New Medical Technologies And Public Voices

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What role should patients and consumers play in the development of new medical technology?

- Public involvement in health technology assessment (HTA) is now a common practice in the U.S.
  - What is the value of public involvement
  - Are current mechanisms for patient and consumer voice in the FDA process sufficient?
  - What more should the agency do?

The value of including patients and consumers in a deliberative process

- Potential to broaden the meaning of benefits and risks
- Increase attention to patient heterogeneity and the value of conditionality
- Enhance legitimacy and trust in the process

Current and Proposed FDA Initiatives

- Patient Representative Program
- Research Advocacy Program
- FDA Patient Network
- New Benefit-Risk Assessment Tool

The importance of reaching out to a broader range of voices

- How representative are representatives?
- Deferring to experts
- Avoiding the "urgency narrative"
- Including the voice of consumers and patients
- Balancing the need for more voices and the value of regular interaction among small groups

Broadening the scope of involvement

- Move beyond the review process
- A "citizens council" to address policy questions?
  - Supplement existing programs with additional deliberative methods
    - deliberative polling
    - citizen juries
    - consensus conferences
    - town hall meetings

Public input requires commitment!

- Training should focus on the process of deliberation in addition to substance
- Regular interaction is valuable
- Genuine deliberation requires:
  - bidirectional conversation between scientists and advocates;
  - engagement from the outset in framing and implementation;
  - ongoing collaboration between meetings;
  - clear expectations on all sides;
  - equal participation so advocates do not feel as though they are second in rank

Preliminary recommendations

Greater outreach to identify a broader range of stakeholders

- The FDA should adopt an active, rather than a passive approach.
  - Reaching out to groups that have worked with the FDA in the past and posting information on the web site is a good start
  - The FDA should work with professional associations, universities, industry and advocacy groups to identify a broader range of participants

Develop new mechanisms for public input

- Move beyond advisory and review committees
  - These mechanisms are important, but do not reflect the range of decisions in which public input is relevant
  - Conflict of interest requirements for participation on Advisory and Review committees restrict the number of participants who can engage with the FDA

The FDA should encourage "representatives" to report back to the groups they represent – and encourage them to seek input from groups

The FDA should provide training on the process of deliberation

- This training should be offered to scientific experts as well as patient and consumer advocates

Use the new benefit-risk assessment tool to solicit information from a broader set of stakeholders

- This tool encourages "moral reasoning" and should not be limited to the review process
- If the FDA proves sufficient training and technical information, this tool can empower public representatives to address a range of important questions

Develop evaluations of each process designed to encourage public participation

- To what extent are these processes fair, flexible, and transparent?