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RESEARCH PAPER

Attainment of NICE blood pressure targets among older people with newly diagnosed hypertension: nationwide linked electronic health records cohort study

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Abstract

Background: it is not known if clinical practice reflects guideline recommendations for the management of hypertension in older people and whether guideline adherence varies according to overall health status.
Aims: to describe the proportion of older people attaining National Institute for Health and Care Excellence (NICE) guideline blood pressure targets within 1 year of hypertension diagnosis and determine predictors of target attainment.
Methods: a nationwide cohort study of Welsh primary care data from the Secure Anonymised Information Linkage databank including patients aged ≥65 years newly diagnosed with hypertension between 1st June 2011 and 1st June 2016. The primary outcome was attainment of NICE guideline blood pressure targets as measured by the latest blood pressure recording up to 1 year after diagnosis. Predictors of target attainment were investigated using logistic regression.
Results: there were 26,392 patients (55% women, median age 71 [IQR 68–77] years) included, of which 13,939 (52.8%) attained a target blood pressure within a median follow-up of 9 months. Success in attaining target blood pressure was associated with a history of atrial fibrillation (OR 1.26, 95% CI 1.11, 1.43), heart failure (OR 1.25, 95% CI 1.06, 1.49) and myocardial infarction (OR 1.20, 95% CI 1.10, 1.32), all compared to no history of each, respectively. Care home residence, the severity of frailty, and increasing co-morbidity were not associated with target attainment following adjustment for confounder variables.
Conclusions: blood pressure remains insufficiently controlled 1 year after diagnosis in nearly half of older people with newly diagnosed hypertension, but target attainment appears unrelated to baseline frailty, multi-morbidity or care home residence.

Keywords: hypertension, older people, blood pressure, frailty, treatment target

Key Points

- Population-level routine data enable the evaluation of the care and outcomes of older people living with hypertension.
- Blood pressure remains insufficiently controlled in nearly half of older people 1 year after a new diagnosis of hypertension.
- Blood pressure target attainment in older people appears unrelated to baseline frailty, multi-morbidity or care home residence.

Introduction

More than two-thirds of adults over the age of 65 years have hypertension [1], which contributes to an estimated 7.7–10.4 million deaths annually worldwide [2–4]. Blood pressure (BP) treatment can reduce that risk, yet fewer than half of those treated for hypertension reach guideline-recommended BP targets [5].

There is a concern that people who are older, have multiple long-term conditions or are living with frailty are particularly vulnerable to the harms associated with BP-lowering treatment (such as syncope, falls and kidney injury) [6–9]. It is possible that these factors may predict plausible grounds for not adhering to guideline targets as clinicians adopt a personalised approach to BP management. Indeed, National Institute for Health and Care Excellence (NICE) guidelines recommend the application of clinical judgement in those with frailty or multi-morbidity or aged over 80 years [10]. The lack of a robust evidence base to inform treatment and optimise benefits over risks means that clinicians must make a judgement of whether to follow guidelines or not in the context of multi-morbidity and frailty.

The Secure Anonymised Information Linkage (SAIL) Databank holds population-scale individual-level linked routinely collected data sources. This population-level routine data offers a unique opportunity to evaluate the care and outcomes of people with hypertension as managed in the community. It includes older people who are normally excluded from clinical trials and for whom the risks of harm from treatment may be significant, such as care home residents [11]. Therefore, we investigated the proportion of older people that attain NICE guideline BP targets within 1 year of a hypertension diagnosis and determined predictors of BP target attainment.

Methods

Study design

We conducted a retrospective cohort study reported according to the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) guidelines [12] (Appendix S1) (Supplementary data are available in *Age and Ageing* online).

Setting and participants

The study included patients aged 65 years and over when a new clinical code for hypertension was recorded in primary care between 1st June 2011 and 1st June 2016. Patients were followed up for 1 year following their hypertension diagnosis. We excluded patients who on 1st June 2011 were younger than 60 years or already had an established diagnosis of hypertension. We also excluded patients who, during follow up, moved to a different general practitioner (GP), died or were lost to follow-up.

Data source

The SAIL Databank holds population-scale individual-level anonymized health data for the population of Wales, with linked care home data [13]. The following datasets were linked within the SAIL Databank: Welsh Demographic Service (which is an NHS administrative database), Welsh Longitudinal General Practice data set, the Annual District Death Extract recording death record data and a care home registry.

Data cleaning and extraction

As part of data cleaning, readings outside pre-defined clinically plausible ranges were excluded. For systolic BP, plausible readings were defined as between 50 and 300 mm Hg and for diastolic BP, 30–200 mm Hg; for other continuous variables (cholesterol, BMI, weight and height), we excluded extreme readings, i.e. $<0.15\%$ and $>98.5\%$ of the range. Measurements outside these respective ranges were defined as outliers and treated as missing.

The coding of categorical variables was based on positive recording. For example, where a diagnosis of atrial fibrillation had not been coded for an individual, the diagnosis was considered absent. Exceptions were measures of cardiovascular risk (smoking, ethnicity, BP, BMI and cholesterol), which represent required data according to NICE hypertension guidelines at the time of the hypertension diagnosis [14]. For these variables, missing data were assumed to be missing at random and principle models were fitted on the basis of multiple imputation by chained equations with interaction [15–17]. Code lists and their sources are detailed in Appendix S2.

Primary outcome

The primary outcome was attainment of the 2011 NICE hypertension guideline-recommended systolic and diastolic BP targets at the time of annual review, at which point clinicians should provide an 'annual review of care for adults

with hypertension to monitor BP, provide people with support, and discuss their lifestyle, symptoms and medication' [14]. We specifically investigated the achievement of BP monitoring to target whether or not the systolic and diastolic BP measurements recorded by the time of annual review met with a clinic-measured target of a BP of less than 140/90 mm Hg for patients aged less than 80 years or below 150/90 mm Hg for those aged 80 years and older [14]. Given that patients may have multiple encounters with primary care, we extracted the latest BP up to 1 year after hypertension diagnosis. Guideline adherence was considered achieved if both the systolic and diastolic BP readings at the final date of follow-up were equal to or less than the age-based guideline targets.

Prognostic factors

Potential predictors were chosen according to indications for treatment according to the 2011 NICE guidance, alongside key demographic variables (age, sex, deprivation and ethnicity). These included known cardiovascular risk factors and established cardiovascular disease [18]. Patients were also characterised by potential mitigating factors in their hypertension care including care home residence, baseline comorbidity (Quality Outcomes Framework Comorbidity Count [19]) and baseline frailty status (as defined by electronic frailty index [20]). Further details are available in Appendix S3 (Supplementary data are available in *Age and Ageing* online). Point estimates were adjusted for prespecified confounders, which included age, sex, the year of diagnosis, and baseline systolic BP.

Statistical analysis

The study population was described according to key demographic and prognostic factors. Patient characteristics were described using frequencies and proportions for categorical data. Normally distributed continuous data were described using means and standard deviations (SDs) and non-normally distributed data using medians and interquartile ranges (IQRs). The distribution of demographic and prognostic factors in the analytic cohort was compared to the population that were lost to follow up to test for selection bias.

Given the short follow-up and anticipated small loss to follow-up, we undertook logistic regression modelling to determine which prognostic factors were predictive of success in attaining target BP. Two sensitivity analyses were undertaken:

(i) to compare the primary imputed analysis with an imputed analysis using a broader outcome definition that classified patients who had no recorded measurement of BP on follow-up as not attaining BP target on follow up;
(ii) to compare the primary imputed analysis with a complete case analysis.

Extended methods are detailed in Appendix S3 (Supplementary data are available in *Age and Ageing* online).

Ethics

The project was approved by the SAIL Information Governance Review Panel (IGRP).

Results

Study population

The study population included 29,436 patients (Figure 1). During the period of follow up, 2,392 (8.1%) had no recorded measurement of BP, 611 (2.1%) died and 41 (0.1%) moved general practice. The remaining 26,392 patients were included in the analytic cohort. The comparison of those lost to follow-up to the analytic cohort population demonstrated a similar distribution of age and sex, lower BP at baseline and higher proportion of missing cardiovascular risk data (Appendix S4) (Supplementary data are available in *Age and Ageing* online). Descriptive analysis is presented in Table 1.

Data for any of the key cardiovascular risk factors were missing in 20,759 (78.7%) participants. Data were missing for baseline BP in 1,361 (5.2%), deprivation measures in 1,390 (5.3%), ethnicity for 4,308 (16.3%), total serum cholesterol in 7,209 (27.3%), BMI in 10,511 (39.8%) and smoking status in 13,870 (52.6%). Only 519 (2.0%) had a recorded ambulatory BP (ABP) recorded at baseline, with the proportion increasing with time from 2011 (1.2%) to 2016 (2.3%). The mean ABP reading (154/83 mm Hg) was lower than the mean office BP (159/86 mm Hg).

BP target attainment

At a median follow-up of 270 days (IQR 176–331 days), the mean BP was 139/77 mm Hg. Overall, 13,939 (52.8%) of patients attained BP targets within 1 year after the hypertension diagnosis. This proportion was 48.5% (10,705/22,068) in participants under the age of 80 years in whom the target is <140/90 mm Hg. The proportion was higher at 74.8% (3,234/4,324) in participants over the age of 80 years in whom the guideline target is <150/90 mm Hg.

There were a median of four BP measurements during 1-year follow-up and three in patients who attained target BP. By the end of follow-up, antihypertensive treatment was prescribed for 91.1% (mean of 1.5 classes of anti-hypertensive medication prescribed per person).

Predictors of BP target attainment

Systolic and diastolic BP at baseline were associated with a reduced likelihood of BP target attainment on follow-up (Figure 2, Appendix S3) (Supplementary data are available in *Age and Ageing* online). Age > 80 years (unadjusted OR

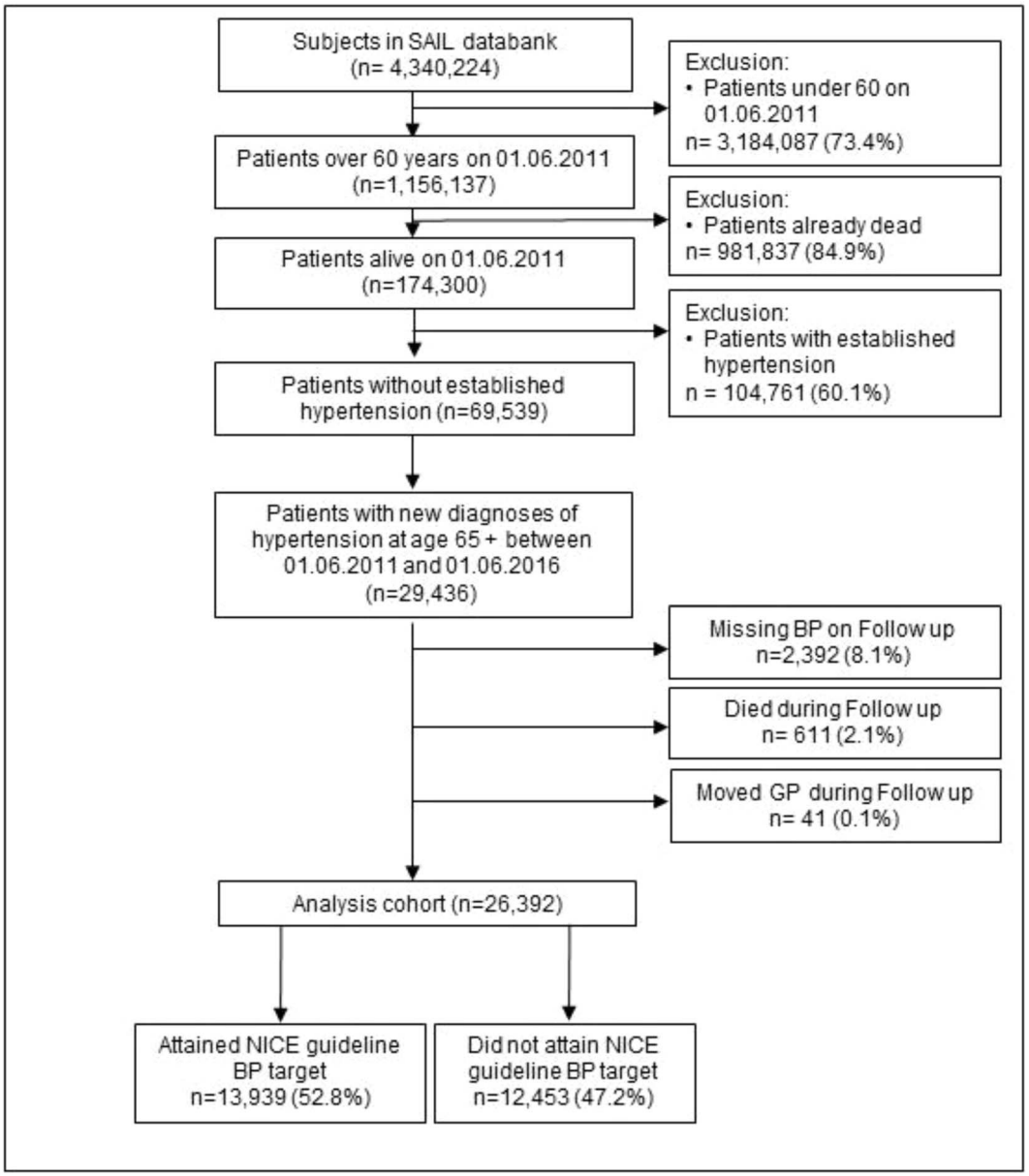

Figure 1. Strengthening the Reporting of Observational Studies in Epidemiology diagram to demonstrate the derivation of the study cohort. Abbreviations: BP: blood pressure; GP: general practitioner; NICE: National Institute for Health and Care Excellence; SAIL: Secure Anonymised Information Linkage databank.

3.15, 95% CI 2.93, 3.39), atrial fibrillation (adjusted OR 1.26, 95% CI 1.11, 1.43), heart failure (adjusted OR 1.25, 95% CI 1.06, 1.49) and myocardial infarction (adjusted OR 1.20, 95% CI 1.10, 1.32) were associated with increased likelihood of target attainment. Prognostic factors that did not consistently predict success or failure to attain BP targets following adjustment included deprivation; ethnicity; a past history of stroke, peripheral artery disease, type II diabetes, rheumatoid arthritis and chronic kidney disease; living in a care home; severity of frailty; and increasing co-morbidity**.** Having missing data predicted failure to meet guideline targets at follow-up (unadjusted OR 0.85, 95% CI 0.80, 0.90), but this did not remain significant following adjustment (adjusted OR 0.97, 95% CI 0.91, 1.03).

Sensitivity analysis

There was no significant difference in the direction or significance of point estimates when the analysis using imputed data was compared to complete case analysis (Appendix S5) (Supplementary data are available in *Age and Ageing* online).

Undertaking sensitivity analysis using a broader outcome definition that classified patients who had no recorded

Table 1. Study population

Variable		All patients in the analytic cohort	NICE target attained	NICE target not attained
Total, *n* (%)		26,392 (100)	13,939 (52.8)	12,453 (47.2)
Demographics				
Age	Median, IQR	71 (68, 77)	72 (68, 79)	71 (67, 75)
Sex	*n* (%)	14,590 (55.3)	7,729 (55.4)	6,861 (55.1)
Deprivation	Most deprived WIMD quintile *n* (%)	5,805 (22.0)	3,138 (22.5)	2,667 (21.4)
	Missing *n* (%)	*1,390 (5.3)*	*764 (5.5)*	*626 (5.0)*
Ethnicity	Non-White *n* (%)	123 (0.5)	68 (0.5)	55 (0.4)
	Missing *n* (%)	*4,308 (16.3)*	*2,047 (14.7)*	*2,261 (18.2)*
Year of diagnosis	2011 *n* (%)	3,005 (11.4)	1,428 (10.2)	1,577 (12.7)
	2012 *n* (%)	5,252 (19.9)	2,637 (18.9)	2,615 (21.0)
	2013 *n* (%)	5,375 (20.4)	2,992 (21.5)	2,383 (19.1)
	2014 *n* (%)	5,297 (20.1)	2,854 (20.5)	2,443 (19.6)
	2015 *n* (%)	5,068 (19.2)	2,734 (19.6)	2,334 (18.7)
	2016 *n* (%)	2,395 (9.1)	1,294 (9.3)	1,101 (8.8)
Baseline anti-hypertensives	# of classes mean (SD)	1.18 (0.83)	1.23 (0.86)	1.13 (0.78)
Record of ambulatory BP	*n* (%)	519 (2.0)	276 (2.0)	243 (2.0)
Cardiovascular risk factors at baseline				
Systolic BP mmHg	Mean (SD)	159 (17.9)	156 (18.1)	163 (16.9)
	Missing *n* (%)	*1,361 (5.2)*	*726 (5.2)*	*635 (5.1)*
Diastolic BP	Mean (SD)	86 (10.5)	84 (10.6)	87 (10.1)
mm Hg	Missing *n* (%)	*1,361 (5.2)*	*726 (5.2)*	*635 (5.1)*
Smoking	Never smoker *n* (%)	10,196 (38.6)	5,479 (39.3)	4,717 (37.9)
	Ex-smoker *n* (%)	1,435 (5.4)	770 (5.5)	665 (5.3)
	Light *n* (%)	334 (1.3)	188 (1.3)	146 (1.2)
	Moderate *n* (%)	375 (1.4)	169 (1.2)	206 (1.7)
	Heavy *n* (%)	182 (0.7)	93 (0.7)	89 (0.7)
	Missing *n* (%)	*13,870 (52.6)*	*7,240 (51.9)*	*6,630 (53.2)*
BMI	Mean (SD)	28.2 (5.15)	27.9 (5.02)	28.5 (5.28)
kg/m^2	Missing *n* (%)	*10,511 (39.8)*	*5,400 (43.4)*	*5,111 (41.0)*
Cholesterol mmol/L	Mean (SD)	5.27 (1.17)	5.18 (1.18)	5.27 (1.17)
	Missing *n* (%)	*7,209 (27.3)*	*3,676 (26.4)*	*3,533 (28.4)*
Family history of CVD	*n* (%)	6,465 (24.5)	3,438 (24.7)	3,027 (24.3)
Cardiovascular disease	MI *n* (%)	2,707 (10.3)	1,781 (12.8)	926 (7.4)
	Stroke *n* (%)	142 (0.5)	96 (0.7)	46 (0.4)
	Heart failure *n* (%)	718 (2.7)	502 (3.6)	216 (1.7)
	PAD *n* (%)	960 (3.6)	555 (4.0)	405 (3.3)
	T2DM *n* (%)	2,954 (11.2)	1,756 (12.6)	1,198 (9.6)
	CKD *n* (%)	2,386 (9.0)	1,500 (10.8)	886 (7.1)
	RA *n* (%)	659 (2.5)	349 (2.5)	310 (2.5)
	AF *n* (%)	1,277 (4.8)	857 (6.1)	420 (3.4)
Overall health status at baseline				
CH residence	*n* (%)	179 (0.7)	128 (0.9)	51 (0.4)
Frailty	Fit *n* (%)	13,036 (49.4)	6,312 (45.3)	6,724 (54.0)
	Mild *n* (%)	10,281 (39.0)	5,625 (40.4)	4,656 (37.4)
	Moderate *n* (%)	2,623 (9.9)	1,685 (12.1)	938 (7.5)
	Severe *n* (%)	452 (1.7)	317 (2.3)	135 (1.1)
Multi-morbidity	2+ comorbidities, *n* (%)	9,480 (35.9)	5,519 (39.5)	3,961 (31.8)

This table describes the population of the study, categorised into NICE guideline target BP attainment and non-attainment. Categorical variables are reported as a frequency and percentage of the population, normally distributed variables are reported as the mean and standard deviation and skewed variables are reported as the median and IQR. Abbreviations: AF: atrial fibrillation, BMI: body mass index, BP: blood pressure, CH: care home, CKD: chronic kidney disease, CVD: cardiovascular disease, DBP: diastolic blood pressure, IQR: interquartile range, kg/m^2: kilogramme per square metre, MI: myocardial infarction, *n*: number, NICE: National Institute for Health and care Excellence, RA: rheumatoid arthritis, SBP: systolic blood pressure, SD: standard deviation, mmHg: millimetres of mercury, mmol/L: millimoles per litre, PAD: peripheral arterial disease, T2DM: type II diabetes mellitus, WIMD: Welsh Index of Multiple Deprivation. Numbers and proportions in italics represent those with missing data for each variable.

BP measurement as not attaining BP target on follow-up, predictors of BP target attainment significant in the primary analysis remained significant despite adjustment. In addition to these factors, a family history of cardiovascular disease, frailty severity, comorbidity count and type II diabetes mellitus increased the likelihood of attaining target BP; hypercholesterolaemia decreased the likelihood of attaining target BP.

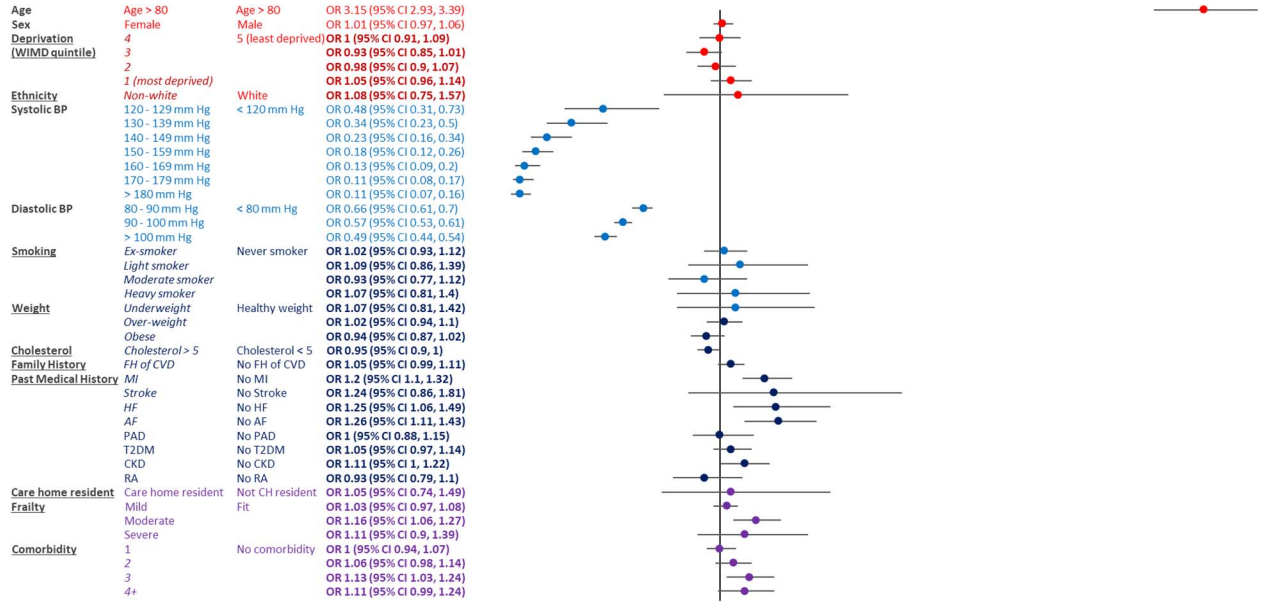

Figure 2. Forest plot displaying associations between predictors and attainment of NICE guideline target blood pressure (n = 26,392). This is a forest plot representing associations between predictors and the attainment of NICE BP targets on follow-up. Point estimates for variables underlined have been adjusted for age, sex, systolic blood pressure (continuous) and the year of hypertension diagnosis. Point estimates for all other variables (not underlined) are unadjusted/univariable. The vertical line represents odds ratio = 1; dots represent the point estimate of the predictor versus the comparator and horizontal lines represent 95% confidence intervals. Point estimates to the left of the vertical line represent risk estimates favouring failure to attain the target, and estimates to the right of the vertical line represent risk factors favouring success to attain the target. Abbreviations: AF: atrial fibrillation; BP: blood pressure; CKD: chronic kidney disease; FH of CVD: family history of cardiovascular disease; HF: heart failure: mm Hg: millimetres of mercury; MI: myocardial infarction; OR: odds ratio; PAD: peripheral arterial disease; PMH: past medical history; RA: rheumatoid arthritis; T2DM: type II diabetes mellitus; WIMD: Welsh Index of Multiple Deprivation.

Discussion

In this study of 26,392 patients aged 65 years or older with newly diagnosed hypertension, approximately half attained their NICE guideline target BP at 1 year following diagnosis. BP target attainment within 1 year of diagnosis was associated with having an established history of atrial fibrillation, heart failure or myocardial infarction. Living in a care home, living with increasing frailty and having co-morbidity were not associated with failure to meet BP targets following adjustment for known confounders. This suggests that clinical practitioners may not be differentiating treatment goals based on these patient characteristics and may not be modifying a person's BP target accordingly. Cardiovascular risk measurement was incompletely recorded for most patients with a new diagnosis of hypertension and a minority had a recorded evidence of ABP monitoring, which is a guideline recommendation for the diagnosis of hypertension.

Despite the prognostic benefit of treating older people with hypertension [21, 22], the attainment of target BP in this study was suboptimal—yet it was higher than has been reported elsewhere in Europe and America [23–27]. These differences may reflect the less intensive BP targets for people over the age of 80 in NICE compared to other guidelines [14] and financial incentivisation for GPs to treat BP to target in hypertension as part of the UK's Quality and Outcomes Framework [28]. Alternative explanations include the lower cardiovascular risk of study patients who were eligible for inclusion because they had not developed hypertension earlier in life. Also, the limited ethnic diversity of our study population may be relevant given the known higher prevalence of hypertension and increased risk of adverse outcomes in minority ethnic groups. We found that BP target attainment increased during the study period, reflecting improving temporal trends in hypertension management [29].

Patients who had established cardiovascular disease had greater odds of attaining target BP, which may be explained by a particular focus on optimal secondary prevention in this group that are at a high risk of event recurrence [30] and perhaps increased adherence to medications among people that have already experienced an adverse event. We also found that increasing age was associated with a greater attainment of target BP. This may be due to the higher guideline target in patients over 80 years of age but may also reflect greater medication adherence in older people [31] and declining systolic trajectories towards the end of life [32].

Overall, frailty, multi-morbidity and care home residence at baseline did not predict a difference in adherence to guideline targets on follow-up. Both increasing frailty and

multi-morbidity showed a trend to better target attainment, but those with the highest frailty and most co-morbidities had wide confidence intervals, presumably due to small numbers.

This finding is inconsistent with studies that report reluctance among physicians to treat hypertension intensively among older people [33]. Indeed, lowering BP with antihypertensives in older people at risk of falls for other reasons increases their risk of future falls [6]. The lack of adjustment in clinical practice among older people for measures of ageing may reflect the uncertainty in the evidence base. Epidemiological studies [34, 35] including in large routine data sets [36] have demonstrated a strong association between antihypertensive treatment and falls in older people. However, this finding is inconsistent across observational studies [37] and interpretation should account for the higher risk of reverse causality and residual confounding in observational research. Choices about antihypertensive medications are made more challenging as BP becomes more variable with age [38], and, as a result, older adults are more susceptive to experience both episodes of hypertension and hypotension and single BP readings are unreliable as measures of BP control in older adults.

Ambulatory BP (ABP) is a more accurate measurement of a person's true BP and can better predict cardiovascular risk in comparison to office BP readings [39]. The recommendation to measure ABP was new in the 2011 NICE hypertension guideline [14], and there is an evidence of increased use over time since guideline change [40]. In this study, only 2% of patients had a record of ABP recording on their record. Possible explanations include the following: ABP is under-recorded in routine data (e.g. average ABP reading is miscoded using office BP codes), there is a lack of ABP resource in primary care [41] or patients are declining ABP.

Using BP variability information from ABP in individuals on treatment for hypertension could help inform the titration of therapy to minimise both their cardiovascular and fall risk. This could complement good, newly available prediction tools that help identify fall risk effectively among older people with hypertension in primary care [42].

Strengths and limitations

We used routine health data from the entire Welsh population, which represents contemporary clinical care. We assessed adherence to the NICE guidelines that are applicable to practice in England and Wales and informed clinical practice at the time. Recording bias was mitigated by using codes taken from published and validated consensus code lists.

However, we recognise the limitations of our work. Differences between the study population and the whole population of older people in the UK may relate to the exclusion of participants with established hypertension from the study population resulting in a healthy participant bias. This is reflected in the lower mortality rate at 1 year (2%) compared to an expected annual rate (3%) in this population [32, 43]. Patients with moderate and severe frailty and care home residents are under-represented compared to comparable studies [20, 44, 45].

Non-White ethnicity represented 0.5% of the study cohort, which is lower than that reported (1.1%) in the census data for Wales [46]. Ethnicity data in this data set were extracted from hospital data; therefore, ethnicity data were only available for those who have had a hospital admission prior to study start. Hospital admissions may be expected to be lower because of healthy participant bias, and this bias may affect different ethnicities disproportionately. For these and other prognostic factors, missing data were likely not missing at random. While multiple imputation is an accepted method of addressing missing data even when there is a possibility that missing data were not missing at random [47], and the correlation between the imputed and the complete case analyses is reassuring, the potential risk of unmodelled and residual bias remains.

Participants lost to follow-up had fewer diagnoses recorded, lower frailty status and fewer anti-hypertensive treatments at baseline and may represent a population with less contact with medical services for whom the findings of this study may not be generalisable. Patients with missing data on cardiovascular risk assessment represent a key group of interest in progressing population BP control—and a population that may require more targeted management approaches to improve NICE target achievement.

Hypertension was defined in this study according to hypertension codes entered by primary care providers. Hypertension in primary care is known to be under-recorded, and when hypertension is coded, it may not always represent a new diagnosis. For example, in participants, newly registered at a GP practice, a historic diagnosis of hypertension may be identified as a new diagnosis of hypertension when it is not. However, new registration at a GP practice is relatively uncommon in this population where only 1% of adults 65 or older were registered for less than 1 year at a GP practice [48].

This study's use of binary targets to assess overall hypertension management does not account for patients with proteinuria and type I diabetes or chronic kidney disease, for whom disease specific guidelines take precedence and the target BP is lower. To better understand current treatment decisions to inform how to improve current management will require analysis in larger data sets using a more granular analysis of BP trajectory and treatment intensity during follow-up.

Conclusion and future implications

Over half of older people reach their target BP within 1 year of a new diagnosis of hypertension. People with established concomitant cardiovascular disease were more likely to meet their BP target. Current guidelines recommend that

hypertension management in the context of competing risks and frailty is tailored to the individual. We did not find evidence that people with frailty, people living in residential care and people with multi-morbidity were being managed more conservatively. Greater guidance is required to tailor treatment to the older person with hypertension.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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Declaration of Conflicts of Interest: None.

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Data Availability Statement: The data used for the study is third-party data and is held by the SAIL Databank at Swansea University on behalf of healthcare providers in Wales who are the original data owners. This study was approved by the Secure Anonymised Information Linkage (SAIL) Information Governance Review Panel (project 0826) in Wales. All data were anonymised prior to access and analysis. We did not have special access to this data; it is available to anyone via an application to SAIL. All proposals to use SAIL data are subject to review by an independent Information Governance Review Panel (IGRP). Before any data can be accessed, approval must be given by the IGRP. The IGRP gives careful consideration to each project to ensure proper and appropriate use of SAIL data. When access has been approved, it is gained through a privacy protecting safe haven and remote access system referred to as the SAIL Gateway. SAIL has established an application process to be followed by anyone who would like to access data via SAIL https://www.saildatabank.com/application-process.

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