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The Urgent Need for More Clinical Pharmacology Studies in Older Patients to Improve Drug Therapy in a Rapidly Growing at Risk Cohort

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It is widely appreciated that the increasing fraction of public and private resources devoted to the maintenance of human health is unsustainable into the future [1,2]. With increasing age comes an increasing probability of acquiring chronic diseases that involve drug therapy as a major component of the management plan. It is increasingly clear that the elderly demonstrate a greater variability in their response to drug administration in comparison to their younger cohorts [3]. The Institute of Medicine Report indicated that drug therapy is associated with a substantial burden of morbidity and mortality that impacts resource utilization [4]. Thus, it is in the interest of society to implement strategies that are likely to minimize the fraction of health care resources devoted to resolving these drug-related adverse patient events.

The United Nations report on human demographics clearly indicates an increasing fraction of the population that is considered elderly [5]. We have some long-standing data that support the expectation that use of drug therapy as a component of their health maintenance is likely to result in unexpected outcomes, compared to the conventional wisdom presently available in the scientific literature. It is clear from already published studies that the physiological homeostatic response is compromised in the elderly. Thus, its perturbation with drug administration might be expected to result in a greater risk to maintenance of their ability to live independently, and to access inordinate amounts of resources as a consequence [6]. Recent published findings illustrate that in spite of our increasing knowledge of these issues over the last more than 40 years, adverse responses to drug therapy continue to contribute a large fraction of visits to Emergency Departments of hospitals and they increase rapidly and continuously with older age [7]. One strategy to reduce the cost of development of newer and more efficacious drug therapies involves the measurement of biomarkers that are expected to precede the occurrence of more severe morbidity, and that is believed to impact on resource utilization of the health care system. This vision is presently insufficiently developed and validated, and has resulted in misleading recommendations for the optimization of drug use in patients in general and in the elderly cohort in particular [8]. In addition, insufficient elderly patients are included in many clinical pharmacology studies to provide data that might inform optimization of their drug therapy [9].

Given the reticence of many elderly patients to further inconvenience their activities of daily living by participation in drug studies, it will be difficult to accrue strong and robust data that will inform better utilization of prescribed drugs in management of their multiple and mostly chronic diseases. It is generally proposed that older patients have in increased pharmacodynamic response to many drugs to which they are exposed [10]. Thus, multisite studies are almost certainly to be required. Given the fact that this problem is not isolated to the first-world nations, international studies appear to be a reasonable consideration as a strategy to accumulate this knowledge over a relatively brief time period. With the increased heterogeneity of the elderly cohort due to reduced physiologic homeostatic capacity and the burden of multiple and chronic diseases, such studies are almost certain to require a larger sample size than has been reported to date. In addition, the increased prevalence of frailty with increasing age is almost certain to confound analysis and interpretation of data from such studies [11,12]. The cost of such studies will be high and not likely to be funded solely by the corporate sector. Thus charitable funding agencies and governments are almost certainly required to contribute to the resources necessary to enable the completion of such clinical trials. In order to provide these data in a relatively short time span and not deplete the availability of suitable study subjects, the development of international disease registries would be desirable. However, current restrictions of privacy legislation in many jurisdictions make this suggestion difficult to implement. In addition, the concern about cognitive capability to provide informed consent by the elderly study participant is a lingering problem [13].

It is clear that the task to provide robust data that will inform optimal drug therapy of the aged is not simple. However, it is not impossible. The need is great and the opportunity is virtually incontestable. If we are to provide more efficient drug therapy at sustainable cost, then it is imperative that we not delay this initiative. It is time to establish a framework by which we are able to accomplish the optimization of drug therapy in the elderly. The Journal encourages such studies and welcomes their completion and submission as manuscripts for consideration by the Editorial Board.

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