

Biospecimen Reporting for Improved Study Quality (BRISQ)

Scott D. Jewell, Ph.D.
Department of Pathology and
Comprehensive Cancer Center
The Ohio State University

March 24, 2010

Biospecimen Research / Science

PREANALYTICAL PHASE

- Biospecimen Science advanced through evidence-based studies (\$\$\$)
- Self reporting documentation
- Education

IT MATTERS HOW . . .

- studies are designed
- specimens are handled
- assays are performed
- data are analyzed
- conclusions are stated

**. . . IMPORTANT PORTIONS OF THIS
INFORMATION ARE NOT BEING
PROVIDED IN PUBLISHED REPORTS**

BRN 2009

**Development of Biospecimen
Reporting Criteria for Publications**

Pierre Hainaut and Lisa McShane

CONSORT – Design, conduct, analysis, and interpretation of randomized clinical trials

REMARK – Reporting recommendations for tumor marker prognostic studies

STARD – Standards for the reporting of diagnostic accuracy studies

STROBE – Strengthening the reporting of observational studies in epidemiology

Goals of REMARK

*RE*porting recommendations for tumor *MARKER* prognostic studies

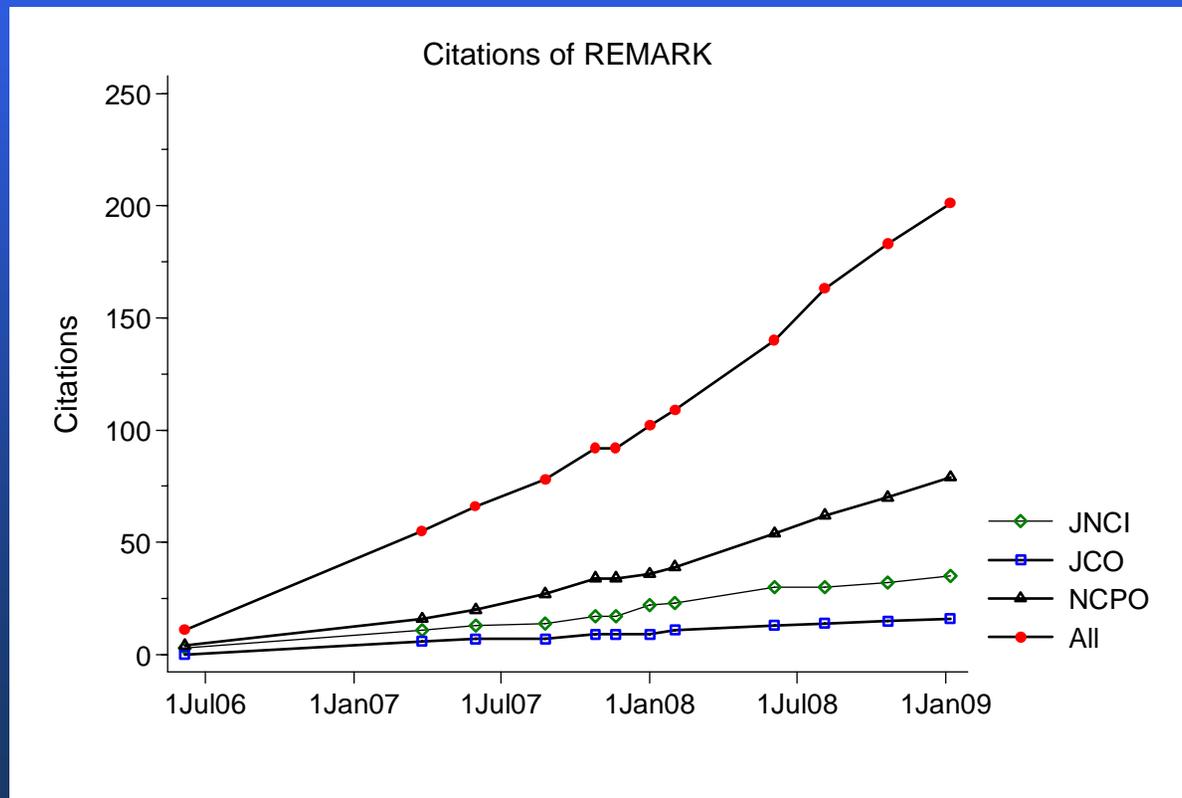
- Recommend elements and formats for presentation to facilitate
 - Evaluation of **appropriateness** of study design, methods, and analysis
 - Evaluation of **quality** of study design, methods, and analysis
 - **Comparisons** across studies, including formal meta-analyses
- Ultimately improve study quality?

STARD and REMARK Guidelines

- **STARD: ST**Andards for Reporting of Diagnostic accuracy (Bossuyt et al.)
 - Published (2003): *Clin Chem, Ann Intern Med, Radiol, BMJ, AJCP, Clin BioChem, Clin Chem Lab Med*
 - Re-published (2003-4): 8 journals
- **REMARK: RE**porting recommendations for tumor **MARK**er prognostic studies (McShane et al.)
 - Published (2005): *BJC, EJC, JCO, JNCI, NCPO*
 - Re-published (2006): *BCRT, Exp Oncol*

Awareness of REMARK

- Mentioned in instructions to authors and/or reviewers: JCO, BCRT, CCR
- Citations



(Graph courtesy of Doug Altman)

WHAT CAN WE DO THAT MAY IMPROVE INFORMATION ABOUT PREANALYTICAL DATA

- Identification of unreported data that should exist
- Data that is value-added to the evaluation and strength of the reported research
- Develop action plan
 - Working group formed to develop reporting guidelines
 - Engage science community through
 - Publication
 - Establish agreement with journal editors to use the guidelines

WORKGROUP MEMBERSHIP

- Laboratory scientists/biomarker experts
- Clinicians
- Pathologists
- Statisticians
- Journal editors
- Past or present society leadership

BRISQ Elements

Table Format of **Tier 1** (most important), **Tier 2**, and **Tier 3** guidelines

“**Tier 1**”, *Items necessary to report*

- organ(s) from which the biospecimens were derived
- manner in which the biospecimens were stabilized and preserved

BRISQ Elements

“Tier 2”, Items advisable to report

These are data elements another researcher may find helpful to know but, which have deemed slightly less crucial or less likely to be available in the biospecimens' annotation

- demographics of the patient population
- method of enrichment for relevant components

BRISQ Elements

“Tier 3”, Additional Items

These include information about conditions that might be useful to know concerning the biospecimens but are not known to be as likely to influence research results or are unlikely to be available to researchers

- environmental factors to which patients were exposed
- type of storage container in which the biospecimens were kept

BRISQ Elements

Guidelines do not dictate where or in what order the biospecimen data elements must be reported

Standard operating procedures (details), ex. blood-collection protocols, would be provided or referenced in the manuscript

Most Tier I items be reported directly in the manuscript to the extent possible, not reference to another publication

BRISQ Elements

Referenced documents should be publicly available and curated with version control.

Use curated supplementary websites to report detailed descriptions that are too lengthy to be accommodated by journal page restrictions

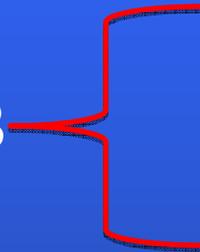
BRISQ Elements

- I. Pre-Acquisition
- II. Acquisition
- III. Stabilization / Preservation
- IV. Storage / Transport
- V. Quality Assurance Measures

Fluid vs.
tissue



Tier 1, 2, 3



Item
Number



Location



I. Pre-Acquisition

T1: **Clinical characteristics of patients**. Stated in standard terminology, provide available medical information known or believed to be pertinent to the condition of the biospecimens.

T1: **Vital state**. State whether the patient donors were alive or deceased when biospecimens were obtained (i.e. pre- or postmortem).

T3 **Disease state**. *For premortem biospecimens, state the patient condition relative to disease and treatment, if known (e.g. during- or post-therapy; acute, chronic, or terminal stage).*

T3 **Cause of death**. *For postmortem biospecimens, state the cause of death and other diseases present at the time of death, if known.*

T3 **Agonal state**. *For postmortem biospecimens, list the agonal state of the donors if known, i.e. their physical condition immediately preceding death (e.g. prolonged degeneration or relatively healthy*

III. Stabilization / Preservation

T1: Mechanism of stabilization. State the initial process by which biospecimens were stabilized during the collection process (e.g. snap or controlled-rate freezing, fixation, additive, none).

T1: Type of long-term preservation. List the process by which the biospecimens were sustained after collection (e.g. freezing; formalin fixation, paraffin embedding; additive; none). Please note, this might or might not differ from the mechanism of stabilization.

T1: Constitution and concentration of fixative/preservation solution. State the make-up of any formulation employed to maintain the biospecimens in a non-reactive state (e.g. 10 percent neutral-buffered formalin or 10 USP Heparin Units/mL).

T2: Time in fixative/preservation solution. State the time or range of times that biospecimens were exposed to the preservation medium (e.g. 16 to 24 hours in formalin).

T2: Temperature during time in preservation solution. State the temperature of the medium during the preservation process (e.g. fixation was performed between 20 and 25 °C).

BRISQ Elements

	Pre-Acq	Acq	Stability	Storage	QA Measure
Tier 1	8	1	3	3	1
Tier 2	3	3	4	2	4
Tier 3	5	1		8	2

Conclusions

- Help authors, reviewers, and publishers –evaluate if sufficient information is provided to assess the management of biospecimens
- Readers will be able to evaluate, interpret, compare, and or reproduce results
- Not every BRISQ reporting item will be applicable to each study
- Critical unknown elements should be fully acknowledged
- Absence of Tier 1 item(s), exclude publication?, should bring discussion on the implication of the work.

Conclusions

- Hope that BRISQ sensitizes the biobanking and research communities
 - Encourage voluntary compliance
 - Importance of tracking pre-analytical data
 - Wide-spread documentation of biospecimen management

Future

- Editors and working group session input – Friday, March 26, 2010.
- Comment period from the scientific public
- Publish the guidelines
- Follow the use in publications and perceived impact
- Re-define and re-publish
- Educate

Contributors to BRISQ

Douglas Clark	Olga Potapova
Renata Greenspan	Peter Riegman
Daniel Hayes	Yaffa Rubinstein
Pierre Hainaut	Edward Seijo
Scott Jewell	Stella Somiari
Andrea Kelly	Jim Vaught
Paula Kim	Peter Watson
Elizabeth Mansfield	Heinz-Ulrich Weier
Lisa McShane	Claire Zhu
Helen Moore	