

Wyoming Preferred Drug List Advisory Committee
Minutes
April 15, 2004
Cheyenne, Wyoming

Members Present: Marion Smith, Bill Harrison, Scott Johnston, Becky Drnas, Chad Panning, Bill Marsh, Bob Schultz, Joyce Dailey,

Ex-officio: Gary Melinkovich, Aimee Lewis, Deb Devereaux (by phone)

Members Excused: James Broomfield, Mike DeBisschop

Guests: Laura Miller, Sandra Deaver, Antoinette Brown, Mark Helfand (by phone – EPC), Susan Carson (by phone – EPC), UW Intern Kate Ramirez, Barbara Boner (Novartis), Betty Iverson (Wyeth), Dyan McGrath (Astra Zeneca), Susan Trieu (Astra Zeneca), Paul Houghton (Ortho-McNeil), Matt Martin (Ortho-McNeil), Nancy Brown (Pfizer), Jon Siler (BMS), Brad Cheney (BMS), Emilie Senecal (BMS), Scott Willard (Boehringer Ingelheim), Dennis Sagendorf (Purdue), Jeff Jenkins (Merck), Brian Leugs (PhRMA), Debbie Kavanaugh (Pfizer Medical), Jillmarie Yanchick (Pfizer Medical), Merrell Magelli (Pfizer Medical), Chris Lepore (Johnson & Johnson), Vaun Olhausen (Schering-Plough), Lori Howarth (Berlex), Robert Calder (Merck)

The meeting was called to order with introductions and comments by Aimee Lewis at 10:00 am. PDL Process and Mission Statement for committee were reviewed.

Statin Review:

Mark Helfand, MD, gave an overview of the Statin review. Discussion included summary of the Prove-It trial and implications for the Statin report.

Public Comments:

Dr. Robert Calder (Merck) commented on stroke data recently published. Zocor resulted in a 25% reduction in risk of stroke. Statement on page 27 of Statin review does not reflect current Zocor labeling regarding maximum dose that can be used with gemfibrozil and niacin.

Susan Trieu (Astra Zeneca) asked the committee to consider dose equivalences when considering Crestor in addition to HDL raising effect and the number of patients who reach goal levels.

Debbie Kavanaugh (Pfizer) discussed the Ascot trial which was stopped early due to positive results with Lipitor. Ms. Kavanaugh emphasized the flexible starting dosage of Lipitor.

Jon Siler (BMS) emphasized prescriber choice and the safety data for Pravachol. Mr. Siler asked the committee to preserve unrestricted access to Pravachol. Emilie Senecal spoke about the decreased risk of drug-drug interactions with Pravachol as it is not metabolized via cytochrome P-450.

Committee Discussion:

Question 1: Does the evidence show that one statin is more effective than another?

In general, they are all equal if want less than 40% lowering of LDL. Increase in HDL is important, and all statins result in increased HDL although not significantly. Crestor seems to better at raising HDL levels, however, results are mixed and not conclusive.

Committee should focus more on clinical outcomes. Rosuvastatin vs. placebo or head to head trials not available. Two possibilities should be considered: 1. Rosuvastatin works the same so should have the same effect. 2. Long term benefit and toleration are not known.

DECISION: ALL STATINS ARE EQUALLY EFFECTIVE AT EQUIVALENT DOSAGES

Motion by Scott Johnson, Second by Bill Harrison, all in favor, none opposed

Question 2: Does the evidence show that one statin is safer than another?

Marion Smith began the discussion by saying that some are safer in terms of side effects, especially when high doses are used. Drug-drug interactions were discussed. Pravastatin and fluvastatin have lowest potential for drug interactions followed by rosuvastatin.

Question regarding rosuvastatin and renal failure.

Susan Trieu (Astra Zeneca) clarified drug interactions with rosuvastatin. Crestor is hydrophilic in nature and is not metabolized by cytochrome P-450 system, which results in fewer drug interactions. Ms. Trieu also clarified that renal failure was more common at doses of 80mg. Because the LDL lowering was not greatly increased at this dosage and side effects were much worse, approval of 80 mg dosage was not sought.

DECISION: ALL STATINS ARE EQUALLY SAFE WITH SOME ADVANTAGE TO PRAVASTATIN AND ROSUVASTATIN. *THIS WAS LATER CLARIFIED TO INCLUDE FLUVASTATIN.**

Motion by Scott Johnston, Second by Becky Drnas, all in favor, none opposed.

Proton Pump Inhibitor Update:

Susan Carson, MPH, (EPC) gave an overview of the updated PPI review.

Committee Discussion:

DECISION: ALL PROTON PUMP INHIBITORS ARE EQUALLY SAFE AND EFFECTIVE.

Motion by Bill Harrison, Second by Bill Marsh, all in favor, none opposed.

Non-Steroidal Anti-inflammatory Drug (NSAIDs) review:

Mark Helfand, MD, gave an overview of the NSAID report.

Public Comments:

Dr. Robert Calder (Merck) discussed the increase in heart attacks with Vioxx during the VIGOR trial. While there was an increased risk, the reason for this is not known. It may be due to a protective benefit from naproxen. There is not enough evidence to show the actual cause. Vioxx was also recently approved for acute migraine pain.

Scott Willard (BI) mentioned that Mobic does not currently require prior authorization. Mr. Willard referred to page 45 in the study which showed the withdrawal rate due to side effects. Mobic has a lower rate of withdrawal than diclofenac. Mobic is approved for osteoarthritis, not rheumatoid arthritis.

Jillmarie Yanchick (Pfizer) spoke about Bextra and Celebrex. The American Pain Society says that these are better than the others. Ms. Yanchick said that the average age of Wyoming Medicaid clients is 57 years. 20% of those on NSAIDs have ulcers, while 0% on Celebrex and Bextra have ulcers. Ms. Yanchick also pointed out the cardiac warning on rofecoxib due to hypertension.

Committee discussion:

There are two questions to be considered – Effectiveness and Safety. If effectiveness is the same, then safety becomes the key. There is no evidence that shows that Mobic reduces GI events. Rofecoxib has the advantage of fewer GI events, but disadvantage of increased cardiac events.

DECISION: THERE IS NO DIFFERENCE BETWEEN TRADITIONAL NSAIDs AND COX – IIs IN EFFECTIVENESS.

Motion made, seconded and all in favor.

There is increased cardiac side effects with rofecoxib. The Class trial was never published regarding celecoxib, and there are no studies on valdecoxib safety.

DECISION: COX – IIs ARE SAFER THAN TRADITIONAL NSAIDs FOR GI BLEEDING. COX – IIs HAVE INCREASED RISK FOR THROMBOTIC EVENTS THAN TRADITIONAL NSAIDs.

Motion made, seconded and all in favor.

Aimee Lewis suggested that they break the class into subgroups including traditional NSAIDs and COX – IIs.

DECISION: THERE IS NO EVIDENCE THAT ONE TRADITIONAL NSAID IS MORE EFFECTIVE THAN ANOTHER TRADITIONAL NSAID; ONE SEMI-SELECTIVE IS MORE EFFECTIVE THAN ANOTHER SEMI-SELECTIVE; OR THAT ONE COX – II IS MORE EFFECTIVE THAN ANOTHER COX – II.

Motion made, seconded and all in favor.

A question was raised regarding the clinical significance of allergic reactions associated with the COX – IIs. The committee felt that this was a decision that should be made by each individual practitioner. Dr. Helfand responded that this was not addressed in the studies reviewed.

DECISION: THERE IS NO EVIDENCE THAT SHOWS THAT ONE TRADITIONAL NSAID IS SAFER THAN ANOTHER TRADITIONAL NSAID. THERE IS INSUFFICIENT EVIDENCE TO SHOW THAT ONE COX – II IS SAFER THAN ANOTHER COX – II.

Motion made, seconded and all in favor.

There being no further business, the meeting was adjourned at 1:10 pm by Dr. Marion Smith.