Antipsychotic Prescribing in Care Homes Before and After Launch of a National Dementia Strategy: An Observational Study in English Institutions over a 4year Period

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ABSTRACT

Objectives: To assess associations between the launch of the National Dementia Strategy (NDS) and antipsychotic prescribing in long-term residential care (LTC) in England.

Setting and participants: Retrospective analysis of prescribing patterns in 616 LTC institutions (31,619 residents) following launch of the NDS, using information from electronic medicines management system.

Primary and secondary outcome measures: Antipsychotic prescribing point-prevalence (PP) for all residents in a cross-section of LTC settings over a 4-year period following NDS launch. Secondary outcomes included: dosages, length of treatment and use of recommended second-generation antipsychotics (SGA) versus first-generation antipsychotics (FGA). Associations between facility-level PP values and institutional characteristics, resident demographics were explored. Variations across geographical areas examined. Prescription net ingredient costs calculated.

Results: No statistically significant difference was observed in overall prescribing rates over the 4-year period (Kolmogorov-Smirnov test p=0.60), and there was no significant shift towards newer SGAs (KS test p=0.32). Dosages were above the maximum indicated in only 1.3% of cases, but duration of prescribing was excessive in 69.7% of cases. Care homes in the highest prescribing quintile were more likely to be located in a deprived area (Rate Ratio [Q5/Q1] RR = 5.89, 95% CI 4.35, 7.99), registered for dementia (RR =3.38, 95% CI 3.06, 3.73), and those in the lowest quintile were more likely to be served by a single GP practice (RR = 0.48; 95% CI 0.37, 0.63); p<0.001 all. A six-fold variation in PP levels was observed between geographical areas. The average annual expenditure on antipsychotics was £65.6 per person resident (2012 prices).

Conclusions: The NDS in England was not associated with reduced PP levels or the types of antipsychotic prescribing in care homes. Further research is needed to explore why. Clear standards specifying recommended agents, dosages and length of treatment, together with routine monitoring and greater accountability for antipsychotic prescribing, may be required.

Strengths and limitations of this study

- 1. To our knowledge, this is the first UK study to examine long term impact of a national policy initiative on antipsychotic prescribing in care homes. The samples studied are many times those of other UK antipsychotic utilisation studies.
- 2. Prescribing rates, antipsychotic agent type (including unlicensed antipsychotics), and length of treatment were unchanged.
- 3. The factors preventing sustained change in antipsychotic prescribing and regional variations observed remain unclear.
- 4. One limitation of this observational study is the lack of comparable national data to demonstrate representativeness of the study sample.
- 5. A further limitation of this study is the lack of clinical and staffing data to complement the detailed prescription data.

INTRODUCTION

There continues to be considerable international debate about the optimum care of older people with dementia, especially those living in care homes ¹⁻⁴. In England it is estimated that 46% of new admissions to care homes are for reasons of dementia ⁵, and more than one-third of people with dementia (36.5%) now live in care homes⁶. For antipsychotics, which were originally developed for use in patients with schizophrenia or psychosis, there is evidence of 'off-label' prescribing of unlicensed medicines for behavioural and psychological symptoms in dementia (BPSD) ^{4 7}.

In the 1990s, calls in the United States (US) for control of the use of first-generation antipsychotics (FGA) for BPSD led to the Omnibus Budget Reconciliation Act (OBRA) which introduced regulation stipulating recommended dosages for their use in nursing homes ^{8 9}. In the United Kingdom (UK), thioridazine (trade name Melleril©), a commonly used FGA, was banned in 2008 following evidence of cardiac toxicity and limited effectiveness ¹⁰. Prior to its ban, thioridazine was the most commonly prescribed antipsychotic in UK long-term residential care (LTC), accounting for 51-74% of prescriptions ^{11 12}. With the introduction of second-generation antipsychotics (SGA) ¹³, concerns continued to be raised in the UK and the US about their use for BPSD treatment ^{14 15}. In the US, no antipsychotic has been approved to date by the Food and Drug Administration for BPSD ¹⁶. In the UK, the Medicines & Healthcare products Regulatory Agency has licensed only one antipsychotic (risperidone), for short-term BPSD treatment (up to 6 weeks) and for persistent aggression ¹⁷. Australia and Canada have similarly only approved risperidone ^{18 19}. In most countries therefore use of other antipsychotics remains unlicensed or off-label ²⁰. It has recently been argued that wide-spread off-label prescribing for BPSD requires regulatory intervention to safeguard vulnerable older people ²¹.

Inappropriate prescribing of antipsychotic medication is recognised as a marker of poor care ^{3 22}, especially if prescriptions are not regularly reviewed by the prescribing physician ²³. Although the principle of protecting older people's human rights when they cannot consent to treatment is well developed with respect to the use of physical restraints and deprivation of liberty, it is acknowledged that protection against inappropriate use of 'chemical restraints' is less well developed ²⁴. To date, controlled trials have demonstrated limited clinical efficacy for use of antipsychotics in BPSD, with only small effect sizes reported on global behavioural disturbance ²⁵. Long term use of antipsychotic drugs is also associated with increasing concerns about serious adverse effects including mortality ²⁶. The European Federation of Neurological Societies task force recommended in 2007 that all antipsychotics be used with caution in elderly patients with dementia, although no specific guidance was provided on dosage or length of treatment ²⁷.

In 2009, the UK Department of Health commissioned a policy review on antipsychotic use in dementia. The resulting report concluded that usage was unacceptably high and recommended a two thirds reduction over a period of 3 years as a target ²⁰. The UK Royal College of Psychiatrists confirmed that older people could safely be withdrawn from agents like risperidone over a 2–4 week period with no adverse consequences ^{28 29}. This policy review also stipulated that SGA agents should be prescribed in preference to FGA agents; that the lowest possible effective dose should be prescribed for the shortest period (ideally less than 12 weeks); and that treatment should be reviewed at least monthly with reduction or cessation actively considered at each review ²⁰. Similar recommendations were incorporated as guidelines in a National Dementia Strategy (NDS) launched in February 2009, 9^{30 31}.

In England, the majority of care home residents (60%) are in residential homes typically with no on-site nursing staff ^{32 33}. Although general practitioners (GPs) prescribe and are responsible for monitoring medication in care homes, medicines management (ordering, administering) is undertaken by social care staff who may have no formal training in medication practice ³⁴. In the US, administration of antipsychotic treatment by untrained staff unaware of safety issues is reported to have been a contributory pressure leading to the OBRA initiative.

In this paper, we report the findings of a large scale study in England that examines antipsychotic prescribing in nursing and residential homes following the introduction of the NDS. To date UK research on medication use in care homes remains limited ³⁵⁻³⁷, with no large-scale

studies of antipsychotic prescribing levels generally or long-term impact of the NDS. Our research investigated whether prescribing levels changed over the 4 years following introduction of the NDS guidance; the degree to which recommendations in terms of the types of agents prescribed and the length of treatment have been achieved; and variations in the patterns of prescribing between different institutions and geographical areas.

OBJECTIVES

- To assess whether the implementation of the National Dementia Strategy was associated with a decrease in prescribing of antipsychotics in long-term residential care (LTC) and, where prescribed, a shift towards newer SGAs.
- To examine differences in prescribing patterns between LTC institutions and different geographical areas, including the agents prescribed, dosages and length of exposure.
- To explore the characteristics of high/low prescribing LTC institutions.
- To consider the potential use of data on prescribing in UK LTC.

METHODS

Overview and Data Preparation

Prescription data were provided via a double-barcode electronic medicines management (EMM) system designed for care homes (see supplementary file 1). This source had previously been used to examine drug administration patterns in care homes ³⁵. Data were downloaded by the company for all care homes with the EMM system for the period 2009 – 2012 downloaded in two separate anonymised files and merged for analysis. The first contained details of all antipsychotic prescriptions, and the second de-identified resident data and anonymised LTC characteristics. Data were analysed at two time points: 1st January 2009 (prior to NDS launch) and 31st December 2012 (4 years post-NDS). For each time point, a complete dataset was examined to include all residents, there were no exclusions. Because the number of care homes which had implemented the EMM system increased over this period, a data sub-set was extracted for a cohort of care homes with the EMM system in place throughout the 4-year period (Cohort C). The National Research Ethics Service, National Patient Safety Agency, London W1T 5HD approved this retrospective study, which was designated a service evaluation [Ref: 04/02 28 October 2009].

For each prescription, dosage was converted to an equivalent daily dose in mg; administration format was classified as tablet, liquid or injection; trade names were re-coded to a common single British National Formulary (BNF) name ³⁸. All non-risperidone use was defined as off-label. Care homes were characterised in terms of: type of institution (e.g. nursing, residential home); registration status (e.g. registered for 'dementia' or 'old age only'); number of beds; any self-declared specialism (e.g. Alzheimer's care); and geographical location.

Dosages were compared to an 'indicative' maximum daily dosage (IDD), pre-defined for each agent. Three different sources were used in turn since there is no comprehensive UK guidance on IDD levels for older people. First, if the BNF contained a recommended dose for 'agitation and restlessness' in older people or less specifically for 'elderly patients' this was used as 'best available' evidence. Secondly, if the US OBRA recommendations specified a maximum dosage, this was used ^{8 9}. Finally, for all other agents the upper dosage reported in a UK survey of hospital specialists in old age psychiatry for dementia was used ³⁹. The length of exposure (LOE) was estimated by summing repeat antipsychotic prescriptions for each individual resident until the final prescription; due to the time consuming nature of this process, such analysis was limited to the licensed agent (risperidone).

Measurements

We calculated the following:

- Prescribing levels in terms of point-prevalence (PP) i.e. the percentage of residents prescribed at least one antipsychotic at each time point.
- For each prescription, the observed daily dosage classified in terms of 'indicative' maximum daily dosage (IDD) for that agent. Dosage was categorised as 'recommended' (≤IDD), 'high'

(>100% - 200% IDD) or 'excessive' (>200% IDD). Cases of *pro re nata* (PRN) or "as needed" prescribing were recorded separately.

- LOE values were compared to the recommended 6 weeks ¹⁷ and 12 week maximum ^{20 30}.
 LOE was categorised as 'recommended' (≤6 weeks treatment), 'acceptable' (>6 to <12 weeks) or 'excessive' (≥12 weeks).
- Net ingredient cost of each antipsychotic prescription, excluding any dispensing costs or fees, was estimated using BNF unit prices (accessed 6th December 2012).
- Primary medical support was categorised in terms of the number of GP practices serving an LTC facility plus the size of these practices (i.e. number of doctors). An additional proxy measure of quality was whether these included a teaching practice.
- LTC neighbourhoods were classified as 'deprived' or 'non-deprived', with deprived defined as a neighbourhood in the top 10 per cent of Index of Multiple Deprivation scores nationally
- Each LTC was linked to the body responsible for health services in its geographical area (i.e. Primary Care Trusts (PCTs) at this time); PCTs were coterminous with local government authorities responsible for provision of LTC social care services ⁴¹.

Statistical Analysis

A comparative descriptive design was adopted comparing cross-sectional and longitudinal data. Numerical data were summarised using mean and SD or median and range depending on data distribution. Stata (version 12) was used for all analyses.

Sample descriptors and prescribing patterns

Prescribing patterns were analysed to include PP levels for all antipsychotics and for FGAs / SGAs separately, dosages in terms of IDD levels, and LOE for risperidone. The mean annual expenditure on antipsychotics per resident was estimated by summing the cost of all prescriptions in an LTC setting and dividing by the total number of residents; costs were adjusted to 2012 prices ⁴².

Trend in prescribing

Cumulative distribution plots of PP values were produced for all antipsychotics, and separately for FGA and SGA agents. The 2-sample Kolmogorov-Smirnov nonparametric statistical test (ks2-test) was used to compare distributions at baseline and 48 months ⁴³. Plots for the common sub-set (*Cohort C*) were similarly compared.

Characteristics of high/low prescribing institutions

Care homes were placed into quintiles based on their baseline PP level; if an organisation was placed in a particular quintile, all residents in that home were placed in the same quintile. Quintiles were compared for categorical variables (i.e. resident demographics and care home characteristics). Rate ratios were derived for the fifth quintile divided by the first quintile and 95% confidence interval limits reported using a delta-method standard error.

Geographical variations

For each PCT area, the mean prescribing level (PP value across all care homes), ratio of SGA:FGA prescriptions, and the proportion of off-label (i.e. non-risperidone) prescriptions were estimated. For risperidone, the proportion of cases in which this was the first-line therapy was calculated, together with PP values for risperidone.

RESULTS

Sample descriptors

Table 1 shows details of baseline and 48 month samples. The mean age of residents was 83.7 years (baseline) and 78.8 years (48 months) and the majority were female (71.9% vs 68.0%). Cohort C demonstrated a similar age/gender breakdown. At baseline, 55% of care homes operated in a 'multi-practice' context (served by \geq 4 GP practices), with only 13.7% served by a single GP practice; 24% had access to at least one teaching GP practice. Number of GP practices was not related to care home size, so in the multi-practice model individual GP practices were caring for 3 - 13 residents versus 30 - 41 patients in the single practice model. 48% of care homes were registered for dementia and the remainder for 'old age only'.

	То	otal	Cohort C	
Sample characteristics	<i>Baseline</i> (1 Jan 2009)	Month 48 (31 Dec 2012)	Baseline (1 Jan 2009)	<i>Month 48</i> (31 Dec 2012)
Number of homes	211	616	166	166
Number of residents	8,357	31,619	6,979	9,006
Resident Demographics				
Women, %	71.9	68.0	71.9	69.1
Age years (mean)	83.7	78.8	83.8	80.1
65–74 years, %	8.9	16.9	8.8	14.4
75–84 years, %	34.8	44.5	34.8	45.5
85 years and over, %	52.5	30.3	52.8	34.0
Care Home Characteristics				
Mean size (number of residents)	39.6	51.3	42.0	54.3
Median size [IQ range]	37 [18]	46 [30]	39 [19]	49 [28]
Type of home (% all homes)				
Residential home, %	47.9	25.8	48.8	48.2
Nursing home, %	39.3	23.5	39.2	34.9
Dual registered*, %	12.8	50.7	12.1	16.9
Medical support (% all homes)				
1 GP practice, %	13.7	11.0	11.5	8.4
2-3 GP practices, %	31.3	29.7	31.9	29.5
4+ GP practices	55.0	59.3	56.6	62.1

Table 1 - Care Home and Resident Characteristics

* Providing both nursing and residential care.

Pattern of antipsychotic agents prescribed

Table 2 provides a detailed breakdown of antipsychotic prescribing over the 48 month period. This shows that mean PP rates did not reduce significantly; 18% at baseline vs. 19% at 48 months post-NDS. Further analysis indicates that nursing and residential homes exhibit similar PP rates; 17.3% and 18.6% respectively at baseline, and 21.0% and 19.2% at 48 months. SGAs are the most frequently used agents (68% of all prescriptions), as recommended in the NDS, with no significant differences between nursing and residential homes. Similar patterns are observed in Cohort C. FGA agents are prescribed less often than SGAs, with haloperidol the most commonly used. Although 6 residents were still prescribed the banned FGA thioridazine at baseline, by 2012 this figure had fallen to zero.

Residents were very rarely (0.7% at baseline and 1.67% at 48 months) prescribed more than one antipsychotic at the same time. Most antipsychotics were administered in tablet form (82%) with 17% as an oral liquid. The average annual expenditure on antipsychotics was £65.6 per person resident (2012 prices). Expenditure was slightly higher in nursing homes (£71.0) than residential homes (£60.4).

The vast majority of treatments at baseline (82%) were above the recommended 6 weeks; at the end of 2012 this figure had risen to 87.3%, with 69.7% and 77.6% respectively above 12 weeks. In contrast, dosages were within IDD levels in 98.7% of cases at baseline; PRN prescriptions were extremely rare (<1%).

	Total		Cohort C		
Prescribing	Baseline (1 Jan 2009)	<i>Month 48</i> (31 Dec 2012)	Baseline (1 Jan 2009)	<i>Month 48</i> (31 Dec 2012)	
Point-prevalence (PP), %					
All Antipsychotics					
Mean (standard deviation)	18.0 (±12.0)	19.0 (±15.2)	18.3 (±11.9)	18.0 (±12.3)	
Median [Inter-quartile range]	15.2 [11.8]	15.4 [14.0]	15.3 [11.4]	15.1 [12.7]	
Second-Generation Agents (SGAs)					
All Second-Generation Agents	12.5	14.6	12.8	13.9	
Quetiapine	5.1	4.7	4.9	3.9	
Risperidone	4.0	5.3	4.2	6.4	
Olanzapine	2.1	3.0	2.3	2.9	
First-Generation Agents (FGAs)					
All First-Generation Agents	5.9	5.4	5.8	5.2	
Halperidol	2.5	3.0	2.3	2.4	
Daily dosage, %*					
Recommended	98.7	NA	98.6	NA	
High	0.3	NA	0.3	NA	
Excessive	1.0	NA	1.1	NA	
Length of exposure, %**					
Recommended	18.0	12.8	18.2	10.2	
Acceptable	12.3	9.7	12.2	6.4	
Excessive	69.7	77.6	69.7	83.5	

Table 2 - Breakdown of Antipsychotic Prescribing Patterns

* Percentage of total prescriptions with following daily dosage: 'Recommended' = \leq Maximum IDD; 'High' = >100% to 200% IDD; 'Excessive' = >200% IDD. ** Percentage of risperidone prescriptions with following LOE: 'Recommended' \leq 6 weeks; 'Acceptable' >6 to <12 weeks; 'Excessive' \geq 12 weeks.

** Percentage of risperidone prescriptions with following LOE: 'Recommended' ≤ 6 weeks; 'Acceptable' >6 to <12 weeks; 'Excessive' ≥ 12 week NA, not applicable

Trends in prescribing

Figure 1 displays cumulative distribution PP plots at baseline and 48 months post-NDS for all care homes (Figure a) and separately for Cohort C (Figure b). No statistically significant decreases were observed for either (Kolmogorov-Smirnov test p=0.60 and p=0.74 respectively). For SGAs and FGAs separately, a similar analysis indicates no significant shift towards newer SGAs (KS test p=0.32) or away from FGAs (KS test p=0.26).

Characteristics of high/low prescribing institutions

Table 3 presents the characteristics of residents and LTC institutions in the highest and lowest prescribing quintiles. In terms of care home characteristics, size and type of institution (nursing or residential) show no clear differences. However, the highest quintile is more likely to include residents in institutions situated in a deprived neighbourhood (Rate Ratio [Q5/Q1] RR = 5.89, 95% confidence interval [CI] 4.35, 7.99), those in homes registered for dementia (RR = 3.38, 95% CI 3.06, 3.73), or residents in homes served by 4 or more GP practices (RR = 1.38; 95% CI 1.30, 1.46). In terms of resident characteristics, older residents aged 85 years plus were less likely to be in the upper quintile (RR = 0.63, 95% CI 0.58, 0.68) and younger residents aged 65-74 more likely (RR = 1.75, 95% CI 1.41, 2.17). 75-84 year olds have a 95% CI in-which does not overlap with the other two groups suggesting they are more likely to be in the upper quintile than those aged 85+ but less likely than those aged 65-74. There was a slight gender difference (females RR = 0.86, 95% CI 0.82, 0.90).

Table 3 - Care homes and residents in high and low prescribing quintiles(Baseline sample)

		Quintile		
	Total population	Q1 (Lowest)	Q5 (Highest)	Rate Ratio (RR, 95% CI)
CARE HOME CHARACTERISTIC	Q5/Q1			
Home Type				
Residential home – No. (%)	3703 (44.3)	831 (46.3)	737 (51.5)	1.11 (1.04, 1.19)
Nursing home – No. (%)	3422 (41.0)	682 (38.0)	561 (39.2)	1.03 (0.95, 1.13)
Dual registered – No. (%)	1232 (14.7)	282 (15.7)	133 (9.3)	0.59 (0.49, 0.72)
All				P<0.001
Registered for dementia	3359 (48.0)	335 (22.3)	913 (75.4)	3.38 (3.06, 3.73)
Registered for old age, not dementia	3644 (52.0)	1168 (77.7)	298 (24.6)	0.32 (0.29, 0.35)
				P<0.001
Area Deprivation				
Deprived neighbourhood – No. (%)	459 (6.1)	48 (2.9)	219 (17.1)	5.89 (4.35, 7.99)
Non-deprived neighbourhood – No.	7089 (93.9)	1598 (97.1)	1059 (82.9)	0.85 (0.83, 0.88)
(%)				
All				P<0.001
Practices serving home				
1 GP practice – No. (%)	866 (10.4)	180 (10.0)	68(4.8)	0.48 (0.37, 0.63)
2-3 GP practices – No. (%)	3011 (36.0)	729 (40.6)	387(27.0)	0.67 (0.60, 0.74)
4+ GP practices – No. (%)	4480 (53.6)	886 (49.4)	976 (68.2)	1.38 (1.30, 1.46)
All				P<0.001
Care Home Size*				
Small – No. (%)	545 (6.5)	183 (10.2)	95 (6.6)	0.65 (0.51, 0.82)
Medium – No. (%)	2887 (34.6)	554 (30.9)	643(44.9)	1.45 (1.33, 1.59)
Large – No. (%)	4925 (58.9)	1058 (58.9)	693(48.5)	0.82 (0.77, 0.88)
All				P<0.001
Age/Gender of Residents	8,357	1,795	1,431	
Women – No. (%)	6,011 (71.8)	1,343 (74.8)	922 (64.4)	0.86 (0.82, 0.90)
Age 65-74 – No. (%)	744 (8.9)	129 (7.2)	181 (12.6)	1.75 (1.41, 2.17)
Age 75-84– No. (%)	2,911 (34.8)	554 (30.9)	564 (39.4)	1.28 (1.16, 1.40)
Age 85+ – No. (%)	4,392 (52.5)	1,071 (59.7)	536 (37.5)	0.63 (0.58, 0.68)
All	· ·			P<0.001

Abbreviations: NA, not applicable.

* Small = ≤ 24 residents; Medium = 25-39 residents; Large ≥ 40 residents.

CI: confidence interval.

P values in the Rate Ratio column are from Pearson's chi-squared test of associated between the characteristic variable and the first and fifth quintile indicator.

Geographical variations

Table 4 presents PCT-level data for the 26 geographical areas in which care homes are located. PCT areas, arranged in order of decreasing PP rate, demonstrate a six-fold variation in prescribing level between 5.7% and 37.5% (overall mean 17.6%). The proportion of prescriptions for SGAs similarly shows an eight-fold difference, ranging between 11.1% and 89.5% (mean 62.9%), with SGA use unrelated to overall PP value. Rates of off-label (non-risperidone) prescribing vary between 5.4% and 31.3% (mean 13.9%). For risperidone, an overall PP value of 3.7% masks large geographical differences (range 0% to 6.2%). Detailed analysis of risperidone prescriptions also indicates that, although this was the first-line treatment in 75.2% of cases when prescribed, this figure varies between 0% and 100% in individual PCTs as shown in the final column.

	PRESCRIBING PATTERNS				
	Antipsychotic prescriptions			Risperidone prescriptions	
PRIMARY CARE TRUST (PCT) AREA	Point- prevalence All (%)	Proportion SGA agents (%)	Point- prevalence off-label prescribing (%)	Point- prevalence (%)	Percentage which are first-line prescriptions (%)
AREA 1	37.5	11.1	31.3	6.2	0
AREA 2	24.8	49.4	22.7	2.1	83.3
AREA 3	24.3	33.3	21.6	2.7	100.0
AREA 4	24.1	89.4	20.0	4.1	81.8
AREA 5	23.5	67.8	21.0	2.5	90.0
AREA 6	22.0	66.7	16.0	6.0	100.0
AREA 7	20.9	60.6	19.2	1.7	87.5
AREA 8	20.6	37.7	18.2	2.4	83.3
AREA 9	19.9	70.0	13.8	6.1	78.8
AREA 10	19.2	19.0	18.7	0.5	100.0
AREA 11	17.6	60.5	12.4	5.2	63.2
AREA 12	17.5	54.5	17.5	0	NA
AREA 13	17.3	78.6	15.9	1.4	100.0
AREA 14	17.0	39.4	13.4	3.6	57.7
AREA 15	15.6	68.2	13.4	2.2	50.0
AREA 16	15.5	76.9	14.5	1.0	100.0
AREA 17	15.1	75.7	10.2	4.9	81.2
AREA 18	15.1	60.0	15.1	0	NA
AREA 19	14.3	89.5	13.4	0.9	0
AREA 201	14.1	74.1	13.4	0.7	100.0
AREA 21	13.4	69.4	11.3	2.1	100.0
AREA 22	13.2	25.0	10.6	2.6	0
AREA 23	11.8	29.6	10.5	1.3	0
AREA 24	10.8	85.7	5.4	5.4	100.0
AREA 25	8.7	80.0	7.5	1.2	100.0
AREA 26	5.7	66.7	5.7	0	NA
Total	17.6	62.9	13.9	3.7	75.2

Table 4 - Prescribing Patterns by Geographical Area (Baseline sample)

NA, not applicable

DISCUSSION

This study has used data on many more care home residents than any similar UK study. This shows that reductions in the prescribing of antipsychotics driven by the National Dementia Strategy have not been sustained in care homes. Furthermore, we demonstrate that contrary to guidance older antipsychotic agents are still being used extensively rather than safer, second-generation antipsychotics. We observed that most residents were prescribed antipsychotics within acceptable dosages however, in the majority of cases, length of treatment was excessive. These results differ from an analysis of UK GP practice records over 16 years which identified a fall in levels of prescribing of antipsychotics at the point when dementia is first recorded, from 19.9% in 1995 to 7.4% in 2011⁴⁴. A recent study in England found that the launch of the NDS was linked to an increase in diagnosis rates and prescriptions for anti-dementia medications from 2006/2007 to 2011/2012⁴⁵. A trend towards earlier diagnosis may explain the fall in antipsychotic prescribing reported in 2011 in the first study⁴⁴. Neither study provided separate figures for care homes. In the US, differences in prescribing rates in nursing homes before and after the introduction of OBRA have been reported⁴⁶.

English studies of antipsychotic prescribing levels in care homes are limited, usually based on small samples (<1,000 people) typically undertaken in a single geographical area ²⁰. Even so, similar rates to those found in our study have been reported; 17.8% for residential and 21.9% for nursing homes in a single-region study ⁴⁷, 20% for a single-city study in 65 care homes ⁴, and 24.5% in a single-region study among 934 residents ¹². Elsewhere, it has been suggested that up to 27% of UK care home residents may be receiving antipsychotics ⁴⁸. More recently, a survey of care home managers in the East of England identified a rate of 12%; although this was self-reported by 299/737 managers so response bias cannot be ruled out ⁴⁹. Internationally, US rates appear to be slightly higher, although studies are limited to nursing homes ⁵⁰. Rates of 27.6% in 2000-2001 ³, 28% in 2005 ³, and 25% in 2011 ⁵¹ have been reported for large scale population samples. In contrast to these US figures, which are based on 2-3 million Medicare beneficiaries, smaller scale studies in other parts of the world generally report higher levels of antipsychotic use ⁴⁶. Reported rates in 2005-2006 include 30.3% and 36.9% in two Canadian LTC facilities ⁵², 25.1% in 40 Australian nursing homes ¹⁸, and 39%-42% in 41 institutions in Finland ⁵³. The rates observed in our study are therefore comparatively low.

Although we found no decrease in overall prescribing levels, it is also important to consider why we observed no shift towards SGAs, why off-label prescribing remained high, and why length of treatment continued to exceed the recommended 6-12 weeks (although dosages were within an acceptable range). A comparable 2005 analysis of data for US nursing home residents found 73.5% were receiving SGAs, 13.4% FGAs and 13.04% both ³. In our study, the proportion of SGAs was similar at 69%, but <2% residents were prescribed more than one agent. In Australia, a much lower level (40%) of SGA use has been reported in a cohort study of 2,005 residents ⁵⁴. In our baseline cohort, the most commonly prescribed SGAs were quetiapine, risperidone and olanzapine. This is similar to self-reported preferences in a survey of UK hospital specialists in old age psychiatry ³⁹. In terms of dosage levels, there is no other recent UK evidence available. However, a US study found that 17.2% of 1,096 nursing home residents were prescribed antipsychotic doses (excluding PRN) that exceeded maximum levels ³. Our study indicates a lower level of 1.3% in England. Our findings also confirm that off-label prescribing continues to be a problem. In March 2012, the US Centers for Medicare and Medicaid Services launched a quality initiative that recommended a 15% decrease in off-label prescribing of unlicensed antipsychotics in nursing homes over nine months ⁵⁵. No similar quality initiative has been launched in the UK.

The key drivers influencing excessive treatment length are unclear. No data are published on who initiates antipsychotic treatment in LTC in England (e.g. hospital clinicians or GPs), although there is research on continuation of treatment. A study in one UK region found that 79% of residents in 10 care homes who were prescribed risperidone or olanzapine were under GP-only care, and monitored only infrequently ¹³. Similarly, a study of 65 English care homes identified infrequent monitoring with only 25% of residents who were prescribed an antipsychotic receiving a medication review by their GP in the preceding 12 months ⁴. More recently, a British Geriatrics Society Inquiry found that continuation of therapy is largely

managed by GPs, with evidence that they may fail to undertake regular reviews as recommended ⁵⁶. The excessive treatment length observed in our cohort may therefore be associated with a lack of regular review by GPs or community pharmacists. An added reason offered for continuation of antipsychotic treatment in care homes is to reduce distress of staff ⁵⁷

⁵⁸. Against this, there is evidence of wide variability in distress amongst care staff exposed to the same resident behaviour, and poor agreement amongst senior staff about which of their residents present with challenging behaviour ⁵⁹. In fact, research from Denmark indicates that behavioural problems are a determinant for the use of antipsychotics, irrespective of the resident's diagnosis ⁶⁰.

The large variations we observed in antipsychotic use between care homes may be due to various factors such as clinical need, staffing levels or broader organisational factors such as leadership and investment in staff development⁶¹. Although we found residents in care homes registered for dementia were over-represented in our highest prescribing quintile indicating a link with clinical need, other factors appeared to have a greater impact. Since we lacked clinical data to complement the detailed prescription data, this could not be explored further. However, researchers elsewhere have identified that clinical need does not appear to be a key driver influencing prescribing rates. A Canadian study which recorded a three-fold variation among 485 nursing homes found that residents were prescribed antipsychotics irrespective of clinical indication ⁶². Similarly, for 16,586 newly admitted nursing home residents, a US study reported that someone entering a home which exhibits the highest prescribing rate is 1.37 times more likely to receive antipsychotics, after adjusting for potential clinical indications, than someone admitted to the lowest prescribing facilities ².

⁶Prescribing culture' has therefore been suggested as an important factor influencing antipsychotic use in nursing home ^{2 63-66}. In our study, although we could not measure prescribing culture, residents in homes served by a single GP practice were more likely to be in the lowest prescribing quintile, compared to LTC settings with more complex multi-practice medical support. Treatment culture may be influenced by a more consistent message provided by one practice, with requests to continue use of antipsychotics addressed more appropriately. In the multi-practice context, where up to 21 GP practices served a single care home, the lack of consistent messages may emerge, especially important in residential homes where medication is managed by non-clinical social care staff who may require more consistent advice and support ³⁴.

Interestingly, our findings also indicate that residents in care homes located in deprived neighbourhoods are significantly over-represented in the highest prescribing quintile. Although there is no other similar UK research, a US study of 17,000 care homes has identified that, compared to 'not-for-profit' or government-owned homes, residents in 'for-profit' nursing homes are more likely to be prescribed antipsychotics; this finding was explained by lower nurse staffing levels 6 ". Evidence on a direct relationship between staffing levels and antipsychotic use is currently lacking ⁶⁸. However, a measurable and sustained reduction in nursing staff burden has been reported in a double-blind, placebo-controlled randomised controlled trial (RCT) of risperidone treatment in 279 older nursing home residents with dementia ⁶⁹. A more recent RCT has found that medication also reduces informal carer time by half, but is not cost-effective compared with placebo when examining the primary clinical outcome of change in depressive symptoms ⁷⁰. Although we did not have staffing details in our study, six homes in the sample were identified by the Care Quality Commission (CQC) as having inadequate staffing levels and all were located in deprived neighbourhoods. Placing this in context, the mean annual expenditure on antipsychotics we observed was £65.60 per resident. This is <1% of the annual cost of a UK residential home place for a person with dementia (£32,241⁷²).

Finally, very few studies have examined geographical variations in prescribing in LTC. A recent survey of US nursing homes identified a three-fold geographical difference, with lower antipsychotic prescribing levels in Hawaii (12.4%) than in Louisiana (33.5%); this was based on self-reported rates so response bias cannot be excluded ⁵¹. Our study identified even larger geographical differences in off-label prescribing, and similar variations in whether the licensed agent was prescribed as first-line therapy. There is no evident reason for this.

The current study presents data from a larger sample of care homes than other UK studies to date, but there are a number of limitations. Firstly, a lack of data on care home characteristics at a national-level means that it is not possible to demonstrate representativeness of the sample. Because these care homes were early adopters of the EMM innovation, it could be argued that they might also be high performers in terms of resident care, leaving little room for improvement in antipsychotic prescribing levels. However, the large range we observed in antipsychotic use between care homes, and in the types of antipsychotics prescribed and lengths of treatment, would seem to contradict this hypothesis. A further limitation was the absence of electronic health records in the facilities studied, to complement the comprehensive electronic prescription data and identify all residents with a diagnosis of dementia. However, the majority of people with dementia in the UK did not have a formal diagnosis during this period ²⁰, so it would have been difficult to identify such residents confidently using routine data ¹⁷. The UK is not unusual, and barriers to the introduction of electronic health records in long-term care facilities are recognised internationally ⁷³. Finally, although there is a possibility that the NDS may have had an impact on antipsychotic use in care homes at the time of its launch with central support, our data clearly indicates that this was not sustained over time.

Policy and research implications

The National Dementia Strategy was not associated with sustained change in the use of antipsychotics in people resident in care homes. The economic burden of dementia in the UK is estimated to be £4 billion per year, more than cancer, heart disease and stroke combined ⁷⁴. Further strategies may be required to achieve control and reduce the inappropriate use of antipsychotics in care homes ⁷⁵. As a first step, standards specifying recommended agents, dosages and length of treatment would be helpful. Secondly, consideration should be given to routine reporting of patterns of prescribing for care home residents that are subject to regulatory scrutiny; the National Dementia Strategy did not include long term monitoring mechanisms let alone enforcement mechanisms. Antipsychotic prescribing patterns in UK care homes are not open to public scrutiny nor routinely reported by regulatory inspection. Finally, research is needed to explore why prescribing appears to have been unaffected by the NDS.

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CONTRIBUTORS

AS and DW conceived the idea for the study. TM found and imported the relevant data. AS, AK, DO and TP completed the analyses. AS, DW and CB wrote the first draft of the manuscript and AS is the guarantor. All authors contributed to and agreed the final version.

DATA SHARING

Additional data may be available on request from the corresponding author.

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