Angela McCaskill

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Director/es
Montero Marco, Jesica
Gasch Gallén, Ángel

Universidad Zaragoza
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Tesis Doctoral

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Autor

Angela McCaskill

Director/es

Montero Marco, Jesica
Gasch Gallén, Ángel

UNIVERSIDAD DE ZARAGOZA
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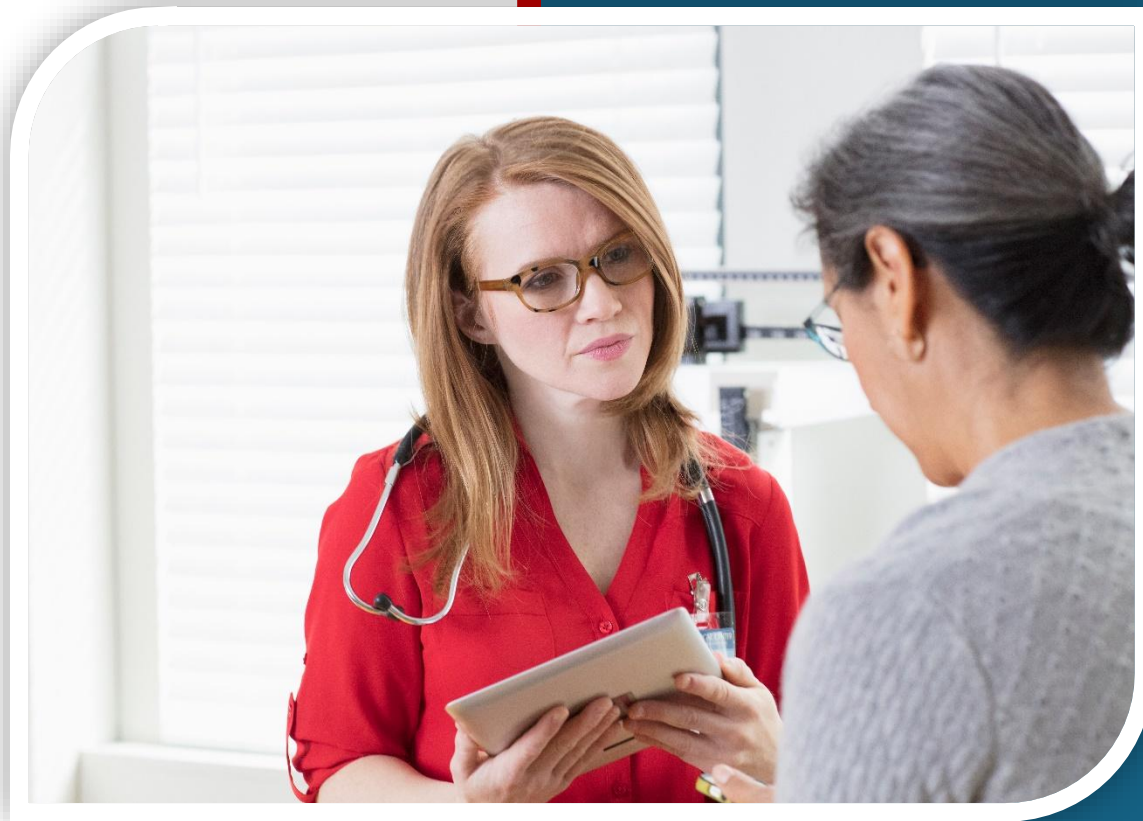
Autor

Angela McCaskill

Director/es

Ángel Gasch Gallén
Jesica Montero Marco

Facultad de Ciencias de la Salud
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"Let us never consider ourselves finished nurses. We must be learning all of our lives."
Florence Nightingale

Contents

Abstract

Background Healthcare organizations strive to provide high-quality healthcare that is people-centred. ISO 7101, an international standard for healthcare quality, outlines requirements for people-centred care. One theme discussed in subclause 8.10.5 of the standard is health literacy (HL). HL affects both individual and population health, with low general HL leading to increased morbidity, poor health service utilization, and increased healthcare spending. This study described the process of implementing subclause 8.10.5 Health literacy in specialty consultations in Aragon, Spain, and determined the effects of implementation on patient general HL scores and perceptions of quality of care. The study also established the psychometric properties of the HLS$_{19}$-Q12 survey used in this investigation.

Methods A sample of 150 patients from specialty consultations completed the internationally- validated HLS$_{19}$-Q12. Factor analysis and Cronbach's alpha were used to validate the Spanish version of the HLS$_{19}$-Q12. HL scores were calculated using the scale factsheet, and the patient population sociodemographic profile was determined using frequency analysis. Independent sample t-test, one-way ANOVA, and a generalized linear model (GLM) analysis were performed to examine key relationships with respect to sociodemographic variables and HL scores. Paired samples t-test assessed the difference between patient HL scores pre- and post-nursing interventions. Frequency analysis and Pearson correlation where used to examine frequencies of nursing HL strategies used and associations with HL scores. Paired samples t-test and Wilcoxon signed-rank test determined relationships between implementation of ISO 7101 subclause 8.10.5, HL scores, and quality of care perceived.

Results The HLS$_{19}$-Q12 used in Spain in the Spanish language was found to be valid and reliable ($\alpha = 0.87$). General patient HL was limited, with 60% of participants having general HL categorized as inadequate or problematic, and 40% sufficient or excellent. Income level had a significant effect on HL scores, F= 2.129, ($p < 0.05$), as did different work situations, F = 3.762, ($p < 0.001$). According to GLM analysis, education, health status, income, and the number of appointments were the strongest predictors of the HL score. There was a statistically significant effect of nursing interventions on HL score (t = -10.00, $p < 0.001$). Mean general HL scores increased post-implementation of ISO 7101 subclause 8.10.5 as did the mean score of perception of quality of care received. Wilcoxon test for both variables was significant (P<.001), and effect size was large (d ≥ 0.8).

Conclusions The results of the HLS$_{19}$-Q12 in this specific population provide a unique view into the HL scores of patients in specialty consultations, providing actionable HL data for decision makers in this health sector of Aragon, Spain. The study further reveals that implementation of ISO 7101, subclause 8.10.5 Health literacy had a significant, positive effect on general HL scores, and patients' perceptions of quality of care received. This is believed to be the first academic research published regarding the implementation of the ISO 7101 standard, and these findings can be used to inform decision making by healthcare policy makers and management as they seek to increase HL and patient perceptions of quality of care.

Resumen

Antecedentes Las organizaciones sanitarias se esfuerzan por proporcionar una atención sanitaria de alta calidad centrada en las personas. La ISO 7101 es una norma internacional para la calidad de la asistencia sanitaria que describe los requisitos para la atención centrada en las personas. Un tema discutido en la subcláusula 8.10.5 de la norma es la alfabetización en salud (AS). La AS afecta tanto a la salud individual como a la de la población en numerosos niveles y se ha demostrado que una AS general baja conduce a un aumento de la morbilidad, una mala utilización de los servicios de salud y un mayor gasto sanitario. Este estudio describió el proceso de implementación de la norma subcláusula 8.10.5 Alfabetización en salud en consultas especializadas en un hospital de tercer nivel en Aragón, España. Además, determinó los efectos de la implementación en las puntuaciones generales de AS de los y las pacientes, así como las percepciones de la calidad de la atención. El estudio también estableció las propiedades psicométricas de la encuesta HLS19-Q12 utilizada en esta investigación.

Métodos Una muestra de 150 pacientes de consulta especializada completaron el HLS19-Q12 validado internacionalmente. Se utilizó el análisis factorial y el alfa de Cronbach para validar la versión española del HLS19-Q12. Las puntuaciones de EA se calcularon mediante la ficha de la escala y el perfil sociodemográfico de la población de pacientes se determinó mediante análisis de frecuencias. Se realizó una prueba t de muestra independiente, un ANOVA de un factor y un análisis de modelo lineal generalizado (MLG) para examinar las relaciones clave con respecto a las variables sociodemográficas y las puntuaciones de AS. La prueba t de muestras pareadas evaluó la diferencia entre las puntuaciones de AS del paciente antes y después de las intervenciones de enfermería. El análisis de frecuencias y la correlación de Pearson se utilizaron para examinar las frecuencias de las estrategias de EA de enfermería utilizadas y las asociaciones con las puntuaciones de AS. Las muestras pareadas, la prueba t y la prueba de rangos con signo de Wilcoxon determinaron las relaciones entre la implementación de la subcláusula 8.10.5 de la norma ISO 7101, las puntuaciones de AS y la calidad de la atención percibida.

Resultados Se encontró que el HLS19-Q12 utilizado en España en lengua española es válido y fiable (α = 0,87). La EA general de los y las pacientes fue limitada, con un 60% de los participantes con EA general categorizada como inadecuada o problemática, y un 40% suficiente o excelente. El nivel de ingresos tuvo un efecto significativo en los puntajes de AS, F= 2,129, ($p < 0,05$), al igual que las diferentes situaciones de trabajo, F = 3,762, ($p < 0,001$). Según el análisis de MLG, la educación, el estado de salud, los ingresos y el número de citas fueron los predictores más fuertes de la puntuación de AS. Hubo un efecto estadísticamente significativo de las intervenciones de enfermería sobre la puntuación de AS (t = -10,00, $p < 0,001$). Las puntuaciones medias generales de AS aumentaron después de la implementación de la subcláusula 8.10.5 de la norma ISO 7101, al igual que la puntuación media de la percepción de la calidad de la atención recibida. La prueba de Wilcoxon para ambas variables fue significativa ($p<.001$) y el tamaño del efecto fue grande (d ≥ 0.8).

Conclusiones Los resultados del HLS19-Q12 en esta población específica proporcionan una visión única de las puntuaciones de EA de los y las pacientes en consultas especializadas, proporcionando datos de EA para los responsables de la toma de decisiones en este sector sanitario de Aragón, España. El estudio revela además que la implementación de la norma ISO 7101, subcláusula 8.10.5 Alfabetización en salud tuvo un efecto significativo y positivo en las puntuaciones generales de AS y en las percepciones de los y

las pacientes sobre la calidad de la atención recibida. Al considerarse esta la primera investigación académica publicada sobre la implementación de la norma ISO 7101, sus hallazgos se pueden utilizar para informar la toma de decisiones por parte de los responsables de las políticas y la gestión de la atención sanitaria, al ofrecer una base de evidencia científica que proporciona estrategias efectivas para aumentar la AS y mejorar las percepciones de los y las pacientes sobre la calidad de la atención.

Chapter 1: Description of the problem

Problem 1: The need for healthcare quality management systems

The Lancet Global Health Commission on High Quality Health Systems reported that "high-quality health systems could save over 8 million lives each year in low-middle income countries." [1] Across higher income OECD countries the situation is also concerning, where there are millions of preventable premature deaths of people under the age of 75 that could have been avoided had healthcare provision been better. [2] The quality of healthcare services and care provision in countries from all World Bank economic categories is highly varied, facing economic challenges, and inconsistent adherence to science-based best practices. [3] While healthcare systems were already stressed pre COVID-19, the global pandemic exposed additional weaknesses in health systems, and further left some countries with significant healthcare debt. The need to deliver high-quality healthcare is multidimensional, driven by factors such as population growth and ageing, climate change, workforce shortages, economics, and the latest technologies.

Population growth and ageing

Populations are ageing, with almost every country in the world seeing a population shift to more older people as a proportion of the total population. In June 2019, the United Nations predicted that the world's population is expected to grow by 2 billion people in the following 30 years. Along with this increase, the world's population is living longer, with people aged 65 and older being the fastest growing category. [4] An increased aged population requires governmental planning on a systemic scale. More individuals will require access to social protections, which includes healthcare systems capable of providing safe, quality healthcare in a timely manner.

Climate change

Evidence shows the effects of climate on population health. [5] As the world continues to face increasing floods, drought, pollution, and rising temperatures, the impacts on both physical and mental health are notable. Climate change affects the most fundamental sources of health – clean air, safe drinking water, sufficient food, and secure shelter. As of October 2021, the WHO predicts, "The direct damage costs to health (i.e., excluding costs in health-determining sectors

such as agriculture and water and sanitation), is estimated to be between USD 2-4 billion/year by 2030."[6(no page)]

Climate change effects human health and wellbeing on multiple levels. Increasing food shortages, low birth weights, lengthened transmission seasons of mosquito borne pathogens, heat stroke, hypothermia, and lack of potable water are all associated with climate events.[7] Climate change also has negative impacts on mental health such as leading to depression, anxiety, stress, anger and uncertainty. Furthermore, individuals with existing psychological illness may not be able to access care when infrastructure is down or destroyed, so the impact is multiplied.[8]

Another worrisome result of climate change is an increase in displaced populations. Weather extremes cause harm to infrastructure and related economic productivity. Crops, agriculture and fishing are harmed, forcing people to leave their homes to seek food, shelter, and sources of income. Displaced populations often face food shortages, lack of sanitary living conditions, and threats of violence. They may not have access to healthcare or have a minimal understanding of how to use the existing health resources. Already stressed health systems may not have the capacity to serve these additional displaced populations. Given these critical impacts of climate and population displacement, it is important quality of care be at the forefront of service planning and delivery.[9]

Workforce shortages

The World Health Organization predicted a shortage of approximately 18 million health workers by 2030, with the largest impact in low- and lower-middle income countries. They further warned that "countries at all levels of socioeconomic development face, to varying degrees, difficulties in the education, employment, deployment, retention, and performance of their workforce."[10(no page)] In the USA, the American Hospital Association reported that America will face a shortage of up to 124,000 physicians by 2033, with an additional need to hire at least 200,000 nurses annually to meet the demand and replace retiring nurses.[11] The Organization for Economic Cooperation and Development expressed a similar concern in 2021. They offer Italy as an example of a country where 56% of the doctors are over the age of 55. They warn that healthcare workers will naturally retire, which will lead to even more staffing shortages.[12] These global shortages reinforce the need

for healthcare organizations to plan for the future, while protecting and effectively managing its current human resources. High-quality healthcare management is one such tool to address workforce challenges.

Healthcare spending

While in some countries patients can barely afford to pay for basic healthcare, in other countries government funded healthcare costs are increasing and unsustainable. In 2021 the WHO reported that global spending on health had "doubled in real terms over the past two decades, reaching $8.5 trillion in 2019 and 9.8% of global GDP (up from 8.5% in 2000)."[13] An additional stressor to healthcare spending will be the predicated amount of aged populations in most countries by 2050. Not only will there be more patients to serve, but also older patients tend to have comorbidities, requiring more medical services and funding for other social protections.[14]

Direct care of patients can be costly, yet the administrative costs of providing services is also a critical component of spending. In the USA, office costs amount to 34% of total health care expenditures. This compares to the UK (16%) and the Netherlands (20%).[15] Data from 50 countries (low-, middle- and high-income categories) showed that spending on health system governance and administrative functions rose in 2020 by an average of 7% in 2/3 of the countries.[14]

Innovative technologies

Digital healthcare and AI are promising and continue to lead to advances in healthcare provision. The potential of AI and its applications are limitless, currently including genomics, pharmaceutical discoveries and prescribing, operations, supply chains, research of complex disease, disease prediction, surgical robots, robots that perform patient care duties both in home and at the hospital, and social AI such as contact tracing.[16,17]

While innovative technologies are necessary for the advancement of health systems and care delivery, they are subject to the 'pacing problem.' This dilemma was described by Downes (2009) in his popular book *The Laws of Disruption: Social, political, and economic systems change incrementally, but technology changes exponentially*.[18(pp. 2–3)] The pace of regulation and law to control related risks to health, safety, and privacy lag behind the introduction of these

technologies into the market. The introduction of such technologies must be created and governed by the need to also provide high-quality care that is foremost safe, effective and user-centric.

Problem 2: Low health literacy

Health literacy (HL) is a multidimensional concept that affects how individuals access, process, judge, manage, and act upon health information.[19] The information may come from traditional sources such as doctors and nurses, but can also come from one's environment such as the media, television shows or commercials, school, work, or friends and family. HL affects the health, wellbeing, and quality of life of individuals and communities.[20–23]

Individuals with sufficient to high HL are more apt to take advantage of preventive care, follow doctor and nurse instructions, take medication as prescribed, and use health information to navigate often complex health systems. Populations with higher HL have less disparity in health outcomes, are more equitable, and more prosperous.[22]

In contrast, individuals with low or inadequate HL may not use preventive services, adequately follow doctors' orders, correctly take medication, do not manage chronic conditions as well, and may fail to seek out and use medical information. This can lead to an increased used of emergency services, hospital readmissions, and an overall increase in morbidity and mortality. As a result, people with low HL may experience a decrease in quality of life and overall feelings of wellbeing.[24–26]

Health literacy has been shown to have a relationship to sociodemographic factors, with vulnerable populations being at greater risk.[27,28] The elderly, poor, less educated, and refugee or immigrant populations are most at risk. Low HL may continue the cycle of vulnerability because chronically ill people can experience increases in work or school absences, causing a decrease in learning and loss of income. Also, caregivers may leave the workforce to care for their ill loved ones, further threatening household earning potential. Finally, medical costs can be expensive, which compounds the effects of illness on already financially challenged patients and families.[22,29–32]

Low HL leads to increased healthcare spending. Both private and public payors pay for preventable use of high cost services such as the emergency room and inpatient care.[29,31,33] In addition, governments social payouts may increase in order to support those who are on disability due to prolonged illness.[31,34]

The increasing use of digital health poses additional challenges to HL. Digital health skills include the ability to use digital tools for accessing information, problem solving, making appointments, safety, and communications. While some individuals navigate printed information with ease, they may find it more difficult to access, use, and judge digital data. An OECD 2023 publication found that people in numerous countries such as Germany, Hungary, Poland, Lithuania, and Italy are lacking basic digital skills.[12] These findings signal potential problems for patients and caregivers who are expected to use digital platforms to make appointments, access prescriptions, interpret diagnostic results, or manage their conditions.

Health literacy in Europe

Prior studies suggest that HL is generally low across Europe. The first comparative European health survey in 2015 reported that in eight surveyed countries, 47% of the sample had HL considered insufficient or problematic. In Spain in particular, 58.3% had HL that was insufficient or problematic.[35] A 2021 study systematically reviewed the prevalence of low HL in Europe and found that a third to nearly half of individuals had low HL. The data also showed that countries in northern Europe had higher levels than other EU nations.[36] In one of the largest HL surveys across 17 countries (2022), it was reported that all countries except for two (Austria and Ireland) had a dominance of HL that was limited (inadequate and problematic combined).[37]

Chapter 2: History of standardized solutions for healthcare quality

The primary study of quality began in the early 20th century, focusing on statistical process control. The practice of statistical process control became more popular in the 1950s with the works of W. Edwards Deming who popularized the famous plan, do, check, act cycle.[38] Initially, the idea of quality was associated with design, manufacturing and a physical product; however, over time the concept has expanded to include services, including healthcare delivery.

In 1966, Avedis Donabedian, often considered to be the father of quality in healthcare, defined the Donabedian model. He based his model on structures, processes and outcomes of healthcare delivery.[39] Since that time, additional models and frameworks were created such as the standards from the Joint Commission, the WHO External Quality Assessment scheme (EQA), the European Foundation for Quality Management (EFQM) model, and the WHO 2006 guideline document, *Quality of care. A process for making strategic choice in health system*s.[40,41] In 2018 the WHO published a comprehensive guidance document called *The Handbook for national quality policy and strategy*.[42] It incorporates ideas that have existed since the beginning of the quality movement, such as those of the Juran quality trilogy: quality planning, quality control, and quality improvement.[43] Many of the existing guidelines and models build upon quality learning over the decades, incorporating some of the traditional elements, while adding new or additional ones. These tools are useful for establishing, implementing, managing and evaluating the effectiveness of a quality management system.

A systematic review of literature in 2015 studied the effect of quality improvement strategies in healthcare. In particular, the research focused on the effects of ISO 9001 and the European Foundation for Quality Management (EFQM) model on hospital performance.[44] The findings indicate that implementing an ISO 9001 quality management system can increase patient satisfaction, control costs, and improve patient safety. Another study examined ISO 9001 certification in 45 Bulgarian hospitals. Hospital managers interviewed about the certification process highlighted several advantages, including a greater focus on patients, fewer errors, and enhanced patient safety. They also emphasized that the standard's emphasis on process identification and the use of performance indicators fostered continuous improvement.[45]

A larger study explored the relationships between ISO 9001 certification, hospital accreditation and quality management in 73 European hospitals. It analyzed four measures of quality and safety related to the organization's accreditation and certification status. Findings indicate that both are positively related to clinical leadership, systems for patient safety and clinical review, however, they did not find a positive association with clinical practice.[46]   Research has also explored the differences among hospitals that were ISO certified, accredited by an external agency, or had neither designation. In the selected sample it was found that hospitals that were either certified or accredited were better and safer than those who were neither. In particular, ISO certified hospitals excelled in the dimension of patients' rights.[47]

Many healthcare quality standards or schemes highlight the importance of improvement. A 2018 joint document from the WHO, OECD, and World Bank highlights the need to establish and enforce minimum standards, while also promoting ongoing improvement.[48] Leatherman, et al. analyzed the role of quality improvement in health systems strengthening in developing countries. Their research found that establishing standards, along with continuous feedback mechanisms, were key components of successful quality improvement interventions.[49] The Bellagio Forum for High-Quality Health Systems declared that stronger measurement promotes accountability and helps countries to "learn, adapt, and improve."[50(p.e1145)] The WHO's Handbook for National Quality Policy and Strategy (2018) reinforces this idea with references to improvement methods, interventions, mechanisms and programs. It also states that as countries build their quality strategies, planning, control and improvement are necessary.[42]

Chapter 3: ISO 7101: 2023 Management systems for quality in healthcare organizations

History of the ISO 7101 standard

The ISO 7101 healthcare quality management systems standard is the first international consensus standard for healthcare quality and was published in October of 2023. The standard was born out of my final project while pursing my master's degree in global health. Based on the numerous healthcare sector challenges outlined in Chapter 1 of this document, I endeavored to create a framework that combined both the current knowledge of quality experts in global health with the tried-and-true structure of an ISO quality management systems standard. To achieve this end, I cross-mapped the requirements of ISO 9001:2015 and the elements of the framework set forth by the Lancet's Global Health Commission on High Quality Health Systems in their 2018 publication, "High-quality health systems in the Sustainable Development Goals era: time for a revolution."[1,51]

Based on the comparison, I concluded that there were many overlapping and complementary areas in both documents; however, gaps existed as well. ISO 9001 lacked some essential healthcare specific elements included in the Lancet's framework for high-quality healthcare, while the Lancet's framework lacked the management systems approach and continual improvement structure defined in ISO 9001. From these observations my conviction grew that an internationally recognized healthcare quality standard could be a viable solution for improving healthcare quality on an international scale. In January of 2020, the three year journey to write ISO 7101 began in collaboration with the International Organization for Standardization (ISO) in Geneva, Switzerland.

ISO standards are created through country technical committees. The United States American National Standards Institute (ANSI) technical committee 304 nominated me to lead the work group who would write the standard through the ISO platform. The final team was comprised of approximately 50 global health experts, representing all WHO regions and all World Bank income categories. The ISO 7101 standard was designated as a 'high-profile' standard by ISO, which meant it was viewed as a priority and of notable societal value (**Figure 1**).

Fig. 1 ISO portal designation as Project Leader and classification of ISO 7101 as a High Profile standard

Description of ISO 7101

In October 2023, ISO 7101: *Management systems for quality in healthcare organizations – Requirements* was published. ISO 7101 follows what is called the "harmonized structure" (HS). The HS is a structured template shared by all ISO management systems standards (MSS).[52] The HS makes it easier to implement and comply with multiple ISO MSS at the same time. For example, ISO 9001 follows the HS.[52] Therefore, an organization wishing to also implement ISO 7101 will find the process easier, as the standard format (clauses, numbering, and some content) is the same in both standards. Healthcare specific requirements are presented throughout ISO 7101, yet the reader will still recognize common HS elements found in other ISO MSS such as leadership, planning, documented information, operation, performance evaluation, internal audit, management review, and improvement.

The scope of ISO 7101 includes establishing requirements for organizations who aim to demonstrate their ability to consistently meet service user, stakeholder, and applicable statutory and regulatory requirements; enhance service user experience during the continuum of care, continually improve healthcare quality; and create and maintain processes that ensure timely, safe, effective, efficient, equitable, and people-centred care.[53] The graphic below shows the main elements of healthcare quality addressed in ISO 7101 and the clause numbers of the standard that correspond with the Plan, Do, Study and Act cycle (**Figure 2**).[53]
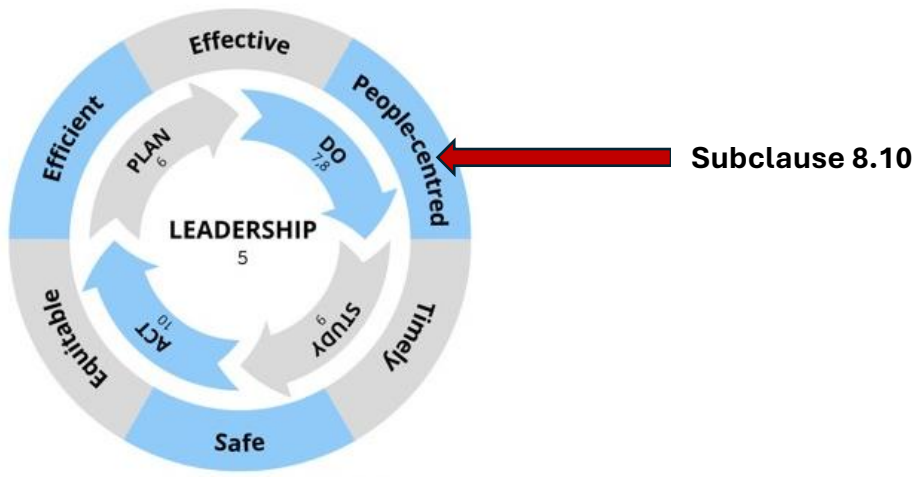
Fig. 2 Healthcare Quality PDSA Cycle

ISO 7101 requirements

The ISO 7101 standard is copyrighted through ISO. The following is a paraphrased list of some of the content themes it includes. These topics are in addition to those already required by all MSS.

– Service user focus (patients, families, caregivers)
– Access to care (including mention of universal health coverage)
– Risk management and risk culture
– Communication (internal, external and with service users)
– Healthcare facilities management and maintenance
– Contingency planning for facilities and services
– Environmental responsibility
– Waste management
– United Nations Sustainable Development Goals
– Emerging technologies
– Service design in healthcare
– Healthcare quality indicators
– People-centred care
– Service user experience
– Compassionate care
– Inclusivity and diversity
– Health literacy
– Co-production of care
– Workforce wellbeing
– Patient safety
– Ethics

Subclause 8.10.5 Health literacy

ISO 7101 contains 10 clauses, with major clause headings 4-10 outlining 'shall' requirements. A 'shall' requirement indicates mandatory actions that an organization must take. Within the major clauses there are numerous subclauses. Clause 8 of the standard contains the bulk of requirements for healthcare operations. Subclause 8.10 is dedicated to people-centred care (**Figure 2**). Within this subclause there is a further subclause, 8.10.5 Health literacy. This subclause outlines requirements for organizations who endeavor to promote and improve service user (patients, families, and caregivers) and workforce HL. In order to promote service user and workforce HL, the standard states that an organization must:

a) include health literacy in planning, evaluation measures, patient safety, and quality improvement efforts;

b) provide workforce training in health literacy;

c) integrate populations served in the design and implementation of health information and services;

d) consider caregiver support systems when the patient might not be able to understand information (e.g., pediatric, dementia, and special needs populations);

e) use HL techniques in communications and ensure listener understanding at all points of contact;

f) address HL in situations that are deemed high-risk, including detailed information before performing procedures that require informed consents, care transitions and communications about medication;

g) encourage and empower people to use health information and promote their ability to make informed decisions;

h) utilize a range of health literacy skills while avoiding stigmatization of patients and caregivers, and

i) educate service users regarding prevention and management of their current or potential conditions.

This subclause also includes a note indicating that patient education can be achieved using a variety of tools such as handouts, verbal counseling, visual aids, and digital platforms.[53]

A possible new standard to address problems 1 and 2

Based on the prior arguments regarding the need for high-quality healthcare and problem of low HL (Chapter 1), the benefits of quality management standard implementation (Chapter 2), the publication of a new quality standard focused entirely on healthcare organizations (Chapter 3), we decided to implement ISO 7101 subclause 8.10.5 to explore the relationships between implementation of the standard, health literacy scores and quality of care perceived. As the standard was new and no information was available about its efficacy or impact, we aimed to produce the first usable data for healthcare management and policy makers.

While ISO 7101 is a comprehensive MSS, the decision was made to implement only subclause 8.10.5 of the standard for multiple reasons. First, the standard is a holistic one, outlining hundreds of requirements for a complete quality management system. Full implementation and analysis of results would have lasted as much as two years. Secondly, full-scale implementation would have required a significant commitment from the study site's top governance to provide both human and financial resources. This was not realistic or feasible. Further, a full scope implementation of ISO 7101 requires participation from every service level of a healthcare organization including laundry and nutrition services, planning and logistics, human resources, infection prevention and control, and so forth. An undertaking of this magnitude was also not possible. Finally, a full scale implementation would have required a larger research team, which was not an option at the time. Therefore, given the time allotted for the project, permissions granted, size of the research team, and financial considerations, the decision was made to implement only subclause 8.10.5 in specialty care settings.

Chapter 4: Research objectives

This study had multiple objectives. In order to measure general HL in the sample population, we first needed a validated tool. Therefore the following research objective was defined:

- *Objective 1. Validate the HLS$_{19}$-Q12 in Spain and in the Spanish language, as well as describe the sociodemographic profile of the study population.*

Once the HLS$_{19}$-Q12 had been validated, we needed to calculate HL scores, therefore the following research objective was defined:

- *Objective 2. Calculate general HL scores in the patient population using the newly validated HLS$_{19}$-Q12, and examine the relationship between sociodemographic variables and those scores.*

Once scores were calculated, we examined the relationship between the nursing intervention of using an HL checklist and HL scores. For this end, the following objective was defined:

- *Objective 3. Examine the relationship between nurses' use of a health literacy checklist (intervention) and pre- and post-patient HL scores, and the effects of frequency and types of strategies used.*

Finally, we wanted to test our hypothesis that implementation of ISO 7101 subclause 8.10.5 was a possible solution to the problem of low HL. As ISO 7101 is a quality management system standard, we also wanted to see if implementation had an effect on the quality of care perceived. To accomplish this, the following objectives were defined:

- *Objective 4: Describe the process of implementing ISO 7101 subclause 8.10.5 in specialty consultations.*
- *Objective 5:. Determine if there is a relationship between the implementation of ISO 7101 subclause 8.10.5 Health literacy and pre- and post-implementation HL scores.*
- *Objective 6: Determine if the implementation of ISO 7101 subclause 8.10.5 Health literacy had an effect on patients' perceptions of the quality of care received.*

Chapter 5: Methodology

Recruitment and description of participants

The study was approved on 16 March 2023 by the Government of Aragon, Department of Health, CEICA following law 14/2007, 13 July for Biomedical Investigations and Applicable Ethics Principals, with approval number PI23/083. It was further approved on 23 February 2023 by the Aragones health services (SALUD) to be conducted in the Hospital Clínico Universitario "Lozano Blesa," Zaragoza.

The patient sample consisted of patients who regularly attended specialty consultations in the Hospital Clínico Universitario, which is located in health sector III of the autonomous community of Aragon. The sector is one of eight sectors in Aragon and covers a population of approximately 300,000 people. In addition to 22 health centers and 119 local clinics, specialty care is provided in three locations.[54] It is from two of these specialty locations that the study population was recruited. For this investigation, the types of specialty consultations included: Diabetes, Ostomy, Cardiology, and Digestive. Inclusion criteria for the participants were: 1) age 18 or older, 2) willingness to complete the HLS_{19}-Q12 survey two times (before and after HL interventions), and 3) the patient had the necessity to make three visits to the specialty consultation within the 12-month period of data collection.

In order to obtain the sample group, the principal researcher visited each specialty consultation on predetermined days each week. The patients who happened to have appointments on those days are the ones who were asked to participate in the study, given that they satisfied the inclusion criteria. The principal researcher followed the predefined recruitment schedule during an eight month period. 166 total participants met selection criteria and 100% agreed to participate.

Sample size was determined based on the first objective of the research project, which was to validate the Spanish version of the HLS_{19}-Q12 in this study population in Spain. As we used confirmatory factor analysis, comparative fit index, and principal component analysis to validate a 12-item survey, we calculated that 166 patients was sufficient to secure a medium effect size (Cohen's d = 0.5), with a significance level of 0.05, and a power of 80%.

Data collection

Data collection was conducted during face-to-face specialty nursing consultations with patients. Reponses were captured on paper in one of the following ways: 1) by the patient alone, 2) face to face interview with the principal researcher, 3) patient with the help of a family member or caregiver, 4) patient with help of the principal researcher, or 5) by the specialty nurse. The HLS$_{19}$-Q12 had been previously validated using the paper-assisted personal interview (PAPI) mode, so these were acceptable data collection methods.[55]

Completion method depended on factors such as the patients' ability to read, vision, patients' level of patience when it came to answering questions, and elderly patients' tendency to defer to family or caregivers for completion of tasks. The principal researcher was present while the surveys were being completed in the event that the participant requested clarification. Once completed, the researcher reviewed the survey to verify that it was completed correctly and in its entirety. All data was anonymized.

A questionnaire with 15 sociodemographic questions was included as the first page of the HLS$_{19}$-Q12 instrument. Questions addressed age, sex, gender, marital status, education, occupation, country of origin, living situation, work, residence (rural or urban), self-classification of health status, net monthly income, use of aids or assistive devices, self-reported illness, and number of appointments they previously had at the consult not including that day's appointment.

Measurement tools

HLS$_{19}$-Q12

The HLS$_{19}$-Q12 (**Appendix A**) was chosen to measure HL scores because it had been successfully validated in 17 countries to assess and benchmark general HL in adult populations.[37] The HLS$_{19}$-Q12 was further an attractive measurement tool because it has only 12 questions, which increased the likelihood that participants would finish the survey, while also recognizing the fact that both patients and nurses may have limited time.[56]

The HLS$_{19}$-Q12 is a subjective, perception based instrument, which uses a 4-point Likert scale to record patient's responses concerning 12 health-related tasks. Respondents are asked to rate the

difficulty level of health related items by selecting "very difficult," "difficult," "easy," "very easy," or "I don't know." In accordance with Type P calculations described by Pelikan et al. 2022, scores were calculated as the sum of the item's numeric values scaled to a range from 0 to 100.[37] A response was considered invalid (missing or 999) if the participant answered, "I don't know." If there were more than two invalid responses in a survey, that survey was disqualified from the study. The categories of HL were: > 83.33 = Excellent, > 66.67 and ≤ 83.33 = Sufficient, > 50 and ≤ 66.67 = Problematic, and ≤ 50 = Inadequate.[37]

Translation to Spanish

At the start of this study, there was no published evidence that the 12-item short form of the survey had been used and validated in Spain, nor translated to Spanish. The principal researcher contacted the International Coordination Centre (ICC) of M-POHL, which is responsible for authorizing the use of the HLS instrument, to determine if a Spanish language version was available. The Spanish language version used in this study was provided by the ICC and had been translated by the Hamburg Center for Health Economics, University of Hamburg, for use in the 11th wave of the European Covid Survey (ECOS) Corona Research.[25] (**Appendix B**). The Spanish survey was not adapted for use in this study with the Spanish population.

Perceptions of quality of care received

Patient perceptions of quality of care received were assessed on a 4-point Likert Scale, by responding to the statement, "*Based on your perceptions regarding quality of care, the quality of care you receive in this outpatient clinic is": No quality (1)Low quality (2) Medium quality (3)High quality (4)*. This statement was included at the end of the HLS_{19}-Q12.

Health literacy checklist

The intervention in this study was the use of a HL checklist. The checklist was created by the principal researcher based on the following: 1) selected HL items from the HLS_{19}-Q12, 2) research regarding the most effective patient education strategies, and 3) research showing that the use of more than one teaching strategy is most effective.[37,57–59] The checklist consisted of seven questions aimed at reinforcing the patients' understanding of and access to health information. These questions were based on the HLS_{19}-Q12. Three were open ended and allowed for continued

dialogue between patient and nurse if needed or desired. The checklist also required that the nurse use the HL strategy of summarizing or reinforcing the important points of that days' appointment. The concluding subclause of the checklist required that the nurse use a minimum of two HL strategies listed in the checklist such as teach back or show back, along with the use of one or more visual aids.

Statistical analysis

This study used IBM SPSS 27 to analyze the survey data. To validate the HLS_{19}-Q12, factor analysis was performed including Standardized Root Mean Square Residual (SRMSR), Root Mean Square Error of Approximation (RMSEA), and Comparative Fit Index (CFI). CFI was extracted via CFA analysis using SPSS AMOS. Principal Component Analysis (PCA) test was further conducted to determine construct validity.

Frequency analysis was used to create the sociodemographic profile of the patient population and analyze general HL of the sample. Independent sample t-test and one-way ANOVA were used examine relationships between HL and sociodemographic data. We further analyzed the combined effect of the sociodemographic characteristics on patient HL scores using a multiple generalized linear regression, as the dependent variable was not normally distributed as per Shapiro Wilk test.

Frequency and descriptive statistics were used to measure before and after HL scores. The Shapiro-Wilk test was used to test for normality. To examine the difference between before and after HL scores, paired samples t-tests and Wilcoxon tests were performed.

Frequency analysis was utilized to assess how often the nurses used each HL technique on the checklist. Pearson correlation determined which specific strategies as well as number of strategies had a significant association with HL scores post intervention.

Before assessing relationships between patients' HL scores pre- and post- implementation of ISO 7101 Subclause 8.10.5 Health Literacy, the Shapiro-Wilk test was used to determine normality of distribution. The test results were not significant (HLS_{19}_Q12p_score_1 p = 0.316; HLS_{19}_Q12p_score_2 p = 0.082), therefore paired samples t-test was used. In the case of

perception of quality-of-care variables (pre- and post-implementation of ISO 7101 Subclause 8.10.5 Health Literacy), the Shapiro-Wilk test results did not follow a normal distribution, hence, Wilcoxon signed-rank test was used.

Chapter 6: Results

Objective 1: Validation the HLS$_{19}$-Q12 in Spain and in the Spanish language

The reliability of the instrument was evaluated using Cronbach's alpha. This test helped to measure the internal consistency of the data. Cronbach's alpha was 0.87, suggesting high or good internal consistency of the survey items (**Table 1**).

Table 1
HLS$_{19}$-Q12 Psychometric properties including results from the Spanish population

Country	Cronbach's alpha	Single-Factor Confirmatory Factor Analysis		
		SRMSR	RMSEA	CFI
Austria	0.67	0.07	0.03	0.97
Belgium	0.82	0.08	0.05	0.98
Bulgaria	0.78	0.07	0.04	0.99
Czech Republic	0.78	0.05	0.03	0.99
Denmark	0.75	0.06	0.03	0.98
France	0.81	0.05	0.02	1.00
Germany	0.73	0.07	0.04	0.97
Hungary	0.76	0.07	0.03	0.98
Ireland	0.72	0.06	0.03	0.97
Israel	0.80	0.06	0.03	0.99
Italy	0.85	0.05	0.04	0.99
Norway	0.73	0.07	0.04	0.97
Portugal	0.87	0.05	0.02	1.00
Russian Federation	0.86	0.05	0.04	0.99
Slovakia	0.81	0.06	0.04	0.99
Slovenia	0.82	0.04	0.02	1.00
Spain	**0.87**	**0.07**	**0.05**	**0.96**
Switzerland	0.72	0.07	0.03	0.98

Data from Table 2: The HLS$_{19}$ Consortium of the WHO Action Network M-POHL (2022): The HLS$_{19}$-Q12 Instrument to measure General Health Literacy. Factsheet.[55] Data for Spain is from this current study.

The Kaiser-Meyer-Olkin (KMO) measure was used to measure sampling adequacy for each variable. Results showed an adequate KMO value of 0.863, supporting that the data was suited for factor analysis.

Bartlett's Test of Sphericity Approx. (X_2=341.526, df = 66, p <0.001) showed statistically significant results confirming correlations did not occur by chance and that factors analysis could be performed. PCA was performed on all 12 items (ALF_1 – ALF_12). The threshold for factor loading values was 0.3, which meant any factor loading below 0.3 was not associated with the extracted component.[60] Per results in **Table 2**, all items were accepted going forward.

Table 2
PCA for the 12 items on the HLS_{19}-Q12

Component Matrix[a]	
	Component
	1
ALF_1	0.679
ALF_2	0.690
ALF_3	0.644
ALF_4	0.744
ALF_5	0.561
ALF_6	0.722
ALF_7	0.586
ALF_8	0.534
ALF_9	0.692
ALF_10	0.566
ALF_11	0.570
ALF_12	0.783

Extraction Method: Principal Component Analysis.
a. 1 components extracted.

Description of the sociodemographic profile of the study population

Frequency analysis was performed to create a sociodemographic profile of the 166 respondents (**Table 3**). Most of the patients were 61-70 years old (28.3%), followed by those who were 51-60 years old (18.1%) and 71-80 years old (18.1%). A small proportion of the sample size were below age 30 (10.8%). Most respondents visited the 'Diabetes' specialty clinic, equaling 47.6% of the sample size, whereas 9% visited 'Cardiology.'

Sixty-eight percent of patients were able to complete the survey on their own. The remainders required the assistance of the researcher, family member, caregiver, or specialty nurse. More than half of respondents were male (62.7%) and 37.3% female. These numbers were the same for gender responses. As shown in **Table 3,** the majority of patients were married or living with a domestic partner (60.8%), and the majority (38.0%) had achieved a primary education level. Ninety-five percent of participants were of Spanish origin.

Table 3
Sample population socio-demographics by sex (cisgender)

		Woman		Man	
		Count	Column N %	Count	Column N %
Age	<= 30	10	16.1%	8	7.7%
	31 - 40	4	6.5%	6	5.8%
	41 - 50	6	9.7%	10	9.6%
	51 - 60	12	19.4%	18	17.3%
	61 - 70	13	21.0%	34	32.7%
	71 - 80	9	14.5%	21	20.2%
	81+	8	12.9%	7	6.7%
Specialty Clinic	Cardiology	5	8.1%	10	9.6%
	Digestive	6	9.7%	15	14.4%
	Diabetes	34	54.8%	45	43.3%
	Ostomy	17	27.4%	34	32.7%
Completed by	Patient alone	41	66.1%	72	69.2%
	Face to face interview	6	9.7%	12	11.5%
	Patient with the help of a familiar member or caregiver	14	22.6%	16	15.4%
	Patient with help of the principal researcher	1	1.6%	1	1.0%
	By the advanced practice nurse	0	0.0%	3	2.9%
Marital Status	Married or domestic partner	34	54.8%	67	64.4%
	Widowed	14	22.6%	8	7.7%
	Divorced	4	6.5%	9	8.7%
	Separated	1	1.6%	1	1.0%
	Never married	9	14.5%	19	18.3%
Education level	Primary education	25	40.3%	38	36.5%
	ESO (Secondary)	8	12.9%	9	8.7%
	High school	3	4.8%	9	8.7%
	Vocational training	9	14.5%	26	25.0%

	Student	12	19.4%	17	16.3%
	Master's degree	5	8.1%	4	3.8%
	Doctorate	0	0.0%	1	1.0%
Origin	Spain	57	91.9%	101	97.1%
	Other	5	8.1%	3	2.9%
Living situation	Nobody	12	19.4%	15	14.4%
	With my partner	19	30.6%	48	46.2%
	Partner & family	15	24.2%	24	23.1%
	Children	8	12.9%	6	5.8%
	Parents	7	11.3%	7	6.7%
	Other family members	1	1.6%	4	3.8%
	Friends	0	0.0%	0	0.0%
	I don't have a permanent residency	0	0.0%	0	0.0%
Work	Unemployed	9	14.5%	6	5.8%
	Work full-time	14	22.6%	26	25.0%
	Work part-time	7	11.3%	2	1.9%
	Retiree with contributory pension	16	25.8%	55	52.9%
	Retiree with a non-contributory pension	6	9.7%	5	4.8%
	Currently studying	4	6.5%	4	3.8%
	Disability or sick leave	6	9.7%	6	5.8%
Residence	Rural	25	40.3%	28	26.9%
	Urban	37	59.7%	76	73.1%
I would classify my health as	Very good	1	1.6%	7	6.7%
	Good	25	40.3%	49	47.1%
	Regular	32	51.6%	34	32.7%
	Bad	4	6.5%	13	12.5%
	Very bad	0	0.0%	1	1.0%
Net Monthly Income	< 600 €	6	9.7%	7	6.7%
	601 – 800 €	7	11.3%	4	3.8%
	801 – 1000 €	4	6.5%	10	9.6%
	1001 – 1.200 €	8	12.9%	9	8.7%
	€1,201 – €1,500	5	8.1%	15	14.4%
	€1,501 – €2,000	5	8.1%	15	14.4%
	> €2,001	10	16.1%	19	18.3%
	Spouse's pension	2	3.2%	0	0.0%
	I'd rather not answer	13	21.0%	18	17.3%
	I don't know	2	3.2%	7	6.7%
How many appointments have you had	1-2	21	33.9%	39	37.5%
	3-4	14	22.6%	22	21.2%
	5-6	9	14.5%	7	6.7%

in this outpatient clinic not including today?	>6 visits	18	29.0%	36	34.6%

While sociodemographic information was analyzed for all 166 participants, HL scores were calculated for 150 of them. This was due to the fact that 16 surveys were disqualified because they had more than two invalid responses as described in the methodology section of this work. **Table 4** summarizes the mean scores for each of the 12 items on the survey. Respondents found it most difficult to 'understand advice concerning your health from family or friends' (2.95 ± 0.80), 'to decide how you can protect yourself from illness using information from the mass media' (2.99 ±1.30), and 'to make decisions to improve your health and well-being' (3.02± 0.75).

Table 4
Global descriptive results of the HLS$_{19}$-Q12 items in the study population

Item	On a scale from very easy to very difficult, how easy would you say it is . . .	Q25	Median	Q75	Mean	Std. Deviation
1	to find out where to get professional help when you are ill?	3.00	3.00	4.00	3.12	0.697
2	to understand information about what to do in a medical emergency?	3.00	3.00	3.00	3.09	0.601
3	to judge the advantages and disadvantages of different treatment options?	2.25	3.00	3.00	2.86	0.603
4	to act on advice from your doctor or pharmacist?	3.00	3.00	4.00	3.31	0.602
5	to find information on how to manage mental health problems?	2.00	3.00	3.00	2.47	0.854
6	to understand information about recommended health screenings or examinations?	3.00	3.00	4.00	3.17	0.587
7	to judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable?	3.00	3.00	4.00	3.18	0.695
8	to decide how you can protect yourself from illness using information from the mass media?	2.00	2.00	3.00	2.41	0.825

#						
9	to find information on healthy lifestyles such as physical exercise, healthy food or nutrition?	3.00	3.00	4.00	3.18	0.621
10	to understand advice concerning your health from family or friends?	2.00	3.00	3.00	2.83	0.642
11	to judge how your housing conditions may affect your health and wellbeing?	3.00	3.00	3.00	3.03	0.604
12	to make decisions to improve your health and wellbeing?	3.00	3.00	3.00	2.99	0.711
Total		2.00	2.00	3.00	2.38	0.783

Overall, the median HL score of respondents was 67 and the mean was 66 (SD: 13.63). As seen in **Figure 3**, 59% of patients had HL categorized as inadequate or problematic, while only 41% had sufficient or excellent HL.

	Frequency	Percent
Inadequate	16	10.7
Problematic	73	48.7
Sufficient	49	32.7
Excellent	12	8.0
Total	150	100.0

Fig. 3 General health literacy of the study population

ANOVA tests were used to explore whether HL scores significantly differed with respect to sociodemographic variables. **Table 5** presents the mean HL scores for different patient groups categorized by sociodemographic factors.

Patients' age did not have a significant influence on HL scores (F = 1.436, p = 0.205), however, the youngest age group (<= 30 years) (n = 16) had significantly greater HL scores than patients aged 61-70 years and 71-80 years.

The study found no significant difference in HL scores between distinct categories of specialty consultations (F = 2.210, p = 0.100), however, patients attending diabetes consultations had significantly greater HL scores (M = 68.59) than patients in ostomy consultations (M = 62.12).

Education level did not have a significant impact on HL scores (F = 1.509, *p* = 0.179). The patient with a 'doctorate' had the highest HL score (M = 91.67), while patients with primary education had the lowest scores (M = 63.27).

The study found a statistically significant difference in HL scores between patients with different work situations (F = 3.762, *p* < 0.001). Patients who were currently studying recorded the highest HL scores (M = 79.15), which was significantly higher than patients working part-time, retirees with contributory pension, and patients with disability or sick leave.

Income level also had a significant effect on HL scores (F= 2.129, *p* < 0.05). Patients within €1,501 – €2,000 income range had the highest score on average (M = 72.30), which was significantly greater than other listed income levels.

Finally, there was no significant difference in HL scores with respect to how the questionnaire was completed (F = 1.473, *p* = 0.214). However, patients who completed the questionnaire via face-to-face interviews record the lowest score on average (M = 60.34). Patients completing the questionnaire alone had the highest score on average (M = 67.83).

Table 5
Patient sociodemographic profiles and general health literacy scores: ANOVA tests

	N	Mean	Standard Deviation	95% Confidence Interval for Mean		Min	Max	F	*p* value
				Lower	Upper				
Specialty clinic									
Diabetes	71	68.58	12.86	65.54	71.63	36.11	100.00		
Cardiology	14	66.63	11.87	59.77	73.48	45.45	88.89		
Digestive	20	66.40	12.31	60.64	72.17	47.22	91.67		
Ostomy	45	62.12	15.23	57.54	66.70	2.78	91.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	2.12	0.100
Survey completed by									
Patient alone	104	67.83	12.55	65.39	70.27	36.11	100.00		
By the nurse	3	66.46	8.25	45.96	86.96	60.00	75.76		
Patient with help	26	63.33	18.22	55.97	70.69	2.78	91.67		
Face to face interview	16	60.33	11.31	54.30	66.36	42.42	88.89		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.47	0.214
Age									
<= 30	16	72.90	12.30	66.34	79.45	44.44	88.89		

31 - 40	10	70.55	14.91	59.88	81.21	47.22	96.67		
41 - 50	16	66.92	10.02	61.57	72.26	47.22	80.56		
51 - 60	26	67.23	18.54	59.75	74.72	2.78	100.00		
61 - 70	44	64.61	13.99	60.35	68.86	36.11	93.94		
71 - 80	24	61.61	7.54	58.42	64.79	44.44	80.56		
81+	14	65.26	12.37	58.12	72.41	50.00	91.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.44	0.205
Sex									
Woman	52	68.06	13.12	64.41	71.72	44.44	93.94		
Man	98	65.17	13.84	62.39	67.94	2.78	100		
Total	150	66.18	13.63	63.98	68.37	2.78	100.00	1.543	0.216
Marital status									
Widowed	17	67.78	12.64	61.28	74.29	51.52	93.94		
Never married	26	67.42	19.06	59.72	75.12	2.78	100.00		
Married/domestic partner	94	66.36	12.33	63.84	68.89	36.11	96.67		
Divorced	12	59.62	10.76	52.79	66.46	38.89	80.56		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.81	0.522
Education									
ESO (Secondary)	14	70.52	9.87	64.82	76.22	45.45	81.82		
Student	25	69.18	13.21	63.72	74.63	44.44	96.67		
High school	11	67.34	9.79	60.76	73.91	52.78	80.56		
Master's degree	9	66.91	8.35	60.49	73.34	54.55	80.56		
Vocational training	33	65.69	13.76	60.81	70.57	41.67	91.67		
Primary education	57	63.27	15.22	59.23	67.31	2.78	100.00		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.51	0.179
Living situation									
Parents	14	68.54	22.40	55.60	81.47	2.78	88.89		
Partner & family	38	68.38	13.99	63.78	72.98	47.22	91.67		
Children	12	65.61	17.79	54.30	76.92	38.89	93.94		
Nobody	23	65.61	10.86	60.91	70.30	54.55	100.00		
With my partner	60	64.75	10.68	61.99	67.51	36.11	96.67		
Other family members	3	62.12	17.91	17.62	106.61	41.67	75.00		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.47	0.798
Work									
Currently studying	7	79.14	8.36	71.41	86.88	63.89	88.89		
Retiree with a non-contributory pension	10	72.07	8.09	66.28	77.86	63.89	91.67		
Unemployed	13	70.76	13.09	62.85	78.67	52.78	93.94		
Work full-time	38	69.41	12.31	65.37	73.46	47.22	96.67		
Disability or sick leave	12	65.57	12.66	57.52	73.62	47.22	91.67		
Retiree with contributory pension	64	61.79	14.39	58.19	65.38	2.78	100.00		

Work part-time	6	58.67	9.00	49.22	68.11	44.44	69.70		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	3.76	0.002
I would classify my health as									
Very good	7	71.94	8.20	64.35	79.54	60.61	83.33		
Good	69	66.78	15.66	63.02	70.55	2.78	100.00		
Regular	59	65.80	11.69	62.75	68.85	36.11	91.67		
Bad	14	62.57	12.65	55.27	69.88	38.89	80.56		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.75	0.559
Net monthly income									
< 600 €	13	69.89	10.56	63.50	76.27	55.56	91.67		
601 – 800 €	8	54.25	22.40	35.52	72.98	2.78	77.78		
801 – 1000 €	14	61.78	14.11	53.63	69.93	44.44	100.00		
1001 – 1.200 €	16	71.12	11.16	65.16	77.07	55.56	93.94		
€1.201 – €1.500	19	62.20	11.52	56.64	67.75	44.44	80.56		
€1.501 – €2.000	18	72.29	14.75	64.95	79.63	36.11	96.67		
> €2.001	26	68.00	11.75	63.26	72.75	52.78	91.67		
I don't know	8	68.69	19.35	52.51	84.88	38.89	88.89		
Spouse's pension	2	68.33	2.35	47.15	89.51	66.67	70.00		
I'd rather not answer	26	63.19	10.67	58.88	67.50	41.67	84.85		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	2.13	0.031
How many appointments have you had in this outpatient clinic not including today?									
1-2	54	67.07	13.27	63.45	70.69	36.11	91.67		
3-4	30	65.72	12.08	61.21	70.24	44.44	100.00		
5-6	12	61.17	21.56	47.47	74.87	2.78	80.56		
>6 visits	54	66.63	12.75	63.15	70.11	44.44	96.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.64	0.588

HL scores were also examined by sex and gender. All participants identified as cisgender. While the results indicated no significant difference in the HL scores between men and women, t = 1.543, p = 0.216, the mean HLS of women was slightly higher (M = 68.06 ±13.12) than for men (65.17 ±13.84). The distribution of HL for men and women showed that 51% of the men had problematic HL while only 5.1% had excellent HL. In the case of women, 44.2% had problematic HL, while 13.5% had excellent HL **(Figure 4).**
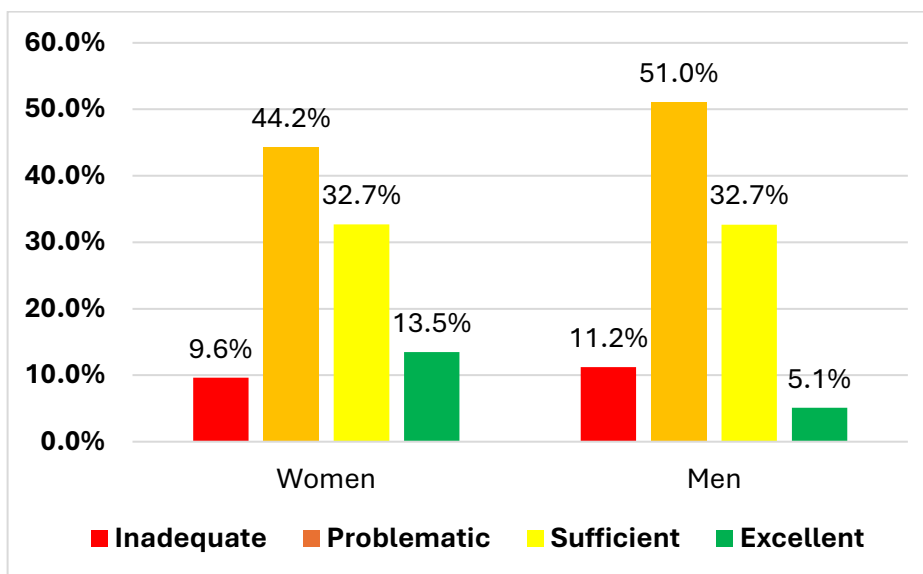
Fig. 4 Distribution of general HL categories for women and men (cisgender)

To determine the significance of each variable in predicting HL scores (the dependent variable), we used a generalized linear model (**Table 6**). The overall model was statistically significant (χ^2 = 83.484, p < 0.01), and the McFadden's Pseudo-R^2 value was 0.427. Education and net monthly income were highly significant predictors of HL (p < 0.01) when other sociodemographic variables were controlled. Parameter estimates showed that the respondents with the highest educational qualification, i.e., doctorate, had significantly greater HL scores than other educational qualifications. In the case of net monthly income, respondents within the income range €1,501 – €2,000 had significantly greater HL scores than others. Work status was a statistically significant predictor of HL score (p < 0.05). Having 5-6 outpatient appointments was significantly associated with a lower HL score compared to having more than six appointments (p < 0.05). With respect to self-stated heath status, patients who self-reported their health as 'very good' had significantly higher HL scores than all other categories (very bad, bad, regular, and good) (p < 0.05).

Table 6
Generalized linear model – Parameter estimates

Parameter	B	Std. Error	Lower Interval	Upper Interval	*p* value
(Intercept)	110.265	15.893	79.116	141.415	0.000
Specialty clinic					

Cardiology	3.486	4.188	-4.723	11.695	0.405
Digestive	-1.638	3.490	-8.478	5.203	0.639
Diabetes	3.694	2.648	-1.496	8.884	0.163
Ostomy	-				

Age

<= 30	6.630	8.552	-10.132	23.391	0.438
31 - 40	-0.927	6.621	-13.904	12.050	0.889
41 - 50	-3.579	5.639	-14.632	7.474	0.526
51 - 60	1.994	5.111	-8.024	12.012	0.696
61 - 70	-4.362	4.099	-12.397	3.672	0.287
71 - 80	1.500	4.406	-7.135	10.136	0.733
81+	-				

Sex

Woman	1.827	2.253	-2.589	6.243	0.417
Man	-				

Marital status

Married/domestic partner	-1.821	4.752	-11.134	7.492	0.702
Widowed	1.518	5.355	-8.977	12.013	0.777
Divorced	-7.158	5.380	-17.702	3.386	0.183
Separated	12.592	13.273	-13.422	38.607	0.343
Never married	-				

Education

Primary education	-33.229	11.672	-56.105	-10.353	0.004
ESO (Secondary)	-26.787	11.907	-50.124	-3.450	0.024
High school	-32.837	11.776	-55.917	-9.757	0.005
Vocational training	-35.773	11.604	-58.516	-13.030	0.002
Student	-33.170	11.499	-55.707	-10.632	0.004
Master's degree	-47.520	12.623	-72.260	-22.780	0.000
Doctorate	-				

Origin

Spain	-5.946	4.914	-15.576	3.685	0.226
Other	-				

Living Situation

Nobody	10.629	8.277	-5.595	26.852	0.199
With my partner	9.135	8.296	-7.124	25.395	0.271
Partner & family	9.714	8.550	-7.043	26.471	0.256
Children	12.068	9.658	-6.862	30.997	0.211

Parents	-2.752	8.330	-19.079	13.575	0.741
Other family members	-				
Work					
Unemployed	-0.427	5.633	-11.466	10.613	0.940
Work full-time	-3.213	4.523	-12.078	5.651	0.477
Work part-time	-10.396	7.209	-24.524	3.733	0.149
Retiree with contributory pension	-10.277	4.509	-19.115	-1.439	0.023
Retiree with a non-contributory pension	-3.240	5.820	-14.647	8.167	0.578
Currently studying	7.623	8.002	-8.060	23.306	0.341
Disability or sick leave	-				
Residence					
Rural	-3.666	2.445	-8.458	1.127	0.134
Urban	-				
I would classify my health as					
Very Bad	-32.823	14.047	-60.354	-5.291	0.019
Bad	-13.536	5.799	-24.902	-2.171	0.020
Regular	-11.542	4.967	-21.277	-1.806	0.020
Good	-10.194	4.963	-19.921	-0.467	0.040
Very Good	-				
Net monthly income					
< 600 €	8.510	4.390	-0.093	17.113	0.053
601 – 800 €	-7.880	4.697	-17.086	1.325	0.093
801 – 1000 €	1.850	4.125	-6.234	9.935	0.654
1001 – 1.200 €	9.421	3.838	1.898	16.943	0.014
€1.201 – €1.500	-0.083	3.585	-7.111	6.944	0.981
€1.501 – €2.000	13.309	3.858	5.747	20.871	0.001
> €2.001	5.926	3.831	-1.583	13.435	0.122
Spouse's pension	1.864	8.884	-15.548	19.275	0.834
Others	-				
How many appointments have you had in this outpatient clinic not including today					
1-2	1.684	2.542	-3.297	6.665	0.508
3-4	-1.185	2.832	-6.735	4.365	0.676
5-6	-9.963	4.313	-18.417	-1.509	0.021
>6 visits	-				
(Scale)	105.72[a]	12.208	84.311	132.574	

Overall Results

Omnibus Test (Likelihood Ratio Chi-Square)	83.484	0.001
R^2McF	0.427	

Dependent Variable: HLS$_{19}$_Q12p_score_1

Model: (Intercept), Specialty clinic, Age, Sex, Marital Status, Education level, Income, Origin, Living situation, Work, Residence, Health Status, Numbers of appointments in outpatient clinic

"-" represents the reference category

a. Maximum likelihood estimate (Type III)

Distribution Family = Normal; Link function = Identity

Objective 3: Examination of the relationship between nurses' use of a health literacy checklist (intervention) and before and after patient HL scores

The intervention was the nurses' use of the HL checklist during three total visits with each patient. Post-intervention HL scores were available for 149 participants, as one participant did not return to complete the final HLS$_{19}$-Q12. Paired samples t-test assessed the difference between HL scores pre- and post-intervention (**Table 7**). The paired samples correlation test showed that the mean difference between the two scores was -9.943, with a standard deviation of 11.51. There was a statistically significant effect of the intervention on HL scores (t = -10.002, $p < 0.001$). Cohen's d was negative and 0.864, which indicated a large effect size.

The Wilcoxon test was used to confirm the effect of the intervention. The mean score in the pre-intervention group (HLS$_{19}$_Q12_group_1) was lower (2.39) than the mean score in post-intervention group (HLS$_{19}$_Q12_group_2), 2.96. The z-statistic was -7.121, and the asymptotic significance was <0.001, showing a statistically significant difference in the scores of both groups. Based on mean ranks, it was proven that HL scores post-intervention was greater than HL scores pre-intervention.

Most of the respondents in group 1 had HL scores that were 'problematic' equaling 48.7% (73 patients) of the valid sample, followed by 32.7% (49 patients) who had 'sufficient' knowledge. After HL interventions, most patients had HL scores that were 'sufficient' equaling 55% of the valid sample (82 patients) and 20.1% (30 patients) were 'excellent'. Post-intervention only 24.8% scored 'problematic,' showing improvement in group 2. No participants had HL that was 'inadequate' after the nursing intervention.

The same HL score component was treated as a continuous variable for better understanding of the intervention's outcome on patients' HL. The results of the continuous variable (HLS$_{19}$_Q12 score) showed that before intervention the mean HL score (score 1) was 66.18 (+/-13.63), whereas post intervention, the mean HL score (score 2) improved to 75.90 (+/- 9.95).

Table 7
Health literacy pre-and post-nursing health literacy interventions

Before intervention

	Classification	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Inadequate	16	9.6	10.7	10.7
	Problematic	73	44.0	48.7	59.3
	Sufficient	49	29.5	32.7	92.0
	Excellent	12	7.2	8.0	100.0
	Total	150	90.4	100.0	
Missing	System	16	9.6		
Total		166	100.0		

After intervention

	Classification	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Problematic	37	22.3	24.8	24.8
	Sufficient	82	49.4	55.0	79.9
	Excellent	30	18.1	20.1	100.0
	Total	149	89.8	100.0	
Missing	System	17	10.2		
Total		166	100.0		

HL scores pre- and post-intervention were also analyzed by sex (cisgender). For the pre-intervention HL survey, a greater percentage of men had 'inadequate' or 'problematic' HL than women. Women showed a greater percentage of 'excellent' HL than the lesser categories of 'sufficient,' 'problematic,' or 'inadequate.' Post-intervention, the percentage of men whose HL was categorized as 'excellent' had increased from 41.7% to 76.7% (**Figure 5**). Descriptive statistics showed that the mean HL improved post-intervention for both women and men (**Table 8**).
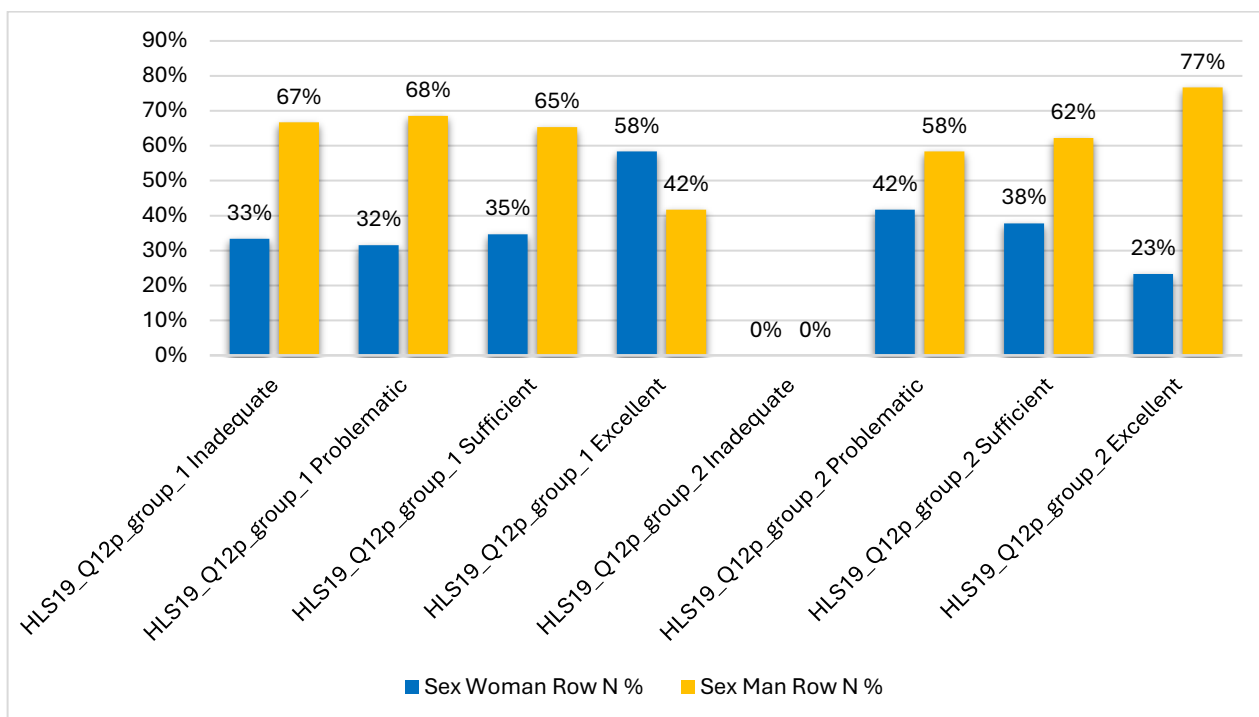
Fig. 5 HL categorization pre- and post-intervention by sex (cisgender)

Table 8
Before and after intervention HL mean score by sex (cisgender)

	Woman Mean	Man Mean
HLS$_{19}$_Q12_score_1	68.07	65.81
HLS$_{19}$_Q12_score_2	75.45	76.25

Frequency of health literacy strategies used by specialty practice nurses

Frequency analysis was used to quantify the nurses' use of specific interventions (tools, or techniques) chosen from the HL checklist (**Table 9**) . Verbal teach back method was the most frequent technique used over the course of the three appointments, selected by nurses 79% of the time. In regard to the subclause of the HL checklist that required the nurse to select a visual aid, use of a computer image was the most popular choice at 46%, followed by a physical model

or device 31% of the time. The least frequently used verbal/action technique was the show back method (17%), and the least often selected visual aid was a poster (0.6%).

Table 9
Frequency of health literacy interventions used by nurses

	Appointment 1		Appointment 2		Appointment 3		Overall	
	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Verbal/Action								
Teach back (Verbal)	133	80.6%	126	76.4%	132	80.0%	391	79.0%
Show back what you have learned (Action)	37	22.4%	27	16.4%	20	12.1%	84	17.0%
None	19	11.5%	8	4.8%	4	2.4%	31	6.3%
Visual Aids								
Educational Brochure	38	23.0%	14	8.5%	10	6.1%	62	12.5%
Poster	0	0.0%	1	0.6%	2	1.2%	3	0.6%
Notes from the visit	10	6.1%	6	3.6%	11	6.7%	27	5.5%
Computer image	71	43.0%	81	49.1%	76	46.1%	228	46.1%
Picture on phone or app	2	1.2%	2	1.2%	7	4.2%	11	2.2%
Physical model or device	51	30.9%	55	33.3%	47	28.5%	153	30.9%
None	40	24.2%	18	10.9%	20	12.1%	78	15.8%

The study further examined the association between the total number of techniques used in all three appointments with the same patient and that patient's HL score after the intervention. There was no significant correlation between total number of techniques used from the checklist and HL scores post intervention.

Relationship between the type of health literacy intervention used and patient health literacy scores

Pearson correlation was used to determine whether any of the HL interventions used in the appointments had a significant association with HL scores post intervention (**Table 10**). The 'show back what you have learned (action)' technique had a significant negative relationship with HLS after intervention ($r = -0.140$, $p < 0.1$) (correlation is marginally significant). Moreover, the use of physical model or device visual aid also had a significant negative link with HL scores after intervention ($r = -0.153$, $p < 0.1$).

Table 10

Correlations between type of health literacy intervention and post intervention scores

		$HLS_{19}\_Q12p\_score$ post intervention
$HLS_{19}\_Q12p\_score$	Pearson Correlation	1
	Sig. (2-tailed)	
	N	148
Verbal teach back	Pearson Correlation	0.128
	Sig. (2-tailed)	0.120
	N	148
Action show back what you learned	Pearson Correlation	-0.140
	Sig. (2-tailed)	0.090
	N	148
Neither teach back nor show back	Pearson Correlation	-0.017
	Sig. (2-tailed)	0.840
	N	148
Educational brochure	Pearson Correlation	0.063
	Sig. (2-tailed)	0.449
	N	148
Poster	Pearson Correlation	-0.079
	Sig. (2-tailed)	0.342
	N	148
Notes from visit	Pearson Correlation	0.021
	Sig. (2-tailed)	0.804
	N	148
Computer image	Pearson Correlation	0.074
	Sig. (2-tailed)	0.371
	N	148
Picture on phone or app	Pearson Correlation	-0.011
	Sig. (2-tailed)	0.895
	N	148
Physical model or device	Pearson Correlation	-0.153
	Sig. (2-tailed)	0.063
	N	148
Did not use any visual aids	Pearson Correlation	0.026
	Sig. (2-tailed)	0.752
	N	148

Objective 4: Description of the process of implementing ISO 7101 subclause 8.10.5 in four specialty consultations

Management commitment and nurse training

The quality management system described in ISO 7101 requires a strong expression of top management commitment. To achieve this requirement, the Director of Nursing came to the training and delivered a message regarding the importance of the implementation of the HL checklist, highlighting the potential to improve service user HL, and produce results that could provide knowledge for evidence-based nursing practice. In a further show of management support, two nurse managers attended the course. These nurses voiced commitment and participated in training, but were not involved with direct patient care.

This subclause also requires that healthcare workforce receive education to become health literate, and to use HL techniques to educate service users. Training occurred face-to-face in a group format with an instructor who was an expert in HL, global health systems, and was also a nurse. The course included an overview of the definition and meaning of HL, the importance of HL, descriptions of populations at risk for low HL levels, strategies clinicians could use to improve patients' HL, role play of HL strategies among nurses, with some acting as patients, and group feedback regarding the HL checklist that the nurses would be using in the study.

Inclusion of patients and caregivers

Subclause 8.10.5 requires that populations served, including patients, caregivers and family members, be considered in the design and provision of services. This was achieved by using an HL checklist that was prescriptive, but open ended enough to address the needs and concerns of service users at that moment of interaction. For example, the checklist encouraged patients to ask for additional information, talk about their emotional status, explore their use of social media for health information, and even show back care techniques they learned. In this manner, nurses were not just telling the service user '*what to do*', but rather including them in the process by switching the aim of the conversation to '*how can we work together and what do you need from us*?'

Confirmation of understanding of health information

Subclause 8.10.5 e) requires that organizations use HL strategies in communications with confirmation of understanding. This was accomplished by having the nurses ask various questions from the checklist such as "*Do you understand all the follow-up instructions and details for your next appointment*?", "*Have you understood all the information from the doctor (if there has also been a consultation) and from me today*?", and "*What are the questions you have about your health situation or medication?*"

Use of a wide range of health literacy skills

Another requirement of the standard is to provide service users with education regarding prevention and management of their current or potential conditions, while using a range of HL skills. This was accomplished using the HL checklist (**Table 11**). During each patient visit, nurses were required to ask a series of questions, and also choose from a varied list of educational tools they could use with the patient. Nurses were instructed to use the techniques they felt were most effective with each patient given the patient's preferred learning style or level of education and understanding.

Table 11

Health literacy checklist

Questions to ask at each visit	Asked? Y or N	Nurse's Initials	Comments (if needed or desired)
What are the questions you have about your health situation or medication?			
What kind of additional information do you think might help you manage your situation?			
If there is a caregiver at the time of the consultation, ask them (where appropriate) if they have questions or need more information about handling the situation. (Put NA if no caregiver is present)			
Have you understood all the information from the doctor (if there has also been a consultation) and from me today?			
Do you know what to do or where to go in case of an emergency?			
How is your mood or emotions and how could I help you or recommend resources?			
Do you use media as a source of health information, and if so, do you have any questions about what you've heard or read?			
Summarize the most important points of that day's visit. Examples: • Today we talked about . . . • Now you know how to. . . • Remember . . .			
Do you understand all the follow-up instructions and details for your next appointment? **Make sure the patient has 2 more appointments scheduled**			
Actions to be taken on each visit	**Completed Y or N**	**Nurse's Initials**	**List the methods used and the visual aid used in the boxes below**
Choose at least one on each visit: 1. Teach back (Verbal) 2. Show back what you have learned (Action)			
Use one or more visual aids 1. Educational Brochure 2. Poster 3. Notes from the visit 4. Computer Image 5. Picture on phone or app 6. Physical model or device			

Document any notes or comments that may be helpful in improving patient care in the office (or in the SALUD health system in general):

This ISO 7101 standard is written for healthcare organizations of any type and size. Therefore, there were minor requirements of the standard that were not applicable to the specialty consultation, outpatient setting such as "*high-risk situations*, including detailed information before performing procedures that require informed consents."[53] When a requirement fell outside of the scope of a specialty consultation, it was not possible to implement it in the study. This is a permissible omission when implementing ISO standards in an organization.

Use of the health literacy checklist with the patient sample

Once the nurse training portion of implementation was complete, implementation was then directed towards patients. Once a patient was enrolled in the study, at the beginning of the first patient visit they were asked to complete the HLS_{19}-Q12 (survey 1). During the next three consultations, the nurses used the HL checklist as the intervention. After the third use of the HL checklist, patients were asked to complete the HLS_{19}-Q12 a second time (**Figure 6**).
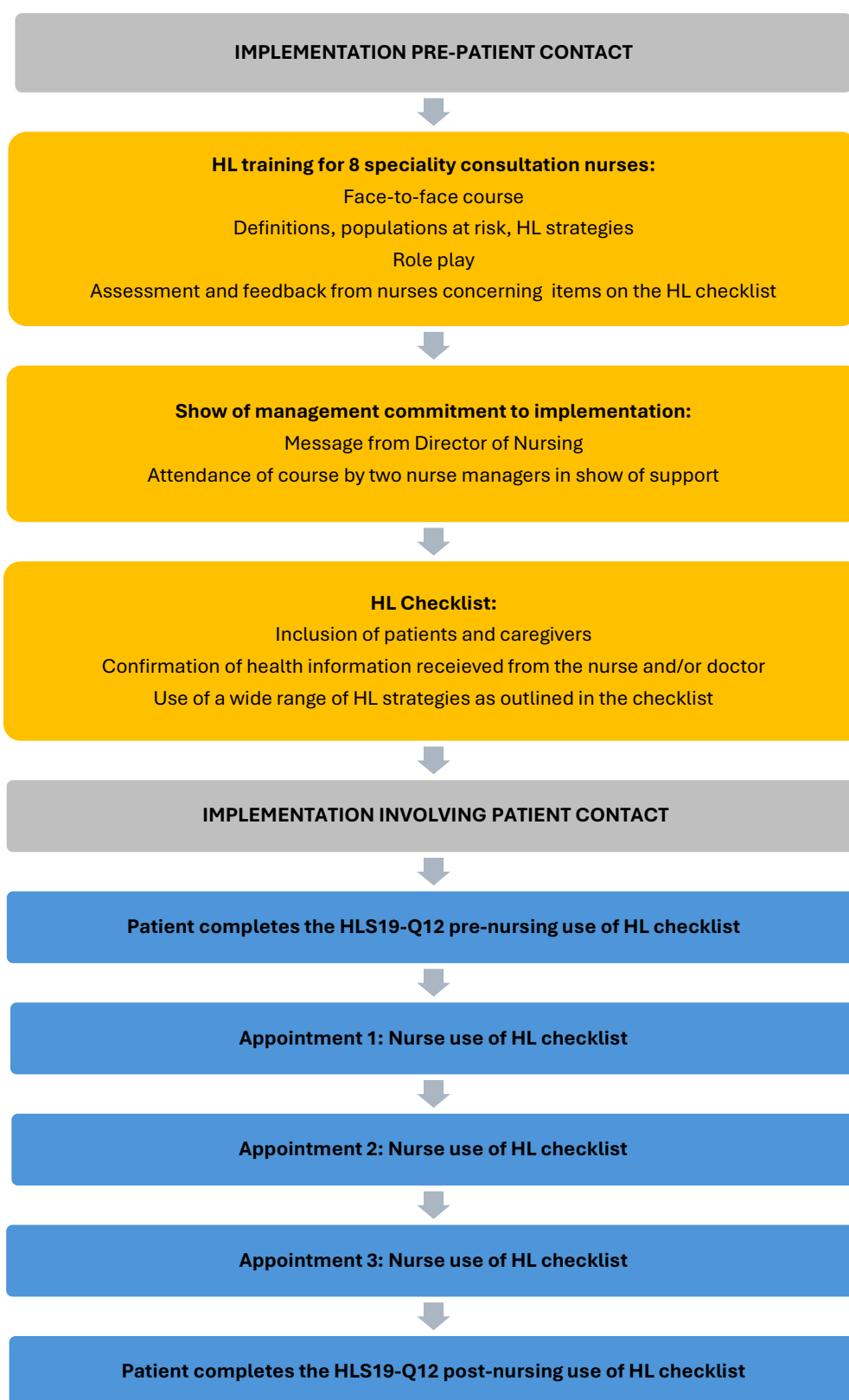
IMPLEMENTATION PRE-PATIENT CONTACT

HL training for 8 speciality consultation nurses:

Face-to-face course

Definitions, populations at risk, HL strategies

Role play

Assessment and feedback from nurses concerning items on the HL checklist

Show of management commitment to implementation:

Message from Director of Nursing

Attendance of course by two nurse managers in show of support

HL Checklist:

Inclusion of patients and caregivers

Confirmation of health information receieved from the nurse and/or doctor

Use of a wide range of HL strategies as outlined in the checklist

IMPLEMENTATION INVOLVING PATIENT CONTACT

Patient completes the HLS19-Q12 pre-nursing use of HL checklist

Appointment 1: Nurse use of HL checklist

Appointment 2: Nurse use of HL checklist

Appointment 3: Nurse use of HL checklist

Patient completes the HLS19-Q12 post-nursing use of HL checklist

Fig. 6 Process flow of implementation ISO 7101 subclause 8.10.5 Health literacy

Objective 5: Implementation of ISO 7101 Subclause 8.10.5 and health literacy scores

According to the paired sample statistics, the mean HL score of sample patients increased after the implementation of ISO 7101 Subclause 8.10.5 Health literacy from 66.35 to 76.29. As seen in **Table 12**, this difference was statistically significant (t = -10.00, p < 0.001), meaning that there was a significant effect of the implementation of ISO 7101 Subclause 8.10.5 Health literacy on patients' HL scores. Moreover, Cohen's d was -0.86, which is considered a large effect size. Wilcoxon test demonstrated the significative difference between scores observed before and after implementation (z= -7.12, p<0.001).

Table 12
Statistical results for general HL scores pre-and post-implementation of subclause 8.10.5

	Mean	Median	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	Significance	
					Lower	Upper		One-Sided p	Two-Sided p
HLS$_{19}$-Q12 score pre-implementation	66.17	66.67	13.62	1.09					
HLS$_{19}$-Q12 post-implementation	75.89	75.76	9.95	0.83					
Paired Differences pre-post implementation	-9.94		11.50	0.99	-11.90	-7.97	-10.00	$P<.001$	$P<.001$

			Stder^a	Point Estimate	Lower	Upper
Paired Samples Effect Sizes HLS$_{19}$-Q12 score pre- and post-implementation		Cohen's d	11.50	-0.86	-1.06	-0.66
		Hedges' g	11.57	-0.85	-1.05	-0.66

	Z	Asymp. Sig. (2-tailed)
HLS$_{19}$-Q12 score pre-and post-intervention Wilcoxon Signed Ranks Test	-7.12^b	$P<.001$

a. Standardizer. The denominator used in estimating the effect sizes.
   Cohen's d uses the sample standard deviation of the mean difference.
   Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor.
b. Based on negative ranks

Scores were categorized according to the HLS_{19}-Q12 scoring instructions. As shown in **Figures 7 and 8**, there were no patients classified as having 'inadequate' post implementation of ISO 7101, Subclause 8.10.5.
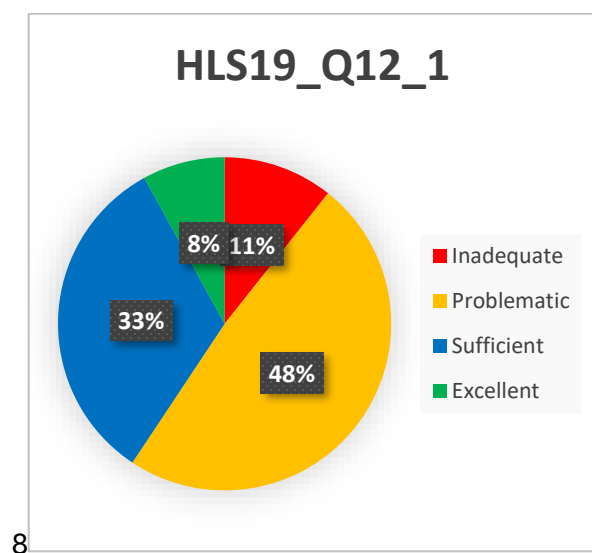
Fig. 7 Patient general HL pre-implementation
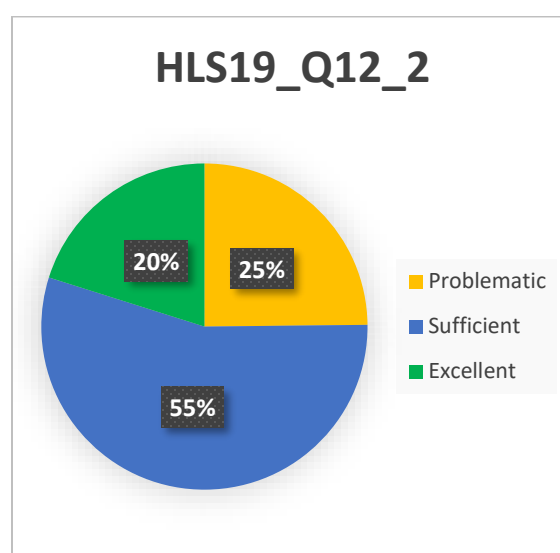
Fig. 8 Patient general HL post-implementation

Objective 6: Implementation of ISO 7101 Subclause 8.10.5 and perception of quality of care

The mean score of perception of quality of care improved after the implementation of ISO 7101 Subclause 8.10.5 (from M = 3.87 to M = 3.99). The Wilcoxon test statistics revealed a significant difference (Z = -3.900, p < 0.001), meaning that the effect of the implementation of ISO 7101 Subclause 8.10.5 Health literacy on the perception of quality of care was statistically significant (**Table 13**).

Table 13
Statistical results perception of quality of care received pre-and post-implementation of subclause 8.10.5

	Mean	Std. Deviation	Minimum	Maximum
Perception of quality of care received pre-implementation	3.87	0.33	3	4

Perception of quality of care received post-implementation	3.99	0.08	3	4

	Ranks			
	Negative Ranks	1[a]	10.00	10.00
Perception of quality of care received pre-and post	**Positive Ranks**	18[b]	10.00	180.00
	Ties	133[c]		
	Z	**Asymp. Sig. (2-tailed)**		
Wilcoxon Test[d]	-3.90[d]	$P<.001$		

a. 2_Perception of quality of care received < Perception of quality of care received.
b. 2_Perception of quality of care received > Perception of quality of care received.
c. 2_Perception of quality of care received = Perception of quality of care received.
d. Based on negative ranks.

Chapter 7: Discussion

This study served to validate the HLS$_{19}$-Q12 in specialty consultations in Spain, in the Spanish language. This is significant as, to the extent of our knowledge, the survey had not been validated in Spain or in the Spanish language at the time of this investigation. However, it has been validated and used in various studies in other European countries.[19,55,61–63] When compared to the validation statistics of 17 other European countries, its use in Spain with our sample population showed comparable psychometric properties as seen in **Table 2**.[55] Alpha coefficients reported for its use in the 17 countries varied from 0.67 to .87.[64] Cronbach alpha for this study was 0.87.

This study further created a sociodemographic profile of the population of patients in Zaragoza health sector III who attend specialty consultations. This is valuable information because research shows that sociodemographic variables are associated with HL in both positive and negative ways.[24,26,27,33,65,66] The better a health system or hospital knows and understands the sociodemographic profile of the population it serves, the better poised it is to create processes and policies that address their specific HL needs.[26,29]

Next, using the newly validated HLS$_{19}$-Q12, HL scores were calculated for this patient sample. The comprehensive project describing results of the HLS$_{19}$-Q12 across large general populations in 17 countries reported a median HL score of 64 with a mean of 65. [37] This study population had a median score of 67 and mean score of 66, which is slightly higher, but in alignment with the findings from the 17 country study. Results showed that 59% of respondents had HL categorized as inadequate or problematic, while 41% had sufficient or excellent HL. In comparison, a study using the HLS$_{19}$-Q12 in Portugal reported notably higher HL with only 30% of the population categorized as inadequate or problematic, and 70% possessing sufficient or excellent HL.[62]

The HLS$_{19}$-Q12 was built on the conceptual framework and definition of comprehensive, general HL developed in the HLS-EU study that led to the development of the HLS-EU-Q16, a 16-tem version.[37] A study in Romania using the HLS-EU-16 to survey a large, general population reported that 40% of the sample had inadequate or problematic HL, as compared to the 59% in this study. [61] The HLS-EU-Q16 was also used in two Spanish studies to assess HL of large, general populations in the regions of Catalonia and Valencia.[67,68] In Catalonia only 15.4% of those

surveyed had problematic or inadequate HL, while in Valencia, a similar 12.8% of survey participants presented with problematic or inadequate HL.[25] These studies report much lower percentages of problematic HL than in this current study sample. The findings of this research suggest that patients attending specialty consultations may experience lower HL than in larger, general populations.

In total, 56% of participants found it difficult or very difficult to decide how to 'protect themselves from illness using information from the mass media.' In fact, this was the survey item with the second lowest mean score. These findings are in line with research that shows public uncertainty and distrust with "fake news," social media, and artificial intelligence, and highlights the need to ensure that individuals are equipped to identify health misinformation received from mass media sources. [29,69–71]

The study found a statistically significant difference in the HL between patients with different work situations. The category of "studying" was included in the choices of work situation. Patients who were currently studying recorded the highest HL scores. This could be that individuals who are already in learning mode and are actively exploring new ideas and concepts are more open or receptive to processing current and new health information.

Our results showed that income had a relationship to HL scores. In fact, net monthly income was determined to be a highly significant predictor of HL. A study in Valencia, Spain found that population subgroups such as low-income individuals presented with a higher degree of inadequate or problematic HL.[25] Our findings support this and other studies that show suggest a relationship between low-income levels and limited HL. [24,26,29]

Numerous studies site the relationship between age and HL, stating that older individuals generally have lower scores. [25,27,72] Twenty-seven percent of participants in this sample were over age 70, yet our results did not support previous findings. The influence of older age could have been diminished by the presence of younger family members and caregivers at the appointment during which the survey was completed. The principal researcher noted that older participants frequently deferred to the opinions or help of the person accompanying them during the visit when completing the survey.

Self-reported health status had borderline significance in predicting HL (p ≈ 0.05). This contrasts the findings of a large European study by Sorensen et. al (2015) which found that people who reported their health status as 'very bad or 'bad' experienced the highest proportion of limited HL.[35] We suggest that the difference in findings may be caused by the modest sample size of this current research.

In total, 56% of participants found it difficult or very difficult to decide how to 'protect themselves from illness using information from the mass media.' In fact, this was the survey item with the second lowest mean score. These findings are in line with research that shows public uncertainty and distrust with "fake news," social media, and artificial intelligence and highlights the need to ensure that individuals are equipped to identify health misinformation received from mass media sources. [29,69–71]

There was no statistical relationship between the number of times the patient had visited the specialty consultation and their HL. Instead, the number of appointments was found to be of borderline significance in predicting HL scores. This is noteworthy, as it suggests that the mere quantity of visits does not necessarily mean that patients are understanding, learning, and better equipped to manage and act upon healthcare information.

Results further showed that patients who self-reported as having diabetes had significantly higher mean HL scores than those who reported having cardiovascular disease, digestive illness, hypertension, cancer, or respiratory conditions. This is not surprising, as people with diabetes often require quarterly condition management appointments, and many attend educational sessions regarding medication management, nutrition, and lifestyle practices. It is also a condition that normally requires lifelong management.[73] This suggests that frequent interactions with healthcare providers where health information is exchanged over extended periods of time may improve patient HL.

This research also examined the relationship between nurses' use of a HL checklist and patient pre-and post-HL scores in specialty consultations. It further studied the effects of frequency and types of strategies used. Our data showed a statistically positive relationship between nurses' use of the checklist and patient HL scores. In the present study the mean HL score was 66 before HL

intervention, and post-intervention it increased to 76. In one of the first large scale studies of HL across 17 European countries using the HLS_{19}-Q12, the mean HL score was 65.[37] After the use of the checklist in this study, the mean HL score was notably higher than that of the larger European population previously studied.

Research suggests that individuals with moderate to high levels of HL are more likely to utilize preventive care, adhere to medical advice from doctors and nurses, take medications as prescribed, and effectively navigate the often complex healthcare system using available health information.[22] One promising outcome of this study is the likelihood that the participants who did experience an increase in HL will be able to benefit from these same positive health behaviors.

It is interesting to note that post intervention, males had a larger increase in mean HL scores than women. This could be influenced by the fact that women have historically been assigned the role of caregiver, and therefore they have accumulated more knowledge around healthcare and health information over their lives.[74,75] In as such, their scores were higher than the men before the intervention, which left less room for improvement post intervention.

In relation to types of HL strategies used, 79% of the time nurses chose the 'teach back' technique. This technique has been proven to be an effective tool for increasing patient learning and clarifying misunderstandings.[76,77] While statistics did not show a significant relationship between this technique and HL scores in this study, the combination of this technique with other items on the checklist could be the source of improved HL scores. Notably, 'use of a computer image' was the visual aid tool most frequently used by the nurses in this study. Friedman et. al found that computers can be an effective health teaching strategy.[57]

There were no statistically significant positive relationships found between the number or type of HL techniques used on HLS. Nonetheless, the overall patient scores did improve significantly post intervention. This suggests that the first part of the checklist, which contained the seven questions and one summarizing technique that allowed for open ended discussion and deeper dialogue may be key to engaging and educating patients. It implies that the quality of the interaction is more important than the mere quantity of strategies used with the patient. Another possible explanation

is that the HL checklist required the use of multiple techniques. This supports research reporting that the use of multiple strategies produces better learning and behavior outcomes.[57,58,78]

Nurses are some of the few relationships of trust that patients have during which they obtain and process heath information. Hence, nurses can play a pivotal role in improving patient HL.[79,80] Our findings support previous work showing that nurses contribute significantly to support and advance patient HL.[81] A study in Spain found that patients receiving care from advanced practice nurses had higher satisfaction scores, felt they received more time and dedication in consultation, and received more informations.[82] Likewise, our results show the value of nurses with specialized disease knowledge in increasing patient HL. In particular, the use of specialized and experienced nurses in this study is promising for promoting and formalizing the field of advanced practice nursing in Spain.

We endeavored to describe the implementation steps of ISO 7101 standard subclause 8.10.5., then evaluated the effect of implementation on patient pre-and post-implementation HL scores, and the effect of implementation on patients' perceptions of quality of care received. Studies have described implementation of other well-established standards such as ISO 9001 and those of the Joint Commission; however, at the time of this study, there was no information available about ISO 7101. This is believed to be the first published work.[45] Our description of implementation serves as an example to other organizations of what worked well.

ISO 7101 is a healthcare quality management standard, and therefore, one aim is to improve quality of care. The concept of quality can be highly subjective and multidimensional.[83] This study assessed subjective, patient perspectives of quality of care received. It is interesting to note that on a 4-point scale from 1-4, with 4 being the highest level, the mean score for quality rankings was already very high before intervention at 3.87. This could have been the result of several factors. First, the appointments were held at specialty consultations, where the care is usually more individualized, and clinicians may have more time to spend with their patient. Furthermore, patients with chronic conditions tend to have regular repeat visits to specialty consultations. As such, they begin to cultivate relationships with the clinic staff and healthcare providers. Based on their deeper relations with these providers, perceptions of quality of care could be higher.[84]

Our investigation provides decision making data for governments at the health systems level. When policy makers convene to discuss guidelines and policies that should be followed by their service providers, information regarding the implementation of ISO 7101 as compared to other healthcare standards is valuable. Importantly, the implementation of subclause 8.10.5 presents a possible new strategy to confront the problem of low HL across Europe. [35,36]

Limitations

This study had certain limitations, such as sample size, non-randomization, and the specificity of care delivery site being specialty consultations. Nevertheless, a strength of this research was the unique opportunity to evaluate HL of a population that represents the most frequent users of specialty care settings in Spain. This includes the aged, and individuals suffering from chronic conditions.[85]

As the sample size for this study was small, we recommend the additional use of the HLS_{19}-Q12 in Spain on a sample size similar to those in the 17 country validation studies (n >1,000). [37] The investigation surveyed a non-randomized sample of patients in a specialized care setting. Results of the survey in Spain should further be evaluated with a randomized sample of patients in a more general care setting.

A further limitation was the lack of a control group of patients who did not receive the nurse intervention. This minimizes the certainty that the improvement in HL score was not due to external factors that could have influenced the results. Another limitation was the inability to control for differences among the nurses and their teaching styles. Some nurses could have been more effective in using the checklist than others, and only their patients showed improvements in HL scores.

The current study had a significantly homogenous patient profile. In 2023 the OECD reported unprecedented amounts of new permanent immigrants and asylum seekers.[86] As countries around the world are facing continued migration, health systems will need to provide care to increasingly diverse populations. It is valuable to explore whether certain HL techniques work better with specific cultures and ethnic backgrounds.

To obtain the most accurate measurement of patients' perceptions of quality of care, providing a definition of quality of care to patients before they are asked to rank quality of care received is recommended. Ratings based on specific indicators would provide management with more actionable data upon which to make targeted process improvements.

Future research

Beyond the limitations, our findings open the door for a multitude of future research endeavors. While most HL studies have been conducted in the United States and Europe, it would be an equitable and valuable endeavor to use the HLS_{19}-Q12 in Latin American countries to determine how HL scores compare to those of the European countries addressed in HL literature. Latin America embraces a rich mix of cultures, Indigenous beliefs and languages.[87] These populations could present additional sociodemographic variables and practices such as the use of alternative medicine or spiritual healers.[88] Therefore, it is necessary to determine if the HLS_{19}-Q12 is valid among such diverse patient profiles.

In the same stream of thought, the Spanish language used in Latin American countries can differ from than that used in Spain.[89] It would be valuable to revisit the appropriateness of the Spanish translation if the HLS_{19}-Q12 is used in Latin America.

Spain has a decentralized healthcare system, with each autonomous community being responsible for its own services. This study evaluated a specific population in the community of Aragon. This version of the HLS_{19}-Q12 should be given to patients in other autonomous communities to discover if HL scores vary significantly. This could serve as a useful benchmarking tool for health services across Spain's 17 communities.

Most HL studies examine the behaviors and characteristics of patient populations.[24,27,61,62] However, healthcare providers' knowledge and awareness of HL has not been as readily studied. In agreement with Gibson et. al (2022), clinical staff could improve their teaching effectiveness with patients by receiving structured HL training.[90] One worthy direction for future research is to explore the HL consciousness of healthcare providers themselves, in order to determine if they understand the concept of HL, the role it plays in health outcomes, and whether they possess the

necessary skills to transmit health information in ways that are understandable and meaningful to patients.[81,90–92]

Given the rapidly increasing use of virtual care settings and telemedicine, it is necessary to continue to analyze how these venues affect general HL, as well as how a person's general HL influences their use of such care settings. When healthcare providers choose these care mediums, the current general HL of patients, and opportunities to improve general HL, should be considered in the design, functionality and ease of use.

The use of the internet and social media as sources of health information can lead to confusion and misinformation. The study of e-health literacy has become more frequent, and it is valuable to continue exploring ways to improve HL in these venues.[93,94]

In this study, only subclause 10.8.5 of the standard was implemented. While a sizeable endeavor, the complete ISO 7101 standard should be implemented and studied in a healthcare organization. This would provide a more holistic and realistic view of the overall results that the standard may yield once implemented.

One goal of a management system standard is to have sustained improvement over the course of time. This study looked at a period of one year, which is on the short side for an ISO management systems standard of this type. Further research should use a longitudinal lens, looking at the results, sustainability and implementation of the standard over a longer period of time.

Chapter 8: Conclusions

This study served to validate the HLS_{19}-Q12 survey in the Spanish language in a population of patients attending specialty consultations in Spain. The validated survey was then given to participants, and HL scores were calculated. In addition, participants provided answers that led to the creation of a sociodemographic profile, which was analyzed along with HL scores with the goal of identifying any signification associations. Finally, the study described a controlled exercise in the implementation of ISO 7101, Subclause 8.10.5 in the specialty consultations, and measured two outcome variables.

Our initial set of findings calls for reflection on the level of HL within this sample population. The results provide information that can be used by Zaragoza health sector III in the autonomous community of Aragon to develop or modify clinical processes in specialty consultations to ensure patients receive, understand, and act upon health information effectively. While this study focused on this specific health sector, the information is also valuable for other regions of Spain, and even other countries in the world. Patients that attend specialty consultations are often some of the most vulnerable and aged ones. By focusing on improving their HL, it may be possible to improve the health and wellbeing of patients, while reducing human and financial resource burdens on the larger health system.[22,34]

Another significant finding is that implementing ISO 7101, Subclause 8.10.5 had a positive, statistically significant association with patient HL. We provide data from the first academically reported implementation of the standard, which healthcare organizations can use as they seek to implement quality standards that lead to better patient health outcomes, improved HL, and increased perceptions of quality of care.

Chapter 9: Contribution to the United Nations Sustainable Development Goals (UN SDGs)

The United Nations SDGs were adopted by UN member states in 2015. The goals outline strategies to improve health, education, spur economic growth and reduce inequalities.[95] Academic research plays a vital role in contributing to the UN SDGs. Research should aim to provide information, data, and tools to help nations, communities, and individuals progress towards obtainment of the SDGs. This research addressed many of the SDGs, as is discussed in this section. The following assertions are not part of our scientific investigation, and are based on our understanding of the contributions of our findings to enhance progress towards five of the UN SDGs.

Source: https://www.un.org/sustainabledevelopment/news/communications-material/. Accessed 13 June 2024

Goal 1 No Poverty

The ability to work is a significant factor in keeping people out of poverty. Unhealthy individuals often have to leave the workforce, may have multiple work absences due to sickness or doctor's appointments, or may not be able to perform at a level where they are able to grow and advance in their careers. This research suggests a resource that can be used to keep people and populations healthier, allowing them to work and providing more protections against poverty.

Goal 3 Good Health and Well-being

Source: https://www.un.org/sustainabledevelopment/news/communications-material/. Accessed 13 June 2024

Goal 3 is dedicated to ensuring healthy lives and the promotion of well-being for all at all ages. More specifically, goal 3 has 9 major targets. The current study helps facilitate progression towards most of these targets, as the main focus of the targets is to reduce, and prevent occurrences of factors leading to poor health.

Goal 4 Quality Education

Education not only occurs in school, but also in the workplace and even during clinical consultations. When care providers implement HL strategies, they are working to ensure that their service users are adequately educated and empowered to understand, manage and act upon health information received. As this study determined, implementation of HL strategies one way to provide effective, high-quality health education to service users.

Goal 5 Gender Equality

Traditionally caregivers have been women. This often means that women are not able to attend school or work due to their chosen or assigned roles. It also means that when someone in the family is sick or has a long term chronic condition, it is usually the woman who is required to stay at home and care for that individual. This removes women from the workplace and perpetuates stereotypes of the woman as less important, less powerful, and having less agency. Improving health outcomes through improved HL is one way to promote gender equality, as more women will be able to receive an education, work, and contribute to the larger society in visible and meaningful ways. At a minimum, reducing the need for women in the caregiver role allows them more choice as to education, work, and how they prefer to spend their personal time.

Goal 10 Reduced Inequalities

Vulnerable populations face numerous risk factors. They are more apt to become ill, exposed to detrimental factors such as violence, pollution, unclean living environments, cramped housing arrangements where infectious disease spreads more quickly, lack of access to nutrition and clean water, and experience lower education and income levels. These factors lead to marked inequalities in regard to access to knowledge, power, agency, voice, and ability to navigate complex social and health services. By increasing the HL level of vulnerable service users, they will be better equipped to manage their conditions, prevent future health challenges, and access the assistance they need to stay healthy. In turn this increases their access to education and work, while decreasing inequalities.

Chapter 10: Published articles

1. Validation of the Spanish version of the Health Literacy Survey (HLS$_{19}$-Q12) in secondary care specialty consultations

2. Measuring health literacy using the HLS$_{19}$-Q12 in specialty consultations in Spain

3. The effect of nurse health literacy interventions on patient health literacy scores in specialty consultations: a quasi-experimental study

4. Implementation of ISO 7101, 8.10.5 Health literacy and effects on patient health literacy and perceived quality of care

Themed Paper - Original Research

Validation of the Spanish version of the Health Literacy Survey (HLS19-Q12) in secondary care specialty consultations*

A. McCaskill [a,*], A. Gasch-Gallen [a,c,d], J. Montero-Marco [b,e]

[a] Department of Physiatry and Nursing, Faculty of Health Sciences, University of Zaragoza, C/Domingo Miral, s/n 50009, Zaragoza, Spain
[b] Research Unit, Hospital Clínico Universitario Lozano Blesa, Avda. San Juan Bosco, 15, 50009, Zaragoza, Spain
[c] GIIS094-Research Group Nursing Research in Primary Care in Aragón (GENIAPA), Spain
[d] GIIS011-Aragonese Research Group in Primary Care Institute of Research of Aragón, Spain
[e] GIIS081-Research Group in nursing care, Sector III Zaragoza, Spain

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ABSTRACT

Objectives: This study sought to validate the HLS19-Q12 in Spain and in the Spanish language, as well as describe the sociodemographic profile and the general health literacy of the study population.
Study design: Descriptive cross-sectional.
Methods: Factor analysis and Cronbach's alpha were used to validate the Spanish version of the HLS19-Q12. Health literacy scores and associated categories were calculated using the scale factsheet, and the patient population sociodemographic profile was determined using frequency analysis.
Results: The HLS19-Q12 used in Spain in the Spanish language was found to be both valid and reliable (Cronbach's alpha = 0.87). The sociodemographic profile was primarily male and aged, and the majority of patients were of Spanish origin and had diabetes. General patient health literacy was limited, with 60% of participants having general health literacy categorized as inadequate or problematic, and 40 % sufficient or excellent.
Conclusions: This study validated the HLS19-Q12 in Spain, created a sociodemographic profile of the sample population, and calculated their health literacy scores. This contribution provides another valuable validated tool and associated data to the increasingly important field of health literacy.

Introduction

Patients attend appointments with clinicians with expectations of a physical treatment, undergoing a procedure, receiving a prescription, or learning of a diagnosis.[1-3] However, at the same time, patients receive valuable information about their condition or health status. This important information not only informs the patient of their current condition, but instructs them on how to manage it, suspend worsening of symptoms, and even prevent the occurrence of new medical conditions. Furthermore, family members and/or caregivers who accompany patients during their appointments may hear the same information and use it as a tool to manage and improve their own health.[4,5] These clinical points of contact are invaluable opportunities to increase the health literacy (HL) of service users (patients, family members, and/or caregivers).

Health literacy is a multidimensional concept that encompasses willful actions that affect individuals, communities, and entire populations on numerous levels. While the definition has evolved over time, this article uses the definition developed by Sorenson et al. for the Consortium Health Literacy Project European:

> Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgements and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.[6,7]

HL is a subject of concern because studies show that low HL leads to poor outcomes on both the individual and population level.[8] On an individual level, people with low HL are less likely to take medications as prescribed, adhere to treatment regimens for chronic conditions, take steps to prevent health problems, act correctly and promptly when

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facing acute conditions, and seek medical help when needed.[9] Low HL is linked to increased hospitalization, readmissions, and increased use of emergency services.[8,10] Consequences of low HL include increases in morbidity and mortality, and decreased quality of life and wellbeing.[11]

On a population level, healthy societies are more productive societies. HL affects the economy as a whole because, as mentioned above, individuals with low HL are more likely to be ill and remain ill. As a consequence, individuals face economic hardships related to school and work absences, and additional loss of wages from caregivers who are forced to leave the workforce. The economy suffers from lost productivity, private and public benefit payouts, and increased healthcare spending.[8,9,12–14] Communities with higher HL have less disparity in health outcomes, increased equity and are more prosperous.[8]

Various scales have been used to measure HL, however, not all scales measure the same types or dimensions of HL, nor do they target the same populations. The Health and Literacy Scale (HALS), the Rapid Estimate of Adult Literacy in Medicine (REALM), the Health Literacy Questionnaire (HLQ), and the European Health Literacy Survey Questionnaire (HLS-EU-Q) are some of the oldest and newest examples.[15–18] While each scale may have benefits or challenges, it is necessary and useful to have a common language, methodology, or scale by which HL can be measured across both specialized and more general, larger populations. In this way, evidence-based lessons can be shared, and data can be used to make meaningful comparisons and improvements in HL on both individual and population levels.

This study examined a more recent HL survey called the HLS$_{19}$-Q12, which was developed from a longer survey, the HLS$_{19}$-Q47 (47 questions).[19] With only 12 questions, the scale is more attractive and feasible in settings where both patients and healthcare providers have limited time. The shorter length also increases the likelihood of a participant's willingness to complete the questionnaire.[20,21]

The HLS$_{19}$-Q12 was validated internationally in 17 countries and in 17 languages using multiple types of data collection with acceptable psychometric and validity properties.[22,23] However, during its initial validation study, Spain was not one of the countries; and at that time there was not a Spanish version of the instrument.[22] Therefore, this study aimed to validate the HLS$_{19}$-Q12 in Spain and in the Spanish language, as well as describe the sociodemographic profile and the general health literacy of the sample population.

Methods

This validation and cross-sectional study was part of a larger project that examined patient HL scores before and after nursing interventions that were aimed at increasing patient HL. The entire project ran for a period of 12 months, between April 2023–2024; however, the data for validation of the HLS$_{19}$-Q12 and initial sociodemographic questionnaire were collected during the first eight months.

Selection and description of participants

The patient sample consisted of patients who regularly attended specialty consultations in Zaragoza health sector III of the autonomous community of Aragon. The sector is one of eight sectors in Aragon and covers a population of approximately 300,000 people. In addition to 22 health centers and 119 local clinics, specialty care is provided in three locations.[24] It is from two of these specialty centers that the study population was recruited. For this investigation, the types of specialty consultations included: Diabetes, Ostomy, Cardiology, and Digestive. Inclusion criteria for the study were 1) age 18 or older, 2) willingness to complete the HLS$_{19}$-Q12 two times (before and after health literacy interventions), and 3) the patient had the necessity to make three visits to the specialty consult within the 12-month timespan of the study.

In order to obtain the sample group, the principal researcher visited each specialty consultation on predetermined days each week. The patients who happened to have appointments on those days are the ones

who were asked to participate in the study. If the patient met inclusion criteria, the nurse introduced the patient to the principal researcher who then proceeded to provide a description of the study protocol, explain the purpose of the study, introduce the HLS$_{19}$-Q12, address privacy and confidentiality, and discuss informed consent. Over a recruitment period of eight months, 166 total participants met selection criteria and were asked to participate in the study. 100 % agreed to participate. All participants signed informed consents forms.

Sample size was determined based on the primary objective of the study, which was to validate the Spanish version of the HLS$_{19}$-Q12 in this study population in Spain. As we used confirmatory factor analysis, comparative fit index, and principal component analysis to validate a 12-item survey, calculations determined that 166 patients was sufficient to secure a medium effect size (Cohen's d = 0.5), with a significance level of 0.05, and a power of 80 %.

Data collection and measurements

Data collection was conducted during face-to-face specialty nursing consultations with patients. Responses were captured on paper in one of the following ways: 1) by the patient alone, 2) face-to-face interview with the principal researcher, 3) patient with the help of a family member or caregiver, 4) patient with help of the principal researcher, or 5) by the specialty nurse. The HLS$_{19}$-Q12 had been previously validated using the paper-assisted personal interview (PAPI) mode, so the methods used in this study were acceptable.[23]

Survey completion preference depended on factors such as the patients' ability to read, vision, patients' level of patience when it came to answering questions, and elderly patients' tendency to defer to family or caregivers for completion of tasks. The principal researcher was present during all initial visits where surveys were administered, and data collected. Once the participant finished the survey, the researcher briefly reviewed it to verify that it was completed correctly and in its entirety. All data was anonymized.

A questionnaire with 15 sociodemographic questions was included as the first page of the HLS$_{19}$-Q12 instrument. Questions addressed age, sex, gender, marital status, education, occupation, country of origin, living situation, work, residence (rural or urban), self-classification of health status, net monthly income, use of aids or assistive devices, self-reported illnesses, and number of appointments they previously had at the consult, not including that day's appointment.

The HLS$_{19}$-Q12

The HLS$_{19}$-Q12 Health Literacy Survey is a subjective, perception-based instrument, that uses a 4-point Likert scale to record a patient's perceptions concerning 12 health-related tasks. Respondents are asked to rate the difficulty level of health-related items by selecting "very difficult," "difficult," "easy," "very easy," or "I don't know."[22] (see Supplemental Table 1)

In accordance with Type P calculations described by Pelikan et al., 2022, scores were calculated as the sum of the item's numeric values scaled to a range from 0 to 100.[22] A response was considered invalid if the participant answered, "I don't know." If there were more than two invalid responses in a survey, that survey was disqualified from the study. Scores were then categorized based on the following scale: >83.33 = Excellent, >66.67 and ≤83.33 = Sufficient, >50 and ≤66.67 = Problematic, and ≤50 = Inadequate. In total, 16 surveys were disqualified based on invalid responses. Therefore, HL scores were calculated for 150 patients.

Translation to Spanish

At the start of this study, there was no published evidence that the 12-item short form of the survey had been used and validated in Spain, nor translated to Spanish. The principal researcher contacted the

International Coordination Centre (ICC) of M-POHL, which is responsible for authorizing the use of the HLS instrument, to determine if a Spanish language version was available. The Spanish language version used in this study was provided by the ICC and had been translated by the Hamburg Center for Health Economics, University of Hamburg, for use in the 11th wave of the European Covid Survey (ECOS) Corona Research[25] (see Supplementary Table 2). The survey was not adapted for use in this study with the Spanish population.

Statistics

This study used IBM SPSS 27 to analyze the survey data. To validate the HLS_{19}-Q12, factor analysis was performed including Standardized Root Mean Square Residual (SRMSR), Root Mean Square Error of Approximation (RMSEA), and Comparative Fit Index (CFI). CFI was extracted via CFA analysis using SPSS AMOS. Principle Component Analysis (PCA) test was further conducted to determine construct validity. Frequency analysis was used to create the sociodemographic profile of the patient population.

Results

Validation of the HLS_{19}-Q12 in this Spanish population

The reliability of the instrument was tested using Cronbach's alpha. This test helped to measure the internal consistency of the data. Cronbach's alpha was 0.87, suggesting high or good internal consistency of the survey items (Table 1).

The Kaiser-Meyer-Olkin (KMO) measure was used to measure sampling adequacy for each variable. Results showed an adequate KMO value of 0.863, supporting that the data was suited for factor analysis.

Bartlett's Test of Sphericity Approx. ($X_2 = 341.526$, df = 66, p < 0.001) showed statistically significant results confirming correlations did not occur by chance and that factor analysis could be performed. PCA was performed on all 12 items. The threshold for factor loading values was 0.3, which meant any factor loading below 0.3 was not associated with the extracted component.[26] Per results in Table 2, all items were accepted going forward.

Sociodemographic profile

Frequency analysis was performed to create a sociodemographic profile of the 166 respondents. Most of the patients were 61–70 years old (28.3 %), followed by those who were 51–60 years old (18.1 %) and 71–80 years old (18.1 %). A small proportion of the sample size were below age 30 (10.8 %). Most respondents visited the 'Diabetes' specialty clinic, equaling 47.6 % of the sample size, whereas 9.0 % visited 'Cardiology.' Sixty-eight percent of patients were able to complete the survey on their own. The remainders required the assistance of the researcher, family member, caregiver, or specialty nurse. More than half of respondents were male (62.7 %) and 37.3 % were female. All participants identified as cisgender. As shown in Table 3, the majority of patients were married or living with a domestic partner (60.8 %), and the majority (38.0 %) had achieved a primary education level. Ninety-five percent of participants were of Spanish origin.

Health literacy in this patient population

Referring to the 12 items on the HLS_{19}-Q12, respondents found it easier to 'act on advice from their doctor or pharmacist' (3.31 ± 0.60), and to 'judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable' (3.18 ± 0.70). Participants scored lower when asked how difficult it was 'to decide how you can protect yourself from illness using information from the mass media' (2.41 ± 0.83), 'to find information on how to manage mental health problems' (2.47 ± 0.85), and 'to understand advice concerning your health from family or friends' (2.83 ± 0.64) (Table 4).

Based on all 12 items, the median HL score was 67 and the mean was 66. As described in the HLS_{19}-Q12 factsheet, participants' scores were categorized into categories of HL.[23] We observed that 60 % of participants had HL scores categorized as inadequate or problematic, while 40 % had HL scores categorized as sufficient or excellent (See Fig. 1).

Discussion

The study served to validate the HLS_{19}-Q12 in the Spanish population, in the Spanish language. As to the extent of our knowledge, the survey had not been validated in Spain or in the Spanish language at the time of the investigation. However, it had been validated and used in various studies in other European countries.[19,23,27] When compared to the validation statistics of 17 other European countries, its use in Spain with the sample population showed comparable psychometric properties (Table 1).[23] Alpha coefficients reported for its use in the 17 countries varied from 0.67 to 0.87.[28] Cronbach's alpha for this study was 0.87.

This study further generated a sociodemographic profile of the population of patients in Zaragoza health sector III who attend specialty consultations. This is valuable information because research shows that sociodemographic variables are associated with HL in both positive and

Table 1
HLS_{19}-Q12 Psychometric properties including results from the Spanish population.

Country	Cronbach's alpha	Single-Factor Confirmatory Factor Analysis		
		SRMSR	RMSEA	CFI
Austria	0.67	0.07	0.03	0.97
Belgium	0.82	0.08	0.05	0.98
Bulgaria	0.78	0.07	0.04	0.99
Czech Republic	0.78	0.05	0.03	0.99
Denmark	0.75	0.06	0.03	0.98
France	0.81	0.05	0.02	1.00
Germany	0.73	0.07	0.04	0.97
Hungary	0.76	0.07	0.03	0.98
Ireland	0.72	0.06	0.03	0.97
Israel	0.80	0.06	0.03	0.99
Italy	0.85	0.05	0.04	0.99
Norway	0.73	0.07	0.04	0.97
Portugal	0.87	0.05	0.02	1.00
Russian Federation	0.86	0.05	0.04	0.99
Slovakia	0.81	0.06	0.04	0.99
Slovenia	0.82	0.04	0.02	1.00
Spain	0.87	0.07	0.05	0.96
Switzerland	0.72	0.07	0.03	0.98

Data from Table 2: The HLS_{19} Consortium of the WHO Action Network M-POHL. (2022): The HLS_{19}-Q12 Instrument to measure General Health Literacy. Factsheet.[23] Data for Spain is from this study.

Table 2
PCA for the 12 items on the HLS_{19}-Q12.

Component Matrix[a]	
Item 1	0.679
Item 2	0.690
Item 3	0.644
Item 4	0.744
Item 5	0.561
Item 6	0.722
Item 7	0.586
Item 8	0.534
Item 9	0.692
Item 10	0.566
Item 11	0.570
Item 12	0.783

Extraction Method: Principal Component Analysis.
[a] 1 component extracted.

Table 3
Sample population sociodemographic profile.

		Woman		Man	
		N	%	N	%
Age	≤ 30	10	16.1	8	7.7
	31–40	4	6.5	6	5.8
	41–50	6	9.7	10	9.6
	51–60	12	19.4	18	17.3
	61–70	13	21.0	34	32.7
	71–80	9	14.5	21	20.2
	81+	8	12.9	7	6.7
Specialty clinic	Cardiology	5	8.1	10	9.6
	Digestive	6	9.7	15	14.4
	Diabetes	34	54.8	45	43.3
	Ostomy	17	27.4	34	32.7
Completed by	Patient alone	41	66.1	72	69.2
	Face-to-face interview	6	9.7	12	11.5
	Patient with the help of a familiar member or caregiver	14	22.6	16	15.4
	Patient with help of the principal researcher	1	1.6	1	1.0
	By the advanced practice nurse	0	0.0	3	2.9
Marital status	Married or domestic partner	34	54.8	67	64.4
	Widowed	14	22.6	8	7.7
	Divorced	4	6.5	9	8.7
	Separated	1	1.6	1	1.0
	Never married	9	14.5	19	18.3
Education level	Primary education	25	40.3	38	36.5
	ESO (Secondary)	8	12.9	9	8.7
	High school	3	4.8	9	8.7
	Vocational training	9	14.5	26	25.0
	Student	12	19.4	17	16.3
	Master's degree	5	8.1	4	3.8
	Doctorate	0	0.0	1	1.0
Origin	Spain	57	91.9	101	97.1
	Other	5	8.1	3	2.9
Living situation	Nobody	12	19.4	15	14.4
	With my partner	19	30.6	48	46.2
	Partner & family	15	24.2	24	23.1
	Children	8	12.9	6	5.8
	Parents	7	11.3	7	6.7
	Other family members	1	1.6	4	3.8
	Friends	0	0.0	0	0.0
	I don't have a permanent residency	0	0.0	0	0.0
Work	Unemployed	9	14.5	6	5.8
	Work full-time	14	22.6	26	25.0
	Work part-time	7	11.3	2	1.9
	Retiree with contributory pension	16	25.8	55	52.9
	Retiree with a non-contributory pension	6	9.7	5	4.8
	Currently studying	4	6.5	4	3.8
	Disability or sick leave	6	9.7	6	5.8
Residence	Rural	25	40.3	28	26.9
	Urban	37	59.7	76	73.1
I would classify my health as	Very good	1	1.6	7	6.7
	Good	25	40.3	49	47.1
	Regular	32	51.6	34	32.7
	Bad	4	6.5	13	12.5
	Very bad	0	0.0	1	1.0 %
Net monthly income	<600 €	6	9.7	7	6.7
	601–800 €	7	11.3	4	3.8
	801–1000 €	4	6.5	10	9.6
	1001–1.200 €	8	12.9	9	8.7
	€1201 – €1500	5	8.1	15	14.4

Table 3 (*continued*)

		Woman		Man	
		N	%	N	%
	€1501 – €2000	5	8.1	15	14.4
	> €2001	10	16.1	19	18.3
	Spouse's pension	2	3.2	0	0.0
	I'd rather not answer	13	21.0	18	17.3
	I don't know	2	3.2	7	6.7
How many appointments have you had in this outpatient clinic not including today?	1–2	21	33.9	39	37.5
	3–4	14	22.6	22	21.2
	5–6	9	14.5	7	6.7
	>6 visits	18	29.0	36	34.6

Table 4
Global descriptive results of the HLS$_{19}$-Q12 items.

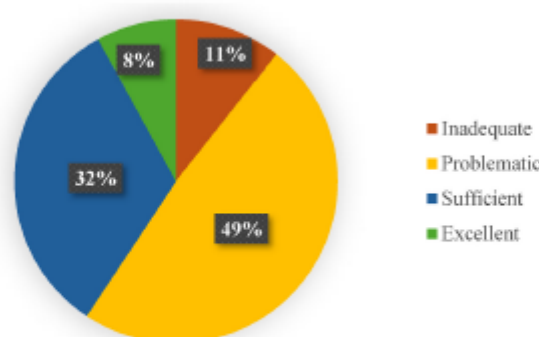| Item	On a scale from very easy to very difficult, how easy would you say it is …	Q25	Median	Q75	Mean	Std. Deviation
1	to find out where to get professional help when you are ill?	3.00	3.00	4.00	3.12	0.697
2	to understand information about what to do in a medical emergency?	3.00	3.00	3.00	3.09	0.601
3	to judge the advantages and disadvantages of different treatment options?	2.25	3.00	3.00	2.86	0.603
4	to act on advice from your doctor or pharmacist?	3.00	3.00	4.00	3.31	0.602
5	to find information on how to manage mental health problems?	2.00	3.00	3.00	2.47	0.854
6	to understand information about recommended health screenings or examinations?	3.00	3.00	4.00	3.17	0.587
7	to judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable?	3.00	3.00	4.00	3.18	0.695
8	to decide how you can protect yourself from illness using information from the mass media?	2.00	2.00	3.00	2.41	0.825
9	to find information on healthy lifestyles such as physical exercise, healthy food or nutrition?	3.00	3.00	4.00	3.18	0.621
10	to understand advice concerning your health from family or friends?	2.00	3.00	3.00	2.83	0.642
11	to judge how your housing conditions may affect your health and wellbeing?	3.00	3.00	3.00	3.03	0.604
12	to make decisions to improve your health and wellbeing?	3.00	3.00	3.00	2.99	0.711
Total		2.00	2.00	3.00	2.38	0.783

Fig. 1. Percentage of patients with inadequate, problematic, sufficient, or excellent health literacy.

negative ways.[9,11,29–32] The more a health system or hospital knows and understands the sociodemographic profile of the population it serves, the better poised it is to create processes and policies that address its patients' specific HL needs.[6,30]

Using the newly validated HLS$_{19}$-Q12, we calculated HL scores for this patient sample. Over half of the patients (60 %) had limited (problematic or inadequate) HL scores, which is in agreement with a large European study that reported 58 % of the Spanish population had low HL.[33] The validation report describing methodology and results of the HLS$_{19}$-Q12 across 17 countries documented a median HL score of 64 with a mean of 65. Similarly, this study population had a median HL score of 67 and a mean of 66.[22]

Our findings are in keeping with a report that indicated one-third to nearly half of Europeans had low HL.[34] The results warrant reflection concerning the state of HL in this current study population. As research shows, this large percentage of patients is more likely not to use preventive care services, to have difficulty adhering to treatment and medication regimens, more frequently use emergency services, and have overall poorer health outcomes.[6,14,30,35]

Looking at the specific responses to the 12-item survey, respondents found it most difficult to judge and trust health information from outside sources such as the media and friends or family members. These findings are congruent with the uncertainty and distrust in "fake news," social media, and artificial intelligence.[36–38] Respondents also found it difficult to find information on how to manage mental health problems. This is a meaningful finding, as the *State of Health in the EU (Spain) Country Profile 2023* reported that the burden of mental health issues in Spain is high, and that one in six people experienced mental health issues before the COVID-19 pandemic.[39]

Our study provides information for Zaragoza health sector III of the autonomous community of Aragon regarding the HL of patients attending specialty consultations. These results should be considered when creating or altering processes for healthcare delivery to ensure that patients receive, understand, and act upon health information in effective ways. Improving HL can positively affect health outcomes for individual patients and the larger community, while decreasing human and financial resource burdens on the health system.[8,14]

Limitations and future research

This study had certain limitations, such as sample size, non-randomization, and the specificity of care delivery site being specialty consultations. Nevertheless, a strength of this research was the unique opportunity to evaluate HL of a population that represents the most frequent users of specialty care settings in Spain. This includes the aged, and individuals suffering from chronic conditions.[40]

While most HL studies have been conducted in the United States and Europe, it would be an equitable and valuable endeavor to use the HLS$_{19}$-Q12 in Latin American countries to determine how HL compares to HL in Europe. Latin America embraces a rich mix of cultures, indigenous beliefs and languages.[41] These populations might present with additional sociodemographic variables that were less considered when studying European populations, such as the use of alternative medicine or spiritual healers.[42] Therefore, it is necessary to determine if the HLS$_{19}$-Q12 is valid among such diverse patient profiles. In the same stream of thought, the Spanish language used in Latin American countries can differ from than that used in Spain.[43] It would be useful to revisit the appropriateness of the current Spanish translation of the HLS$_{19}$-Q12 if used in Latin America.

Spain has a decentralized healthcare system, with each autonomous community being responsible for its own services. This study evaluated a population in the community of Aragon; hence, the HLS$_{19}$-Q12 should be given to patients in other autonomous communities to discover if HL scores vary significantly. This could serve as a useful benchmarking tool for health services across Spain's 17 communities.

Conclusions

This study contributes to the advancement of health literacy measurement and study in various ways. It serves to validate the use of the HLS$_{19}$-Q12 in Spain and in the Spanish language. A sociodemographic profile was created that can be used to inform policy decisions regarding HL for this specific population. The calculated HL scores provide valuable data showing the need to address low HL in this patient population. The findings add to a growing body of knowledge around HL, aimed at increasing the effectiveness of healthcare provision and improving health and wellbeing for all populations served.

Author statements

CRediT authorship contribution statement

A. McCaskill: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. A. Gasch-Gallen: Conceptualization, Methodology, Writing – review & editing, Supervision. J. Montero-Marco: Conceptualization, Methodology, Writing – review & editing, Supervision.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2024.09.022.

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RESEARCH   **Open Access**

Measuring general health literacy using the HLS19-Q12 in specialty consultations in Spain

Angela McCaskill[1*], Angel Gasch-Gallen[1,2,3] and Jesica Montero-Marco[4,5]

Abstract

Background General health literacy (general HL) affects both individual and population health on numerous levels, with low general HL leading to increased morbidity, poor health service utilization, and increased healthcare spending. This study calculated health literacy scores of a population attending specialty consultations in the community of Aragon, Spain. It further produced a sociodemographic profile and examined the relationships between patients' scores and sociodemographic variables.

Methods A sample of 150 patients from specialty consultations completed the internationally- validated HLS19-Q12 to measure adult general HL. A 4-point-Likert scale gathered information regarding 12 items of health literacy. Final scores were divided into four categorical levels: excellent, sufficient, problematic, or inadequate. Independent sample t-test, one-way ANOVA, and a generalized linear model (GLM) analysis were performed to examine key relationships with respect to sociodemographic variables and health literacy scores.

Results The survey was completed by 150 subjects aged 18 and over in specialty clinics in Aragon, Spain. 59% of respondents had inadequate or problematic general HL, while 41% had sufficient or excellent general HL. Income level had a significant effect on health literacy scores, $F = 2.129$, ($p < 0.05$), as did different work situations, $F = 3.762$, ($p < 0.001$). Patients who self-reported as having diabetes had a significantly higher health literacy score, $t = 2.356$ ($p < 0.05$) than those reporting other health conditions. According to GLM analysis, education, health status, income, and the number of appointments were the strongest predictors of the heath literacy score.

Conclusions General HL in this patient population was limited, and lower than in some comparable studies. The sociodemographic profile constructed, and associations with health literacy established, provide policy makers, healthcare administrators, and clinicians with information to consider new policies, processes and strategies to improve general HL in this specific population.

Keywords General health literacy, Health literacy scores, HLS19-Q12, Patient education, Limited health literacy

*Correspondence:
Angela McCaskill
angelamccaskill@outlook.com
[1]Department of Physiatry and Nursing, Faculty of Health Sciences, University of Zaragoza, C/Domingo Miral, Zaragoza s/n 50009, Spain
[2]Group GIIS094, Aragon Health Research Institute, Avda. San Juan Bosco, 13, Zaragoza 50009, Spain
[3]Aragonese Research Group in Primary Care B21_23R, Government of Aragón, Calle Andador Aragüés del Puerto no. 3, Zaragoza 50015, Spain
[4]Research Unit, Hospital Clínico Universitario Lozano Blesa, Avda. San Juan Bosco, 15, Zaragoza 50009, Spain
[5]GIIS0B1-Care Research Group, Aragon Health Research Institute (IIS Aragón), Avda. San Juan Bosco, 13, Zaragoza 5009, Spain

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Background

Each year billions of clinical consultations take place in a variety of settings such as outpatient departments, doctors' offices, community health centers and patients' homes, via telephone and online video platforms [1, 2]. In 2023, the Spanish population made an average of 4.8 visits per person per year to a health professional. This number did not include remote consultations, consultations with advanced practices nurses, or visits to private healthcare providers [2]. Therefore, the actual number of annual visits per person is undoubtedly higher than reported. Each of these visits presents a valuable opportunity to improve the general health literacy (HL) of patients, family members, and caregivers.

As described by Sorenson, et al. for the European Health Literacy Project Consortium, health literacy entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information [3]. The information may come from traditional points-of-contact such as doctors and nurses, or other sources such as the internet, digital health information, television shows or commercials, school, work, or friends and family.

HL affects the health, wellbeing and quality of life of individuals and communities [4–6]. Research has shown a link between HL and health outcomes at both patient and population levels. People with sufficient to high general HL are more likely to take advantage of preventive care, to follow the doctors' and nurses' instructions, to take medication as prescribed, and to use health information to navigate the sometimes complex health care system. Populations with higher general HL have less disparity in health outcomes, are more equitable, and more prosperous [6].

On the other hand, people with low or inadequate general HL may be less likely to use preventive services, follow doctors' instructions, take medications correctly, manage chronic conditions and seek and use medical information. This can lead to an increase in the use of emergency services, hospital readmissions and an overall increase in morbidity and mortality. People with low general HL may experience a decrease in quality of life and diminished overall feelings of wellbeing [7–9].

HL has been shown to have a relationship to sociodemographic factors, with vulnerable populations being at greater risk. The elderly, low-income, individuals with low education, and refugee or migrant populations are most at risk [6]. Low HL may continue the cycle of vulnerability because chronically ill people may experience increases in work or school absences, causing a decrease in learning and loss of income [10]. Caregivers may be required to leave the workforce to care for their ill loved ones, further threatening household earning potential. Medical costs can be expensive, which compounds the effects of illness on already financially-challenged patients and families [11–13].

Low HL may also lead to increased healthcare spending. Both private and public payors make payments for preventable use of high-cost services such as the emergency room and inpatient care [10–12, 14, 15]. In addition, government social payouts may increase in order to support those who are on disability due to prolonged illness.

Provided the robust evidence that HL is associated with health outcomes and wellbeing, it is important to study HL in varied populations. This is because certain types of populations could require additional, customized or innovative approaches to improving HL. One example of such a population are patients who regularly attend specialty consultations. The need for specialty consultations are often related to having a prolonged illness or a clinical condition that requires ongoing monitoring and care. This is a key type of patient to consider, as they are more frequently presented with health information, and will need to make decisions about their ongoing care, and how to best manage their conditions based on their understanding of the information. Thus, the objectives of this study were to measure general HL in this patient population using the HLS_{19}-Q12, and subsequently examine the relationship between the participants' sociodemographic variables and their scores.

Methods

Study design and participants

The study used a cross-sectional design, with a sample consisting of adult patients who regularly attended one of the following specialty consultations: Digestive, Cardiology, Diabetes and Ostomy. To be considered for inclusion, patients had to be 18 years of age or older, willing to complete the HLS_{19}-Q12, and have the necessity to make three visits to the specialty consultation within the 12-month study period.

The principal researcher visited each specialty consultation on predetermined days each week in order to recruit participants. The patients who had appointments on those days are the ones who were asked to participate in the study, given they met inclusion criteria. The principal researcher followed a predefined weekly schedule of visits to the four specialty clinics during a seven-month period from April – October 2023. In total, 166 participants met criteria and were invited to be in the study at the time of their appointment. All invited patients agreed to participate. They were given a written description of the study protocol, signed informed consent, and completed the HLS_{19}-Q12. Completed surveys that did not meet the required scoring criteria were removed. This resulted in 150 valid surveys to be analyzed.

Administration of the HLS$_{19}$-Q12 was 'face-to-face' with the patient; however, the manner in which the data was captured depended on various factors. Patients with lower literacy and vision problems preferred that the questions be read aloud by either the nurse or the primary researcher. Elderly patients had a tendency to defer to family or caregivers to mark their verbal responses on the survey. In summary, all responses were captured on paper in one of the following ways: (1) by the patient alone, (2) 'face-to-face' interview with the principal researcher, (3) patient with the help of a family member or caregiver, (4) patient with help of the principal researcher, or (5) by the specialty practice nurse. The principal researcher was available in the event that a participant requested clarification. All surveys were reviewed to verify that they were completed in full, prior to the patient leaving the appointment.

The HLS$_{19}$-Q12

The HLS$_{19}$-Q12 was chosen for the study because it had been successfully validated in 17 countries to assess and benchmark general HL in adult populations [16]. The HLS$_{19}$-Q12 was further an attractive measurement tool because it only consists of 12 questions, which increased the likelihood that participants would finish the survey, while also recognizing the fact that patients, caregivers, and nurses may have limited time [17]. A 4-point Likert scale allowed participants to respond to how easy or difficult they found it to complete certain health literacy-related tasks. Respondents were asked to choose, 1 "very difficult," 2 "difficult," 3 "easy," 4 "very easy," or option 5 (or 999) "I don't know." The Spanish version of the HLS$_{19}$-Q12 used in this study was provided by the International Coordination Centre (ICC) of M-POHL and was translated by the Hamburg Center for Health Economics, University of Hamburg, for use in the 11th wave of the European Covid Survey (ECOS) Corona Research. (Supplemental Material 1) [18].

Statistical analysis

This study used IBM SPSS 27 to analyze the survey data. Frequency analysis was used to explore general HL. We performed independent sample t-test and one-way ANOVA to examine key relationships with respect to demographics and other characteristics. We further analyzed the predictive nature of sociodemographic characteristics on patients' HL score using a generalized linear model (GLM) with a normal distribution family and an identity link function. The dependent variable (HL score) was not normally distributed as per Shapiro Wilk test. Point estimates are presented as mean±sd.

HL scores were calculated and categorized according to instructions provided in the HLS$_{19}$-Q12 Instrument to Measure General Health Literacy Factsheet (2023) [19].

In accordance with Type P calculations, scores were calculated as the sum of the item's numeric values scaled to a range from 0 to 100 [16]. A response was considered invalid if the participant answered, "I don't know." If there were more than two invalid responses in a survey, that survey was disqualified from the study. Scores were then categorized based on the following scale: > 83.33 = Excellent, > 66.67 and ≤ 83.33 = Sufficient, > 50 and ≤ 66.67 = Problematic, and ≤ 50 = Inadequate. When combined, problematic and inadequate HL were considered "limited" general HL [16] [p.10].

Results

The HLS$_{19}$-Q12 was scored for 150 participants. Table 1 summarizes the scores for each of the 12 items on the survey. Respondents found it most difficult 'to decide how you can protect yourself from illness using information from the mass media' (2.41±0.83), 'to find information on how to manage mental health problems' (2.47±0.85), and 'to understand advice concerning your health from family or friends' (2.83±.64).

The sample of patients had a median score of 67 and mean of 66±13.63. As seen in Fig. 1, 59.3% of patients had HL an inadequate or problematic level of HL, while 40.7% had sufficient or excellent HL.

Relationship between patient sociodemographic profiles and general HL

ANOVA tests were used to explore whether HL scores significantly differed with respect to sociodemographics. Table 2 presents the mean HL score for different patient groups categorized by sociodemographic factors. The complete sociodemographic profile of the study population is provided in Supplemental Material 2.

Overall, the study found no significant difference in HL scores between different categories of specialty consultations (F = 2.210, p = 0.100). Patients' ages did not have a significant influence on HL score (F = 1.436, p = 0.205), however, the youngest age group (<= 30 years) (n = 16) had significantly greater HL scores than patients aged 61–70 years and 71–80 years.

HL score was examined by sex and gender. All participants identified as cisgender. While the results indicated no significant difference in the HL scores between men and women (t = 1.543, p = 0.216), the mean HL score of women was slightly higher (68.06±13.12) than for men (65.17±13.84). The distribution of HL for men and women showed that 51% of the men had problematic HL while only 5.1% had excellent HL. In the case of women, 44.2% had problematic HL, while 13.5% had excellent HL (Fig. 2).

The study found a statistically significant difference in HL scores between patients with different employment situations (F = 3.762, p < 0.001). Patients who

Table 1 Descriptive results of the HLS$_{19}$-Q12 items

Item	On a scale from very easy to very difficult, how easy would you say it is…	Q25	Median	Q75	Min	Max	Mean	Std. Deviation
1	to find out where to get professional help when you are ill?	3.00	3.00	4.00	1	4	3.12	0.697
2	to understand information about what to do in a medical emergency?	3.00	3.00	3.00	1	4	3.09	0.601
3	to judge the advantages and disadvantages of different treatment options?	2.25	3.00	3.00	1	4	2.86	0.603
4	to act on advice from your doctor or pharmacist?	3.00	3.00	4.00	1	4	3.31	0.602
5	to find information on how to manage mental health problems?	2.00	3.00	3.00	1	4	2.47	0.854
6	to understand information about recommended health screenings or examinations?	3.00	3.00	4.00	1	4	3.17	0.587
7	to judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable?	3.00	3.00	4.00	1	4	3.18	0.695
8	to decide how you can protect yourself from illness using information from the mass media?	2.00	2.00	3.00	1	4	2.41	0.825
9	to find information on healthy lifestyles such as physical exercise, healthy food or nutrition?	3.00	3.00	4.00	1	4	3.18	0.621
10	to understand advice concerning your health from family or friends?	2.00	3.00	3.00	1	4	2.83	0.642
11	to judge how your housing conditions may affect your health and wellbeing?	3.00	3.00	3.00	1	4	3.03	0.604
12	to make decisions to improve your health and wellbeing?	3.00	3.00	3.00	1	4	2.99	0.711
Total		2.00	2.00	3.00	1	4	2.38	0.783

		Frequency	Percent
Limited general HL	Inadequate	16	10.7
	Problematic	73	48.7
	Sufficient	49	32.7
	Excellent	12	8.0
	Total	150	100.0

Fig. 1 General health literacy categories of the study population

were currently studying recorded the highest HL score (79.15±8.36), which was higher than patients working part-time, retirees with contributory pension, and patients with disability or sick leave.

Income had a statistically significant effect on HL (F=2.129, $p < 0.05$). Patients within €1,501 – €2,000 net monthly income range had the highest score on average (72.30), which was significantly greater than other listed income levels.

The relationship between types of patient self-reported illness and HL score was analyzed (Table 3). Statistically significant differences in HL scores were observed with respect to diabetes (t=2.356, $p < 0.05$) and digestive disease (t = -2.034, $p < 0.05$). Patients who self-reported as having diabetes had significantly higher HL scores (68.40±12.61) than others (63.18±14.45). Patients who self-reported as having digestive disease had significantly lower HL scores (61.96±16.31) than others (67.36±12.59).

To determine the significance of each variable in predicting HL scores (the dependent variable), we used a generalized linear model (Table 4). The overall model was statistically significant (χ^2=83.484, $p < 0.01$), and the McFadden's Pseudo-R^2 value was 0.427. Education and net monthly income were highly significant predictors of HL ($p < 0.01$) when other sociodemographic variables were controlled. Parameter estimates showed that the respondents with the highest educational qualification, i.e., doctorate, had significantly greater HL scores than other educational qualifications. In the case of net monthly income, respondents within the income range €1,501 – €2,000 had significantly greater HL scores than others. Work status was a statistically significant predictor of HL score ($p < 0.05$). Having 5–6 outpatient appointments was significantly associated with a lower HL score compared to having more than six appointments ($p < 0.05$). With respect to self-stated heath status, patients who self-reported their health as 'very good' had significantly higher HL scores than all other categories (very bad, bad, regular, and good) ($p < 0.05$).

Discussion

This study used the HLS$_{19}$-Q12 to calculate HL score and determine general HL of a patient population attending specialty consultations in the region of Aragon, Spain. It further created a sociodemographic profile and examined relationships between those variables and HL scores. It is believed that this was the first time the HLS$_{19}$-Q12 has been used in Spain, and in the Spanish language.
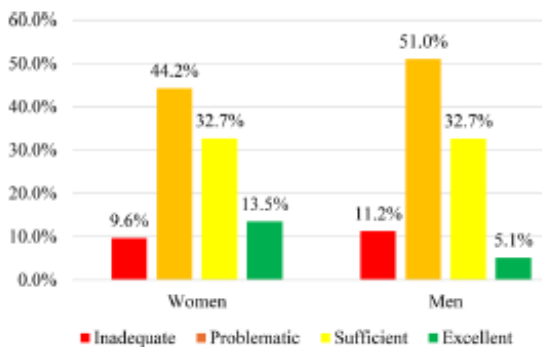
The comprehensive project describing results of the HLS$_{19}$-Q12 across large general populations in 17 countries reported a median HL score of 64 with a mean of 65 [16]. This study population had a median score of 67 and mean score of 66, which is in alignment with the findings from the 17 country study. Our results showed that 59% of respondents had HL categorized as inadequate or problematic, while 41% had sufficient or excellent HL.

Table 2 Patient sociodemographic profiles and general health literacy scores: ANOVA tests

	N	Mean	Standard Deviation	95% Confidence Interval for Mean		Min	Max	F	p value
				Lower	Upper				
Specialty clinic									
Diabetes	71	68.58	12.86	65.54	71.63	36.11	100.00		
Cardiology	14	66.63	11.87	59.77	73.48	45.45	88.89		
Digestive	20	66.40	12.31	60.64	72.17	47.22	91.67		
Ostomy	45	62.12	15.23	57.54	66.70	2.78	91.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	2.12	0.100
Survey completed by									
Patient alone	104	67.83	12.55	65.39	70.27	36.11	100.00		
By the nurse	3	66.46	8.25	45.96	86.96	60.00	75.76		
Patient with help	26	63.33	18.22	55.97	70.69	2.78	91.67		
Face to face interview	16	60.33	11.31	54.30	66.36	42.42	88.89		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.47	0.214
Age									
<= 30	16	72.90	12.30	66.34	79.45	44.44	88.89		
31–40	10	70.55	14.91	59.88	81.21	47.22	96.67		
41–50	16	66.92	10.02	61.57	72.26	47.22	80.56		
51–60	26	67.23	18.54	59.75	74.72	2.78	100.00		
61–70	44	64.61	13.99	60.35	68.86	36.11	93.94		
71–80	24	61.61	7.54	58.42	64.79	44.44	80.56		
81+	14	65.26	12.37	58.12	72.41	50.00	91.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.44	0.205
Sex									
Woman	52	68.06	13.12	64.41	71.72	44.44	93.94		
Man	98	65.17	13.84	62.39	67.94	2.78	100		
Total	150	66.18	13.63	63.98	68.37	2.78	100.00	1.543	0.216
Marital status									
Widowed	17	67.78	12.64	61.28	74.29	51.52	93.94		
Never married	26	67.42	19.06	59.72	75.12	2.78	100.00		
Married/domestic partner	94	66.36	12.33	63.84	68.89	36.11	96.67		
Divorced	12	59.62	10.76	52.79	66.46	38.89	80.56		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.81	0.522
Education									
ESO (Secondary)	14	70.52	9.87	64.82	76.22	45.45	81.82		
Student	25	69.18	13.21	63.72	74.63	44.44	96.67		
High school	11	67.34	9.79	60.76	73.91	52.78	80.56		
Master's degree	9	66.91	8.35	60.49	73.34	54.55	80.56		
Vocational training	33	65.69	13.76	60.81	70.57	41.67	91.67		
Primary education	57	63.27	15.22	59.23	67.31	2.78	100.00		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	1.51	0.179
Living situation									
Parents	14	68.54	22.40	55.60	81.47	2.78	88.89		
Partner & family	38	68.38	13.99	63.78	72.98	47.22	91.67		
Children	12	65.61	17.79	54.30	76.92	38.89	93.94		
Nobody	23	65.61	10.86	60.91	70.30	54.55	100.00		
With my partner	60	64.75	10.68	61.99	67.51	36.11	96.67		
Other family members	3	62.12	17.91	17.62	106.61	41.67	75.00		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.47	0.798
Work									
Currently studying	7	79.14	8.36	71.41	86.88	63.89	88.89		
Retiree with a non-contributory pension	10	72.07	8.09	66.28	77.86	63.89	91.67		
Unemployed	13	70.76	13.09	62.85	78.67	52.78	93.94		

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Table 2 (continued)

	N	Mean	Standard Deviation	95% Confidence Interval for Mean		Min	Max	F	*p* value
				Lower	Upper				
Work full-time	38	69.41	12.31	65.37	73.46	47.22	96.67		
Disability or sick leave	12	65.57	12.66	57.52	73.62	47.22	91.67		
Retiree with contributory pension	64	61.79	14.39	58.19	65.38	2.78	100.00		
Work part-time	6	58.67	9.00	49.22	68.11	44.44	69.70		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	3.76	0.002
I would classify my health as									
Very good	7	71.94	8.20	64.35	79.54	60.61	83.33		
Good	69	66.78	15.66	63.02	70.55	2.78	100.00		
Regular	59	65.80	11.69	62.75	68.85	36.11	91.67		
Bad	14	62.57	12.65	55.27	69.88	38.89	80.56		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.75	0.559
Net monthly income									
<600 €	13	69.89	10.56	63.50	76.27	55.56	91.67		
601–800 €	8	54.25	22.40	35.52	72.98	2.78	77.78		
801–1000 €	14	61.78	14.11	53.63	69.93	44.44	100.00		
1001–1.200 €	16	71.12	11.16	65.16	77.07	55.56	93.94		
€1.201 – €1.500	19	62.20	11.52	56.64	67.75	44.44	80.56		
€1.501 – €2.000	18	72.29	14.75	64.95	79.63	36.11	96.67		
> €2.001	26	68.00	11.75	63.26	72.75	52.78	91.67		
I don't know	8	68.69	19.35	52.51	84.88	38.89	88.89		
Spouse's pension	2	68.33	2.35	47.15	89.51	66.67	70.00		
I'd rather not answer	26	63.19	10.67	58.88	67.50	41.67	84.85		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	2.13	0.031
How many appointments have you had in this outpatient clinic not including today?									
1–2	54	67.07	13.27	63.45	70.69	36.11	91.67		
3–4	30	65.72	12.08	61.21	70.24	44.44	100.00		
5–6	12	61.17	21.56	47.47	74.87	2.78	80.56		
>6 visits	54	66.63	12.75	63.15	70.11	44.44	96.67		
Total	150	66.17	13.62	63.97	68.37	2.78	100.00	0.64	0.588

Fig. 2 Distribution of general HL categories for women and men (cisgender)

Table 3 Self-reported illness and general health literacy score

Self-Reported Illness		N	Mean	Standard Deviation	*p* value
Hypertension	Yes	45	65.61	9.81	0.699
	No	105	66.42	15.00	
Diabetes	Yes	86	68.40	12.61	0.020
	No	64	63.18	14.45	
Cardiovascular disease	Yes	32	68.00	14.68	0.394
	No	118	65.68	13.35	
Respiratory disease	Yes	9	60.21	9.04	0.176
	No	141	66.56	13.80	
Digestive disease	Yes	33	61.96	16.31	0.044
	No	117	67.36	12.60	
Cancer	Yes	40	65.95	12.70	0.905
	No	110	66.26	14.00	

In comparison, a study using the HLS_{19}-Q12 in Portugal reported notably higher HL with only 30% of the population categorized as inadequate or problematic, and 70% possessing sufficient or excellent HL [20].

The study found a statistically significant difference in the HL between patients with different work situations. The category of "studying" was included in the choices of work situation. Patients who were currently studying recorded the highest HL scores. This could be

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Table 4 Generalized linear model – parameter estimates

Parameter	B	Std. Error	Lower Interval	Upper Interval	*p* value
(Intercept)	110.265	15.893	79.116	141.415	0.000
Specialty clinic					
Cardiology	3.486	4.188	-4.723	11.695	0.405
Digestive	-1.638	3.490	-8.478	5.203	0.639
Diabetes	3.694	2.648	-1.496	8.884	0.163
Ostomy	-				
Age					
<= 30	6.630	8.552	-10.132	23.391	0.438
31–40	-0.927	6.621	-13.904	12.050	0.889
41–50	-3.579	5.639	-14.632	7.474	0.526
51–60	1.994	5.111	-8.024	12.012	0.696
61–70	-4.362	4.099	-12.397	3.672	0.287
71–80	1.500	4.406	-7.135	10.136	0.733
81+	-				
Sex					
Woman	1.827	2.253	-2.589	6.243	0.417
Man	-				
Marital status					
Married/domestic partner	-1.821	4.752	-11.134	7.492	0.702
Widowed	1.518	5.355	-8.977	12.013	0.777
Divorced	-7.158	5.380	-17.702	3.386	0.183
Separated	12.592	13.273	-13.422	38.607	0.343
Never married	-				
Education					
Primary education	-33.229	11.672	-56.105	-10.353	0.004
ESO (Secondary)	-26.787	11.907	-50.124	-3.450	0.024
High school	-32.837	11.776	-55.917	-9.757	0.005
Vocational training	-35.773	11.604	-58.516	-13.030	0.002
Student	-33.170	11.499	-55.707	-10.632	0.004
Master's degree	-47.520	12.623	-72.260	-22.780	0.000
Doctorate	-				
Origin					
Spain	-5.946	4.914	-15.576	3.685	0.226
Other	-				
Living Situation					
Nobody	10.629	8.277	-5.595	26.852	0.199
With my partner	9.135	8.296	-7.124	25.395	0.271
Partner & family	9.714	8.550	-7.043	26.471	0.256
Children	12.068	9.658	-6.862	30.997	0.211
Parents	-2.752	8.330	-19.079	13.575	0.741
Other family members	-				
Work					
Unemployed	-0.427	5.633	-11.466	10.613	0.940
Work full-time	-3.213	4.523	-12.078	5.651	0.477
Work part-time	-10.396	7.209	-24.524	3.733	0.149
Retiree with contributory pension	-10.277	4.509	-19.115	-1.439	0.023
Retiree with a non-contributory pension	-3.240	5.820	-14.647	8.167	0.578
Currently studying	7.623	8.002	-8.060	23.306	0.341
Disability or sick leave	-				
Residence					
Rural	-3.666	2.445	-8.458	1.127	0.134
Urban	-				

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Table 4 (continued)

Parameter	B	Std. Error	Lower Interval	Upper Interval	p value
I would classify my health as					
Very Bad	-32.823	14.047	-60.354	-5.291	0.019
Bad	-13.536	5.799	-24.902	-2.171	0.020
Regular	-11.542	4.967	-21.277	-1.806	0.020
Good	-10.194	4.963	-19.921	-0.467	0.040
Very Good	-				
Net monthly income					
<600 €	8.510	4.390	-0.093	17.113	0.053
601–800 €	-7.880	4.697	-17.086	1.325	0.093
801–1000 €	1.850	4.125	-6.234	9.935	0.654
1001–1.200 €	9.421	3.838	1.898	16.943	0.014
€1.201 – €1.500	-0.083	3.585	-7.111	6.944	0.981
€1.501 – €2.000	13.309	3.858	5.747	20.871	0.001
> €2.001	5.926	3.831	-1.583	13.435	0.122
Spouse's pension	1.864	8.884	-15.548	19.275	0.834
Others	-				
How many appointments have you had in this outpatient clinic not including today					
1–2	1.684	2.542	-3.297	6.665	0.508
3–4	-1.185	2.832	-6.735	4.365	0.676
5–6	-9.963	4.313	-18.417	-1.509	0.021
>6 visits	-				
(Scale)	105.72[a]	12.208	84.311	132.574	
Overall Results					
Omnibus Test (Likelihood Ratio Chi-Square)	83.484				0.001
R^2McF	0.427				

Dependent Variable: HLS_{19}_Q12p_score_1

Model: (Intercept), Specialty clinic, Age, Sex, Marital Status, Education level, Income, Origin, Living situation, Work, Residence, Health Status, Numbers of appointments in outpatient clinic

"-" represents the reference category

a. Maximum likelihood estimate (Type III)

Distribution Family=Normal; Link function=Identity

that individuals who are already in learning mode and are actively exploring new ideas and concepts are more open or receptive to processing current and new health information.

The ANOVA results showed that income had a relationship to HL score. A study in Valencia, Spain found that population subgroups such as low-income individuals presented with a higher degree of inadequate or problematic HL [8]. Our findings support this and other studies that suggest a relationship between low-income levels and limited HL [7, 9, 11].

Numerous studies cite the relationship between age and HL, stating that older individuals generally have lower scores [8, 21–23]. Our results did not support previous findings. The influence of older age could have been diminished by the presence of younger family members and caregivers at the appointment during which the survey was completed. The principal researcher noted that older participants frequently deferred to the opinions or help of the person accompanying them during the visit when completing the survey.

As shown in Table 4, individuals who reported their health status as 'very good' had significantly higher HL than those who reported their health status as any of the inferior categories. This finding is in keeping with a large European study by Sorensen et al. (2015) which found that people who reported their health status as 'very bad' or 'bad' experienced the highest proportion of limited HL.

In total, 56% of participants found it difficult or very difficult to decide how to 'protect themselves from illness using information from the mass media.' This was the survey item with the second lowest mean score. These findings are in line with research that shows public uncertainty and distrust with "fake news," social media, and artificial intelligence [11, 24–26], and highlights the

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need to ensure that individuals are equipped to identify health misinformation received from mass media sources.

There was no statistically significant relationship between the number of times the patient had visited the specialty consultation and their HL score, except in the case of those who had 5–6 prior appointments. Patients who had 5–6 appointments had a significantly lower HL score than those who had >6. This is noteworthy, as it suggests that the quantity of visits does not necessarily reflect the quality of those encounters. A mere visit does not necessarily mean that patients are understanding, learning, and better equipped to manage and act upon healthcare information.

Results further showed that patients who self-reported as having diabetes had significantly higher mean HL scores than those who reported having cardiovascular disease, digestive illness, hypertension, cancer, or respiratory conditions. This is not surprising, as people with diabetes often require quarterly condition management appointments, and many attend educational sessions regarding medication management, nutrition, and lifestyle practices. It is also a condition that normally requires lifelong management [27]. This suggests that frequent interactions with healthcare providers where health information is exchanged over long periods of time may improve patient HL.

Limitations and future research

This study presents both valuable opportunities as well as weaknesses. The sample size for this study was small, and we recommend the additional use of the HLS_{19}-Q12 in Spain on a sample size similar to those in the 17 country validation studies ($n > 1,000$) [16]. We surveyed a non-randomized sample of patients in a specialized care setting. The HLS_{19}-Q12 should further be administered to a randomized sample of patients in a more general care setting. Finally, as no other studies could be found that specifically measured the HL of patients in specialty consultations, our ability to make direct comparisons was limited.

While various studies have measured general HL, reinforced that HL is often low, and determined that a relationship exists between certain sociodemographic variables and general HL, more studies are needed to explore the solutions to these identified problems [7, 9, 11, 21, 22, 28]. One worthy direction for future research is to explore the HL awareness and skills of healthcare providers themselves. This is essential to determine if healthcare providers understand the concept of HL, the role it plays in health outcomes, and whether they possess the necessary skills to transmit health information in ways that are understandable and meaningful to patients [4, 29–31].

Since it has been shown that HL affects populations, further research is warranted on what countries can do at the systems level to increase general HL. Health policies, literacy campaigns, amending or creating service design and healthcare delivery should continue to be explored [6, 32]. In the private sector, hospitals and care networks are often more agile and able to restructure services to meet users' needs in innovative and alternative ways. Thus, studies should determine how HL is or can be addressed in these private care settings [33].

Given the rapidly increasing use of virtual care settings and telemedicine, it is necessary to continue to analyze how these venues affect general HL, as well as how a person's general HL influences their use of such care settings. When healthcare providers choose these care mediums, the actual HL of patients, in addition to opportunities to improve general HL, should be considered in the design, functionality and ease of use.

Finally, increasing numbers of people are looking to the internet and even using social media to diagnose and treat their medical concerns. Our results showed that people struggled with trusting health information from mass media. Therefore, while the study of e-health literacy has become more frequent, we recommend continued research that identifies ways to minimize disinformation and improve both general and e-health literacy when using the internet [34, 35].

Conclusion

This study contributes to an important and growing examination of HL in Europe. The results of the HLS_{19}-Q12 in this specific Spanish population provide a unique view into the HL of patients in specialty consultations, which can be used for comparison in current and future HL studies. It further provides actionable HL data for decision makers in this health sector of Aragon, Spain, and highlights a need to measure HL on a larger population scale. Results show which sociodemographic variables are associated with HL. This information allows policymakers as well as healthcare management to better tailor HL strategies taking into account those variables.

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Declarations

Ethics approval and consent to participate
The study was approved on 16 March 2023 by the Government of Aragon, Department of Health, CEICA following law 14/2007, 13 July for Biomedical Investigations and Applicable Ethics Principles. It was also approved on 23 February 2023 by the Aragonese Health Services (SALUD) to be conducted in the Hospital Clínico Universitario "Lozano Blesa" Sector Zaragoza. Written informed consent was obtained by all study participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Article 3

The effect of nurse health literacy interventions on patient health literacy scores in specialty consultations: a quasi-experimental study

Angela McCaskill[1*], Angel Gasch-Gallen[1] and Jesica Montero-Marco[2]

Abstract

Background Patient health literacy (HL) affects health and wellbeing on both individual and population levels. The ability to receive, understand, manage and act upon health information can be positively influenced by nurses' use of HL strategies. This study examined the relationship between nurses' use of a HL checklist (intervention) and before and after patient HL scores, and the effects of frequency and types of strategies used in specialty consultations in Spain.

Methods This quasi-experimental, non-randomized study used the HLS_{19}-Q12 to calculate HL scores for 149 patients. Calculations were performed both before and after a nursing intervention that consisted of using a HL checklist. Paired samples t-test assessed the difference between patient HL scores pre- and post-nurse intervention. Frequency analysis and Pearson correlation where used to examine frequencies of nursing HL strategies used and associations with HL scores.

Results The mean difference between the HLS_{19}-Q12 scores before and after intervention was −9.94, with a standard deviation of 11.50. There was a statistically significant effect of the intervention on HL score ($t = -10.00$, $p < 0.001$). No participant had HL classified as 'inadequate' after the nursing intervention. Verbal teach back method was the most frequent strategy used by nurses, and the use of a computer image was the most frequent visual aid.

Conclusions The use of a standardized HL intervention by nurses was shown to have a positive effect on patient general HL scores in specialty consultations in Spain. These results not only suggest that the use of a HL checklist can be an effective HL tool, but also reinforce the potential of nurses to make a positive impact on both individual and population health. Overall, these findings provide data that can be used by health systems, hospitals management, and nurse education programs to adopt strategies to improve patient HL and health outcomes, while potentially lowering costs and ineffective resource utilization related to inadequate HL.

Keywords Health literacy, Health literacy strategies, Patient education, Standardization in patient education, Population health, Health literacy checklist

*Correspondence:
Angela McCaskill
angelamccaskill@outlook.com

[1]Department of Physiatry and Nursing, Faculty of Health Sciences, University of Zaragoza, C/Domingo Miral, s/n 50009, Zaragoza, Spain
[2]Research Unit, Hospital Clínico Universitario Lozano Blesa, Avda. San Juan Bosco, 15, Zaragoza 50009, Spain

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Introduction

Health literacy (HL) is a multidimensional concept, addressing the resources and tools that people have to obtain, process, make judgements, manage, and act upon health information in ways that improve their health, wellbeing, and quality of life [1–3]. HL strategies are the actions that clinicians can use to ensure that patient health education is received and understood in meaningful, actionable, and empowering ways. The goal of HL teaching is that patients will be able to process, understand, make judgements about, ask informed questions, and act upon a variety of sources of health information received [1, 3].

Much has been written about the importance of health literacy (HL) among individuals and populations. Low HL has been linked to poor disease management, problems with medication adherence, and inconsistent use of preventative healthcare services, all leading to increased levels of morbidity and mortality [4–6]. Further, low HL imposes a burden on already struggling health systems due to patients' increased use of emergency services, higher readmissions rates, and elevated costs related to health spending, disability payments, and loss of work and productivity [7–9].

In one retrospective study of 92,749 patients using the US Veteran's Administration healthcare system over the course of three years, patients with inadequate or marginal HL cost the health system $143 million more than patients with adequate HL [10]. Another study examining the link between patients' HL and their use of emergency services found that individuals with limited HL had significantly higher rates of emergency service use (OR: 1.57, 95% CI: 1.02–2.43) and were more likely to experience a potentially preventable hospital admission (OR: 1.65, 95% CI: 1.00-2.73) [11].

The scope of HL goes far beyond just teaching [12]. Clinicians should educate patients with the goal of equipping them to follow clinical instructions, adhere to prescribed treatments, and take actions to improve their health. There is agreement in health education literature that certain educational strategies are more effective than others in soliciting changes in patient behavior [13–15]. Some items cited as being more effective include the use of visual aids, inviting questions, demonstrations, summarizing and repeating instructions, teach back and show back techniques, the use of computers, and the use of multiple strategies instead of just one [16–20].

In particular, literature suggests that nurses play a pivotal role in the important quest of patient education and improved HL [21]. Nurses provide information about medication, how to care for lesions, and how to perform procedures such as giving oneself an injection of insulin [22]. They may also help patients understand how to obtain a doctor's appointment, request a prescription refill, or know where to look for additional support such as social services. Nurses are often the communication interface between patients and doctors, and even act as mediators between patients and their family members or caregivers.

Researchers have approached the study of HL from various angles. Some researchers created and validated HL measurement instruments, and subsequently used them to measure HL in various countries and in distinct settings [1, 13, 23–30]. These efforts resulted in a body of information that has facilitated an important assessment of HL around the world, and especially in Europe. Another dimension of HL that has been examined is the effectiveness of different HL strategies, teaching techniques and methods [13, 18, 31–35]. Those studies are also of import, as they showed that certain HL interventions are more useful in changing patient behaviors and improving health outcomes [36].

While HL measurement tools have been created and used to calculate HL scores, and researchers have explored the effectiveness of specific educational strategies, few studies bring these two endeavors together. Further, we found scarce research that has done this before with a focus on the role of nurses. Therefore, the aim of this study was to examine the relationship between nurses' use of a health literacy checklist and pre- and post-intervention HL scores, and the effects of frequency and types of HL strategies used.

Methods

A quasi-experimental, non-randomized, pre-and-post-test method was used because it was a viable method to explore the effect of the nursing intervention on post-intervention HL scores. This method also enabled us to capture data about the frequency and types of HL strategies used by the nurses. The study ran for a period of 12 months, between April 2023–2024. It was approved on 16 March 2023 by the Department of Health, Ethical Research Committee of Aragón: PI23/083 following law 14/2007, 13 July for Biomedical Investigations and Applicable Ethics Principles. It was further approved on 23 February 2023 by the Aragones health services (salud). All participants were given a take home description of the study and signed consent forms.

Selection of study sites

Top nursing management selected the four specialty consultations that would participate in the study. To select the sites, the number of patient visits per year to each type of consultation was examined. It was determined that there was a higher probability that patients would require three appointments within the 12-month study period at the diabetes, ostomy, cardiology, and digestive
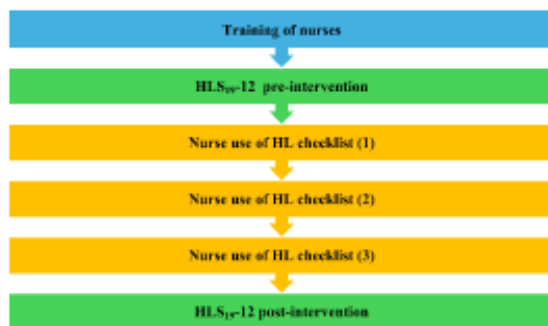
Fig. 1 Process flow of the study design

clinics. Therefore, these were the consultation types selected for the study.

Selection and description of participants

The patient sample consisted of individuals who regularly attended specialty consultations in Zaragoza health sector III of the autonomous community of Aragon. Specialty consultations included: diabetes, ostomy, cardiology, and digestive. Inclusion criteria for the study were (1) age 18 or older, (2) willingness to complete the HLS_{19}-Q12 survey two times (before and after HL interventions), and (3) the patient had the necessity to make three visits to the specialty consultation within the 12-month period of data collection. There were no other exclusions.

To obtain the sample group, the principal researcher followed a predefined weekly schedule of recruitment from April – November 2023. The principal researcher visited each specialty consult on predetermined days each week. The patients who had appointments on those days and satisfied selection criteria were invited to

participate in the study. All 166 participants asked agreed to be in the study. After loss of patients due to missed appointments and invalid survey completion, before and after HL scores were calculated for 149 patients.

Training of specialty clinic nurses

A total of eight nurses participated in the study intervention. These nurses were chosen because they were the nurses already working in the chosen consultations. These nurses were considered to have advanced knowledge in their fields of practiced based on the fact that they had all passed exams for permanent positions, had more than 10 years of experience, and received specialized training for the medical condition they treat. In order to standardize the nursing intervention, the nurses participated in training. Each nurse agreed to attend the HL training course, consistently ask the questions on the HL checklist, use the strategies as instructed on thechecklist, and ensure that each patient enrolled in the study completed three visits to the consultation within a 12-month period (Fig. 1).

Nurse training was conducted by the principal researcher who was an advanced degree nurse. She also had vast professional experience as a patient and clinician educator, and was the project leader for an international healthcare quality standard that outlined requirements for HL [37]. Nurse training consisted of (1) an in person endorsement by the Director of Nursing highlighting the importance of the study for best clinical practice and patient outcomes, and an expression of her commitment and support of the study, (2) an overview of HL and why it is important, (3) a discussion of populations at risk for low HL levels, (4) a review of strategies clinicians could use to improve patients' HL, (5) role play between nurses

Table 1 Statistical results for general HL scores pre- and post-nursing intervention

	Mean	Median	Std. Deviation	Std. Error Mean						
HLS_{19}-Q12 score pre-intervention	66.17	66.67	13.62	1.09	95% Confidence Interval of the Difference				Significance	
HLS_{19}-Q12 post-intervention	75.89	75.76	9.95	0.83	Lower	Upper	*t*		One-Sided p	Two-Sided p
Paired Differences pre-post intervention	-9.94		11.50	0.99	-11.90	-7.97	-10.00		$P < 0.001$	$P < 0.001$
				Stder[a]	Point Estimate					
Paired Samples Effect Sizes			Cohen's*d*	11.50	-0.86	-1.06	-0.66			
HLS_{19}-Q12 score pre- and post-intervention			Hedges'*g*	11.57	-0.85	-1.05	-0.66			
	HLS_{19}-Q12 score pre-and post-intervention Wilcoxon Signed Ranks Test								Z	Asymp. Sig. (2-tailed)
									-7.12[b]	$P < 0.001$

a. Standardizer. The denominator used in estimating the effect sizes. Cohen's d uses the sample standard deviation of the mean difference. Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor

b. Based on negative ranks

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and pretend patients in hypothetical teaching situations, and (6) a description of the nurses' roles and responsibilities in the study. Finally, nurses reviewed the content and wording of the HL checklist prior to its use. This was done to ensure that it was appropriate and understandable by both the nurses and the patient population they treated.

Data collection and measurements

The health literacy survey named the HLS_{19}-Q12 was used to assess general adult HL. The HLS_{19}-Q12 had been validated internationally in 17 countries and in 17 languages using different types of data collection with acceptable psychometric properties and validity [30, 38]. It was further an attractive tool because it consists of only 12 questions, which minimizes the use of both patient and nurses' time.

The HLS_{19}-Q12 is a subjective, perception based instrument, that uses a four-point Likert scale to record patient's perceptions concerning 12 health related items. Respondents were asked to rate the difficulty level of health related items by selecting "very difficult," "difficult," "easy," "very easy," or "I don't know." In accordance with Type P calculations, scores were calculated as the sum of the item's numeric values scaled to a range from 0 to 100 [30]. If there were more than two invalid responses in a survey, that survey was disqualified from the study. Scores were then categorized based on the following scale: > 83.33 = Excellent, > 66.67 and ≤ 83.33 = Sufficient, > 50 and ≤ 66.67 = Problematic, and ≤ 50 = Inadequate [30].

The survey was completed during face to face consultations with patients. Reponses were captured on paper in one of the following ways: (1) by the patient alone, (2) an interview with the principal researcher, (3) patient with the help of a family member or caregiver, (4) patient with help of the principal researcher, or (5) by the specialty nurse. The HLS_{19}-Q12 had been previously validated using the paper-assisted personal interview (PAPI) mode, so these were acceptable data collection methods [38]. The principal researcher was present for the completion of the surveys in case the patient had questions. All data was anonymized using a unique participant identifier.

The intervention in this study was the use of an HL checklist (Additional file 1). The checklist was created by the principal researcher based on three inputs. First, select items were chosen from the HLS_{19}-Q12. Second, the teaching strategies included in the checklist were selected based on research suggesting that those were some of the most effective strategies. Lastly, studies suggest that the use of more than one teaching strategy is most effective. Therefore, the checklist also required this practice from the nurses [13, 18, 30, 39].

The checklist consisted of seven questions aimed at reinforcing the patients' understanding of, and access to, health information. Three questions were open ended and allowed for continued dialogue between the patient and nurse if needed or desired. The checklist also required the HL strategy of summarizing or reinforcing the important points of that days' appointment. The final section of the checklist required that the nurse use a minimum of two HL strategies listed in the checklist. For example, using the teach back or show back method along with the use of one or more visual aids. The checklist length and questions were chosen with the goal that its use would not require more than 10 min. This is key, given that both clinicians and patients are often short on time during consultations.

The nurses used the checklist with participants during all three of their appointments. The first use was after the initial HLS_{19}-Q12 was completed by the patient. The second time was during the patient's next regularly scheduled appointment. The final time was during the patient's third visit. The patient also completed the post-intervention HSL_{19}-Q12 at the end of the third appointment.

Data analysis

IBM SPSS 27 was used to analyze survey data. To examine the difference between before and after HL scores, paired sample t-test and Wilcoxon tests were performed. Cohen's d was used to determine effect size, with a d ≥ 8 considered to be a large effect. Frequency analysis was utilized to assess how often the nurses used each HL technique on the checklist. Pearson correlation determined which specific strategies as well as number of strategies had a statistically significant association with health literacy scores (HL scores) post-intervention. This study assumed a significance level of 0.05.

The Shapiro-Wilk test was used to test for normality before using paired sample t-test. Results were significant, so the null hypothesis of normal distribution was rejected. An outlier identified via boxplot was removed from the dataset, then the data assumed normal distribution.

Results

Patient heath literary scores pre- and post-nursing intervention

Paired sample t-test assessed the difference between HL scores pre- and post-intervention. The paired sample correlation test showed that the mean difference between the two scores was −9.94, with a standard deviation of 11.50. The significance level indicated a statistically significant effect of the intervention on HL score (t = -10.00, $p < 0.001$). Cohen's d was negative and 0.86, which indicated a large effect size, and that the mean HL score of

Table 2 Health literacy pre-and post-nursing health literacy intervention

Pre-intervention

Classification		N	Percent	Valid Percent	Cumulative Percent
	Inadequate	16	9.6	10.7	10.7
	Problematic	73	44.0	48.7	59.3
	Sufficient	49	29.5	32.7	92.0
	Excellent	12	7.2	8.0	100.0
	Total	150	90.4	100.0	
Missing	System	16	9.6		
Total		166	100.0		

Post-intervention

Classification		N	Percent	Valid Percent	Cumulative Percent
	Problematic	37	22.3	24.8	24.8
	Sufficient	82	49.4	55.0	79.9
	Excellent	30	18.1	20.1	100.0
	Total	149	89.8	100.0	
Missing	System	17	10.2		
Total		166	100.0		

the pre-intervention group was lower than the mean for the post-intervention group.

The Wilcoxon test was used to confirm the effect of the intervention. The mean score in $HLS_{19}\_Q12\_group\_1$ was lower (2.39) than the mean score in $HLS_{19}\_Q12\_group\_2$ (2.96). The z-statistic was −7.12, and the asymptotic significance was <0.001, showing a statistically significant difference in the scores of both groups. Based on mean ranks, it was proven that overall sample HL scores post-intervention were greater than pre-intervention.

The same HL score component was treated as a continuous variable for better understanding of the intervention's outcome on patients' HL scores. The results of the continuous variable (HLS_{19}_Q12 score) showed that pre-intervention, the mean HL score was 66.17 (SD:13.62), whereas post-intervention, the mean HL score improved to 75.89 (SD: 9.95).

Most of the respondents in group 1 (pre-intervention) had HL that was 'problematic' equaling 48.7% (73 patients) of the valid sample, followed by 32.7% (49 patients) who had 'sufficient' HL. After HL interventions, most patients had HL that was 'sufficient' equaling 55% of the valid sample (82 patients) and 20.1% (30 patients) were 'excellent'. In post-intervention group 2, only 24.8% (37 patients) scored 'problematic,' showing marked improvement. No participants had HL that was 'inadequate' after the nursing intervention (Table 2).

HL scores post-intervention were also analyzed by sex. All respondents identified as cisgender. For the pre-intervention HL survey, a greater percentage of men had 'inadequate' or 'problematic' HL than women. Women showed a greater percentage of 'excellent' HL than the lesser categories of 'sufficient,' 'problematic,' or
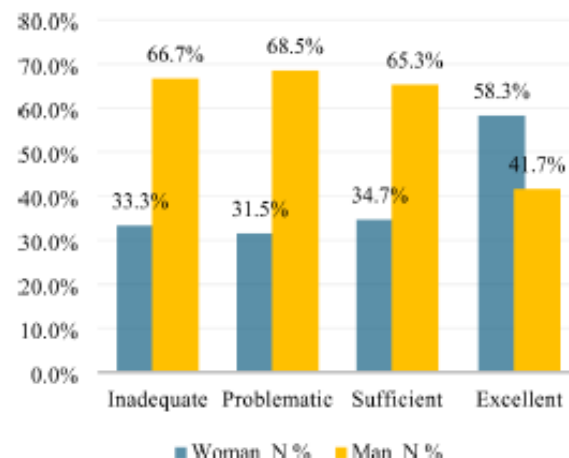
Fig. 2 Percentage of participants by sex with inadequate, problematic, sufficient or excellent HL pre-intervention (cisgender)
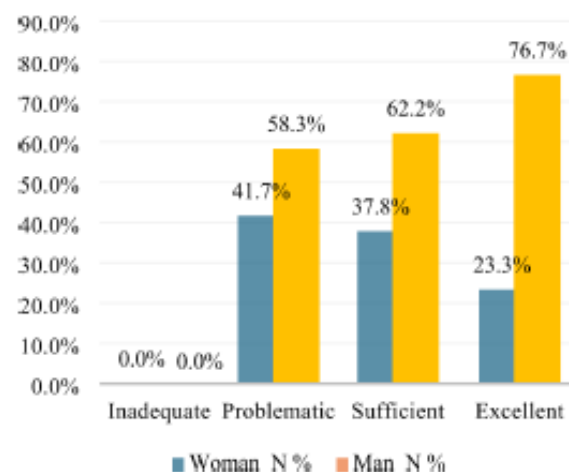
Fig. 3 Percentage of participants by sex with inadequate, problematic, sufficient or excellent HL post-intervention (cisgender)

'inadequate'. Post-intervention, the percentage of men whose HL was categorized as 'excellent' had increased from 41.7 to 76.7% (Figs. 2 and 3). Descriptive statistics showed that the mean HL score improved post-intervention for both women (68.07 to 75.45) and men (65.81 to 76.25).

Frequency of health literacy strategies used by specialty practice nurses

Frequency analysis quantified the nurses' use of specific strategies (tools, or techniques) chosen from the HL checklist. Verbal teach back method was the most frequent technique used over the course of the three appointments, selected by nurses 79% of the time. In regard to the section of the HL checklist that required the nurse to select a visual aid, use of a computer image

Table 3 Frequency of health literacy strategy used

	Appointment 1		Appointment 2		Appointment 3		Overall	
	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Verbal/Action								
Teach back what you have learned (Verbal)	133	80.6%	126	76.4%	132	80.0%	391	79.0%
Show back what you have learned (Action)	37	22.4%	27	16.4%	20	12.1%	84	17.0%
None	19	11.5%	8	4.8%	4	2.4%	31	6.3%
Visual Aids								
Educational Brochure	38	23.0%	14	8.5%	10	6.1%	62	12.5%
Poster	0	0.0%	1	0.6%	2	1.2%	3	0.6%
Notes from the visit	10	6.1%	6	3.6%	11	6.7%	27	5.5%
Computer Image	71	43.0%	81	49.1%	76	46.1%	228	46.1%
Picture on phone or app	2	1.2%	2	1.2%	7	4.2%	11	2.2%
Physical model or device	51	30.9%	55	33.3%	47	28.5%	153	30.9%
None	40	24.2%	18	10.9%	20	12.1%	78	15.8%

Table 4 Correlations between type of health literacy strategy and post-intervention HL scores

		HLS_{19}_Q12p_score post-intervention
HLS_{19}_Q12p_score	Pearson Correlation	1
	Sig. (2-tailed)	
	N	148
Verbal teach back	Pearson Correlation	0.128
	Sig. (2-tailed)	0.120
	N	148
Action show back what you learned	Pearson Correlation	-0.140
	Sig. (2-tailed)	0.090
	N	148
Neither teach back nor show back	Pearson Correlation	-0.017
	Sig. (2-tailed)	0.840
	N	148
Educational brochure	Pearson Correlation	0.063
	Sig. (2-tailed)	0.449
	N	148
Poster	Pearson Correlation	-0.079
	Sig. (2-tailed)	0.342
	N	148
Notes from visit	Pearson Correlation	0.021
	Sig. (2-tailed)	0.804
	N	148
Computer Image	Pearson Correlation	0.074
	Sig. (2-tailed)	0.371
	N	148
Picture on phone or app	Pearson Correlation	-0.011
	Sig. (2-tailed)	0.895
	N	148
Physical model or device	Pearson Correlation	-0.153
	Sig. (2-tailed)	0.063
	N	148
Did not use any visual aids	Pearson Correlation	0.026
	Sig. (2-tailed)	0.752
	N	148

**Correlation is significant at the 0.01 level (2-tailed)

*Correlation is significant at the 0.05 level (2-tailed)

was the most popular choice at 46%, followed by a physical model or device 31% of the time. The least frequently used verbal/action technique was the show back method (17%), and the least often selected visual aid was a poster (0.6%) (Table 3).

The study further examined the association between the total number of techniques used in all three appointments with the same patient and that patient's HL score after the intervention. There was no statistically significant correlation between total number of techniques used from the checklist and HL score post-intervention.

Relationship between the type of health literacy intervention used and patient health literacy score

Pearson correlation was used to determine whether any of the HL strategies used in the appointments had a statistically significant association with HL score post-intervention. The 'show back what you have learned (action)' technique had a statistically significant negative relationship with HL scores after intervention, $r = -0.140$, $p < 0.1$ (correlation is marginally significant). Moreover, the use of physical model or device visual aid also had a statistically significant negative link with HL scores post-intervention, $r = -0.153$, $p < 0.1$. There were no positive statistically significant associations revealed (Table 4).

Discussion

This research examined the relationship between nurses' use of a HL checklist and patient pre-and post-HL scores in specialty consultations in Spain. It further studied the effects of frequency and types of strategies used. Our data showed a statistically positive relationship between nurses' use of the checklist and patient HL scores. In the present study the mean HL score was 66 before HL intervention, and post-intervention it increased to 76. In one of the first large scale studies of HL across 17 European countries using the HLS_{19}-Q12, the mean HL score was 65 [30]. After the use of the checklist in this study, the

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mean HL score was notably higher than that of the larger European population previously studied.

Research suggests that individuals with moderate to high levels of HL are more likely to utilize preventive care, adhere to medical advice from doctors and nurses, take medications as prescribed, and effectively navigate the often complex healthcare system using available health information [6]. One promising outcome of this study is the likelihood that the participants who did experience an increase in HL will be able to benefit from these same positive health behaviors.

It is interesting to note that post-intervention, men had a larger increase in mean HL score than women. This could be influenced by the fact that women have historically been assigned the role of caregiver, and therefore they accumulate more knowledge around healthcare and health information over the course of their lives [40, 41]. In as such, their scores were higher than the men before the intervention, which left less room for improvement post-intervention.

In relation to types of HL strategies used, 79% of the time nurses chose the "teach back" technique. This technique has been proven to be an effective tool for increasing patient learning and clarifying misunderstandings [19, 42]. While statistics did not show a significant relationship between this technique and HL scores in this study, the combination of this technique with other items on the checklist could be the source of improved HL. In regard to visual aid, "use of a computer image" was the tool most frequently used by the nurses in this study. Friedman et al. (2010) found that computers can be an effective health teaching strategy [18].

There were no statistically significant positive relationships found between the number or type of HL techniques used on HL scores. Nonetheless, the overall patient scores did improve significantly post-intervention. This suggests that the first part of the checklist, which contained the seven questions and one summarizing technique that allowed for open ended discussion and deeper dialogue may be key to engaging and educating patients. It also implies that the quality of the interaction is more important than the mere quantity of strategies used with the patient. Another possible explanation is that the HL checklist required the use of multiple strategies. This supports research reporting that the use of multiple strategies produces better learning and behavior outcomes [13, 16, 18].

Contact with nurses are some of the few relationships of trust that patients have during which they obtain and process heath information [43]. Hence, nurses can play a pivotal role in improving patient HL [44]. Our findings support previous work showing that nurses contribute significantly to support and advance patient HL [22]. A study in Spain found that patients receiving care from advanced practice nurses had higher satisfaction scores, felt they received more time and dedication in consultation, and received more information [45]. Likewise, our results show the value of nurses with specialized disease knowledge in increasing patient HL. In particular, the use of specialized and experienced nurses in this study emphasizes the potential benefits of promoting and formalizing the field of advanced practice nursing in Spain.

Strengths and limitations

This study was novel in various ways. First, it looked at before and after intervention HL scores of a patient population. This is in contrast to many studies that set a baseline by measuring HL scores of a sample population, but do not perform interventions and reevaluate HL scores afterwards [27, 46]. The investigation was further important in that it not only used a new HL checklist, but sought to illuminate which HL techniques worked best within a patient population. The results of this study can be used to inform future exploration regarding which HL strategies are most effective in increasing HL.

Nurses use various standard assessment tools such as the Glasgow Coma Scale, the Braden Scale, Morse Fall Scale, and the GAD-7 [47–49]. Our findings open a discussion concerning the need for a short, standardized tool for HL that clinicians can easily use with patients. The Agency for Healthcare Research and Quality's Health Literacy Universal Precautions Toolkit is one such option [50]. However, the checklist in this research is shorter and specifically aimed at meeting the HL needs of the patient at the exact moment of patient, caregiver, or family member contact.

While this study used the checklist in specialty consultations, none of the questions were specific to any of the specialty consultations. Rather, the questions were general and could be used in all types of healthcare settings. Further, the list of HL strategy options on the checklist were varied and applicable in many settings, only depending on what resources are available to nurses at the time of interaction with the patient (e.g., computers, brochures, physical models, posters). Therefore, the creation of a rapid and feasible HL checklist based on the results from this study could be a viable tool for nurses to use in their daily interactions with patients and caregivers in a variety of care delivery settings.

Various study limitations should be considered when interpreting our findings. The HL checklist created for this project had not been validated. Therefore, future research involving validation of the checklist could strengthen these findings, while also providing an additional validated tool for use by researchers and clinicians. Further, there was no control group of patients who did not receive the nursing intervention. This makes it difficult to prove causality and lessens the certainty that the

improvement in HL scores was not due to external factors that could have influenced the results. Another limitation was the inability to control for differences among the nurses and their teaching styles. Some nurses could have been more effective in using the checklist than others, and perhaps only their patients showed improvements in HL scores. Finally, the study took place in specialty consultations, and the results may not be generalizable to all care settings.

Future research

While this study explored which HL interventions were statistically significant in improving HL scores in specialty consultations, further explorations should consider investigating teaching techniques that are most effective in various care settings [15]. For example, some techniques might work better in specialty consultations where there is more frequent follow up with the same patients, whereas others might be more impactful during the less-often general practitioner visit, or in a rapid setting like the delivery of emergency services.

According to the self-reported sociodemographic data, the profile of this sample population was significantly homogenous. In 2023 the OECD reported unprecedented amounts of new permanent immigrants and asylum seekers worldwide [51]. As countries around the globe are facing continued migration, health systems will need to provide care to increasingly diverse populations. In future studies, it would be valuable to explore whether certain HL strategies work better with patients from specific cultures and linguistic backgrounds. Similarly, nurses come from a diversity of backgrounds and ethnicities. These factors could influence the types of strategies used, and some nurses might not feel as comfortable using certain strategies based on cultural norms and power differentials. Therefore, this would be a valuable extension of our work.

Conclusion

This study aimed to take HL research a step further, providing data that can be used by nursing education programs, as well as hospitals and health systems as they seek to create processes and protocols that increase service user (patients, families, and caregiver) HL. The results suggest that nurses' use of a standardized checklist aimed at improving patient HL was effective. While some strategies on the checklist were shown to be more impactful than others, a mix of strategies appears to work the best. Nurses' use of engaging questions, and summarizing what was discussed or learned during the appointment may be the techniques that most positively influenced HL scores in this patient population.

Data availability

Data is available upon request to the primary author.

Declarations

Ethics approval and consent to participate

The study was approved on 16 March 2023 by the Government of Aragon, Department of Health, CEICA following law 14/2007, 13 July for Biomedical Investigations and Applicable Ethics Principles with approval number PI23/083 . It was further approved on 23 February 2023 by the Aragones health services (salud) to be conducted in the Hospital Clínico Universitario "Lozano Blesa" Sector Zaragoza. All study participants were provided with a description of the study, signed informed consent, and were given a copy of the consent form.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Publisher's note

Article 4
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JHQR-D-24-00158R2: editorial decision

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We are glad to inform you that your article "Implementation of ISO 7101, 8.10.5 Health literacy and effects on patient health literacy and perceived quality of care" (Ref. JHQR-D-24-00158R2) has been accepted for its publication in Journal of Healthcare Quality Research.

We appreciate and value your contribution to Journal of Healthcare Quality Research. We regularly invite authors of recently published manuscript to participate in the peer review process. If you were not already part of the journal's reviewer pool, you have now been added to it. We look forward to your continued participation in our journal, and we hope you will consider us again for future submissions.

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Journal of Healthcare Quality Research

Implementation of the new healthcare standard ISO 7101, clause 8.10.5 Health literacy and effects on patient health literacy and perceived quality of care

ABSTRACT

Objective: This quasi-experimental, non-randomized study described the process of implementing ISO 7101 subclause 8.10.5 Health literacy in specialty consultations, then determined the effects of implementation on patient general health literacy scores and perceptions of quality of care.

Method: Implementation steps were outlined, nurses were trained and used a standardized health literacy checklist with patients. The HLS_{19}-Q12 was used to calculate patients' general health literacy scores pre- and post-implementation of subclause 8.10.5. Paired samples t-test and Wilcoxon signed-rank test determined relationships between implementation, health literacy score, and quality of care perceived.

Results: Mean general health literacy scores increased post-implementation from 66.35 to 76.29, as did the mean score of perception of quality of care received (M = 3.87 to M = 3.99). Wilcoxon test for both variables was significant ($P<.001$), and effect size was large ($d \geq 0.8$).

Conclusions: Implementation of ISO 7101, subclause 8.10.5 Health literacy had a positive, statistically significant impact on patient general health literacy scores and perceptions of quality of care. This is valuable information for healthcare management decision makers as they implement new standards and seek to improve patient health outcomes.

1

Introduction

Health systems, hospitals and clinics around the world aim to provide effective, safe, timely, and equitable care. This endeavor is increasingly difficult due to a large percentage of ageing populations, rising healthcare costs, workforce shortages, climate events, mass immigration, and the residuals of a global pandemic [1,2]. Amongst the various actions healthcare organizations take to confront such issues is the implementation of healthcare quality standards.

Quality standards exist on both national and international levels. Many are required by national governments or payor systems, while others are voluntary. In some countries healthcare organizations might receive higher reimbursement rates or preferential consideration if they have achieved certification. Whatever the motivator, research shows that the implementation of quality standards can lead to improved patient safety, better health outcomes, and decreased organizational and clinic risk [3–5].

In 2018, there were three international actors that called attention to the dire need for improved healthcare quality: The World Health Organization in *The Handbook for national quality policy and strategy*, the Lancet Commission for High Quality Health Systems in their article, *High-quality health systems in the Sustainable Development Goals era: time for a revolution*, and the OECD, WHO and World Bank in a joint publication titled, *Delivering quality health services. A global imperative for universal health coverage* [6–8]. These global players provided guidance and issued a call to action for improving healthcare quality.

Healthcare standards have existed in the market for years, including familiar ones from the Joint Commission, the International Society for Quality in Health Care (ISQua), and Accreditation Canada's HSO standards [9–11]. While these standards are specific to healthcare, a general quality standard, ISO 9001, has been implemented by hospitals worldwide to create management systems based on the plan, do, check, act improvement cycle [5,12–15].

ISO 7101:2023 Management systems for quality in healthcare organizations

In 2020 an expert workgroup of healthcare providers, quality and risk managers, independent consultants, and academics from both public and private entities gathered to create a new healthcare quality management systems standard through the International Organization for Standardization (ISO) [2]. They endeavored to create a standard that was healthcare specific while including the internationally recognized and proven practices of an ISO management systems standard. After three years of global collaboration, the first ever ISO standard for healthcare quality was published [16,17].

ISO 7101 contains 10 clauses, with clauses 4-10 outlining mandatory requirements. Clause 8.10 of the standard is dedicated to people-centered care. One dimension of people centered care as described in the standard is ensuring the health literacy (HL) of service users (patients, families, caregivers). HL is a measure of the ability of service users to receive, understand, and act upon health information provided to them [18]. Subclause 8.10.5 of the standard outlines requirements for organizations who endeavor to foster service user and workforce HL (Supplementary Information 2).

Why is health literacy important?

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Health literacy was included in the standard because quality care should be effective and produce favorable health outcomes. One way to achieve this is through improving HL. Low HL is linked to poor management of chronic disease, decreased capacity to understand and follow doctors' orders, diminished medication adherence, more frequent use of emergency services, and higher rates of hospital readmissions[19]. Low HL is considered a social determinant that contributes to inequalities and economic hardship, with vulnerable populations being at greatest risk [20–22]. Studies reveal that general adult HL in Europe is low, with almost one half of people struggling to understand basic health-related information [23,24].

Study objectives

Upon effective implementation of the ISO 7101 standard, an organization should be able to show objective evidence that they have satisfied requirements of the standard, and that the system is effective. With a new standard in the market, the question remains: "How do we know that implementation of the standard is effective in satisfying requirements of the standard and producing desired outcomes?" In the particular case of ISO 7101, subclause 8.10.5, objective evidence would consist of verification that implementation of HL requirements did have a positive effect on HL. In an attempt to answer this question, this study had three objectives: 1) describe the process of implementing ISO 7101 subclause 8.10.5, 2) determine if there was a relationship between the implementation of ISO 7101 subclause 8.10.5 Health literacy and pre- and post-implementation general HL scores, and 3) determine the effects of implementation on patients' perceptions of quality of care received.

Methods

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Study design

This quasi-experimental, non-randomized study lasted for 12-months between April 2023 - 2024. It was approved on 16 March 2023 by the Government of Aragon, Department of Health, CEICA following law 14/2007, 13 July for Biomedical Investigations and Applicable Ethics Principals, with approval number PI23/083. It was further approved on 23 February 2023 by the Aragones health services (Salud) to be conducted in the Hospital Clínico Universitario "Lozano Blesa." Participants received a verbal overview of the study, a take home copy of the protocol, and all signed informed consent.

The sample consisted of patients who regularly attended one of the following clinics: Diabetes, Ostomy, Cardiology, and Digestive. Inclusion criteria were: 1) age 18 or older, 2) willingness to complete the HLS_{19}-Q12 survey two times (pre-and post-implementation), and 3) the patient had the necessity to make three visits to the consultation within the 12-month period of data collection. There was no other exclusion criteria.

Using G*Power (version 3.1.9.7) to calculate sample size, it was determined that to achieve 80% power, detect a large effect, at a significance level of 0.001, a minimum of 15 participants were needed [25]. To recruit the participants, the principal researcher visited each consultation on predetermined days each week, following the schedule for eight months. Patients with appointments on those days who met inclusion criteria were asked to participate. 166 patients met selection criteria and agreed to participate. All patients took the initial health literacy survey; however, after participant loss, pre-and-post surveys were collected for 134 patients. Loss was due to, 1) the patient not attending all

their medical appointments, or 2) their responses to the HLS$_{19}$-Q12 did not meet the scoring criteria for valid responses as defined in the scoring sheet [26].

Statistics

Data was analyzed using IBM SPSS 27. The Shapiro-Wilk test was used to determine normality of distribution. For patients' general HL scores (before and after the implementation of ISO 7101 clause 8.10.5 Health literacy), the Shapiro-Wilk test results were not significant (HLS19_Q12p_score_1 p = 0.316; HLS19_Q12p_score_2 p = 0.082), therefore paired samples t-test was used. In the case of perception of quality of care (pre- and post- implementation), the Shapiro-Wilk test results did not follow a normal distribution, hence, Wilcoxon signed-rank test was used. Cohen's d was considered to have a large effect size when $d \geq 0.8$. We also added a page to the HLS$_{19}$-Q12 to capture information to construct a sociodemographic profile of the participants (Supplementary Information 1).

Assessment of general health literacy

The HLS$_{19}$-Q12 measures comprehensive, general HL and solicits responses regarding an individual's ability to access, understand, evaluate and use health information regarding health care, disease prevention, and health promotion [26]. It was chosen to assess general HL because it had been validated internationally in 17 countries with adult participants 18 years of age and older. Cronbach alphas coefficients in all countries ranged from 0.67 to 0.87, indicating internal consistency for most countries. It was also validated with various types of data collection, which was important for our study given that data was collected face-to-face [27]. Further, it was an attractive survey as it has only

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12 items, which is a feasible option for healthcare providers and patients who have limited time [28,29].

The four-point Likert scale allowed for participants to respond to questions choosing, 'very difficult.' 'difficult,' 'easy,' 'very easy,' and 'I don't know.' Participant responses were used to calculate their general HL score. Using Type P calculations, scores were calculated as the sum of the item's numeric values scaled to a range from 0 to 100 [27]. A response was considered invalid if the participant answered, 'I don't know.' Two or more invalid responses disqualified the survey. Scores were then categorized based on the following scale: > 83.33 = Excellent, > 66.67 and ≤ 83.33 = Sufficient, > 50 and ≤ 66.67 = Problematic, and ≤ 50 = Inadequate.

Assessment of patients' perceptions of quality of care received

Patient perception of quality of care received was assessed on a four-point Likert scale by responding to the statement, "*Based on your perceptions regarding quality of care, the quality of care you receive in this outpatient clinic is:*" No quality(1), Low quality(2), Medium quality(3), High quality(4). As the main focus of the study was to examine the effects of implementation of 8.10.5 Health literacy, this study did not take a deep dive into the dimensions of quality, and did not use a validated assessment for measuring perception of quality. Doing so would have lengthened the survey considerably.

Results

Research objective 1: Describe the process of implementing ISO 7101 subclause 8.10.5

The first step was to implement ISO 7101 subclause 8.10.5 Health literacy in the specialty consultations. This subclause required that healthcare workforce receive education to

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become health literate, and to use HL strategies to educate service users. Eight nurses from the selected consultations agreed to participate in the study and received HL training. These nurses were the only nurses providing care in the included consultations.

Training occurred face to face in a group format with an instructor who was an expert in HL, wrote healthcare standards, and was also a nurse. The course included an overview of the definition of HL, the importance of HL, descriptions of populations at risk for low HL, strategies clinicians could use to improve patients' HL, role play of HL strategies among nurses (with some acting as patients), and nursing feedback regarding the HL checklist they would be using in the study (Table 1).

The quality management system described in ISO 7101 requires a strong expression of top management commitment. To achieve this, the Director of Nursing delivered a message regarding the importance of the implementation of the checklist, highlighting the potential to improve service user HL, and produce results that could provide evidence for best nursing practice. In a further show of commitment, two nurse managers attended. These managers verbalized support and participated in training, but were not involved with patient care.

Inclusion of patients and caregivers

Subclause 8.10.5 requires that populations served, including patients, caregivers and family members, be considered in the design and provision of services. This was achieved by using a checklist that was prescriptive, but open enough to address the expressed needs and concerns of service users at that moment of interaction. The checklist encouraged patients to ask for additional information, talk about their emotional status,

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explore their use of social media for health information, and 'show back' care techniques they learned. Nurses were not just *telling* the service user *what to do*, but rather including them in the process by switching the aim of the conversation to *'how can we work together?, and what do you need from us?'*

Confirmation of understanding of health information

Subclause 8.10.5 e) requires the use of HL strategies in communications with confirmation of understanding. This was accomplished by nurses asking questions from the checklist such as "*Do you understand all the follow-up instructions and details for your next appointment?*", "*Have you understood all the information from the doctor (if there has also been a consultation) and from me today?*", and "*What are the questions you have about your health situation or medication?*"

Use of a wide range of health literacy skills

Subclause 8.10.5 requires that clinicians provide service users with education regarding prevention and management of their current or potential conditions, while using a range of HL skills. This was also accomplished through the checklist. During each patient appointment, nurses were required to ask a series of questions, and also choose from a varied list of educational strategies to use with the patient.

Table 1 Health literacy checklist

Questions to ask at each visit	Asked? Y or N	Nurse's Initials	Comments (if needed or desired)
What are the questions you have about your health situation or medication?			
What kind of additional information do you think might help you manage your situation?			
If there is a caregiver at the time of the consultation, ask them (where appropriate) if they have questions or need more information about handling the situation. (Put NA if no caregiver is present)			
Have you understood all the information from the doctor (if there has also been a consultation) and from me today?			
Do you know what to do or where to go in case of an emergency?			

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	Completed Y or N	Nurse's Initials	List the methods used and the visual aid used in the boxes below
How is your mood or emotions and how could I help you or recommend resources?			
Do you use media as a source of health information, and if so, do you have any questions about what you've heard or read?			
Summarize the most important points of that day's visit. Examples: • Today we talked about . . . • Now you know how to. . . • Remember . . .			
Do you understand all the follow-up instructions and details for your next appointment? **Make sure the patient has 2 more appointments scheduled**			
Actions to be taken on each visit	**Completed Y or N**	**Nurse's Initials**	**List the methods used and the visual aid used in the boxes below**
Choose at least one on each visit: 1. Teach back (Verbal) 2. Show back what you have learned (Action)			
Use one or more visual aids 1. Educational Brochure 2. Poster 3. Notes from the visit 4. Computer Image 5. Picture on phone or app 6. Physical model or device			

Implementation of the HL checklist

Next, implementation was directed towards patients. At the beginning of their first visit, each patient was asked to complete the HLS_{19}-Q12. During the next three consultations, the nurses used the checklist as part of implementation. After the third use of the checklist, patients completed the HLS_{19}-Q12 again (Figure 1).

10
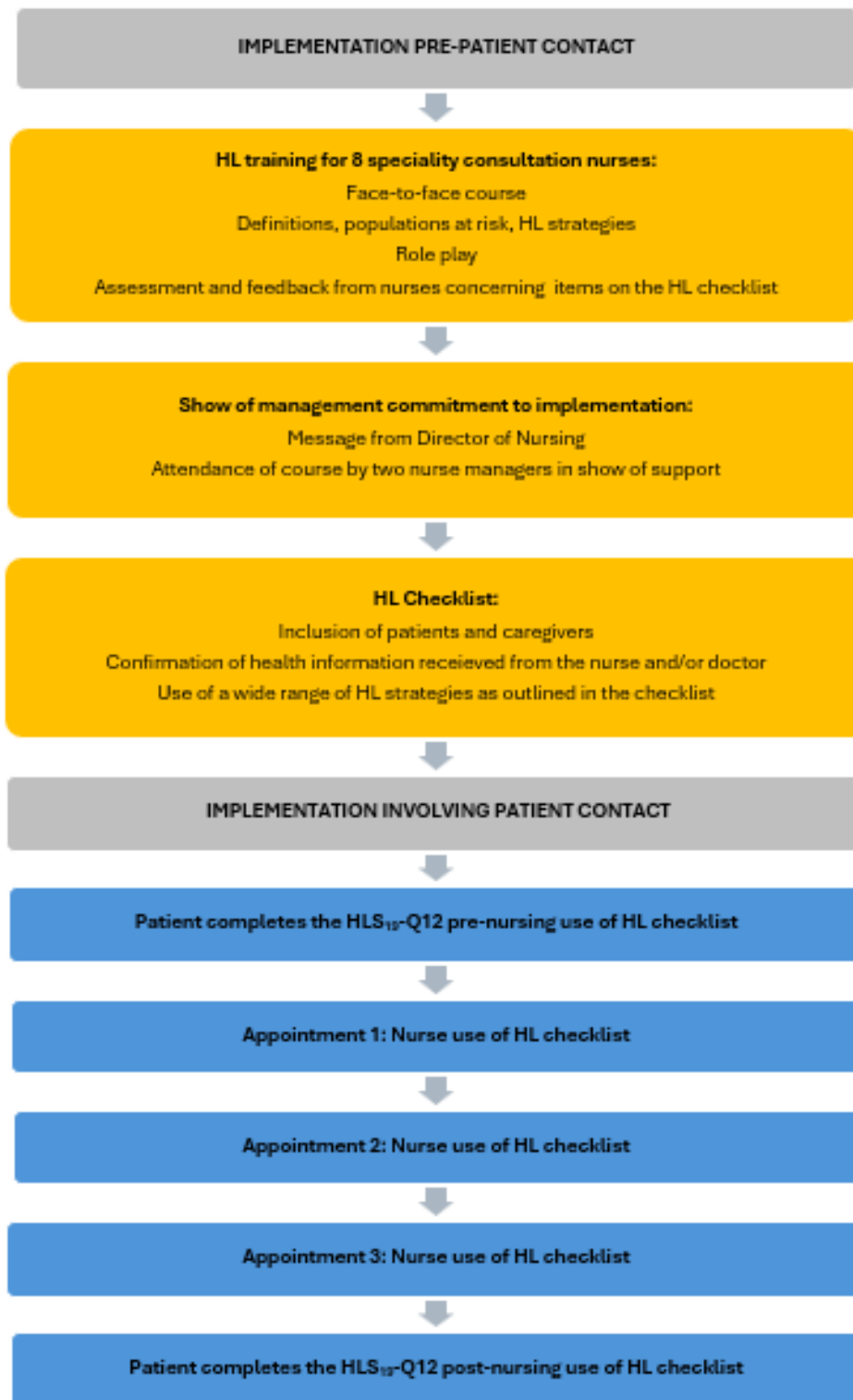
Fig. 1 Process flow implementation of ISO 7101 subclause 8.10.5 Heath literacy

Research objective 2: Determine the relationship between implementation of ISO 7101 subclause 8.10.5 Health literacy and pre- and post-implementation general HL scores

According to the paired sample statistics, the mean general HL score of sample patients increased after the implementation of ISO 7101 subclause 8.10.5 Health literacy from 66.35 to 76.29, with a mean increase of 9.94. This difference was statistically significant (t = -10.00, *P*<.001), meaning that there was a significant effect of the implementation of ISO 7101 subclause 8.10.5 Health literacy on patients' general HL scores (Table 2). Moreover, Cohen's *d* was -0.86, which is considered a large effect size. Wilcoxon test demonstrated the significant difference between scores observed before and after implementation (z= -7.12, *P*<.001).

Table 2 Statistical results for general HL scores pre-and post- implementation of subclause 8.10.5

	Mean	Median	Std. Deviation	Std. Error Mean					
HLS_{19}-Q12 score pre-implementation	66.17	66.67	13.62	1.09	95% Confidence Interval of the Difference			Significance	
					Lower	Upper	t	One-Sided p	Two-Sided p
HLS_{19}-Q12 post-implementation	75.89	75.76	9.95	0.83					
Paired Differences pre-post implementation	-9.94		11.50	0.99	-11.90	-7.97	-10.00	P<.001	P<.001

			Stder*	Point Estimate		
Paired Samples Effect Sizes HLS_{19}-Q12 score pre- and post-implementation	Cohen's d		11.50	-0.86	-1.06	-0.66
	Hedges' g		11.57	-0.85	-1.05	-0.66

HLS$_{19}$-Q12 score pre-and post-intervention Wilcoxon Signed Ranks Test	Z	Asymp. Sig. (2-tailed)
	-7.12[b]	P<.001

a. Standardizer. The denominator used in estimating the effect sizes. Cohen's d uses the sample standard deviation of the mean difference. Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor.
b. Based on negative ranks.

This study also analyzed pre- and post-implementation general HL scores according to sex and gender. All participants identified as cisgender. Both men and women experienced increases in HL scores. The mean score for women was 68.07 pre-implementation and 75.45 post. Pre-implementation mean score for men was 65.81 and 76.25 post.

The HLS$_{19}$-Q12 scoring divides scores into categories of HL described as 'inadequate, problematic, sufficient, and excellent.' Before implementation, 11% of the total sample had general HL that was categorized as 'inadequate.' Post implementation, there were no patients classified as having 'inadequate' HL (Figures 2,3). Combined 'sufficient' and 'excellent' scores improved from 41% to 75%.

13
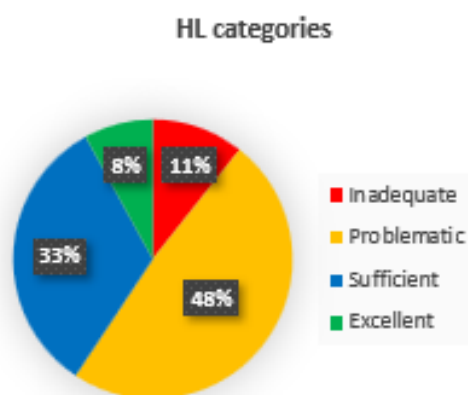
Fig. 2 Patient general HL pre-implementation
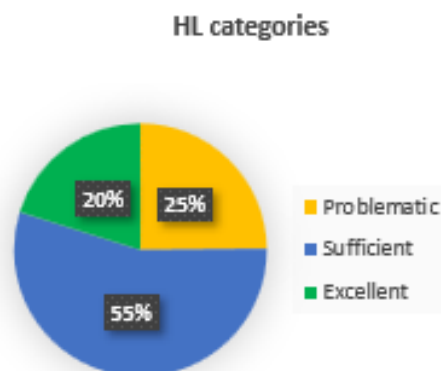
Fig. 3 Patient general HL post-implementation

Research objective 3: Determine the relationship between implementation of ISO 7101 subclause 8.10.5 Health literacy and patients' perceptions of quality of care received.

Pre-and post-implementation data regarding quality of care was available for 152 participants. Mean score of perception of quality of care improved after the implementation (M = 3.87 to M = 3.99). The Wilcoxon test revealed a significant difference (Z = -3.90, *P*<.001) meaning that the effect of the implementation of ISO 7101 subclause 8.10.5 Health literacy on the perception of quality of care was statistically significant (Table 3). While 18 individuals ranked the quality of care higher post implementation, 133 participants reported no change in their perceptions.

Table 3 Statistical results perception of quality of care received pre-and post-implementation of subclause 8.10.5

	Mean	Std. Deviation	Minimum	Maximum
Perception of quality of care received pre-implementation	3.87	0.33	3	4
Perception of quality of care received post-implementation	3.99	0.08	3	4

		Ranks		
	Negative Ranks	1[a]	10.00	10.00
Perception of quality of care received pre-and post	Positive Ranks	18[b]	10.00	180.00
	Ties	133[c]		
		Z	Asymp. Sig. (2-tailed)	
Wilcoxon Test[d]		-3.90[d]	P<.001	

a. 2_Perception of quality of care received < Perception of quality of care received.
b. 2_Perception of quality of care received > Perception of quality of care received.
c. 2_Perception of quality of care received = Perception of quality of care received.
d. Based on negative ranks.

Discussion

This study had three objectives. We endeavored to describe the implementation steps of ISO 7101 standard subclause 8.10.5. We evaluated the effect of implementation on patient pre-and post-implementation HL scores, and we examined the effect of implementation on patients' perceptions of quality of care received.

Studies have described implementation of other well-established standards such as ISO 9001; however, at the time of this study, there was no information available about ISO 7101. This is believed to be the first published work [14]. Our description of implementation serves as an example to other organizations of what worked well.

As previously argued, individuals with low or inadequate general HL are often less likely to utilize preventive services, adhere to medical instructions, take medications properly,

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or seek medical information. This can contribute to a higher reliance on emergency services, increased hospital readmissions, and increased healthcare spending[22,30,31]. Our results suggest that trained practitioners who consistently adhere to the requirements in ISO 7101 subclause 10.8.5 may contribute to improvements in patient HL, thereby minimizing the negative effects of low HL.

One goal of ISO 7101 is to improve quality of care. This study assessed subjective, patient perspectives of quality of care received. On a four-point scale with 4 being the highest quality level, the mean score was very high before intervention (3.87). This could have been the result of various factors. The appointments were held at specialty consultations, where the care is usually more individualized, and clinicians may have more time to spend with their patient. Patients with chronic conditions tend to have regular repeat visits to specialty consultations. They may begin to cultivate relationships with the clinic staff and healthcare providers. Based on their deeper relations with these providers, perceptions of quality of care could be higher [32].

This investigation provides decision making data for governments at the health systems level. When policy makers convene to discuss guidelines and policies that should be followed by their service providers, information regarding the implementation of ISO 7101 as compared to other healthcare standards is valuable. Importantly, the implementation of subclause 8.10.5 presents a possible new strategy to confront the problem of low HL across Europe [23,33].

Limitations and future research

In this study, only subclause 10.8.5 of the standard was implemented. The complete ISO 7101 standard should be implemented and studied in a healthcare organization. This would provide a more holistic and realistic view of the overall results that the standard may yield. It would also be valuable to repeat this type of investigation in a general care setting such a primary care clinic or in a hospital.

With regard to the study design, there was no control group of patients. This made it challenging to establish causality and reduced the confidence that the improvement in HL scores was not influenced by external factors. Another limitation was lack of control over differences among nurses and their teaching methods. Some nurses may have been more effective in using the checklist, which could have led to increases in HL scores only with their patients.

Quality management systems standards should produce sustained improvement over time. This study examined a period of one year, which is short for an ISO management systems standard. Further research should take a longitudinal lens, looking at sustainability of implementation and longer term outcomes.

Conclusions

This study revealed two major findings. First, the implementation of ISO 7101, subclause 8.10.5 Health literacy had a significant, positive effect on general HL scores. Second, implementation had a positive effect on patients' perceptions of quality of care received. This is believed to be the first academic research published regarding the implementation

of the ISO 7101 standard, and these findings can be used to inform decision making by healthcare policy makers and management.

Declarations

Transparency declaration

The corresponding author, on behalf of the other authors, guarantees the accuracy, transparency and honesty of the data and information contained in the study, that no relevant information has been omitted and that all discrepancies between authors have been adequately resolved and described.

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Appendix A

HLS$_{19}$-Q12 English version

It is not always easy to get understandable, reliable, and useful information on health-related topics. With the following questions we would like to find out which tasks related to handling health information are more or less easy or difficult. On a scale from very easy to very difficult, how easy would you say it is ...

	Very difficult (1)	Difficult (2)	Easy (3)	Very easy (4)	Don't know (5)
... to find out where to get professional help when you are ill? (1)	○	○	○	○	○
... to understand information about what to do in a medical emergency? (2)	○	○	○	○	○
... to judge the advantages and disadvantages of different treatment options? (3)	○	○	○	○	○
... to act on advice from your doctor or pharmacist? (4)	○	○	○	○	○
... to find information on how to handle mental health problems? (5)	○	○	○	○	○
... to understand information about recommended health screenings or examinations? (6)	○	○	○	○	○
... to judge if information on unhealthy habits, such as smoking, low physical activity or drinking too much alcohol, are reliable? (7)	○	○	○	○	○
... to decide how you can protect yourself from illness using information from the mass media? (8)	○	○	○	○	○
... to find information on healthy lifestyles such as physical exercise, healthy food or nutrition? (9)	○	○	○	○	○
... to understand advice concerning your health from family or friends? (10)	○	○	○	○	○
... to judge how your housing conditions may affect your health and well-being? (11)	○	○	○	○	○
... to make decisions to improve your health and well-being? (12)	○	○	○	○	○

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Appendix B

HLS₁₉-Q12 Spanish version

No siempre es fácil conseguir información comprensible, fiable y útil sobre temas relacionados con la salud. Con las siguientes preguntas queremos averiguar qué tareas relacionadas con el manejo de la información sanitaria son más o menos fáciles o difíciles. En una escala de muy fácil a muy difícil, ¿cómo de fácil diría que es …

	Muy difícil (1)	Difícil (2)	Fácil (3)	Muy fácil (4)	No lo sé (5)
… encontrar dónde obtener ayuda profesional cuando se está enfermo? (1)	○	○	○	○	○
… comprender la información sobre qué hacer en caso de emergencia médica? (2)	○	○	○	○	○
… juzgar las ventajas e inconvenientes de las distintas opciones de tratamientos? (3)	○	○	○	○	○
… seguir los consejos de su médico o farmacéutico? (4)	○	○	○	○	○
… encontrar información sobre cómo actuar ante problemas de salud mental? (5)	○	○	○	○	○
… entender la información sobre las revisiones o chequeos médicos recomendados? (6)	○	○	○	○	○
… juzgar si la información sobre hábitos poco saludables, como el tabaquismo, la escasa actividad física o el consumo excesivo de alcohol, es fiable? (7)	○	○	○	○	○
… decidir cómo se puede proteger ante una enfermedad utilizando la información que publican los medios de comunicación? (8)	○	○	○	○	○
… encontrar información sobre estilos de vida saludables como el ejercicio físico, la alimentación sana o la nutrición? (9)	○	○	○	○	○
… entender los consejos sobre su salud de sus familiares o amigos? (10)	○	○	○	○	○
… juzgar cómo las condiciones de su vivienda pueden afectar a su salud y bienestar? (11)	○	○	○	○	○
… tomar decisiones que mejoren su salud y bienestar? (12)	○	○	○	○	○

Translation provided by the Hamburg Center for Health Economics. The HLS₁₉ Consortium of the WHO Action Network M-POHL (2022): The HLS₁₉-Q12 Instrument to measure General Health Literacy. The survey can only be used with permission of the HLS₁₉ consortium. https://m-pohl.net/tools.

Appendix C

Published articles additional information

Journal name	Article title	Quartile / SCI	Impact factor / JCR	Journal subject areas	Justification co-authorship
Public Health (Elsevier)	Validation of the Spanish version of the Health Literacy Survey (HLS$_{19}$-Q12) in secondary care specialty consultations	*Public, Environmental & Occupational Health (61/408; Q1)*	3.9	public health theory, models and frameworks, epidemiology, need or impact assessments with a strategic/population level focus, management and re-design of health and social care services/support, wider determinant services such as education, welfare, employment services to improve public health, health protection including control of communicable diseases, health promotion, disease prevention, development of public health programs, health governance	**A. McCaskill:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. **A. Gasch-Gallen:** Conceptualization, Methodology, Writing – review & editing, Supervision. **J. Montero-Marco:** Conceptualization, Methodology, Writing – review & editing, Supervision
BMC Public Health (Springer Nature)	Measuring general health literacy using the HLS$_{19}$-Q12 in specialty consultations in Spain	*Public, Environmental & Occupational Health (85/408; Q1)*	3.5	social determinants of health, the environmental, behavioral, and occupational correlates of health and disease, and the impact of health policies, practices and interventions on the community	**A. McCaskill:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. **A. Gasch-Gallen:** Conceptualization, Methodology, Writing – review

					& editing, Supervision. **J. Montero-Marco:** Conceptualization, Methodology, Writing – review & editing, Supervision.
BMC Nursing (Springer Nature)	The effect of nurse health literacy interventions on patient health literacy scores in specialty consultations: a quasi-experimental study	*Nursing (15/193; Q1)*	3.5	evidence-based nursing care; nursing research methods; nursing service delivery, utilization, and evaluation; nursing administration and human resources	**A. McCaskill:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. **A. Gasch-Gallen:** Conceptualization, Methodology, Writing – review & editing, Supervision. **J. Montero-Marco:** Conceptualization, Methodology, Writing – review & editing, Supervision.
Journal of Healthcare Quality Research (JHQR) Elsevier **(In manuscript preparation prior to publication)**	Effects of implementation of ISO 7101 subclause 8.10.5 Health literacy on patient general health literacy scores, and perceived quality of care in specialty consultations in Spain	*Health care Sciencies & Services (145/174; Q4)*	1.1	public health and health administration, including health education, epidemiology, medical statistics, health information, health economics, quality management, and health policies	**A. McCaskill:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. **A. Gasch-Gallen:** Conceptualization, Methodology, Writing – review & editing, Supervision. **J. Montero-Marco:** Conceptualization, Methodology, Writing – review & editing, Supervision.