



**Essex County Council, Thurrock Borough Council,
Southend-on-Sea Borough Council**

Health Overview and Scrutiny Committees

Health Overview and Scrutiny Report: Cancer Drug Usage in South Essex

January 2006

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Executive Summary

Access to the best cancer care is an important issue, and of particular concern to cancer patients and their friends and families. Media coverage of the 'post-code lotteries' that appear to surround access to some chemotherapy drugs reflect the real concern of patients that access to care should be fair and reflect real needs.

In 2004 the Department of Health (DH) published a report that looked at widespread variations in cancer drug usage across the 34 cancer networks in England¹ and appeared to show the South Essex Cancer Network (SECN) as the lowest cancer drug user of the 34 cancer networks. There was understandable public concern that this could mean cancer patients in South Essex were not getting the best treatment.

The Essex County Council, Thurrock and Southend-on-Sea Health Overview and Scrutiny Committees have jointly completed a detailed review of usage of the cancer drugs included in the DH report and found:

- South Essex 5-year survival rates are as good or better than the national average for the vast majority of cancers;
- The data quality of the DH report was flawed and did not fairly represent drug usage in South Essex;
- Prescribing practices vary across the country with clinical preference but this does not imply variations in the quality of care received;
- NICE approved cancer drugs are a treatment option and a high usage of these drugs is not necessarily an indicator of good clinical care;
- The DH report could penalise networks with efficient handling and usage of cancer drugs rather than encourage low levels of waste as found in the SECN;
- The audit programme undertaken by the SECN remains incomplete and was presented in a way that was difficult for a lay panel to interpret;
- The Southend Patient and Public Involvement Forum has commented on the "dedication of local clinicians and the high regard in which the people of Southend hold cancer treatment in Southend hospital"; and
- The absence of an oncology pharmacist and the apparent difficulties in resourcing the audit programme could be linked to the level of resourcing of a small cancer network.

¹ Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director, 2004.*

Despite concerns about the value of the DH report, the panel recognises the importance of reassuring the public and makes two key recommendations:

- That Essex SHA should ask the SECN to complete its audit report using a standardised system of reporting to include actual numbers of patients referred; patients treated and with what therapies; avoiding percentages instead of numbers and avoiding reports that are number free. (Zero should be stated as zero).
- That the SHA should report publicly on the suitability of commissioning arrangements to the DH and include either a clinical, financial and organisational justification of maintaining such a small cancer network, or clear proposals for boosting the resources of the network.

We hope all readers will find this report a thorough investigation of cancer drug usage in South Essex and that the relevant NHS agencies act on its findings.

1 Introduction

In Essex county, as nationally, around one third of people will develop cancer at some point in their life and a quarter of Essex residents will die from it. Ensuring that people receive effective cancer treatment could save many lives. Reducing geographical inequalities in treatment and survival rates is a high priority for the NHS.

In June 2004 the Department of Health (DH) published a report that looked at widespread variations in cancer drug usage across the 34 cancer networks in England². The report reviewed usage of 16 cancer drugs appraised by NICE and found that the South Essex Cancer Network (SECN) was in the lowest 20% of networks for use of 12 of these drugs. This appeared to show the SECN as the lowest cancer drug user of the 34 cancer networks.

The Essex, Southend-on-Sea and Thurrock Health Overview and Scrutiny Committees were concerned about what this meant for cancer patients in South Essex. The committees formed a joint panel to investigate the reasons behind the apparently low performance of SECN; consider any remedial action taken; and decide what, if any, further action might be needed to safeguard the healthcare provision of South Essex residents. Membership of this panel is set out in appendix one.

This report sets out the reasons for carrying out this study, its objectives, the evidence considered by the panel and their findings. First, it considers the importance of NICE appraisals of cancer drugs and the findings of the Department of Health report.

1.1 NICE Technology Appraisals

NICE, the National Institute for Health and Clinical Excellence (formerly the National Institute for Clinical Excellence) carries out appraisals of drugs and devices, including cancer drugs. NICE undertakes a review of the available clinical and economic evidence, measuring how well the treatment works and whether or not it represents value for money.

The Secretary of State for Health can refer a treatment to NICE for appraisal. This can be because there is variation in its use across the country³. An appraisal is intended to help end any 'post-code lottery' by issuing clear guidance as to whether or not a treatment works and when it should be used. Since January 2002, the NHS has been legally obliged to provide funding and resources in England and Wales for medicines and treatments recommended in a NICE technology appraisal.

² Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director*, 2004.

³ See <http://www.nice.org.uk/page.aspx?o=251106>.

At the time of the Department of Health report, NICE had appraised 16 cancer drugs and issued guidance on how these drugs should be used. Figure 1 below shows these drugs and the type of cancer that they are recommended for use in treating.

Figure 1: NICE appraised cancer drugs and type of cancer they can be used to treat

Drug	Cancer Type⁴
Capecitabine (Xeloda)	Breast & bowel cancer
Docetaxel (Taxotere)	Breast & lung cancer
Fludarabine (Fludara)	Leukaemia (CLL)
Gemcitabine (Gemzar)	Lung and pancreatic cancer
Imatinib (Glivec)	Chronic myeloid leukaemia
Irinotecan (Camppto)	Bowel cancer
Oxaliplatin (Eloxatin)	Bowel cancer
Paclitaxel (Taxol)	Breast, ovarian & lung cancer
Pegylated Liposomal doxorubicin (Caelyx)	Ovarian cancer
Raltitrexed (Tomudex)	Bowel cancer –for use in clinical trials only
Rituximab (Mabthera)	Non-Hodgkin's lymphoma
Tegafur uracil (Uftoral)	Bowel cancer
Temozolamide (Temodal)	Brain cancer
Topotecan (Hycamptin)	Ovarian cancer
Trastuzumab (Herceptin)	Breast cancer
Vinorelbine (Navelbine)	Breast & lung cancer

Not all cancer drugs have been appraised by NICE⁵ and four commonly used cancer drugs were used as comparator drugs in the DH study. This was to enable a comparison of the use of NICE appraised cancer drugs with the use of drugs that have not been appraised by NICE. These drugs are set out in figure 2 overleaf.

⁴ See Department of Health. *Letter to Strategic Health Authorities*, 8 July 2004, available at <http://www.dh.gov.uk/assetRoot/04/08/56/51/04085651.pdf>.

⁵ Cancer Bacup, a cancer information service aimed at people living with cancer and recognised by the NHS, provides information on 49 chemotherapy drugs at <http://www.cancerbacup.org.uk/Treatments/Chemotherapy/Individualdrugs>.

Figure 2: Standard cancer drugs, used as comparators in DH study

Drug	Cancer Type ⁶
Carboplatin (comparator)	Multiple cancer types
Cisplatin (comparator)	Multiple cancer types
Doxorubicin (comparator)	Multiple cancer types
Epirubicin (comparator)	Multiple cancer types

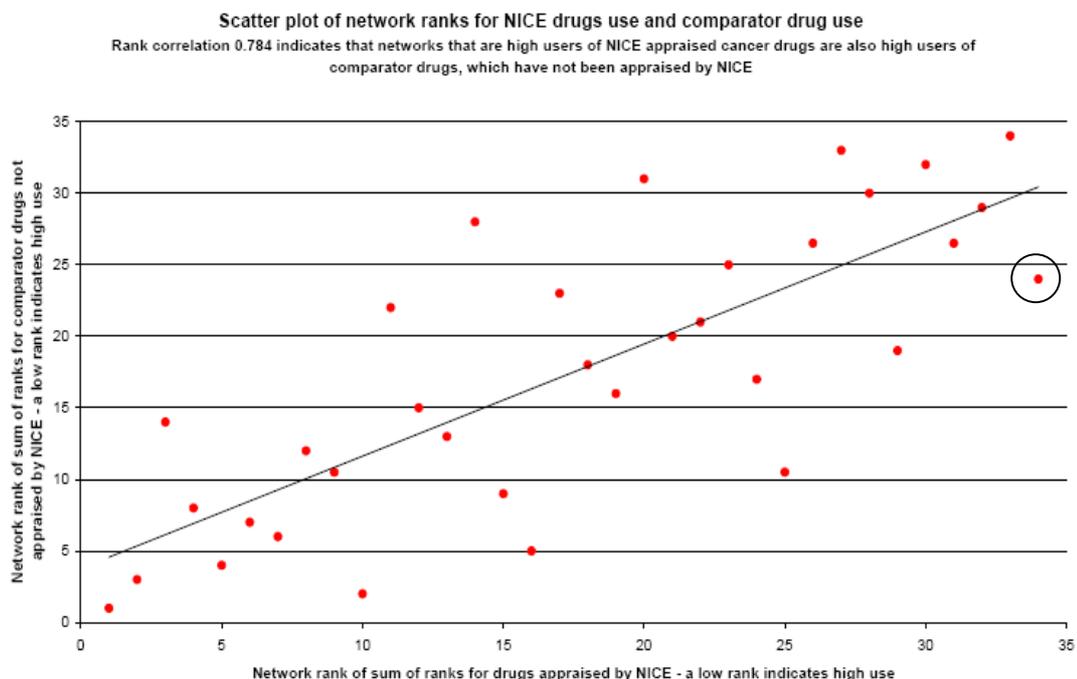
It should be noted that a drug that has not been appraised by NICE is not necessarily less effective than one that has been appraised. Many of the cancer drugs appraised by NICE have been recommended for use as options for second or third line treatments rather than as the initial drug of choice for patients. The low use of NICE appraised drugs does not necessarily imply poor clinical care.

1.2 Department of Health Report

The DH study demonstrates that there is wide variation in the usage of some cancer drugs and this raises the concern that some networks may not be providing the best treatment for patients.

Figure 3 shows the 34 cancer networks with the SECN appearing furthest to the right.

Figure 3: Cancer networks ranked for use of cancer drugs⁷



⁶ See Department of Health. *Letter to Strategic Health Authorities*, 8 July 2004.

⁷ Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director*, 2004, p39.

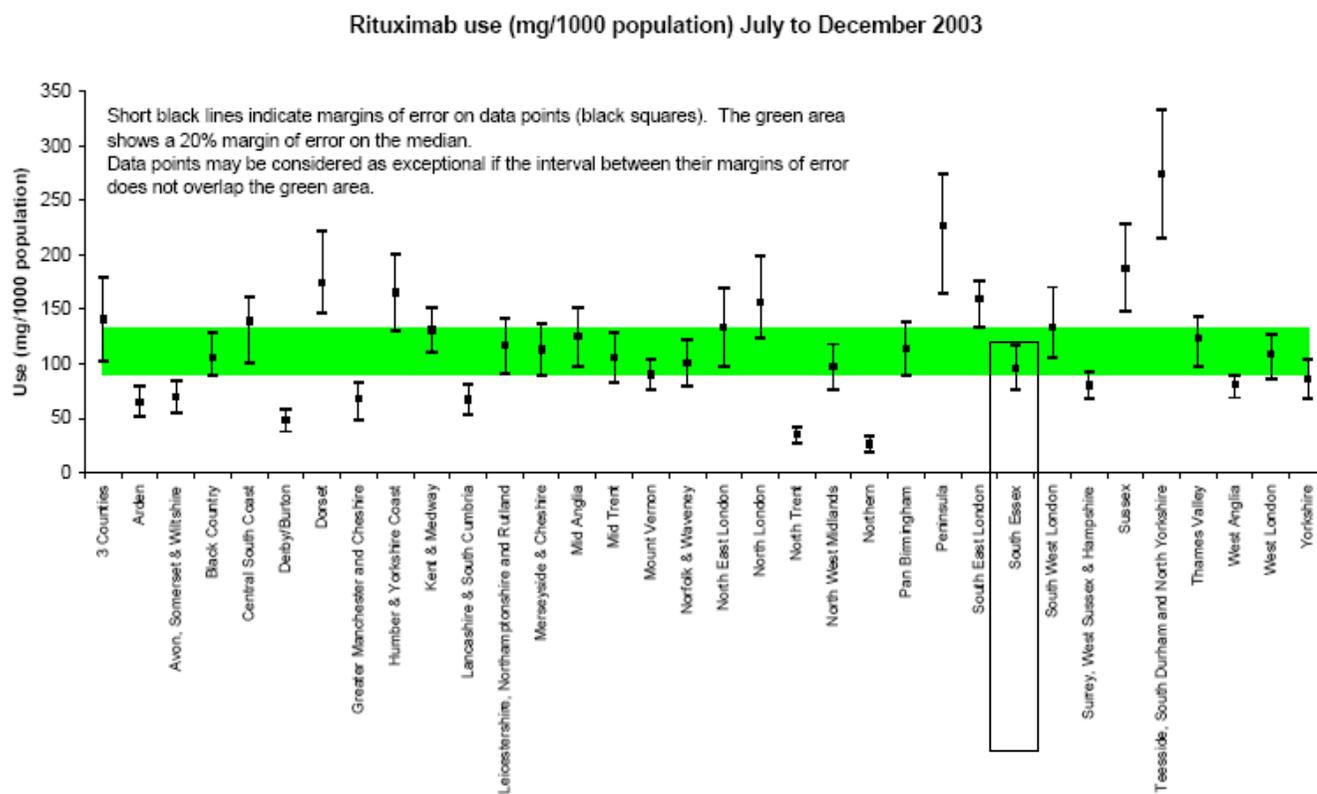
The SECN is represented by the dot on the far right screen showing that it had the lowest usage for the NICE approved cancer drugs but that 10 other networks had lower usage of the four standard cancer drugs, which have not been appraised by NICE and were used as comparators.

In measuring cancer drug usage, the report allows for a 20% margin of error. Networks are considered to be low users of a drug if the margins of error do not overlap with 20% either side of the national median. For some drugs the recorded usage could be within 20% of the national median but the network will still be ranked in the bottom 20% of networks. This happened to the SECN for two drugs: rituximab and the comparator drug Carboplatin.

Cancer drug usage was measured for July to December 2002 and recorded in mg per 1000 population to allow networks to be compared. No consideration is given to the number of cancer patients, demography, case mix and appropriateness of prescribing. The DH report contains caveats about the reliability of the data and concerns about data quality are considered Overleaf.

For some drugs the SECN was within 20% of the national median. For example, figure 4 shows the usage for rituximab was within the margin of error for the national median.

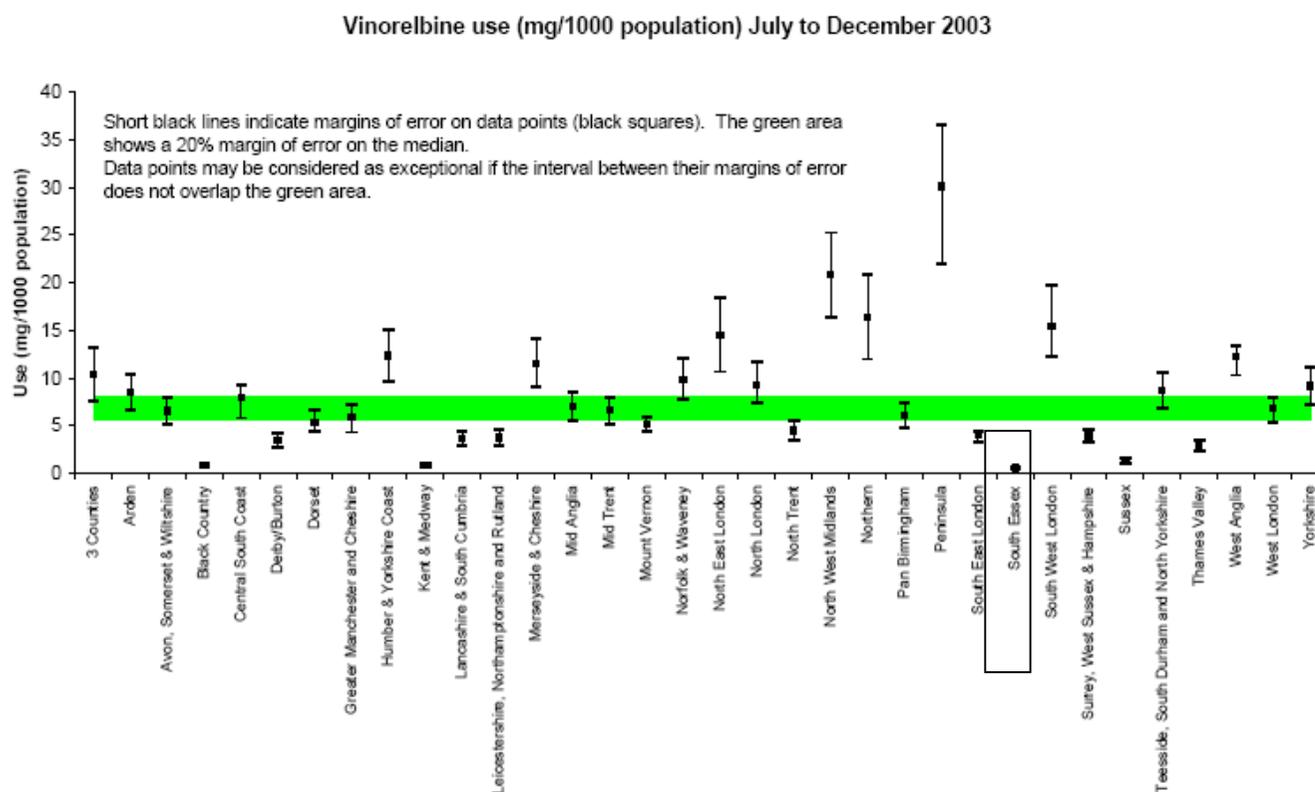
Figure 4: Cancer networks ranked for use of rituximab⁸



⁸ Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director, 2004*, p19.

For some drugs the SECN was far lower than the national median. For example, figure 5 shows use of Vinorelbine was 91% below the national median (see figure 5).

Figure 5: Cancer networks ranked for use of vinorelbine⁹



⁹ Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director, 2004*, p29.

The apparently low usage of NICE approved cancer drugs in South Essex raised concerns about inequity of health service provision. Essex, Southend-on-Sea and Thurrock agreed that a study would be carried out to consider the reasons for the SECN apparently performing very poorly, and to ensure that the situation had improved since the data for the DH report was collected.

The DH report found that a number of factors contributed to variations in cancer drug usage, in particular they found:

- i. Capacity issues - the use of chemotherapy in England had increased rapidly over the last five years and in some places there were capacity problems such as a lack of suitable space to prepare or administer toxic drugs or shortages of specialist staff. This was reported to affect some drugs more than others, depending on how they are prepared and given to patients.
- ii. Clinical issues - the use of drugs appeared to be heavily dependent on individual doctors' perceived usefulness of the drugs.

The report found that networks that were high users of NICE approved drugs were also comparatively high users of the comparator drugs. It also found that participation in clinical trials might impact on drug usage.

In July 2004 the DH requested all Strategic Health Authorities (SHAs) to report on their cancer networks where they are in the lowest twenty percent of prescribers for each drug¹⁰. They were asked to report on any remedial action being taken and the collective commissioning arrangements in place in the network. The SECN provided a report to the SHA in response to the DH report¹¹.

1.3 Objectives of this scrutiny study

The panel have taken the DH report and the SECN's report to the SHA as the starting point for this scrutiny study. The objectives of the study were agreed by the three HOSCs and are set out below:

- **To investigate avoidable inequity of cancer drug usage in Essex and consider the reasons for low cancer drug usage.**
- **To review any remedial action taken and any improvements to date.**
- **To propose any further remedial action that may be required.**

¹⁰ See Department of Health. *Letter to Strategic Health Authorities*, 8 July 2004.

¹¹ South Essex Cancer Network. *South Essex Cancer Network Response to National report on NICE Cancer Drug Usage*. November 2004.

2 Approach

The panel held a training session when they considered the SECN report to Essex SHA and the SHA response to this. It allowed Members to become familiar with the key issues and begin to consider reasons for the apparently low usage of cancer drugs in South Essex.

In addition, Members and witnesses suggested a number of possible explanations. These hypotheses were each studied to uncover if there was sufficient evidence to support them as explanations for the variation in drug usage. This report outlines the evidence for each possible explanation for the variation in drug usage:

- Capacity issues:-
 - Low staff numbers resulted in lower levels of prescribing.
 - Efficient storage and use of drugs showed up as lower usage than for other networks.
 - Restrictions on prescribing.
- Clinical issues:-
 - The SECN was not prescribing NICE appraised drugs appropriately.
 - Other networks were over prescribing the drugs.
- Data quality:-
 - Poor data quality showed lower usage for SECN than for other networks.
 - The small size of the network (one of the smallest in England) could distort the figures as for some drugs very few patients would be affected.
- Cross-boundary patient flows:-
 - Cross boundary patient flows might be higher in South Essex than elsewhere resulting in low drug usage in the SECN.

The following people attended panel meetings to give evidence and the panel is grateful for their contributions, which were invaluable:

6th January 2005

Dr Colin Trask, Lead Clinician, South Essex Cancer Network;

Mr Kevin McKenny, Network Manager, South Essex Cancer Network;

Dr Linda Hastings, formerly of Essex SHA;

Dr Richard Needle, Chief Pharmacist, Essex Rivers Healthcare NHS Trust;

and

Dr Stephen Cook, Chairman, Kent & Medway Cancer Network Drugs sub-Committee

23rd March 2005

Dr Paul Watson, Medical Director, Essex SHA;

Dr Colin Trask, Lead Clinician, South Essex Cancer Network; and
Mr Kevin McKenny, Network Manager, South Essex Cancer Network;

In addition, the panel received written evidence from the South Essex Cancer Network, the Kent and Medway Cancer Network and Essex SHA and Professor Mike Richards, National Clinical Director for Cancer and his colleagues at the DH who was central to the success of the study (see appendix 3).

The report sets out the analysis of this data, considering the evidence for and against possible explanations for the low cancer drug usage found in the SECN.

3 Evidence

This section sets out the evidence found for each of the hypotheses set out in section 3 above. This evidence is set out in 4 sections looking at:

- Capacity issues;
- Clinical issues;
- Data quality; and
- Cross-boundary patient flows.

3.1 Capacity issues

This section looks at any evidence that capacity issues are responsible for the very low cancer drug usage recorded in the SECN. It looks at staffing levels, efficiency in storage and use and any financial constraints on the prescriptions of drugs.

3.1.1 Clinical Staffing

The panel wanted to consider whether medical staffing levels could have contributed to the variation in cancer drug usage found in the SECN. The DH report clearly considered staffing levels to be a likely explanation of at least some of the variation found, noting that capacity issues included “shortages of specialist pharmacists, nurses or doctors”¹².

However, the report also found that:

¹² Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director*, 2004, p5.

There is no evidence of a relationship between the number of consultant oncologists and haematologists in those networks that are broadly co-terminous with SHAs and the usage of NICE approved drugs in those networks i.e. usage did not appear to increase or decrease with high or low numbers of these consultants¹³.
(Department of Health, 2004)

The panel asked both the SECN and the Kent and Medway Cancer Network (K&MCN) to submit details of those staff able to prescribe chemotherapy during the period July – December 2002. SECN had a total of 10.2 wte (whole time equivalent) staff in post and able to prescribe in this period.

- 7.2 wte oncology consultants (approximately 1 per 98,500 population); and
- 4 wte consultant haematologists (approximately 1 per 177,375 population).

The Kent and Medway Cancer Network (K&MCN), which serves around twice as many people as the SECN had the following staff:

- 12 full-time and 2 part-time oncology consultants - approximately 1 per 138,000 population (including the service to Hastings & Rother).
- Approximately 12 wte posts for consultant haematologists, equating to approximately 1 per 132,000 population (Hastings & Rother provide their own in-house haemato-oncology service).

The SECN had proportionately more oncologists and fewer haematologists than the K&MCN during the period of the DH study and Members considered whether or not staffing figures might impact on prescribing levels.

Dr Trask told Members that staffing would not have been responsible for any low levels of prescribing as staff worked extra hours if necessary to ensure that all patients were treated according to clinical need. Whilst it was not possible to produce numerical data, there was no reason to disbelieve this claim.

The SECN now has 6 wte consultant haematologists. It does not have the funding for a cancer pharmacist. This is a role that could provide leadership in the oncology pharmacy service, and play a central role in ensuring a high quality cancer pharmacy service:

Unfortunately, unlike many networks, SECN does not have funding for a lead cancer pharmacist. This post would play a fundamental role in partnership with network management teams, chairs of the site specific tumour boards, GP cancer leads and chief pharmacists and pharmacy

¹³ Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director*, 2004, p5.

staff (primary and secondary care) to help ensure the delivery of a high quality oncology pharmacy service across the whole network. The role would also facilitate network wide audit of NICE oncology medicines to measure compliance with NICE guidelines plus any other relevant drugs of interest to the Network Chemotherapy Board¹⁴. (SECN, 2004)

3.1.2 Storage and handling of drugs

Dr Trask considered that the SECN is particularly efficient at the storage, prescribing and handling of the cancer drugs and that the consequent low levels of waste would impact on the recorded levels of usage of these drugs¹⁵.

Members were advised by Dr Cook, Chairman, Kent & Medway Cancer Network Drugs Sub-Committee, that whilst an unopened vial of a drug could have a shelf life of years, once it has been opened and reconstituted this could only be 24 hours (depending on the drug). Similarly, Dr Needle, Chief Pharmacist, Essex Rivers Healthcare NHS Trust, indicated two drugs pose particular problems for wastage because of their instability. The scope for sharing Trastuzumab and Rituximab is restricted, as they cannot be shared beyond one session¹⁶. Minimal wastage of these drugs could be achieved by, for example, treating patients requiring the same drug in the same session so that very little of the drug is thrown away.

Dr Cook explained to Members that “Banding” systems would also enable efficient usage of cancer drugs. Such a system would allow batches of drugs to be prepared at given levels and then used for individual patients in the same “band” as the batch. Such a system would allow a variation of 5% from the prescription, either way. Batch production may only take place in an aseptic unit licensed for Specials Manufacture by the Medicines & Healthcare Products Regulatory Agency. The SECN states that all cancer drugs are prepared on site in a unit next to the patient treatment area¹⁷.

If a network were more efficient in its use of cancer drugs it would mean less of the drug would be purchased to treat the same number of patients compared to less efficient networks. This would mean that the figures for usage, which are not based on the amount actually administered to patients, might appear low.

Dr Needle and Dr Cook advised that other networks would also use drugs efficiently and that this would only be likely to account for a small amount of the variation, around 2 per cent¹⁸. This figure is not based on precise figures

¹⁴ South Essex Cancer Network. *South Essex Cancer Network Response to National report on NICE Cancer Drug Usage*. November 2004.

¹⁵ Notes of training day held on 23 November 2004.

¹⁶ See the minutes from the cancer drug usage scrutiny study panel meeting held on 6 January 2005 and Appendices to the Minutes of the Health/NHS Overview and Scrutiny Joint Committee held on 6th January 2005.

¹⁷ South Essex Cancer Network. Letter to Ms Door. 5 October 2005.

¹⁸ As above.

but is the opinion of the witnesses. This degree of variation would not account for the wide variation from the national median shown in the SECN drug usage.

3.1.3 Financial restrictions on prescribing

Members asked witnesses whether there had been financial restrictions on prescribing the NICE approved cancer drugs. The SECN and the SHA witnesses assured Members that as long as the drugs were prescribed according to the agreed protocol established by the SECN there were no such restrictions. PCTs have also confirmed that there are no financial restrictions on the use of NICE approved drugs.¹⁹

Members were also told by the SHA and SECN that there were no restrictions on the non-chemotherapy drugs required to support chemotherapy treatment or on cancer drugs that had not been approved by NICE. Dr Trask cited the rigorous protocols determining which drugs were used and how they were used as the reason for this freedom from financial constraints. National variation in the rigour with which protocols are developed and applied could lead to variation in prescribing. These included the length of time a first level drug should be used prior to the use of second or third level drugs.

3.2 Clinical issues

3.2.1 Clinical preference in using NICE appraised drugs

The DH study noted that clinical preference is a likely reason behind variations in usage of specific drugs:

It appears that the use of drugs is heavily dependent on individual doctors' perceived usefulness of the particular drugs and, in some cases, the choice between different drugs that exist.²⁰

(Department of Health, 2004)

In response to the DH report, the SECN has undertaken an audit programme to review usage of cancer drugs during the period of the study. The audits have reviewed case notes to establish if patients received appropriate treatment as indicated in the NICE appraisals and the SECN agreed chemotherapy protocol. NICE appraisals result in national guidance, or protocols, and the SECN will have local protocols for cancer drugs that have not been appraised by NICE.

The audit report has been agreed with the SHA and provides some evidence on the appropriateness of prescribing in the SECN. Details are set out in appendix five. The audit programme was designed to consider the usage of

¹⁹ Letters from Southend-on-Sea and Billericay, Brentwood and Wickford PCTs. October 2005.

²⁰ Department of Health. Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director, 2004, p5.

the NICE approved drugs considered in the 2004 DH report. The SECN have submitted information about the progress of these audits and the findings to date.

Six of the eight planned audits have been completed. These audits found very few deviations from the NICE guidance, all of which were explained to the satisfaction of the SHA. Instances where NICE approved drugs were not used included when patients had a life expectancy of less than three months, or where patients refused treatment (see appendix 4). There will inevitably be an element of clinical judgement on prognosis and this alongside clinical attitudes towards the balance of chemotherapy benefits and side effects could impact on patient and clinician decisions about treatment options. The contribution of the audit results to the explanation of low drug use is taken up in the discussion.

The panel considered whether the SECN usage of drugs indicated for use only as second or third line treatment was lower in relation to the national median than those drugs that are advised as options for use in first line treatment²¹.

²¹ Second line treatments are treatments administered after a first course of chemotherapy has been administered and further treatment is required. Third line treatments would be used following two other courses of chemotherapy treatment.

Figure 6 shows the level of variation from the national median and whether the drugs can be used as a first line treatment.

Figure 6: SECN cancer drug usage variation from the national median

DRUG	% Variation (SECN from national median)	Indicated as a first line treatment option? ²²
CAPECITABINE	-32%	Yes (for colorectal cancer only)
CARBOPLATIN*	-7%	Non NICE drug
CISPLATIN*	-30%	Non NICE drug
DOCETAXEL	-38%	Yes (for lung cancer only)
DOXORUBICIN*	-28%	Non NICE drug
EPIRUBICIN*	+9%	Non NICE drug
FLUDARABINE	-54%	No
GEMCITABINE	+44%	Yes (for lung cancer only)
IMATINIB	-46%	Yes
IRINOTECAN	-51%	No
OXALIPLATIN	-57%	Yes
PACLITAXEL	-52%	Yes (for lung cancer only)
PEG LIP DOX	-32%	No
RALTITREXED	n/a	No (recommended for use in clinical trials only)
RITUXIMAB	-7%	Yes
TEMOZOLOMIDE	-59%	Yes
TOPOTECAN	-100%	No
TRASTUZUMAB	-76%	No
URACIL/TEGAFUR	n/a	Yes (only if anthracycline treatment is inappropriate)
VINORELBINE	-91%	Yes for lung cancer

The 12 drugs identified in **BOLD** are those that are ranked 20% or more below the national median from the NICE approved cancer drugs included in the study.

*These drugs have not been appraised by NICE and have been included in this work as comparators.

The variations for the five drugs not recommended for use as a first-line treatment from the national median were between -32% and -100% whereas

²² As indicated in the SECN audit plan (see appendix five).

for NICE approved drugs indicated for use (at least in some cases) as a first line treatment, the variation was between +44% and –91%.

The average variation from the national median for drugs not appraised by NICE is –14%. This compares with –37.56% for NICE appraised drugs that are indicated for use as first line treatments and –53.25% for those NICE appraised drugs that are not indicated for use as a first line treatment (excluding Raltitrexed and Topotecan). These figures assume the drugs are prescribed uniformly regardless of cancer type and as such can only be taken as impressionistic. However, there does appear to be relatively higher usage of the comparator drugs; and of first line drugs over second and third line drugs that are NICE approved. The panel recognise that some drugs that have been approved for use in multiple cancer types have only been approved for use as a first line drug for one cancer type.

Members considered whether clinician preference and the high usage of one drug could balance low usage of another drug, explaining the low usage of some drugs in the SECN. The data in figure 6 indicates the SECN is a relatively high user of Gemcitabine and a low user of other drugs that can be used as first line treatments for lung cancer (Docetaxel, Paclitaxel and Vinorelbine). This appears to indicate clinician preference for Gemcitabine over other drugs. Similarly the audit report shows a low usage of Capecitabine for Colorectal Cancer but high use of the alternative treatment regime of 5FU and Folinic Acid, which was not audited in the DH report.

However, these drugs are also indicated for use in other cancer types. Detailed figures for their usage in each cancer type has not been available to the panel, so it is not possible to be certain of a link.

Professor Richards was asked if this was a likely explanation of the SECN figures. He acknowledged that this could occur for drugs used in the same condition, for example Paclitaxel and Docetaxel (e.g. for breast cancer) and Irinotecan and Oxaliplatin (for bowel cancer). However, he stated that this did not appear to have happened in the SECN²³.

3.2.2 Duration of treatment

Members wanted to look at whether or not variations in the length of a course of treatment could explain the low cancer drug usage in the SECN. If the SECN was giving shorter than average courses of treatment this may show as lower drug usage. Alternatively, with regard to drugs indicated as second and third line treatments, other networks could be progressing to these treatments more quickly, moving more rapidly through treatment options.

The DH report did not make any references to varying lengths of courses of chemotherapy. However, the House of Commons Public Accounts Committee did question Professor Richards on this issue in relation to

²³ Professor Mike Richards. *Letter to Councillor Roger Dyson*. 5 January 2005.

Trastuzumab (Herceptin)²⁴. The evidence given was that some patients would receive treatment for a few weeks and some for several years²⁵.

3.2.3 Late presentation

A possible explanation of low cancer drug usage is that some patients are presenting late to their GP with cancer symptoms, or are diagnosed late, and are not living long enough to receive treatment, or have a prognosis that is too poor to receive treatment. There is no evidence that this is unique to South Essex.

Dr Trask was very clear in stating that patients would ordinarily only be given drugs if they were fit enough to receive them, which means when they have their prognosis they are fit enough to survive the treatment regime for three months. However he indicated that a few patients with a worse prognosis might receive treatment depending on individual circumstances²⁶.

Dr Needle and Dr Cook both stated that 3 months was an arbitrary point that would not be used as an automatic cut off point for receiving NICE appraised chemotherapy drugs in their networks²⁷.

The NICE appraisals themselves indicate that those patients considered for treatment should be expected to live for 3 months or more. For example the NICE patient leaflet about Temozolomide states it is only indicated for use when "it is expected that they [the patient] will live for 12 weeks or more, at the start of the Temozolomide treatment"²⁸.

The Healthcare Commission, formerly the Commission for Healthcare Improvement, publish annual performance (star) ratings for each NHS trust. These include an assessment of the acute trust's achievement for the key cancer target: over 95% of patients should be seen within two weeks of urgent GP referral for suspected cancer to outpatient appointment with a specialist²⁹. The two acute trusts in the SECN, Southend Hospital NHS Trust and Basildon and Thurrock University Hospitals NHS Foundation Trust, achieved this target in 2002/03, 2003/04 and 2005/06.

In all years the core cancer target was that no patient with suspected breast cancer would wait more than two weeks to be seen in hospital. Both Basildon and Southend achieved this target each year.

²⁴ House of Commons Committee of Public Accounts. *Tackling cancer in England: saving more lives. Second Report of Session 2004-05*. December 2004.

²⁵ Herceptin is a biological treatment that can be administered over several years. Cytotoxic chemotherapy cannot be given over such a long period of time because of toxicity. See SECN Letter to Ms Door, 5 October 2005.

²⁶ See Appendices to minutes of Cancer Drug Usage Scrutiny Panel Meeting on 6th January 2005.

²⁷ As above.

²⁸ See for http://www.nice.org.uk/pdf/Temozolomide_patient_leaflet_english.pdf.

²⁹ Where GP referrals are received within 24 hours of the GP appointment. For further information see <http://www.healthcarecommission.org.uk>.

The 2002/03 performance ratings also included a performance indicator to measure the number of patients treated within one month of diagnosis of breast cancer. Basildon and Southend were above the national average with a compliance rate of 100%.

The 2003/04 and 2004/05 performance ratings also included measures of the number of breast cancer patients treated within 31 days of diagnosis and the number of patients treated within 62 days of urgent GP referral. Again, both Basildon and Southend exceeded the national average with 100% compliance in both years.

The SECN have provided data for 2004/05 that shows the compliance with waiting time targets. Figure 7 shows the wait for first chemotherapy treatment for all cancers.

Figure 7: Patients first treated with Chemotherapy³⁰

	Quarter 1 04/05	Quarter 2 04/05	Quarter 3 04/05	Quarter 4 04/05
Number of patients first treated within 31 days	50	84	60	52
Total number of patients first treated	50	84	61	52
Percentage of patients first treated within 31 days	100%	100%	98.4%	100%
	Quarter 1 04/05	Quarter 2 04/05	Quarter 3 04/05	Quarter 4 04/05
Number of patients first treated within 62 days	17	19	19	21
Total number of patients first treated	19	22	22	26
Percentage of patients first treated within 62 days	89.5%	86.4%	86.4%	80.8%

The SECN have advised that the main reason for breaches is either Complex Diagnostic Pathway or Delay to Diagnostic Tests, not capacity in chemotherapy³¹.

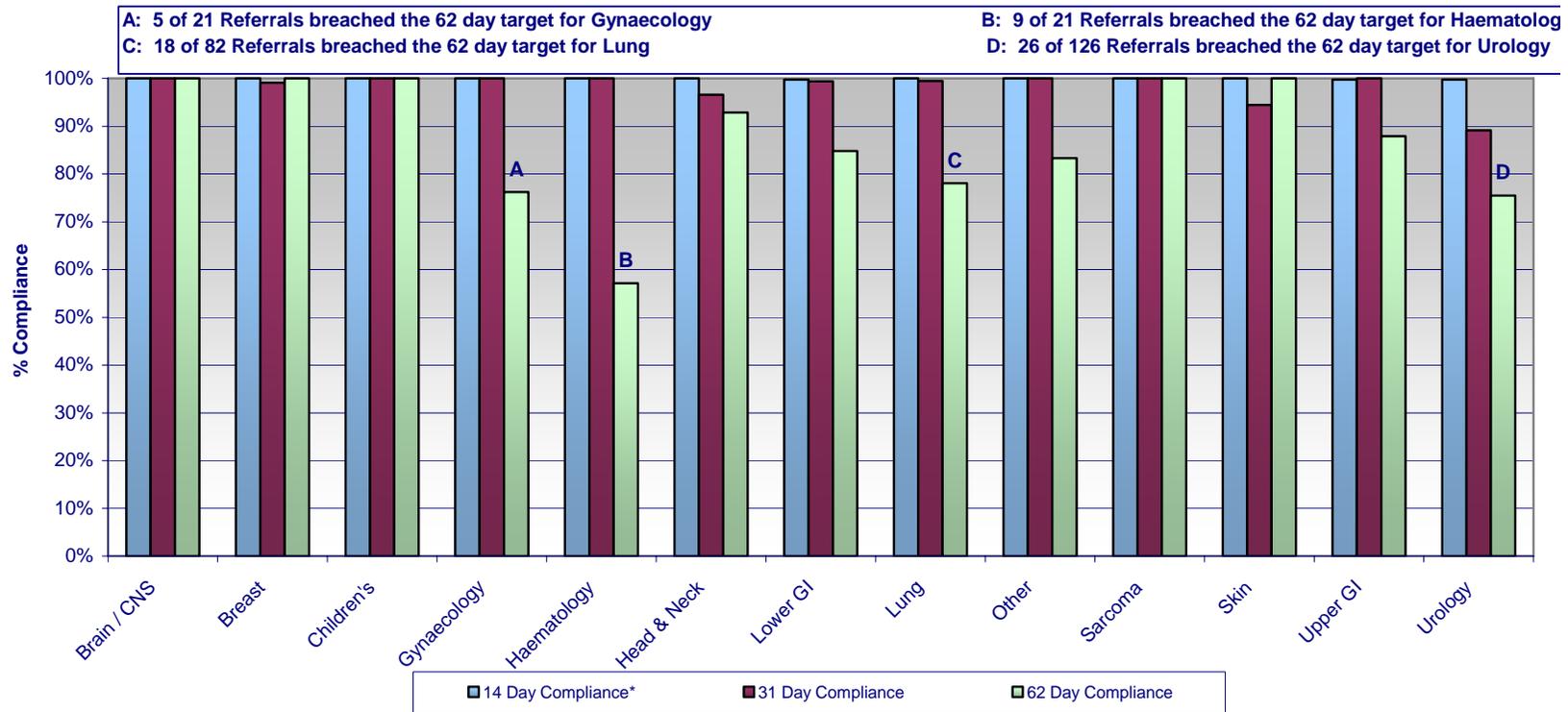
Figure 8 shows a breakdown of compliance with waiting times by cancer type. It is not specific to chemotherapy but includes other treatment options.

³⁰ Information provided by SECN on 1 July 2005.

³¹ As above.

Figure 8: Southend Hospital NHS Trust Compliance With Cancer Waiting Times 2004/05³²

**Southend Hospital NHS Trust % Compliance with Cancer Waiting Times Targets
2004/05 (Apr 04 - Mar 05)**



*Referrals received within 24 hrs

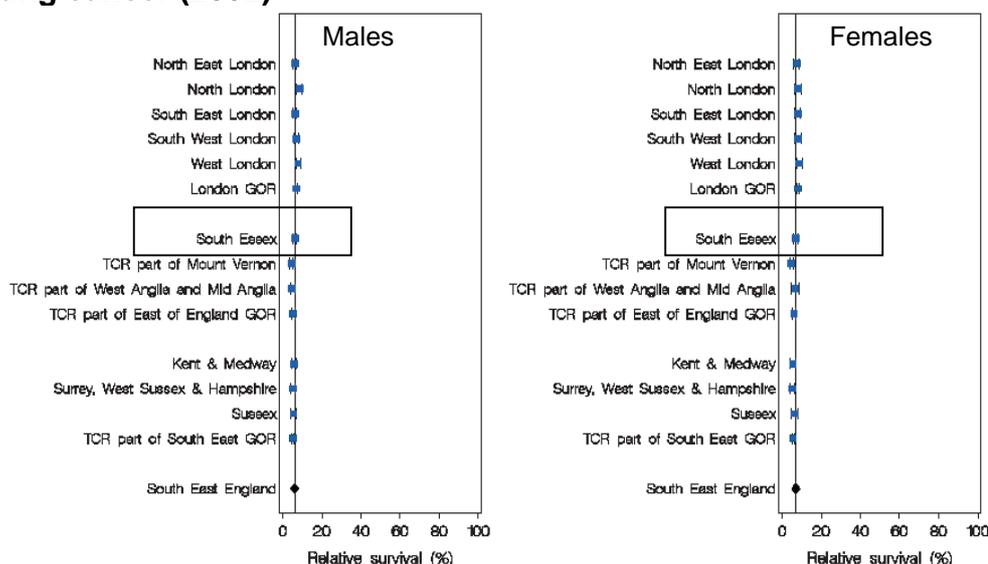
³² Information provided by SECN on 29 June 2005.

3.2.4 Survival rates

Five-year survival rates, which are collected nationally, may provide the best indicator for the quality of the treatment regimes available to Essex residents. This data will not be available for patients diagnosed in the period of the DH study until 2009. However, the most recent data available from the Thames Cancer Registry (TCR) indicates that people diagnosed with cancer in the SECN area have an average or higher than average five year survival rate for those cancers where data is available³³.

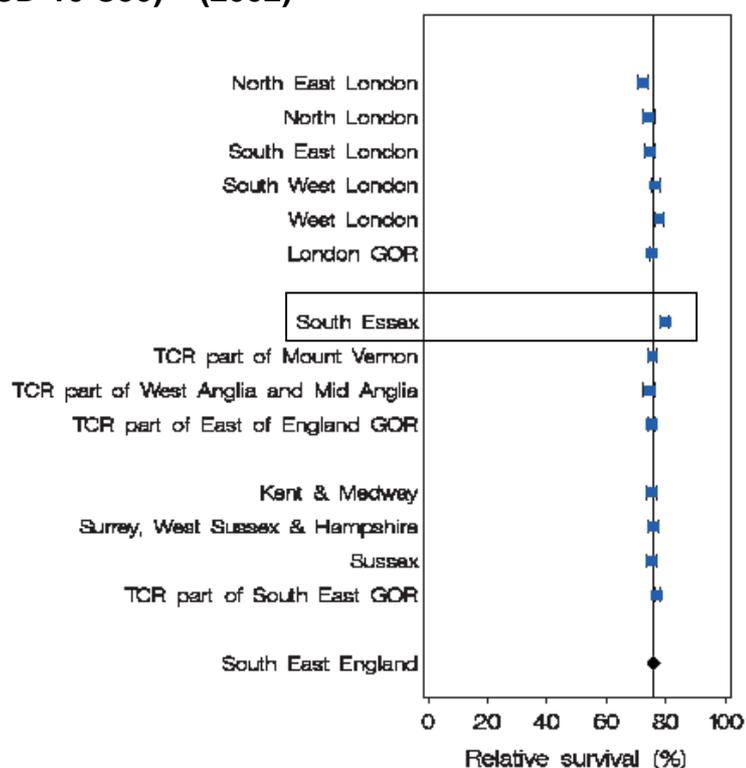
Figures 97, and 10 are examples of relative survival rates for common cancers from the TCR report *Cancer in South England 2002*. They show figures for lung and breast cancer. Further information can be found in the TCR report.

Figure 9: Relative five-year survival rates for males and females with lung cancer (2002)



³³ Thames Cancer Registry. *Cancer in South England 2002*. Thames Cancer Registry, 2004.

Figure 10: Relative five-year survival for females with breast cancer (ICD-10 C50)³⁴ (2002)



This five-year survival rate data implies that the care received by cancer patients in the SECN is associated with good outcomes. However, the data could hide the relatively short gains in survival that can sometimes be obtained through the use of some cancer drugs. There is a lot of work underway to develop more effective methods of measuring trends in life expectancy for cancer patients and the TCR report reflects this.

3.3 Data quality

This section considers the evidence regarding possible problems with the data used in the DH report, which were raised by the SECN. Indeed some difficulties with the data and the need for improved information systems were highlighted in the DH report. In considering the impact of each potential problem with the data, the panel have taken into account whether this would be a difficulty shared across all cancer networks.

³⁴ Period of analysis of relative survival is 1998-2002. Figures are 5-year estimates with 95% confidence intervals. See Thames Cancer Registry. *Cancer in South England 2002*. Thames Cancer Registry, 2004.

Networks do not share data systems and it has not been possible to get accurate data to assess the scale of the issues raised. The panel has instead relied on evidence from a number of witnesses:

- Dr Colin Trask from the SECN;
- Dr Stephen Cook from the K&MCN;
- Dr Richard Needle from the Mid-Anglia Cancer Network; and
- Professor Mike Richards, National Clinical Director for Cancer.

3.3.1 IMS and adjusted data

The panel considered if figures for drugs obtained directly from suppliers such as Baxter Healthcare would be included in the SECN figures for drug usage.

Dr Cook, from the K&MCN indicated that the Baxter Healthcare data was likely to have been included in their figures for cancer usage for the network. This is echoed by Professor Richards:

Significant errors could arise if hospitals do not report all of their drug usage to IMS Health. We know this arose initially in some hospitals, where reconstituted drugs³⁵ were purchased from an independent supplier (Baxter Healthcare). We were, however, able to correct for this³⁶. (Professor Richards, 5 January 2005)

Dr Trask gave evidence that if drugs were directly obtained by the SECN from external suppliers such as Baxter Healthcare they may not appear in the data used in the final report.³⁷ However, the SECN do not outsource chemotherapy³⁸.

The DH sent the data to each network for checking and invited them to correct the figure if they thought they were significantly wrong. Professor Richards informed the panel that “in most cases networks accepted the figures from IMS Health or altered them by only 10 - 20%”. He considered this small in comparison to the variations between networks, which could be 300, or 400%³⁹. The SECN was one of the networks that made changes to the IMS Health (IMS) data and in all but two cases these changes suggested a lower usage of the cancer drugs.

The SECN submitted data gathered by an oncology pharmacist and only included figures on the usage of the named drugs under the NICE approved indications, as requested. Some of these drugs may be used in alternative indications, which would mean usage would appear higher in networks that did not adjust the IMS data⁴⁰.

³⁵ Reconstituted drugs are drugs that have been prepared ready for use.

³⁶ Professor Mike Richards. *Letter to Councillor Roger Dyson. 5 January 2005.*

³⁷ See minutes of the cancer drug scrutiny study panel meeting on 6 January 2005.

³⁸ SECN, Letter to Ms Door. 5 October 2005.

³⁹ As above.

⁴⁰ The SECN suggested Capecitabine would be an example of this. The drug can be the preferred treatment for upper gastro-intestinal tumours although this is not currently NICE

Figure 11 shows both the original data and the adjusted data for the SECN.

Figure 11: Variation of the SECN provided data from the IMS Health data

	Original SECN IMS Data Provided Feb 04	Adjusted SECN Data Provided Feb 04	Variation (SECN adjusted data from IMS data)
Network Population:	709,494	709,494	
Drug	Amount (mg Per 1000 population)	Amount (mg Per 1000 population)	
CAPECITABINE	10,864.3	9,488.6	-12.7%
CARBOPLATIN*	298.1	279.1	-6.4%
CISPLATIN*	36.1	32.3	-10.5%
DOCETAXEL	13.1	8.1	-38.2%
DOXORUBICIN*	29.7	28.2	-5.1%
EPIRUBICIN*	92.0	79.8	-13.3%
FLUDARABINE	7.2	9.2	+27.8%
GEMCITABINE	1,315.9	1,195.9	-9.1%
IMATINIB	1,084.7	982.1	-9.5%
IRINOTECAN	33.9	22.7	-33.0%
OXALIPLATIN	10.4	8.2	-21.2%
PACLITAXEL	26.4	20.5	-22.3%
PEG LIP DOX	1.0	1.3	+30.0%
RALTITREXED	0.0	0.0	
RITUXIMAB	117.9	96.4	-18.2%
TEMOZOLOMIDE	9.5	12.3	+29.5%
TOPOTECAN	0.0	0.0	
TRASTUZUMAB	11.6	8.9	-23.3%
URACIL/TEGAFUR	0.0	0.0	
VINORELBINE	0.4	0.6	+50.0%

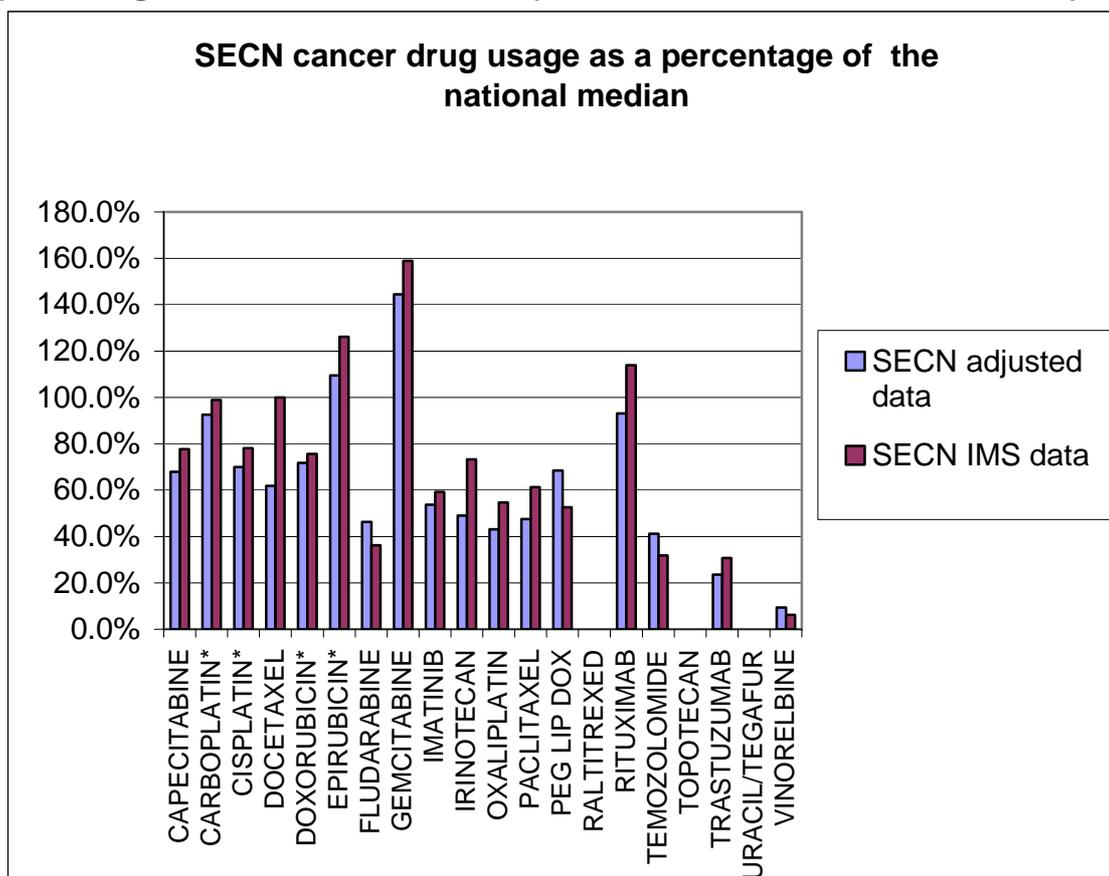
The 12 drugs identified in **BOLD** are those that are ranked 20% or more below the national median from the NICE approved cancer drugs included in the study.

*These drugs have not been appraised by NICE and have been included in this work as comparators.

indicated. The SECN would not have included figures for this usage of the drug but it might be included for those networks that accepted the IMS data. See SECN, Letter to Ms Door. 5 October 2005.

The impact of these changes on the SECN cancer drug usage variation from the national median is shown in figure 12 below.

Figure 12: SECN cancer drug usage (IMS and SECN adjusted data) as a percentage of the national median (where the national median is 100%)



The impact of adjusting the IMS data varies for each of the drugs. For Rituximab the IMS data placed the SECN above the national median, which would of course indicate it would not have been in the lowest 20 of networks for this drug. Similarly, the IMS data shows the SECN to be at the national average for use of Docetaxel. The SECN provided data showed higher usage than the IMS data for 4 drugs all of which remained in the lowest 20%. These were Fludarabine, Pegylated Liposomal Doxorubicin (Peg Lip Dox), Temozolamide, and Vinorelbine.

The IMS data may have over-estimated the usage of drugs in all networks and had other networks adjusted their IMS data there may have been a fairer position showing the SECN slightly less out of line with other networks, but most unlikely to be by a degree sufficient to change the broad overall ranking of the SECN.

3.3.2 Private patients and clinical trials

Cancer drugs used for private patients and those participating in clinical trials were not recorded in the DH study. Members asked witnesses if this could have disproportionately affected the figures for the SECN. However, Dr Cook and Dr Needle assured Members that this discrepancy would be likely to have a similar effect on all cancer networks. This is reflected in the correspondence from Professor Richards who thought this would account for only a small part of the variation in drug usage observed across networks.

3.3.3 Network size

Members **considered** the possibility that the small network size (it is the one of the smallest networks in England) may distort the figures making usage look lower than it actually is. The SECN has a recorded population of only 709,494 at the time of the DH study. K&MCN is over twice as large with a recorded population of 1,582,227 in the same period.

Cancer drug usage was measured in mg per 1000 population this indicates size has been taken into account in the figures. However, for some cancers patient numbers will be very low and the treatment of one or two patients would make a significant difference to the cancer drug usage figures.

Figure 13 shows the number of cancer registrations in each cancer network in the Thames Cancer Registry (TCR) area in 2002.

Figure 13: cancer registrations in South East England by cancer network, 2002⁴¹.

Number of new cases, crude rate and age standardised rate (ASR:European standard) per 100,000.						
All malignant neoplasms (excl. BCC of skin) (ICD-10 C00-C97)						
Cancer Network	Males			Females		
	Number	Crude rate	ASR(E)	Number	Crude rate	ASR(E)
North East London	2512	329.36	370.33	2579	332.82	307.96
North London	2571	371.32	396.48	2456	339.74	306.92
South East London	2852	382.25	414.58	2835	369.24	330.06
South West London	2563	400.53	426.81	2599	391.53	348.8
West London	2779	313.06	341.69	2698	300.81	272.22
TCR part of Mid Anglia	1834	385.66	333.21	1805	362.1	275.09
TCR part of Mount Vernon	1367	430.28	332.54	1323	400.54	277.02
TCR part of West Anglia	302	464.94	394.9	250	374.71	279.14
South Essex	1716	501.75	407.65	1713	470.48	333.75
Kent & Medway	3496	452.62	369.64	3515	430.23	312.73
Surrey, West Sussex & Hampshire	2644	422.09	348.51	2716	413.58	296.77
Sussex	2800	532.12	361.4	2864	499.17	301.87
TCR part of Central South Coast	670	798.57	461.43	686	730.95	395.03
South East England	28106	405.11	374.08	28039	387.96	306.9

The SECN had a higher incidence of cancer than the South East England average for both males and females. There does not appear to be an unusual level of incidence compared with other networks in the TCR area. However, the possibility that network size has had some impact on the results for less frequently used drugs cannot be ruled out.

3.3.4 House of Commons Committee of Public Accounts Report

The House of Commons Committee of Public Accounts published *Tackling cancer in England: saving more lives* in December 2004⁴². It looked in detail at the use of Herceptin and includes evidence from Professor Richards on the reasons for the wide variation in cancer drug usage found in the Department of Health study. The figures for Herceptin support Dr Trask's evidence that if

⁴¹ See http://www.thames-cancer-reg.org.uk/data/documents/report2002/all_malignant_c_n_2002.htm. For more detailed information about specific tumour types see Thames Cancer Registry. *Cancer in South England 2002*. Thames Cancer Registry, 2004.

⁴² House of Commons Committee of Public Accounts, *Tackling Cancer in England: saving more lives. Second Report of Session 2004-05*. December 2004

the period spanned by the Department of Health study had been an entire year, the SECN usage of the drug would have been higher than it was in the period studied.

The evidence in the Committee’s report showed mg of Herceptin sold to the networks from quarter 1 in 2000-01 to quarter 2 2003-04. In the period of the DH study (July to December 2003/quarters 2 and 3 2002-03) the SECN is shown to have purchased a total of 13,500mg or an average of 6,750mg per quarter. Figure 14 shows mg of Herceptin sold to the SECN from quarter 1 2000-01 to quarter 2 2003-04.

Figure 14: Volume in mg sales of Herceptin to the SECN for quarter 1 2000-02 to quarter 2 2003-04⁴³

Year	Q1	Q2	Q3	Q4	Total	Quarterly Average
2000-01	450	2,100	1,200	1,500	5250	1312.5
2001-02	5,700	5,700	10,500	15,000	36900	9225
2002-03	18,000	10,500	3,000	3,750	35250	8812.5
2003-04	4,050	2,550			6600	3300

The figures in **BOLD** are those covering the period of the DH study.

Those networks that bought most of their Herceptin in quarter 1 and/or quarter 4 would appear to have a lower usage than networks who either spread their purchasing evenly throughout the year or who did the bulk of their purchasing in quarters 2 and 3. If the whole of 2002-03 period is measured then sales to the network would have been a total of 35,250mg and an average of 8812.5mg per quarter or an average of 17625mg for 6 months. This quarterly average is 30.56% higher than the average of 6,750mg per quarter for the period of the DH study. If only quarters 2 and 3 are taken into account, the SECN is the 8th lowest purchaser of Herceptin. If the whole of 2002-03 is taken into account, the SECN is the 10th lowest purchaser of Herceptin. This variation indicated the potential risks associated with drawing conclusions about prescribing behaviour based on only 6 months data of drug sales. It should also be noted that this does not take population into account. The panel did not have detailed data available for the other drugs studied in the DH report.

3.4 Cross-boundary flows

This section sets out the evidence regarding the potential impact of cross-boundary patient flows on cancer drug usage. Professor Richards suggested that in the case of South Essex the large number of patients resident in the area, receiving treatment outside the network without a compensating in-flow of patients, could explain the very low usage of some cancer drugs in the network.

⁴³ As above.

The panel requested detailed information from the SHA and SECN about the number of patients with different cancer types treated in and out of the area during the period of the study. This data was unavailable due to the information systems currently in use by the SECN. Instead the panel relied on proxy data from the Thames Cancer Registry on total numbers of patients receiving chemotherapy and information, which Professor Richards has indicated is the best proxy data available. The panel also received SECN and K&MCN data on usage of the drugs covered by the DH study⁴⁴.

3.4.1 Thames Cancer Registry Data

The Thames Cancer Registry (TCR) is the organisation responsible for the collation and analysis of information on cancer incidence, prevalence, and survival for residents of South East England. This is one of 12 cancer registries and includes Essex, London, Hertfordshire, Kent, Surrey and Sussex. Due to the TCR boundaries only data for part of Mid Anglia, Mount Vernon and Central South Coast Cancer Networks is available.

The data obtained by Essex SHA shows where patients received their first hospital chemotherapy treatment. It does not cover the period of the national study of NICE approved cancer drugs, as this data is not yet available from the TCR. The data provided covers patients diagnosed in 2002. The data was contained in a letter from Dr Hastings and is available from the TCR⁴⁵.

From the TCR data and population data it is possible to consider the scale of cross-boundary patient flows for chemotherapy although the data available does not allow us to look at cross-boundary flows for specific cancer types or for chemotherapy treatment with individual NICE approved drugs. Similarly, the area or network of residence was assigned according to the PCT of referral/diagnosis.

⁴⁴ The Kent and Medway Cancer Network supplied data, which, like the SECN data, excludes private patients use.

⁴⁵ See correspondence from Dr Linda Hastings on 9 February 2005 and Thames Cancer Registry. *Cancer in South England 2002*. Thames Cancer Registry, 2004.

Figure 15 shows the number of patients with chemotherapy recorded by area of residence and the percentage of these treated in their home network (i.e. the network in which the patient is resident).

Figure 15: Patients diagnosed in 2002 receiving chemotherapy who are treated in home network

Network of residence	Number of patients recorded with chemotherapy	Percentage treated in home network	Number of patients treated in home network (approximate)
North East London	969	89	862
North London	1004	81	813
South East London	1075	86	925
South West London	969	86	833
West London	1045	47	491
South Essex	647	81	524
TCR part of Mid Anglia	618	90	556
TCR part of Mount Vernon	658	74	487
TCR part of West Anglia	54	0	0
Kent & Medway	1370	84	1151
Surrey, West Sussex & Hampshire	1190	56	666
Sussex	805	77	620
TCR part of Central South Coast	164	63	103

The figures show that 81% of patients resident in South Essex who received chemotherapy received their first hospital chemotherapy treatment within the network. Whilst actual patient numbers vary, the proportion is similar to figures for Kent and Medway (84%) and higher than Surrey, West Sussex and Hampshire (56%) and Sussex (77%).

It is important to note that for some networks the data only covers the TCR part of the area and actual figures for the whole network may differ. Further analysis of this data will only look at whole networks outside of London: South Essex, Kent and Medway, Surrey, West Sussex and Hampshire and Sussex.

Cancer networks will also have patient in-flows: patients from outside the area who receive their treatment in the network.

Figure 16 shows patient in-flows for networks across the TCR region.

Figure 16: Patients recorded as having chemotherapy in 2002 that were not resident in the network but were resident in the TCR area.

Network of residence	Number of out-of- area patients treated with chemotherapy ⁴⁶	Comments
South Essex	6	1% of Mid-Anglia patients treated
Kent & Medway	64	8% of Sussex patients treated
Surrey, West Sussex & Hampshire	48	2% of West London patients treated 3% of Sussex patients treated 2% of Central South Coast patients treated
Sussex	24	2% of Surrey, West Sussex & Hampshire patients treated

There is wide variation in the number of out-of-area patients treated by each cancer network. Similarly, networks may have treated patients from outside the TCR area, which would impact on total patient numbers and drug usage⁴⁷.

Patient numbers from the above tables can be added together to give an indication of total patient numbers treated per 1000 population. The population figures used by the TCR were the mid-2002 population estimates from the Office of National Statistics⁴⁸.

⁴⁶ Figures are approximate using the percentages given in the TCR data. All figures are rounded up to whole numbers.

⁴⁷ This may be of particular relevance for London, which is why figures for London networks have been excluded from the remaining tables.

⁴⁸ See mid-2002 population estimates at <http://www.statistics.gov.uk/statbase/Expodata/Spreadsheets/D8543.xls>.

These figures have been used in figure 17, which shows the number of patients recorded with chemotherapy per 1000 population.

Figure 17: Patients treated in 2002 who were resident in the TCR area.

Cancer Network	Total Population (1000s)	Number of patients treated in network	Number treated per 1000 population (to 2 decimal places)	Percentage variation from SECN
South Essex	706.1	530	0.75	-
Kent & Medway	1339.7	1215	0.91	21.3
Surrey, West Sussex & Hampshire	1283.6	714	0.56	-25.3
Sussex	1064.8	644	0.60	-19.4

The SECN appears to be treating significantly more patients per 1000 than Surrey, West Sussex & Hampshire but fewer than Kent and Medway.

However, even taking cross-boundary patient flows into account the number of patients treated by the SECN does not vary significantly from the average for the TCR (excluding London). The average number of patients treated per 1000 population in the TCR is 0.8 and the SECN is close to this average, treating 0.75 patients per 1000. The average for the four 'complete' networks shown in figure 11 is even closer to the SECN figure at 0.71. Therefore only a small variation from the average might be expected in the amount of cancer drugs used per 1000 population.

Figure 18 shows the SECN variation from the national median for the cancer drugs studied.

Figure 18: Data used in the Department of health report (provided by the SECN).

	National IMS Median	Adjusted SECN data provided Feb 2004	% Variation (SECN from national median)
Drug	Amount (mg per 1000 population.)	Amount (mg per 1000 population.)	
CAPECITABINE	13,977.0	9,488.6	-32%
CARBOPLATIN*	301.6	279.1	-7%
CISPLATIN*	46.2	32.3	-30%
DOCETAXEL	13.1	8.1	-38%
DOXORUBICIN*	39.3	28.2	-28%
EPIRUBICIN*	72.9	79.8	9%
FLUDARABINE	19.9	9.2	-54%
GEMCITABINE	828.1	1,195.9	44%
IMATINIB	1,829.9	982.1	-46%
IRINOTECAN	46.3	22.7	-51%
OXALIPLATIN	19.0	8.2	-57%
PACLITAXEL	43.1	20.5	-52%
PEG LIP DOX	1.9	1.3	-32%
RALTITREXED**	0.0	0.0	
RITUXIMAB	103.5	96.4	-7%
TEMOZOLOMIDE	29.9	12.3	-59%
TOPOTECAN	0.1	0.0	-100%
TRASTUZUMAB	37.8	8.9	-76%
URACIL/TEGAFUR**	0.0	0.0	
VINORELBINE	6.4	0.6	-91%

*These drugs have not been appraised by NICE and have been included in this work as comparators. The 12 drugs identified in **BOLD** are those that are ranked 20% or more below the national median from the NICE approved cancer drugs included in the study.

**Networks were not ranked for the use of these drugs.

The data shows that for many of the cancer drugs studied the variation is significantly larger than might be expected. For example, 59% less Temozolomide is used than the national median.

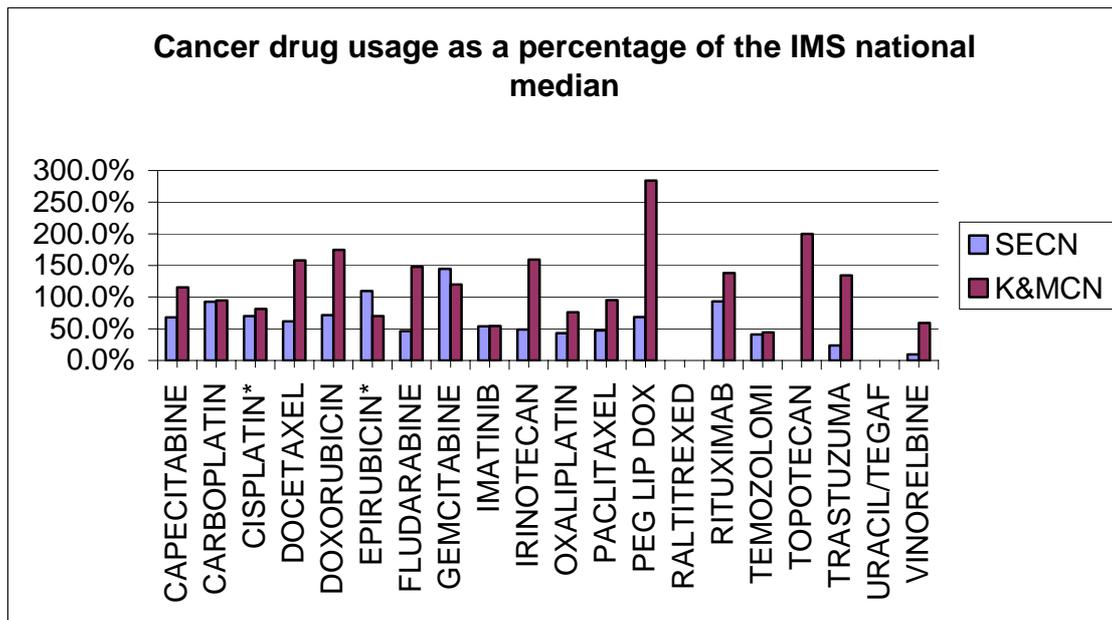
We have not been able to obtain the preferred data set showing actual patient numbers prescribed each NICE approved cancer drug for the period of the national study into variations in cancer drug usage and it is important to recognise the limitations of the data available.

However, the figures indicate that the SECN is treating a similar proportion of patients per 1000 population to other networks, although with respect to differences between individual networks there are bigger variations. This indicates that in this case cross-boundary patient flows at most only account for a minority of the variation in cancer drug usage and that an alternative explanation must be found.

Dr Trask and Dr Paul Watson suggested that the most similar cancer network to the SECN within the TCR area is the K&MCN. Dr Watson stressed that the K&MCN would face similar issues to the SECN in terms of its cross-boundary flows as it bordered by water on two sides and would receive very few patients, if any from London. The K&MCN also provided its own data rather than the IMS data and this has been used for comparison with the SECN to ensure the figures are as comparable as possible.

Figure 19 below shows the percentage variation from the national median of both the SECN and the K&MCN for each of the cancer drugs studied by the Department of Health.

Figure 19: SECN and K&MCN cancer drug usage as a percentage of the national median (where the national median is 100%).



The SECN is closer to the national median for 3 drugs: Capecitabine; Cisplatin; and Doxorubicin. Of these, only Capecitabine has been appraised by NICE. The only drug for which the SECN has a higher usage than the K&MCN is Epirubicin, which is not one of the NICE appraised drugs.

4 Discussion

In gathering the evidence the Panel wished to test a number of potential explanations for the wide variation in cancer drug usage found in the SECN and sought data to allow these theories to be tested.

It was not possible to obtain the preferred data due to the limitations of information systems used by the SECN. These limitations are common to many cancer networks and indeed the DH report recommends improving information technology systems.

However, Professor Richards assured that the data used is the best proxy data available and the Panel is confident that it has adequately considered the various possible explanations of the low cancer drug usage recorded in the SECN.

The evidence presented above allows consideration of how different factors have contributed to the low cancer drug usage of the SECN:

- Capacity issues;
- Clinical issues;
- Data quality; and
- Cross-boundary patient flows.

4.1 Capacity Issues

There is no conclusive evidence that capacity issues around staffing and finance were responsible for the low cancer drug usage in the SECN.

4.1.1 Clinical Staffing

In the absence of any contrary evidence, the panel accepts Dr Trask's position that staffing levels are not responsible for low levels of prescribing. However, the panel note that there is no lead cancer pharmacist who could have a key role in undertaking audits of cancer drug use and measuring compliance with NICE guidelines and local protocol.

4.1.2 Storage and handling of drugs

The panel recognise that the SECN has efficient processes for the storage and handling of cancer drugs and commends this good practice. The evidence does not suggest this is responsible for more than a small proportion of the variation in cancer drug usage found.

4.1.3 Financial restrictions on prescribing

There did not appear to be any financial constraints on prescribing where the SECN rigorously applied NICE guidelines and local protocols. The panel noted that variation between networks in how rigorously protocols were developed and applied might explain some of the variations in cancer drug usage between networks.

4.2 Clinical Issues

There is evidence that clinical issues contribute to the variations in cancer drug usage.

4.2.1 Clinical preference in using NICE appraised drugs

The panel recognises the difficulties in undertaking retrospective audits and that auditing the under use or non-use of drugs requires manually trawling through patients records looking for patients who may have been suitable cases for use of a drug but did not receive it. Clinicians then need to consider if the decision not to prescribe that drug, and the treatment that was provided, was the correct course of action.

However, the panel has significant concerns regarding the audit report from the SECN (appendix five) and is disappointed that there are currently no plans to complete it. Particular concerns for the panel included:

- Audit 2: The use of Trastuzumab (Herceptin) in advanced breast cancer
 - 9 patient records are still being retrieved
- Audit 3: the use of Capecitabine, Irinotecan and Oxaliplatin in advanced colorectal cancer
 - 11 of 35 patients did not receive treatment. 8 of these are described as too ill for treatment and 3 refused treatment.
 - 10 patients, nearly 30% received De Gramont therapy rather than Capecitabine.⁴⁹
 - 9 patients were too ill for second line therapy (4 had died).
 - Only 3 patients were offered third line therapy.
- Audit 4: The use of Capecitabine, Docetaxel, Paclitaxel, Vinorelbine in advanced breast cancer
 - This is incomplete and no data has been submitted
- Audit 5: The use of Gemcitabine, Paclitaxel or Vinorelbine, and Docetaxel in lung cancer
 - 20 notes have been reviewed so far. It is not clear what proportion of patients this represents. 2 refused treatment.
 - 12 of these 20 did not receive chemotherapy
- Audit 6: The use of Paclitaxel, Pegylated Liposomal Doxorubicin and Topotecan in advanced ovarian cancer
 - No numbers were given, only percentages making it impossible to judge the audit results.
- Audit 7: Fludarabine in B-cell chronic lymphocytic leukaemia

⁴⁹ This is a therapy regime in which patients receive Fluorouracil and folic acid. Fluorouracil is a chemotherapy drug that has not been appraised by NICE but is considered an alternative treatment to Capecitabine.

- 7 of 11 patients were left to 'watch and wait'. (Whilst this is an option in NICE guidance, it is not known if a similar proportion of patients are treated in this way in other networks.)
- Audit 8: The use of Temozolomide in malignant glioma.
 - 4 patients were treated with Lomustine, a chemotherapy drug that has not been appraised by NICE. It is not clear if this is a commonly used treatment option in other networks.

The evidence in the audit report does not satisfy the panel that appropriate treatment is always provided. The incompleteness of some audits is a strong concern. It is not clear if the numbers of patients refusing treatment or described as too ill to receive treatment are comparable with figures for other networks. Without extra resources, the network has struggled to find the staff time to complete the audit programme.

The available evidence suggests clinical preference is a strong factor in the variations in cancer drug usage, with the SECN often using drugs that have not been appraised by NICE. This is not in itself a cause for concern if the drugs used have a strong evidence base for their use and are an appropriate alternative treatment. The SECN has developed rigorous protocol for the use of cancer drugs and has indicated that it does not wait for NICE appraisal to introduce a drug but introduces them as research evidence is published⁵⁰. The panel does not consider the available evidence sufficient for it, as a lay body, to determine the reasons for clinical preference for certain treatment regimes.

Although it is not clear evidence of clinical quality, the panel also notes the very positive view of the Southend Patient and Public Involvement Forum who have commented on the dedication of local clinicians and the high regard in which the people of Southend hold cancer treatment in Southend hospital⁵¹.

4.2.2 Duration of treatment

There is no available evidence about variations in the duration of chemotherapy treatment in different cancer networks. However, the panel noted it was possible that the rigorous protocols implemented in the SECN could be less rigorous in other networks. The panel noted that many chemotherapy drugs would not be tried again after patients have progressed to a new drug. Some networks could move from first to second and on to third line treatments more quickly than other networks and this could lead to variations in the cancer drug usage. It has not been possible to compare the duration of chemotherapy treatment in the SECN with other networks, or to look at how rapidly different networks progress through treatment options.

⁵⁰ An example given is the introduction of Oxaliplatin as a first line treatment for metastatic Colorectal Cancer prior to the formal NICE appraisal publication in August 2005. See Letter from SECN, October 2005.

⁵¹ Email from Southend-On-Sea PCT Patient and Public Involvement Forum, 8 December 2005.

4.2.3 Late presentation

There is no evidence that the SECN currently faces a problem with patients presenting late with cancer symptoms, or that there are long delays in diagnosing patients. The SECN has had success in meeting the cancer waiting times targets, which is evidence that following urgent GP referral there are no long delays in patients receiving diagnosis or treatment. The panel noted that areas of deprivation could have higher levels of late presentation with cancer symptoms to the GP and that this could be occurring in the SECN.

4.2.4 Survival rates

The five-year survival rate data does not indicate any cause for concern, with the SECN performing well in comparison to other networks in the TCR area. However, these figures could well mask small gains in survival resulting from the use of NICE approved cancer drugs, particularly in the case of those cancers where five-year survival rates are poor (e.g. lung cancer).

The panel recognise work developing analysis of survival data is being undertaken by the TCR and other organisations and would be concerned if this work uncovered any variations in life expectancy.

4.3 Data quality

The evidence suggests that data quality had some unfavourable impact on the SECN figures for drug usage. The exclusion of data from private patients and clinical trials was not unique to the SECN and is likely to have impacted on many networks. Similarly, the selection of quarters 2 and 3 in 2001-02 as the period of the study will have been to the advantage of some networks over others. Whilst these factors may have disadvantaged the SECN this disadvantage does not appear sufficient to entirely explain the low levels of drug usage found in the network.

There is no evidence that the size of the SECN, one of the smallest networks in England, was a factor in the low drug usage. However, given the small numbers of patients involved it has not been possible to rule it out as a contributing factor for some drugs as the limitations of the audit data shows.

There remain strong concerns about the quality of data and the limitations of the DH report in enabling a meaningful comparison of cancer networks. The panel also notes that the DH report and the publicity surrounding it implied that there was a clear correlation between high usage of NICE appraised cancer drugs when there is not the robust evidence to support such a view.

4.4 Cross-boundary flows

Cross-boundary flows appear to account for some, although by no means all, the variation found in cancer drug usage. The careful analysis of the TCR data and the figures for cancer drug usage in the SECN and K&MCN indicate that the SECN treats a similar proportion of chemotherapy patients per 1000

population as the TCR average. However, the panel noted wide variation between different networks with the K&MCN, for example, treating over 20% more patients.

A difference of 20% might explain the variations between the two networks for some drugs such as Carboplatin or Imatinib, where the variation was very small. It would not explain the large differences in use of other drugs such as Docetaxel or Herceptin (Trastuzumab).

The limitations in the available data have prevented the panel from reviewing the cross-boundary patient flows for individual cancer types or treatment regimes. Professor Richard's recognition of the data constraints and acknowledgement that the TCR data was the best available proxy data was a welcome support to this study.

4.5 Conclusions

The panel notes the serious limitations with the data used in the 2004 DH report and recognises the concerns of the SECN that their cancer drug usage was unfairly represented in that report. However, the panel remained concerned that the recorded variations in drug usage were sufficiently wide to merit detailed consideration.

The panel explored many reasons for the apparently low usage of NICE approved cancer drugs in the SECN. It has not been possible to attribute a specific proportion of this variation to individual reasons because of data constraints. The limits of the information systems currently available to the SECN, and other cancer networks, mean that accurate monitoring of chemotherapy administration has not routinely taken place. The electronic prescribing system and electronic patient record should greatly improve the information that is routinely available and will contribute to effective clinical audits. The panel is concerned that the SECN take all practical steps to ensure they have effective information systems in place for the interim period.

It is clear that different combinations of factors will explain some variations found for individual drugs. The incomplete audit report from the SECN hinders the panel's ability to attribute causes to these variations. However, despite the limitations of the available data, the panel has concluded that an important factor in the variations in cancer drug usage in the SECN is clinical practice.

The panel recognise that the prognosis for many patients receiving chemotherapy is poor and that clinicians and patients need to take decisions about the best course of action. Sometimes it will be in the best interests of the patient not to undergo chemotherapy because it will be felt the benefits of some extra weeks or months of life are outweighed by the impact of the sometimes debilitating side-effects of chemotherapy. The panel recognises the difficult decisions that need to be taken and that clinician approaches to these decisions can influence patients. The panel has not considered if the

SECN presents options in the same way as other networks but it may be an issue for the SECN to review.

The question that the panel is not qualified to answer, is whether a clinical preference for one drug over another NICE approved drug is putting patients at a disadvantage in some circumstances. The NICE appraised drugs have been approved as options for treatment in certain circumstances and do not necessarily represent better care than drugs that have not been appraised. The available survival rate does not indicate any cause for concern but the very small gains in survival from chemotherapy in some circumstances could be hidden in this data.

A number of 'league tables' are published in the NHS each year and what a table measures does not always reflect high quality services for patients. Perverse incentives can be created through the use of unsuitable targets. It is possible for inappropriate and over-prescribing to be encouraged if high drug usage is used as a proxy measure for whether or not patients are receiving the best treatment. This report has found serious concerns about the data quality and appropriateness of the measurements used in the prescribing of cancer drugs which may be inaccurate and do not necessarily indicate poor clinical care. The panel hopes that any future reporting from the DH on cancer drug usage will use more robust, comparable data. With this in mind, the evidence does suggest some areas in which the SECN could take further action.

In July 2004 the DH requested Essex SHA to report on the SECN performance; on any remedial action being taken; and on the collective commissioning arrangements in place in the network. The SHA and the SECN agreed that the SECN would undertake an audit on the use of NICE recommended drugs. This audit report was presented in November 2004. It was incomplete, but on the basis of the evidence that had been produced the SECN asked the SHA to release it from its obligation to continue with a time consuming manual study that could only be undertaken by the small team of heavily worked clinicians. The SHA agreed to the request and reported positively to the DH.

It is the view of the panel that the SHA decision was misjudged given the audit outcomes described in this report and its incompleteness. The panel can well understand the sympathy that the SHA felt for the small and busy medical team, which had suddenly had the extra audit work thrust upon it. However, given the seriousness of the issue and the significant public concern surrounding the original DH report, it would have been better to provide extra support to the SECN to enable them to complete the audit report.

It is the view of the panel that the size of the SECN and subsequent levels of resourcing could impact on the capacity of the network to carry out effective clinical audit and support the role of a specialist cancer pharmacist. The panel would hope that arrangements are in place to ensure adequate resourcing of the network to ensure its size does not impact on the quality of the care it is able to provide.

The DH is expected to publish an updated review of NICE appraised cancer drug usage in 2006. The SECN have not revised the IMS data for this report and the three authorities will read this report with interest, particularly:

- The relative position of the SECN in this report;
- Any improvements in the data quality and validity of the report;
- Any recommendations for action.

The panel is also pleased to note that initial feedback from the Cancer Peer Review visit to the SECN in March 2005 has been positive with an indication that the report (to be published in January 2006) will describe prescribing arrangements in the SECN as robust.

5 Recommendations

Despite the limitations of the DH report, and concerns about the validity of the data, the panel recognises the importance in reassuring the public and makes the following recommendations:

- That Essex SHA should ask the SECN to complete its audit report using a standardised system of reporting to include actual numbers of patients referred; patients treated and with what therapies; avoiding percentages instead of numbers and avoiding reports that are number free. (Zero should be stated as zero).

The SHA has agreed to ask the SECN to complete its audit report⁵².

- That the SHA should report on the suitability of commissioning arrangements to the DH and include either a clinical, financial and organisational justification of maintaining such a small cancer network, or clear proposals for boosting the resources of the network.

⁵² Paul Watson, Letter to Ms Door, 2nd December 2005.

Appendix One: Panel Membership

The membership of the joint scrutiny study panel comprised 5 Councillors from each of the three authorities:

Essex

Councillor R Dyson (Chairman)
Councillor W Dick
Councillor R Pearson
Councillor J Reeves
Councillor D Dadds

Southend-on-Sea

Councillor J Cushion
Councillor A Robertson
Councillor M Flewitt
Councillor K Robinson
Councillor A Crystall

Thurrock

Councillor A Arnold
Councillor J Everett
Councillor M Pearce
Councillor D Cooper
Councillor C Kent

Appendix Two: Glossary

DH	Department of Health
IMS	IMS Health
GOR	Government Office Region
HOSC	Health Overview and Scrutiny Committee
K&MCN	Kent and Medway Cancer Network
NICE	National Institute for Clinical Excellence (now National Institute for Health and Clinical excellence)
SECN	South Essex Cancer Network
SHA	Strategic Health Authority
TCR	Thames Cancer Registry

Appendix Three: Description of cancer drugs studied

The table below lists the cancer drugs studied in the Department of Health report, the type of cancer it is used to treat and whether or not it can be used as a first line treatment:

Drug	Cancer Type ⁵³	Indicated as a first line treatment option? ⁵⁴
Capecitabine (Xeloda)*	Breast & bowel cancer	Yes (colorectal cancer only)
Carboplatin (comparator)	Multiple cancer types	Non NICE drug
Cisplatin (comparator)***	Multiple cancer types	Non NICE drug
Docetaxel (Taxotere)*	Breast & lung cancer	Yes (lung cancer only)
Doxorubicin (comparator)*	Multiple cancer types	Non NICE drug
Epirubicin (comparator)	Multiple cancer types	Non NICE drug
Fludarabine (Fludara)*	Leukaemia (CLL)	No
Gemcitabine (Gemzar)	Lung and pancreatic cancer	Yes (lung cancer)
Imatinib (Glivec)*	Chronic myeloid leukaemia	Yes
Irinotecan (Campto)*	Bowel cancer	No
Oxaliplatin (Eloxatin)*	Bowel cancer	Yes
Paclitaxel (Taxol)*	Breast, ovarian & lung cancer	Yes (lung cancer)
Pegylated Liposomal doxorubicin (Caelyx)*	Ovarian cancer	No
Raltitrexed (Tomudex)**	Bowel cancer	No (use in clinical trials only)
Rituximab (Mabthera)	Non-Hodgkin's lymphoma	Yes
Tegafur uracil (Uftoral)**	Bowel cancer	Yes
Temozolamide (Temodal)*	Brain cancer	No
Topotecan (Hycamptin)*	Ovarian cancer	No
Trastuzumab (Herceptin)*	Breast cancer	Yes (if anthracycline treatment is inappropriate)
Vinorelbine (Navelbine)*	Breast & lung cancer	Yes (lung cancer)

*The SECN was in the lowest 20% of networks for usage of these drugs.

**Networks were not ranked for these drugs.

***The margin of error on the data for this drug indicates usage is within the lower end of the median range.

⁵³ See Department of Health letter to Strategic Health Authorities of 8 July 2004, available at <http://www.dh.gov.uk/assetRoot/04/08/56/51/04085651.pdf>.

⁵⁴ As indicated in the SECN audit plan (see appendix 4)

Appendix Four: Documentary Evidence

Cancer Bacup, *Individual chemotherapy Drugs* at <http://www.cancerbacup.org.uk/Treatments/Chemotherapy/Individualdrugs>.

Department of Health. *Variations in Usage of Cancer Drugs Approved by NICE: Report of the Review undertaken by the National Cancer Director*, 2004. Available at <http://www.dh.gov.uk/assetRoot/04/08/38/95/04083895.pdf>

Department of Health. *Letter to Strategic Health Authorities*, 8 July 2004. Available at <http://www.dh.gov.uk/assetRoot/04/08/56/51/04085651.pdf>.

Healthcare Commission. Web pages detailing performance ratings. Available at www.healthcarecommission.org.uk

House of Commons Committee of Public Accounts, *Tackling Cancer in England: saving more lives. Second Report of Session 2004-05*. December 2004

Kent and Medway Cancer Network. *Summary of network with cancer drug usage figures*. Submitted to panel on 6 January 2005.

Kent and Medway Cancer Network. *Supplementary data on cancer drug usage*. Submitted to panel on 6 January 2005

National Audit Office. *Tackling Cancer in England: saving more lives. Report by the comptroller and auditor general*. HC364 Session 2003-04:19 March 2004

National Institute for Clinical Excellence. *Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer) – Information for Patients*. April 2001. Available at http://www.nice.org.uk/pdf/Temozolamide_patient_leaflet_english.pdf

South Essex Cancer Network. South Essex Cancer Network Response to National report on NICE Cancer Drug Usage. November 2004.

South Essex Cancer Network. *South Essex Cancer Network Report on Usage of NICE Cancer Drugs*. March 2005. Available at Appendix Five.

Thames Cancer Registry. *Cancer in South England 2002*. Thames Cancer Registry, 2004.

Office of National Statistics. *Mid-2002 population estimates*. Available at <http://www.statistics.gov.uk/statbase/Expodata/Spreadsheets/D8543.xls>

Correspondence

Department of Health. *Email to Ms Godfrey.* 7 April 2005.

Dr Linda Hastings. *Letter to Ms Godfrey.* 9 February 2005.

Mr Malcolm McCann, Dr Colin Trask and Mr Kevin McKenny. *Letter to Ms Door.* 5 October 2005.

Mr Kevin McKenny. *Email to Ms Godfrey.* 6 May 2005.

Mr Kevin McKenny. *Email to Ms Godfrey.* 29 June 2005.

Mr Kevin McKenny. *Email to Ms Godfrey.* 1 July 2005.

Mr Kevin McKenny. *Letter to Ms Door.* 1 July 2005.

Mr Kevin McKenny. *Letter to Ms Door.* 1 December 2005.

Professor Mike Richards. *Letter to Councillor Roger Dyson.* 5 January 2005.

Professor Mike Richards. *Letter to Councillor Roger Dyson.* 16 March 2005.

Dr Paul Watson. *Letter to South Essex Cancer Network.* 4 May 2005.

Dr Paul Watson. *Letter to Ms Door.* 6 October 2005.

Dr Paul Watson. *Letter to Ms Door.* 2 October 2005.

Panel Meetings

Minutes of each of the panel meetings are available on the Essex County Council website at <http://194.72.123.51/applications/agenda/default.htm>.

Meetings were held on the following dates:

- 23 November 2005 (private Members training session)
- 6 January 2005
- 23 March 2005
- 13 June 2005 (private meeting to discuss draft report)

Appendix Five: SECN Audit Report on usage of NICE Cancer Drugs

AUDIT PROGRAMME OCT 2004 – APRIL 2005					
All audits will be supported by the network acute trust Research and Audit Departments					
	Clinical Lead	Drug / Tumour type	NICE Indication	Methodology	Audit Results
1.	Dr Ayed Eden	The use of Imatinib (Glivec) in Chronic Myeloid Leukaemia (CML)	<p>Chronic Myeloid Leukaemia September 2002; Imatinib recommended as a treatment option for the management of Philadelphia-chromosome positive CML in chronic phase adults who are intolerant of interferon-alpha, or where interferon has failed to control the disease.</p> <p>Recommended as an option for the treatment of adults with PH+ve CML in accelerated phase or blast crisis provided they have not received Imatinib treatment at an earlier stage.</p> <p>October 2003: Imatinib is recommended as first-line treatment for people with PH+ve CML in the chronic phase.</p>	<p>Basildon Hospital 1 patient identified (diagnosed October 2003).</p>	<p>Basildon Hospital a) 100% (1/1) complied with NICE indications. As patient diagnosed in October started on hydroxyurea then converted to Imatinib as per new NICE guidance that glivec should be given first level treatment.</p>
				<p>Southend Hospital 0 patients were diagnosed between July and December '03</p> <p>Between July '02 and July '03, 1 patient was diagnosed</p>	<p>Southend Hospital This patient commenced treatment with Interferon Alpha, treatment was changed to Glivec in March '03 due to poor tolerance – as per Sept 2002 NICE guidelines. – 100% (1/1) compliance.</p>
2.	Dr Colin Trask	The use of Trastuzumab (Herceptin) in Advanced Breast cancer	<p>Monotherapy recommended as an option for people with tumours expressing HER2 3+, who have received at least two chemotherapy regimens for metastatic breast cancer. Prior treatment must have included at least one anthracycline and a</p>	<p>All new Southend Breast cancer patients over 6 month period that have been tested for HER2 3+ and review notes</p>	<p>27 out of 75 HER-2 positive (new patients)</p> <p>22 patients were adjuvant - 1 patient randomised to receive Herceptin in Hera Trial. (otherwise not licensed in this scenario)</p> <p>4 neo-adjuvant - Herceptin not licensed in this setting</p>

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			<p>taxane, where these treatments are appropriate. It should also have included hormonal therapy in suitable oestrogen receptive positive patients.</p> <p>Combination treatment with Paclitaxel is recommended as an option for HER2 3+ patients, who have not received chemotherapy for metastatic breast cancer and in whom anthracycline chemotherapy is inappropriate.</p>	<p>A switch to early testing has been adopted</p> <p>Preliminary Additional Data on metastatic disease over a 12 month period</p>	<p>1 recurrence - Herceptin not indicated</p> <p>60 patients identified with metastatic disease</p> <p>27 patients HER 2 –ve</p> <p>18 patients HER 2 +ve received Herceptin +/- Taxanes</p> <p>3 received anthracyclines as primary therapy</p> <p>2 patients had inadequate LVEF</p> <p>1 patient died prior to treatment</p> <p>9 patients notes being retrieved for audit</p> <p>Conclusions</p> <ul style="list-style-type: none"> Clinical data collection ongoing - initial results confirm use of Herceptin is appropriate.
3.	Dr Pauline Leonard	<p>The use of Capecitabine, Irinotecan, Oxaliplatin in Advanced Colorectal Cancer</p>	<p><i>Capecitabine: as option for the first line treatment of metastatic colorectal cancer as alternative to 5FU and folinic acid.</i></p> <p><i>Irinotecan: in patients who have failed an established 5FU containing treatment regimen.</i></p> <p><i>Oxaliplatin: first line therapy in combination with 5 FU and folinic acid, to 'down stage' metastases confined solely to the liver which may become respectable</i></p>	<p>SECN</p> <p>35 Patient notes reviewed.</p> <p>24/35 patients received chemotherapy for metastatic disease</p> <p>11 patients did not receive treatment. 8 patients were too ill to undergo treatment, 3 patients refused treatment.</p> <p>24 patients underwent 1st line chemotherapy for metastatic disease,</p> <ul style="list-style-type: none"> 10 De Gramont, (3 in CR08 study, 1 FOCUS 2 study) 6 Capecitabine 2 patients entered Capecitabine/ De Gramont preference study 	

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				<ul style="list-style-type: none"> • 1 Irinotecan (after progression on adjuvant therapy) • 4 Irinotecan & Modified De Gramont (combination) • 1 Carboplatin (patient had 2 primary cancers) <p>6 patients were entered into clinical trials</p> <p>50% patients notes recorded that patients were offered choice of intravenous or oral chemotherapy.</p> <p>13 patients did not receive 2nd line therapy, 4 patients had died, 9 patients not well enough for treatment.</p> <p>11 patients underwent 2nd line chemotherapy for metastatic disease</p> <ul style="list-style-type: none"> • 3 patients received single agent Irinotecan • 4 patients received Irinotecan in combination • 3 received Oxaliplatin in combination • 1 received Capecitabine. <p>3 patients were offered 3rd line therapy</p> <ul style="list-style-type: none"> • 2 patients received Oxaliplatin and Capecitabine in combination • 1 patient refused treatment <p>Of the 35 notes reviewed;</p> <ul style="list-style-type: none"> • 0 patients were identified as undergoing neo-adjuvant treatment prior to liver resection. • 1 patient underwent liver resection in 1999 • 1 patient underwent surgery in 2002. This patient was entered into the EORTC study comparing immediate surgery vs. primary chemotherapy with Oxaliplatin followed by surgery. Patient was randomised to immediate surgery. <p>Conclusion 35 notes reviewed;</p> <ul style="list-style-type: none"> • Oxaliplatin, Capecitabine and Irinotecan are integral to the SECN treatment protocols for colorectal cancer. The audit demonstrates appropriate use of these drugs in the treatment of advanced colorectal cancer. • Patients were selected appropriately to undergo chemotherapy according to their performance status and patient choice.
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4.	Dr Colin Trask	The use of Capecitabine, Docetaxel, Paclitaxel, Vinorelbine in Advanced Breast Cancer	<p><i>Capecitabine: recommended in combination with Docetaxel where anthracycline containing regimen unsuitable or has failed; also Monotherapy is recommended as an option where drug previously not received in combination, or where anthracycline and taxane containing regimens have failed or contraindicated.</i></p> <p><i>Docetaxel: as an option for the treatment of advanced breast cancer where initial cytotoxic therapy (including an anthracycline) has failed or is inappropriate.</i></p> <p><i>Paclitaxel: as an option for the treatment of advanced breast cancer where initial cytotoxic therapy (including an anthracycline) has failed or is inappropriate.</i></p> <p><i>Vinorelbine: Monotherapy not recommended as a first line treatment for advanced breast cancer. Recommended as one option for second-line or later therapy when anthracycline based regimens have failed or are unsuitable.</i></p>	On going
5.	Dr Pauline Leonard	The use of Gemcitabine, Paclitaxel, or Vinorelbine, Docetaxel	<p><i>Gemcitabine, Paclitaxel and vinorelbine should be considered as part of first line chemotherapy options for advanced NSCLC. Combination</i></p>	<p>SECN</p> <p>20 notes reviewed so far.</p>

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		<p>in Lung Cancer</p>	<p><i>of these three agents individually with platinum based chemotherapy, where tolerated, is likely to be the most effective approach.</i></p> <p>Docetaxel: monotherapy should be considered where second line treatment is appropriate for patients with locally advanced or metastatic NSCLC when relapse has occurred after prior chemotherapy.</p>	<p>12/20 did not receive chemotherapy</p> <ul style="list-style-type: none"> • 6 patients were too unwell to undergo chemotherapy • 2 patients had other ongoing medical concerns that precluded them from chemotherapy, but underwent radiotherapy • 4 patients underwent radiotherapy. <p>8/20 patients offered 1st line chemotherapy</p> <ul style="list-style-type: none"> • 2 patient refused treatment • 6 patients underwent treatment with Gemcitabine and Carboplatin <p>Was 2nd line treatment offered to these patients?</p> <ul style="list-style-type: none"> • 2 patients died before completing 1st line treatment • 3 patients were too unwell to undergo 2nd line treatment • 1 patient subsequently received 4 cycles of Docetaxel <p>The audit demonstrates appropriate use of these drugs in the treatment of NSCLC. Patients were selected appropriately to undergo chemotherapy according to their performance status and patient choice.</p>
6.	Dr Alan Lamont	<p>The use of Paclitaxel, Pegylated Liposomal Doxorubicin, and Topotecan in Advanced Ovarian Cancer</p>	<p>Paclitaxel: women with ovarian cancer should be offered the choice of either Paclitaxel in combination with a platinum-based compound or a platinum based compound alone.</p> <p><i>Paclitaxel should be considered as second line treatment for women who have not received it previously as part of their second line treatment.</i></p> <p>Peg Lip Dox: Should be considered as one option for the second-line (or subsequent) treatment, where disease is</p>	<p>SECN</p> <p>Network policy to offer patient choice of treatment with Carboplatin or Carboplatin and Paclitaxel in combination as first line treatment.</p> <p>Audit demonstrates 10% of patients choose combination treatment. Paclitaxel remains drug of choice for relapse disease.</p> <p>Further relapse therapy identifies through TCA (Tumour chemo-sensitivity Assay) analysis.</p>

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			<p><i>initially resistant or refractory to first line platinum based chemotherapy.</i></p> <p>Topotecan: <i>Should be considered as one option for the second-line (or subsequent) treatment, where disease is initially resistant or refractory to first line platinum based chemotherapy.</i></p>		
7.	Dr Ayed Eden	Fludarabine in B-cell Chronic Lymphocytic leukaemia	Oral preparation recommended as second-line therapy for B-cell CLL, for patients who have failed or are intolerant of first line chemotherapy, and who otherwise would have received combination chemotherapy of either CHOP, CAP or CVP (COP)	<p>BASILDON HOSPITALS 11 patients highlighted that were diagnosed between July – December 2003.</p> <p>Case notes were reviewed.</p>	<p>BASILDON HOSPITALS</p> <p>a) 91% (10/11) complied with the NICE guidelines - 64% (7/11) were left to watch and wait and 27% (3/11) were treated with Fludarabine second line.</p> <p>b) 9% (1/11) did not comply with NICE guidance because they were on the CLL5 trial. They were randomised to start Fludarabine first line</p>
				<p>SOUTHEND HOSPITAL</p> <p>5 patients diagnosed between July and December '03.</p> <p>July '02 – June '03 9 patients diagnosed</p>	<p>SOUTHEND HOSPITAL</p> <p>80% (4/5) were on 'watch and wait' 20% (1/5) received Fludarabine as second line treatment</p> <p>77% (7/9) remain on surveillance 11% (1/9) remains in remission after 1st line therapy 11% (1/9) Was not suitable for Fludarabine after first line therapy and therefore received Aletuzimab.</p>

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8.	Dr Alan Lamont	Temozolomide in malignant Glioma	<p>Recommended for recurrent disease who have failed first-line chemotherapy.</p> <p>Not recommended for first line chemotherapy outside the context of a clinical trial</p> <p>Not licensed for adjuvant treatment of malignant glioma.</p> <p>Identify from prescription records patients given CCNU (1st line Glioma treatment) in first 6 months of 2003 and review names against death. If patient lived longer than 2 months review notes</p>	<p>Basildon Hospital</p> <p>A total of 8 patients were diagnosed or admitted with grades III/IV glioma between January and June 2003 at Basildon hospital.</p>	<p>Basildon Hospital</p> <p>One patient who developed glioma secondary to cranial irradiation for ALL was treated with temozolomide since he was not suitable for first line chemotherapy. Two patients received dexamethasone and/or radiotherapy. All these patients were not suitable for chemotherapy. One patient was not suitable for any treatment. Four patients were treated with Lomustine, 3 died within 3 months of initiating treatment. One patient lived for 6 months during which she responded to Lomustine.</p> <p>Conclusions</p> <p>Only one patient received temozolomide because he was not a candidate for other chemotherapy following treatment for ALL. The rest of the patients who received first line treatment either responded to Lomustine or had a life expectancy of less than 3 months. Hence temozolomide treatment was not indicated as recommended by the NICE guidelines. These results show that NICE guidelines are being adhered to.</p>
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WORKING DRAFT – FOR CONSULTATION

				<p>Southend Hospital</p> <p>6 patients were identified from prescription records as having received CCNU.</p>	<ul style="list-style-type: none"> • 1 patient died from pulmonary embolus while responding to CCNU • 1 patient died after 2 cycles of CCNU • 1 patient died within 6 weeks of diagnosis not suitable for Temozolomide • 1 patient died within 1 month of disease progression not suitable for Temozolomide • 1 patient received 6 cycles of CCNU, patient deteriorated rapidly – patient request for low dose CCNU to continue. • 1 patient lived for 6 months after diagnosis during which she responded to Lomustine <p>• Conclusion Temozolomide treatment was not indicated for these patients as recommended by the NICE guidelines. These results show that NICE guidelines are being adhered to.</p>
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Acknowledgements

The members of the Essex County Council, Thurrock Borough Council and Southend on Sea Borough Council would like to thank the following people who provided invaluable help and advice throughout the scrutiny review:

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- Mr Kevin McKenny, Network Manager, South Essex Cancer Network
- Dr Richard Needle, Chief Pharmacist, Essex Rivers Healthcare NHS Trust
- Professor Mike Richards, National Clinical Director for Cancer
- Dr Colin Trask, Lead Clinician, South Essex Cancer Network
- Dr Paul Watson, Medical Director, Essex SHA

