CADTH Symposium 2009

Collaboration in Drug Reviews: Getting patients involved

Linda Wilhelm
Chair, Best Medicines Coalition

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Collaboration: The patient perspective

- Making the case for patient collaboration
- Finding a Canadian model that works
- Who are the patients?
- Building accountability and moving forward
Collaboration: Patients’ historical view

- Regulators work in isolation - in their own world with a narrow focus
- Patients feel like a football being passed back and forth, always told it is someone else’s jurisdiction
- Breakthrough drugs take forever to get where they are desperately needed
Collaboration: Together with patients

- Efficient and effective technology reviews must involve all “experts” - including patients
- Difficult to understand real value without hearing patient perspective, which often vary greatly from clinical data
- Patient input must be meaningful and substantive to truly add value
Collaboration: Critical considerations

- Patient input especially critical when considering breakthrough or unique treatments
- Patients need to be involved in answering key questions: What is the true definition of breakthrough? (not just first in class; not just lifesaving)
- Body of evidence on breakthroughs is constantly building and often traditional rules of evaluation don’t apply
**Collaboration: Improved outcomes**

- Real life patient input isn’t just “politically correct” or a demonstration of inclusiveness; it leads to decisions which improve health outcomes and, oftentimes, overall health care savings.

- **Examples:**
  - Rheumatoid arthritis: Biologics can’t be effectively evaluated using traditional trials in isolation.
  - Cox-2: Patient input necessary to understand risk/benefit profile some critical patient populations.
Collaboration: Effective models

- Collaborative models involving patients not just hypothetical
- Some examples in Canada and internationally:
  - Health Canada: progressive licensing; OCAPI
  - Ontario: Committee to Evaluate Drugs
  - Quebec: Conseil du Medicament
  - Internationally: Scottish Medical Consortium; Australian Medical Services Advisory Committee and Consumers Health Forum; German Institute for Quality and Efficiency in Health Care; U.K.'s NICE
Collaboration: Layers of involvement

- Reforms necessary to allow for patient integration throughout process:
  - Clinical trials need to reflect real patient outcomes
  - Patients need to be consulted on initial decisions (breakthrough status or fast-tracking)
  - Patient advisory committees needed at CADTH and provincially to input on direction and broad policy
  - Patients need representation on review committees with resources to consult with broader community
  - Individual patients/groups need to be consulted as specific drugs are reviewed
  - Patients need to be involved through post-marketing phases as issues arise
Collaboration: Guiding principles

- Patient engagement principles identified through national consultations for a report by BMC for Health Canada in 2005/2006:
  1. Patients/consumers as equal or most important partner
  2. Two-way communication
  3. Fair, transparent, accountable consultations
  4. Clear rationale for decisions based on evidence, etc.
  5. Educated participants from government and patient/consumer community
**Collaboration: Identifying patients**

- Need to put to rest debate over “objective citizen” versus “patient advocate”
- Broad consensus that input is best provided by those who have direct experience - these are actual patients
- System and issues are complicated - therefore need experienced, informed patients are part of process (education, community connections)
- Up to policy makers to work with recognized patient groups to identify people who are willing and able to represent broad patient community interests
Collaboration: Accountability

- From a patient’s perspective it is no longer acceptable to decision-makers to operate in isolation without patient input.
- Imperative that review agencies integrate patients into their process - this should no longer be viewed as “nice to do” or something that is done as a “last minute add on”.
- Policy-makers must be accountable for proactively seeking and integrating patients and for doing so in a transparent and respectful manner.
Collaboration: Next steps

- Time has come for provinces and national bodies to incorporate patient perspective into their decision-making process.
- Need to move beyond the rhetoric to take steps to make true collaboration a reality as part of our national pharmaceutical review system.
- There are models in existence to guide the facilitation of patient involvement - none are perfect but we need to move forward expediently.