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The Management of Schizophrenia in Clinical Practice (MOSAIC) Registry: A focus on patients, caregivers, illness severity, functional status, disease burden and healthcare utilization

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ABSTRACT

Background: The Management of Schizophrenia in Clinical Practice (MOSAIC), a disease-based registry of schizophrenia, was initiated in December 2012 to address important gaps in our understanding of the impact and burden of schizophrenia and to provide insight into the current status of schizophrenia care in the US. Recruitment began in December 2012 with ongoing assessment continuing through May 2014.

Methods: Participants were recruited from a network of 15 centralized Patient Assessment Centers supporting proximal care sites. Broad entry criteria included patients diagnosed with schizophrenia, schizophreniform or schizoaffective disorder, presenting within the normal course of care, in usual treatment settings, aged ≥18 years and able to read and speak English.

Results: By May 2014, 550 participants (65.8% male, 59.8% White, 64.4% single, mean age 42.9 years), were enrolled. The majority had a diagnosis of schizophrenia (62.0%). Mean illness duration at entry was 15.0 years. Common comorbidities at entry were high lipid levels (26.9%), hypertension (23.1%) and type II diabetes (13%). Participants were categorized by baseline overall Clinical Global Impression—Schizophrenia Severity Score as minimally (9.1%), mildly (25.3%), moderately (39.9%), markedly (22.3%) and severely (3.4%) ill. Most commonly used second generation antipsychotics at entry were risperidone (17.8%), clozapine (16.5%), olanzapine (14.0%), aripiprazole (13.6%) and quetiapine (5.6%).

Abbreviations: AE, adverse event; B-CATS, Brief Cognitive Assessment Tool for Schizophrenia; BMI, body mass index; CAINS, Clinical Assessment Interview for Negative Symptoms; CGI-SCH, Clinical Global Impression—Schizophrenia; CHMC, Community Mental Health Center; COPD, chronic obstructive pulmonary disease; CRO, Contract Research Organization; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; FGA, first generation antipsychotic; GED, General Education Degree; IEQ, Involvement Evaluation Questionnaire; IRB, institutional review board; KI, key informant; MINI, Mini International Neuropsychiatric Interview; MOSAIC, Management of Schizophrenia in Clinical Practice; NSA-4, 4-Item Negative Symptom Assessment; PAC, Patient Assessment Center; PANSS, Positive and Negative Syndrome Scale; PSP, Personal and Social Performance; SD, standard deviation; SGA, second generation antipsychotic; SQLS, Schizophrenia Quality of Life Scale; TC, treatment center; WPAI, Work Productivity and Activity Impairment.

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Conclusions: No large-scale patient registry has been conducted in the US to longitudinally follow patients with schizophrenia and describe symptom attributes, support network, care access and disease burden. These data provide important epidemiological, clinical and outcome insights into the burden of schizophrenia in the US.

1. Introduction

Schizophrenia, a chronic and debilitating multifaceted syndrome that afflicts over 60 million individuals worldwide (Perälä et al., 2007), has a considerable adverse impact not only on the patient's health and well-being, but also on their families and wider society (Knapp et al., 2004). The economic impact of schizophrenia on healthcare budgets is substantial, typically between 1.5 and 3% of national healthcare expenditure (Knapp et al., 2004). In the United States (US), schizophrenia is associated with annual direct and indirect costs of over $60 billion covering hospitalizations, the need for long-term medical management, housing, emergency room visits, legal expenses, psychosocial support and disability payments as well as life-time lost vocational productivity (Wu et al., 2005). Notably, the economic burden extends well beyond the healthcare system to other care organizations and public sector bodies, such as social service (welfare) agencies, housing departments and the criminal justice system (Knapp et al., 2004). As a result of the shift of burden of care from hospitals, most people with schizophrenia are now being cared for in the community where caregivers often experience significant stress, depression and/or anxiety and have high levels of emotional and financial burden (Martens and Addington, 2001; Saunders, 2003).

Overall, there is paucity of large scale studies in the US to assess the potential unmet need for treatment in schizophrenia. While a number of studies have utilized data from the US Schizophrenia Care and Assessment Program (US-SCAP), a 3-year, prospective, observational, non-interventional study (n = 2327) of schizophrenia treatment in usual-care settings in the US conducted between July 1997 and September 2003 (Ascher-Svanum et al., 2006, 2010; Cuyún Carter et al., 2011), many worldwide studies have not included populations from the US. For example, The Schizophrenia Outpatient Health Outcomes (SOHO) study, a 3-year, prospective, observational study designed to assess the comparative costs and outcomes of antipsychotic drug treatment in over 10,000 patients, was conducted in 10 Western European Countries (Haro et al., 2003, 2006). Likewise, the Worldwide-Schizophrenia Outpatient Health Outcomes (W-SOHO) study, which was undertaken to provide longitudinal data about the course of illness, treatment patterns and clinical and functional outcomes for more than 17,000 patients, was conducted in 37 countries in the following six regions: Southern Europe (n = 5788), North Europe (n = 4291), Central and Eastern Europe (n = 2175), Latin America (n = 2566), Northern Africa and the Middle East (n = 1341) and East Asia (n = 1223) (Karagianis et al., 2009; Haro et al., 2011). As such, there continues to be a dearth of “real-world” data to fill in the many information gaps in the US. Notably, a better understanding of clinical stages and disease progression along a continuum of illness for patients in usual care is needed to advance scientific understanding of the disease and its treatment (Tandon et al., 2009). Furthermore, there is limited quantification of the totality of the burden of schizophrenia on the patient, the family, the healthcare system and society.

Disease registries have been increasingly used for medical disorders such as diabetes, asthma, congestive heart failure and depression (Casalino et al., 2003), where they have provided substantial insights about the natural history and management of these conditions (Metzger, 2004; Schmittdiel et al., 2005). While some schizophrenia registries have been established to examine certain aspects of the disease (e.g., antipsychotic use, long-term treatment and clinical and functional outcomes) (Olivares et al., 2009; Peuskens et al., 2010), few have attempted to examine the entirety of the disease in a global approach.

In 2012, the Management of Schizophrenia in Clinical Practice (MOSAIC) disease-based registry (NCT01746134) was initiated to address some of the information gaps in our understanding of the impact and burden of schizophrenia and also to provide insight into the current status of schizophrenia care in the US. Through the collection of real-world data relating to a diverse representation of patients with a diagnosis of schizophrenia, schizoaffective disorder or schizophreniform disorder, the objectives of this prospective, non-interventional, MOSAIC registry were to: (i) describe the longitudinal course of schizophrenia; (ii) document the patterns of treatment in usual mental healthcare settings at all stages in the illness trajectory; and (iii) estimate the burden of disease from the perspective of patients, caregivers and providers (clinical and societal). Recruitment to the registry began in December 2012 with ongoing assessment continuing through May 2014. At the time of study discontinuation, 550 participants and 229 caregivers had been enrolled in the registry. Here, we present various data sets for these 550 participants enrolled in the schizophrenia MOSAIC registry. Data collected include information on symptoms, cognition, functioning and treatments received. In addition, data on medical co-morbidities and the characteristics of patients across the life-span were examined.

2. Methods

2.1. Patient Assessment Centers

A network of 15 centralized Patient Assessment Centers (PACs) was formed to act as foci of clinical oversight and evaluation, each with up to 10 peripheral clinical treatment centers (TCs) at a variety of practice settings (Fig. 1). The majority of study sites were located at Community Mental Health Centers (CHMC) (69%), with the remainder located in academic departments of psychiatry (38%). PACs had a mean of 2.8 TCs.

Clinicians at TCs recruited and referred patients along with medical record information centrally to the respective PACs. Throughout the course of the study, participants continued to visit their treating clinician for usual care according to their clinician's treatment plan; treatment decisions were conducted at the discretion of the treating clinician for the entire time the participant was in the registry. Each PAC served as a research base for standardized data collection from participants and available caregivers/key informants (structured interviews, patient reported outcomes and medical record abstraction) (Fig. 2). For functional and disease status measures, PACs utilized independent evaluators who were not treating clinicians of the participants. Raters were trained simultaneously at a single National Investigators' Meeting by PhD level assessors using case vignettes. Competency and reliability of ratings were established by PhD level rater trainers.

The primary role of the PACs was to conduct all routine and follow-up participant assessments and coordinate complete data collection from all data sources, including TCs' medical chart data. While treatment decisions were made at the treating clinician level, PACs were selected based on their associated experience and expertise in the area of psychiatric research. Each center was tasked with establishing and maintaining a high degree of research rigor and assessments that occurred there. The PAC assessors were required to be a PhD or MD with treating and rating experience in psychiatry. Frequent MOSAIC steering committee meetings and regular communication with the Contract Research Organization (CRO) ensured that any required protocol clarifications were dealt with promptly. All PAC principle investigators assumed responsibility for local site data quality. Central

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