Helping
Cardiovascular
Professionals
Learn.
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Hot Topics I:
Public Access to
Proprietary Cardiac Safety Data

Cardiac Safety Research Consortium
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Ralph Brindis, MD MPH FACC
President-Elect, ACC
Senior Advisor for CV Disease
N.Cal Kaiser Permanente

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Cynic's View?

Public Access to Proprietary Cardiac Safety Data: Isn't this an Oxymoron?

Once Data is released to the Public it is no longer Proprietary!!

Realist's View ?

Even a Thin Pancake has Two Sides !!

Dick Kovacs, Indiana

Proprietary Data

- Issues and rights of ownership
- Recognition that there is a high cost in data collection
- Should one be required to “Give away” things of substantial value?
  - The recipe for coca-cola?

Industry View

- What actually is Proprietary Data?
  - Pre-market safety and efficacy data
  - Post- market release data
    - Utilization patterns, off label use, safety and efficacy and more
  - Business-related data for marketing strategy
    - Issues with industry competition
- Who decides What should be in the Public Domain??

Proprietary Data - Public Access

- Already “agreement” on need for public access
  - Issues of mechanisms of public access and practicality
- “Solutions” - problems of data format and validity
  - Photocopying summary basis for approval and combing through mountains of papers for safety and efficacy data and rebuilding of datasets by hand
  - Post-hoc public discussions at advisory committees
  - Accessing clinical trials via clinicaltrials.gov
  - Web based solutions at www.accessdata.fda.gov

Proprietary Data
Issue of *Timely* Public Access

Why should we accept any delays in getting safety/ efficacy information to the public?

- Withholding data only tarnishes corporate reputations of companies trying to manage with "spin control"
  - Oraflex, Vytorin
- Prescribers deserve and should demand near "real time" safety data
  - Ex: MD could accurately assess bleeding risk of prasugrel and individual pt risk/benefits
  - Why need to wait for publication of toxicity data years later?
    - Ex: Neseritide
- Need assurance of validity of data – trusted third party, longitudinal databases, feedback to prescribers and sponsors in near real time

Proprietary Data

- Sponsors "tighter" with data than outside observers would feel necessary
  - Data on compounds no longer patent protected
  - Data on failed compounds
  - Phase I data on healthy normal controls (baseline incidence of NSVT in healthy normal subjected to Holter monitoring?)

Industry Concerns
How will Raw Data be Used

- High fear of misinterpretation of raw data by external analytical centers
- Marketplace easily misled by reports that are “out of bounds”
  - Negative stories have big financial impact out of proportion to reality - Vytorin
- Industry competitive forces also in play

Industry Concerns
How will Raw Data be Used

"The Boogie Men"

Class Action Lawyers

The Press and their own agenda

The Pulitzer Prize !

Stock Analysts - Financial Ramifications

Examples

- Breast Implants – company financially ravaged by incorrect data
- DES and Late Thrombosis
  - Dec 2006 FDA hearing – open process, town hall, broad-based invites for testimony, and expert FDA panel
  - Circus atmosphere- Financial Analysts, Class Action Lawyers, and the Press

Examples

Sildenafil

- Letterman/Leno shows- “death by Viagra”
- Physician and public safety concern despite pre-approval safety studies of Pfizer and FDA approval
  - Questions unanswered???
- Academia/ACC/ decides to develop expert consensus document for use of Sildenafil in CAD pts
- Pfizer partners and willingly shares original research and pre-clinical data after confidentiality agreement signed with ACC Writing Group
- Pfizer- opportunity to review and comment prior release

Academic/Professional Society NCDR Data Transparency

Aggregate De-identified

- Debate over Annual reports- “free”
  - What should it include and depth
- Sale of data marketable to industry
  - Clinical data queries
  - Marketing questions
- Free release or sale of raw data to external bodies
  - CMS (pt.identified), FDA, Industry
    - Different rules of engagement?

Academic/Professional Society NCDR Data Transparency

Aggregate and non-Aggregate De-identified

- ICD Registry – initially industry funded - CMS mandate and to look at pt. subgroups for extending coverage decisions for ICDs
  - Companies wanted raw data
  - "We paid for it – we should be able to do our own analyses"
  - Companies wanted their data blinded to their competitors (benchmarked against pooled aggregated data)

Academic/Professional Society NCDR Data Transparency

Concern of misuse or misinterpretation of raw data by external analytical centers

- Similar Manuscripts generated with different results and different conclusions on same data
  - Findings published as peer reviewed manuscript
  - Marketing piece that promotes device or drug without vetting with NCDR R&P committee, without prior publication in peer reviewed journal and listing NCDR as data source

Academic/Professional Society NCDR Data Transparency Hospital / MD "Safety"

Hospital and Physician Specific
Public Reporting of
"Proprietary" Data

Academic/Professional Society NCDR

By contract, the NCDR cannot release any hospital/physician data to outside parties without the expressed written consent of the hospital/physician

Academic/Professional Society NCDR Data Transparency

Present NQF Challenges

- NQF approval of STS and NCDR Performance Measures
  - Risk adjusted mortality, CABG LIMA use, etc.
- Consumers and Purchasers on NQF Boards unhappy that Measures not fully reported in Public Domain
  - Endorsing Inferior Outcomes Measures (administrative data non-risk adjusted as alternatives!)

CV Profession Guidance

Standards for Statistical Models Used for Public Reporting of Health Outcomes: AHA Statement of QCOR IWG* (ACCF endorsed)

*_Circulation_ 2006;113:456-462

ACCF 2008 Health Policy Statement on Principles for Public Reporting of Physician Performance Data*

*_J Am Coll Cardiol_ 2008;51:1993-2001

Standards for Measures Used for Public Reporting of Efficiency in Health Care (AHA & ACCF)*

*_Circulation_. 2008;118:1885-1893

ACC Principles for Public Reporting of Quality Physician Performance Data

1. The driving force behind physician performance measurement and reporting systems should be to promote quality improvement.

2. Public reporting programs should be based on performance measures with scientific validity.

J Am Coll Cardiol 2008;51:1993-2001

ACC Principles for Public Reporting of Physician Performance Data

3. Public reporting programs should be developed in partnership with physicians.

4. Every effort should be made to use standardized data elements to assess and report performance and to make the submission process uniform across all public reporting programs.

J Am Coll Cardiol 2008;51:1993-2001

ACC Principles for Public Reporting of Physician Performance Data

5. Performance reporting should occur at the appropriate level of accountability (the "accountable unit").

6. All public reporting programs should include a formal process for evaluating the impact of the program on the quality and cost of healthcare including an assessment of unintended consequences.

J Am Coll Cardiol 2008;51:1993-2001

Guiding Principles of Public Reporting

- Proper Attribution of the Measure
  - Assign to individual, group, or organization responsible for care
  - Procedure for attribution should be stated clearly & justified
  - Collective attribution (all the people & institutions that were a part of the care)

Circulation. 2008;118:1885-1893

Breaking Down the Barriers for Sharing Proprietary Data

1. Integrity and Trust
2. Integrity and Trust
3. Integrity and Trust
4. Advisory Group Concept
   - Independent body with confidentiality agreements
   - Looks at data with a “different lens” – not from industry’s financial viewpoint

HRS/ACC/AHA 2006 Device Performance Guidelines

- Recommended Device manufacturing companies publish 2x year product performance reports (lead/device concerns)
  - "Understandable format"
  - Engage independent experts on committees that meet regularly to review data and advise:
    - Device performance, communication, and actions
    - Increase transparency and accuracy of information to MDs and patients
      - Influence their healthcare decisions

Breaking Down the Barriers for Sharing Proprietary Data

- AdvaMed
  - Standardizing reporting practices & definitions
  - Focusing on providing information to help guide physicians and patients make appropriate decisions
  - Avoiding a “data dump” that might mask important information or lead to an inappropriate conclusion

Successes

- Contributions of data by sponsors to trusted third party collaborations:
  - ILSI/HESI preclinical QT safety data
  - But… resistance obtaining clinical information (assessing risk of TdP from existing data)
- FDA transparent effort to balance promotional spin from sponsors especially at launch
  - Recent Pitivastatin teleconference to discuss and obtain expert reaction to safety data after approval

Successes

- Use of large pharmacy databases in lieu of FDA or sponsor data
  - Vanderbilt group's use of Tennessee Medicaid Pharmacy Database to calculate risk of sudden death with oral erythromycin

Disappointments

- Spontaneous reporting via MedWatch
  - Underreporting – but how much?
- Phase IV commitments
  - Pfizer sponsored "Large Simple Trial" to estimate mortality in pts on antipsychotics
    - Any data reported to date?
- Safety signals discovered in course of research or data analysis should be expeditiously publicized to protect patients
  - Academic advancement/publicity secondary to pt. safety

Perfect World

- Safety monitoring for drugs and devices hardwired into distribution system at point of care
  - Drugs and devices with real risk – need real time data gathered into existing databases managed at point of care and capable of tracking pts longitudinally – UPIs!!
  - Post approval safety monitoring should be a public trust shared:
    - Sponsors, regulators, and trusted third parties (academics, ACC/HRS, patient advocates)
  - Real time data feedback to prescribers at “point of care” ! (Hertz Car analogy)

Perfect World

- Prescribers and Device implanters can respond rationally to data
  - If presented clearly and in real time
- Presently, we make decisions daily without adequate data; imagine how much more effective we could be with transparent & timely (real time) safety data
  - Bjork-Shiley 60 degree convex-concave valve
  - Telectronics Accufix-J lead

Perfect UPI World

Leverage and Integration of:

- Longitudinal Registries
- RCTs
- National Death Index
- Telephonic Device interrogation data
- Pharmacy data with adherence
- IT integration strategies
- Image data sharing IT initiatives

Happy Halloween !!!!!