**Facilitator Guide**

**Description**: This guide is intended to help the faculty deliver this interactive 60-minute discussion on basic concepts of biostatistics and their rational application when considering diagnostic tests and cancer screening. The module also provides an introduction to medical decision-making and clinical reasoning. Residents will have the opportunity to explore the diagnostic approach to acute heart failure exacerbation and the utility of BNP as a diagnostic aid in patients with different pre-test probabilities. Residents will then 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. The slides also have some presentation notes so you may want to print out a version with the notes along with this guide to help prepare for the presentation.

**Learning Objectives**:

* Review the concepts of sensitivity, specificity and predictive values and their application to high value care decision-making.
* Practice applying these concepts to support high value care decisions when considering diagnostic and screening tests.
* Explore the benefits and harms (including costs) 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 this session will not require statistical calculations, and instead 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 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 works 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 two session handouts for participants. For the heart failure case, there is a three page handout. For the cancer screening cases, there is a one page High Value Cancer Screening handout.

**References:**

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

2.Croskerry P. A Universal Model of Diagnostic Reasoning. Academic Medicine. 2009;84(8):1022

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

4.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]

5.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]

6.Cohen JT, Neumann PJ, 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]

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

8.Pinsky, Paul F. Cost-effectiveness of CT screening in the National Lung Screening Trial. *New Engl J Med*. 2015 Jan 22;372(4):387

**Handout for Heart Failure/BNP cases:**

Doust, et al. The role of BNP testing in hearth failure. Am Fam Physician. 2006 Dec 1;74(11):1893-1900.

**Handout for Screening Cases**

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]

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]

**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 required. | 3 minutes |
| 2 | **Review of biostatistical concepts**   * Have the residents break up into small groups. Review the scenario on slide 3 of the rapid response team trying to identify a sepsis recognition tool. Ask the students to define the terms at the bottom of the slide, and decide which of the test features they want to prioritize. Come back together as a group- ask each group to define a term and survey all groups about which feature they would prioritize for the sepsis tool. Slide 4 provides the definitions in table form once the residents have answered. * Depending on the knowledge in the room, you can proceed through the next few slides (#5-9) quickly as review or spend more time on the concepts. * Slide 5 demonstrates graphically the definitions: healthy people and people who have a disease have test results on a spectrum (x-axis) and overlap. We determine a cutoff where a test is considered positive, which creates four different groups: true positives, true negatives, false positives, and false negatives. * Sensitivity prioritizes identifying disease (where false negative would be very bad- i.e., HIV test). * Specificity prioritizes minimizing false negatives (needed in high stakes treatment areas like cancer). | 5 minutes |
| 3 | **Diagnostic reasoning process**   * Transition to the next section of the module by explaining that in order to understand how diagnostic testing and properties of diagnostic tests factor in to our medical decision making, we actually need to start with trying to understand our clinical reasoning process. * Present the dual process model of clinical reasoning on slide #10- a physician encounters a patient, and right away the doctor either recognizes or does not recognize the syndrome. If the presentation is recognized (i.e. “This is definitely hemorrhagic shock”) no further reasoning or testing is required, and the physician proceeds to diagnosis. This is called System 1 thinking- it is fast and usually accurate, but can be prone to errors. If a patient presentation is not recognized, System 2 is engaged, in which the physician uses deliberate, rational reasoning to weigh options and come to a diagnosis. This type of thinking is definitely necessary, especially in novel or complex cases; however it would be way too time consuming to use all the time. If you are stressed, distracted, or pressed for time, you lose the ability to be deliberate, and errors ensue. With practice and experience, cases or presentations that might have required System 2 end up become automatic (simulation is also a great way to achieve this). In reality, doctors use both systems, and toggle between the two as more information comes in. * Whether its conscious or unconscious (automatic), we are always incorporating the biostatistical concepts we discussed at the start of the session as we take care of patients. Go over schematic on slide #11 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 post-test probability. * Discuss the role of diagnostic testing. We are looking to cross a diagnostic threshold where the   post-test probability is high enough to start treatment for a specific disease slide #12. Point out that sometimes the pre-test probability is so high that no testing is required before initiating treatment. Alternatively, diagnostic tests are appropriate when there is an intermediate pre-test probability. When deciding whether to order a test, have to consider the features of the test (how much will it change your certainty about the diagnosis) and whether it will change your management.   * Introduce concept of likelihood ratios (LRs) on slide #13. Let them know that they will get a handout with this likelihood ratio tool and get practice using it in a few minutes. On slide #14, ask residents to guess the likelihood ratios for the list of common tests and exam maneuvers. Give them 30 seconds to a minute to jot down guesses on a piece a paper. Reveal the LR answers, and asks whether there were any big surprises. On slide #15, show how LR incorporates into the diagnostic reasoning schematic we showed earlier in the presentation. 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 | **Heart failure exacerbation and BNP case handout**:   * Distribute handout for cases, have residents break into 3 groups, and assign each group a different case to work on. Have the residents first guess the pre-test probability, and then check their guesses on the chart on page 2 of the handout. Then, from the pretest probability, have them determine whether they want to order a BNP to help make the diagnosis and justify their answer. Using the likelihood ratio figure on page 3 of the handout, have the residents calculate the post-test probabilities. Likelihood ratios of the three levels of BNP results are listed on page 2 of the handout. Have the groups take turns answering the questions- the first case should not have wanted to order the test in the first place (and confirmed this with their calculations). The other second group may be on the fence and the third group is likely to think that the test is of benefit, especially at the highest cutoff level. | 15 minutes |
| 5 | **High Value Screening**   * After the case, transition to a discussion of common screening tests. For slide #17, review the ideal characteristics for screening tests. In small groups, ask the residents to compile a list of potential harms from screening and to share a story of a time they have seen a patient harmed by inappropriate screening slide #18. Have the group report out the harms they listed and themes from the stories that were shared. * Use slides #19-20 to review the harms of 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 over-diagnosis and pseudo-disease. * 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. Pseudo-disease: 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. In general, good screening tests should show a decreased mortality rate, not just an increased survival time. * Review the screening cascade graphic- it really just depicts the concepts just discussed. Point out the situations where harm occurs. | 10 minutes |
| 6 | **Screening Value Framework and Cases**   * Show figure on slide #19. Emphasize that the value of cancer screening strategies depends on screening   intensity (population screened, frequency, sensitivity) and is determined by balance of benefits, harms, and costs. Low-value care can result from either low benefits or high harms and costs. Low-intensity strategies are initially low value 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).   * High Value Cancer Screening (Slide #23): Distribute the High Value Cancer Screening handout. As a large group, go over different scenarios and explore how residents would approach each one. The first case (ovarian cancer screening) is straightforward because it is never recommended. Residents may bring up patients with family members and high anxiety about developing ovarian cancer- we have a module dealing with barriers to high value care where this can be explored further. Second case also may bring up issues with patient anxiety. Use this case as a chance to review the actual recommendations and options for FOBT. Third case relates to shared decision making and how patient’s values and comorbidities should come in to play when discussing screening. For all of them, should also consider downstream testing before offering screening. * Slide #24: 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 trans-rectal biopsy before ordering PSA, breast biopsy before ordering mammography, etc. | 10 minutes |
| 7 | **Cost-effectiveness and QALY**   * Introduce theconcept of quality-adjusted life years (QALYs) as a population-based measure of cost effectiveness.For slide #26,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 |
| 8 | **Summary**   * Slide #24: 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. | 2 minutes |