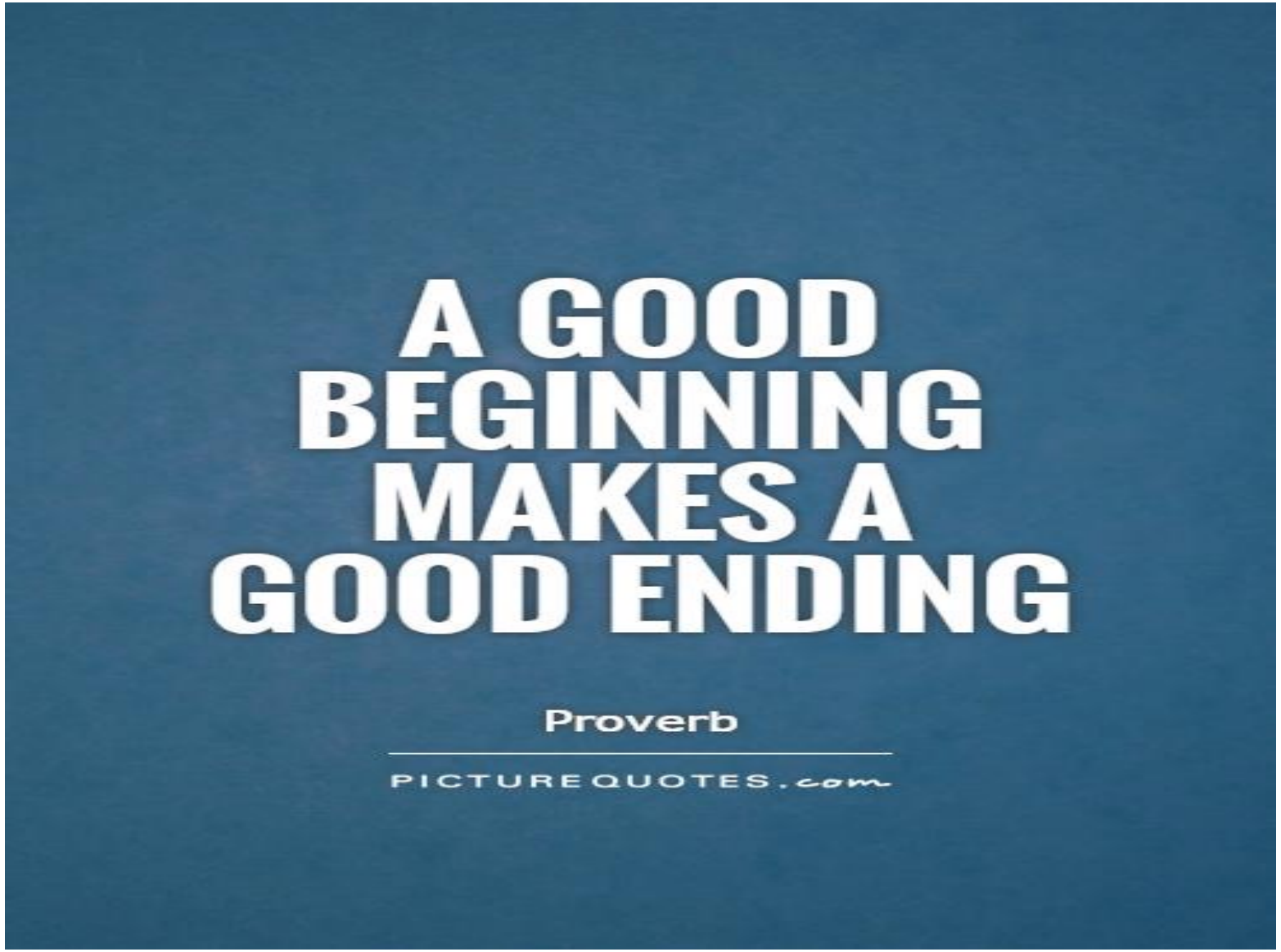
Decision making in research Ethics

Deductive Reasoning

Ethical Theory ➡ Principle ➡ Rules ➡ Judgment

Jeff Cooper
Albany Medical Center, Ethical Decision Making, 2001, p. 2


A GOOD BEGINNING MAKES A GOOD ENDING
Proverb
PICTUREQUOTES.com

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Ethical considerations in research and interventions related to breastmilk and breastfeeding – focusing on vulnerability of research and intervention participants

Professor Violet Naanyu
School of Arts & Social Sciences
Moi University

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Highlights

- Vulnerabilities
- Vulnerable populations in research/programming
  - ✓ Breastfeeding women
- Research & research ethics
- Breastmilk, breastfeeding & associated ethical considerations

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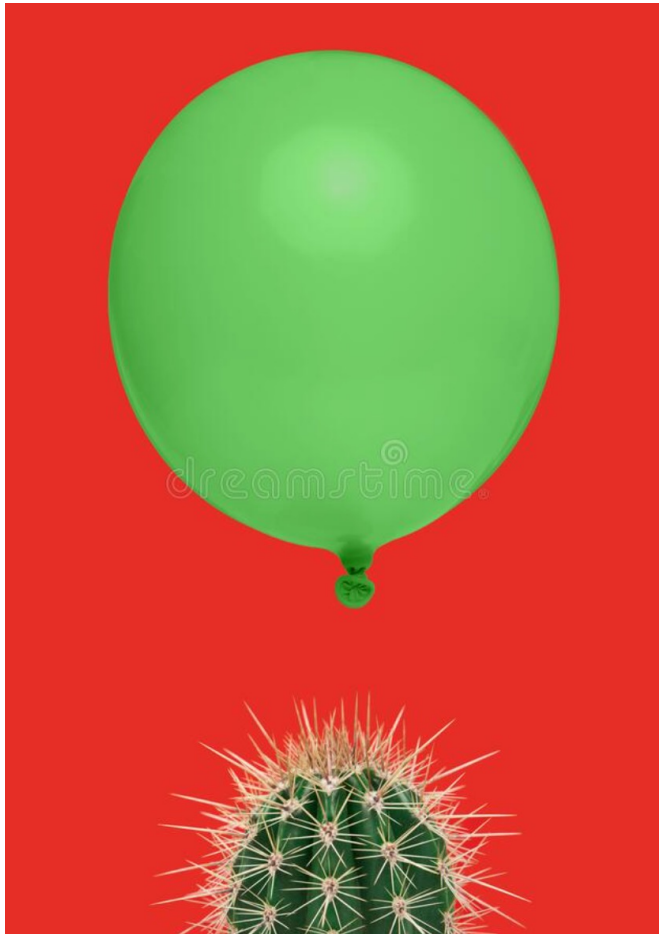
Vulnerability

- Inability to anticipate, cope, or resist harm
- Having possibility of incurring identifiable harm while substantially lacking ability to and/or means to protect oneself



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Vulnerable populations

Vulnerable populations in research:
Disadvantaged sub-segment of the community

Reflections & discussion:
Who is vulnerable where you live (your main residence)?
Who is vulnerable where you work?

Why are they vulnerable?
Should they be enrolled in research?

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Vulnerable participants in research & interventions related to breastmilk & breastfeeding* - 1

1. Institutional vulnerability:

Person who is under the official authority of others (e.g. Parents, guardians, warders) who may have their own benefits in whether the individual agrees to enroll in the study

2. Deferential (submissive) vulnerability:

Influence of other people in a participant's life in determining their decision to enroll in the study (e.g. Relatives, friends, physicians)

*Essays, UK. (November 2018). Vulnerable Subjects Research. Retrieved from https://www.ukessays.com/essays/human-rights/vulnerable-subjects-research.php?vref=1

Vulnerable participants in research & interventions related to breastmilk & breastfeeding* - 2

3. Economic & infrastructural vulnerability:

-Hope for new resources/facilities

-People of low economic background may be exploited or join trials with hope of getting benefits (e.g. income, housing & healthcare)

-Payment for participation or free access to services might induce enrolment

*Essays, UK. (November 2018). Vulnerable Subjects Research. Retrieved from https://www.ukessays.com/essays/human-rights/vulnerable-subjects-research.php?vref=1

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Research

- **Research** is any kind of study designed to find responses to worthwhile questions by means of a systematic & scientific approach
- The **research process** is the methodical approach to finding & examining a variety of reliable scholarly resources on a particular topic
- **Major goals of research**:
  - ✓ Establishing facts
  - ✓ Analyzing information
  - ✓ Reaching new conclusions

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What is the most important consideration in research?

'The value & benefits of research are vitally dependent on the integrity of the research...' *

*Singapore Statement on Research Integrity (2010)

What is ethics?

- The study of right (good) & wrong (bad) human behaviour

- A moral/ethical paediatrician is:
  - ✓ Principled/upright
  - ✓ Right/true/factual
  - ✓ Fair/Just
  - ✓ Decent

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Afya Ya Watoto Wetu

Creator: Christos Georghiou|
Credit: Dreamstime

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What is research ethics?

- **Research ethics** focuses on analysis of ethical issues that are raised when people are involved as research participants.

- There are 3 **objectives in research ethics**:
  1. To **protect** human participants
  2. To ensure that research is conducted in a way that **serves interests** of individuals, groups and/or society as a whole
  3. To examine specific research projects for their **ethical soundness** (management of risk, protection of confidentiality, & the process of informed consent)

Ethical considerations in research related to breastfeeding

Case 1:

Case 28. Breastfeeding and mother-to-child HIV transmission

(See document for download on www.LactaHub.org/Workshop)

Ref: Cash, Richard, Wikler, Daniel, Saxena, Abha, Capron, Alexander M & World Health Organization. (2009). Casebook on ethical issues in international health research / edited by Richard Cash [... et al]. World Health Organization. https://apps.who.int/iris/handle/10665/44118

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Ethical considerations in research & interventions related to breastfeeding

Case discussion:

1. Since only the woman's HIV status is relevant to the risk being studied is it appropriate to seek consent from both the woman & her partner? What if the **woman does not wish** to reveal her HIV status to her partner?
2. What **role should the husband in this case have** in the decision about whether or not to breastfeed, given that it could seriously affect the health of his child?
3. Given that a previous (albeit flawed) study has already shown a **risk** of HIV-transmission through breastfeeding, is it appropriate to do this study?
4. Comment on the **risk-benefit ratio** of this study for participants. Do you see any way to improve the ratio?

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Ethical considerations in research & interventions related to breastfeeding & breastmilk in Kenya

a. Breastfeeding

1. Respect for autonomy
2. Informed consent
3. Spousal consent
4. Assent
5. Mother-child bonding
6. Women's empowerment
7. Compensation
8. Benefit sharing
9. ?
10. ??

b. Breastmilk

1. Respect for autonomy
2. Informed consent
3. Health risks
4. Quality of breastmilk
5. Accessibility & equity
6. Fair compensation
7. Cultural norms
8. Feedback of results from any analyses
9. ?
10. ??

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Ethical considerations: Breastfeeding interventions for public space? Office?-1

- Autonomy?
- Rights?
- Safety?
- Health benefits?
- Mother-child bonding?
- ?
- ??

The protesting moms made a point of breastfeeding their babies outside parliament's precincts
Photo credit: Sam Wanjohi

Their march was precipitated by a restaurant's refusal to allow a mom to breastfeed at one of their tables, directing her instead to the unsanitary lavatory.
Story by J. Mueni, May 15, 2018. Kenyan Moms Petition Parliament For Right To Breastfeed In Dignity. Capital News.

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Ethical considerations: Breastfeeding interventions for public space? Office?-2

- Autonomy?
- Rights?
- Safety?
- Health benefits?
- Mother-child bonding?
- Cultural norms?
- ?
- ??

Photo credit: Simon Maina/ AFP

Kenyan women march towards a restaurant after a female client was allegedly thrown out for breastfeeding and not covering up.
The Conversation, July 30, 2021.

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Ethical considerations: Recruiting entrepreneurs/employees/trainees…

- Justice?
- Rights?
- Safety?
- Health benefits?
- Mother-child bonding?
- Cultural norms?
- ?
- ??

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Ethical considerations: Breastfeeding interventions for students…

- How do we reach breastfeeding adolescents?
- Health benefits?
- Mother-child bonding?
- Consent?
- Assent?
- Rights?
- Approvals in educational settings?

‘An education taskforce wants all secondary schools to have a room where teen mums can breastfeed…This will encourage them to return to school by making it easier to take care of their babies.’
Lewis Nyaundi, The Star, 28 March 2020

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Ethical considerations for human milk banks in Kenya

A nurse arranges bottles of human milk at the Human Milk Bank at the Pumwani Maternity Hospital in Nairobi, Kenya on October 17, 2019/ Reuters

- Respect for autonomy?
- Informed consent?
- Health risks?
- Quality of breastmilk?
- Storage concerns?
- Accessibility & equity?
- Fair compensation?
- Cultural norms?
- ?
- ??

Kenya launches first breast milk bank to help newborns.

Ayenat Mersie, Reuters, October 22, 2019

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Summary: Ethical considerations in research & interventions related to breastfeeding -1

1. Arrangements for informing participant's general provider…& procedures for seeking the participant's consent to do so
2. Suitability of the investigator(s) - qualifications & experience - for the proposed research/intervention
3. Plans to withdraw or withhold standard therapies for the purpose of the research, & justification for such action
4. Adequacy of medical supervision & psychosocial support for the research participants

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Summary: Ethical considerations in research & interventions related to breastfeeding -2

5. Description of plans to make study products available to the research participants following the research
6. Provisions for compensation/treatment in case of the injury/disability/death of a research participant attributable to participation in the research
   Any insurance & indemnity agreements?
7. Description of any financial costs to participants
8. Descriptions of rewards & compensations for participants

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Summary: Ethical considerations in research & interventions related to breastmilk

1. Respect for human dignity
2. Beneficence
3. Justice
4. Community considerations

….While ensuring infants receive safe, high-quality milk.

Refs: Thibeau S, Ginsberg HG. Bioethics in Practice: The Ethics Surrounding the Use of Donor Milk. Ochsner J. 2018 Spring;18(1):17-19.

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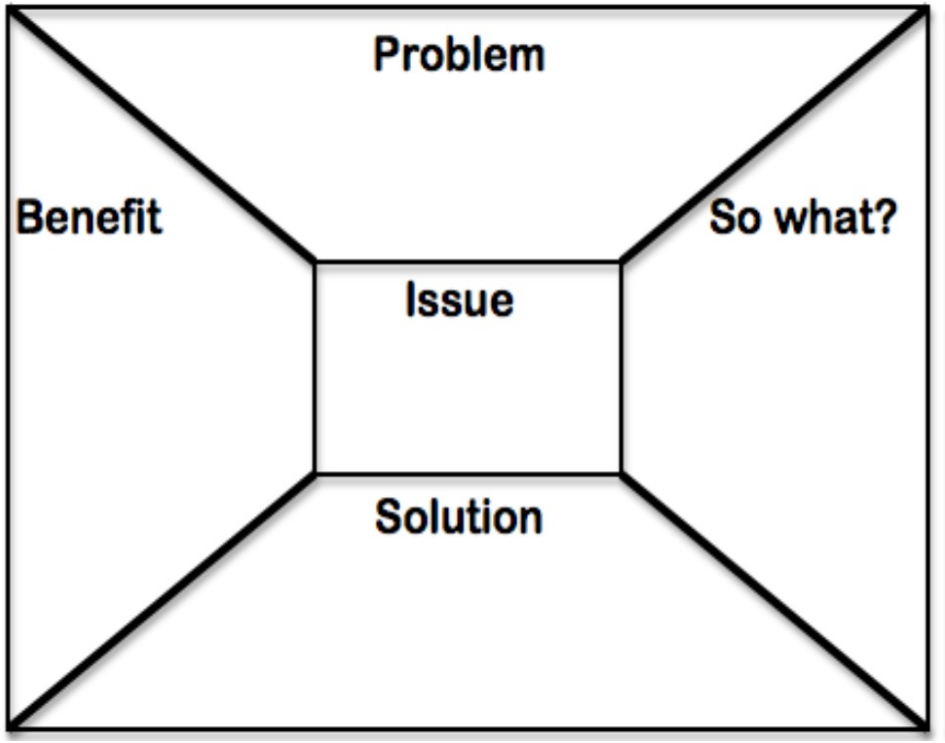
Summary: Broad community considerations

- Impact & relevance of the research on the local Kenyan community
- Steps taken to consult Kenyan communities during design & implementation
- Research contribution to locals' capacity building
- Community feedback of research findings
- Availability & affordability of successful study products



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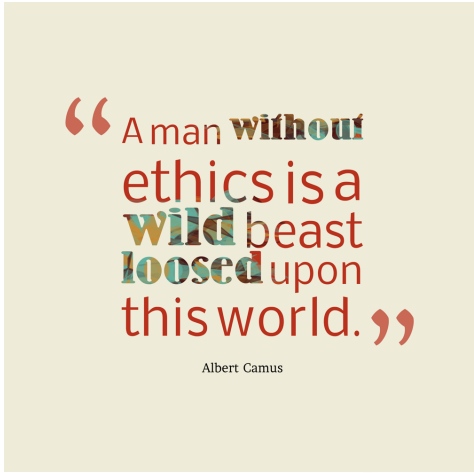
Conclusion

- Individual posses human rights & we must watch out **for the vulnerable**
- Access to research may provide benefits to breastfeeding participants that are otherwise unavailable
- Focus on ethics facilitates development of relevant breastfeeding guidelines
- Conducting sound, relevant research informs breastfeeding policies



Thank you!

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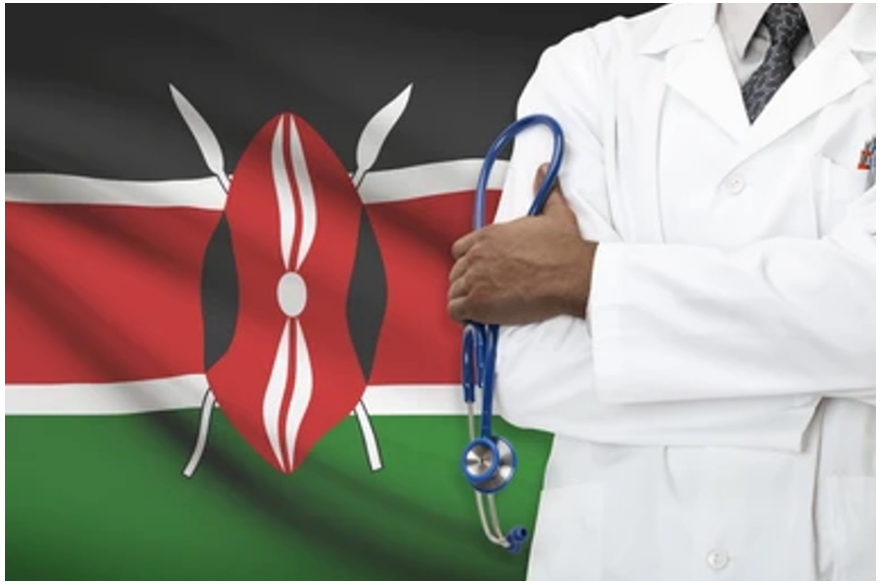

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Conflict of interest in research and interventions related to breastfeeding and breastmilk

Dr. Stephen Ombok Muhudhia
Paediatrician and Bioethics Specialist
The Nairobi Hospital

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Primary and secondary interests

- Explain what you understand by primary and secondary interests?
- Do people experience difficulties related to multiple interests?
- How do they manage the issues?

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A high-profile academic and researcher

- A Professor of neonatology in a high-ranking University Hospital. She is involved in teaching medical students, caring for newborn babies and doing research. She carried out research on the benefits of breastmilk for preterm infants of HIV-infected mothers. She published her results in a high impact journal.

- She was later appointed as a director of a formula milk manufacturing company with very good emoluments and benefits, including dividends from profits the company made.

- The formula milk manufacturing company sponsored a symposium on infant nutrition and requested the professor, on her capacity as a “thought leader” to present a paper on the benefits of micronutrients added to breastmilk formulas. Most of the contents of the paper were prepared by technical experts of the formula milk company. On reading the paper she found that it stated that micronutrients added to breastmilk had marked benefit for premature babies. However, there was no data to support this fact.

- She was later awarded a grant by the same company for research to investigate the benefits to preterm infants of formula milk fortified with probiotics.

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Discussion

- What is the Professor's primary interest in the first request?
- What is the primary interest in the research to be undertaken?
- Are there any issues that may arise, potential, real, or perceived in the first request? In the research to be undertaken?
- Collectively, we refer to these challenging situations as conflicts of interest

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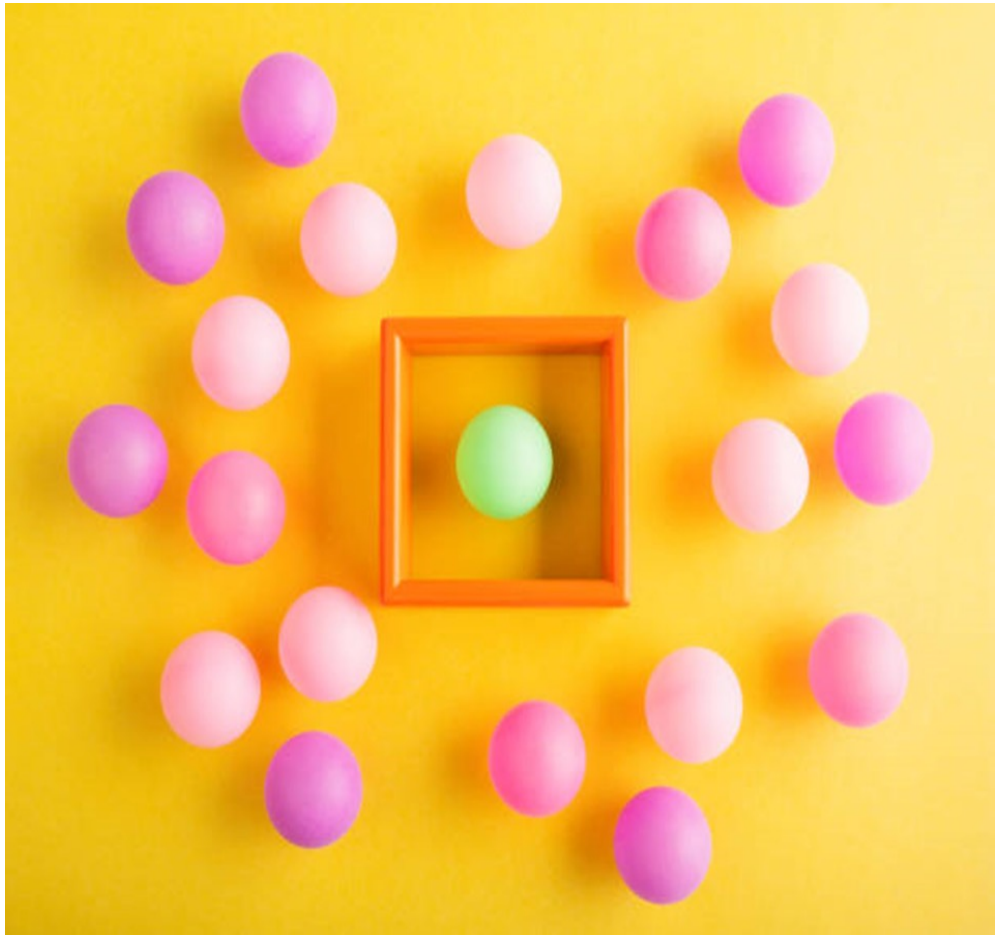
Competing interests

- There are situations where two or more competing interests create the **perception,** or the **reality,** of an **increased risk of bias or poor judgment.**
- Conflicts encountered in the profession of science are not inherently bad; they are to be expected.
- It's how they are **handled** that can lead to **untoward, inappropriate, or bad outcomes.**



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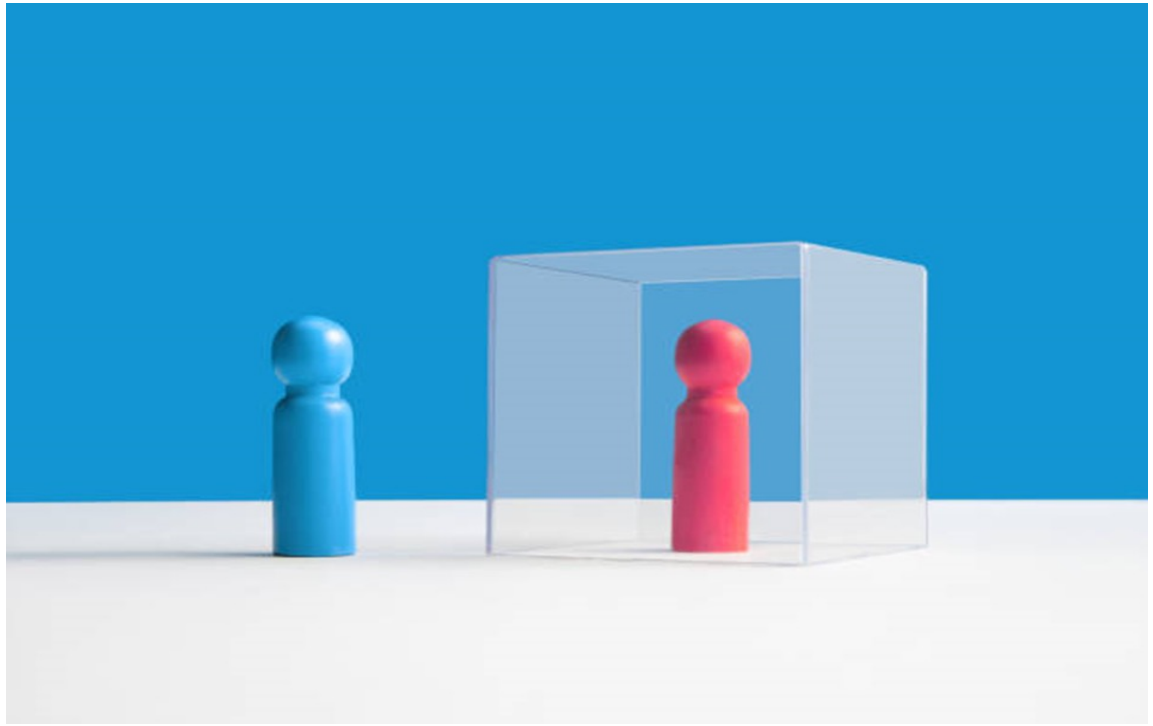
Conflict of Interest: Definition



- A situation where two or more competing interests create the **perception** or the **reality** of an **increased risk of bias or poor judgment.**
- The risk may be **actual or potential**. Such challenging situations come up regularly in both our personal and professional lives.
- Collectively, we refer to these as **conflicts of interest**.

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Conflict of Interest (CoI) in research

- In the context of research, “a conflict of interest (CoI) is a set of circumstances or conditions in which professional judgement of a **primary interest**, such as the integrity and quality of the research, tends to be **unduly influenced by a secondary interest,** such as personal financial gain”[1].

- CoIs can incline researchers towards bias in favor of their secondary interest and thus undermine the reliability of research the results

(1) Emanuel E.J., & Thompson D.F. (2008). The concept of conflict of interest. In: Emanual, E.J., Grady, C., Crouch, R.A, Lie, R.K., Miller, F.G., & Wendler, D.D. The Oxford Textbook of Clinical Research Ethics. Oxford: Oxford University Press, 758-766.

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Perceptions are important

- **Perceived impropriety** can result in consequences as damaging as if intentional misconduct had been committed.
- When large sums of money are involved, it may be **difficult** for the public, legislators, the judicial system, and even colleagues **to be convinced that results were not biased for personal gain.**
- A researcher's **reputation**, research funding, and **employment** can depend as much on **perceptions of integrity as on integrity itself**.

Source- Office of Research Integrity. https://uaf.edu/ori/responsible-conduct/conflict-of-interest/

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Consequences

- Scientists have a professional, fiduciary, and ethical interest in the **responsible conduct of research**, these interests may be compromised by personal interest. It can result in unethical behavior or criminal misconduct.
- Conflicts of interest **do not necessarily amount to research misconduct.**
- If the **potential for personal gain** is great, then principles that guide responsible conduct in research may be compromised.
- In an extreme case, it is conceivable that scientists could **knowingly compromise principles of good scientific practice** in pursuit of a particular research finding or outcome.

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Consequences

- Conflicts of interest **increase the temptation** to **commit misconduct**.
- Conflicts of interest **increase the risk** of **unintentional bias.**
- Scientists may prefer topics, methods, and approaches for which support is available.
- Scientists may be unconsciously biased in the:
  - enrollment of subjects for a clinical trial,
  - choices about data selection, statistical methods, and presentation of results
  - evaluation of data dependent on subjective judgments,
  - reading of objective measurements.

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Consequences

- Conflicts of interest **can lead to harmful** misperceptions of scientists and the scientific enterprise.
- When large sums of money are involved, **it may be difficult** for the public, legislators, the judicial system, and even colleagues **to be convinced that results were not biased for personal gain.**
- Perceived impropriety can result in consequences as damaging as if intentional misconduct had been committed.
- a researcher's reputation, research funding, and employment can depend as much on **perceptions of integrity as on integrity itself.**

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Drivers of conflicts of interest

- Financial interest, is one of the major drivers for CoI; non-financial interests could compromise the responsible conduct of research.

- Examples of non-financial drivers are:
  - career advancement,
  - need to have publishable research results,
  - service to patients or students,
  - fame, power,
  - family and friendships.

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Role of research process

- Research processes and guidelines on good practice mitigate the adverse consequences of conflicts of interest,

- Scientific practices such as:
  - objectivity,
  - blinding of experimenters,
  - repetition of studies,
  - peer review,
  - disclosure,
  - Data sharing

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Management of CoI

- **Comply with regulations**
- A variety of regulations and guidelines govern the disclosure and management of conflict of interest.
- Researchers should adhere to institutional and governmental requirements for **identifying, disclosing**, and **managing conflicts of interest**.
- **Professional societies and journals** are an important source for guidance on the management of conflicts of interest. These are quite variable in their scope and rarely enforced.

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Management of CoI

Avoid and minimize conflict

- Although it is not possible to avoid all sources of conflict, it is in the best interests of the scientific community and of individual scientists to recognize conflicts of interest and to **take steps to nullify or mitigate** those conflicts.

Mitigation

- Adverse consequences of conflicts of interest will eventually be mitigated by the structure of science:

  objectivity, blinding of experimenters, repetition of studies, peer review, disclosure, and so on.

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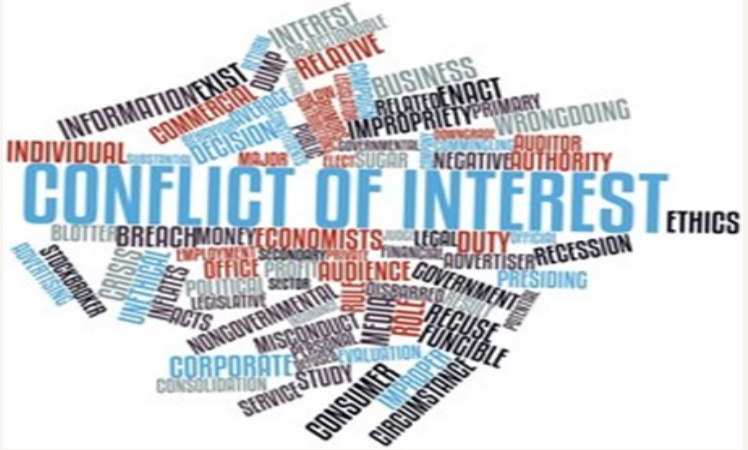
Management of CoI

Disclose interests

- If conflicts cannot be avoided, they should be disclosed.
- At minimum, the institution and any other parties with a significant interest should be made aware of the extent and nature of the conflict. This includes the audience at meeting presentations as well as journal editors (before submitting or refereeing manuscripts).

Manage potential conflicts

- At every step of the research process, attempts should be made to isolate the conflicted individuals from all decision-making functions.
- Steps should be taken to maximize the objectivity of:
  - participant selection,
  - data collection,
  - selection of data for publication,
  - interpretation of the findings.
- These functions should be the responsibility of, or should be **reviewed by, an unconflicted individual or group.**



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Conclusion

- We often find ourselves in situations where **two or more competing interests create the perception** -- or the **reality** -- of an increased **risk** of bias or poor judgment.
- Conflicts in the profession of science are **not inherently bad**. They are to be expected. It's **how they are handled** that can lead to untoward, inappropriate, or bad outcomes.
- **Keep learning**; both the potential for conflicts of interest and the strategies for dealing with those conflicts are **evolving.** Considering the potential for misperceptions of a researcher's motives, **it is best to assume that good intentions are not enough**. Seek out information so as to comply with the spirit and letter of current regulations

References

- Office of Research Integrity. https://uaf.edu/ori/responsible-conduct/conflict-of-interest/
- World Health Organization. (2016). Addressing and managing conflicts of interest in the planning and delivery of nutrition programmes at country level: report of a technical consultation convened in Geneva, Switzerland, on 8–9 October 2015. World Health Organization. https://apps.who.int/iris/handle/10665/206554
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EFBRI – Ethical Framework Informing Breastfeeding Research and Interventions

Professor Nikola Biller-Andorno
Institute of Biomedical Ethics and History of Medicine, University of Zurich

26 April 2023

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Outline

- Introducing EFBRI (research ethics framework)
- Using EFBRI with case studies
- Current projects:
    - Ethics of breastfeeding and lactation intervention framework version 2.0
    - Ethical red flags toolkit
- Next steps?

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International Research Ethics

The key challenge of international research ethics is “to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in standards of healthcare” (CIOMS 2002).

- Need for global standards
- But: context matters in application (e.g. socio-economic conditions)

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The importance of research ethics in breastfeeding

- To protect mothers and their infants, aiming to advance the health and well-being in vulnerable situations while respecting (and possibly enhancing) women's autonomy.
- Research involving stem cells, embryos
- Currently, there is little guidance informing biomedical research in breastfeeding and lactation (-> CIOMS guideline 19, Geneva 2016)
- The creation of an evolving ethics framework - EFBRI

EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

Access now

EFBRI is an open access compilation of ethical principles to guide biomedical research in breastfeeding and lactation. Built on established international standards by the University of Zurich (UZH), it was created to streamline research processes for people working with breastfeeding mothers and children. With EFBRI, researchers and other stakeholders can align their work to universal research ethics standards – confidently and efficiently.

www.LactaEthics.org

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EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

Features:

- Open access compilation of ethical principles to guide research on breastfeeding and lactation
- Based on a review of relevant (Swiss) national and international laws and guidelines
- Bridging research and practice
- Evolving
  - **Learning document**: Feedback from research community; assess need for clarification or more detail
  - Aim for **interactive format**: easily searchable
  - **Modular system** spanning across different types of research (biomedical research, under consideration: implementation research, data sciences)

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EFBRI: Why? For whom?

- A globally applicable ethics framework specifically focused on research with breastfeeding mothers and children.
- The Framework aims to provide support to a diverse range of stakeholders such as researchers, reviewers, healthcare practitioners, study participants, health care policymakers and planners, implementation specialists, educators and funders.
- Current guidance needs to reflect the dynamic nature of biomedical research and evolving global consensus.

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EFBRI's normative basis

- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), Confederation of Switzerland
- Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), Confederation of Switzerland
- The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Bio-medicine (ETS No 164), 1997, Oviedo (Spain), ratified by Switzerland in 2008
- World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964/2013)
- International Ethical Guidelines for Health-related Research Involving Humans, Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2016)
- Universal Declaration of Human Rights (1948)

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How was EFBRI developed?

Step 1: **The fundamental principles elaborated in the laws and guidelines** forming EFBRI's normative basis were compared and consolidated where they overlapped. There were no explicit conflicts between documents.

Step 2: These principles were examined with a view to their applicability against relevant research protocols and against a **review of the breadth of human-milk-related research** (including the physiology of breastfeeding; infant nutrition; gene-nutrient interactions; the effects of hormones; models of metabolic functions; outcomes of changes in diet; infant and/or maternal health issues; impediments to breastfeeding; and the social and economic implications of breastfeeding) to **ensure that the scope and content of the framework would be relevant to research broadly focused on breastfeeding and lactation**.

Step 3: The document was **reviewed and revised together with a Technical Advisory Board** with legal as well as medical and clinical research expertise (in both neonatal care and gynecology).

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Introduction of EFBRI Principles

1. Purpose of Research and Scientific Relevance
2. Human Research
3. Research Infrastructure
4. Research Protocol
5. Review by Ethics Committees
6. Consent for Participation in Research
7. Additional Requirements for Research Involving Vulnerable Groups
8. Use of Biological Material
9. Use of Embryos for Research
10. Use of Placebo
11. Research in Emergency Situations
12. Data Protection
13. Right of Participants to Their Own Data

2. Human Research

a) Conducting research on human participants,

b) Selection of participants,

c) Prediction of the risks, burdens and benefits,

d) Minimising risks,

e) Incentives for participation.

- Has consent been appropriately obtained in writing?
- Are there no alternatives of comparable effectiveness to research on humans?
- Are the risks incurred by participants not disproportionate to the benefits of the research?
- Does it comply with regulations surrounding scientific integrity, i.e. conflict of interest issues
- Are scientific quality requirements met?

Additional Requirements for Research Involving Vulnerable Groups

a) When can research involving vulnerable populations be justified?

b) What if these vulnerable populations include:

   i. Women of child-bearing potential,

   ii. Pregnant and breastfeeding women,

   iii. Minors.

c) When can you carry out a research project with an expected direct benefit on adults who lack capacity?

10. Use of Placebo

a) Are the benefits, risks, burdens and effectiveness of the new intervention tested against the best known proven intervention?

b) For any intervention that is less effective than the best proven intervention, the use of a placebo or no intervention is necessary to determine its efficacy and safety.

Case Study 1 (1/2)

Effects of Bottles, Cups, and Dummies on Breast Feeding in Preterm Infants: Randomised Controlled Trial

Collins CT., Ryan P., Crowther CA., McPhee AJ., Paterson S., Hiller JE. 2004. Effect Of Bottles, Cups, And Dummies On Breast Feeding In Preterm Infants: Randomised Controlled Trial. *BMJ 329; 193.* https://doi.org/10.1136/bmj.38131.675914.55

Abstract

Objective To determine the effect of artificial teats (bottle and dummy) and cups on breast feeding in preterm infants.

Design Randomised controlled trial.

Setting Two large tertiary hospitals, 54 peripheral hospitals.

Participants 319 preterm infants (born at 23-33 weeks' gestation) randomly assigned to one of four groups: cup/no dummy (n = 89), cup/dummy (n = 72), bottle/no dummy (n = 73), bottle/dummy (n = 85). Women with singleton or twin infants < 34 weeks' gestation who wanted to breastfeed were eligible to participate.

Interventions Cup or bottle feeding occurred when the mother was unable to be present to breast feed. Infants randomised to the dummy groups received a dummy on entry into the trial.

Main outcome measures Full breast feeding (compared with partial and none) and any breast feeding (compared with none) on discharge home. Secondary outcomes: prevalence of breast feeding at three and six months after discharge and length of hospital stay.

Results 303 infants (and 278 mothers) were included in the intention to treat analysis. There were no significant differences for any of the study outcomes according to use of a dummy. Infants randomised to cup feeds were more likely to be fully breast fed on discharge home (odds ratio 1.73, 95% confidence interval 1.04 to 2.88, P = 0.03), but had a longer length of stay (hazard ratio 0.71, 0.55 to 0.92, P = 0.01).

Conclusions Dummies do not affect breast feeding in preterm infants. Cup feeding significantly increases the likelihood that the baby will be fully breast fed at discharge home, but has no effect on any breast feeding and increases the length of hospital stay.

Case Study 1 (2/2)

Key Ethical Issues	EFBRI Framework
• Random allocation to control group needs to be ethically reflected • Mitigating risks for forming undesirable practice, i.e. creating dependencies for bottle feeding'; protect 'non-interference' with the mother's intention to breastfeed	**Principle 2 (Human Research)** a. iii.) the risks incurred by that person in participating are not disproportionate to the potential benefits of the research; iv. regulations concerning scientific integrity are complied with, especially with regards to handling conflicts of interest; and v. scientific quality requirements are met. c.) Careful assessment of the predictable risks and burdens in relation to the foreseeable benefits to individuals and groups involved in the research should be documented. **Principle 5 (Review by Ethics Committee)** a.) The responsible ethics committee is that of the country and state in whose territory the research is conducted. **Principle 7 (Additional Requirements for Research Involving Vulnerable Groups)** a. iv.) Special protections are taken allowing no more than minimal risks for procedures that offer no potential individual benefits

Case Study 2 (1/2)

The effect of participatory women's groups on infant feeding and child health knowledge, behaviour and outcomes in rural Bangladesh: a controlled before-and-after study

Younes L., Houweling TAJ, Azad K., et al. 2014 The effect of participatory women's groups on infant feeding and child health knowledge, behaviour and outcomes in rural Bangladesh: a controlled before-and-after study. *J Epidemiol Community Health.* 69; 374-381. https://doi.org/10.1136/jech-2014-204271

ABSTRACT

Background: Despite efforts to reduce under-5 mortality rates worldwide, an estimated 6.6 million under-5 children die every year. Community mobilisation through participatory women's groups has been shown to improve maternal and newborn health in rural settings, but little is known about the potential of this approach to improve care and health in children after the newborn period.

Methods: Following on from a cluster-randomised controlled trial to assess the effect of participatory women's groups on maternal and neonatal health outcomes in rural Bangladesh, 162 women's groups continued to meet between April 2010 and December 2011 to identify, prioritise and address issues that affect the health of children under 5 years. A controlled before-and-after study design and difference-in-difference analysis was used to assess morbidity outcomes and changes in knowledge and practices related to child feeding, hygiene and care-seeking behaviour.

Findings: Significant improvements were measured in mothers' knowledge of disease prevention and management, danger signs and hand washing at critical times. Significant increases were seen in exclusive breastfeeding for at least 6 months (15.3% (4.2% to 26.5%)), and mean duration of breast feeding (37.9 days (17.4 to 58.3)). Maternal reports of under-5 morbidities fell in intervention compared with control areas, including reports of fever (-10.5% (-15.1% to -6.0%)) and acute respiratory infections (-12.2% (-15.6% to -8.8%)). No differences were observed in dietary diversity scores or immunisation uptake.

Conclusions: Community mobilisation through participatory women's groups can be successfully adapted to address health knowledge and practice in relation to child's health, leading to improvements in a number of child health indicators and behaviours.

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Case Study 2 (2/2)

Key Ethical Issues	EFBRI Framework
• Informed consent • Financial incentives for volunteers who are part of recruiting research participants	**Principle 2 (Human Research)** e.) No person may receive payment or any other pecuniary benefit for participation in a research project with an expected direct benefit. Participation in a research project with no expected direct benefit may be appropriately remunerated. **Principle 5 (Review by Ethics Committee)** c.) Funders can establish additional review systems to ensure the proposals they decide to support meet international research ethics standards (cf. WMA, CIOMS and WHO, documents listed on p.1). **Principle 6 (Consent for Participation in Research)** a.) The necessary consent must be specific, expressly given and documented. It should be made clear that consent may be freely withdrawn at any time, without having to state any reason.

Case Study 3 (1/2)

A cluster randomised trial to determine the efficacy of the “feeding buddies” programme in improving exclusive breastfeeding rates among HIV-infected women in rural KwaZulu-Natal, South Africa

Reimers P., Israel-Ballard K., Craig M., et al. 2018. A Cluster Randomised Trial to Determine the Efficacy of the "Feeding Buddies" Programme in Improving Exclusive Breastfeeding Rates Among HIV-Infected Women in Rural KwaZulu-Natal, South Africa. *AIDS Behav*. 22; 212-223. https://doi.org/10.1007/s10461-017-1865-8

ABSTRACT

This cluster randomised trial in KwaZulu-Natal South Africa, evaluated the implementation of a *Feeding Buddies* (FB) programme to improve exclusive breastfeeding (EBF) amongst human immunodeficiency virus infected mothers. Eight clinics were randomly allocated to intervention and control arms respectively. Pregnant women attending the prevention of mother-to-child transmission program and intending EBF were enrolled: control (n=326), intervention (n=299). Interviews of mothers occurred prenatally and at post-natal visits (day 3, weeks 6, 14 and 22). Breastfeeding results were analysed (Stata) as interval-censored time-to-event data, with up to four time intervals per mother. EBF rates at the final interview were similar for control and intervention groups: 44.68% (105/235) and 42.75% (109/255) respectively (p = 0.67). In Cox regression analysis better EBF rates were observed in mothers who received the appropriate training (p = 0.036), had a community care giver visit (p = 0.044), while controlling for other factors. Implementation realities reduced the potential effectiveness of the FBs.

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Case Study 3 (2/2)

Key Ethical Issues	EFBRI Framework
• Provide clinical support management to support vulnerable mothers • Privacy and confidentiality	**Principle 7 (Additional Requirements for Research Involving Vulnerable Groups)** a. iv.) The risks are minimised and outweighed by the prospect of potential individual benefit. **Principle 12 (Data protection)** a.) Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

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EFBRI challenges and opportunities

- Dynamic and broad research field
- EFBRI is positioned where ethical research principles meet ethical principles governing practical implementation
- Explicit user feedback and suggestions from real-life cases will help build a comprehensive resource
- Work towards global understanding of ethical issues regarding breastfeeding research, facilitating international research and collaboration, review and funding activities

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Key messages and outlook

- EFBRI is an **ethical framework** (and not a code of conduct) – as such it leaves room for specification and interpretation.
- Context matters! Issues may appear and be – for good reason – be judged differently depending on cultural, social, economic and political factors (such as vulnerability of study participants).
- EFBRI is a synthesis of relevant Swiss and international norms relevant to the scope of breastfeeding and lactation research – it is not a legal text.
- EFBRI is complementary to national laws, good clinical practice and safety standards.
- EFBRI is not a text carved in stone, it is a process involving all those who are interested in contributing to protecting the dignity and rights of participants in breastfeeding research.

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A resource for evidence-based breastfeeding intelligence

Current Work
(2023)

26 April 2023

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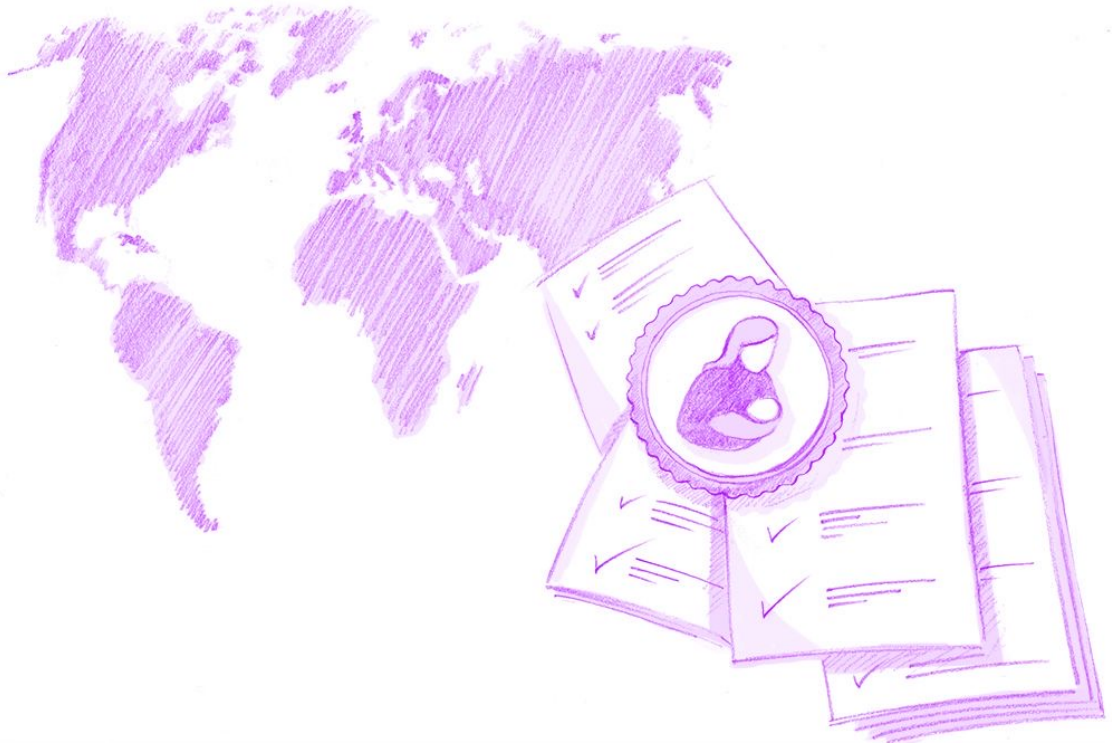
Ethics of breastfeeding and lactation intervention framework version 2.0



- Ethics framework for **breastfeeding interventions sensu lato** (e.g., training programmes, counselling, peer support, home visits, lactation support);
- Publication of EFBRI 2.0 and of a tool for EFBRI 2.0 application on https://lactahub.org (Ethical Red Flags Toolkit) (forthcoming).

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Ethics of breastfeeding and lactation intervention framework version 2.0

Key Ethical Considerations of EFBRI 2.0:

- Vulnerability
- Sensitivity to Social and Cultural Context
- Responsibility and Accountability
- Informed Consent
- Ethics of Health Promotion and Communication
- Ethics of Financial and Non-Financial Incentives
- Risk-Minimization and Equitable Distribution of Benefits and Risks
- Conflict of Interest
- Implementation of Post-Intervention Support

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Ethical Red Flags Toolkit

The ethical red flags toolkit is a way for researchers to identify the main ethical concerns and issues within a list of common breastfeeding and lactation interventions, targeting one of the seven main clusters;

- Knowledge
- Resources
- Legal/Policy
- Common Practices
- Attitudes
- Maternal Health
- Infant Health

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Ethical Red Flags Toolkit

Each of the interventions are screened from a list of 24 identified ethical categories which form the main ethical issues in breastfeeding and lactation intervention research:

1. Informed Consent
2. Data Ethics
3. Confidentiality
4. Privacy
5. Responsibility
6. Sensitive to Social/Cultural Context
7. Risk Disclosure
8. Fairness and Compensation
9. Training Capability & Effectiveness
10. Conflict of Interest
11. Preventing Harm/Risks
12. Respect
13. Trust
14. Accountability & Integrity
15. Intersectional Approach
16. Maternal Autonomy
17. Proportionality
18. Transparency
19. Public & Community Engagement
20. Vulnerability
21. Social Inclusivity
22. Stigmatisation
23. Exploitation
24. Evidence-Based Training

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e.g. Maternal Health

Categories of interventions	Examples of the intervention	Main ethical issue/s	Description of ethical issues
1. Homevisits (by midwives/nurses/ peers)	- Midwife homevisiting program - HCW homevisiting program - Community workers or peers homevisiting program	11. Preventing Harm/Risks	- Being aware of different family dynamics and the role of authority/ power in families, as well as being alert to any potential danger women and their infants may be exposed to in their homes.

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Next Steps?

- Gather feedback for frameworks,
- Develop interactive features for the ethical red flags toolkit,
- Conduct case studies to solidify existing frameworks on research ethics and intervention ethics

EFBRI – An Evolving Ethical Framework Involving Breastfeeding Research and Interventions on LactaHub

www.LactaEthics.org

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Thank you for your attention

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Thank you very much for joining our LactaHub Workshop!

Would you like to keep current on this topic and other related news? **Sign up for our LactaNews letter: www.LactaHub.org/LactaNews**

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Thank you very much and see you soon!