Assignment 1
Guidelines and Performance Measures

David M. Schlossman, M.D.
Medical Informatics 406
Northwestern University
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1. Clinical Guideline Sets

1.1 American Society of Clinical Oncology (ASCO) clinical practice guideline on chemotherapy for stage IV non-small cell lung cancer

Suitability for CDS: This guideline and the corresponding guideline from the National Comprehensive Cancer Network (NCCN) form the basis of the clinical chemotherapy pathways for lung cancer which are embedded in our practice's electronic medical record and used by our nine medical oncologists every day.
AGREE Criteria: These guidelines fulfill the AGREE criteria extremely well. The clinical questions addressed and patients to whom the guidelines apply are specific and well described. All ASCO guideline panels are composed of experts in medical, surgical, radiation, and gynecologic oncology, basic biology, and pharmacology. They encompass academic and community practitioners, fellows in training, and major investigators from relevant clinical trials. Panels are required to include community members, patients, and members of advocacy groups. The systematic literature review methods are clearly described and comprehensive. The panel's draft document is reviewed by an outside group of experts selected by the editorial staff of the *Journal of Clinical Oncology* and the final guidelines must be approved by the ASCO Board of Directors. There is a defined process for guideline update, and tools such as a Decision Aid Set are available. The guideline is editorially independent and there is a strict conflict of interest policy. Supporting details can be found at:

American Society of Clinical Oncology Guideline Procedures Manual, Expert Panel Version 4.0 (January 25, 2011) Retrieved from http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Clinical%20Affairs%20(derivative%20products)/Manual/Methodology%20Manual%201.25.11.pdf

National Guideline Clearinghouse Guideline Summary Retrieved from http://guidelines.gov/content.aspx?id=34452#Section396

1.2 American College of Chest Physicians (ACCP) guideline on Anti-thrombotic therapy for venous thromboembolic disease

Suitability for CDS: These guidelines are quantitative and contain ordered steps and specific recommendations that would easily form the basis of an algorithm suitable for CDS. Venous thromboembolism is a common problem in cancer patients. I use these guidelines on paper and would like to see them incorporated in my EMR.
AGREE Criteria: You will be happy to know I can spare you this paragraph. The ACCP scrupulously applies all the AGREE criteria and actually quotes them in its manual on Evidence-based Guideline Development Process. You can see this at http://www.chestnet.org/accp/guidelines/development-process?page=0,7 and see the National Guideline Clearinghouse summary of the guideline at http://guidelines.gov/content.aspx?id=12957&search=venous+thromboembolism.

1.3 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guideline for assessment of cardiovascular risk in asymptomatic adults

Suitability for CDS: This guideline was developed to assist healthcare providers in determining a cost-effective strategy for assessing apparently healthy adults for the presence of subclinical atherosclerosis and the risk of developing cardiovascular events. It focuses on global risk scoring (Framingham Risk Score), family history, standard blood tests, and noninvasive imaging modalities. It is somewhat complex but the steps are precisely enough defined to fit an algorithm and be suitable for clinical decision support.
AGREE Criteria: ACCF/AHA has an extensive 88 page guideline methodology and policies manual which addresses most of the criteria. The clinical questions addressed are very precisely described and the patients to whom the guideline applies a well-defined. As regards stakeholder involvement, the manual specifies "a broad spectrum of healthcare practitioners… to diversify representation from different geographical regions, genders, ethnicities, and experts from both academic and nonacademic settings." They specifically mention including pharmacologists, QI representatives, statisticians, performance measures experts, and senior practicing clinicians. This is the one manual that I found that does not specifically mention including patients or patient advocacy representatives on the guideline writing panel. Their Relationships with Industry (conflict of interest) policy is strict and comprehensive. The systematic literature review methodology is high-quality and the recommendations are appropriately linked to supporting evidence with accompanying specification of the strength of that evidence. The initial guideline written by the panel is subject to outside peer review and is updated periodically. The recommendations are clear and specific, but I did not find any tools for practitioners to use in implementing the guideline. There is a heart attack risk assessment tool for patients on the AHA website. Supporting details can be found at:

Methodology Manual and Policies from the ACCF/AHA Task Force on Practice Guidelines Retrieved from http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm_319826.pdf.

National Guideline Clearinghouse Guideline Summary Retrieved from http://guidelines.gov/content.aspx?id=25310&search=risk+assessment.

2. Performance Measures

2.1 AMA PCPI Oncology Performance Measure #2/CMS PQRS Measure #71: Hormonal Therapy for Stage IC-IIIC ER/PR Positive Breast Cancer

Description: The percentage of patients with hormone receptor positive breast cancer who were prescribed tamoxifen or an aromatase inhibitor (AI) during the 12 month reporting period.
Numerator: The number of patients who were prescribed tamoxifen or AI during the 12 month reporting period.
Denominator: The total number of female patients aged 18 and older with stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer, except those with a documented medical reason for not prescribing tamoxifen or AI or with date of diagnosis > five years from the reporting date.
Site of use: Physician's office (usually an oncologist) where breast cancer patients are treated.
Challenges: The provider must remember to submit the information (a CDS could help with this) and must have a billing system that can properly submit three numerator CPT quality measure codes along with the usual ICD-9 diagnosis code and CPT billing code for the visit.
Suitability: There is very high quality data from multiple sources demonstrating that adjuvant endocrine therapy lowers the risk of tumor recurrence and improves five and ten year overall survival in this group of breast cancer patients. There is also evidence that many female breast cancer patients who should be receiving this therapy are not. Improving performance in this area has the potential to save lives. Publication of this data will assist breast cancer patients in selecting higher-quality providers and motivate providers to use this life-saving intervention. This measure has been endorsed by the NQF.

2.2 AMA PCPI Oncology Performance Measure #3/CMS PQRS Measure #72: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients

Description: The percentage of patients with stage III colon cancer who received adjuvant chemotherapy.
Numerator: The number of patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12 month reporting period.
Denominator: The total number of patients aged 18 years and older with stage IIIA through IIIC colon cancer seen during the reporting period.
Site of use: Physician's office (usually an oncologist) where colon cancer patients are treated.
Challenges: The provider must remember to submit the information (a CDS could help with this) and must have a billing system that can properly submit two numerator CPT quality measure codes along with the usual ICD-9 diagnosis code and CPT billing code for the visit.
Suitability: There is very high quality data from multiple sources demonstrating that adjuvant chemotherapy in patients with stage III colon cancer lowers the risk of tumor recurrence by 30% and improves overall five year survival by 22-32%. The data are unclear as to whether all patients who would benefit from this therapy are receiving it. The measure is intended to determine whether and how often chemotherapy is administered. Publication of this data will

assist colon cancer patients in selecting higher-quality providers and motivate providers to use this life-saving intervention wherever appropriate. This measure has been endorsed by the NQF.

For further details, the AMA PCPI Oncology Measure Set which includes these two measures can be downloaded at http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi.

2.3 The Joint Commission National Hospital Inpatient Quality Measure HF-3: Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) and Angiotensin Receptor Blockers (ARB) in Congestive Heart Failure

Description: The percentage of patients hospitalized for congestive heart failure for whom either ACEI or ARB are prescribed at the time of discharge.
Numerator: The number of patients hospitalized for congestive heart failure and sampled during the reporting period who receive a prescription for either ACEI or ARB at the time of discharge.
Denominator: All patients admitted to the hospital for inpatient acute care with an ICD-9 Principal Diagnosis Code for heart failure and chart documentation of left ventricular ejection fraction less than 40%, no ICD-9 Principal or Other Procedure Code of left ventricular assistive device or Heart Transplant, age greater than or equal to 18 years, and Length of Stay less than or equal to 120 days sampled during the reporting period.
Site of use: Inpatient acute care hospitals
Challenges: Hospitals must choose a sampling period for reporting (either monthly or quarterly), determine all discharges which meet the denominator criteria during each period, select a subset (sample) of those discharges large enough to meet the minimum sample size requirement, for each of those discharges determine whether ACEI and/or ARB therapy was prescribed or not prescribed, and report the data by the approved mechanism. Physicians must remember to evaluate left ventricular ejection fractions on each of their patients admitted with an ICD-9 code in the heart failure group, document whether each of those patients was or was not prescribed an ACEI or ARB at the time of discharge, and to document the medical reason for not prescribing if the patient was discharged without a prescription for one of these drugs. A CDS could be very helpful in reminding the physicians of the requirements.
Suitability: High quality data from multiple large prospective randomized clinical trials has consistently demonstrated a mortality reduction of approximately 15% as well as alleviation of symptoms and improvement in clinical status when ACEI or ARB are prescribed for patients with heart failure. The data are unclear as to whether all patients who would benefit from this therapy are receiving it. This measure is intended to determine whether and how often ACEI or ARB therapy is prescribed for heart failure patients at the time of hospital discharge. Publication of this data will assist heart failure patients in selecting high-quality providers and motivate providers to use this life saving therapy wherever appropriate. This measure has been endorsed by the NQF.

For further details, the Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures, version 4.0c can be downloaded at http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx.

Critique of a Published Clinical Decision Support System

Venous thromboembolism (blood clots, usually in the legs, with pieces breaking off and traveling to the lungs) is one of the most common preventable causes of hospital related deaths in the United States. A number of randomized controlled clinical trials in hospitalized medical patients have demonstrated that prophylactic anti-coagulation or mechanical measures can safely prevent this potentially life-threatening complication. Yet despite the availability of evidence-based guidelines which support the use of prophylaxis, studies in North America and Europe have shown that only 30-40% of the patients who might benefit from this intervention actually receive it (Amin and Deitzelzweig, 2009). Between 2000 and 2004, Kucher et al. (2005) at Brigham and Women's Hospital investigated whether a computer alert program reminding clinicians to use prophylaxis in appropriate patients would increase the use of this treatment and decrease the incidence of deep vein thrombosis (DVT) in hospitalized patients.

A computer program was developed to screen inpatient medical records for the presence or absence of eight common clinical factors that increase a patient's risk of DVT. A risk score was computed and the program then reviewed the charts of patients at increased risk to determine the presence or absence of orders for mechanical (lower extremity intermittent pneumatic compression devices or compression stockings) or pharmacologic (standard or low molecular weight heparin) prophylaxis. The research identified 13,922 patients felt to be at increased risk of DVT of whom 2506 (18%) were not receiving prophylaxis. The 2506 eligible patients were randomized into an intervention group whose physicians received one electronic alert regarding their risk of DVT and a control group where no alert was issued. Physicians receiving the alert had the opportunity to order prophylaxis on the same computer screen by choosing from a list of mechanical and pharmacologic options. The screen also contained a link to the hospitals evidence-based DVT prevention guidelines should the clinician wish to review the evidence.

Prophylactic measures were ultimately ordered for 421/1255 patients in the intervention group and 182/1251 patients in the control group (33.5% and 14.5% respectively, $P < 0.001$). The researchers then followed the patients in both groups for 90 days (both in the hospital and after discharge as outpatients) to see how many sustained a clinically diagnosed DVT or pulmonary embolism. This clinical outcome was, in fact, the primary endpoint of the study. The result was that 4.9% of the intervention group and 8.2% of the control group suffered a thrombotic event during the monitoring period, so the computer intervention decreased the 90 day thromboembolic risk by 41% which was significant at the $P=0.001$ level. From a safety standpoint, there were no significant differences between the groups in major or minor hemorrhage risk or in overall death rate at 30 and 90 days.

I liked this study because it is evaluated both a process outcome and a clinical outcome. It took advantage of the extensive integrated data system that was present at the institution, and the decision support was “successful” in the sense that it did increase the rate of appropriate prophylaxis in a high-risk patient group and decrease the rate of adverse clinical events. Because 82% of the originally identified high risk patients were already on prophylaxis, the effect of the decision support in the entire population was small and there was no effect on overall survival. The study was not blinded, and many physicians had patients in both the intervention and control groups. I am surprised that physicians receiving the alert only put patients on prophylaxis 33.5% of the time. In a population this ill, a significant number patients may have had contraindications to pharmacologic prophylaxis with a heparin type drug, but it is hard to think of a reason why mechanical prophylaxis could not have been used. A subsequent study at another institution used a continuous flashing alert that remained visible to everyone involved in the patient's care until the primary attending physician clicked on the alert button which triggered the display of a chart containing prophylaxis guidelines and a request to order

appropriate prophylaxis (Kucher et al., 2009). This system was more successful in achieving physician compliance than the previous system but did raise some concerns about alert fatigue.

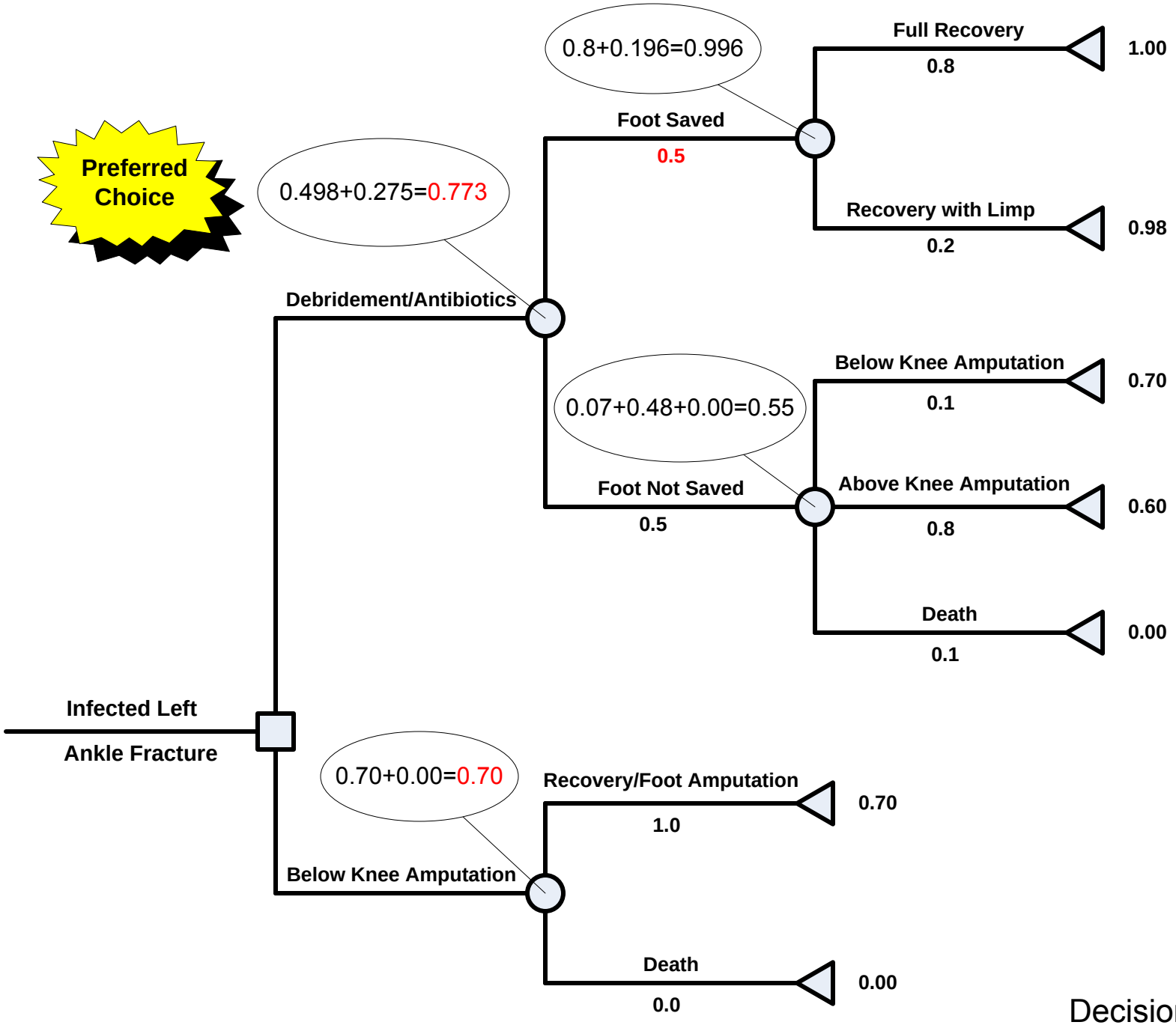
References

Amin, A. and Deitzelzweig, S. (2009). Optimizing the Prevention of Venous Thromboembolism: Recent Quality Initiatives and Strategies to Drive Improvement. *Joint Comm J Qual Pat Safety 35*: 558-564.

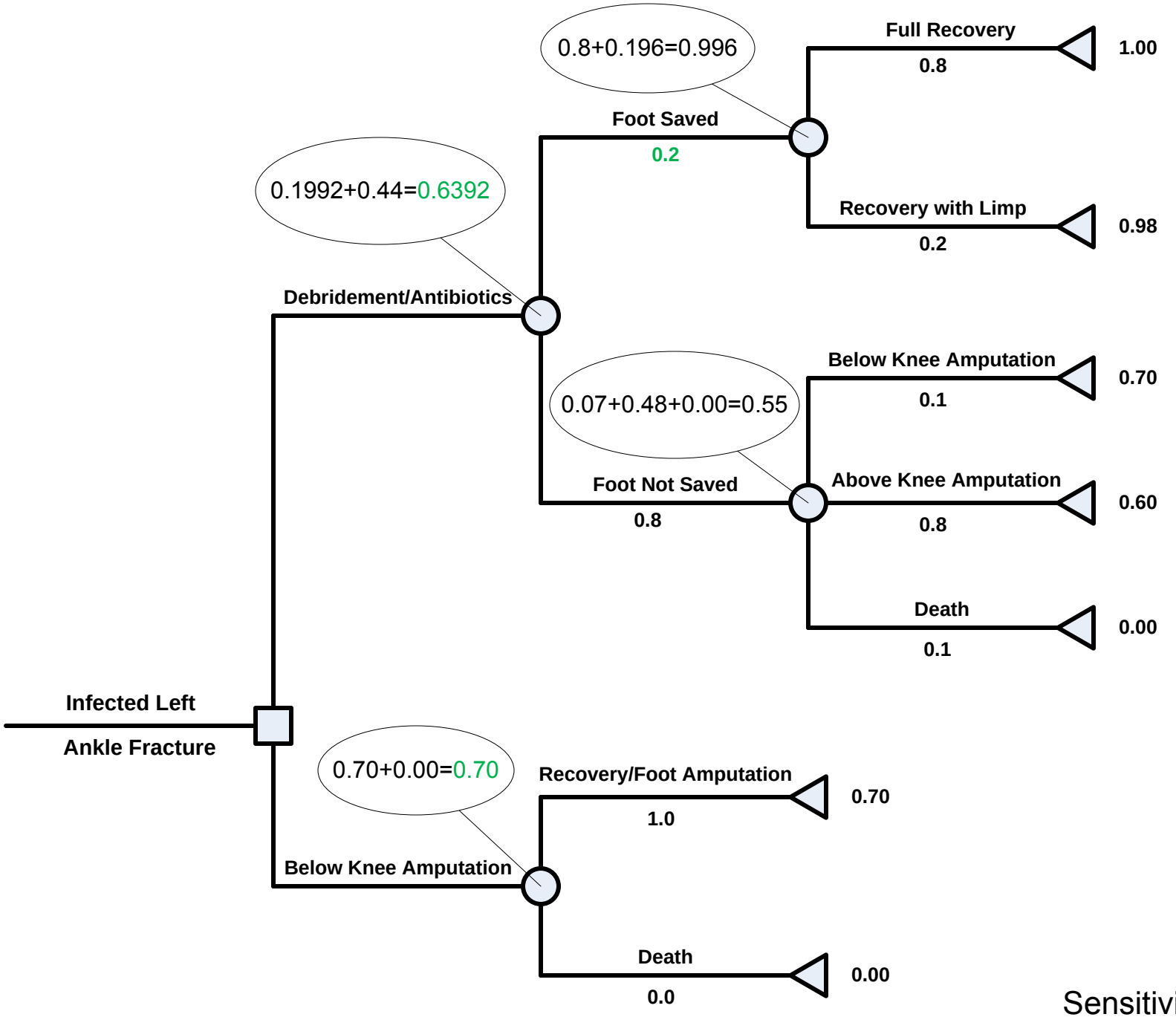
Kucher, N., Koo, S., Quiroz, R., Cooper, J., Paterno, M., Soukonnikov, B., and Goldhaber, S. (2005). Electronic Alerts to Prevent Venous Thromboembolism Among Hospitalized Patients. *N Eng J Med 352*: 969-977.

Kucher, N., Puck, M., Blaser, J., Bucklar, G., Eschmann, E., and Luscher, T. (2009). Physician Compliance with Advanced Electronic Alerts for Preventing Venous Thromboembolism among Hospitalized Medical Patients. *J Thromb Hemostas 7*: 1291-1296

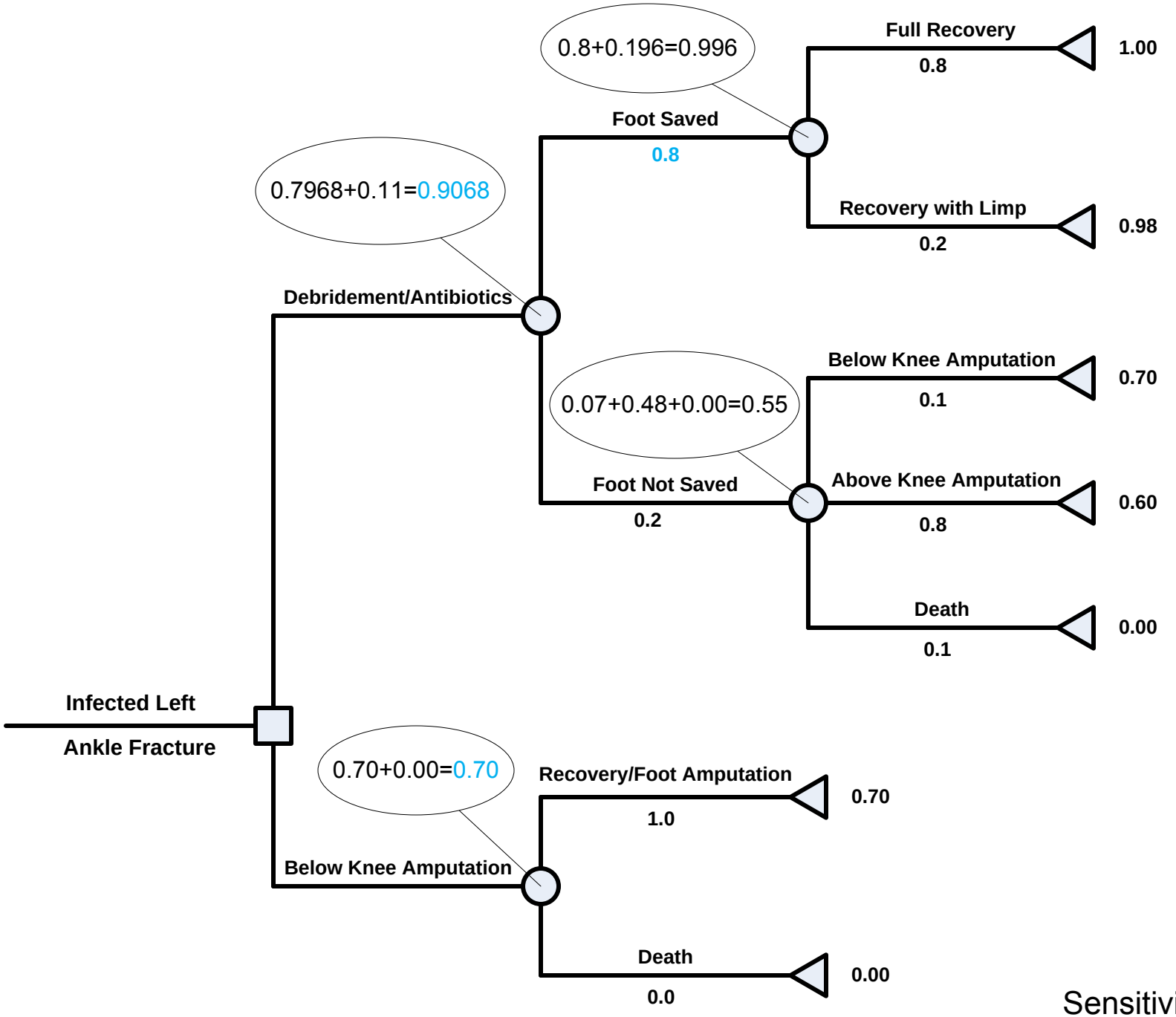
Using a Decision Tree and Sensitivity Analysis to Determine Best Therapy for an Infected Ankle Fracture



Decision Tree Assignment
David M. Schlossman, M.D.
April 15, 2012



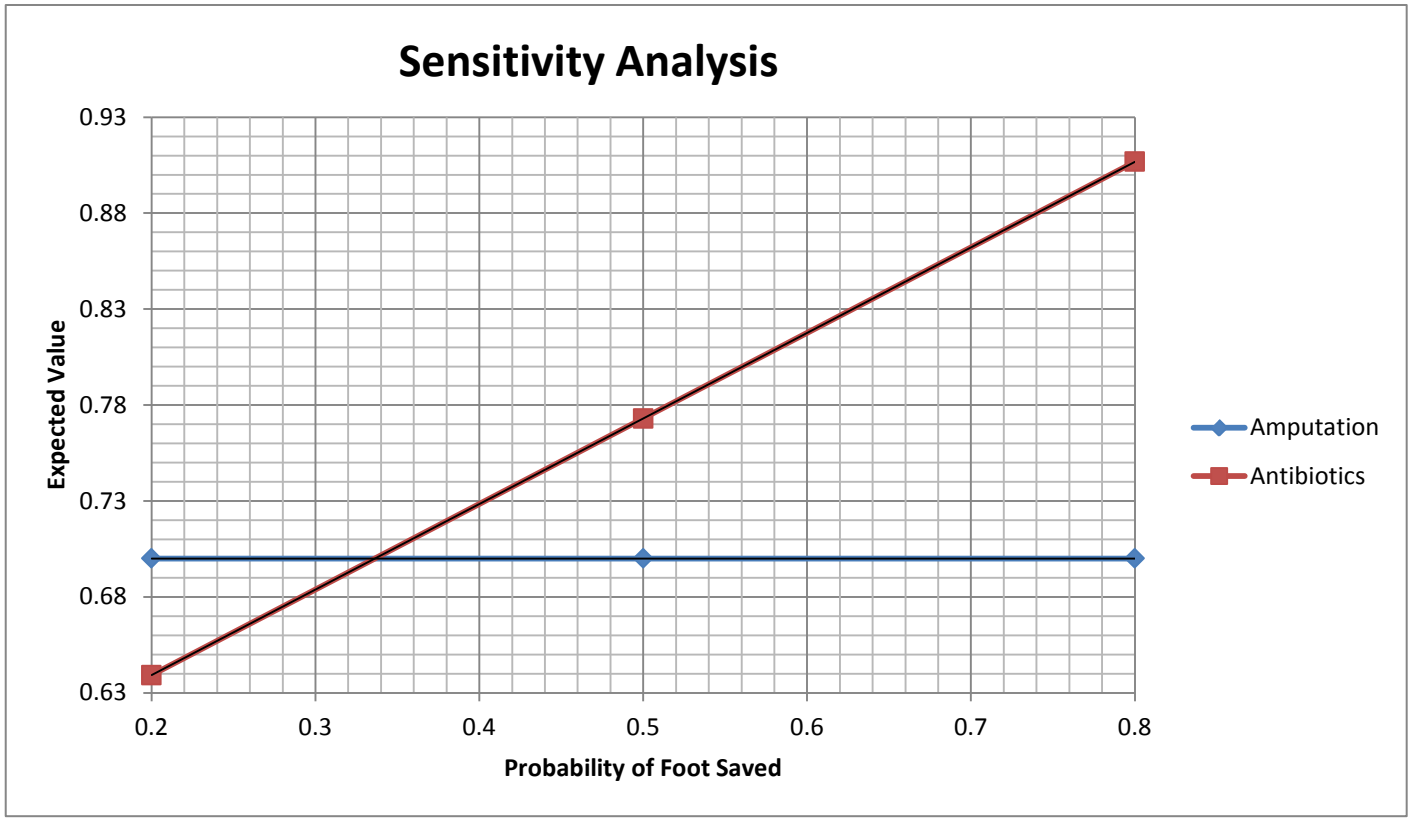
Sensitivity Analysis Lower
David M. Schlossman, M.D.
April 15, 2012



Sensitivity Analysis Upper
David M. Schlossman, M.D.
April 15, 2012

Sensitivity Analysis
David M. Schlossman, M.D.
April 15, 2012

Probability Foot Saved	Expected Values Amputation	Expected Values Antibiotics
0.2	0.7	0.6392
0.5	0.7	0.773
0.8	0.7	0.9068



Probability Threshold = 0.34

Probability Revision Techniques

Session 5 Assignment

David M. Schlossman, M.D.
Medical Informatics 406
Northwestern University

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Technique 1: 2x2 Table

Step 1: Use prevalence to fix column totals. Assume hypothetical cohort of 10000 patients: 13% x 10000 = 1300.

Test Result	Lyme Disease	No Lyme Disease	Total by Row
Positive			
Negative			
Total by Column	1300	8700	10000

Step 2: Use sensitivity to fill in disease column: 81% x 1300 = 1053

Test Result	Lyme Disease	No Lyme Disease	Total by Row
Positive	1053		
Negative	247		
Total by Column	1300	8700	10000

Step 3: Use specificity to fill in non-disease column: 96% x 8700 = 8352

Test Result	Lyme Disease	No Lyme Disease	Total by Row
Positive	1053	348	
Negative	247	8352	
Total by Column	1300	8700	10000

Step 4: Compute row totals: 1053 + 348 = 1401

Test Result	Lyme Disease	No Lyme Disease	Total by Row
Positive	1053	348	1401
Negative	247	8352	8599
Total by Column	1300	8700	10000

a) What is the probability that a Connecticut resident presenting with aseptic meningitis has Lyme disease given a positive result for the test?

Looking at the positive test row, the probability is 1053/1401 = 0.7516 or approximately 75%.

b) What is the probability the person does not have Lyme disease given a negative test result?

Looking at the negative test row, the probability is 8352/8599 = 0.9713 or approximately 97%.

Technique 2: Bayes' Formula

a) As derived in the Hunink and Glaszniou textbook, page 141-142, formula 5.4

$$P(D+|R+) = \frac{P(R|D+)\,P(D+)}{P(R|D+)\,P(D+) + P(R|D-)\,P(D-)}$$

P(R | D-) = 1 – P(R- | D-) so if patient has a positive test

P(Lyme disease | positive test) = $\frac{0.81\ x\ 0.13}{(0.81\ x\ 0.13)+((1-0.96)\ x\ 0.87)} = \frac{0.1053}{0.1401} = 0.7516$

b) Using a derivation similar to the one on page 141-142, we can say

(1) P(R-, D-) = P(D- | R-) P(R-) (joint probability in terms of conditional probabilities)

Divide both sides by P(R-)

(2) P(D- | R-) = P(R-, D-)/ P(R-)

Negative test results can occur as true negatives among the non-diseased and false negatives among the diseased.

(3) P(R-) = P(R-, D-) + P (R-, D+)

Each term on the right hand side of (3) can be factored according to the laws of conditional probability, but we will now condition on the absence of disease rather than on the test result.

(4) P(R-) = P(R- | D-) P(D-) + P (R- | D+) P(D+)

Substituting (4) into (2) gives a modified Bayes' formula conditioned on absence of disease

$$P(D-|R-) = \frac{P(R-|D-)P(D-)}{P(R-|D-)P(D-) + P(R-|D+)P(D+)}$$

So if a patient has a negative test

P(No Lyme disease | negative test) = $\frac{0.96\ x\ 0.87}{(0.96\ x\ 0.87)+((1-0.81)x\ 0.13)} = \frac{0.8352}{0.8599} = 0.9713$