Development of a health literacy screening tool for use in patients with cancer.

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Abstract:
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Geoffrey Saunders
M.Phil Thesis
Development of a health literacy screening tool for use in patients with cancer.
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Background: The objective of this study is the development of a cancer specific health literacy screening tool and to compare it with the Newest Vital Sign (NVS)

Methods: Following a pilot study to develop a six point cancer tool, 350 patients attending outpatient clinics at the Christie Hospital were invited to self-complete the tool under development and the NVS.

Findings: A total of 214 patients participated. Mean score achieved on the cancer tool and the NVS were: 4.35 (SD 1.55) and 4.39 (SD 1.91) respectively. 45.8% patients scored 4 or less on the cancer tool; 38% patients scored 4 or less on the NVS. No significant differences were seen in gender, age or educational achievement on scores achieved with the cancer tool, however age but neither gender nor educational achievement were significant factors for scores achieved with the NVS. Internal consistency was good for the NVS (Cronbach’s alpha 0.752) and adequate for the cancer tool (Cronbach’s alpha 0.578).

Discussion: Although the cancer tool does usefully identify cancer patients at risk of poor health literacy, further refinement is required to ensure a closer comparison to the NVS. This study demonstrates that the NVS is a useful tool for self administration.
Declaration

I declare that no portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Development of a health literacy screening tool for use in patients with cancer.

Chapter One. Introduction

1.1 Health Literacy

The access to healthcare and use of medicines is influenced by a number of factors, resulting in up to one half to one third of all medicines prescribed for long term conditions not being used as intended \(^1\). In the UK, the National Institute for Health and Clinical Excellence (NICE) guidance on Adherence \(^2\) identifies a number of barriers influencing shared decision making and adherence such as: communication difficulties, cultural issues, low health literacy and physical limitations. Pharmacists providing care to patients within all healthcare settings should be aware of the implications for health outcomes of low health literacy and should be able to screen for patients at risk of having low health literacy.

1.1.1 Definition

Health literacy as a concept has been defined by many researchers and commentators in the field \(^3, 4, 5\). However, the definition of health literacy as proposed by Ratzan and Parker in their introduction to the 2000 National Library of Medicine Health Literacy citation list is seen as the standard definition used in this area:

Health literacy: ‘The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions’ \(^6\).

Defining health literacy in this manner establishes the link between the individual’s ability to read written information pertaining to health related matters and then use this information to make a positive decision to improve their own health. This can be in the form of an appointment card, the label on a bottle of tablets, the results of a test, an invitation to screening or any of a number of other common pieces of information.
By improving the understanding of individuals of health related matters it is hoped that there would be, amongst other things, higher uptake of screening programmes, closer adherence to treatment recommendations and improved attendance at medical appointments with all the expected gains in health benefits associated with these health interventions.

In the US, this definition has since been used as the basis for the Institute of Medicine report on health literacy: A Prescription to end Confusion issued in 2004 (7). This being a major piece of work aimed at health professionals reviewing the impact that health literacy has both on individual patients and from a public health point of view. It explores the concept of health literacy as well as tools for identifying patients with low levels of health literacy together with strategies to improve the health literacy of the population. This publication has been seen as highlighting the problem of low levels of health literacy in the United States and promoting a heightened awareness amongst healthcare professionals.

1.1.2 Historical Perspective

Although health literacy as a concept was first postulated in 1974 as a function of the educational system, health system and mass communication (8) it was not until the 1990s that the concept became firmly established as a way of describing the way patients interact with health services. Prior to the definition by Ratzan and Parker (2000) mentioned above a number of other definitions had been put forward, each giving a slightly different perspective. The definition used by the Joint Committee on National Health Education Standards states: ‘the capacity of individuals to obtain, interpret and understand basic health information and services and the competence to use such information and services in ways which enhance health’ (9). In 1999 the American Medical Association adopted the definition of health literacy as ‘the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment’ (10). Thus the definition of health literacy has evolved as a way of describing an individual patient’s approach to their own health care in all environments.
1.2 Evolution of Health Literacy Theories

A number of different authors have postulated different models of how patients operate within health literacy. Initial thinking centred mainly on literacy and numeracy skills and was seen as part of health promotion. This functional view of health literacy went some way to understand the health information needs of patients but fails to address the decision making skills required to adequately navigate the healthcare system. Looking at the concept of health literacy from viewpoints other than those of educationalists, for instance from a clinical or public health point of view, has enabled the development of models of health literacy with a broader outlook, recognising that people function at different levels with differing priorities.

1.2.1 Three Tier Model

One such model is the Three Tier Model of health Literacy. In 2000 Nutbeam proposed a three tier model of health literacy as it was recognised that patients operate at more than one level within healthcare systems (11).

At the most basic level, functional health literacy describes the process whereby patients receive information from and communicate with health professionals. At an individual level this considers whether individual patients use their literacy skills within the healthcare setting for instance to: access healthcare screening programmes, adhere to treatment plans or make appointments. Improved health literacy skills at this level result in improvements to individual patient’s health through prompt identification of disease and improved adherence to prescribed treatment plans. At a public health level there are improvements to health through increased uptake of screening and immunisation programmes.

The next level, interactive health literacy, considers how the development of personal skills influences the way the individuals are able to act independently on the knowledge they receive either in written form or during an interaction with a healthcare professional. With improved motivation and self confidence patients incorporate the advice received into decisions about their own healthcare needs. Again perceived benefits to the individual are mainly around early detection of disease and improved adherence to treatment plans. At this level there may be public health gains through more interaction and awareness.
The third tier of this model, critical health literacy builds on the first two tiers: utilising more advanced skills in knowledge and understanding together with social skills, patients can critically analyse conflicting health related information and apply this to their own well being. At this level individuals are likely to be able to act as advocates for a wider social group influencing policy and strategy development thereby having an impact on healthcare at this level.

Table 1.1 Levels of Health Literacy (from Nutbeam 2000) (11)

<table>
<thead>
<tr>
<th>Health Literacy Level and Educational goal</th>
<th>Content</th>
<th>Outcome: Individual benefit</th>
<th>Outcome: Community/social benefit</th>
<th>Examples of educational activity</th>
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<td>Functional health literacy: communication of information</td>
<td>Transmission of factual information on health risks and health services utilization</td>
<td>Improved knowledge of risks and health services, compliance with prescribed actions</td>
<td>Increased participation in population health programmes (screening, immunisation)</td>
<td>Transmit information through existing channels, opportunistic interpersonal contact and available media</td>
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<tr>
<td>Interactive health literacy: development of personal skills</td>
<td>As above and opportunities to develop skills in a supportive environment</td>
<td>Improved capacity to act independently on knowledge, improved motivation and self confidence</td>
<td>Improved capacity to influence social norms, interact with social groups</td>
<td>Tailor health communication to specific need; facilitation of community self-help and social support groups; combine different channels for communication</td>
</tr>
<tr>
<td>Critical health literacy: personal and community empowerment</td>
<td>As above and provision of information on social and economic determinants of health, and opportunities to achieve policy and/or organisational change</td>
<td>Improved individual resilience to social and economic adversity</td>
<td>Improved capacity to act on social and economic determinants of health, improved community empowerment</td>
<td>Provision of technical advice to support community action, advocacy communication to community leaders and politicians; facilitate community development</td>
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This model enhances the simplistic views of health literacy by providing a framework in which patients operate at levels beyond merely reading and understanding health related literature.

1.2.2 Risk Asset Model

In a refinement of his original model, Nutbeam proposed an alternative view of health literacy as either a risk or an asset (12).
In the risk model, low health literacy is seen as a risk factor for poor health outcomes in individuals and that strategies need to be developed to put into place to identify individuals at risk and to provide improved access to healthcare information tailored to individual patient needs. This ensures that information is presented to patients in a way that can be understood and retained. Expected outcomes would be enhanced capability for self management which in turn would produce improved clinical outcomes.

Figure 1.1 Conceptual Model of Health Literacy as a risk (from Nutbeam 2008) (12)

The asset model looks at health literacy from a health educational point of view and sees health literacy as an asset to be developed in individual patients to improve their own use of healthcare resources. Building on prior understanding by providing tailored information, patients will have developed knowledge which together with increased social skills will result in enhanced health literacy. The resulting changed health behaviours will produce improved health outcomes. By promoting advocacy and engagement patients will be encouraged to operate at the highest tier of the
three tier model influencing policy development and improving health outcomes for a wider social group.

Figure 1.2 Conceptual model of Health Literacy as an asset (from Nutbeam 2008) (12)

Both of the models are linked together, the risk model considers health literacy as an existing state to direct the interaction between the patient and healthcare provider whereas the asset model sees health literacy as a goal to be achieved through the
use of educational processes to advance individuals along a continuum allowing them to operate at different levels within the health care system. Both models can be used to enhance healthcare of the individual and the wider group.

1.3 Health Literacy Movement

Health literacy has been promoted as a tool for consumers ensuring best use of health care resources\(^3\). In this way the use of health literacy as a partnership between health care providers and patients has been promoted. The National Consumer Council 2004 report on health literacy included in its recommendations: “It is crucial that patients have access to material to inform themselves as, when and how they wish, and to use it in discussion with health professionals.”\(^{13}\) This has resulted in the development of organisations such as Health Literacy Consulting which through its website (www.healthliteracy.com), publications and establishment of a health literacy month promotes the awareness of the importance of understandable health information. Whilst the development of the use of health literacy has mainly taken place in the US, there is a growing interest in other countries including the UK with involvement from academics, clinicians and policy makers across the healthcare spectrum and has led to the formation of the Health Literacy Group UK. This has resulted in a number of publications raising awareness of health literacy concepts with healthcare professionals\(^{14, 15}\).

1.4 Health Literacy and Policy development

The promotion of adequate health literacy, alongside recognition of patients with poor health literacy is seen as a key component for the delivery of health policy in that it supports patients as they take on more responsibility for the management of their own health, particularly in the context of the treatment of long term conditions and the increased use of ambulatory care\(^{16}\). In order to successfully navigate the health system patients are required to develop the skills that enable them to access screening programmes, interpret complex health messages from a number of sources, monitor disease parameters and adjust therapy as appropriate.
The 2005 Department of Health paper - Choosing Health through Pharmacy (17) has a section entitled Promoting Health Literacy highlighting ways in which pharmacists can actively promote health literacy both with patients and other healthcare staff.

1.4.1 US Perspective

The 1992 National Adult Literacy Survey revealed the extent of inadequate literacy in the US adult population; more than 47% (90 million) of US adults have difficulty locating, matching and integrating information in written texts with accuracy and consistency (18). As a result of which a concerted effort was made to achieve a greater understanding of the impact poor literacy has on health outcomes. The Institute of Medicine of the National Academies published in 2004, Health Literacy: A prescription to end confusion, summarising the development of the concept of health literacy and putting forward a number of recommendations to federal government to fund research into the use and further development of tools associated with assessing health literacy. Further recommendations to embed health literacy concepts into the provision of health care are also included in the publication (4). These include recommendations to educators to include health related tasks into lesson plans and for professional schools and continuing professional education programmes to include health literacy in their curricula and areas of competence.

The National Institutes of Health are currently funding a number of research projects examining the effect of health literacy on patient experiences of healthcare, details of which are accessible on the NIH website (http://www.nih.gov/clearcommunication/healthliteracy.htm). In addition to a number of NIH publications explaining the relevance of health literacy, the NIH publication Healthy People 2010: Understanding and Improving Health includes health literacy as a major objective for health communication (19).

1.4.2 UK Perspective

The UK Department of Health has also recognised the influence that health literacy has on the health of individuals, in that “low levels of health literacy impacts negatively on an individual’s ability to take action to improve their health” (20). Health literacy is seen as a key factor in reducing health inequalities. In the policy paper
Health Inequalities: Progress and next steps \(^{(21)}\) strategies to improve health literacy are presented:

- Extend the Skilled for Health programme to adults with poor basic skills
- Improvements to school food, personal, social and health education (PSHE) lessons and the Healthy Schools programme.
- Develop a better understanding of how people view their own health, the behaviours that affect their health and how they interact with health services.
- Build on the Healthy Foundations large-scale research in order to create a more sophisticated understanding of people’s behaviour and what motivates them to improve their health.

A major Skilled for Health project aimed at improving literacy and numeracy in the context of health care was launched in 2003 \(^{(22)}\). Skilled for Health was originally piloted as community based projects resulting in the provision of materials aimed at increasing basic skills and health needs. Currently a strategy is being developed to significantly increase the provision of Skilled for Health courses through the provision of teaching materials delivered locally by accredited health trainers resulting in a programme which aims to:

- Contribute to reducing health inequalities by improving health among those communities that demonstrate the worst health outcomes
- Enhance the ability of individuals within those communities to make informed decisions about health and well-being in a variety of different settings
- Use health improvement topics that embed skills for life learning as an incentive to engage and recruit individuals who do not traditionally participate in public health or adult learning initiatives. \(^{(23)}\)

1.5 Health Literacy and Pharmacy

Health literacy as a concept has key ramifications for the practice of pharmacy as the pharmaceutical profession relies heavily on printed material for the provision of information about medicines supplied to individuals, from the information provided on medicine labels instructing patients how and when to use the product, patient information leaflets advising patients about likely side effects of their prescribed drugs and what to do about any untoward effects they may experience, or insurance
(possibly less relevant to the UK setting) or exemption forms the patients may be required to complete in order to receive their prescription medicines at a reduced cost. In 2003, Youmans et al. added to the standard definition of health literacy with the observation that it:

‘Includes the ability to use (literacy) skills to read and understand health-related information, such as medication labels and insurance forms’ (24).

Pharmacists require a good understanding of the impact that low levels of health literacy can have on patients well being and the outcome of their disease treatment. This is becoming increasingly important in the treatment of chronic conditions as patients are encouraged to take on greater responsibility for the management of their own disease.

The phrase ‘medication literacy’ has been used to describe “a person’s ability to make decisions that are right for them, allowing the medicines’ safe and effective use” (25). These skills can be considered a subset of the wider set of skills involved in Health Literacy and are supported by providing patients with understandable information whether verbal or written that has been tested by patients (26).

In a recent review of health literacy and outcomes, Berkman et al (2011) conclude that: low health literacy is associated with poorer health outcomes and poorer use of health care services (27). Specifically they identified that “Low health literacy was consistently associated with more hospitalisations, greater use of emergency care, lower receipt of mammography screening and influenza vaccine, poorer ability to demonstrate taking medications appropriately, poorer ability to interpret labels and health messages, and among elderly persons, poorer overall health status and higher mortality rates.”

In the cancer arena, with the development of more orally active anti-cancer drugs, patients are being required to take a more active role in their own treatment as they take on the responsibility of following complex treatment regimens at home. These often involve pulsed or variable dosing combination regimens of drugs which may have severe side effects, necessitating a good understanding of the treatment regimen itself and what to do in the event of an untoward side effect occurring. This is in stark contrast to the use of traditional chemotherapy where patients attend to
have their treatment administered to them and have little responsibility for the process other than attending their prearranged appointments. Following the publication of the report of the National Chemotherapy Advisory Group (2010)\(^{(28)}\), this is likely to become even more of an issue with cancer teams striving to provide more chemotherapy services closer to where patients live.

With the advent of vaccines actively targeted against HPV, knowledge of prevention strategies against the development of cervical cancer has become increasingly important requiring an increase in public health literacy in relation to HPV and its link with the development of cervical cancer\(^{(29)}\).

Pharmacy staff need to be able to screen for patients at risk from low levels of health literacy and to have strategies in place in order to be able to modify the way that information is imparted to this group of patients in a way that more closely matches their individual requirements.

1.6 Assessing Health Literacy

Much work has been carried out in this area with previous work focussing on how health literacy can be assessed in individual patients with more recent work developing screening tools that can be used in the clinical setting to identify patients potentially at risk of having low levels of health literacy\(^{(30, 31, 32, 33)}\).

As previously alluded to, health professionals need to be able to identify patients with reduced health literacy in order to counteract some of the sequelae outlined above. Most importantly by identifying patients with low or marginal levels of health literacy, health professionals can tailor their information giving to the individual needs of the patient. The measurement of health literacy involves more than just measuring literacy level or educational attainment as this will not take into account the ability of patients to apply information to the healthcare setting. Nor is it sufficient to ask patients if they are able to read or understand the information provided as many individuals with poor levels of literacy will tend to cover up any deficiencies through embarrassment either by denying any problem or by developing coping strategies e.g. by claiming to have forgotten their reading glasses.

The ideal tool for assessing health literacy would be quick to administer, ideally self administered, sensitive and applicable to the health care setting where the
assessment has taken place. The reliability and validity of such a tool should be demonstrated before it is accepted for general use.

A number of assessment tools have been developed in the US for use in English populations with some developed further for use in Spanish speaking populations. To date no tools have been developed for use in health care systems other than the US and there is limited use of disease specific tools, although some of the tools developed for use in the US have been evaluated in UK populations (34, 35).

The main tools in current use are the Rapid Estimate of Adult Literacy in Medicine and the Test of Functional Health Literacy in Adults with their shortened variants plus the Newest Vital Sign.

1.6.1 Tools to assess health literacy

The Rapid Estimate of Adult Literacy in Medicine (REALM) health literacy assessment tool was developed in the early 1990’s and consists of a list of 66 health related terms of increasing complexity that are read aloud by the subject, with the pronunciation checked by the observer (31). It can be administered in a relatively short time by the observer after minimal training. The authors claim that it takes two to three minutes to complete but this is not always borne out in practice with completion times of twice that length being found in clinical practice (30). The test gives a gradated result of reading ability which as it is health related is thought to directly reflect functional health literacy. Pronunciation is assumed to be indicative of understanding. This concept is not valid in languages other than English due to phonetic spelling systems.

Although the test is stated to have evidence of validity (0.88 -0.97 correlation with other literacy tools) (36) and is widely used, it has several disadvantages. It has to be administered face to face and cannot be self administered. It relies on pronunciation as a surrogate for understanding but does not test for the ability to apply knowledge in the healthcare setting. The results are reported in terms of school grade reading
ability, based on the American educational system which may not correspond exactly to educational years in other settings.

The Test of Functional Health Literacy in Adults (TOFHLA) is a comprehensive instrument for the measurement of functional health literacy, consisting of 17 numeracy items and 50 literacy questions based on three prose passages developed from materials in clinical use such as medication labels and appointment slips and patient information such as preparation for investigations\(^{(30)}\).

The numeracy items require a patient to interpret the written information they are presented with and the literacy items are based on the “cloze technique” whereby subjects are required to choose the most appropriate word from a short list to fill in the blanks of a short passage. The passages are chosen for their readability, ranging from 4\(^{th}\) grade to 10\(^{th}\) grade levels, roughly equivalent to year 5 to sixth form levels in the English educational system.

At an average time of 22 minutes to administer the TOFHLA is not suitable as a rapid screening tool and only grades subjects into one of three levels of health literacy; inadequate, marginal or adequate. It is recognised as a comprehensive tool\(^{(7)}\) and is widely used particularly as a comparison when developing shorter screening instruments. As it does not rely on pronunciation the TOFHLA can be developed for use in other languages.

1.6.2 Screening tools

REALM-revised

A shortened version of the rapid estimate of adult literacy in medicine, the REALM-r was devised because in clinical practice the time to administer the test was found to be twice as long as originally claimed\(^{(32)}\). By eliminating items from the word list that had the potential to skew the results and solely concentrating on terms that have a maximal discrimination function, that is a 50/50 correct/incorrect split, a list of only eight items was produced. This shortened version can be administered in a much shorter time and so has the potential for use as a screening tool in a busy clinical setting\(^{(36)}\). Unlike the full version, the REALM-r does not provide an estimate of
reading level, merely an indication of whether the subject is at risk of poor literacy. There is no gradation of the result; more than one incorrect response indicates a risk of poor literacy.

Although the REALM-r is a much shorter test to administer and could potentially be administered to all patients attending a busy clinic, it only measures reading ability and carries the assumption that this is a measure of health literacy as the eight terms that make up the test are commonly used in the medical setting. Patients identified as being at risk of poor literacy would need to undertake further assessment in order to determine their required level of support.

Short TOFHLA

The short test of functional health literacy in adults (s-TOFHLA) was developed from the original TOFHLA, although at an average time of 12 minutes to administer this still remains of limited practical use in a busy clinical environment\(^{(33)}\). This was achieved by reducing the number of numeracy items from 17 to four and the prose passages from four to two. The items for inclusion were chosen for their ability to discriminate between subjects whilst retaining the practical link to the health setting. The two prose passages retained represent both ends of the readability scale.

As with the full TOFHLA this is a test of both numeracy and literacy skills requiring the subject to interpret health related information, again results are reported as one of three grades of health literacy performance; inadequate, marginal or adequate. Similarly, the s-TOFHLA is available in a language other than English, namely Spanish\(^{(33)}\).

It would appear that although the TOFHLA and its shortened form are superior to the REALM and REALM-r in that they examine a wider range of attributes and by the way they are constructed directly examine health literacy, they are of limited use as routine screening tools due to the length of time they take to administer.

Newest Vital Sign

The Newest Vital Sign (NVS) is a screening tool for poor health literacy consisting of six questions based on nutritional information from an ice cream container\(^{(37)}\). It requires subjects to perform numerical as well as reading tasks and also expects
subjects to apply some interpretation to the information that they read. Although this instrument is based on nutritional information it is thought to screen for poor health literacy as many patients with chronic conditions manage their disease through healthy lifestyle choices, using standard nutritional information to achieve this.

The NVS can be administered in a relatively short time and is available in a language other than English as it looks at the ability to apply numerical skills and reasoning rather than merely assessing pronunciation. In this sense it is a truer measure of health literacy than the REALM or its shorter variant the REALM-r. Being an instrument with only six items, it does not discriminate greatly between different levels of health literacy but is thought to be a useful identifier of patients at risk of poor levels of health literacy, subjects providing incorrect answers to more than two items are considered not to have adequate health literacy skills and should be assessed further to determine the level of support that they require.

1.6.4 Critique of health literacy tools

Table 1.2 Characteristics of generic health literacy screening tools

<table>
<thead>
<tr>
<th>Tool</th>
<th>REALM (31)</th>
<th>REALM-r (32)</th>
<th>TOFHLA (30)</th>
<th>s-TOFHLA (33)</th>
<th>NVS (37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to complete:</td>
<td>3-5 min</td>
<td>1-2 min</td>
<td>22 min</td>
<td>12 min</td>
<td>3 min</td>
</tr>
<tr>
<td>Measure(s):</td>
<td>Reading</td>
<td>Reading</td>
<td>reading and numeracy</td>
<td>reading and numeracy</td>
<td>reading and numeracy</td>
</tr>
<tr>
<td>Use</td>
<td>Assessment</td>
<td>Screening</td>
<td>Assessment</td>
<td>Screening</td>
<td>Screening</td>
</tr>
<tr>
<td>Parts:</td>
<td>66 medical terms to pronounce</td>
<td>8 medical terms to pronounce</td>
<td>3 prose passages and 17 numeracy items</td>
<td>2 prose passages and 4 numeracy items</td>
<td>6 questions relating to a nutrition label</td>
</tr>
<tr>
<td>Scoring:</td>
<td>0-18 &lt;3rd grade</td>
<td>0-59 inadequate</td>
<td>0-59 inadequate, 60-74 marginal</td>
<td>0-1 probably inadequate</td>
<td>2-3 possibly inadequate</td>
</tr>
<tr>
<td></td>
<td>19-44 4-6th grade</td>
<td>60-74 marginal</td>
<td>60-74 marginal</td>
<td>4-6 adequate</td>
<td>75-100 adequate</td>
</tr>
<tr>
<td></td>
<td>45-60 7-8th grade</td>
<td>75-100 adequate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>61-66 &gt;9th grade.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;6: risk of poor literacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
As can be seen from the table above, a number of tools have been developed for the assessment of health literacy in individual patients. It can be argued that some are more useful than others depending on the setting in which they are to be used. As research tools producing health literacy scores that can be used to compare populations then both the REALM and TOFLHA are more robust methods in terms of the way that they produce aggregated scores on a continuous scale, however the length of time taken to complete the tests precludes them as useful tools within the busy clinical setting.

The shorter tools REALM-revised, TOFHLA-s and NVS are all designed for use in the clinical setting to enable the rapid identification of patients at risk of health literacy deficits.

The design of the tools are either as health literacy assessment tools resulting in an aggregated score corresponding to a grade reading score which can be repeated over time to demonstrate improvement of an individual’s health literacy, or as a screening tool producing a score on a limited scale resulting in a probability of an individual either having adequate health literacy or being at risk of poor health literacy.

The existing tools as described have been developed for use in the United States, a very different health care setting from the UK. In addition most of the tools use surrogates for assessing health literacy and may not reflect patients’ true levels of ability. The use of generic tools has resulted in the development of scenarios that may not be relevant to individual patients; indeed based on comments received at the pilot stage of this study the NVS use of nutritional information could well be confusing to patients expecting a more health orientated set of questions.

In order to properly assess the effects of poor health literacy in patients with cancer an assessment tool specifically designed for use within that specific health setting using scenarios familiar to that group of patients is likely to be required. Such a tool should assess literacy, numeracy and the ability to apply information to make an informed decision about individual health needs.
When considering the care of patients in the UK it is useful to consider whether there are any health literacy tools that could be used within this setting.

All the health literacy instruments discussed above have been developed in the U.S. To date there have been few studies looking at the transferability of these tools to the UK setting (34, 35). This is important as some of the instruments report outcomes as US grade reading ability. This is based on the US educational setting and may not correlate directly to the educational stages in the UK. In addition material contained within some of the instruments, for instance one of the prose passages included in both TOFHLA instruments - the rights and responsibilities of a Medicaid patient - has no direct equivalence in the UK health system. Two instruments which have been studied in the UK health system are REALM and TOFHLA (34, 35).

Ibrahim et al (2008) (34) compared the use of the Rapid Estimate of Adult Literacy in Medicine with a general measurement of literacy developed in the UK, the Basic Skills Assessment Initial Test (38) in a population of 300 coronary heart disease patients admitted to cardiology units. They found a significant correlation between the two instruments (r = 0.70; p < 0.001) The mean score achieved on the REALM was 62.1, with 19% scoring less than 60 grading them as having inadequate health literacy. This level of poor health literacy corresponds with the Skills for Life Survey which reported levels of poor literacy as 16% in the UK adult population (40). In addition to comparing the two instruments, four screening questions were asked in order to attempt to identify patients likely to have low scores with three of the four questions showing a significant relationship with the scores achieved.

The authors concluded that the REALM has been validated for use in the UK population as a screening tool to detect patients at risk of having poor health literacy both in research and everyday clinical practice settings (34).

Von Wagner et al (2007) studied the use of the modified version of the Test of Functional Health Literacy in Adults (35). A total of 759 subjects, chosen at random were assessed in their own homes by trained administrators. Because of the random process of selection, a variety of health states were included. The TOFHLA was modified from its American form by the inclusion of UK style medication labels and a
prescription charge exemption form. In the original version of the TOFHLA there is a section on eligibility for financial aid for healthcare, the authors were unable to find a UK equivalent so decided to keep that section informing patients that it was ‘hypothetical’. Of the subjects who completed the test, 11.4% were found to have either inadequate or marginal health literacy. The authors felt that the relatively low level of poor health literacy found in the population in their study as compared to previous studies could be explained by their sampling technique as this was based on the general population as a whole rather than cohorts of patients with specific diseases who may already be at increased risk of poor health literacy (35).

1.7 Disease specific tools

To date there have been few tools developed to assess health literacy in specific disease groups. The best example of a disease related health literacy tool is the Literacy assessment in diabetes (LAD) (39). This is a readability tool based on the REALM assessment using terms familiar to patients with diabetes. As with the REALM assessment, this measure of health literacy is based on the patient’s ability to correctly pronounce a series of medical terms based on the assumption that this equates to adequate comprehension. Other authors have identified the need for health literacy assessments for patients with specific medical conditions, for example, breast cancer although it could be questioned whether it is necessary to subdivide a disease such as cancer to this extent (41).

1.8 Health Literacy and Cancer

1.8.1 Studies of health literacy in the cancer setting

To understand the use of health literacy in the provision of cancer services and to determine any gaps in the knowledge base a review of the literature was undertaken. A search strategy was designed to ensure that relevant papers were identified. The following databases were searched: Cumulative Index to Nursing and Allied Health Literature, Embase, International Pharmaceutical Abstracts, Medline and PsychInfo
from 1948 to the present date. No limits were placed on language of publication. Search terms included the expanded terms for ‘cancer’ and were combined with ‘tool or instrument or survey’ and/or with the phrase ‘health literacy’.

Predetermined criteria were used to identify patient studies using a validated method of assessing health literacy and to measure outcomes within individual disease settings. From a potential pool of 79 papers identified, only 7 studies were judged to fit the criteria with a further three studies reviewed as there was some measurement of literacy and/or numeracy with a degree of outcome measurement. The remaining studies were rejected as there was no formal consideration of participants’ health literacy.

Table 1.3 Summary of published articles assessing health literacy in the cancer setting

<table>
<thead>
<tr>
<th>First author year of publication</th>
<th>Citation</th>
<th>U.S.A. Healthcare Setting</th>
<th>Number of participants</th>
<th>Tool used to evaluate Health literacy</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu 2006&lt;sup&gt;44&lt;/sup&gt;</td>
<td>T Wu, J Bancroft. Filipino American women’s perceptions and experiences with breast cancer screening Oncology Nursing Forum 2006; 33: 71</td>
<td>Community based</td>
<td>11</td>
<td>None</td>
<td>Health literacy not formally measured although reported as a risk factor</td>
</tr>
<tr>
<td>Hahn 2007&lt;sup&gt;17&lt;/sup&gt;</td>
<td>E Hahn, D Cella, D Dobrez. The impact of literacy on health-related quality of life measurement and outcomes in cancer outpatients. Quality of Life Research 2007; 16: 495-507</td>
<td>Out patient cancer clinics</td>
<td>415</td>
<td>None</td>
<td>Literacy assessed using Passage Comprehension subtest of the Woodcock Language Proficiency Battery</td>
</tr>
<tr>
<td>Hawley 2008&lt;sup&gt;45&lt;/sup&gt;</td>
<td>S Hawley, N Janz, A Hamilton et al. Latina patient perspectives about informed treatment decision making for breast cancer. Patient education and counselling 2008;73: 363-370</td>
<td>Cancer registry registrants</td>
<td>925</td>
<td>Health literacy assessed with 2 Questions</td>
<td>Questions: how often respondents had (1) trouble understanding written information about breast cancer and (2) someone help them read written information from the hospital or clinic.</td>
</tr>
</tbody>
</table>
As previously stated, low levels of functional health literacy affect every aspect of patients’ interaction with the health service. This is just as true with cancer patients with access to screening and preventative services through to making decisions about treatment options and adhering to treatment plans.

In breast cancer, studies have looked at women’s attitudes to breast cancer screening programmes, perceptions of the risk of developing breast cancer and making decisions about treatment options (42, 43, 44). In a study looking at risk perception of breast cancer survival and screening mammography benefit in a sample of women patients without a history of breast cancer, 254 women drawn from a random sample of patients attending two primary care clinics agreed to complete questionnaires. Ethnicity but not numeracy or level of academic achievement was a predictor for accuracy of risk assessment (42). In another study, drawn from the same population as the previous study, 254 women were interviewed to ascertain their perception of their personal risk of developing breast cancer. Low health literacy and numeracy were associated with inconsistent use of risk assessment scales (43). Focus group participants drawn from a local Filipino community confirmed that cultural awareness is another important element in ensuring that women from various ethnic minorities are educated in the benefits of attending screening programmes (44). In a survey of 925 women identified with breast cancer by the local cancer registry, low or moderate levels of health literacy were associated with dissatisfaction in decision making in patients with newly diagnosed breast cancer deciding between therapeutic options (45).

In a study examining strategies for improving communication with patients about colorectal cancer screening, 382 patients of a larger cohort recruited from out patient clinics completed health literacy assessments. Improved communication in patients with low health literacy levels improved attendance rates for colorectal screening by approximately 20% when compared to a control group (46). The link between health literacy and knowledge of colorectal screening has been confirmed in a study of 50 patients recruited from outpatient clinics (47). However in a study of 136 patients recruited through community clinics a connection between health literacy and knowledge about colorectal screening was not demonstrated (48). The authors suggest that the ethnicity of their study population (46% Latino) and the then public
health focus on colorectal cancer and common screening methods might explain this difference.

In a study of 96 oncology outpatients, subjects with lowest health literacy levels demonstrated the highest level of discrepancy between written and oral collection of family history of cancer \(^{(49)}\).

Men’s beliefs about benign prostatic hypertrophy and prostate cancer were explored after viewing a decisional aid in the form of a video. 188 men recruited from community organisations viewed the decision aid video and were then interviewed to ascertain their understanding. Men with lower functional health literacy were more likely to persist in their misconceptions about risks of developing prostate cancer \(^{(50)}\).

When assessing health-related quality of life (HRQOL) in cancer patients a number of different techniques have been used including the use of talking touch screens allowing self administration of the instrument in use. HRQOL assessments were completed by 415 patients recruited from out patient cancer clinics. Patients with low levels of health literacy were able to use the touch screens effectively and were no more likely to report lower health related quality of life \(^{(51)}\).

1.8.2 Limitations of the studies

To date most studies of the effects of health literacy on patients with cancer have concentrated on access to screening programmes and understanding of the risk of developing malignant disease. There has been no work looking at the effect of health literacy on patients’ adherence to treatment plans in the treatment of cancer. Other disease states have been studied. Kripalani et al (2006) reported that patients with coronary heart disease and low health literacy were less likely to identify all of their medications \(^{(52)}\). In a study of HIV patients, those with low health literacy performed worse during a mock exercise to examine management of medication \(^{(53)}\).

Among patients with type 2 diabetes, inadequate health literacy is independently associated with worse glycaemic control and higher rates of retinopathy \(^{(54)}\). In this study, 408 patients were included and were found to have a mean s-TOFHLA score of 21 with 52% graded as having either inadequate or marginal health literacy. Mean
HbA1c was 8.5%. For every 1-point decrease in the s-TOFHLA score there was a 0.02 increase in HbA1c percentage score. Overall patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycaemic control (HbA1c < 7.2%) and were more likely to report diabetic induced retinopathy.

Patients of low health literacy were associated with medication underuse and higher blood pressure\(^{(55)}\). 806 patients attending diabetic clinics were questioned about their beliefs and concerns about their antidiabetic and antihypertensive medications. HbA1c and blood pressure was monitored, functional health literacy was assessed using a three item tool\(^{(56)}\). The authors concluded that medication underuse because of concerns about harmfulness of medication, particularly antihypertensives, was associated with, amongst other things, low health literacy and higher blood pressure readings.

Subjects with low literacy were less adherent with their glaucoma medications\(^{(57)}\): 197 patients with open angle glaucoma participated in a study, functional health literacy was assessed using the REALM and adherence to therapy was assessed using repeat prescription dispensing rates. Fifty-two percent of patients were graded as having less than adequate health literacy; patients with adequate levels of health literacy on average had 50% more repeat prescriptions dispensed than patients with less than adequate health literacy.

1.9 Implications for Patients

Improving outcomes for patients with cancer requires implementation of policies at every stage of the patient journey. Screening and early detection of disease, informed choice of treatment options, concordance with treatment plans, appropriate use of medication all require patients to make appropriate decisions about their own health. Patients with poor health literacy are less likely to access health care and are also less likely to utilise medications as expected, deriving fewer benefits \(^{(7)}\). Greater understanding of health literacy by health professionals is likely to result in more effective interactions with patients and production of information accessible by patients with different health literacy needs.
1.10 The requirement for a cancer specific health literacy screening tool.

Most health literacy instruments are generic rather than disease specific, indeed the NVS uses nutritional rather than health related information as the basis for the assessment. Additionally there is no evaluated health literacy instrument developed for the UK health care system, although work is ongoing to produce a UK version of the NVS \(^{(58)}\). The use of concepts familiar to patients will allow a better understanding of the terms used and hence a truer assessment of health literacy. By designing a tool specifically aimed at patients with cancer it is expected that there would be a greater engagement with patients resulting in a more meaningful result. This is an interesting and novel route to explore, in that it might increase relevance to UK patients with cancer.
Chapter Two. Aim and Objectives

2.1 Aim

To develop a health literacy screening tool for use in patients with cancer

2.2 Objectives

To identify an appropriate model for a health literacy screening tool
To design and pilot a health literacy screening tool applicable to the cancer setting
To further refine the cancer tool under development based on feedback obtained in the pilot setting
To use the cancer tool in a population of cancer out-patients
To compare the use of the cancer tool with an established tool
3.1 Questionnaire design

To test for poor health literacy an appropriate section of prose is required. It should be meaningful to the cohort of patients being studied and should be easily understood by the majority of the general population. This tool should contain sufficient information that requires the ability to read, use numeracy skills and provide for the application of knowledge in the healthcare setting. Involving patients in the design of the tool will improve understanding and ensure its relevance.

Testing individuals’ understanding of the prose passage developed could take a number of different forms: patients could feedback verbally what they are going to do, they could read the passage back with the inference that reading aloud equates with understanding, they could be interviewed on a one to one basis by a researcher, or they could answer set questions either verbally or in a written form.

For this study the decision was made to test understanding using a predetermined set of questions which would be answered in a written form. This decision was made on the basis of consistency, the ability to test for understanding of a number of different concepts and that this would be the most effective use of the resources available.

A questionnaire was designed using cancer specific scenarios using the Newest Vital Sign (NVS)\(^{37}\) as a model.

3.1.1 Choice of NVS as comparator

The NVS was chosen as the comparator as it demonstrates all the qualities of a useful health literacy screening tool for use in routine practice. It is quick to administer: at an average completion time of three minutes it has one of the shortest completion time of all the screening tools in use. The length of time taken to administer has been substantiated in other papers\(^{59,60}\).

The NVS tests literacy, numeracy and the ability to apply knowledge in the health setting. It does not rely on pronunciation as a proxy for understanding. Because of its
brevity and ease of use this tool lends itself to self completion allowing clinical staff to concentrate on other duties. All these qualities allow the use of the NVS in a busy clinical setting to identify patients at risk of poor health literacy.

The NVS consists of a copy of a nutritional label from an ice cream tub followed by six questions. Four of which test numeracy skills and two assess the ability to apply knowledge in the healthcare setting.

A level of readability cannot be assigned to the information contained in the NVS: being a nutritional label it has no standard sentence structure. However patients with long term conditions need to be able to use similar information to make daily decisions to maintain a healthy state.

It is important that any comparator is also designed for self completion so that it could be routinely used in clinical practice.

3.2 Pilot study

Using the NVS as an example, a health literacy screening tool was developed for use in patients with cancer. The intention was to use terms and scenarios familiar to patients undergoing treatments for cancer, which can encompass chemotherapy or radiotherapy. In order to keep the topic relevant to as many patients as possible, rather than focusing on individual treatments for specific diseases, the decision was made to use a scenario involving the use of anti sickness medication which was likely to be familiar to most if not all patients as many treatments for cancer can cause patients to feel sick, in which case they will need to be familiar with the use of anti sickness medication.

The prose passage chosen describes the use of antiemetics and was supplemented with the instructions from a tablet bottle label. Initially a patient information leaflet supplied by the manufacturers of an antiemetic was considered \(^{61}\). The Simple Measure of Gobbledygook (SMOG) readability score was used to analyse the text \(^{62}\). This generic readability measure is increasingly being advocated as a tool for designing written health information that is easily read by the majority of the population \(^{63}\). The passage chosen from the leaflet was found to have a SMOG
readability score of 24, which is equivalent to the complexity of a research paper and is only understood by a small percentage of the population. A generic leaflet about antiemetics produced by CancerBacup (64) was examined and although the passage chosen had an improved SMOG score of 16.2 this was still only likely to be understood by a minority the population. By using an iterative process, rewriting the passage, shortening sentences and substituting some of the medical terminology with easier to understand alternatives, a passage with a SMOG index of 13 was obtained: by comparison the average Sun editorial has a SMOG index of 14 (62).

Text passage developed for Cancer tool:

Some cancer treatments, including certain anti cancer drugs, are known to cause you to feel sick and to be sick. If you need these drugs, anti sickness drugs will be given before the cancer treatment has started. It may also be continued for a few days after the treatment has finished.

When someone feels or is sick due to the cancer itself, it can take a while to control this symptom. You will be given anti sickness drugs and, if possible, the cause of the sickness will be treated.

Whatever the cause of the sickness, the anti sickness treatment should be taken regularly so that the sickness does not have a chance to come back. If you have any symptoms which are new, become worse, or last more than a few days, let your doctor or nurse know.

Instruction label for Dexamethasone Tablets

<table>
<thead>
<tr>
<th>Dexamethasone 2mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take TWO tablets</td>
</tr>
<tr>
<td>TWICE daily</td>
</tr>
<tr>
<td>For TWO days</td>
</tr>
<tr>
<td>TAKE WITH OR AFTER FOOD</td>
</tr>
<tr>
<td>DO NOT TAKE AFTER 6PM</td>
</tr>
</tbody>
</table>
The six accompanying questions were written with the intention of testing literacy, numeracy and the ability to apply knowledge in the healthcare setting.

Cancer tool questions:

1. When should you start taking anti sickness treatment?
2. If you become constipated, what should you do?
3. Should you take the anti sickness tablets if you haven’t been sick at all?
4. Should you only take the anti sickness drugs on the same day that you have anti cancer treatment?
5. How many dexamethasone tablets should you take during one day?
6. What is the latest time that you would take dexamethasone?

3.3 Involvement of the Cancer Network patient user partnership

As part of the pilot study, a brief description of the project outline (see appendix 2) was presented at a meeting of the Greater Manchester and Cheshire Cancer Network patient user partnership. Approximately twelve attendees were present, representing user groups across the Greater Manchester and Cheshire region. The members of the partnership were asked to complete the health literacy screening tools to be used in the study and to feedback any comments they had about the style and content of the forms. Several members of the Network partnership took the forms back to their local user groups and invited comments.

Seven completed questionnaires were returned from various members of a number of Patient user partnerships within Greater Manchester. Comments received related to typographical errors, ordering of information and questions and the choice of key words.

Changes made as a result consisted of corrections to the typographical errors and a change to the order of the screening tools presented. No changes were made to the quoted definition of health literacy or to the existing tool: the NVS.
3.4 Main Study

3.4.1 Study sample

Patients attending out patient clinics at the Christie Hospital, a tertiary referral centre for the treatment of cancer in Manchester, were approached by the researcher and invited to participate in the study. The outpatient department was visited at different times each day to ensure that a wide selection of disease types were selected. Outpatients were selected over inpatients as these patients, being ambulant, were thought to be less likely to have their cognitive functions impaired by comorbidities as the majority of cancers are treated on an out patient basis with only the most severely ill patients being admitted to the inpatient areas. These patients usually suffer from the complications of cancer or its treatments for instance infections or other oncological emergencies making them unable to complete questionnaires.

3.4.2 Study Procedures

Patients participating in the study were required to supply basic demographic details: age, gender, postcode area, age at completion of full time education and clinic attending. The patients were then asked to self complete two health literacy screening tools; the Newest Vital Sign(NVS) (37) and the Cancer tool under development. Each screening tool was designed to take approximately three minutes to complete, allowing patients to complete the forms whilst waiting to be called for their appointments. Patients left their completed forms in a collection box before leaving the department which was collected on a regular basis by the researcher.

3.4.3 Recruitment

All patients approached were given a verbal explanation of the study by the researcher together with a written information sheet. They were given an opportunity to pose additional questions before receiving the self completion forms. No record was kept of patients who either declined to participate or were deemed to be ineligible for the study through not complying with the eligibility criteria.

3.4.4 Timeframe

Patients were recruited during a three week period during August 2010 to minimise approaching individuals on more than one occasion as the majority of patients on
active treatment receive their chemotherapy on three or four weekly cycles. The three week period was chosen as it gave adequate time to recruit the desired number of participants.

3.4.5 Inclusion/exclusion criteria

All patients approached had to be able to comply with the following criteria to be considered for inclusion in the study:

1. Must be able to give informed consent
2. Must have a good understanding of English
3. Must have a diagnosis of cancer
4. Must be aged 16 or over

Patients unable to comply with any of the above criteria were considered ineligible for the study.

3.4.6 Numbers

A total of 350 patients were approached and agreed to participate in the study with a total of 214 forms returned for analysis. The number of patients approached was predetermined at 350 with the expectation of generating at least 200 useable forms for analysis based on an expected response rate of 50-60%.

3.5 Study approval

Ethical approval for this study was received from the NHS Research Ethics Committee prior to commencement of the study. Additionally the approval of the Christie NHS Foundation Trust research and development department was sought. Approval was received from both bodies, see appendices 3 & 4.
3.6 Analysis

The questionnaires were completed unsupervised; all forms returned with at least one question completed were analysed.

All data was entered onto an Excel spreadsheet and data analysis was performed using IBM SPSS Statistics v.19.

Each questionnaire was scored against the specimen answers supplied in the marking scheme with each correct answer scoring one point.

Missing or incomplete answers were deemed to be incorrect (as per confirmatory e-mail from B.Weiss, lead author of NVS) See appendix 5.

Using the scoring system devised for the NVS, a maximum of six points is possible with patients scoring four points or below assumed to be at risk of poor health literacy \(^{(37)}\).
3.6.1 Questions and marking scheme

Full copies of papers issued to patients are included in appendices 6 & 7.

**Newest vital sign**

This information is on the back of a container of a pint of ice cream.

<table>
<thead>
<tr>
<th>Nutrition Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serving Size</strong></td>
</tr>
<tr>
<td><strong>Servings per container</strong></td>
</tr>
<tr>
<td><strong>Amount per serving</strong></td>
</tr>
<tr>
<td>Calories</td>
</tr>
<tr>
<td>Fat Cal</td>
</tr>
<tr>
<td>%DV</td>
</tr>
<tr>
<td><strong>Total Fat</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Sat Fat</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Sodium</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Total Carbohydrate</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Dietary Fiber</td>
</tr>
<tr>
<td>Sugars</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

*Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.
1. If you eat the entire container, how many calories will you eat?
   Answer  (1,000 is the only correct answer)

2. If you are allowed to eat 60g of carbohydrates as a snack, how much ice cream could you have?
   Answer  (Any of the following: 
   
   One cup, or any amount up to one cup 
   
   Half the container 
   
   Two servings)

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
   Answer  (33 is the only correct answer)

4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
   Answer  (10% is the only correct answer)

   Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves and bee stings.

5. Is it safe for you to eat this ice cream?
   Answer  (No)

6. Why not?
   Answer  (Because it has peanut oil)
Cancer Tool

Some cancer treatments, including certain anti cancer drugs, are known to cause you to feel sick and to be sick. If you need these drugs, anti sickness drugs will be given before the cancer treatment has started. It may also be continued for a few days after the treatment has finished.

When someone feels or is sick due to the cancer itself, it can take a while to control this symptom. You will be given anti sickness drugs and, if possible, the cause of the sickness will be treated.

Whatever the cause of the sickness, the anti sickness treatment should be taken regularly so that the sickness does not have a chance to come back. If you have any symptoms which are new, become worse, or last more than a few days, let your doctor or nurse know.

Instruction label for Dexamethasone Tablets

<table>
<thead>
<tr>
<th>Dexamethasone 2mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take TWO tablets</td>
</tr>
<tr>
<td>TWICE daily</td>
</tr>
<tr>
<td>For TWO days</td>
</tr>
<tr>
<td>TAKE WITH OR AFTER FOOD</td>
</tr>
<tr>
<td>DO NOT TAKE AFTER 6PM</td>
</tr>
</tbody>
</table>
1. When should you start taking anti sickness treatment?
Answer  (Before the cancer treatment has started)

2. If you become constipated, what should you do?
Answer  (Let your doctor or nurse know)

3. Should you take the anti sickness tablets if you haven’t been sick at all?
Answer  (Yes)

4. Should you only take the anti sickness drugs on the same day that you have anti cancer treatment?
Answer  (No)

5. How many dexamethasone tablets should you take during one day?
Answer  (4 is the only answer)

6. What is the latest time that you would take dexamethasone?
Answer  (6PM or earlier)
3.6.2 Data Analysis

Descriptive statistics were used to describe the patient group, for instance mean and standard deviation of patient age, mean and standard deviation of age on completion of full time education and proportion of male to female participants.

The tools were considered separately for mean scores achieved by individual participants and percentage of participants correctly answering each question.

The effect (if any) of gender, age bands or age on completion of education on total scores achieved with either tool were assessed using Chi square tests.

The internal consistency of each tool was examined using Cronbach alpha scores in an attempt to identify any questions which could improve the performance of the cancer tool after removal.

Any correlation between scores achieved using both tools was assessed using Pearsons coefficient.

Paired samples t-test was used to identify any significant difference between scores achieved on both tools.

A significance level of p<0.05 was used to determine statistical significance.
Chapter Four: Results

4.1 Patient Numbers and characteristics

A total of 350 patients attending outpatient appointments at The Christie Hospital were invited to participate in the study; 214 patient questionnaires were completed and returned, giving a response rate of 60%. As this was a self completed exercise some questions were answered inconsistently or left blank, an example of this was in answer to the question “Clinic attended” many patients responded “Christie” or “Chemotherapy” making it impossible to categorise patients by tumour type.

4.1.1. Gender of participants

Figure 4.1: Gender of Participants

![Participants](image)

116 (54%) patients were female, 82 (38%) male with the gender of 16 patients not disclosed.
4.1.2 Age of participants

Figure 4.2: Age distribution of participants

Mean age was 58.9 years with a range of 20-87 and a standard deviation of +/-12.7 years.

All patients were adults; persons below the age of 16 were specifically excluded.

Not all patients disclosed their age hence n=197.
4.1.3 Completion of full time education

Figure 4.3: Age distribution at completion of full time education

Mean age on completion of education was 17.5 years with a range of 14-28 and a standard deviation of +/-6.1 years. Three outliers reported completing full time education at 40, 66 and 71 years respectively. Although there are secondary peaks at ages 18 and 21; the chart shows that the majority of patients completed secondary but not further or higher educational courses.

64% patients completed their education aged 16 or below.
4.2 Performance of Questionnaires

4.2.1 Newest Vital Sign

Table 4.1 NVS- Overall scores for each question

<table>
<thead>
<tr>
<th>Question no.</th>
<th>Question</th>
<th>Total correct</th>
<th>Percentage correct</th>
<th>Total incorrect</th>
<th>Percentage Incorrect</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVS1</td>
<td>If you eat the entire container, how many calories will you eat?</td>
<td>169</td>
<td>79</td>
<td>45</td>
<td>21</td>
</tr>
<tr>
<td>NVS2</td>
<td>If you are allowed to eat 60g of carbohydrates as a snack, how much ice cream could you have?</td>
<td>141</td>
<td>66</td>
<td>73</td>
<td>34</td>
</tr>
<tr>
<td>NVS3</td>
<td>Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?</td>
<td>137</td>
<td>64</td>
<td>77</td>
<td>36</td>
</tr>
<tr>
<td>NVS4</td>
<td>If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?</td>
<td>132</td>
<td>62</td>
<td>82</td>
<td>38</td>
</tr>
<tr>
<td>NVS5</td>
<td>Is it safe for you to eat this ice cream?</td>
<td>174</td>
<td>81</td>
<td>40</td>
<td>19</td>
</tr>
<tr>
<td>NVS6</td>
<td>Why not?</td>
<td>169</td>
<td>79</td>
<td>45</td>
<td>21</td>
</tr>
</tbody>
</table>
Figure 4.4 Percentage correct scores for NVS
Thirty-eight percent of patients scored 4 or less on the NVS: these patients are deemed to be at risk of poor health literacy.
Table 4.2 NVS - Effect of gender, age or educational achievement

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>At risk of poor health literacy (%)</th>
<th>Not at risk of poor health literacy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>29 (35)</td>
<td>53 (65)</td>
</tr>
<tr>
<td>Female</td>
<td>51 (44)</td>
<td>65 (56)</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>25 (29)</td>
<td>61 (71)</td>
</tr>
<tr>
<td>Age&gt;65</td>
<td>49 (44)</td>
<td>62 (56)</td>
</tr>
<tr>
<td>Completion of full time education &lt;17</td>
<td>52 (44)</td>
<td>66 (56)</td>
</tr>
<tr>
<td>Completion of full time education &gt;17</td>
<td>19 (23)</td>
<td>63 (77)</td>
</tr>
</tbody>
</table>

Table 4.3 NVS - Percentage Risk of poor health literacy

<table>
<thead>
<tr>
<th>Gender =M</th>
<th>Gender =F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
<td>44</td>
<td>0.847</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>Age&gt;65</td>
<td>P</td>
</tr>
<tr>
<td>29</td>
<td>44</td>
<td>0.017</td>
</tr>
<tr>
<td>Education &lt;17</td>
<td>Education &gt;17</td>
<td>P</td>
</tr>
<tr>
<td>44</td>
<td>23</td>
<td>0.09</td>
</tr>
</tbody>
</table>

Using Chi-square test for independence, age (<65>) p=0.017 but not educational achievement (school leaving age <17>) p=0.09 or gender p=0.874 was a significant factor for scores achieved with the NVS.
Table 4.4 NVS - performance of individual items

<table>
<thead>
<tr>
<th>NVS</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item-Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Cronbach's Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVS</td>
<td>3.98</td>
<td>1.803</td>
<td>.452</td>
<td>.226</td>
<td>.707</td>
</tr>
<tr>
<td>Q1</td>
<td>4.09</td>
<td>1.655</td>
<td>.454</td>
<td>.283</td>
<td>.708</td>
</tr>
<tr>
<td>NVS</td>
<td>4.11</td>
<td>1.594</td>
<td>.494</td>
<td>.296</td>
<td>.695</td>
</tr>
<tr>
<td>Q3</td>
<td>4.13</td>
<td>1.629</td>
<td>.443</td>
<td>.202</td>
<td>.713</td>
</tr>
<tr>
<td>NVS</td>
<td>3.94</td>
<td>1.840</td>
<td>.508</td>
<td>.843</td>
<td>.697</td>
</tr>
<tr>
<td>Q5</td>
<td>3.96</td>
<td>1.768</td>
<td>.552</td>
<td>.851</td>
<td>.684</td>
</tr>
</tbody>
</table>

With a Cronbach score of 0.737 for the entire scale, the NVS demonstrated good internal consistency with none of the items underperforming.
### 4.2.2 Cancer Tool

#### Table 4.5 Cancer Tool- Overall scores for each question

<table>
<thead>
<tr>
<th>Question no.</th>
<th>Question</th>
<th>Total correct</th>
<th>Percentage Correct</th>
<th>Total incorrect</th>
<th>Percentage Incorrect</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>When should you start taking anti sickness treatment?</td>
<td>121</td>
<td>57</td>
<td>93</td>
<td>43</td>
</tr>
<tr>
<td>C2</td>
<td>If you become constipated, what should you do?</td>
<td>120</td>
<td>56</td>
<td>94</td>
<td>44</td>
</tr>
<tr>
<td>C3</td>
<td>Should you take the anti sickness tablets if you haven’t been sick at all?</td>
<td>149</td>
<td>70</td>
<td>65</td>
<td>30</td>
</tr>
<tr>
<td>C4</td>
<td>Should you only take the anti sickness drugs on the same day that you have anti cancer treatment?</td>
<td>180</td>
<td>84</td>
<td>34</td>
<td>16</td>
</tr>
<tr>
<td>C5</td>
<td>How many dexamethasone tablets should you take during one day?</td>
<td>169</td>
<td>79</td>
<td>45</td>
<td>21</td>
</tr>
<tr>
<td>C6</td>
<td>What is the latest time that you would take dexamethasone?</td>
<td>184</td>
<td>86</td>
<td>30</td>
<td>14</td>
</tr>
</tbody>
</table>
Questions one and two (“when should you start taking your anti sickness treatment?” and “if you become constipated what should you do?) appear to have been answered incorrectly by a larger proportion of participants than questions 3-6.
45.8% patients scored 4 or less on the cancer tool; these participants are could be considered to be at risk of poor health literacy using the same score thresholds as the NVS tool.
Table 4.6 Cancer Tool- Effect of gender, age or educational achievement

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>At risk of poor health literacy (%)</th>
<th>Not at risk of poor health literacy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>35 (42)</td>
<td>47 (58)</td>
</tr>
<tr>
<td>Female</td>
<td>57 (49)</td>
<td>59 (51)</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>35 (41)</td>
<td>51 (59)</td>
</tr>
<tr>
<td>Age &gt;65</td>
<td>53 (48)</td>
<td>58 (52)</td>
</tr>
<tr>
<td>Completion of full time education &lt;17</td>
<td>56 (47)</td>
<td>62 (53)</td>
</tr>
<tr>
<td>Completion of full time education &gt;17</td>
<td>25 (34)</td>
<td>47 (66)</td>
</tr>
</tbody>
</table>

Table 4.7 Cancer Tool - Percentage risk of poor health literacy

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>48</td>
<td>0.177</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>Age &gt;65</td>
<td>P</td>
</tr>
<tr>
<td>42</td>
<td>49</td>
<td>0.933</td>
</tr>
<tr>
<td>Education &lt;17</td>
<td>Education &gt;17</td>
<td>P</td>
</tr>
<tr>
<td>47</td>
<td>34</td>
<td>0.108</td>
</tr>
</tbody>
</table>

Using Chi square test for independence, no significant differences were seen in gender p=0.933, age (<65>) p=0.177 or educational achievement (school leaving age <17>) p=0.108 on scores achieved with the cancer tool, although higher proportions of females, those aged over 65 and those who ceased education <17 were at found to be at risk of poorer health literacy as observed with the NVS tool.
Table 4.8 Cancer tool: performance of individual items

<table>
<thead>
<tr>
<th>Cancer Tool</th>
<th>Scale Mean if Item Deleted</th>
<th>Scale Variance if Item Deleted</th>
<th>Corrected Item-Total Correlation</th>
<th>Squared Multiple Correlation</th>
<th>Cronbach's Alpha if Item Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 Cancer</td>
<td>3.92</td>
<td>1.234</td>
<td>.417</td>
<td>.214</td>
<td>.452</td>
</tr>
<tr>
<td>Q2 cancer</td>
<td>3.92</td>
<td>1.357</td>
<td>.290</td>
<td>.170</td>
<td>.524</td>
</tr>
<tr>
<td>Q3 Cancer</td>
<td>3.78</td>
<td>1.577</td>
<td>.141</td>
<td>.044</td>
<td>.590</td>
</tr>
<tr>
<td>Q4 Cancer</td>
<td>3.62</td>
<td>1.641</td>
<td>.236</td>
<td>.082</td>
<td>.541</td>
</tr>
<tr>
<td>Q5 Cancer</td>
<td>3.69</td>
<td>1.444</td>
<td>.363</td>
<td>.164</td>
<td>.488</td>
</tr>
<tr>
<td>Q6 Cancer</td>
<td>3.62</td>
<td>1.509</td>
<td>.430</td>
<td>.204</td>
<td>.476</td>
</tr>
</tbody>
</table>

Overall Cronbach score for the entire series was 0.560 indicating that removing question 3 (Should you take the anti sickness tablets if you haven’t been sick at all?) would have a very minor effect of bringing the Cronbach alpha score to 0.59.
### 4.3 Comparison of Cancer tool with NVS

**Table 4.9 Scores for individual items**

<table>
<thead>
<tr>
<th>Item</th>
<th>correct</th>
<th>Incorrect</th>
<th>Percentage correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>121</td>
<td>93</td>
<td>57</td>
</tr>
<tr>
<td>C2</td>
<td>120</td>
<td>94</td>
<td>56</td>
</tr>
<tr>
<td>C3</td>
<td>149</td>
<td>65</td>
<td>70</td>
</tr>
<tr>
<td>C4</td>
<td>180</td>
<td>34</td>
<td>84</td>
</tr>
<tr>
<td>C5</td>
<td>169</td>
<td>45</td>
<td>79</td>
</tr>
<tr>
<td>C6</td>
<td>184</td>
<td>30</td>
<td>86</td>
</tr>
<tr>
<td>NVS1</td>
<td>169</td>
<td>45</td>
<td>79</td>
</tr>
<tr>
<td>NVS2</td>
<td>141</td>
<td>73</td>
<td>66</td>
</tr>
<tr>
<td>NVS3</td>
<td>137</td>
<td>77</td>
<td>64</td>
</tr>
<tr>
<td>NVS4</td>
<td>132</td>
<td>82</td>
<td>62</td>
</tr>
<tr>
<td>NVS5</td>
<td>174</td>
<td>40</td>
<td>81</td>
</tr>
<tr>
<td>NVS6</td>
<td>169</td>
<td>45</td>
<td>79</td>
</tr>
</tbody>
</table>
Figure 4.8 Distribution of correct scores achieved by individuals

Figure 4.9 Scatter plot comparing score achieved using cancer tool with NVS
Table 4.10 Pearson Correlation Characteristics

<table>
<thead>
<tr>
<th>Tool</th>
<th>Pearson Correlation</th>
<th>Sig. (2-tailed)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Tool total correct</td>
<td>.447**</td>
<td>.000</td>
<td>214</td>
</tr>
<tr>
<td>NVS total correct</td>
<td>.447**</td>
<td>.000</td>
<td>214</td>
</tr>
</tbody>
</table>

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

At r=0.447 there is a moderate correlation between scores achieved using the two tools (p< 0.01).

Table 4.11 Paired Samples Statistics

<table>
<thead>
<tr>
<th>Pair 1</th>
<th>NVS total correct</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Tool total correct</td>
<td>4.36</td>
<td>210</td>
<td>1.569</td>
<td>.108</td>
<td></td>
</tr>
</tbody>
</table>

A paired samples test comparing scores achieved by individuals on both tools showed no significant difference between the two (p=0.883).
Chapter 5: Discussion

5.1 Patient Demographics and Characteristics

Patients attending outpatient oncology clinics at The Christie Hospital, a tertiary referral centre for the treatment of cancer, were recruited to this study over a three week period. The main waiting area within outpatients was visited at different times and on different days in order to recruit a large number of participants that were a representative sample of the Christie outpatient population. At that time, all outpatient clinics with the exception of endocrinology and haematology-oncology were held in the main outpatients area. Thus patients were potentially receiving systemic treatment, were under treatment review or were on long term follow up for a variety of different solid tumours.

5.1.1 Patient numbers

A total of eligible 350 patients were issued with the patient information sheet and questionnaires after a brief description of the study and an invitation to participate. Patients were left to complete the questionnaires unsupervised as they waited to be called for their appointments. Consent to participate in the study was deemed to have occurred by the act of placing completed questionnaires in the collection box. No data were collected on ineligible patients or patients who declined to participate or returned blank questionnaires.

In line with the methodology outlined previously all returned forms with at least one question completed were analysed. Questions left blank were scored as incorrect. This is in keeping with the methodology developed by Weiss et al who confirmed that in their study any unanswered questions were marked as incorrect by the interviewer. (Personal Communication) Appendix 5.

A total of 214 returned forms were included in the analysis giving a response rate of 60%. This is considered a good response rate for a paper based survey with no reminders or incentives.
5.1.2 Gender of participants

Thirty-eight percent of patients were male, 54% female with the gender of 16% of participants not disclosed. Whilst the male to female ratio of approximately 2:3 observed in this study does not reflect the overall incidence of cancer in the general population, it is likely to reflect the attendance at outpatient clinics at The Christie for the treatment and monitoring of different disease states. In the UK during 2008, there were 155,326 new cases of cancer in males compared to 154,201 new cases in females \(^\text{(65)}\). However the predicted ten year survival for patients diagnosed in 2007 was only 39.3% in males as opposed to 51.0% in females \(^\text{(65)}\). So although the annual incidence of cancer in males is slightly higher than in females, the prevalence of cancer is higher in females. Overall registrations at The Christie reflect the national incidence with a ratio of 49:51 (Christie Informatics). The difference in prevalence coupled with the differences in the treatment strategies for individual diseases could account for the over representation of females in this sample.

For instance when considering standard treatments for the two commonest gender related oncological diseases; female patients requiring adjuvant chemotherapy for breast cancer attend for treatment on a three weekly basis as opposed to male patients with prostate cancer requiring hormonal manipulation who usually receive treatment in primary care necessitating fewer outpatient attendances \(^\text{(66)}\).

5.1.4 Age of Patients

The mean age of the patients at 58.9 (+/-12.7) years is consistent with the age of the population of cancer patients receiving treatment; 53% of all cancers are diagnosed in people aged 50-74 \(^\text{(65)}\). This is comparable to the mean age (62.75 years) of new registrations at the Christie (Christie Informatics).

5.1.5 Completion of education

Mean age on completion of education was 17.5 years; three outliers reported completing full time education at 40, 66 and 71 years respectively. This is possibly either due to the question being misunderstood or due to patients returning to education in later life. As the questionnaires were completed unsupervised, it is not possible to clarify the answers. Although there were secondary peaks at 18 and 21; fewer than one third of participants completed further or higher educational courses.
Whilst educational attainment is not a measure of health literacy, previous authors have used this as a proxy to predict for poor understanding of health related information and lower health outcomes\(^{(42)}\). In general educational attainment has been shown to be a poor proxy for level of health literacy with no influence on the results obtained with numerous health literacy tools\(^{(36, 67)}\).

5.2 Performance of the questionnaires

5.2.1 Newest Vital Sign

5.2.1.1 Performance of individual items

The percentage correct score was calculated for each question in the tool. With the score for each question falling in the range of 62-81%, none of the questions appear as outliers. The internal consistency was further explored using Cronbach alpha. This was good, \( r = 0.752 \), and no item was shown to be reducing the overall consistency score. This compares favourably with the results reported by Weiss et al. In their study, 250 participants completed the NVS with Cronbach alpha = 0.76\(^{(37)}\).

5.2.1.2 Individual Participants’ Performance

The NVS is intended to be used as a screening tool to identify patients at risk of having poor health literacy; it does not measure the absolute health literacy of individuals. Instead of resulting in a grade score linked to the American educational system, a score between 0 and 6 is produced with participants answering more than two questions incorrectly assumed to be at risk of poor health literacy.

The mean score achieved on the NVS was 4.39 with 38% patients scoring less than 4: that is at risk of poor health literacy. Whilst this level of poor health literacy is higher than that reported in previous studies of the use of health literacy screening tools in a UK adult population (19% Ibrahim\(^{(34)}\), 11.4% Von Wagner\(^{(35)}\)) estimates of inadequate literacy in the UK adult population range from 16%\(^{(40)}\) to 52%\(^{(68)}\).
5.2.2 Cancer tool

5.2.2.1 Performance of individual questions

The percentage correct score was calculated for each question in the tool. With the score for each question falling in the range 56 to 86%, two of the questions appear as outliers (Q1 57%, Q2 56%).

Questions one and two (“when should you start taking your dexamethasone tablets?” and “if you become constipated what should you do?”) appear to have been answered incorrectly by a larger proportion of participants than questions 3-6. This is possibly because a number of participants gave answers based on their own experience rather than based on the information supplied. Although for individual patients this may have been correct, for the purposes of scoring the tool these answers were deemed incorrect.

A sample of answers given that illustrate this are:

<table>
<thead>
<tr>
<th>Question one</th>
<th>Question two</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day after treatment</td>
<td>Take Fybogel or similar</td>
</tr>
<tr>
<td>Next day after chemo</td>
<td>Take medication (Movicol doesn’t work for me)</td>
</tr>
<tr>
<td>With food</td>
<td>Take Senna</td>
</tr>
<tr>
<td>When told to</td>
<td>Drink more</td>
</tr>
<tr>
<td>The day after chemo</td>
<td>Eat vegetables, baked beans etc!</td>
</tr>
<tr>
<td>-anti sickness drip given with chemo</td>
<td></td>
</tr>
</tbody>
</table>

The internal consistency was further explored using Cronbach alpha. This was moderate, \( r = 0.578 \) with the removal of question 3 (“should you take the anti sickness tablets if you haven’t been sick at all?”) found to improve the overall consistency score (\( r \) if item deleted = 0.590). The impact of this is minimal.
5.2.2.2 Participant’s individual Performance

As with the NVS, the cancer tool is designed to produce a score between 0 and 6 with scores of 4 and below equating to risk of poor health literacy.

The mean score achieved on the Cancer Tool was 4.35 with 45.8% of patients being identified as at risk of poor health literacy. Although this is a higher percentage than the one obtained using the NVS in the same population, this is still within the range of measured inadequate literacy in the UK population as previously described \(^{(40, 68)}\).

With a Pearson correlation coefficient of \(r=0.447\) there is a moderate positive correlation between the scores achieved by individual patients using the two screening tools. Although the cancer tool has been shown to identify patients at risk of poor health literacy the results achieved are not as reliable as the NVS. This may be due to the design of individual questions, internal consistency as measured by Cronbach’s alpha score suggests that the tool can be further improved.

5.3 Reflections on the Research

5.3.1 Strengths

As already stated there is currently no health literacy screening tool designed for use in cancer patients, furthermore no health literacy tool to date has been designed specifically with the UK healthcare system in mind.

This study is the first reported using a cancer specific health literacy assessment tool in a UK setting. It was conducted in an outpatient setting and demonstrated that an estimate of individual patient’s health literacy needs can be identified in a timely manner using a self completed questionnaire. The study was conducted over several weeks allowing patients with different disease states to be recruited. With a response rate of more than 60% 214 questionnaires were analysed, this acceptable response rate increases confidence in the applicability of the results to a larger population.
In this study, the comparator tool, the NVS, was used in a novel way. Instead of being administered face to face by a trained administrator, patients were left to complete the assessment themselves with no involvement from the researcher. With a good level of internal consistency as measured by Cronbach’s alpha $r=0.752$, the NVS has been shown to be suitable for self completion by patients. This level of correlation compares favourably with the level of internal consistency $r=0.76$ reported by the authors of the paper describing the development of the NVS $^{(37)}$. This is important as although the NVS can be administered face to face in under 3 minutes by a suitably trained healthcare professional, there are obvious benefits to the running of a busy outpatient clinic if the tool can be self completed with no loss in effectiveness of discriminating patients at risk of poor health literacy.

5.3.2 Weaknesses

This study was carried out in the main outpatient waiting area with patients being invited to participate after a brief explanation of the study. Participants may have been discouraged from completing the questionnaires because of the perceived lack of privacy. Patients were expected to physically read and write in the self completion forms unsupervised: patients wholly illiterate will have been identified as non responders rather than having low levels of health literacy.

Because of the nature of the recruitment process it is not known whether the patients who declined to participate or to return their questionnaires were more or less likely to be at risk of poor health literacy than those participating. Recruitment may have been improved by providing a separate area for participants to complete the questionnaires away from the general seating area to improve privacy. The response rate may have been increased if the researcher had checked back with participants to encourage them to complete the forms that they had received. This would have entailed a greater use of facilities within the out patient area which is not always available and a greater use of the researchers time.

Although gender was not shown to be a significant factor in the scores achieved on either tool there was a higher number of female participants. Whilst this probably reflects the ratio of male to female patients receiving treatment or monitoring of their disease there is no clear evidence that the results have been affected as no data
were collected about patients who were not recruited or did not return the questionnaire.

The study was carried out in a naturalistic setting: patients were not supervised as they completed their questionnaires; one participant commented: 
people are getting help from relatives to complete forms.

Whilst this is not an ideal way to measure individual patient’s risk of poor health literacy it does reflect the support mechanisms that many patients develop to increase their level of understanding.

Although the screening tool under development was used by a large number of patients with different types of cancer at various stages of treatment, information on clinic attended and therefore type of cancer being treated was poorly recorded making it difficult to draw any conclusion relating the results of this study to a more diverse population of patients with cancer.

5.3.4 Limitations

The NVS and the cancer tool are not designed to measure individual’s levels of health literacy hence no assumptions can be made about the absolute level of health literacy of a population. What the tools can do is identify those patients at risk of having poor levels of health literacy allowing healthcare professionals to target interventions accordingly.

Pharmacists are not experts in information design; specialist input may be required to optimise these tools.

The NVS has not yet been validated for use in the UK, although work is underway to produce a UK version (58). However for reasons outlined above it was felt to be the most practical model for use in the outpatient setting. The NVS has been compared to the TOFHLA which is considered to be the gold standard research tool which in turn has been validated for use in the UK setting (35).
5.4 Key findings

Approximately 2 in 5 of patients attending outpatient clinics at The Christie Hospital are at risk of poor health literacy, this is confirmed by both tools used: the NVS identified 38% as being at risk of poor health literacy; the Cancer tool identified 45.8% of patients as being at risk of poor health literacy.

There was a moderate, positive correlation between the two screening tools \((r=0.447)\) so a patient identified as being at risk for poor health literacy by the NVS is likely to be identified by the cancer tool as such. Whilst this is not a strong correlation, this study has demonstrated that it is possible to design a health literacy screening tool capable of identifying patients at risk of poor health literacy that is comparable with an existing tool. Internal consistency of the cancer tool at Cronbach alpha \(r= 0.578\) shows that the tool can be further improved. This is a potential area for further research exploring possible alternative items for inclusion in the tool.

Internal consistency of the NVS as measured by Cronbachs alpha was not altered by using the tool as a self completion exercise \((r=0.752)\) as opposed to a face to face interview \((r=0.76)\) \(^{57}\).

A paired samples tests comparing scores achieved by individuals on both tools showed no significant difference between the two \((p= 0.883)\). There is no evidence to suggest that the two assessment tools necessarily discriminate between participants differently.

5.5 Implications of findings;

5.51 For policy

This study has confirmed that a considerable proportion of patients with cancer are at risk of poor health literacy. Previous studies have shown that patients with low levels of health literacy are less likely to present for screening or to respond to early signs of cancer \(^{44,47}\). These patients are more likely to present with a higher stage of cancer at diagnosis with poorer resulting outcomes \(^{69}\). As identified by the NICE guidance on medicines adherence \(^{2}\) poor health literacy is one of the barriers that influence decision making and adherence.
The use of health literacy screening tools in this way follows Nutbeam’s model conceptualising health literacy depending on the setting; that is either a risk or an asset that individual patients have. It does not take into account the societal perspectives developed in other models previously outlined (12).

The prevalence of risk of poor health literacy is such that the question could be posed whether individual healthcare professionals can do much to improve the literacy skills of the public rather they should re-examine their own activities and assumptions to remove literacy related barriers (70). More time should be spent in developing good information systems that can deliver personalised information at a level relevant to the individual patient. As highlighted by Schwartzberg 2005 “Plain language communication should be considered a critical skill, along with other competencies for those in health professions” (4).

5.5.2 For practice

This study has demonstrated that it is possible to design a health literacy screening tool that does identify those patients with cancer at risk for poor health literacy.

This study has also demonstrated that the tools in question are suitable for self completion by patients removing the need for a healthcare professional to administer the tool. This would allow the use of the tool as a pre-screening mechanism to ensure that patients most at risk of poor health literacy are easily identified.

Healthcare professionals can use the results from a screening tool such as this to ensure that interventions to improve patients understanding of their healthcare are targeted at those patients most in need.

This has significant implications for the care and treatment of patients with cancer. With up to 40% of patients attending out patient appointments having difficulty in understanding health related materials, a sizeable proportion cannot possibly be expected to fully participate in decisions about their own healthcare. These patients potentially have difficulty in interpreting instructions on medication labels, appointment forms, instructions for preparing for scans, guidance for accessing specialist health care in an emergency or any of a number of information sources available to them. All of the foregoing can potentially have important consequences on the treatment outcomes for these patients.
Despite the efforts of a number of different agencies to provide comprehensive patient centred information on cancer and its treatment, this study along with other research has demonstrated that current patient literature in the form of patient information leaflets, labels or instructions, is beyond the scope of understanding of the majority of the patients these are designed for (71). This has major implications for the Cancer Networks who are tasked by the report of the National Chemotherapy Advisory Group as well as the National Chemotherapy Peer Review measures to provide comprehensive high quality patient information at every stage of the cancer journey (28, 72).

5.6 Future research

Further work is required to improve the internal consistency of the cancer tool. Using an iterative process developing and refining the questions and further field testing with more patient cohorts the difference in the performance of the individual questions could be decreased.

Having established the high prevalence of poor health literacy in patients with cancer, further questions are raised:

What are the needs of patients with cancer identified with risk of low levels of health literacy?

Does risk of low level of health literacy predict for poor outcomes from cancer treatment?

There is a potential for the cancer tool under development to be used as a mass screening device to identify a cohort of patients at risk of poor health literacy who could be followed within a longitudinal study to ascertain whether their level of health literacy predicts long term disease outcomes.
Chapter 6: Conclusions

This thesis has confirmed that approximately 40% patients with a diagnosis of cancer attending outpatient clinics are at risk of having poor health literacy. The fact that a significant proportion of cancer patients are at risk of poor health literacy is a public health issue and steps should be taken to improve health professionals understanding of the issues involved in health literacy. Patients should be supported at all stages of the cancer journey by information in a form that matches their own level of understanding.

This thesis has demonstrated that it is possible to design a Health Literacy Screening tool specifically for patients with a diagnosis of cancer that will identify patients at risk of poor health literacy. Additionally this thesis has demonstrated that the existing health literacy screening tool the NVS is suitable for use as a self-completion tool.
References


3. Osborne H. Health Literacy from A to Z. Sudbury, Massachusetts: Jones and Bartlett; 2005


43. Schapira M, Davids S, McAuliffe T, Nattinger A. Agreement between scales in the measurement of breast cancer risk perceptions. Risk Analysis 2004; 24: 665-673

44. Wu T, Bancroft J. Filipino American women's perceptions and experiences with breast cancer screening Oncology Nursing Forum 2006; 33: 71


51. Hahn E, Cella D, Dobrez D. The impact of literacy on health-related quality of life measurement and outcomes in cancer outpatients. Quality of Life Research 2007; 16: 495-507


53. Waldrop-Valverde D, Jones D, Jayaweera D, Gonzalez P, Romero J, Ownby R. Gender Differences in medication management capacity in HIV infection; the role of health literacy and numeracy. AIDS Behav. 2009; 13: 46-52


Appendices

Appendix 1: Summary of search strategy to identify publications examining health literacy and cancer outcomes

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<thead>
<tr>
<th>Search term</th>
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<th>Database: IPA</th>
<th>Database: Medline</th>
<th>Database: PsychInfo</th>
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<td>11151</td>
<td>6993</td>
<td>489081</td>
<td>10921</td>
</tr>
<tr>
<td>and 2 Tool or instrument or survey</td>
<td>5209</td>
<td>3</td>
<td>7</td>
<td>18740</td>
<td>2</td>
</tr>
<tr>
<td>and 3 “health literacy”</td>
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<td>0</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>1 and 3</td>
<td>36</td>
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<td>0</td>
<td></td>
<td>5</td>
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Appendix 2: Letter to members of Greater Manchester and Cheshire Cancer Network Patient User Partnership.

I am currently undertaking a research project with the pharmacy practice unit at the University of Manchester.

The aim of the project is to develop and evaluate a screening tool to identify patients with cancer at risk of having low levels of health literacy.

Although low levels of health literacy have an adverse impact on individual's health there is no screening tool evaluated for use in the UK, moreover the tools in existence tend to be generic rather than disease specific. Some attempt has been made to assess existing tools in a UK population.

The study will involve the development and evaluation of a cancer specific health literacy screening tool. The design will be based on an existing generic American tool, the Newest Vital Sign (NVS), using examples familiar to patients receiving treatments for cancer within the UK health system. As a member of the patient involvement group of the local cancer network you are invited to comment on the format of the proposed tool.

In-patients and patients attending outpatient clinics at the Christie Hospital, the tertiary cancer treatment centre in Manchester, will be invited to participate in the study. All patients approached will be given an explanation of the study and will have an opportunity to question the researcher before being recruited to the study. Participation in the study will be entirely voluntary and will have no prejudice with regards to any treatment patients may be receiving for their disease.

Participants will be required to complete two health literacy screening tools; the NVS and the tool under development. Each tool takes approximately 3 minutes to complete.

All information collected will be treated as confidential in line with Caldicott principles.

Participants will be informed at the time of consent of how they will be able to access a summary of the study findings.

Please send any comments about the questionnaire to me at the address below.

Many Thanks for your input.

Geoff Saunders
Consultant Oncology Pharmacist
The Christie, Wilmslow Road
Manchester M20 4BX

tel: 0161 442 4164
mobile: 07970 451923
geoff@nhs.net
Appendix 3: Confirmatory Letters from NW Research Ethics Committee

NORTH WEST 10 RESEARCH ETHICS COMMITTEE – GREATER MANCHESTER NORTH
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ
Tel: 0161 625 7817
Email: cynthia.carter@northwest.nhs.uk

Dr Darren Ashcroft
Clinical Reader in Medicines Usage and Safety & Director,
Centre for Innovation in Practice
University of Manchester
Stopford Building
M13 9PT

07 June 2010

Dear Dr Ashcroft

Study Title: Development of a UK based Health Literacy tool specific to patients with cancer

REC reference number: 10/H1011/30

Protocol number:

The Research Ethics Committee reviewed the above application at the meeting held on 24 May 2010. Thank you for attending to discuss the study.

Ethical opinion

The Chair welcomed you and Mr Geoff Saunders to the meeting. You were asked by the Committee to clarify the following issues.

You explained that the intention is to use outpatients only in the study but that if sufficient numbers could not be recruited, they would look to inpatients. This was accepted by the Committee but it was requested that the PIS should reflect this to be consistent with the details in the IRAS form.
You confirmed that the screening tool had been tested with a patient group and that they took an average of three minutes to complete each one. Some Committee members had completed the ice cream tool in less than five minutes and it was accepted that the time would not be onerous.

Formal consent is not required as completion and return of the tools would be implied consent. You agreed to remove the Consent form as it would not, therefore, be needed.

It was clarified that Mr Saunders is the student in the study.

The researchers agreed to submit the PIS on NHS Trust headed paper.

You were thanked for attending and left the room.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.
Other conditions specified by the REC

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

1. Submit a revised Participant Information sheet (PIS) on NHS Trust headed paper and include inpatients as well as outpatients to be consistent with the information in the IRAS form

2. Remove the Consent form from the study as completed screening tools are to be returned directly to the researchers

Please ensure that you submit revised documentation with version numbers and dates to the REC co-ordinator for acknowledgement.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tbody>
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<td>REC application</td>
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<td>05 May 2010</td>
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<tr>
<td>Protocol</td>
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<td>Investigator CV</td>
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<td>Participant Information Sheet</td>
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</tr>
<tr>
<td>Participant Consent Form</td>
<td>1</td>
<td>17 February 2010</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
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<td>27 April 2010</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>1</td>
<td>01 May 2010</td>
</tr>
<tr>
<td>CV Greg Saunders</td>
<td></td>
<td>01 May 2010</td>
</tr>
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Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk

10/H1011/30 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

Dr Peter Stanley Klimiuk

Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

“After ethical review – guidance for researchers” SL-AR2
Copy to: Geoff Saunders, Consultant Oncology Pharmacist, Christie Hospital
Mohammed Zubair, The University of Manchester
Lifen Wang, R&D office for The Christie NHS Foundation Trust
## Attendance at Committee meeting on 24 May 2010

### Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
</tr>
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<tbody>
<tr>
<td>Mr John Addison</td>
<td>Manager</td>
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<tr>
<td>Mr David Asher</td>
<td>Lay Member</td>
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<tr>
<td>Mr R Trevor Benn</td>
<td>Lay Member</td>
<td>Yes</td>
</tr>
<tr>
<td>Mrs Yvonne Clowes</td>
<td>Clinical Research Manager (Infectious Diseases)</td>
<td>No</td>
</tr>
<tr>
<td>Mr Ken Cook</td>
<td>Clinical Services Manager</td>
<td>Yes</td>
</tr>
<tr>
<td>Mrs Debbie Hamburger</td>
<td>Social Worker (Lay Member)</td>
<td>Yes</td>
</tr>
<tr>
<td>Miss Annie Herbert</td>
<td>Medical Statistician</td>
<td>Yes</td>
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<tr>
<td>Miss Cheryl Hunter</td>
<td>PhD Student</td>
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<tr>
<td>Dr Peter Stanley Klimiuk</td>
<td>Consultant Rheumatologist</td>
<td>Yes</td>
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<tr>
<td>Dr Jillian McCarthy</td>
<td>Senior Lecturer in Health &amp; Social Care</td>
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<tr>
<td>Mr Jack Ramsay</td>
<td>Lay Member</td>
<td>No</td>
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<tr>
<td>Ms Clementinah Rooke</td>
<td>Postgraduate Researcher &amp; Bank Nurse</td>
<td>No</td>
</tr>
<tr>
<td>Dr Narveshwar Sinha</td>
<td>Staff Grade Ear Nose &amp; Throat Surgeon</td>
<td>No</td>
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<tr>
<td>Dr Mahesh Yadav</td>
<td>Consultant Paediatrician &amp; Neonatal Lead</td>
<td>Yes</td>
</tr>
<tr>
<td>Mr Mohammed Zubair</td>
<td>University Research Practice Co-ordinator</td>
<td>No</td>
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### Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Cynthia Carter</td>
<td>Research Ethics Committee Co-ordinator</td>
</tr>
</tbody>
</table>
Dear Mr Saunders

Full title of study: Development of a UK based Health Literacy tool specific to patients with cancer

REC reference number: 10/H1011/30

Thank you for your email dated 9 June 2010. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 7 June 2010. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

<table>
<thead>
<tr>
<th>Document</th>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering Letter</td>
<td>Email</td>
<td>09 June 2010</td>
</tr>
</tbody>
</table>
You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

10/H1011/30 Please quote this number on all correspondence

Yours sincerely

Ms Cynthia Carter
Committee Co-ordinator

Copy to: Dr Darren Ashcroft darren.ashcroft@manchester.ac.uk

Mohammed Zubair, The University of Manchester

Lifen Wang, R&D office for The Christie NHS Foundation Trust
Appendix 4: Confirmatory Letter from Christie Research and Development Office

Dear Mr Saunders

ID: 10_SERVICE_04  Development of a UK based Health Literacy tool

Re: Research & Development Approval

Thank you for providing the Research & Development (R&D) office with your clinical trial information. The above study was considered by the R&D Clinical Trials Resource Group (CTR), where based on the information provided the impact of the study on the Trust's resources was reviewed. The review was carried out in line with the Research Governance Framework. I am now happy to authorise Trust R&D approval on the understanding that you abide by the Investigator Agreement. Following approval by the CTRG and verification of relevant Regulatory approval from ethics, the MHRA and ARSAC (where applicable), the following documents as listed on the ethics approval letter have been approved by R&D:

- Protocol version 1 dated August 2009
- Patient information sheet version 1.1 dated 09 June 2010
- Consent form version 1 dated 17 February 2010
- Health Literacy Assessment tool questionnaire  version 1 dated 01 May 2010

Please ensure that anyone involved in this study are listed on the IRAS form and on the study delegation log and attend GCP training at least every 2 years.

Please notify the R&D office immediately of any amendments to the protocol including the number of patients to be recruited from The Christie. Please note that all amendment documentation as approved by ethics must be submitted to the R&D department.

You must also send Annual Progress, Safety and End of Study Reports to the R&D office as soon as they are available and notify the R&D office of any changes to the study status.
Please refer to the relevant Christie SOP (R&D022) which can be found on the Trust intranet (http://christienet/departments/Research_and_development) or by emailing lifen.wang@christie.nhs.uk.

Yours sincerely

[Signature]

Angela Ball
Appendix 5: Personal Communication from Dr. B Weiss

e-mail from bdweiss@u.arizona.edu

Geoff
If a patient can’t answer a particular question, we recommend just saying something like “that’s OK; let’s go on to the next question” and continuing on. The question that was not answered is scored as incorrect. It does not invalidate the whole set of questions.
Also, you should know that I’ve been working with a group in London to create and validate a UK version of the NVS. Via this message I’ll link you with Dr Gillian Rowlands, who is leading the project there. Our UK-NVS is just about ready for use, and you might find it useful.
- Barry

From: Saunders Geoffrey (THE CHRISTIE NHS FOUNDATION TRUST) [mailto:geoff@nhs.net]
Sent: Wednesday, March 02, 2011 7:37 AM
To: bdweiss@u.arizona.edu
Subject: Use of the NVS screening tool
Dear Dr Weiss,
I am currently undertaking a study of health literacy in cancer patients and wonder whether you can answer a question for me as I have not been able to obtain a manual for the use of the NVS tool. Some patients are unable to provide an answer to one or more of the questions, in this case would you score the answer to the individual question as incorrect or would this invalidate the whole set of questions?
I look forward to your reply
Regards
Geoff
Geoff Saunders
Consultant Oncology Pharmacist
Christie Hospital
Manchester M20 4BX
01614463000
07817087377
Appendix 6: Participant information sheet

Development of a UK based Health Literacy tool specific to patients with cancer

Participant Information Sheet

Introduction

You are being asked to participate in a research study conducted in association with the University of Manchester. In order to help you decide whether or not to take part, this information sheet provides you with further details about the study. The information sheet explains the purpose of the study and what it will involve.

What is the purpose of this study?

The aim of this study is to compare a health literacy screening tool designed for patients with a cancer diagnosis with a standard screening tool already being used by patients in the United States of America. The study is being conducted by researchers from the Pharmacy department at the Christie Hospital in association with the University of Manchester and will contribute to the award of a postgraduate degree.

Why have I been chosen?

We would like to involve a group of participants that is representative of patients with cancer in general. For this reason we are approaching patients attending out-patient clinics at the Christie Hospital during a three week period. In addition we may approach some in patients on the wards at The Christie

What will I be asked to do if I decide to take part?

On the following pages are some pieces of information followed by some questions. We should like you to read the information and then answer the questions, don't worry if you cannot answer them all, this is not a test about you. If you have any comments to make about any aspect of this research, please write it in the space provided. Once you have completed the questionnaire please put the form in the box provided.

Do I have to take part?

Participation in this research study is entirely voluntary, if you make the decision not to complete the form it will have no effect on your relationship with the staff caring for you or the treatment you are offered.

What are the benefits of taking part?

We expect that the findings from this study will help us design a screening tool that will enable us to identify patients with cancer who are at risk of not fully understanding the
information that they are given about their disease or its treatment and may not derive all the benefits of their treatment that we expect.

Will my taking part in the study be kept confidential?

Yes. The information that you provide will be used to compare the two health literacy screening tools. No personal identifying information will be used and no individuals will be identified.

What will happen to the results of the research study?

The results of the study will be published in reports to be held at the University of Manchester. It is our expectation that the results will also be published in reports to be released into the public domain. It is our intention to produce a summary of the work for presentation to the Greater Manchester and Cheshire Cancer Network.

What if I need to make a complaint about the study?

If there are any issues about this study that you would prefer not to discuss with members of the research team, please contact the Research Practice and Governance Co-ordinator by either writing to: The Research Practice and Governance Co-ordinator, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PT, by e-mailing: research-governance@manchester.ac.uk or by telephoning 01612757583 or 01612758093.

Who is organising and funding the research?

The University of Manchester is providing sponsorship and funding for this study.

Who has reviewed the study?

This study has been reviewed by the NHS Research Ethics Committee.

Where can I obtain further information if I need it?

If you require further information then you are welcome to contact Geoff Saunders 01614463000, e-mail geoff@nhs.net

We would like to thank you for considering participating in this study and for taking the time to read this information sheet.
Health Literacy Research Project.

Health literacy has been defined as: 'The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions'.

A number of tools to identify different levels of health literacy have been developed but none have been designed for patients with cancer or for patients based in the United Kingdom. This research study aims to compare a screening tool designed for patients with a cancer diagnosis with a standard screening tool already being used by patients in the United States of America.

On the following pages are some pieces of information followed by some questions. We should like you to read the information and then answer the questions, don't worry if you cannot answer them all, this is not a test about you. If you have any comments to make about any aspect of this research, please write it in the space provided. Once you have completed the questionnaire please put the form in the box provided.

The information that you provide will be used to compare the two health literacy screening tools. No personal information will be used and no individuals will be identified. Once the report is complete you will be able to see a summary on the cancer network website.

Participation in this research project is entirely voluntary, if you make the decision not to complete the form it will have no effect on your relationship with the staff caring for you or the treatment you are offered.

For any details about this project please contact:

Geoff Saunders
Consultant Oncology Pharmacist
Pharmacy Department
Christie Hospital
Wilmslow Road
Manchester M20 4BX

01614463000

You may wish to keep this sheet to refer to in the future.
Some cancer treatments, including certain anti-cancer drugs, are known to cause you to feel sick and to be sick. If you need these drugs, anti-sickness drugs will be given before the cancer treatment has started. It may also be continued for a few days after the treatment has finished.

When someone feels or is sick due to the cancer itself, it can take a while to control this symptom. You will be given anti-sickness drugs and, if possible, the cause of the sickness will be treated.

Whatever the cause of the sickness, the anti-sickness treatment should be taken regularly so that the sickness does not have a chance to come back. If you have any symptoms which are new, become worse, or last more than a few days, let your doctor or nurse know.

Instruction label for Dexamethasone Tablets

<table>
<thead>
<tr>
<th>Dexamethasone 2mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take TWO tablets</td>
</tr>
<tr>
<td>TWICE daily</td>
</tr>
<tr>
<td>For TWO days</td>
</tr>
<tr>
<td>TAKE WITH OR AFTER FOOD</td>
</tr>
<tr>
<td>DO NOT TAKE AFTER 6PM</td>
</tr>
</tbody>
</table>

1. When should you start taking anti-sickness treatment?
   Answer ..........................

2. If you become constipated, what should you do?
   Answer ..........................

3. Should you take the anti-sickness tablets if you haven’t been sick at all?
   Answer ..........................

4. Should you only take the anti-sickness drugs on the same day that you have anti-cancer treatment?
   Answer ..........................

5. How many dexamethasone tablets should you take during one day?
   Answer ..........................

6. What is the latest time that you would take dexamethasone?
The Newest Vital Sign

This information is on the back of a container of a pint of ice cream.

<table>
<thead>
<tr>
<th>Nutrition Facts</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving Size</td>
<td>½ cup</td>
</tr>
<tr>
<td>Servings per container</td>
<td>4</td>
</tr>
<tr>
<td>Amount per serving</td>
<td></td>
</tr>
<tr>
<td>Calories</td>
<td>250</td>
</tr>
<tr>
<td>Fat Cal</td>
<td>120</td>
</tr>
<tr>
<td>%DV</td>
<td></td>
</tr>
<tr>
<td>Total Fat</td>
<td>13g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>28mg</td>
</tr>
<tr>
<td>Sodium</td>
<td>55mg</td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>30g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>2g</td>
</tr>
<tr>
<td>Sugars</td>
<td>23g</td>
</tr>
<tr>
<td>Protein</td>
<td>4g</td>
</tr>
</tbody>
</table>

*Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.
1. If you eat the entire container, how many calories will you eat?
   Answer ................................

2. If you are allowed to eat 60g of carbohydrates as a snack, how much ice cream could you have?
   Answer ................................

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
   Answer ................................

4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
   Answer ................................

Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves and bee stings.

5. Is it safe for you to eat this ice cream?
   Answer ................................

6. Why not?
   Answer ................................
Please answer the following questions about yourself:

Age .......... years  Sex  Male/Female

Clinic attended ..............................................

First part of postcode ..................

Age on completing full time education ........ years

Thank you for completing these questions. If you would like to write any comments please use the space below:

Please put completed forms in the box provided.

For any details about this project please contact:

Geoff Saunders
Consultant Oncology Pharmacist
Pharmacy Department
Christie Hospital
Wilmslow Road
Manchester M20 4BX

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