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The Effect of Treatment Discontinuation Definitions on Estimates of Treatment Persistence – A Multi-Indication Study with Health Insurance Claims Data

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INTRODUCTION

- **Background:** Estimates of treatment duration can differ depending on definitions of discontinuations and applied statistical methods (e.g., treatment duration as a time-to-event variable is typically characterized by its median, while financial models typically use mean values for forecasts)
- **Objective:** Investigate the effect of different definitions on treatment discontinuation in four agents and indications

METHODS

- **Data source:** Claims data from the German AOK PLUS sickness fund (~3.4mn patients)
- **Agents & indications:** 1) Macitentan in pulmonary arterial hypertension (PAH); 2) Abiraterone acetate plus prednisone (AAP)[1] in metastatic castration-resistant prostate cancer (mCRPC); 3) Darunavir in HIV; 4) Paliperidone in schizophrenia (SCH)
- **Analysis of treatment duration:**
  - Treatment duration was measured from first prescription between 1/1/2011-6/30/2020 until discontinuation, using various gap definitions (30, 60, 90, 120 and 180 days, depending on indication) between the run-out date of the last prescription and the next prescription[2]
  - Median time to treatment discontinuation was calculated by Kaplan-Meier analysis
  - Mean duration of treatment was estimated with parametric fitting (exponential and Weibull distributions)

[1] We assumed abiraterone acetate was combined with prednisone as per label indication

[2] We assumed that patients consumed all accumulated medications (stockpiling); hospitalizations were considered part of the treatment periods

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RESULTS

- 103 PAH, 1,134 mCRPC, 147 HIV and 1,538 SCH patients were identified
- Differences in median time to discontinuation across gap definitions were largest for darunavir in HIV (5.8 [30-day gap] – 26.2 months [90-day gap]) followed by paliperidone in SCH (46.6 [90-day gap] – 57.9 months [180-day gap]), macitentan in PAH (26.7 [30-day gap] – 35.8 months [180-day gap]), and AAP in mCRPC (7.4 [30-day gap] – 9.5 months [90-day gap])
- Mean estimates showed 3-fold differences across various gap-length definitions (darunavir in HIV) and statistically significantly different estimates depending on the choice of distribution (paliperidone in SCH), see **Table 1**

Table 1: Median and mean times to treatment discontinuation (in months)

	PAH (N = 103)			mCRPC (N = 1,134)		
Gap definition	**30 days**	**90 days**	**180 days**	**30 days**	**60 days**	**90 days**
Median time to treatment disc. (95% CI)	26.7 (10.8-36.4)	29.2 (16.2-36.8)	35.8 (24.7-51.5)	7.4 (6.9-8.2)	8.6 (7.9-9.2)	9.5 (8.9-10.0)
Mean time to treatment disc. (95% CI) – exp. model	35.7 (26.9-44.4)	40.7 (30.3-51.7)	48.9 (35.7-62.1)	11.9 (11.2-12.6)	13.1 (12.3-14.0)	14.2 (13.3-15.1)
Mean time to treatment disc. (95% CI) – Weibull model	46.2 (26.9-65.5)	50.9 (29.8-72.1)	59.6 (34.0-85.1)	11.9 (11.2-12.7)	13.1 (12.3-13.9)	14.1 (13.2-14.9)
	HIV (N = 147)			**SCH (N = 1,538)**		
Gap definition	**30 days**	**60 days**	**90 days**	**90 days**	**120 days**	**180 days**
Median time to treatment disc. (95% CI)	5.8 (4.9-6.3)	22.7 (16.2-26.2)	26.2 (19.3-33.9)	46.6 (41.6-53.5)	48.7 (43.1-58.8)	57.9 (48.6-69.4)
Mean time to treatment disc. (95% CI) – exp. model	9.7 (8.1-11.3)	30.0 (24.7-35.4)	35.3 (28.9-41.6)	73.6 (68.3-78.8)	76.5 (71.0-82.0)	82.5 (76.4-88.6)
Mean time to treatment disc. (95% CI) – Weibull model	9.6 (7.9-11.4)	30.4 (24.6-36.1)	35.5 (28.8-42.2)	99.3 (86.7-112.0)	101.7 (88.8-114.6)	103.2 (90.6-115.8)

KEY TAKEAWAY

Estimates of treatment duration in real-world data vary substantially depending on the applied statistical methods and rules of gap filling and discontinuation.

CONCLUSIONS

We recommend conducting sensitivity analyses of underlying assumptions and methods, and the consideration of scenario planning to ensure that medication consumption forecasts are robust and consistent.

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DISCLOSURES

FK, JH, SN, XL and LDS are employees of Janssen Global Services. ML is an employee of Cytel. MG and TW are employees of IPAM. TW has received honoraria from several pharmaceutical/consultancy firms, e.g., Roche, Abbvie, Merck, GSK, BMS, Bayer.