Global Evaluation of Real-World Studies on Biosimilar Usage in Oncology

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Background

- Biosimilars are drug products which are “highly similar” to their reference biologics, or bio-originator, and are required to show the same clinical effectiveness, quality and safety profile to their reference biologic counterparts in order to be approved for marketing.
- Globally, biologics make up approximately 25% of the pharmaceutical marketplace.
- Reluctance persists among clinicians and patients to use biosimilars to their full extent, which highlights the need for more training, education and real-world evidence (RWE) to emphasize the utility of these therapies.
- Many countries have rich data repositories documenting clinical care or have developed databases or registries to collect real-word patient data. However, these systems – and the patient data within – vary from country to country, which further emphasizes the need for more robust harmonization across currently fragmented or disparate data sources.
- As biosimilar products continue to be developed and approved, the need for quality RWE to underline their inherent value is paramount.

Objectives

- This systematic review was conducted in order to explore current systems used to house patient data on biosimilar use in oncology and identify the utility of the data extracted.

Methods

- **Literature Search:** Conducted using Pubmed, MedlinePlus, Scopus, Ovid, and ClinitcalTrials.gov. Included papers were published between April 1, 2012-July 27, 2019. Keywords used included *biosimilar, cancer/oncology,* and *observational/real world study.* The phrase “Biosimilar in (oncology OR cancer) AND (real world evidence OR observational research)” was used in order to conduct the Pubmed search. Studies published in any country were included if they were written in English.

- **Study Selection:** After duplicate studies were removed, titles and abstracts of each study were independently reviewed. Next, the full text of articles were reviewed for inclusion. Studies selected satisfied the following criteria: 1. Study population: cancer patients; 2. Intervention: biosimilars; 3. Study design: observational/real-world; 4. Utilization of a database or registry to measure outcomes.

Results

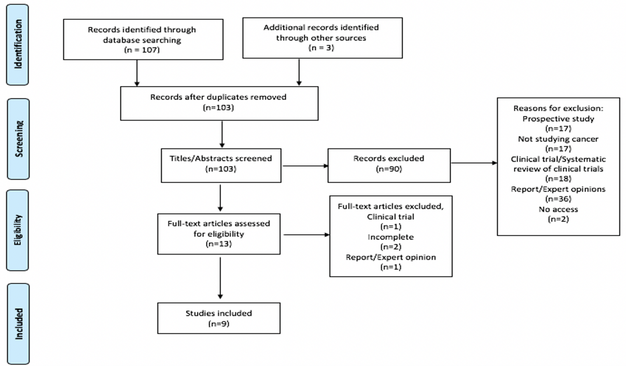

Fig 1: There were 9 studies published from 2012-2019 included in this systematic review that appropriately met the inclusion and exclusion criteria.

Database Type	Data Extracted	Strengths	Weaknesses	# of Studies	Location
ETPR	Specialists complete an ETPR reporting exact drug name, number of dispensed packages, dosing regimen and indication for use. The data is anonymized and linked to claims databases	The ability to explore dispensing records for biosimilars and how marketing along with policy changes affected prescribing patterns	Using this database may have poor external validity due to only including the Italian population. May not have captured those biosimilars dispensed in the hospital	4	Italy
Global Safety Database	Cumulative exposure and adverse event data was collected from spontaneous reports	A worldwide safety analysis that accounts for the limitations of clinical trials (small sample size, controlled environment, etc.)	Voluntary reporting in a spontaneous setting that may have missing medical information	1	53 countries
EHR	Demographic data, diagnoses, treatment plans, medical histories, allergies, laboratory data, and test results	Reflects the real-world situation that is based on an unselected group of patients that are part of the day-to-day routine	No data about the performance status of the patient or comorbidities that could cause neutropenia	2	Italy
Claims Data	ICD-9,10 and CPT, or HCPS codes for neutropenia, fever, or infection were used. National Drug Code (NDC) numbers for dispensed medications, quantity dispensed, dose, number of days supply, and death date	Search criteria can be streamlined and adjusted according to inclusion criteria	Data is dependent on the accuracy of claims coding. Presence of diagnosis code does not prove the presence of disease	2	United States

Table 1: Database/registry sizes ranged from 245 to 60 million lives covered, and include cost information.

Limitations

- Only studies published in English were included in this systematic review. It is possible that studies published in other languages may have used databases that were not included in this review.
- Some studies had objective data from comparison trials, while one had data generated from self-reported patient outcomes.
- Most studies were conducted in order to compare biosimilars to reference products. It is possible that authors did not report all capabilities contained within registries/databases, which was the focus of this review.

Conclusion

- All databases/registries included in this review were used to perform retrospective analyses to convey the real-world outcomes that biosimilars have in oncology patients without the limitations of clinical trials.
- In the United States (US), claims data was used most often in order to follow oncology patients on biosimilars, but coding errors pose a limitation to this database type.
- Currently in the US, there is no registry specifically for following patients that use biosimilars like the ETPR used in Italy.

Next Steps

- There is great opportunity for the development of a US-based registry that would allow access to real-world biosimilar data
- A US-based registry would give prescribers and researchers access to real-world outcomes in the oncology patient population, and could influence prescribing patterns.

References

1. Pittman WL, Wern C, Glode AE. Review of biosimilars and their potential use in oncology treatment and supportive care in the United States. *J Hematol Oncol Pharm.* 2019;9(3):133-141.
2. Peyrin-Biroulet L, Lonnfors S, Roblin X, Danese S, Avedano L. Patient perspectives on biosimilars: a survey by the european federation of crohn’s and ulcerative colitis associations. *J Crohns Colitis.* 2017;11(1):128-133. doi:10.1093/ecco-jcc/jjw138.
3. Cohen H, Beydoun D, Chien D. et al. Awareness, knowledge, and perceptions of biosimilars among specialty physicians. *Adv Ther.* 2017;33(12): 2160–2172. doi:10.1007/s12325-016-0431-5.
4. Teeple A, Ellis LA, Huff L, et al. Physician attitudes about non-medical switching to biosimilars: results from an online physician survey in the United States. *Curr Med Res Opin.* 2019;35(4)611-617. doi:10.1080/03007995.2019.1571296.
5. Naeim A, Henk HJ, Becker L, et al. Pegfilgrastim prophylaxis is associated with a lower risk of hospitalization of cancer patients than filgrastim prophylaxis: a retrospective United States claims analysis of granulocyte colony-stimulating factors (G-CSF). BMC cancer. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3559272/. Published January 8, 2013.
6. Ingrasciotta Y, Giorgianni F, Bolcato J, et al. How Much Are Biosimilars Used in Clinical Practice? A Retrospective Italian Population-Based Study of Erythropoiesis-Stimulating Agents in the Years 2009-2013. BioDrugs : clinical immunotherapeutics, biopharmaceuticals and gene therapy. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4561997/. Published August 2015.
7. Abboud CN, Lang N, Fung H, et al. Real-world safety experience of tevagrastim/ratiograstim/biograstim and tbo-filgrastim, short-acting recombinant human granulocyte colony-stimulating factors. SpringerLink. https://link.springer.com/article/10.1007/s00520-018-4522-5. Published November 15, 2018.
8. Puértolas I, Frutos Pérez-Surio A, Alcácera MA, Andrés R, Salvador MDT. Effectiveness of biosimilar filgrastim vs. original granulocyte colony-stimulating factors in febrile neutropenia prevention in breast cancer patients. European journal of clinical pharmacology. https://www.ncbi.nlm.nih.gov/pubmed/29152672. Published March 2018.

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