NIH Award from the National Cancer Institute

Principal investigator: June M. McKoy, medicine: geriatrics, Feinberg School of Medicine

- **Project:** Adverse Drug Reactions In Geriatric Cancer Patients
- **Start Date:** September 30, 2009
- **Total Award Amount:** $100,000

How the results of this project will benefit society:

Dr. June M. McKoy is an academic geriatrician seeking further training and mentorship relevant to pharmacovigilance and pharmacosurveillance studies in order to improve medication safety for older cancer patients. Her main area of interest is serious adverse drug reactions (sADRs) in older cancer patients and the completeness and quality of adverse event reporting in this milieu. It is of critical importance that we improve completeness, quality, and assignment of causality within the domain of serious adverse cancer drug events reports in order to enhance pharmaceutical safety among this vulnerable population, and in so doing redress cancer health disparities.

The problem the project is trying to solve:

The long-term objective of this proposal is to build on work previously done in the domain of adverse drug reactions by focusing on novel concepts relative to completeness, quality, and causality assignment among geriatric cancer patients. Serious adverse drug reaction in elderly cancer patients is a health disparities issue that raises patient safety and policy concerns. Adverse drug events reports for older cancer patients are often incomplete and of poor quality, delaying causality assignment with resultant poor health outcome.

How the project will work:

This proposal will address three specific aims: (1) (For cancer patients of all ages) To evaluate the quality and completeness of adverse event reports in the MedWatch database and the RADAR Program database (RADAR-I & RADAR-II) for patients <65 vs patients >65 years of age; (2) (For cancer patients > 65 years of age only) To compare the completeness of adverse event reports in the two databases; (3) (For cancer patients > 65 years of age only) To evaluate the quality of causality assessments using the Naranjo tool in the two databases. This proposed study is novel in that while adverse drug events have been evaluated among the general population, no study has previously addressed the completeness of adverse event reports for elderly cancer patients. For Aims 1 & 2 we will review two databases: RADAR I &II and the MedWatch database. For Aim 3, we will employ the Naranjo tool to assess causality. Dr. McKoy’s underlying hypotheses are that reports of sADRs are not as complete for older vs younger cancer patients (> 65 years vs <65 years); quality and completeness of sADR reports for patients >65 years are superior in RADAR databases compared with MedWatch database; causality assessment is less often correctly assigned in cancer patients > 65 years in MedWatch database vs RADAR database.

This award is funded under the American Recovery and Reinvestment Act of 2009, NIH Award number: 3K01CA134554-02S1.