Perception and knowledge of general practitioners on COPD management according to the GOLD23 ~~guidelines~~ document and reimbursement criteria for drugs prescription: an explorative e-Delphi study

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COPD is the fourth leading cause of death in Western countries with an estimated prevalence ranging 4-10% in adult population.[1,2] In the last decades, pharmacotherapy of COPD was often revised with the aim to support a personalized approach accounting for the burden of symptoms and exacerbations to assess the disease severity. In the context of the Italian general practice, the publication of the latest GOLD23 <https://www.goldcopd.org> occurred early after the release of NOTA 99/(Italian Medication Agency: AIFA), e new directive regulating the reimbursement criteria for COPD medications. These criteria extended the prescription authority of GPs to fixed combinations of LABA/LAMA besides posing more rules on the needs of spirometry evaluation and registration, and pneumologist referral for those exposed to LABA/LAMA/ICS free combinations. As largely demonstrated in prior studies, there are several concerns on COPD management in primary care, including the proper choice of initial treatment, poor medications adherence, missing values for spirometry investigations, and proper use of ICS. Paradoxically, these concerns might have been augmented by some contradictions between GOLD23 and NOTA99, particularly those related to disease severity and subsequent pharmacological therapy choices. As in previous GOLD22, NOTA99 continues to classify patients in the D category, while it was reorganized by the ABE system in GOLD23. Therefore, it changes the patient's category that could potentially be eligible to receive a LABA/LAMA combination, regardless of being staged in group B or E, giving more importance to the patient's symptomatology and type of exacerbations, respectively.

Thus, given that this background provides a further role of GPs in the management of COPD, perception and knowledge of individual GPs of the most recent GOLD23 along with NOTA99 directives, need to be clarified. We therefore conducted an explorative Delphi study among GPs, with the endorsement of the Italian College of General Practitioners and Primary Care (SIMG), with the aim to develop a series of specific items which might be subsequently re-proposed to a larger cohort of GPs. The Delphi methodology has been validated by RAND/UCLA.[3] On the bases of prior Delphi studies on COPD, the largest number of responders physicians were around 200;[4] no GPs,[5] or a low proportion of them,[6,7] were generally involved. We therefore randomly selected up 600 GPs, members of SIMG, to be involved in this study.

A scientific committee formed by 3 GPs, 2 pneumologists, and 1 epidemiologist, developed a tool including 27 items which explored four domains: first, general information on GP's workload and level of access to spirometry evaluations in primary care clinics (7 items); knowledge on early recognition of COPD and related features (e.g. exacerbations) (7 items); third, perception of the clinical application of the NOTA 99 (7 items); fourth, use and management of the triple therapy LABA\LAMA\ICS in comparison to other available therapies (6 items). The level of agreement with 21 statements was assessed on a Likert-type scale ranging from 1 to 9, which expressed the minimum and maximum agreement value. A value of 5 indicates a neutral position. The final items were assembled into a web-based electronic(e)-Delphi, which was tested by 10 GPs who were not part of the final surveyed cohort.

In September 2023, the panel of 600 GP was contacted by the SIMG presidency via an informative email regarding the purpose of this e-Delphi. The following day, the web-based electronic(e)-Delphi was sent via email. Participating GPs received a second email containing those items with the absence of consensus among GPs being revealed by the first wave.

Responses to the first 7-item section were reported as proportions. For the other items, median value and its respective 10th and 90th percentile range (IPR) was calculated. Inter-percentile Range Adjusted for Symmetry (IPRAS) calculation was obtained to manage the degree of asymmetry between the nine points of the scale employed. It was calculated using this formula: 2.35 + (1.5 * Absolute Asymmetry Index (AI)), where AI is an absolute number from the difference between the midpoint of the IPR (90th-10th percentile/2) and the neutrality point, which is 5. The ratio of IPRAS to IPR, also known as the Disagreement Index (DI), allowed us to define whether there was a wide or limited dispersion of the responses provided by the participants for the individual items. A DI >=1 indicated a high dispersion of responses (disagreement), while a DI below 1 indicated the opposite.[3]

As a whole, 422 GPs (response rate: 70.3%) completed the e-Delphi. The results are detailed in Table 1 with the item-specific response rate. 61.4% of GPs were male, with mean age 51.7 years (SD: 14.2); on average, 21.3 years (SD: 14.6) of professional experience and an average number of patients equal to 1312 (SD: 459). For 33.7% of GPs, there was the opportunity of accessing spirometry directly in their clinics. Only 16.1% reach up to 20 spirometry tests/year. When spirometry was prescribed by GPs to be conducted in a hospital, waiting times were, in most cases, over 6 months (14.9%).

For what concerns the second 7-item section, all 422 responders provided a generally 'very high' level of consensus. As for item 7 (i.e. the GPs is directly responsible for the diagnosis, staging, and treatment of COPD), it shows a 'good' degree of consensus. The 'absence' of consensus, with a high level of disagreement, concerned the use of computerized records (i.e., prescriptions associated with antibiotic and steroid therapy) to facilitate early diagnosis of COPD.

Findings related to the 7 items on the clinical application of NOTA99 reported some variability in the responses. Although most of them showed 'good' agreement, the two items concerning the GP's perception of the symptomatic picture (using mMRC and CAT scales) of COPD and the first-choice use of LABA or LAMA or LABA/LAMA combination clearly indicated the presence of uncertainties.

The results regarding the 5-item section on knowledge and perception of the triple therapy LABA/LAMA/ICS For the first two items, there was a general agreement to not use the triple therapy in patients without (or with mild single) exacerbations, regardless of the symptomatologic picture. As reported in item 4, when FEV1 is <50%, there was a 'good' agreement regarding the use of the triple therapy, and eosinophilia levels was considered a correct trigger for resorting to the triple therapy. There was no consensus that the presence of a triple therapy in open was a reason for referral to a specialist.

These findings provided preliminary evidence on perception and knowledge of the Italian GPs on the implementation of GOLD23 ~~guidelines~~ document and NOTA99 directives. While there was a general consensus among GPs on almost all the examined domains, there are still crucial aspects needing further investigation. Namely, a poor access to spirometry, GPs' subjective assessment of the symptoms type with which to tailor

patient's therapy, and re-evaluation of free-triple therapy through specialist's referral. The extension of this e-Delphi would be therefore functional to confirm the need to reduce the knowledge gaps in COPD management by GPs, given their growing role in the recognition and treatment of this disease.

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