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General practitioners cannot predict health literacy of their own patients

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Abstract

Objectives General practitioners (GPs) should be able to identify people with limited Health Literacy to adequately tailor patient information. Concordance between GPs' estimations of patients' HL and patients' self-reported HL was examined.

Design Cross-sectional study with paper based questionnaires (patients and GPs).

Setting GPs across 41 general practices (primary care) in two Flemish provinces (Belgium) in 2016-17.

Participants Adults without severe impairments (physical, mental, sensory) visiting practices of participating GPs.

Main outcome measures Patients' self-reported HL, using HLS-EU-Q16 (scale output: inadequate, problematic, adequate). GPs estimated HL on a corresponding scale. GP –patient acquaintance (frequency of GP visits and number of years patients have been consulting their GP). Generalized linear logit model (GPs' correct HL estimation as reference) was used to assess if patients' characteristics and/or GP -patient acquaintance impacts GP's HL under- or overestimation.

Results 1469 patients completed the study. Their mean age was 54.8 (SD 16.5) years and 63% were female; 8% (107/1399) had primary, 40% (563/1399) secondary; 48% (675/1399) higher education. GPs underestimating HL is more likely in patients with primary education than those with higher education, odds ratio 12.2 (95% confidence interval 4.80 to 30.99) for primary education; the likelihood to overestimate HL is higher in patients with a higher education compared to secondary education, odds ratio 1.38 (1.06 to 1.80) (N= 1260). There's an increased likelihood of HL underestimation when patients are seeing their GP less than one year compared to over ten years, odds ratio 4.48 (1.67 to 12.00) (N= 1260) .

Conclusions Intuitively assessing HL is difficult. The level of education and the number of years patients' have been consulting their GP impact HL perception. GPs need to be aware of HL and it being different from 'literacy'.

Article Summary

Article focus

- Correspond GPs' estimations of their patients' health literacy with patients' self-reported health literacy?

Key findings

- The results show that health literacy is significantly overestimated in patients with higher education and those seeing their GP for over ten years.
- GPs significantly underestimate health literacy in patients with primary and secondary education and those seeing their GP less than one year.

Strengths and limitations of this study

- This is an extensive study, with a large number of patients participating across several general practices.

- Paper-based HLS-EU-Q16 questionnaires were used to stimulate patients to self-report health literacy.
- Voluntary GP and patient participation was potentially selective due to the relatively small research window, survey weariness, reluctance to disclose difficulties regarding health communication.

Introduction

Healthcare is facing enormous challenges. Care is shifting towards managing rather than curing diseases due to the aging of the population and the rising prevalence of chronic diseases and multi-morbidity. As a result, doctor-patient interactions are transforming into partnerships in which patients' needs, values and beliefs influence the course of the care process [1,2]. Besides being responsive to patients' needs, the complexity of healthcare forces healthcare professionals to also take into account patients' health literacy (HL).

HL is defined as one'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' [3]. With the focus on patients managing their care, patients' knowledge, motivation, understanding and skills with regard to health information are important prerequisites to guarantee high quality care.

HL impacts on accessibility and utilization of care, doctor-patient communication, self-care, and, subsequently, health outcomes [4–7]. 47% of the population in eight European countries, and 40% of the Belgian population experience difficulties processing health-related information, hence, have problematic or inadequate HL [8–14]. Overall, people with limited HL may find it difficult to understand medication instructions, have poorer medication adherence [7,10,15,16] , use preventive services less [7,17], have low self-efficacy [18–20], struggle with self-managing chronic diseases [7] and have a worse health status than those with adequate HL [7,21]. Most at risk are non-native speakers, the elderly, and those with limited education [10,13,22,23]. To ensure patients receive appropriate care, healthcare professionals should make sure patients are (being) informed, have sufficient understanding, are given the opportunity to discuss treatment options and are involved in decision making [2].

Awareness of people's understanding of health information and their ability - and willingness - to be involved in (decisions about) their care is essential to tailor information and guide patients through the health care system [24,25]. General practitioners (GPs) in particular are well-placed to ensure people receive the care that meets patients' needs. By communicating effectively and facilitating patients' involvement in their care process, GPs may contribute to improving health outcomes[4,7,24]. However, this requires GPs to be able to identify patients with limited HL.

To date, studies investigating health care professionals' abilities to identify people with limited HL are scarce. Moreover, the few – American - studies that were carried out, demonstrated health care professionals' inability to identify people with limited HL and predominantly overestimating HL[26–28].

The aim of this research was to explore the concordance between patients' self-reported HL and GPs' HL estimations.

Methods

Study design

Cross-sectional study with paper based questionnaires (patient and GPs).

Sample size

It was aimed to reach 39 GPs, 39 general practices and 2000 participants, in correspondence with previous research on patient satisfaction in Belgian general practices [29].

Enrollment

To recruit GPs, the researcher (HS) contacted 79 GPs working in two Belgian provinces of interest (Vlaams-Brabant and Limburg) (Fig. 1). Five GPs were in the direct network of the research team and immediately agreed to participate. Additionally, 73 out of 122 GPs responsible for organizing regional quality meetings for their peers were contacted through phone calls and email, resulting in 19 invites for the researcher to attend these GPs' regional quality meeting. During these meetings, GPs were informed about the HL-conceptual framework, the purpose and study design of this research. Following these meetings, 57 GPs across 46 general practices agreed to participate, although seven declined before setting up the research. Also, (some of) the colleagues within the practice of a GP who had agreed to participate signed up as well (38 GPs), leading to a variable number of participating GPs per practice. Enrollment and start-up took place between October 2016 and December 2017.

Setting and participants

In each general practice, the research window was set to be minimal one month. Participation (GPs and patients) was voluntary, written informed consent from the latter was obtained prior to medical consultation. Adult patients of participating GPs' were eligible for inclusion. Patients were excluded when having a severe: cognitive impairment, sensory disability, psychological or psychiatric disorder. This exclusion was indicated by the participating GP.

Data collection

Patient survey

In the waiting room, patients self-reported their age, gender, education, housing and occupational status (as proxies for socio-economic status). HL was measured using HLS-EU-Q16. Where a patient marked two adjacent Likert-scores, the lower (the one referring to experiencing difficulties) score was registered. Where a patient marked two Likert-scores within two points of each other, the middle value was registered (e.g. if 2 and 4 marked, 3 was registered).

GP survey

Prior to participation, GPs where educated about HL and how to fill out the GP questionnaire. Participating GPs' age, year of graduation, years working in current general practice were registered. This information was collected independently from the patient survey.

At the end of a participating patient's medical consultation, each GP registered patients' : age, HL-estimation (on a scale inadequate, problematic, adequate), GP-patient acquaintance (frequency of GP visits, number of years being consulted by that patient).

Data analysis

Demographic data and HL (self-reported and estimated) were analyzed using descriptive statistics. Chi-square was used to test association of patients' HL level with patients' demographics (age, gender, education). Generalized linear logit model (with GPs' correct HL estimation as the reference) was used to assess if patients' education, age, gender and GPs' age, gender, number of years since graduation, number of years patients consult with their current GP, frequency of GP visits impacted under- or overestimation of HL by GPs; Missing values for a variable were not included in analyses. Statistical significance was assessed as $p < 0.05$. Data were analyzed with R.

Ethical approval

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of the data collected.

Patient and public involvement

Patient were not involved in this research. However, prior to this study, the design has been explained in the context of the feasibility testing of the Dutch HLS-EU-Q16. Consequently, some patients were invited to comment on the study design. Patients did not interpret results nor did they contribute to the writing.

Results

1835 surveys were filled out and returned. After checking for exclusion criteria, data represented 45 general practices, 83 GPs and 1674 eligible patients. Subsequently, some surveys were excluded because at least eight of 16 items of HLS-EU-Q16 were left unanswered, or data on HL were missing (from the part of GP and/or patient) (Fig. 2). Hence, the number of participants reduced to 1469 patients.

Sample characteristics

Patients were 54.8 years old (SD 16.5); 63% were female; 48% was highly educated (N= 1399). The mean age of GPs was 42.8 years old (SD 13.5); 53% GPs were female (N= 80). Regarding GP-patient acquaintance, approximately 10% of the patients are seeing their GP for less than one year, 45% for over than 10 years (N= 1454). GPs were working on average 14.3 (SD 13.4) years in their current practice, with a maximum of 48 years (Table 1). Fifteen of the 41 general practices were solo practices; in 18 general practices, the number of GPs varied from three to seven. Six practices were located in four different regions with high population density, ten practices were located in five different multicultural regions.

Health Literacy (mis)match

Most patients self-reported adequate HL (63%). GP's estimated HL of their patients to be adequate in 90%. HL of more than one third of the patients was overestimated by their GP. Of nearly all patients with inadequate, HL was overestimated by their GP (99%) (Table 2).

Explaining health literacy estimations

Generalized logit model odds ratio's demonstrate GPs' under- or overestimation HL of patients to be significantly affected by the educational level of the patient, the number of years patients have been visiting their regular GP and the GPs' gender (N= 1260).

Patients' educational level

HL of patients with 'higher education' is more likely to be underestimated compared to those with 'secondary education' (OR = 1.38 with 95% CI [1.06 ; 1.80]). HL overestimation is significantly higher for patients with 'primary education' versus 'higher education'; and 'secondary education' versus 'higher education', respectively 12.2 (with 95% CI [4.80 ; 30.99]) and 4.1 times (with 95% CI [1.95 ; 8.42]) (Fig. 3 (bottom)).

Length of GP-patient acquaintance

It is more likely GPs overestimate HL of patients they know 'over 10 years', compared to 'one up to five years' (OR =1.64 with 95% CI [1.25 ; 2.14]). The odds of underestimating HL are higher for patients who have been seeing their GP for a time: HL is more likely underestimated in patients seeing their GP 'less than one year' versus 'more than 10 years' (OR = 4.48 with 95% CI [1.67 ; 12.00]) and 'one up to five years' compared to 'more than 10 years' (OR = 3.10 with 95% CI [1.60 ; 5.97], (Fig. 3 (middle)).

Gender of GPs

Comparing under- and overestimating HL, the odds of overestimating HL versus underestimating when a GP is female is 0.5 times the odds of HL overestimation versus HL underestimation when a GP is male (Fig. 3 (top)).

Table 1 Sample characteristics

	Patients (n= 1455)	General practitioners (n= 80)
Gender (% female)	63%	53%
Mean age (SD); [range]	54.8 (SD 16.5); [18-100]	42.8 (SD 13.5); [25-73]
Educational attainment (n= 1399)		N/A
no formal education	3.9%	
primary education	7.6%	
secondary education	40.2%	
higher education	48.2%	
Number of years patients have been visiting GP		
< 1 y	9.8%	
1 - 5 y	29.9%	
6 - 10 y	15.4%	
> 10 y	44.8%	
Years graduated	N/A	17.3 (SD 13.3)
Years working in current practice		14.3 (SD 13.4)

Table 2 GPs' Health Literacy estimation per level of self-reported Health Literacy (n= 1469)

Self-reported HL	GPs' HL estimation			
Adequate (n= 927)	**Correct**	92.6%		
	Incorrect	7.4%	7.2%	▽
			0.2%	▽▽
Problematic (n= 327)	**Correct**	9.5%		
	Incorrect	90.5%	90.2%	△
			0.3%	▽
Inadequate (n= 215)	**Correct**	0.9%		
	Incorrect	99.1%	80.0%	△△
			19.1%	△

GPs estimate HL one (▽/△) or two (▽▽/△△) levels lower/higher than self-reported HL

Discussion

Our findings demonstrate GPs' predominantly overestimating their patients' HL. Patient's level of education and the length of patients' relationship with their GP significantly impacts both HL over- and underestimation. Regarding education, HL is more likely to be overestimated in highly educated patients; Comparing educational levels, HL is significantly underestimated (12.2 times) when having a primary education and when having secondary education (4.1 times) compared to higher education.

Comparison with previous studies

The majority of GPs perceived their patients to have adequate HL, although 10% of patients' self-reported inadequate HL[9,12]. This corresponds to previous research in a hospital setting demonstrating doctors' HL overestimation outnumbering underestimation with nearly 2-to-1 [26]. A similar outcome was reported, focusing on nurses [28]. Just one study described primary care physicians overestimating patients literacy [27].

Education

GPs seem to seek guidance in patients' educational level when estimating HL, although we are not sure patients ever explicitly disclosed their educational level to GP. Numerous studies have demonstrated the correlation between HL and education [9,22,23] : lower HL is observed in people with lower educational levels, although highly educated people may also have poor HL [12,23]. Despite of its correlation with HL, there's a fundamental difference between literacy and HL, which is emphasized in several studies [9,12,23] Undoubtedly, literacy is a vital skill to function with or within the contemporary health care system. However, complementary, advanced skills are necessary to execute instructions, interact with healthcare professionals and critically appraise information [20,30,31]. If our findings are an expression of GPs' presuming highly educated patients do not experience difficulties acting upon health information, these results are potentially problematic.

GP – patient acquaintance

The significant HL overestimation in patients seeing their GP for over ten years we found remarkable because we would have expected long standing doctor-patient relationships to contribute to GPs' better understanding of their 'long-term' patients, for instance, their background, social network,… In comparison, the HL underestimations when patients have been seeing their GP for a relatively short period of time we would find less surprising, if this would express a cautious approach due to GPs and patients being less acquainted. Little comparable research was found that could explain our findings. Consequently, we turned to studies focusing on continuity of care, a key dimension of good primary care[32]. If we would consider continuity of care and a long relationship to be analogous, findings of previous studies are in contrast to the one's we reported. For instance, it is reported to correlate with improved adherence to physicians' instructions[33] and better communication[34]. Also, being cared for less than one year by the same care provider was associated with decreasing communication excellence [35]. Although (dis)satisfaction with communication may stem from being unaware of patients' HL, we did not find studies linking their results to patients' knowledge, their understanding of or the processing of health information.

Implications & recommendations for clinical practice

GPs in our research were often not able to estimate HL of their patients. We would recommend GPs to perform some sort of HL assessment, instead of going by intuition. Therefore, feasible alternatives

for clinical practice should be considered [36], such as using single item questions [28,37], preferably tested by the target group to avoid comprehension problems [38–40], but, above all, asking patients directly about their understanding and the kind of information and/or (practical) support they might need, will in general turn out to be much easier.

Moreover, educating (future) GPs and making them familiar with the HL-concept and the implications of low HL is a prerequisite to address HL [41]. GPs should get to know their patients. In particular it is important to know who is experiencing barriers to care and how to reach them. Being able to identity people with limited HL will help GPs to tackle health inequalities, for example by adequate information exchange. Hence, GPs should be equipped with a variety of strategies they can integrate in their day-to-day practice to communicate on a low HL-level [41–43].

Strengths and limitations

GP participation was potentially selective, although several attempts to contact and motivate GPs were undertaken. Given, selection bias may have occurred in the relatively small research window. Some patients might not have had the chance to participate because of not visiting their GP, some patients may have felt reluctant [44] or ashamed to disclose HL information [45,46]. Survey weariness, the length or usability of a paper-based questionnaire may have discouraged patients from participating, particularly more vulnerable patients (illiterate, non-natives). Nevertheless, many patients with low HL and low education participated. People experiencing barriers to care may have been missed. If so, their participation would have enriched data if the reason for not visiting their GP or for not participating would be linked to HL, for example because of low trust in GPs or poor self-related health [47]. Some GPs had the impression the majority of participating patients were natives and/or involved, empowered patients, thus, not reflecting the diversity in their patient population. This limitation also makes our findings more powerful. If patients whose HL is incorrectly estimated, do not represent minority groups or patients experiencing some vulnerability, this implies GPs assuming these patients to adequately function in a healthcare setting. It certainly, would have been interesting to see if results would have been different with a more diverse sample.

This research is based on self-reported HL, which is inherently prone to subjectivity, as opposed to objective HL tools with the purpose of examining people succeeding in specific problem-solving tasks. Nonetheless, self-reported questions are considered valid and feasible methods to assess HL [48–50]. Both self-reported and objective HL measurements benefit of being tailored to targeted groups. Unless it's part of the design, tests relying on vocabulary unfamiliar to the target group –terms they do not come across in everyday live - enhances the difficulty of a particular tool. Consequently reflecting understanding of the tool itself rather than one's HL[39]. Mindful of potential comprehension problems, HLS-EU-Q16's feasibility was tested prior to this study [38]. In correspondence with other studies, the level of abstraction or lacking experience regarding some health-related tasks in health care, health promotion and disease prevention made it difficult to answer some items, but overall HLS-EU-Q16 was considered a feasible instrument[38,39].

Conclusion

Intuitively assessing patients' HL is difficult. Patients' education is not a good indicator for their HL. Consequently, GPs should be aware of HL and it being different from 'literacy' (i.e. education). It would be beneficial to facilitate and encourage GPs to get a profound understanding of their patients

and their lives. With the redesigning of health care to integrated care there's an opportunity to promote in-depth communication as the cornerstone for everyone to access adequate care. To be incorporated in daily practice, GPs should be allowed to invest a sufficient amount of time to getting to know their patients.

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Contributors

HS was responsible for study concept and design (with valuable input from BA and NC) and for data acquisition and for initial analyses. Data interpretation with all authors (HS, BA, FV, NC) led to a manuscript drafted by HS. All authors substantially contributed to critically reviewing the manuscript and all read and approved the final version. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at *www.icmje.org/coi_disclosure.pdf* and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of collected data.

Transparency

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant registered) have been explained.

Data sharing

The dataset used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Figure legends

Fig. 1 Recruitment of general practitioners

Fig. 2 Flowchart excluded questionnaires

Fig. 3 Health Literacy (mis)match versus GPs' gender (top), GP-patient acquaintance (middle), patients' education (bottom)

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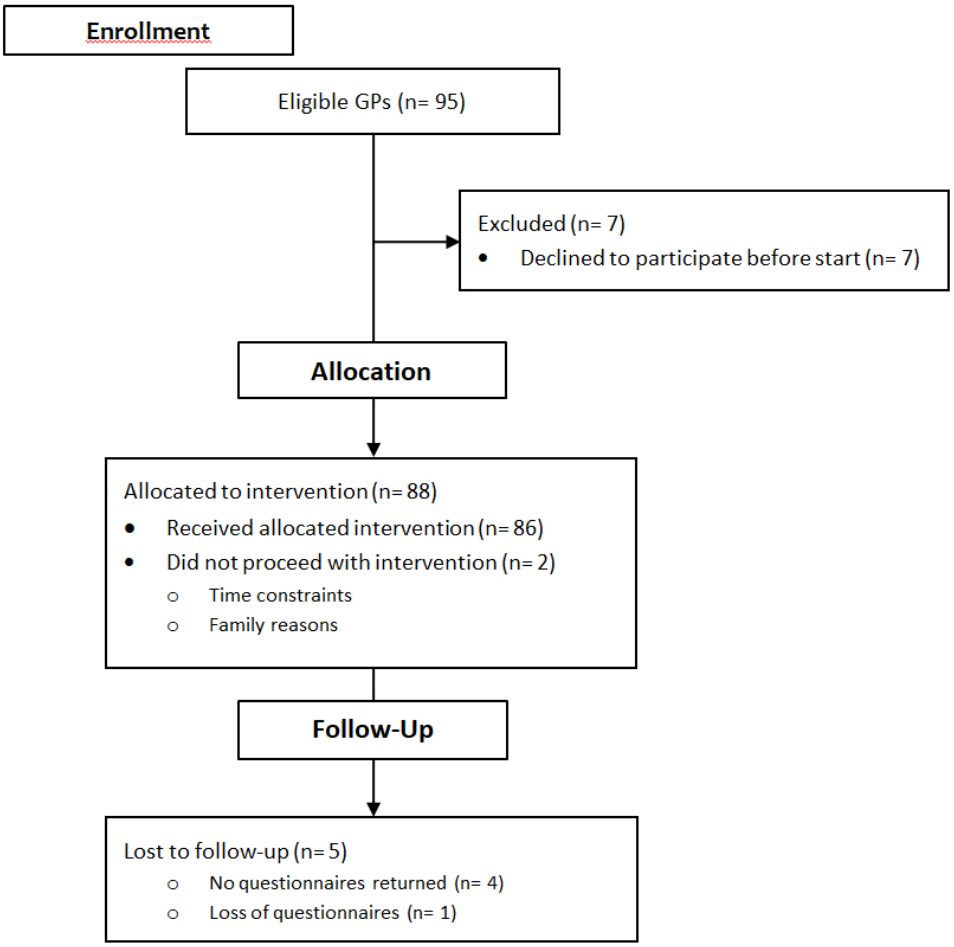

Fig. 1 Recruitment of general practitioners

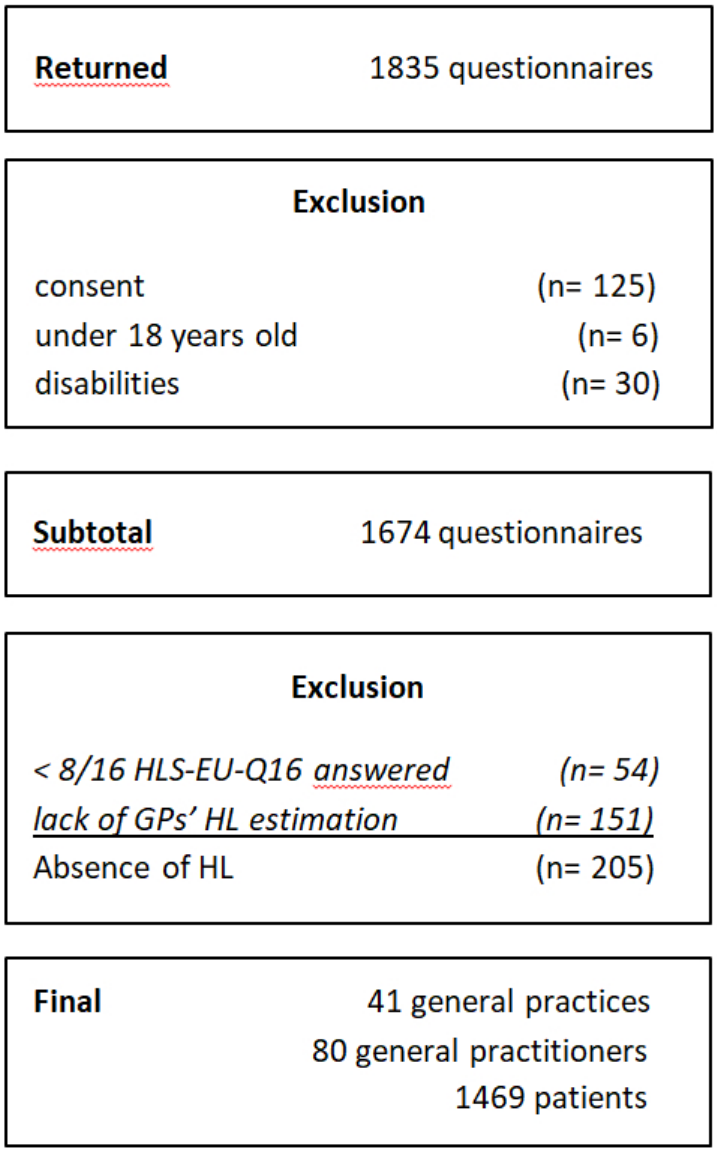

Fig. 2 Flowchart excluded questionnaires

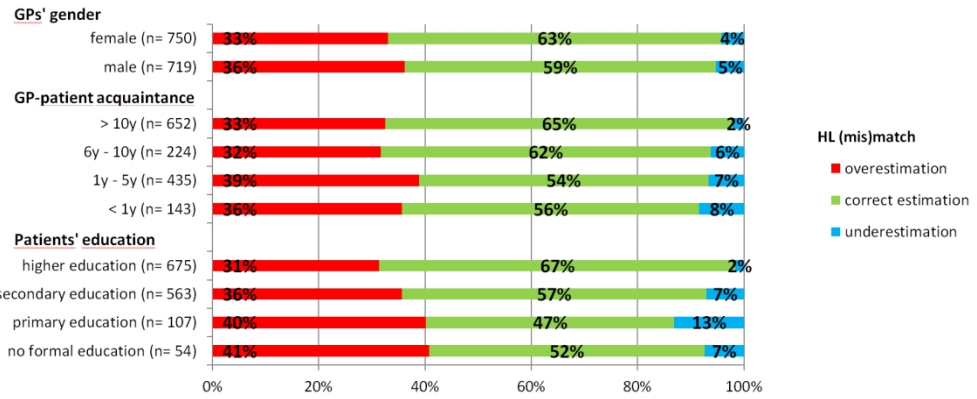

Fig. 3 Health Literacy (mis)match versus GPs' gender (top), GP-patient acquaintance (middle), patients' education (bottom)

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General practitioners' predictions of their own patients' health literacy: a cross-sectional study in Belgium

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General practitioners' predictions of their own patients' health literacy: a cross-sectional study in Belgium

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Abstract

Objectives To support patients in their disease management, providing information that is adjusted to patients' knowledge and ability to process health information (i.e. health literacy) is crucial. To ensure effective health communication, general practitioners (GPs) should be able to identify people with limited health literacy. To this end, agreement between patients' health literacy and GPs' estimations thereof and characteristics impacting on health literacy disagreement were examined.

Design Cross-sectional survey of general practice patients and GPs undertaken in 2016-17

Setting Forty-one general practices in two Dutch-speaking provinces in Belgium.

Participants Patients (18 years of age and older) visiting general practices. Patients were excluded when having severe impairments (physical, mental, sensory), as documented by a participating GP.

Main outcome measures Patients' health literacy was assessed with HLS-EU-Q16 (scale output: inadequate, problematic, adequate). Using a simple scale (inadequate; problematic; adequate) GPs indicated estimations on patients' health literacy. Agreement between patients' health literacy and GPs' estimations thereof was measured using Kappa statistics. Generalized linear logit model examined the impact of patients' sex, age, education, number of years consulting their GP, sex of GP on GPs' higher/lower health literacy estimates (over-/underestimating) than patients' actual health literacy.

Results Health literacy of patients (n= 1375) was inadequate (201), problematic (299), adequate (875). GPs' estimations corresponded for 2% inadequate, 43% problematic, 143% adequate health literate patients. There was a slight agreement between patients' health literacy and GPs' estimations thereof (Kappa = .033). The likelihood for GPs to over- or underestimate patients' health literacy increases with decreasing educational level of patients; and decreasing number of years patients have been consulting with their GP.

Conclusions Intuitively assessing health literacy is difficult. Patient's education, the number of years patients have been consulting with their GP and sex of the GP impact on GP's perception of a patient's health literacy.

Article Summary

Strengths and limitations of this study

- This is an extensive study, with a large number of patients participating across several general practices.
- Paper-based HLS-EU-Q16 questionnaires were used to stimulate patients to fill out the health literacy survey.
- Voluntary GP and patient participation was potentially selective due to the relatively small research window, survey weariness, reluctance to disclose difficulties regarding health communication.

Introduction

Healthcare is facing enormous challenges. Care is shifting towards managing rather than curing diseases due to the aging of the population and the rising prevalence of chronic diseases and multi-morbidity. As a result, doctor-patient interactions are transforming into partnerships in which patients' needs, values and beliefs influence the course of the care process [1,2]. Besides being responsive to patients' needs, the complexity of healthcare forces healthcare professionals to also take into account patients' health literacy (HL).

Health literacy is defined as one'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' [3]. With the focus on patients managing their care, patients' knowledge, motivation, understanding and skills with regard to health information are important prerequisites to guarantee high quality care.

Health literacy impacts on accessibility and utilization of care, doctor-patient communication, self-care, and, subsequently, health outcomes [4–7]. Research in eight European countries demonstrated that 47% of the population experience difficulties processing health-related information, hence, have problematic or inadequate health literacy [8–14]. Since the development of the conceptual framework of the HLS-EU consortium, health literacy research in Europe - and Belgium – is expanding.[3] In Belgium, the most renowned studies have focused on the prevalence, with 40% of the Belgian population being low health literate; on health literacy being an intermediary for tobacco use, health status, physical activity and the pricing of medication[9] and on the use of healthcare services and the associated costs.[14] This research of Vandenbosch et al[14] found no significant effect between someone's health literacy and the use of healthcare services such as the emergency room nor GP consultations. However, people with lower health literacy levels were found to have significantly more hospitalizations and more GP visits at home than those with adequate health literacy.[14]

Overall, people with limited health literacy may find it difficult to understand medication instructions, have poorer medication adherence [7,10,15,16] , use preventive services less [7,17], have low self-efficacy [18–20], struggle with self-managing chronic diseases [7] and have a worse health status than those with adequate health literacy [7,21]. Most at risk are non-native speakers, the elderly, and those with limited education [10,13,22,23]. To ensure patients receive appropriate care, healthcare professionals should make sure patients are (being) informed, have sufficient understanding, are given the opportunity to discuss treatment options and are involved in decision making [2].

Awareness of people's understanding of health information and their ability - and willingness - to be involved in (decisions about) their care is essential to tailor information and guide patients through the health care system [24,25]. General practitioners (GPs) in particular are well-placed to ensure people receive the care that meets patients' needs. By communicating effectively and facilitating patients' involvement in their care process, GPs may contribute to improving health outcomes[4,7,24]. However, this requires GPs to be able to identify patients with limited health literacy.

To date, there are few studies investigating health care professionals' abilities to identify people with limited health literacy are scarce. Moreover, the Northern American studies that exist, demonstrated health care professionals' inability to identify people with limited health literacy and predominantly overestimating health literacy[26–28]. To assess health literacy, these studies relied on so called "objective" (health) literacy tools (NVS[29], REALM[30,31], REALM-R[32]). Their sample sizes were relatively

small, with the number of participants ranging from 65 to 182. Despite these differences in study design, non-academic primary care physicians, residents, and nurses all overestimated patients' health literacy. They estimated health literacy at the highest level for respectively 74 out of 100 patients; 164 out of 182 patients; 44 of 65 patients. The corresponding Kappa's (0.19 and 0.09) demonstrated the little agreement between healthcare professionals' estimations and patients' actual health literacy.

The aim of this research was to explore the agreement between patients' health literacy and GPs' health literacy estimations and examine characteristics impacting on health literacy (dis)agreement.

Methods

Study design

Cross-sectional study with paper based questionnaires (patient and GPs).

Recruitment

To recruit GPs, the researcher (HS) contacted 79 GPs working in two Belgian provinces of interest (Vlaams-Brabant and Limburg) (Fig. 1). Five GPs were in the direct network of the research team and immediately agreed to participate. Additionally, 73 out of 122 GPs responsible for organizing regional quality meetings for their peers were contacted through phone calls and email, resulting in 19 invites for the researcher to attend these GPs' regional quality meeting. During these meetings, GPs were informed about the health literacy conceptual framework, the purpose and study design of this research. Ultimately, 95 GPs expressed their intent to participate (with number of GPs participating varying per general practice). Seven of those GPs declined to participate before the research was set up in their practice. Of the remaining GPs, three were unable to carry out the research; four GPs returned zero questionnaires returned, whereas three others returned between one and three questionnaires. For one GP, no questionnaires were returned due to the loss of completed questionnaires (Fig 1). Recruitment and start-up took place between October 2016 and December 2017.

Sample size

This study used purposive sampling for the recruitment of GPs and patients. It was aimed to reach 2000 patients. Compared to the general population of the Dutch-speaking part of Belgium, women and people aged 65 years and older were over-represented ,with 63% women (compared to 51% in adult population of Dutch-speaking region), and 31% people aged 65 years and older (compared to 25% in adult population of Dutch-speaking region).

Setting and participants

In each general practice, the research window was set to be minimal one month. Participation (GPs and patients) was voluntary, written informed consent from the latter was obtained prior to medical consultation. Men and women 18 years of age and older consulting with a participating GP were eligible for inclusion. Patients were excluded when having a severe cognitive impairment, sensory disability, psychological or psychiatric disorder. This exclusion was documented by the participating GP.

Measures

Health literacy

Health literacy of patients was assessed with HLS-EU-Q16. Derived from the 47-item European Health Literacy Survey Questionnaire (HLS-EU-Q47[3]), this 16-item version measures 11 of 12 sub-dimensions of health literacy as defined by the conceptual model developed by the HLS-EU consortium.[33] These dimensions result from integrating three health relevant domains (health care, disease prevention, health promotion) and four competencies relevant for the processing of health information (access, understand, appraise, apply).[33] HLS-EU-Q16 highly correlates with the 47-item version, but it does not allow statements on the sub-dimensions of health literacy.[33–35] The Dutch HLS-EU-Q16 has been used in Belgium[9] and the Netherlands[36,37].

Items are formulated as questions ("How easy would you say it is to find information on treatments of illnesses that concern you?", "How easy would you say it is to understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?") Each question was rated on 4-point Likert scales ("very difficult", "difficult", "easy", and "very easy"). These scores are dichotomized, by coding responses 0 = "(very) difficult" and 1 = "(very) easy". After summing the answers, a score between 0 and 16 can be obtained. Consequently, patients were categorized as having *inadequate health literacy* (scoring 0-8 points), *problematic health literacy* (scoring 9-12 points)*, adequate health literacy* (scoring 13–16 points).

As opposed to patients' health literacy assessment, GPs' estimations of their patients' health literacy was restricted to indicating either inadequate; problematic; adequate health literacy on a simple scale. To this end, GPs were educated on the health literacy concept and the associated HLS-EU questionnaires, at least twice. Amongst others, GPs were informed about how categories of health literacy were determined, allowing them to scale their patients' health literacy into one of the three categories.

Where a patient marked two adjacent Likert-scores, the lower (the one referring to experiencing difficulties) score was registered. Where a patient marked two Likert-scores within two points of each other, the middle value was registered (e.g. if 2 and 4 marked, 3 was registered).

Other variables

Patients self-reported their sex (male; female), age (continuous) and educational attainment (no formal education; primary education; secondary education; higher education). GP-patient acquaintance was documented by GPs based on the number of years patients have been visiting their GP (< 1 year; 1 - 5 years; 6 - 10 years; > 10 years). GPs also indicated whether the consultation concerned a replacement for a colleague (yes; no).

GPs' (sex (male; female), age and years graduated (both continuous) were registered independently from the patient survey.

Data collection

Prior to participation, GPs were educated about health literacy. At that moment, the research in general and the GP survey in particular, were presented. Subsequently, GPs could agree to participate. When participating GPs received the study surveys, the concept health literacy was explained once again and instructions on how to fill out the GP survey were repeated. Boxes labeled with a participating GP's name were set out in the waiting area. These boxes contained white envelope's, with each one of them consisting of a consent form and a both a patient and a GP survey,

labeled with a unique number. Leaflets with pictogram instructions were distributed throughout the waiting area to inform patients about the research.

In the waiting room, prior to their consultation with a participating GP, patients would voluntarily choose to fill out the patient survey (patient characteristics and HLS-EU-Q16). During consultation, patients would give their GP the GP survey. Subsequently, at the end of a participating patient's medical consultation, GPs than registered patients' age, GP-patient acquaintance and their own health literacy estimation of that patient in the separate GP survey. Patient surveys were collected in separate envelope's than GP surveys. Not only to stimulate patients to answer truthfully but also to ensure GPs had no access to patients' responses.

Statistical analyses

Demographic data and health literacy (patients and estimations by GPs) were analyzed using descriptive statistics. Kappa statistics were calculated to measure agreement between patients' health literacy and GPs' estimations of these patients' health literacy.[38] Generalized linear logit model (with reference group: GPs' health literacy estimations being equal to patients' health literacy) was used to assess if patients' sex, age and education, GP-patient acquaintance and GPs' sex, age, years since graduation and them replacing for a colleague impacted under- or overestimation of health literacy by GPs (GPs' estimates of patients' health literacy being respectively lower and higher than patients' health literacy). Missing values on the initially considered variables were excluded from analyses. Finally, analysis on variables with significant results encompassed only three variables (patient's education, sex of GP and the number of years patients had been consulting their GP). Statistical significance was assessed as $p < 0.05$. Data were analyzed with R.[39]

Ethical approval and consent

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of the data collected.

Patient and public involvement

Patients were not involved in this research. However, prior to this study, the design has been explained in the context of the feasibility testing of the Dutch HLS-EU-Q16. Consequently, some patients were invited to comment on the study design. Patients did not interpret results nor did they contribute to the writing of the manuscript.

Results

1835 surveys were filled out and returned. The number of participants reduced to 1469 (and 80 GPs across 41 general practices) due to the exclusion of questionnaires (because more than half of the questions of HLS-EU-Q16 were unanswered; data on health literacy were missing (from the part of GP and/or patient); less than four questionnaires were returned) (Fig. 2). For the majority of these questionnaires the exclusion was based on a missing health literacy estimation by the GP. Consequently, patients' health literacy of this excluded subset could not be included in this research, although available. Of these 148 patients, 26 (17.6%) had inadequate health literacy, 27 (18.2%)

problematic and 95 (64.2%) adequate health literacy. Characteristics of excluded patients can be found in the supplementary file.

To analyse data using the generalized logit model, patients with missing values were excluded (14 and 70 missing values for patient's gender and education; 14 for GP-patient acquaintance; 11 for GPs doing a replacement for a colleague). Analyses were performed on the final dataset of 1375 patients (Table 1).

Sample characteristics

Patients were on average 54.6 years old (SD 16.4); 63.9% were female; 48.2% was highly educated (Table 1). Regarding GP-patient acquaintance, approximately 10% of the patients have been consulting their GP for less than one year, 45.1% for over than 10 years .

The mean age of GPs was 42.8 years old (SD 13.5); 53% GPs were female (N= 80).GPs were graduated on average 17.3 (SD 13.3) years ago and were working on average 14.3 (SD 13.4) years in their current practice, with a maximum of 48 years (Table 1). Fifteen GPs were working solo;; whereas the remaining GPs were working in group practices of three to seven GPs. Six practices were located in four different regions with high population density, ten practices were located in five multicultural regions.

Health Literacy agreement

Patients' health literacy was adequate, problematic and inadequate in respectively 63.6% (n= 875), 21.7% (n= 299) and 14.6% (n= 201) of 1375 patients, whereas GPs estimated patients' health literacy respectively 90.3% (n= 1241), 9.5% (n= 130), 0.3% (n= 4). (Fig. 3). For each health literacy level, this corresponds with an agreement of respectively 143%; 43% and 2% for patients with adequate, problematic, inadequate health literacy (Table 1). Based on these data, there was slight agreement between patients' health literacy and GPs' estimations thereof, $\kappa = 0.033$ (95% CI, 0.00124 to 0.0648), $p < 0.05$.

Characteristics impacting on health literacy (dis)agreement

Patient's education, sex of GP and the number of years a patient has been consulting with their GP were retained as these three variables were shown to significantly impact on GPs estimating health literacy of their patients to be lower (under-estimate) or higher (over-estimate) than patients' actual health literacy.

Patients' educational level

Health literacy is more likely to be underestimated when a patient has no formal education (OR 5.58, 95% CI: 1.60 to 19.50); primary education (OR 14.13, 95% CI: 6.54 to 30.54); secondary education(OR 5.05, 95% CI: 2.65 to 9.61), compared to patients with higher education (Table 2). GPs are more likely to overestimate patients' health literacy in patients with primary education (OR 2.02, 95% CI: 1.22 to 3.13); secondary education (OR 1.34, 95% CI: 1.04 to 1.73), compared to those with higher education (Table 2).

Length of GP-patient acquaintance

The odds of underestimating health literacy are higher for patients who have been seeing their GP for a relatively short time: health literacy is more likely underestimated in patients consulting with

their GP less than one year (OR 6.7, 95% CI: 1.10 to 3.70); between one and five years (OR 4.81, 95% CI: 2.79 to 16.09); between six and ten years (OR 3.70, 95% CI: 2.53 to 9.14) compared to patients who have been consulting with their GP for more than ten years (Table 2). Overestimation of health literacy is more likely in patients consulting with their GP between one and five years, compared to 'more than ten years' (OR 1.51, 95% CI: 1.17 to 1.94) (Table 2).

Sex of GPs

The odds of underestimating health literacy when a GP is male is 2.02 times the odds of making an underestimation when a GP is female (Table 2).

Table 1 Patient and GP characteristics

	Overall sample	Generalized logit model	Patient's health literacy		
			Inadequate	Problematic	Adequate
Total N	1469	1375	201	299	875
PATIENT	% (N)	% (N)	% (N)	% (N)	% (N)
Sex					
female	63% (919)	63.9% (878)	60.7% (122)	63.2% (189)	64.8% (567)
Missing values	1% (14)	0% (0)	0% (0)	0% (0)	0% (0)
Age					
18y-24y	4% (57)	3.9% (54)	5.5% (11)	5.0% (15)	3.2% (28)
25y-34y	11% (154)	10.4% (143)	12.4% (25)	12.7% (38)	9.1% (80)
35y-44y	13% (192)	13.2% (182)	12.9% (26)	13.4% (40)	13.3% (116)
45y-54y	20% (294)	20.2% (278)	13.4% (27)	14.0% (42)	23.9% (209)
55y-64y	21% (311)	21.5% (296)	25.4% (51)	19.7% (59)	21.3% (186)
65y-74y	19% (283)	19.3% (265)	18.4% (37)	22.1% (66)	18.5% (162)
75y-84y	10% (153)	9.7% (134)	9.0% (18)	11.4% (34)	9.4% (82)
85y-104y	2% (25)	1.7% (23)	3.0% (6)	1.7% (5)	1.4% (12)
mean age (SD)	54.8 (16.5)	54.6 (16.4)	54.1 (17.4)	54.7 (17.7)	54.7 (15.7)
Missing values	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Educational attainment					
no formal education	3.9% (54)	3.9% (54)	7.0% (14)	5.0% (15)	2.9% (25)
primary education	7.6% (107)	7.6% (104)	11.9% (24)	8.0% (24)	6.4% (56)
secondary education	40.2% (563)	40.3% (554)	42.8% (86)	42.5% (127)	39.0% (341)
higher education	48.2% (675)	48.2% (663)	38.3% (77)	44.5% (133)	51.8% (453)
Missing values	5% (70)	0% (0)	0% (0)	0% (0)	0% (0)
Number of years patients have been visiting GP					
< 1y	9.8% (143)	9.5% (130)	11.9% (24)	9.0% (27)	9.0% (79)

1y - 5y	29.9% (435)	30.0% (412)	30.3% (61)	34.8% (104)	28.2% (247)
6y - 10y	15.4% (225)	15.5% (213)	14.4% (29)	14.0% (42)	16.2% (142)
> 10y	44.8% (652)	45.1% (620)	43.3% (87)	42.1% (126)	46.5% (407)
Missing values	1% (14)	0% (0)	0% (0)	0% (0)	0% (0)

Table 1 Patient and GP characteristics (continued)

			Patient's health literacy		
	Overall sample	**Generalized logit model**	**Inadequate HL**	**Problematic HL**	**Adequate HL**
Total N	1469	1375	201	299	875
GENERAL PRACTITIONER	% (N)	% (N)	% (N)	% (N)	% (N)
Sex					
female	51.1% (750)	51.4% (668)	47.3% (95)	50.5% (151)	52.7 (461)
Missing values	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Age					
25y-34y	28.9% (425)	28.5% (392)	29.4% (59)	31.1% (93)	27.4% (240)
35y-44y	19.5% (287)	20.0% (275)	18.9% (38)	19.7% (59)	20.3% (178)
45y-54y	25.1% (368)	25.2% (346)	21.9% (44)	24.7% (74)	26.1% (228)
55y-64y	20.8% (305)	20.4% (281)	20.4% (41)	19.4% (58)	20.8% (182)
65y-74y	5.7% (84)	5.9% (81)	9.5% (19)	5.0% (15)	5.4% (47)
75y-84y	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Doing a replacement					
yes	5.6% (82)	5.4% (74)	9.0% (18)	3.7% (11)	5.1% (45)
Missing values	0.7% (11)	0% (0)	0% (0)	0% (0)	0% (0)
Health literacy estimation					

inadequate	0.3% (5)	0.3% (4)	1.0% (2)○	0% (0) ▽	0.2% (2) ▽▽
problematic	9.5% (139)	9.5% (130)	17.9% (36)△	9.4% (28)○	7.5% (66) ▽
adequate	90.2% (1325)	90.3% (1241)	81.1% (163)△△	90.6% (271)△	92.2% (807)○
Agreement patients' health literacy & GPs' estimations thereof					
over-estimation	34.6% (508)	34% (470)	99% (199)	91% (271)	N/A
equal estimation	60.7% (891)	61% (837)	1% (2)	9% (28)	92% (807)
under-estimation	4.7% (70)	5% (68)	N/A	0% (0)	8% (68)
Total N	1469	1375	201	299	875

GPs estimate health literacy equal to ○ /one level lower ▽/one level higher △) or two levels lower ▽▽/ two levels higher △△)/than patients' actual health literacy

Table 2 Odds ratios and 95% confidence intervals for patient and GP characteristics impacting GPs' estimations of patients' health literacy ($p < 0.05$)

		GP's estimation of patient's health literacy*	Odds Ratio	95% confidence interval
Patient education [a]	**no formal education**	under-estimation**	5.58	1.60 to 19.50
	primary education	under-estimation	14.13	6.54 to 30.54
		over-estimation***	2.02	1.22 to 3.13
	secondary education	under-estimation	5.05	2.65 to 9.61
		over-estimation	1.34	1.04 to 1.73
GP-patient acquaintance [b]	<1 year	under-estimation	6.7	1.10 to 3.70
	1 - 5 years	under-estimation	4.81	2.79 to 16.09
		over-estimation	1.51	1.17 to 1.94
	6 - 10 years	under-estimation	3.70	2.53 to 9.14
GPs' sex [c]	male	under-estimation	2.02	1.69 to 8.09

[a] compared to patients with higher education

[b] compared to patients having been consulting their GP for over 10 years

[c] compared to female GP

* Reference group: *GPs' estimation of a patient's health literacy = patient's health literacy*

** health literacy under-estimation: *GPs' estimation of a patient's health literacy < patient's health literacy*

*** health literacy over-estimation: *GPs' estimation of a patient's health literacy > patient's health literacy*

Discussion

Our findings demonstrate GPs' predominantly estimate patients' health literacy to be adequate. Discordance between patients' actual health literacy and what GPs estimate it to be results in estimation of health literacy to be higher, whereas for others, GPs estimate it to be lower than patients' actual health literacy. These respectively over- and underestimations of health literacy are significantly affected by patients' level of education and the length of patients' relationship with their GP and the sex of the GP. Health literacy is more likely to be over- or underestimated with decreasing educational level, compared to higher education. The likelihood to over- or underestimate health literacy is also higher in patients who have been consulting their GP a relatively short period of time (less than ten years), compared to patients who have been consulting their GP for over ten years.

Comparison with previous studies

The majority of GPs perceived their patients to have adequate health literacy, although 10% of patients' had inadequate health literacy.[9,12] This corresponds to previous research in a hospital setting demonstrating doctors' health literacy overestimation outnumbering underestimation with nearly 2-to-1 [26]. A similar outcome was reported, focusing on nurses.[28] Only one study described primary care physicians overestimating patients literacy.[27]

Education

GPs seem to seek guidance in patients' educational level when estimating health literacy, although we are not sure patients ever explicitly disclosed their educational level to GP. Numerous studies have demonstrated the correlation between health literacy and education [9,22,23] : lower health literacy is observed in people with lower educational levels, although highly educated people may also have poor health literacy [12,23]. Despite of its correlation with health literacy, there's a fundamental difference between literacy and health literacy, which is emphasized in several studies. [9,12,23] Undoubtedly, literacy is a vital skill to function with or within the contemporary health care system. However, complementary, advanced skills are necessary to execute instructions, interact with healthcare professionals and critically appraise information. [20,40,41] Our findings particularly indicate that for patients with primary education there is an increased likelihood for GPs to over-but also to under-estimate their health literacy.

GP – patient acquaintance

That a long standing doctor-patient relationships would contribute to GPs' having a better understanding of their 'long-term' patients, for instance, knowing their background, social network,… is what we would have expected. The results presented in this study indicate that this also translates in the estimations GP make about their patients' health literacy. For patients who have been consulting their GP for ten years or less, chances are in particularly higher that GPs underestimate their health literacy of patients, with the highest odds in patients visiting their GP less than a year, which could indicate a cautious approach due to GPs and patients being less acquainted, compared to those who have been consulting with their GP for more than ten years. Overestimation of health literacy, on the other hand, was only found in patients seeing their GP between one and five years.

To explain our findings, we turned to studies focusing on continuity of care, as a key dimension of good primary care.[42] We consider GP-patient acquaintance, as described in this research, to be analogous to what is referred to as continuity of care and a long relationship in previous studies.

Findings presented in these studies than support our results, as it is reported to correlate with improved adherence to physicians' instructions[43] and better communication[44]. Moreover, being cared for less than one year by the same care provider was associated with decreasing communication excellence. [45] Although (dis)satisfaction with communication may stem from being unaware of patients' health literacy, we did not find studies linking their results to patients' knowledge, their understanding of or the processing of health information.

Implications & recommendations for clinical practice

GPs in our research were often not able to estimate health literacy of their patients. We would recommend GPs to perform some sort of health literacy assessment, instead of going by intuition. Therefore, feasible alternatives for clinical practice should be considered [29], such as using single item questions [28,46], or prompt lists[47] preferably tested by the target group to avoid comprehension problems [48–50], but, above all, by supporting patients to understand information. Besides asking patients directly about their understanding and the kind of information and/or (practical) support they might need, patients should be provided tools to ensure they understand but can also recall what has been said[16,51]. Two examples worth mentioning are the Ask me 3 questions[52] campaign or the use of the teach-back method[53].The former is designed to help patients receive appropriate information on: "What is my main problem?; "What do I need to do (about the problem)?; "Why is it important for me to do this?. The latter refers to a method that consists of asking patients to repeat back what was just said (instructions, next steps to be taken). Based on their answers, it will be clear when there is a need for clarification. Moreover, educating (future) GPs and making them familiar with the health literacy concept and the implications of low health literacy is a prerequisite to address health literacy [54]. GPs should get to know their patients. In particular it is important to know who is experiencing barriers to care and how to reach them. Being able to identify people with limited health literacy will help GPs to tackle health inequalities, for example by adequate information exchange. Hence, GPs should be equipped with a variety of strategies they can integrate in their day-to-day practice to communicate on a low health literacy level [54–56].

Strengths and limitations

GP participation was potentially selective, although several attempts to contact and motivate GPs were undertaken. Given, selection bias may have occurred in the relatively small research window. Some patients might not have had the chance to participate because of not visiting their GP, some patients may have felt reluctant [57] or ashamed to disclose health literacy information [49,58,59]. Also, the voluntariness of patients participating impacted on the study sample. This not only resulted in a small fraction of GPs presumable patient population to take part in the research – the number of patients per GP was below 30, whereas we would expect a GP's patient population to be around 1000 patients-; it is likely, for some patients (for instance, literate patients) participation would be more easy, hence, would be more eager to participate than others. Survey weariness, the length or usability of a paper-based questionnaire may have discouraged patients from participating, particularly more vulnerable patients (illiterate, non-natives). Nevertheless, many patients with low health literacy and low education participated. People experiencing barriers to care might have been missed. If so, their participation would have enriched data if the reason for not visiting their GP or for not participating would be linked to health literacy, for example because of low trust in GPs or poor self-related health [60]. Some GPs had the impression the majority of participating patients had a profile not reflecting the diversity of their patient population. Patients were felt to be Dutch-

speaking, illiterate and/or involved, empowered patients, predominantly without migration background (except for those general practices in the multicultural regions; thus,. This limitation also makes our findings more powerful. If incorrect health literacy estimations imply that GPs assume these particular patients to adequately function in a healthcare setting, this would make those patients more vulnerable to not accessing appropriate care. After all, if participating patients did not represent minority groups or patients experiencing some vulnerability, GPs' relatively high scores on patients' health literacy, would indicate GPs are lacking awareness of "un-obvious" patients to be at risk of experiencing difficulties with health-related information. It would be interesting to examine how a more diverse sample - patients who are illiterate, with limited Dutch proficiency, with different backgrounds, with certain comorbidities, but also patients GPs visited at home[14] and not in their practice - would impact results.

This research relies on HLS-EU-Q16 to measure comprehensive health literacy. As opposed to the original 47-item version, this 16-item version was developed for quicker assessment of health literacy. However, assessment with HLS-EU-Q16 does not allow statements on a health literacy sub-dimension. The output of these 16 items, covering only 11 of the 12 dimensions, is an overall health literacy score[3]. Hence, GPs were required to give an overall health literacy score as well, instead of them being able to score a particular sub-dimension. For GPs, patients and researchers future research could aim to assess certain sub-dimensions and GPs' predictions being in (dis)agreement with a patient's health literacy sub-dimension. In this study, however, HLS-EU-Q16 was purposively chosen to allow easy assessment of health literacy in general population.

Responses on the HLS-EU-Q16 are prone to subjectivity because patients' - self-perceived - health literacy is assessed[61] , whereas tools, designed to examine people succeeding in specific problem-solving tasks are regarded as (measuring) more "objective" health literacy.[61] Nonetheless, self-reported questions are considered valid and feasible methods to assess health literacy [62–64]. Both self-perceived and objective health literacy measurements benefit of being tailored to targeted groups. Unless it's part of the design, tools relying on vocabulary unfamiliar to the target group, consisting of terms they do not come across in everyday live, enhances the difficulty of a particular tool. Consequently, the output will reflect someone's ability to understand the tool itself (its design, the questions, answer options,..), rather than one's health literacy[49]. Mindful of potential comprehension problems, feasibility of HLS-EU-Q16's was tested prior to this study [48]. In correspondence with other studies, the level of abstraction or lacking experience regarding some health-related tasks in health care, health promotion and disease prevention made it difficult to answer some items, but overall HLS-EU-Q16 was considered a feasible instrument[48,49].

Finally, almost 10% of participants were excluded from final analyses due to missing data on health literacy. However, looking into detail, 148 data were excluded solely because they lacked GPs' health literacy estimations, not because patients' health literacy not be assessed. Excluded data often originated from GP surveys that were returned blank or incomplete. Possible explanations are that GPs did not receive a GP survey from their patients; or GPs on their part might have been lacking time.

Conclusion

Intuitively assessing patients' health literacy is difficult. Both patients' education and GP-patient acquaintance as well as the sex of the GP impact on the estimations GPs make regarding patients'

health literacy. With decreasing educational levels, the likelihood to incorrectly estimate patients' health literacy increases, suggesting patients' education is not a good indicator for their health literacy. Consequently, GPs should be aware of health literacy and it being different from 'literacy' (i.e. education). It would be beneficial to facilitate and encourage GPs to get a profound understanding of their patients and their lives. A long standing relationship between GP and patient seem to contribute to getting to know patients as GPs are better at predicting health literacy of patients who they have been consulting with for more than ten years. With health care being redesigned to be more integrated, there's an opportunity to promote in-depth communication as the cornerstone for everyone to access adequate care. To be incorporated in daily practice, GPs should be allowed to invest a sufficient amount of time on getting to know their patients.

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Contributors

HS was responsible for study concept and design (with valuable input from BA and NC) and for data acquisition and for initial analyses. Data interpretation with all authors (HS, BA, FV, NC) led to a manuscript drafted by HS. All authors substantially contributed to critically reviewing the manuscript and all read and approved the final version. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at *www.icmje.org/coi_disclosure.pdf* and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of collected data.

Transparency

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant registered) have been explained.

Data sharing

The dataset used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Figure legends

Fig. 1 Recruitment of general practitioners

Fig. 2 Flow diagram excluded questionnaires

Fig. 3 GPs' health literacy estimations and patients' health literacy (n= 1375)

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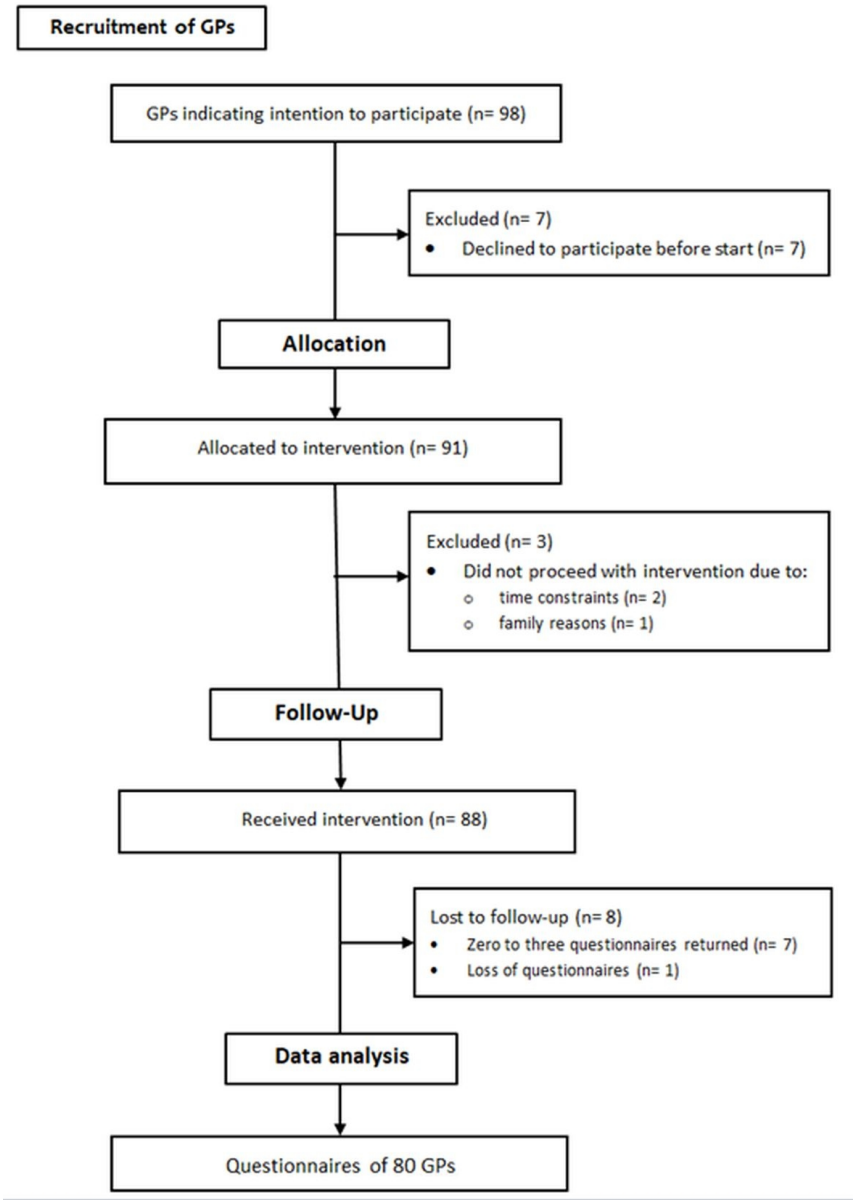
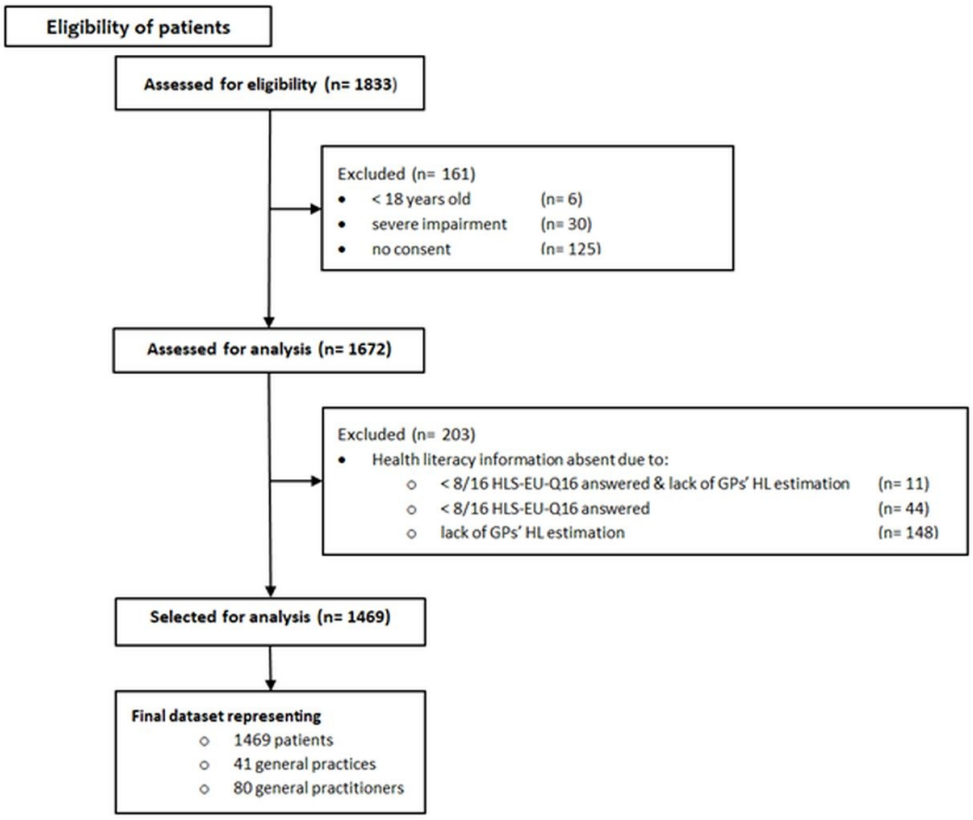


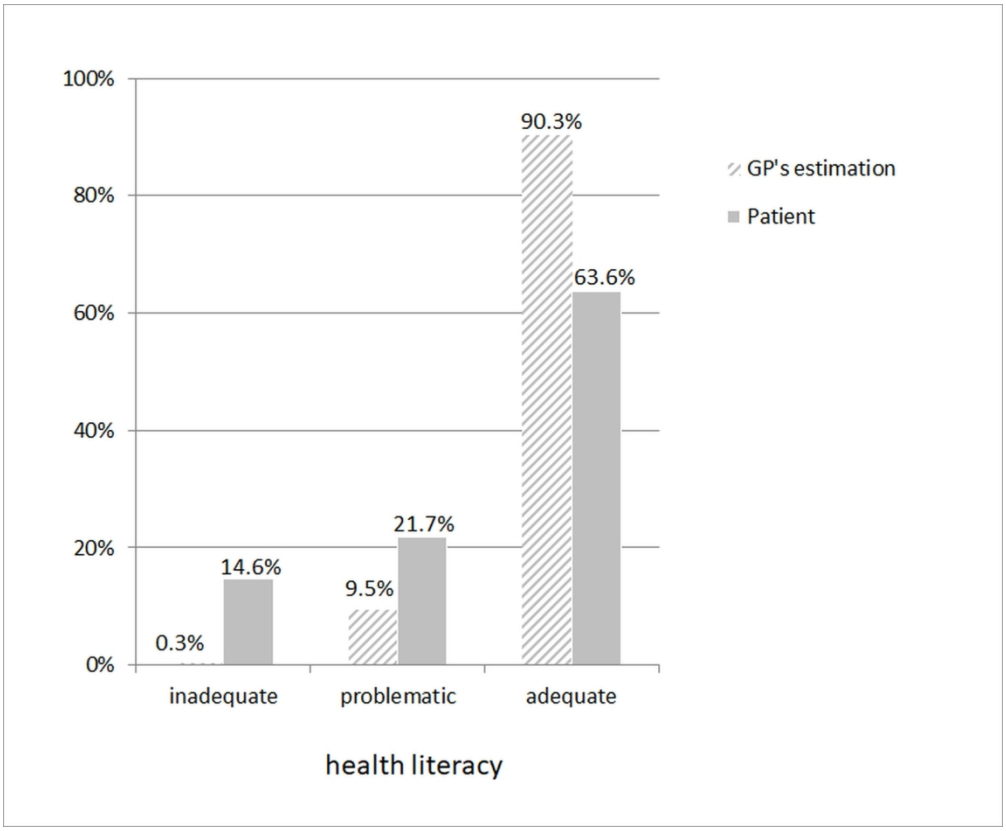
Recruitment of general practitioners

99x140mm (300 x 300 DPI)



Flow diagram of excluded questionnaires

104x90mm (300 x 300 DPI)



GPs' health literacy estimations and patients' health literacy (n= 1375)

109x90mm (600 x 600 DPI)

Appendix - Characteristics of excluded patients

	< 8/16 HLS-EU-Q16 answered & lack of GPs' HL estimation	< 8/16 HLS-EU-Q16 answered	lack of GPs' health literacy estimation	
N	11	44	148	
HLS-EU-Q16				
Number of items scored				
0	7	19		
1		1		
2	1	1		
3	0	2		
4	0			
5	0	1		
6	0	2		
7	3	18		
8			18	
9			2	
10			1	
11				
12			2	
13			2	
14			4	
15			5	
16			114	
Missing values	0	0	0	
Health literacy score on 16				
0	7	19 (1/7/11)*		
1		2 (1/0/1)	1	
2	1			
3		2 (0/1/1)		
4		1 (0/0/1)		= 26 inadequate health literacy
5		4 (1/1/2)	2	
6	1	7 (0/1/6)	7	
7	2	9 (0/1/8)	4	
8			12	
9			8	
10			4	= 27 problematic health literacy
11			8	
12			7	
13			9	
14			20	= 95 adequate health literacy
15			15	
16			51	

* (GP's estimation that a patient's health literacy is inadequate/problematic/adequate)

	< 8/16 HLS-EU-Q16 answered & lack of GPs' HL estimation	< 8/16 HLS-EU-Q16 answered	lack of GPs' health literacy estimation
N	11	44	148
Patient			
Sex			
female	6	28	85
male	4	13	61
Missing values	1	3	3
Education			
no formal education	1	6	11
primary education	0	8	13
secondary education	7	14	56
higher education	2	6	61
Missing values	1	10	8
Number of years patients consulting GP			
<1y		5	2
1-5y		12	7
6-10y		3	6
>10y		24	29
Missing values	10	0	105
General practitioner			
Sex			
female	6	17	83
male	5	27	66
Missing values	0	0	0
GPs' health literacy estimation			
inadequate		3	
problematic		11	
adequate		30	
Missing values	11		149
Usual doctor or replacement			
1 (replacement)		2	2
2 (usual GP)		41	21
Missing values	11	1	126

STROBE Statement

Checklist of items that should be included in reports of observational studies

Section/Topic	Item No	Recommendation	Reported on Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5, Fig. 1 & Fig. 2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	5-15&16
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6&7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	

Section/Topic	Item No	Recommendation	Reported on Page No
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5, 7, Fig. 1 & Fig. 2
		(b) Give reasons for non-participation at each stage	5, 7, Fig. 1 & Fig. 2
		(c) Consider use of a flow diagram	Fig. 1 & Fig. 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 &Table1
		(b) Indicate number of participants with missing data for each variable of interest	7 & Table 1
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	7,8,
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8 & Table 2
		(*b*) Report category boundaries when continuous variables were categorized	6
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14,15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

**Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.*

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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General practitioners' predictions of their own patients' health literacy: a cross-sectional study in Belgium

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General practitioners' predictions of their own patients' health literacy: a cross-sectional study in Belgium

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Abstract

Objectives To support patients in their disease management, providing information that is adjusted to patients' knowledge and ability to process health information (i.e. health literacy) is crucial. To ensure effective health communication, general practitioners (GPs) should be able to identify people with limited health literacy. To this end, (dis)agreement between patients' health literacy and GPs' estimations thereof was examined. Also, characteristics impacting health literacy (dis)agreement were studied.

Design Cross-sectional survey of general practice patients and GPs undertaken in 2016-17.

Setting Forty-one general practices in two Dutch-speaking provinces in Belgium.

Participants Patients (18 years of age and older) visiting general practices. Patients were excluded when having severe impairments (physical, mental, sensory).

Main outcome measures Patients' health literacy was assessed with HLS-EU-Q16. GPs indicated estimations on patients' health literacy using a simple scale (inadequate; problematic; adequate). (Dis)agreement between patients' health literacy and GPs' estimations thereof (GPs' estimations being equal to/ higher/lower than patients' health literacy) was measured using Kappa statistics. The impact of patient and GP characteristics, including duration of GP-patient relationships, on this (dis)agreement was examined using generalized linear logit model.

Results Health literacy of patients (N= 1375) was inadequate (N= 201; 14.6%), problematic (N= 299; 21.7%), adequate (N= 875; 63.6%). GPs over-estimated the proportion patients with adequate health literacy: adequate (N= 1241; 90.3%), problematic (N= 130; 9.5%) and inadequate (N= 4; 0.3%). Overall, GPs' correct; over- ; underestimations of health literacy occurred for respectively 60.9%; 34.2%; 4.9% patients, resulting in a slight agreement (Kappa = .033). The likelihood for GPs to over- or underestimate patients' health literacy increases with decreasing educational level of patients; and decreasing number of years patients have been consulting with their GP.

Conclusions Intuitively assessing health literacy is difficult. Patients' education, the duration of GP-patient relationships and GPs' gender impact GPs' perceptions of patients' health literacy.

Article Summary

Strengths and limitations of this study

- This is an extensive study, with a large number of patients participating across several general practices.
- Paper-based HLS-EU-Q16 questionnaires were used to encourage patients to fill out the health literacy survey.
- Voluntary GP and patient participation was potentially selective due to the relatively small research window, survey weariness or reluctance to disclose difficulties regarding health communication.

Introduction

Health care is facing enormous challenges. Care is shifting towards managing rather than curing diseases due to the aging of the population and the rising prevalence of chronic diseases and multi-morbidity. As a result, doctor-patient interactions are transforming into partnerships in which patients' needs, values and beliefs influence the course of the care process [1,2]. Besides being responsive to patients' needs, the complexity of health care forces health care professionals to also take into account patients' health literacy (HL).

Health literacy is defined as 'one'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 health care, disease prevention and health promotion to maintain or improve quality of life during the life course' [3]. With the focus on patients managing their care, patients' knowledge, motivation, understanding and skills with regard to health information are important prerequisites to guarantee high quality care.

Health literacy impacts on accessibility and utilization of care, doctor-patient communication, self-care, and, subsequently, health outcomes [4–7]. Research in eight European countries demonstrated that 47% of the population experiences difficulties processing health-related information, hence, has problematic or inadequate health literacy [8–14]. Since the development of the conceptual framework of the HLS-EU consortium, health literacy research in Europe - and Belgium – is expanding [3]. In Belgium, the most renowned studies have focused on the prevalence, with 40% of the Belgian population being low health literate; on health literacy being an intermediary for tobacco use, health status, physical activity and the pricing of medication [9] and on the use of health care services and the associated costs [14]. This research of Vandenbosch et al found no significant effect between someone's health literacy and the use of health care services such as the emergency room or GP consultations [14]. However, people with lower health literacy levels were found to have significantly more hospitalizations and more GP visits at home than those with adequate health literacy [14].

Overall, people with limited health literacy may find it difficult to understand medication instructions, have poorer medication adherence [7,10,15,16] , use preventive services less [7,17], have low self-efficacy [18–20], struggle with self-managing chronic diseases [7] and have a worse health status than those with adequate health literacy [7,21]. Most at risk are non-native speakers, the elderly, and those with limited education [10,13,22,23]. To ensure patients receive appropriate care, health care professionals should make sure patients are (being) informed, have sufficient understanding, are given the opportunity to discuss treatment options and are involved in decision making [2].

Awareness of patients' understanding of health information and their ability - and willingness - to be involved in (decisions about) their care is essential to tailor information and guide patients through the health care system [24,25]. General practitioners (GPs) in particular are well-placed to ensure patients receive the care that meets their needs. By communicating effectively and facilitating patients' involvement in their care process, GPs may contribute to improving health outcomes [4,7,24]. However, this requires GPs to be able to identify patients with limited health literacy.

To date, there are few studies investigating health care professionals' abilities to identify people with limited health literacy. Moreover, the Northern American studies that exist, demonstrated health care professionals' inability to identify people with limited health literacy and predominantly over-estimating health literacy [26–28]. To assess health literacy, these studies relied on so called "objective" (health) literacy tools (NVS [29], REALM [30,31], REALM-R [32]). Their sample sizes were relatively small, with

the number of participants ranging from 65 to 182 [26–28]. Despite differences in study design, non-academic primary care physicians, residents, and nurses all overestimated patients' health literacy. They estimated health literacy to be adequate for respectively 74% ; 90% patients; 68% patients [26–28]. The corresponding Kappa's (0.19 and 0.09) demonstrated the 'little' agreement between health care professionals' estimations and patients' actual health literacy.

The aim of this research was to explore the agreement between patients' health literacy and GPs' health literacy estimations thereof as well as to examine characteristics impacting on this health literacy (dis)agreement.

Methods

Study design

Cross-sectional study with paper based questionnaires (patients and GPs).

Recruitment

To recruit GPs, the researcher (HS) contacted 79 GPs working in two Belgian provinces of interest (Vlaams-Brabant and Limburg) (Fig. 1). Five GPs were in the direct network of the research team and immediately agreed to participate. Additionally, 73 out of 122 GPs responsible for organizing regional quality meetings for their peers, were contacted through phone calls and emails. This resulted in 19 invites for the researcher to attend these regional quality meetings. During these meetings, the researcher informed GPs about the health literacy conceptual framework, the purpose and study design of this research. Ultimately, 98 GPs expressed their intent to participate (with a varying number of participating GPs per general practice). The number of participating GPs reduced to 88 because GPs declined to participate before the research was set up (N= 7) or because they were unable to carry out the research (N= 3). Subsequently, GPs were excluded from data analysis when fewer than four questionnaires per GP were returned to the researcher (zero questionnaires (N= 4), between one and three (N= 3) and loss of completed questionnaires (N= 1)) (Fig 1). Recruitment and start-up took place between October 2016 and December 2017.

Sample size

This study used purposive sampling for the recruitment of GPs and patients. It was aimed to reach 2000 patients. Compared to the general population of the Dutch-speaking part of Belgium, women and people aged 65 years and older were over-represented, with 63% women (compared to 51% in the adult population of the Dutch-speaking region), and 31% people aged 65 years and older (compared to 25% in the adult population of the Dutch-speaking region) [33].

Setting and participants

In each general practice, the research window was set to be minimal one month. Participation (GPs and patients) was voluntary, written informed consent from the latter was obtained prior to medical consultation. Men and women, 18 years of age and older, consulting with a participating GP, were eligible for inclusion. Patients were excluded when having a severe cognitive impairment, sensory disability, psychological or psychiatric disorder. This exclusion was documented by the participating GPs.

Measures

Health literacy

Health literacy of patients was assessed with HLS-EU-Q16. Derived from the 47-item European Health Literacy Survey Questionnaire (HLS-EU-Q47 [3]), this 16-item version measures 11 of 12 sub-dimensions of health literacy as defined by the conceptual model developed by the HLS-EU consortium [34]. These dimensions result from integrating three health relevant domains (health care, disease prevention, health promotion) and four competencies relevant for the processing of health information (access, understand, appraise, apply) [34]. HLS-EU-Q16 highly correlates with the 47-item version, but it does not allow statements on the sub-dimensions of health literacy [34–36]. The Dutch HLS-EU-Q16 has been used in Belgium [9] and in the Netherlands [37,38].

Items were formulated as questions ("How easy would you say it is to find information on treatments of illnesses that concern you?", "How easy would you say it is to understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?") Each question was rated on 4-point Likert scales (very difficult; difficult; easy; and very easy). These scores were dichotomized, by coding responses 0 = '(very) difficult' and 1 = '(very) easy'. After summing the answers, a score between 0 and 16 was obtained. Consequently, patients were categorized as having *inadequate health literacy* (scoring 0-8 points), *problematic health literacy* (scoring 9-12 points), *adequate health literacy* (scoring 13–16 points).

As opposed to patients' health literacy assessment, GPs' estimations of their patients' health literacy was restricted to indicating either inadequate; problematic; adequate health literacy on a simple scale. To this end, GPs were educated on the health literacy concept and the associated HLS-EU questionnaires, at least twice. Amongst others, GPs were informed about how categories of health literacy were determined, allowing them to scale their patients' health literacy into one of the three categories.

Where a patient marked two adjacent Likert-scores, the lower (the one referring to experiencing difficulties) score was registered. Where a patient marked two Likert-scores within two points of each other, the middle value was registered (e.g. if 2 and 4 marked, 3 was registered).

Other variables

Patients self-reported their gender (male; female), age (continuous) and educational attainment (no formal education; primary education; secondary education; higher education). The duration of GP-patient relationship was documented by GPs, based on the number of years patients have been visiting them (< 1 year; 1 - 5 years; 6 - 10 years; > 10 years). To determine if patients were consulting their usual GP or not, GPs indicated whether they were substituting for a colleague (yes; no).

GPs' gender (male; female), age and years since graduation (both continuous) were registered independently from patients' surveys.

Data collection

Prior to participation, GPs were educated about health literacy. At that moment, the research in general and the GP survey in particular, were presented. Subsequently, GPs could agree to participate. When participating GPs received the surveys, the concept health literacy was explained once again and instructions on how to fill out the GP's survey were repeated. Boxes labeled with a participating GP's name were set out in the waiting area. These boxes contained white envelopes, each with a consent form and both a patient and a GP survey, labeled with a unique number. Leaflets

with pictogram instructions were distributed throughout the waiting area to inform patients about the research.

In the waiting room, prior to their consultation with a participating GP, patients would voluntarily choose to fill out the patient survey (patient characteristics and HLS-EU-Q16). During consultation, patients would give their GP the GP survey. Subsequently, at the end of a participating patient's medical consultation, GPs registered patient's age, duration of GP-patient relationship and their own health literacy estimation of that patient in a separate GP survey. Patient and GP surveys were collected in separate envelopes. Not only to encourage patients to answer truthfully, but also to ensure GPs had no access to patients' responses.

Statistical analyses

Demographic data and health literacy (of patients and estimations by GPs) were analyzed using descriptive statistics. Kappa statistics were calculated to measure agreement between patients' health literacy and GPs' estimations of these patients' health literacy [39]. A generalized linear logit model was used to assess if patient and GP characteristics impacted on GPs estimating health literacy higher/lower (over-/underestimation). GPs' correct estimation (equal to patients' health literacy) was used as the referent group. Patient variables included gender, age and education, the duration of GP-patient relationship. GP variables included gender, age, years graduated and them substituting for a colleague. Missing values on the initially considered variables were excluded from analyses. Finally, analysis on variables with significant results encompassed only three variables (patients' education, the duration of GP-patient relationship and GPs' gender). Statistical significance was assessed as $p < 0.05$. Data were analyzed with R [40].

Ethical approval and consent

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of the data collected.

Patient and public involvement

The study design of this research was discussed in the feasibility study on the Dutch HLS-EU-Q16, prior to this study [41]. Based on these participants' recommendations, adjustments were made to the patient survey's layout. Patients did not interpret results nor did they contribute to the writing of the manuscript.

Results

1833 surveys were filled out and returned. The number of participants reduced to 1469 (and 80 GPs across 41 general practices) due to the exclusion of questionnaires (not eligible (N= 161); data on health literacy were missing (N= 203)) (Fig. 2). The exclusion of questionnaires because of missing health literacy data, predominantly resulted from a lacking health literacy estimation by a GP. Consequently, 148 patients were excluded although patients' health literacy was available. Health literacy of these patients was inadequate (N= 26; 17.6%) , problematic (N= 27; 18.2%) and adequate (N= 95; 64.2%). Characteristics of excluded patients can be found in the supplementary file.

To analyse data using the generalized linear logit model, patients with missing values were excluded (14 and 70 missing values for patients' gender and education; 14 for the duration of GP-patient relationship; 11 for GPs substituting for a colleague). Analyses were performed on the final dataset of 1375 patients (Table 1-3).

Sample characteristics

Patients were on average 54.6 years old (SD 16.4); 63.9% were female; 48.2% was highly educated (Table 1). Regarding the duration of GP-patient relationship, approximately 10% of the patients have been consulting their GP for less than one year, 45.1% for more than 10 years (Table 1).

The mean age of GPs was 42.8 years old (SD 13.5); 53% of GPs were female (N= 80). GPs were graduated on average 17.3 (SD 13.3) years and were working on average 14.3 (SD 13.4) years in their current practice, with a maximum of 48 years (Table 2). Fifteen GPs were working solo; whereas the remaining GPs were working in group practices employing three to seven GPs. Six practices were located in four different regions with high population density, ten practices were located in five multicultural regions.

Health Literacy agreement

Patients' health literacy was adequate, problematic and inadequate in respectively 63.6% (N= 875), 21.7% (N= 299) and 14.6% (N= 201) of 1375 patients, whereas GPs over-estimated the proportion of patients with adequate health literacy, while underestimating the proportion patients with problematic and, in particular, inadequate health literacy: adequate (N= 1241; 90.3%), problematic (N= 130; 9.5%) and inadequate (N= 4; 0.3%) (Fig. 3). Correct estimation of health literacy by GPs, across all categories, occurred for 837/1375 (60.9%) of patients. Health literacy levels were over-estimated for 199+271/1375 (34.2%) of all patients, respectively amongst patients with inadequate and problematic health literacy. Health literacy levels were underestimated for 68/1375 (4.9%) of all patients, in fact, this only concerned patients with adequate health literacy (Table 3). Based on these data, there was slight agreement between patients' health literacy and GPs' estimations thereof, $\kappa = 0.033$ (95% CI, 0.00124 to 0.0648), $p < 0.05$.

Characteristics impacting on health literacy (dis)agreement

Only three variables significantly impacted on the (dis)agreement between GPs' estimations of and patients' actual health literacy: patients' education, the duration of GP-patient relationship and the gender of GPs-.

Patients' educational level

Health literacy is more likely to be underestimated when a patient has no formal education (OR 5.58, 95% CI: 1.60 to 19.50); primary education (OR 14.13, 95% CI: 6.54 to 30.54); secondary education (OR 5.05, 95% CI: 2.65 to 9.61), compared to patients with higher education (Table 4). GPs are more likely to over-estimate patients' health literacy in patients with primary education (OR 2.02, 95% CI: 1.22 to 3.13); secondary education (OR 1.34, 95% CI: 1.04 to 1.73), compared to those with higher education (Table 4).

Duration of GP-patient relationship The odds of underestimating health literacy are higher for patients who have been seeing their GP for a relatively short time: health literacy is more likely underestimated in patients consulting with their GP for less than one year (OR 6.7, 95% CI: 1.10 to

3.70); between one and five years (OR 4.81, 95% CI: 2.79 to 16.09); between six and ten years (OR 3.70, 95% CI: 2.53 to 9.14) compared to patients who have been consulting with their GP for more than ten years (Table 4). Over-estimation of health literacy is more likely in patients consulting with their GP between one and five years, compared to 'more than ten years' (OR 1.51, 95% CI: 1.17 to 1.94) (Table 4).

Gender of GPs

The odds of a male GP underestimating health literacy is 2.02 times the odds of a female underestimating patients' health literacy (Table 4).

Table 1 Patient characteristics

	Overall sample	Generalized logit model	Patient's health literacy		
			Inadequate	Problematic	Adequate
	% (N)	% (N)	% (N)	% (N)	% (N)
Gender					
female	63% (919)	63.9% (878)	60.7% (122)	63.2% (189)	64.8% (567)
Missing values	1% (14)	0% (0)	0% (0)	0% (0)	0% (0)
Age					
18y-24y	4% (57)	3.9% (54)	5.5% (11)	5.0% (15)	3.2% (28)
25y-34y	11% (154)	10.4% (143)	12.4% (25)	12.7% (38)	9.1% (80)
35y-44y	13% (192)	13.2% (182)	12.9% (26)	13.4% (40)	13.3% (116)
45y-54y	20% (294)	20.2% (278)	13.4% (27)	14.0% (42)	23.9% (209)
55y-64y	21% (311)	21.5% (296)	25.4% (51)	19.7% (59)	21.3% (186)
65y-74y	19% (283)	19.3% (265)	18.4% (37)	22.1% (66)	18.5% (162)
75y-84y	10% (153)	9.7% (134)	9.0% (18)	11.4% (34)	9.4% (82)
85y-104y	2% (25)	1.7% (23)	3.0% (6)	1.7% (5)	1.4% (12)
mean age (SD)	54.8 (16.5)	54.6 (16.4)	54.1 (17.4)	54.7 (17.7)	54.7 (15.7)
Missing values	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Educational attainment					
no formal education	3.9% (54)	3.9% (54)	7.0% (14)	5.0% (15)	2.9% (25)
primary education	7.6% (107)	7.6% (104)	11.9% (24)	8.0% (24)	6.4% (56)
secondary education	40.2% (563)	40.3% (554)	42.8% (86)	42.5% (127)	39.0% (341)
higher education	48.2% (675)	48.2% (663)	38.3% (77)	44.5% (133)	51.8% (453)
Missing values	5% (70)	0% (0)	0% (0)	0% (0)	0% (0)
Duration of GP-patient relationship					
< 1y	9.8% (143)	9.5% (130)	11.9% (24)	9.0% (27)	9.0% (79)
1y - 5y	29.9% (435)	30.0% (412)	30.3% (61)	34.8% (104)	28.2% (247)

6y - 10y	15.4% (225)	15.5% (213)	14.4% (29)	14.0% (42)	16.2% (142)
> 10y	44.8% (652)	45.1% (620)	43.3% (87)	42.1% (126)	46.5% (407)
Missing values	1% (14)	0% (0)	0% (0)	0% (0)	0% (0)
Total N	**1469**	**1375**	**201**	**299**	**875**

Table 2 GP characteristics

	Overall sample	Generalized logit model	Patient's health literacy		
			Inadequate HL	Problematic HL	Adequate HL
	% (N)	% (N)	% (N)	% (N)	% (N)
Gender					
female	51.1% (750)	51.4% (668)	47.3% (95)	50.5% (151)	52.7 (461)
Missing values	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Age					
25y-34y	28.9% (425)	28.5% (392)	29.4% (59)	31.1% (93)	27.4% (240)
35y-44y	19.5% (287)	20.0% (275)	18.9% (38)	19.7% (59)	20.3% (178)
45y-54y	25.1% (368)	25.2% (346)	21.9% (44)	24.7% (74)	26.1% (228)
55y-64y	20.8% (305)	20.4% (281)	20.4% (41)	19.4% (58)	20.8% (182)
65y-74y	5.7% (84)	5.9% (81)	9.5% (19)	5.0% (15)	5.4% (47)
75y-84y	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Substituting for a colleague					
yes	5.6% (82)	5.4% (74)	9.0% (18)	3.7% (11)	5.1% (45)
Missing values	0.7% (11)	0% (0)	0% (0)	0% (0)	0% (0)
Total N	**1469**	**1375**	**201**	**299**	**875**

Table 3 GP health literacy estimation

	Overall sample	Generalized logit model	Patient's health literacy		
			Inadequate HL	Problematic HL	Adequate HL
	% (N)	% (N)	% (N)	% (N)	% (N)
Health literacy estimation					
inadequate	0.3% (5)	0.3% (4)	1.0% (2)○	0% (0) ▽	0.2% (2) ▽▽
problematic	9.5% (139)	9.5% (130)	17.9% (36)△	9.4% (28)○	7.5% (66) ▽
adequate	90.2% (1325)	90.3% (1241)	81.1% (163)△△	90.6% (271)△	92.2% (807)○
Agreement between patients' health literacy & GPs' estimations thereof					
over-estimation	34.6% (508)	34% (470)	99% (199)	91% (271)	N/A
equal estimation	60.7% (891)	61% (837)	1% (2)	9% (28)	92% (807)
underestimation	4.7% (70)	5% (68)	N/A	0% (0)	8% (68)
Total N	**1469**	**1375**	**201**	**299**	**875**

GPs estimate health literacy equal to ○ /one level lower ▽/one level higher △) or two levels lower ▽▽/ two levels higher △△)/than patients' actual health literacy

Table 4 Odds ratios and 95% confidence intervals for patient and GP characteristics impacting GPs' estimations of patients' health literacy (p < 0.05)

	Health literacy disagreement [a]	Odds Ratio	95% confidence interval
Patients' education *(referent category: higher education)*			
no formal education			
	Underestimation [b]	5.58	1.60 to 19.50
primary education			
	underestimation	14.13	6.54 to 30.54
	over-estimation [c]	2.02	1.22 to 3.13
secondary education			
	underestimation	5.05	2.65 to 9.61
	over-estimation	1.34	1.04 to 1.73
Duration of GP-patient relationships *(referent category: > 10 years)*			
<1 year			
	underestimation	6.7	1.10 to 3.70
1 - 5 years			
	underestimation	4.81	2.79 to 16.09
	over-estimation	1.51	1.17 to 1.94
6 - 10 years			
	underestimation	3.70	2.53 to 9.14
GPs' gender *(referent category: female)*			
male			
	underestimation	2.02	1.69 to 8.09

[a] **GPs' estimations versus patients' health literacy, with r**eference group: *GPs' estimations of patients' health literacy = patients' health literacy*

[b] underestimation: *GPs' estimations of patients' health literacy < patients' health literacy*

[c] over-estimation: *GPs' estimations of patients' health literacy > patients' health literacy*

Discussion

Our findings demonstrate that GPs' estimates of patients' health literacy showed a high rate of agreement with the assessment using HLS-EU-Q16 for patients with adequate literacy. However, GPs' estimates showed a low level of agreement with the HLS-EU-Q16 for patients identified with inadequate or problematic literacy. Consequently, GPs considerably over-estimated health literacy levels in patients identified with inadequate or problematic literacy using HLS-EU-Q16. Furthermore, GPs over-estimate the proportion of patients with adequate and underestimate the proportion of patients with inadequate health literacy. GPs' health literacy over- and underestimations are significantly affected by patients' education and the duration of GP-patient relationships, as well as GPs' gender. Health literacy is more likely to be over- or underestimated with decreasing educational level, compared to higher education. The likelihood to over- or underestimate health literacy is also higher in patients who have been consulting their GP a relatively short period of time (less than ten years), compared to patients who have been consulting their GP for over ten years.

Comparison with previous studies

The majority of GPs perceived their patients to have adequate health literacy, although 10% of patients had inadequate health literacy [9,12]. This corresponds to previous research in a hospital setting, demonstrating that these doctors' health literacy overestimations outnumber their underestimations with nearly 2-to-1 [26]. A similar outcome was reported, focusing on nurses [28]. Only one study described primary care physicians over-estimating patients' health literacy [27].

Education

GPs seem to seek guidance in patients' educational level when estimating health literacy. We are, however, not sure patients ever explicitly disclosed their educational level to their GPs. Numerous studies have demonstrated the correlation between health literacy and education [9,22,23] : lower health literacy is observed in people with lower educational levels, although highly educated people may also have poor health literacy [12,23]. Despite of its correlation with health literacy, there's a fundamental difference between literacy and health literacy, which is emphasized in several studies [9,12,23]. Undoubtedly, literacy is a vital skill to function with or within the contemporary health care system. However, complementary, advanced skills are necessary to execute instructions, interact with health care professionals and critically appraise information [20,42,43]. Our findings particularly indicate that for patients with primary education there is an increased likelihood for GPs to over- but also to underestimate their health literacy.

Duration of GP-patient relationship Our findings indicate that a long standing doctor – patient relationship helps GPs to get a better understanding of their patients, or at least of their health literacy. When seeing patients for a longer period of time, it is most likely GPs will have a better notion of their patients' wishes, health beliefs and their preferences. Moreover, it enables them to get more insight in the lives of their patients: their living circumstances, meaningful relationships, social network,…

More specifically, health literacy of patients who have been consulting their GPs for more than ten years is more likely correctly estimated. In contrast, chances are particularly high that health literacy of patients who have been consulting their GP less than one year, is underestimated. This result could indicate a more cautious approach on the part of GPs, being less acquainted with these

patients. Over-estimation of health literacy, on the other hand, was only found in patients seeing their GPs between one and five years.

To explain these findings, we turned to studies focusing on continuity of care, as a key dimension of good primary care [44]. Consequently, we are putting the duration of GP-patient relationship on an equal footing with continuity of care as described in previous studies. Findings presented in these studies support our results, as continuity of care correlates with improved adherence to physicians' instructions [45] and better communication [46]. Moreover, being cared for less than one year by the same care provider was associated with decreasing communication excellence [47]. Although (dis)satisfaction with communication may stem from being unaware of patients' health literacy, we did not find studies linking their results to patients' knowledge, their understanding of, or the processing of health information.

Implications & recommendations for clinical practice

GPs in our research were often not able to estimate health literacy of their patients. We would recommend GPs to perform some sort of health literacy assessment, instead of going by intuition. Therefore, feasible alternatives for clinical practice should be considered [29], such as using single item questions [28,48], or prompt lists [49] preferably tested by the target group to avoid comprehension problems [41,50,51], but, above all, by supporting patients to understand information. Besides asking patients directly about their understanding and the kind of information and/or (practical) support they might need, patients should be provided tools to ensure they understand, but can also recall what has been said [16,52]. Two examples worth mentioning are the Ask me 3 questions campaign [53] or the use of the teach-back method [54].The former is designed to help patients receive appropriate information on: "What is my main problem?"; "What do I need to do (about the problem)?"; "Why is it important for me to do this?" . The latter refers to a method that consists of asking patients to repeat back what was just said (instructions, next steps to be taken). Based on their answers, it will be clear when there is a need for clarification. Moreover, educating (future) GPs and making them familiar with the health literacy concept and the implications of low health literacy is a prerequisite to address health literacy [55]. GPs should get to know their patients. In particular it is important to know who is experiencing barriers to care and how to reach these patients. Being able to identify people with limited health literacy will help GPs to tackle health inequalities, for example by adequate information exchange. Hence, GPs should be equipped with a variety of strategies they can integrate in their day-to-day practice to communicate on a low health literacy level [55–57].

Strengths and limitations

GP participation was potentially selective, although several attempts to contact and motivate GPs were undertaken. Given, selection bias may have occurred in the relatively small research window. Some patients might not have had the chance to participate because of not visiting their GP, some patients may have felt reluctant [58] or ashamed to disclose health literacy information [50,59,60]. Also, the voluntariness of patients to participate impacted on the study sample. This not only resulted in a small fraction of GPs' presumable patient population that took part in the research – the number of patients per GP was below 30, whereas we would expect a GP's patient population to be around 1000 patients-; it is likely, that participating in research is more easy for some patients (for instance, literate patients) than for others. Hence, they would be more eager to participate than others. Survey weariness, the length or usability of a paper-based questionnaire may have discouraged

patients from participating, particularly more vulnerable patients (illiterate, non-natives). Nevertheless, many patients with low health literacy and low education participated. People experiencing barriers to care might have been missed. If so, their participation would have enriched data if the reason for not visiting their GP or for not participating would be linked to health literacy, for example because of low trust in GPs or poor self-related health [61]. Some GPs had the impression that the majority of participating patients had a profile not reflecting the diversity of their patient population. Patients were felt to be Dutch-speaking, illiterate and/or involved, empowered patients, predominantly without migration background (except for those general practices in the multicultural regions). This limitation also makes our findings more powerful. If incorrect health literacy estimations imply that GPs assume that these particular patients function adequately in a health care setting, this would make those patients more vulnerable to not accessing appropriate care. After all, if participating patients did not represent minority groups or patients with some vulnerability, GPs' relatively high scores on patients' health literacy would indicate that GPs lack awareness on these "un-obvious" patients to experience difficulties with health-related information. It would be interesting to examine how a more diverse sample - patients who are illiterate, with limited Dutch proficiency, with different backgrounds, with certain comorbidities, but also patients GPs visited at home [14] and not solely within their practice - would impact results.

This research relies on HLS-EU-Q16 to measure comprehensive health literacy. As opposed to the original 47-item version, this 16-item version was developed for quicker assessment of health literacy. However, assessment with HLS-EU-Q16 does not allow statements on a health literacy sub-dimension. The output of these 16 items, covering only 11 of the 12 dimensions, is an overall health literacy score [3]. Hence, GPs were required to give an overall health literacy score as well, instead of them being able to score a particular sub-dimension. Future research could aim to assess certain sub-dimensions and the (dis)agreement of GPs' predictions with patients' health literacy with respect to a particular sub-dimension. In this study, however, HLS-EU-Q16 was purposively chosen to allow easy assessment of health literacy in general population.

Responses on the HLS-EU-Q16 are prone to subjectivity because patients' - self-perceived - health literacy is assessed [62], as opposed to tools designed to examine people succeeding in specific problem-solving tasks, which are regarded as more "objective" [62]. Nonetheless, self-reported questions are considered valid and feasible methods to assess health literacy [63–65]. Despite the differences between self-perceived and objective health literacy measurements, both benefit of being tailored to targeted groups. Unless it is part of the design, tools relying on vocabulary unfamiliar to the target group - consisting of terms this target group does not come across in everyday life - enhances the difficulty of a particular tool. Consequently, the output will reflect someone's ability to understand the tool itself (its design, the questions, answer options,..), rather than one's health literacy [50]. Mindful of potential comprehension problems, feasibility of HLS-EU-Q16 was tested prior to this study [41]. In correspondence with other studies, the level of abstraction or lacking experience regarding some health-related tasks in health care, health promotion and disease prevention made it difficult to answer some items, but overall HLS-EU-Q16 was considered a feasible instrument [41,50].

Finally, almost 10% of participants were excluded from final analyses due to missing data on health literacy. However, looking into detail, 148 data were excluded solely because they lacked GPs' health literacy estimations and not because patients' health literacy could not be assessed. Excluded data

often originated from GP surveys that were returned blank or incomplete. Possible explanations are that GPs did not receive a GP survey from their patients; or GPs on their part might have been lacking time to complete the survey.

Conclusion

Intuitively assessing patients' health literacy is difficult. Patients' education, the duration of GP-patient relationship, as well as the gender of the GP impact on the estimations GPs make regarding patients' health literacy. With decreasing educational levels, the likelihood for GPs to incorrectly estimate patients' health literacy increases, suggesting patients' education is not a good indicator for patients' health literacy. Consequently, GPs should be aware of the health literacy concept and it being different from 'literacy' (i.e. education). It would be beneficial to facilitate and encourage GPs to get a profound understanding of their patients and their lives. A long standing relationship between GPs and patients can contribute to GP-patient acquaintance. Based on our findings, consulting with a particular GP for more than ten years may lead to GPs making more correct estimates on these patients' health literacy. With health care being redesigned to be more integrated, comes an opportunity to promote in-depth communication as the cornerstone for everyone to access adequate care. To be incorporated in daily practice, GPs should be allowed to invest a sufficient amount of time in getting to know their patients.

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Contributors

HS was responsible for study concept and design (with valuable input from BA and NC) and for data acquisition and for initial analyses. Data interpretation with all authors (HS, BA, FV, NC) led to a manuscript drafted by HS. All authors substantially contributed to critically reviewing the manuscript and all read and approved the final version. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at *www.icmje.org/coi_disclosure.pdf* and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the

submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval

This study was approved by the Ethical Committee of Hasselt University (CME2015/553). Prior to participation, participants received a full explanation of the purpose of the study, their rights as participants, anonymity and confidentiality of collected data.

Transparency

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant registered) have been explained.

Data sharing

The dataset used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Figure legends

Fig. 1 Recruitment of general practitioners

Fig. 2 Flow diagram of excluded questionnaires

Fig. 3 GPs' health literacy estimations and patients' health literacy (N= 1375)

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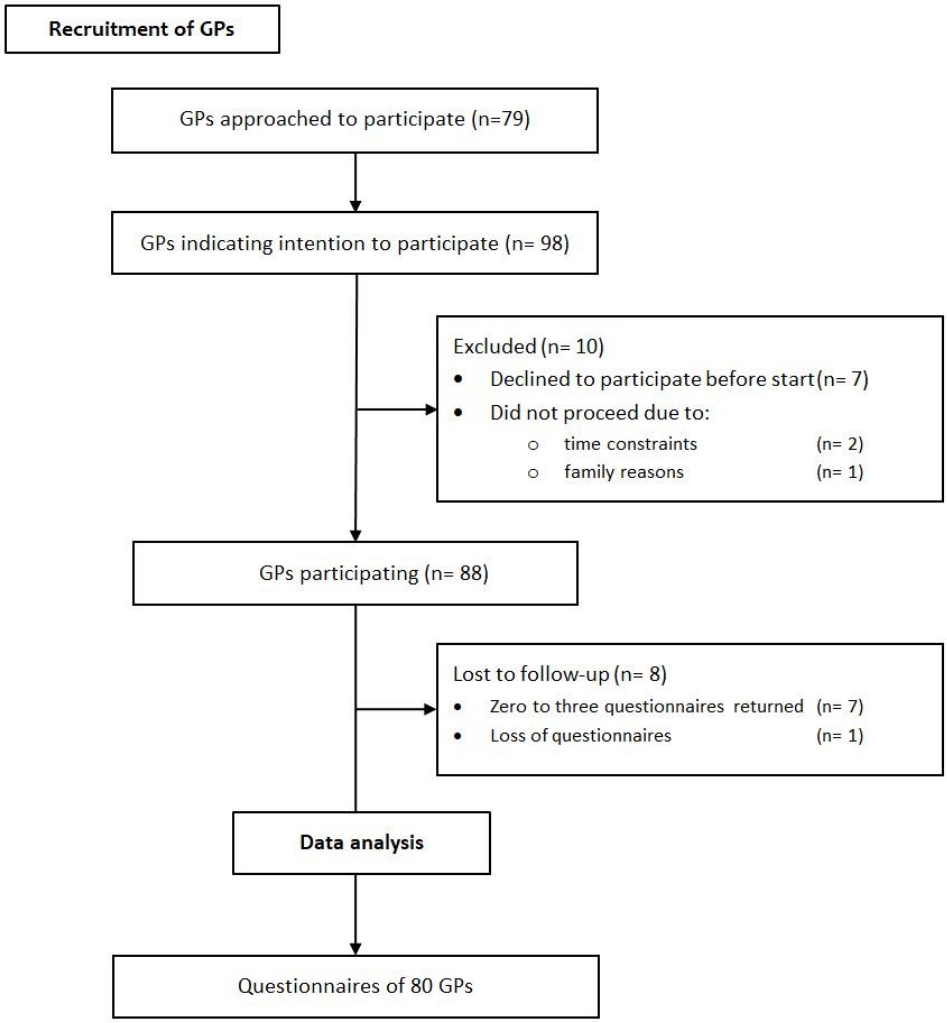

Fig. 1 Recruitment of general practitioners

75x77mm (300 x 300 DPI)

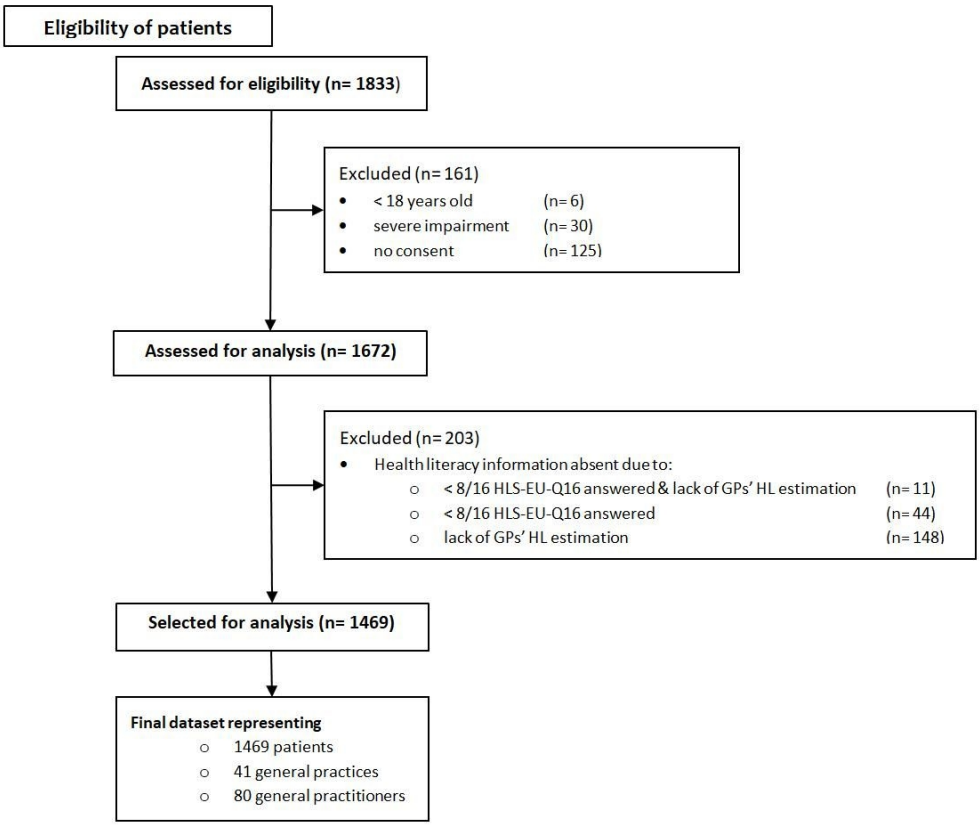

Fig. 2 Flow diagram of excluded questionnaires

95x78mm (300 x 300 DPI)

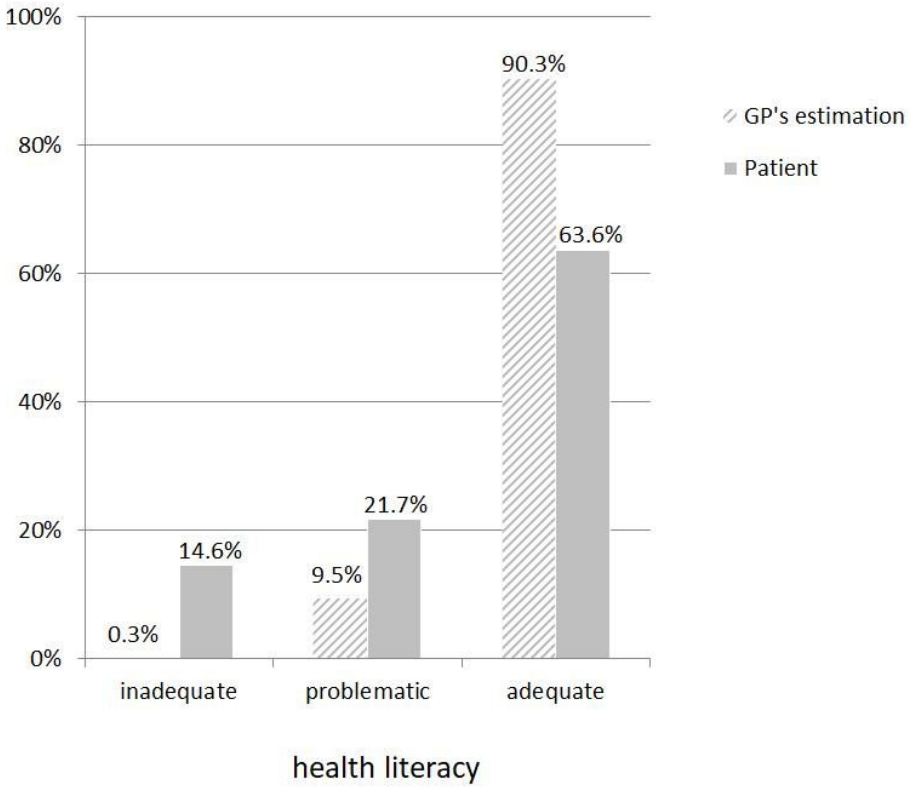

Fig. 3 GPs' health literacy estimations and patients' health literacy (N= 1375)

69x59mm (300 x 300 DPI)

Appendix - Characteristics of excluded patients

		< 8/16 HLS-EU-Q16 answered & lack of GPs' HL estimation	< 8/16 HLS-EU-Q16 answered	lack of GPs' health literacy estimation	
	N	**11**	**44**	**148**	
HLS-EU-Q16	**Items scored (n)**				
	0	7	19		
	1		1		
	2	1	1		
	3	0	2		
	4	0			
	5	0	1		
	6	0	2		
	7	3	18		
	8			18	
	9			2	
	10			1	
	11				
	12			2	
	13			2	
	14			4	
	15			5	
	16			114	
	Missing values	0	0	0	
	Health literacy score on 16				
	0	7	19 (1/7/11)*		
	1		2 (1/0/1)	1	
	2	1			
	3		2 (0/1/1)		N= 26 inadequate health literacy
	4		1 (0/0/1)		
	5		4 (1/1/2)	2	
	6	1	7 (0/1/6)	7	
	7	2	9 (0/1/8)	4	
	8			12	
	9			8	N= 27 problematic health literacy
	10			4	
	11			8	
	12			7	
	13			9	N= 95 adequate health literacy
	14			20	
	15			15	
	16			51	

* (GP's estimation that a patient's health literacy is inadequate/problematic/adequate)

Appendix - Characteristics of excluded patients (continued)

		< 8/16 HLS-EU-Q16 answered & lack of GPs' HL estimation	< 8/16 HLS-EU-Q16 answered	lack of GPs' health literacy estimation
N		**11**	**44**	**148**
PATIENT	**Gender**			
	female	6	28	85
	male	4	13	61
	Missing values	1	3	3
	Education			
	no formal education	1	6	11
	primary education	0	8	13
	secondary education	7	14	56
	higher education	2	6	61
	Missing values	1	10	8
	Duration GP-patient relationship			
	<1y		5	2
	1-5y		12	7
	6-10y		3	6
	>10y		24	29
	Missing values	10	0	105
GENERAL PRACTITIONER	**Gender**			
	female	6	17	83
	male	5	27	66
	Missing values	0	0	0
	GPs' health literacy estimation			
	inadequate		3	
	problematic		11	
	adequate		30	
	Missing values	11		149
	Usual GP or substitution			
	Usual GP		41	21
	Substitution		2	2
	Missing values	11	1	126

STROBE Statement

Checklist of items that should be included in reports of observational studies

Section/Topic	Item No	Recommendation	Reported on Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5, Fig. 1 & Fig. 2
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	5-15&16
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6&7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	

Section/Topic	Item No	Recommendation	Reported on Page No
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5, 7, Fig. 1 & Fig. 2
		(b) Give reasons for non-participation at each stage	5, 7, Fig. 1 & Fig. 2
		(c) Consider use of a flow diagram	Fig. 1 & Fig. 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 &Table1-3 & Fig. 3
		(b) Indicate number of participants with missing data for each variable of interest	7 & Table 1-3
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	7,8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8 & Table 4
		(*b*) Report category boundaries when continuous variables were categorized	6
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14,15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

**Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.*

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.