DO PRESCRIBING DATA REFLECT ACTUAL TREATMENT IN PEOPLE WITH HIV?

Trio Health

00499

Joseph J. Eron[1], Dushyantha Jayaweera[2], Gregory D. Huhn[3], Kelsey Milligan[4], Scott Milligan[4], Paul E. Sax[5], Keith Spitz[4], Richard A. Elion[6]

[1]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [2]University of Miami, Miami, FL, USA; [3]Rush University Medical Center, Chicago, IL, USA; [4]Trio Health Analytics, La Jolla, CA, USA; [5]Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA, USA; [6]George Washington University School of Medicine, Washington, DC, USA

1. BACKGROUND

Data created during the care continuum are challenging to assemble, and disparate sources may account for varied results in both patient care and observational studies. For example, EMR systems capture and contain data important at the point of care though usually do not contain dispensing data of prescribed therapies, reflecting what the patient is actually receiving. Pharmacies record prescription and dispensing data from which possible days with drug coverage may be determined, though actual adherence by the patient may or may not be known [FIGURE 1].

To assess the potential limitations of single source data in accurately portraying care for patients, we compared treatment patterns inferred from prescription data present in EMRs to those inferred from pharmacy dispensing data.

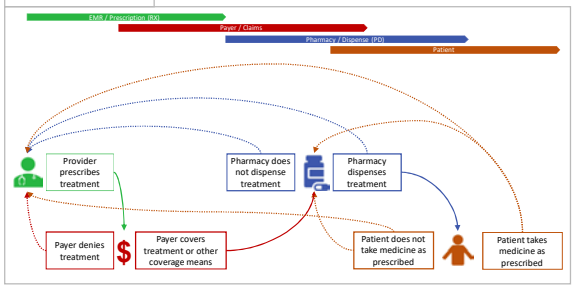
2. METHODS

Antiretroviral (ARV) prescription (RX) and pharmacy dispense (PD) data were obtained for 1270 treatment-experienced PWH serviced by 8 HIV treatment centers and their associated 340B pharmacies [FIGURE 2]. Geographic distribution was: 574 East (Mid Atlantic, New England, South Atlantic), 249 Central (Midwest, East and West South Central), and 447 West (Pacific and Mountain). Follow up was ≥12 months (m) post index, where index was defined as the first ARV regimen switch between 2014 to 2017. Final data collection was in June 2019 with assessments made as of Dec 2018. Treatments continuing beyond Dec 2018 were censored at Dec 31 2018. A discontinuation of treatment was assigned based upon addition of a new ARV drug or exhaustion of all regimen components. All patients in this sample marked as discontinued initiated a different subsequent ART therapy by/before June 30 2019. Time to discontinuation was assessed by Kaplan-Meier analysis with log-rank test. Adherence was based upon proportion of days between the regimen start and stop (or date of censure) with all drugs (see Sax PE et al. PLoS One. 2012;7(2):e31591). There were no restrictions on length of gap allowed during treatment, provided the same regimen was used before and after the gap.

3. RESULTS

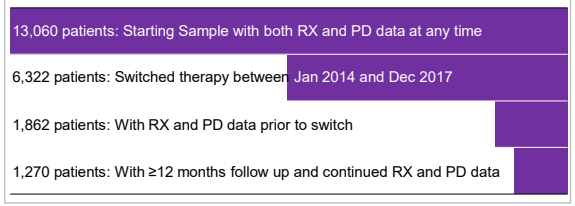
- Mean (range) follow up was 29 (12-64) months
- Discontinuation rates, calculated as of Dec 2018, were 46% (588) based on RX v. 43% (540) PD (p=0.060)
- Median time to discontinuation was 29.1 months based on RX v. 29.2 months PD (p=0.448) [FIGURE 3]
- Time to discontinuation/censoring differed by >90 days (+/-) for 29% (374) of PWH; 20% (258) discontinued therapy more than 90 days earlier than indicated by RX [FIGURE 4]
- 90% (1143) PWH achieved ≥80% adherence based on RX v. 92% (1166) PD (p=0.129); 86% (1087) achieved ≥95% adherence based on RX v. 87% (1110) PD (p=0.202) [FIGURE 5]
- Of PWH with <80% adherence by RX, 41% (52/127) had ≥80% adherence by PD [FIGURE 6]
- Changes in multi-tablet regimen (MTR) due to early discontinuation of a component (>90 d before discontinuation of remaining regimen drugs) was indicated in 16% (75/478) PWH by RX and 13% (63/478) by PD (p=0.311)
- Of PWH with a change in MTR by PD, 14% (9/63) were not reflected by RX as having any early drug discontinuation and an additional 37% (23/63) were indicated as having a change that differed >90 d from observed by PD
- In total, 37% (473) of study PWH had days covered differences exceeding 90 days, differences in adherence at 80% threshold, and/or differences in multi-tablet regimen composition identified by comparing PD to RX data [FIGURE 7]

FIGURE 1



Information sufficient for each stakeholder to service the patient flows left to right (solid arrows), though flow right to left (dotted arrows) may be limited.

FIGURE 2



RX and DP data were collected from patients that had both RX and PD data before, during, and after the treatment evaluated to minimize the potential for data collection issues to contribute to observed differences.

FIGURE 3

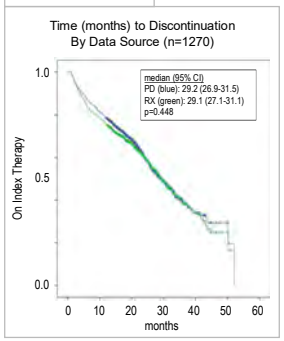
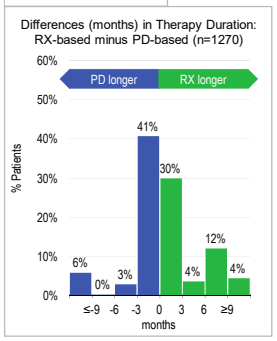


FIGURE 4



Months to discontinuation were not different based on RX vs. PD data sources [FIGURE 3], though duration of therapy differed by >90 days (+/-) for 29% (374) of PWH [FIGURE 4]. 20% (258) of patients inferred to be on therapy by RX actually discontinued therapy more than 90 days earlier.

FIGURE 5

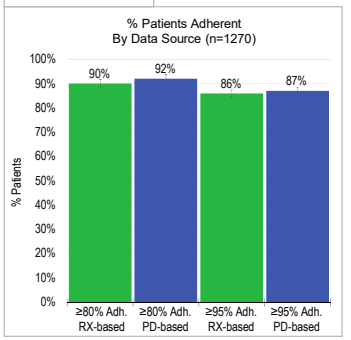
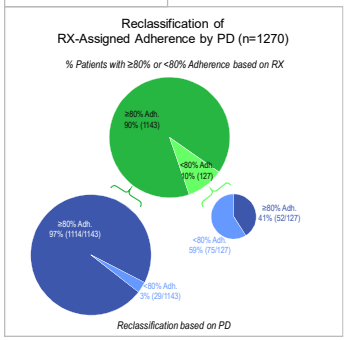
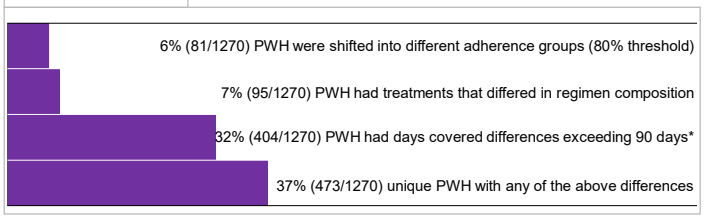


FIGURE 6



The %s of patients with ≥80% or ≥95% adherence were not significantly different between sources [FIGURE 5]; however 41% patients classified as having <80% adherence by RX were reclassified as ≥80% adherence by PD [FIGURE 6].

FIGURE 7



*In total, 37% (473/1270) of study patients had differences in treatment as inferred by RX in comparison to PD. *Note that differences in duration accounted for 374 of the 404 PWH and the remaining 30 differed in days covered during treatment as opposed to at the end of treatment.*

4. CONCLUSIONS

- For more than a third of people with HIV, prescriptions for ART do not directly correlate with what is dispensed to the patient.
- This discordance is particularly common with multi-tablet regimens.
- Clinicians should consider the possibility of ART not being fully dispensed, especially in those with a suboptimal treatment response.

5. LIMITATIONS

While dispensing data may be more accurate than prescription data in reflecting treatment, dispensing data is still only a surrogate for actual patient adherence.

Additionally, the limitations observed with single source data may not translate into a clinically meaningful difference – further studies need to be conducted to determine if an association exists.

Dr. Sax consults for Gilead, GSK/ViiV, Merck, Janssen. He has received research grants from Gilead, Merck, GSK/ViiV. He holds editorial positions at UpToDate, Medscape, NEJM Journal Watch, Open Forum Infectious Diseases. Dr. Eron consults for Merck, ViiV Healthcare, Gilead and Janssen. The University of North Carolina receives research funding from ViiV Healthcare, Gilead and Janssen from which he receives support as an investigator. Kelsey Milligan, Keith Spitz, and Scott Milligan are employees of Trio Health. Richard A. Elion received grants from Gilead and Proteus, serves on the Advisory boards for Gilead and ViiV, and is a speaker for Gilead and Janssen. Drs. Elion, Eron, Dushyantha, Huhn, and Sax serve on Trio Health's Scientific Advisory Board. Dr. Jayaweera has received research grant support from Gilead, ViiV Healthcare and Janssen. Dr. Huhn advises for and/or received grants from Gilead, ViiV, Janssen, Proteus, and Theratechnologies.

CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS. **Boston, Massachusetts, March 8–11, 2020**