

LactaWebinar

Join us for a conversation on the ethics principles compiled in
EFBRI – An Evolving Ethical Framework
Informing Breastfeeding Research and Interventions

Thursday, 10 March 2022

This LactaWebinar is organised by the the Institute of Biomedical Ethics and History of Medicine (University of Zurich),
The Global Health Network (University of Oxford) and LactaHub – A Resource for Evidence-based Breastfeeding Intelligence



**University of
Zurich**^{UZH}



Technical information



Questions: If you are joining us on **Zoom**, please ask your question in the non-public Q&A section. If you are tuning in via The Global Health Network **Facebook** page, please send your question to The Global Health Network via Facebook Messenger. **We will answer as many questions as possible during the webinar Q&A.**



Technical issues: If you cannot hear or see us, please check your computer preferences, close other programmes, and check your sound level. If issues persist, you might need to close and restart the Zoom meeting, or join via Facebook.



Knowledge sharing: In the spirit of open access and knowledge sharing, we are recording this meeting to make it accessible for a wider audience on LactaHub.



Video and audio: Your camera is automatically deactivated and all microphones are muted.

Join us for a conversation on EFBRI today with



Prof. Dr. med. Dr. phil. Nikola Biller-Andorno

Co-creator of EFBRI; Director of the Institute of Biomedical Ethics and History of Medicine (University of Zurich), Switzerland, a WHO Collaborating Centre for Bioethics



Dr. Katharina Lichtner

Managing Director, Family Larsson-Rosenquist Foundation, Switzerland; Initiator of LactaHub, a partnership project of The Global Health Network (University of Oxford) and the Family Larsson-Rosenquist Foundation



Dr. Farah Asif

Clinical Research Administrator, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Pakistan; Initiative lead: Developing a Policy Statement and Recommendations for Pakistan's Ethics Review Framework and IRBs in Support of Public Health Emergency Preparedness and Response



Dr. Stephen Ombok Muhudhia

Specialist Paediatrician, Nairobi Hospital, Kenya; Adjunct Professor of Bioethics at Trinity International University; Co-Director of Trinity International University's Africa Bioethics Initiative program; Member of the Scientific, Ethics and Research Unit (SERU) of the Kenya Medical Research Institute (KEMRI)

Moderated by



Dr. Supriya Subramani

Postdoctoral Researcher (Stehr-Boldt Fellow), Institute of Biomedical Ethics and History of Medicine (University of Zurich), Switzerland, a WHO Collaborating Centre for Bioethics



Arancha De La Horra

Chair of this LactaWebinar; Clinical Research Specialist, The Global Health Network (University of Oxford), UK

Our agenda for today

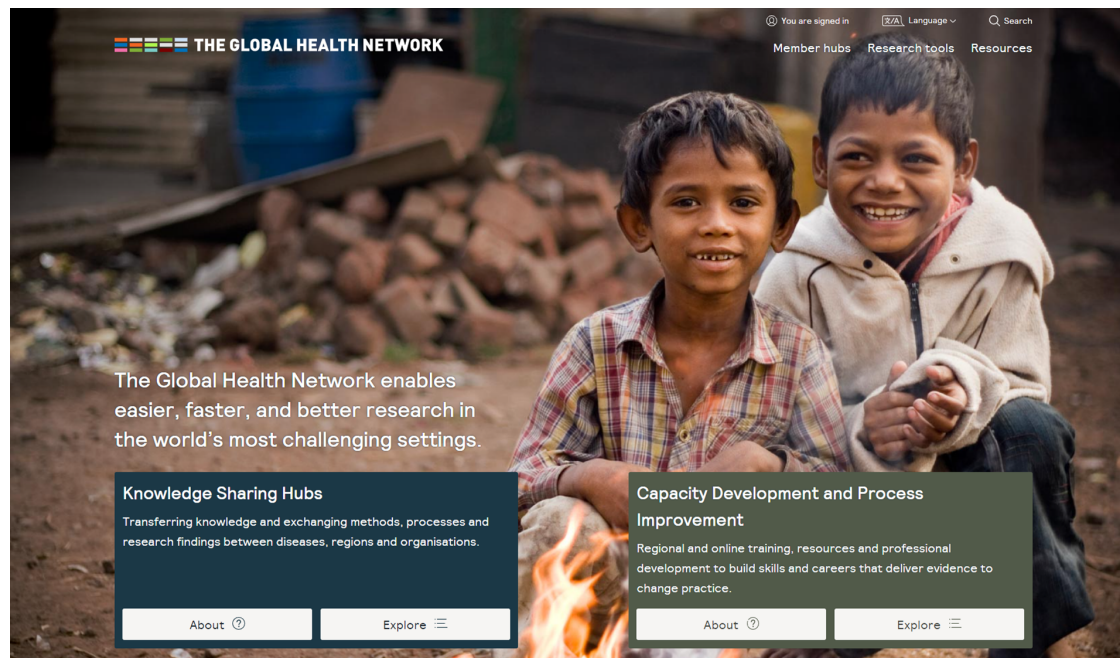
- 10 min. **Update from The Global Health Network and LactaHub**
Arancha de la Horra (Chair)
- 10 min. **Introduction to LactaHub's LactaEthics vision**
Dr. Katharina Lichtner
- 25 min. **Tour of EFBRI on LactaHub**
Prof. Dr. med. Dr. phil. Nikola Biller-Andorno
- 20 min. **Expert conversation on the practical application of ethical frameworks**
with Dr. Farah Asif, Dr. Stephen Ombok Muhudhia and
Prof. Dr. med. Dr. phil. Nikola Biller-Andorno,
moderated by Dr. Supriya Subramani
- 20 min. **Q&As**
moderated by Arancha de la Horra (Chair)



Update from The Global Health Network and LactaHub

Arancha de la Horra (Chair)

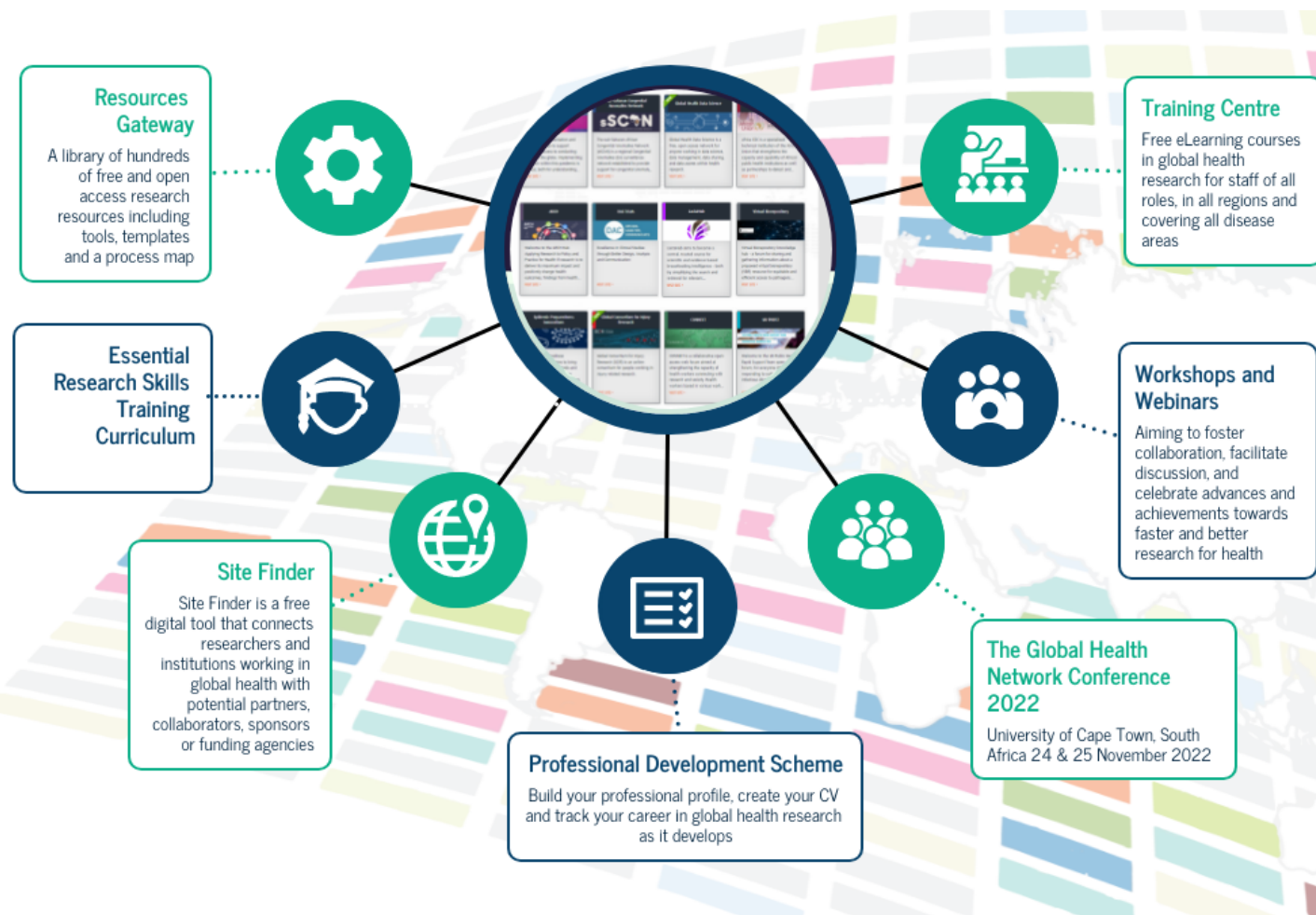
The Global Health Network (University of Oxford) – enabling research by sharing knowledge



www.theglobalhealthnetwork.org



The Global Health Network aims to facilitate easier, faster and better research in the world's most challenging settings



LactaHub is a resource for evidence-based breastfeeding intelligence

- Partnership project of **The Global Health Network** (University of Oxford) and the **Family Larsson-Rosenquist Foundation**
- Knowledge platform **freely available worldwide**
- Providing **objective research & scientific** and **evidence-based knowledge** about **breastfeeding** and **breastmilk** and is continuously curated by experts
- Community in the TGHN section **Women and Child Health**
- Direct Link: **www.LactaHub.org**

Improving availability, accessibility and use of relevant resources for health practitioners, policy makers and researchers



EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions



Reference Book: Breastfeeding and Breast Milk – from Biochemistry to Impact



LactaMedia - A Clinical Image Collection on LactaHub



PROVIDE - A Training Compendium on Providing Mothers' Own Milk in NICU Settings



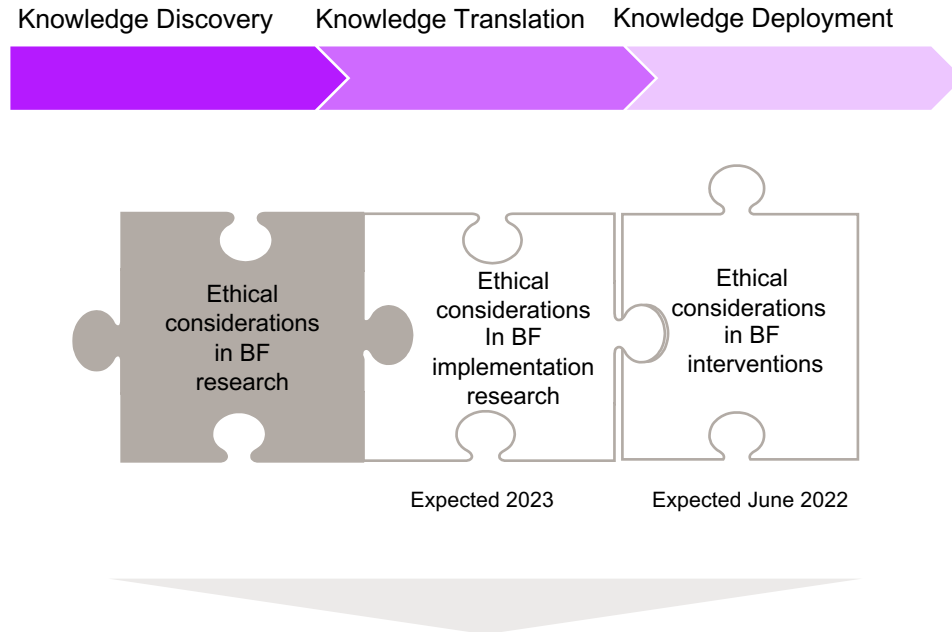
LactaPedia - A Glossary of Lactation for Science and Medicine



Introduction to LactaHub's LactaEthics vision

Dr. Katharina Lichtner

Research and implementation in lactation and breastfeeding involves vulnerable populations most of the time



EFBRI is a modular evolving framework which is pragmatically applicable in a global context

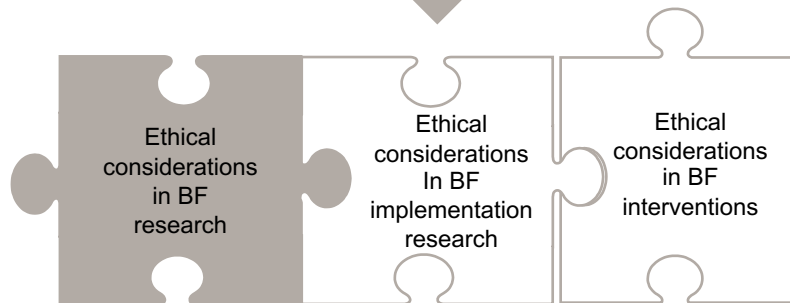
EFBRI can lay the groundwork for best practice ethics in healthcare research, policy, implementation and funding activities

Underlying standards

- 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)



EFBRI outlines how existing ethical conventions and declarations could be applied to questions and activities in research, implementation research and interventions in the field of breastfeeding and breastmilk

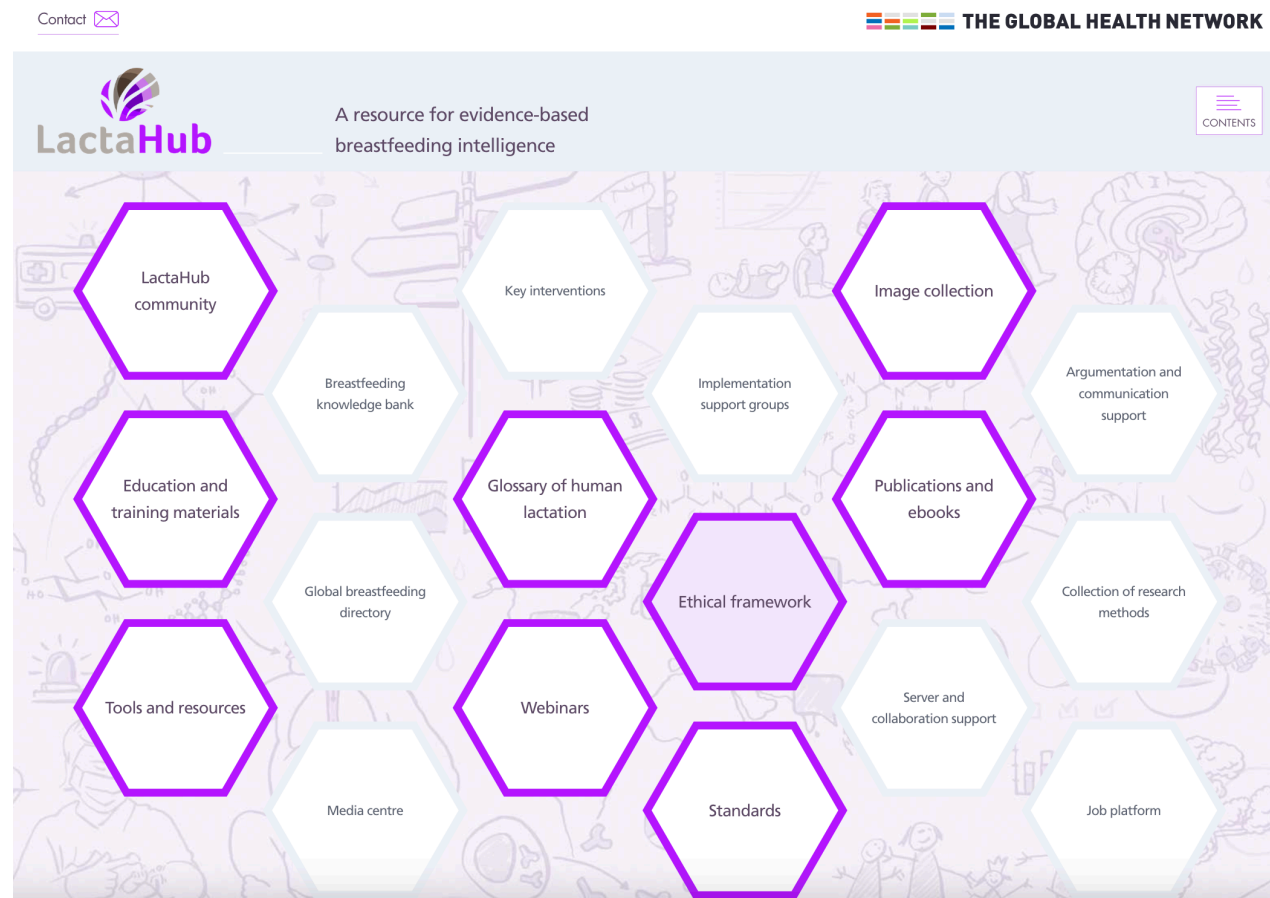




Tour of EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions on LactaHub

Prof. Dr. med. Dr. phil. Nikola Biller-Andorno

EFBRI was launched on LactaHub in November 2021





To directly access EFBRI visit: www.LactaEthics.org

Contact 

 THE GLOBAL HEALTH NETWORK



A resource for evidence-based
breastfeeding intelligence


CONTENTS

**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.



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)

EFBRI: Why? For whom?

- Biomedical research must be conducted in an ethical manner to protect the dignity, identity and integrity of all human beings.
- 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, healthcare policymakers and planners, implementation specialists, educators and funders.
- Current guidance needs to reflect the dynamic nature of biomedical research and evolving global consensus.

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)
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- Universal Declaration of Human Rights (1948)

How was EFRBI developed?

Step 1:

The fundamental principles elaborated in the laws and guidelines forming EFRBI'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).



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



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

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 breast feeding 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.

Case Study 2 (2/2)

Key Ethical Issues	EFBRI Framework
<p>Informed consent and transparency</p> <p>Financial incentives for volunteers who are part of recruiting research participants</p>	<p>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.</p> <p>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).</p> <p>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.</p>

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 to EBF were enrolled: control ($n = 326$), intervention ($n = 299$). Intervention mothers selected FBs to support them and they were trained together (four sessions). 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.

Case Study 3 (2/2)

Key Ethical Issues	EFBRI Framework
<p>Provide clinical support management to support vulnerable mothers</p> <p>Privacy and confidentiality</p>	<p>Principle 7 (Additional Requirements for Research Involving Vulnerable Groups) v) The risks are minimised and outweighed by the prospect of potential individual benefit.</p> <p>Principle 5 (Review by Ethics Committee) b) If a research project is carried out according to a standard protocol but in different geographical locations (multi-center research projects), authorisation is required from the ethics committee which is responsible at the site of activity of the project coordinator (the lead committee).</p> <p>Principle 12 (Data protection) a) Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.</p>

EFBRI: challenges and opportunities

- Council for International Organisations of Medical Sciences (2002): “The challenge to 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 health care”
- 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.

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 – 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.

Next steps: Gather feedback, develop interactive features, produce module on ethical issues in breastfeeding and lactations interventions

Thank you for your attention

Gratefully acknowledged:

- Dr. Mirriam Tyebally Fang for her key role in the compilation of the Framework
- Dr. Supriya Subramani and Rasita Vinay for their work on future EFBRI content and their assistance in the preparation of the webinar

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

www.LactaEthics.org



Expert conversation on the practical application of ethical frameworks

Dr. Farah Asif

Dr. Stephen Ombok Muhudhia

Prof. Dr. med. Dr. phil. Nikola Biller-Andorno

Moderated by Dr. Supriya Subramani

Q&As

Moderated by Arancha de la Horra (Chair)



Follow-up webinar: Use of Financial Incentives for Participants in Health and Breastfeeding Research

- **Wednesday, 13 April 2022, 2:00 PM London**
- **Registration on www.LactaEthics.org**
- Experts will discuss the ethical questions around financial incentives in health research and health programmes. They will explore arguments for and against financial incentives, drawing on cases from different regions of the world, including breastfeeding research.
- Organised by the **Institute of Biomedical Ethics and History of Medicine** (University of Zurich) with support from **Swiss Medical Weekly**, **The Global Health Network** (University of Oxford) and **LactaHub**
- The webinar is part of the webinar series of the **Forum for Global Health Ethics**



Thank you very much!

Please, help us develop EFBRI by sharing your feedback and suggestions: **ethics@lactahub.org**

Links

www.LactaEthics.org

www.ibme.uzh.ch

www.LactaHub.org

www.theglobalhealthnetwork.org