1040 Outcomes Research With Policy Implications

Sunday, March 07, 2004, Noon-2:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 1:00 p.m.-2:00 p.m.

1040-67 The Impact of the National Privacy Act on the Effectiveness and Costs of a Six-Month Follow-Up Study of Acute Coronary Syndromes

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Objective: To determine the potential impact of the new privacy act (HIPAA) on post discharge outcomes (effectiveness and costs) in patients with Acute Coronary Syndromes (ACS).

Methods: We studied follow-up (FU) success at 6 months, and costs of FU in two cohorts of consecutive discharges with ACS between 5-1-99 and 4-24-03 at the University of Michigan Health System. The first interval represented usual outcomes assessment, with 6 month phone interviews which first sought verbal consent from patients, then proceeded with a brief questionnaire. In the second interval, using methodology recommended by our IRB as being HIPAA compliant, we first mailed a consent to each discharged patient, asking permission to call the patient in order to add their clinical data to a database and obtain FU information. We tracked overall success of consent for the 6 month FU, incremental costs of securing FU, including estimated materials, mailing, phone, personnel costs, and assessed for differences in types of patients successfully consented.

Results: Overall consent for FU dropped from 96.5 % to 35.9% after initiation of HIPAA compliant procedures, p<.0001. Per patient costs increased by an estimated $17.00. More than one half of patients did not reply to the consent letter. After receiving the letter, 2.6% of patients refused to be contacted and 1.5% of letters were returned to sender. Patients successfully consented for FU after HIPAA were more likely to be married (p<.0001), older (p=0.01) and have a history of hypertension (p<0.004) or hyperlipidemia (p=0.04) versus those that did not respond, refused, or never received the letter. Widowers were less likely to respond (p<.0001). There were no differences with regard to gender, or other comorbid conditions between those that did or did not consent.

Conclusions: Adjusting outcomes research methodology to accomodate new regulations associated with HIPAA resulted in substantial reduction in our ability to successfully track care patterns and outcomes in pts discharged after admission for ACS, and was associated with greater costs. This pilot study suggests that HIPAA may significantly alter the way we study long term patient outcomes in cardiology.

1040-68 Excessive Inducement Into Clinical Trials Using Monetary Incentives: Truth or Fallacy?

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Background: While use of monetary incentives to enhance recruitment into clinical trials is controversial, scant empiric data exist on how monetary incentives actually influence patients' enrollment decisions. Thus, we asked whether and to what degree monetary incentives influence patients' willingness to participate (WTP) in a cardiovascular clinical trial.

Methods: From 13 Maryland-based cardiology and medicine clinics, we approached 1440 randomly selected patients to participate in a cross-sectional, self-administered survey, which contained a 1-page description of a cardiovascular drug trial with random assignment of a different level of monetary incentive. Monetary incentive for joining randomly varied between $25, $250, $500, $750, and $1250. Using 5-point Likert response scaling, patients reported their WTP (0 = not at all likely, 5 = very likely) and their rated importance of joining a trial for altruistic reasons and for receiving monetary incentive.

Results: 789 (70%) of 1132 eligible individuals responded. Magnitude of monetary incentive had no impact on WTP (WTP=32%, 36%, 34%, 33%, 38% for $25, $250, $500, $750 and $1250 respectively, p=0.80), even after stratifying individuals by socioeconomic status, age, gender, and race. Individuals who considered monetary incentive important to join a trial, however, expressed greater WTP (OR=1.24, 95% CI 1.11-1.38, p=0.001 per ordered increase in importance), as did individuals who considered it important to join a trial to help other people (2.32, 95% CI 1.92-2.81, p=0.001 per ordered increase in importance). Lower income and education levels were both strongly and independently associated (1.33, 1.08-1.63, p=0.01 and 1.66, 1.26-2.16, p=0.001 per ordered decrease in income and education, respectively) with reports of monetary incentive being either extremely or very important to joining a trial. All subgroups felt similarly about the importance of joining a trial to help other people.

Conclusions: Monetary incentives did not adversely influence WTP in this hypothetical experiment, although persons with lower income and education were more likely to believe that monetary incentives are important for joining trials.