

BACKGROUND

A **biologic drug** is a type of medicine that is used to treat diseases like diabetes, cancer, and rheumatoid arthritis. Usually, a biologic drug must be injected into the body instead of taken by mouth. Biologic drugs are complex molecules used to treat very specific conditions.

Biosimilars are biologics that are highly similar to, and have no clinically meaningful differences in safety, purity, and potency from an existing FDA-approved biologic. They are approved by the US Food and Drug Administration (FDA) like all other prescription drugs.

Reference Biologic	Biosimilar
Biologics are engineered by scientists and made in living organisms	Biosimilars are made in a similar way and work the same in the body
Biologics are expensive and can cost up to \$100,000 or more per year	Biosimilars usually cost about 25% less than the originator

OBJECTIVE

Some patients with cancer who are treated with chemotherapy are given a medicine to help their bodies fight infection. These medicines are called granulocyte-colony stimulating factors, but we usually call them GCSFs. Some GCSF biosimilars are available.

We wanted to see how well GCSF biosimilars worked in preventing fever from infection compared to the reference biologics when given to patients who need them.

PROJECT DESIGN

We worked billing data from four health insurance companies to study information doctors must send in to get payment for treating patients. This information does not include any way to know who the patient is, but it gives information on how diseases were treated and some information about what happened after treatment. Table 1 lists the drugs included in this study.

Table 1. Products included in this study.

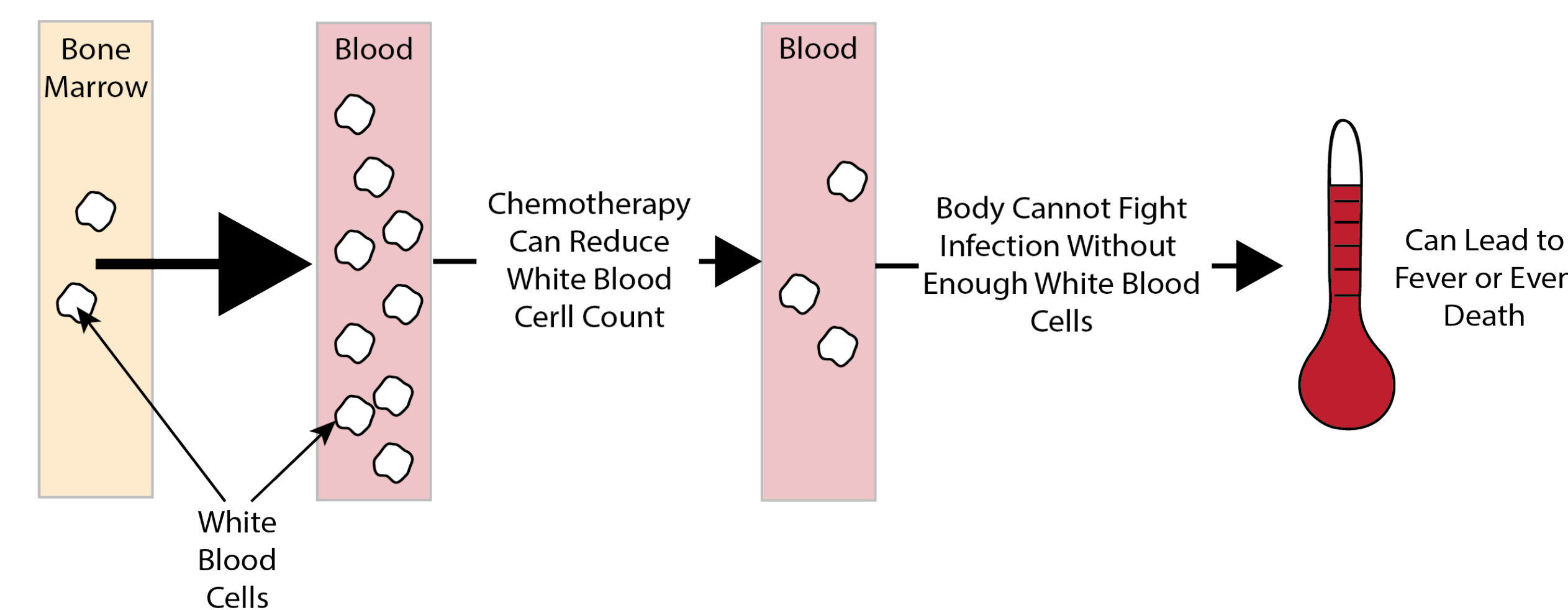
Reference Biologics	Biosimilars
Filgrastim (Neupogen®)	Filgrastim-sndz (Zarxio®)
	tbo-Filgrastim (Granix®)
Pegfilgrastim (Neulasta®)	Pegfilgrastim-cbqv (Udenyca®)
	Pegfilgrastim-jmdb (Fulphila®)

Note: the four letters at the end of biosimilar names allow us to tell them apart.

BIOSIMILAR medications work the same as reference biologic drugs for preventing severe illness from infection in patients with cancer treated with chemotherapy.

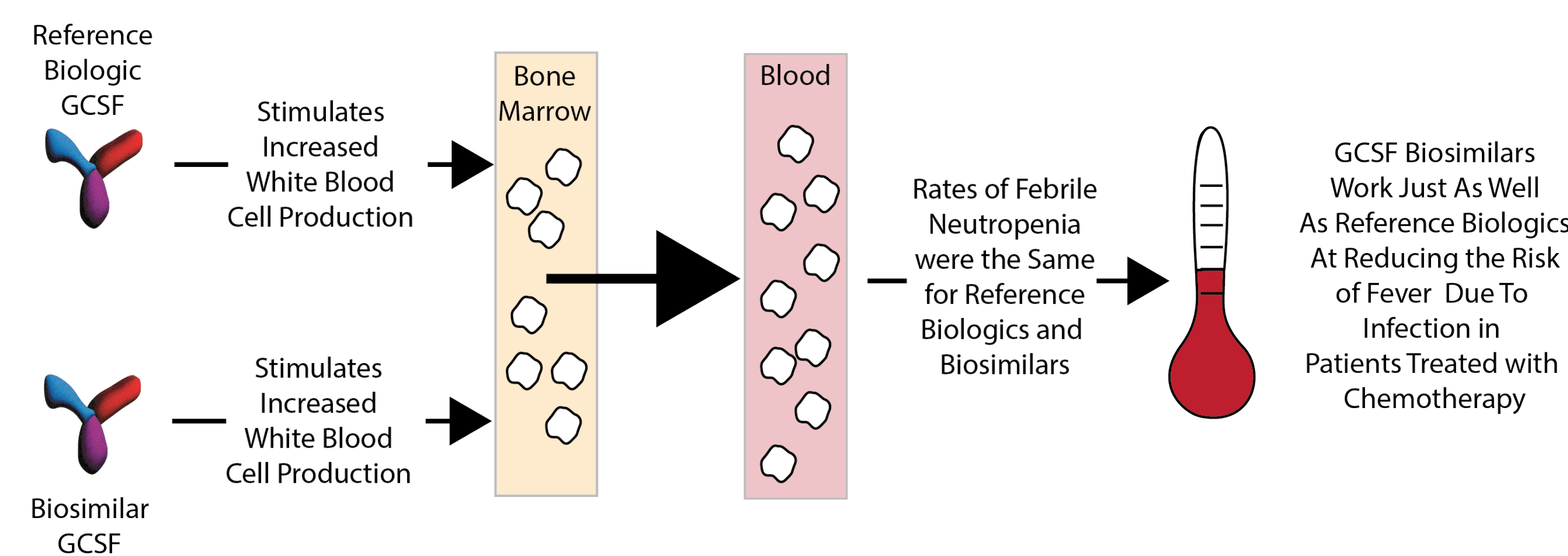
PROJECT HIGHLIGHTS

Infections can happen because the chemotherapy can reduce the number of white blood cells in the blood. White blood cells help your body fight infection.



Reference Biologic or Biosimilar Used	Number of Patients	Number of Febrile Neutropenia Events
Filgrastim (reference biologic)	284	13 (4.6%)
Filgrastim-sndz (biosimilar)	201	5 (2.5%)
Tbo-filgrastim (like a biosimilar)	80	2 (2.5%)
Pegfilgrastim (reference biologic)	15,115	346 (2.3%)
Pegfilgrastim-cbqv (biosimilar)	484	11 (2.3%)
Pegfilgrastim-jmdb (biosimilar)	342	8 (2.3%)

Febrile Neutropenia means getting a fever from an infection when you have a low white blood cell count.



Comparison	Relative Risk	Confidence Interval
filgrastim-sndz to filgrastim	0.46	0.17 – 1.28
tbo-filgrastim to filgrastim	0.30	0.06 – 1.36
tbo-filgrastim to filgrastim-sndz	0.54	0.10 – 2.77

Comparison	Relative Risk	Confidence Interval
pegfilgrastim-cbqv to pegfilgrastim	0.83	0.41 – 1.69
pegfilgrastim-jmdb to pegfilgrastim	1.03	0.56 – 1.92
pegfilgrastim-jmdb to pegfilgrastim-cbqv	1.11	0.45 – 2.74

Confidence Interval: This is a calculation from statistics that shows whether the Relative Risk is actually different between the products. A interval with a range that includes 1.0 means there is no difference between the products compared.

Relative Risk: This measures how likely a person provided a GCSF product is to develop a fever from infection after a dose of chemotherapy. If this number is 1.00 the risk is exactly the same between the two products. If the number is less than 1.00, the risk is lower with the product listed first compared to the product listed second. If the number is higher than 1.00 the risk is higher for the product listed first compared to the product listed second.

PATIENT/COMMUNITY IMPACT

Infections can happen because chemotherapy can cause a lower number of white blood cells. White blood cells help your body fight infection. When we looked at data from patients who got chemotherapy along with either a reference biologic or a biosimilar to help the body make white blood cells, we found that the biosimilar medicines worked just as well as the reference biologic to prevent a low number of white blood cells. This helped patients' bodies fight infections while they were being treated with chemotherapy.

It is important to know that biosimilars work just the same as the reference biologic products in preventing fever and infection. Having biosimilars to use gives doctors and patients more choices of the same medicine and this could make it easier for patients to get the medicine if they need it. Biosimilars also may cost less than the reference biologic.

DEMOGRAPHICS

This study is focused on patients with cancer who are treated with certain chemotherapy. Other biosimilars are important for many other patients with inflammatory conditions like rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, and some eye conditions.

CONCLUSIONS

- GCSF biosimilars to help prevent fever due to infection when getting chemotherapy for cancer work **just as well** as the reference biologics.
- GCSF biosimilars do not cause more side effects than the reference biologics.

RECOMMENDATIONS

If you are treated with a biologic medicine like GCSFs for cancer or other diseases, ask your doctor if there is a biosimilar available, and if it is a good choice for you. Using biosimilars can have a big impact on the cost of healthcare. They can also increase your ability to have access to important biologic treatments.

CONTACT INFORMATION



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