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Objectives

- Identify the multiple interests that motivate family physicians and other health care professionals to engage in global health activities.
- Consider candidly whether or not these motivations may create conflicts of interest.
- Share ideas for and experiences with addressing these ethical challenges.

Abstract

Health care professionals participate in global health efforts for multiple reasons. Many do so from a humanitarian commitment to serve and others as an expression of deeply held religious faith. Some participate to advance their academic/research interests (including the opportunity to publish). Most also enjoy encountering new places and new cultures. Such multiple interests can lead to conflicts of interest. If so, how should they be navigated? Do they need to be publically declared (in a manner similar to the "Conflict of Interest Form" the speakers were required to complete for this presentation)? How might the core obligations of medical ethics guide us in these considerations? When we work in the arena of global health, we are inviting our patients, our partnering organizations, our colleagues, our trainees, and our host countries and cultures to trust certain things about us. Are we transparent enough with our motivations to allow their trust to be well-placed and secure? What risks do we take – for ourselves and our US institutions – by asking these questions?

My COI History

CME Policy and Procedures for Full Disclosure and Identification and Resolution of Conflicts of Interest

The following policy governs all American Academy of Family Physicians (AAFP)-produced CME activities of all types, including live, performance improvement in practice, point of care, enduring materials, medical journals.

1. Disclosure of Financial Relationships

The existence of any financial relationship or interest an individual in a position to control content currently has, or has had, within the previous 12 months, and 12 months into the foreseeable future, must be disclosed in writing to the AAFP prior to confirmation of the individual's participation. Any conflicts of interest must be identified and resolved prior to the individual's confirmation as an activity planner, faculty, author, or other content controlling role. It is necessary to update disclosure information should the status change during the course of the CME activity.

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Because the review, identification, and resolution process must take place prior to the activity, all individuals in a position to control content must return the disclosure information by the due date. Additional clarification is asked of those who participate in speakers' bureaus to assist the AAFP reviewers in understanding the nature of the speakers' bureau relationship (a list of recommended speakers acting independently of any guidance or direction from a commercial interest versus a list of speakers who are acting as agents, or who are contractually bound as agents of the commercial interest) in order to assure that participation will not be in conflict with previous commitments. Additional clarification is asked about manuscript preparation to clarify the role of the author and any others who participated in creation of a manuscript for print or other enduring educational materials.

The disclosure information will be reviewed and, should a potential conflict be identified, additional information or dialogue may be required. Failure to disclose within the necessary timeframe will result in withdrawal of the invitation to participate.

Acknowledgement of all relevant disclosures as determined by the AAFP - including nothing to disclose or existence of affiliation(s), and/or financial relationship(s) or interest(s) - for every individual who serves in a position to control content of the educational activity must be presented in writing to the learners prior to presentation or publication.

2. Disclosure of Unlabeled/Investigational Uses of Products

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AAFP believes that it is important for faculty and authors to clarify for learners when an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed within an educational activity. Faculty and authors should disclose that the product is not labeled for the use under discussion or that the product is still investigational.

For live activities, should an unplanned discussion of unlabeled or investigational uses of a product occur (usually in the course of a question and answer session), faculty should clarify for the learners that the use under question/discussion is unlabeled or investigational prior to answering the question or responding to the discussion point.

Acknowledgement of planned discussion of unapproved or investigational uses of products should be presented in writing to the learners prior to the start of the activity, or (for enduring materials/medical journals) at the point that first mention is made of the unapproved/investigational use in the activity.

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- a. The AAFP will inform all individuals who are invited to serve in roles that can control the content of an educational activity (faculty, planners, authors, editors, staff, etc.) of the AAFP Policy on Full Disclosure. Confirmation of service is contingent upon provision of online disclosure by the date requested, and review of disclosure information and resolution of any conflicts of interest.
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- d. Should a potential conflict of interest be identified, the individual will be contacted and asked for clarification or additional information. Upon receipt and review of this additional information, methods of resolution will be identified and discussed with the individual. Resolution methods may include, but not be limited to, one or more of the following:
- i. Peer review of content prior to the activity to ensure evidence-based content using best available, highest strength of evidence. The activity faculty or authors must be responsive to revision requirements of
- ii. Assigning a different topic for the individual
- iii. Assigning a different faculty/author for a topic
- iv. Cancellation of the faculty/author
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- f. On-site and post-activity audits will be conducted at random to ensure that AAFP CME activities are unbiased and reflect fair balance.

Full Disclosure for CME Activities

Which of the following role(s) do you hold.



f. On-site and post-activity audits will be conducted at random to ensure that AAFP CME activities are unbiased and reflect fair balance. **Full Disclosure for CME Activities** Which of the following role(s) do you hold. (Check all that apply): AAFP Physician Leadership Author Content Developer Editor Moderator Peer Reviewer Planning Committee Member Presentation Faculty Staff Applicant * Required Disclosure of financial relationships within the prior 12 months of the completion date of this form and 12 months into the foreseeable future: A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. • Neither I nor an immediate family member (parent, sibling, spouse, partner, or child) has a financial relationship with or interest in a commercial interest. I have or my immediate family member (parent, sibling, spouse, partner, or child) has a financial relationship with or interest in a commercial interest. ■ I have read the AAFP policy on full disclosure. If I have indicated a financial relationship or interest, I understand that this information will be reviewed to determine whether this relationship precludes my participation, and I may be asked to provide additional information. I understand that failure or refusal to disclose, false disclosure, or inability to resolve conflicts of interest will disqualify me from participating in this activity. * Required. Pressing the Submit button will act as your digital signature for this form. Submit **↑** TOP Home / CME Faculty Development / Conflict of Interest Form CME Report CME Careers My Account Journals Primary+ Press Center About AMERICAN ACADEMY OF FAMILY PHYSICIANS Patient Care Pav Dues Chapter Staff Contact STRONG MEDICINE FOR AMERICA Med School & Residency Member Benefits Congress of Delegates Practice Management * Favorites Info From Sponsors Shop

"Conflict of Interests"

- Institutionalized phrase loses its "pause effect"
- Second slide Does anyone actually read it and pay attention to it?

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Should we ask about other "relevant" interests – beyond financial relationships – that might create "conflicts"?

AAFP form is titled: CME Policy and Procedures for Full Disclosure and Identification and Resolution of Conflicts of Interest

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Should we not just assume and acknowledge that each of us has multiple, probably conflicting interests at this conference? What are they?

Brief Journal Club

 McCoy MS, Emanuel EJ. Why There Are No "Potential" Conflicts of Interest. *JAMA*. 2017;317(17):1721-22.

Why There Are No "Potential" Conflicts of Interest

- McCoy MS, Emanuel EJ. Why There Are No "Potential" Conflicts of Interest. JAMA. 2017;317(17):1721-22.
- "All professions have a primary interest. In medicine, the physician's primary interest is to promote the well-being of patients through direct care, and the biomedical researcher's primary interest is to produce generalizable knowledge."
- "Similar to all people, physicians and researchers also have multiple secondary interests – to earn money, to become well-known, to engage in activities of professional societies, to pursue hobbies – which exist alongside their primary interests."

Why There Are No "Potential" Conflicts of Interest

- McCoy MS, Emanuel EJ. Why There Are No "Potential" Conflicts of Interest. JAMA. 2017;317(17):1721-22.
- "Conflicts of interest arise in those situations when a physician's or a researcher's professional
 judgment concerning a primary interest is at risk of being biased by a secondary interest,
 resulting in possible harm to patients or the integrity of research."
- "Conflicts of interest in medicine can thus lead to harm via 3 steps in a causal chain: (1) a
 physician or a researcher has a secondary often financial interest that threatens to bias his
 or her professional judgment; (2) the secondary interest does in fact bias the judgment of the
 physician or researcher; and (3) this biased judgment results in harm to patients or to the
 integrity of research."
- "Importantly, only the first of these 3 steps is necessary for a COI. A COI describes a situation in which there is a risk of bias and resulting harm, not a situation in which bias or harm necessarily occurs."

Why There Are No "Potential" Conflicts of Interest

- McCoy MS, Emanuel EJ. Why There Are No "Potential" Conflicts of Interest. JAMA. 2017;317(17):1721-22.
- "The rationale for limiting COI is grounded in the ethical imperative to minimize risk to patients, the integrity of research, and other activities. Thus, failing to limit COIs to the extent possible is unethical even if those conflicts never result in patient harm or compromised research."
- "A relationship that presents a COI may be justified all things considered if its benefits are significant enough to outweigh its risks. But not losing sight of the underlying conflict focuses attention on the need to minimize risks through appropriate COI policies."

Brief Journal Club

 McCoy MS, Emanuel EJ. Why There Are No "Potential" Conflicts of Interest. *JAMA*. 2017;317(17):1721-22.

Reactions?

- Institutionalized phrase loses its "pause effect"
- Second slide Does anyone actually read it and pay attention to it?
 - Now we can say we have!
- How do we "free" the two words conflict and interests?

Interests

- Etymology Medieval Latin interesse it concerns or (literally)
 it is between
- Other words?
 - Justification, motive, rationale, reason, cause
- How do we get depth and complexity back into interests?
- Alternative phrase?
 - Conflict of values
 - Conflict of objectives

Conflict

- Etymology Latin conflictus to strike together or to contend
- Definition discord of action, feeling, or effect; antagonism or opposition, as of interests or principles

- What is the spectrum that merits the word conflict?
- Are there other words that work or help?
- Variance, difference, disunity, interference, competition, contention, contest, dispute, dissent, friction, opposition, antagonism, divided loyalties, run-in

A Caregiver's Aim Re Informed Consent: A Spectrum

 $----\rightarrow----\rightarrow----\rightarrow-----\rightarrow-----\rightarrow-----\rightarrow-----\rightarrow$ To educate? To recommend? To persuade? To coerce?

The aim to educate is often complicated by competing interests and objectives and by disagreements among the various healthcare professionals involved in a patient's care. The reasoning must be fully understood, clearly articulated, and ethically compelling if the aim to educate and make recommendations to a patient or a patient's family and friends crosses the threshold into persuasion or shifts further toward coercion.

Multiple motivations

Mutually compatible and reinforcing

Agreeable and prioritizing

Conflicting

- The circumstance in which a person finds that one of his or her activities, interests, etc., can be advanced only at the expense of another of them.
- The circumstances of a public officeholder, business executive, or the like, whose personal interests might benefit from his or her official actions or influence.
- A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest.

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- What is the goal?
 - Have only one interest and, therefore, no conflicts?
 - Transparency? Disclosure?
 - Management?
 - Resolution?

What are our multiple interests for global health?

Primary Interests

Secondary Interests

Factors Influencing a Decision

Which are 'primary' and which are 'secondary'?

Rovers J, Japs K, Truong E, Shah Y. Motivations, barriers and ethical understandings.
 on a medical service trip: a mixed methods study. BMC Medical Education. 2016;16:94.

Cost of the trip

Receiving class credit

Interacting with other cultures

Time commitment

Improved personal confidence

Threat of crime

Interacting with other health professionals

Substandard working conditions

Substandard living conditions

Educational opportunity

Philanthropy (helping others)

Language barriers

Help build my resume/CV

Paperwork/administrative barriers

Develop my clinical skills

Pure enjoyment

Improved interpersonal skills

Opportunity for travel

Improved foreign language skills

Exposure to infectious diseases

Prefer to use free time for leisure, not volunteering

Someone asked me to volunteer

Motivations for Global Health Involvement

- Primary or Secondary or Not Applicable
- Use as a point of reference your most recent GH experience. Which of these motivations were primary and which were secondary?
- Would your answers/descriptions be recognizable to other participants? How would they align with the stated goals and objectives of the experience?

Professional Personal global health motivations

- Clinical care
- Public health
- Collaboration with colleagues
- Research
- Education
- "Gain experience"

- Travel interests
- Political interests
- Ethnic interests
- Family
- Religious or "faith" interests

Professional Personal

- These professional and personal considerations are ways of answering the questions:
 - "What led you to do this?"
 - "What keeps you doing this?"
- Defining ethics as "having to do with the determination of what should be done in a situation, all things considered" encourages a thorough and frank discussion of the answers to these questions.

"Why are you doing this?"

- When are you asked this question? By whom?
- Do your answers change based on the audience?
- Variations on the "theme" are permissible, but the "theme" must be detectable!

"Why are you doing this?"

- Story
- The question "Why are you doing this?"
- My answer
- What if the answer is personal/religious/secondary?
- What if the motivation is secondary but the answer is not?

In what situations, do we experience multiple or competing interests?

- Defining goals
- Recruiting partners/donors
- Selection of participants
 - Gender
 - Diversity
 - Other
- Selection of sites
- Others

In what situations, do we experience multiple or competing interests?

- Selection of sites
 - One early memory
 - Safari trip to Africa requested opportunity to lecture at a mission hospital – Why?
 - My first trip to Israel/Palestine with Doug Brown in 2004
 - Requested meeting at Ben Gurion University
 - Received invitation to speak at Grand Rounds
 - Received invitation to visit Ramallah and meet Dr. Barghouti

Are there benefits to having multiple motivations?

- Disillusioning experiences
 - Other motivations can keep us engaged
- Like being a fan of a losing team
 - Other motivations get you to the game

What do we invite patients and their families to trust about us?

... that we will be very careful (non-maleficence)

... that we aim to make a valued difference in the patient's well-being (beneficence)



... that we will honor the patient's perspective/expectations (self-determination)

... that we will not be biased and will be good stewards of limited resources (fairness/justice)

Assessing 'integrity'

(patients and family members as well as medical team members)

Stable **Distressed Thriving Holding** <u>Shaken</u> **Attentive Distracted Informed** Confused Calm **Motivated** Hopeful **Hopeless** Joyful **Despondent Confident** Insecure

'Integrity' here has to do with the basis upon which a person's life has meaning and balance. A person reveals the basis for her integrity when she shares her core beliefs and life values, when she explains how she sustains these beliefs and values. Fear, loneliness, and guilt as well as happiness, contentment, and wonder are windows into a patient's integrity.

Agitated
Apathetic
Honeless

Despairing

'Distressed' here has to do with the loss of peace, joy, hope, resolve individuals – patients, family members, medical team members – experience (to varying degrees) when faced with unsettling life experiences – such as illness or injury – that threaten to overwhelm their core beliefs and values.

Full disclosure – one of my "secondary" interests

It remains an experience of unparalleled (incomparable) value that we have learned to see for once the great events of world history *from below* – i.e., through the perspective of the barred, the suspects, the badly treated, the powerless, the oppressed, the scoffed, in short the perspective of those who suffer. (It is) only in this time when neither bitterness nor envy has cauterized the heart (1) that we see with new eyes great and small, fortunate and unfortunate, strong and weak; (2) that our view of greatness, humaneness, justice, and compassion has become clearer, more free, more incorruptible; (3) indeed, (that we see) personal suffering is a more suitable key, a more fruitful principle, than is personal good fortune for exploring the world by observation and action.

Dietrich Bonhoeffer December 1942

Thank you

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