

skewed distribution of health care expense were used to calculate adjusted mean expense for users of each product.

RESULTS: SSRI users included children and adults. Unadjusted total paid charges were lowest for users of fluoxetine. However, both the paroxetine and sertraline populations were significantly sicker as measured by the Charlson comorbidity index (difference = 0.11, $p < 0.05$). Adjusted for age, gender, and comorbidities, the mean paid charges were 15% higher for paroxetine ($p < .001$) compared to fluoxetine and not significantly different for sertraline compared to fluoxetine. When total pharmacy charges are added to the non-pharmacy charges, the paroxetine is 20% and sertraline is 27% lower than fluoxetine. Users of paroxetine are about 50% more likely to switch among the SSRIs. Switchers have 34% higher total charges.

CONCLUSIONS: The use of SSRIs represents an important and growing portion of medical expense. This paper illustrates that total medical care cost should be used in making population-level treatment choices.

PCN11

UK SCHIZOPHRENIA CARE AND ASSESSMENT PROGRAM (UK-SCAP)—A PROSPECTIVE, OBSERVATIONAL STUDY OF THE TREATMENT AND OUTCOMES OF DRUG THERAPY FOR SCHIZOPHRENIA IN A NATURALISTIC SETTING

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OBJECTIVES: The Schizophrenia Care and Assessment Program (SCAP) is a prospective observational study established in the US and Australia to comprehensively measure characteristics of care for schizophrenia patients in actual clinical practice while comparing a wide range of clinical, humanistic, and economic outcomes among older and newer medications. A feasibility study was conducted to investigate the potential for adapting SCAP to Western European countries and to determine appropriate study design.

METHODS: The feasibility study was carried out in several countries in Europe and included (1) interviews with providers and planners of healthcare in national associations of psychiatrists, medical associations and national and regional government (2) literature searches on a range of aspects and outcomes of schizophrenia and (3) interviews to assess the key operational aspects of conducting a SCAP study in representative clinical sites.

RESULTS: The feasibility study indicated that a UK-SCAP would capture the treatment and budgetary issues raised by UK prescribers and administrators. The wide range of outcomes assessments in SCAP (including sociodemographics, clinical status and treatments, functional status, general health status, quality of life, resource utilisation and carer burden) will distinguish the study and complement data from clinical trials. UK-SCAP will enroll approximately 600 inpatients and outpatients (limited exclusion criteria)

from late-1999 and will follow this cohort for 3 years. The primary outcomes measurement tools will be the SCAP instrument, developed from items derived from established measures and validated in the US SCAP study.

CONCLUSION: It is important to complement information from randomized clinical trials with information from “real life” settings. As new drug therapies have shown promise for improved treatment of schizophrenia, more research is needed to understand the clinical, humanistic, and economic opportunities of these therapies.

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HEALTH ECONOMICS FOR N-OF-1 TRIALS

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Series of N-of-1 trials have long been used to help decide the usefulness of interventions in psychology, often where conventional trial designs are impractical or unethical. Recently, N-of-1 trials have been adopted to make decisions on the usefulness of a proven therapy in individual patients. Their use is increasing because many people do not respond to a proven treatment, a greater desire to individualize therapy to enhance the risk/benefit ratio, and cost-containment pressures. N-of-1 trials reduce between-subject variability. They are useful in chronic diseases, where the effects of the active treatment are unlikely to carry-over to the next treatment period. N-of-1 trials provide a unique vehicle for the collection of economic data. Unlike most crossover trials, N-of-1 trials typically involve repeated episodes of the alternative treatments being administered over consecutive cycles. This means that each patient in a series of N-of-1 trials provides multiple observations for each treatment considered. As the required sample size for the economic components of clinical trials have been shown to be large, such trials offer an alternative to large samples that may be unfeasible. In addition, N-of-1 trials provide the means to estimate individual cost-effectiveness ratios, which may be incorporated into the patient, or clinician, decision making process. The problem of follow-up must be addressed, particularly as evaluations measuring QALYs necessarily require a life time horizon. However, if an intermediate outcome can be identified, enabling extrapolation, then this problem can be addressed. Specific examples of the use of this design will be illustrated from the field of dementia, where the ‘number needed to treat’ to obtain benefit in one patient is high from symptomatic improvement by approved cholinergic agents. The role of economic data from N-of-1 trials to help drug development will also be discussed.

ECONOMIC AND OUTCOMES ISSUES OF CARDIOVASCULAR DISEASE

PCV1

DIRECT COSTS OF MAINTAINING NORMAL SINUS RHYTHM IN PATIENTS WITH ATRIAL