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Advancing Health Literacy research and practice across different Public Health domains

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Ad Alice, tutte e due

“Medicine is a social science and politics is nothing else but medicine on a large scale. Medicine as a social science, as the science of human beings, has the obligation to point out problems and to attempt their theoretical solution; the politician, the practical anthropologist, must find the means for their actual solution”

Rudolf Virchow

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Summary

Health Literacy is defined as the set of “knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course” and, due to its importance has become a central topic in Public Health research and practice. The research activities carried out during my PhD focused on advancing existing knowledge and practical solutions offered by the Health Literacy research field within different Public Health domains, namely the quality management of Healthcare Organizations, Disease Prevention, and Health Promotion, all of which requiring different approaches and tailored solutions. In the first chapter of this thesis, an overview of the Public Health domains is provided, together with a brief introduction to the history of the concept of Health Literacy. The following three chapters present an overview of the PhD research activities, which were developed and adapted accordingly to the specific characteristics of the Italian Public Health context. In total, four studies are presented: a first study attempting to validate a Health Literacy screening tool for clinical settings, a second study developing an organizational self-assessment tool on Health Literacy practices, a third study developing a questionnaire to measure Vaccine Literacy, and a fourth study validating a rating scale of eHealth Literacy. Finally, the last chapter provides an overview of the implications of the study findings for future Public Health research and practice.

Key words: Public Health, Health Literacy, Healthcare, Disease Prevention, Health Promotion

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Chapter 1. Health Literacy as a Public Health goal

This chapter will provide the reader with an overview of Public Health, discussing the difference between its three domains of action, along with an introduction to Health Literacy, by outlining a brief history of the concept and its relevance in Public Health research and practice. Finally, the chapter defines the scope of the current dissertation by providing an overview to the various research activities carried out within the PhD project.

1.1 Introduction to Public Health, definitions and domains

Public Health, while being mostly renowned to the public for its medical aspects and consequences (e.g. control of epidemics), is a discipline that covers an extremely large and varied field of research and practice. While many different definitions exist, the most concise and effective one was proposed in 1998 by Nutbeam in the World Health Organization (WHO) "Health Promotion Glossary" (1), adapting from a previous definition by Acheson (2):

> Public Health is the science and art of preventing disease, prolonging life and promoting health through the organized efforts of society.

Later on, in 2011 the WHO in its "Glossary of globalization, trade and health terms" expanded the definition, providing also a general description of Public Health activities (3):

> "Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Activities to strengthen public health capacities and service aim to provide conditions under which people can maintain to be healthy, improve their health

and wellbeing, or prevent the deterioration of their health. Public health focuses on the entire spectrum of health and wellbeing, not only the eradication of particular diseases. Many activities are targeted at populations such as health campaigns. Public health services also include the provision of personal services to individual persons, such as vaccinations, behavioral counselling, or health advice.

While these specifications may help in better understanding Public Health real-life practice, they still don't provide a clear differentiation between different areas of action, that should in turn be covered by different health services. Of course, it is impossible to completely overcome this issue, as Public Health actions are very context-dependant, the possibilities being affected both by the health-related issues at stakes, and by the infrastructural, cultural, human and financial resources available. The complex relation between health-related needs and the Public Health actions needed to address them often makes it very difficult, when not straight impossible, to draw any comparison on Public Health action outcomes in significantly different context. It is important to stress that, at a societal level, any given health-related issue should always be considered as competing for resources and attention with other societal needs, which may or may not be health-related. In this sense Public Health plays an important role in shaping the societal and political agenda, by identifying health-related needs, and advocating for actions aimed at tackling them.

A clearer schematization of Public Health can be obtained by identifying different Public Health domains or macro-areas, encompassing all the spectrum of Public Health research and practice. These domains are the following (4):

1. **Health Promotion**, also referred to as Health Improvement. This domain covers all activities that are aimed at improving population health and reducing health inequalities at the population level. Actions in this domain require working with partners not only in the

health sector, but in other public and private contexts such as schools and workplaces. It also involves engagement with the community, targeting structural health determinants (e.g. access to food, housing, employment), as well as working with individuals and their families within the communities to improve health through the adoption of healthier lifestyles.

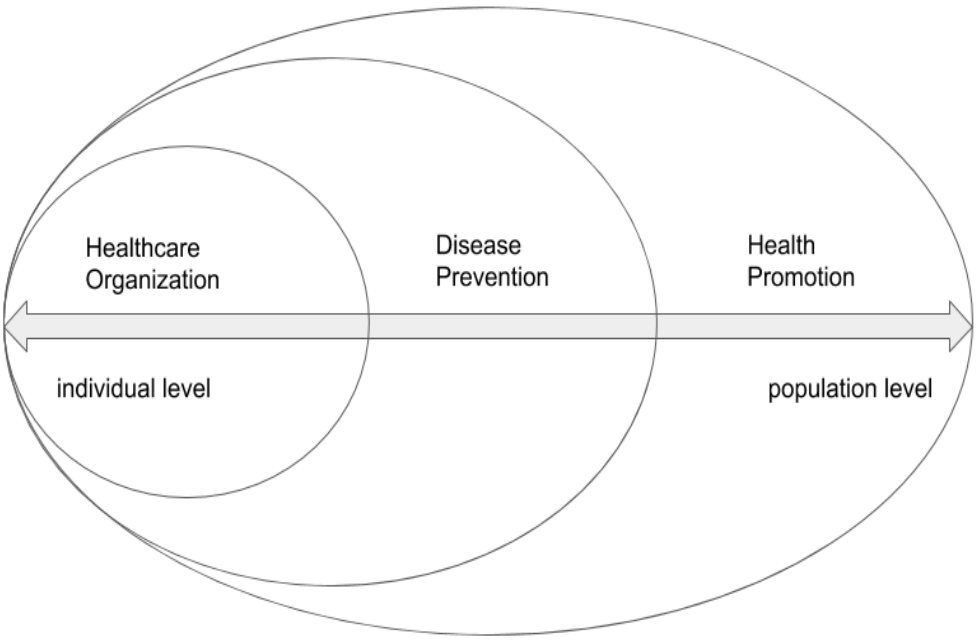
2. **Disease Prevention**, also referred to as Health Protection. It includes all actions taken for the prevention and control of communicable diseases. It deals with the regulation for clean air, water and food as well as preventing or managing environmental health hazards. It also provides preventive and security services for possible diseases caused by chemicals or radiations, as well as responses to emergencies, disasters or-bioterrorism.

3. **Healthcare Organization**, also referred to as Health Service Quality Improvement. It includes all activities that aim at improving healthcare delivery, by promoting quality standards of care and patient safety and supporting the adoption of clinically effective and evidence-based care practices. Public Health activities in this domain can be carried out at different levels, from the planning and prioritization of services, to the auditing and evaluation of the provided healthcare services.

While it is true that most Public Health activities can be clearly attributed to one of these domains, it is also true that in case of complex public health actions (e.g. actions aimed at reducing the health impact of a chronic disease) it may be difficult in practice to make a clear distinction between these domains. Instead, these three

domains should be considered in a hierarchical order since their actions are aimed at targeting the population at different scales as shown in Figure 1. In this sense, Health Promotion should be considered the domain with the wider scope, as its actions target the whole population, whereas Disease Prevention mostly focuses on healthy subjects that comprise the majority of the population, while downscaling again we reach Healthcare Organization that focuses its action only on the sick individuals.

Figure 1. Hierarchical representation of the three Public Health domains



1.2 Health Literacy: concept history and evolution

In the process of modernization that took place over the past century, western societies were able to overcome most of the “traditional” health issues affecting them, such as the heavy burden of infectious diseases, early childhood mortality, and, in general, all the consequences of poor nutrition and sanitation that are still affecting several contemporary “third world” societies. While an in-depth analysis of the complex societal changes that took place as a result of this phenomenon is outside the

scope of this dissertation, it is important to understand that the current health-related needs western societies are facing are all relatively new, as the societal context is also changing, with a transition into an “aging society” with a rising burden of chronic, non-communicable diseases. Also, the situation is worsened by important lifestyle changes that also took place in recent years, most notably with issues due to unhealthy dietary patterns, use of tobacco, drugs and alcohol starting from an increasingly young age, and a general reduction in physical activity at the population level.

The shift towards chronic health-related needs brought a change in the delivery of healthcare services, which adapted accordingly by offering an ever-increasingly specialized care. This process increased the complexity of the healthcare systems involved in the care process, which underwent a sort of “industrial revolution”, with a growing need for standardization and quality management (5). Almost paradoxically, while it is well accepted that this process is a necessary step to reach a better delivery of healthcare services, from the layman perspective this process multiplied the difficulties in the navigation of the same healthcare services. A few examples of these new difficulties are the increased accessibility to difficult-to-understand medical information, choices between different treatment options, increase in “bureaucratic” paperwork and, in general, more informed decisions to be taken with the direct involvement of the patients.

Thus, in modern societies, citizens have an ever-increasing responsibility in making correct health-affecting choices in order to provide at best for the protection and maintenance of their own health, those of their relatives, of their community, and of the society as a whole. In this context, issues connected to the correct use of health-related information by the public have also become more an- more central to the Public Health discourse. Most of these issues are now included, although in different forms, under the term “Health Literacy”.

Not surprisingly, the term Health Literacy first made its appearance within the academic Public Health field in a 1974 paper by Simonds titled “Health Education as a Social Policy”. In his paper Simonds argued in favor of introducing health education in national policies including a broad range of different stakeholders: health insurance system, healthcare, education, and mass communication industry (6). More specifically, he coined the term “health literacy” to describe specific health-related standard school curricula, recognising that health education should encompass a wide range of disciplines, including social, medical and life sciences. Simonds identified improvements in health literacy as the final outcome of the health education process, comparing health literacy to the already established “literacies” in education, like use of language (“literacy”) and mathematical skills (“numeracy”).

In the following years, the term began to be employed in clinical context within the healthcare field, mostly referring to the patient’s ability in understanding and applying medical terms and information. During the ’80s, the usage of the term stood firmly close to its educational counterparts, as it referred almost exclusively to the patient’s ability in reading medical documents (e.g. medical appointments, hospital brochures, discharge letters, etc.) and doing basic numerical operations for medical purposes (e.g. counting pills, managing drug administration patterns, etc.) (7). In these first years, a large number of tests and measurement tools for health literacy were developed, with Health Literacy measures being interpreted into an “ability deficit” framework: the focus of these measures was to highlight a low level or an absence of proper health literacy, which was seen as a risk factor for the health of the individual taking the test.

A first major event that opened the way for different views in the field of Health Literacy happened only years later, in 1991, when the American National Literacy Act first adopted a broader definition of the term “literacy” (8):

> "…the term "literacy" means an individual's ability to read, write, and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential"

As the definition of the generic term "literacy" broadened, and the use of the term "Health Literacy" gained traction within academia, different interpretations and definitions of health literacy emerged. These new definitions surpassed the previously healthcare-oriented ones, by stating that health literacy not only referred to the ability of using medical information in healthcare settings, but also to the ability of obtaining, processing, and understanding health-related information in order to make the correct choices to promote and maintain good health (9). This change also brought other important consequences in the development of the concept of health literacy, most notably by proposing a new "ability asset" framework, which regarded health literacy not only as a risk factor for the individual, but also as an ability that could be improved to empower individuals in controlling personal, social and environmental determinants of health (10).

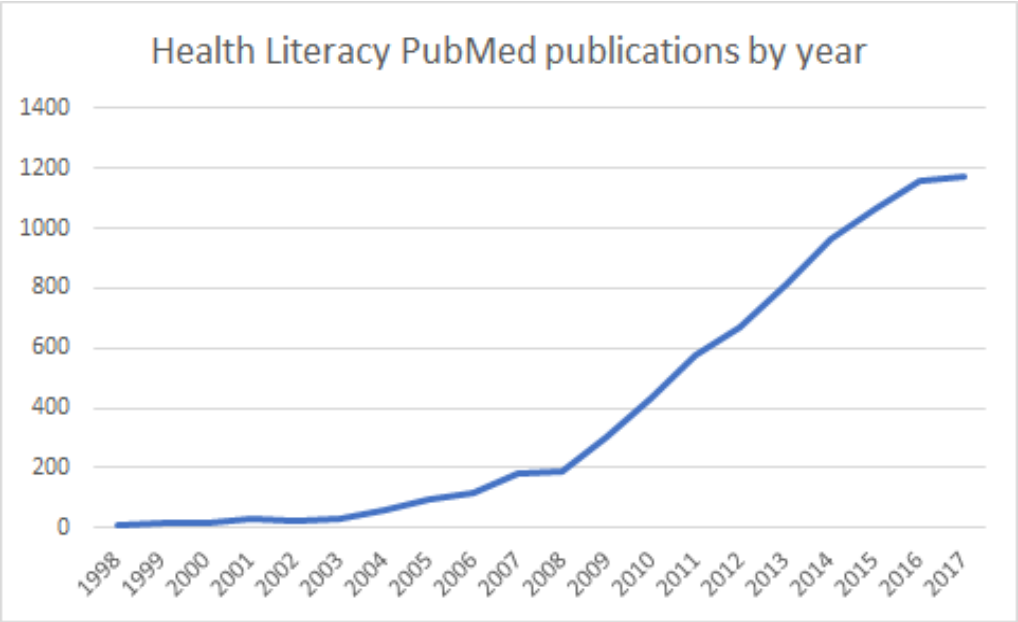
Following this new conceptualization, in 1998 the WHO proposed its definition of health literacy in its health promotion glossary:

> "Health literacy implies the achievement of a level of knowledge, personal skills and confidence to take action to improve personal and community health by changing personal lifestyles and living conditions. Thus, health literacy means more than being able to read pamphlets and make appointments. By improving people's access to health information, and their capacity to use it effectively, health literacy is critical to empowerment. Health literacy is itself dependent upon more general levels of literacy.

> Poor literacy can affect people's health directly by limiting their personal, social and cultural development, as well as hindering the development of health literacy" (11).

Since then, the number of published papers referring to Health Literacy has been growing on a yearly basis. A non-exhaustive, yet suggestive figure of this phenomenon can be easily drawn by the number of papers published in PubMed in the last 20 years (from 1998 to 2017, total=7293), represented in Figure 2.

Figure 2. Number of HL papers published in PubMed (1998-2018)



As the term Health Literacy was adopted in different research fields, an even higher number of theoretical models, definitions, and measurement tools appeared, all of which indiscriminately going under the same name "Health Literacy". While these all maintained some core principle of the original definition, they were also differentiated according to the previous theoretical frameworks of the various research fields. As a consequence, Health Literacy is often a source of confusion and

debate among scholars coming from different backgrounds, making it harder to compare study results, most notably because of the different definitions and theoretical frameworks used in different studies, along with the absence of a gold standard in the choice of the measurement tools used (12 13 14 15).

It is possible, however, to highlight some well-established health-related outcomes of a low Health Literacy:

- worse physical and cognitive status, especially in the older segments of the population (16,17);
- lack of knowledge of one's own health issues, with low self-management skills both in case of acute and chronic issues (18,19);
- worse overall quality of life, with higher morbidity and mortality (20-23)
- scarce adoption of healthy lifestyles (24)
- increased, inappropriate use of healthcare services (e.g. emergency care) (25);
- low medication adherence and increase in drug-related problems (25,26);
- low use of preventive services (e.g. screening programs) (27)
- ineffective communication with health professionals (28,29)
- increased work inability, due to long-term medical conditions and poor health (30)

The consequences of all these health-related outcomes also contribute to an overall increase in healthcare expenditure, with costs for both the individual and the society as a whole (31). Such an argument had the power to resonate within the Public Health field to a level that in 2004 the Institute of Medicine described the high

prevalence of low health literate US citizens as a “silent epidemic”. In the years, a number of authors tried to estimate healthcare costs of a low level of HL, and in 2009 Eichler et al. conducted a first systematic review on the subject, evaluating such costs to be around 3 to 5% of the total healthcare expenditure (32).

1.3 Relevant Theoretical Models of Health Literacy in Public Health

While this dissertation is not be concerned with a specific discussion of the theoretical models for Health Literacy, it is necessary to point out that some models and definitions have been more widely accepted than others and are now relevant in the field of public health. For the purpose of the current dissertation, I would refer to two of these “general” Health Literacy definitions.

The first definition which is relevant to Public Health has been proposed by Nutbeam in 2000 (33) and describes three different “types”, or “levels” of health literacy (basic/functional, communicative/interactive, critical). These can be considered as hierarchical levels, with an increasing need for personal empowerment of the subject in order to be able to protect and improve health both at a personal and at the community level:

- **Basic/functional literacy**. Basic skills in reading and writing, sufficient to be able to function effectively in everyday situations, broadly compatible with the narrow definition of ‘health literacy’ referred to above.

- **Communicative/interactive literacy**. More advanced cognitive and literacy skills which, together with social skills,

can be used to actively participate in everyday activities, to extract information and derive meaning from different forms of communication, and to apply new information to changing circumstances.

- **Critical literacy**. More advanced cognitive skills which, together with social skills, can be applied to critically analyze information, and to use this information to exert greater control over life events and situations.

The second and more recent definition was proposed by Søresen et al. in 2012 (12) and is the result of a review and integration of 17 different definitions, also providing a comprehensive theoretical model for future research. The resulting definition reads:

> "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 judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."

This definition clearly appears as being the most comprehensive and useful in Public Health actions as all the three previously described domains of Public Health are represented on the same level. The same authors proposed an adaptation of this definition, that could be used to make the Public Health approach easier to understand, from a population to an individual level, by substituting the words "...healthcare, disease prevention and health promotion..." with "...being ill, being at risk and staying healthy...". According to the definition, the theoretical model

proposed also identifies a “core process” of Health Literacy, which is described as a cyclic activity that requires four different competences:

1. “Access”, as the ability to seek, find and obtain health information;
2. “Understand”, as the ability to comprehend the health information that is accessed;
3. “Appraise”, as the ability to interpret, filter, judge and evaluate the health information that has been accessed;
4. “Apply”, as the ability to communicate and use the information to make decision to maintain and improve health.

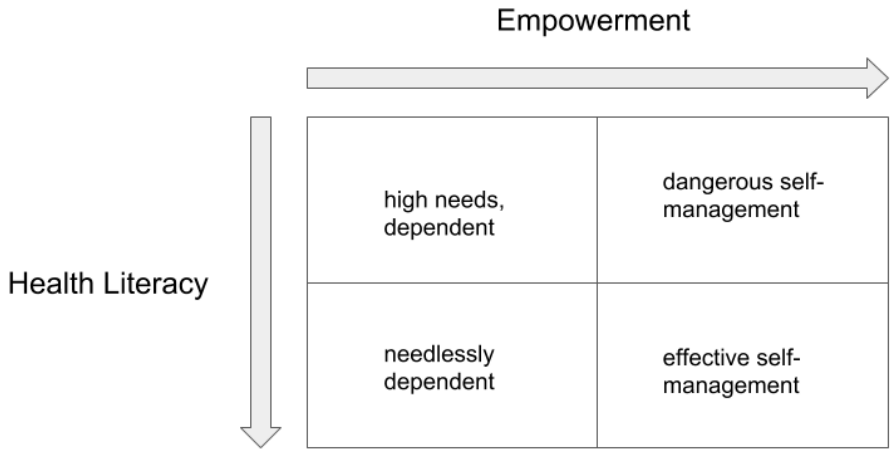
These competences should not be regarded as fixed or immutable, as they are developed in time and are determined by the cognitive and psychosocial status of the subject. Also, past and new personal experiences and learning processes play a role in shaping the competences through the life course. All these factors influencing these Health Literacy competences are described in the theoretical model as “antecedents”, that are subsequently divided into “proximal antecedents” and “distal antecedents”. Proximal antecedents refer both to personal factors (e.g. age, ethnicity, gender, socioeconomic status, education, working status, psychological characteristics, cognitive, social and physical skills) and situational factors (e.g. current status of social support, media use, peer influence, past experiences), while distal antecedents refer to social and environmental determinants of health (e.g. demographic and cultural factors, language, political issues, presence of Public Health actions or lack thereof, national policies).

A final remark concerning the evolution of the conceptualization of Health Literacy should cover its relationship with another concept which is sometimes erroneously interpreted as being the same: the concept of empowerment (usually

referred to as patient empowerment, or psychological empowerment). It is not rare that Public Health practitioners, researchers or other stakeholders (e.g. public administrators, policy makers) use these two terms interchangeably, referring to the ability to undertake political and social actions to protect and promote individual or community health (34). While it may be unclear at first, as these two term clearly appear to be intertwined, there are important differences that should be clarified before proceeding in the dissertation: while in an Health Literacy-based approach it is envisaged that the subject first reaches a certain level of self-awareness, necessary to proceed then to the understanding of what is relevant for one's health, in an empowerment-based approach the specific knowledge to make an informed choice could be overlooked, and the action would instead focus on ensuring that the subject is able to make the choice he wants, independently of its health consequences.

A clear and actual example of the difference between Health Literacy and empowerment can be seen in relation to child immunization and parent's vaccine hesitancy, an occurrence that has increased in recent years in developed countries. In this case, it is self-apparent that a higher level of individual empowerment (i.e. parents being able to opt out vaccination) is not in direct relation with choices that have positive health consequences, both for their children and for the community. In the case against child immunization, hesitant parents do not take into consideration that vaccination led to the virtual elimination of a number of severe child diseases, and that there is no evidence of the link between vaccination and childhood autism disorder, information that requires at least a basic level of health literacy to be understood and acted upon. Figure 2 shows the relationship between health literacy and empowerment, as already discussed by Schultz and Nakamoto (35).

Figure 2. Relation between Health Literacy and Empowerment



1.4 Measuring Health Literacy - differences between measures and what they tell us

As mentioned previously, a large number of different Health Literacy measurement tools have been developed and tested over the years, adapting to the different approaches (e.g. clinical settings, population-based surveys) and the underlying theoretical frameworks. It is important to note that, due to the complexity of the theory behind Health Literacy and its continuous adaptation to the needs of an evolving context of health information (e.g. the availability of online health information), it has been impossible to develop a one-fits-all measure of Health Literacy. Thus, different measures have been proposed for different purposes on a case-by-case basis, trying to adapt the tool used (e.g. questionnaire, interview, screening tool) to capture different features and characteristics of the underlying Health Literacy construct measured (e.g. by differentiating between different health literacy types, levels or required abilities). Due to the huge number of different Health Literacy measures available at present (over 100 in October 2018), this dissertation will only cover the most relevant ones, both in terms of historical value, as these

measures represent the foundation of the science of Health Literacy, and in terms of relevance to the Public Health field. A semi-complete collection of published instruments, collected in an online database of the University of Boston, is available for free at https://healthliteracy.bu.edu/.

While it can be said that there is no such thing as a "gold standard" Health Literacy measure, it is also true that during the years some measurement tools for Health literacy have been preferred over the others. In particular, two Health literacy instruments developed during the 90' became widely used:

1. the Rapid Estimate of Adult Literacy in Medicine (REALM, 1993) (36). One of the first measures specifically developed for Health Literacy, the REALM is a reading test composed of 66 items (health-related words) that should be read aloud by the subject and carefully rated by an interviewer as correct answers or errors. The test is designed for adult subjects, and provides a functional measure of Health Literacy by assessing the subject's reading skills and knowledge of health-specific vocabulary;

2. the Test of Functional Health Literacy in Adults (TOFHLA, 1995) (37). Developed shortly after the REALM, the TOFHLA is a two-section, 67-item test. The first section is composed by 50 cloze items, with words related to health and use of healthcare services. The second section is composed by 17 open-ended questions testing the numeracy skill of the subject in health-related tasks (e.g. calculating the correct time to take pills or dates for medical examination). The test is designed for adults and, while it is preferably administered

by an interviewer, it can also be adjusted to be used as a self-administered test. This test provides a functional measure of Health Literacy by assessing knowledge of health-specific vocabulary and numeracy skills.

It is important to note that these two tests have been used in the large majority of empirical health literacy research, and studies using these two measures make up a large portion of the findings that are present in the scientific literature, so their results are still relevant to the Health Literacy discourse. Also, many of later developed instruments share the structure of these two "classic" tests, so that in the course of time it has become a common occurrence referring to other tests as being REALM- or TOFHLA- based.

Over the years, however, with new definitions being proposed and expanding the conceptual borders of Health Literacy, it has become apparent that these two tests presented some limitations that should be acknowledged:

- first, and as already discussed in the introduction, they were able to identify an "ability deficit" but could not be easily used to assess improvements in the same ability, thus limiting their use when Health Literacy was conceptualized in an "ability asset" framework. The "ability deficit" framework became less and less adopted over the years as its shortcomings became more apparent in clinical practice. In fact, the use of Health Literacy "deficit" tests in clinical practice was not well received by patients and in the end did not lead to any relevant improvement in the clinical practice of healthcare professionals, with "universal precautions" being proposed as the most effective solution to communication issue (38);

- a second limitation was due to the fact that the two measurement tools were developed within a clinical setting, with the presence of particular requirements for the administration of the test (e.g. presence of a healthcare professional as the interviewer, little time constraints) which limited the transferability of the test use to different Public Health activities (e.g. population-based surveys);

- a third, and possibly most important limitation lies in the fact that both tests are only able to capture functional aspects of Health Literacy (13), leaving out a whole spectrum of different Health Literacy "levels" (communicative, critical) as proposed by Nutbeam (33), or "abilities" as proposed by Søresen et al. (12).

Despite these limitations, these tools can still be considered useful as they are able to collect an objective measure of functional Health Literacy, and this is the reason why similar limitations can be also found for some of the more recently developed measurement tools (e.g. METER, Newest Vital Signs). At present, there are two alternative relevant methods worth mentioning that are being used to create rating scales in order to provide a measure of Health Literacy:

- Subjective tests. These methods include all those measurement tools that, instead of trying to assess the actual ability of the users, are designed to capture the self-referred ability as perceived by the subject. While the subjective nature of the measure can be regarded as a weakness, an important reason why these tests can be a useful tool in public Health research and practice is that these measures are better suited

to capture the “social” vs. the “individual” aspect of Health Literacy, and are therefore better suited to study environmental factors that contribute to Health Literacy. In this sense, subjective measures can be more useful to understand accessibility issues to health information or services, that may be due to differences in the design of the health information, or in the organization of a particular healthcare service. Also, these tests are usually much easier to administer and can be easily adapted to be used in population-based studies (e.g. conducting surveys).

- Knowledge tests. These represent an interesting and useful alternative to measuring Health Literacy as they tend to be easy to develop and can usually be used as self-administered tools. Usually these tests are composed by items represented by questions with only one correct answer (either yes/no or multiple choice), focusing on a specific subject that is assessed in depth, from symptoms recognition to self-management (9). These instruments have been developed for a number of subjects, for example diabetes (39), back pain (40), asthma (41), heart failure and hypertension (42), and they are especially useful when designing educational interventions that are targeted at the specific needs of patients. Moreover, these measures can be a useful outcome indicator when evaluating such interventions. However, the narrow scope of these tools also represents a limitation in itself, as it is unable to capture a general, non-situational (e.g. diabetes-related knowledge of diabetic patients), Health Literacy skill. In case of an action aimed at a specific disease or condition, these

measures are considered as outcomes, while other measures should be used to control for their moderating effect.

The presence of different methods, all used to yield measures which are indistinctly reported as “Health Literacy”, generates an inevitable confusion when trying to compare study results, or when conducting literature reviews to generate stronger evidence. For the purpose of this dissertation, Health Literacy measures collected with instruments that provide an assessment of objective abilities will be named “objective”, while the self-referred ones will go under the name “subjective” Health Literacy measures. In case the measurement tool employed in the study did only provide an assessment of health- or disease-specific knowledge, it won’t be directly referred as Health Literacy.

1.5 Scope of the current Thesis

The research objective of the PhD was to explore different possibilities in advancing Health Literacy in Public Health research and practice within the three previously described domains, in order to provide further guidance for the development of practical solutions to be used across, or specifically designed for, very different settings.

One of the reasons behind the choice for such a broad scope is the fact that, in Italy, Health Literacy as a Public Health issue is still an under-recognized and under-researched scholarly field. Even in the presence of available data (e.g. poor general literacy and numeracy (43) and the occurrence of recent events (important decrease of vaccination coverage and the introduction of compulsory vaccination (44), that are suggestive of an underlying Health Literacy issue for Italy, only few studies have already been published, and to date little is known about the Health Literacy of the general Italian population (or specific segments of it).

Another reason, which is also connected to the previous one, is the current scarcity of validated Italian versions of Health Literacy measurement tools. During the PhD project, I worked on the validation of a number of different tools, which - depending on their features - could be better suited for different purposes, and consequently for the further advancement in Health Literacy research and practice within a particular Public Health domain. As there is no such thing as a one-fits-all Health Literacy measure, the broad range of possible Public Health actions across different domains makes it imperative to use different tools and rating scales, which should be chosen accordingly to the specific needs of the proposed action. For example, an objective measure would be useful when there is a need to assess differences in individual skill levels that may have affected the impact of a certain action in an homogeneous population, while a subjective measure could be more appropriate when evaluating the impact of an action aimed at improving the accessibility of a new or renovated healthcare service. Therefore, the availability of translated, culturally-adapted and validated Health Literacy measurement tools is a prerequisite to successfully advance Health Literacy research and practice in Public Health. In 2015, at the beginning of the PhD project, there was only one published Health Literacy measurement tool which had been translated and validated for an Italian population (45), while another one had only been adapted for the Swiss-Italian population (46), and it had the limitation to be dependent on the characteristics of the Swiss healthcare organization, as some items of the tool directly referred to insurance reimbursements that are very context-specific. The initial scarcity of available measurement tools shaped a consistent part of the PhD activities, with alternating successes and failures in the development and use of different tools.

The last but not least reason for the variety in this dissertation is that covering all three Public Health domains permitted to avoid pauses and interruptions. Conducting research in Public Health is a complex and time-consuming process, due to the relatively long time required to conduct an original research in Public Health, and the difficulties that arises when cooperation with other stakeholders is needed to

successfully conduct the research (e.g. municipality in the case of public health promoting activities, local health authority for disease prevention, hospital management for healthcare organization, etc.). During the PhD project, it was possible to find at least one research activity for each one of the three Public Health domains. However, as discussed, a prerequisite to secure collaboration with other stakeholders (at the local, national or international level) was to make the research relevant to all actors involved. As every stakeholder could only invest a limited amount of resources in the research activity, it was easier to find more stakeholders across different Public Health domains instead of many stakeholders in only one domain.

All these factors contributed to shape the PhD project during these three years, resulting in a broad research activity which, starting from the necessary research needed for the Italian adaptation of Health Literacy measurement tools, spread out to cover all three Public Health domains. This wide scope had the obvious limitation of not achieving conclusive results for any of the domains under investigation, yet it managed to develop a foundation for future Health Literacy research and practice for Public Health professionals in Italy, working either in Health Promotion, Disease Prevention or Healthcare Organization.

Table 1 presents an overview of the research activities conducted within the PhD project for the three Public Health domains, conveniently divided into different studies. Each study is reported with a brief description of the study aim, research questions, actions and tools, methods, and study results. As a single study could be designed to answer to multiple research questions, each research question is also presented separately. In the following chapters, one for each Public Health domain, a report of each of these studies is provided, with a description of the context and study rationale. For each study, a number of relevant research questions have been identified, which are then presented by describing the methods used to answer them and summary of the results, together with possible implications for future Public Health research and practice.

Table 1. Studies conducted as PhD research activities

PH domain - study aims	**Research question**	**HL actions and tools**	**Methods**	**Results**
Healthcare organization study 1 - Validation of two different screening tools (NVS and Brief Health Literacy Screener) for the usage in the Italian adult population accessing healthcare services	1) Is the NVS tool able to effectively discriminate between different levels of Health Literacy?	The NVS is an objective, interview- based HL screening tool that provides an objective measure of general HL	Descriptive analysis, comparison with expected results from prior studies	Positive results. The NVS has a sufficient capacity to discriminate different HL levels and can be considered a valid tool.
	2) Is the Brief Health Literacy Screener test valid for the Italian population as it is proposed in its final form, or is there the need to identify different items, better suited for the Italian population?	The Brief Health Literacy Screener is a subjective, interview- based HL screening tool that provides a measure of general HL	Replication of the original study by Chew et al., and selection of useful items by assessing specificity and sensitivity in comparison to the NVS	Negative results. It was not possible to replicate the original study results. Also, no item proposed in the original study, taken singularly or in combination, showed sufficient specificity and sensitivity to be considered valid.
Healthcare organization study 2 - Development of a self-assessment tool to evaluate compliance to quality standards for Health Literate Organizations (HPH-HLO)	1) Are the proposed quality standards of the HPH-HLO self-assessment tool applicable in the context of Italian Healthcare quality management?	The HPH-HLO self-assessment tool is an instrument proposed by the HPH international network of the WHO, which has been proposed as a quality management tool for healthcare organizations	Translation and discussion over the standard applicability with Italian healthcare quality managers with experience in international accreditation. Consensus among the international working group	Project still ongoing. This project, initially intended to produce a first approved version of the HPH-HLO tool by early 2018, experienced some delays. The final version was only delivered at the end of July 2018, and it was not possible to test it in a real Healthcare organization setting.
	2) How can the standards be used to assess changes over time and system readiness?	The HPH-HLO self-assessment tool is not yet designed to be able to capture system readiness in relation to the proposed standards	Revision of the whole HPH-HLO tool and proposal of a different format organized according to a Plan, Do, Check, Act framework	Positive, preliminary results. It was possible to produce a revised version of the tool. However, there was no possibility to further test the revised format for the timing of delivery of the final version of the HPH-HLO tool. (see research question 1))

<u>Disease Prevention study 1 -</u> Validation of an Italian measurement tool of Vaccine Literacy (IT-VLq) based on the Ishikawa HL questionnaire in an Italian population of parents of children aged 0-8	1) Is the IT-VLq tool a valid instrument to measure Vaccine Literacy?	The IT-VLq is a subjective, self-administered tool that provides several measures of HL which are specific to vaccination	Psychometric validation of the scale, by evaluating its factorial structure and internal consistency	Positive results. The IT-VL-q showed good psychometric properties and, in its two dimensions (functional and critical-communicative) can be considered a valid tool as a subjective measure of Vaccine Literacy
	2) What is the relation between Vaccine Literacy (IT-VLq) and HL (IT-S-TOFHLA)?	The IT-S-TOFHLA is an objective, self-administered tool that provides a general measure of HL	Correlation analysis (Spearman correlation coefficients) between results of IT-VLq and S-TOFHLA	Negative results. It was impossible to compare results from the two tests, as the IT-S-TOFHLA has an insufficient capacity to discriminate different HL levels and cannot be considered a valid tool to measure objective Health Literacy.
	3) What is the relation between Vaccine Literacy (IT-VLq) and vaccine related knowledge?	Vaccine related knowledge were measured using a 10-items questionnaire (vaccine quiz)	Correlation analysis (Spearman) between results of IT-VLq and vaccine related knowledge	Mixed results. While the functional dimension of VL was found to be positively related with vaccine-related knowledge, no relation was found for the critical-communicative dimension
	4) Does Vaccine Literacy of parents relate with the immunization status of the children?	Immunization status of the children was assessed in relation to compliance to the local vaccination schedule	Correlation analysis (non- parametric) between the results of IT-VLq and immunization status of the children	Mixed results. It was possible to establish the relation between higher subjective Critical-communicative Vaccine Literacy and vaccine hesitancy, while no relation was found for the functional dimension of Vaccine Literacy. Parents with higher levels of Vaccine Literacy were found to be less compliant to recommended vaccinations for their children.

Health promotion study 1 - Translation and validation of the Italian version of the eHealth literacy scale (IT-eHEALS)	1) Is the IT-eHEALS tool a valid instrument to measure eHealth Literacy?	The IT-eHEALS is a subjective, self-administered tool that provides a measure of eHealth Literacy.	Psychometric validation of the scale, by evaluating its internal consistency	Positive results. The IT-eHEALS showed good psychometric properties and can be considered a valid tool as a subjective measure of eHealth Literacy
	2) What is the relation between eHealth Literacy (IT-eHEALS) and functional HL (studying or working experiences in the healthcare sector)?	Studying or working in the healthcare sector can be considered a proxy measure of higher functional HL. A higher level of functional HL should correlate with an higher eHealth Literacy.	Correlation analysis (non-parametric) between experiences in the healthcare sector and results of the IT-eHEALS	Positive results. The study found evidence of a strong relation between eHealth Literacy and Health Literacy, supporting the founding theoretical model and further validating the eHEALS as a measure of subjective eHealth Literacy

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Chapter 2. The role of HL in the quality management of Healthcare Organizations

HL is of specific importance within healthcare, because persons with limited HL are less likely to use preventive services, tend to request treatment at later stages, and have more hospitalizations, a higher risks of incurring in medical treatment errors and sub-optimal outcomes as compared to persons with better HL (1). HL thus significantly contributes to healthcare quality and patient safety. Public Health activities in Healthcare Organizations aim at improving healthcare delivery and can be carried out at different levels. HL-oriented communication with patients contributes to patient satisfaction (2), reduces the likelihood of malpractice claims (3) and improves work satisfaction of the staff (4-6). Based upon the relational understanding of HL, HL can be improved not only by training individuals but also by reducing the administrative, bureaucratic and cognitive demands of healthcare systems and organizations and offering compensatory support, e.g. making relevant information easily accessible, or applying principles of simple language in written and oral information, etc. In this context, from an initial use of HL measurement tools as instruments used in "frontline" clinical setting, HL has become more a whole organization approach, with the definition of criteria and standards defining the so-called "Health Literate Healthcare Organizations".

2.1 HL use in clinical settings

The first HL measures (REALM, TOFHLA) were developed in clinical settings, where doctor-patient communication plays a central role. The first purpose of HL measurement was to obtain an indicator of the patient's ability in the use of medical information. Such HL indicators, collected by the hospital nurse like a clinical parameter (e.g. blood pressure), were collected in the attempt to identify those patients which would require special attention when communicating clinical and health-related matters. Using such measures, healthcare professionals developed different approaches, which led to the definition of a number of so-called clinical "good practices". Examples of these practices are the "teach-back" technique and the "Ask Me 3" ® educational program, which have since then been used worldwide in the

training of healthcare professionals, in order to improve practices in doctor-, and nurse-, patient communication.

Regarding rating scales used in clinical setting, almost every measurement tool used in clinical settings was initially designed to provide an objective general HL measure, as in the case of the TOFHLA, REALM, and NVS, with new instruments being designed to be increasingly easy to administer, and less time-demanding. Among the possible drawbacks of objective HL measures there is the perception of a stigma for patients who failed at answering the questionnaires (e.g. failing to spell a medical term correctly, difficulties in reading/counting), that could in turn result in a loss of the patient's trust in the clinical process. In the pursuit of tools that not only reduced the time and difficulties related to the questionnaire administration, but also addressed this issue, subjective measures (so-called HL "screening" questionnaires), such as the Brief Health Literacy Screener (7), were developed. Moreover, in recent years an increasing number of tools has been developed targeting (and evaluating) only a specific health issue (such as diabetes literacy, BPCO literacy, cancer literacy, etc.).

While it has been argued that measuring HL has little use in clinical practice, and the adoption of so-called "universal precautions" has been proposed instead, HL measurement tools developed in clinical settings are still widely used, and HL could be an important variable within a research activity aimed at improving the quality in healthcare. Thus, the first study conducted within the PhD project aimed at the validation of an Italian version of a subjective screening HL tool, namely the Brief Health Literacy Screener, as this is one of the simplest tools to administer in a busy setting, while its design also allows for its use in telephone- or internet-based surveys. Moreover, the study aimed at providing data for a further validation of the Italian version of the NVS, which was the only available HL measurement tool in Italian at the time of the study.

2.2 HL use in Quality and Patient Safety management

As the concept of HL evolved to consider the role of the Healthcare environment in shaping one's ability in the use of health-related information, different attempts were made to practically use HL measures and related findings in the quality management of Healthcare Organizations. In this context, HL issues have been expanded to also include how Healthcare environments are structured and how this relates with the users' capacity to access and use the different services provided: the ability of the user to effectively navigate the Healthcare environment and its services, understanding and applying the information is therefore related to the very design of the healthcare organization. In this view, healthcare organizations need to be specifically designed and structure the offer of their services with the aim to favor the access of users of every possible level of health literacy, or else the positive health outcomes of low health-literate users will be systematically limited (8).

Starting from these assumptions, an effort was made in 2012 to define a set of 10 attributes that an Healthcare organization should possess in order to become a "Health Literate Healthcare Organization" (HLHO), that is, an healthcare organization that makes it easier for people to navigate, understand, and use the information and services provided to take care of their health (9). Health Literate Healthcare Organizations recognize that miscommunication that negatively affects patient care and outcomes is very common. Misunderstandings occur not only in clinical situations, such as when treatment options and medicine instructions are discussed, but also when receptionists ask for a signature on a form, or when discussing over covered services and financial responsibilities. Health Literate Healthcare Organizations also recognize that individuals who ordinarily have adequate health literacy may have difficulty in processing and using information when they are sick, frightened, or otherwise impaired. Systems must therefore be redesigned to accommodate the unpredictability of limited health literacy skills. Finally, Health Literate Healthcare

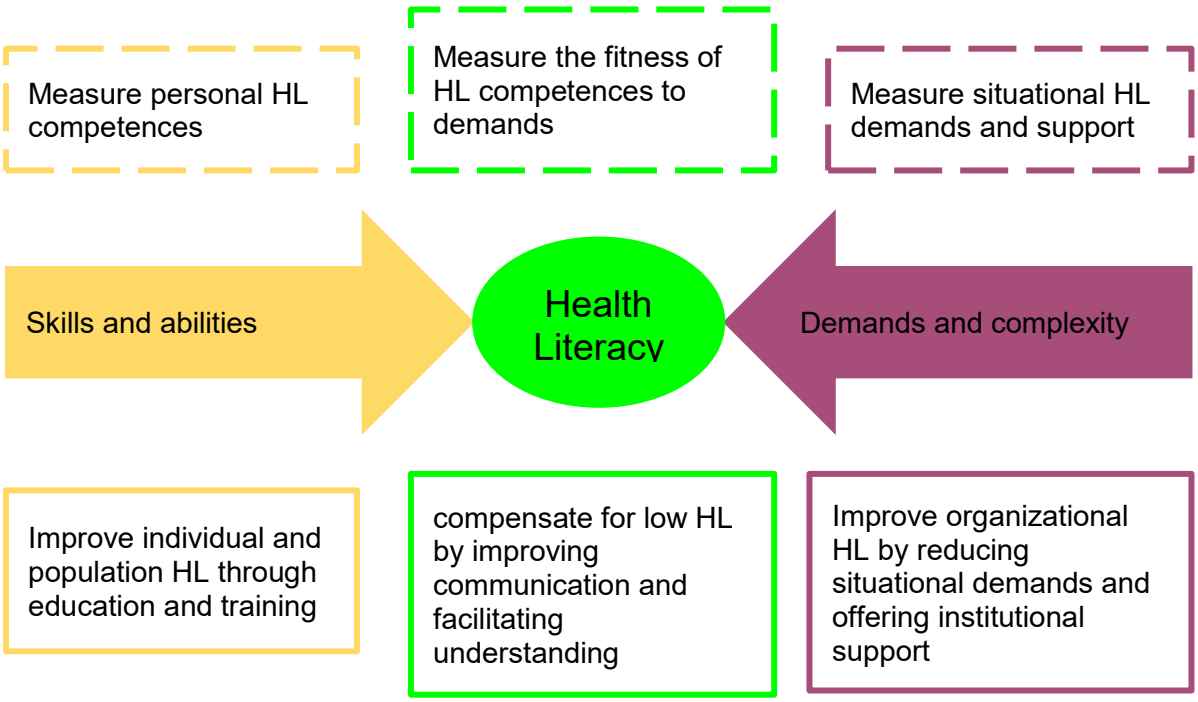
Organizations recognize that literacy, language, and culture are intertwined, and their health literacy efforts augment efforts to reduce disparities and improve the organization's linguistic and cultural competence (10,11). Under the stewardship of healthcare organizations that are committed to being health literate, everyone benefits from communication that is clear and easy to understand.

The 10 attributes of an HLHO as described by Brach are the following. A Health Literate Healthcare Organization:

1. Has leadership that makes health literacy integral to its mission, structure, and operations.
2. Integrates health literacy into planning, evaluation measures, patient safety, and quality improvement.
3. Prepares the workforce to be health literate and monitors progress.
4. Includes populations served in the design, implementation, and evaluation of health information and services.
5. Meets the needs of populations with a range of health literacy skills while avoiding stigmatization.
6. Uses health literacy strategies in interpersonal communications and confirms understanding at all points of contact.
7. Provides easy access to health information and services and navigation assistance.
8. Designs and distributes print, audiovisual, and social media content that is easy to understand and act on.
9. Addresses health literacy in high-risk situations, including care transitions and communications about medicines.
10. Communicates clearly what health plans cover and what individuals will have to pay for services.

The combination of these attributes would lead to the creation of an Healthcare environment that makes it simpler to access and use healthcare services; this should be true for all the users, regardless of their level of HL. To do so, the attributes should be acquired by applying so-called “universal precautions”, keeping in mind that anybody is at risk of harm potentially caused by ineffective communication and wrong use of the information received (12). Following the description of the ten attributes of HLHO, several different organizational tools have been developed to help healthcare organizations in their journey to become HLHO. The second study on healthcare organizations carried out during the PhD project aimed at the development of one such tool in collaboration with the Health Promoting Hospitals (HPH) Network of the World Health Organization, namely the HPH-HLO instrument. The approach of the proposed tool, illustrated in Figure 3, aims to integrate HL approaches to act both at the clinical level, addressing individual skills and abilities, and at the organizational level, by trying to reduce demands and complexity of the Healthcare Organization.

Figure 3. Approaches needed to improve Health Literacy in Healthcare Organizations



2.3 Healthcare Organization Study 1 - Validation of two different screening tools (NVS and Brief Health Literacy Screener) for use in the Italian adult population accessing healthcare service

The first study carried out as a PhD activity focused on the development of easy-to-administer rating scales to be used in clinical settings, namely the Newest Vital Sign (NVS) and the Brief Health Literacy Screener. The study aim was to answer two different research questions:

1. Is the NVS tool able to effectively discriminate between different levels of Health Literacy?
2. Is the Brief Health Literacy Screener test valid for the Italian population as it is proposed in its final form, or is there a need to identify different items, better suited for the Italian population?

Research question 1. Is the NVS tool able to effectively discriminate between different levels of Health Literacy?

The NVS is an interview-based measurement tool which seeks to provide an objective assessment of HL at the individual level, and was first developed by Weiss in 2005 (13). The subject taking the test is provided with a food label, and asked to answer a limited number of questions (five in the original formulation), whose answers can be all found on the food label (although some may require the subject to further elaborate the information). Although the correct reading and interpretation of a food label might be seen as having little to do with HL, the NVS showed a good level of correlation with the TOFHLA, and therefore was proposed as an easier-to-administer alternative to it. Due to the simplicity of the test administration, the NVS became widely used, was the first test to be translated and its Italian version had been, although partially, validated by Capecchi et al. in 2015 (14). A limitation of this first

Italian validation was that the study only aimed at assessing the face and construct validity of the tool, by collecting data from a sample of experts only. Thus, the first research activity conducted during the PhD aimed at a further validation of the Italian version of the NVS by collecting data which were representative of the Italian adult population of people accessing healthcare services and consequently testing the capacity of the tool to discriminate between different levels of Health Literacy.

The research was designed and conducted in 2016 as a part of a larger study project, which also involved the validation of another HL screening tool (see the next section on the Brief Health Literacy Screener measurement tool). Data collection activities took place at the reservation service desk located inside the Udine Academic Hospital, which provides reservation services for healthcare services for the whole regional healthcare system. From May to June 2016, a total of 221 people were asked oral and written informed consent to participate in the study, of which 141 accepted and successfully took the test, resulting in 141 NVS collected and included for further analysis. To test the capacity of the NVS to discriminate between various HL levels, we looked at their distribution in the population. Looking at results from prior studies (although not conducted in the Italian adult population), we were expecting a low HL level in more than 10% of the study population, with higher rates of low HL for older subjects. To further validate the results of the NVS, we computed Receiver Operating Characteristics (ROC) curves, calculating sensitivity and specificity for age and educational attainment levels in our sample.

HL levels of the study population in relation to different age groups are reported in Table 2. Our study sample was predominantly composed by females (61,7%; n=87), with a good representation of different age groups and HL levels. Educational attainment was divided into four different levels, according to the first stages of the Italian education system division (up to 5th grade, 7,1%, n=10; up to 8th grade,26,2%, n=37; up to 12th grade, 49,7% n=70; any graduation, 17,0% n=24) As expected,

insufficient to moderate HL levels were well represented in the study sample, with low HL levels showing an increase in frequency in relation with age.

Table 2. Study sample HL levels by age group

age	whole sample (n=141)	insufficient HL (n=33)	moderate HL (n=27)	sufficient HL (n=81)
18-45	31 (22,0%)	1 (3,0%)	6 (22,2%)	24 (29,6%)
46-64	63 (44,7%)	8 (24,3%)	14 (51,8%)	41 (50,6%)
65+	47 (33,3%)	24 (72,7%)	7 (26,0%)	16 (19,7%)

As expected, older age and lower levels of educational attainment both correlate with lower levels of health literacy. ROC curves for age and educational attainment are presented in Figures 4 and 5. Both age and educational attainment show a sufficient level of specificity and sensitivity regarding NVS results, with an Area Under the Curve (AUC) >0.7, providing further validation of the NVS as an objective measure of HL.

Figure 4. ROC curve - age (3 classes 18-45, 46-64, 65+)

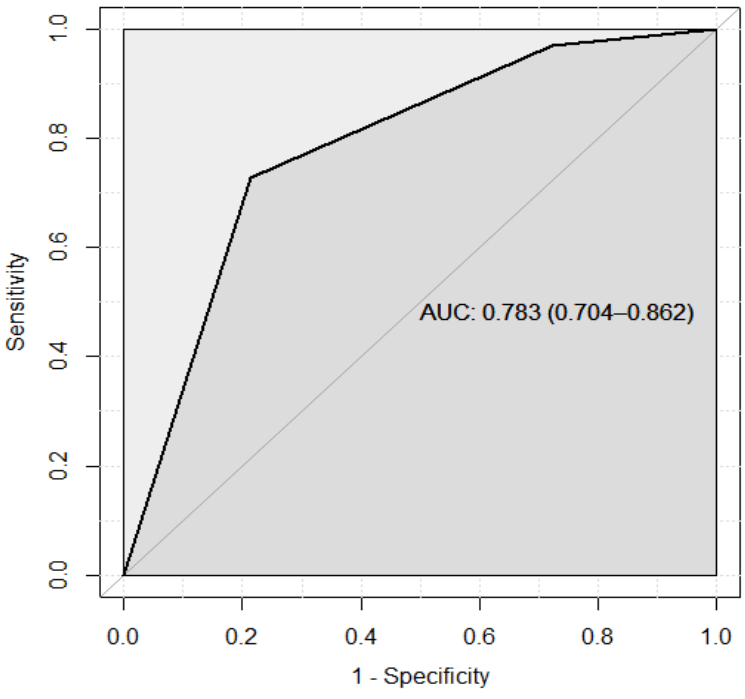
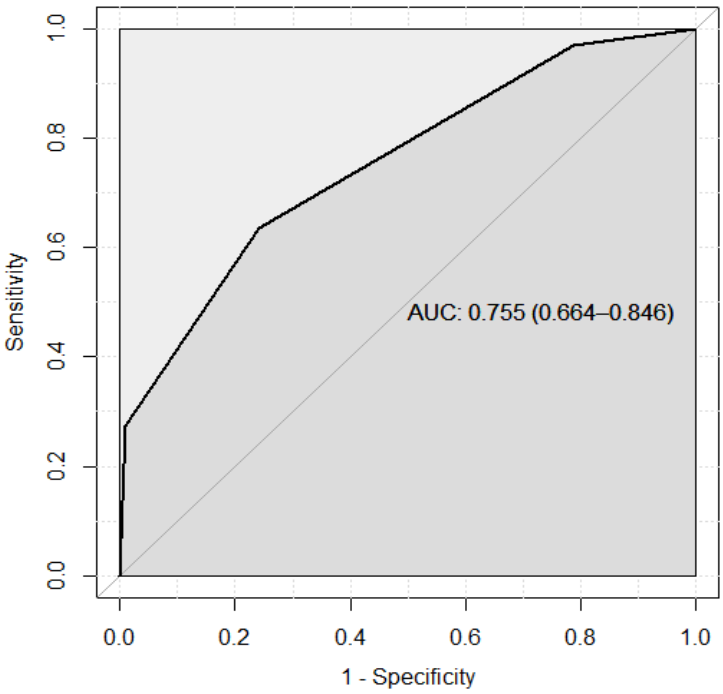


Figure 5. ROC curve - Educational attainment (4 levels)



As this first research activity was very limited in scope, no further analysis was conducted to investigate other psychometric properties of the NVS as a test. Nonetheless, our results are in line with the study that was to able verify the construct validity of the NVS, demonstrating that it can be effectively used to discriminate between various HL levels in the Italian adult population.

Research question 2. Is the Brief Health Literacy Screener test valid for the Italian population as it is proposed in its final form, or is there a need to identify different items, better suited for the Italian population?

The Brief Health Literacy Screener test is a subjective HL measurement tool developed in 2004 by Chew et al. (7) to be used as a screening tool in busy clinical settings, the main characteristic of the tool being its simple and fast administration. The tool is composed of three questions, which can be answered by the subject taking the test on a 5-point Likert scale. In the original study, the three questions were selected from a bigger pool of 16 questions, based on their capacity to predict the

same results as the S-TOFHLA, by computing the Receiver Operating Characteristic (ROC) curve for each question and selecting questions for an Area Under the Curve (AUC) > 0,7. The questions identified by Chew were:

1. “How often do you have someone help you read hospital materials?”
2. “How confident are you filling out medical forms by yourself?”
3. “How often do you have problems learning about your medical condition because of difficulty understanding written information?”

Due to its simplicity, the Brief Health Literacy Screener tool could represent a useful instrument in Public Health research (for an example of its use, see 15), since it can be proposed either in a self-administered or interview-based format, and most importantly can be easily used for data collection process in phone- or internet-based surveys. However, the original study sample recruited in the Chew study could hardly be considered representative of the population accessing Italian healthcare services, as it was almost completely composed by highly educated males (95% of males, with 85% having completed higher education). Thus, the second research activity of the PhD project aimed at the replication of the original validation study of the Brief Health Literacy Screener by Chew et al. (7), to confirm its results. Due to the limitations of the original study, another possibility that was taken into consideration from the beginning of this research activity was that our study result would differ from the original one, resulting in another set of questions out of the original 16 questions used in the Chew study.

The original Items of the Brief Health Literacy Screener were translated by the research team, following established good practices [16]: the original English questionnaire was initially distributed among the research team, producing a first set of translations that were later merged into a single draft version. The draft of the

Italian items was then back-translated into English by an interpreter and reviewed by the research team for correctness. Translated items were pre-tested for comprehensibility on a small sample of Italian adults (N=34) and were adjusted accordingly. Like the original version of the questionnaire, the questionnaire was composed of 16 items measured with a 5-point Likert scale.

Data collection activities were carried out as previously described in research question 1, and a total of 141 completed questionnaires were collected and included for further analysis. Table 3 reports the distribution of age, gender and educational attainment of our study sample compared to the original study by Chew. To test the validity of the Brief Health Literacy Screener to effectively screen for low levels of HL, we compared the results of the Brief Health Literacy Screener to those of the NVS described in the previous section, by computing specificity and sensitivity of the items and drawing for each one the corresponding ROC curve. To test the relation between HL and demographic characteristics of the study sample, ROC curves were also computed for age and educational attainment.

Table 3. Comparison of study participants characteristics

	Chew study	**Our study**
N° participants	**n=332**	**n=141**
Age, years	**n (%)**	**n (%)**
18-45	60 (18)	31 (22)
46-64	161 (49)	63 (45)
65+	111 (33)	47 (33)
Gender	**n (%)**	**n (%)**
Men	314 (95)	54 (38)
Women	18 (5)	87 (62)
Education	**n (%)**	**n (%)**

< third grade	13 (4)	10 (7)
Fourth - eighth grade	35 (11)	37 (26)
High school	126 (37)	70 (50)
> High school	158 (48)	24 (17)
Health literacy*	**n (%)**	**n (%)**
Adequate	292 (88)	81 (57,4)
Marginal	25 (7,5)	27 (19,2)
Inadequate	15 (4,5)	33 (23,4)

*Health literacy measured with S-TOFHLA (Chew study) and NVS (our study)

Results of the analysis conducted on the 16 Items of the original study by Chew, compared to those of the original study by Chew, are presented in Figures 6 and 7. Contrary to the original Chew study findings (Figure6), our study (Figure 7) could not identify any item, taken separately or in combination, with a sufficient sensitivity or specificity (AUC > 0.7) to be considered valid to be used as a screening tool for low levels of HL (using the NVS as reference).

Figure 6. ROC curves for best selected items of the original study by Chew

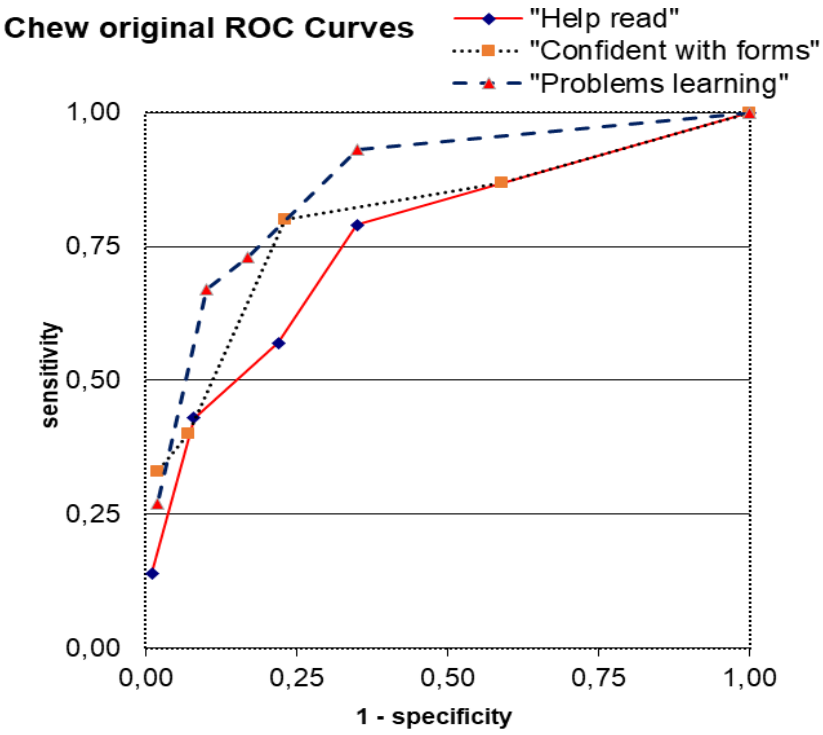
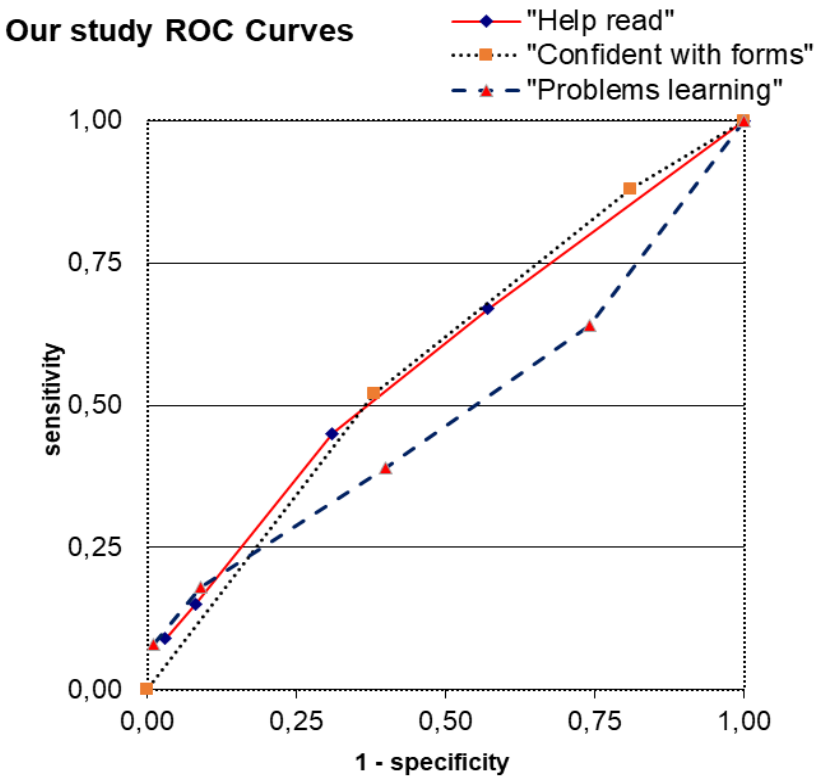


Figure 7. ROC curves for best selected items of our study



This first study presented several limitations that should be acknowledged. First of all, the recruitment method of the study sample does not allow for a generalization of our results to the whole Italian adult population. Still, the good level of response rate (65%), and the good distribution of different demographic characteristic of our sample (more diverse in comparison with the original study by Chew) could be considered representative of a population accessing the healthcare system and thus in line with the general objective of testing HL measures for the use in clinical settings. Another limitation concerns the use of the NVS instead of the S-TOFHLA as a reference measure for the validation of the Brief Health Literacy Screener. However, results to the first research question showed the good level of construct validity of the NVS, that could therefore be used as a reference measure of functional HL. Moreover, this was the first study to explore the prevalence of low levels of HL in the Italian adult population accessing healthcare services, so it was not possible to rely on prior estimates of the prevalence of different levels of HL to establish a sufficient sample size to be recruited for the study.

In conclusion, the study demonstrated the validity of the NVS as a reliable and easy-to-administer tool to evaluate HL levels. It also provided a proof of non-replicability regarding the use of the Brief Health Literacy Screener, that at the contrary cannot be considered a valid screening tool in the Italian adult population. This poses a serious question when interpreting data from other studies that did not conduct a validation before using the same measurement tool in a population different from the one involved in the original study by Chew.

Future studies should expand the use of the NVS to a larger and more representative sample of the Italian adult population, to provide a better estimate of the prevalence of low levels of HL and to further validate the NVS as a rating scale, by assessing its correlation with outcomes of clinical relevance (e.g. hospital admission, drug adherence, use of preventive services, etc.). As a general recommendation, in the absence of interventions of proven efficacy specifically targeted at low-level HL patients and considering the relative high prevalence of low HL subjects in the population accessing healthcare services, universal and organizational precautions are recommended to address HL issues in the Healthcare Organization Public Health field.

2.4 Healthcare Organization Study 2 - Development of a self-assessment tool to evaluate compliance to quality standards for Health Literate Healthcare Organizations

Following the results and conclusions of the first study, the second study focused on the development of an organizational tool to evaluate the organization's compliance to internationally recognized HL relevant standards. Compliance to these standards would require the healthcare organization to locally apply good practices implemented as universal precautions to address HL issues, based on a previously Austrian-developed self-assessment tool (17). This study was carried out in collaboration with the Health Promoting Hospital network of the WHO working group

on Health Literate Healthcare Organization (HPH-HLO) of the, coordinated by an Austrian team led by professor Jürgen M. Pelikan. The study aimed at answering two different research questions:

1. Are the proposed quality standards of the HLO self-assessment tool applicable in the context of Italian healthcare quality management?
2. How can the standards be used to assess changes over time and system readiness?

Research question 1. Are the proposed quality standards of the HLO self-assessment tool applicable in the context of Italian healthcare quality management?

Building upon "Ten Attributes of Health Literate Organizations" (8) the WHO Collaborating Centre for Health Promotion in Hospitals and Health Care (WHO-CC-HPH) in Vienna developed a self-assessment tool based upon the "Vienna Concept of a Health Literate Health Care Organization" (V-HLO) (17). However, V-HLO expands the concept of the ten attributes by introducing specific aspects relevant to HPH, including the "Five standards" published by WHO/Euro (18) and "18 HPH core strategies" (19). In addition, there is explicit reference to concepts of quality management. In detail, V-HLO specifies how healthcare organizations and systems can make health-related information more accessible, understandable, appraisable, and applicable to the three (HPH) target groups: patients, staff and citizens. V-HLO defines four action domains:

1. access to and living in healthcare organizations;
2. treatment and care;
3. disease prevention;
4. health promotion.

In order to make the concept of V-HLO applicable to the practice of healthcare organizations, an organizational self-assessment tool for hospitals as the largest

healthcare organizations was developed following criteria of the International Society for Quality in Healthcare (ISQua) process. This self-assessment tool consists of 9 standards, 22 sub-standards and 160 measurable elements. To investigate the feasibility of the self-assessment tool, nine Austrian hospitals piloted the tool (17). Results of the first feasibility study showed that:

A. the self-assessment tool is very understandable and usable for healthcare staff;
B. the items are considered as relevant;
C. the effort to conduct the self-assessment is considered reasonable;
D. variation in measurements between standards and between organizations suggest that the tool can support organizational self-assessment for planning of measures to improve organizational health literacy as well as benchmarking between organizations.

As the V-HLO has proven to be useful for Austrian healthcare services, the aim of the current study was to develop an international version of the V-HLO self-assessment tool with other countries, by translating the self-assessment tool and adapting it to other healthcare contexts (in this case, the Italian healthcare context). In order to do so, a first English translation of the original Austrian tool was circulated at the beginning of 2017 among partners for a preliminary translation and a first round of evaluation of the applicability of the standards in a different setting. The working group formed to develop the Health Promoting Hospital tool for Health Literate Healthcare Organization (HPH-HLO) involved partners from 12 different countries worldwide (US, Italy, Austria, Australia, Norway, Germany, Switzerland, Canada, Belgium, Israel, Taiwan, Denmark). More specifically, partners were asked to provide a translated version of the tool, along with comments on the feasibility of the application of the tool to the local context. Comments were required for each standard, sub-standard, and measurable item of the tool. The structure of the first version of the tool is represented in Table 4. Originally, the self-assessment tool was divided into 9 main standards, subsequently divided into 20 sub-standards, comprising a total of 160 measurable items.

Table 4. Original structure of the HPH-HLO self-assessment tool

STANDARDS	SUB-STANDARDS
1. Establish management policy and organizational structures for HL	1.1. The organization understands HL as an organizational responsibility (5 items) 1.2. The organization ensures quality assurance of HL (11 items)
2. Develop materials and services in participation with relevant stakeholders	2.1. The organization involves patient representatives in the development of materials and services (5 items) 2.2. The organization involves staff in the development of materials and services (2 items)
3. Qualify staff for health-literate communication with patients	3.1. The organization ensures that staff are trained for health-literate communication in diagnosis, therapy, treatment and care, and discharge preparation (14 items)
4. Provide a supportive environment – health-literate navigation and access	4.1. The organization ensures barrier-free contact by internet and telephone (14 items) 4.2. The organization provides all information needed for accessing the organization (6 items) 4.3. There is sufficient orientation support in the entrance area for patients and visitors to easily find their way (7 items) 4.4. The organization has an easy-to-follow navigation system and signage (7 Items) 4.5. Patients and visitors have access to free health information (5 items)
5. Apply HL principles in routine communication with patients	5.1. Face-to-face communication with patients follows HL principles (11 items) 5.2. Written and audio-visual material are designed according to HL principles (10 items) 5.3. The organization provides resources to guarantee translation support when needed (12 items) 5.4. Communication in high-risk situations follows HL principles (8 items)
6. Improve the HL of patients and significant others	6.1. Patients (and significant others) are supported to improve HL for disease-related self-management (7 items) 6.2. Patients (and significant others) are supported to improve HL for healthy lifestyles (4 items)
7. Improve the HL of staff	7.1. Staff are supported to improve the HL they need for managing job-related health risks (8 items) 7.2. Staff are supported to improve HL for healthy lifestyles (3 items)
8. Contribute to HL in the region	8.1. The organization supports HL in continuous and integrated care (11 items) 8.2. The organization contributes to the development of HL in the regional population (3 items)
9. Share experiences and be a role model	9.1. The organization supports the dissemination and further development of concepts and practice of health-literate health care (5 items)

After the initial translation of the standards, and emerging from the first round of comments, a second, more specific evaluation round was proposed. This second round was carried out by collecting more standardized feedbacks, in which each partner was requested to comment on each item of the tool using a standardized questionnaire:

1. Do you consider this standard / its sub-standards / its indicators as relevant for your healthcare system?
2. Is the wording of this standard / its sub-standards / its indicators clear enough?
3. Is it possible to easily translate this standard / its sub-standards / its indicators into your language?

The second evaluation round led to some major revisions of the tool, most notably the inclusion of a rationale for each standard, the addition of 2 sub-standards under standards 1 and 5, and the removal of 17 measurable items, which were not considered relevant by the working group. Thus, the final version of the HPH-HLO self-assessment tool (represented in Table 5) comprised 9 main standards, subsequently divided into 23 sub-standards, for a total of 143 measurable items.

Table 5. Final structure of the HPH-HLO self-assessment tool

STANDARDS	SUB-STANDARDS
1. Make health literacy a priority across all levels of the organization and across all communication channels	1.1. The leadership / management of the organization is committed to monitoring and improving organizational health literacy (4 items) 1.2. The organization accepts health literacy as an organizational responsibility (4 items) 1.3. The organization ensures the quality of organizational health literacy interventions by quality management measurement (9 items)
2. The organization involves relevant patient and staff groups by active participation in development and evaluation of specific documents, materials and its services related to	2.1. The organization involves patients in the development and evaluation of patient-oriented documents, materials and its services (4 items) 2.2. The organization involves staff in the development and evaluation of staff-oriented documents, materials and services (2 items)

promoting organizational health literacy	
3. Health literacy is part of staff development. The organization has curricula for basic and continuous staff training in patient communication following principles of health literacy	3.1. Health literacy is understood as an essential professional competence for all the staff working in the organization. This is confirmed by documents such as job advertisements, staff development plans etc. (6 items)
4. The organization is designed with features that help people find their way and uses language, symbols and signage that is easy to understand also by users with low levels of (health) literacy	4.1. The organization enables first contact via website navigation and telephone (14 items) 4.2. The organization provides the information necessary for arrival and hospital stay (5 items) 4.3. Support is available at the main entrances to help patients and visitors (7 items) 4.4. The navigation system of the organization is clear and easy-to-understand (8 Items) 4.5. Health information for patients and visitors is available for free (4 items)
5. Patient communication follows health literacy best practices. This is applicable to all forms of communication and to diverse situations, e.g. admission, anamnesis, ward rounds and discharge. Thereby, communication needs of all patient groups are considered	5.1. Spoken communication with patients is easy-to-understand and act on (9 items) 5.2. Design and distribution of written materials are easy-to-understand and act on (5 items) 5.3. Design and distribution of computer applications and new media are easy-to-understand and act on (4 items) 5.4. Information and communication in native language is offered by specific, trained personnel and material resources (11 items) 5.5 Easy-to-understand and act on communication, also in high-risk situations, is seen as a necessary safety measure (7 items)
6. The organization promotes health literacy of patients and their relatives beyond stay in the hospital (as far as possible and partly in cooperation with primary care professionals and social networks outside the hospital)	6.1. The organization supports patients in gaining and improving their health literacy with regard to their disease-specific self-management (6 items) 6.2. The organization supports patients in gaining and improving their health literacy with regard to development of more healthy lifestyles (2 items)
7. The organization promotes health literacy of staff both with regard to the self-management of occupational health and safety risks and with regard to healthy lifestyles	7.1. The organization supports staff in developing and improving their own health literacy for self-management of occupational health and safety risks (8 items) 7.2. The organization supports staff in developing and improving their health literacy for healthy lifestyles (2 items)
8. When discharged, patients are well informed about their future treatment and recuperation process. The organization is publicly engaged, and collaborates with others to improve population health	8.1. The organization promotes continuous and integrated care (11 items) 8.2. The organization contributes to the improvement of health literacy of the local population within the realm of its possibilities (3 items)
9. The organization actively supports and promotes the implementation of organizational health literacy practices beyond its boundaries in the region	9.1. The organization supports the dissemination and further development of health literacy in the region and beyond (5 items)

A consensus on the final version of the tool was reached only in July 2018, and while the first expected result of the study (a final version of the tool approved by all partners) has been achieved, the research question of the study remains at present unanswered, as it was not yet possible to test the self-assessment tool in a real healthcare organization setting, and the study is still ongoing.

Research question 2. How can the standards be used to assess changes over time and system readiness?

Figure 8 shows an example of the structure of the final version of the self-assessment tool (standard objective, rationale, sub-standard, measurable items).

Figure 8. Structure example of the final version of the HPH-HLO tool (English version)

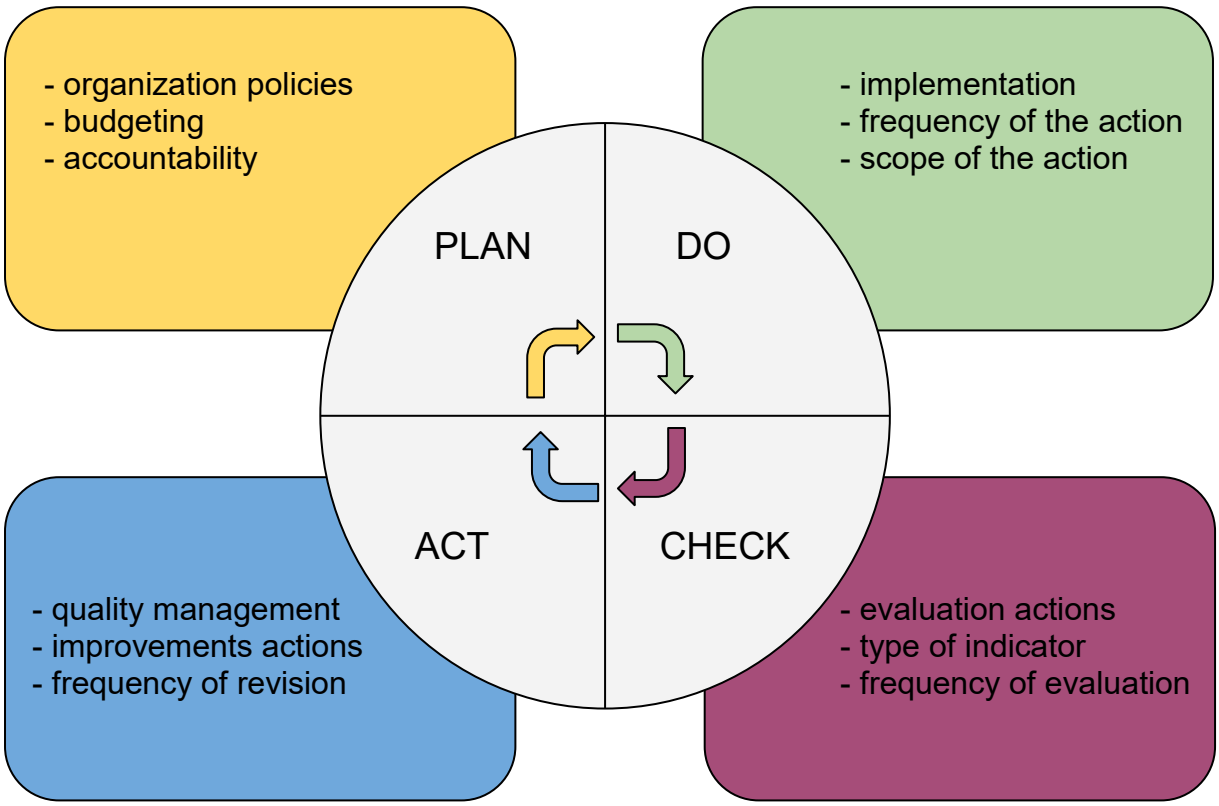
Standard 1

Objective: Make health literacy a priority across all levels of the organization and across all communication channels

Standard 1. **Organizational health literacy is integrated into organizational structures, processes, culture and assessment of the health care organization.**					
Rationale: Since health literacy of patients´ impacts outcomes of health care, health literate organizations see improving organizational health literacy (OHL) as a main value of the organization. To achieve this a health literate health care organization makes health literacy an integral element of its structures, processes, culture and assessment. This requires the management to establish and maintain a culture whereby health literacy is considered as part of all decision making within the organization. By this a health literate health care organization establishes commitment to foster and improve health literacy through health care practices employed at all levels of the organization and by integrating health literacy into planning, evaluation measures, service user safety and quality improvement (Brach et al., 2012). Health literacy has to pervade the whole organization (Brach 2017).					
Sub-Standard 1.1. **The leadership / management of the organization is committed to monitoring and improving organizational health literacy.**	**Yes** 76-100%	**Rather yes** 51-75%	**Rather no** 26-50%	**No** 0-25%	**N/A**
Indicator 1.1.1. The leadership / management of the health-literate health care organization ensures that health literacy is built into all aspects of the organization, explicitly measured, regularly monitored, and continuously improved.	☐	☐	☐	☐	☐

As it can be seen from the example above, the measurable item (indicator) of the final version of the self-assessment tool can be rated on a simple 5-item scale. While this rating method could provide a simplification when assessing the adherence to an established good practice, it can be difficult to interpret (and therefore to rate) when the measurable item does not represent a well-defined action. To overcome this issue, I proposed a practical solution by rewriting possible ratings to the tool's measurable items under a Plan, Do, Check, Act (PDCA) framework, which is designed to capture all the different moments that are relevant in establishing a good practice, and therefore could be more appropriate when assessing system readiness for a specific action (for a description of the PDCA framework see Figure 9).

Figure 9. The PDCA framework



In order to provide a proof of concept for the possibility of adapting the self-assessment tool to the PDCA framework, a revision and rework of the tool was carried out in August 2017 (using the working, interim version of the HPH-HLO tool).

Each standard was divided into four sections according to the PDCA framework:

1. **PLAN (the organization defines health literacy targets that are integrated into organization policies, human and financial resources, and quality management)**: includes indicators needed to assess the existence of organizational policies targeting HL and their integration among different services of the same organization, financial availability and budgeting for relevant actions, and identification of personal responsibility and accountability. Due to the different nature of planning activities for the different standards, the items vary widely between different standards. For an example of PLAN section, see Figure 10.
2. **DO (the organization ensures that actions are taken regarding health literacy)**: includes indicators for all actions that are relevant to current standard. This is the section where most measurable items of the original tool may be found, as most of the original self-assessment tool items represent good practices that require actual implementation. To facilitate the rating of the items, possible answers were changed as shown in Table 6. For an example of DO section, see Figure 11.
3. **CHECK (the organization ensures a quality assessment process to evaluate health literacy actions)**: includes a set of indicators which is similar for every standard, aimed at ensuring the assessment of the set-up of a specific quality management procedure for the evaluation of the actions included in each standard. This is arguably one of the most important actions when establishing a good practice at the organizational level, as the absence of an evaluation of taken actions would lead to a possible waste of resources (even in the short term, not knowing whether the practice is actually useful), and eventually to giving up good practices (in the midterm, for loss of personal and organizational commitment). To facilitate the rating of the items, possible answers were changed as shown in Table 6. For an example of DO section, see Figure 12.

4. **ACT (the organization ensures a quality process to refine health literacy actions, based on evaluation results from previous actions)**: includes indicators to assess the presence of advanced quality management processes aimed at the continuous quality improvement of the actions relevant to each standard. The presence of such organizational processes is the final aim of any quality management process and ensures the maximum level of system readiness for the implementation of good practices in healthcare organizations. For an example of DO section, see Figure 13.

Table 6. Proposed PDCA changes to the rating scales of measurable items

Original tool - all sections	**Revised tool - DO section**	**Revised tool – CHECK/ACT sections**
Yes (76-100%)	Actions are being implemented, with the involvement of the whole organization (100%)	Yes, for all structures of the organization (100%)
Rather yes (51-75%)	Actions are being implemented in most structures of the organization (>50%)	Yes, for most structures of the organization (>50%)
Rather no (26-50%)	Actions are being implemented, yet only in a limited number of structures of the organization (<50%)	Yes, only for a limited number of structures of the organization (<50%)
No (0-25%)	No action is being currently implemented (0%)	No, actions are not being evaluated (0%)
Not applicable (N/A)	Not applicable (N/A)	Not applicable in case no action is being implemented (N/A)

In conclusion, similarly to the results regarding the first research question, the study provided the basis to develop a self-assessment tool actually capable of assessing changes over time and system readiness in the implementation of organizational HL good practices, yet the tool still needs to be tested in real healthcare organization settings, to see whether it can actually be used as an efficient quality management and benchmark tool to compare different organizations for mutual learning and quality improvement.

Figure 10. HPH-HLO revised tool - Plan section example

Standard 1 - Make health literacy a priority across all levels of the organization and across all communication channels **Organizational health literacy is integrated into organizational structures and processes, including organizational self-assessment.**

The organization understands health literacy as a corporate responsibility.

1.1. PLAN - The organisation define health literacy targets that are integrated into organisation policies, human and financial resources, and quality management.			
1.1.1. Organizational documents such as the mission statement, goals, and policies, explicitly define health literacy as a corporate responsibility.			
☐ *One (or more) document is present that apply to the whole organisation*	☐ *One (or more) document is present, yet it does not apply to the whole organisation and covers most of the structures within the organisation (>50%)*	☐ *One (or more) document are present, yet it does not apply to the whole organisation and covers only a limited number of structures within the organisation (<50%)*	☐ *There is no such a document for the organisation*
1. Health literacy is integrated into other organizational policies, such as quality management, health promotion, risk management, human resource management, facility management, etc.			
please, identify all organisation policies that explicitly refer to health literacy			
1.1.2. Financial resources for health literacy activities are available and can be found in the organisation budget.			
☐ *The organisation has planned financial resources for health literacy activities, for all structures within the organisation*	☐ *The organisation has planned financial resources for health literacy activities, for most of the structures within the organisation (>50%)*	☐ *There are planned financial resources for health literacy activities, only for a limited number of structures within the organisation (<50%)*	☐ *The organisation has no planned financial resources for health literacy activities*
1.1.3. Personal responsibility and accountability for health literacy are clearly defined, e.g. through a health literacy officer, a health literacy team.			
☐ *The organisation has defined personal responsibility and accountability for health literacy for all structures within the organisation*	☐ *The organisation has defined personal responsibility and accountability for health literacy for most of the structures within the organisation (>50%)*	☐ *The organisation has defined personal responsibility and accountability for health literacy, yet only for a limited number of structures within the organisation (<50%)*	☐ *The organisation has not defined personal responsibility and accountability for health literacy*
1.1.3.1. In case that personal responsibility and accountability for health literacy are defined, who is responsible the organization?			
Identify all persons/roles that are responsible for health literacy within the organization (e.g. health literacy officer, health literacy team, link professionals, etc.)			
1.1.3.2. In case that personal responsibility and accountability for health literacy are defined, how many people are responsible for it in the organization?			
For every persons/roles identified in the previous question, define the number of people involved within the organisation			

Figure 11. HPH-HLO revised tool - Do section example

1.2. DO - The organisation ensure that actions are taken regarding health literacy				
1.1. The organization understands health literacy as a corporate responsibility.	*Actions are being implemented, with the involvement of the whole organisation*	*Actions are being implemented in most of the structures of the organisation (>50%)*	*Actions are being implemented, yet only in a limited number of structures of the organisation (<50%)*	*No action is being implemented at the moment*
1.2.1.1. Organizational documents such as the mission statement, goals, and policies, explicitly define health literacy as a corporate responsibility.	☐	☐	☐	☐
1.2.1.2 Health literacy activities and outcomes are part of the organization's annual report.	☐	☐	☐	☐
1.1.3. Financial resources and personnel for organizational health literacy are available.	☐	☐	☐	☐
1.1.4. Organizational health literacy interventions are planned and implemented.	☐	☐	☐	☐
1.1.5. Health literacy is integrated into other organizational units and policies, such as quality management, health promotion, risk management, human resource management, facility management, etc.	☐	☐	☐	☐

Figure 12. HPH-HLO revised tool - Check section example

1.3. CHECK **The organisation ensure a quality assessment process to evaluate health literacy actions.**				
1.3.1. Health literacy interventions are regularly assessed and monitored using a set of defined indicators and measures.	*for all structures within the organisation*	*for most of the structures within the organisation (>50%)*	*only for a limited number of structures within the organisation (<50%)*	*Not Applicable in case of no actions*
1.3.1.1. Actions are currently not being assessed .	☐	☐	☐	☐
1.3.1.2. An assessment is in place for the collection of quality measures. Data collection is not a routine process and is only carried out sporadically	☐	☐	☐	☐
1.3.1.3. An assessment process is in place for the collection of quality measures. Data collection is a routine process with a scheduled plan.	☐	☐	☐	☐
1.3.1.4. In case of routine data collection process, what is the frequency of it?				
☐ every six month or less	☐ every year	☐ every second year	☐ more than two years	

Figure 13. HPH-HLO revised tool - Act section example

1.4. ACT - The organisation ensure a quality process to refine health literacy actions, based on results from previous actions.				
1.4.1. Health literacy interventions are continuously refined on the basis of regular quality assessments.	*for all structures within the organisation*	*for most of the structures within the organisation (>50%)*	*only for a limited number of structures within the organisation (<50%)*	*Not Applicable in case action are not being assessed*
1.4.1.1. There is no system in place for the use of quality measures in the revision of implemented actions targets/objectives	☐	☐	☐	☐
1.4.1.2. There is a system in place for the use of quality measures in the revision of implemented actions targets/objectives, yet it does not have a defined schedule	☐	☐	☐	☐
1.4.1.3. There is a scheduled system in place for the use of quality measures in the revision of implemented actions targets/objectives	☐	☐	☐	☐
1.4.1.4. In case of routine revision process, what is the frequency of it?				
☐ every six month or less	☐ every year	☐ every second year	☐ more than two years	

References - Chapter 2

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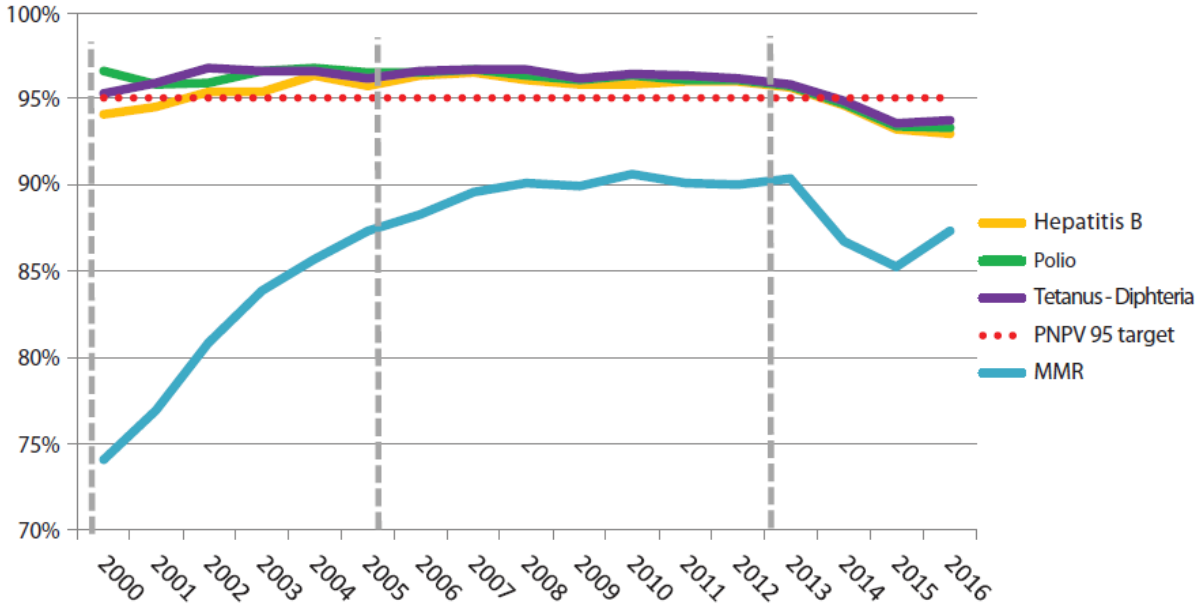
Chapter 3. HL developments in Disease Prevention: the emerging concept of Vaccine Literacy

While it has been established that low levels of HL are related to lesser usage of different preventive services (1), Disease Prevention as a Public Health domain has only recently seen an increase in attention and interest in actions aimed at the improvement of individual and population levels of HL (2). In the last few years, the focus of such actions has mainly revolved around interventions to address two main issues: the rising concern over the surge of antimicrobial resistance and the decline in vaccination coverage in pediatric age.

3.1 Vaccine Literacy and vaccine hesitancy

To address the latter issue, the concept of "Vaccine Literacy" (VL) have been proposed in 2011 by Ratzan (3). VL looks at HL from the point of view of attitudes and hesitancy toward vaccinations in order to better define and understand the main determinants of vaccine uptake. Specifically, "vaccine literacy is not simply knowledge about vaccines, but also developing a system with decreased complexity to communicate and offer vaccines as *sine qua non* of a functioning health system" (4). As in the case of HL, VL does not only relate to the individual level of skill, but should be regarded as a relational ability, in which the design of the preventive services also plays a fundamental role in shaping the attitudes and the final decision on vaccination (5). In light of recent trends showing a steady decline in immunization coverage (especially in western countries; Figure 14 shows the trend of vaccination coverage in Italy from 2000 to 2016) a number of studies have been carried out to better understand the determinants of such attitudes and behaviors, with the aim of countering the rise of the so-called "vaccine hesitancy", described as the combination of reluctance, doubts and loss of trust in vaccinations as an effective and safe practice for prevention, even in subjects who are adherent to vaccine programs (6).

Figure 14. Italian trends of vaccine coverage for selected vaccines



In this context, several studies have tried to establish the correlation between Health Literacy and vaccine hesitancy, with mixed results. In fact, the relation between HL and vaccination have been described as positive (7), non-existent (8), or negative (9), although it should be noted that the cited studies use different HL measurement tools. Thus, the development of specific VL tools is needed to further advance the field and provide useful results to better understand determinants of vaccine hesitancy, and to be able to develop better designed Public Health interventions to address this issue (the last one implemented in Italy, as controversial as efficient in the short term, being the introduction of compulsory vaccination (10).

At the moment, only a very limited number of studies exist on the development of VL measurement tools (4). In this context, the aim of the PhD activity was to develop and validate an Italian measurement tool of VL, designed as a rapid and easy-to-administer self-rated questionnaire able to capture a self-assessed measure of VL. Considered the importance of child immunization, the focus of the study carried out in the PhD activity was to validate the tool in a population of parents of children aged from 0 (newborns) to 8 years old. The decision to focus on this age range was taken

for several reasons: firstly, resource-wise, it was not possible to recruit a large enough population to cover parents of all age groups; the second reason was due to the fact that at 8 years old of age the children are at the end of the pre-adolescent immunization cycle (the second cycle being provided to adolescents starting from 12 years old); a third reason, connected to the previous ones, is based on the possibly different perception toward vaccinations between parents of children and parents of adolescents, the latter - being less emotionally involved with the anti-vaccination narrative of vaccine-related autism - have been excluded, reducing the probability of introducing a study bias. In this context, the newly developed VL tool is intended be an useful resource to assess the VL level of the parents population, to provide guidance on how interventions aimed at improving VL levels can actually reduce vaccine hesitancy and increase the adherence to recommended immunization practices.

3.2 Disease Prevention Study 1 - Validation of an Italian measurement tool of Vaccine Literacy (IT-VLq) based on the Ishikawa HL questionnaire in an Italian population of parents of children aged from 0 to 8 years old

The study carried out as a PhD activity focused on the development of an easy-to-administer VL rating scale, namely the Italian Vaccine Literacy Questionnaire (IT-VLq). To validate the IT-VLq, the study also included a set of different measures:

- Demographic variables: age, sex, citizenship.
- Socio-economic variables: working status, educational attainment, household income.
- HL, using a recently translated and culturally adapted version of the S-TOFHLA (11).
- Vaccine knowledge, using a 10-items questionnaire developed by the Italian Society of Pediatrics, called Vaccine Quiz.

- Adherence to vaccination recommendations as non-compliance of the parents to recommended vaccinations, indirectly measured by collecting administrative data on the vaccination status of the child.
-

The study aim was to answer four different research questions:

1. Is the IT-VLq tool a valid instrument to measure Vaccine Literacy?
2. What is the relation between Vaccine Literacy (IT-VLq) and HL (S-TOFHLA)?
3. What is the relation between Vaccine Literacy (IT-VLq) and vaccine-related knowledge?
4. Does Vaccine Literacy of parents relate with the immunization status of the children?

The development of the IT-VLq took place during November-December 2017, and was based on a previously validated questionnaire by Ishikawa (12), the so-called Ishikawa HL test, which is a self-rated questionnaire comprising three different sub-scales, founded on the Nutbeam definition of functional, communicative and critical HL (13). The choice of using an Ishikawa-like designed was based upon a previous experience in VL questionnaire developed in the same year by Aharon (8). Thus, starting from the original Ishikawa instrument, a translation of the tool was carried out following established good practices (14): the original English tool was initially distributed among the research team, producing a first set of translations that were later merged into a single draft version. The draft of the Italian instrument was then back-translated into English by an interpreter and reviewed by the research team for correctness. Translated items were circulated among a group of Italian HL researchers to assess for comprehensibility (N=12) and items were adjusted accordingly. The final version of the IT-VLq is composed of 14 items divided into three sub-scales (functional VL, 5 items; communicative VL, 5 items; critical VL, 4 items), measured using a 4-point Likert scale. The final Italian version of the scale is presented in Figure 15.

Figure 15. Final version of the IT-VLq (Italian)

Per ciascuna riga, marcare con una "X" la casella scelta

Nel leggere materiale informativo relativo ai vaccini per bambini, hai…

	Mai	Raramente	Qualche volta	Spesso
Trovato materiale con caratteri di stampa troppo piccoli da leggere.	☐	☐	☐	☐
trovato parole o espressioni che non conoscevi.	☐	☐	☐	☐
trovato che i contenuti erano troppo difficili da capire.	☐	☐	☐	☐
avuto bisogno di molto tempo per leggere e capire quello che hai trovato.	☐	☐	☐	☐
avuto bisogno dell'aiuto di qualcuno per aiutarti a leggere e/o comprendere quello che hai trovato.	☐	☐	☐	☐

Da quando è nato/a tuo figlio/a, in merito ai vaccini, hai...

	Mai	Raramente	Qualche volta	Spesso
cercato informazioni sui vaccini che ti interessavano.	☐	☐	☐	☐
raccolto informazioni sui vaccini da diverse fonti.	☐	☐	☐	☐
compreso il significato delle informazioni ottenute riguardo ai vaccini.	☐	☐	☐	☐
discusso con qualcuno dei tuoi pensieri riguardo ai possibili effetti sulla salute della vaccinazione.	☐	☐	☐	☐
utilizzato le informazioni ottenute per prendere decisioni riguardo alle vaccinazioni di tuo figlio/a.	☐	☐	☐	☐

Da quando tuo/a figlio/a ha l'età in cui si fanno le vaccinazioni, hai….

	Mai	Raramente	Qualche volta	Spesso
considerato se le informazioni ricevute o trovate erano adatte alla sua situazione specifica	☐	☐	☐	☐
valutato se l'informazione ricevuta o trovata era corretta e attendibile.	☐	☐	☐	☐
controllato personalmente se l'informazione ricevuta o trovata era corretta e attendibile.	☐	☐	☐	☐
raccolto ulteriori informazioni per prendere decisioni riguardo alla salute di tuo/a figlio/a.	☐	☐	☐	☐

Research question 1. Is the IT-VLq tool a valid instrument to measure Vaccine Literacy?

Data collection activities of the study took place in January 2018, by directly recruiting a sample of parents accessing the local child vaccination service of Udine healthcare authority. In total, out of 398 persons asked, 255 persons agreed to participate to the study (response rate=64%) and agreed to sign an informed consent for the inclusion in the study. The sample was of people of young age (Mean±StDev=35,0±6,3), predominantly consisting of females (n=210; 82,3%), of Italian citizenship (n=225; 88,2%), currently working (n=180; 70,6%), and with an high level of education, with almost half of the subjects having at least a university degree (n=126; 49,4%).

To provide an initial validation of the tool, we first tested the dimensionality of the scale applying Principal Component Analysis. Contrary to the expectations, we only found the IT-VLq to be explained by a 2-factorial model (contrary to the initial hypothesis of a 3-factorial model, in accordance with the 3 theoretical dimensions of functional, communicative and critical VL). The two factors identified explained 46% of the total variance of the results, with eigenvalue of factor 1= 3.44 (24%), and eigenvalue of factor 2 = 3.13 (22%):

- Factor 1 comprises 8 items: all the critical items and 4 out of five of the communicative items. For this reason, it will be referred as the Critical-communicative VL scale.
- Factor 2 comprises 6 items: all the functional items and 1 of the communicative items. These will be referred to as the Functional VL scale.

We then calculated Cronbach alpha of each scale to assess internal consistency. The

two scales showed an optimal level of internal consistency as measured by Cronbach alpha (Functional VL=0,80; Critical-communicative VL=0,82). In order to assess construct validity of the scale, we assessed the correlation of the two scales with socio-economic variables using a non-parametric test (Kruskal-Wallis). Results of the analysis are reported in Table 7.

Table 7. Correlation between VL and socio-economic variables

Variable	**Functional VL**	**Critical-communicative VL**
Educational attainment	Chi square = 35.00 P<.0001	Chi square = 6.53 **P=.16**
Working status	Chi square = 11.50 P<.05	Chi square = 12.86 P<.05
Household income	Chi square = 20.04 P<.001	Chi square = 14.40 P<.01

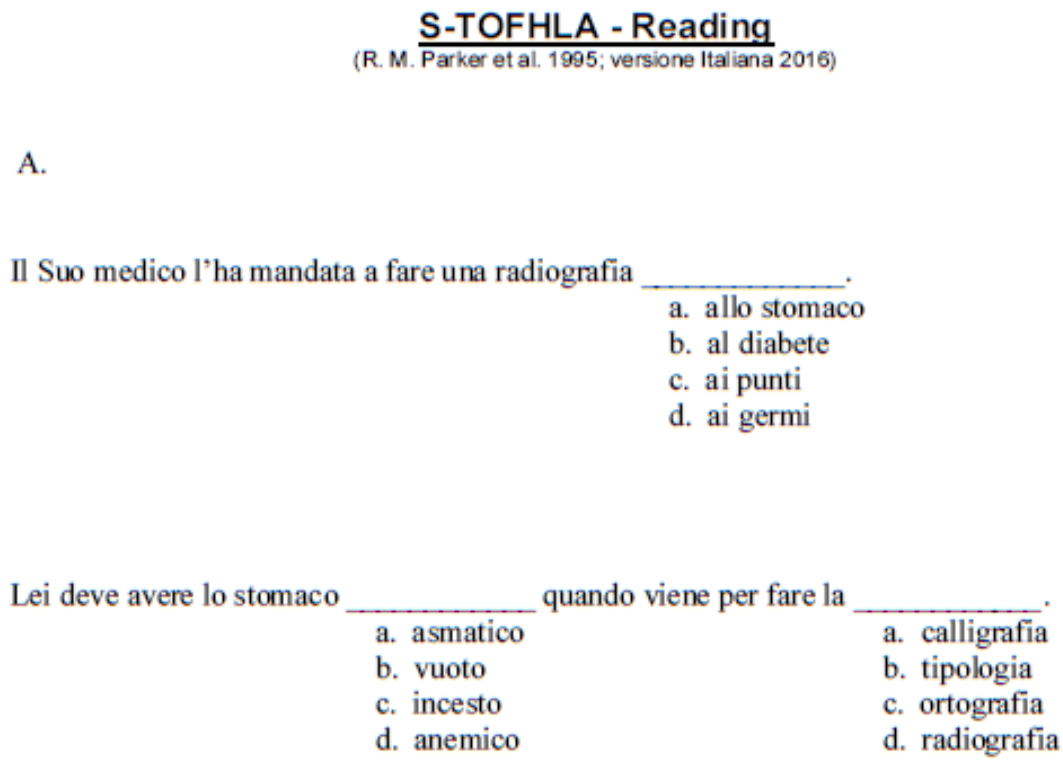
In our study sample, higher Vaccine Literacy scores for the two sub-scales were positively associated with current working status and an higher household income, while higher levels of educational attainment were only positively correlated with the Functional VL measure. These results are in line with those previously reported by both Aharon and Ishikawa (8,12), further validating the instrument as a valid tool for the measure of self-reported VL, which consists of two sub-scales that should be scored separately.

Research question 2. What is the relation between Vaccine Literacy (IT-VLq) and HL (S-TOFHLA)?

In our study, we also aimed at establishing the correlation between self-reported VL and HL. To do so, we collected a measure of HL using a recently validated Italian version of the Short form of the Test of Functional Health Literacy in Adults IT-

S-TOFHLA (11). The test was chosen among others for the possibility to collect data using a self-compiled questionnaire and without having to directly interview every single study participant (e.g. using the NVS tool). The IT-S-TOFHLA comprises two different sections: a first reading section which uses the cloze methodology, presenting sentences with blank spaces and offering different possibilities to complete the text; the second section instead is about numeracy, and uses an open-question format. Examples of items for the reading and numeracy sections are reported in Figures 16 and 17, respectively.

Figure 16. Items example of IT-S-TOFHLA reading section


S-TOFHLA - Reading

(R. M. Parker et al. 1995; versione Italiana 2016)

A.

Il Suo medico l'ha mandata a fare una radiografia _____.

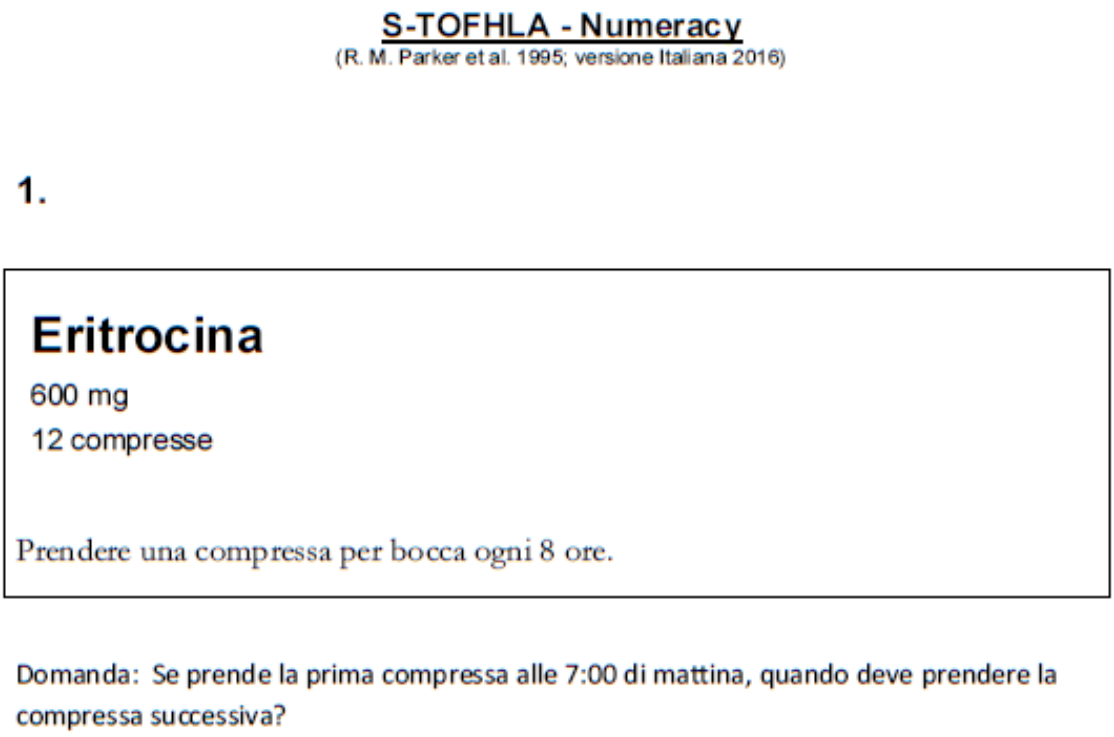
a. allo stomaco
b. al diabete
c. ai punti
d. ai germi

Lei deve avere lo stomaco _____ quando viene per fare la _____.

a. asmatico
b. vuoto
c. incesto
d. anemico

a. calligrafia
b. tipologia
c. ortografia
d. radiografia

Figure 17. Items example of IT-S-TOFHLA numeracy section



However, the first validation of the test was conducted assessing only comprehensibility and basic psychometric properties of the scale, not evaluating the actual capability of the test to discriminate between different levels of HL. To our knowledge, our study was the first to collect population data using this tool, so that at the beginning of our study we could not know for sure whether using this test would actually prove useful in evaluating functional HL in the study population. Unfortunately, results of the IT-S-TOFHLA in our population (reported in Table 8) did not allow to discriminate between different levels of functional HL, so we could not apply any test to verify the correlation between the two constructs of VL and HL.

Table 8. Results of the IT-S-TOFHLA

Health literacy levels	***Frequency (%)***
Adequate HL	*242 (96,4)*
Marginal HL	*6 (2,4)*
Inadequate HL	*3 (1,2)*

Research question 3. What is the relation between Vaccine Literacy (IT-VLq) and vaccine-related knowledge?

In the initial selection of measurement tools for our study, we could not locate any standard or internationally-recognized measure of vaccine-related knowledge. Thus, in order to collect such a measure, we decided to use a questionnaire which had recently been developed by the Italian Society of Pediatrics, called Vaccine Quiz. The original test, reported in Figure 18, comprises ten questions with possible answers Yes/No/Don't know. The questionnaire has not yet been translated into English following good translational practices, so that the following translation of the items should be taken as a mere indication of the content and not as a formal translation:

1. Before getting a vaccine shot, blood tests are needed in order to avoid severe reactions
2. If a person has already contracted a disease, he can still be vaccinated for the same disease
3. Getting multiple vaccine shots at a time can weaken immune system defences
4. If a child gets a vaccine shot, he cannot go to school the day after
5. Autistic children cannot not be vaccinated
6. It is possible to start vaccination at any age
7. Children affected by chronic/complex medical conditions cannot be vaccinated
8. Vaccines can cause sudden infant death syndrome
9. Starting vaccination immediately after two months of age is too early
10. Vaccines are not useful, because natural immunity is present for some diseases

Figure 18. Original version of the Italian Vaccine Quiz to test for vaccine-related knowledge

Per ciascuna delle seguenti affermazioni, indica se VERO o FALSO o NON SO	**VERO**	**FALSO**	**NON SO**
1. Prima di eseguire un vaccino bisogna fare gli esami del sangue per evitare reazioni gravi.	☐	☐	☐
2. Chi ha già contratto una malattia può essere vaccinato per quella malattia.	☐	☐	☐
3. Eseguire più vaccini in contemporanea può indebolire il sistema immunitario.	☐	☐	☐
4. Il bambino che viene sottoposto ad un vaccino non può andare a scuola il giorno successivo.	☐	☐	☐
5. I bambini affetti da autismo non possono essere vaccinati.	☐	☐	☐
6. È possibile iniziare a vaccinarsi a qualsiasi età.	☐	☐	☐
7. I bambini affetti da patologie croniche/complesse non possono essere vaccinati.	☐	☐	☐
8. I vaccini possono causare la sindrome da morte improvvisa del lattante (morte in culla).	☐	☐	☐
9. Iniziare a vaccinare al compimento dei 2 mesi di vita è troppo presto.	☐	☐	☐
10. Non serve vaccinare, perché esiste l'immunità naturale per alcune malattie.	☐	☐	☐

To obtain a measure of vaccine-related knowledge, we created a score rating each correct answer as counting 2 points, each don't know as 1 point, and each wrong as 0 points. We then summed up the results and obtained a score ranging from 0 to 20. In order to assess the correlation between the two VL scales and vaccine-related knowledge, we calculated Spearman correlation coefficients. Our results could find a positive statistically significant association between vaccine-related knowledge and Functional VL (Spearman coefficient=0,25, P<.0001), while that was not true for Critical-communicative VL (Spearman coefficient=-0,10, **P=.10**). To our knowledge, no prior studies provided a measure of correlation between VL and vaccine-related knowledge, so we do not yet have similar studies we could compare our results with.

Research question 4. Does Vaccine Literacy of parents relate with the immunization status of the children?

To further validate the IT-VLq (a subjective measure), we decided to collect a real-life, objective outcome measure. To do so, we extracted relevant vaccination data from the administrative information system of the local healthcare organization, which allowed to link every parent participating in the study with the information on vaccination of the respective child. We then confronted the data collected on vaccination status of the children with the recommended vaccination schedule at the local level (see Table 9), looking for three different measures of non-compliance behaviors (taking out of the data set children with specific medical prescriptions to not vaccinate):

1. **Missing at least one vaccination**. This represents the most inclusive measure of non-compliance, and may have low specificity as the vaccination could be missing also in relation to accidental delays due to the complex management of the vaccination services, thus resulting in a false positive measurement;

2. **Missing more than a single type of vaccination**. This represents an intermediate level of non-compliance, and while it may be more specific for anti-vaccination behaviors, a positive result could still be attributed to a delay, having missed even a single scheduled event (e.g. not having attended multiple vaccinations recommended at 5th month, the child being at the 6th month of age).

3. **Missing more than a single dose of any particular vaccine**. This measure is the most specific, as it represents the voluntary non-compliance to a specific recommended preventive action, which would be very likely due to vaccine hesitancy of the parent.

Table 9. Recommended vaccination for children 0-8 years old (local guidelines)

Vaccine	3rd month	5th month	7th month	9th month	13th month	14th month	15th month	6-7 years old
Diphtheria-Tetanus-Pertussis	X	X			X			X
Poliomielitis	X	X			X			X
Hepatitis B	X	X			X			
Haemophilus influenzae B	X	X			X			
Measles-Rubella-Mumps-Varicella						X		X
Pneumococcus	X	X			X			
Meningococcus B			X	X				
Meningococcus C					X			

We assessed the correlation of the two VL scales and the score of vaccine-related knowledge with the measures of non-compliance using a non-parametric test (Kruskal-Wallis). Results of the analysis are reported in Table 10. Contrary to our initial expectations, yet in line with previous results reported by Aharon (8), higher scores of Critical-communicative VL were related to an increased probability of non-compliance, while no correlation could be established with results of Functional VL. Also, in contrast with the findings of Aharon, our results show a statistically significant direct correlation between a decrease in vaccine-related knowledge and non-compliance behaviors.

Table 10. Correlation between VL scales and selected measures of non-compliance

Measures of non-compliance	Frequency (% of total respondents)	Functional VL	Critical-communicative VL	Vaccine-related knowledge
Missing at least one vaccination	99 (38.8%)	Chi square= 1.03 **P=.30**	Chi square= 0.13 **P=.71**	Chi square= 13.79 P<.001
Missing more than a single type of vaccination	43 (16.8%)	Chi square= 2.93 **P=.08**	Chi square= 3.86 P<.05	Chi square= 5.20 P<.05
Missing more than a single dose of any particular vaccine	18 (7.0%)	Chi square= 0.30 **P=.57**	Chi square= 6.77 P<.01	Chi square= 4.55 P<.05

In conclusion, in our study we were able to provide an initial validation of a consistent subjective measure of VL, and to further explore the relation between the construct measured and actual measures of non-compliance to vaccination in an Italian population of parents of children aged from 0 to 8 years old. Also, we could establish that subjective VL is composed of two distinct factors (Functional VL and Critical-communicative), which in turn have different relations with socio-economic characteristics, and, most importantly, with actual non-compliance behaviors (for the Critical-communicative VL scale). In accordance to previously reported results by Aharon, parents who self-rate themselves as being more able to communicate and take critical decisions about vaccination are the most likely ones to be non-compliant to official recommendations. In contrast with results by Aharon, we found vaccine-related knowledge to be correlated with both Functional VL and non-compliance behaviors, with the most knowledgeable parents having more Functional VL and being more prone to vaccinate their child (inverse relation with non-compliance behaviors).

A limitation of the current study is due to the choice of recruiting a very specific population of parents accessing preventive services, which cannot be considered representative of the whole Italian population of parents (regarding this point, our sample was composed predominantly by highly educated females). Secondarily, we were not able to assess the relation between VL and HL, as the IT-S-TOFHLA has proven not to be a valid tool to measure HL in the target population.

Future studies should verify the replicability of our preliminary results on VL, by expanding the study sample in order to reach more generalizable conclusions. Our results can be seen as an important starting point for future Public Health interventions aimed at addressing the issue of vaccine hesitancy. First, it would be important to have actions to sustain subjective Functional VL, by providing easier-to-access information on vaccines; secondarily, actions should be aimed at the reduction of subjective Critical-communicative VL, by adopting persuasive communication strategies that challenge preconceptions and help the individual in understanding that coming to an informed decision in critical choices such as vaccination is a very delicate process, which requires the mediation of an healthcare professional specialized in preventive medicine.

References - Chapter 3

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Chapter 4. HL in Health Promotion: the emerging role of eHealth Literacy

While clinical settings of healthcare organizations were the first to adopt HL as a relevant measure, Health Promotion can now be regarded as the Public Health domain which, in time, has been most influenced by the diffusion of the concept of Health Literacy. As HL became more and more central to Health Promotion research and practice, many different Health Promotion activities were developed accordingly. The current chapter – without making any pretense to cover the wide variety of approaches and good practices in Health promotion - presents the research activities carried out during the PhD, which focused on the assessment of the relation between Health Literacy and the Internet.

4.1 IC-Health Project – health promoting interventions aimed at improving digital health-related skills

During my PhD project, I have been able to participate in a European project, called IC-Health, funded under the Horizon 2020 program and aimed at the creation of Massive Open Online Courses (MOOCs) to improve the Digital Health Literacy of European citizens. In the context of the IC-Health project, Digital Health Literacy (commonly known as eHealth Literacy) referred to the ability to effectively use the Internet for health-related purposes and was directly linked to HL.

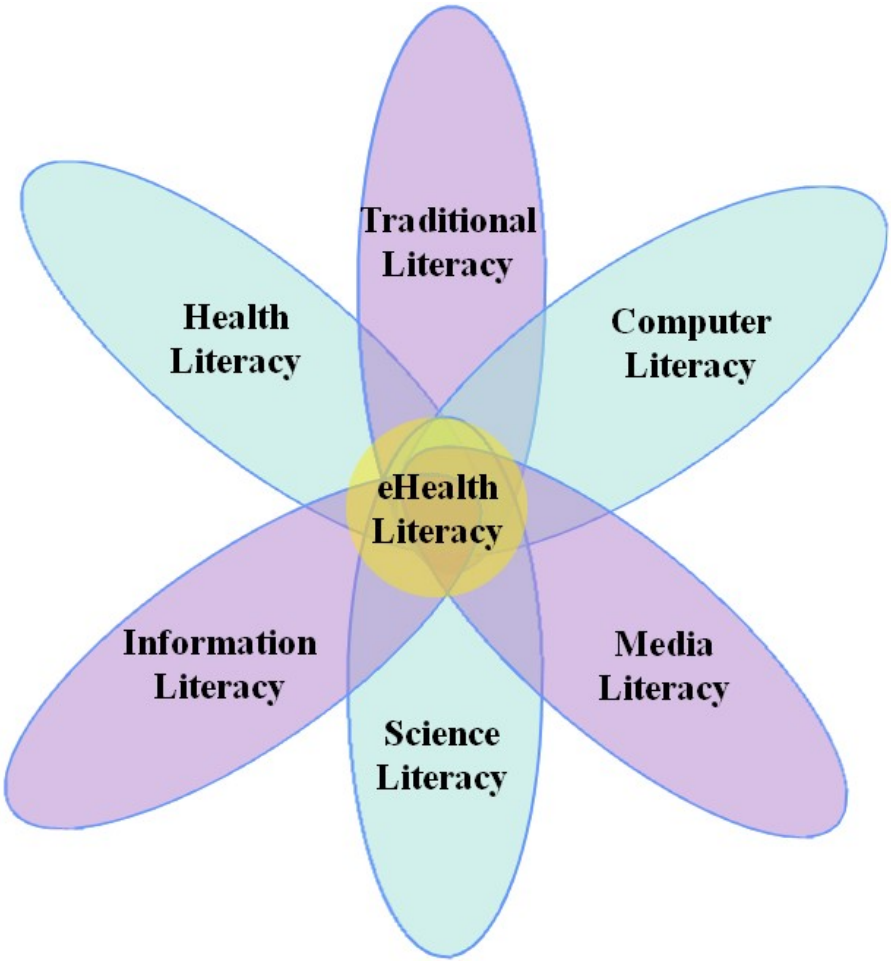
At the start of the PhD project, an evaluation study of this educational intervention was envisaged, yet the time frame of the project made performing such a formal evaluation impossible, due to the delivery of the MOOCs in October 2018. Thus, the PhD research activity aimed at providing a first validation of the measurement tools required to evaluate these MOOCs, in order to be able to assess the outcomes of such interventions in the future. During the PhD, I have been able to provide a first validation of an Italian version of the most established measure of subjective eHealth literacy, called the eHealth Literacy Scale (IT-eHEALS). To evaluate the IC-Health MOOCs, a pre-post study using a questionnaire including IT-eHEALS

would have to be administered to study participants at the beginning and after completion of the MOOC. For this purpose, it is proposed a pre-post intervention analysis using ANOVA. Positive changes in IT-eHEALS score will be considered the main outcome. Other outcome measures should also include attitudes and behaviors in the use of Internet for health-related purposes, uptake of proactive health behaviors, improved patient-provider communication, and health-related quality of life.

4.2 Health Promotion Study 1 - Translation and validation of the Italian version of the eHealth Literacy Scale (IT-eHEALS)

The eHEALS is a measurement tool first proposed by Norman and Skinner in 2006, after three years of experimentation in a teenage health promotion program. Drawing from the increasingly popular concept of Health Literacy, Norman and Skinner developed the concept of eHealth Literacy. In the same year, these authors proposed both a theoretical model (4) and a tool to measure the new construct (5). In their view, eHealth Literacy was defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem." The proposed model, called "lily model" (see Figure 19), described eHealth Literacy as the interplay of six core skills or literacies (traditional literacy, health literacy, information literacy, scientific literacy, media literacy, and computer literacy).

Figure 19. Lily model of eHealth Literacy



The measurement tool, called eHealth Literacy Scale (eHEALS), was based on the principles of the social cognitive theory and self-efficacy theory, using Likert scales for self-assessed, subjective responses, so that measures should be considered as precursors of behavior change and skill development (6). In this sense the eHEALS can be considered a measure of subjective, self-assessed eHealth Literacy. Figure 20 presents the original eHEALS tool as proposed by Norman and Skinner.

Figure 20. The eHealth Literacy Scale - eHEALS (original English version)

1. I know **what** health resources are available on the Internet
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
2. I know **where** to find helpful health resources on the Internet
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
3. I know **how** to find helpful health resources on the Internet
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
4. I know **how to use** the Internet to answer my questions about health
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
5. I know how to use **the health information** I find on the Internet to help me
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
6. I have the skills I need to **evaluate** the health resources I find on the Internet
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
7. I can tell **high quality** health resources from **low quality** health resources on the Internet
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree
8. I feel **confident** in using information from the Internet to make health decisions
   1) ☐ Strongly Disagree 2) ☐ Disagree 3) ☐ Undecided 4) ☐ Agree 5) ☐ Strongly Agree

The study aimed at the validation of the IT-eHEALS, and was divided into two research questions:

1. Is the IT-eHEALS tool a valid instrument to measure eHealth Literacy (dimensionality, internal consistency)?
2. What is the relation between eHealth Literacy (IT-eHEALS) and functional HL (studying or working experiences in the healthcare sector)?

The development of this study will be presented in the form of an original article, accepted for publication in the Journal of Medical Internet Research (article in pre-print. All previous references are numbered based on the order of appearance in the Journal article)

Original Journal Article – validation of the IT-eHEALS measurement tool (Research questions 1 and 2)

Original Paper

Correlation Between eHealth Literacy and Health Literacy Using the eHealth Literacy Scale and Real-Life Experiences in the Health Sector as a Proxy Measure of Functional Health Literacy: Web-Based Survey

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Abstract

Background: The eHealth Literacy Scale (eHEALS) is a tool for the self-assessment of perceived comfort and skills in using the internet as a source for health-related information. Although evidence exists of the reliability and construct and structural validity of the scale, there is a lack of evidence in relation to what is proposed by Norman and Skinner in their theoretical lily model of eHealth literacy; in particular it is not clear whether having a higher level of health literacy can positively influence electronic health (eHealth) literacy as measured by the eHEALS.

Objective: Our study aim was to assess whether real-life experiences from studying or working in the health field, as a proxy of higher functional health literacy, correlate with self-referred eHealth literacy as measured by the eHEALS.

Methods: A Web-based survey was conducted among adults living in Northeast Italy using an Italian version of the eHEALS (IT-eHEALS). In order to be able to measure the effect of higher functional health literacy on eHealth literacy, we divided our sample into two groups, respectively characterized by studying or working experience in the health sector and by lack thereof. Mean differences between eHEALS were calculated using t test and effect size evaluated using Cohen d. To ensure the validity of the IT-eHEALS, we evaluated its psychometric properties (internal consistency and dimensionality) and construct validity (by evaluating its correlation with respondents age, gender, educational attainment, self-rated health, use of internet for health-related purposes, and working status).

Results: A total of 868 respondents that completed the IT-eHEALS were included for analysis, of which 259 had working or studying experience in the health field. Mean (SD) eHEALS total score was 28.2 (6.2) for the whole sample, with statistically significant differences (P<.001) between the two groups, with the higher health literate group scoring significantly better (31.9 (5.9) vs 26.7 (5.6), respectively), with a standardized mean difference (Cohen d) of 0.9. Interestingly, we found a weak, yet significant, correlation between eHealth literacy and respondent characteristics for the higher health literate group only, as measured by positive Spearman correlation coefficients for age (0.11, P=.001), educational attainment (0.19, P=.002) and self-rated health (0.14, P=.024). Also, in line with current literature, correlation of eHEALS score with frequency of internet use for health-related purposes was significant for both groups (0.32, P<.001 and 0.15, P<.001 for higher and lower health literacy group, respectively). In our study we could not find any difference related to gender, while a significant difference for working status was only present when considering the sample as a whole (P=.03).

Conclusions: Our study demonstrates a sizeable effect of higher levels of functional health literacy on the eHEALS score, corroborating what was initially proposed by Norman and Skinner in the lily model of eHealth literacy.

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KEYWORDS

eHealth literacy; health literacy; effect size; eHEALS; lily model

Introduction

Health Information and the Internet

Use of the internet for health-related purposes poses a particularly important challenge, as it has been shown that wrong or incomplete information available on the internet may have negative consequences for the user—including on doctor-patient relationships, participation in prevention and screening programs, or adherence to medical treatment [1]. Today, the availability and accessibility of quality health-related internet information is still an issue, and agreement on a specified set of quality standards for health websites has recently been proposed as a new public health priority [2]. The problem of providing quality health-related information has become even more complex in the current Web 2.0 environment, as the search strategy for relevant information depends not only on the searcher's ability, but also on the influence of intermediators and apomediators, with the latter effectively pushing the search towards or away from relevant items [3].

eHealth Literacy and the eHEALS

In 2006, after three years of experimentation in a teenage health promotion program, Norman and Skinner developed the concept of eHealth literacy, drawing from the increasingly popular concept of health literacy. In the same year, the authors proposed both a theoretical model [4] and a tool to measure the new construct [5]. In their view, eHealth literacy was defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem." The proposed model, called "lily model", described eHealth literacy as the interplay of six core skills or literacies (traditional literacy, health literacy, information literacy, scientific literacy, media literacy, and computer literacy). The measurement tool, called eHealth literacy scale (eHEALS), was based on the principles of the social cognitive theory and self-efficacy theory, using Likert scales for self-assessed, subjective responses, so that measures should be considered as precursors of behavior change and skill development [6]. In this sense the eHEALS can be considered a measure of subjective, self-assessed eHealth literacy.

To further improve this first attempt to measure eHealth literacy, recent years have seen the development and validation of more comprehensive, and thus complex, eHealth literacy evaluation tools [7-9]. It should be noted, though, that despite all the possible issues coming from the simple eight-item structure of the eHEALS, its simplicity is also a strength of the tool. In fact, at the time of its development, the eHEALS was explicitly conceived so that it would have been easy to administer, taking into consideration the expressed needs of health professionals who said that they wouldn't use a long instrument in their practice [10]. This "strength in simplicity" facilitated the adoption of the eHEALS, and its widespread use has been highlighted in the findings of several literature reviews. In 2012 Collins and colleagues reviewed the use of health literacy screening tools in eHealth applications [11] and found that the eHEALS was the most used for the purpose of developing a computer-based instrument to screen individuals accessing eHealth applications, alone or in combination with other screening tools for health literacy. In a 2015 review of existing tools to measure eHealth literacy and their use by Karnoe and Kayser [12], the authors found that, out of eight different tools for measuring eHealth literacy, only the eHEALS had been used in studies other than the one it was originally published in. The same authors argue that the eHEALS, while easy to administer, provides a measure that is not able to pinpoint whether inadequate eHealth literacy is a result of insufficient health literacy, digital literacy, or a combination hereof. In other words, it is still not clear whether a higher level of self-referred eHealth literacy (using the eHEALS), is correctly due to differences in levels of functional health literacy or is just a result of high levels of perceived self-efficacy.

Aim of Current Study

The sheer amount of unchecked health-related information on the internet can be seen either as a limit or as a resource by different respondents with different skills and experiences in the health field. Considering the subjective, self-referred nature of the eHEALS, one possibility could be that people with less knowledge in the health field would trust the information more as they would be less able to discern the real quality of their internet search findings, scoring higher in the scale. The aim of our study is to test the lily model, by assessing whether and to what extent differences in health literacy levels account for variations in the eHEALS score. To our knowledge, no prior study using the eHEALS explored whether the scale behaves as intended in populations with different sets of core skills or literacies as described in the lily model, in our case based on differences in health literacy levels. In their description of the lily model of eHealth literacy, Norman and Skinner use the definition of health literacy given by the American Medical Association [13], which can be arguably referred to as a basic "functional" level of health literacy [14]. There are several possible measures of functional health literacy using measurement tools that are grounded on different theories. Yet, functional measures of health literacy have been shown to correlate with studying or working experiences in the health field [15], with physicians, researcher in the health field, and nurses showing higher health literacy levels in comparison with the general population. Therefore, we chose to recruit a large sample of respondents, divided into two groups, by asking them whether they had real-life experiences in studying or working in the health sector (eg, physicians, nurses, health alliance professionals). By doing so, we were able to compare a highly health-literate group with the rest of the general population.

Methods

Survey Design and Administration

In order to test our hypothesis, during November and December 2016 a Web-based survey was conducted by contacting people using two different recruitment strategies. Recruitment was

performed using: (a) the mailing list of the student body (undergraduate and post-graduate) from the University of Udine (obtained with permission from the University), and (b) Facebook contacts of the public health research team members, who were then asked via Facebook to further disseminate the survey to their contacts. Decision to participate in the survey was voluntary and no incentives were offered to respondents. The survey was first pretested for usability and functionality by the members of the research team. The survey was administered using the software SurveyMonkey. All participants were asked to read and approve an informed consent form telling them that the study was managed by the University of Udine and that the survey would require approximately 15 minutes. As the survey did not collect any data that could be directly linked to participants' sensitive data or information that could potentially affect their health, no approval by the Ethical Committee was deemed required under Italian legislation.

Measures

Collected measures covered socio-demographic characteristics (gender, age, highest educational level attained, working status), self-perceived health status, internet health-related behaviors (use for health-related search and frequency), working or studying experiences in the health sector, and an Italian adaptation of the eHEALS scale. Age was collected as a discrete variable, in number of years. Educational attainment was first collected using an 8-item scale, later aggregated into a 3-item scale in line with the aggregation methodology used by Eurostat in relation to International Standard Classification of Education levels [16]. The final set of education levels used for analysis were: (low) 8th grade or lower, (middle) 9-13th grade, (high) university degree or higher. Working status was collected asking participants whether they were currently working, studying, or neither working nor studying (classified as "other"). Self-rated health was collected using a 5-item Likert scale, ranging from "very bad" to "excellent," with the midpoint rated as "good." Health-related internet use was measured asking the frequency of internet use for health-related purposes (using a 5-item Likert scale ranging from "not more than 5-6 times a year" to "several times a week"). To differentiate for real-life experiences in the health sector, participants were asked whether they had experiences in studying or working in the health sector using a yes/no question. Regarding the Italian version of the eHEALS, we were unable to retrieve a previously reported version of the tool (I-eHEALS) presented in a conference abstract by De Caro et al [17] (via request to the corresponding author), and a new Italian translation of the 8 eHEALS items was produced by the research team (IT-eHEALS). The translation process was carried out following established good practices [18]: the original English tool was initially distributed among the research team, producing a first set of translations that were later merged into a single draft version. The draft of the Italian instrument was then retranslated into English by an interpreter and reviewed by the research team for correctness. Translated items were pretested for comprehensibility on a small sample of Italian adults (N=24) and items were adjusted accordingly. Like the original version of the test, the IT-eHEALS is composed of 8 items measured with a 5-point Likert scale. For every respondent of the sample that completed all 8 IT-eHEALS items, the total score ranges from 8 to 40 (calculated by adding up the single items' scores), with a higher score indicating a higher self-referred eHealth literacy.

Statistical Analysis

Sample Selection and Descriptive Analysis

To test our hypothesis, we selected the subsample of respondents who completed all of the 8 IT-eHEALS items. All collected data were screened to search for missing values or for any incorrect data inclusion. When not plausible, records were excluded from the analysis upon discussion among the research team. Then, the sample was divided into two groups based on having experiences of studying or working in the health sector or not. In this paper, we will refer to the group currently studying or working in the health sector as EHS+, and to the other as EHS-. Descriptive statistics (frequency, percentage, mean [SD]) were calculated for socio-demographic variables (gender, age, educational attainment, and working status), self-rated health, and internet health-related behaviors for all groups. A comparative analysis using Wilcoxon-Mann Whitney test and Chi-square (or Fisher Exact) Test, respectively for continuous and categorical variables, was conducted to detect statistically significant group differences ($P<.05$).

IT-eHEALS Scale Validity

Since we used a newly developed and adapted Italian version of the eHEALS (IT-eHEALS), we also assessed the scale by examining its psychometric properties and construct validity. Psychometric properties were examined by measuring internal consistency (Cronbach alpha) and conducting a principal component analysis to assess the dimensionality of the scale. Construct validity was assessed using a hypothesis testing approach. Based on prior studies, it was hypothesized that participants who (a) are younger [19], (b) use the internet for health-related purpose more frequently [20], (c) have a better self-rated health [17,21], and (d) have higher educational attainment [19], would have higher self-referred eHealth literacy scores. Spearman rho index was used to assess correlations between IT-eHEALS total score and (a) age, (b) internet use, (c) self-rated health and (d) educational level in the two groups of IT-eHEALS respondents. Also, we used *t* test and analysis of variance (ANOVA) to evaluate the difference in IT-eHEALS scores for gender and working status, respectively.

Relation Between Health and eHealth literacy

Finally, differences between eHEALS means and SDs in the EHS+ and EHS- groups were calculated using *t* test, and effect size was evaluated using Cohen *d*. Analysis was conducted using SAS software version 9.4 for Windows (SAS Institute Inc, Cary, NC, USA).

Results

Socio-Demographic Characteristics

In total, the two internet surveys led to the recruitment of 1136, of which 868 completed all eight IT-eHEALS items, leading to a final sample of 868 respondents that were included for analysis. Table 1 shows the socio-demographic characteristics of the whole sample and differences between the EHS+ and

EHS- groups. The two groups differ significantly (P<.001) in relation to working status and frequency of internet use for health-related purposes. In the EHS+ group, most of the respondents are working (139/259, 53.7%), while in EHS- the majority are studying (303/609, 49.7%). Regarding internet use for health-related purposes, 27.4% (71/259) of EHS+ respondents use the internet more than once a week, while only 5.42% (33/609) of the EHS- respondents do so, suggesting differences in health-related internet behaviors between the two groups. Also, respondents in the EHS+ group are significantly older, with a mean age of 31.5±12.1 years vs 28.7±9.7 years for the EHS- group (*P*=.008).

Validity of the IT-eHEALS Scale

IT-eHEALS showed a high degree of internal consistency with a Cronbach alpha of .90, with slight, negligible differences between the two groups (.87 in EHS-, .91 in EHS+). Principal Component Analysis in the whole sample confirmed the unidimensionality of the scale (eigenvalue=4.9 with 61.1% of variance explained). All IT-eHEALS items show high loadings on the first component (ranging from 0.68 to 0.83). Table 2 shows Spearman correlation coefficients with age and educational attainment. Correlation coefficients of total mean scores on the IT-eHEALS with selected variables are significant but low, with the exception of age, educational attainment, and self-rated health in EHS-. The correlation with frequency of internet use for health-related purposes was significant in both groups.

We did not find any difference in relation to gender. When assessing the whole sample, there was a significant difference for working status (*P*=.03) that was not present when considering EHS+ and EHS- separately in both groups.

Table 1. Descriptive and comparative analysis of study sample.

Variable	Whole sample (N=868), n (%)	EHS+[a] (N=259), n (%)	EHS-[b] (N=609), n (%)	*P* value[c]
Gender				. 85
Male	231 (26.6)	70 (27.0)	161 (26.4)	
Female	637 (73.4)	189 (73.0)	448 (73.6)	
Educational attainment				.057
Low	22 (2.5)	5 (1.9)	17 (2.8)	
Middle	457 (52.7)	121 (46.7)	336 (55.2)	
High	383 (44.1)	129 (49.8)	254 (41.7)	
No response	6 (0.7)	4 (1.6)	2 (0.3)	
Working status				<.001
Working	391 (45.1)	139 (53.7)	252 (41.4)	
Studying	416 (47.1)	113 (43.6)	303 (49.7)	
Other	61 (7.0)	7 (2.7)	54 (8.9)	
Self-rated health				.27
Very bad	6 (0.7)	1 (0.4)	5 (0.8)	
Poor	62 (7.1)	21 (8.1)	41 (6.7)	
Good	455 (52.4)	123 (47.5)	332 (54.5)	
Very good	281 (32.4)	90 (34.7)	191 (31.4)	
Excellent	64 (7.4)	24 (9.3)	40 (6.6)	
Frequency of internet use for health-related purposes				<.001
No more than 5-6 times/year	282 (32.5)	62 (23.9)	220 (36.1)	
No more than 2-3 times/year	135 (15.5)	31 (12.0)	104 (17.1)	
Once a month	238 (27.4)	58 (22.4)	180 (29.6)	
Once a week	109 (12.6)	37 (14.3)	72 (11.8)	
Several times a week	104 (12.0)	71 (27.4)	33 (5.4)	

[a]EHS+: Group with studying or working experiences in the health sector.

[b]EHS-: Group without studying or working experiences in the health sector.

[c]*P* values are calculated for mean differences between groups EHS+ and EHS-.

Table 2. Spearman correlations between eHealth Literacy Scale total score for selected variables.

Variable	Whole sample		EHS+[a]		EHS-[b]	
	Spearman correlation coefficient	*P* value	Spearman correlation coefficient	*P* value	Spearman correlation coefficient	*P* value
Age	0.11	.002	0.22	.001	0.02	.65
Educational attainment	0.11	.001	0.19	.002	0.06	.13
Self-rated health	0.07	.038	0.14	.024	0.02	.70
Frequency of internet use for health	0.28	<.001	0.32	<.001	0.15	<.001

[a]EHS+: Group with studying or working experiences in the health sector.

[b]EHS-: Group without studying or working experiences in the health sector.

Table 3. Italian version of eHealth Literacy Scale (eHEALS) items and total score statistics.

eHEALS score	Whole sample (N=868), mean (SD)	EHS+[a] (N=259), mean (SD)	EHS-[b] (N=609), mean (SD)	*P* value[c]
Item 1	3.8 (0.9)	4.2 (0.8)	3.6 (0.8)	<.001
Item 2	3.5 (0.9)	3.9 (1.0)	3.4 (0.9)	<.001
Item 3	3.6 (1.0)	4.0 (0.9)	3.4 (0.9)	<.001
Item 4	3.7 (0.9)	4.1 (0.9)	3.5 (0.9)	<.001
Item 5	3.7 (0.9)	4.1 (0.9)	3.6 (0.9)	<.001
Item 6	3.5 (1.2)	4.2 (1.0)	3.2 (1.1)	<.001
Item 7	3.8 (1.0)	4.2 (0.8)	3.6 (1.0)	<.001
Item 8	2.7 (1.2)	3.2 (1.2)	2.4 (1.1)	<.001

[a]EHS+: Group with studying or working experiences in the health sector.

[b]EHS-: Group without studying or working experiences in the health sector.

[c]*P* values are calculated for mean differences between groups EHS+ and EHS-.

Health Literacy and the eHEALS

Table 3 shows the mean (SD) item score and the statistical significance of the difference between the EHS+ and EHS- groups (see Multimedia Appendix 1 for item descriptions). Considering the whole sample of IT-eHEALS respondents, mean values for items range from 3.8 (item 1) to 2.7 (item 8). Differences between the two groups were significant for all IT-eHEALS items ($P<.001$), with the mean (SD) total score significantly higher in EHS+ compared to EHS- (31.9 [5.9] vs 26.7 [5.6], $P<.001$). The standardized mean difference (Cohen *d*) was 0.9, demonstrating a sizeable effect of higher levels of functional health literacy on the eHEALS score.

Discussion

Study Findings

Correlation Between Health Literacy and eHealth Literacy

In our study we were able to demonstrate that real-life working or studying experiences in the health sector, as a proxy of higher levels of health literacy, positively correlate with self-referred eHealth literacy as measured by the eHEALS. This finding is in line with the original lily model of eHealth literacy proposed by Norman and Skinner, where eHealth literacy is described as the interconnection of different core skills, including health literacy. Our findings emphasize that there are different factors other than internet and computer skills that can lead to different results when measuring eHealth literacy.

Psychometric Characteristics and Construct Validity of the eHEALS

Regarding the validity of the IT-eHEALS in the Italian population, we found high internal consistency, as shown by the Cronbach alpha and the inter-item correlation analysis, with comparable results with other translation of the eHEALS [19-26]. Our principal component analysis shows that the IT-eHEALS can be better explained by a single component structure, supporting its unidimensionality. While authors of two past studies using the eHEALS argued that the scale could have been multidimensional [24,27], our results are in line with other studies that confirmed the unidimensional nature of the scale, which allow for the calculation of a total mean score of all the eHEALS items [20,28,29]. Regarding the construct validity of the eHEALS, interpretation of our findings should be taken cautiously due to possible bias introduced by the sampling technique and keeping in mind that the sample was composed of young adults aged 20-30. Also, as already noted by Diviani et al [20], most of eHEALS validation studies have been conducted among specific populations, with different results showing no consistent association of eHEALS scores with the personal characteristics of the respondents, such as gender, education, or age. In fact, while some studies found significant correlation of eHealth literacy levels with age [19,26],

education [19], gender [26] and self-rated health [17,21], other studies found no correlation for the same variables. In particular, several other studies found no correlation between the eHEALS and gender [19-21], age [20], and education [20]. Our study findings show that the IT-eHEALS have a weak, positive correlation with age, educational attainment, and self-rated health. It must be noted that, interestingly, when considering our two subsamples separately, these correlations show a level of significance only in EHS+, while this is not true for EHS-, suggesting a correlation between different levels of functional health literacy and self-referred eHealth literacy. Regarding gender, we found no correlation with the eHEALS score, a result that is comparable with other studies involving a similar young and highly educated population [20,21]. Also, in line with similar studies [20], we found a weak level of correlation with the frequency of internet use for health-related purposes in all groups. Overall, these results suggest that the eHEALS should be considered a valid tool that can be used to assess the perceived comfort and skills in using the internet for health-related purposes.

Study Limitations

Our study has some limitations that should be acknowledged.

Sample Composition

A first limitation of our study lies in the recruitment strategy used, which led to a study sample which is composed by respondents who are mostly young and highly educated, and therefore could not be considered representative of the adult Italian population, limiting the generalizability of our findings. While the English version of the scale has been applied in a variety of samples, most of the validating studies of the eHEALS in other languages have only been conducted among specific populations. Regarding gender, our sample has an overrepresentation of female respondents, so that our results shall be taken cautiously when trying to generalize to the general adult population. Also, it should be noted that the use of Facebook in our recruitment strategy made it impossible to assess number and characteristic of nonrespondents, an important limitation that should also be considered when interpreting results. While these are common shortcoming of similar validation studies, we believe that its composition characteristics (higher education level, younger age) are somewhat representative of the most active population of health information seekers in the internet, as reported by the latest 2017 EU Digital Scoreboard statistics for Italy about health information seeking in the general population (see Multimedia Appendix 2). Moreover, our study population was sufficient to address our aim, namely the recruitment of a sample large enough to be divided into two comparable groups characterized by study or work experiences in the health sector. In relation to this point, we are also aware that the two groups were not equally distributed for some of the socio-demographic and health-related internet behavior factors; since our methodology did not allow us to select our sample composition beforehand, we cannot be sure whether group differences are an effect of the selected variable for group inclusion (in our case people with experiences in the health sector having different baseline characteristics compared to the general population for age, working status and use of internet for health-related purposes), or whether there are other reasons for these differences that are not due to the recruitment techniques we used.

Measures

Another limitation of our study lies in the fact that we only included one measure of internet health-related behavior, as comparing different measures was outside the original scope of the study. While it should be acknowledged that this measure has not been previously validated, our results suggest that the two groups may indeed be different in terms of internet health-related behaviors, yet these should be further explored with a larger number of measures before reaching definitive conclusions on the health literacy role in explaining behavioral differences in this field. Also, we did not include any validated measures of either subjective or objective health literacy, which could have been used to quantitatively assess different levels of health literacy. Instead, we asked for real-life experiences in the health field as a proxy, which have been showed to correlate only with objective health literacy tests [15]. Our results show that there is a correlation between these experiences and the eHEALS, yet we suggest that future studies also include other validated measures of health literacy to better correct results and to explore the correlation of the eHEALS with both subjective and objective measures of health literacy. Another limitation of the present study is the lack of an objective measure of eHealth literacy skill, making it unclear whether the differences between groups in health-related internet behaviors could also be related to actual, objective eHealth literacy skills. At the moment, there are mixed results regarding the correlation between eHEALS and objective measures of competencies on health-related internet use: using different measures of eHealth literacy objective competencies, Neter and Brainin found moderate correlation [30], while van der Vaart et al found no correlation [23]. This is also common to other measures used in the field of health literacy and is probably due to the subjective nature of the tools used [31], and even in the presence of a moderate correlation, Neter and Brainin recommend assessing the two constructs separately [30]. As these authors are providing the methodological base for more objective eHealth literacy measures, we also encourage future studies to include measures based on these methodologies [30,32]. This would not only lead to a better comprehension of the relation between subjective and objective measures, but it would also contribute to the possibility of expanding the item bank of objective measures for future studies, with possible use of advanced theories for test development such as Item Response Theory or the Rasch model [20,31].

eHEALS Version

It must be noted that after our study was conducted, a validation study of another Italian version of the eHEALS (I-eHEALS) was published by Diviani et al, using a sample population of Italian-speaking Swiss respondents [20]. As we used a different Italian translation of the eHEALS, it remains unclear whether results could be comparable to their results. While there are minor differences in the phrasing of the items, our scale shows good internal consistency and construct validity. For this reason, we believe that the two currently available Italian translations

of the eHEALS (I-eHEALS and IT-eHEALS) can both be considered valid and, in our opinion, can be used interchangeably (see Multimedia Appendix 1 for eHealth Literacy Scale Italian versions).

Conclusions

This study demonstrates that, as proposed in the lily model of eHealth literacy, eHEALS scale results are affected by a higher level of health literacy, measured via real-life experiences in the field of health as a proxy. We believe that this is an original result, which could be relevant in the current stage of scientific discussion regarding the use of the eHEALS and further advancements in measuring eHealth literacy. Despite its several limitations, and in absence of simple, easy-to-administer measurement tools, the eHEALS can still be considered a valid tool to assess self-perceived comfort and skills in using the internet for health-related purposes. It should still be used for comparison in the elaboration of new eHealth literacy measures, which should be designed including new items and different subscales in order to be able to capture all the proposed "literacies" of the construct [4]. For these reasons, we believe that the absence of correlation of the eHEALS with objectively measured internet related skills as found by different authors does not undermine the validity and the usability of the scale per se, and that the eHEALS can still be applied in clinical and health promotion activities, for example to identify different needs for the participants to an eHealth intervention or to evaluate intervention results.

Authors' Contributions

PDG, MP, ADO, LB, LA, and AC discussed and drafted the questionnaire for the surveys and discussed and approved the IT-eHEALS translation of the original eHEALS. AC and ADO managed data collection activities. PDG and GB analyzed collected data and interpreted results. PDG and GB drafted the manuscript, which was revised and approved by MP and SB. The study did not receive any funding.

Conflicts of Interest

None declared.

Multimedia Appendix 1

eHealth Literacy Scale Italian versions.

[PDF File (Adobe PDF File), 140KB - jmir_v20i10e281_app2.pdf]

Multimedia Appendix 2

Internet health-information seeking behavior in the Italian adult population.

[PDF File (Adobe PDF File), 349KB - jmir_v20i10e281_app3.pdf]

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Abbreviations

ANOVA: analysis of variance
eHEALS: eHealth Literacy Scale
eHealth: electornic health
EHS+: Group with studying or working experiences in the health sector
EHS-: Group without studying or working experiences in the health sector
I-eHEALS: Swiss-Italian version of the eHealth Literacy scale
IT-eHEALS: Italian version of eHealth Literacy Scale

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Chapter 5. Implications for future Public Health research and practice

This chapter aims at providing a final, brief overview of the studies' findings' implications across the three Public Health domains.

5.1 Healthcare Organizations

- Screening of patient's Health Literacy using measurement tools is still problematic at the clinical setting level, for reasons related to both the validity of the tools and the generally low level of Health Literacy of the population accessing healthcare services. Instead, application of organization-wide universal precautions is recommended.
- Organizational self-assessment tools to improve the quality management of aspects related to Health Literacy (also including universal precautions) are now available, and their use constitutes a promising Public Health approach. However, future studies are needed to test the applicability and sustainability of their possible uses (e.g. quality improvement, benchmarking, financial incentives, etc.).

5.2 Disease Prevention

- Contrary to vaccine-related knowledge, a higher level of subjective Critical-communicative Vaccine Literacy appears related to an increase in vaccine hesitancy attitudes and behaviors. Future studies need to confirm these results, while also working on the development of more objective measures of Vaccine Literacy.
- Interventions aimed at countering the effect of vaccine hesitancy should take into account the study results by acknowledging the two different dimensions

of subjective Vaccine Literacy and act accordingly. While the first dimension (functional) needs to be sustained as it relates to better vaccine-related knowledge, the second (critical-communicative) should be discouraged by adopting effective communication strategies that challenge preconceptions and help the individual in understanding the importance of the mediation of healthcare professionals specialized in preventive medicine in coming to an informed decision

5.3 Health Promotion

- Despite several limitations, and in the absence of simple, easy-to-administer measurement tools, the eHEALS can be still considered a valid instrument to assess subjective eHealth Literacy, as a measure of self-perceived comfort and skills in using the Internet for health-related purposes.
- The eHEALS should be used when implementing Health Promotion activities aimed at the improvement of eHealth Literacy, in order to identify different participants' needs and/or to assess the intervention results. However, due to the limited correlation of the scale results with objective skills, it should always be used in conjunction with other outcome measures (e.g. Internet health-related behaviors and attitudes, improvements in patient-provider communication, objective measures, etc.).