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BUDGET-IMPACT MODEL OF ADALIMUMAB-BIOSIMILAR SANDOZ IN THE MANAGEMENT OF AUTOIMMUNE DISEASES IN THE MIDDLE EAST

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Background

- Autoimmune diseases (ADs) have partially overlapped clinical manifestations of inflammation[1].
- The estimated prevalence of ADs in Europe and the United States (US) is 5.3% and 3.2%, respectively[2]. However, limited data on the AD prevalence is available in the Middle East (ME) region[3].
- The recommended therapies for management of ADs include conventional disease-modifying antirheumatic drugs (DMARDs) and newer biologic drugs[2].
- Adalimumab is a monoclonal antibody and DMARD that works by inactivating tumor necrosis factor-alpha (TNFα) have reformed the management of ADs[4].
- Biosimilars offer similar efficacy and safety at a lower cost than the reference drug, thus potentially reducing the per-patient costs and expanding treatment access among patients[5].

Objective

- To estimate the budgetary impact (BI) of adopting adalimumab-biosimilar Sandoz in the management of ADs from a healthcare system's perspective for selected sectors in five countries of ME (the Kingdom of Saudi Arabia [KSA], Kuwait, Lebanon, United Arab Emirates [UAE] and Qatar).

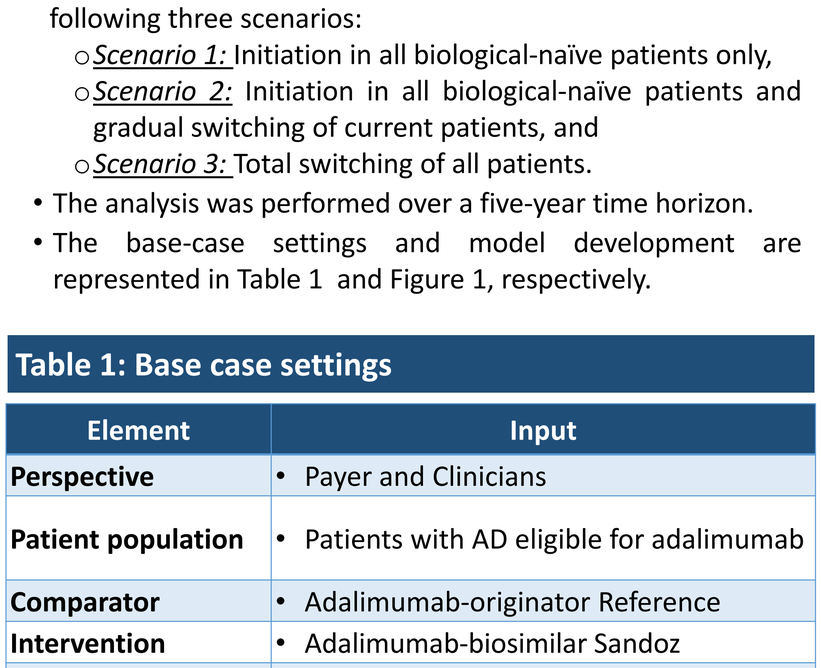
Method

- An excel-based BI model was developed that compared without adalimumab-biosimilar Sandoz (*Scenario 0*) with the following three scenarios:
  - *Scenario 1:* Initiation in all biological-naïve patients only,
  - *Scenario 2:* Initiation in all biological-naïve patients and gradual switching of current patients, and
  - *Scenario 3:* Total switching of all patients.
- The analysis was performed over a five-year time horizon.
- The base-case settings and model development are represented in Table 1 and Figure 1, respectively.

Table 1: Base case settings

Element	Input
Perspective	• Payer and Clinicians
Patient population	• Patients with AD eligible for adalimumab
Comparator	• Adalimumab-originator Reference
Intervention	• Adalimumab-biosimilar Sandoz
Analytical tool	• Microsoft® Excel®
Time Horizon (years)	• 5 years

Figure 1: Model development



- Model inputs included are drug acquisition cost, market share over five years (2022-2026) and population inputs.
- Population inputs depicting total number of active and new users of adalimumab are represented in Table 2.
- These model inputs were derived from national epidemiology statistics, published literature, and opinion of 31 experts (payers' and clinicians').
- All costs were reported in 2021 United States Dollar (USD).

Table 2: Population inputs

	KSA (MoH)	UAE (SEHA)	Lebanon (NSSF)	Qatar (HMC)	Kuwait (MoH)
Number of Adalimumab Patients (at year end 2021)	8,484	360	1,236	400	2,136
Expected Incremental New Adalimumab Patients Over 5 years (2022-2026)	3,162	140	597	205	1,015

MoH: Ministry of Health; SEHA: Abu Dhabi Health Services Company; NSSF: National Social Security Fund; HMC: Hamad Medical Corporation

Result

- The introduction of Adalimumab-biosimilar Sandoz for the management of ADs decreased the overall net budget over a five-year time horizon versus without administration of Adalimumab-biosimilar Sandoz (Scenario 0).
  - *Scenario 1:* Exhibited cost savings of USD 36,058,726 (8%)
  - *Scenario 2:* Exhibited cost savings of USD 123,606,365 (26%), and
  - *Scenario 3:* Exhibited cost savings of USD 181,971,458 (39%)
- Overall net budget impact (drug acquisition cost) is provided in Figure 2a and 2b, respectively.

Figure 2a: Total annual incremental cost associated with introduction of adalimumab-biosimilar Sandoz over 5 years

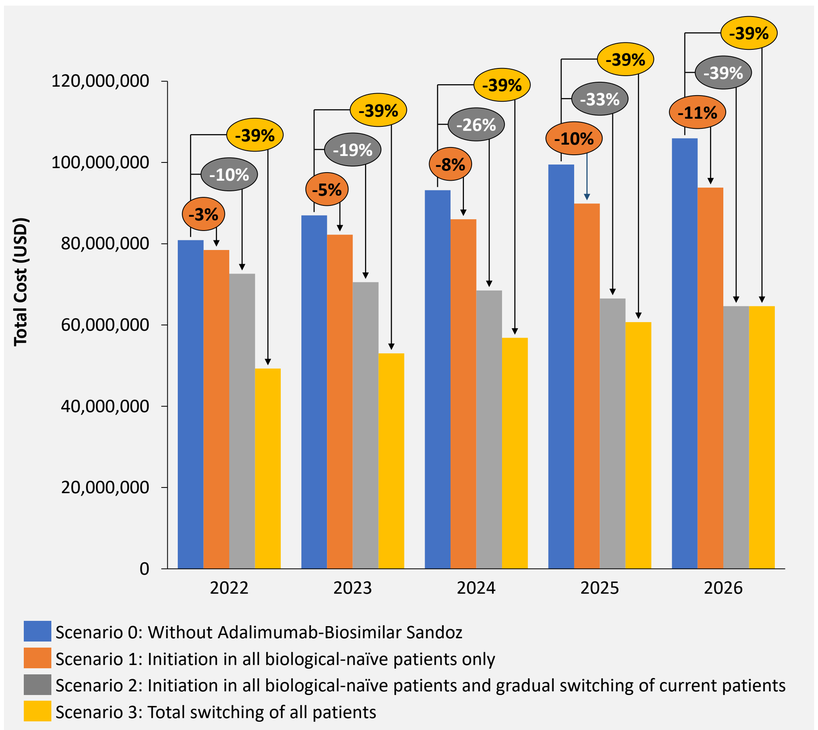
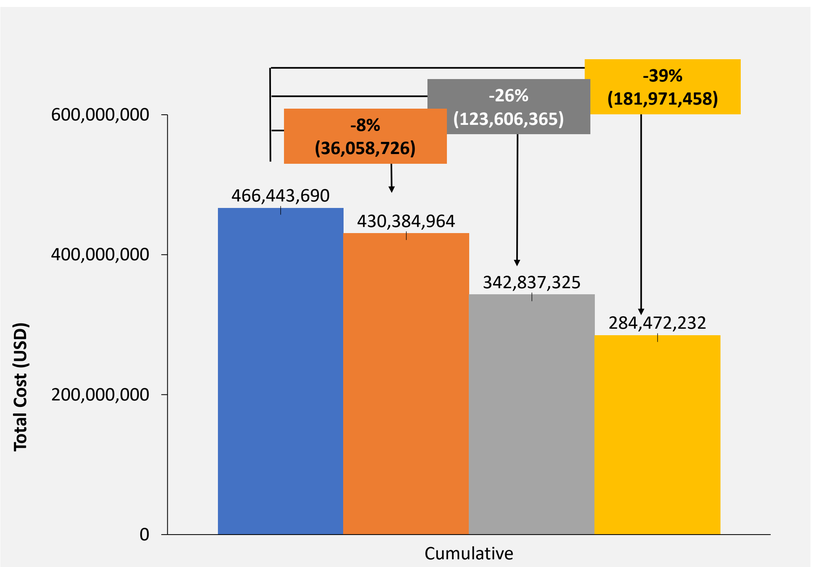
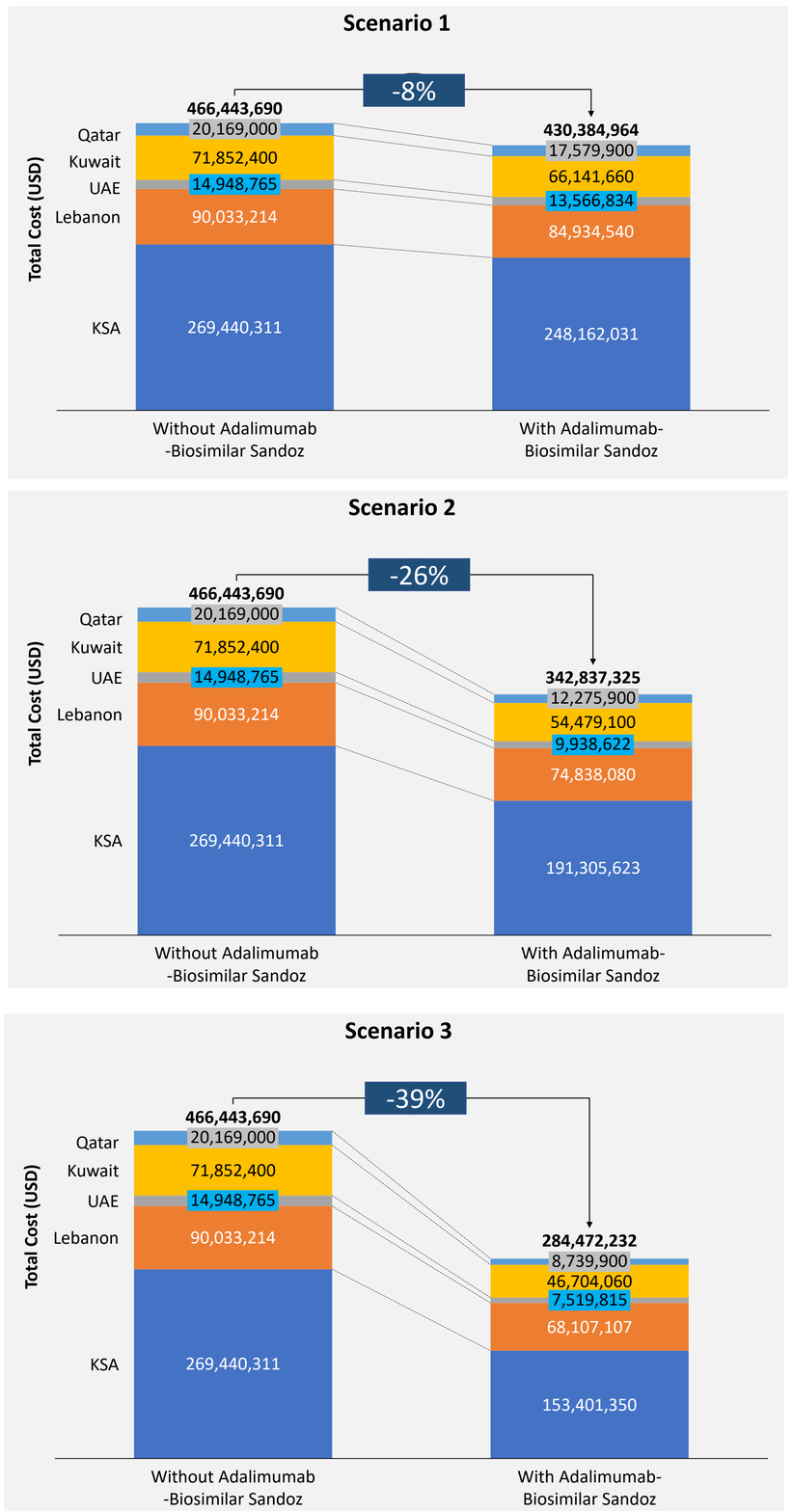


Figure 2b: Total cumulative incremental cost (2022-26)



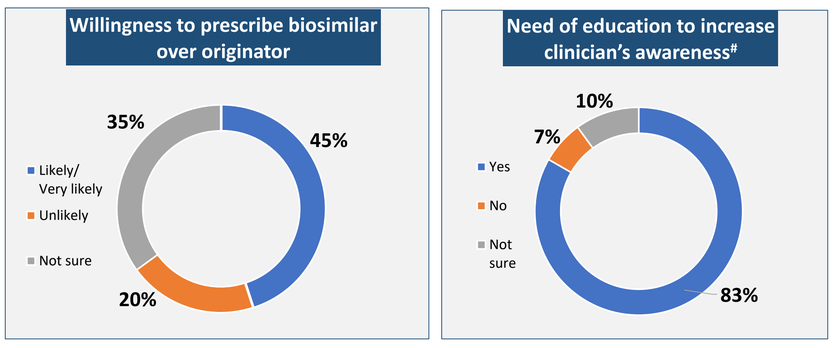
- Overall net budget impact (drug acquisition cost) by country with all the three scenarios is specified in Figure 3.
- Furthermore, based on the analysis, 45% of the respondents would like to switch to biosimilars (Figure 4).
- This lower preference to biosimilars despite similar clinical benefits can be attributed to lower awareness as 83% of respondents believe there is a need for education to improve their awareness (Figure 4).

Figure 3: Overall net budget impact (drug acquisition cost): By country



KSA: Kingdom of Saudi Arabia; UAE: United Arab Emirates

Figure 4: Payers' and clinicians' perspective* on biosimilar



*These findings are based on 30 respondents from 5 countries in scope; # Not sure includes both type of respondents who responded, 'Not sure' and who did not provide any response

Conclusion

- Use of adalimumab-biosimilar Sandoz generates potential savings which can help in optimum healthcare system sustainability to the treatment of autoimmune diseases in the Middle East.
- The most effective scenario was "*Scenario 3:* Total switching of all patients" with a potential maximum decrease (39%) in the overall net budget.
- Education and awareness on biosimilar will be a key driver for healthcare sustainability.

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