



# Impact of Health Literacy on Multiple Patient Variables: A Single-Center Observational Study in Lebanon

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## Main Information

**Primary registry identifying number**

LBCTR2023065377

**Protocol number**

N/A

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

14/06/2023

**Primary sponsor**

No sponsor

**Primary sponsor: Country of origin**

No sponsor

**Date of registration in primary registry**

19/09/2023

**Date of registration in national regulatory agency**

14/06/2023

**Public title**

Impact of Health Literacy on Multiple Patient Variables: A Single-Center Observational Study in Lebanon

**Acronym**

**Scientific title**

Impact of Health Literacy on Multiple Patient Variables: A Single-Center Observational Study in Lebanon

**Acronym**

**Brief summary of the study: English**

The aim of this study is to assess health literacy among patients receiving care at Lebanese American University Medical Center - Rizk Hospital and to investigate its impact on several patient outcomes. Health literacy refers to an individual's capacity to obtain, understand, evaluate and apply health information and services in order to make informed decisions about their own healthcare. Poor health literacy is being increasingly recognized in the medical literature as a predictor of health-related outcomes such as more frequent use of emergency care and hospitalizations, adverse drug events and medication errors, inadequate knowledge of antibiotic use and antibiotic resistance resulting in misuse, and poorer quality of life; making it a major public health matter. Research on this topic in Lebanon has only just started to emerge with only two studies having assessed and published results on health literacy in Lebanese samples. None of those studies, however, explored health literacy's effect on health-related outcomes. As such, this cross-sectional study seeks not only to report the level of health literacy in our patient population, but also to evaluate its effect on the following patient outcomes: quality of life, increased need for health services, adverse drug events, antibiotic misuse, and adequacy of antibiotic knowledge. Data was collected via face-to-face interviews using a questionnaire. These findings will help improve and tailor our patient education practices to target inadequacies in the health literacy of our patient population.



## Brief summary of the study: Arabic

الهدف من هذه الدراسة هو تقييم مستوى التنوّز الصحي (أو الثقافة الصحيّة) لدى المرضى المستفيدين من خدمات المركز الطبي للجامعة اللبنانية الأمريكية - مستشفى رزق، وتقدير تأثيره على النتائج المتعلقة بسلامة وصحة هؤلاء المرضى. يُقصد بالتنوّز الصحي قدرة الفرد على الحصول على المعلومات والخدمات الصحية وفهمها وتقييمها وتطبيقها لاتخاذ قرارات بشأن صحته وعلاجه. تشير الدراسات إلى أن التنوّز الصحي المنخفض يعكس نتائج صحية سلبية مثل الحاجة المتكررة لخدمات الطوارئ والاستشفاء، والآثار الجانبية للأدوية والأخطاء الدوائية، والمعرفة الضعيفة بالمضادات الحيوية مما يؤدي إلى سوء استخدامها، وتدني جودة الحياة. بدأت البحوث حول هذا الموضوع في لبنان حيث قامت دراسات بتقييم ونشر النتائج حول التنوّز الصحي لدى المرضى اللبنانيين. ومع ذلك، لم تدرس أي من تلك الدراسات تأثير التنوّز الصحي على النتائج الصحية. لذلك، تهدف هذه الدراسة إلى الإبلاغ عن مستوى التنقيف الصحي في عينة المرضى لدينا، كذلك تسعى إلى تقييم تأثيرها على النتائج التالية للمرضى: جودة الحياة، زيادة الحاجة للخدمات الصحية، الأحداث والأخطاء الدوائية، سوء استخدام المضادات الحيوية، ومستوى المعرفة بالمضادات الحيوية. تم جمع المعلومات من خلال مقابلات مع المرضى. ستساعد نتائج هذا المشروع في تحسين ممارسات تنقيف المرضى لوتكيفها لاستهداف أوجه القصور في مستوى الثقافة الصحية لمرضاينا.

## Health conditions/problem studied: Specify

No specific health condition or problem was set as inclusion criteria (included were noncritically ill inpatients at LAUMC-RH)

## Interventions: Specify

No intervention was performed. A face-to-face interview was conducted using a questionnaire.

## Key inclusion and exclusion criteria: Inclusion criteria

- Aged 18 years or older
- Provided informed consent

## Key inclusion and exclusion criteria: Gender

Both

## Key inclusion and exclusion criteria: Specify gender

## Key inclusion and exclusion criteria: Age minimum

18

## Key inclusion and exclusion criteria: Age maximum

100

## Key inclusion and exclusion criteria: Exclusion criteria

- Has cognitive impairment or an altered mental status at the time of the study
- Is critically ill
- Does not speak Arabic or English

## Type of study

Observational

## Type of intervention

N/A

## Type of intervention: Specify type

N/A

## Trial scope

N/A

## Trial scope: Specify scope

N/A

## Study design: Allocation

N/A

## Study design: Masking

N/A

## Study design: Control

N/A

## Study phase

N/A

## Study design: Purpose

N/A

## Study design: Specify purpose

N/A

## Study design: Assignment

N/A

## Study design: Specify assignment

N/A

## IMP has market authorization

## IMP has market authorization: Specify

## Name of IMP

## Year of authorization

## Month of authorization

<b>Type of IMP</b>	
<b>Pharmaceutical class</b>	
<b>Therapeutic indication</b>	
<b>Therapeutic benefit</b>	
<b>Study model</b>	<b>Study model: Explain model</b>
Other	Single-center observational cross-sectional study. The subjects were recruited from the inpatient settings at LAUMC-RH. Patients staying at the hospital were approached and screened for eligibility, after which data of interest will be collected through face-to-face interviews using a questionnaire. Informed consent will be sought prior to conducting the interview and after explaining the purpose of the study and stating that all data will be treated confidentially and that withdrawal from the study would be possible at any time.
<b>Study model: Specify model</b>	Two copies of the informed consent form will be handed to the patient stating the purpose of the study and providing the contact information of the principal investigators and the LAU institutional review board (IRB) office. One copy is to be signed and returned to the interviewer and another is to remain with the participant for future reference.
Cross-sectional	
<b>Time perspective</b>	<b>Time perspective: Explain time perspective</b>
Prospective	The study took place from November till May.
<b>Time perspective: Specify perspective</b>	
N/A	
<b>Target follow-up duration</b>	<b>Target follow-up duration: Unit</b>
0	N/A
<b>Number of groups/cohorts</b>	
1	
<b>Biospecimen retention</b>	<b>Biospecimen description</b>
None retained	N/A
<b>Target sample size</b>	<b>Actual enrollment target size</b>
100	135
<b>Date of first enrollment: Type</b>	<b>Date of first enrollment: Date</b>
Actual	15/11/2022
<b>Date of study closure: Type</b>	<b>Date of study closure: Date</b>
Actual	31/05/2023

**Recruitment status**

Complete

**Recruitment status: Specify****Date of completion**

31/05/2023

**IPD sharing statement plan**

No

**IPD sharing statement description**

N/A

**Additional data URL****Admin comments****Trial status**

Approved

## Secondary Identifying Numbers

No Numbers

## Sources of Monetary or Material Support

No Sources

## Secondary Sponsors

No Sponsors



## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Katia El Harake	Ashrafiyeh, Beirut	Lebanon	76700599	katia.elharake@lau.edu	Lebanese American University - LAUMC-RH
Scientific	Hanine Mansour	Blat, Byblos	Lebanon	76731512	hanine.mansour@lau.edu.lb	Lebanese American University

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese American University Medical Center - Rizk Hospital	Katia El Harake, Hanine Mansour, Soumana Nasser, Elsy Ramia	Pharmacists	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	14/09/2022	Joseph Stephan	irb@lau.edu.lb	01786456 ext. (2546)

## Countries of Recruitment

Name
Lebanon

## Health Conditions or Problems Studied

No Problems Studied

## Interventions

No Interventions



## Primary Outcomes

Name	Time Points	Measure
Health literacy level	At time of interview	European Health Literacy Survey Questionnaire—modified short version “HLS-EU-Q16”

## Key Secondary Outcomes

Name	Time Points	Measure
Quality of life	At time of interview	EQ-5D-5L questionnaire
Antibiotic consumption practices and knowledge about antibiotics	At time of interview	Questions adapted from the WHO validated antibiotic resistance: multi-country public awareness survey
Health services used in the previous year	At time of interview	Number of doctor visits, hospital admissions, emergency department visits per patient report
Adverse drug events in the previous year	At time of interview	Number of adverse drug events per patient report

## Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files