

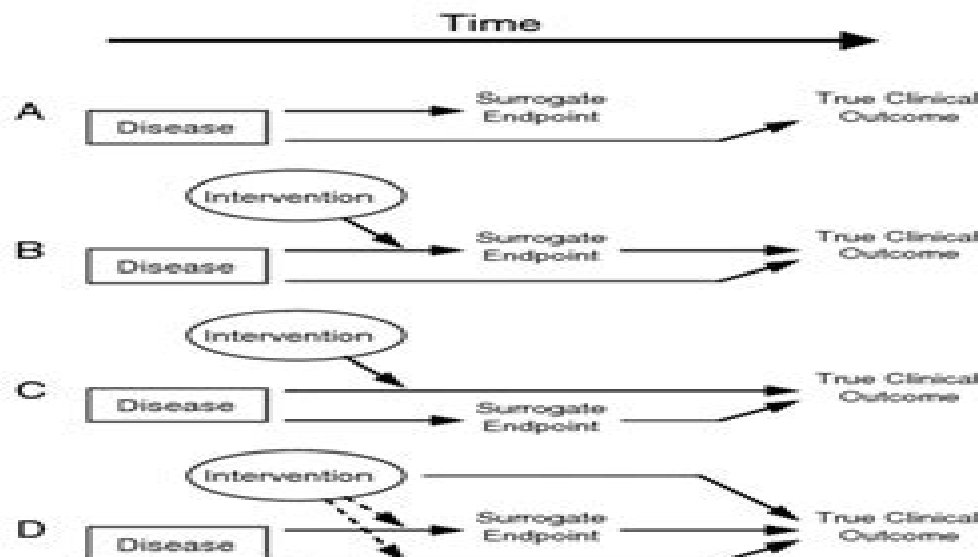


FIGURE 7-1 Reasons for failure of biomarker (surrogate) endpoints. (A) The surrogate is not in the causal pathway of the disease process. (B) Of several causal pathways of disease, the intervention affects only the pathway mediated through the surrogate. (C) The surrogate is not in the pathway of the intervention's effect or is insensitive to its effect. (D) The intervention has mechanisms of action independent of the disease process.

NOTE: Dotted lines = mechanisms of action that might exist.

SOURCE: Fleming and DeMets, 1996. Adapted, with permission, from the *Annals of Internal Medicine*. Copyright 1996 by the American College of Physicians.

case occurs in mother-to-child transmission of HIV. In pregnant women with HIV, there is a very strong negative correlation between maternal CD4 (helper T-cell) count and likelihood of HIV transmission to the infant, he said. Thus, one might suppose it would be useful to give the mother interleukin-2 (IL2) late in pregnancy in order to raise her CD4 count closer to normal levels. However, doing so has no effect on transmission because CD4 count is not part of the causal mechanism for HIV transmission.

Many diseases have biomarkers that are not in their pathophysiologic pathways, Dr. Fleming noted. Examples include carcinoembryonic antigen, a biomarker for ovarian cancer, and prostate-specific antigen (PSA); such biomarkers are useful for disease diagnosis and assessing prognosis,

Perspectives On Biomarker And Surrogate Endpoint Evaluation Discussion Forum Summary

JR Anderson



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