

HEART OF THE MATTER

Translating Clinical Trials to the Medicare Patient

The translation of clinical trial results to the bedside has always been a complex and often uncertain exercise. The specific patient who precisely fits the evidence-based data is usually the exception to the rule.

Randomized clinical trials by their nature are focused on specific disease states with the exclusion of other concurrent medical problems. They include populations that often have little resemblance to the patients that you and I see in the clinic or hospital free of any comorbidity. The entry restrictions are crafted to identify patients who are most likely to benefit from the drug or device under study and to ensure their safety during its progress. Although not exclusive to the younger patient, the trials tend to recruit younger patients with little comorbidity.

The demographic restrictions on the design and management of clinical trials make it even

more difficult to apply their results to guidelines and quality standards. Unfortunately, we have few data which reflect on either the safety or efficacy when "proven" therapy is applied to the general and particularly the Medicare patient.

The Medicare population is considerably older than patients entered into randomized clinical trials, with a greater mortality and morbidity burden of comorbid disease. However, they now represent the majority of patients admitted to the hospital with acute myocardial infarction. A recent publication using data collected over 9 years from 1992-1993 to 2000-2001 from the Medicare database sheds light on important trends that occurred in that population from that period (Circulation 2006;114:2806-14).

During that time, the Medicare MI patients increased in age from 75.7 years to 78.3 years and a quarter of those patients were

over 85. The incidence of ST-segment elevation MI decreased from 37.4% to 23.5%. Because of the increased incidence of concomitant morbidity such as diabetes, chronic renal disease, and pulmonary disease, only about a third of patients surviving their MIs were "ideal patients" to whom guidelines or quality standards could be applied. During the study period the days in the hospital decreased from 10.1 days to 6.9 days. Although mortality adjusted for comorbidity had decreased during that period, the 1-year crude mortality increased from 27.6% to 31.0%.

It is clear from these observations that much of the clinical trial research that influences "evidence-based" medicine does not fully describe the reality of the world we function in. The science of clinical trials, highly refined in the last 50 years, has provided an immense amount of information about medical therapeutics. Yet it provides only a snapshot in time in a clinical environment that is changing rapidly around us. This is particularly true when studying degenerative diseases such as cardiovascular disease, which is

influenced by a rapidly aging population. This study emphasizes the striking difficulty associated with the application of MI guidelines and standards to the Medicare population that has to a large degree been essentially excluded from contemporary clinical research studies. It is clear that a more dynamic access to the Medicare database could provide important insight into the risks and benefits of cardiac ther-

apy. The sooner we have that information, the sooner we can be more effective at applying appropriate therapy to the real world and our aging patients. ■

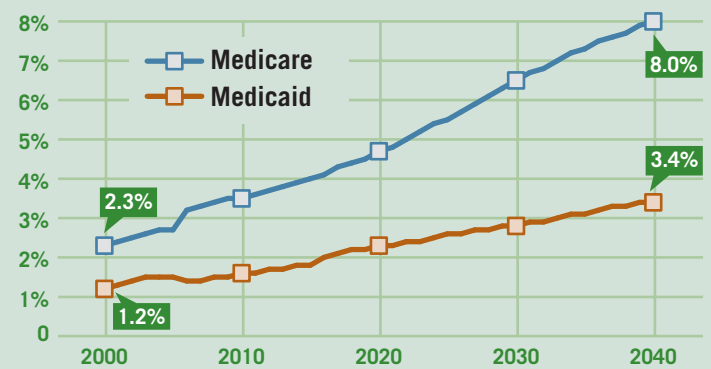
DR. GOLDSTEIN, *medical editor of CARDIOLOGY NEWS, is professor of medicine at Wayne State University and division head, emeritus, of cardiovascular medicine at Henry Ford Hospital, Detroit.*



BY SIDNEY GOLDSTEIN, M.D.

DATA WATCH

Medicare Expected to Increase at a Faster Rate Than Medicaid as Percent of GDP



Notes: Based on 2005 and 2006 data. GDP is gross domestic product. Source: Government Accountability Office

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