Policy Drives Practice: How Ethics and Evidence Intersect to Change Behavior
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Faculty Disclosure Information
• I have no financial relationships to disclose.
• I will not discuss “off label” and/or investigational use in my presentation.

Kathleen A. Marinelli MD, IBCLC, FABM, FAAP
I am however quite biased toward breastfeeding and the use of human milk...

True Confessions...
• I have never used the Audience Response System giving a presentation before.
• This is a new presentation for me.
• I am not an ethicist.
• So we are off on a journey together!

Audience Response System
What is your profession?
1. Lactation consultant
2. Dietician
3. Nurse Practitioner
4. Nurse
5. Physician
6. Other

Audience Response System
Where do you practice?
1. Atlanta inside the perimeter
2. Atlanta outside the perimeter
3. Elsewhere in Georgia
4. In Connecticut
5. In another state

Audience Response System
What is your work setting?
1. Academic hospital
2. Non-academic hospital
3. Private practice
4. Clinic
5. Non-clinical
6. Other

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Objectives

- Define the basic ethical principles applied in health care
- Describe how ethical principles and evidence-based practice drive clinical policy
- Determine using cases how policy drives practice
- Decide if we can validate the statement “Evidence-based, ethical breastfeeding policy drives behavior toward best practices, which in turn, should determine better health outcomes.”

Ethical Principles

- Beneficence - to do good
- Non-maleficence - to do no harm
- Respect for Autonomy
- Justice

- Truthfulness

Beneficence

- Compassion
- Taking positive action to help others
- Desire to do good
- Core principle of our patient advocacy

Nursing and Midwifery Council Code of Standards, Performance and Ethics for Nurses and Midwives (NMC, 2015)

**Non-maleficence (Primum non nocere)**

- Avoidance of harm or hurt; core of medical oath and nursing ethics.
- Extends to making sure you are doing no harm in the beneficent act of using technology to extend life or in using experimental treatments that have not been well tested.

**Autonomy**

- Autonomy is Latin for "self-rule"
- Agreement to respect another's right to self-determine a course of action
- Support of independent decision-making
- Principle of human dignity
- An obligation to respect the decisions made by competent people concerning their own lives.

**Justice**

- Equal and fair distribution of resources, based on analysis of benefits and burdens of decision
- Justice implies that all citizens have an equal right to the goods distributed, regardless of what they have contributed or who they are
- An obligation to treat all people equally, fairly, and impartially

**Truthfulness**

- Facet of moral character denoting positive and virtuous attributes such as integrity, truthfulness, straightforwardness
- Includes straightforwardness of conduct, absence of lying, cheating, and theft
- Being trustworthy, loyal, fair, and sincere
- The concept of Informed Consent

**1950’s**

Keeping these principles in mind...

How do we determine policies?

2016...


http://stream.advocatehealth.com/flashfiles/gsam/obVT/4230.jpg

http://media.jrn.com/images/nursery01_22202227_ver1.0_640_480.jpg

**Audience Response System**

What changed?

1. Hospitals stopped stocking formula
2. Staffing decreased and nurseries had to close
3. Policies were put into place that changed practice
4. Insurance companies stopped covering nursery stays
Emerging Evidence

• 1920’s: women encouraged to raise their infants “scientifically” (Raising by the book)
  • Cod liver oil, orange juice, artificial feeding
  • Suggestion of “alarming number of young women unable to breastfeed” (Parents magazine 1938)
• 1950’s on—women sought to be well-informed, wanted right to choose how to feed their infants

Lawrence and Lawrence 2016

Emerging Evidence

• 1940’s—Edith Jackson MD-Yale New Haven School of Medicine and the Grace New Haven Hospital awarded federal grant
  • 1st Rooming-In Unit in the US
  • 1st program to prepare women for childbirth modeled after British obstetrician Grantley Dick-Read’s Child Birth Without Fear
• 1956—La Leche League
  • Doula support described (Raphael 1976)

Emerging Evidence

• 1997—comparison of costs of WIC and Medicaid for food and health care in CO, administrative and health care costs for a formula-fed infant minus the rebate for the first 180 days of life
  • $273 higher than for breastfed infant (not including pharmacy costs for illness) (Montgomery 1997)
  • Culture changes
  • Goals—Healthy People

Breastfeeding Rates


Breastfeeding Rates

Ross Mother’s Survey

So what have we seen?

- Increased initiation
- Increased duration
- Increased exclusivity

**Audience Response System**
Has it been evidence-based?
1. Yes
2. No
3. I don’t know...
4. Do I care?????....

Baby-Friendly Hospital Initiative

- **Launched in 1991 globally; 1997 USA**
- Key component of the WHO/UNICEF Global Strategy for Infant and Young Child Feeding
- Based on:
  - adherence to the Ten Steps to Successful Breastfeeding (Ten Steps; WHO 1989);
  - the 1981 WHO Code for Marketing of Breast Milk Substitutes (Kyenkye-Isabirye, 1992; Naylor, 2001; UNICEF/WHO 2009);
  - and endorses the integration of facility-level and community-level services (UNICEF/WHO 2009)

Quality assessment and improvement system

1. **Policy**: includes
   1. written breastfeeding (BF) policies endorsing the Ten Steps and the 1981 WHO Code;
   2. not accepting infant formula for free or at reduced cost;
   3. and forbidding direct or indirect marketing of infant formula to mothers.
2. Development of human resources:
   1. BF training of maternity ward staff.

Audience Response System
Are you familiar with the Ten Steps to Successful Breastfeeding?
1. Yes
2. No

<table>
<thead>
<tr>
<th>Table 1: WHO/UNICEF Ten steps to successful breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have a written breastfeeding policy that is routinely communicated to all health care staff.</td>
</tr>
<tr>
<td>2. Train all health care staff in the skills necessary to implement this policy.</td>
</tr>
<tr>
<td>3. Inform all pregnant women about the benefits and management of breastfeeding.</td>
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<tr>
<td>4. Help mothers initiate breastfeeding within a half-hour of birth.</td>
</tr>
<tr>
<td>5. Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants.</td>
</tr>
<tr>
<td>6. Give newborns infants no food or drink other than breast milk, unless medically indicated.</td>
</tr>
<tr>
<td>7. Practice rooming-in: allow mothers and infants to remain together 24h a day.</td>
</tr>
<tr>
<td>8. Encourage breastfeeding on demand.</td>
</tr>
<tr>
<td>9. Give no artificial foods or pacifiers to breastfeeding infants.</td>
</tr>
<tr>
<td>10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.</td>
</tr>
</tbody>
</table>
Impact of the Baby-Friendly Hospital Initiative

- Adherence to the BFHI Ten Steps has a positive impact on short-term, medium-term and longer-term BF outcomes.
- There is a dose–response relationship between the number of BFHI steps women are exposed to and the likelihood of improved breastfeeding outcomes.


Community support (step 10) is key for sustaining the short-term breastfeeding benefits obtained from the BFHI steps requiring implementation only at the maternity ward.
- Avoiding in-hospital supplementation appears to be a key step for breastfeeding success, perhaps reflecting adequate implementation of the rest of Ten Steps.


Audience Response System

- Does policy drive practice in BFHI?
  1. Yes
  2. No
  3. I don’t know

“... increased implementation of the Ten Steps is associated with increased breastfeeding. Further, it suggests that hospitals with comprehensive breastfeeding policies are likely to have better breastfeeding support services and better breastfeeding outcomes.”

Rosenberg 2008

CHANGING DIRECTIONS....

Audience Response System

Of those of you who work in or are affiliated with a NICU, does your NICU use Donor Human Milk?

1. Yes
2. No
If you use donor human milk, do you require signed informed consent?

1. Yes
2. No

Do you require signed informed consent to use formula for supplementation?

1. Yes
2. No

Which ethical principle does informed consent relate to?

1. Beneficence
2. Non-maleficence
3. Respect for Autonomy
4. Justice
5. Truthfulness
6. None of the above

If you dispense donor human milk, do you have a donor milk policy?

1. Yes
2. No
3. I don’t know

What do we know about the use of donor milk for premature and fragile babies?

- decrease in the incidence of NEC
- decreased feeding intolerance
- shorter time to full feeds
- shorter length of stay
- lower hospital and physician charges

Case

- BG Zoe is a 1100 gm 27 week infant born to a 31 yo G1P1 African-American mom on Medicaid with chorioamnionitis. Mom was sick after delivery and got started expressing milk on day 2 of life without much colostrum production. The NICU staff ordered enteral feeds to start on the infant at 18 hours.
Audience Response System
What do they do?
1. Wait until they have mom’s milk.
2. Use preterm formula.
3. Use pasteurized donor milk.
4. Ask another mother if they can use some of her milk for this infant.

Audience Response System
Does this relate to Beneficence?
1. Yes
2. No
3. I don’t know

Audience Response System
Does this relate to Non-maleficence?
1. Yes
2. No
3. I don’t know

Audience Response System
Does this relate to Respect for Autonomy?
1. Yes
2. No
3. I don’t know

Audience Response System
Does this relate to Justice?
1. Yes
2. No
3. I don’t know

The Effect of a Donor Milk Policy on the Diet of Very Low Birth Weight Infants
• Our NICU infants are eligible to receive DM if:
  • they are born ≤ 1800 grams or ≤ 32 weeks gestation
  • Per policy, all VLBW infants may receive DM for up to 10 weeks or until they achieve 50% of full oral feedings, whichever comes first.
• Policy went into effect October 1, 2010

Marinelli KA, Lussier MM, Brownell E, Hanson VC, Hagadorn JI 2014
Case

- Ms Smith has 33 week twins at CT Children’s due to PIH. Twin A weighs 1535 gms; Twin B weighs 1875 gms. Ms Smith expects to breastfeed and wants both infants to receive only human milk. However although she started expressing in the first few hours despite preeclampsia, she does not have enough milk for both. The donor milk policy states infants must be born ≤ 1800 grams or ≤ 32 weeks gestation to deceive donor milk. She has signed consent.

Audience Response System

According to this policy, only Twin A is eligible for Donor Milk. What ethical principle(s) does this violate?

1. Beneficence
2. Non-maleficence
3. Respect for Autonomy
4. Justice
5. None of the above
6. All of the above

Audience Response System

Does policy drive practice in donor milk use in the NICU?

1. Yes
2. No
3. I don’t know

Practice changed policy... we modified the donor milk policy so that when one twin qualifies, both twins receive donor milk.
Affordable Care Act

- Patient Protection and Affordable Care Act
  August 1, 2012
- Health plan coverage guidelines developed by the Institute of Medicine;
- authorized under provisions of the Patient Protection and Affordable Care Act;
- released by the U.S. Department of Health and Human Services (DHHS);
- require health insurance plans to cover certain women’s preventive services including “breastfeeding support, supplies, and counseling.”

Breastfeeding Support and Counseling Services

- Lactation consultation services
  - prenatal and postpartum breastfeeding education and support groups
  - individual consultations to address specific problems
  - include inpatient counseling
  - up to a total of six (6) outpatient lactation consultations
  - Additional consultations may be covered under medically necessary circumstances identified by and/or prescribed by a recognized provider

Audience Response System

Does “Model Policy: Payer Coverage of Breastfeeding Support and Counseling Services, Pumps and Supplies” change practice?

1. Yes
2. No
3. Sometimes
4. I don’t know

Food for thought....

- Workplace lactation policies
- Paid parental leave policies
- Hospital breastfeeding policies—for patients; for staff
- Kangaroo Mother Care NICU policy
- Baby-Friendly NICU
- Skin-to-skin care in the postpartum unit
Can we validate the statement “Evidence-based, ethical breastfeeding policy drives behavior toward best practices, which in turn, should determine better health outcomes.”

1. Yes
2. No
3. I don’t know

Can we now validate the statement “Evidence-based, ethical breastfeeding policy drives behavior toward best practices, which in turn, should determine better health outcomes.”

Thank You!
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