ABSTRACT

**Aim:** The aim of this study was to investigate physicians' opinions on the required information about biosimilars and the need for biosimilars related education.

**Methodology:** The study included a survey that was prepared using a survey from a previous study and after face validation and content validation, it was prepared as an online form using the SurveyMonkey platform.

**Results:** The majority of physicians stated that the most important information about biosimilars are studies that provide clinical immunogenicity data for the biosimilar and reference product (93.33%) in addition to studies that directly compare clinical efficacy and safety between reference products and biosimilars (88.89%). The majority of physicians stated that tracking safety events with biosimilars (94.45%) and access to information on studies comparing biosimilars with reference biologics (91.11%) are important issues related to biosimilars in professional environments.

**Conclusion:** The present study highlights the needs of physicians for biosimilar education. More efforts are needed to increase the awareness regarding biosimilars by different formats in order to integrate biosimilars into clinical practice and to counsel patients about biosimilars.

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1. INTRODUCTION

Biological medicines are drugs produced through biological processes. They have noticeably altered the management pathway of numerous chronic and life-threatening diseases, affecting the life of several patients positively. Nevertheless, the prices of these biological medicines are generally high. The arrival of expensive innovative medicines increasingly challenges healthcare systems to find avenues to optimize spending while ensuring access to these medicines for their patients [1].

Several organizations are replacing the innovator biologics with their biosimilars, often to take advantage of the financial benefits, which can be quite significant for an organization. One analysis estimated that between 2017 and 2026, the approval of biosimilars will decrease direct spending on biologic drugs by $54 billion [2]. The key considerations when introducing biosimilars into clinical practice include selection of biosimilars most suited to the organization, and buy-in from physicians, demonstration of a positive financial analysis and acceptance by patients [3].

Biosimilars are biologic products that are highly similar to a licensed reference biologic with regard to their quality characteristics, efficacy, pharmacology, safety, such that there are no significant differences between the biosimilar and reference product when used in clinical practice [4–6]. For an organization considering a switch from an innovator biologic to its biosimilar, it is critical to ensure buy-in from the doctors who will be ordering the drug for their patients. A recent review about the use of biosimilar found that more education is needed for physicians about biosimilars [7]. Pharmacists, who are the medication experts, are the ideal health care professionals to discuss with physicians and to provide them with an appropriate education about biosimilars [8].

Although physicians had positive attitudes towards biosimilars, prescribing was limited, mainly for patients already being treated with biologic medicines [9]. Education and national recommendations for switching and substitution of biologic medicines are needed to support the uptake of biosimilars [9].

To date, there is a lack of published data about the awareness and the knowledge of physicians about biosimilars [10]. So, the aim of this study was to investigate physicians' opinions on the required information about biosimilars and the need for biosimilars related education.

2. METHODOLOGY

The present study focus on physicians’ opinions on the required information about biosimilars and the need for biosimilars related education. The survey was prepared using a validated questionnaire of a previous study [11] and after face validation and content validation, it was prepared as an online form using the SurveyMonkey platform [12].

The survey contained 5 parts which are the importance of types of information for making decisions to use biosimilar products, the importance of issues related to biosimilars in professional environments, the source of received information about biosimilars, the need for education related to biosimilars and the preferred education format to learn more about biosimilars.

In the present study, only physicians were included; other health care professionals were excluded. The subject personnel data were not collected, and the participants’ responses were nameless. Data were collected and analyzed descriptively using Microsoft Excel software. The descriptive data then were represented by the frequencies and percentages for each variable.

3. RESULTS AND DISCUSSION

The majority of physicians stated that for making decisions to use biosimilar products many information are important such as studies that provide clinical immunogenicity data for the biosimilar and reference product (93.33%), studies that directly compare clinical efficacy and safety between reference products and biosimilars (88.89%), inclusion in international and Saudi Arabia clinical practice guidelines and standards of treatment (85.55%), and studies that show pharmacokinetic similarities between reference products and biosimilars (84.45%). The importance of types of information for making decisions to use biosimilar products is shown in Table 1.

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Likewise, Ventola reported that studies that directly compare clinical efficacy and safety between reference products and biosimilars (90%), studies that show pharmacokinetic similarities between reference products and biosimilars (88%) and guideline and compendia inclusion (88%) are important [13].

On the other hand, other information regarding the acquisition cost differences and payer decisions and requirements are less important. This result is in contrast with the study of Ventola who reported that the acquisition cost differences (86%) and payer decisions and requirements (87%) are important [13]. Cook et al reported that the physicians’ understanding of biosimilars is poor, and the needs are high for more education. Moreover, before the prescribing of biosimilars it is important to know their efficacy, safety and cost [14].

The importance of issues related to biosimilars in professional environments are shown in Table 2. The majority of physicians stated that tracking safety events with biosimilars (94.45%), access to information on studies comparing biosimilars with reference biologics (91.11%), knowledge about biosimilars among interdisciplinary colleagues (90.00%), and preparing to integrate biosimilars into clinical practice including educating patients about biosimilars (85.56%) are important issues related to biosimilars in professional environments.

Similar results were found by Karateev and Belokoneva who reported that the most important issues related to biosimilars in professional environments were tracking safety events with biosimilars (99%), access to information on studies comparing biosimilars with reference biologics (96%) and knowledge about biosimilars among interdisciplinary colleagues (86%) [11].

On the other hand, the majority of the respondents reported that naming conventions for biosimilars (44.75%) and tender policy with the preferences to local manufacturers (43.8%) are less important. Likewise, Karateev and Belokoneva reported that naming conventions for biosimilars and tender policy with the preferences to local manufacturers are less important than other issues [11].

The information about biosimilars were received from many resources, especially internet (42.22) and published literature (30.00). Table 3 shows the source of received information about biosimilars.

Karateev and Belokoneva reported that the most common sources of information about biosimilars were conferences and other live meetings (77%) in addition to published literature (in native language; 69%), medical representatives or events organized by pharmaceutical company (68%) and internet (61%) [11].

The majority of the respondents said that they need to learn more about biosimilar (87.78%) and no one said that he is satisfied with his current knowledge of this area (0.00%). Table 4 shows the need for education related to biosimilars.

The last part includes information about the preferred education format to learn more about biosimilars and is shown in Table 5. The results show that online educational websites (38.89%) and regional/local live meetings (34.44%) are the preferred education format followed by national meetings/symposia (26.67%).

The present study found that the preferred education format to learn more about biosimilars is online educational websites followed by regional/local live meetings. In contrast to that, Karateev and Belokoneva reported that the preferred education format is conferences and other live meetings [11].

The present study found that most of the physicians requested more information about biosimilars. Barbier et al reported that 67% of physicians requested more information and that pharmacists and physicians preferred to be informed by their respective professional associations [15]. Halabi et al stated that the approval and use of biosimilars must be supported by scientifically sound evidence and that educational resources should be provided to healthcare professionals and patients [16]. Okoro reported that as biosimilars differ from generic medicines, it is imperative that healthcare specialists involved in their use have adequate critical information about their prescribing practices, interchangeability and traceability and that physicians may require additional information from clinical pharmacists to make a decision about biosimilar use [17].
Table 1. The importance of types of information for making decisions to use biosimilar products

| Statement                                                                 | Not at all important n(%) | Not important n(%) | Neutral n(%) | Important n(%) | Extremely important n(%) |
|---------------------------------------------------------------------------|----------------------------|--------------------|--------------|----------------|--------------------------|
| Studies that directly compare clinical efficacy and safety between reference products and biosimilars | 0 (0.00)                   | 0 (0.00)           | 10 (11.11)   | 48 (53.33)     | 32 (35.56)               |
| Studies that show pharmacokinetic similarities between reference products and biosimilars  | 2 (2.22)                   | 2 (2.22)           | 10 (11.11)   | 56 (62.23)     | 20 (22.22)               |
| Studies that show chemical/physical similarities between reference products and biosimilars | 0 (0.0)                    | 2 (2.22)           | 26 (28.89)   | 49 (54.45)     | 13 (14.44)               |
| Inclusion in international and Saudi Arabia clinical practice guidelines and standards of treatment | 0 (0.00)                   | 4 (4.44)           | 9 (10.00)    | 49 (54.44)     | 28 (31.11)               |
| Studies that provide clinical immunogenicity data for the biosimilar and reference product | 0 (0.00)                   | 0 (0.00)           | 6 (6.67)     | 58 (64.44)     | 26 (28.89)               |
| Studies that compare activity with in vitro functional assays between reference products and biosimilars | 2 (2.22)                   | 3 (3.33)           | 15 (16.67)   | 62 (68.89)     | 8 (8.89)                 |
| Acquisition cost differences                                              | 2 (2.22)                   | 6 (6.67)           | 39 (43.33)   | 37 (41.11)     | 6 (6.67)                 |
| Payer decisions and requirements                                           | 2 (2.22)                   | 8 (8.89)           | 42 (46.67)   | 27 (30.00)     | 11 (12.22)               |
| Colleague and expert opinion                                               | 4 (4.44)                   | 2 (2.22)           | 27 (30.00)   | 34 (37.78)     | 23 (25.56)               |
Table 2. The importance of issues related to biosimilars in professional environments

| Statement                                                                 | Not important at all n(%) | Not important n(%) | Neutral n(%) | Important n(%) | Extremely important n(%) |
|--------------------------------------------------------------------------|---------------------------|--------------------|--------------|----------------|--------------------------|
| Access to information on studies comparing biosimilars with reference biologics | 2 (2.22)                  | 0 (0.00)           | 6 (6.67)     | 44 (48.89)     | 38 (42.22)               |
| Knowledge about biosimilars among interdisciplinary colleagues           | 0 (0.00)                  | 2 (2.22)           | 7 (7.78)     | 47 (52.22)     | 34 (37.78)               |
| Switching between reference biologics and biosimilars                   | 0 (0.00)                  | 0 (0.00)           | 24 (26.66)   | 52 (57.78)     | 14 (15.56)               |
| Tracking safety events with biosimilars                                 | 0 (0.00)                  | 0 (0.00)           | 5 (5.55)     | 62 (68.89)     | 23 (25.56)               |
| Preparing to integrate biosimilars into clinical practice including educating patients about biosimilars | 0 (0.00)                  | 0 (0.00)           | 13 (14.44)   | 53 (58.89)     | 24 (26.67)               |
| Physician authority to decide on the most suitable biologic for each patient | 0 (0.00)                  | 0 (0.00)           | 18 (20.00)   | 59 (65.56)     | 13 (14.44)               |
| Establish reasonable and scientifically justified approach to interchangeability and automatic substitution | 0 (0.00)                  | 0 (0.00)           | 20 (22.22)   | 50 (55.56)     | 20 (22.22)               |
| Naming conventions for biosimilars (unique vs. same non-proprietary names) | 2 (2.22)                  | 6 (6.67)           | 42 (46.67)   | 27 (30.00)     | 13 (14.44)               |
| Tender policy with the preferences to local manufacturers                | 2 (2.22)                  | 3 (3.33)           | 45 (50.00)   | 25 (27.78)     | 15 (16.67)               |
Table 3. The source of received information about biosimilars

| Statement                                           | Responses (n) | Percentage |
|-----------------------------------------------------|---------------|------------|
| Conferences/live meetings                           | 19            | 21.11      |
| Published literature                                | 27            | 30.00      |
| Internet (online education and/or self-study including publications) | 38            | 42.22      |
| Colleagues                                          | 14            | 15.56      |
| Medical representative or event organized by pharmaceutical company | 12            | 13.33      |
| Other                                               | 2             | 2.22       |
| No education on biosimilars to date                 | 7             | 7.78       |

Table 4. The need for education related to biosimilars

| Statement                                           | Responses (n) | Percentage |
|-----------------------------------------------------|---------------|------------|
| I have a great need to learn more about this topic   | 44            | 48.89      |
| I have a basic understanding of biosimilars, but would like to learn more | 35            | 38.89      |
| I am well informed about biosimilars, but want to learn more as new developments occur | 11            | 12.22      |
| I am satisfied with my current knowledge of this area, no further education needed | 0             | 0.00       |

Table 5. The preferred education format to learn more about biosimilars

| The preferred education format to learn more about biosimilars | Responses (n) | Percentage |
|----------------------------------------------------------------|---------------|------------|
| National meetings/symposia                                     | 24            | 26.67      |
| Regional/local live meetings                                  | 31            | 34.44      |
| Online educational websites                                   | 35            | 38.89      |
| Medical societies’ communications via internet                 | 9             | 10.00      |
| Monographs or product-specific dossiers                       | 9             | 10.00      |
| Directly from pharmaceutical companies (medical representative or mailing) | 18            | 20.00      |
| Other                                                          | 1             | 1.11       |

4. CONCLUSION

The present study highlights the needs of physicians for biosimilar education. More efforts are needed to increase the awareness regarding biosimilars by different formats such as online continuous educations, meetings and conferences in order to integrate biosimilars into clinical practice and to counsel patients about biosimilars.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

As per international standard or university standard, respondents’ written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Author has declared that no competing interests exist.
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