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.

Biosimilars are made in a similar way and work the same in the body. Biosimilars usually cost about 25% less than the originator.

Biologics are engineered by scientists and made in living organisms. Biologics are expensive and can cost up to $100,000 or more per year.

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 GCSFs are biosimilars. It is important to know that biosimilars work just the same as the reference biologic products in preventing fever and infection.

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 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.

### 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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www bbcic.org

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**Objectives:**

- To study infections can happen because chemotherapy can cause a lower number of white blood cells.
- To compare biosimilar GCSFs to reference biologics in preventing infection.
- To evaluate the safety and efficacy of biosimilar GCSFs.

**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.

**Methodology:**

We worked billing data from four health insurance companies to study 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.

### Project Highlights

- **Comparison of Febrile Neutropenia**
  - Pegfilgrastim-jmdb (biosimilar) vs Pegfilgrastim (reference biologic): Relative Risk = 0.46, Confidence Interval = 0.17 – 1.28
  - Tbo-filgrastim vs Filgrastim: Relative Risk = 0.30, Confidence Interval = 0.06 – 1.36
  - Pegfilgrastim-cbqv vs Pegfilgrastim: Relative Risk = 0.54, Confidence Interval = 0.10 – 2.77

- **Comparison of Neutropenia Events**
  - Pegfilgrastim-jmdb vs Pegfilgrastim-dbqv: Relative Risk = 0.83, Confidence Interval = 0.41 – 1.69
  - Pegfilgrastim-cbqv vs Pegfilgrastim: Relative Risk = 1.03, Confidence Interval = 0.58 – 1.92
  - Pegfilgrastim-cbqv vs Pegfilgrastim-dbqv: Relative Risk = 1.11, Confidence Interval = 0.45 – 2.74

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

### Table 1. Products included in this study.

<table>
<thead>
<tr>
<th>Reference Biologic</th>
<th>Biosimilars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filgrastim (Neupogen)</td>
<td>Pegfilgrastim</td>
</tr>
<tr>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
</tr>
<tr>
<td>Pegfilgrastim (reference biologic)</td>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
</tr>
<tr>
<td>Pegfilgrastim-cbqv (biosimilar)</td>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
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<td>Pegfilgrastim-cbqv (biosimilar)</td>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
</tr>
</tbody>
</table>

**Predictive Model:**

Relative Risk: This measures how likely a person provided a GCSF to help prevent fever due to infection when getting chemotherapy for cancer work just as well as the reference biologics. Biosimilars also may cost less than the reference biologic.

**Patients/Community Impact:**

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.

**Biologics and Biosimilars Collective Intelligence Consortium, A non-profit, scientific collaborative.**

**A Short $200,000,000,000 Question:**

- **For the product listed first compared to the product listed second:**
  - If the number is higher than 1.00 the risk is higher
  - If the number is less than 1.00 the risk is exactly the same between the two products.
  - If the number is 1.00 the risk is the same.

**Febrile Neutropenia:**

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

**Table 1. Products included in this study.**

<table>
<thead>
<tr>
<th>Reference Biologic or Biosimilar Used</th>
<th>Number of Patients</th>
<th>Number of Febrile Neutropenia Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filgrastim (reference biologic)</td>
<td>234</td>
<td>13 (4.6%)</td>
</tr>
<tr>
<td>Pegfilgrastim-sndz (biosimilar)</td>
<td>201</td>
<td>5 (2.5%)</td>
</tr>
<tr>
<td>Tbo-filgrastim (like a biosimilar)</td>
<td>80</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Pegfilgrastim (reference biologic)</td>
<td>15,115</td>
<td>346 (2.3%)</td>
</tr>
<tr>
<td>Pegfilgrastim-cbqv (biosimilar)</td>
<td>494</td>
<td>11 (2.3%)</td>
</tr>
<tr>
<td>Pegfilgrastim-jmdb (biosimilar)</td>
<td>342</td>
<td>8 (2.3%)</td>
</tr>
</tbody>
</table>