

**Cancer Network Pharmacist Forum**

**A Report into the Uptake of Patient  
Access Schemes in the NHS**

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### Section One: Executive Summary

Patient Access Schemes (PAS) sometimes referred to as risk share schemes or market access schemes allow drugs companies to offer discounts or rebates to reduce the cost of a drug to the National Health Service (NHS). They are seen as a way of improving access to new medicines for NHS patients. It is essential that the benefits and costs of the PAS are assessed as carefully as those of the medicines themselves to ensure that they offer the NHS genuine value for money.

This research project aimed to assess the impact of the introduction of PAS for cancer medicines on front line NHS staff; identify any problems with current schemes; gain feedback on how the schemes are working in the real world; and identify what makes a good scheme. The research question was,

***‘What has been the impact on pharmacy of implementing Risk Share Schemes to improve access to cancer medicines in the National Health Service?’***

A survey using an on-line questionnaire as the data collection tool was used to offer a non experimental design that described reality. The survey gathered data on, uptake of schemes, impact on capacity and suggestions for improving schemes. The questionnaire asked about PAS for four specific cancer medicines that were in operation for at least 12 months between 2007 and 2009. The specific drug schemes were erlotinib (Tarceva®) (pre-NICE) for lung cancer, sunitinib (Sutent ®) for renal cell cancer or GIST, bortezomib (Velcade®) for multiple myeloma and cetuximab (Erbix®) for advanced colorectal cancer.

Data was collected from 31 Trusts including 756 patients entered in PAS, the research showed:

- Refunds for two of the common PAS were not being passed on to the funding PCT in 50% of cases
- The NHS currently does not have capacity to manage more PAS without funding staff time to manage, co-ordinate and track the schemes
- Funding needs to be found for staff time dedicated to tracking and managing PAS, preventing missed claims and reducing the risk to the NHS
- There is no one preferred scheme; however simpler schemes with fewer requirements for data collection and monitoring are preferred
- The development of a set of national standard templates for PAS to allow manufacturers to select a familiar ‘off the shelf scheme’ would benefit the NHS
- There is a need for flexibility around any time limits for processing claims, ideally at least 90 days should be allowed to process claims
- In general schemes linked to measurement of a clinical response, took longer to administer and were associated with more problems
- There should not be any pressure on Trusts and PCTs to adopt a PAS scheme pre NICE even if it has Department of Health approval. Local pre NICE decision making groups must be able decide if PAS are acceptable.

### Section Two: Introduction

Patient Access Schemes (PAS) sometimes referred to as risk share schemes or market access schemes allow drugs companies to offer discounts or rebates to reduce the cost of a drug to the National Health Service (NHS). They are seen as a way of improving access to new medicines for NHS patients. It is essential that the benefits and costs of the PAS are assessed as carefully as those of the medicines themselves to ensure that they offer the NHS genuine value for money.

Patient Access Schemes are not new; they were first developed in 2002 in response to a negative National Institute of Clinical Excellence (NICE) ruling on expensive new drugs for multiple sclerosis<sup>1</sup>. However it is in the last two years that PAS started gaining prominence and becoming more common. This was in response to high cost new medicines, often in cancer, being rejected by NICE as not cost effective for use in the NHS. This led to these medicines being unavailable for use by clinicians and patients and the pharmaceutical industry being unable to 'sell' their products, creating a great deal of political pressure and negative reporting in the media.

Drug pricing is a complex issue and is controlled in the UK by the Pharmaceutical Price Regulation Scheme (PPRS) which is an agreement between the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI). The PPRS is designed to ensure that safe and effective medicines are available on reasonable terms to the NHS and ensure the UK has a strong, efficient and profitable pharmaceutical industry.

The 2009 PPRS<sup>2</sup> recognizes that schemes have some value in improving the cost-effectiveness to enable NICE approval but states that there is a need to 'ensure that the cumulative burden on the NHS is manageable'. They also state that 'there is proper consultation with the NHS before such schemes are adopted' and that 'schemes should be the exception rather than the rule'.

The British Oncology Pharmacy Association (BOPA) issued a position statement on risk share schemes in March 2009 which summarized the issues around management of financial, governance and administrative risks<sup>3</sup>. In particular BOPA called for the DH take a lead in defining acceptable risk-sharing schemes and establish clear principles for their NHS-wide adoption.

NICE recently undertook a consultation on patient access and flexible pricing schemes as part of a review of the single and multiple technology appraisal processes<sup>4</sup>. In this NICE propose that manufacturers can submit a scheme after it issues an Appraisal Consultation Document (ACD) if the ACD is negative. This in effect allows manufacturers the chance to try for approval at full price and then have chance to "reduce" the cost. NICE propose to allow schemes to be submitted after final guidance is issued. The PPRS states access schemes should be exception rather than rule, however in oncology the use of schemes appears to becoming the norm. In England the DH has worked with NICE to set up a Patient Access Scheme Liaison Unit (PASLU) to examine the ability to implement (across the NHS) patient access schemes proposed by manufacturers as part of submission to NICE.

The Scottish Medicines Consortium (SMC) is investigating how it could assess and evaluate these schemes if they are to be incorporated within its assessments, currently SMC does not consider PAS.

There are many schemes currently on offer from manufacturers, most of which have been assessed by the Medicines, Pharmacy and Industry Group at the Department of Health. This assessment included informal consultation with NHS front line staff and commissioning experts. It was recognised however that a more formalized method for assessing these schemes was needed and hence the DH in conjunction with NICE formed PASLU.

Informal advice from the NHS experts to the DH when assessing schemes has been that whilst individual schemes may have a small impact, front line staff cannot manage multiple schemes all of which run in different ways. There is a call for standardization of schemes and an accurate assessment of the impact on staffing capacity to run the schemes. When the NHS has challenged the manufacturers on the capacity impact of these schemes it was found there was little or no evidence of the true capacity burden. This was one of the drivers for this research.

Pharmacy departments tend to lead on the introduction of new cancer medicines and hence have become heavily involved in both the assessment of and the implementation of PAS. It is recognized that the main burden running these scheme will fall on pharmacy, though there is also impact on doctors, nurses, and NHS finance staff.

### **Section Three: Aims and Objectives**

The Cancer Network Pharmacist Forum (CNPF) members agreed that a research project was needed to look at the impact of Patient Access Schemes on pharmacy in the NHS. The research question was:

‘What has been the impact on pharmacy of implementing Patient Access Schemes to improve access to cancer medicines in the National Health Service?’

The aims of the project were:

1. To assess the impact on pharmacy services of managing patient access schemes
2. To gain feedback from users of schemes on what factors are important in making a good scheme
3. To find out what if any capacity is needed to manage patient access schemes, specifically how much extra time is needed for each patient episode (prescription)
4. To compare four common schemes for oncology medicines

## **Section Four: Study Design and Methods**

### **4.1 Outline of Research Method Chosen**

A survey using an online questionnaire as the data collection tool was used to offer a non experimental design that described reality. The survey focuses on four key areas, uptake of schemes, feedback on specific types of schemes, impact on capacity and suggestions for improving schemes. The questionnaire asked about four specific schemes that had been in operation for at least 12 month between July 2007 and July 2009.

The specific schemes that data was collected on were.

- Erlotinib (Tarceva®) (pre-NICE) for lung cancer
- Sunitinib (Sutent ®) for renal cell cancer or GIST (DH approved)
- Bortezomib (Velcade®) for multiple myeloma (DH approved)
- Cetuximab (Erbix®) for advanced colorectal cancer

The questionnaire asked specific questions relating to the running of each scheme. There was a series of general questions about the schemes to allow comparison of schemes. Each scheme asked for an assessment of the time taken running the scheme per patient episode, given as a choice of 0 to 5 minutes, 6 to 10 minutes etc. In addition a subjective assessment of the rating of the scheme was required. This was to see if any one type of scheme was more favourable than the other.

Pharmacists from the North of England Cancer Network (NECN) helped to design the questionnaire. A pilot study of the nine acute Trusts within the NECN was undertaken to refine the questionnaire. The project was discussed at the CNPF meeting in June 2009, the questionnaire was reviewed and minor amendments made the following suggestions by the CNPF group.

The pilot and discussion with CNPF raised a few minor issues of clarity around the design of the questionnaire which was then amended accordingly e.g. menu options were changed. The pilot showed that the questionnaire took 15 minutes to complete on average.

The questionnaire consisted predominantly of closed questions of the Yes/No or select from a list variety. Where appropriate comments sections were included to gather qualitative data. The focus group proved useful in selecting areas for comments. A Likert scale was used in a questions assessing opinions on PAS.

### **4.2 Data Management and Analysis**

The online survey software 'Survey Monkey' was used as the data collection tool. Northumbria Trust and NECN have accounts with the software providers. The survey was accessed via a web link distributed electronically. Respondents simply clicked the link and were taken directly to the survey. Results were available for analysis online and were download into an excel spreadsheet database. Analysis was possible down to the individual response level to see the details of particular responses. The software facilitates comparison of open-ended questions.

### **4.3 Sample Selection**

The survey was distributed electronically using the British Oncology Pharmacy Association (BOPA) membership list. The BOPA list was chosen for convenience as it is the largest source of representation of oncology pharmacists who were the key audience for the survey. Pharmacists were asked to either complete the survey themselves or pass on to the pharmacist most involved in PAS in their Trust. Respondents were emailed in July 2009 and then reminders sent 6 weeks later in August. The survey was closed to respondents in mid September 2009.

This gave a sample size of 131 NHS Trusts in the UK. The sample size in terms of number of individuals sent the questionnaire was larger as many Trusts have more than one BOPA member. In addition the members of the CNPF group were asked to promote the questionnaire.

### **4.4 Literature Review**

A literature review was undertaken using the following data sources for articles relevant to the area of study using Athens Authentication to access Clinical Evidence electronic databases at National Library for Health NELH <http://www.library.nhs.uk/Default.aspx>

- PubMed
- Medline and Embase electronic databases (from 1996 to December 2007)
- The Cochrane Database Of Systemic Reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Proceedings of ASCO and ESMO via their website archives.

Search terms used; Risk Share; Risk Share Schemes; Patient Access Scheme; Drug Pricing Schemes;

### **4.5 Study Limitations**

The estimate sample size was 131; a return rate of 28% was achieved. Given the return rate it is not possible to draw firm statistically significant conclusions about the impact of PAS across the entire UK from the data collected. It must be recognized that practices at sites that did not respond may differ from those that did with a resulting affect on the data set outcomes.

The results do not capture the views of nursing, medical staff or finance staff, as it was felt that pharmacy departments were responsible for co-ordinating the introduction of new medicines in organisations and therefore for leading on the implementation of PAS.

The survey focused on secondary care, the views of Primary Care Trusts (PCTs) on PAS were not sought. It is recognised that further research is needed to examine the impact of PAS on PCTs.

**Section Five: Results**

The results are presented as both quantitative data and qualitative data

**5.1 Respondents**

A total of 64 responses were received. Of these 3 were excluded as due to lack of data completeness leaving a total of 61 responses for analysis. Note not all respondents completed all questions.

Responses were received from 37 NHS Trusts. It was expected that there would be multiple replies from each Trust as different members of staff are involved and it was deemed important to get different perspectives.

This gave a response rate of 28% of target NHS Trusts. (37 out of 131)

**Table One List of Trusts who responded**

Blackpool Fylde and Wyre Hospitals NHS Foundation Trust	Northumbria Healthcare NHS Foundation Trust
Brighton & Sussex University Hospitals NHS Trust	Nottingham University Hospitals NHS Trust
City Hospitals Sunderland NHS Foundation Trust	Private sector Hospital unnamed
Colchester Hospital University NHS FT	Royal Cornwall Hospitals Trust
County Durham and Darlington NHS FT	Shrewsbury and Telford Hospitals NHS Trust
Derby Hospitals NHS Foundation Trust	South Devon Healthcare
East And North Herts (Mount Vernon)	South Tees Hospitals NHS Trust
East Kent Hospitals University NHS FT	South Tyneside NHS Foundation Trust
East Lancashire Hospitals NHS Trust	St Mary's Hospital Isle of Wight
Gateshead Health NHS Foundation Trust	Trafford Healthcare NHS trust
Kettering General	University College Hospital London
Lancashire Teaching Hospitals NHS FT	United Lincolnshire Hospitals NHS Trust
Mid Essex Hospitals NHS Trust	University Hospitals Of Leicester
Milton Keynes Hospital NHS Foundation Trust	University Hospitals Of Morecambe Bay NHS
Newcastle upon Tyne Hospitals NHS FT	West Middlesex University Hospital
North Cumbria University Hospitals NHS Trust	Western Health and Social Care Trust N Ireland
North Tees and Hartlepool NHS FT	Weston General Hospital
North West London Hospitals NHS Trust	Whipps Cross University Hospital
Northampton General Hospital	

*Role of Respondents*

Responses were predominantly from clinical (51%) then aseptic staff (25%), purchasing staff and chief pharmacists.

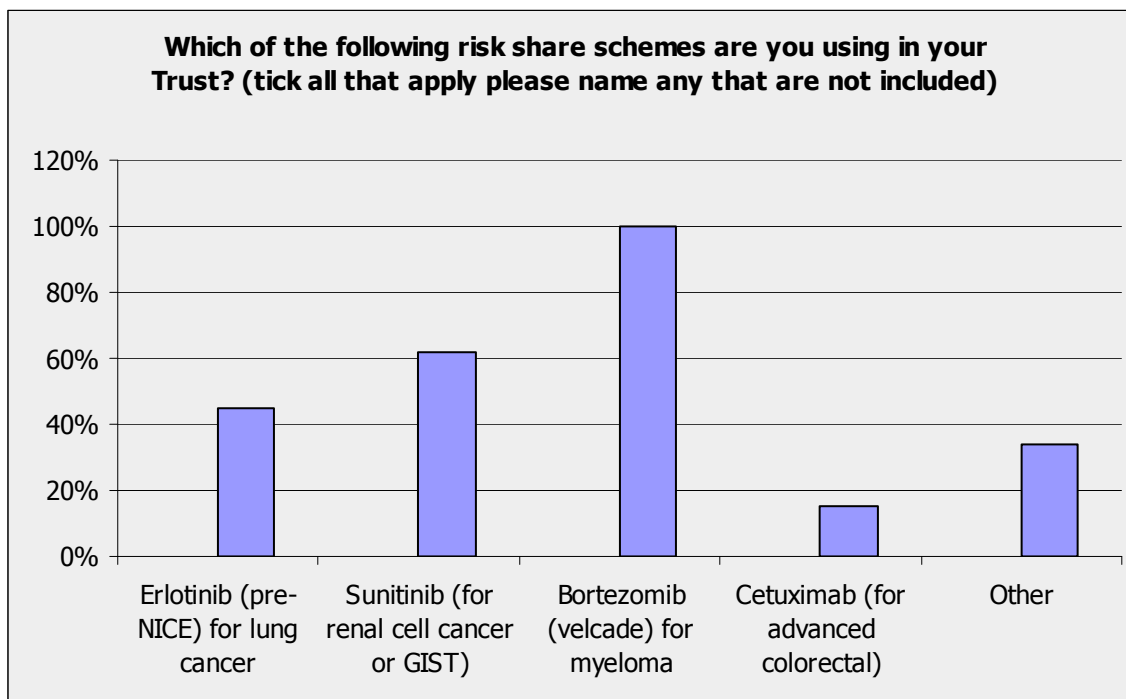
**Table Two: Respondents Job Roles**

<b>Please indicate your position:</b>	<b>Response Count</b>	<b>Response Percent</b>
Purchasing Pharmacist/Technician	9	14.8%
Aseptic Pharmacist/Technician	15	24.6%
Clinical Pharmacist/Technician	31	50.8%
Chief Pharmacist	3	4.9%
Other	3	4.9%
<b>TOTAL</b>	<b>61</b>	

## Section 5.2 Uptake of Schemes

Of the 61 respondents 45 indicated that one or more of the four schemes were running in their Trusts. The scheme with the greatest uptake was bortezomib (100%) followed by sunitinib then (62%) erlotinib (45%) then cetuximab (15%).

Chart One: Uptake of Schemes



Sixteen respondents indicated they were using schemes for other drugs, the drugs listed were:

- Lapatinib (Tyverb) for breast cancer
- Lenalidomide (Revlimid) Multiple Myeloma
- Pemetrexed (Alimta) for NSCLC
- Ranibizumab (Lucentis) for macular degeneration
- Sorafenib (Nexavar) for liver cancer

Question 2 asked how many patients have received the drug since the risk share scheme was introduced.

Table Three: Number of patients Affected by Schemes

Approximately how many patients have received the drug since the scheme was introduced?	Number of Patients (to July 09)
Erlotinib	180
Sunitinib	278
Bortezomib	295
Cetuximab	3
<b>TOTAL</b>	<b>756</b>

## Section 5.3: Comment on Individual Schemes

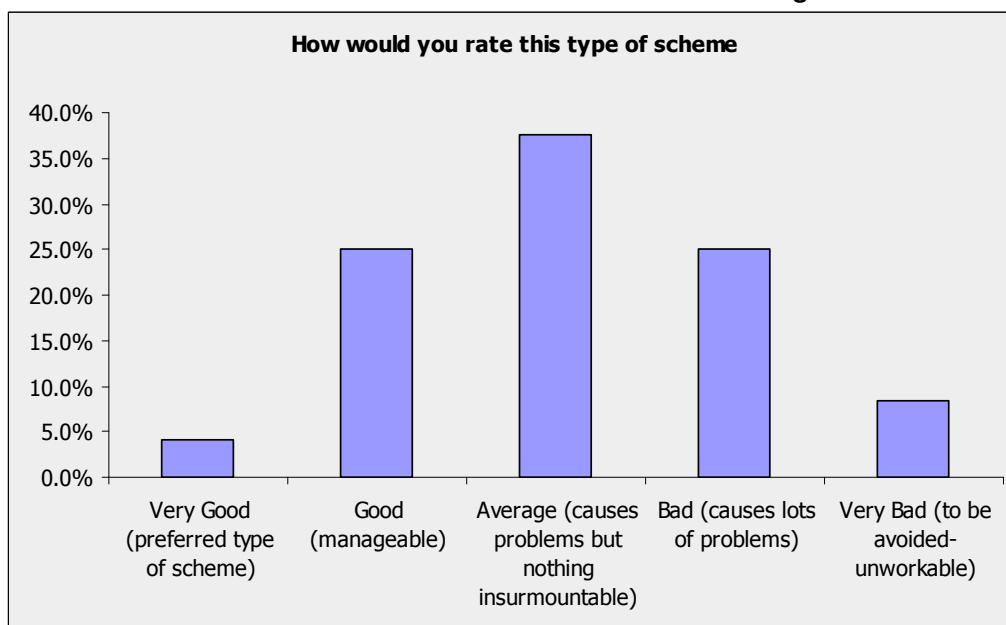
### 5.3.1 Erlotinib TAP

This scheme has an automatic discount as credit note supplied against orders of erlotinib and or other Roche medicines by agreement and should have been credited automatically by Roche.

Q1 Average time per patient was calculated at **17.5 minutes**.

Q3 The subjective ratings for the scheme were evenly grouped around average.

Chart Two: Erlotinib Scheme rating



### Comments and Rating

Respondents were asked for comments on this scheme (Q2) replies included;

- *Difficult to administer retrospectively*
- *An untidy way of doing business. The benefits of savings difficult to pass onto the directorate involved.*
- *Without doubt the best!*
- *This is not a true risk share. It is a back door discount. It is very simple to manage - but doesn't really share any risk with anyone.*
- *Extremely difficult to maintain monitoring of systems which invariably are manual and can not easily be tracked regardless of how well the system is set up initially*
- *Created some accounting issue with regards to credit note.*
- *How are we expected to pass this onto the PCT? Our supply process will automatically charge the PCT for all erlotinib that is dispensed. It creates a lot of work to actually identify these patients so the cost is not passed on.*

- *The use of a credit note scheme represents a logistical nightmare as the credit will be applied to the next order to the wholesaler and as a result may well be applied to the purchase of other drug line(s) This then falsely depresses the purchase price of other lines on Trust stock control systems and makes it virtually impossible a) For computer systems to assign the savings to the intended drug b) Allow pass through of the savings to a PCT on an individual patient basis if current funding is based upon tariff exclusion and pass through to the individual patient's PCT*
- *Credit notes are difficult to manage since not attached to drug orders*
- *On balance the scheme would have improved access to Erlotinib Pre-NICE but we had no eligible patients during that period.*
- *Problems with need to pass credit note against correct drug or savings not attributed to correct directorate.*

### **5.3.2 Sunitinib for renal cell cancer and GIST**

This scheme has the first cycle free and then a 5% discount on list price. The scheme required each patient to be registered with a form sent to manufacturers and free stock supplied for the first cycle.

#### ***Scheme Specific Questions***

- Q1 The average time per patient was calculated at **19 minutes**
- Q3 95% of respondents stated the pharmacist was responsible for ensuring patient registration form was sent to Pfizer:
- Q4 In only 38% of cases was the registration form filled in by the consultant and sent to pharmacy
- Q5 Asked how the claim forms were reconciled with free stock, the majority 50% reported a paper based filing system, though 25% did not keep records.
- Q6 This questions asked how the refund (free cycle) was entered onto the pharmacy system. The majority of respondents indicated that the free stock was added on stock at zero cost.
- Q7 Respondents indicated that they were not able to ensure refund was matched to and individual patient.
- Q8 Asked if the discount was passed on to PCT who funded the drug, this was only confirmed in 47% of cases.

#### ***Comments and Rating***

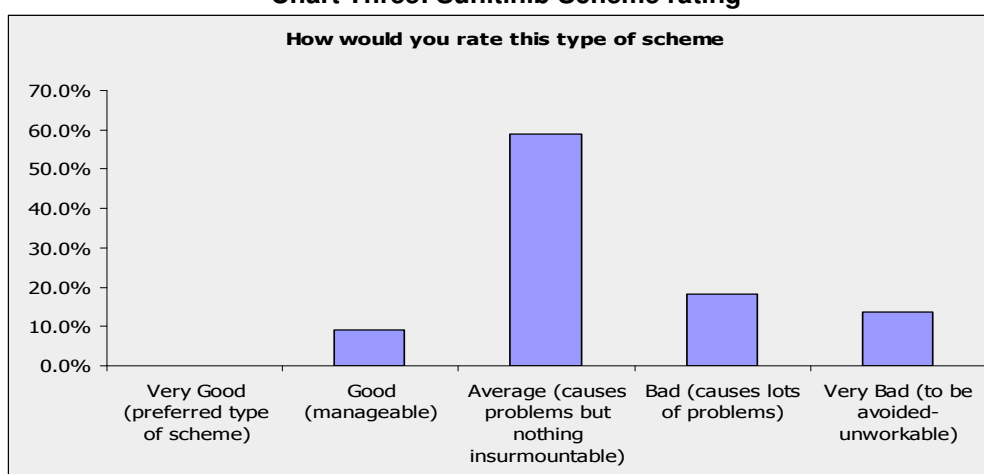
Respondents were asked for comments on this scheme (Q2) replies included;

- *Consultants were initially very good at completing form. Enthusiasm wore off after about 6 months. It isn't in anyone's job description to chase the clinician to complete the form so it rarely gets done.*
- *Unworkable scheme. Cannot show true cost per patient as free stock supplied retrospectively. Also free stock is supplied in the form of a credit note against a previous invoice. Cannot separate out free stock from normal supplies.*
- *Prefer discounted price. Quite a lot of form filling required by pharmacy staff and medical staff to obtain information and therefore discount from company.*
- *The scheme requires quite complex patient level data to be matched against order/invoice numbers which is far to complex. Patient initials, DOB, dose, date of 1st cycle should be sufficient. Use of order numbers is irrelevant as due to numbers the drug is ordered as stock and allocation is purely arbitrary. Each month I spend about half a day sorting out risk share and cleaning up data (removing 1st cycle pts) for the finance dept to recharge.*

- *Free stock is difficult to upload onto our Stock Control Computer System (JAC)*
- *Easy to apply. Free stock invoices easier to manage. Cost per drug evens out. OK provided all drug used by one speciality so see benefit of free stock*
- *I have to identify the patient, complete the forms chase up the prescriber for signatures then send off and again how do we pass this saving onto the PCT with the systems in place.*
- *Difficult to assess the cost of managing the scheme as the clinical team are really only registering the patient with Pfizer. I have no idea how long it takes purchasing/finance to subsequently untangle things at a later date - indeed whenever I've asked I am yet to be confirmed that the credit has come back to the Trust*
- *Requires good communication with consultants*
- *As a one-off at the start it seems to be easier to manage from a pharmacist point of view*
- *Very complex - since the credit note is not patient specific so can be difficult to confirm which patients have had first cycle free. Also due to timing of credit it can't be linked to the drug cost so has to be manually adjusted to the drug budget.*
- *not ideal - better to get discount at source*
- *we set discounted price on the pharmacy computer and wait for credit note before passing invoice*
- *This is not a true risk share. It is a back door discount. It is very simple to manage - but doesn't really share any risk with anyone.*
- *without doubt the best!!!!*
- *untidy way of doing business. the benefits of savings difficult to pass onto the directorate involved. I have included time for identifying the patient PCT in order to calculate any credit they may be given*
- *difficult to administer retrospectively*

Q9 The subjective ratings for the scheme were average (58%) with some respondents (30%) indicating they thought the scheme bad or very bad.

**Chart Three: Sunitinib Scheme rating**

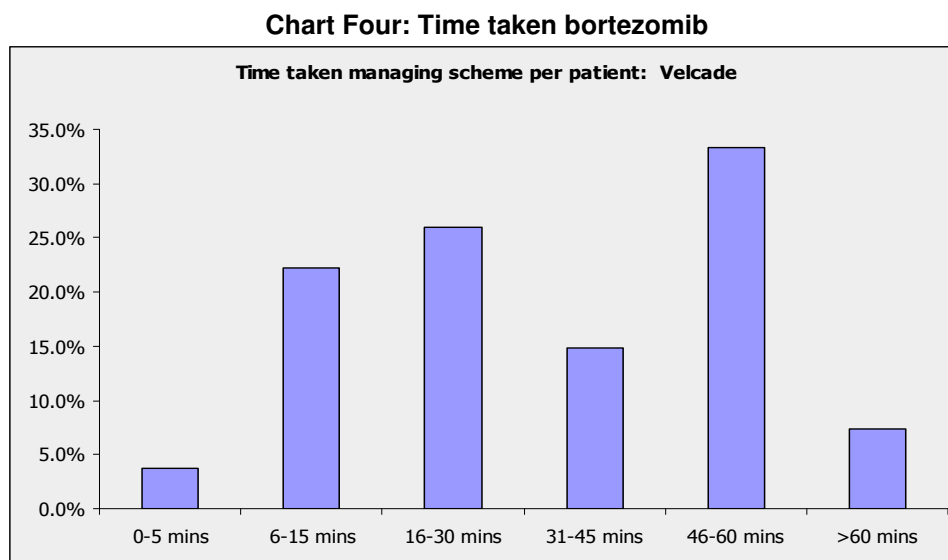


### 5.3.3 Bortezomib (Velcade) for Multiple Myeloma

In this NICE endorsed scheme patients have a biomarker of response to drug measured (serum M protein) if patient hasn't responded after 4 cycles a 'refund' can be claimed, but all claims must be made within 60 days.

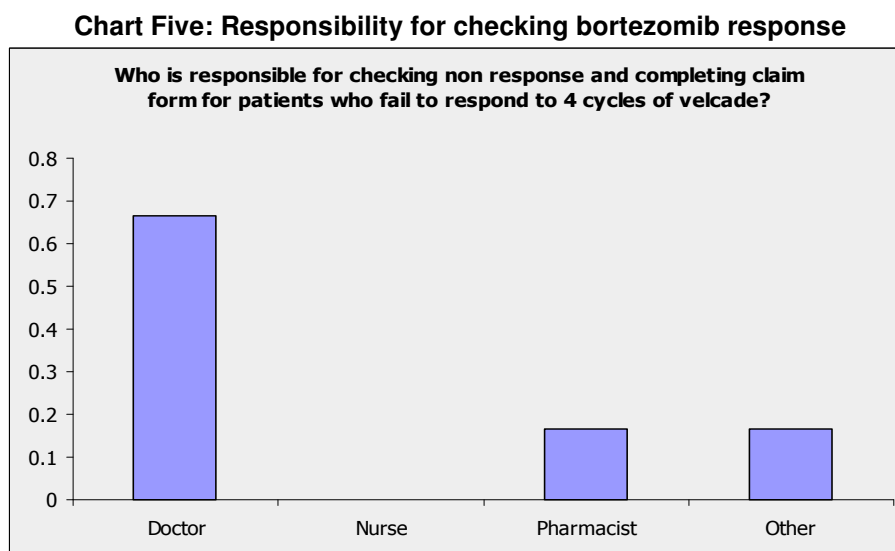
#### **Scheme Specific Questions**

Q1 The time taken to run this scheme showed considerable variation, averaging out at time **37.5 minutes** per patient



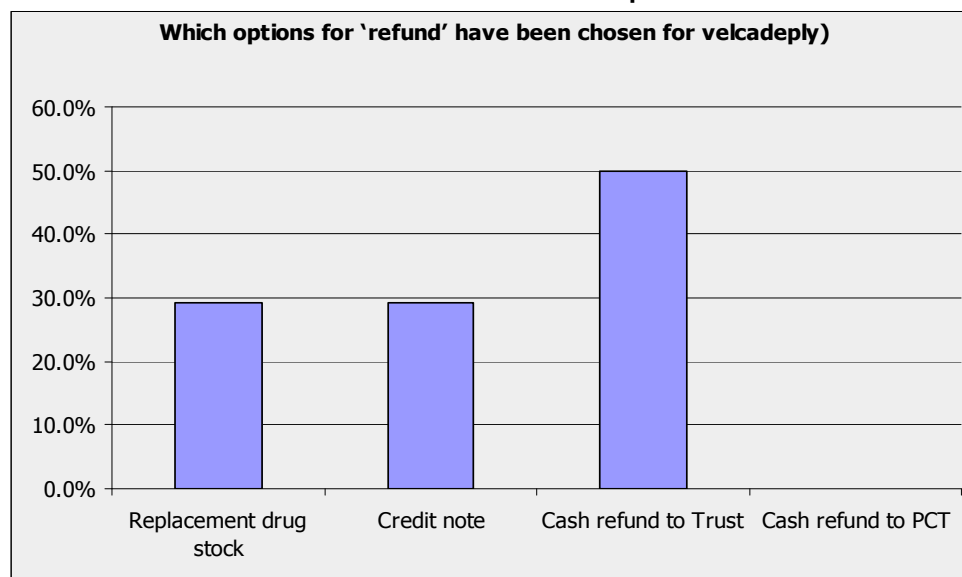
Q3-4 When asked how many patients had not responded after 4 cycles and how many claims were then submitted, the majority of respondents could provide an answer to number of patients, average 2 patients per Trust. But the same respondents could not then verify how many claims had been submitted. There was a lack of data completeness to the answers to these questions.

Q5: Asked who was responsible for checking response and completing claim forms the role of the doctor in this scheme was highlighted.



- Q6 When asked if all refunds had been received only 55% of respondents were able to report they had.
- Q7 The scheme offered the choice of 'refund', either as replacement stock, a credit note or cash refund. All options were used.

**Chart Six: Velcade refund options**



- Q8 When asked how the refund is entered onto pharmacy system, most respondents were either unsure; or indicated this was done manually; or said it was left to the Trust finance department.
- Q9 When asked how they ensured the refund is matched to patient, most respondents replied they were unable to do this.
- Q10 Asked if the Velcade discount was passed on to the funding PCT, this was only confirmed in 47% of cases.

### **Comments and Rating**

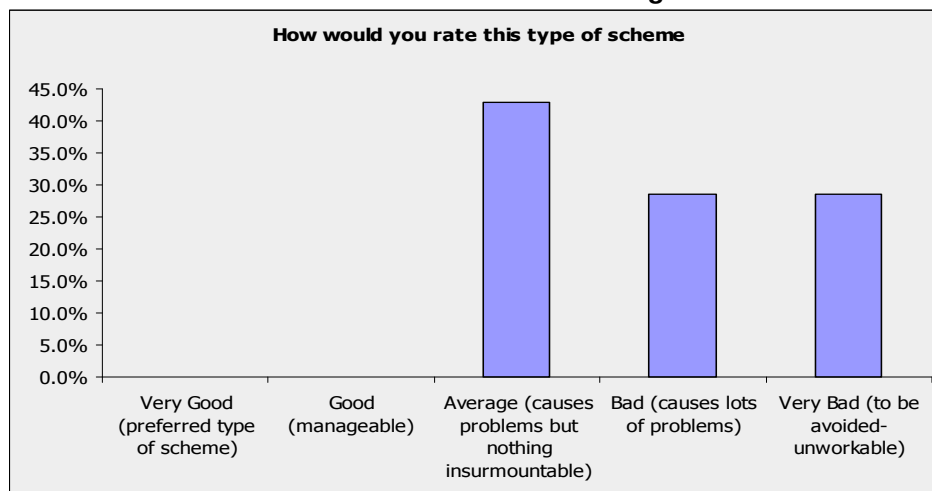
Respondents were asked for comments on this scheme (Q2) replies included;

- *Requires huge investment of time to monitor patients and ensure refund timescales met. As with sunitinib issues around assigning the rebate to patients and adjusting the drug budget/expenditure reports is a nightmare.*
- *OK but did not realise the 60 day rule, therefore missed claim!*
- *it seems to be the best scheme in terms of risk to the NHS but it is still cumbersome to pharmacy staff to keep track of events*
- *Relies on very good record keeping and honesty!*
- *Relies on good communication. Pharmacists are in clinic and have access to patient letters. If a patient hasn't responded, the refund is claimed*
- *Unfortunately, unable to really quantify how much time I spend on this kind of scheme. In addition, most patients developed complications and we were unable to show if a respond was reached*
- *Confusing!*

- *When the consultants want to initiate the treatment, we need to request them filling in the PBR (audit) form forward to PCT for approval. Then, we wait for confirmation from PCT to go ahead. When the patient started the treatment, e.g. Velcade, you have to keep track of the number of cycles, if they have stopped and does it entitled for VRS scheme. Then, asking for Serum M protein to be done, chasing up the consultant the claim form. It is a time wasting process.*
- *Straightforward - but the refund went into the general drug budget - not against the drug line as would alter the average cost of the drug on the system*
- *There is a lack of continuity in the clinic making it a challenge to identify non-responding patients as a result, the pharmacy team now remind the MDT at the start of cycle 4 of the need to assess response etc. This is a step in the right direction but still potentially misses patients who do not get as far as 4 cycles treatment (for whatever reason)*
- *Real pain. If vial sharing can't reclaim-but tracking if vial shared difficult. Huge population served by one big centre so typically 15 to 20 pts a week for treatment*
- *Very time consuming in keeping track of patients response. Claiming in time is imperative as company have refused to refund money as we did not submit claim form within time frame (this is not clear from their scheme).*
- *Very labor intensive as have to go and track down pt level data and clinician response / blood levels etc. Even tracking notes can take considerable time*
- *Good that have choice of options for 'refund'.*
- *Again have to work out how to reconcile free stock on computer system*
- *Some patients relapse at 4 -6 cycles, therefore little benefit but no refund!*
- *I am unaware as to whether the consultant would remember to inform pharmacy to claim the refund.*
- *Sometimes difficulty in meeting company deadlines, particularly if patients have been treated cross site - lost funding for 1 patient because of this*
- *Results shown response not available when patient attends for 5th cycle. Always have to go ahead with treatment then follow up when results come through.*

Q11 The subjective ratings for the scheme showed 60% thought it was bad or very bad and 40% thought it average. No respondents thought it good.

**Chart Seven: Velcade Rating**



### **5.3.4 Cetuximab for 2<sup>nd</sup>/ 3<sup>rd</sup> line metastatic colorectal cancer**

In this scheme weekly cetuximab is given, all patients are scanned patients after six weeks to evaluate tumour response. If patient has progressive disease (i.e. no response to treatment or no stable disease) the company will issue replacement stock or credit note if a 'Patient Reimbursement Form' is faxed within 5 working days of the scan.

#### ***Scheme Specific Questions***

- Q1 The average time per patient was calculated at **45** minutes
- Q3-4 Not enough data was gathered to give any meaningful response to questions asking how many patients have not responded after 6 weeks and how many claims were submitted.
- Q5 When asked who is responsible for checking non response and completing claim form all respondents replied pharmacists or combination pharmacist and doctor.

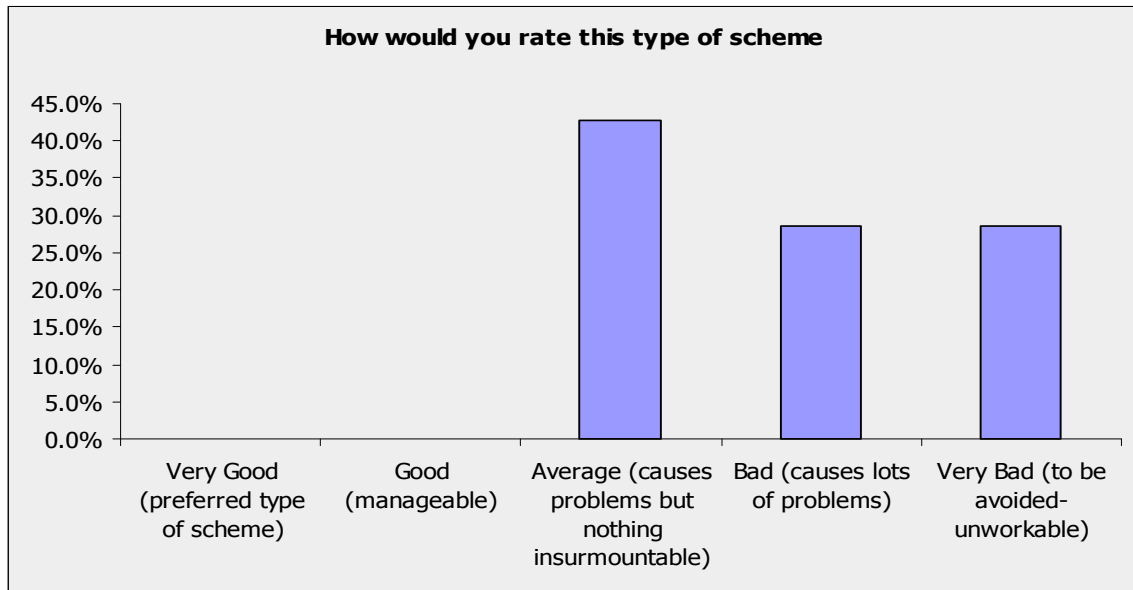
#### ***Comments and Rating***

Respondents were asked for comments on this scheme (Q2) replies included;

- *Difficult to work with*
- *Narrow time window for applying for refund!*
- *Not using as 5 days is quite a tight deadline*
- *It will be impossible to return form within 5 working days of scan, therefore leaving us at financial risk.*
- *5 working days is a joke-how is anyone supposed to keep track on an ongoing basis*
- *Not the sort of thing pharmacy know is happening (date of scan)*
- *difficult to manage retrospectively*
- *Not using but from the description above, this sounds like the VRS but the claim window seems incredibly tight, the time limit of 5 working days could cause issues*
- *Not running scheme or giving drug. The scans were not at the time where we would ordinarily scan the patient therefore seen as an additional scan.*
- *5 working days is not currently a good window to get these rebates - for your co-ordinator to be on holiday would mean you lose out. Not ideal*
- *A labour intensive scheme, but with free stock we can at least book on to the pharmacy system and this will lead to an automatic price adjustment and therefore accurately impact on budgets/expenditure*
- *5 working days of a scan is IMPOSSIBLE to work with. Even 5 days after scan report is impossible. That means no-one can take a week off without ensuring someone responds to scan results...*
- *Replacement / credit note of limited use if may not need free stock and company only sells a very narrow product range.*
- *very complex & difficult*

Q7 The subjective ratings for the scheme were 58% thought it was bad or very bad 42% thought it average no respondents thought it was good.

**Chart Seven: Cetuximab Rating**

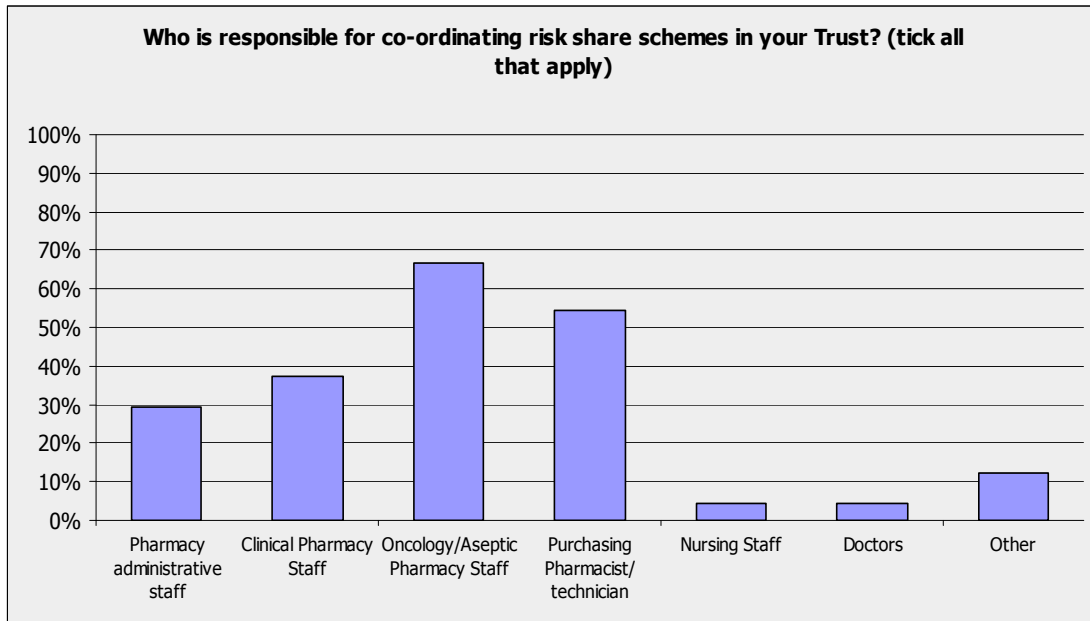


**Section 5.4: Results on questions on Capacity for Schemes**

Q1: 50% of respondents reported that they monitored capacity for schemes in their Trust.

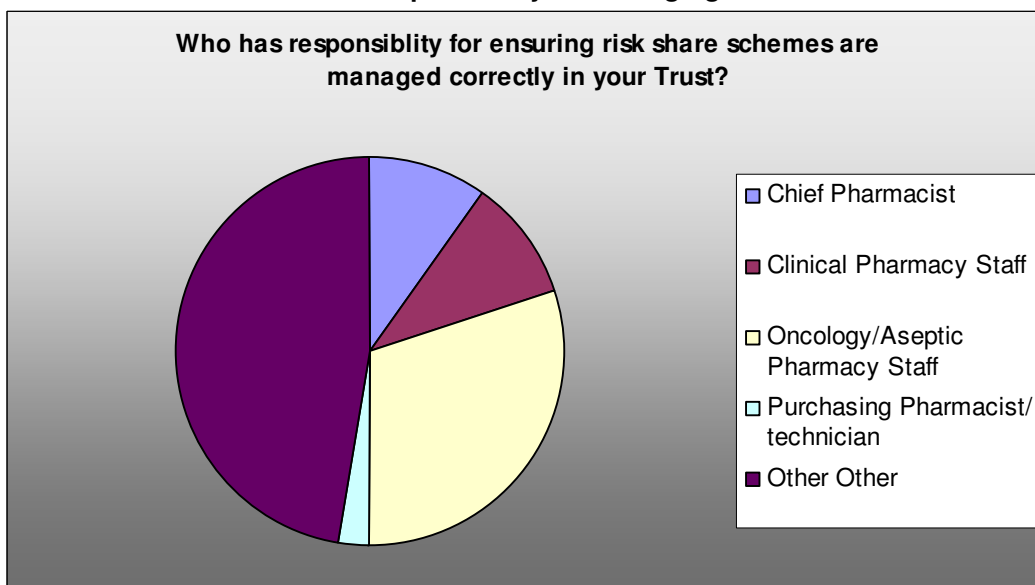
Q2: When asked who was responsible for co-coordinating schemes in the Trust, the majority of respondents felt it was either the pharmacy purchasing staff or oncology/aseptic staff. Other replies included, finance, medical secretaries, medicines management pharmacist or network pharmacist.

**Chart Eight: Responsibility for co-ordinating Schemes**



Q3: When asked who was responsible for managing schemes in the Trust, the majority of respondents replied other, to enable them to input specific job titles on analysis of responses felt it was either pharmacy purchasing staff or aseptic staff were most likely to be responsible.

**Chart Nine: Responsibility for managing Schemes**

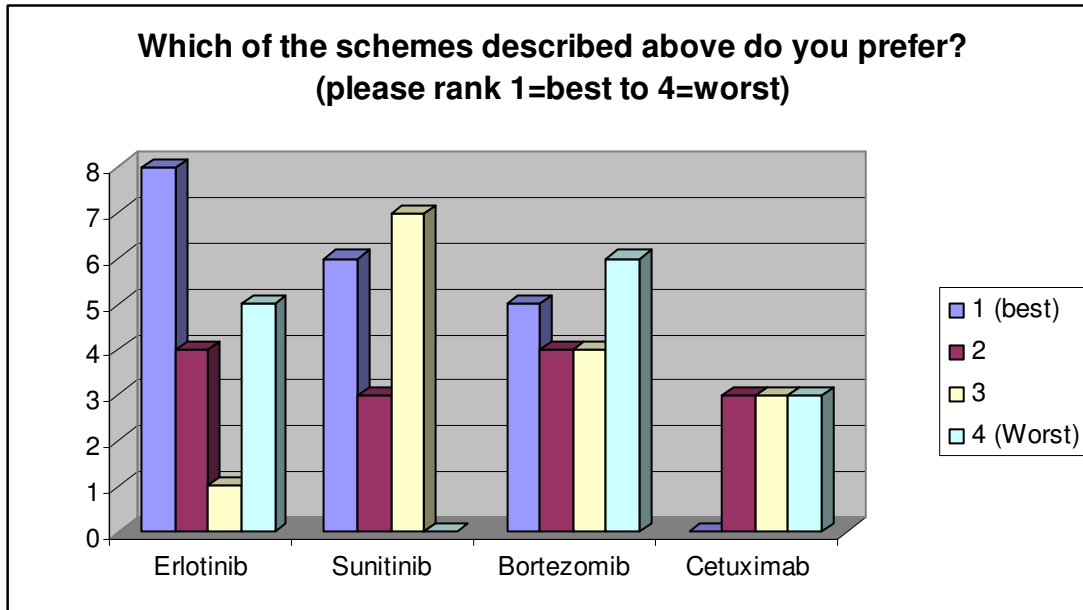


Q4: 73% of respondents reported that they did NOT have capacity to take on any more schemes. A variety of comments were received on what capacity would be needed to allow additional schemes; a selection of these comments is reported below

- *Someone based in Pharmacy to manage this.*
- *More admin time - the current focus of staffing cuts within this Trust.*
- *A spend to save pharmacy person employed to look at these schemes would ensure they are carried through to completion. I think this is glossed over*
- *At present can cope due to the small number of patients / schemes. If for example the lenalidomide use increases would need a member of staff to manage the scheme.*
- *increased A+C time*
- *Currently in debate with procurement and finance. Given the varied nature of schemes at present it is not a case of one size fits all within our organization and we are reaching a view that we have to assess and manage on a scheme by scheme basis*
- *Need overall structure to manage schemes*
- *Have had funding to appoint a technician to co-ordinate schemes*
- *Administrative support.*
- *Haven't got capacity to manage current schemes but they get done and other area's suffer*
- *Need pharmacy resource to put in for rebates etc and to monitor that it had been received. There seem to be so many different types of scheme running it would be better to have a standardised approach agreed. This would reduce pharmacy staff time on working out for each one how to handle credit/replacement stock or whatever option industry has decided*
- *Extremely under resourced for pharmacists*
- *Increase in admin staff with an understanding of oncology! In reality this will be technicians*
- *Allocated pharmacy funded staff. Currently only 2 schemes in operation but will have significant impact as more come on board especially as all different types of schemes.*
- *Staff dedicated to manage them*
- *There are no systems in place, as each is unworkable, a direct discounted price is needed.*

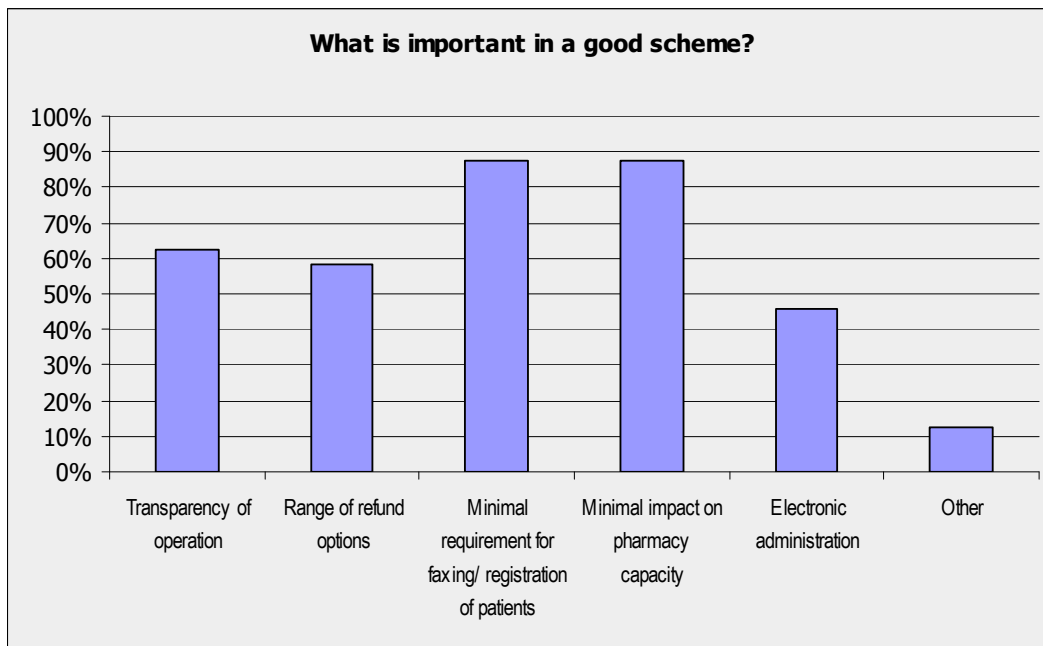
Q5: There was no consensus over which of the schemes was best or worse, although there was a trend towards the cetuximab and bortezomib being the worst schemes. The erlotinib scheme appeared to divide opinion most. This probably reflects the different way pharmacy computer systems are set up and local preferences.

Chart Ten: rating of Schemes



Q6 When asked what was important for a good scheme, minimal impact on pharmacy capacity and minimal requirement for registering patients are most important for a good scheme.

Chart Eleven: Importance features of a good scheme



Q7 This question asked for suggestions to manage the future implementation of schemes, a selection is listed below

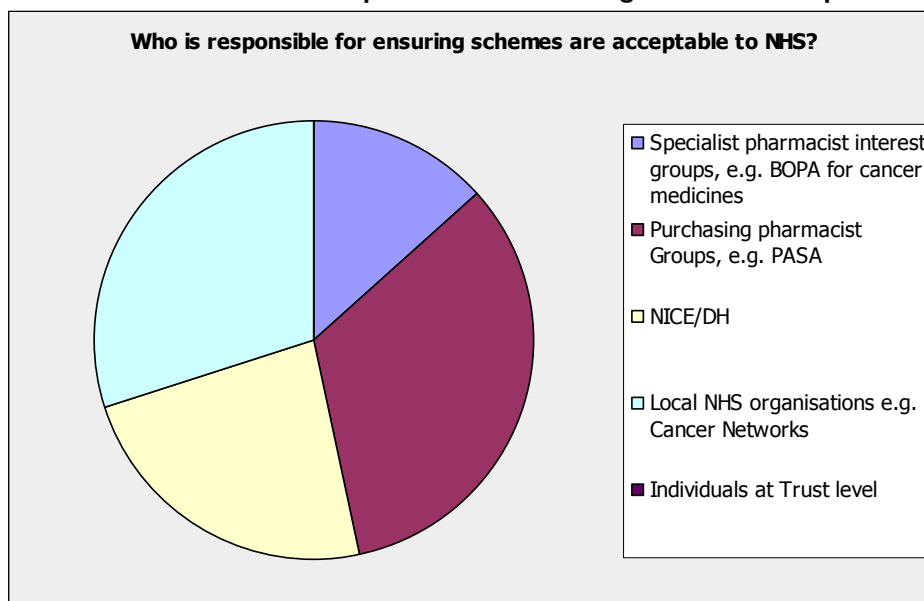
- *Future schemes should have minimal impact and MUST be taken into account by the NICE costing tool. Even then it is unlikely that any funding to support the additional time required by such schemes will be made available.*
- *Ideally all schemes should carry the same format, with the risk being more towards the company rather than the NHS.*
- *If electronic that they come with some data protection assurance- this has been a big issue for us. That minimal data is collected, and that an easy tick box entry is possible. NICE could consider staffing implications of schemes*
- *Should be looking to a scheme that shares the "risk" between pharma and NHS*

*All current schemes require the NHS to claim within a time window which places a risk on the NHS and then it is not always clear (when I have asked) to finance whether a refund has been received before it is then apportioned to the relevant PCT*

- *Prior consultation with end users especially clinical oncology pharmacy personnel*
- *We don't want to take on any more future schemes. This is a burden to the acute trust with no benefit to them directly, the PCT's benefit financially.*
- *At least 1st cycle free makes it easy for the NHS to calculate that it will get a discount. The lenalidomide model of 'pay after 2 years' is absolute rubbish. If their drug doesn't work then the NHS pays and if the drug is amazingly effective, they'll pay! Surely with a risk share, if it doesn't work they should make a contribution or else who shares the risk? So I don't mind 1st cycle free type schemes if they are easy to manage and require only basic, easily obtainable information. In terms of managing implementation there should be someone on the ground or group to advise DOH on acceptance of these schemes.*
- *Pharma should ideally be given a list of types of schemes that would be acceptable to NHS. The administrative burden of these schemes should be taken into account when reviewing and be reflected in guidance.*
- *The need to register the patient with the company is the most difficult part, so any scheme which stops this would be beneficial*
- *Pharmacy time needs to be resourced so that one individual can monitor these schemes*
- *Consistent approach for all drugs*

Q8 Responsibility for these schemes was felt to be a national issue with leadership needed from BOPA, purchasing pharmacists and DH.

**Chart Twelve: Who is responsible for ensuring schemes acceptable**



Q9 Finally we looked at preferences for future

**Table Four: Future Management of PAS**

Answer Options	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
Risk Share Schemes are an important way to secure access to high cost cancer medicines.	7%	43%	16%	9%	10%
Managing risk share schemes should be done by pharmacy as part of normal procurement function.	1%	33%	17%	23%	11%
Risk share schemes are here to stay- Trusts should just get on with them and not put barriers in way.	0%	15%	19%	35%	17%
Risk share schemes should not be accepted unless the capacity to manage them is properly resourced and has been included in the scheme.	41%	40%	1%	4%	0%
NICE and the department of Health should discourage the further spread of risk share schemes	21%	21%	30%	14%	0%
There should be a national DH approved template for Risk Share Schemes.	31%	44%	3%	6%	1%

### Section 6: Discussion:

#### 6.1 Adoption of Patient Access Schemes in the NHS

The wide spread use of Patient Access Schemes is a relatively new phenomenon. Consequently there is a lack of published evidence on the impact of these schemes on the NHS and on the ability of the NHS ensure the benefits of the schemes are maintained. The majority of recent publications are discussion/opinion pieces on the use of the schemes<sup>5,6</sup>. This research aimed to provide evidence to test the anecdotal opinion that these schemes were not being well managed within the NHS.

The concept of Risk Share Scheme has been established for some time, with reports of a pilot scheme in use in primary care using a statin for cholesterol control. Chapman et al (2003) reported on the benefits of working with the pharmaceutical industry on 'Outcomes Guarantee' where drug manufacturers agree to refund the NHS if a drug fails to meet agreed performance targets<sup>7</sup>. In this early version of a PAS patients were started on atorvastatin with the clinical aim of lowering LDL cholesterol below 3mmol/l. If the treatment did not for a particular patient, i.e. target cholesterol was not reached a financial rebate was made to cover the cost of prescribing.

The next major development was with beta interferon and glatiramer for multiple sclerosis in 2002/3. Following public pressure after a negative NICE decision, the Department of Health (DH) endorsed an MS Risk Share scheme<sup>8</sup>. This scheme was not without controversy, Sudlow and Counsell argued in the BMJ that the scheme would lead to many practical problems<sup>9</sup>. They also questioned the evidence for the scheme making these drugs cost effective stating that the scheme was 'scientifically unsound and impractical'. The experience of undertaking the monitoring study for the MS scheme was reported by Picken et al in 2009<sup>10</sup>. Their work focused on tracking clinical outcomes of patients enrolled into the scheme to ensure that the scheme was operating as intended and meeting predicted outcomes. They conclude that risk sharing schemes can deliver their objectives but that 'conflicts of interest remain in this highly controversial area'. They did not report on capacity to run the scheme or the impact on the NHS.

There was concern raised by the House of Commons Select Committee on Health on the benefit of PAS<sup>11</sup>. When reviewing top-up fees they reported they '*had serious concerns about the effectiveness of risk sharing schemes where they place the burden of proving the success of the scheme on the NHS and not on pharmaceutical companies*'. '*Risk-sharing schemes should be used with caution.*'

The first scheme endorsed by NICE for high cost cancer medicines was the Velcade Response Scheme (VRS) which was incorporated into their appraisal of bortezomib (Vecade®) for the treatment of multiple myeloma<sup>12</sup>. Patients who respond to bortezomib after four cycles continue the treatment fully funded by the NHS while patients who do not respond are taken off the drug and the cost of the drug refunded by the manufacturer. Response is assessed by measuring the serum M protein or other biochemical response markers (Bence-Jones protein excretion marker/BJP).

This means the NHS should only pay for the drug when it works. The average value of the drug claimed when refunding four cycles is approximately £12,198 (cost of 16 vials of bortezomib).

The acceptance of the Velcade scheme by NICE and the publication of the revised PPRS was seen to ‘open the door’ to the UK pharmaceutical industry to develop schemes for high cost medicines that would struggle to reach the costs effectiveness thresholds set by NICE. The NICE approach to Velcade generated interest globally with much debate on the relevance of industry developing clinically biomarkers that would support patient access schemes. For example in the USA reimbursement by insurers for erythropoietin stimulating agents is linked to patients achieving a specific haemoglobin level<sup>13</sup>. In the UK PAS schemes have gained widespread acceptance by the industry who acknowledge that there may be difficulties in developing all products and ‘risk-sharing plans may become a staple feature of the market in the future’<sup>14</sup>.

Use of PAS is part of a series of measures designed to improve access to high cost cancer medicines. In his November 2008 report to The Secretary Of State for Health, the National Cancer Director recommended that the DH should work with the pharmaceutical industry to promote more flexible approaches to the pricing and availability of new drugs<sup>15</sup>. The impact of PAS and can already be seen, table five below show lists cancer medicines approved by NICE since 2009 where use of a PAS has helped make them cost effective. We can see that out of the seven appraisals use of PAS has allowed four to be approved that otherwise would not. Note the end of life guidance from NICE has also had an impact on some of these appraisals.

**Table Five: NICE Appraisals outcomes since Jan 09**

<b>Date</b>	<b>Drug</b>	<b>Title</b>	<b>Access scheme ?</b>	<b>Approved?</b>
Oct 09	Topotecan	Cervical cancer (recurrent)	No	Yes
Sept 09	Sunitinib	GIST	Yes	Yes
Sept 09	Pemetrexed	Lung cancer (non-small cell, 1st line)	No	Yes
Aug 09	Cetuximab	Colorectal cancer (1st line)	Yes	Limited
Jul 09	Rituximab	Leukaemia (chronic lymphocytic, 1st line)	No	Yes
Jun 09	Cetuximab	Head and neck cancer (squamous cell carcinoma)	No	No
Jun 09	Lenalidomide	Multiple myeloma	Yes	Yes
Mar 09	Suntinib	Renal cell carcinoma	Yes	Yes

### 6.2 *Issues with Specific Schemes*

#### 6.2.1 *Erlotinib*

Of the four schemes studied in this work, the simplest was perceived to be the erlotinib (Tarceva) TAP scheme. We found that it took on average 17.5 minutes of staff time to administer the scheme per patient episode. It was perceived as the best of the four schemes as it was the simplest to operate since there was no need for tracking of forms for individual patients as a discount in form of credit note was processed automatically by the manufacturer. The problems encountered appeared to be general problems with handling credit notes and maintaining financial flows. This scheme was abandoned when NICE approved erlotinib in November 2008 and was replaced by a straightforward discounted price.

#### 6.2.2 *Sunitinib*

The next scheme studied was Pfizer's scheme for sunitinib (sutent) for renal cell carcinoma initially and subsequently for gastro intestinal stromal tumours (GIST). The responses to the sutent scheme highlight the difficulty of processing free stock and ensuring financial accountability. Pharmacy computer systems are not set up to handle free stock. This can have a detrimental effect on the average price of a drug and make the charging/ recharging of drug costs between trust finance departments and Primary Care Trusts (PCT) who pay for the cancer medicines very problematic.

The other recurring issue this scheme raised was the need for pharmacy to have good communication with the consultant starting patients on sunitinib. The success of the sunitinib scheme depends on the prescriber communicating with pharmacy and completing the claim form every time a new patient is started on the scheme. The results showed that in only 38% of cases was the form completed and sent to pharmacy by the prescriber. This shows the need for Trusts to put in place systems for prospectively tracking patients on schemes and for regular audit/ review to ensure all PAS patients have been registered and documentation completed.

It was troubling to learn that virtually none of the respondents were successfully managing to track the discounts and link the discount to a particular patient. This may explain why only half of respondents thought the PCT was receiving the discount. Those that knew PCTs were getting discount reported a variety of mechanisms for ensuring this happened. The common theme was they had a computer system that was able to highlight the free stock so that the finance department were able to identify the costs.

As an example of the financial risk to the NHS, a review of the costing template for NICE TA169 "Renal cell carcinoma – sunitinib" estimates that implementation of the scheme whereby the manufacturer funds the first cycle would save NHS England £7,224,890 per annum. This research suggests that for this single scheme only £3,396,398 may be getting passed on to PCT's, leaving £3,828,492 per annum unaccounted for at best and, at worst, left unclaimed by the NHS.

One of the good points on the suture scheme was the lack of time limit for making claims. Pfizer have indicated that at least two large cancer centres had not made any claims and ended up making retrospect claims for a years worth of first cycle refunds. This has promoted the company to review the scheme and there is suggestion that a time limit may be imposed. The perspective from the company is that retrospective claims cause problems with their financial targets and performance figures.

### 6.2.3 Cetuximab

There was not enough data gathered on the cetuximab scheme to draw any firm conclusions but opinion was unanimous that the restricted time period (5 days) for processing claims was unworkable. It appears the NHS needs great flexibility in being allowed to make claims retrospectively and a tight timescale for getting rebate will mean the schemes will not work.

The cetuximab scheme was also found to take significant amounts of time per patient episode, an average of 45 minutes. In general the two drugs with schemes linked to measurement of response, cetuximab and bortezomib, took longer to administer and were associated with more problems. This reflects the relative complexity of this type of scheme. In discussion with MerckSerono manufacturers of cetuximab it was found that the 5 day claim timeframe was not initially perceived to be a barrier by the manufacturer (personal communication Oct 2009). One possible explanation for this was that the scheme being adopted by PCTs and Trusts following prior approval for use of cetuximab. Approval of use of drug was not dependant on the scheme, the drug was approved for clinical reasons and the scheme was adopted after approval. This raises the important point that the NHS will inevitably take on any type of scheme if given no choice even if they cannot be managed and will hence not deliver the planned benefits.

### 6.2.4 Bortezomib

We gathered greatest amount of data on the bortezomib (Velcade) VRS scheme. This was to be expected as at the time of study it has been in operation the longest and was NICE approved, hence a must do for NHS Trusts. Like cetuximab this response based scheme took longer to administer, average 37.5 minutes per episode. The scheme has issues with tracking and ensuring all patients are stopped on bortezomib after non responders are claimed for. A key feature of the comments was the difficulty in pharmacists managing the scheme when they were not directly involved in the clinical management and testing of patient response. Those that were managing the VRS successfully had allocated a member of staff to track all patients manually and follow up on a monthly basis. This was noted as being a time consuming process and very labour intensive. The 60 day claim period was sited as being too tight, with some Trusts reporting missing claims. Further anecdotal reports received whilst this work was underway indicate that many centres have missed multiple claims for bortezomib, losing significant sums of income. What we are not able to provide is evidence for this as there is a political sensitivity regarding this issue, one respondent who did not wish to be named indicated that *'we have missed four velcade claims in our Trust but we cannot be seen to publicly admit to losing nearly £50,000 for fear of disciplinary action'*

It can therefore be seen that if the scheme and others like it are not managed effectively and claims are missed the NHS could lose significant income.

Janssen-Cilag the manufacturers of bortezomib have a slightly different view of the running of the scheme. They undertook some market research on NHS views on the bortezomib VRS Access Scheme which was published in a newsletter. They have highlighted that 'getting the best out of the VRS depends on good patient tracking and prompt submission of claims.'<sup>14</sup> The company has taken the implementation of the VRS seriously and its representatives have worked with pharmacy and their local NHS contacts to ensure the scheme runs smoothly, but there is only so much they are able to do.

The replies to this scheme indicated that Trusts did make use of the multiple methods of claiming refunds, stock, credit or cash. This supports the advice that all schemes should offer all three options for any refunds.

### 6.3 Capacity for Schemes

Capacity to run and manage these schemes is a major issue for the NHS. The bulk of the burden has fallen on pharmacy due to their role in medicines management and procurement. The research confirms that pharmacy staff have the major role in making sure these schemes work. However PAS also impact on nursing, medical, administration and finance department time.

There is a growing feeling that without funding being identified and staff allocated to manage schemes the NHS cannot take on any more schemes. 73% of respondents reported that they did not have capacity to take on any more schemes. There is a strong argument for funding staff to run schemes to ensure that no claims are missed and no income is lost. For a scheme such as the bortezomib VRS it can be seen that missing just two claims could cost £24,000, roughly equivalent to the annual salary of an NHS administrator/ clerical grade staff (AFC band 4 to 6). Therefore investing in staff to track and co-ordinate schemes could pay for itself.

The pharmaceutical industry make assumptions on how long schemes should take to manage and hence their impact on capacity. On the surface most of these assumptions appear sound, in that the schemes should not take too long as they only require filling in a form and routine monitoring of patients. However the clinical reality is much different. The research has highlighted NHS concerns on the ability of IT systems to process the rebates/ free stock / credits. It is well known that the NHS does not successfully collect data on cancer patients; the department of health is developing a mandatory chemotherapy data set to address this issue. It is not easy to monitor patients on schemes prospectively, the research showed that this has to be done by manually using laborious paper based tracking systems.

The research showed that there was no one scheme that was preferred, it appears the ability to successfully run a scheme depends on many local variables and can't easily be predicted. There will be no national scheme that suits all!

It is possible to model the amount of staff time that is needed to run a PAS, this can be done in various ways. For example a process map could be developed that outlines the tasks involved in each step of the scheme and works out the grade of staff needed for each step of the process, the time taken and the cost for that time. An example of a process map is given in figure 13 below. Some of the steps would only happen once when the scheme is set up, nonrecurring costs, others would happen for every patient on the scheme, recurring costs. The sum of these costs could then be used to produce a 'tariff' of running costs that could be built into the economic model. One consequence of this would be to change the economic model raising the scheme drug price meaning the industry would have to accept this extra cost if the scheme is still to meet the same cost effectiveness threshold.

**Figure Thirteen: Suggested Process map for Velcade patients**

1. Scheme registration /agreement signed off and sent to Janssen Cilag
2. Develop monitoring spreadsheet / filing system
3. Develop Procedures for running scheme
4. Training staff in managing scheme
5. Track patient each cycle /collate prescriptions
6. Check to ensure staff reminded to response with clinician after 4 cycles
7. Clinician checks response after 4 cycles
8. Decision made on continuing treatment
9. Claim form completed for non-responders
10. Completed claim form sent to Janssen Cilag
11. Staff to monitor how and when refund received
12. Refund checked against claim
13. Finance department process refund
14. Finance confirms receipt of rebate and advise pharmacy
15. Pharmacy monitoring /tracking system updated

Trust could then negotiate with their PCT to either receive direct funding for staff to manage the schemes, highlighting that this will benefit the PCT as it would ensure all discounts are received and passed onto the PCT. An alternative option would be for pharmacy to receive the tariff for each patient on a PAS, the greater the activity the greater the funding. Thought it must be noted that this option would generate variable income making it more difficult to fund staff on a recurrent basis.

80% of respondents agreed that risk share schemes should not be accepted unless the capacity to manage them is properly resourced and has been included in the scheme. Therefore it is crucial that the funding issue for staff be addressed if the schemes are to work.

Finally respondents indicated that there needs to be set of national DH approved templates for Risk Share Schemes. This would limit variation in schemes and allow the NHS to adapt to manage schemes that have similar design.

### Section 7: Conclusions

The general view from pharmacy was that they would rather not have PAS schemes and would prefer a straight forward discount. However being realistic it must be accepted that at present, there's little room for discussion about whether NHS should or should not accept these schemes, only about how they should and should not work. This research supports the view that these schemes are not working properly in the NHS.

Pharmacy departments believe the current schemes are too complex as they rely on patient level data which isn't collected as standard in the NHS and on retrospective rebates which can conflict with many NHS financial flows. This in turn means that much NHS staff time appears to be spent manually tracking patients, retrospectively adjusting stock control systems and ensuring financial systems account for the true cost of the drug. The variations between the different schemes add to this complexity.

The research shows that there is a lack of capacity to manage schemes which will both prove a barrier to implementation of further schemes and the efficient management of current schemes. There needs to investment in staff to implement and manage these schemes the local NHS. Funding for staffing must be built into the assessment of schemes by NICE and DH.

We must acknowledge that the NHS has its part to play in making these schemes work and that some of these difficulties could be overcome by better use of IT and a willingness to adapt to more modern ways of working.

The research showed that there appears to be a great deal of frustration with PAS and a desire to see improvements to the way the NHS, through NICE and the DH supports the implementation of these schemes. The formation of Patient Access Scheme Liaison Unit, PASLU, is seen as a positive step. Ideally PASLU will develop templates for standard schemes or at least agree a standard structure/ set of data/ principles for the schemes that industry should be asked to follow.

The purpose of PAS is to allow drug prices to better reflect value to NHS patients and increase access to cost-effective innovative medicines. This research shows that the NHS may be failing in delivering this worthy purpose and unless properly managed and supported the NHS will bear the financial risk of the schemes. The risk to the pharmaceutical industry is that the NHS will cease to accept PAS if they are not workable in practice.

It can only be in the best interests of the NHS, and the pharmaceutical industry and ultimately patients to work together to develop PAS that are robust, manageable and deliver what they promise, namely cost effective use of new therapies within the NHS.

## **Section 8: Acknowledgements**

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Members of the Cancer Network Pharmacist Forum

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David Thomson, BOPA Chair/ Lead Pharmacist, Yorkshire Cancer Network

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