Diversity Of Patient Support Programs For Severe Asthma Treated With Biologic Therapies – A Systematic Literature Review

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Introduction

- According to a 2019 global burden report, asthma affected an estimated 262 million people and caused 455 000 deaths[1]. Up to 10% of adults and 2.5% of children suffer from severe asthma (SA)[2].
- Biologic therapies are used in patients with SA as an add-on treatment to improve the level of disease control and consequently reduce the continuous use of oral corticosteroids and the number of exacerbations leading to hospitalizations or emergency room visits[2,3].
- Patient support programs (PSPs) provide education, monitoring, and assistance to improve adherence to therapy in patients with chronic diseases[4] and prove valuable in supporting at-home administration of biologics.

Objective

The objective of this research was to understand the services and characteristics of PSPs for patients with SA treated with biologic therapies that address the treatment and disease management needs and burden in this population.

Methods

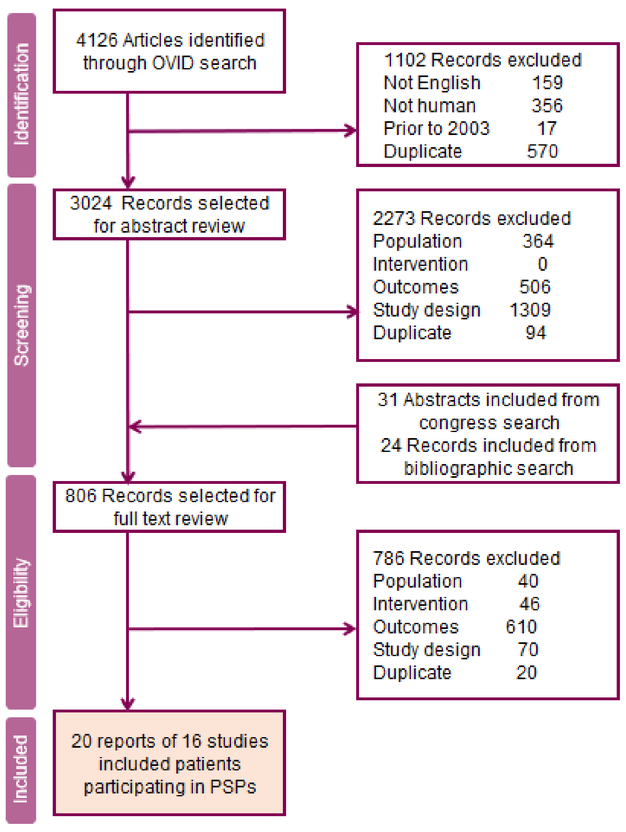
- A systematic literature review (SLR) was conducted in accordance with the principles outlined in Cochrane and NICE published guidelines[5,6].
- Searches were performed via Ovid platform in the following databases: MEDLINE®, Embase®, Cochrane collaboration, and EconLit. Additionally, manual searches were performed for relevant abstracts published at international conferences of interest.

Table 1. PICOS criteria

Patient population	• Patients diagnosed with SA treated with biologics (benralizumab, omalizumab, mepolizumab, dupilumab, reslizumab)
Interventions	• Patient support programs
Outcomes measures	• Adherence, persistence • Treatment discontinuation, time to discontinuation, reasons for discontinuation • Severe exacerbations (hospitalizations due to asthma attack/symptom worsening, emergency room visits due to symptom worsening) or moderate exacerbations (leading to steroid use) • Healthcare resource use • Asthma symptom control PROs (e.g., ACQ, ACT, and others) • Disease-related HRQOL PROs (AQLQ, SGRQ) • General HRQOL measures (such as EQ-5D, SF-36, SF-12, and others)
Study design	• Interventional studies (non-controlled studies, healthcare practitioner-led educational initiatives, single-arm studies) • Prospective and retrospective observational studies • Systematic reviews and meta-analyses (for cross-checking only)
Time limits	• English Language • 2003-current

ACQ: Asthma Control Questionnaire, AQLQ: Asthma Quality of Life Questionnaire, ACT: Asthma Control Test, EQ-5D: EuroQol 5 dimensions, HRQOL: health-related quality of life, PRO: patient-reported outcomes, SA: severe asthma, SGRQ: St. George's Respiratory Questionnaire, SF-36: 36-Item Short Form Survey, SF-12: 12-Item Short Form Survey

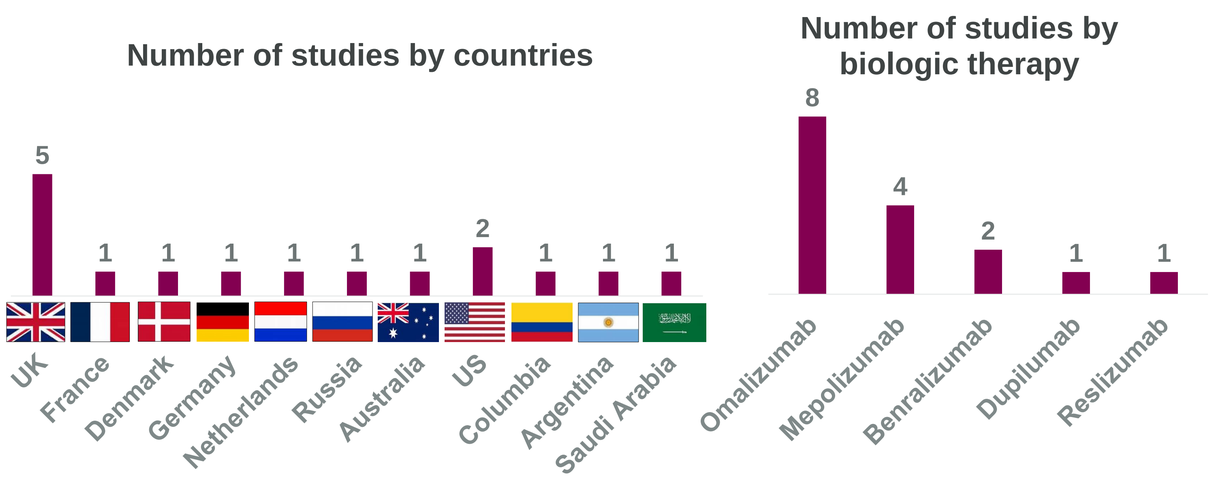
Figure 1. PRISMA diagram



- The SLR focused on prospective or retrospective observational studies involving patients with SA treated with biologic therapies (benralizumab, omalizumab, mepolizumab, dupilumab, reslizumab).
- Studies published after the launch of the first biologic therapy (omalizumab) for the treatment of severe eosinophilic asthma were retrieved (2003 onwards).

Results

Figure 2. Characteristics of included studies



- Most of the studies included patients treated with omalizumab, followed by mepolizumab, and benralizumab, and were based in European countries (Figure 2).
- Four main categories of support activities have been identified (Figure 4) and half of the studies reported on PSPs designed to support transitioning to at-home administration of biologics (Figure 3).

Abbreviations: ACQ: Asthma Control Questionnaire, AQLQ: Asthma Quality of Life Questionnaire, ACT: Asthma Control Test, EQ-5D: EuroQol 5 dimensions, HRQOL: health-related quality of life, PRO: patient-reported outcomes, PSP: patient support programs, SA: severe asthma, SGRQ: St. George's Respiratory Questionnaire, SF-36: 36-Item Short Form Survey, SF-12: 12-Item Short Form Survey, SLR: systematic literature review.

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Results

Figure 3. Categories of PSPs

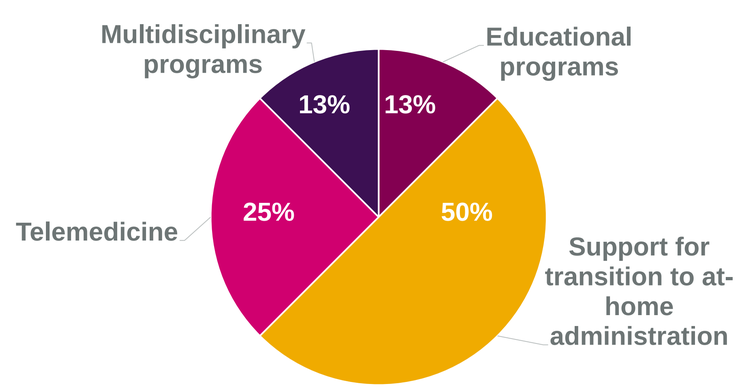


Figure 4. Key support areas offered by PSPs for patients with SA treated with biologic therapies

Support for transition to at-home administration

- Training for drug self-administration at the clinic and supervised injections
- Virtually assisted at-home administration and spirometry
- Remote monitoring of disease control and treatment adherence

Telemedicine

- Smartphone apps and web-based platforms for remote supervision by healthcare provider and patient-reported outcomes collection
- Communication facilitation with the healthcare provider
- Administration reminders and scheduling of visits

Multidisciplinary programs

- Specialists for addressing issues related to comorbidities and lifestyle: psychologists, nutrition specialists, tobacco addiction, specialists, physical therapists
- Holistic approach for preventing exacerbations and the necessity of step-up therapy

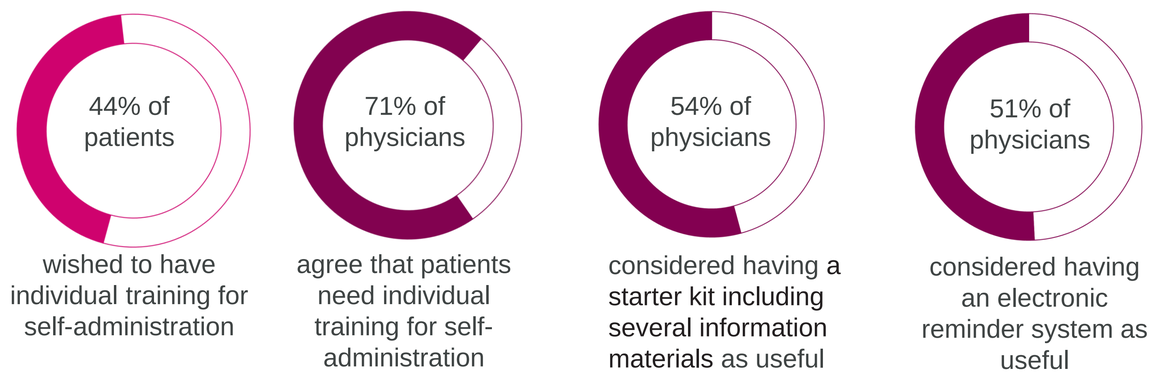
Educational programs

- Targeted at improving adherence
- Educate on the importance and role of adequate asthma therapy administration

PSPs supporting the transition to at-home administration of biologics

- In a recent German survey involving patients treated with omalizumab and their physicians, **both patients and physicians felt that transitioning to at-home administration requires support and close monitoring to increase confidence and ensure correct administration** (Figure 5) [7].

Figure 5. Types of support services for patients with SA treated with biologic therapies during transition to at-home administration (from Timmermann et al., 2020 [7])



Limitations

- The SLR was limited to English-language publications of trials or studies which lead to a possibility of language bias.
- Many of the studies that included patients who participated in a PSP, did not describe in detail the services offered.

Conclusions

- Patients with SA treated with biologics participate in a variety of programs and support actions:
  - Education related to the importance of good treatment adherence
  - Support for transitioning to at-home administration
  - Remote monitoring of disease control and treatment adherence
  - Holistic individualized approach to lifestyle changes and comorbidities management.
- Particular importance was given to the need for support during transitioning to at-home administration. Both physician and patient concerns related to safety and correct administration of biologic therapy outside of the hospital setting may be addressed by participation in a PSP.
- This diversity may reflect the context in which the PSPs were created, owing to the perceived gaps in patient care within the local setting, such as knowledge gaps or difficulties in transitioning to self-administration at home.
- However, similarities among the PSPs, particularly education and training, also illustrate an emerging consensus on solving gaps in patient care. Further studies quantifying the impact of PSPs may demonstrate whether these elements do address those disparities.

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