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Objective: We undertook scoping reviews of the literature in order to identify patient outcomes sensitive to the quality of nursing services in ambulatory cancer chemotherapy settings to guide the development of an outcomes based quality measurement system.
Methods: A 2 stage scoping review to identify potential outcome areas which were subsequently assessed for their sensitivity to nursing. Data sources included the Cochrane Library, Medline, Embase, the British Nursing Index, Google and Google scholar
Results: We identified a broad range of outcomes potentially sensitive to nursing. Individual trials support many nursing interventions but we found relatively little clear evidence of effect on outcomes derived from a systematic reviews and no evidence associating characteristics of nursing services with outcomes.
Conclusion: The purpose of identifying a set of outcomes as specifically nurse-sensitive for quality measurement is to give clear responsibility and create an expectation of strong clinical leadership by nurses in terms of monitoring and acting on results. It is important to select those outcomes that nurses have most impact upon. .Patient experience, nausea and vomiting, mucositis and safe medication administration were outcome areas most likely to yield sensitive measures of nursing service quality in ambulatory cancer chemotherapy.

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Dear Professor Molassiotis

Please find our manuscript, which we ask you to consider for Publication the European Journal of Oncology Nursing

All authors contributed significantly to the conception writing and revision of the paper and meet the criteria for authorship. We have no conflicts of interest of which we are aware.

Yours Sincerely

Peter Griffiths

***Conflict of Interest Statement**

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None

***Title Page (with authors and addresses)**

Outcomes sensitive to nursing service quality in ambulatory cancer chemotherapy: systematic scoping review

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Outcomes sensitive to nursing service quality in ambulatory cancer chemotherapy: literature review

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Outcomes sensitive to nursing service quality in ambulatory cancer chemotherapy: systematic scoping review

Background

Introduction

There is a long standing and enduring interest in identifying patient outcomes that are sensitive to nursing care. There are an increasing number of measurement systems that include or focus on outcomes in order to demonstrate or monitor the quality of nursing care. The most notable and probably the largest scale examples are widely implemented in US hospitals: for example Collaborative Alliance for Nursing Outcomes (CALNOC) and the American Nurse's Association backed National Database of Nursing Quality Indicators™ (NDNQI®). These systems allow benchmarking of performance between comparable units and enable individual clinical units to monitor the quality of care delivered over time. While such systems are by no means exclusively targeted at acute inpatient settings, the vast majority of development has been undertaken in such areas (Griffiths *et al.*, 2008a), although there are several extensive reviews which identify outcomes that are potentially sensitive to nursing care in a range of settings and specialties (e.g.Doran, 2003), including cancer care (e.g.Gobel *et al.*, 2006). In this paper we describe the results of a series of scoping reviews undertaken in order to identify patient outcomes that could form the basis of a quality measurement system to include monitoring nurse-sensitive outcomes in ambulatory cancer chemotherapy.

Ambulatory chemotherapy is frequently a nurse-led care and treatment management environment, where quality of nursing care may potentially have a significant impact on patient outcomes and experience. In the UK the quality of services has been identified as variable(Mort *et al.*, 2008, National Chemotherapy Advisory Group, 2009), and it seems clear that variable quality is an issue in other countries worldwide (e.g. Malin *et al.*, 2006, Weingart *et al.*, 2007, Arora, 2009, Ekwall *et al.*, 2011, Hjörleifsdóttir *et al.*, 2010). Although the causes of variable quality do not relate exclusively to nursing practice, assessment of the quality of care provided by

nurses in this context is a high priority because of the role they take in administering therapy and providing on-going support and assessment in both the management of toxicities and the complex psychosocial challenges faced by patients undergoing cancer treatment.

There are many potential nurse-sensitive outcomes in ambulatory cancer chemotherapy which might provide a focus for assessment of quality by measuring the impact of nursing on patient outcomes. Nurse-sensitive outcomes are defined by the US Oncology Nursing Society (ONS) as *"...those outcomes arrived at, or significantly impacted, by nursing interventions."* (Given *et al.*, 2004). The ONS framework gives an indication of many possible outcomes across the broad domains of symptom experience, function and safety. Since quality indicators can never fully measure 'quality' as a whole, it is important that across a system there are a range of indicators(Mainz, 2003). The ONS definition also raises an important caveat when selecting areas to focus on, in that "*…interventions [*which result in nurse-sensitive outcomes] *must be within the scope of nursing practice and integral to the processes of nursing care; an empirical link must exist."* Our previous review of outcome metrics in nursing (Griffiths *et al.*, 2008a) identified that although claims for the sensitivity of nursing are legion, the empirical basis for such claims is often scant and the evidence-base for interventions around even widely accepted nurse-sensitive outcomes, such as pressure ulcers, can be surprisingly elusive (Jull and Griffiths, 2010).

There is no absolute criterion for establishing what constitutes a sufficient evidence base that an outcome is nurse-sensitive. Previous reviews have used overviews of intervention studies as evidence that an outcome is nurse-sensitive (e.g. , 2003, Gobel *et al.*, 2006) but have applied limited research synthesis or formal critical appraisal because of the breadth of the exercises. It is unclear from these whether the nursing interventions represent a fully evidence-based approach and are definitively established as sufficiently effective to enter routine practice. It is only when this is established that there can be certainty that a good quality nursing service, which routinely and effectively uses established effective nursing interventions, can deliver better outcomes than one of lower quality.

In part because of the difficulty in identifying appropriate patient outcomes for quality measurement, there is a significant emphasis on using care processes, as opposed to patient outcomes, as quality measures. There is much argument over the relative merits of process and outcome measures (Lilford *et al.*, 2004, Donabedian, 2005). Desires within the nursing profession for articulation of its important contribution and among the public for improved standards point toward outcomes as a significant component of any indicator system, as their importance is more clearly understood and harder to contest. Furthermore, since a process measure is established as a measure of quality because its relationship to outcome is known (Donabedian, 1966), the starting point for developing any system should be identifying the relevant outcomes.

Thus this review was undertaken to identify an evidence base for nursing sensitive outcomes in ambulatory chemotherapy as a forerunner to developing a set of indicators for use routinely as part of quality improvement efforts. The work aimed to replicate the approach taken in our previous work(Griffiths *et al.*, 2008b) but with a more detailed focus on this clinical setting. To do this we undertook a series of literature reviews in consultation with clinical experts. Because of the breadth of the topic area we used scoping review methodologies. Scoping reviews "*'aim to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available…* [suitable for] *…an area is complex or has not been reviewed comprehensively before'* P194 *(Mays et al., 2001)* . The aim of the review was to identify outcomes for which there is a strong evidence-base to establish that associated nursing interventions should form part of routine nursing practice or outcomes that are strongly associated with nursing related organisational characteristics, such as workforce capacity or characteristics. Thus we aimed to identify outcomes that would vary with the quality of a nursing service either because of its organisational characteristics or because of its use of evidence-based interventions.

Methods

We broadly followed the approach to scoping reviews outlined by Arskey and colleagues(Arksey and O'Malley, 2005). The project progressed in 2 stages.

Stage 1. The databases Medline, Embase and the British Nursing Index, Google and Google scholar were searched to identify indicator systems and potential areas for nurse-sensitive outcomes. Searching continued until November 2009. We sought papers that proposed quality measures or provided overviews of nurse-sensitive outcomes that could be relevant to ambulatory chemotherapy. Searching was iterative but based around a core strategy of combinations of terms for “nurse”, “cancer / oncology” and “outcome / quality/ measurement / metrics” combined (Boolean ‘AND’). Although we focussed our searches on cancer care we considered material from other clinical areas where we came across it. Where evidence was derived from clinical settings other than ambulatory chemotherapy its relevance was assessed by a clinical reference group consisting of senior nurse consultants, specialists and managers of ambulatory chemotherapy services.

Stage 2. We undertook searches of Medline and the Cochrane library for research evidence supporting the outcomes that were identified as a priority by the reference group or which were identified in a large number of sources during stage 1. The searches were again iterative but based around a core structure of keyword / index term for the outcome AND terms for cancer AND nurse. We sought primary research evidence from controlled trials or observational studies for sensitivity of particular outcomes to known markers of quality and quantity of nursing care (for example well-staffed units, units recognised as high quality, units with good leadership or teamwork) and we sought systematic reviews or evidence-based guidelines for evidence of clearly effective nursing interventions. In seeking evidence for interventions we did not seek to comprehensively review all possible interventions for each domain, but rather to identify authoritative evidence-based guidance or reviews that addressed outcomes / problems within that domain. Therefore we stopped searching and study retrieval once we had identified such a source from recent years. As is consistent with our scoping review methodology we did not formally assess the quality of each source but we selected only sources that showed evidence of a formal process of searching for and selecting evidence and offered explicit quality assessment. So for example for fatigue we used a National Institutes of Health ‘State-of-the-Science’ conference statement(Patrick *et al.*, 2004), a broad systematic overview(Stone, 2002) and three

Cochrane reviews on specific interventions (Cramp and Daniel, 2008, Goedendorp *et al.*, 2009, Minton *et al.*, 2008). We noted the availability of effective pharmacotherapy because in some jurisdictions nurses can prescribe and in other cases access to effective therapy may be regulated by referral or other actions by a nurse.

We assessed the strength of evidence and recommendations using a single simple grading system(Guyatt *et al.*, 2006) , selected because it encompassed both the strength of the evidence and the associated benefits and because it was consistent with widely endorsed recommendations for such systems(GRADE Working Group, 2004) . Evidence was graded as high quality, moderate or weak (A-C) depending on the quality and volume of underlying research (see table 1) and the recommendation was graded as strong (1) or moderate (2) depending on the balance of benefits vs risk or other caveats to applicability. Where guidelines used other grading systems, we mapped their recommendations onto this framework. We also considered how the evidence related to nursing practice in ambulatory cancer chemotherapy. Based on these lines of evidence for a particular outcome we determined whether the outcomes were *definitely* (unambiguous recommendations, strong evidence grade and clear nursing role), *likely* (strong recommendation, moderate evidence)*, possibly* (less strong recommendation / evidence or less clear nursing role) or only *potentially* (scant research evidence but some support) sensitive to nursing care.

Results

The initial searches yielded 28 sources – mostly published papers but also web sources including the sources from the Oncology Nursing Society's outcomes resource area at (http://www.ons.org/research/outcomes). While many of these sources contained indicator statements (giving broad descriptions of attributes of a quality service or its outcomes), we found no systems that had developed these into measurement systems relevant to ambulatory chemotherapy. We grouped potential indicators into 28 domains (see additional material). The domains had varying degrees of generality, depending upon the descriptions found within the literature. For example, the 'safety' domain was identified from literature which described

processes where a number of potential adverse events could result from failures in critical aspects of care but the specific events (outcomes) were not necessarily highlighted. For example, safe medication administration processes could reduce the consequences of drug errors (both toxicity and ineffective treatment), extravasation injury and infection. For some domains, the link to outcome was even more general and specific outcomes could not be inferred at any level (e.g. workforce knowledge and skill).

The domains were not mutually exclusive but served to organise the diverse material found. Because of the broad scope of the searches and range of potential sources this is unlikely to be a completely comprehensive list, but we reached a stage where additional sources ceased to add new domains (suggesting saturation of the categories at this level). The initial list was considered by the reference group who noted omissions and identified priority areas to review, which they viewed as important from a patient or service perspective. Because of limited resources we decided to focus on domains where outcomes could be identified and which appeared in six or more sources or were identified as priority areas by the reference group. We had anticipated using formal consensus methods with the reference group to determine priority areas, but as most areas they suggested as priorities were already on our high frequency list we simply added other areas that any member of the group identified as a priority. Although a small number of omissions were noted none were identified as priority areas. This gave a list of 11 outcome domains (see table 2). The following sections summarise the evidence found for each domain. Within each section we discuss how the outcome might be sensitive to nursing service quality.

Communication & Knowledge

Patients undergoing cancer chemotherapy face significant challenges and uncertainty. Detailed knowledge is required to support self-care and self-management and is presumed to reduce psychological distress(National Comprehensive Cancer Network, 2009) and play a part in managing other symptoms such as nausea and vomiting(Naeim *et al.*, 2008, Tipton *et al.*, 2007) and pain(Devine, 2003, Syrjala *et al.*, 2008). While studies on the effect of information giving and communication in these areas are somewhat equivocal, the provision of accurate information and

skilled communication is intrinsically important and makes a major contribution to the quality of patient experience(Sitzia and Wood, 1998). Although we identified a systematic review of communication skills training, the outcomes reported were changes in professional behaviours(Moore *et al.*, 2004). Although changes in nurses' communications with simulated patients were identified, the significance of this for actual patients is unclear(Moore *et al.*, 2004). We found no reviews which measured the impact of variation or training in communication skills among nurses on patient knowledge or satisfaction with communication.

However, a number of interventions intended to impact upon other nurse-sensitive outcomes, such as fatigue and septicaemia, act via the mechanism of knowledge and / or rely on effective communication skills. In so far as these are supported by evidence the impact upon knowledge can be presumed and has been demonstrated in some cases (e.g. Syrjala *et al.*, 2008). Individual trials of interventions designed to improve communication skills among nurses(Rask *et al.*, 2009) and a nurse-delivered patient information support service (Passalacqua *et al.*, 2009) did not lead to improved outcomes (perceived communication quality or satisfaction with knowledge) but in neither case was it clear that the intervention was successfully implemented.

We conclude from this evidence that there is a presumed patient benefit that seems likely to arise from a high quality nursing service because a quality service will be more likely than a low quality service to identify patient need (through communication skills) and deliver appropriate information successfully. However, it may best be regarded as a process indicator, on the pathway to a number of important outcomes, and as an element of experience (see below).

Diarrhoea

The rapidly dividing cells of the gastrointestinal tract render it vulnerable to cytotoxic chemotherapy and diarrhoea is a frequent symptom following chemotherapy(Rubenstein *et al.*, 2004). While there is some evidence to support recommendations (1 A/B) for specific drug therapies for the treatment and prevention of diarrhoea or abdominal discomfort(Rubenstein *et al.*, 2004) we found no evidence which suggested the impact of nursing interventions or variation

in nursing service quality on any measure of diarrhoea or abdominal discomfort. There is an assumed patient benefit from a high quality nursing service because a quality service will be more likely than a low quality service to identify the patient problem through assessment and ensure that recommended therapies are prescribed and so we conclude that the outcome is potentially sensitive to nursing.

Experience

The experiences that patients have of care are important and represent an essential component of quality. Patient experiences of care are also strong indicators of quality care(Donabedian, 1988) and it is clear that there has been significant variation in the quality of patient experience of cancer chemotherapy nursing in the past(Sitzia and Wood, 1998). However, we did not find evidence for nursing interventions or aspects of service quality which were clearly associated with variation in the patient experience in ambulatory chemotherapy settings, although satisfaction is often used as an outcome in nursing intervention studies.

A single US study compared patient reported outcomes, including satisfaction with care, for 270 patients cared for by either nurses with a specialist certification in oncology or non-certified nurses across several settings including ambulatory settings(Coleman *et al.*, 2009). No differences were found in levels of satisfaction associated with certification but the power of the study was low, the period of follow up unclear and the design (observational) weak. While the literature seems to focus on summary ratings of satisfaction, as opposed to specific reports of experience, it seems that provision of information and quality of communication are areas of common concern for patients(Sitzia and Wood, 1998). More generally, issues of confidence and trust in nursing staff have been highlighted as important aspects of patient experience(Maben and Griffiths, 2008).

The intrinsic nature of experience as both an aspect and an indicator of quality means that despite the absence of clear evidence about what nurses do to generate positive (or negative) patient experiences, it should be regarded as an indicator of quality that will probably vary with

the quality of nursing care. The literature reviewed suggests, but does not clearly identify, from the patient's point of view, what aspects of experience matter most.

Fatigue

Fatigue is a nearly universal experience among patients undergoing cytotoxic chemotherapy although specific causes are poorly understood(Wagner and Cella, 2004), probably because so many factors converge for the patient undergoing treatment for cancer. Factors leading to fatigue include direct effects of the tumour, treatment side effects, co-morbid conditions, co-morbid symptoms and psychological strain. There is some evidence (grade B/C) from reviews, including high quality systematic reviews, supporting exercise, psychosocial interventions and drug therapy for patients with anaemia (Wagner and Cella, 2004, Patrick *et al.*, 2004, Stone, 2002, Cramp and Daniel, 2008, Goedendorp *et al.*, 2009, Minton *et al.*, 2008). Patients might also benefit indirectly from therapies targeted at specific problems such as breathlessness(Bredin *et al.*, 1999) .

From this we conclude that the outcome is possibly sensitive to the quality of nursing because a quality service will be more likely than a low quality service to identify the patient problem through assessment and ensure that recommended therapies are prescribed. There is a potential direct effect from nurse-delivered non-pharmacological therapies. The potential involvement of nurses in delivering psychosocial interventions is high but these may not form part of routine care, instead comprising additional sessions over a short (10 minutes) to long (3 hours) duration and delivered over a number of weeks (see for example (Armes *et al.*, 2007)).

Nausea & Vomiting

Nausea and vomiting are common and distressing symptoms associated with most chemotherapy regimens. Although the effectiveness of drug treatments is well established(Naeim *et al.*, 2008, Tipton *et al.*, 2007) (1A) the benefits of other therapies and the direct contribution of nursing is not, although a number of potential nursing interventions are supported by grade 1-2 B/C recommendations. These include pre-assessment, targeted screening, structured follow up(Naeim *et al.*, 2008), and interventions such as acupuncture, acupressure, guided imagery,

music, progressive muscle relaxation, support and information (Naeim *et al.*, 2008, Klein and Griffiths, 2004). Generally, careful assessment, matching preventative regimes to likely need (1B) and provision of dietary advice (2C) may have an impact upon the outcome.

Although process measures showed some difference no differences in patient reported nausea were associated with being cared for by nurses with certification in oncology compared to non-certified nurses in an observational study, but this study suffered from a number of weaknesses (see section on Experience) including low power(Coleman *et al.*, 2009). A multi centre observational (pre-post) study of 249 chemotherapy patients found some evidence (grade C) of improvement in nausea and vomiting from the implementation of an evidence-based clinical practice protocol identifying interventions for nurses combined with structured symptom assessment(Kearney *et al.*, 2008).

As with fatigue, the evidence suggests that patients will probably benefit from a high quality nursing service because a quality service will be more likely than a low quality service to identify the patient problem through assessment and ensure that recommended therapies are prescribed. There is a potential direct effect from nurse-delivered non-pharmacological therapies such as the provision of advice on self-care, some of which would readily form part of routine practice.

Nutrition

Patients with cancer often present with anorexia and weight loss due to the disease process and may subsequently suffer further challenges due to treatment side effects. In relation to ambulatory chemotherapy treatment, induced nausea and vomiting are key contributing factors(Brown, 2002). We found no strong evidence to support the sensitivity of this outcome to nursing. There is some evidence from a good quality systematic review to support the use of appetite stimulant drugs for people with cancer(Yavuzsen *et al.*, 2005) (grade B). A review of interventions, including nutritional supplementation and counselling, provided some limited evidence of improved nutrition and wellbeing(Brown, 2002) (grade B/C).

Benefit from a high quality nursing service might be assumed because nurses will be more likely to identify the patient problem through assessment, ensure that recommended therapies are

prescribed and appropriate advice and support given. However, the effectiveness of these treatments is supported by only modest evidence.

Oral Mucositis

Oral mucositis is a common and potentially debilitating side effect of many common chemotherapy regimes. It is associated with significant adverse outcomes such as infection and death(Rubenstein *et al.*, 2004). Good oral care and client education is recommended and seen as a core part of the nursing role although precise protocols vary hugely and strong evidence of effect is lacking (Grade 1/2C)(Rubenstein *et al.*, 2004). There are a number of potentially effective agents for treating mucositis but evidence is weak and of poor quality (Grade B)(Clarkson *et al.*, 2007). There is stronger (but variable) evidence for preventative interventions likely to be nurse-led or based on advice from nurses, including the use of; honey (grade B), ice chips (grade A), and oral care (grade B). A multi-centre observational study of patients undergoing chemotherapy gave some evidence (grade C) of improvement in oral symptoms from the implementation of an evidence-based clinical practice protocol for nurses(Kearney *et al.*, 2008).

From the evidence we conclude that patients might benefit from a high quality nursing service because a quality service will be more likely identify problems through assessment and ensure that recommended preventative actions are taken There is also a potential direct effect from nurse-delivered non-pharmacological therapies which could form part of routine practice, including provision of advice on self-care.

Pain

Pain is a common and debilitating symptom associated with cancer although estimates of its prevalence in the population as a whole vary greatly with little data available on incidence(Patrick *et al.*, 2004, Breivik *et al.*, 2009). Given that many patients undergoing cancer chemotherapy may be asymptomatic, having had tumours detected via screening programmes, or not had pain as a presenting symptom(Breivik *et al.*, 2009) it is likely that prevalence is lower in this population than

the general population of people with cancer. Apart from local discomfort it is not a treatment side effect although pain progression or reduction may be an indicator of treatment effectiveness. There is a substantial literature on approaches to pharmacological management of pain and many guidelines(Caraceni *et al.*, 2009) which are recommended for practice (level 1) but management of pain is often suboptimal(Breivik *et al.*, 2009). There is evidence from a number of trials and observational studies that use of such guidelines results in reduced levels of pain for patients (e.g. (Zech *et al.*, 1995, Du Pen *et al.*, 1999), evidence level A/B), but we could find no high quality systematic reviews of guideline implementation for this clinical topic. Patient training and information giving is also recommended (level 1) and associated with improved pain management in several trials and a systematic review(Devine, 2003, Syrjala *et al.*, 2008) although results are not consistent (grade B).There is also evidence (grade B) from a systematic review to support psychological interventions such as guided imagery(Devine 2003). No differences in outcome were found associated with specialist certification of nurses but the study design was weak (see section on experience) (Coleman *et al.*, 2009).

A high quality nursing service will be more likely to identify this patient problem through assessment and ensure that recommended therapies are prescribed. There is a possible direct effect from nurse-delivered non-pharmacological therapies thorough provision of advice on self-care although the precise nursing role in the ambulatory chemotherapy setting is somewhat unclear, since it is not a problem that is directly related to treatment, and it is likely that much of the care would be delivered elsewhere. As with fatigue management it may well also be that psychosocial interventions require additional therapy to be delivered outside the routine clinical encounter (see for example Yates *et al.*, 2004)

Safe medication administration

The administration of medication is a high risk activity and drug errors are common(Walsh *et al.*, 2009). When the medications being administered are cytotoxic the risk of harm is particularly high. While drug errors are primarily related to systems failures, nurses have a role in detection and prevention before harm is done to the patient(Walsh *et al.*, 2009). Furthermore, the

administration process itself is risky requiring skilled assessment of patient fitness and patency of intravenous access(Walsh *et al.*, 2009). Patient education is a key challenge for patients receiving oral medication where a lack of concordance poses a significant risk(Jacobson *et al.*, 2009). Many of the potential impacts of nursing relate to assessment of toxicities(Walsh *et al.*, 2009) and are reflected in other outcomes considered in this review (e.g. nausea and vomiting, mucositis, septicaemia). Administration of vesicant drugs poses a significant risk associated with many commonly used drugs(Wickham *et al.*, 2006). We found no specific evidence from reviews relating to nursing interventions or approaches to increase safety in ambulatory chemotherapy but there are strong expert recommendations(Jacobson *et al.*, 2009, Wickham *et al.*, 2006, Wengström and Margulies, 2008) (level1 C) and evidence-based recommendations on intravenous drug administration from general settings (level 1 A/B) relating to the safe administration of medication which points to diverse aspects of assessment (including fitness to receive drugs) and technique (including prevention of infection and the treatment and prevention of injury from vesicant drugs) which fall within the scope of nursing practice. Evaluation (before and after) of a multifaceted nurse-led programme designed to increase the quality of care related to chemotherapy-related toxicities(Moore *et al.*, 2008) showed sub optimal care processes at initiation of the project and resulted in improvements in those processes but the study did not report patient outcomes.

This outcome is therefore probably sensitive to nursing intervention and overall service quality. There is presumed patient benefit from a high quality nursing service because a quality service will be more likely than a low quality service to properly assess and reduce errors and adverse reactions and ensure that recommended preventative actions are taken. A high quality service is also more likely to identify and remedy contributing factors. There is a potential direct effect from nursing technique (hygiene, assessment and correct use/placement of devices) which form part of routine practice.

Septicaemia / Febrile Neutropaenia

Febrile neutropaenia is a common and life-threatening complication of many chemotherapy regimens(Krell and Jones, 2009, Cameron, 2009). Delays in treatment and reductions in dose are common, resulting in reduced treatment effectiveness(Cameron, 2009). There is a role for chemo-prophylaxis and treatment with antibiotics(Cameron, 2009). However, much emphasis is placed on patient education, self-care and appropriate support and assessment(Cameron, 2009). Preventative actions by patients are believed to impact on rates of infection but specifics of appropriate advice are contested(Nirenberg *et al.*, 2006) (level 2 C). The provision of telephone support, including dedicated help lines (generally by nurses) is common(Cameron, 2009), but we could find no reports of the impact of these on outcomes. There is considerable uncertainty around the appropriate content for self-care advice(Nirenberg *et al.*, 2006). However, there is evidence of variation in both practice and in outcomes(Mort *et al.*, 2008, Nirenberg *et al.*, 2006). Early self-referral when experiencing symptoms is a key action believed to impact on outcomes(Cameron, 2009).

The outcome is thus identified as nurse-sensitive because it is assumed that patients benefit from a high quality nursing service because it will be more likely than a low quality service to reduce risk, educate patients appropriately, provide referral guidance and appropriate advice and support. Although outside the scope of practice in many areas nurses may also ensure that recommended prophylactic therapies are prescribed and taken. However the appropriate advice and support mechanisms remain uncertain.

Wellbeing & Function

A sense of wellbeing and the ability to perform normal activities and roles are severely challenged by both the direct consequences of cancer, the psychological sequelae of diagnosis and the physical and psychological impact of treatments, which include toxicities associated with cancer chemotherapy. Prevalence of major depression may be as high as 42% among people with cancer(Patrick *et al.*, 2004) although there is huge variation in estimates. Much of the variation in functional outcomes for individuals is likely to be mediated by psychological wellbeing and by the

impact of toxicities. The frequent suggestion of benefit of psycho-educational interventions for diverse symptoms such as fatigue, nausea and pain clearly suggests that the causal pathway is complex. Sleep disturbance is also heavily implicated in the complex causal pathway(Reich, 2008, Clark *et al.*, 2004). We could find no studies specifically addressing nursing interventions to support physical or role function. Guidelines support screening for distress, education, counselling and identifying those in need of onward referral as interventions (Grade 1 B/C) (National Comprehensive Cancer Network, 2009) all of which could be delivered by nurses in the ambulatory chemotherapy setting, but the evidence base is modest or weak. A systematic review(Osborn *et al.*, 2006) identified evidence for benefits from cognitive behaviour therapy for depression and anxiety (grade A). A review of interventions for sleep disturbance suggest that mindfulness based stress reduction techniques and expressive writing may have some benefit on sleep in diverse groups of people with cancer but no evidence derives from those receiving current chemotherapy (grade B). Individual trials of interventions designed to improve communication skills among nurses(Rask *et al.*, 2009) and a nurse-delivered patient information support service(Passalacqua *et al.*, 2009) did not lead to reductions in patient's expressed wellbeing but in neither case was it clear that the intervention was successfully implemented.

Thus there is an assumed patient benefit from a high quality nursing service because a quality service will be more likely to identify patient problems and ensure that actions are taken. A high quality nursing service is also more likely to identify and remedy contributing factors including specific side effects such as nausea and vomiting. There is a potential direct effect from nurse-delivered non-pharmacological therapies some of which could form part of routine practice although many would need to be delivered as part of a programme of support similar to interventions for fatigue and evaluation of brief interventions is limited(Turner *et al.*, 2011).

Discussion & conclusions

We did not identify any existing outcomes based systems of quality measurement that focussed on nursing sensitive outcomes relevant to ambulatory cancer chemotherapy. There have been attempts to develop such systems in other ambulatory settings (e.g. Griffin and Swan, 2006) but

the generic outcomes identified there were not highly relevant to this specific setting. We identified a large number of outcomes potentially sensitive to nursing in ambulatory cancer chemotherapy. Our focussed scoping of evidence around a shortlist of possible outcomes suggested that the evidence to support a link between nursing and outcomes was often relatively weak. While there are many trials of nursing interventions, we found relatively little clear evidence that would establish the interventions as fully supported by evidence (i.e. clear evidence of effect derived from a high quality systematic review of trials) sufficient to use as a routine quality measure. Although we have not assessed evidence for all possible outcomes identified we assessed those where the claims for sensitivity to nursing could be said to be strongest, based on the frequency they appeared in our sources and the priority ascribed by clinicians in our reference group.

In acute care settings the sensitivity of a range of outcomes to nursing has been established through observational studies which show relationships between outcomes and presumed dimensions of service quality such as leadership, training, staffing levels (Aiken *et al.*, 2008, Aiken *et al.*, 2003, Aiken *et al.*, 2002). Similar findings have been shown in surgical oncology settings (Friese *et al.*, 2008). We found little equivalent evidence for ambulatory chemotherapy and although we did identify one observational study exploring the specialist certification of nurses (Coleman *et al.*, 2009) the small size of the study renders its failure to show associations between specialist training and patient outcome rather uninformative. Although we did not identify any evidence that would allow factors such as staffing level or training to be considered as direct quality indicators these factors are heavily implicated in variations in quality in other settings. We would recommend that any system developed to monitor or demonstrate the quality of nursing care incorporated measures and reports of contextual factors including level and skill mix of nurse staffing, specialist qualifications of nurses and quality of the practice environment.

In many cases the nursing contribution to patient outcomes was based upon a presumed link between accurate problem identification and provision of access to therapies (some nurse-delivered, some not) with modest direct evidence of actual benefit from actions by nurses. In several cases the degree of sensitivity to nursing would depend upon the precise roles nurses

fulfil within a setting. For example, if nurses act as independent prescribers for treatments of toxicities then patient outcomes are likely to be more dependent on the input of nurses than if they are not. If nurses were not administering intravenous medications then many aspects of safe medication administration we identified would not be 'nurse-sensitive' at all. On the other hand, we have not considered evidence of outcomes that may reflect and be sensitive to care from the wider clinical team who provide supportive care for patients undergoing cancer chemotherapy. Under some circumstances this support (for example nutritional support) could be primarily provided by nurses. However, where a nursing role was significantly developed we would have expected such outcomes to be identified in our searches (as it was for nutrition) and so, while we might have missed potential contributions of nurses, it seems unlikely that nurses are routinely providing these services or that substantial evidence exists of benefit associated with nurses, since if there was we would have expected to see it represented in the results of our searches or recommendations from our reference group.

Evidence from acute settings makes it clear that not all outcomes that are sensitive to nursing could usefully be adopted as nurse-sensitive quality measures. The apparent oxymoron – an outcome sensitive to nursing that is not a nurse-sensitive outcome – is an important distinction. Consider for example mortality. There is considerable evidence that establishes that a significant amount of the variation in inpatient mortality is associated with registered nurse staffing levels (Kane *et al.*, 2007). Clearly, the outcome is sensitive to nursing. However, it seems unlikely that nursing (on its own) makes the largest contribution to inpatient mortality. After adjusting for patient level factors, the contribution of the medical profession in identifying the best treatments and competently performing appropriate procedures is likely to be the single biggest determinant of a hospital's death rate and evidence of staffing outcome associations support this view (Jarman *et al.*, 1999). Therefore if used as a quality measure, while nursing should certainly be considered, it is not specifically implicated in variation in the outcome.

However, this point highlights a significant limitation in our review. We have not attempted to assess how much variation in patient outcome is associated with nursing. Where large scale observational studies show associations with nursing quality factors, these associations can be

used to assess the degree of variability that is associated with nursing. This can be extended to assess the degree of variation compared to other factors and thus assess the likely utility of the outcome as a direct measure of quality(Mant, 2001). Alternatively, if there are robust estimates of the relative benefit associated with an evidence-based intervention this too can be used. However, no suitable studies were found to make such estimates. Consistent with our scoping review methodology we did not undertake systematic reviews of individual interventions. Rather we relied on existing reviews. This could also mean that there are interventions and outcomes for which such evidence does exist but which have not yet been systematically reviewed. However, until such research is undertaken neither we nor the practice community can judge what the conclusion of such a review would be, and so we do not see this as a limitation to our work per se. However, more focussed and comprehensive searching on individual interventions might yet yield additional evidence from reviews.

The outcomes identified and evidence reviewed suggests that the clearest direct impact of nurses in ambulatory chemotherapy is likely to be on the safety and experience dimensions of quality. Any nursing impact on treatment effectiveness is primarily indirect and is largely mediated by nurses' ability to support patients in managing the toxicities of treatment. In our previous report on metrics(Griffiths *et al.*, 2008b) we identified the importance of involving patients in identifying important aspects of experience that should be assessed. Some important issues have been raised in this review which could act as a focus. Provision of information and quality of communication have in the past been identified as significant areas of concern for patients (Sitzia and Wood, 1998) and clearly seem to remain prominent issues (Arora, 2009). While much of the relevant research has utilised the broad term 'patient satisfaction', this is unhelpful as satisfaction scores are only weakly associated with specific and important aspects of patient experience (Jenkinson *et al.*, 2002). What is essential is to specifically identify what experiences matter to patients.

Conclusion

The rhetoric of nursing's influence on important patient outcomes in this area is not currently matched by the strength evidence base. We found that patient experience, nausea and vomiting, oral mucositis and safe medication administration were the outcome areas most likely to be sensitive to nursing in ambulatory cancer chemotherapy, based on the lines of evidence considered. Communication and provision of information to patients are likely to be important mechanisms in achieving these outcomes. Our next step is to develop a prototype set of indicators and pilot these across a number of ambulatory chemotherapy units focussed on enabling their routine and standardised collection at the point of care to support continuous improvements to the quality of nursing care.

In coming to this conclusion we do not imply that other outcomes are unimportant or not amenable to nursing interventions. It is simply that the evidence available does not support their use for quality measurement. It may be that other outcomes are less easily attributable to nursing specifically. Consideration of a wider range of outcomes could contribute to a broader suite of cancer care (as opposed to treatment) outcomes. Within this suite, the purpose of identifying some as specifically nurse-sensitive would be to give clear responsibility and clinical leadership to nurses for monitoring and acting on results. Just as delivering the best surgical outcomes require an informed, engaged, quality ward nursing team, the delivery of optimal nursing outcomes in ambulatory cancer chemotherapy will still require the involvement of the wider multidisciplinary team.

While there is considerable scope for routine collection of patient reported outcomes to be used to develop an evidence-base for interventions and approaches to service delivery and thus to rectify limitations(Wheeler *et al.*, 2010), caution must be adopted when selecting areas for quality measurement, since these form a basis on which the quality of a service is judged. The aim of identifying quality measures is to measure quality, not to set a research agenda and, in so far as any system of measurement is liable to be used as a performance measure, the empirical basis of the claim that an outcome is sensitive to nursing is a crucial consideration. To put it simply, if

nurses are to be held accountable for an outcome and the quality of nursing services judged because of it, the evidence base for the link between nursing and that outcome should be clear. However, although we have cautioned against including areas where the evidence base is weak in routine quality measures this weakness in evidence also highlights the need for further research, both observational and experimental, to guide nursing intervention and organisation of nursing services.

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Table 1 Evidence grading (based on Guyatt et al 2006)

Grade	**Type of evidence**
A high-quality evidence	RCTs without important limitations or overwhelming evidence from observational studies
B moderate quality evidence	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies
C low-quality or very low-quality evidence	Observational studies or case series

Table 2 Summary of consensus and evidence assessments

Outcome	*Recommendation/ evidence*	Assessment of sensitivity to nursing
Communication and Knowledge	1B	Likely
Diarrhoea	1 A/B	Possible
Experience	-	Likely
Fatigue	(1)B/C	Possible
Nausea and vomiting	1A/B	Likely
Nutrition	B/C	Possible
Oral mucositis	1ABC	Likely
Pain	1A/B	Possible
Safe medication administration	*1C*	Likely
Septicaemia	*2C*	Possible
Wellbeing and function	1B/C	Possible

Potential quality outcome domains

Outcomes (domain)	Example indicator areas
Anaemia[1 2]	Assessment for related symptoms [2]
Cardiac toxicity	Assessment using validated tool[3]
Constipation[4-7]	Assessment of bowel habits using validated tools[8]
	Constipation[4-7]
	Dietary assessment[6]
Diarrhoea[1 4 7]	Altered mucous membranes[3-5]
	Assessment of bowel habits using validated tool[8]
	Diarrhoea[1 4 7]
Dyspnoea[4-6 9]	Assessment of dyspnoea using validated tools[6 8 10]
	Dyspnoea[4-6]
	Patient education for managing dyspnoea[6]
	Patient support for managing dyspnoea[6]
Education & Communication	Emergency support phone line manned 24/7 [3]
	Family education[8 16 18]
	Patient knows contacts (emergency & other) during chemo [3 19]
	Patient education re: treatment/processes/side effects/what to do/febrile neutropaenia/holistic assessment/contacts – who and how [3 8 16 18 19 24]
	Patient satisfaction with education [21]
	Staff communication with family[18]
	Staff communication with patient [18]
Experience	Control of treatment choices[9]
	Patient choice about place of treatment [3]
	Patient feel there is trusted relationship with staff [20 21]
	Patient satisfied with way staff communicate to them[19 20]
	Patient confidence in staff[20]
	Patient involvement in care and treatment[19]
	Patient knows contacts (emergency & other) during chemo [3 19]
	Patient satisfaction with technical care [3 18 19]
	Patient satisfaction with nurse management – symptom management, information giving & support [3 21 22]
	Patients wait time (wait for treatment)[3 19 23]
	Support at home available [3]
Family well being	Emotional strain on family/caregiver[6]
	Family education[6]
	Family support[18]
	Psychological counselling[18]
	Routine assessment of anxiety routinely using validated tool[8]
Fatigue[4-6]	Ability to undertake ADLs[4 5 11 12]
	Assessment of fatigue using validated tool[6 10]
Fertility[3]	Fertility counselling
Hypertension[3]	Assessment of BP[3]
Hypersensitivity reactions[4 5]	Rash[3]
(Oral) Mucositis[4 6 13]	Assessment for infection (fungal/herpes)[13]
	Assessment of nutritional status (weight loss/anorexia/ malnutrition/ dehydration)[6 7 10]
	Assessment of oral cavity regularly using validated tools[6 13]
	Clear and regular documentation[6]
	Has pt been told to use soft bristle toothbrush & replace

	it regularly? [6 14]
	Infection
	Nutritional Status[6 7 10]
	Patient education about specifics of oral hygiene in mucositis [6 13]
	Patient education about the use of oral care protocols[13 14]
	Referral to dental professional[6 14]
Nausea & Vomiting [1 4-6 9]	Assessment – frequency/intensity
	Counselling anxious patients [6]
	Frequency/intensity of nausea (pt report) [4]
	Nutritional assessment[7]
	Prescription of appropriate antiemetic regime[6]
	Pt education [6]
	Regular assessment and documentation using validated tools (self-reporting where possible)[6]
Nutrition[7]	Assessment from first point of contact and then ongoing using validated tool[6 10]
	Cachexia[10]
	Care plan developed from point of contact[6]
	Malnourished[6 10]
	Nutritional counselling[10]
	Oral mucositis [13]
Pain[4-6 8 16]	Assessment of pain using validated tools[6]
	Education interventions [6]
	Level of pain assessed using validated tools [1 6 8 17]
	Patient comfort level[7 18 19]
	Referrals to other services such as massage providing short term relief [6]
Peripheral Neuropathy (chemotherapy induced)[4 6]	Hand and foot syndrome (Palmar-Plantar Erythrodysesthesia)[3]
	Regular assessment of physical condition monitoring of symptoms[6]
	Routine assessment of stance, gait & balance[6]
Septicaemia	Assessment for signs of infection [15]
	Avoidance of permanent or semi permanent catheters
	Early identification[3 15]
	Febrile neutropaenia[3-6 15]
	Frequent oral care (tooth brushing & gentle flossing as tolerated)[6 15]
	(Oral) Mucositis[4 6 13]
	Patient education[3 15]
Skin ulcer[5 11 12]	Skin ulcer[5 11 12]
Sleep disturbances/ Insomnia[4 5]	Sleep disturbances/ Insomnia[4 5]
Wellbeing & Function	Ability to carry out usual activities[4 5 11 12]
	Activities of Daily Living (ADL)[4 5 18]
	(Patient) Anxiety[4-6 18 19]
	Anxiety assessment using validated tool [3]
	Assessment of fatigue using validated tool[6 10]
	Compliance [3 20]
	Coping[4 7 18]
	Depression[4-6 10 18]
	Fatigue[4-6]
	Instrumental Activities of Daily Living (IADL)[4 5 18]
	Needle phobia assessment [3]
	Patient-family communication[9 18]

	Performance status[3 12]
	Psychological counselling[6]
	Quality of life[5 6]
	Return to usual function[4 18]
	Routine assessment of anxiety using validated tool[6 8]
	Routine assessment of depression using validated tool[6]
	Sleep disturbances/ Insomnia[4 5]
	Spiritual care services available [8]
	Spiritual distress[4 5 9]

Safety

Outcome	**Indicator**
Safety[12]	Availability of hand washing facilities/hygiene
	Cleanliness of environment [19 20]
	Nosocomial infection[25]
	Patient education re: treatment/processes/side effects/what to do/febrile neutropaenia/holistic assessment/contacts – who and how[3 8 16 18 19 24]
	Reporting of incidents/near misses[22 26]
Safe medication administration	Aseptic technique used at all times for IV insertion to any site[6]
	Avoidance of permanent or semi permanent catheters[6]
	Barrier precautions taken when inserting central venous catheters[6]
	Catheter type/size assessed for complications – type & duration of IV therapy[27]
	Catheters replaced no more frequently than 72 hours unless otherwise indicated [6]
	Central line associated blood stream infection [22 25]
	Cleanliness of environment [19 20]
	Clear documentation of care plan[6]
	Dressings over IV sites changed promptly when soiled/damp or loosened [6]
	Extravasation incidents[5 24 27]
	Insertion site assessed for possible complications[6 24 27]
	Intravenous Infection[27]
	Needle phobia assessment [3]
	Number of central lines/IV lines
	Number of days central lines in place[6]
	Number of incidents[3 22]
	Nurse canulating to administer drug [3]
	Nurse knowledge[18 24 27]
	Nurse skill[18 27]
	Paediatric IV infiltration rate
	Patient education re: treatment/processes/side effects/what to do/febrile neutropaenia/holistic assessment/contacts – who and how [3 8 16 18 19 24 27]
	Phlebitis rate [3 24]
	Re-admission: length of stay with toxicity[3 5 18]
	Reporting of incidents/near misses[22 26]
	Safety standards for devices[20 24]
	Sclerosis of central line sites [3]
	Septicaemia[3 15]
	Vein pain[3 24 27]
	Venous assessment (specifically those on vesicants)[3 24]

Processes, structures and workforce

Outcome	**Indicator**
Care Delivery processes	Advocacy for pt/family[18]
	Care planning[8]
	Continuity of care[8]
	Correct nursing diagnosis[18]
	Improved documentation[8 18]
	Patients wait time (wait for treatment)[3 19 23]
	Referrals to resources[8 18 19 23]
	Use of guidelines/policy [3 24]
	Use of research[6 18]
Internal Regulations/Compliance	Compliance with organisations safety standards[20 24]
	Use of guidelines/policy [3]
	Internal regulations[18]
	Safety standards for devices[20 24]
Resource Utilisation	Emergency visits[4 20 23]
	Homecare Visits[4]
	Out-of-pocket-costs (family)[4 5]
	Re-admission: length of stay with toxicity [3 5 18]
Workforce organisation / management	Staff support (staff/peer/administrative)[18 23]
	Identified lead nurse [28]
	Practice Environment [26]
	Team working [26]
	Leadership[26]
Workforce Resources	Lack of personnel[18]
	Nursing hours per patient/day[21]
	Nurse retention[18]
	Nurse turnover[23 25]
	Practice environment (size, space, patient comfort, privacy) [19 25 26]
	Staffing levels: number of nurses to workload [3]
	Staff mix: Health care support worker/nurse grade/band [3]
	Waiting time for treatment[3 19 20]
Workforce Skill & Knowledge	Nurse knowledge[18 24]
	Nurse skill[18]
	RN certification (level 3 training accredited course) [3]
	RN education[3]
	Staff mix: Health care support worker/nurse grade/band [3 23 25]
Workforce Wellbeing	Job satisfaction[18 21 23 25]
	Perceived lack of time [3 18]
	Multiple job expectations[18]
	Practice Environment Scale [26]
	Staff communication – interdisciplinary (with each other and/or pt/family)[8 18]
	Nurse retention[18]
	Nurse turnover[23 25]
	Staff resistance [18]
	Staff support (staff/peer/administrative)[18 23]

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The 'long list' of domains

Topic	Number of sources	Priority Areas identified by reference group
Wellbeing & Function	13	**
Safe Medication Administration	12	**
Safety	9	
Care Delivery Processes	8	
Pain	8	
Education & Communication	7	*
Workforce Resources	7	
Workforce Wellbeing	7	*
Diarrhoea	6	**
Fatigue	6	
(Oral) Mucositis	6	*
Dyspnea	5	
Experience	5	
Nausea & Vomiting	5	**
Resource Utilisation	5	
Septicaemia	5	**
Workforce Skill & Knowledge	5	
Constipation	4	
Internal Regulations/Compliance	4	
Nutrition	4	*
Workforce Organisation / Management	4	
Family Well Being	3	
Hypersensitivity Reactions	3	
Peripheral Neuropathy (chemotherapy induced)	3	
Skin Ulcer	3	
Anaemia	2	
Sleep Disturbances/ Insomnia	2	
Cardiac Toxicity	1	
Fertility	1	
Hypertension	1	

(items marked ** received higher prioritisation than those with *)

Appendix 4: The 'shortlist' of outcome areas

Topic	Ranking (based on number of sources)
Wellbeing & Function	1
Safe Medication Administration	2
Pain	3
Education & Communication	4
Diarrhoea	5
Fatigue	6
(Oral) Mucositis	7
Patient Experience	8
Nausea & Vomiting	9
Septicaemia	10
Nutrition	11

Appendix 5. Suggestions for Specific Indicators of Safety and Effectiveness

Table 5 Suggested indicators					
Measure	**Source of Measure**	**Numerator**	**Denominator**	**Exclusions**	Notes
Safe medication administration					
Incidence of extravasation of cytotoxic drug per thousand treatment cycles	Safety reporting systems	All reported incidents of extravasation	All patients receiving IV cytotoxic chemotherapy per cycle	Patients on oral only medication	Possible issues of under reporting or recording. Ambiguity when 'suspected'
Extravasation resulting in ulceration per thousand treatment cycles	Safety reporting systems	All reported incidents of extravasation	All patients receiving IV cytotoxic chemotherapy per cycle	Patients on oral only medication	Possible issues of under reporting / recording. Needs risk adjustment for regimen
Patient report of pain or irritation at the infusion site per thousand treatment cycles	Patient self report	Patients reporting pain, irritation or discomfort at a previous infusion site on or since the previous infusion.	All patients receiving IV cytotoxic chemotherapy per cycle	Patients attending for first cycle of chemotherapy	Potential for recall or presentation bias. Will require a standard mechanism for recording and collating
Other issues / areas					
Drug administration errors	Safety reporting systems	?	?		Unclear the extent to which available measures relate to nursing role
Drug errors	Safety reporting systems	?	?		Unclear the extent to which available measures relate to nursing role
Management of toxicities					
Documented Assessment of severity of nausea and vomiting (% per treatment cycle)	Clinical record audit	All patients attending for chemotherapy treatment with a record of the severity of nausea and vomiting after last treatment cycle	All patients attending for chemotherapy treatment	Patients attending for first cycle of chemotherapy	Documented assessment does not necessarily lead to improved outcomes. Could be labour intensive
Patients reporting severe nausea following treatment (% per treatment cycle)	Patient self report	All patients reporting 'severe' nausea after last treatment using the C-SAS[83] item / assessed at attendance for chemotherapy	All patients with assessments recorded	Patients attending for first cycle of chemotherapy	Will require a standard mechanism for recording and collating. Will require risk adjustment. Choice of denominator may lead to adverse conclusions if recording / reporting is selective. Will need to be risk adjusted for regimen
Severe vomiting following treatment (% per treatment cycle)	Patient self report	All patients reporting 'severe' vomiting after last treatment using the C-SAS[83] item / assessed at attendance for chemotherapy	All patients with assessments recorded	Patients attending for first cycle of chemotherapy	Will require a standard mechanism for recording and collating. Will require risk adjustment. Choice of denominator may lead to adverse conclusions if recording / reporting is selective. Will need to be risk adjusted for regimen