



Which is more important for doctors in a middle-income country, a national guideline or the medical literature? An adherence survey of trastuzumab use for breast cancer in Iran



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ABSTRACT

Introduction: Most national standard therapeutic guidelines in the world recommend a 52-week trastuzumab regimen for breast cancer treatment. In contrast, the national guideline published by the Iranian Ministry of Health recommends a nine-week regimen. Since guidelines are not necessarily followed in daily practice, we assessed the extent to which current routine practice in Iran as a middle-income country matches the recommendations found in these guidelines.

Methods: 128 Iranian oncologists were asked to complete an online anonymous questionnaire. Concurrently, a 3-year retrospective claims database analysis was conducted using data from the Social Security Organization, a health insurer which covers approximately 50% of the Iranian population, to enable comparisons with the questionnaire results.

Results: With a 41% (52/128) response rate, doctors reported a relatively high absolute adherence (86%) to the guideline for HER2 receptor testing but a low rate of absolute adherence (6%) to the guideline for duration of trastuzumab treatment. Doctors indicated that the planned duration was 9 weeks in only 33% of patients; in most cases, the plan was 52-week treatment. Patients with a 9-week treatment plan received trastuzumab for 8.6 weeks on average while patients with 52-week plans received treatment for 29.2 weeks. The general trends found in the survey were confirmed in the claims database analysis of 1295 HER2-positive patients.

Conclusions: Resource-sensitive guidelines may be beneficial in middle-income countries where limited budgets cannot accommodate all innovative technologies. However, Iranian physicians appear to rely more on the medical literature than on national guidelines regarding trastuzumab use. Policymakers, doctors and other stakeholders need to reach some consensus about the optimal way to treat patients. A national guideline needs to be accompanied with country-specific economic evaluations.

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1. Introduction

A standard treatment guideline (STG) is “a systematically developed statement designed to assist doctors and patients in making decisions about appropriate health care for specific clinical circumstances” [1]. STGs are also one of the measures used by

policymakers to provide standardized guidance to practitioners and promote efficient use of funds [1], especially when they decide to reimburse a new and expensive intervention.

If the sustainable reimbursement of innovative, but expensive, medical technologies presents an important challenge to policymakers in high-income countries, it is a near impossible for policymakers in middle-income countries (MICs). Policymakers in these countries need to take particular care in reimbursement decisions when the total budget impact of reimbursing a drug may be exceptionally high. If the aim of reimbursement is to address the goal of maximizing health given limited available resources, then

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STGs may help in this endeavor [1]. For example, Iran has attempted to manage the use of monoclonal antibodies, such as trastuzumab, by using national guidelines [2]. Trastuzumab for breast cancer was probably chosen by Iranian policymakers as one of the treatments to be assigned to its own guideline because of its high cost per individual and the high probability of a substantial budget impact. In fact, budget concerns probably explain why trastuzumab was not reimbursed when it first entered the Iranian pharmaceutical market in 2007 [3]. The standpoint of the Ministry of Health and Medical Education (MoHME) appears to have changed 5 years later when it published the first version of the guideline for trastuzumab use in 2012 [4]; trastuzumab was reimbursed 1 year later [5]. The main recommendation in this STG is a 9-week treatment regimen in women with human epidermal growth factor receptor 2 (HER2)-positive breast cancer, which was based mostly on expert opinion and literature reviews; however, since national STGs may represent the culmination of compromises between policymakers and clinicians, they may not reflect how clinicians actually treat their patients. In fact, informal discussions with Iranian clinicians suggested that trastuzumab use in daily practice deviates substantially from what the guideline recommends.

The aim of this study was to investigate clinician adherence to the Iranian guideline for treating HER2-positive breast cancer. Specifically, we compared what Iranian doctors do in daily practice with the recommendations found in the current guideline for treating HER2-positive breast cancer and explored the degree of association between socioeconomic parameters and trastuzumab consumption.

2. Methods

2.1. General study design

Two different approaches were used to assess clinician adherence. The first approach was to conduct a survey of clinicians to determine the extent to which clinicians adhere to the guidelines for trastuzumab, and the second approach was a claims database analysis. Details regarding these two approaches are provided below.

3. Clinician survey

3.1. Study population

The target population in this survey comprised the specialists working in the areas of oncology, who are eligible to manage breast cancer in Iran ($n \sim 264$). They can work in the public sector (e.g., Ministry of Health, Social Security Organization (SSO), and state hospitals and clinics), private sector (e.g., private hospitals, clinics, and doctors' offices) or both.

An invitation to participate in the survey, including an internet address link to the questionnaire, was emailed to all specialists in the target population with a known email address ($n = 128$). Specialists who preferred to receive the questionnaire by mail were sent a copy in a sealed envelope.

3.2. Questionnaire

An online anonymous questionnaire was created on the SurveyMonkey website (<https://www.surveymonkey.net>). This questionnaire examined treatment preferences in four stages of breast cancer: (1) breast cancer without local or distant recurrence symptoms, (2) contralateral breast cancer or new primary non-breast cancer, (3) ipsilateral loco-regional recurrence, and (4) distant recurrence.

Table 1
The profile of the respondents.

	Health care sectors	Number of participants (%)	Total (%)
University instructors	Public sector only	10 (19)	36 (69)
	Private sector only	2 (4)	
	Both public and private sectors	24 (46)	
Others	Public sector only	6 (12)	16 (31)
	Private sector only	4 (8)	
	Both public and private sectors	6 (12)	
Total		52	52 (100)

Feedback from four oncologists was used to develop and refine the questionnaire. A pilot study utilizing the questionnaire was then performed by sending the questionnaire to 10 respondents, five of whom responded within 2 weeks. The final version of the questionnaire containing 30 questions was then sent out to all oncologists.

4. Database analysis

A retrospective claims database analysis was conducted using the SSO database. The SSO insures almost 50% of the Iranian population (~ 38 million) [6]. The database, however, does not contain some clinical information such as disease stage or diagnosis coding (e.g., ICD-10). The HER2-positive patients were therefore identified based on the National Health Service's coding by applying four filters to the database: cancer patient, woman, history of a mammography, and trastuzumab use in the past 2 years. The combination of these filters yielded a total of 1298 patients. Data cleaning and exploratory data analysis were then conducted, followed by data extraction. The data analysis was performed at both the national and provincial levels; an additional analysis compared trastuzumab use between the provinces.

5. Statistical analysis

Microsoft Excel, Access 2013, and R (version 3.1.0) software were used to perform the analyses. Results from the survey and database analysis were compared and the differences between them were tested for statistical significance using Pearson's χ^2 tests for categorical variables and t -tests for interval variables (including variables with a nonnormal distribution given the central limit theorem). Finally, multiple linear regression analysis was used to examine the relationship between the independent variables and trastuzumab use among different provinces. An alpha = 0.05 was used to assess statistical significance.

6. Results

6.1. Clinician survey

Of the 128 clinicians invited to participate in the survey, 52 (41%) responded and 48 (38%) completed the entire questionnaire. A description of the respondents is shown in Table 1. The respondents were divided into two main groups of university instructors and other specialists.

6.2. HER2 test

The first part of the questionnaire focused on how doctors determine if a patient has HER2-positive breast cancer. Most respondents (84%) reported that they first use the immunohistochemistry (IHC) test and then, depending on the result of the IHC test, order a fluorescence in-situ hybridization (FISH) test.

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