National characteristics and trends in antiretroviral treatment in Australia can be accurately estimated using a large clinical cohort

Robin Huang, Kathy Petoumenos*, Richard T. Gray, Hamish McManus, Nila Dharan, Rebecca Guy, David A. Cooper

The Kirby Institute, UNSW Sydney, Sydney, NSW, Australia

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Abstract

Objectives: Cohort studies are often used as a national surveillance tool to monitor trends in HIV treatment and morbidity outcomes. However, there are limited studies validating the accuracy of using cohorts as a representation of the overall HIV-positive population. We compared data from a large Australian HIV-positive cohort study (Australian HIV Observational Database [AHOD]) and a 10% longitudinal sample from Australia's subsidized prescription medication scheme (Pharmaceutical Benefits Scheme [PBS]) to assess the use of cohorts for providing representative data for surveillance and monitoring purposes.

Study Design and Setting: Basic demographics and treatment information from July 1, 2013, to March 31, 2016, were divided into half-yearly periods to compare HIV trends between AHOD (*n* = 2,488) and PBS (*n* = 18,409) patients.

Results: In both data sets, most patients were men, aged above 50 years, and primarily resided in New South Wales. Both data sets revealed a significant shift toward the increased use of integrase strand transfer inhibitors and a gradual decline in the use of protease inhibitors and nonnucleoside reverse-transcriptase inhibitors among the treated population in Australia. Similarly, a substantial increase in the use of once daily, single-tablet, fixed-dose combination regimens was also observed.

Conclusion: Our results show that observational cohort studies can serve as useful surrogate surveillance tools for monitoring patient characteristics and HIV treatment trends.   © 2018 Elsevier Inc. All rights reserved.

Keywords: Cohort; HIV infection; Antiretroviral treatment; Observational data; Treatment monitoring; Surveillance

1. Introduction

Antiretroviral therapy (ART) has dramatically improved over the recent decade, with newer antiretroviral regimens becoming more effective, convenient, and well tolerated [1]. During this period, there have been significant changes in treatment initiation recommendations with most recent guidelines recommending immediate initiation of ART for all HIV-infected individuals irrespective of immunological and virological indicators [2]. Together with the introduction of newer antiretroviral regimens, these changes have dramatically improved the quality of life for people living with HIV (PLHIV), resulting in higher life expectancies reaching close to that of the general population, especially for those living in high-income countries such as Australia [3]. In the current context of treatment for all and treatment as prevention, it is important to monitor demographic profiles and patterns of ART use among PLHIV because they are key components of the HIV care continuum. For countries without national HIV surveillance data, observational cohort studies of sufficient size have often been used to provide estimations for treatment and other morbidity outcomes [4−6]. However, the accuracy of using cohorts as a representation of the general population has often remained untested.

There were an estimated 25,313 PLHIV in Australia at the end of 2015, with 75% of the population estimated to be receiving ART [7]. To date, there are no national surveillance data available providing detailed demographic profiles, patterns of ART use, and clinical characteristics of HIV-positive patients in Australia. Since the early ART era, trends in treatment uptake have been reported predominantly via the Australian HIV Observational Database (AHOD), a prospective cohort study

What is new?

Key Findings

- Similar demographic profiles were observed between a large Australian HIV-positive cohort study (Australian HIV Observational Database [AHOD]) to a 10% longitudinal sample from Australia's subsidized prescription medication scheme (Pharmaceutical Benefits Scheme [PBS]) data. In both data sets, most patients were men, aged above 50 years, and primarily resided in New South Wales.

- Very similar treatment trends were observed between the two data sets. A significant shift toward the increased use of integrase strand transfer inhibitors and a gradual decline in the use of protease inhibitors and nonnucleoside reverse-transcriptase inhibitors were observed over the 3-year reporting period (2013-2016).

What this adds to what was known?

- Cohort studies are often used as a national surveillance tool to monitor trends in HIV treatment and morbidity outcomes. However, there are limited data validating the accuracy of using cohorts as a representation of the overall HIV-positive population. In our comparison of the AHOD cohort to the PBS data, our results show that minimal differences were observed between the two data sets.

What is the implication and what should change now?

- Observational cohorts, especially those of sufficient sample size, can serve as useful surrogate surveillance tools for monitoring patient characteristics and HIV treatment trends.

In this study, we compare patterns of ART use in Australia using the 10% PBS sample and AHOD data to (1) derive a more comprehensive picture of ART trends in Australia and (2) evaluate the accuracy of using AHOD data at capturing characteristics of Australia's HIV-positive population as part of routine surveillance and monitoring.

2. Methods

The AHOD is an observational cohort study of HIV-infected individuals attending specialized general practitioner sites, sexual health clinics, and tertiary referral centers throughout Australia. It has been ongoing since 1999 with most of the patients recruited before 2004 with a second round of recruitment initiated in 2008. The primary objectives of AHOD are to monitor (1) patterns of ART use, including the efficacy of different treatment regimens related to demographic factors and markers of HIV disease stages; (2) patterns of toxicities/adverse events associated with antiretroviral treatment use; and (3) HIV- and non-HIV-related causes of death [8]. All data collected in AHOD are provided by the clinical or tertiary site that each AHOD participant attends in. No data are self-reported.

The PBS is a universal program provided by the Australian government that subsidizes prescription medications to all residents of Australia, as well as certain foreign visitors covered by a Reciprocal Health Care Agreement. Data on dispensed prescriptions (a 10% randomized sample) are updated every quarter by the PBS and supplied to a number of approved clients including the company "Prospection" that provides a dashboard interface (PharmDash) for its users to query the data [14]. The 10% PBS sample is randomized at a patient level and is de-identified and rescaled to 100% (multiplied by 10) [15]. The Australian Bureau of Statistics has validated the representativeness of the 10% ensuring equal probability of selection and that the selection method does not appear to be biased and will allow for valid inferences at a broad person level [15]. We also conducted an internal validation in 2015 by comparing the number of people on ART from a 100% cross-sectional PBS sample to the 10% sample. We found the 10% estimate had an error of only 2% nationally. Owing to its accuracy, the 10% PBS sample has been used in the HIV, viral hepatitis, and sexually transmissible infections in Australia: Annual Surveillance Report since 2015 to report estimates for the number of people taking ART each year [7]. Finally, the 10% PBS sample has been used to analyze treatment for hypertension and coronary heart disease [16,17].

The PBS sample provides a comprehensive coverage of certain demographic and treatment information on patients who were dispensed any HIV medication sold in the Australian market (and available on the PBS) at any point in time since mid-2013. The data set contains 170 million script claims and 3 million patients, including all PBS-listed drugs with HIV indications [7,15]. Currently,

of more than 4,000 HIV-positive patients in care throughout most states and territories in Australia [8]. Although many valuable insights have been gained through AHOD [9—12], studies evaluating whether the AHOD cohort is representative of the general HIV-positive population in Australia have never been done.

Recently, data from Australia's Pharmaceutical Benefits Scheme (PBS) have become available to access through the dashboard interface "PharmDash" provided by the company "Prospection" [13]. The data set provides monthly summarized data (updated quarterly) and includes all PBS-listed drugs with HIV indications and tracks patients over time to provide insight to PBS script-purchasing behavior. By analyzing and comparing the PBS data summaries to the AHOD cohort, a more precise representation of the treatment trends in Australia can be uncovered.