

## Hormonal replacement therapy prescribing in menopausal women in the UK: A descriptive study

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# 1 Hormonal Replacement Therapy Prescribing in Menopausal Women in the UK: A

## 2 Descriptive Study

### 3 Abstract:

4 **Background:** Recent studies on the prescribing of hormonal replacement therapy (HRT)  
5 medicines to treat symptoms of menopause are lacking.

6 **Aim:** To describe the prescribing of HRT in a cohort of UK menopausal women.

7 **Design and setting:** Population-based drug utilization study using IQVIA Medical Research  
8 Database.

9 **Method:** Primary care data of women with recorded menopause and/or 50 years and older  
10 between January 2010 and November 2021 were extracted from the database. The  
11 incidence rate (IR) of women who received their first prescription for HRT was calculated  
12 annually using person-years at risk (PYAR) as the denominator. IRs of HRT were estimated  
13 by type and route of administration. Relative changes in annual IR were expressed as  
14 percentages and the average percentage change was assessed using linear regression.  
15 Annual prescribing prevalence per 100 women was calculated using mid-year menopausal  
16 population estimates.

### 17 Results:

18 The IR of prescribing of HRT increased from 5.01 in 2010 to 18.16 per 1000 PYAR in 2021, a  
19 relative increase of 13.64% (95% CI 6.97-20.30) per year. IR of fixed combinations of HRT  
20 increased from 3.33 to 12.23 per 1000 PYAR in 2010 and 2021, respectively. Transdermal  
21 formulations of HRT increased from 1.48 to 14.55 per 1000 PYAR in 2010 and 2021,

22 respectively. The overall proportion of women in receipt of a prescription for HRT changed  
23 from 7.89% in 2010 to 6.8% in 2020.

24 **Conclusion:**

25 Our study shows steady increase in the number of women receiving their first prescription  
26 for HRT during the study period which suggests regained acceptance of HRT medicines.

27 **Key words:** Menopause – Hormonal replacement therapy – HRT – perimenopausal

28 **How this fits in:**

- 29 - Recently, there has been increased societal interest in prescribing of HRT and  
30 management of symptoms of menopause.
- 31 - New users of HRT have markedly increased in recent years; particularly new users of  
32 non-oral formulations, fixed combinations of oestrogen and progesterone and in  
33 younger menopausal women (aged 50-59 years).
- 34 - The increase in new users of symptomatic menopause treatment should inform  
35 guidance on support for general practitioners (GP) for prescribing of HRT and  
36 management.

37

## 38 Introduction:

39 Women going through menopausal transition typically experience symptoms starting seven  
40 years before the last menstrual period McNeil and Merriam[1]. During menopausal  
41 transition, women commonly report genitourinary and vasomotor symptoms, sleep  
42 disturbances, cognitive decline and mood disorders such as depression and anxiety Santoro,  
43 Roeca, Peters and Neal-Perry[2]. The National Institute of Healthcare Excellence (NICE)  
44 recommend the use of hormone replacement therapy (HRT) to relieve symptoms of  
45 menopause with careful monitoring National Institute for Health and Care Excellence[3].  
46 HRT is composed of oestrogen and progesterone used in single form or in combination  
47 BNF[4]. In addition to oestrogen and progesterone, menopausal women may require  
48 testosterone supplementation for low sexual desire National Institute for Health and Care  
49 Excellence[3]. There are no recent studies on the prescribing of HRT in menopausal women  
50 using patient-level data; previous studies in the UK have described prescribing rates until  
51 2015 Burkard, Moser, Rauchet al.[5, Bromley, de Vries and Farmer[6].Therefore, this study  
52 aimed to describe the prescribing of HRT medicines in UK menopausal women from 2010  
53 until 2021.

## 54 Method:

55 Anonymised patient data were extracted from IQVIA Medical Research Database (IMRD-UK)  
56 that incorporates data supplied by The Health Improvement Network (THIN), a propriety  
57 database of Cegedim SA7], in March 2022. The study was approved by the IQVIA Scientific  
58 Review Committee (reference number 22SRC001).

## 59 Study population

60 Our study population comprised menopausal women (peri-or postmenopausal) during the  
61 study period (1 January 2010 to 2 November 2021). Women receiving a menopausal  
62 recording before their 50<sup>th</sup> birthday were included. Women with no recording of  
63 menopause (91%) were assumed to be menopausal from the age of 50 onwards. This age  
64 cut-off was based on results of previous studies Sarri, Davies and Lumsden[8]. In our  
65 dynamic cohort, women entered the cohort on the date of their first menopausal recording  
66 if earlier than their 50<sup>th</sup> birthday, or their 50<sup>th</sup> birthday, plus a 6-month registration with the  
67 practice prior to the entry date. Women were censored on the earliest of the following  
68 dates; transfer out of the practice, death, or the last collection date of a primary care  
69 practice.

#### 70 **Study variables**

71 Primary care records indicating menopause were retrieved for adult females using the code  
72 list in [Table S1](#). Code lists for prescriptions of HRT medicines were based on BNF Chapter  
73 6.4.1, except for oestrogen receptor modulators. Types of hormone replacement therapy  
74 were based on ATC classification: oestrogens, progestogens and combination regimens of  
75 oestrogen and progestin (OP) in sequential preparations or fixed combinations [9].

76 Separately, prescriptions for testosterone hormonal therapy were retrieved. Code lists of  
77 testosterone were based on BNF Chapter 6.4.2(see [Table S2](#) for code list). Routes of  
78 administration were grouped as: Oral route including tablets and capsules, local route  
79 including gels, creams and vaginal pessaries, and transdermal formulations (patches and  
80 transdermal implants).

#### 81 **Statistical Analysis:**

82 To describe our cohort, the proportion of menopausal recording was estimated in; 1) all  
83 women 2) women over 50 years-old. The following variables were reported to describe our  
84 cohort: 1) Age at first menopausal recording in 10-year-band age groups, and 2) HRT status.  
85 The number of menopausal women who received their first prescription for HRT (incidence  
86 rate of prescribing) was calculated annually using person-years at risk (PYAR) as the  
87 denominator. Annual incidence rates of prescribing were estimated per 1000 PYAR with  
88 95% confidence intervals assuming Poisson distribution. A first prescription was defined as  
89 the first recorded prescription, with no previous recorded prescription of this medication  
90 class. Relative changes in yearly incidence rates were expressed as percentages and the  
91 average percentage change in HRT prescribing throughout the study period was assessed  
92 using linear regression. Incidence rates for prescribing of HRT were estimated separately by  
93 type of HRT, route of administration, and age group. The prescribing prevalence was  
94 calculated using mid-year population estimates as the denominator. The mid-year  
95 population was estimated by calculating the number of menopausal women on the 1<sup>st</sup> of  
96 July of each year. The annual prevalence was expressed per 100 women for the years with  
97 full data availability (2010-2020). Analyses were conducted using STATA version 17.

## 98 Results:

99 During our study period, 1,908,177 menopausal women contributed person-years to IMRD-  
100 UK. A record of menopause was found for 9% (n=433,025) of women of all ages and 19.5%  
101 (n=419,953) of women aged  $\geq 50$  years-old. Amongst women with a menopausal recording,  
102 33.62% were 60-69 years old. Most women with a record indicating menopause (77.7%)  
103 received prescriptions for HRT medicines (Table 1).

104 *Prescribing incidence of HRT medicines*

105 The incidence rate of first prescriptions for HRT medicines increased from 5.01 (95% CI 4.87  
106 to 5.14) in 2010 to 18.16 (95% CI 17.66 to 18.67) per 1000 PYAR in 2021, an average annual  
107 increase of 13.64% (95% CI 6.97 to 20.30) per year (figure 1 and [Table S3](#)).

108 The highest absolute increase in new prescriptions for types of HRT was observed in fixed  
109 combinations of oestrogen and progesterone: From 3.33 per 1000 PYAR (95% CI 3.22 to  
110 3.45) in 2010 to 12.23 per 1000 PYAR (95% CI 11.88 to 12.59) in 2021; an average annual  
111 increase of 17.6% (95% CI 11.51 to 23.85). New prescriptions for oestrogen only HRT  
112 increased from 2.53 (95% CI 2.43 to 2.63) per 1000 PYAR in 2010 to 10.64 (95% CI 10.30 to  
113 10.98) per 1000 PYAR in 2021; an average annual increase of 16.7% (95% CI 10.50 to 22.80).

114 New prescriptions for sequential preparations of oestrogen and progesterone increased  
115 from 2.33 (95% CI 2.23 to 2.42) per 1000 PYAR in 2010 to 2.51 (95% CI 2.35 to 2.67) per  
116 1000 PYAR in 2021, with a 4.3% (95% CI 0.98 to 7.80) average annual change. Lastly, new  
117 prescriptions of progestins increased from 1.98 (95% CI 1.90 - 2.07) per 1000 PYAR in 2010  
118 to 6.19 (95% CI 5.94 - 6.46) per 1000 PYAR in 2021 with an average annual increase of  
119 13.24% (95% CI 5.40 – 21.0)(figure 2 and [Table S4](#)).

120 Results stratified by route of administration showed an increase in all non-oral formulations  
121 of HRT: Incident prescriptions for transdermal formulations increased from 1.48 (95% CI  
122 1.41 to 1.55) per 1000 PYAR in 2010, to 14.55 (95% CI 14.17 to 14.94) per 1000 PYAR in  
123 2021, an average annual increase of 31.51% (95% CI 20.90 to 42.12). First prescriptions for  
124 locally administered HRT increased from 0.56 (95% CI 0.52 to 0.61) per 1000 PYAR in 2010 to  
125 5.91 (95% CI 5.68 to 6.16) per 1000 PYAR in 2021, or a 34.11% (95% CI 20.67 to 47.56)  
126 average annual increase (Figure 3 and [table S5](#)). The prescribing incidence of oral  
127 formulations increased on average 1.67% (95% CI -0.58 to 3.92) per study year from 6.28

128 (95% CI 6.11 to 6.46) per 1000 PYAR in 2010 to 10.45 (95% CI 10.08 to 10.84) per 1000 PYAR  
129 in 2021 (see table S6). The rate of first prescriptions for testosterone hormonal therapy was  
130 relatively constant during the study period, from 0.16 (95% CI 0.14 to 0.19) in 2010 to 0.33  
131 (95% CI 0.28 to 0.39) per 1000 PYAR in 2021 ([Table S6](#)).

132 The absolute increase in incident HRT prescribing by age was mostly observed in younger  
133 menopausal women (50-59 years): The incidence rate increased from 19.17 (95% CI 18.6 to  
134 19.76) per 1000 PYAR in 2010 to 54.11 (95% CI 52.54 to 55.72) per 1000 PYAR in 2021 (see  
135 figure 4-A), a 11.71% (95% CI 4.45 to 18.98) average annual increase. In 60-69 year-olds, first  
136 prescriptions for HRT increased on average 7.73% (95% CI 1.72 to 13.74) per year from 2010  
137 until 2021 (see figure 4-B and [Table S7](#)).

#### 138 *Prescribing prevalence of HRT medicines*

139 The annual prescribing prevalence of HRT medicines was 7.89 per 100 women in 2010 and  
140 6.86 per 100 women in 2020, an average change of -0.38% (95% CI -1.40 to 0.79) (figure 5  
141 [Table S8](#)).

#### 142 **Discussion:**

##### 143 Summary:

144 We observed an increase in new prescribing of HRT medicines from 2010 to 2021. The most  
145 prominent increase was seen in in the prescribing of HRT for younger women (50-59 years),  
146 non-oral routes of administration and fixed combinations of oestrogen and progesterone.

##### 147 Comparison with existing literature:

148 Our results update previous reports that described the prescribing of HRT in the UKBurkard,  
149 Moser, Rauch, Jick and Meier[5, Bromley, de Vries and Farmer[6]. Prescribing rates of HRT  
150 medicines have been affected by early results of the WHI trialRossouw, Anderson,



151 Prentice et al.[10, Manson, Chlebowski, Stefanick et al.[11]. Following the trial, prescribing of  
152 HRT in the UK decreased between 2000 to 2005 and then remained relatively constant until  
153 2015 Burkard, Moser, Rauch, Jick and Meier[5, Vinogradova, Denning, Hippisley-Cox et al.[12].  
154 Similar trends have been observed internationally Heinig, Braitmaier and Haug[13, de Jong-  
155 van den Berg, Faber and van den Berg[14, Jewett, Gangnon, Trentham-Dietz and  
156 Sprague[15]. We found a rapid increase in incident prescribing of HRT from 2015 onwards,  
157 except for the year 2020. A decrease in prescribing in 2020 may be a result of the decline in  
158 healthcare utilization due to restrictions imposed during the covid-19 pandemic Mansfield,  
159 Mathur, Tazareet et al.[16]. As 2020 was the last full year of data collection, this also affected  
160 the estimates of annual change in the prescribing prevalence. The increase in incident  
161 prescribing of HRT from 2015 onwards could be explained by the publication of the NICE  
162 guidelines for management of menopause National Institute for Health and Care  
163 Excellence[3], and publication of the sub-group analyses of the WHI trial Manson,  
164 Chlebowski, Stefanick, Aragaki, Rossouw, Prentice, Anderson, Howard, Thomson, LaCroix,  
165 Wactawski-Wende, Jackson, Limacher, Margolis, Wassertheil-Smoller, Beresford, Cauley,  
166 Eaton, Gass, Hsia, Johnson, Kooperberg, Kuller, Lewis, Liu, Martin, Ockene, O'Sullivan,  
167 Powell, Simon, Van Horn, Vitolins and Wallace[11, Manson, Aragaki, Rossouw et al.[17]. The  
168 increase in prescribing may also be driven by raised awareness of  
169 menopause Whitehead[18]. Several menopause support organizations are raising awareness  
170 on menopause issues and educating healthcare professionals on menopause  
171 management Whitehead[18, 19, 20]. Since the first publication of the initial WHI, more  
172 research was conducted on different formulations and types of HRT medicines Stuenkel[21].  
173 Studies have shown that non-oral formulations of HRT are associated with a lower risk of  
174 VTE compared with oral formulations of HRT Cobin and Goodman[22, Renoux, Dell'Aniello

175 and Suissa[23, Sweetland, Beral, Balkwillet al.[24]. In our study, the rise in new prescriptions  
176 of HRT medicines was marked in non-oral formulations. In addition, we observed a 17%  
177 relative increase in prescribing of fixed combinations of OP compared with 4% increase in  
178 sequential preparations. This could be in response to safety reports indicating that  
179 progesterone used in sequential combinations such as medroxyprogesterone acetate are  
180 associated with higher VTE riskSweetland, Beral, Balkwill, Liu, Benson, Canonico, Green and  
181 Reeves[24, Baber, Panay and Fenton[25]. Testosterone is indicated for women suffering  
182 from hypoactive sexual desire disorder (HSDD) as second-line treatment after HRTNational  
183 Institute for Health and Care Excellence[3]. Use of testosterone replacement was limited in  
184 our study as testosterone formulations are only available in male doses through specialists  
185 prescribingHamoda, Panay, Arya and Savvas[26].

186 The results of the sub-group analyses of WHI suggest that HRT is not associated with  
187 increased risk of cardiovascular disease if started soon after menopause or in young  
188 menopausal women, generating the “timing hypothesis” National Institute for Health and  
189 Care Excellence[3, Manson, Chlebowski, Stefanick, Aragaki, Rossouw, Prentice, Anderson,  
190 Howard, Thomson, LaCroix, Wactawski-Wende, Jackson, Limacher, Margolis, Wassertheil-  
191 Smoller, Beresford, Cauley, Eaton, Gass, Hsia, Johnson, Kooperberg, Kuller, Lewis, Liu,  
192 Martin, Ockene, O'Sullivan, Powell, Simon, Van Horn, Vitolins and Wallace[11, Baber, Panay  
193 and Fenton[25, Lobo, Pickar, Stevenson et al.[27]. In our study, the absolute rates of new  
194 prescribing of HRT were highest (11.7% per year) in 50-59 year-old women throughout the  
195 study period. These results are consistent with previous reports using UK primary care data,  
196 in which the prevalence of HRT prescribing up to 2016 was higher in 50-59 year-olds  
197 Burkard, Moser, Rauch, Jick and Meier[5, Vinogradova, Denning, Hippisley-Cox, Taylor, Moore  
198 and Coupland[12]. However, the relative increase in new prescribing of HRT in women aged

199 60-69 during the study period was 7.7% per year, showing that the increase in HRT  
200 prescribing is not just driven by the youngest menopausal age group.

201 Our study shows that the overall proportion of women who received a prescription for HRT,  
202 both new users and prevalent users, increased until 2019, but that the increase was highest  
203 for new prescriptions. This suggests that clinical guidelines were followed and HRT are used  
204 for the short term management of menopausal symptoms National Institute for Health and  
205 Care Excellence[3]. In women with early menopause, HRT is recommended until they reach  
206 the age of natural menopause National Institute for Health and Care Excellence[3].

207 However, it may not have affected the prescribing prevalence of HRT in our study as a small  
208 proportion of our cohort were recorded as 'early menopausal'. Our study shows that  
209 menopausal onset is not well recorded in primary care records. Only 19% of women over  
210 the age of 50 had a record of menopause. Therefore, it is hard to infer menopausal onset  
211 from our study.

212 Strengths and limitations:

213 Our study provides up to date information on the prescribing of HRT in the UK using patient-  
214 level data. Moreover, our study is the first to report on the prescribing of testosterone in  
215 menopausal women. Menopausal onset is not well recorded in primary care databases, thus  
216 we assumed that women were menopausal on or after the age of 50 years-old. Some  
217 women may have had their menopausal onset before or after the age of 50 and we may  
218 therefore have underestimated the incidence and prevalence of prescribing of HRT. An  
219 underestimation of prescribing may have also occurred as some women may be treated in  
220 specialist centres and prescriptions issued outside primary care practices are not recorded  
221 in the IMRD-UK database. In addition, IMRD-UK has a unique patient identifier per practice.

222 Thus, women switching practices would be identified as receiving new prescriptions rather  
223 than repeat prescriptions. Further, indications for medicine use are not recorded in IMRD-  
224 UK database. Therefore, medicines such as progestins and sequential hormonal preparation  
225 may have been prescribed for other conditions than menopause management. Lastly, the  
226 IMRD-UK database only has information on the prescribing of medications, but information  
227 on whether prescriptions were redeemed or consumed is not available.

#### 228 Implications for practice:

229 Increased prescribing of medicines used for the management of symptoms of menopause  
230 may reflect improved awareness by women and healthcare professionals. Our findings  
231 suggest that the initial decrease in HRT prescribing after the first WHI trial has recovered.  
232 HRT therapy offers holistic management for menopausal symptoms, in addition to  
233 preventing osteoporosis and improving quality of life Julie Ayres and Heather Currie[28].  
234 Given the recent increase in HRT prescribing, we support the recommendation of the British  
235 Menopause Society that all healthcare professionals should have a basic understanding of  
236 menopause, in addition to including a GP with special interest in menopause in each  
237 primary care team Currie, Abernethy and Gray[29]. To improve our understanding of  
238 menopause and its management in the UK primary care setting, we recommend enhancing  
239 recording of natural and medical causes of menopause by GPs. Furthermore, we support the  
240 recommendation of NICE guidelines to review and weigh the risk/benefits of HRT treatment  
241 regularly National Institute for Health and Care Excellence[3].

#### 242 [Declarations](#)

243 **Funding:** No specific funding was received for this study.

244 **Ethical approval:** This study was approved by the scientific review committee of IMRD-UK  
245 reference number: 22SRC001

246 **Competing interest:**

247 We declare no competing interest

248 **Acknowledgements**

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250 Education and the Saudi Culture Bureau.

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252 *Table 1: Demographics of study cohort*

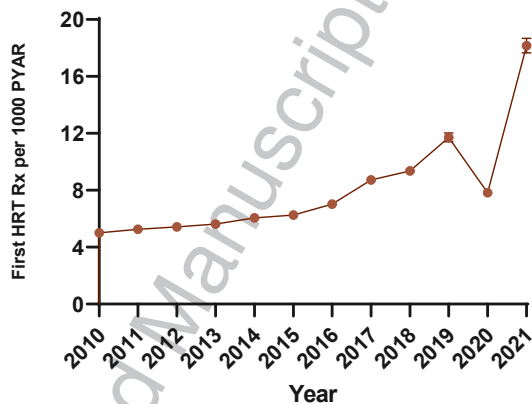
	Women with menopausal recording (n=433,025)	Women aged ≥50 years-old and/or with menopausal recording (n= 1,908,177)
Age groups*	Women n (%)	Women n (%)
<30	401 (0.10)	401 (0.02)
30-39	2,078 (0.50)	2,078 (0.11)
40-49	26,013 (6.20)	26,013 (1.36)
50-59	127,172 (30.3)	583,679 (30.59)
60-69	141,103 (33.62)	481,214 (25.22)
70-79	93,824 (22.35)	381,102 (19.97)
>80	29,164 (6.95)	433,690 (22.73)
HRT Prescription status		
HRT Rx	336,465 (77.70)	611,106 (31.80)
No HRT Rx	96,560 (22.30)	1,310,535 (68.20)

253 \*Age of women at latest date of data collection

254 N=number, HRT=Hormone replacement therapy, Rx=prescription,

255

256 *Figure 1: Annual incidence rate of prescribing of HRT medicines.*

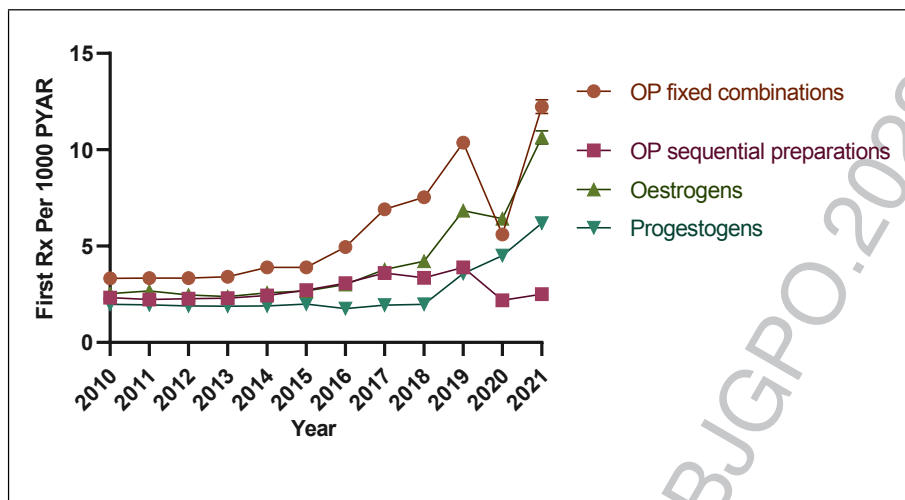


257

258 HRT= Hormonal replacement therapy Rx=Prescription, PYAR=person-year-at-risk

259

260 *Figure 2: Annual incidence rate of prescribing of HRT medicines by type of HRT.*



261

262 Rx=Prescription PYAR=Person-year-at-risk OP=Oestrogen-Progesterone

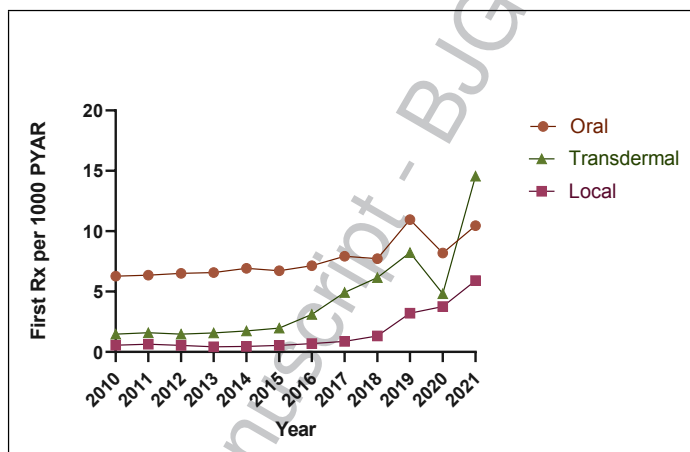
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267 *Figure 3: Annual incidence rate of prescribing of HRT medicines by route of administration*



268

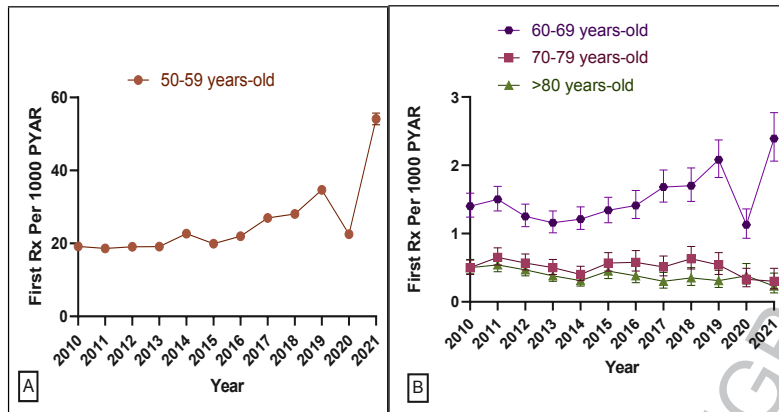
269 Rx=Prescription PYAR=Person-year-at-risk

270

271

272

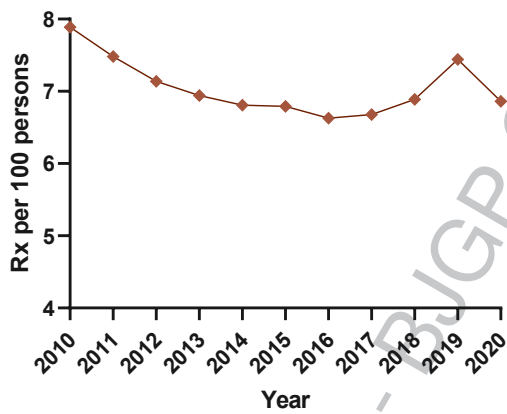
273 *Figure 4: Annual incidence rate of prescribing of HRT medicines by age group.*



274

275 Rx=Prescription PYAR=Prescription-year-at-risk

276 *Figure 5: Annual prevalence of prescribing of HRT*



277  
278

Rx=prescriptions



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# **Hormonal Replacement Therapy Prescribing in Menopausal Women in the UK: A**

## **Descriptive Study**

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