**Facilitator’s Guide**

**Description**: This guide is intended to help the faculty deliver this 60-minute discussion on basic concepts of biostatistics and their rational application when considering diagnostic tests and cancer screening. Residents will have the opportunity to explore the diagnostic approach to pulmonary embolism (PE) in several common scenarios and the utility of pursuing CTA vs. D-dimer testing based on an individual patient’s pretest probability of PE. In the second half of the module, residents will focus on tailoring a cancer screening plan to an individual patient and understand how screening can lead to significant harm. This is the third in a series of six modules.

**Learning Objectives**:

•Identify key statistical concepts for high value care.

•Practice applying these concepts to support high value care decisions when considering diagnostic and screening tests.

•Explore the benefits and harms (including cost) of routine screening.

•Develop an approach to customize screening recommendations to an individual patient and his/her unique risk factors, values, and concerns.

**Key Points of the Session:**

* Provide reassurance that they will not be expected to perform statistical calculations as part of the session, and convey the importance of understanding the concepts underlying key statistical measures that are commonly used.
* Focus on the process by which testing and treatment decisions are made and, specifically, how biostatistics aid in understanding the potential effectiveness of different interventions.
* Encourage insight into their own decision making processes as trainees and an understanding that individual patients merit different approaches to diagnosis, screening, and treatment.
* Emphasize that biostatistics do not tell us what should be done with any particular patient, but rather provide us with additional data to know which interventions will likely be of high value and cost-effective.

**Audience and Setting:** The intended audience for this module is Internal Medicine residents. A large group setting with time and space for small group work within the session is best.

**Equipment Required**: A computer with projector for PowerPoint presentation, a white board or flip chart for recording group work.

**Prework:** Print copies of the attached handouts for participants. For the pulmonary embolism cases, there are three pages of handouts that should be stapled together. An equal number of each handout should be prepared to create 3 small groups. For the cancer screening cases, distribute the handout entitled “Table 1” that is at the end of this document.

**Presentation #3 — Instructions by Slides**

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| **Step** | **Description** | **Estimated Time** |
| 1 | Welcome participants, distribute handouts, and go over learning objectives. Be sure to point out that there will be a brief review of biostatistics but that no calculations will be performed. | 3 minutes |
| 2 | **Slides 3-7:** Basic review of biostatistical concepts. On slide 3, briefly go over definitions and transition to the 2x2 table by saying that these concepts are often easier to visualize. When going over sensitivity and specificity, make sure to explain that there is no “free lunch” and that often we maximize one at the expense of the other.**Slide 4:** Sensitivity. Explain that sensitivity deals with people with disease. (“Be Sensitive to those who have disease.”) Explain that very sensitive tests are required for situations in which consequences of a false negative would be very bad (e.g., screening donated blood for HIV).**Slide 5**: Specificity. Explain that specificity deals with people without disease. (“Negative people get specific.”) Very specific tests are needed for situations in which a false positive would be very bad (e.g., cancer). | 5 minutes |
| 3 | **Slides 8-12**: Role of diagnostic testing. Transition to diagnostic testing by explaining that whether we realize it or not, we are always using those biostatistical concepts when ordering diagnostic testing. Go over schematic on **slide 8** by explaining that we start by creating a pretest probability (usually based on disease prevalence), then decide on the appropriate diagnostic test (based on which one maximizes sensitivity and specificity), which leads to our posttest probability.**Slide 9**: *For bullet point number two*, emphasize that depending on the risks of treatment, sometimes when a pretest probability is high enough, treatment can be initiated without additional testing. Also, emphasize that unique pt presentations/symptoms and pt demographics are essential to formulating clinical judgment about the pretest probability of a specific disease. *For bullet point three*: Testing should be applied in a sequential fashion until clinicians reach a “threshold” after which our posttest probability is high enough that we are confident that a patient either has or does not have a disease.**Slide 10**: Introduce concept of how to use likelihood ratios (LRs) and distribute LR handout to group (reference for LRs: *Evidence Based Physical Diagnosis* book by McGee).**Slide 11**: Have residents guess what the LR is for common physical exam maneuvers.**Slide 12**: Diagnostic testing schematic (from slide 8) now incorporates LR. Reiterate that you start with a pretest probability, order a diagnostic test based on sensitivity/specificity (which gives you the LR), that leads to the posttest probability (which equals pretest probability × LR). | 5 minutes |
| 4 | **Pulmonary embolism (PE) cases on slide 13 and PE case handout**: Distribute handout for cases, have residents break into 3 groups, and assign each group one case to work on. Have them calculate pretest probability of PE based on Well’s criteria (attached on second page of handout, with pretest probability in far right column). Then, from the pretest probability, have them choose which test to order and calculate LR based on that. For the **low-probability case (case 1),** discussion should center around whether D-dimer is even necessary or, if based on history and physical exam, they feel comfortable ruling out PE. **For moderate-probability case (case 3),** have residents look at how posttest probability would change if they ordered a CTA (right choice in this case) or D-dimer testing. **For high-probability case (case 3),** discussion should center around whether CTA is even needed or if treatment can be initiated without it on the basis of high pretest probability (especially given fact that it will be hard to get CTA because of the patient’s obesity). | 15 minutes |
| 5 | **Slides 14-17:** After case, transition to screening by saying that the same type of statistical concepts apply to cancer screening. For **slide 14**, go over ideal characteristics for screening tests. **Slide 15 and 16:** Harms associated with screening: Explain that screening is like any other test or treatment in that it has harms associated with it. For *false positives*, explain that by maximizing sensitivity at the cost of specificity (again reiterate there is no free lunch), false positives occur, which then in turn lead to increased anxiety, costs, and potential harms from follow-up testing. For *lead-time bias*, explain that survival time is determined by time from diagnosis to death. With screening, survival time can increase, even though patient ends up dying at the exact same time he/she would have without the test. It seems that they lived longer, but actually they just knew about disease longer. For length-time bias, discuss overdiagnosis and pseudodisease. Start by asking: Will finding a disease help the patient? Some diseases are very slow growing, or may even regress. Therefore, they may not cause any trouble and in fact may not be a “disease” at all. Psuedodisease: How do we know which ones will be invasive, and which will not be a problem? By nature, screening tests tend to pick up cancers that are more indolent and have better prognoses: Discuss graphic that shows screening picking up 100% of the slowly progressive disease and only 50% of the rapidly progressive disease.Facts to incorporate:Prostate cancer—Risk that cancers detected by prostate-specific antigen testing are overdiagnosed may be over 60%.Mammography may lead to overdiagnosis in 1 in 3 women.In general, good screening tests should show a decreased mortality rate, not just an increased survival time.**Slide 17**: Screening cascade graphic that shows concepts just discussed. Point out that when a positive test occurs, benefit is derived when earlier treatment works better. Then point out the different situations in which harm occurs. | 10 minutes |
| 6 | **Slide 18**: Screening Value Framework from ACP paper on high value screening (reference 3). “The value of cancer screening strategies is linked to screening intensity (population screened, frequency, and sensitivity of test used) and is determined by the balance among benefits (e.g., cancer mortality reduction), harms (e.g., anxiety from false-positive test results, harms of diagnostic procedures, labeling, and overdiagnosis leading to overtreatment), and costs. **Low-value care can result from either low benefits****or high harms and costs. Low-intensity strategies are initially low because of low benefits (*left)****.* ***As intensity increases, benefits* increase rapidly with acceptable levels of harms and costs, and value follows an upward trend**. Screening strategies provide optimal value when the informed patient or public believes that the balance between benefits and harms or costs is optimal (*middle).* The *top* of the value curve is flat because different patients or groups may view different intensities as providing the best balance. **Further increases in screening intensity beyond the optimal level lead to slower increases in benefits, with disproportionately rapid increases in harms and costs. Thus, value decreases; higher-intensity screening becomes low-value screening (*right*).** | 2 minutes |
| 7 | **Screening value cases (Slide 19):** Distribute screening value handout. As a large group, go over different scenarios and explore how residents would approach each one. **The first case (mammography)** is open to interpretation because different expert groups disagree on recommendations for women aged 40-49. (USPTF recommends against screening.) Can incorporate data on breast cancer overdiagnosis here. **Second case** (very ill patient) is there to demonstrate that screening should not be offered to patients with a life expectancy less than 15-20 years. If time permits, can also discuss how comorbidities (such as COPD) might affect sedation and fact that this should also often be considered. **Third case** relates to shared decision making and how patient’s values should come in to play when discussing screening. For all of them, should also consider downstream testing before offering screening. **Slide 20**: Discuss importance of screening smarter. *For first bullet point*, refer back to value framework and optimal intensity screening. *Bullet point two*: As many as 50% of people over 75 report that their physician recommends continued screening. Also, 10% of women with advanced non–breast cancer underwent mammography, and 15% of men with advanced non–prostate cancer underwent PSA testing. *Bullet point three*: Make sure patient would consider transrectal biopsy before ordering PSA, breast biopsy before ordering mammography, etc. | 10 minutes |
| 8 | **Slides 21-23:** Show spectrum of cost-effectiveness and explain that different tests lie along the spectrum (as demonstrated by **Slide 22).** Introduce concept of QALY. **For slide 23,** discuss how lung cancer is a recent example of a “successful” screening test and that a recent study demonstrated its cost effectiveness based on QALY <$100K. | 5 minutes |
| 9 | **Slide 24**: Summary. Reiterate that diagnostic testing and screening should be based on characteristics of the test in question and on an individual patient’s values and goals. | 5 minutes |

**References:**

1. Glaser AN. *High-Yield Biostatistics*. 3rd ed. Philadelphia: Lippincott Williams and Wilkins; 2004.

2. McGee S. *Evidence-Based Physical Diagnosis*. Philadelphia: Elsevier Saunders; 2012.

3. Harris RP, Wilt TJ, Qaseem A; High Value Care Task Force of the American College of Physicians. A value framework for cancer screening: advice for high-value care from the American College of Physicians. Ann Intern Med. 2015 May 19; 162:712-7. [PMID: 25984846]

4. Owens, D, Qaseem A, Chou R, Shekelle P; Clinical Guidelines Committee of the American College of Physicians*.* High-value, cost-conscious health care: concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions.Ann Intern Med. 2011 Feb 1;154(3):174-80. [PMID: 21282697]

5. Cohen JT, Neumann PJ, Weinstein MC. Does preventive care save money? Health economics and the presidential candidates. N Engl J Med. 2008 Feb 14;358(7):661-3. [PMID: 18272889]

6. Institute of Medicine. *The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary*. Washington DC: National Academics Press; 2010.

7. Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. BMJ. 2012;344:e3502. [PMID: 22645185]

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9. Welch HG, Schwartz L, Woloshin S. *Overdiagnosed: Making People Sick in the Pursuit of Health.* Boston, MA: Beacon Press; 2011.

10*.* Moriates C, Arora V, Shah, N. *Understanding Value-Based Healthcare*. New York: McGraw-Hill Education; 2015.

**Handout for Screening Cases (Slide 19)**

**From:** Harris RP, Wilt TJ, Qaseem A; High Value Care Task Force of the American College of Physicians. A value framework for cancer screening: advice for high-value care from the American College of Physicians. Ann Intern Med. 2015 May 19; 162(10):712-7. [PMID: 25984846]

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