



Christine A Larson, Ph.D.

University of Kentucky,
Lexington, Kentucky.

The author has twelve years of business development experience for Fortune 500 firms in the pharmaceutical and financial services industries and recently completed doctoral work in evidence-based medicine at the University of Kentucky.

Patents are pending on the health solutions developed and will be commercially available to assist other consumers who experience similar health outcomes after undergoing this surgical procedure.

The dissertation upon which this article is based: "Evidence-Based Medicine: An Analysis of Incidental Bilateral Oophorectomy at Time of Hysterectomy for Benign Conditions," is considered to be the first scientific analysis of this surgical procedure conducted by a former patient.

"Alternative Medicine," (2007), the author's first publication, introduced the concept of evidence-based medicine to the US consumer by exploring the science underlying both alternative and conventional medicine, with issues to consider in its absence. Medical reviews and endorsements on preliminary research in evidence-based medicine can be accessed at the company website: www.savvyconsumerguide.tohealthcare.com

Correspondence to:
Christine A Larson, PhD
Savvy Consumer, LLC,
PO Box 22571, Lexington,
Kentucky 40522-2571 USA.
E: c.larson@qx.net

Smart Money's on Evidence-Based Medicine:

A Consumer's View on Incidental Bilateral Oophorectomy at the Time of Hysterectomy for Benign Conditions

The Chinese translation for the word crisis is 'opportunity riding on dangerous winds.' The dangerous economic winds we find ourselves in provide an opportunity to shed light on issues involving healthcare, using the sub-prime debacle as an illustration. The sub-prime debacle largely occurred because fundamentals of responsible mortgage-lending practices were ignored:

- First, do not lend money to those who cannot repay.
- Second, do not purchase homes you cannot afford.

Sub-prime mortgages were loans based on false fundamentals, making them a type of 'bogus stock'. Financial institutions and investment banks across the country proceeded to 'make a market' in this 'bogus stock', with remarkable success. When the real estate market declined, mortgage payments mushroomed, customers could not afford monthly payments, foreclosures escalated, banks became saddled with bad debt that could not be absorbed and financial institutions were threatened, some folded, putting the economy itself at risk.

When fundamentals of responsible practices in any industry are ignored, the outcome is not favourable, as the sub-prime debacle illustrates. But this phenomenon is not isolated to financial institutions and banking, however. Fundamentals exist in every industry that provide a basis for responsible practices, be it finance and mortgage lending, clinical trials and pharmaceuticals, or therapies used in healthcare. In the pharmaceutical industry, when science is ignored or minimised, as it was in the case of Vioxx, outcomes will not be favourable for the manufacturers or the end-users, the patients.

Cardiovascular effects were evidenced in early clinical trials of Vioxx, but the senior scientist was prohibited from releasing the evidence due to its proprietary nature. The drug was later approved by the FDA and released onto the market, resulting in a 'sudden spike in cardiac deaths' among members in a managed-care company's database. The common denominator was Vioxx. The drug was later recalled at the request of the FDA.

Pharmaceutical products or treatments used in healthcare are only as good as the fundamental science that supports them. Evidence-based medicine is the foundation of responsible medical practice.

Sackett (1996) defines evidence-based medicine, as: "...the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." Science is limited, however, and decisions are required, often in the absence of proper scientific guidance. What are the implications of this absence of science? Samuel Nussbaum (2003), chief medical officer of Anthem, Inc, at the Disease Management Congress stated that: '... < 50% of medicine is science-based,' i.e. half of medical practice

has no proof of efficacy through randomised clinical trials. David Eddy (2006), a former Stanford heart surgeon, now health economist, noted that 20-50% of medicine is evidence-based, which means that 50-80% of medical practice lacks scientific proof of efficacy through randomised clinical trials. The implications are that decisions are required in the absence of scientific support and assumptions are made. Assumptions, however, are not a substitute for scientific proof of efficacy.

In a 'BusinessWeek' (2006) feature story, 'Medical Guesswork', a US corporate executive noted that: "There is a massive amount of spending on things that really don't help patients and even put them at greater risk. Everyone that's informed on the topic knows it, but it is such a scary thing to discuss that people are not willing to talk about it openly" – the proverbial elephant in the room. This lack of evidence-based medicine often creates a high-stakes, high-cost 'trial and error' scenario that results in unresolved health problems, perhaps compounded by a decline in health status. With reference to protocols used in clinical medicine, the 50-80% that lack scientific support encompass all clinical specialties, with obstetrics and gynaecology being no exception.

Post-operative health outcomes following a hysterectomy with an incidental bilateral oophorectomy for treatment of non-cancerous uterine fibroids was the impetus for this research. Of particular interest was the scientific support for this surgical procedure in women without risk factors. A literature review indicated significant scientific gaps that existed with both procedures and scant long-term data on outcomes, particularly troublesome from the patient's perspective. AHRQ (2001) concludes: '...a broad range of patient outcomes need assessment...it is critical to understand the effects of treatment (or time) on the presenting symptoms and to measure the value of particular outcomes in individual women.' AHRQ's (2001) summary statement of particular relevance: '...very few studies provide information...on the symptoms that led women to seek treatment in the first place or in the long-term outcomes that effect the patient's quality of life.'

Culiner (1958) first raised questions on the use of incidental bilateral oophorectomy at the time of hysterectomy for benign conditions. Gibbs (1971) popularised the procedure, claiming 'prophylaxis is the cure' in preventing deaths from ovarian carcinoma, which is difficult to detect and, when found at late stages, has an 80% mortality rate. Clinical decision-making incorporates a risk-benefit ratio in determining the usefulness of a treatment in a particular case. The risk profile of this prophylactic surgical procedure includes Culiner's (1958) reference to: '...an endocrine imbalance that cannot be corrected artificially,

cardiovascular effects and osteoporosis.' Epidemiologists, public health experts and gynecologists over the last 55 years have added adverse health outcomes of an increasingly severe and debilitating nature to this risk profile.

Colditz (1987) reports a higher incidence of coronary vascular disease. Shoupe (1999) reports a higher incidence of dementia, depressive and mood disorders, increased incidence of coronary vascular disease and sexual dysfunction. Parker et al. (2005, 2009) reports a higher incidence of heart disease, cancer and stroke, all-cause mortality and premature death, as did Schuster et al. (2008). Rocca et al. (2006, 2007, 2008) reports a higher incidence of cognitive decline, dementia and neurological disorders.

This researcher's initial post-operative health outcomes included high blood pressure and cholesterol, pre-diabetes, and weight gain and may in fact serve as a prototype for many women post-operatively who undergo this surgical procedure. That downward health trajectory was reversed through proprietary medical research, with my health fully restored in 2005. However, as Parker et al. (2005, 2009), Rocca et al. (2006, 2007, 2008) and Schuster et al. (2008) point out, that initial health trajectory, for many, will continue its downward spiral, with end-points of chronic disease, disability, and premature death.

Culiner (1958) said it best, a half-century ago: "If the ovaries appear normal, of there is no history of carcinoma, if the patient understands and accepts the risks, the ovaries usually can be conserved at hysterectomy for benign conditions." ■

References

- Carey, John. "Medical Guesswork." *Businessweek*, 72-79. May 29, 2005.
- Colditz, G., Willett, W., Stampfer, M., Rosner, B., Speizer, F., Hennekens, C. "Menopause and the risk of coronary heart disease in women," *New England Journal of Medicine*, 1987; 316: 1105-10.
- Culiner, Alex. "The Controversial Ovary," *California Medicine*. 1958 July; 89 (1): 30-32.
- Gibbs, E. Kent. "Suggested prophylaxis for ovarian cancer." *Obstetrics and Gynecology*. 1971.
- Larson, Christine A. "Alternative Medicine." Greenwood Press, Westport, Connecticut and London, England. 2007.
- Larson, Christine A. "Smart Money's on Evidence-Based Medicine," *Business Lexington*, October 31, 2008. Copyright retained under Savvy Consumer, LLC. w/ permissions granted.
- Matcher, David B. Agency for Health Research Quality. "Management of Uterine Fibroids: Volume #1 Evidence Report." Duke Evidence-Based Practice Center, Durham, NC. 2001.
- Matcher, David B. Agency for Health Research Quality. "Management of Uterine Fibroids: Volume #2 Evidence Tables and Bibliography." Duke Evidence-Based Practice Center, Durham, NC. 2001.
- Nussbaum, Samuel. Presentation to the Disease Management Congress, reference to Dartmouth Atlas Project Research. 2003.
- Parker, W.H., Broder, M.S., Liu, Z., Shoupe, D., Farquhar, C., Berek, J.S., "Ovarian Conservation at Time of Hysterectomy for Benign Disease." *Obstetrics and Gynecology*, 2005; 106: 219-26.
- Parker, W.H., Broder, M.S., Chang, Eunice, Feskanich, Diane, Farquhar, Cindy, Liu, Zhimae, Shoupe, Donna, Berek, Jonathon, Hankinson, Susan, Manson, Joanne. 2009. "Ovarian Conservation at the Time of Hysterectomy and Long-Term Health Outcomes in the Nurse's Health Study." *Obstetrics and Gynecology*, 2009, Vol 113, No. 5, May: 1027-1037.
- Rocca, W., Grossardt, B., de Andrade, M., Melton, J., "Survival patterns after oophorectomy in premenopausal women: a population-based cohort study." *Lancet Oncology*. 2006 October; 7 (10): 821-8.
- Rocca, Walter B., Brandon R. Grossardt, Yonas Geda, Bobbie Gostout, James A. Bower, Demetrius M. Maraganore, Marcia de Andrade and C. Joseph Melton. 2008 (March 17)., Vol. 15, No. 6. "Long-term risk of depressive and anxiety symptoms after early bilateral oophorectomy." *Menopause: The Journal of The North American Menopause Society*.
- Rocca, W.A.; Bower, J.H.; Ahlskog, J.E.; Grossardt, B.R.; de Andrade, M.; and Melton, L.J. 2007 (March 28). "Increased risk of cognitive impairment or dementia in women who underwent oophorectomy before menopause." *Neurology* 2007; 69:1074-1083.
- Rocca, W.A.; Bower, J.H.; Ahlskog, J.E.; Grossardt, B.R.; de Andrade, M.; and Melton, L.J. 2008. "Increased risk of parkinsonism in women who underwent oophorectomy before menopause." *Neurology* 70: 200-209.
- Rocca, Walter A., Brandon R. Grossardt, Demetrius M. Maraganore. 2008.
- "The Long-Term Effects of Oophorectomy on Cognitive and Motor Aging Are Age Dependent," *Neurogenerative Disease* 2008; 5: 2587-260.
- Schuster, Lynn; Bobbie Gostout; Brandon Grossardt; and Walter Rocca. 2008 (March). "Prophylactic oophorectomy in premenopausal women and long-term health." *Menopause International*.
- Shoupe, Donna. 1999. "Rationale for Ovarian Conservation in Women." *Menopausal Medicine*.

**Oncology
Pharma™**

www.oncologypharma.com

Bio-Pharma Resource

The Global Oncology Pharma web portal is a resource for Bio-Pharma oncology focused professionals and provides:

- News
- Blogs
- LinkedIn groups
- Market Reports
- Conferences & Webinars
- CROs
- Twitter
- Consultants
- Recruitment Services
- Companion Diagnostics

5% of each order goes to the International Cancer

Advocacy Network www.askican.org

NOMINATIONS OPEN

Macmillan has launched annual Excellence Awards for Macmillan professionals, celebrating outstanding leadership in key areas critical to Macmillan's strategic aims.

These areas include:

- service improvement
- innovation
- partnership
- team-working.

To find out more and make nominations by 31 March 2012, please visit macmillan.org.uk/professionalsawards

©Macmillan Cancer Support, Registered charity in England and Wales (261017), Scotland (SC039907) and the Isle of Man (604). MAC13549_ON