

Disclosure of Significant Adverse Events

Jeff Kirby
Department of Bioethics
Dalhousie University

Overview

- A little bit of theory: key disclosure ethics principles and values
- A sample ethics-informed disclosure of significant adverse events decision-making framework

Principles and values at play in disclosure of adverse events

- Respect for persons
 - Truth-telling
 - Trust
 - Autonomy
- Patient welfare:
 - Nonmaleficence
 - Beneficence
- Justice

Ethics principles

- Sometimes ethics principles, and the moral obligations that arise from them, are in tension/conflict

Truth

- A primary value
 - 'something we value for its own sake'
 - as individuals
 - as a society

Truth

- Truth fullness and honesty
 - widely respected human virtues

Truth-telling

- A principle we try to live by
- A key component of institutional accountability

Truth-telling

- Should this be an absolute principle?
 - At any cost?

Fiduciary relationships

- Usually involve power imbalances in:
 - knowledge
 - status
- Based on trust
 - truth-telling a vital component

Individual autonomy

- Individual autonomy:
 - A person should have the right and opportunity to pursue her or his life plans
 - In the context of disclosure, this translates to the 'the right to know' and make choices about one's health care treatment
 - Autonomy, as an ethics principle, has been valorized/privileged since the 1970s in western countries and particularly in the US

Autonomy

- Paradigm shift in disclosure standards in the mid-1990s (Dana Farber Cancer Institute case in Boston); modern emphasis on 'patient safety'
- Current strong presumption in favour of disclosure – 'right to know'

Relational autonomy

- Recognition that our identities and moral agency as individuals are constituted, in part, by our relationships with others
- The choices and decisions we make affect, and are affected by, significant others

Nonmaleficence

- As old as the Hippocratic Oath: 'first, do no harm' or as little as possible, i.e., mitigate burdens to individuals (and society)

Beneficence

- Obligation of health care providers and organizations to benefit individual patients, their families and to citizens-at-large

Justice

- Formal Justice (Aristotle)
 - Like individuals/patient populations should be treated alike and dissimilar individuals/patient populations should be treated dissimilarly
 - In order to justify different treatment, there is a need to demonstrate a *relevant* difference between individuals/patient populations

Justice

- Traditional distributive justice
 - Fair/proper distribution of benefits and burdens
 - Also, fair distribution of scarce or limited health resources
 - Consider possible 'opportunity costs' of choosing one option over another, e.g., to staff time and money allocated to other health care services

Justice

- Social justice

- Some individuals and social groups are more vulnerable than others
 - Persons qua 'patients'
 - Multiple other axes
- Important to consider the effects of decision making on vulnerable individuals and social groups

Moral obligation

- Obligation of health care providers and others involved in 'the health care delivery enterprise' to be honest and open in communication with patients, their legitimate substitute decision makers, families and the public

Ethics-informed Disclosure of
Significant Adverse Events Decision
Making Framework

Process steps

- 1. Identify and assemble relevant stakeholders
 - Consider inclusion of participant(s) from group(s) that will/could be directly affected
 - Consider inclusion of members of the public: citizens/'health-receivers'
 - Consider participant(s) from Department of Health, where appropriate

Process steps

- 2. Identify the legitimate decision makers
 - e.g.,
 - Ad hoc committee/working group consensus (if possible)
 - Executive management and CEO
 - Board of Directors

Process steps

- 3. Identify and reflect on the values and ethics principles at play in disclosure of adverse events circumstances and the potential for conflict/tension among them

Process steps

- 4. Identify the issue and its context from relevant standpoints and perspectives
 - e.g.,
 - Potentially exposed persons and their 'families'
 - Involved health care providers
 - Health care organization
 - Society/public-at-large

Process steps

- 5. Gather and examine all relevant information/evidence
 - Includes 'best possible quantification' of risk (relevant experts) and risk classification:
 - perceived
 - theoretical
 - evidence-based, etc.

Process steps

- 6. Determine if the relevant circumstances should be handled/treated as a potential 'adverse event' as defined (and intended) by the health care organization's Disclosure Policy
 - E.g., Capital Health's:
 - "An adverse event is an unexpected and undesired incident directly associated with the care provided to the patient, or the environment in which the care was provided, which does, or can be reasonably expected to, negatively affect the patient's physical and/or psychological health and/or quality of life."

Process steps

- 7. Identify and assess possible disclosure options through brainstorming and facilitated discussion
 - E.g.,
 - Non-disclosure of adverse event
 - Disclosure to those directly affected
 - Public disclosure

Process steps

- 8. Identify the benefits and burdens of the disclosure options, and to whom

Process Steps

- 9. Assess alignment of the possible options with key disclosure principles and values:
 - Autonomy
 - Truth-telling
 - Trust
 - Patient welfare: beneficence and nonmalificence
 - Justice

Process steps

- 10. Choose the disclosure option(s) that will be 'go forward'
 - Includes articulation of the values and principles underlying choice
 - Check: ensure that the selected option is consistent with health care organization's core values

Process steps

- 11. Develop and implement a comprehensive care and communication strategy
 - Includes:
 - Specific care plans for harmed or potentially harmed patients
 - Prevention of further occurrences: 'systems change', relevant education, etc.
 - Optimal communication to patients/families and the public, where appropriate

Process steps

- 12. Review the disclosure decision and monitor/evaluate the outcomes