Validation of an Italian tool to assess vaccine literacy in adulthood vaccination: a pilot study

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Abstract

Vaccine Literacy (VL) is based on the same idea of Health Literacy (HL): it involves people's knowledge, motivation and competence to find, understand and use information to take decisions about children's and adults' vaccination. Using general measures, the association between HL and Vaccine Hesitancy has been shown to be inconsistent. HLVa-IT is a new tool, specific for the self-assessment of three VL scales, functional, interactive and critical about adults' immunization. Following a face validation process, HLVa-IT has been used to assess VL levels in a population of 50-75 years of age at the Public Health Unit of Latina (Latium, Italy). In order to validate its theoretical construct, it was administered at the same time with a Vaccine Quiz (VQ), assuming that subjects showing good knowledge about vaccination should have adequate VL. The consistent positive correlation for all three VL scales with the VQ score (Spearman's r=0.320, P=0.0004; r=0.389. P=0.0001 and r=0.306, P=0.0022, respectively), as well as with the educational degree, confirm the valid construct of HLVa-IT. A criterion validity of this tool has also been sought verifying its relation with acceptance of vaccines (VA) recommended in the adult/senior age. A positive association with VA observed only on the functional scale in the population \geq 65 years, does not permit to accept a predictive validity, confirming that direct effect of Health Literacy is more clearly verifiable on knowledge than behavior outcomes. Nevertheless, HLVa-IT has shown suitable psychometric characteristics for the subjective measure of VL in individuals and in population studies. It is desirable that more specific tools are validated and extensively used, with the aim of assessing peoples' VL skills and defining interventions aimed at their improvement.

Introduction

Health literacy (HL) relates to the abilities to meet the complex demands of health: it entails people's knowledge, motivation and competence to find, understand and use health information in order to take decisions concerning healthcare, disease prevention and health promotion (1). Limited Health Literacy has been independently associated with poor use of health services and outcomes, as well as greater costs (2,

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3); on the contrary, high levels of Health Literacy can facilitate communication and promote equity, empowerment and patient centeredness (4, 5).

Although active immunization has proved its efficacy to control vaccine-preventable diseases, vaccination coverage has remained steady or decreased the past few years in Italy, while Vaccine Hesitancy has emerged, generating refusal or delay in vaccine acceptance (VA) (6). This behavior results from a complex decision-making process that is influenced by different factors summarized into the so-called "3 Cs" model, including three domains: complacency, confidence and convenience (7) and in the "4 Cs" model, also including the domain of calculation (8). When reviewing these factors, limited HL is taken into account infrequently, although it is considered a component of convenience and a con-cause of low uptake of vaccines, and even if it is accepted that the success of communication strategies is limited by the difficulties in interesting low-literate individuals (9). In fact, information about vaccines is quite complex: its comprehension requires certain literacy skills.

To address these issues, the concept of "Vaccine Literacy" (VL) has been proposed (10) on the same idea of Health Literacy: it is not simply knowledge about vaccines, but it entails motivation and competence to deal with information about immunization, diseases prevention and also health promotion (11). Limited or insufficient Health Literacy was associated with reduced adoption of protective behaviors such as immunization (12). However, using different general literacy measures, the correlation between Health Literacy and Vaccine Hesitancy, has been shown to be inconsistent (sometimes positive, sometimes negative) (13). Thus, the development of specific VL tools is required to further advance in the vaccination realm and provide data useful to understand better the determinants of Vaccine Hesitancy about children's and adults' immunization.

The main objective of the study was to evaluate a new self-rated test aimed at measuring VL about adults' vaccination, HLVa-IT (Health Literacy Vaccinale degli adulti in Italiano), in order to share with the scientific community a validated tool for VL measurement.

Methods

HLVa-IT

HLVa-IT has been built on the so-called Ishikawa test (14¹), a self-rated questionnaire specific to chronic patients, including three Health Literacy scales (15). A similar tool has been employed in previous experiences to assess parents' VL about children vaccinations (16) also adapted and used in Italian (17). Starting from the original instrument, a translation of this new tool has been carried out following established practices (18): yet, some questions were specifically adapted to the vaccination domain and cultural characteristics of the Italian population. HLVa-IT is composed of 14 items (questions) divided into three scales: functional VL (items number 1 to 5); interactive, also called communicative VL (items number 6 to 10); critical VL (items number 11 to 14). From the psychometric point of view, functional VL questions are more about language capabilities, involving the semantic system, while the interactive/critical questions regard more the cognitive efforts, such as problem solving and decision making. The answers are supplied by the interviewee according to a Likert scale with four possible choices (4-never, 3-rarely, 2-sometimes, 1-often, for the functional scale; 1-never, 2-rarely, 3-sometimes, 4-often, for the interactive

¹ https://healthliteracy.bu.edu//documents/74/ FCCHL%20scale.pdf. [Last accessed 2020, Feb 24]

and critical scale) (see Annex 1: HLVa-IT translated into English).

HLVa-IT is a self-rated, one page paperand-pencil test. The three scales are evaluated separately, although the interactive and critical scales can be integrated and analyzed together, being contiguous, with similar psychometric characteristics. The score is obtained from the mean value of the answers to each scale, and is comprised between 1 and 4: a higher value corresponds to a higher VL level.

Since in adults (including parents) are not required mandatory vaccinations, contrary to what happens with children, in HLVa-IT the VL scales are preceded by two filter questions. Before completing the functional VL section, interviewees have to reply to the following question: "Have you ever read vaccine materials, such as leaflets or posters in doctor's or public health offices, recommending vaccinations?". If the reply to this question is affirmative, the person is allowed to fill in the following section of the questionnaire. Also, before completing the interactive/critical section, participants have to reply affirmatively to the question, "Have you ever thought or been advised to vaccinate yourself against one or more diseases?"

Face validity

Before the utilization of HLVa-IT in the survey, a face validity process has been carried out through Google Forms®, with the aim of validating the apparent and external significance of HLVa-IT, through the judgement of the items provided for in the test, by a panel of experts in the vaccination field. Evaluators were asked to fill in a specific questionnaire to score on four aspects: reliability, comprehensibility, sensitivity and efficiency² for each of the 14 items of the test, for a total of 56 judgements. The scores ranged from 1 (minimum) to 5 (maximum value) and were codified according to the following scale: item perfectly adequate score =5; very adequate item = 4; sufficiently adequate item = 3; inadequate item = 2; completely inadequate item = 1. Average scores of all items were calculated with MedCalc Statistical Software version 18.2.1 (19), as well as Cronbach's alfa, correlation coefficients and others tests, parametric or non-parametric, according to the data distribution.

Vaccine Quiz (VQ)

To carry out the validation study, HLVa-IT was joined into the same paper questionnaire with an another test, performance-based, including twelve true/false/don't know statements, to measure the levels of knowledge about vaccination (Vaccine Quiz - VQ). The "don't know" option was included to avoid casual responses. This questionnaire was derived from a similar test developed for infancy vaccination (20): the score is obtained by adding the exact answers, assigning 1 point to each answer, for a maximum of 12 – Annex 2.

Vaccine Acceptance (VA)

Additionally, three questions were included regarding acceptance of vaccines (VA) recommended in Italy to the adult age group (tetanus booster every 10 years; pneumococcal and influenza for 65 years and older): in order to respect anonymity a subjective anamnestic criterion was chosen (self-reported vaccination status), instead of recovering data from the official vaccination records – Annex 3.

Answers were categorized, on the basis of the answers, attributing the value "1" to those who responded affirmatively to the

² reliability = how the questions included in the test appeared to be reliable, i.e. suitable to measure its theoretical construct, considering the Italian socio-cultural situations:

comprehensibility = how the questions seemed understandable to the adult population (>18 y.s of age);

sensitivity = how the questions appeared to be able to identify variations in the measures under investigation;

efficiency = how efficient the questions appeared in detecting the aspects related to the test construct.

question: "have you been vaccinated?" and the value "0" (zero) to those who responded negatively, or did not remember, or, in the case of tetanus, had been vaccinated more than 10 years earlier. Subjects under 65 years of age were not required to answer questions related to influenza and pneumococcal vaccination because not target of the vaccination strategy, if not belonging to a high risk group. VA was also evaluated through the sum of "all vaccines received" and the parameter "at least one vaccine received" (Table 1).

Sociodemographic data have been categorized to identify the sex, the age class, the native language and the education degree (four categories, 1 to 4) and other variables. The variable "profession" was not pre-coded in the questionnaire, therefore it was only treated at descriptive level in the analysis.

Objectives of the pilot study

Primary objective of the survey was to validate the theoretical construct of HLVa-IT, looking for the direct correlation of the scores observed for each VL scale with the VQ score, assuming that subjects showing good knowledge about vaccination have adequate VL. For VQ to be a solid tool to validate HLVa-IT, its association with the self-reported vaccination status (vaccine acceptance - VA) was sought.

As secondary objective, a criterion validity of HLVa-IT has been searched,

verifying its direct association with VA. Moreover, secondary objectives were to measure VL levels in a selected Italian adult population (age 50-75) and to assess the relation of VL levels and responses to VQ, and VA with demographic variables (age, gender, educational degree, language).

Sample size

It was not possible to calculate the size of the sample to be recruited prior to initiation of the survey, since no data on the expected prevalence of responses to HLVa-IT nor to VQ were available. It was therefore based on previous cross-sectional studies performed with similar tests (17). In the perspective of future surveys and to check the suitability of the sample enrolled, following the end of the study, the observed VQ mean score (=6.7) served to define an arbitrary cut-off value =7 (concurrent with the observed median). At 95% CI, 50% expected prevalence of responses ≥ 7 and an accuracy of $7\%^3$, the sample size of the study should have been =196 subjects, consistent with the questionnaires collected (n=200). VQ was preferred for this estimate as an objective measure, instead of one or more of the VL subjective scales.

Data collection

The questionnaires were distributed along with an explicative note reporting instructions and information about the aim of the survey.

Table 1 – \	Variables	included	in th	ie study
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Variable	Acronym	Parameter	Measure
Vaccine acceptance	VA	- Tetanus, Pneumo, flu vaccines received	Categorical (0-1)
		- All vaccines received	Score 0-3
		- At least 1 vaccine received	Categorical (0-1)
Vaccine quiz	VQ	- True/false statements about vaccines	Score 0-12
(knowledge)		- Vaccine quiz score ≥ 7	Categorical (0-1)
Vaccine literacy	VL	- Functional	Score 1-4
(HLVA-it)		- interactive (communicative)	Score 1-4
		- Critical	Score 1-4

They were administered randomly to persons of both sex, previous verification of their age (limits 50 -75 years), attending the waiting rooms of clinical or administrative offices of the Local Health Unit of Latina (Latium, Italy) by one operator trained specifically for this study, who remained present and collected the forms when filled up. Interviewees were invited not to consult any source of information (e.g. smartphone) before and during the compilation, for which there was no time limit.

Statistical analysis

Filled questionnaires were selected according to the adequacy and quality of the compilation, in particular of the VL scales: incomplete sections of one or more of the three scales had to be excluded from the analysis, as also those compiled by whom although responding negatively to one or both of the "filter" questions, filled in the relevant section. This selective exclusion was possible because the functional and interactive/critical VL scales are independent from each other and separated by the two filter questions. This population was considered for the statistical analysis.

Analysis of data has been performed as follows, using MedCalc Statistical Software version 18.2.1 and XLSTAT software version 2014.5.03 (19, 21):

Descriptive statistics tables, summarizing means, SD, medians, CIs and normality test of the collected data (Kolmogorov-Smirnov).

Principal Component Analysis of the VL scales, internal consistency of the VL scales and of VQ through the alpha coefficient of Cronbach, inter-item correlations, average inter-items correlation;

Correlation coefficient (Pearson's or Spearman's, according to the normality of

the data distribution) between VQ score and VA, between each of the three VL scales and the VQ score, as well as between each of the three VL scales and the VA parameters.

Tests (parametric or non-parametric according to the data distribution) to confirm the correlation between variables.

The predictive value of some variables was also investigated, through the Receiver Operating Characteristic (ROC) curve analysis.

Before its start, the study received the favorable opinion from the Ethics Committee of the National Institute of Health (Rome, Italy).

Results

Face validity

In total 120 forms were randomly sent out to as many experts, nationwide through Google Forms®. Fifty-two experts answered with valid evaluations from April 7 to May 28, 2019, (48 years of average age; males 56%, females 44%). Thirty-three were academic or public health physicians / epidemiologists /specialized in hygiene and preventive medicine (hygienists); the remaining experts were general practitioners, pediatricians or pharmacists.

By stratifying the population into "hygienists" and "non-hygienists", no main significant differences were observed in the responses. Table 2 reports the mean scores attributed to functional and interactive/critical questions for each feature. Both the scores attributed to functional VL items and those for interactive/critical VL showed high consistency (Cronbach's alpha =0.9271 and =0.9644, respectively).

Average scores regarding reliability, comprehensibility, efficiency and sensitivity for items of functional and interactive/critical scales were quite high, ranging from 3.86±0.68 (Functional

³ Corresponding to a broader 95% CI than observed in the study (6.34 to 7.06)

Table 2 - Mean scores attributed by 52	2 evaluators to functiona	l and interactive/critical	questions for each feature.
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	Mean	95% CI	SD
Functional VL Reliability	4.08	3.90 to 4.27	0.67
Functional VL Comprehensibility	4.22	3.97 to 4.46	0.87
Functional VL Efficiency	3.97	3.78 to 4.15	0.66
Functional VL Sensitivity	3.86	3.67 to 4.05	0.68
Interactive/critical VL Reliability	4.07	3.88 to 4.25	0.66
interactive/critical VL Comprehensibility	4.16	3.96 to 4.35	0.70
Interactive/critical VL Efficiency	3.95	3.74 to 4.16	0.75
Interactive/critical VL Sensitivity	3.87	3.66 to 4.07	0.74

Sensitivity) to 4.22±0.87 (Functional Comprehensibility). Pairwise comparison (repeated measures ANOVA) showed significant differences only between: functional comprehensibility vs functional sensitivity (P=0.0435) and interactive/critical comprehensibility vs Interactive/critical sensitivity (P=0.0047). Free comments provided by few of the evaluators allowed to adjust some of the items, in terms of better comprehensibility.

In conclusion, face validity indicated that HLVa-IT was suitable for use in field studies to complete its validation process.

Pilot study

A total of 200 anonymous questionnaires were collected, compiled by as many people ≥50 years and ≤75 years of age, interviewed from July 16, to August 8, 2019. The average time taken by respondents to fill in the

form was about 5 minutes. Before starting the analysis, a double independent crosscheck was carried out to verify the correct tabulation of data. None of the variables considered in the study presented a normal distribution at the Kolmogorov-Smirnov test, so that non-parametric tests were employed for the analysis. In Table 3 the main statistical variables are reported.

The mean age was 63.25 years with a standard deviation of 6.89 and a median of 63; the prevailing gender was female (about 66% of the population), the average educational grade was 2.6 (considering a minimum of 1 corresponding to primary schools and a maximum of 4 corresponding to the university degree). The total number of vaccines administered was approximately 0.8 vaccines/individual and the proportion of subjects who had received at least one vaccination corresponded to just over half

Table 3 – Description of the variables in the population

	N	Mean	95% CI	SD	Median	95% CI
Age	198	63.25	62.29 - 64.22	6.89	63.00	62.00- 64.00
Educational degree	186	2.63	2.51 to 2.76	0.87	3.00	2.15 to 3.00
All vaccines received	193	0.81	0.69 to 0.93	0.83	1.00	0.00 to 1.00
≥1 vaccine received	193	0.55	0.48 to 0.62	0.50	1.00	0.00 to 1.00
Vaccine quiz (VQ) score	194	6.70	6.34 to 7.06	2.56	7.00	6.00 to 8.00
Functional VL score	122	3.23	3.10 to 3.36	0.71	3.20	3.00 to 3.60
Interactive VL score	105	2.92	2.72 to 3.12	1.02	3.20	3.00 to 3.60
Critical VL score	103	2.86	2.65 to 3.08	1.09	3.25	2.77 to 3.50

of the population (55%).

Only 5 out of the 196 persons who filled in the section about the profession were working in the health sector; 79 reported to be retired, 20 were employed, 6 workers, 13 teachers, 53 housewives, 9 self-employees and 11 carried out other activities or were in different social conditions. The variable "mother tongue" was not considered in the analysis as only 5 out of 200 recruited subjects were non-native Italian-speaking and did not - except one - enter the VL assessment, having negatively answered to the filter questions.

The analysis limited to the population aged 65, corresponding to 40% of the total enrolled subjects, was also performed. The mean age was 70.2 years, mostly females (54%), the level of education was similar to that of the total population, while all vaccines received per subject increased from 0.8 to 1.2 on average per person, as well as the proportion of subjects who had received at least one vaccination. In the population ≥ 65 years old also the VQ score was higher (7.02) than in the total population (average 6.70), although not significantly (P= 0.3347, Mann-Whitney), while the educational level was slightly higher in the population < 65 years of age (P= 0.2935, Mann Whitney test).

Internal consistency of HLVa-IT

The Principal Component Analysis of HLVa-IT identified two main factors representing 62.70% of the total variability: all items of the interactive/critical scale loaded on the first factor (eigenvalue =5.81), while those of the functional scale on the second (eigenvalue =2.97), confirming that interactive and critical scales belong to the same domain (Figure 1). This is consistent with the data obtained from a study where a measure with a construct very similar to HLVa-IT (i.e., its correspondent for childhood vaccinations, HLVp-IT) was employed (17). Cronbach's alfa was

calculated on the answers to the questions of each of the HLVa-IT scales, functional (α =0.8157), interactive (α =0.8814) and critical (α =0.9021), as well as on interactive/critical (α =0.9369). These values indicated a solid consistency and remained high (above 0.75 for functional and above 0.85 for interactive and critical) progressively dropping every single question, no item strongly affecting the reliability of the test.

Inter-item correlation coefficients were significant for all pairs of questions. The average inter-item correlation indexes were 0.48 (functional), 0.55 (interactive) and 0.65 (critical), the latter being quite high and revealing a possible repetitiveness of some of the critical scale questions, in particular question n 11 vs n 12 and question n 12 vs n 13⁴-r=0.825 and r=730, respectively, despite the same items assessed at the "face validity" appeared significantly different from each other in terms of reliability (question n 11 vs n 12 P=0.0001; n 12 vs n 1⁴ P=0.0141, Wilcoxon test) and comprehensibility (between n 11 vs n 12, P=0.0125).

Regarding the questions of the VQ, the alpha value was 0.6715, not particularly high, but indicating sufficient internal consistency. Average inter-item for VQ was =0.15.

HLVa-IT (VL) results

Onehundred-twentytwo, 105 and 103 respondents completed the parts of the questionnaire related to functional, interactive and critical VL, respectively. The association between interactive and critical VL scores was highly significant (r=0.780, P=0.0001, confirmed at the Mann Whitey test, P=0.9880); on the contrary, the functional VL score did not correlate with

⁴ Question n 11 - Did you consider whether the information collected was about your condition?

Question n 12 Have you considered the credibility of the sources?

Question n 13 Did you check whether the information was correct?

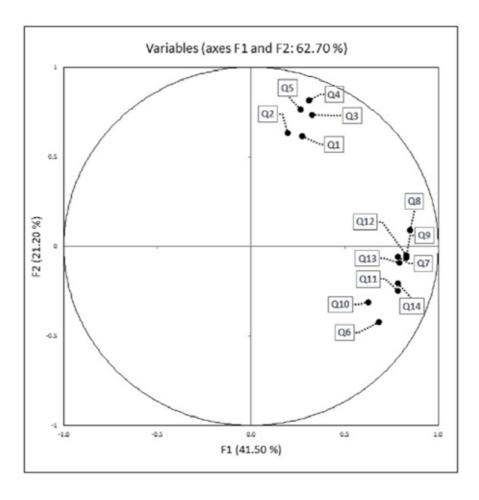


Figure 1 - Principal component analysis correlation circle: projection of functional (Q1-Q5) and interactive/critical (Q6-Q14) questions on two factors (F1 and F2), representing 62.70% of the total variability. Variables close to each other = significantly positively correlated; variables orthogonal = not correlated

Table 4 – Correlation coefficient between sex, age and education and received vaccines

		All vaccines received	Flu	Pneumo	Tetanus ≤ ten years	≥ 1 vaccine received
Age	Correlation coefficient	0.334	0.185	0.262	-0.155	0.310
	Significance Level P	<0.0001	0.0267	0.0015	0.0333	<0.0001
	n	191	144	144	189	191
Sex*	Correlation coefficient	0.199	0.120	0.141	0.144	0.160
	Significance Level P	0.0060	0.1517	0.0912	0.0492	0.0277
	n	190	145	145	188	190
Educational degree	Correlation coefficient	0.040	0.048	0.093	0.102	0.011
	Significance Level P	0.5939	0.5771	0.2785	0.1726	0.8802
	n	180	138	138	179	180

^{* =} positive coefficients show more vaccines received by males than females

either of the other two scales, confirming a different construct, has also shown by the Principal Component Analysis.

The scores of all scales were significantly related to high educational level (Table 4), observation confirmed at the Kruskal Wallis test (functional and interactive HLV, P=0.0011 and P=0.0072, respectively). Regarding the sex, no association was observed, except a significant higher critical VL in females (r=201, P=0.0433).

With regard to the relationship between VL and working activity, there were significant differences between almost all occupational categories, although these observations are purely descriptive.

Vaccine Quiz (VQ) results

In total, 194 interviewees completed this part of the questionnaire, composed by twelve statements. The observed mean score was 6.7, with a range 0-12; the median was 7. VQ score was significantly related to the level of education (r=0.232, p=0.0017), but not to age (r=0.064, P=0.3753) or sex (r=0.013, P=0.8565). The Kruskal Wallis test (P=0.0105) confirmed these observations. Out of all the replies collected, 56% were correct and 17% were wrong, while, for the remaining 27%, interviewees marked the "don't know" box.

Regarding the relationship between the VQ score and working activity, there were significant differences between different occupational groups: teachers and pensioners had significantly higher values than other categories.

Vaccine acceptance (VA) results

In total, 193 subjects answered the three questions related to acceptance of influenza, pneumococcus and tetanus vaccines: 28 subjects (14%) reported having been vaccinated against tetanus in the last ten years, 143 (75%) more than ten years earlier, while 11% were not aware of their vaccination status. Only those vaccinated

in the previous ten years were included in the analysis, as a likely more appropriate indicator of positive vaccination behavior and in accordance with the Ministry of Health's recommendation. Thirty-five (24%) subjects reported having been vaccinated against pneumococcus and 93 (64%) against influenza. Subjects \geq 65-year-olds were more often vaccinated against influenza and pneumococcus (χ -square p=0.0040 and p=0.0003, respectively) than those under 65 (as expected, because recommended under 65 only for high risk categories), whereas for tetanus (P=-0.0262) it was the opposite.

Moreover, the sum of "all vaccines received" (values from 0 to 3) and the binary variable "at least one vaccine received" were analyzed, as synthetic indicators of VA. Both were significantly associated with the age of respondents (Table 4). Age was also related to influenza (flu) and pneumococcal vaccinations and, inversely, with tetanus vaccination (Table 4).

There was no significant association between VA and the educational degree. Proportionally, the males appeared to accept vaccination more than females (chi-square test, P=0.0280); this is also confirmed by including tetanus vaccination in the analysis without considering the ten-year time limit (P= 0.0114). Difference between genders, however, did not exist (P=0.0752) if tetanus vaccination was excluded from the analysis and only pneumococcal and influenza vaccinations were considered.

As for the relationship between working activity and VA (total number of all vaccines received), there were significant differences between the occupational groups, in particular pensioners (as a target group for vaccination) showed higher VA than the categories of employees, housewives and self-employees. The category of health workers (2 doctors, 2 nurses and 1 physiotherapist), while presenting the highest values, also showed a broad standard deviation, significantly differing only from the category of employees. As already

mentioned, these observations are purely descriptive.

Correlation between VQ and VA

A significant positive correlation was observed between VQ score and both the parameters "at least one vaccine received" (Spearman's r=201, P=0.0051) and "all vaccines received" (r=195, P=0.0067), confirmed at the Kruskal Wallis test (P=0.0374 and P=0.0054).

Among the answers to each of the twelve statements included in the VQ (Annex 2) significant differences were observed (P<0.0001, Friedman test): answers to questions n 2 and 11 turned out particularly low. Figure 2 shows the greater VQ scores in subjects receiving at least one vaccine in comparison to those not vaccinated, by each single statement.

In the logistic regression analysis, correct responses to statements 6, 7, 9 and 10 were shown to contribute significantly more than the others to the prediction the dependent

variable "at least one vaccine received" (P= 0.0075, 0.0491, 0.0477 and 0.0477, respectively). Most of these statements regard vaccinations recommended to the adult/senior population, while very few interviewees were aware of shingles vaccine (statement n 2), probably because this vaccine is not offered to all age classes.

Correlations HLVa-IT/VQ and HLVa-IT/VA
Table 5 summarizes significant pairwise
correlations according to the study

correlations according to the study objectives.

A consistent positive correlation was shown between all the VL scales and the VQ score, as well as with the educational level Also, VL scales were significantly associated with VQ score \geq 7 and education (Kruskal Wallis – table 5).

Regarding VA, while in the general population no significance appeared between any of the three VL scales and VA, in those ≥ 65 years a significant correlation was observed between functional VL and the

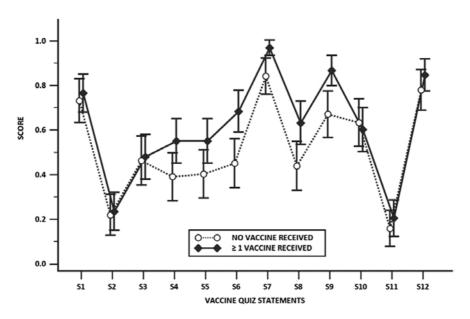


Figure 2 - Average score of each statement included in VQ (S1 to S12 - see annex 2), clustered by vaccination status

	Functional VL	Interactive VL	Critical VL
Vaccine	r=0.320	r=0.389	r=0.306
Quiz	P=0.0004	P=0.0001	P=0.0022
(VQ)	N=117	N=100	N=98
	KW P=0.0106	KW P=0.0020	KW P=0.0386
Educational degree	r=0.240	0.331	r=0.237
	P=0.0087	0.0009	P=0.0212
	N=118	N=98	N=94
	KW P=0.0011	KW P=0.0072	KW P= 0.1114
≥ 1 vaccine received	r=0.293	r= 0.233	r=0.218
(≥65 years)	P=0.0478	0.1377	0.1768
	N=46	N=42	N=40
	KW P=0.0491	KW P=0.1358	KW P=0.1736

Table 5 - Pairwise correlation coefficients (Spearman's r) and kruskall wallis (KW) significance levels between VL scales and VQ, Educational degree and VA (at least one vaccine received – age \geq 65 y.s)

variable "at least one vaccine received" (r= 0.293, P=0.0478).

Filter questions

Although not included in the study objectives, the replies to the two filter questions were also analyzed, as a possible indicator of the respondents' interest in vaccination.

Sixty-one percent and 63% of subjects replied affirmatively to the 1st and 2nd filter questions, respectively. Affirmative responses to both question were significantly associated with higher VQ score (r=0.293, P=0.0001 and r=0.2120, P=0.0029, respectively).

On the opposite, negative responses to the 2nd filter question only were inversely correlated with "at least one vaccine received" and "all vaccines received" (r=-321, <0.0001, and r=-348, <0.0001, respectively, showing a population far-off from vaccination. In its simplicity, this question could work as a quick VL screener, able to identify those at risk of non-immunization.

The ROC (receiver operating Characteristic) curve for flu vaccination in subjects 65 years of age (AUC=0.782, P=0.001) indicates that the response to the 2nd filter question can provide meaningful

information about the likelihood of predicting acceptance of a recommended vaccination, such as influenza (Figure 3). This was confirmed at the chi-square test (P=0.0001).

Discussion

Communicating about vaccines is complex, comprehension of information requiring adequate transmission from the health providers and certain literacy skills of the public (22). Moreover, media play an important role in guiding healthrelated information and significantly influence knowledges (23). To decide to be immunized, adults have to understand and use information about vaccine-preventable diseases, the risks they entail, the benefit/ risk ratio of immunization and much more (24). Moreover, the nature of immunization is changing. The introduction of newer vaccines inducing protection from strainspecific instead of disease-specific infections (e.g., pneumococcal) is transforming vaccination from preventive intervention to health promotive too, at a time when the prevalence of those specific diseases is low, differently than for older vaccines whose

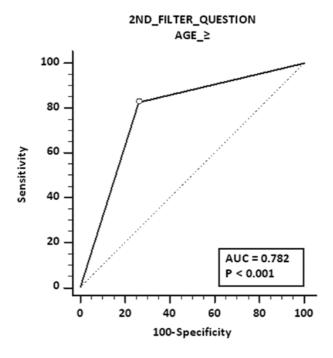


Figure 3 - ROC of the "2nd filter question" (classification variable: flu vaccine received) in the population ≥65 years of age; Youden index =0.5644, associated criterion >0; sensitivity =82.76; specificity =73.68

success has been proven targeting highly prevalent and visible diseases (11).

This is also the case for antigenically variable pathogens, such as flu: studies showing low effectiveness of seasonal influenza vaccine can affect an individual's perception of the ability of this vaccine to protect against the disease (25). Despite vaccines' effectiveness can be low, due to strain mismatch, low coverage rates or other, an individual should understand that this information is mainly for public health purposes and doesn't takes away from the importance of getting vaccinated. People have to be "vaccine literate" enough, to appraise these aspects.

In this survey VL was assessed in an adult population through the administration of a new self-rated test, HLVa-IT, included in a two-pages paper questionnaire, together with a Vaccine Quiz (VQ) and three questions

about the immunization status of the interviewees (Vaccine Acceptance - VA), about vaccinations recommended for adults and over 65 years of age, i.e. tetanus, pneumococcus and influenza. The average scores of functional, interactive and critical VL were 3.23, 2.92 and 2.86, respectively, the possible maximum score being equal to 4. These values are comparable to those observed in a previous study, carried out using a test with a similar construct and administered to parents of children ≤ 8 years age (17), where the functional VL score was lower on average (3.0) than interactive/ critical VL (score 3.3), probably related to the different, younger age class.

In our study, among the three VL scales, the functional one appeared to be the most consistent (only eight subjects excluded from the analysis). Considering the psychometric character of the interactive and critical

questions, the higher number of sections not properly filled in it is not surprising. Interviewees faced the need to think and reflect on their behavior, in an environmental situation probably not perfectly suitable for the administration of this kind of questionnaire.

Almost all the sections relating to VQ and VA were filled in properly. The average VQ score was moderately high (6.7, possible maximum score =12); a relatively higher VQ score was observed in the elderly than in subjects <65 years of age, which is not unexpected, albeit they had significant lower educational level: it has been observed that the older population may have a good level of knowledge on basic health topics as a result of increased access to medical practice and health services (26).

The average number of vaccines received was about 0.8 per individual, being the influenza vaccine administered to 64% of the interviewees, followed by pneumococcal (24%) and tetanus (14%). The number of vaccines administered was significantly higher in subjects \geq 65 years, as target group of recommendations, and in males than in females, in particular tetanus, reasonably reflecting the different occupational status. Results allowed to assess a significant positive correlation between VQ and VA. However, the causal link between the two variables is not well-defined. Possibly, individuals accepting to be vaccinated are more in contact with health services, thus acquiring skills and knowledge, or those with the lowest levels of VL have the least access to information which can decrease vaccine acceptance ('inverse information law') (27). In any case, the association VQ/VA was consistent, thus permitting to consider the VQ reliable to measure construct validity of HLVa.IT

Actually, the scores of the HLVa-IT scales were significantly related to the VQ score, as well as to the educational levels of the participants. The consistent positive correlation for functional, interactive and

critical VL with the VQ score confirmed the valid construct of HLVa-IT.

The significant positive association observed between the functional scale and the variable "at least one vaccine received", although limited to the population ≥ 65 years of age, represents a valid VL model to be pursued, i.e. the alignment of recommendation/communication and provision of services with the skills of users. However, this observation does not allow for the time being to accept a predictive validity of HLVa-IT, i.e. the ability to indicate how likely an individual will accept to be vaccinated. Actually, the role of VL in predicting VA is influenced by several factors, such as age, population settings, vaccine under evaluation and measure employed, and it is generally more evident on knowledge than on behavior outcomes. Although it is accepted that adequate levels of Health Literacy are associated with better outcomes, it is still unclear how they act (2, 28).

Nevertheless, these data are analogous to what observed in other experiences (16, 17), where measures with a construct similar to that of HLVa-IT (i.e., correspondents for childhood vaccinations) were employed. In these populations, parents with high communicative VL were more at risk of non vaccinating their children, which was not the case for functional VL.

By analyzing the question n 5 of the functional scale ("Did you or would you need someone to help you understand the texts?"), significant correlations with the VQ score and the educational level were shown. This item has similar psychometric properties a self-rated general Health Literacy tool, validated in Italian, the SILS-IT (Single item literacy screener), consisting of a single question that showed a significant correlation with an objective test, the Newest Vital Sign (29). This suggests the opportunity to adapt on a Likert scale the question n 5, as well as the 2nd filter question: "Have you

ever thought or been advised to vaccinate yourself against one or more diseases?": 37% of the participants answered negatively to this question, representing a relevant context where VL should be improved. On the one hand, they should be more motivated and informed, and on the other, services should communicate with them more effectively. Therefore, question n 5 and

the 2nd filter question could be employed as quick screeners of VL levels, useful in the vaccination realm.

According to the Principal Component Analysis, interactive and critical scales appear to belong to the same domain, which is consistent with previous results (17) and the structure itself of the questionnaire where the two scales have been merged in

Annex 1 - HLVa-IT (English translation)

"Have you ever read vaccine materials, such as leaflets or posters in doctor's or public health units offices, recommending vaccinations?"

 \square NO \square YES – If yes, fill in the box below, marking with an X the boxes corresponding to your choice (choose only one answer for each question)

1 /				
READING THE MATERIAL:	Never	Rarely	Some times	Often
Score =	4	3	2	1
1 Did you find that the material as a whole (texts and/or images) was difficult to read?				
2 Did you find words you didn't know?				
3 Did you find that the texts were difficult to understand?				
4 Did you need much time to understand them?				
5 Did you or would you have needed someone to help you understand them?				

[&]quot;Have you ever thought or been advised to vaccinate yourself against one or more diseases?"

 \square NO \square YES – If yes, fill in the box below, marking with an X the boxes corresponding to your choice (choose only one answer for each question)

WHEN SEARCHING INFORMATION:	Never	Rarely	Some times	Often
Score =	1	2	3	4
6 Have you consulted more than one source of information?				
7 Did you find the information you were looking for?				
8 Did you understand the information found?				
9 Have you had the opportunity to use the information?				
10 Did you discuss what you understood about vaccinations with your doctor or other people?				
11 Did you consider whether the information collected was about your condition?				
12 Have you considered the credibility of the sources?				
13 Did you check whether the information was correct?				
14 Did you find any useful information to make a decision on whether or not to get vaccinated?				

Annex 2 – Vaccine quiz (VQ) (English translation)

STATE WHETHER, IN YOUR OPINION, THE FOLLOWING CLAIMS ARE TRUE OR FALSE:						
It is possible to start vaccinating at any age	□ True	□ False	□ Don't know			
There is no vaccine for shingles	□ True	□ False	□ Don't know			
To protect against tetanus, vaccination is offered to adults	□ True	□ False	□ Don't know			
free of charge every ten years						
Vaccines can cause autism, encephalitis, asthma or epilepsy	□ True	□ False	□ Don't know			
Too many vaccines weaken the immune system	□ True	□ False	□ Don't know			
Vaccine-preventable diseases are not serious, cannot require	□ True	□ False	□ Don't know			
hospitalization or be fatal						
Vaccines are not only for children. They can also help adults	□ True	□ False	□ Don't know			
to maintain good health						
The pneumococcal vaccine protects against certain types	□ True	□ False	□ Don't know			
of pneumonia						
Influenza and pneumococcal vaccines are recommended and	□ True	□ False	□ Don't know			
free of charge from age 65						
No one has been dying of measles for decades	□ True	□ False	□ Don't know			
Pregnant women cannot be vaccinated	□ True	□ False	□ Don't know			
Vaccination is an important prevention option for patients	□ True	□ False	□ Don't know			
with chronic diseases						

Annex 3 – Vaccine acceptance (VA) (English translation)

Have you been vaccinated	☐ Yes, in the last	□ No,	□ Don't	☐ Yes, more than
against tetanus?	10 years	never	remeber	10 years ago
Have you been vaccinated	□ Yes	□ No,	□ Don't	
against influenza?		never	remeber	
Have you been vaccinated	□ Yes	□ No,	□ Don't	
against pneumococcus?		never	remeber	

one section. In a possible revision of HLVa-IT, the opportunity to combine some pairs of questions (n 11 with n 12 or n 12 with n 13) could be considered, having shown high inter-item correlation indexes, indicating possible repetitiveness, which anyway does not affect the validity of the test, all items measuring the same construct.

The environment where the survey was carried out (waiting rooms in public health offices) can be considered a limit of the study as well as the non-access to the vaccination records of the interviewed persons, although

this was a methodological choice. Also the fact that the knowledge test (VQ) was used for the first time can be considered a limit, even if the statements included were derived from largely diffused questionnaires, in Italy and outside (20, 30) and in this same study a significant strong correlation with VA has been proven.

In conclusion, although a confirmatory study is desirable, the results of this pilot survey suggest that HLVa-IT can be considered a reliable measure of VL. The availability of a tool measuring all VL scales, from the

lowest (functional) to the highest (interactive/ critical), is relevant to healthcare providers, given the complexity of the communication regarding vaccinations. HLVa-IT appears to have the right psychometric characteristics to be used as a self-rated measure of VL in adult individuals by briefly trained health professionals and in an outpatient environment. In particular, it can be employed to assess VL in the populations target of recommendation, before the planning and implementation of communication campaigns to promote vaccination. Measuring VL will be useful in order to adapt interventions to the needs of users and to address the issue of Vaccine Hesitancy in situations like the last one implemented in Italy, as controversial as efficient, being the introduction of mandatory vaccination (31).

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Riassunto

Validazione di uno strumento in italiano per la misura della vaccine literacy nella vaccinazione degli adulti: uno studio pilota

La Vaccine Literacy (VL) si basa sulla stessa idea della Health Literacy (HL): essa comprende conoscenze, motivazioni e competenze delle persone per trovare, comprendere e utilizzare le informazioni utili per prendere decisioni sulla vaccinazione dei bambini e degli adulti. Impiegando strumenti di misura della HL generale, l'associazione tra questa e la Vaccine Hesitancy si è dimostrata incostante. Il test HLVa-IT è un nuovo strumento specifico per l'autovalutazione delle tre scale della VL, funzionale, interattiva e critica riguardo l'immunizzazione degli adulti. A seguito di un processo di Face Validity, HLVa-IT è stato utilizzato per misurare i livelli di VL in una popolazione di 50-75 anni di età presso l'Unità Sanitaria Locale

di Latina (Lazio, Italia). Al fine di convalidarne il costrutto teorico, è stato somministrato contemporaneamente un Quiz sui vaccini (VQ), presumendo che i soggetti che mostrano una buona conoscenza della vaccinazione debbano essere dotati di livelli adeguati di VL. Una correlazione significativa di tutte e tre le scale della VL con il punteggio ottenuto al VQ (r=0.320, P=0.0004; r=0.389. P=0.0001 e r=0.306, P=0.0022, rispettivamente), così come con il grado di istruzione, confermano la validità del costrutto di HLVa-IT. È stato inoltre ricercata una validità di criterio di questo strumento verificandone la correlazione con l'accettazione dei vaccini (VA) raccomandati in età adulta/anziana. Un'associazione positiva con la VA è stata osservata solo per la scala funzionale nella popolazione ≥65 anni, il che non permette di accettarne una validità predittiva, confermando che gli effetti diretti della HL sono più chiaramente verificabili sul grado di conoscenza rispetto a quelli relativi ai comportamenti. Tuttavia, il test HLVa-IT ha mostrato caratteristiche psicometriche adeguate per la misura soggettiva della VL individuale e negli studi di popolazione. È auspicabile che vengano validati e ampiamente utilizzati più strumenti di misura specifici, con l'obiettivo di valutare le competenze delle persone e di definire gli interventi volti al loro miglioramento.

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