

Biostat 226

Assignment 1: Due 1/19/10 at class time

Do your best to correctly calculate the sample size for the published trial assigned to you, below.

All studies listed are noninferiority trials, all outcomes are binary, and all trials contrast the groups via the difference between rates.

Some publications may not provide all the information you need; in this sense, it provokes a real-world exercise. Make the most of what's presented, and justify your choices.

Some authors may have calculated the sample size incorrectly. The objective is not to replicate what they did but to try to make the correct calculation. Try to identify anything they might have done incorrectly.

Please rely on today's lecture notes, which include the Shiffman et al 2007 example and a link to software: <http://www.epibiostat.ucsf.edu/biostat/joan/>

Please limit your write-up to one page and send it to me at joan@biostat.ucsf.edu

Student	Publication
Nisha Bansal	Stone GW, Lansky AJ, Pocock SJ, et al; HORIZONS-AMI Trial Investigators. Paclitaxel-eluting stents versus bare-metal stents in acute myocardial infarction. N Engl J Med 2009; 360: 1946-59.
Lisa Brown	Topol EJ, Moliterno DJ, Herrmann HC, et al; TARGET Investigators. Do Tirofiban and ReoPro Give Similar Efficacy Trial. Comparison of two platelet glycoprotein IIb/IIIa inhibitors, tirofiban and abciximab, for the prevention of ischemic events with percutaneous coronary revascularization. N Engl J Med 2001; 344: 1888-94.
<i>Classroom Example</i>	Shiffman ML, Suter F, Bacon BR, et al; ACCELERATE Investigators. Peginterferon alfa-2a and ribavirin for 16 or 24 weeks in HCV genotype 2 or 3. N Engl J Med 2007; 357: 124-34.
Tamara Castillo	Reboli AC, Rotstein C, Pappas PG, et al; Anidulafungin Study Group. Anidulafungin versus fluconazole for invasive candidiasis. N Engl J Med 2007; 356: 2472-82.
Adithya Cattamanchi	Kearon C, Ginsberg JS, Julian JA, et al; Fixed-Dose Heparin (FIDO) Investigators. Comparison of fixed-dose weight-adjusted unfractionated heparin and low-molecular-weight heparin for acute treatment of venous thromboembolism. JAMA. 2006; 296:935-42.
Ralph Charlton	Fowler VG Jr, Boucher HW, Corey GR, et al; S. aureus Endocarditis and Bacteremia Study Group. Daptomycin versus standard therapy for bacteremia and endocarditis caused by Staphylococcus aureus. N Engl J Med 2006; 355: 653-65.
Larissa Duncan	Petri M, Kim MY, Kalunian KC, et al; OC-SELENA Trial. Combined oral contraceptives in women with systemic lupus erythematosus. N Engl J Med 2005; 353: 2550-8.
Ramin Farzaneh	Van Gelder IC, Hagens VE, Bosker HA, et al; Rate Control versus Electrical Cardioversion for Persistent Atrial Fibrillation Study Group. A comparison of rate control and rhythm control in patients with recurrent persistent atrial fibrillation. N Engl J Med 2002; 347:1834-

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Elena Flowers	Gallant JE, DeJesus E, Arribas JR, et al; Study 934 Group. Tenofovir DF, emtricitabine, and efavirenz vs. zidovudine, lamivudine, and efavirenz for HIV. N Engl J Med 2006; 354: 251-60.
Maurice Garcia	Ginzler EM, Dooley MA, Aranow C, et al. Mycophenolate mofetil or intravenous cyclophosphamide for lupus nephritis. N Engl J Med 2005; 353: 2219-28.
Jennifer Gibbs	Vincenti F, Larsen C, Durrbach A, et al; Belatacept Study Group. Costimulation blockade with belatacept in renal transplantation. N Engl J Med 2005; 353: 770-81.
Loris Hwang	Walsh TJ, Teppler H, Donowitz GR, et al. Caspofungin versus liposomal amphotericin B for empirical antifungal therapy in patients with persistent fever and neutropenia. N Engl J Med 2004; 351: 1391-402.
Vivek Jain	Abdulla S, Oberholzer R, Juma O, et al. Safety and immunogenicity of RTS,S/AS02D malaria vaccine in infants. N Engl J Med 2008; 359: 2533-44.
Jeremy Keenan	Sundar S, Jha TK, Thakur CP, et al. Injectable paromomycin for Visceral leishmaniasis in India. N Engl J Med 2007; 356: 2571-81.
Christine Kistler	Serruys PW, Morice MC, Kappetein AP, et al; SYNTAX Investigators. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. N Engl J Med 2009; 360: 961-72.
Jeffrey Meadows	Lai CL, Gane E, Liaw YF, et al; Globe Study Group. Telbivudine versus lamivudine in patients with chronic hepatitis B. N Engl J Med 2007; 357: 2576-88.
Justin Parekh	Lacroix J, Hébert PC, Hutchison JS, et al; TRIPICU Investigators; Canadian Critical Care Trials Group; Pediatric Acute Lung Injury and Sepsis Investigators Network. Transfusion strategies for patients in pediatric intensive care units. N Engl J Med 2007; 356: 1609-19.
Michelle Rook	Yadav JS, Wholey MH, Kuntz RE, et al; Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med 2004; 351: 1493-501.
Grace Shih	Buller HR, Davidson BL, Decousus H, et al; Matisse Investigators. Subcutaneous fondaparinux versus intravenous unfractionated heparin in the initial treatment of pulmonary embolism. N Engl J Med 2003; 349: 1695-702. Erratum in: N Engl J Med 2004; 350: 423.
Ramya Srinivasan	Perilongo G, Maibach R, Shafford E, et al. Cisplatin versus cisplatin plus doxorubicin for standard-risk hepatoblastoma. N Engl J Med. 2009; 361:1662-70.
Emily Tan	Loeb M, Dafoe N, Mahony J, et al. Surgical mask vs N95 respirator for preventing influenza among health care workers: a randomized trial. JAMA. 2009; 302:1865-71. Epub 2009 Oct 1.
Erica Wang	Schuetz P, Christ-Crain M, Thomann R, et al; ProHOSP Study Group. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. 2009; 302:1059-66.