risk of TM by hormone receptor status adjusting for age. **RESULTS:** Among the 86255 women with invasive breast cancer, 38621 (45%) underwent TM, 10261 (12%) were Her2 positive, and 9512 (11%) were Black. For Black women with T1 tumors, after adjusting for age, the odds of TM were 1.3 (95% CI 1.1, 1.6) times higher for estrogen receptor (ER)(+) and Her2(+) tumors compared to women who were ER(+) Her2(-), 1.4 (95% CI 1.1, 1.8) times higher for ER(+)Her2(+) compared to ER(-)Her2(-), and 1.4 (95% CI 1.0, 1.8) times higher for ER(-)Her2(+) compared to ER(-)Her2(-). For White women with T1 tumors, after adjusting for age, the odds of TM were 1.4 (95% CI 1.3, 1.5) times higher for ER(+)Her2(+) compared to ER(+)Her2(-), 1.1 (95% CI 1.0, 1.2) times higher for ER(+) Her2(+) compared to ER(-)Her2(-), and 1.7 (95% CI 1.5, 1.9) times higher for ER(-)Her2(+) compared to ER(-)Her2(-). Similar Results were seen for stage T2 tumors. **CONCLUSIONS:** For both Black and White women with early stage tumors, Her2 positivity predicts TM. Further research should investigate the role of Her2 positivity in influencing the surgical decision-making of early stage breast cancer patients.

HM3

A REVIEW OF THE LITERATURE REGARDING BIOSIMILARS: WHAT IS THE EVIDENCE FOR EQUIVALENCE?

Raisch DW[1], Chen C[2], Tuenter H[3], Bennett C[4], IJzerman MJ[5]
[1]*University of New Mexico, Albuquerque, NM, USA,* [2]*University of New Mexico College of Pharmacy, Albuquerque, NM, USA,* [3]*University of Twente, Enschede, The Netherlands,* [4]*University of South Carolina College of Pharmacy, Columbia, SC, USA,* [5]*University of Twente and MIRA Institute for Biomedical Technology & Technical Medicine, Enschede, The Netherlands*

OBJECTIVES: Although European Medicines Association approved 21 biosimilars from 2007-2014; the Food and Drug Administration approved its first, filgrastim, in 2014. Regulatory approvals require pharmacokinetic/pharmacodynamic studies and efficacy/safety trials with fewer patients and shorter durations than for reference biologicals. Cost savings are 20%-30%. However, uptake of biosimilars may be delayed since clinicians and decision makers may have concerns about clinically-relevant differences in effectiveness, safety, and/or immunogenicity. Therefore, our objective was to review published literature regarding studies of effectiveness, safety, immunogenicity, and costs of biosimilars versus reference biologicals. **METHODS:** We searched electronic databases using the term "biosimilar pharmaceuticals" as a major topic, with filters for English language and human species. Our inclusion criteria were: study design for comparison of biosimilars and data included in Results. We excluded editorials, in vitro studies, and descriptive summaries. **RESULTS:** We identified 174 articles. Inclusion/exclusion criteria left 19 equivalence studies for the following: epoetins (n=4, 21.1%), filgrastims (n=10, 52.6%), monoclonal antibodies (MABs) (n=2, 10.5%), tumor necrosis factor blockers and MABs (n=1, 5.3%), and interferon (n=2, 10.5%). The median sample size was 104, but there were 3 large studies (n=6177, n=904, n=606). Fifteen studies (79.0%) reported comparative effectiveness. Most studies also reported on safety (n=12, 63.2%), immunogenicity (n=6, 33.6%), and/or costs (n=3, 15.8%). Cost studies included a budget impact model regarding potential savings from adopting biosimilars versus reference biologics for rheumatic disease, a model of cost savings comparing biosimilar versus reference epoetins, and a survey of uptake and associated cost savings from various biosimilar filgrastims across European Union countries. **CONCLUSIONS:** Most current published data on biosimilar equivalence focus primarily on effectiveness, evaluate relatively small numbers of patients, and report minimal data on safety, immunogenicity, or cost savings. To increase uptake, biosimilar manufacturers and regulators should consider conducting post-marketing surveillance research to provide additional data on safety, immunogenicity and costs.

HM4

HOW MUCH EVIDENCE DO WE NEED BEFORE IMPLEMENTING PHARMACOGENOMIC TESTING IN THE CLINIC?

Guzauskas GF, Serbin M, Veenstra DL
University of Washington, Seattle, WA, USA

OBJECTIVES: Consensus on the evidence required to recommend clinical pharmacogenomic testing is unclear. A formal assessment of pharmacogenomic evidence levels in relation to other clinical interventions, such as avoiding drug-drug interactions (DDI), may be helpful for policymakers. The objective of this study was to quantitatively compare the evidence levels of two contested drug-attenuating interactions with clopidogrel antiplatelet therapy, and assess the value of obtaining additional evidence to inform clinical practice guidelines. **METHODS:** We developed analogous value of information (VOI) decision models for: (1) avoidance of proton pump inhibitors (PPIs) in clopidogrel patients, and (2) pharmacogenomic-guided antiplatelet selection, both versus no intervention. Interaction-specific parameters and model structures were the only dissimilarities. We calculated the expected value of obtaining perfect information (EVPI) per patient, and the expected population value of obtaining additional information through future studies (EVSI). **RESULTS:** Current evidence for interaction-1 was slightly less uncertain (a 20% probability of making a non-optimal recommendation) than for interaction-2 (23%). The relative risk for cardiovascular death (conferred by concomitant PPI use in interaction-1, and reduced-function CYP2C19 alleles in interaction-2) was the greatest source of uncertainty in both models. The expected value of perfect information for interaction-1 was $139 per patient, compared to $242 per patient for interaction-2. In simulated 10,000-patient clinical trials, the expected population value of future research for interaction-1 was $2 million, versus $110 million for interaction-2. **CONCLUSIONS:** The evidence levels for clopidogrel DDI and pharmacogenomic effects appear to be fairly similar. However, the value of conducting future research on clopidogrel pharmacogenomics is higher because of greater uncertainty about the impact of pharmacogenomic testing on cardiovascular mortality. Our findings imply that evidence-based clinical guidelines for DDI and pharmacogenomic effects should be generally similar with regard to direction and strength of recommendation. This contrasts to some degree with current guidelines and drug labeling.

MEDICATION ADHERENCE STUDIES

MA1

IMPACT OF A PHARMACIST MEDICATION ADHERENCE CONSULTATION PROGRAM ON HEALTH CARE COSTS AND RISK OF HOSPITALIZATION

Wade RL[1], Hill JW[1], Akinbosoye O[2], Jiang Z[2], Mu Y[2], Sun K[1], Karkare S[3], Taitel MS[2]
[1]*IMS Health, Plymouth Meeting, PA, USA,* [2]*Walgreen Co., Deerfield, IL, USA,* [3]*IMS Health, Deerfield, IL, USA*

OBJECTIVES: Non-adherence is associated with poorer health outcomes and increased costs. This study evaluated the impact of a community pharmacist medication adherence consultation on health care costs and the risk of hospitalization. **METHODS:** Patients initiating therapy within 16 drug classes were offered face-to-face or telephonic consultations by a Walgreens pharmacist between 2/7/2013 – 10/6/2013. Consultation included motivational interviewing focused on fitting medication-taking behavior into patients' daily routine, and removing barriers to adherence. Patients were assigned to two groups according to the intensity of consultation: no consultations (NC) and $\geq$ 1 consultations received (CR). Patients were linked deterministically to the IMS Health PharMetrics Plus database such that 6 months of pharmacy and medical claims data pre and post their index date could be analyzed. Cost differences from the pre to post-index periods were compared between NC and CR groups, using difference in differences estimation in a GLM model, controlling for demographic and clinical confounders. **RESULTS:** CR patients (n=58,449) and NC patients (n=53,870) had similar age (48.2 vs. 47.7 years), gender (59.0% vs. 57.7% female) and disease burden (0.61 vs. 0.58 for Charlson Comorbidity Index, CCI). CR patients incurred significantly lower pre- to post-index GLM-adjusted total health care costs (-$266/-4.3% lower, p=0.001), comprised of lower inpatient (-$231, p=0.009), lower pharmacy (-$43, p<0.0001), and similar outpatient costs (-$36, p=0.279); and had a lower probability of hospitalization (OR: 0.92, 95% CI: 0.86, 0.98, p=0.009). CR patients with a CCI equal to 1-2 realized the greatest cost savings (-$688, p=0.001) compared to patients with CCI=0 (-$106, p=0.051), and CCI$\geq$3 ($575, p=0.293). **CONCLUSIONS:** Patients receiving structured pharmacist consultations focused on improving medication adherence were shown to have significantly lower health care costs and risk of hospitalization. Ongoing studies will explore underlying relationships between program participation, adherence, and impact on health outcomes and costs.

MA2

COST OF NON-ADHERENCE TO MEDICATION IN A POST-MI POPULATION

Garrido E[1], Arnold RJ[1], Bansilal S[2], Castellano JM[2], Wei HG[3], Freeman A[4], Garcia-Alonso F[5], Espinosa C[5], Lizano I[5], Spettell C[4], Steinberg G[3], Fuster V[2]
[1]*Icahn School of Medicine at Mount Sinai, New York, NY, USA,* [2]*The Mount Sinai Medical Center, New York, NY, USA,* [3]*Aetna, New York, NY, USA,* [4]*Aetna, Data Science, Hartford, CT, USA,* [5]*Ferrer, Barcelona, Spain*

OBJECTIVES: We have previously demonstrated that full adherence with ACE-Inhibitors (ACEI) or statins in a post-myocardial infarction (MI) population is associated with lower rate of cardiovascular (CV) events compared to partial- or non-adherence. Herein, we sought to determine the direct medical costs attributable to partial- and non- adherence to these therapies. **METHODS:** Data on CV events and resource utilization were collected through a retrospective, nested cohort study in a large US insurer database. We also analyzed two national files for physician and non-physician unit cost weighted averages of CV events (stroke, MI, atherosclerosis or angina), procedures (revascularization and CV tests) and visits (emergency room and outpatient CV visits). We estimated per person cost differences between adherence groups and the sensitivity of the Results using weighted and unweighted averages. A third-party payer economic perspective was adopted; all costs were expressed in 2014$. **RESULTS:** The estimated per patient weighted average annual cumulative medical costs were $5,153 for adherent, $6,470 for partially-adherent and $6,767 for non-adherent patients. This difference was mainly driven by a lower rate of CV events and revascularizations for adherent patients. Applying referenced unweighted averages, we estimated that the MI reference unit cost was $4,325 higher than the weighted average cost (p<0.001); the CV test unit cost was $1,010 higher than the weighted average cost (p=0.001). Using national prevalence data for incident MIs and medication adherence, we project that full adherence may lead to annual savings of $98.2 million and $100.9 million over partial- and non-adherence, respectively. **CONCLUSIONS:** Full adherence to statins and ACEI was associated with reduced per patient monthly direct medical costs of $109.7 and $134.4 over partial- and non-adherence. Using unweighted, rather than weighted, averages overestimated the economic impact, indicating the importance of data type in such analyses. Full adherence to guideline-recommended therapies has tremendous cost-saving implications.

MA3

THE EFFECT OF COST-RELATED MEDICATION NONADHERENCE ON THE DECISION OF TAKING UP MEDICARE PART D AMONG ELDERLY MEDICARE BENEFICIARIES

Han Y, Balkrishna R
University of Michigan, Ann Arbor, MI, USA

BACKGROUND: The sizable fraction of the elderly adults who are left without Part D coverage indicates there are potential barriers in taking up Part D, including information barriers and economical barriers. Few studies have examined how cost-related medication nonadherence (CRN) affected the willingness of taking up Part D among elderly adults using national representative data. **OBJECTIVES:** To estimate the impact of self-reported CRN on the decision of taking up Medicare Part D among Medicare beneficiaries age 65 and above who did not have Part D coverage in 2006 incorporating the effect of complex sample survey design. **METHODS:** This retrospective cross-sectional study used data from the 2006 Health and Retirement Study database (2006 HRS). Information on patient demographics, social and economic factors and health insurance coverage were obtained by survey. The dual-eligible beneficiaries were excluded due to automatically enrollment. A total of 5,826 eligible