Comparison of data fields captured by regional severe asthma registries participating in the International Severe Asthma Registry (ISAR)

Neva Eleangovan,[1] Antony Hardjojo,[1] Lakmini Bulathsinhala,[1] Victoria Carter,[1] Isha Chaudhry,[1] Naeimeh Hosseini,[1] Ruth Murray,[1] Chris Price,[1] David Price.[1]

[1]Optimum Patient Care, Cambridge, UK

Introduction

- The International Severe Asthma Registry (ISAR; http://isaregistries.org/) is the first global adult severe asthma registry.
- It is a joint initiative whereby national registries retain ownership of their own data, but open their borders and share data with ISAR for ethically-approved research purposes.
- The target is to enroll 2,000 new severe asthma patients into ISAR annually, and at least 13,150 patients worldwide by 2022.
- This gives ISAR:
  - Sufficient **statistical power** to answer important research questions,
  - Sufficient **data standardization** to compare across countries/regions and
  - The **structure and expertise** necessary to ensure its continuance, scientific integrity, and clinical applicability of its research.
- The aim of this poster was to:
  - Explore the level of standardization of asthma variables collected by pre-existing asthma registries pre- and post-participation in ISAR, and to highlight additional variables collected for national research interests.
  - Outline the ISAR development process from 2017 to 2019
  - Provide a snapshot of all registries currently collaborating with ISAR.

Methods

- Pre-existing registries were identified by an online search and by approaching known opinion leaders in severe asthma.
- **Inclusion criteria**
  - Adult severe asthma registries
  - Including patients with confirmed severe asthma diagnosis and
  - Data made available for comparison and standardization with ISAR.
- **Exclusion criteria**
  - Collected data on children or were drug-specific
  - General asthma registries or contained overlapping data, and
  - Elected not to participate or were non-contactable.
- Data fields captured by these pre-existing registries (prior to inclusion with ISAR) were compared with the standardized ISAR core and additional variable lists (**Table 1**).

Table 1. Categorization of ISAR core and additional variables

ISAR Core Variable Categories[2]		ISAR Additional Variable Categories
1. Asthma severity	8. Lung function	1. Safety (e.g. severe infection, malignancies, anaphylaxis)
2. Patient details	9. Allergen testing	2. Additional co-morbidities
3. Occupation	10. Asthma control	3. Exacerbation details (e.g. date, rescue steroid & dose)
4. Medical history	11. Asthma medication	4. Medication (e.g. OCS, ICS, ICS+LABA) dose & frequency & reason(s) for medication switching
5. Co-morbidity	12. Adherence	
6. Blood/sputum	13. Management plan	
7. Diagnostics		
ISAR: International Severe Asthma Registry; OCS: oral corticosteroid; ICS: inhaled corticosteroid; LABA: long-acting β_2-agonist		

- The proportion of registries collecting each ISAR variable was calculated, and level of agreement with ISAR variables assessed prior to participation in ISAR.
- Additional non-ISAR variables collected by local registries were also collated and compared across registries.

Results

Initial registry selection for inclusion in ISAR

- Of the twenty-seven identified registries, 8 severe asthma registries, active as of May 2018, covering over 198 sites globally, were included for comparison with ISAR (**Figure 1**).
- Of the 8 registries, 7 are national and 1 is a regional repository. The Severe Asthma web-based Database (SAWD) covers sites in Australia, New Zealand, and Singapore.

Pre-existing national registry match with ISAR and additional variables collected

- There was good agreement between these registries and ISAR for some of the ISAR variable categories, but not for others (**Table 2**).
  - Pre-existing national/regional registries did NOT capture 15-38% of the 65 key ISAR variables compared (i.e. total of 113 core and additional ISAR variables consolidated[1] into 65 key variable groups for comparison) (**Figure 2**).
- All ISAR core- and additional variables are now collected across ISAR participating registries, incl. key biomarkers (i.e. sputum eosinophil count, highest blood eosinophil count, and fractional exhaled nitric oxide).
- Importantly, many local registries also collect additional variables on top of those mandated by ISAR (**Figure 2**).

ISAR time line: creation, evolution & expansion

- ISAR continues to develop (**Figure 3**):
- 2017: **Creation**, with 14 registries committing to collect ISAR's 95 core severe asthma variables
- 2018: **Evolution** of data fields to include additional safety and effectiveness variables
- 2019: **Expansion** to include 32- registries committed to collecting ISAR's core and additional variables (**Figure 4**).
  - All of these registries have committed to collecting ISAR's core and additional variables;
  - many also collect additional, registry-specific variables.

Table 2. Variable categories collected and not collected by registries pre-ISAR

ISAR variable categories collected by most registries pre-ISAR	
Category	**Details**
Patient details	e.g. DOB, gender, height, weight
Medical history	e.g. smoking status, age of asthma onset, hospital & ED visits
Occupation	e.g. current occupation
Co-morbidity	e.g. eczema, AR, CRS, NP
Blood/Sputum	Blood IgE, blood, and/or sputum eosinophil counts
Lung function	e.g. PC20 MCT, FEV_1, FVC, FeNO
Allergen tests	e.g. SPT, serum allergen tests
Asthma medication	e.g. Dose & duration of ICS, OCS, LABA, ICS+LABA, LTRA, LAMA, macrolides, Anti-IgE
Adherence	
ISAR variable categories NOT collected by most registries pre-ISAR	
Asthma severity	e.g. Definition
Patient details	e.g. Ethnicity/race, BMI, BSA
Medical history	e.g. Years since last smoked, date of exacerbation, rescue steroid & dose
Blood/sputum	e.g. Highest blood eosinophil count
Diagnostics	e.g. Chest CT, DEXA
Asthma control	e.g. Day symptoms, activity limitation, nocturnal symptoms, reliever medication use, lung function
Asthma medication	e.g. Anti-IL-5 use
Additional co-morbidities	e.g. Diabetes, pneumonia
Reason(s) for medication switching	e.g. Lack of clinical efficacy, side effects, biologic access restriction, patient preference
Safety	e.g. infection, malignancies, anaphylaxis

DOB: date of birth; ED: emergency department; AR: allergic rhinitis; CRS: chronic rhinosinusitis; NP: nasal polyps; IgE: Immunoglobulin E, MCT: methacholine challenge test; FEV1: forced expiratory volume in one second; FVC: forced vital capacity; FeNO: fractional exhaled nitric oxide; SPT: skin prick test; ICS; inhaled corticosteroid; OCS: oral corticosteroid; LAMA: long-acting β2-agonist; LTRA: leukotriene receptor antagonist; LAMA: long-acting muscarinic receptor antagonist; BMI: body mass index; BSA: body surface area; DEXA: densitometry

Results

Figure 1. Identification and selection of pre-existing asthma registries for inclusion in ISAR

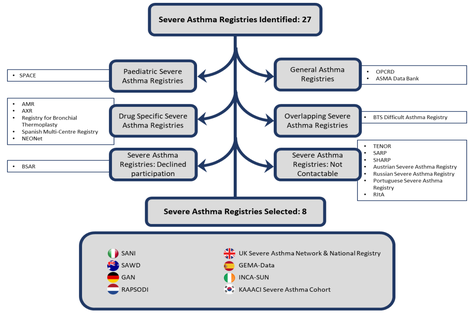
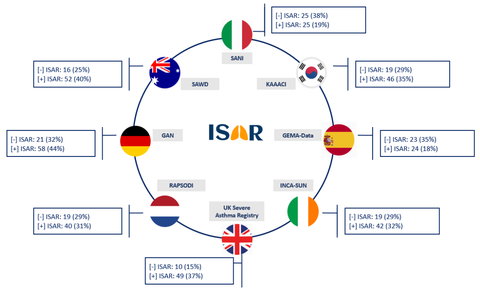


Figure 2: % match with ISAR variables AND additional variables collected by pre-existing registries prior to ISAR



[-] ISAR: ISAR variables not collected (% of total variable groups compared:65)
[+] ISAR: Non-ISAR variables collected (% of total additional variable groups compared: 131)

Figure 3: ISAR time line including variable standardization and registry participation

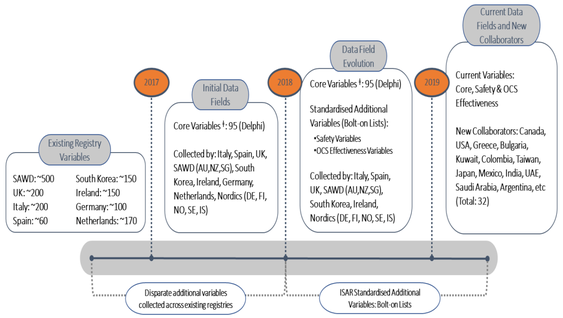
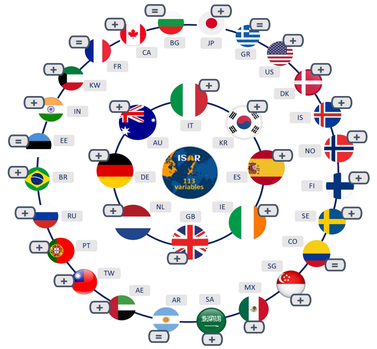


Figure 4: All registries currently collaborating with ISAR



[+] collects ISAR variables (core & additional) PLUS additional registry-specific variables
[=] collects ISAR variables (core & additional)

Conclusions

- Prior to ISAR, there was heterogeneity in the type and quality of data collected by national severe asthma registries. Some inconsistencies in data collection were identified.
- ISAR overcomes inconsistencies in data collected by:
  - Standardizing and consolidating data collection across national and regional registries.
  - Encouraging widespread collection of key variables, particularly biomarkers.
- ISAR and local registries complement each other:,
  - ISAR provides a global view of severe asthma.
  - National registries collect information which is most useful from a resource point of view, and more relevant to local clinical management.
- ISAR improves the quality of data collected locally in order to improve the accuracy and validity of data analyzed globally.

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Conflict of interest statement: