



PROSPECTIVE EXPECTED COST BENEFIT ANALYSIS OF THE USE OF BIOSIMILAR AGENTS INSTEAD OF CONVENTIONAL AGENTS IN ROYAL MEDICAL SERVICES -JORDAN

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ABSTRACT:

Introduction: The term "Biosimilar" refers to biological products that successfully mimic original products (therapeutically and biologically), generally appearing when exclusive rights of the originators drugs are lost. The increased competition in the market as a result of their lower cost in compare with original products is what fuels their growth. And by lowering financial barriers of the biological medicines they provide the opportunity to enhance patient's access to medications and a better healthcare. Investigation on the possibility of interchanging to these products is a necessity due to the possible cost savings gained from switching to biosimilars without the loss of clinical effectiveness or safety.

Purpose: This study aims to estimate the possible cost benefit the Jordanian Royal Medical Services (RMS) has to gain from switching to these biosimilar products instead of conventional agents.

Methodology: In this prospective study data on the RMS usage for several conventional agents and their cost during the period of 2018-7/2023 were gathered and statistical analysis was done to estimate the possible cost benefit the RMS has to gain from converting to biosimilars.

KEYWORDS: Biosimilar, biopharmaceutical, economic evaluation, Cost efficiency, Interchangeability.

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1. INTRODUCTION:

Biosimilars, as their name suggests, are the result of cutting-edge research attempts to duplicate the properties of original biologic therapies. Through a rigorous development process, biosimilars are created to closely mimic their reference medications in terms of therapeutic efficacy, pharmacokinetics, and pharmacodynamics. It is critical to achieve this level of similarity to guarantee that patients can switch safely from reference products to biosimilars without compromising clinical outcomes or safety^[1,2].

The creation of biosimilar medications is a huge advance in modern medicine because it provides a novel method of providing treatment. When the patents on the original medications expire^[3], this resemblance becomes extremely significant since it opens up opportunities for the creation and usage of biosimilar replacements. There is more competition in the pharmaceutical sector because biosimilars are less expensive than the original drugs. This has encouraged the meteoric emergence of biosimilars and has significant potential to change patient access to lifesaving medications^[5].

One of the market's most powerful drivers is the substantial cost savings that biosimilars offer. By entering the market at a lower price point than their originator equivalents and promoting competition, biosimilars pose a danger to the continued availability of costly biologic medications. Patients benefit since the cost of healthcare is reduced because of the possibility of considerable cost savings, but this also put pharmaceutical firms under pressure to use more aggressive pricing strategies^[5,7]. By providing a cost-efficient alternative to expensive biologics, biosimilars allow healthcare practitioners to reach a larger patient population. And as a result, patients who have better access to effective medicines are better able to manage their chronic diseases^[6].

The possibility of interchangeability with standard products is critically studied as biosimilars become more common in clinical settings.

Interchangeability is the capacity of a biosimilar to be switched with its reference product and vice versa without compromising clinical efficacy or safety^[4]. Thorough investigations and regulatory assessments are essential to ensure that patients may switch between these therapeutic options safely, providing a seamless transition that maximizes the benefits of biosimilars while lowering potential risks^[8-10].

Due to the pressing need for healthcare systems to enhance resource allocation and manage escalating treatment costs, a detailed investigation of the potential cost savings and therapeutic benefits associated with the use of biosimilars is necessary. By carefully comparing the cost-effectiveness of biosimilars to conventional agents, policymakers, healthcare professionals, and patients can make informed decisions that uphold the principles of evidence-based medicine while prioritizing economic sustainability^[10].

2. METHOD:

The cost of biosimilars is often lower than that of their original (reference) medications when they are first released on the market. Although the degree of the price reduction can vary, it is not unusual for biosimilars to be priced anywhere between 20% and 70% less than the reference product^[11].

Investigation on the interchangeability of these medications is important due to the possible cost savings from switching to biosimilars without impacting clinical effectiveness or safety. It was anticipated that between 2014 and 2024, US consumers will save \$44.2 billion as a result of interchanging to biosimilars^[12].

In this study, data on the RMS usage for several conventional agents and their cost in Jordanian Dinar (JD) during the period of 1/2018-7/2023 were gathered (Table1) and statistical analysis using Microsoft Excel Spreadsheet Software was done to estimate the possible cost benefit the RMS has to gain from converting to biosimilars.

Table 1: Data on the RMS usage for several conventional agents and their cost in Jordanian Dinar (JD)

| Medication | Active Ingredient | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|----------------------------------|-------------------|-----------|-----------|---------|---------|---------|---------|
| Humira 40 mg/0.8 ml | Adalimumab | 414,949 | 340,979 | 986,856 | 325,454 | 452,591 | 285,379 |
| Remicade 100mg Vial | Infliximab | 0 | 299,790 | 258,889 | 0 | 550,620 | 0 |
| Enbrel 50 mg PFS | Etanercept | 0 | 308,318 | 370,663 | 0 | 14,884 | 65,297 |
| Enbrel PFP 50MG | Etanercept | 0 | 0 | 999,634 | 0 | 866,305 | 321,385 |
| Actemra 20mg/ml,10ml vial | Tocilizumab | 160,027 | 64,011 | 185,141 | 185,141 | 257,987 | 0 |
| Actemra 20mg/ml, 4mlvial | Tocilizumab | 32,472 | 0 | 34,017 | 34,017 | 49,772 | 0 |
| Simponi 50mg/.5ml | Golimumab | 0 | 0 | 145,888 | 0 | 167,616 | 80,316 |
| Simponi 100mg/1ml | Golimumab | 0 | 0 | 133,731 | 0 | 109,642 | 71,004 |
| Stelara 45mg/.5ml | Ustekinumab | 0 | 0 | 74,956 | 0 | 132,768 | 73,277 |
| Stelara 90mg/1ml | Ustekinumab | 0 | 0 | 247,354 | 0 | 416,744 | 298,482 |
| Sterala 130mg Vial | Ustekinumab | 0 | 0 | 74,613 | 0 | 16,776 | 15,972 |
| Cosentyx 150mg "Secukinumab" PFP | Secukinumab | 0 | 74,761 | 64,838 | 132,378 | 319,038 | 131,570 |
| TremfyaGuselkumab 100mg/ml PFS | Guselkumab | 0 | 0 | 0 | 0 | 96,475 | 43,669 |
| Opdivo 40mg | Nivolumab | 6,744 | 4,496 | 56,251 | 185,311 | 128,557 | 66,923 |
| Opdivo 100mg | Nivolumab | 31,800 | 31,800 | 287,374 | 912,980 | 308,165 | 714,585 |
| Vectibix 20mg/ml,5ml Vial | Panitumumab | 0 | 0 | 0 | 0 | 0 | 33,397 |
| Darzalex 400mg Vials. | Daratumumab | 0 | 0 | 179,520 | 448,000 | 67,200 | 445,120 |
| Keytruda | Pembrolizumab | 0 | 0 | 140,580 | 281,160 | 429,795 | 218,925 |
| Tecentriq1200mg/20mL Vial | Atezolizumab | 0 | 0 | 0 | 0 | 0 | 56,899 |
| Herceptin 440mg Vial | Trastuzumab | 2,521,529 | 2,521,529 | 0 | 0 | 0 | 479,566 |
| Perjeta 420mg | Pertuzumab | 0 | 0 | 0 | 0 | 241,795 | 201,496 |
| Herceptin 600mgS.C Vial | Trastuzumab | 0 | 0 | 528,587 | 682,944 | 341,052 | 0 |

| Medication | Active Ingredient | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---------------------|-------------------|---------|---------|---------|---------|---------|---------|
| Avastin 100mg/ml | Bevacizumab | 64,726 | 77,637 | 34,936 | 111,227 | 55,613 | 15,481 |
| Avastin 400mg/ml | Bevacizumab | 82,119 | 139,803 | 62,543 | 135,087 | 62,590 | 24,231 |
| Simulect 20mg Vial | Basiliximab | 17,123 | 17,123 | 14,269 | 14,269 | 0 | 0 |
| Benlysta 400mg Vial | Belimumab | 12,167 | 0 | 0 | 0 | 0 | 0 |
| Benlysta 200mg Vial | Belimumab | 0 | 8,230 | 8,230 | 13,138 | 0 | 5,780 |
| Tysabri vial | Natalizumab | 179,898 | 128,491 | 256,802 | 171,792 | 0 | 306,005 |
| Ocrevus 30mg/ml | Ocrelizumab | 0 | 0 | 0 | 121,582 | 109,311 | 48,288 |

We compared the total cost of the drugs in question in the years 2018 to 2023 with a hypothetical scenario where all patients were switched to biosimilars in order to determine the potential cost savings from switching to biosimilar medications. Since we don't have specific pricing information for the biosimilars, we'll make the following two assumptions:

We assume that all patients previously used the

mentioned drugs were switched to their respective biosimilars.

We assume a 20% cost reduction for each biosimilar compared to its originator drug.

3. RESULTS:

We calculated the total expenditure for each year for both the original drugs and the hypothetical scenario with biosimilars priced 20% lower and the resulted cost savings (Table 2, Figure1).

Table 2: The total expenditure for each year for both the original drugs and the hypothetical scenario

| Year | Total Expenditure (Original Drugs) | Total Expenditure (Biosimilars at 20% Lower Cost) | Cost Savings |
|------|------------------------------------|---|--------------|
| 2018 | 3,523,554 | 2,818,843 | 704,711 |
| 2019 | 4,016,968 | 3,213,574 | 803,394 |
| 2020 | 5,145,672 | 4,116,538 | 1,029,134 |
| 2021 | 3,754,480 | 3,003,584 | 750,896 |
| 2022 | 5,195,296 | 4,156,237 | 1,039,059 |
| 2023 | 4,003,047 | 3,202,438 | 800,609 |

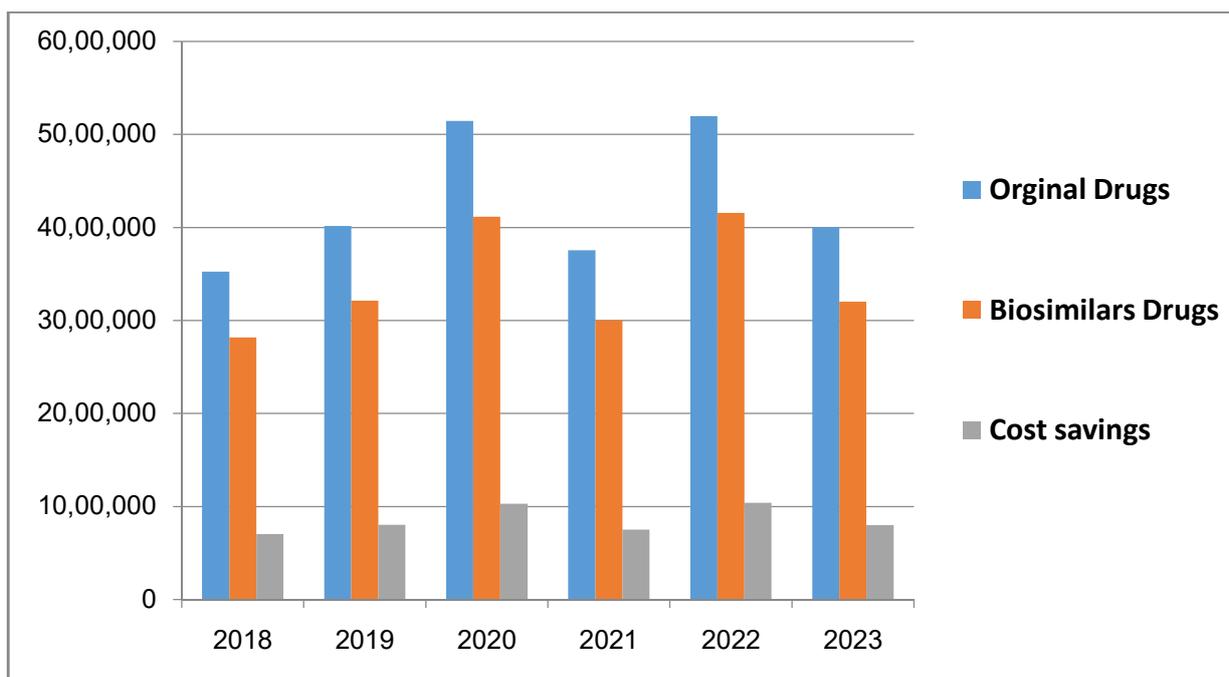


Figure 1: The total expenditure for each year for both the original drugs and the hypothetical scenario

The information in table 2 illustrates the overall cost of original medications and biosimilars as well as the cost savings that resulted for each year from 2018 to 2023. The cost savings represent the difference in spending between the two medicine types, allexpressed in JD.

Note that the actual cost savings from converting to biosimilars will depend on the precise pricing, healthcare legislation, and actual usage patterns. These data calculations are based on assumptions and hypothetical scenarios. However, it provides a general idea of the cost reductions that could result from using biosimilars instead of the original drugs at the RMS.

4. DISCUSSION:

The goal of this study was to investigate if utilizing biosimilar agents in place of traditional ones in medical therapy could result in cost savings. We sought to offer useful insights into the economic effects of the adoption of biosimilars in healthcare by looking at real-world total expenditures for

various medications used in the RMS from 2018 to 2023.

The results of this study have significant effects on how healthcare decisions are made. By replacing conventional agents with biosimilars, it may be possible to reduce costs, which would relieve financial strain on healthcare systems, our findings are applicable to and significant for healthcare decision-makers because this information reflects actual healthcare spending during the mentioned period and it supports patients, physicians, and policymakers in making decisions that are in line with cost-effective healthcare delivery. Leading to increase patient access to pharmaceuticals, and increase overall healthcare affordability [7,10].

The potential for cost savings from switching to biosimilars is heavily influenced by variations in drug pricing, market rivalry, regulatory rules, and our investigation also revealed the biosimilar market is growing at a fastrate and cost savings will probably grow much larger when additional biosimilar products are released and the level of

competition rises. This may foster a competitive climate that is advantageous to healthcare providers as well as patients^[5].

The data on overall spending and cost savings for original medications and biosimilars over this six-year period clearly shows the financial benefits of using biosimilars. Making these treatments a crucial part of healthcare that is both affordable and available. To maximize the advantages of biosimilars, policymakers, healthcare professionals, and patients should take the information provided by this data into account when making decisions concerning drug formularies and treatment options^[6].

5. CONCLUSION:

The adoption of biosimilar medications is increasing patient access to life-saving medications and resulting in significant cost reductions. As biosimilars continue to demonstrate therapeutic equivalence to reference biologics, healthcare policymakers must look into how to include biosimilars into treatment plans. By embracing the potential of biosimilars and facilitating a smooth transition to these therapeutic replacements^[4, 7,10].

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Our study findings support the RMS transition to biosimilars instead of conventional agents and show the promising economic advantages it has to gain from this transition.

Limitations of the Study: It is important to recognize the restrictions on our investigation. The calculation of long-term annual growth rates was hindered by the absence of historical data prior to 2018, the availability of biosimilar alternatives and their acquisition prices, variations in drug pricing, market competition, and other unaccounted factors that may have an impact on cost savings were not taken into account in our dataset are all important considerations when assessing the potential savings from switching to biosimilars.

Future research should concentrate on overcoming those limitations in order to build on these findings. Studies that use longer historical data sets may produce more insightful results about long-term compound annual growth rates. For evidence-based healthcare decision-making, it is also critical to evaluate the clinical efficacy and safety of biosimilars to those of traditional drugs in real-world settings.

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