Evaluation of Evidence Provided by PharmOutcomes New Medicine Service Data

The New Medicine Service (NMS) was commissioned nationally by the NHS in October 2011 for an initial period of 18 months, with future commissioning being dependent upon evidence of the effectiveness of the service being demonstrated.

PharmOutcomes is a multi-purpose web-based data capture system that allows community pharmacy to record and evidence service provision. The NMS module was available to all community pharmacies from the first day that the service was commissioned, with the purpose of helping capture the evidence necessary to support the case for commissioning of the service beyond March 2013.

This report summarises the key points arising from an analysis of the data for the first year of provision of the NMS.

Methodology

A preliminary series of three separate data extractions were performed on the system on 20th June 2012 to include all entries made – one concerning the registration and demographics of patients, a second concerning the intervention phase of the service and a third concerning the follow-up phase of the service with each patient. Data checks on data integrity, orphan records and missing data fields were made and adjustments made to the extraction process to correct any initial errors. This process will be available to future potential users of the data, such as other researchers, without any further work required. A final data extraction was performed on 1st November 2012 to provide the data for this study that encompasses a complete year of recruitment.

The three datasets were combined to provide a longitudinal view of each patient's journey through the system providing 106 variables. Throughout this analysis, only those records that were marked as complete and claimable under the NHS service specification were included. Mapping was carried out between the data fields and the data entry system on PharmOutcomes, which itself matches the NHS service specification, to ensure that the correct interpretation of the data was made.

At this stage, two analyses have been completed:

- Contingency tables and descriptive statistics matched to those matters identified with the patient, the interventions and agreed actions together with any healthy living advice; and
- A Multiple Linear Regression analysis on the patients engaging with the service to determine any independent factors in the local environment that might influence NMS uptake.

Data availability

There are a total of 236,408 medicines recorded on the system from completed NMS which represents a total of 224,554 patients recruited from 1st October 2011 to 30th September 2012.

As a comparator, for the period 1st October 2011 to 31st July 2012, which is the period for which NHS data is available currently, 418,744 NMS were claimed by community pharmacy contractors. 180,299 were recorded on PharmOutcomes as having been completed by this date which, therefore, represents 43.1% of all NMS completed.

Demographics

A variety of demographic data is collected by the PharmOutcomes system. The patients recruited to the service do not appear to favour a particular gender, as shown in Table 1.

Table 1 - Gender of patients recruited

Gender	Female	Male
Number of Patients	119,198 (53.1%)	105,356 (46.9%)

The ethnicity of recruited patients (where stated by the patient) is similar to the prevalence of ethnicity in England, as measured by the 2001 census although this did not meet the typical statistic significance (Student's paired t-Test, with a two-tailed distribution, $p = 0.077$).

17,639 (7.9%) patients declined to state their ethnicity,

Table 2 – Stated ethnicity of recruited patients

Ethnicity	NMS Patients (%)	2001 Census Prevalence	Difference between NMS patient % and Census data
Asian or Asian British – Any other Asian background	1,154 (0.6%)	0.5%	0.1
Asian or Asian British – Bangladeshi	733 (0.4%)	0.6%	-0.2
Asian or Asian British – Indian	4,550 (2.2%)	2.1%	0.1
Asian or Asian British – Pakistani	2,483 (1.2%)	1.4%	-0.2
Black or Black British – African	1,940 (0.9%)	1.0%	0.0
Black or Black British – Any other Black background	570 (0.3%)	0.2%	0.1
Black or Black British – Caribbean	1,519 (0.7%)	1.1%	-0.4
Mixed – Any other mixed background	444 (0.2%)	0.3%	-0.1
Mixed – White and Asian	239 (0.1%)	0.4%	-0.3
Mixed – White and Black African	227 (0.1%)	0.2%	0.0
Mixed – White and Black Caribbean	394 (0.2%)	0.5%	-0.3
Other Ethnic Groups – Any other ethnic group	1,069 (0.5%)	0.4%	0.1
Other Ethnic Groups – Chinese	531 (0.3%)	0.4%	-0.2
White – Any other background	3,254 (1.6%)	2.7%	-1.1
White – British	185,883 (89.8%)	87.0%	2.8
White – Irish	1925 (0.9%)	1.3%	-0.3

Recruitment method

Patients can be recruited by the pharmacist or pharmacy team directly, or they may be referred to the pharmacy by the GP practice. Table 3 illustrates the numbers and percentage of patients by referral method.

Table 3 - Method of entry into the NMS

Method of Entry into Service	Pharmacy recruitment	GP referral	Practice nurse referral
Number of Patients	223,573 (99.6%)	748 (0.3%)	233 (0.1%)

Examining where this may have been affected by local influencing and support from commissioners, local representative committees etc., the top PCT areas for referrals from GP practices are:

PCT area	% of referrals from GP practices
Derby City PCT	1.6%
Isle of Wight NHS PCT	1.6%
Hull Teaching PCT	2.5%
Suffolk PCT	3.6%
North Lincolnshire PCT	4.4%

Number of medicines covered by the NMS per patient

An individual patient may receive a number of NMS interventions, either as part of a single initiation of a number of medicines or as an escalation of therapy where new medicines are added over the course of the period examined. **Error! Reference source not found.** shows the number of medicines for which a patient has received an NMS Intervention.

Table 4 - Number of patients with a number of NMS Medicines

Number of Medicines	1	2	3	4	5	6
Number of Patients	214,211	9,074	1,056	187	23	3

Conditions

Four conditions have been selected for inclusion within the NMS and the recruitment rates for medicines contained within each condition group, as recorded via PharmOutcomes, are shown in Figure 1 and Table 5.
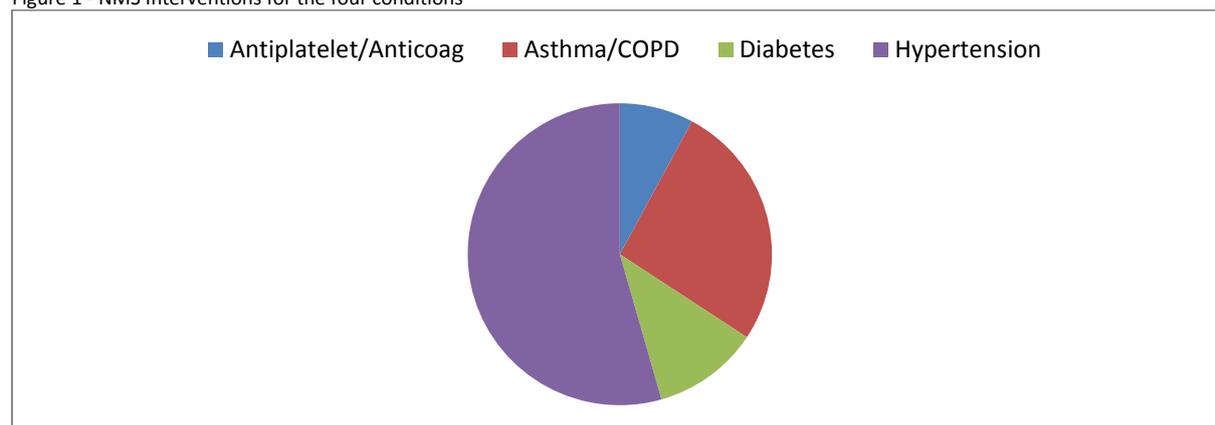
Figure 1 - NMS Interventions for the four conditions

Table 5 - Conditions related to NMS interventions

Condition	Antiplatelet/Anticoag	Asthma/COPD	Diabetes	Hypertension
Number of Interventions	18,607 (7.9%)	62,397 (26.4%)	26,766 (11.3%)	128,638 (54.4%)

Withdrawing from the service

Patients can elect to withdraw from the service at either the Intervention or Follow up stages. PharmOutcomes also records patients that are not contactable within this data field together with the ability for users to remove erroneous patient registrations.

Table 6 details the reasons for patient withdrawal from the service. This data is reported on a per medicine basis, not on a per NMS or per patient basis.

Table 6 - Reasons with withdrawal at intervention and follow up

Reason for Withdrawal	At Intervention	At Follow up
Patient could not be contacted	11	24153
Patient has withdrawn consent for information sharing	1	70
Patient has withdrawn consent to receive the service	3	795
Prescriber has stopped new medicine	16	5886
Remove Erroneous Patient Registration	12	1
Other	23	1758

This data indicates that patients very rarely withdraw consent for information sharing and rarely withdraw their consent to receive the service. The number not contactable at follow up is relatively low as a proportion of the number of medicines and probably less than anticipated, based on wider NHS experience of patient attrition from services.

Timing of the provision of Intervention and Follow Up

The service specification of NMS allows for flexibility in engagement with patients. The period from recruitment of the patient to the service to Intervention is stated to be typically between 7 and 14 days and then a further 14 to 21 days after the Intervention for the Follow up. The notable rises around the particular deadlines are clearly visible in the data shown in Figure 3.

Figure 2 - Period from Recruitment/Registration to Intervention to Follow up
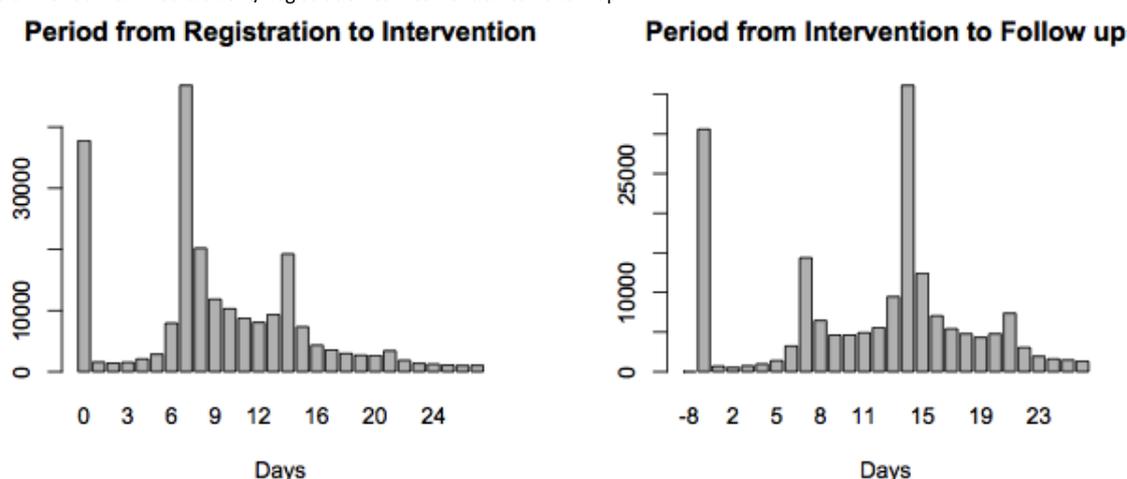
Independent variables linked to NMS provision

A variety of indicators were used to examine potential variables that may influence provision of NMS at a PCT level.

Table 7 - Multiple Linear Regression of Potential PCT-level Variables

Coefficient	Estimate	Std. Error	t value	P Value
Items Per Pharmacy Per Month	-0.0046	0.0021	-2.175	0.032 *
Index of Multiple Deprivations (IMD)	-0.7052	0.4000	-1.763	0.080
Percentage of Population with LTC	2.3792	1.2385	1.921	0.057
Percentage of Population Over 65	-1.8532	1.0626	-1.744	0.080
Percentage of Population Aged 15-64	-1.8490	0.8058	-2.282	0.024 *
Pharmacies Per 100, 000 Population	-0.2277	0.5905	-0.386	0.700
GP Full Time Equivalents	-0.0106	0.0116	-1.915	0.362
Enhanced Services Per Pharmacy	-0.3900	1.0692	-0.365	0.716
(Residual)	210.10	69.058	3.042	0.003 **

Significance Indicators: ***<0.001 **<0.01 *<0.0; Multiple R-squared: 0.09581, Adjusted R-squared: 0.035; F-statistic: 1.576 on 8 and 119 DF, p-value: 0.1390

These include the number of items per pharmacy per month, Index of Multiple Deprivation (IMD), the percentages of population over 65 and aged 15 to 64, the number of pharmacies per 100,000 head of population and the number of enhanced services per pharmacy. Multiple linear regression was used to find those variables that achieved a statistically significant influence on the number of NMS performed in each PCT (Table 7).

An assumption was made that those pharmacies active in delivering NMS had equiproportionate prescription numbers, as the individual pharmacy information is not available.

The results are largely what might be expected: pharmacies with a high prescription count have more opportunity to provide NMS (or are taking those opportunities more). Although not statistically significant, there is the indication that a higher incidence of long term conditions in a locality increases the opportunity to provide NMS.

The statistical significance of the influence of population below the age of 65 is an important observation as much diagnosis of long-term conditions which may become debilitating later in life are diagnosed earlier and it can be poor compliance which can be a factor in poor outcomes.

The very large residual indicates that there are other factors at play in the uptake of NMS beyond those examined in the environment.

Method of provision of the Intervention and Follow up

The ability to use telephone calls to provide both the Intervention and the Follow up is a key part of this service. The design of PharmOutcomes means that this was not set as a mandatory field for the full period of time during which the data was collected and so the data (Table 9) is only for those Interventions and Follow ups where this data was recorded.

Table 8 - Method of provision of the Intervention and Follow up

Condition	Antiplatelet/Anticoag	Asthma/COPD	Diabetes	Hypertension
Intervention in Pharmacy	2827	9440	4212	17976
Intervention by Phone	5646	21122	8265	36811
% by Phone	*67%*	*69%*	*66%*	*67%*
Follow up in Pharmacy	2254	6834	3365	14093
Follow up by Phone	5240	18566	7598	32654
% by Phone	*70%*	*73%*	*69%*	*70%*

Issues at the Intervention stage

For each medicine, whether being taken as prescribed or not, there were a variety of needs that the patient had and which were identified by the pharmacist, as shown in Table 9.

Table 9 - Needs identified at Intervention

Need Identified	Condition	Using as prescribed	Not using as prescribed
Need more information about the medicine	Antiplatelet/Anticoag	1397	73
	Asthma/COPD	3565	643
	Diabetes	1718	140
	Hypertension	6518	401
Side-effects	Antiplatelet/Anticoag	1721	226
	Asthma/COPD	4041	795
	Diabetes	4548	5013
	Hypertension	20175	2345
Negative feelings about the medicine	Antiplatelet/Anticoag	359	111
	Asthma/COPD	1467	747
	Diabetes	649	227
	Hypertension	3274	1097
Uncertainty whether the medicine is working	Antiplatelet/Anticoag	663	24
	Asthma/COPD	4843	719
	Diabetes	1542	84
	Hypertension	7606	281
Concern about remembering to take the medicine	Antiplatelet/Anticoag	191	13
	Asthma/COPD	447	147
	Diabetes	209	35
	Hypertension	772	89

Using the data in Table 5 and Table 9 to calculate the proportion of those patients affected by side-effects provides potential insight into patient attitudes to therapy and disease. The results of this in Table 10 indicate that asthma and COPD therapies have the lowest incidence of side-effects of the four. However, these side-effects cause non-adherence at nearly twice the rate of the other three disease states. Clinical experience indicates that this may be due to patient perception of the ultimate effects of their condition. Thus, the incidence of side-effects for patients on medicines that affect blood clotting is over 30% higher than that for the respiratory conditions; however the proportion of non-adherence is much lower than the latter. These patients will be aware that their condition has a very real risk of morbidity and mortality. Similarly, those patients with a diagnosis of diabetes or hypertension experience side-effects in nearly a fifth of cases but have higher adherence than those using a respiratory medicine.

The engagement with the patient around the understanding of their condition is therefore relatively more important in the respiratory cohort.

Table 10 - Adherence and Non-adherence caused by side-effects

Condition	Experiencing side-effects but using as prescribed	Experiencing side-effects so not using as prescribed	*Ratio of adherent:non-adherent
Antiplatelet/Anticoag	1721/18607 (9.2%)	124/18607 (0.7%)	13.9:1
Asthma/COPD	4041/62397 (6.5%)	513/62397 (0.8%)	7.9:1
Diabetes	4548/26766 (17.0%)	336/26766 (1.3%)	13.5:1
Hypertension	20175/128638 (15.7%)	1567/128638 (1.2%)	12.9:1

* Higher ratio indicates higher adherence and less non-adherence

For the 11,352 medicines that were identified as not being taken as prescribed, a variety of reasons for this situation were elicited in Table 11.

Table 11 - Reasons for not using medicines as prescribed

Reason for not using as prescribed	Number of medicines
Not started the medicine	1642
Prescriber stopped the medicine	1148
Not using as advised	1640
Missed a dose in last 7 days	2410

Incidence of side effects at the Intervention stage

As different levels of side-effects may be expected within each condition area, analysis was performed to examine the rate of adherence to prescribing instructions in Table 12.

Table 12 - Incidence of side effects

Condition	Not using as prescribed		Using as prescribed	
	No side effects	Some side effects	No side effects	Some side effects
Antiplatelet/Anticoagulant	2866	398	13622	1721
Asthma/COPD	11850	1176	45330	4041
Diabetes	3526	926	17766	4548
Hypertension	17071	4511	86881	20175

## Effectiveness of the pharmacy intervention at Follow up

Not all patients were able to be followed up with a second appointment, but as noted previously the use of phone contact will have improved data capture for this critical information.

The data from the PharmOutcomes cohort recording the NMS activity, examining only those patients who did not withdraw at the Follow up stage, indicates that 36,805 (18.1%) medicines were not being taken as prescribed by 35,249 (18.2%) of patients; that is they were not adherent at the Intervention stage.

The same cohort of patients reported they had become adherent to 11,612 of those medicines by the Follow up stage in 11,243 cases. Expressed as a percentage, this indicates that 31.9% of non-adherent patients became adherent to 31.5% of their medicines after the pharmacist's intervention.

The rates of adherence change were evaluated dependent upon the condition indicated by the medication, as seen in Figure 3, which shows the proportion who have changed from non-adherent to adherent at the top and those remaining non-adherent at the bottom.

Figure 3 - Intervention Effectiveness by Condition
Upper/Light = Now adherent after Intervention
Lower/Dark = Remaining non-adherent after Intervention
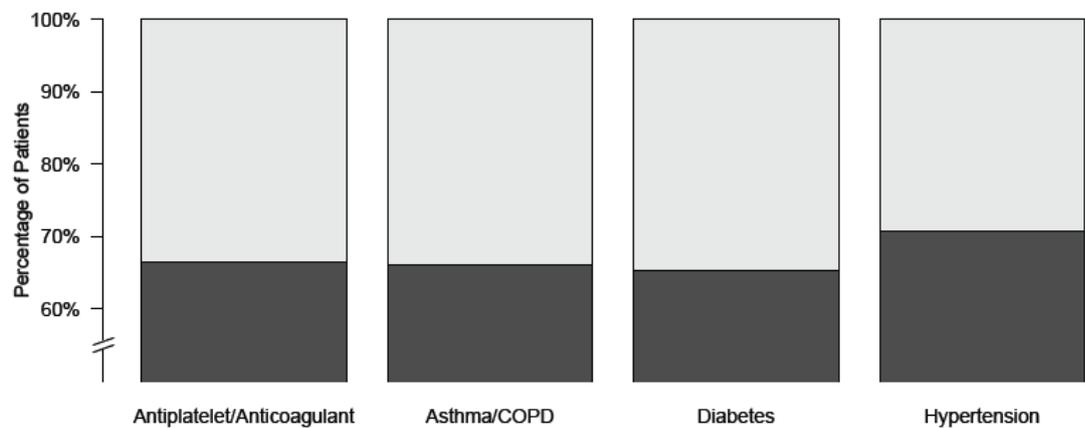
Further analysis was undertaken to evaluate whether this rate was improving as the service embedded into daily practice and is provided in Figure 4. A rapid climb can be seen in the first three months, but this appears to have stabilised into potentially a cyclical pattern.
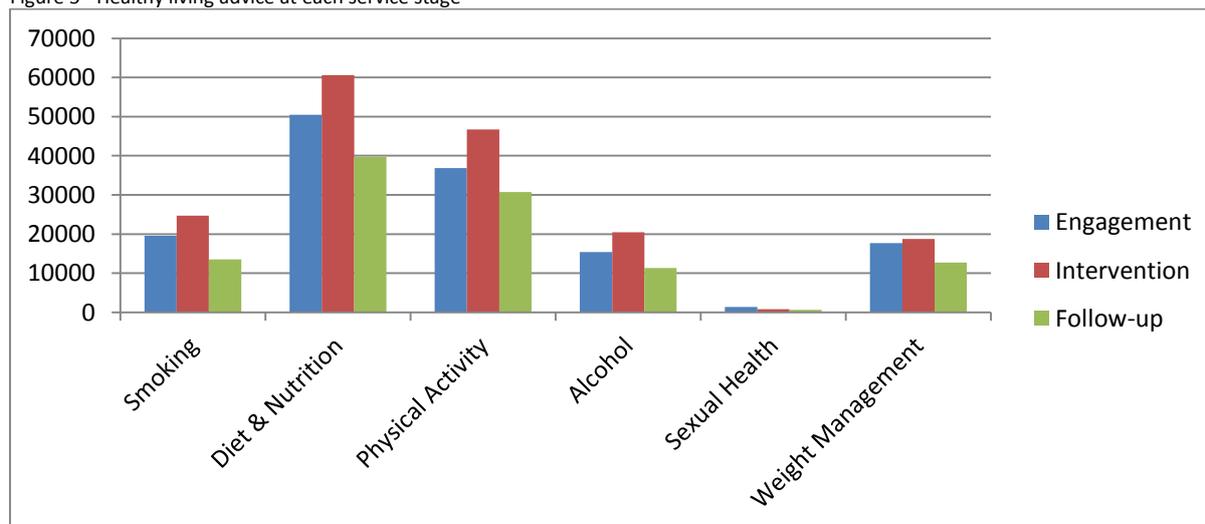
Figure 4 - Conversion Rates from Non-Adherent to Adherent over time
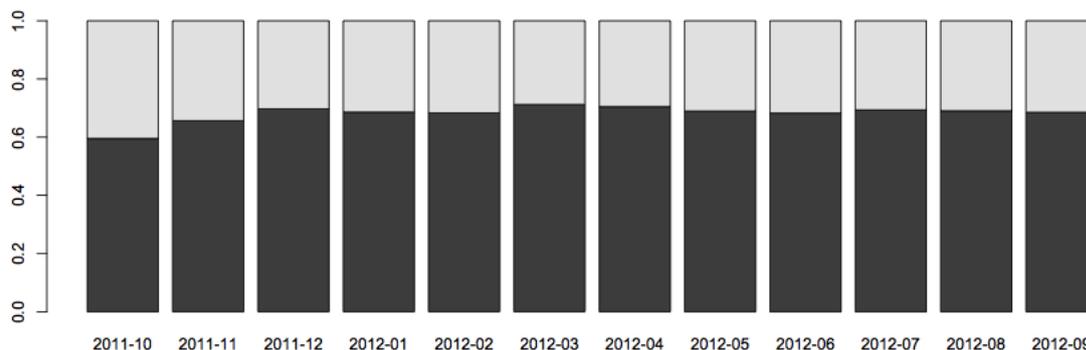
Healthy living advice

The opportunity to give healthy living advice at the recruitment, Intervention and Follow up stages is a key part of the service. A total of 366,702 separate pieces of advice have been recorded via PharmOutcomes.

Figure 5 - Healthy living advice at each service stage

Examination of the data in Figure 5 indicates that the relative levels of advice given may reflect the time available at each stage of the service, with the levels at Intervention higher than those at recruitment and the levels at recruitment are higher than at Follow up.

With the Intervention stage providing the highest number of advice counts, further analysis has been undertaken to determine if the different sorts of advice reflect the condition indicated by the medication. The level of advice giving needs to be tempered with the underlying prevalence for which it is provided. So, for example, whilst smoking advice may be most apposite for respiratory disease not every patient will be a smoker and therefore this advice would be inappropriate. Conversely, a person with diabetes may benefit from advice on diet and nutrition regardless of their health status.

Table 13 - Healthy living advice at Intervention as a percentage of NMS medicines

Condition	Antiplatelet/Anticoag	Asthma/COPD	Diabetes	Hypertension
Smoking	8.3%	13.1%	8.6%	9.9%
Diet & Nutrition	27.2%	12.7%	39.5%	28.7%
Physical Activity	15.2%	15.1%	23.8%	21.8%
Alcohol	10.7%	4.9%	10.4%	9.8%
Sexual Health	0.4%	0.3%	0.4%	0.4%
Weight Management	5.8%	4.3%	14.8%	8.6%

Commentary from the notes made by pharmacists

There is a wealth of information provided in the notes that will be of benefit to the Department of Health commissioned evaluation but a very small sample provides some insight into the issues being tackled by the pharmacists providing the service:

Patient prescribed ramipril as well by GP. Did not know which one to take. Called up GP. This was an error and patient should be taking amlodipine.

Taking Bendroflumethiazide 2.5mg at night instead of in the morning as stated on the label.

Patient does not really know if he needs to take the medication. He gets nervous when he sees GP or nurse and he thinks BP goes up. He feels healthy, good diet and exercise.

Patient stopped using this as a result of suffering from flu but resumed using upon counselling

Not taking medication as prescribed - just one tablet daily instead of two. INR had been tested and unchanged. More information given about medicine - food interactions, medicine interactions, time for warfarin to increase INR, what INR is, when to contact clinic, what to do if missed dose, side effects to watch for, patient re-checked time to take medication with me - explained reasons why normally early evening, check anti-coag card given and reminded to carry

Patient has gone back to using some other capsules she found at home, so I asked her to see GP.

Patient was unsure why she had the medicine - had been prescribed as the result of a survey done at the surgery