Received: 13 June 2023 | Revised: 20 December 2023 | Accepted: 31 December 2023
DOI: 10.1002/hed.27633

ORIGINAL ARTICLE

WILEY

Associations between patient-level health literacy and diagnostic time intervals for head and neck cancer: A prospective cohort study

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Abstract

Background: Health literacy (HL) comprises skills and knowledge required to understand, access, and make decisions about healthcare. Our aim was to examine associations between patient HL and time intervals (defined in the Aarhus statement) along the pathway to treatment of head and neck cancer (HNC).

Methods: A prospective cohort study was conducted from October 2018 to March 2020. Participants completed the Health Literacy Questionnaire (HLQ®) and described key events and dates along the pathway to treatment using validated questionnaires. Correlations between six diagnostic time intervals and domains of HL were explored, and factors predicting exceeding maximum acceptable timeframes were assessed using logistic regression.

Results: One hundred patients with a diagnosis of HNC within the preceding 6 months were recruited. HLQ® Domain 2 (sufficient information to manage health) was significantly negatively associated with four intervals: the patient interval (first symptom to first presentation), primary care interval (first presentation to referral to secondary care), diagnostic interval (first presentation to diagnosis), and total interval (first symptom to treatment onset); correlation coefficients −0.25 to −0.27 ($P < 0.05$). Domain 8 (ability to find good information) was significantly negatively associated with three intervals (primary care interval, diagnostic interval, and total interval; correlation coefficients −0.23 to −0.34; $P < 0.05$). Higher education, age, and comorbidity levels were associated with shorter patient and diagnostic intervals.

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Conclusions: HL may be a potential target to improve timeliness of HNC diagnosis and reduce disparities in outcomes.

KEYWORDS
disparities, head and neck cancer, health literacy, health services, rural health

1 | INTRODUCTION

Health literacy is one of the key social determinants of health and has been linked to cancer-related disparities.[1] Contemporary definitions of health literacy have moved away from reliance on numeracy and literacy skills, and now encompass the "environmental, political, and social factors"[2] that shape a person's ability to navigate and effectively utilize the health system. There is a growing body of evidence investigating the relationship between health literacy and cancer outcomes, and Australian health policy and practice increasingly acknowledges the importance of health literacy[3–5] in the delivery of high-quality cancer healthcare. Higher health literacy is associated with better knowledge of colorectal cancer screening practices,[6] lower rates of cancer-related hospitalizations,[7] and more active participation in cancer care.[8] An estimated 60% of Australians have insufficient health literacy,[3] and lower health literacy is associated with higher costs of care, higher rates of adverse health outcomes, and lower uptake of preventive programs, including cancer screening.

Health literacy can influence cancer-related outcomes across the care continuum, from symptom appraisal and help-seeking, to diagnosis, treatment, and follow-up, meaning patients with difficulty in gaining and interpreting information about their health could have prolonged times to diagnosis and treatment of cancer. However, this relationship has not been well explored. A 2018 systematic review by Humphrys et al.[9] identified only three studies, two qualitative and one quantitative, that investigated the association between health literacy and timeliness of symptomatic cancer diagnosis. The authors concluded that the studies were all of poor methodological quality, with variable definitions of health literacy, and that further research was warranted that clearly defines health literacy and adheres to the principles of the Aarhus Statement,[10] a framework to design and report on studies on early cancer diagnosis.

HNC refers to a group of cancers that arise in the oral cavity, pharynx, larynx, salivary glands, thyroid, nasal cavity or paranasal sinuses, and skin of the head and neck. The incidence of mucosal HNC is relatively low in developed countries and in Australia accounts for some 3% of new cancer diagnoses annually.[11] Although 5-year survival rates have improved to 70% between 2009 and 2013,[11] 56% are diagnosed at advanced stage,[12] and patients in regional and remote Australia have a greater risk of advanced disease at presentation compared with their metropolitan (urban) counterparts.[13] Few studies have reported on rates of health literacy in patients with HNC in Australia, with one study[14] reporting 12.0%–17.2% of patients with lung or HNC had low or limited health literacy, depending on which health literacy instrument was used. A recent study[15] among 597 HNC patients found that some 20% of patients required help reading information, and 29% did not feel confident in completing medical forms. These rates are higher than the general Australian population, with data from the 2018 Australian National Health Survey reporting that 8% of people found it difficult to understand health information, and 12% of people found it difficult to find health information.[16] This suggests that the information needs of patients with HNC are greater than the general population.

To date, no study has explored associations between timeliness of cancer pathways and health literacy for patients with HNC. Understanding whether, and how health literacy influences these cancer pathways could facilitate implementation of health services that ensure equitable access to timely diagnosis and treatment. This is particularly important for patients in regional or remote areas of Australia, who experience poorer outcomes from HNC.[13,17] Therefore, the aim of this study was to examine the pathways to treatment for patients with HNC in New South Wales (NSW), Australia. The primary objective was to explore any correlations between patient health literacy and times to diagnosis and treatment of HNC, and the secondary objective was to compare times to diagnosis and treatment among patients with HNC based on remoteness of residence.

2 | MATERIALS AND METHODS

2.1 | Study design and setting

This study was a multisite, prospective cohort study, designed in line with the Aarhus Statement,[10] an international consensus statement that provides a framework for designing and conducting early cancer diagnosis research. The study was conducted in NSW, the most populous state in Australia, with ∼8 million residents as of June 2018, accounting for 32% of the Australian population.[18] Australia has a universal health system, in which patients have direct access to primary care practitioners who can initiate certain cancer investigations and refer patients to specialists for further management and treatment.

2.2 | Ethical approval and informed consent

Ethical approval was granted by the Sydney Local Health District Human Research Ethics Committee (SLHD HREC) (Protocol No. X17-0442 and HREC/17/RPAH/657), the Aboriginal Health and Medical Research Committee (AH&MRC) HREC (Reference No. 1370/180), and clinical governance was approved by each site. Informed consent for this study was taken as completion of the study questionnaires (implied consent). Individual consent to access primary and specialist care data was obtained from each patient.

2.3 | Eligibility criteria

Patients were eligible for participation if they were within 6 months of a diagnosis of HNC, lived in NSW at diagnosis, aged ≥18 years at diagnosis, and had a primary site of any of the following International Classification of Diseases for Oncology (ICD-O-3)[19] topography codes: C00–14, C30–32, C44.0–44.4, C49.0, C73.0, C76.0, or C77.0. Exclusion criteria were hematopoietic malignancies of the head and neck region, patients with no fixed address, insufficient English to complete questionnaires, ICD-O-3 behavior codes other than malignant neoplasms, and cutaneous melanoma of the head and neck.

2.4 | Recruitment

Patients were recruited from sites in metropolitan (Chris O'Brien Lifehouse/Royal Prince Alfred Hospital HNC Service, Sydney) and regional NSW (Mid North Coast Cancer Institute at Port Macquarie and Coffs Harbor, and Northern NSW Cancer Institute, Lismore). Patients were screened for eligibility by their attending medical officer during routine appointments up to 6 months after diagnosis of HNC. This timeframe was selected based on recommendations from the Aarhus statement[10] to be sensitive to patients immediately after diagnosis and treatment but minimizing the risk of recall bias by asking patients to recall events that occurred before the diagnosis.

2.5 | Study materials and data collection

2.5.1 | Baseline questionnaire

Participants were provided a mailed or emailed copy of the baseline questionnaire. The patient questionnaire was adapted, with permission, from one used in Module 4 of the International Benchmarking Partnership (ICBP)[20] for use in the Australian healthcare system and specifically for patients with HNC. The questionnaire consisted of three sections.

Section 1: Pathways to diagnosis and treatment

Patients were asked to describe their pathway to diagnosis and treatment of HNC, including frequency and dates of visits to primary and specialist care, date of diagnosis, symptoms experienced, and treatment dates. These items aligned with the recommended time points and intervals outlined in the Model of Pathways to Treatment,[21] and the methodological principles in the Aarhus Statement[10] for studies into early cancer diagnosis. From these events and dates, six diagnostic time intervals were calculated spanning the time from first symptom (for symptomatic patients only) to onset of treatment. Five of these intervals are defined in the Aarhus Statement (patient interval, primary care interval, diagnostic interval, treatment interval, and total interval). An additional interval, the post-operative radiotherapy (PORT) interval was defined for the purpose of this study, as PORT is common in people treated with HNC and known to be associated with survival outcomes.[22] For participants who were asymptomatic (did not experience initial symptoms), only the primary care, diagnostic, treatment, and PORT intervals (if applicable) were calculated, as the patient and total intervals are both defined by a date of first symptom, which does not apply to asymptomatic patients. All participants were given an opportunity to provide additional information about their experiences along the pathway to diagnosis and treatment through open-ended questions.

Section 2: Health literacy

Patients completed the Health Literacy Questionnaire (HLQ®),[23] a 44-item instrument developed and validated in Australia. The HLQ® measures health literacy across nine domains: (1) Feeling understood and supported by healthcare providers, (2) Having sufficient information to manage my health, (3) Actively managing my health,

(4) Social support for health, (5) Appraisal of health information, (6) Ability to actively engage with healthcare providers, (7) Navigating the healthcare system, (8) Ability to find good health information, and (9) Understand health information well enough to know what to do. Higher scores reflect higher levels of health literacy for each domain.

Section 3: Sociodemographic information

Sociodemographic data included gender, age at diagnosis (derived from date of birth and date of diagnosis), country of birth, primary language spoken, marital status, living situation, employment status, highest level of education, and health insurance status. Indigenous status was collected from medical records. Geographic data such as remoteness of residence was derived from the patients' residential address, coded according to the Accessibility/Remoteness Index of Australia (ARIA+),[24] and dichotomized into metropolitan or regional/remote.

2.5.2 | Clinical data

Clinical data were collected from electronic medical records and included primary site of tumor, morphology, comorbidities, dates and types of investigations, treatment types and dates, histopathological data, and tumor staging.

2.6 | Sample size

Sample size calculations were based on population estimates from Tan et al.[25] in which there was a significant difference in the treatment interval between outer regional and remote/very remote HNC patients (median [IQR] 37.5 days [18.25, 62 days] and 53 days [33.5, 75.5 days], respectively). This study had a ratio of outer regional to remote/very remote patients of ~2:1. Sample size was calculated based on the treatment interval, comparing the median interval between metropolitan and regional/remote patients. Assuming 80% power, a Type I error rate (alpha) of 0.05, and a ratio of metropolitan to regional/remote patients of 2:1, a total of 158 patients were required for this study. Sample size calculations were conducted using G*Power.[26]

2.7 | Missing data

If patients had missing or unknown data in their questionnaires, these items were collected from electronic medical records. If exact dates could not be found, but could be inferred from medical records, they were entered using a protocol for a "pseudo-exact" date proposed by Neal et al.,[27] adjusted for Southern Hemisphere/Australian dates. If data were missing or could not be inferred, they were coded as missing and not imputed.

2.8 | Statistical analysis

Statistical analyses were conducted using SPSS for Windows Version 24.0 and SAS software (Version 9.4 of the SAS system for Windows; SAS Institute Inc., Cary, NC).

2.8.1 | Descriptive statistics

The distribution of continuous data was assessed visually by plotting histograms. Parametric data are presented as means with standard deviations, and non-parametric data are presented as medians with interquartile ranges. Categorical data are presented as frequencies with percentages. Patients were dichotomized into groups based on remoteness of residence (metropolitan or regional/remote) according to the Accessibility/Remoteness Index of Australia Plus (ARIA+) classification.[24] Differences between groups at baseline were assessed using Student's *t*-tests and Mann–Whitney tests for continuous data and Chi-square tests for categorical data (with Fisher's exact tests, if required, for small groups). All *P*-values were two-tailed, and significance taken at $P < 0.05$.

2.8.2 | Health literacy

Scores for health literacy, measured using the HLQ®, were visually assessed for normality and presented using medians with 75th and 90th percentiles. Questions that comprise Domains 1–5 ask respondents to indicate level of agreement with four response options (strongly disagree to strongly agree) and questions that comprise Domains 6–9 ask respondents to score their abilities with one of five response options (cannot do, very difficult, quite difficult, quite easy, and very easy). Responses to the individual questions within each domain are averaged, resulting in nine scores for each patient (with no overall score).[28] To investigate the associations between domains of health literacy and time intervals (Table 1) along the pathway to treatment, Pearson's product moment correlation coefficient (r) for normal data and Spearman's rank-order correlation coefficient (ρ) for non-parametric data were used. Differences between patient groups (metropolitan or regional/remote) were assessed using Mann–Whitney tests for non-parametrically distributed data.

TABLE 1 Summary and definitions of intervals along the pathway to treatment assessed in the current study, including maximum acceptable timeframes.

Interval	Definition	Maximum acceptable timeframe, derived from OCP-HNC
Patient interval[a]	Time in days from first recognition of symptoms to date of first presentation to a healthcare provider (HCP)	N/A (median value of 14 days used in adjusted analysis)
Primary care interval	Time in days from date of first presentation to HCP to date of referral to secondary care	Three weeks (interval dichotomized into ≤21 days vs >21 days)
Diagnostic interval	Time in days from date of first presentation to date of diagnosis	N/A (median value of 24 days used in adjusted analysis)
Treatment interval	Time in days from date of diagnosis to date of first treatment (surgery date, or first radiotherapy fraction, or first chemotherapy administration)	Four weeks or 28 days (interval dichotomized into ≤28 days vs >28 days)
Post-operative radiotherapy (PORT) interval[b]	Time in days from date of surgery to date of first post-operative radiotherapy fraction (given in the adjuvant setting)	Six weeks or 42 days (interval dichotomized into ≤42 days vs >42 days)
Total interval[a]	Time in months from first recognition of symptoms to date of first treatment (surgery date, or first radiotherapy fraction, or first chemotherapy administration)	N/A (not tested in adjusted analysis as the total interval is the sum of the patient, primary care, diagnostic, and treatment intervals)

Abbreviation: N/A, not applicable, as there is no maximum acceptable timeframe in the literature.

[a] For symptomatic patients only.

[b] This interval is not defined in the Aarhus statement or Model of Pathways to Treatment but is an important interval for patients with HNC who require post-operative radiotherapy.

2.8.3 | Comparison of time intervals

Table 1 outlines the time intervals used in the analysis, including definitions and where possible the maximum acceptable timeframes for the interval, which was derived from the *Optimal care pathways for people with head and neck cancer* (OCP-HNC),[29] an Australian framework for the delivery of high-quality and evidenced-based cancer care published by Cancer Australia. The OCP-HNC suggests maximum timeframes for the primary care interval (21 days), the treatment interval (28 days), and the PORT interval (42 days) (Table 1). Time intervals are presented as median values with 75th and 90th percentiles due to the skewed nature of data. For time intervals with published maximum acceptable timeframes, the interval was dichotomized and the proportion of patients meeting that timeframe was compared based on remoteness of residence (metropolitan vs. regional/remote) using Mann–Whitney tests.

2.8.4 | Predictors of exceeding maximum acceptable timeframes for intervals

Binary logistic regression modeling was used to examine associations between patient and clinical factors with compliance with "optimal" timeframes along the pathway to treatment. Time intervals were dichotomized according to guidance in the OCP-HNC or at the median value if no optimal timeframe was available (Table 1). Remoteness of residence was included in all models as it is a known confounder of some intervals[30] and additional sociodemographic and clinical variables were also assessed in univariable modeling. Explanatory variables that demonstrated P values ≤0.25 on univariate analysis were considered for inclusion in the model.[31] Manual backward variable selection was undertaken, where all potential explanatory variables were included in the model, which was then recalculated after dropping the variable with the least significant association to the outcome variable. This process was continued until all remaining variables in the model were statistically significant. The maximum number of explanatory variables was 1 variable per 10 patients in the model.[32] Results are presented as coefficients with 95% confidence intervals. Assumptions of multicollinearity and independence of observations were checked alongside model fit at each stage.

3 | RESULTS

3.1 | Recruitment and participation

Between October 2018 and March 2020, 131 eligible patients agreed to be contacted about the study. Of these

131 patients, 100 patients completed and returned the baseline questionnaire (74% response rate). As time intervals could be collected from medical records, outcomes were available for between 98% and 100% of patients. The secondary outcome of health literacy, which was collected using the Health Literacy Questionnaire (HLQ®) was completed by 95 patients.

3.2 | Participant characteristics

The median age of patients at diagnosis was 66.5 years, most were male (61%), and only one patient identified as Aboriginal or Torres Strait Islander (Table 2). Most patients (78%) reported very good or good health in the preceding 2 years with almost half (49%) having no comorbidity. Most (72%) patients lived in metropolitan NSW, with the remainder in inner regional (21%) and outer regional (7%) NSW.

3.3 | Patient clinical characteristics

The most frequent tumor sites were cutaneous (37%), oral cavity (20%), oropharynx (19%), and thyroid (11%), with a more varied tumor site profile among patients in regional NSW (Table 3). Stage at diagnosis was comparable between metropolitan and regional patients, with 60% of tumors diagnosed at an early stage. Two patients in metropolitan and two patients in regional NSW were diagnosed with a tumor in situ. The most frequently reported symptoms were a neck lump (31%), fatigue (14%), or an ulcer/sore in the mouth (10%), and patients reported experiencing a median of two symptoms.

3.4 | Health literacy and time intervals

There were several negative correlations between domains of patient health literacy and intervals that occurred up to diagnosis, but not after diagnosis (Table 4). The patient interval was significantly negatively correlated with one domain (Domain 2 [*Having sufficient information to manage my health*]) of the HLQ®. The primary care interval was significantly negatively correlated with two domains (Domain 2 [*Having sufficient information to manage my health*] and Domain 8 [*Ability to find good health information*]) of the HLQ®. The diagnostic interval was significantly negatively correlated with five of the nine domains of the HLQ® (Domain 2 [*Having sufficient information to manage my health*], Domain 6 [*Ability to actively engage with healthcare providers*], Domain 7 [*Navigating the health system*], Domain 8 [*Ability to find good health information*] and Domain 9 [*Understand health information well enough to know what to do*]). The total interval was significantly negatively correlated with three domains (Domain 2 [*Having sufficient information to manage my health*], Domain 8 [*Ability to find good health information*], and Domain 9 [*Understand health information well enough to know what to do*]). No domains of the HLQ® were correlated with the treatment interval or the PORT interval, and there were no differences in domain scores for the HLQ® based on remoteness of residence (Table S1).

3.5 | Predictors of time intervals

Multivariable modeling of the patient interval found that patients with a documented comorbidity had lower odds of a patient interval >14 days ($P = 0.03$) (low comorbidity adjusted odds ratio [AOR] 0.32 [95% CI: 0.13–0.79]; high comorbidity AOR 0.72 [95% CI: 0.28–1.81]) (Tables 5 and S2). After adjusting for remoteness of residence and age at diagnosis, completion of post-secondary school education was associated with lower odds of a diagnostic interval exceeding the median of 24 days (AOR 0.24 [95% CI: 0.09–0.60], $P = 0.003$) (Tables 5 and S4). Increasing age at diagnosis was independently associated with the diagnostic interval, with each one-year increase in age at diagnosis associated with a 4% decrease in the odds of a diagnostic interval exceeding the median (AOR 0.96 [95% CI: 0.93–0.99], $P = 0.02$). There were no significant predictors of a primary care interval >3 weeks, a treatment interval exceeding the recommended 4 weeks, or a PORT interval exceeding 6 weeks (Tables 5, S3, S5, and S6).

3.6 | Impact of remoteness of residence on time intervals

There was no significant difference in the length of the patient, primary care, diagnostic, PORT, or total intervals (Table 6). However, the treatment interval was significantly longer for patients from regional NSW at a median of 48.5 days compared with a median of 31 days for metropolitan patients ($P = 0.011$). Only 21% of patients living in regional NSW met the recommendation to start treatment within 4 weeks of diagnosis, compared with 44% of metropolitan patients ($P = 0.033$), and only 2/11 patients (18%) living in regional NSW commenced PORT within 6 weeks of surgery compared with 7/17 patients (41%) of metropolitan patients ($P = 0.20$). On multivariable modeling, regional patients had a non-significant increased odds of treatment interval >4 weeks (AOR 2.71

TABLE 2 Participant characteristics.

Characteristic	All patients ($N = 100$), N (%)	Metropolitan patients ($N = 72$), N (%)	Regional patients ($N = 28$), N (%)	P
Median age (IQR)	66.5 (17)	67.5 (19)	65 (13)	0.61
Sex, male	61 (61)	42 (58)	19 (68)	0.38
Aboriginality				0.28
Aboriginal, not Torres Strait Islander	1 (1)	—	1 (4)	
Neither Aboriginal nor Torres Strait Islander	99 (99)	72 (100)	27 (96)	
Comorbidity				0.87
None	49 (49)	35 (47)	14 (50)	
Low (1, 2)	39 (39)	29 (40)	10 (36)	
High (3+)	12 (12)	8 (11)	4 (14)	
Education				0.62[a]
Primary school or less	4 (4)	3 (4)	1 (4)	
High school (not completed)	17 (17)	12 (17)	5 (18)	
High school (completed)	22 (22)	13 (18)	9 (32)	
Trade/apprenticeship	19 (19)	15 (21)	4 (14)	
Bachelor's degree	17 (17)	13 (18)	4 (14)	
Master's degree/PhD	12 (12)	10 (14)	2 (7)	
Other	6 (6)	3 (4)	3 (11)	
Missing	3 (3)	3 (4)	—	
Country of birth				0.18
Australia	77 (77)	51 (71)	26 (93)	
The United Kingdom	5 (5)	5 (7)	—	
China	2 (2)	2 (3)	—	
India	2 (2)	2 (3)	1 (4)	
Other	12 (12)	1 (1)	1 (4)	
Language spoken at home				
English	88 (88)	60 (83)	28 (100)	0.045
Other	9 (9)	9 (13)	—	
Missing	3 (3)	3 (4)	—	
Remoteness				N/A
Major city	72 (72)	72 (100)	—	
Inner regional	21 (21)	—	21 (75)	
Outer regional	7 (7)	—	7 (25)	
Health insurance				0.24
Insured	64 (64)	48 (67)	16 (57)	
Uninsured	33 (33)	21 (29)	12 (43)	
Missing	3 (3)	3 (4)	—	
Health card				0.41
Yes	49 (49)	33 (46)	16 (57)	
No	48 (48)	36 (50)	12 (43)	
Missing	3 (3)	3 (4)	—	

(Continues)

TABLE 2 (Continued)

Characteristic	All patients (*N* = 100), *N* (%)	Metropolitan patients (*N* = 72), *N* (%)	Regional patients (*N* = 28), *N* (%)	*P*
Employment				0.86
Full-time	23 (23)	17 (24)	6 (21)	
Part-time	6 (6)	4 (6)	2 (7)	
Home duties	5 (5)	4 (6)	1 (4)	
Retired	54 (54)	39 (54)	15 (54)	
Other	9 (9)	5 (7)	4 (14)	
Missing	3 (3)	3 (4)	—	

Abbreviations: IQR, interquartile range; NC, not collected; N/A, not applicable.
[a]Fisher's exact test.

[95% CI: 0.96–7.61], $P = 0.06$) (Table 5). With regard to the *OCP-HNC* recommendation of seeing a specialist within 3 weeks of referral, 54% of patients living in regional NSW met this recommendation, compared with 61% of metropolitan patients ($P = 0.52$).

4 | DISCUSSION

This study presents a comprehensive investigation of times to diagnosis and treatment of patients with HNC and the relationship with health literacy in the Australian setting. There were negative correlations between most domains of patient health literacy with intervals along the pathway to diagnosis, indicating that higher levels of health literacy facilitate quicker movement along the pathway to HNC diagnosis. However, there were no associations between health literacy and intervals occurring after diagnosis (treatment and PORT intervals). This seems reasonable, given that patient health literacy skills would be unlikely to influence the health system factors that would drive onset of treatment (including PORT). However, patient health literacy skills, such as the ability to engage with healthcare providers, navigate the healthcare system, and finding good health information clearly facilitates timely symptom appraisal, help-seeking, and diagnosis of HNC. There is limited literature exploring the relationship between health literacy and times to diagnosis and treatment of cancer, and so comparisons cannot yet be directly drawn to other studies. A 2018 review by Humphrys et al.[9] identified only three studies that explored this association, each of which was methodologically poor, with only one study utilizing a validated health literacy assessment tool.

We also found that, consistent with previous retrospective research,[30] HNC patients living in regional NSW experienced a significantly longer treatment intervals (median 48.5 days) compared with patients living in metropolitan NSW (median 31 days) ($P = 0.011$). This is likely to reflect the challenges in organizing definitive treatment in resource-limited settings with high demand for services such as in regional areas of Australia. There were no other differences in the median intervals along the pathway to treatment based on remoteness of residence. Patients with more comorbidities presented to their primary care provider sooner and older patients and those with higher levels of education had shorter diagnostic intervals. This suggests that those with greater interaction or experience with health system (older patients and those with comorbidity) and those who can potentially navigate and communicate within the health system better (those with higher education) have more opportunities to have symptoms diagnosed and may be able to self-advocate to achieve a diagnosis more quickly. These findings also lend support to the observed negative correlations between health literacy and intervals along the pathway to treatment—it is possible that patients with more experience in the health system may have had higher health literacy than those with less interaction.

Since our previous retrospective cohort study,[30] the length of the PORT interval has decreased for both metropolitan and regional patients. In the previous study, the median PORT interval was 66 days for regional patients with oral cavity cancer, compared with 42 days for metropolitan patients. Regional patients in the present study had a median PORT interval of 53 days, compared with 47 days for metropolitan patients. Also in contrast with our previous study, there was no significant difference in the PORT interval based on remoteness of residence, and a higher proportion of patients in regional NSW now meet the guidance of commencing PORT within 6 weeks of surgery in this present study, demonstrating an improvement in an important metric of quality care since the previous study. This may be due to the increase in availability of oncology services offering radiation therapy services in regional areas in NSW since our

TABLE 3 Clinical characteristics of patients in the cohort.

Characteristic	All patients ($N = 100$), N (%)	Metropolitan patients ($N = 72$), N (%)	Regional patients ($N = 28$), N (%)	P
Self-rated health over previous 2 years				0.81
Very good	35 (35)	26 (36)	9 (32)	
Good	43 (43)	31 (43)	12 (43)	
Fair	15 (15)	9 (13)	6 (21)	
Poor	4 (4)	3 (4)	1 (4)	
Missing	3 (3)	3 (4)	—	
Primary tumor site				0.04[a]
Oral cavity	20 (20)	18 (25)	2 (7)	
Oropharynx	19 (19)	14 (19)	5 (18)	
Nasopharynx	1 (1)	—	1 (4)	
Hypopharynx	2 (2)	—	2 (7)	
Larynx	1 (1)	—	1 (4)	
Paranasal sinus	4 (4)	3 (4)	1 (4)	
Cutaneous	37 (37)	24 (33)	13 (46)	
Salivary glands	5 (5)	4 (6)	1 (4)	
Thyroid	11 (11)	9 (13)	2 (7)	
Tumor stage				0.63
Early	60 (60)	43 (60)	17 (61)	
Advanced	36 (36)	27 (38)	9 (32)	
Not applicable (Tis)	4 (4)	2 (3)	2 (7)	
Symptoms[b]				N/A
Fatigue	14 (14)	10 (14)	4 (14)	
Unexplained weight loss	4 (4)	4 (6)	—	
Loss of appetite	6 (6)	4 (6)	2 (7)	
Hoarse voice/change in voice	7 (7)	3 (4)	4 (14)	
Changes in breathing	4 (4)	3 (4)	1 (4)	
Difficulty swallowing	9 (9)	7 (10)	2 (7)	
Pain when swallowing	3 (3)	2 (3)	1 (4)	
Mouth pain	8 (8)	5 (7)	3 (11)	
Spitting/coughing up blood	2 (2)	1 (1)	1 (4)	
Persistent sore throat	4 (4)	1 (1)	3 (11)	
Neck lump	31 (31)	22 (31)	9 (32)	
Loose teeth/badly fitting dentures	6 (6)	5 (7)	1 (4)	
Ulcer/sore in mouth	10 (10)	6 (8)	4 (14)	
White/red patches on tongue	3 (3)	3 (4)	—	
Other	49 (49)	37 (51)	12 (43)	
Not applicable (no symptoms)	7 (7)	5 (7)	2 (7)	
Median number of symptoms (IQR)	2 (2)	2 (2)	2 (2)	0.57

Abbreviations: IQR, interquartile range; N/A, not applicable; Tis, tumor in situ.

[a] Fisher's exact test.

[b] Patients could list more than one symptom.

TABLE 4 Correlations between patient health literacy domain scores of the HLQ® with time intervals along pathway to diagnosis and treatment.

	Interval					
	Patient interval	Primary care interval	Diagnostic interval	Treatment interval	PORT interval	Total interval
HLQ® domain	ρ, N	ρ, N	ρ, N	ρ, N	ρ, N	ρ, N
1. Feeling understood and supported by healthcare providers	−0.84, 93	−0.14, 92	−0.12, 93	−0.09, 94	−0.02, 24	−0.14, 94
2. Having sufficient information to manage my health	−0.25[a], 94	−0.27[b], 93	−0.25[a], 94	−0.12, 95	−0.11, 25	−0.26[a], 95
3. Actively managing my health	−0.09, 94	−0.06, 93	−0.03, 94	−0.03, 95	0.31, 25	0.03, 95
4. Social support for health	−0.12, 94	−0.07, 93	−0.04, 94	−0.71, 95	−0.20, 25	−0.04, 95
5. Appraisal of health information	−0.15, 94	−0.07, 93	−0.01, 94	0.01, 95	0.00, 25	0.01, 95
6. Ability to actively engage with healthcare providers	−0.14, 94	−0.17, 93	−0.25[a], 94	−0.05, 95	−0.27, 25	−0.17, 95
7. Navigating the healthcare system	−0.03, 94	−0.19, 93	−0.27[b], 94	−0.09, 95	−0.39, 25	−0.15, 95
8. Ability to find good health information	−0.04, 94	−0.28[b], 93	−0.34[b], 94	−0.16, 95	−0.14, 25	−0.23[a], 95
9. Understand health information well enough to know what to do	−0.19, 94	−0.14, 93	−0.28[b], 94	−0.05, 95	−0.17, 25	−0.20[a], 95

Abbreviations: *n*, number; PORT, post-operative radiotherapy; ρ, correlation coefficient.

[a] Significant at the 0.05 level.

[b] Significant at the 0.01 level.

previous retrospective cohort study, as well as the introduction of the *OCP-HNC*. The *OCP-HNC* impressed the importance of timely commencement of PORT after surgery in HNC patients (within 6 weeks), owing to associations with better survival outcomes.[22] Despite these improvements, the persisting difference in times to treatment for regional and metropolitan patients in NSW remains a concern.

This is the first study to investigate associations between patient health literacy with timeliness of diagnosis and treatment of HNC. One of the strengths of the study is the diversity of patients with HNC included in the study. Recruitment from a high-volume metropolitan center and several regional centers facilitated the enrolment of patients from varied backgrounds, with diverse tumor types and subsites. We recruited patients who were within 6 months of diagnosis, which provided a balance between optimal patient recall and being sensitive to patient wellbeing.[10,33] Another strength is that this is one of the first studies utilizing a validated health literacy assessment tool to explore associations with timeliness of diagnosis and treatment of cancer, which addresses an important gap in the literature previously identified by Humphrys et al.[9] Previous studies have used either non-validated measures or measures that do not reflect the multidimensional characteristics of health literacy. Several limitations should also be addressed. First, there was inconsistent recruitment throughout the study because of minimal resources in the context of busy clinics and treatment centers, with recruitment dependent on the capacity of busy clinicians also managing a clinical workload. Second, we recruited fewer patients than anticipated who lived and were treated in regional NSW. This meant that comparisons to our previous work could not be drawn due to small numbers and is reflective not only of the difficulties in recruiting but also that many patients from regional NSW receive treatment in metropolitan NSW. We were also unable to recruit to our anticipated sample size of 160 patients as recruitment was ceased in March 2020 during the first wave of COVID-19 in NSW,[34] which lowers the power to detect differences in hypothesis testing. In addition, the majority of data was self-reported by patients, which is subject to recall and response biases. To ameliorate these biases, where possible, we attempted to triangulate dates of events along the pathway to treatment with medical records for accuracy and utilized best-practice methodology[10,20] for early cancer diagnosis research, predominantly guided by the ICBP. Finally, our approach of assessing correlations between domains of HL and diagnostic time intervals introduces the potential for spurious correlations to be reported. Both HL and diagnostic time

TABLE 5 Multivariable regression models for intervals exceeding maximum accepted timeframes, with outcomes dichotomized based on timeframes described in the *Optimal care pathways for people with head and neck cancer* (OPC-HNC).

	Patient interval >14 days		**Primary care interval >21 days**		**Diagnostic interval >24 days**		**Treatment interval >28 days**		**PORT interval >42 days**	
Characteristics	**AOR [95% CI]**	***P***	**AOR [95% CI]**	***P***	**AOR [95% CI]**	***P***	**AOR [95% CI]**	***P***	**AOR [95% CI]**	***P***
Remoteness of residence[a]										
Metropolitan	1.00 (ref)	0.48	1.00 (ref)	0.48	1.00 (ref)	0.77	1.00 (ref)	0.06	1.00 (ref)	0.19
Regional	0.71 [0.28–1.81]		1.43 [0.57–3.61]		0.86 [0.32–2.30]		2.71 [0.96–7.61]		4.24 [0.49–36.83]	
Pathway[b]										
GP	NT		1.00 (ref)	0.78	NT		NT		NT	NA
Dentist	—		1.39 [0.34–5.70]		—		—		—	
Other	—		1.40 [0.46–4.33]		—		—		—	
Age at diagnosis (years)	—	NS	—	NS	0.96 [0.93–0.99]	**0.02**	—	NS	—	NS
Tumor site										
Oral cavity	—	NS	—	NS	—	NS	—	NS	1.00 (ref)	0.15
Oropharynx	—		—		—		—		0.49 [0.02–11.19]	
Cutaneous	—		—		—		—		0.29 [0.02–5.03]	
Other	—		—		—		—		0.05 [0.003–0.79]	
Comorbidity										
None	1.00 (ref)	**0.03**	—	NS	—	NS	—	NS	—	NS
Low (1, 2)	0.32 [0.13–0.79]		—		—		—		—	
High (3+)	0.72 [0.28–1.81]		—		—		—		—	
Highest education level										
Secondary	—	NS	—	NS	1.00 (ref)	**0.003**	—	NS	—	NS
Post-secondary	—		—		0.24 [0.09–0.60]		—		—	
Self-reported health status										
Poor/fair	—	NS	—	NS	—	NS	1.00 (ref)	0.26	—	NS
Good	—		—		—		0.48 [0.13–1.72]		—	
Excellent	—		—		—		0.34 [0.09–1.25]		—	

Note: The patient and diagnostic intervals were dichotomized at the cohort median as maximum acceptable timeframes are not available for these intervals. Full regression models for each outcome are available in Tables S2–S6. Bolded values represent *P*-value <0.05.

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; NA, not applicable; NS, not significant on univariable model; NT, not tested in model; PORT, post-operative radiotherapy.

[a] Explanatory variable retained in all models regardless of significance.

[b] Explanatory variable tested and retained only in model for primary care interval.

TABLE 6 Comparison of median time intervals (with 75th and 90th percentiles) along the pathway to treatment experienced by metropolitan and regional patients.

	Metropolitan patients				Regional patients				
Interval (unit)	***N***	**Median**	**75th percentile**	**90th percentile**	***N***	**Median**	**75th percentile**	**90th percentile**	***P***
Patient interval (days)	72	14	60.5	149.1	27	7	73	128	0.29
Primary care interval (days)	72	14	46	167.6	27	16.5	108	260.4	0.43
Diagnostic interval (days)	72	23	73.5	264.9	26	29	154	286.2	0.98
Treatment interval (days)	72	31	48.75	86	27	48.5	60.8	102.8	0.011
Total interval (months)	72	3.0	7.6	14.5	28	4.7	9.7	12.7	0.26
PORT interval (days)	17	47	79.5	95.4	11	53	60	84.8	0.40[a]

Abbreviation: PORT, post-operative radiotherapy.

[a] Exact test (Mann–Whitney).

intervals are complex and likely mediated by variables that were not or could not be accounted for in our analyses. Therefore, caution should be taken when interpreting these correlations as they may not actually reflect any causative relationships and further appropriately powered analyses that account for the potential effects of confounding variables should be undertaken.

The findings have implications for clinician and policymakers. Low patient health literacy, which was correlated with times to diagnosis, may be targeted in two ways. First, patient education campaigns may increase awareness of HNC signs and symptoms, encouraging patients to seek help for red-flag symptoms and would address *individual-level* heath literacy. As summarized by MacPherson,[35] approaches such as national oral cancer awareness days, advice on self-examination, and written information on oral cancer statistics have shown benefit in the short-term on presentations to primary care and detection of malignant lesions, however, data on long-term effectiveness is still lacking and may not reach priority groups most at risk. MacPherson further argues that "multicomponent, theory-based campaigns" targeted toward populations at high risk, which include radio and billboard advertisements, community group-based education sessions,[36] or posters, leaflets, and advertisements on television and radio[37] show potential to lead to behavior change, however, sustainability and cost-effectiveness of these models needs to be considered. Second, healthcare re-design or health system interventions to facilitate movement through the health system for patients with possible cancer would address *environmental-level* health literacy. Health system interventions are complex, involving several different components that are often sensitive to the local healthcare context[38] that impact on the success of the intervention. The *Improving Rural Cancer Outcomes* trial[39] conducted in Western Australia utilized a rigorous design and evaluation to determine the impact of community-based symptom awareness and general practice-based education interventions to reduce time to diagnosis for regional cancer patients, and found no effect either intervention on the outcomes. This shows that despite some promise of primary care interventions to reduce diagnostic delays,[40] the major challenges remain practical ones which cannot always be accounted for in study design. Granular data on adherence to guidelines such as the *OCP-HNC*[29] are lacking in oncology systems and medical records, and even once collected have limited utility if they do not address issues in as close to "real-time" as possible. There is increasing interest in collection and reporting of benchmarks that reflect performance,[41,42] however, there is a lack of consensus on which metrics are most appropriate, readily collectable, and clinically meaningful.

This study is the first known study to investigate associations between patient health literacy and timeliness of events along the pathway to treatment of HNC. While there appear to be improvements in timeliness of treatment commencement in regional NSW, population-based studies of these outcomes are required to investigate changes more thoroughly over time. The findings that higher levels of health literacy may facilitate a more timely progression from symptom assessment to diagnosis of HNC provides potential actions to target at individual, population, and health system levels to ensure equitable access to high-quality cancer care regardless of residence and individual resources.

ACKNOWLEDGMENTS

We would like to acknowledge the International Benchmarking Partnership (ICBP) for permission to modify and use their questionnaire. Open access publishing facilitated by The University of Sydney, as part of the Wiley - The University of Sydney agreement via the Council of Australian University Librarians.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Ethical and governance approval was granted by the Sydney Local Health District Human Research Ethics Committee and study sites (Protocol No X17-0442 and HREC/17/RPAH/657).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Venchiarutti RL, Clark JR AM, Palme CE, et al. Associations between patient-level health literacy and diagnostic time intervals for head and neck cancer: A prospective cohort study. *Head & Neck*. 2024;46(4):857-870. doi:10.1002/hed.27633.