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The development of a side effect risk assessment tool (ASyMS[©]-SERAT) for use in patients with breast cancer undergoing adjuvant chemotherapy



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Abstract Patients with breast cancer receiving chemotherapy are at risk of developing toxicities which can be severe or life threatening. The aim of this study was to develop and test a side effect risk modeling tool (ASyMS[©]-SERAT) for use in patients with breast cancer undergoing adjuvant chemotherapy. The study was conducted in two phases. Phase 1 entailed the development of the ASyMS[©]-SERAT tool using a secondary data set and in collaboration with an expert group of clinicians and an advisory group of patients. In phase 2, the predictive accuracy of the tool was measured using a prospective data set of 24 patients with breast cancer undergoing adjuvant chemotherapy. A high level of accuracy was reported for four of the six symptoms measured (>70%) supporting the future development and application of ASyMS[©]-SERAT in the prediction of chemotherapy-related toxicity. For patients, such information can be used to target information on side effects that they are likely to experience thereby facilitating the provision of tailored information based on their individual needs. For clinicians, knowing the likelihood of potential side effects can assist them in identifying patients who are at greater risk of developing certain toxicities, facilitating more targeted and cost-effective interventions.

Key words breast cancer; chemotherapy; predictive risk modelling; symptoms

Introduction

In the United Kingdom, approximately 44,700 individuals are diagnosed with breast cancer annually (NHS Scotland, 2007; Northern Ireland Cancer Registry, 2007; Office for National Statistics, 2007; Welsh Cancer Intelligence and Surveillance Unit, 2007) and this figure is projected to significantly increase over the next decade (Scottish Executive, 2001). Adjuvant chemotherapy improves disease free and overall survival in early breast cancer by up to 10% in those under 50 years of age, with larger gains reported for those at greater risk (Early Breast Cancer Trialist's Collaborative Group (EBCTCG), 1998). However, adjuvant chemotherapy is associated with significant side effects some of which can be serious and even life threatening (Kuderer, et al., 2006). This not only impacts on quality of life but also on the maintenance of dose intensity treatment, which in itself can impact on disease free and overall survival (Bonadonna, et al., 1995).

The effective monitoring and management of symptoms in this patient group is therefore vital. However, it is now recognised that symptoms in patients with cancer are often poorly assessed and managed (National Institute for Health, 2002). Factors such as inadequate patient provider communication (Cleland, et al., 1986) and poor symptom assessment (Cleland, et al., 1994) have been cited as being contributory factors. The recent changes to the organisation of cancer services may also contribute to the suboptimal management of symptoms. With the focus of care now being in the home and out-patient setting, patients are left to manage the majority of side effects on their own without direct supervision from health care professionals; this may leave them feeling anxious and having lack of control over their illness and treatment (McCaughan and Thompson, 2000). Furthermore, patients with cancer often find the unpredictability and diversity of potential side effects difficult to deal with (Tierney, et al., 1992; Cohn, 1982).

Patient education is fundamental to effective symptom control. It is widely acknowledged that patients with cancer do want information on their disease (Iconomou, et al., 2001) and how to manage the symptoms and side effects associated with their disease and treatment (Skalla, et al., 2004; McCaughan and Thompson, 2000). However, the literature suggests that a large number of people with cancer often report dissatisfaction with the information they receive and poor understanding of what they have been told (Haggerty, et al., 2004; McPherson, et al., 2001). Furthermore, they often report feeling overloaded with the wealth of information provided and as a result experience problems with retaining and retrieving it (Skalla, et al., 2004). Poorly informed patients are reported to be less likely to comply with treatment or advice about their treatment, are more likely to experience a greater level of anxiety and reductions in their quality of life (Groenvold, et al., 2007; Jefford and Tattersall, 2002).

As a consequence, there have been calls for the provision of information on cancer therapies, which is tailored to patient's individual characteristics and needs (Skalla, et al., 2004; Dikken and Sitzia, 1998). Patients want more specific information on potential toxicities of treatment, such as what side effects they are likely to experience, their severity/duration and how to manage them (Skalla, et al., 2004). The provision of such information is likely to make them feel more control of their disease by knowing what to expect and how to deal with problems when they occur. Furthermore, it may prevent unnecessary worry and anxiety over side effects that are less likely to arise (Skalla, et al., 2004).

Risk modelling

Within health care, there is increasing development and use of predictive models to identify patients who are most likely to experience specific disease and/or treatment-related events. Relative to cancer care, such models have tended to focus on predictors of survival and life threatening toxicities such as febrile neutropenia (Chow, et al., 2006; Donohue, 2006; Sanchez, et al., 2006; Lyman, et al., 2005; Vigano, et al., 2000). In relation to the prediction of symptoms, there has been limited work carried out to date (Poleshuck, et al., 2006; Talcott, et al., 2003; Armer, et al., 2003), particularly in relation to the prediction of the side effects of chemotherapy in patients with cancer (Dranitsaris, et al., 2008).

Risk modelling provides a powerful mechanism for identifying patterns in data, which can be used to predict the prevalence of similar events occurring in the future. This information can relate to the likelihood of specific events occurring in isolation or as part of a cluster of other symptoms. The potential for using mathematical risk models to identify and predict disease-related events is reinforced by their prevalence in the literature. Various modelling techniques have been used to assist in the diagnosis of dementia (Cowie, et al., 2006), thrombosis (Werner and Fogarty, 2001) and also to predict survival in patients with breast cancer based (Fleisher, et al., 2008).

The application of risk modelling techniques to the prediction of chemotherapy-related toxicity may therefore have the potential to greatly improve the experiences of patients with cancer receiving chemotherapy by providing information on the side effects that they are likely to experience and thereby facilitating the provision of tailored information based on their individual needs. Furthermore, patients would have information not only on what side effects they are likely to experience but also when they are likely to experience them, which may also assist patients in planning their day-to-day activities. For clinicians, knowing the likelihood of potential side effects occurring can

assist them in identifying those patients who are at greater risk of developing certain toxicities and therefore facilitate more targeted and cost-effective interventions to those in greatest need and who are most likely to benefit. It therefore follows that knowing who is at risk will also allow clinicians to provide more accurate information on planned and ongoing treatment as well as more targeted interventions to assist the patients during and after treatment (Boehmke and Dickerson, 2006).

This paper presents the results of a predictive risk model for patients with breast cancer receiving adjuvant chemotherapy. This takes forward preliminary work (Cowie, *et al.*, 2008) and builds on the remote monitoring of patients using a mobile phone-based Advanced Symptom Management System (ASyMS[©]) (Maguire, *et al.*, 2008; McCann, *et al.*, 2008; Kearney, *et al.*, 2006; Maguire, *et al.*, 2005).

Methodology

Aims

The aim of this study (conducted in two phases) was to develop and pilot test a Side Effect Risk Assessment Model (ASyMS[©]-SERAT) to predict symptoms in patients with breast cancer receiving adjuvant chemotherapy. The secondary aims were to identify additional parameters (patient/disease/treatment characteristics) to incorporate into ASyMS[©]-SERAT.

Phase 1

Phase 1 entailed the development of ASyMS[©]-SERAT using a secondary data set. The primary study which generated the data set was a randomised-controlled trial of a ASyMS[©] in patients with breast, lung and colorectal cancer receiving chemotherapy (Maguire, *et al.*, 2008; McCann, *et al.*, 2008; Kearney, *et al.*, 2006; Maguire, *et al.*, 2005). As the tool was being developed for use in patients with breast cancer receiving adjuvant chemotherapy, only symptom data from patients who had breast cancer who had participated in the primary study was used ($n = 33$).

This development of the tool was also informed via a comprehensive review of the literature and in collaboration with a group of clinicians ($n = 5$) with extensive experience in caring for people undergoing chemotherapy treatment and an advisory group of patients. Six symptoms were selected for inclusion in the tool: nausea, vomiting, mucositis, hand foot syndrome, diarrhoea and fatigue. This set of symptoms was selected as they had been measured in the primary study.

Phase 2

This pilot study used a prospective, observational study design and entailed the prospective testing of the accuracy of ASyMS[©]-SERAT in patients with breast cancer undergoing adjuvant chemotherapy. A secondary objective of this phase of the study was to collect and identify additional data to incorporate into the tool.

Study sample

The study aimed to recruit 40 patients from four clinical sites in Scotland. Eligibility criteria included having a diagnosis of breast cancer, commencing a course of adjuvant chemotherapy, receiving one of four chemotherapy regimes (FEC, FEC-D, Epi-CMF, Taxotere), aged 18 years or over, able to read and write English and deemed by members of the clinical team to be physically and psychologically fit to participate in the

study. Ethical approval was gained from the study sites, and all patients provided written informed consent before their participation in the study. The study was conducted over a 12-month period from June 2007 to May, 2008.

Study measures

Patients were asked to complete a daily paper-based questionnaire which measured the six core symptoms being assessed. The questionnaire used was an integration of the Common Toxicity Criteria Adverse Events (CTCAE) grading system (The National Cancer Institute, 2003) and the Chemotherapy Symptom Assessment Scale (C-SAS) (Brown, et al., 2001) and measured the incidence, severity and distress associated with each symptom. This questionnaire was short, simple and relevant with a standardised scoring method and had undergone reliability testing in a previous study (Cronbach's $\alpha = 0.82$) (Kearney, et al., 2008). Participants were also asked to complete the Symptom Assessment Scale at baseline and precycles 2, 3, 4 and 5 which recorded any additional symptoms that they had experienced since their last chemotherapy treatment. Patient characteristics and disease/treatment data were also collected by designated health professionals at each of these time points. The data collected in this phase of the study was used to test the accuracy of ASyMS[©]-SERAT and to identify any additional predictive patient/disease/treatment-related parameters which may be incorporated into the tool for future development.

Data Analysis

Phase I: the modelling process

The patients in the primary study underwent treatment over four cycles, each of 21 days where treatment was administered at the beginning of each cycle. The risk modelling process investigated three aspects of the occurrence of symptoms:

The pattern of symptoms across all cycles: they are symptoms more likely in some cycles than others?

The pattern of symptoms within a cycle: as the number of days elapsed since treatment grows, how does the risk of suffering from a symptom change?

Cooccurrence of symptoms: Does the presence of any one symptom alter the risk of suffering from any other and does the occurrence of a symptom on 1 day increase the risk of that symptom appearing on following days?

The probability of any patient suffering from a given symptom was calculated for each symptom, for each day across all cycles by calculating the proportion of all patients in the study who experienced each symptom on each day. These probabilities represent a single time series describing the signature of a symptom across a full treatment. The modelling process fitted a model to this data based on the following factors:

- The number of the current cycle (1,2,3,4)
- The days elapsed since the start of the cycle
- The probability of the patient having experienced the given symptom on the previous day.

This final value is calculated by the model for predictions of more than 1 day into the future but uses the patient's actual experience for predicting 1 day ahead. In such cases, the probability is set to one if the patient experienced the symptom and zero if they did not. It was found that the probability of a patient continuing to experience a symptom on subsequent days diminished until either a new cycle started or they suffered a relapse. For this reason, the part of the model responsible for taking into account the patient's recent symptoms is a decaying function that reduces the probability of the symptom occurring for a further day towards zero as the days pass.

The probability data for each symptom was plotted and simple classes of functions were chosen for each. Some symptoms followed a rectified sine wave pattern, whereas others followed the decaying probability model described above. Once the class of model (sine wave or decaying) had been selected by eye, an iterative least squares fitting (Björck, 1996) method was used to tune the parameters of the model to fit the data. The pattern of incidence of each symptom is summarised in Table 1, below a

Table 1 A description of how the risk of symptoms changes throughout treatment

Symptom	Description
Nausea	Peaking on the day of treatment and decreasing rapidly until the next treatment. Any reoccurrence of the symptom follows the same pattern of decay.
Vomiting	Only likely on the first 2 days after treatment, then very unlikely for the rest of the cycle. Reoccurrence of the symptom does not predict further occurrences in the same cycle.
Mucositis	Follows an inverted U shape each cycle (the positive half of a sine wave is used in the model), rising from a low on the day after treatment to a peak around midcycle before falling again. The fourth cycle reaches a higher peak (the symptom is more likely to occur) than the other three.
Fatigue	Shows a peak immediately after treatment. The probability of the symptom occurring then falls gradually at first, speeding towards almost zero by day 10. Any reoccurrence of the symptom follows the same pattern of decay.
Hand Foot	Follows an inverted U shape across each cycle with the each subsequent cycle showing a higher peak (the symptom is more likely to occur) than the previous one.
Diarrhoea	Follows an inverted U shape across each cycle with all cycles carrying equal chance of showing this symptom.

An example of the modelling process for nausea is detailed below to illustrate the process that was followed for each symptom.

Modelling process for nausea

The function that produces the probability of a patient experiencing nausea on a given day, d , is calculated as:

$$P(d) = 0.82 * P(d-1) + ch * 0.6$$

$$\text{where } ch = \begin{cases} 1 & \text{if the patient has received treatment on day } d \\ 0 & \text{otherwise} \end{cases}$$

and $P(d)$ is the probability of a symptom being displayed on day d .

Equation 1 reflects the facts that the probability of a patient feeling nauseous is high directly after treatment but reduces towards zero over a few days and the fact that any further sudden attack of nausea will follow the same pattern of decay. Figure 1 below shows the original data and the model plotted together. The four cycles are marked by a vertical line at days 0, 15, 29 and 43.

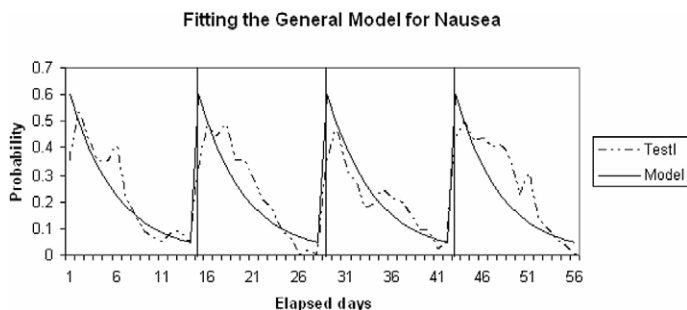


Figure 1 The model for nausea (solid line) plotted with the actual data from the primary study (dotted line).

The model is used by ASyMS[®]-SERAT for predicting the probability of a patient suffering from a symptom on any given day. A simplified model is used rather than the raw data (the dotted line) due to the parsimony assumption that the simplest explanation for a phenomenon is the best. It recognises the fact that the data we have is only a sample and not a complete representation of the underlying dynamics of symptom risk. Note also that the part of the model that takes into account whether or not the patient experienced nausea on the previous day allows the model to predict a high probability of the symptom occurring late in a cycle (where the model shown in Figure 1 is low) if a patient is experiencing the symptom more often than expected.

Figure 2 shows the predictions and the actual pattern of symptoms experienced by an example patient. The solid line shows the model's predictions and the bars show the presence or absence of nausea on the given day. The occurrence of the symptom on a given day brings the model's predictions back to the top of the curve.

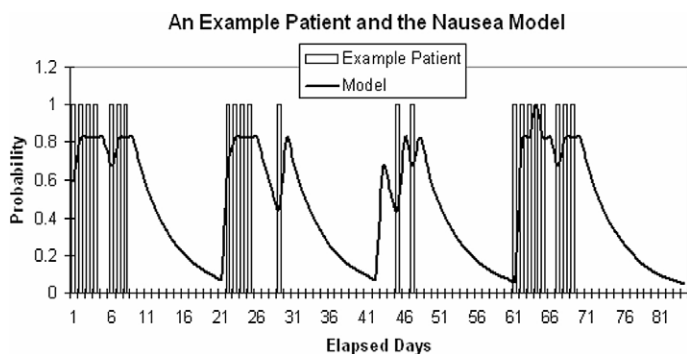


Figure 2 An example patient compared with the predicted probability of the occurrence of nausea.

Phase 2

Data from new patients was converted to probabilities in the same way as before, and the results were compared with the model from phase 1. The figures were calculated as follows:

- For each symptom, a threshold probability was chosen over which the model would predict that a symptom would be experienced.
- For each patient, the predicted presence or absence of a symptom was compared with the actual presence or absence and counts made of the number of times the prediction was correct, the number of false negatives and the number of false positives.

Results

Phase 1

A description of the ASyMS[©]-SERAT tool which was developed in phase 1 is detailed below (Figure 3). An online version of the tool has been developed and will be incorporated into an mobile, phone-based advanced symptom management system (ASyMS[©]), which has been developed to remotely monitor the side effects of chemotherapy in patients with cancer receiving chemotherapy (Maguire, et al., 2005; McCann, et al., 2008; Maguire, et al., 2008).






















Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	17th March	18th March	19th March	20th March	21st March	22nd March
						
23rd March	24th March	25th March	26th March	27th March	28th March	29th March
						
30th March	31st March	1st April	2nd April	3rd April	4th April	5th April
						
6th April						
						

Figure 3 The diary view of 3 weeks worth of predictions for fatigue. Patients may click on a day to see a more accurate risk assessment or a break down of the other possible symptoms.

The tool uses the symptom models described above to predict the likely side effects a patient will experience over the course of their treatment. The patient can receive predictions relating to possible symptoms they are likely to experience across the entire course of the treatment or daily predictions that are updated as they enter data describing their own symptoms. This aspect of the system, where patients enter their own symptoms, allows nurses to monitor the symptoms remotely and facilitates the delivery of relevant and useful advice to the patient based on their current symptoms.

An early version of the system presented patients with predictions of the risk of symptoms occurring as line charts where the vertical axis showed probability and the horizontal axis showed time. Patient groups found the graphs difficult to interpret and based on their perceptions a new visualisation method was developed based on the metaphor of a diary. Patients were shown a diary with the day names and dates shown as normal and with the days remaining until the end of the cycle shown together on the screen. Each day contained an icon depicting one of three states: high, medium or low risk which was represented by a sad face, a face with a neutral expression or a smiling face, respectively.

Patients wishing to plan ahead could see at a glance which days were more likely to be suitable by looking for smiling faces in the days of the diary. Patients found this view easier to understand as it was presented in a form that was recognisable to them (i.e., a diary). Figure 3 shows an example diary page.

Charts showing patients' actual symptom profiles against the expected pattern are available for nurses to allow them to monitor the symptoms. This also allows an alarm to be triggered when a patient deviates too far from the expected pattern of symptoms.

Patients who want more details are able to access more detailed information on their predicted symptoms, as Figure 4 shows. In Figure 4, we see the breakdown of likely symptoms for a given day, 77 days into treatment. The most likely symptom for this patient is mucositis (labelled sore mouth and throat) with vomiting being very unlikely. Users may click on any of the symptoms to see self-care advice on how to manage this symptom. They will also be able to see how many more days they are likely to experience the chosen symptom.

Too great a deviation from the expected pattern of symptoms will alert the patient to seek medical attention, whereas an adherence to the pattern of expected symptoms will reassure the patient (to a degree) that what they are experiencing is normal.

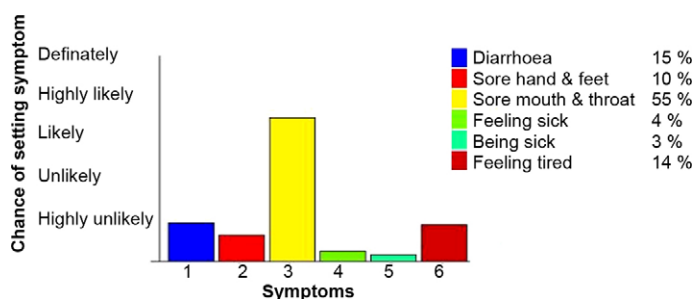


Figure 4 Screenshot of ASyMS[®]-SERAT showing likely side effects for a given patient on a given day (77 days into treatment).

Phase 2

Study sample

Twenty-seven patients were recruited to the study. The initial target of 40 patients was not reached because of patients being recruited to competing clinical trials and

the unusually low number of patients who met the study criteria at the participating sites during the study recruitment phase. However, the final number of participants was sufficient for early pilot testing of the tool (Lancaster, et al., 2004). Demographics for the study group are detailed in Table 2.

Table 2 Demographics of study group

Characteristics	All patients (N = 27)
Mean age (years)	52.9
Sex n (%)	
Male	0 (0)
Female	27 (100)
Deprivation index score (%)	
1	1 (3.7)
2	0 (0)
3	10 (37.0)
4	7 (25.9)
5	2 (7.4)
6	7 (25.9)
Chemotherapy regime n (%)	
FEC	6 (22.2)
FEC-D	8 (29.6)
FEC 100	4 (14.8)
Epi	1 (3.7)
Epi-CMF	5 (18.5)
EPI-Acc	3 (11.1)
Stage of disease n (%)	
1	1 (3.7)
2	13 (48.1)
3	13 (48.1)

Baseline characteristics for all participants recruited to the study.

Values are in numbers and percentages unless stated otherwise.

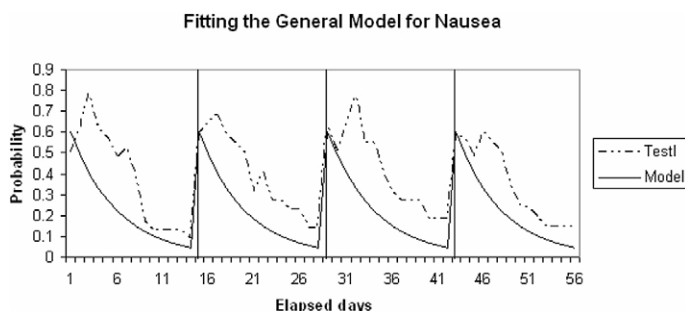
Table 3 shows the results of using each of the models from phase 1 to predict the presence or absence of symptoms for patients during phase 2. Only 24 of the 27 patients recruited to the study were used to predict the accuracy of the ASyMS[®]-SERAT tool as three patients were receiving accelerated Epirubicin, and because of the differences in cycle length (2 weeks) and toxicity profile associated with this regime, they were excluded from the analysis.

Probabilities in the model were converted to a 'Yes' or 'No' value using a simple cut-off point. If the model said 'Yes' when the symptom was not present, the false positive count was incremented. If the model said 'No' when the symptom was present, the false negative count was incremented. Otherwise, the correct count was incremented. By this method, most of the symptoms were predicted reasonably well. Diarrhoea was not well predicted because of far fewer patients experiencing this symptom on the second phase of the study. Note that the vomiting model appears to be very accurate but only because it very rarely predicts vomiting and vomiting very rarely happens.

Table 3 The percentage of predictions made by the models for each symptom that was correct across all patients and all days

	% Correct	% False negative	% False positive
Diarhoea	59.97	3.35	36.68
Hand and foot	71.73	10.12	18.15
Mucositis	64.66	22.25	13.10
Nausea	82.37	2.16	15.48
Vomiting	84.90	2.98	12.13
Fatigue	71.50	0.15	28.35

Figure 5 shows the probability of the daily incidence of nausea from the phase 2 study plotted against the model from phase 1. Although patients in the second phase tended to show higher levels of nausea than those in the first, the pattern of incidence is still very similar.

**Figure 5** The original model plotted against the proportion of patients in the test (phase 2) data that experienced nausea on each day of treatment.

Discussion

This study is one of the first of its kind to develop and test a tool to predict the symptoms in patients with breast cancer undergoing adjuvant chemotherapy. The tool has been developed with extensive input from both patients and health professionals in recognition of the importance of the perceptions of key users in their content and design of such systems to promote in their successful implementation within clinical practice (Langowski, 2005; May, et al., 2003; Ralston, et al., 2004). The corresponding literature review has also ensured that the model is evidence-based integrating individual clinical expertise, with best available evidence and incorporating patients values and expectations into the process (Rycroft-Malone, et al., 2004).

The levels of accuracy of the model from the prospective data set show the potential utility of the system within clinical practice in the management of chemotherapy-related toxicity. For patients, it provides information on what symptoms that they are likely to experience and when and for health professionals such information allows them to target information accordingly and intervene where appropriate. Such predictive information facilitates current transitions within health care delivery (Department of Health, 2007; The Scottish Government, 2007), with health care professionals being able to provide an anticipatory and preventative model of care, accessing relevant services based on patient need.

The authors would like to acknowledge a number of limitations in relation to this study. First, the tool was tested in a small data set of 24 patients, and although this number of participants has been deemed as being sufficient for early pilot testing (Lancaster, et al., 2004), a larger data set would have tested the model in a bigger population and may therefore have strengthened the findings. However, despite this limitation, a relatively high level of accuracy for some of the symptoms measured has been shown for the ASyMS[®]-SERAT tool, supporting its future development and testing in a larger patient population. Second, the data collected in the primary study was collected via a mobile phone-based electronic symptom questionnaire, and although a paper copy of this questionnaire was used in phase 2 of this study to prospectively test the tool, there may be differences in the completion of the questionnaire using these two mediums (Velikova, et al., 1999). Third, the tool has only been developed for use over four cycles of chemotherapy which limits its current application, with most adjuvant breast cancer chemotherapy regimes consisting of at least 6–8 cycles. Future development of the system will address this issue and develop the system for use throughout a patient's entire chemotherapy treatment.

Key points

There is increasing development and use of predictive risk models in healthcare

- Relative to cancer care, current models have focused on predictors of survival and life threatening toxicities.
- Predictive risk models can be developed for use in the management of chemotherapy-related toxicity.
- Future research should focus on the development of such systems and their incorporation into clinical practice.

Conclusion

Although research on the project is still in its infancy and the ASyMS[®]-SERAT tool is very much a prototype system, initial results from the risk modelling analysis are very promising. From initial testing it would seem that through the use of ASyMS[®]-SERAT, accurate, personalised predictions of possible side effects can be made, providing patients with a more informed view of their treatment and clinicians with the information required for preventative measures or management of side effects to be applied where possible.

This complete symptom prediction and management tool will hopefully allow patients to feel more in control of their symptoms, knowing in advance what to expect, and how to manage the symptoms accordingly. A larger, more comprehensive evaluation of the ASyMS[®]-SERAT tool is planned and the development of the system for use in other patient populations.

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