

Persistence to inhaled long-acting maintenance therapy in patients with COPD in UK routine clinical practice

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Introduction

- LAMA monotherapy, ICS/LABA and LAMA/LABA dual therapy, and ICS/LAMA/LABA triple therapy are recommended as maintenance therapies for the treatment of COPD¹
- Whilst dual and triple therapies have previously been administered as multiple inhaler therapies, real-world studies have shown that they have a high risk of discontinuation due to the complexity of the treatment regimen^{2,3}

- Previous real-world studies comparing treatment persistence between different COPD long-acting maintenance therapies have often focused on a limited range of maintenance therapies⁴, used restrictive inclusion criteria and currently, there is no relevant research that has been conducted in the UK which provides purely descriptive data
- This study aimed to describe persistence to different long-acting inhaled maintenance therapies amongst patients with COPD, in UK routine clinical practice

Results

- A total of 74 147 patients were included in this study. **Table 1** details patient demographic and clinical characteristics across all maintenance therapy subgroups
- Median treatment persistence ranged from 1.0 months for ICS/LABA and LAMA/LABA open combination maintenance therapies to 16.6 months for SITT maintenance therapy (**Figure 3**)
- Similar findings were observed when implementing alternative allowable gaps in the sensitivity analyses

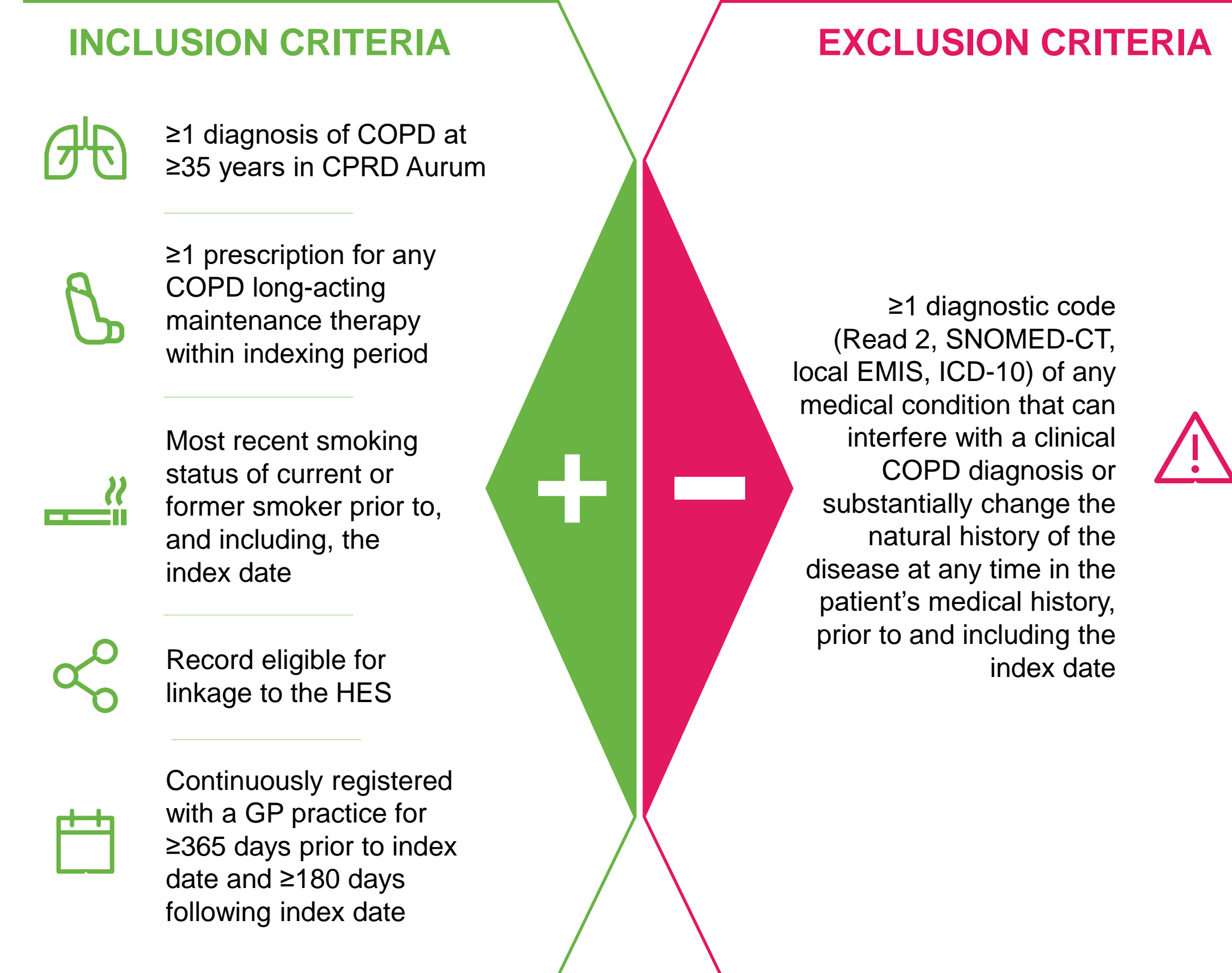
Conclusion

- This study demonstrates high persistence to FDC long-acting dual and triple maintenance therapies, particularly amongst patients initiating SITT
- Overall, this study has effectively helped to describe patients persistence to numerous long-acting maintenance therapies in a UK clinical setting

Methods

- A retrospective cohort study using linked primary care electronic health record data and secondary care administrative data through the CPRD Aurum and HES databases, respectively
- The index date was defined as the first or earliest within-regimen prescription date of each long-acting maintenance inhaler therapy between 15 November 2017 and 30 September 2019 (**Figure 1**).
 - Patients could have more than one index date and were indexed on each maintenance therapy. If they switched maintenance therapy within the indexing period, they were reindexed on the new maintenance regimen. Eligibility criteria are shown in **Figure 2**.

Figure 2: Eligibility criteria



- Medication persistence was defined as the time until treatment discontinuation and was assessed at 6- and 12-months, and at 18-months and longer if sample size permitted following the index date using Kaplan-Meier estimator
- Discontinuation was defined as a gap of >60 days between last day of one prescription to first day of subsequent prescription
- Patients were not censored if there was no switch in maintenance therapy and patients who switched maintenance regimen (i.e. had multiple index dates) within the follow-up period were considered as discontinuing at the point of treatment switch
- Sensitivity analyses were also conducted using a 30- and 90-day allowable gap between prescriptions

Figure 1: Study design

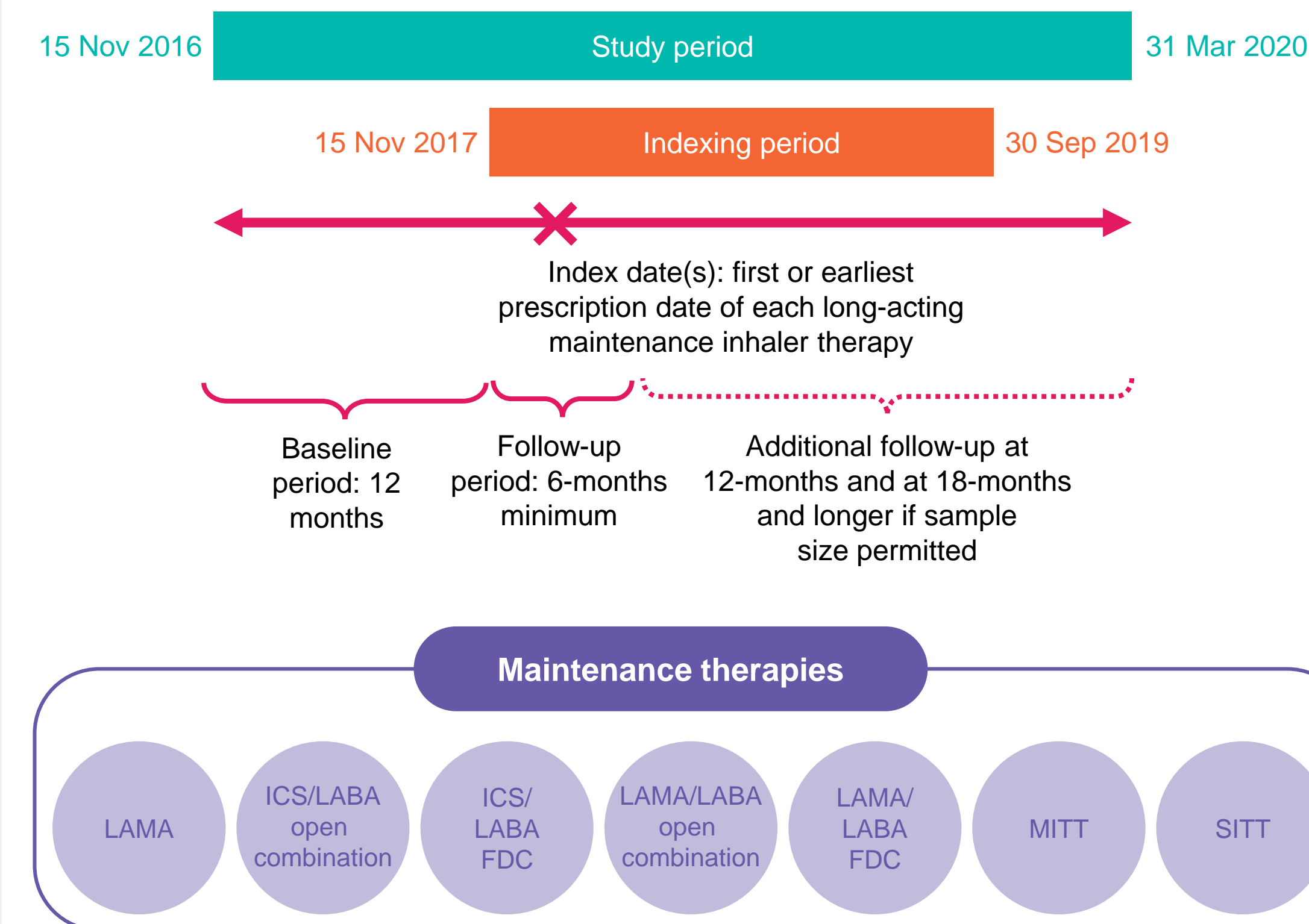


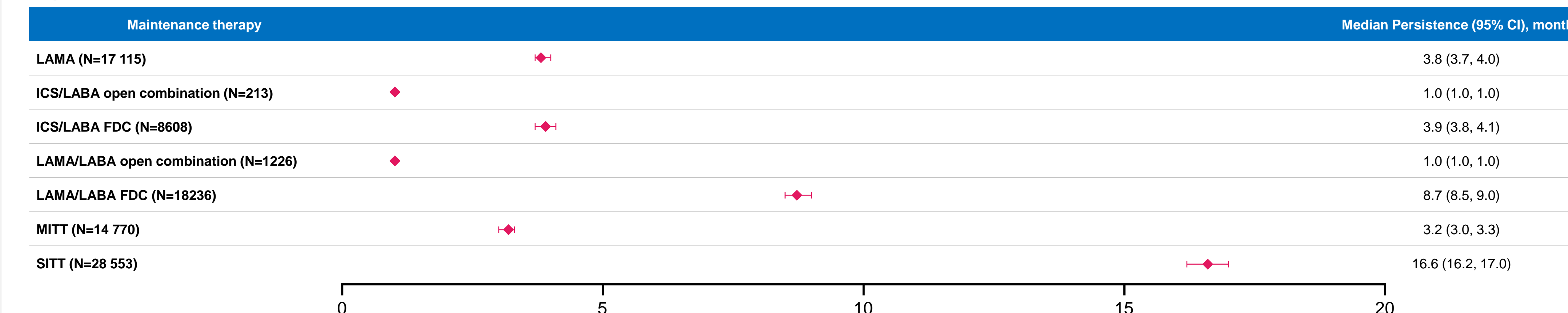
Table 1: Patient demographic and clinical characteristics

	LAMA (n=17,138)	LAMA/LABA Open (n=1,235)	LAMA/LABA FDC (n=18,328)	ICS/LABA Open (n=214)	ICS/LABA FDC (n=8,635)	MITT (n=14,898)	SITT (n=28,772)
Mean (SD) age at index, years	67.7 (10.9)	70.1 (10.1)	69.5 (10.6)	68.7 (11.7)	66.5 (11.7)	67.7 (11.2)	70.2 (10.3)
Male sex, n (%)	9307 (54.3)	652 (52.8)	10 020 (54.7)	105 (49.1)	4521 (52.4)	7781 (52.2)	14 555 (50.6)
Current smoker, n (%)	9698 (57.2)	609 (49.7)	9840 (54.0)	91 (43.3)	4687 (55.1)	7773 (52.7)	13 687 (47.6)
Predicted baseline FEV ₁ ,% mean (SD)	68.8 (19.0)	65 (20.1)	64.7 (19.4)	70.2 (18.8)	67.3 (19.6)	63.7 (20.2)	56.1 (20.5)
Medical Research Council (MRC) Dyspnoea Scale Score, n (%)							
1	2255 (13.2)	154 (12.5)	1571 (8.6)	36 (16.8)	1025 (11.9)	1353 (9.1)	1429 (5.0)
2	5614 (32.8)	483 (39.1)	6129 (33.4)	65 (30.4)	2430 (28.1)	4768 (32.0)	6868 (23.9)
3	2985 (17.4)	346 (28.0)	5328 (29.1)	38 (17.8)	1407 (16.3)	4093 (27.5)	9661 (33.6)
4	851 (5.0)	125 (10.1)	2192 (12.0)	NR	481 (5.6)	1740 (11.7)	7464 (25.9)
5	100 (0.6)	27 (2.2)	365 (2.0)	<5 (<2.3)	62 (0.7)	256 (1.7)	1877 (6.5)
Unknown	5333 (31.1)	100 (8.1)	2743 (15.0)	62 (29.0)	3230 (37.4)	2688 (18.0)	1473 (5.1)
Baseline GOLD 2019 group, n (%)							
A (≤1 moderate exacerbation and MRC score of 1-2)	10 696 (62.4)	575 (46.6)	7827 (42.7)	130 (60.7)	4943 (57.2)	5932 (39.8)	5699 (19.8)
B (≤1 moderate exacerbation and MRC score of ≥3)	3163 (18.5)	389 (31.5)	5883 (32.1)	38 (17.8)	1369 (15.9)	3923 (26.3)	9627 (33.5)
C (≥2 moderate/severe exacerbations OR ≥1 severe and MRC score of 1-2)	2506 (14.6)	162 (13.1)	2616 (14.3)	33 (15.4)	1742 (20.2)	2877 (19.3)	4071 (14.1)
D (≥2 moderate/severe exacerbations OR ≥1 severe and MRC score of ≥3)	773 (4.5)	109 (8.8)	2002 (10.9)	13 (6.1)	581 (6.7)	2166 (14.5)	9375 (32.6)

Limitations

- As eligible patients were required to have at least 6 months of follow-up data, this may introduce survivorship bias. However, this design aspect ensured sufficient observation time to assess study endpoints.
- The study data is less contemporary because of the study end date of 31 March 2020, which was selected to exclude data during the COVID-19 pandemic in the UK

Figure 3: Median treatment persistence



Abbreviations

CI, confidence interval; COPD, chronic obstructive pulmonary disease; CPRD, Clinical Practice Research Datalink; EMIS, Educational Management Information System; FDC, fixed dose combination; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; GP, general practitioner; HES, Hospital Episode Statistics; ICD-10, International Classification of Diseases version 10; ICS, inhaled corticosteroid; LABA, long-acting β₂ agonist; LAMA, long-acting muscarinic antagonist; MITT, multiple inhaler triple therapy; NR, not reported; SD, standard deviation; SITT, single inhaler triple therapy; SNOMED-CT, Systematised Nomenclature of Medicine- Clinical Terms

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