COST-MINIMIZATION ANALYSIS OF SEROLOGIC SCREENING POLICY OPTIONS FOR US ARMY ACCESSION IMMUNIZATIONS

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OBJECTIVES: To develop a cost-minimizing protocol to reduce the administration of unnecessary immunizations through the use of serologic screening to antibodies against selected diseases for which enlisted accessions to the US Army currently receive universal immunization. METHODS: A detailed decision tree containing over 180,000 terminal nodes was constructed using TreeAge software to model the variable costs of serologic screening and immunization series delivery among four policy options: 1) current policy, involving selective varicella serology based on history; 2) universal hepatitis B serology with selective varicella serology; 3) universal serology for hepatitis B, varicella, measles and rubella; and 4) universal serology for hepatitis A and B, varicella, measles and rubella. Parameters for the model included levels of pre-existing immunity to each disease, rates of attrition between vaccine doses, current vaccine and serologic screening costs, and test sensitivity and specificity. Outcome measures included total variable costs per accession, and probability of missed immunization due to false positive test results. Due to the complexity of the tree, expected values were calculated via 10,000 runs of microsimulation repeated 1000 times to construct confidence intervals. RESULTS: All policy options with universal serologic screening demonstrated significant variable cost savings over current policy. Policy option three minimized costs, with savings of $22.71 per accession (95% CI $22.68–$22.74). Cost savings were qualitatively robust to probabilistic sensitivity analysis. Numbers of missed immunizations due to false positive test results were comparable between current and proposed policies, with policy option three resulting in only 244 additional missed immunizations per 100,000 accessions (95% CI 233–256) relative to current policy. CONCLUSIONS: Due to high levels of pre-existing immunity, enlisted accessions to the US Army currently receive multiple unnecessary immunizations. Universal serologic screening to hepatitis B, measles, rubella, and varicella provides significant variable cost savings without a clinically significant increase in disease susceptibility.

BRIEF SUMMARY FORMATS OF DTCA TO IMPROVE CONSUMER COMPREHENSION

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OBJECTIVE: In January 2004, the Food and Drug Administration (FDA) proposed guidelines for the brief summary section of prescription drug direct-to-consumer advertisements. In particular, they mentioned regarding the current consumer unfriendly format which caused information overload and the overall suboptimal usefulness of the brief summaries and requested feedback to improve it. The objective of this study was to develop and evaluate brief summary formats which would be favorable for consumers and to provide practical implementation of FDA’s suggestions. METHODS: A randomized within subjects study was conducted to compare effectiveness of four (2 pre-existing and 2 experimental) brief summary formats. All four formats contained the same information appearing in the brief summary for the prescription drug Pravachol®. A pre-validated reliable survey instrument was administered to students enrolled in the college of pharmacy in second year (N = 70) and third year (N = 77), to test the effectiveness of formats developed on ease of use, attitude towards formats, and satisfaction towards formats. RESULTS: Multivariate analysis of variance test conducted on the data (N = 147), indicated significant positive effect of experimental brief summary format on all measured variables (Wilks’s lambda, p < 0.001). Individual analysis of variance tests on mean scores for the four formats followed by post-hoc Scheffe test revealed that currently existing formats had the lowest scores with respect to ease of use, attitude towards formats, and satisfaction with formats as compared to experimental formats developed. CONCLUSION: The educational potential of the brief summaries may not be served if consumers do not attempt to read them due to their poor design and low readability formats. The FDA should consider these findings and provide clear guidelines to the industry to improve information and format of brief summaries which may improve the expected outcomes associated with these summaries as information sources for consumers.