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The Value of Information in the Health Sciences: First, Do No Harm

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The Value of Information in the Health Sciences:

First, Do No Harm

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ACRL Information Literacy Frame: Information Has Value

Discipline: Science & Engineering

Subject: Nursing; Allied Health; Health Sciences; Interdisciplinary;
Pharmacy; Pre-professional Studies; Medical Ethics

Learning Theory: Vygotsky's Sociocultural Education Theory

Pedagogy: Zone of Proximal Development

Special Population: Undergraduate Students

ACRL Information Literacy Frame: Information Has Value

The lesson in this chapter illustrates one way to challenge students in the health sciences to think beyond simply finding and accepting the validity of scholarly peer-reviewed articles and encourages them to think more critically and skeptically about research. The lesson focuses on the Information Has Value threshold concept in ACRL's *Framework for Information Literacy for Higher Education*. The frame states, "experts understand that value may be wielded by powerful interests in ways that marginalize certain voices."¹ When students enter into their fields of interest in healthcare, they must

recognize their responsibility for “making deliberate and informed choices about when to comply with and when to contest current legal and socioeconomic practices concerning the value of information.”² In the following lesson plan, students examine the privatization of biomedical research and how undisclosed conflicts of interest can, in some cases, lead to accusations of misconduct or fraud. After completing the assignment, students should be more aware of how the “value of information” can influence the integrity of the scientific method.

The ACRL Framework indicates that students should understand that information has different types of values, including educational and influential, as well as the value of learning to negotiate and understand their world.³ When the word “value” is mentioned, most readers automatically think of the monetary implication first. Of course, the monetary value of information is not unique to biomedicine, but in this lesson we focus on how the socioeconomic value of information in healthcare can in some instances be quite substantial. In privatized or commercialized scientific endeavors, corporations, stockholders, and even scientists involved in the research can reap significant rewards, provided the study delivers the desired outcome. The potential of large profits, particularly in the pharmaceutical industry, can occasionally tempt researchers to manipulate or ignore certain data, overlook possibly significant events or side-effects, or endanger the health of clinical trial participants in order to achieve positive results. The Information Has Value frame is used as a guide to students in the health sciences to recognize the powerful socioeconomic dimension and influence of information.

Background for the Lesson Plan

One notable example of overlooking significant events or side-effects occurred in the case of Vioxx or rofecoxib, a painkiller produced by Merck & Co. and approved by the FDA in 1999. Studies evaluated whether it would relieve pain and reduce gastrointestinal complications that the non-selective, non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen, sometimes caused. In the beginning of that year, Merck & Co. started the Vioxx Gastrointestinal Outcomes Research (VIGOR) to compare the gastrointestinal events associated with Vioxx and naproxen. Study participants who took Vioxx reported fewer gastrointestinal events than the naproxen users. The study, however, also indicated that

the Vioxx group had four times the incidence of myocardial infarctions or heart attacks than the naproxen group.⁴ Despite the apparent risks, the study's data and safety monitoring board (DSMB) voted to continue the study at the end of 1999. The DSMB's chair disclosed in February of 2000 that he owned \$72,975 of Merck stock.⁵ Although doubts and questions persisted regarding the cardiovascular risks of Vioxx, the *New England Journal of Medicine (NEJM)* published the results of the VIGOR study in November 2000.⁶

After other studies confirmed cardiovascular risks as well with Vioxx, questionable practices were revealed in the VIGOR study, such as different termination dates for cardiovascular and gastrointestinal events, which allowed investigators to understate the cardiovascular risks while still showing fewer gastrointestinal events.⁷ The investigators also suggested that the difference in risks between the two painkillers could be contributed to the tendency of naproxen to reduce the risk of heart attack, indicating that Vioxx did not cause the heart attacks, but that naproxen reduced the number of heart attacks which would have naturally occurred. Studies conducted outside of Merck also showed increased cardiovascular risks with Vioxx, but Merck refused to acknowledge any association and continued to defend their product with internal studies. Finally, in 2004, after the Adenomatous Polyp Prevention on Vioxx (APPROVe) trial performed by Merck showed an increased cardiovascular risk compared with placebo, Merck withdrew Vioxx from the market.⁸ The following year, *NEJM* issued an "expression of concern," reporting that the researchers had "withheld critical data on the cardiovascular toxicity of Vioxx."⁹

The FDA has estimated that as many as 55,000 people may have died from taking Vioxx.¹⁰ Many patients held Merck liable, with the first plaintiff awarded \$253.5 million in 2006 for responsibility in the death of her husband.¹¹ In 2007, Merck announced that it would pay \$4.85 billion to end thousands of lawsuits over the painkiller. This payout allowed them to avoid approximately 47,000 personal-injury lawsuits and hundreds of class-action cases.¹²

Overview of the Lesson Plan

The Vioxx case illustrates how the "value of information" can tarnish intentions and cause members of the scientific community to forget *primum non nocere*, the dictum "first, do no harm." In the two-part assignment de-

scribed in this chapter, students trace the publication of the VIGOR study, its erratum, and the aftermath of the nearly 107 million prescriptions dispensed for Vioxx between 1999 and 2004.¹³

In the first part of the assignment, students search for the original VIGOR article published by the *NEJM* and answer questions concerning the reliability of the study in class.¹⁴ In the second part of the assignment, they find a specific known article, “What have we learnt from Vioxx?” published by the *British Medical Journal (BMJ)*.¹⁵ It is a four-page article that describes in straightforward language the complicating factors of the study. After locating the full-text article and reading it, they discuss possible solutions for alleviating conflict-of-interest cases in the future in the online discussion area in Canvas, our learning management system (LMS).

This second known *BMJ* article concerning the VIGOR study explains how relationships among stakeholders with opposing priorities can disrupt the integrity of the scientific method. Disseminators, producers, and owners of information may have conflicting priorities. Publishers, government agencies, academic researchers, funding agencies, and corporations may have different views on communicating scientific information. As students move into their professional roles, they need to understand the various stakes the members of the scientific community have in any scientific endeavor. Their roles may require difficult decisions to ensure scientific integrity. Sometimes these choices will be even more problematic because they may diverge from the law or the norms of the current professional culture, especially when stakeholders have contradicting ethical standards.¹⁶

Learning Theory and Pedagogy: Vygotsky’s Sociocultural Education and the Zone of Proximal Development

Since health science students will likely be working with other health professionals when they are practicing, adopting learning theories that mirror this community aspect makes sense in information literacy instruction in the health sciences. Sociocultural learning theory focuses on the roles that social relations, community, and culture play in learning.¹⁷ Lev Vygotsky, the Soviet psychologist, proposed that learning takes place through interaction with others, then is later internalized in the individual.¹⁸ Vygotsky proposed that morality is a cultural practice formed by language

and discourse within the context of the social, cultural, and historical.¹⁹ He introduced the “Zone of Proximal Development” (ZPD) in education as a dynamic process in which students actively participate in their own learning through language and interaction with others.²⁰ Vygotsky stressed the importance of determining a student’s actual developmental level as well as the “level of potential development.”²¹ He believed that students needed a peer’s or a teacher’s help before they reached their actual level of development in an area or endeavor. After they reached a certain level of competence in the area, then they could successfully work independently.²² In the first part of the conflict-of-interest assignment, students can ask peers and the instructor for guidance. In the second part of the assignment, they should be comfortable enough with the concepts to be capable of doing the assignment independently. Vygotsky’s ZPD corresponds well with the framework’s threshold concepts, which helps guide instructors to scaffold information literacy skills through the knowledge practices and dispositions.

Vygotsky drew parallels between student zones and ocean waves, stating that development could be both progressive and regressive.²³ He believed that both forward and backward movement in learning is a natural part of the process, and just like the incoming tide, is finally progressive. “Although the backward movement appears to be regressive, it is a time for making sense of the world and the conflicts within it.”²⁴ This metaphor is an inspiring one during those difficult days when students’ information literacy skills seem not to be improving. Perhaps they are simply taking the time they need to make sense of the world of information and the conflicts within it.

Lesson Plan

Learner Analysis

- This lesson was designed to meet the needs of a classroom of students at varied levels and academic backgrounds. Vygotsky’s ideas about developing a class community where peers and teachers offer guidance to those who have a lower range of skills can help level the field. The goal is to allow each student to work at a level that challenges him without being too difficult and causing frustration or apathy or too easy and causing boredom.

- In the beginning of the semester, students may have difficulty reading scholarly articles. During the semester, we practice breaking difficult articles into chunks, by reading the abstract first, then the introduction, then the conclusion.
- Students may have difficulty finding known articles at the beginning of the semester. During the semester, they concentrate on finding the full text of known articles so they can easily find referenced citations in bibliographies.

Special Populations

- This lesson could work well for nursing, allied health, or pre-professional students in the health sciences. It has also been used for the undergraduates with good success as it helps them navigate information for their own health questions.

Pre-instruction Learner Tasks

- It is helpful, but not necessary, to have this lesson after discussions or lessons on retracted articles and conflict of interest.

Learner Prerequisites

- Learners must have database searching skills.
- Learners must know how to critically evaluate information.

Instructional Context

- The classroom should have computer and internet access.

Pre-instruction Work

- The librarian should locate a study for students to review. In addition to the VIGOR study, we have also had students look at the retracted Andrew Wakefield article, which suggested a connection between autism and the MMR vaccine. The selected study should help them understand the importance of critical thinking when evaluating information; even when the article has been through the peer-review process and published in a top-tier journal, the results may not reveal the entire story. The purpose of the article is to make

students aware that even if an article is accepted after a rigorous peer-review process, without all the data, fraudulent research can be published and can be extremely difficult to recognize as such.

Learning Outcomes and Activities

Learning Outcomes

1. Students will understand how conflict of interest can influence scientific integrity.
2. Students will understand how information may have opposing values for different stakeholders in biomedical research.

Learning Activities

This assignment has two parts or it can be combined into one assignment, depending on available time or constraints. The article could be provided to students to save time.

Part 1—In-class with instructor and peers available for guidance

1. Searching Medline (*10 minutes, optional*)
 - Students conduct a field search in Medline, entering “naproxen” as a keyword, “bombardier” and search in the author field, and “VIGOR” as a keyword.
 - Students answer the following written assignment questions:
 - ▷ How many results did you get?
 - ▷ What is the oldest article (Bombardier et al., 2000).
2. Reading study (*LO2, 15–20 minutes, essential*)
 - Students read the abstract of (Bombardier et al., 2000)
 - Students answer the following written assignment questions:
 - ▷ What two pharmaceuticals are being compared?
 - ▷ What disease or condition are they evaluating?
 - ▷ What outcome are they studying?
 - ▷ How many patients were enrolled in the study?
 - ▷ Does that seem like a reasonable number?
3. Evaluating Article (*LO2, 10 minutes, essential*)
 - Students conduct further evaluation of the journal article. Students answer the following questions:
 - How many times has the article been cited?
 - ▷ How many comments do you see in the full Medline record?

- ▷ Scanning the comments and editorials, what increased risk did investigators see for the Vioxx group?
- ▷ Did the journal retract the article? Why or why not?

Part 2—These learning activities may be completed in class or used as online discussion for homework without instructor or peers available for guidance.

1. Title Search in Medline (*LO1, 5 minutes, essential*)
 - Students conduct a title field search in Medline and answer the following question:
 - ▷ “What have we learnt from Vioxx?” (Krumholz et al., 2007)
2. Reading Study Located (*LO2, 15 minutes, essential*)
 - Students read the article and answer the following questions:
 - ▷ How many patients were enrolled in the VIGOR study?
 - ▷ How many of the seven authors of the study were Merck employees?
 - ▷ Where was the data from the VIGOR trial stored?
 - ▷ How many prescriptions for Vioxx were written between 1999 and September 2004?
 - ▷ Based on the reading and in your own words, how can conflicts of interest such as this be avoided in the future? What policies and procedures should be implemented?

Assessment

For Part 1, students written assignment answers are assessed on the ability to

- search the databases;
- find known articles;
- find the full-text of articles; and
- think critically when evaluating articles and study design.

For Part 2, which may be conducted as an online discussion question, the rubric in Appendix 16A is used to assess students on their written assignment answers and their understanding of:

- how the value of information can influence different stakeholders’ decisions in biomedical research;
- how data can be manipulated, ignored, or withheld to produce positive study results; and

- what measures can be taken to help prevent questionable practices or scientific misconduct resulting from conflicts of interest in biomedical research.

NOTE: The rubric used for the summative assessment of Part 2 can be used for all discussion questions within this lesson if the instructor chooses.

How Success is Measured

Students should convey their awareness that even articles that have been published in highly regarded, peer-reviewed journals should still be carefully evaluated. They should also convey a knowledge of how investigators, publishers, or other stakeholders can place monetary gain above patients' interest by skewing or withholding information. This lesson is successful when students understand that the "value of information" can result in misinformation and that misinformation can prevent healthcare providers from having the necessary information to make informed decisions regarding the health and safety of their patients. It can also prevent individuals from making informed decisions regarding their own health.

Appendix 16A

Discussion Assignments

Purpose: Reflect on what we’re discussing in class and what you’re reading and viewing outside of class, and answer the discussion question in Canvas. Each discussion is worth 12 points.

Directions:

1. Questions are based on class discussion, readings, and student’s selection.
2. Using the grading criteria below, the student will respond to questions.
3. Responses will be at least 200 words.

Rubric

| Grading Criteria for Discussion Questions | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Each discussion question answered for the class is worth a maximum of 12 points. Responses will be evaluated according to the following rubric. | | | | |
| Components | 3 points | 2 points | 1 point | 0 points |
| On Time | Entry is completed by class time (6:00 p.m.) on the due date.0 | Entry is 1 day late | Entry is 2 days late | Entry is more than 2 days late or not completed |
| Content | Entry shows critical thinking skills and contains a well-thought-out answer to each question. | Entry shows critical thinking skills and well-thought-out answers to some questions. | Entry rambles off topic. | Entry is incomplete or irrelevant. |
| Quality | Expresses insights or reflections in your own words to each question. | Express insights or reflections in your own words to some of the questions | Summarizes information but does not express reflections or insights. | Entry is incomplete or irrelevant. |
| Mechanics | Effective use of spelling, grammar, or punctuation. Uses a college-level tone. | Contains some errors in spelling, grammar, or punctuation. Uses a semi-formal tone. | Frequent errors in spelling, grammar, or punctuation. Uses a semi-formal tone. | Excessive use of jargon or slang. Tone is too informal for class. |

Notes

1. Association of College and Research Libraries (ACRL), *Framework for Information Literacy for Higher Education*, February 2, 2015, <http://www.ala.org/acrl/standards/ilframework>.
2. Ibid.
3. Ibid.
4. Harlan M. Krumholz et al., "What Have We Learnt from Vioxx?," *BMJ: British Medical Journal* 334, no. 7585 (2007): 120–21.
5. Snigdha Prakash and Vikki Valentine, "Timeline: The Rise and Fall of Vioxx," *National Public Radio*. (November 10, 2007).
6. Claire Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," *New England Journal of Medicine* 343, no. 21 (November 23, 2000), accessed November 22, 2016, <http://dx.doi.org/10.1056/NEJM200011233432103>.
7. Krumholz et al., "What Have We Learnt from Vioxx?," 121.
8. Alex Berenson et al., "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," *The New York Times on the Web* (2004), http://www.nytimes.com/2004/11/14/business/despite-warnings-drug-giant-took-long-path-to-vioxx-recall.html?_r=0.
9. Gregory D. Curfman, Stephen Morrissey, and Jeffrey M. Drazen, "Expression of Concern: Bombardier et al., 'Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis,' N Engl J Med 2000; 343: 1520-8," *New England Journal of Medicine* 353, no. 26 (2005): 2813.
10. Gardiner Harris, "At F.D.A., Strong Drug Ties and Less Monitoring," *New York Times* 6 (2004). <http://www.nytimes.com/2004/12/06/health/at-fda-strong-drug-ties-and-less-monitoring.html>.
11. Alex Berenson, "Jury Calls Merck Liable in Death of Man on Vioxx," *New York Times* (August 20, 2005): A1, <http://www.nytimes.com/2005/08/20/business/jury-calls-merck-liable-in-death-of-man-on-vioxx.html>.
12. Prakash and Valentine, "Timeline: The Rise and Fall of Vioxx."
13. Krumholz et al., "What Have We Learnt from Vioxx?," 122.
14. Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis."
15. Krumholz et al., "What Have We Learnt from Vioxx?"
16. Justin Biddle, "Lessons from the Vioxx Debacle: What the Privatization of Science Can Teach Us About Social Epistemology," *Social Epistemology* 21, no. 1 (2007).
17. Barbara Rogoff, *Apprenticeship in Thinking: Cognitive Development in Social Context* (New York: Oxford University Press, 1990).
18. Vishalache Balakrishnan and Lise Bird Claiborne, "Vygotsky from ZPD to ZCD in Moral Education: Reshaping Western Theory and Practices in Local Context," *Journal of Moral Education* 41, no. 2 (2012): 227.
19. Ibid., 227.
20. Joan Wink and LeAnn G. Putney, *A Vision of Vygotsky* (Boston: Allyn & Bacon, 2002), 86.
21. Ibid., 86.
22. Balakrishnan and Claiborne, "Vygotsky from Zpd to Zcd in Moral Education: Reshaping Western Theory and Practices in Local Context," 233.
23. Wink and Putney, *A Vision of Vygotsky*.
24. Ibid.

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