Anticoagulation for atrial fibrillation; an observational study of reasons for variation in English Clinical Commissioning Groups.

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Key Words

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Abstract

Background
Despite improvement in anticoagulation for atrial fibrillation, substantial variation in anticoagulation persists between Clinical Commissioning Groups (CCGs) and regions in England.

Aim
We aimed to identify reasons for variation between English CCGs in anticoagulation for atrial fibrillation.

Design and setting
Observational study based on the national Quality and Outcomes Framework for all CCGs for four years, 2012/13 to 2015/16.

Methods
Multiple regression and Pearson correlation coefficients were used to analyse anticoagulation for atrial fibrillation in relation to older age, Index of Multiple Deprivation (IMD), prescription of non-Vitamin K oral anticoagulants (NOACs) and exception reporting, as well as stroke hospital admission and mortality.

Results
The proportion of eligible people in England anticoagulated for atrial fibrillation without any exceptions for clinical complexity or patient dissent, increased incrementally from 65.1% in 2012/13 to 77.9% in 2015/16. In 2015 the number of people eligible to be anticoagulated increased substantially by 290,920 (26%) in association with the use of CHA_2DS_2VASC rather than $CHADS_2$ score. From 2012 to 2015 exception reporting almost halved from 20.1% to 10.2% respectively, indicating changing practitioner perceptions of risk and benefit.

Variation in CCG anticoagulation performance without exception reporting, was not associated with deprivation or NOAC use after adjustment for other factors. There was a strong negative association between exception reporting representing patient complexity, and anticoagulation performance, accounting for 55% of the variation in anticoagulation without exceptions; multiple regression coefficient 0.81 (95% Confidence Interval -0.92 to -0.71) $P<0.001$.

Conclusions
Anticoagulation for atrial fibrillation has improved substantially in England in association with considerable increases in the eligible population as a result of decreased exception reporting and the use of the CHA_2DS_2VASC score. However, there is still substantial room for improvement in most CCGs as even allowing for exceptions, 9 out of 10 CCGs failed to achieve 90% anticoagulation.

How this fits in

Anticoagulation in atrial fibrillation has been suboptimal and variable between CCGs in England despite clear national guidance since 2012 recommending anticoagulation rather than aspirin monotherapy.

This study shows incremental improvement in anticoagulation since 2012. However, although there was a strong inverse relationship with exception reporting which reflects patient complexity, around 40% of the variation in eligible patients remained unexplained, indicating opportunities for further improvement.

There is potential for further improvement in anticoagulation for atrial fibrillation. After allowing for exceptions, 9 out of 10 CCGs fail to achieve 90% anticoagulation.

INTRODUCTION

In 2004, the national Quality and Outcomes Framework (QOF) introduced 'pay for performance' aiming to improve quality in primary care delivery, comprising information on performance for 65 clinical indicators in 209 CCGs in England in 2015/16.[1] In the years since its introduction, QOF has been associated with improved overall performance in target conditions, a reduction in the variation between practices and between CCGs in targeted indices, and reduced inequalities in delivery of care.[2-4] The programme has been considered a cost-effective use of resources and a unique national source of standardised data on major conditions.[5]

Although process measures have substantially improved, it is unclear how much of this is attributable to QOF. Performance in QOF has been associated with little or no reduction in emergency hospital admissions and a failure to demonstrate clear benefits in mortality.[3 6-9] However, it can be difficult to discern a signal of improvement from broad interventions using observational data drawn from highly variable demographic areas, often in the context of pre-existing trends of improvement. In addition, improvement tends to slow over time as clinical management approaches the optimum. [10 11] There is a current national discussion on the future of the QOF programme.[12 13]

Cardiovascular disease has been one of the most improved clinical domains in QOF, with major improvements in control of serum cholesterol, blood pressure and other treatments including anticoagulation. However, it is not clear to what extent these improvements can be attributed to QOF or whether QOF has impacted on outcomes.[14-16] Studies have found a variable association between QOF performance and reductions in hospital admissions or mortality from cardiovascular disease.[17-19]

Optimal anticoagulation treatment for atrial fibrillation has one of the highest impacts of any medical intervention for a common long term condition, reducing stroke by 64% against placebo.[20] In 2001 the $CHADS_2$ score was introduced to stratify risk in order to inform treatment decisions including those who could avoid anticoagulation.[21] NICE AF guidance in 2006 recommended both aspirin and warfarin as options to treat atrial fibrillation and many patients and clinicians opted for the 'easier' medicine. Anticoagulation or antiplatelet use, was introduced as a performance measure in QOF in 2006/7. However, the combined metric made it impossible to determine rates of anticoagulation separately and reflected the prevailing view that either drug was sufficient. However, contemporaneous surveys showed that fewer than 50% of people with atrial fibrillation were on an anticoagulant at this time, most using aspirin monotherapy instead.[22 23] A Scottish survey in 2007 found only 44.4% of people with atrial fibrillation and $CHA_2DS_2VASC \geq 2$ were on anticoagulants at that time, with substantial variation across general practices.[24] In the USA 40% of patients with AF in the period 2008-2012 were on aspirin monotherapy.[25]

In the UK levels of anticoagulation therefore remained low and largely static until 2012 when the Royal College of Physicians updated recommendations to advise *against* the use of aspirin monotherapy in atrial fibrillation, as evidence did not support optimal stroke reduction.[26 27] In 2012 QOF introduced anticoagulation for people with $CHADS_2 \geq 2$ as a performance measure, allowing exceptions to be reported for clinical contraindications or where patients declined treatment. Since 2012 there has been an increase in the rate of improvement in anticoagulation. In 2014 NICE guidance recommended the use of the CHA_2DS_2VASC score which added a younger age group 65-74 years and vascular disease including myocardial infarction to the risk score. In one study this doubled the proportion of individuals eligible for anticoagulation.[28 29] In the latest 2015/16 QOF results, 77.9% of eligible patients

without exceptions, were on anticoagulants. However, this concealed continuing wide variation in anticoagulation between CCGs, ranging from 86% in Corby to 55% in Surrey Heath CCG.[1] Concerns about provider variation in anticoagulation have also been identified in the USA and one study reported improved rates of anticoagulation in association with the extent of non-vitamin K oral anticoagulants (NOAC) use.[30]

In a decade, clinical guidance and available drugs have transformed AF management and NOACs have become drug of choice, currently prescribed to over half of newly anticoagulated patients with increasing evidence of relative benefits.[31] In such a rapidly changing evidence base, this study aimed to review national changes in anticoagulation and exception reporting since 2012 and the factors including NOACs, that might explain continuing variation between CCGs. We also assessed whether CCG anticoagulation performance influenced hospital admissions for stroke or stroke mortality.

METHODS

For each CCG in England we obtained data for the 2012/13, 2013/14 and 2014/15 QOF indicator AF004 which describes the proportion of patients with atrial fibrillation and $CHADS_2$ score ≥2, who were currently treated with anticoagulation therapy. We also obtained the 2015/16 QOF indicator AF007; the percentage of patients with atrial fibrillation and CHA_2DS_2VASC score ≥2, who were currently treated with anticoagulation therapy. The proportions of people exception reported from these indicators were also obtained for the relevant QOF indicator AF007.[1] These exceptions comprised a pre-defined set of indications where treatment was not considered appropriate including medical contraindications e.g. previous major bleeding or palliative care; adverse reactions to anticoagulant treatment or patients who declined anticoagulation.

Mid-year population estimates by age band for 2015 and Census 2011 distributions of ethnic groups for each CCG were available from the Office for National Statistics.[32 33] We aggregated the age bands into the percentage of patients aged 65 and over. The mean score by CCG of the Indices of Multiple Deprivation (IMD) 2015 were used to provide a measure of socioeconomic status.[34]

Age standardised stroke mortality rates over 75 years, by CCG 2012-14, were available from the Public Health England cardiovascular disease profiles.[35] For each CCG 2014/15, we extracted data for the proportion of people on anticoagulants for atrial fibrillation when they were admitted to hospital with stroke, from the Sentinel Stroke National Audit Programme (SSNAP).[36]

The proportion of people on anticoagulants who were prescribed NOACs in 2016 were obtained from the NHS Medicines Optimisation Dashboard and compared to the QOF anticoagulation measures.[37]

The study conformed to the STROBE guidance for reporting https://www.strobe-statement.org/index.php?id=strobe-home

Statistical Analysis

For the two most recent years 2014/15, 2015/16 where data were available, we used Pearson's product-moment correlation to assess the unifactorial relationship between the QOF anticoagulation performance indicators, demographic and NOAC variables and stroke measures. Multiple linear regression was performed to assess the variance of the QOF AF007 performance indicator between CCGs in relation to the proportion of the population 65 years and over, the

proportion of NOAC prescribing as a proportion of all oral anticoagulant prescribing and exception reporting in QOF. STATA 14 was used for these analyses. (STATA Corp 2016)

RESULTS

From 2012/13 to 2015/16 Table 1 shows the number and crude prevalence of atrial fibrillation per 1000 registered patients, and the proportion of these who were eligible for anticoagulation in QOF. For those eligible, the number and proportion who were anticoagulated is described. Also shown are the number and proportion of eligible patients who were exception reported.

Over this period, prevalence of atrial fibrillation increased from 15.2/1000 to 17.1/1000 registered patients. In 2012/13, of those with $CHADS_2$ ≥2 without exceptions, 65.1% (310,580/477,048) were on anticoagulants and after exception reporting 81.3% (310,580/381,822). Table 1 shows a year on year increase in the proportion anticoagulated as well as a decrease in exception reporting. By 2015/16 the proportion on anticoagulants with CHA_2DS_2VASC ≥2 without exceptions had increased to 626,150/803,937, 77.9%, (SD 3.7; Range 86.3 to 55.0). With exceptions excluded, the proportion of patients with CHA_2DS_2VASC ≥2 who were on an anticoagulant was 626,150/722287, 86.7% (SD 2.8; Range 79.8% to 97.4%). As expected, variance reduced as the average performance increased, with a decrease in the interquartile range from 18% in 2014 to 15.9% in 2015. The proportion of patients who were exception reported decreased from 20% in 2012 to 10.2% in 2015.

Even after exceptions were excluded, 30% of CCGs in 2015/16 failed to achieve 85% of eligible patients anticoagulated and only 10% of CCGs achieved 90% or more eligible patients on anticoagulation.

$CHADS_2$ versus CHA_2DS_2VASC

From 2012-2014 the proportion of the total people with atrial fibrillation recorded as eligible for anticoagulation with $CHADS_2$ ≥2 remained fairly stable 56.2%, 59.6% and 55.4% for the three years respectively. However, in 2015/16 this eligibility rose to 81.8%, because an additional 290,920 people were recorded as eligible, largely as a result of the use of CHA_2DS_2VASC ≥2 and also improved recording of this risk score. In other words, an additional 26% of people with AF were considered eligible for anticoagulant treatment in association with the use of the CHA_2DS_2VASC score.

Demographic and interventional associations

The variability in the proportion of people on anticoagulants without any exclusion is examined below for the two most recent years for which there is comparative data; all further analyses are on populations without exclusions. Across all CCGs, the mean percentage of the population aged 65 and over was 17.8% with a mean deprivation score (IMD 2015) of 21.9. There was a small positive correlation between percentage of population aged 65 years and over and the QOF AF007 indicator (proportion of eligible people on anticoagulant); correlation coefficient 0.20, p = 0.003, explaining 0.04 of the variation (R^2). There was no statistically significant correlation between the QOF AF007 performance indicator and the mean IMD 2015 score among CCGs. (Table 2)

NOAC prescribing

In 2015/2016 there was wide variation in prescribing of NOACs as a proportion of all anticoagulants ranging from 73% of all oral anticoagulants in South Kent CCG to 7% in Ipswich and East Suffolk CCG; mean 21.3% (95% CI 20.0% to 22.6%).

In the unadjusted analysis, there was a small positive correlation between the proportion of NOAC used and the QOF AF007 performance indicator ($R^2 = 0.047$). However, this did not remain an independent factor after taking account of age and exception reporting using multiple linear regression. (Table 3)

Exception reporting

Exception reporting for anticoagulation use reduced substantially over time. It averaged 20.0% in 2012/13, 17.0% in 2013/14, 12.9% in 2014/15 and 10.2% in 2015/16. In 2015/16 there was a strong *inverse* relationship between exception reporting in CCGs; the highest performing CCGs had the lowest exception reporting and vice versa. There was a strong negative correlation between the proportion of exceptions and the QOF AF007 performance indicator, correlation coefficient -0.74, p <0.0001, R^2 0.55. (Figure 1) In the multiple linear regression including age and NOAC prescription, exception reporting remained a major factor inversely associated with higher performance; correlation coefficient - 0.72 P<0.001, R^2 0.57 (Table 3).

Stroke measures

Across all CCGs, for those people with atrial fibrillation on admission to hospital with a stroke, 45.0% were already on anticoagulants. (Table 2)

There was a small positive correlation between the percentage of patients with atrial fibrillation before stroke admission on anticoagulants and the QOF AF007 performance indicator, explaining 0.04 of the variance (R^2), correlation coefficient 0.19, p = 0.005.

There was no statistically significant correlation between the QOF AF007 2015 anticoagulation performance indicator among CCGs and total stroke admissions 2015/16, or the proportion of people with stroke in 2015/16 who had atrial fibrillation. There was no statistically significant correlation between AF004 2014 and stroke mortality in people over 75 years 2012-14.

Regional differences

By region a similar inverse relation between exception reporting and anticoagulation performance pattern was present with the highest exception reporting associated with the lowest regional performance. Table 4 shows the English regional distribution of 2015/16 QOF AF007 with and without exceptions excluded and the lower than expected anticoagulation in the London region even allowing for exception reporting.

Figure 2 shows CCG performance by region in 2015/16 in relation to the mean and 95% and 99.8% control limits with and without exceptions and is available as an interactive website.

https://public.tableau.com/views/AFQoFAnalysis/QOFAFprevalenceovertime?%3Aembed=y&%3AshowVizHome=no&%3Adisplay_count=y&%3Adisplay_static_image=y&%3Aretry=yes

Discussion

Although there has been substantial improvement in anticoagulation since 2012, variation in anticoagulation between CCGs with and without exception reporting, remained notable. Our study found that variation was not explained by demographic factors. The delivery of anticoagulation was broadly equitable by age and socioeconomic status with no relation with IMD deprivation score and a small positive association between older age and a higher proportion on anticoagulation.

This study highlights the sharp increase in people recorded as eligible for anticoagulation between 2014 and 2015, most likely as a result of changes in eligibility criteria, from $CHADS_2$ in 2014 to CHA_2DS_2-VASC in 2015. This resulted in an additional 26% of people considered as eligible for anticoagulation in 2015.

Although the use of NOACs varied widely between CCGs, their use was not related to anticoagulation performance once age and exception reporting were taken into account. NOAC use has increased substantially in recent years and now accounts for around half of all newly initiated anticoagulants; atrial fibrillation accounting for at least 65% of this use.[38] Internationally NOACs are rapidly becoming the treatment of choice for anticoagulation.[39] The increase in overall anticoagulation, has been shown in previous studies to be due to switching people previously on aspirin monotherapy to anticoagulation.[22]

Strengths and limitations

This an observational and ecological study that describes associations at the CCG level as individual data were not available. As a national study it is likely to be representative of primary care atrial fibrillation management. Additional research at individual patient and practice level might provide more information on the impact of patient complexity on suitability for anticoagulation and the role of other factors influencing variation.

Available data on NOAC prescribing used in this study relate to indications other than atrial fibrillation and this may obscure the relationship with anticoagulant prescribing for atrial fibrillation. These factors are likely to reduce the strength of the associations we found. Ethnic group was not included as a demographic factor as the distribution is highly skewed geographically.

Comparison with existing literature

Exception reporting was the most notable factor associated with variation in anticoagulation by CCG. The highest rates of anticoagulation occurred in association with the lowest exception reporting. A similar inverse association has been reported for other QOF measures.[36] Exception rates are known to reflect contraindications to treatment in more complex populations who have more co-morbidity and have reduced life expectancy.[40-42] Patient complexity as indicated by exception reporting, is likely to be a major reason for variability in anticoagulation prescribing before exception reporting is are applied, accounting for over half the variation in anticoagulation. However, both the remaining variation after exception reporting, and the substantial recent reduction in exception reporting, suggest that anticoagulation may be warranted in substantially more patients if more people were considered eligible for anticoagulation.

The SSNAP data on stroke is limited to people admitted to hospital with stroke and does not include out of hospital mortality. The individuals admitted are not representative of all patients with AF. In SSNAP, atrial fibrillation was recorded at admission and as such may include new onset or previously undiagnosed cases. Thus atrial fibrillation in newly admitted stroke patients may not be an accurate reflection of longer term diagnosis or management by GPs. The fact that only 45% of people with AF admitted to hospital with a stroke were on anticoagulants in comparison to 78% of those patients known to general practitioners indicates that those admitted were likely to be either newly presenting cases or those not prescribed oral anticoagulants.

We found no association between GP anticoagulation with stroke outcomes or the proportion of people admitted with stroke who had atrial fibrillation. The lack of association of GP anticoagulation

with stroke is not surprising as 80% of stroke admissions do not have atrial fibrillation and the extent to which atrial fibrillation is a new or pre-existing diagnosis at hospital admission is unknown.[36]

There was a small positive association between likelihood of anticoagulation in atrial fibrillation in general practice and the likelihood of anticoagulation in patients with atrial fibrillation on admission to hospital with a stroke, likely to reflect the increasing rates of GP anticoagulation.

Some CCGs in the London region had lower than expected anticoagulation even after exceptions reporting. The reasons for this are not known.

Implications for practice

Other studies have shown that the most important issue is the 10-20% of patients with AF still remaining on aspirin monotherapy, most of whom are eligible for anticoagulation. Almost all the 'gain' in anticoagulation has been in this group, rather than those on no anti-thrombotic therapy at all, for whom there may be good reasons for avoiding anticoagulation.[22 41]

Anticoagulation rates have increased substantially in recent years, despite decreased exception reporting and widening criteria for eligibility. Patient complexity as indicated by exception reporting remains an important factor influencing variation in anticoagulation rates. However, substantial variation between CCGs remains unexplained and even after exception reporting, 1 in 3 CCGs failed to achieve levels of 85% anticoagulation in eligible people CHA_2DS_2-VASC ≥2 and only 1 in 10 CCGs achieved 90% or more, indicating further room for improvement in anticoagulation.

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Ethics approval

All data was anonymised and managed according to the UK NHS information governance requirements. Ethical approval was not required for the use of anonymised data in this observational study.

Competing interests

None

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John Robson designed the study and Kate Homer extracted and analysed the data. Zaheer Ahmed constructed the graphical display of CCG performance in England and Sotiris Antoniou and the other authors contributed to the final manuscript.

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Tables and Figures

Table 1. Quality and Outcomes Framework (QOF) for England annual summary for atrial fibrillation

	AF per 1000 popultn	Number with AF	Number eligible for anti-coagulant*	% Eligible*	Number on anti-coagulant	% on anti-coagulant	Number of exceptions	Exception reported as % those eligible
2012/13	15.2	849,407	477,048	56.2%	310,580	65.1%	95,266	20.0%
2013/14	15.7	883,938	526,686	59.6%	363,991	69.1%	89,512	17.0%
2014/15	16.3	926,551	513,017	55.4%	380,977	74.3%	66,409	12.9%
2015/16	17.1	983,254	803,937	81.8%	626,150	77.9%	81,650	10.2%
*In 2015/15 eligibility was changed from $CHADS_2 \geq 2$ to $CHA_2DS_2VASC \geq 2$; AF atrial fibrillation								

Table 2. Characteristics of Clinical Commissioning Groups in England (n=209)

	Mean	SD	10th centile	Median	90th centile
Demographics					
Total population ONS MYE 2015			124,250	230,346	476,845
% Population ONS MYE 2015 aged 65 and over	17.80	4.57	11.52	18.40	23.34
Total population Census 2011			117,956	221,345	458,976
Average IMD 2015 score	21.91	8.35	11.17	21.28	33.18
QOF performance indicator					
AF007 performance indicator (%) 2015-16	77.57	3.69	73.37	77.69	82.00
% Exceptions from anticoagulation therapy 2015-16	10.41	3.25	6.98	10.18	13.34
Stroke measures					
% atrial fibrillation before stroke patients on anticoagulants 2015-16	44.99	10.41	31.58	45.24	57.14
Prescribing					
% NOAC of total anticoagulants prescribed in Oct-Dec 2016	34.75	9.95	23.06	34.32	46.90
ONS MYE, Office of National Statistics mid-year estimates; SD standard deviation; NOAC non-Vitamin K oral anticoagulants					

Table 3. Multiple linear regression for effect of age, prescribing of NOACs and performance indicator exceptions, on QOF AF007 indicator performance among CCGs in England (n=209 observations)

	Multiple Regression coefficient	P	CI 95% lower	CI 95% higher	Standardised beta coefficient
% Exceptions from anticoagulation therapy	-0.81	0.000	-0.92	-0.71	-0.72
% Population ONS MYE 2015 aged 65 and over	0.10	0.007	0.03	0.18	0.13
% NOAC of total anticoagulants prescribed in Oct-Dec 2016	0.03	0.109	-0.01	0.06	0.08

Table 4. Regional variation in England for exception reporting and anticoagulation performance 2016

Region	% Anticoagulated A007 without exceptions	% Anticoagulated A007 with exceptions	% Exceptions
South	78.56	87.0	9.65
North	78.10	86.9	10.07
Midlands and east	78.08	87.1	10.31
London	74.40	84.1	11.51

Figure 1. Atrial fibrillation QOF AF007. Percentage of exceptions to anticoagulation by CCG, in relation to proportion on anticoagulation without exceptions.

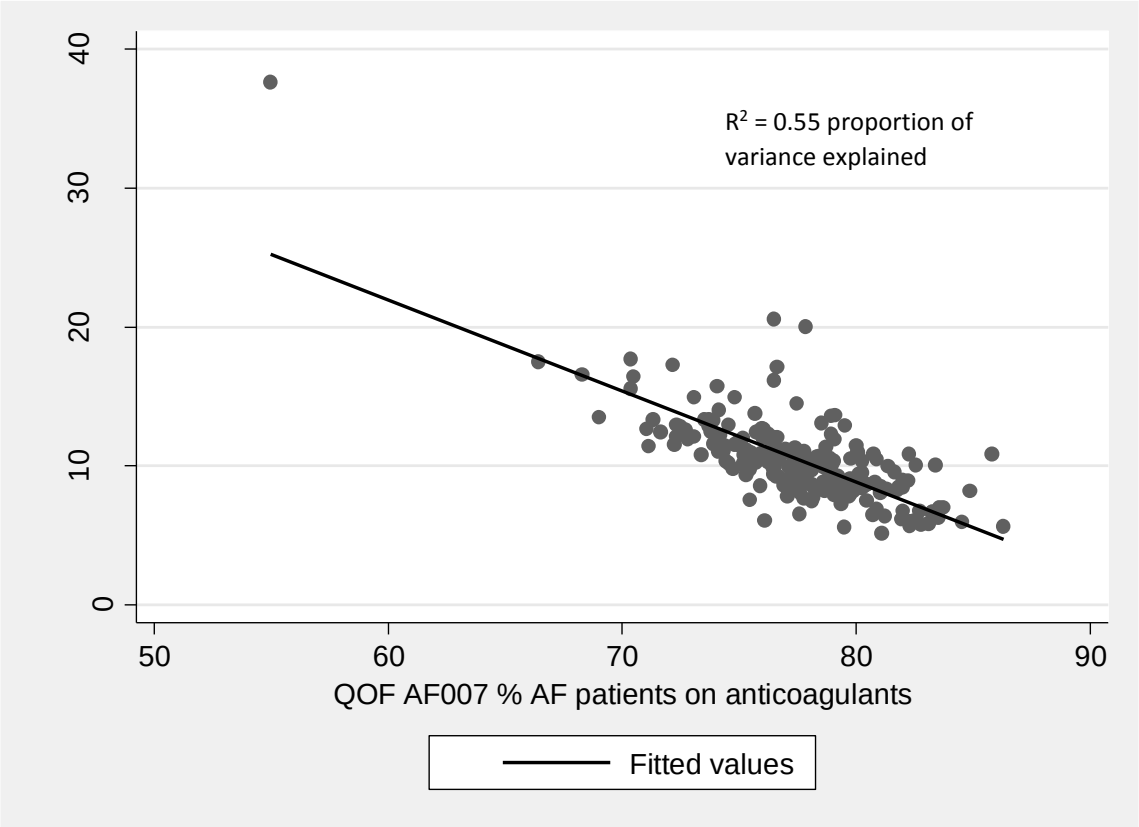

Figure 2

Proportion of people with atrial fibrillation $CHA_2DS_2VASC \geq 2$ on anticoagulation. Distribution in English CCGs by Region with and without exceptions 2015/16.