



Prophylactic bilateral oophorectomy at time of hysterectomy for women at low risk: ACOG revises practice guidelines for ovarian cancer screening in low-risk women^a

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On March 9, 2010, Richard J. Ablin PhD, who was much involved in the discovery of prostate-specific antigen (PSA), made national news with his quote, in an Op-Ed piece published in *The New York Times*¹ and a subsequent March 22, 2010, U.S. National Public Radio interview², that “It’s no better than a coin toss”—describing the PSA test’s ability to predict prostate cancer in men. Ablin pointed out that the PSA test was never intended to be used for routine screening for prostate cancer in asymptomatic men at low risk and that treatments subsequent to its use left many men not only impotent and incontinent but also with reduced quality of life and varying degrees of psychological problems—all without medical necessity.

Ablin was educating U.S. consumers about evidence-based medicine and the perils of overly aggressive screening and treatment in patient populations that, more than likely, would never have developed prostate cancer. His words struck a chord with me, given that my doctoral research on the use of prophylactic bilateral oophorectomy in women at low risk for developing ovarian cancer was being completed at the time. The parallels in Ablin’s

research and my own prompted me to contact him to offer congratulations on his work and to introduce a parallel research area—that of prophylactic bilateral oophorectomy in women at low risk. The result of that telephone call was two invitations to publish the dissertation research findings.

Current Oncology published the first article, “Evidence-Based Medicine: An Analysis of Prophylactic Bilateral Oophorectomy at Time of Hysterectomy for Benign Conditions”³, and *Oncology News* published the second article, “Smart Money’s on Evidence-Based Medicine: A Consumer’s View on Incidental Bilateral Oophorectomy at Time of Hysterectomy for Benign Conditions”⁴.

The parallels in Ablin’s research on prostate cancer and research conducted on oophorectomy in women at low risk involve overly aggressive screening and treatment, with the number needed to treat (NNT) being of critical importance. The NNT is the number of individuals who must be treated to spare one life from mortality attributable to (in this case) prostate or ovarian cancer. For routine screening in men at low risk for developing prostate cancer, 48 is the NNT, according to Otis Brawley MD, chief medical officer of the American Cancer Society^{5,6}. According to Sarah Miles MD, an ovarian conservationist and outcomes researcher interviewed in the dissertation research, the NNT for prophylactic bilateral oophorectomy in women at low risk for developing ovarian cancer is 300.

Miles indicated that she didn’t know of a time when oophorectomy wasn’t the standard, and she commented on the research that she conducted on estrogen deficiency⁷:

Clearly, there was a differential, without estrogen.... [W]ith estrogen deficiency, there was cognitive decline, dementia, decline in memory and problems with bone density. The worst thing is you shorten people’s life-span, most die from coronary vascular disease, you start the clock. 300 Oophorectomies have to

^a Diagnostic and treatment algorithms and a proprietary over-the-counter (OTC) product and treatment regimen were developed that resolved the adverse health outcomes precipitated by this surgical procedure. Commercialization efforts are underway to bring this proprietary OTC product and treatment regimen to other consumers who have experienced similar postoperative health outcomes after undergoing this surgical procedure.

Alternative Medicine (2007), the author’s first publication, introduced the concept of evidence-based medicine to the U.S. 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: <http://www.savvyconsumerguidetohealthcare.com>.

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be performed to prevent one death to ovarian cancer. Leaving them in is smarter medicine. (p. 85)

The dissertation sought to explain why rates of incidental bilateral oophorectomy in women without risk factors had remained at 50% since the late 1980s in spite of the growing body of evidence that documented increasingly severe and debilitating health consequences, up to and including premature death^{8–19}.

In thirty-five interviews conducted with OB/GYN practitioners across the country, health outcomes publications were a central focus. Specifically, how did the OB/GYN practitioners view the publications that had reported severe health consequences associated with the procedure for many (including chronic disease, disability, and premature death) and how quickly did they incorporate this outcomes research into their clinical practice?

When the outcomes studies were referenced in the course of interviews, many of the practitioners being interviewed appeared surprised, with several asking that they be sent copies of the articles being cited.

Thomas Rodman MD, professor of laparoscopic surgery and pelvic pain, indicated that prophylaxis was introduced in medical training and that it was “urged on people.” His final comments⁷:

Prophylaxis was recommended more in general. Gosh, we were taught to recommend prophylaxis, that is, it was beneficial for the patients. (p. 72)

What the health outcomes studies being referenced pointed out was that the procedure had, in fact, been putting many patients at greater risk, inducing a variety of chronic diseases, disability, and (for some) premature death—the exact opposite of what was thought to be the case.

Through the interviews, it became clear that the persistence of oophorectomy in women at low risk was a direct consequence of many specialists not being fully aware of the risks associated with the procedure because the data upon which guidelines from the American Congress of Obstetricians and Gynecologists (ACOG) were based did not include the long-term health outcomes being referenced.

John Schmitt MD, a gynecologic oncologist interviewed in the dissertation research, felt that the preliminary dissertation research findings were sufficiently compelling to publish in advance of the dissertation itself so that the specialists treating benign conditions could be fully aware of the health risks documented in the long-term health outcomes studies that had been conducted by epidemiologists, gynecologists, public health experts, and neurologists. This became my first objective with the research.

Schmitt recommended that an article summarizing the findings be submitted to “The Green Journal”

(*Obstetrics and Gynecology*), ACOG’s official publication, which would provide the broadest dissemination across the OB/GYN specialty. That article, submitted in 2009, was declined for publication with no opportunity for revision.

In April 2010, after I had discussed the research with him, Dr. Ablin, a member of the editorial board of *Oncology News*, issued invitations to publish the dissertation research findings in *Current Oncology* and *Oncology News*.

Given that the ACOG practice guidelines were found to play a significant role in the persistence of oophorectomy in women at low risk, a second objective with the research was to work toward revised ACOG practice guidelines, because those guidelines serve as the medical–legal floor for the specialists.

Derek Smith MD, assistant professor of reproductive endocrinology, who was interviewed for the dissertation research described the importance of ACOG guidelines this way⁷:

ACOG plays an important role in management of benign conditions through technical, committee opinions ... practice guidelines.... If I have a problem, if I follow practice guidelines ... if I need to defend myself in court, ... guidelines are important. (p. 99)

George Stanford MD, director of Minimally Invasive Procedures, Gynecologic Endoscopy, had this to say about the role of ACOG guidelines in oophorectomy⁷:

With surgeons, ... doctors the way they think ... some clinicians adopt quickly; some don’t. ACOG gets a panel and reviews the literature, they revise and come up with guidelines every 10–15 years, and they revisit them again. Studies come, always take them for granted, may still be wrong, it takes a long-time to adjust. On the other hand, medical-legal issues ... (p. 101)

Janet Stewart MD, assistant professor, and director, Division of Obstetrics and Gynecology, had this to say about the role of ACOG guidelines on the persistence of oophorectomy in women without risk factors⁷:

ACOG plays a big role, versus panel of peers, experts coming forward with analysis. ACOG ... quality ... safety ... epidemiology—we don’t have best evidence—the focal point to rally evidence-based medicine is fantastic. (p. 101)

Thomas Martin MD, chair of OB/GYN, with twenty-eight years of clinical practice, on the weight given to ACOG guidelines said, “The guidelines provide parameters, but allow for individual clinical judgment. You don’t want to handcuff the doctor.” Martin emphasized

the need to get patients engaged in decision-making on this elective procedure and concluded the interview with the observation that “It’s their gonads. No man asks to have his testicles removed”⁷ (p. 70).

Andre Johnson MD, assistant chief of OB/GYN, with twenty-three years of practice, indicated that trends during medical education and residency were toward “a much higher use of oophorectomy.” On the impact of ACOG guidelines on that procedure, he commented that “If it comes from ACOG, we need better evidence”⁷ (p. 71).

In April 2012, the American Board of Internal Medicine (ABIM) announced their Choosing Wisely Campaign²⁰, inviting specialty societies to devise their top 5 picks of unnecessary procedures and tests rooted in questionable science, which, if eliminated, would produce better health outcomes and reduce costs. Communications were initiated with ABIM at that time, congratulating them on their initiative, with the article on the dissertation research included, and a recommendation that oophorectomy make number 1 of the top 5 picks for ACOG. At that time, ACOG was not a participant in the program.

In September 2012, ACOG joined ABIM’s Choosing Wisely Campaign²¹, and in February 2013, the ABIM released their top 5 list, of which number 5 announced revised practice guidelines for ovarian cancer screening^{21–25}:

Don’t screen for ovarian cancer in asymptomatic women at average risk.

In population studies, there is only fair evidence that screening of asymptomatic women with serum CA-125 level and/or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening. Because of the low prevalence of ovarian cancer and the invasive nature of the interventions required after a positive screening test, the ... potential harms of screening outweigh the potential benefits.

Given that existing informed consent forms were found (in the dissertation research) to play a significant role in the persistence of the use of oophorectomy in women without risk factors, a third objective with the research was to work toward revised informed consent forms that would include the health outcomes studies referenced in the dissertation and in this editorial.

For the 55,000 specialists who perform this procedure, and for the patients who rely on their advice, ACOG’s decision to place ovarian cancer screening in low-risk women in their top 5 picks—that is, to issue the equivalent of a Practice Alert to the specialty on this surgical procedure—is an important first step. However, ensuring adherence to the revised guidelines from ACOG will require oversight from a governance perspective, particularly in light of the fact that the rate

for this procedure in women without risk factors has remained static at 50% since the late 1980s.

Leah Binder, CEO of the LeapFrog Group, recommends “a few nudges” for the Choosing Wisely Campaign, with nudge number 2 being of particular relevance: “Impose accountability for results”²⁶. The issuance by ACOG of the equivalent of a Practice Alert and their ensuring that the rate of the procedure declines in this patient population provides a golden opportunity for revision of the existing informed consent forms for the procedure so that they include the long-term health outcomes data referenced in the dissertation and this Guest Editorial. Such a revision can assist ACOG in accelerating translation of the revised guidelines into actual clinical practice, something all specialty societies participating in the Choosing Wisely Campaign are seeking to accomplish.

Without revised informed consent forms that include the long-term health outcomes data for oophorectomy referenced in the dissertation and this Guest Editorial, patients without risk factors will continue to unwittingly consent to a procedure, unaware of the adverse health consequences that will be induced for many of them. Interviews conducted with OB/GYN practitioners on the issues surrounding informed consent for prophylactic bilateral oophorectomy at time of hysterectomy for benign conditions during the dissertation research will be published in a future article.

Binder’s concluding comments on the Choosing Wisely Campaign were these: “Accountability is key to whether this initiative goes down in history as the moment our nation turned the corner, or another much-hyped but failed attempt at change”²⁶.

With respect to Dr. Ablin’s research and its impact on prostate cancer screening, the U.S. Preventive Services Task Force (USPSTF) published, on May 29, 2012 (two years after the op-ed “The Great Prostate Mistake” appeared in *The New York Times*), revised guidelines advising against PSA screening²⁷. A draft of the guidelines first released in October 2011 stated that “the USPSTF now recommends that regardless of age, men without symptoms should not routinely have the prostate-specific antigen (PSA) blood test to screen for prostate cancer”^{28,29}.

After those guidelines were published, Dr. Otis Brawley published an editorial on the guidelines, emphasizing the need for informed decision-making and the misconceptions that overdiagnosis can create, making screening appear to be life-saving when it may in fact be accomplishing the exact opposite³⁰, an occurrence strikingly similar to those in the dissertation research findings on the use of prophylactic bilateral oophorectomy in women without risk factors.

CONFLICT OF INTEREST DISCLOSURES

The author reports that there are no financial conflicts of interest.

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