Title:

A 5-year evaluation of the Emergency Contraception (EC) enhanced community pharmacy service provided in Wales

(Previously titled "Effectiveness and acceptability of the Emergency Contraception (EC) enhanced community pharmacy service provided in Wales: a longitudinal evaluation")

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Abstract

Background

Access to Emergency Contraception (EC) has been a core component of attempts to address high teenage pregnancy rates in Wales. A national service was commissioned in 2011, allowing supply of EC free of charge from community pharmacies (CPs). This study investigated five years of the EC service, to describe its use and investigate changes in the pattern of use over time.

Methods

Secondary analyses of data from all NHS funded CP EC consultations in Wales between 1 August 2012 and 31 July 2017 (n=181,359). Data comprised standardized clinical and demographic information, in the form of pre-defined service user responses, submitted for reimbursement by CPs.

Results

Overall service provision remained relatively consistent over the study period, with women between 13 and 59 years of age accessing the service. An association was observed between the time since unprotected sexual intercourse and the day on which the service was accessed ($X^2(18) = 16292.327$, $p<0.001$). Almost half (47.9%) of requests were because no contraception had been used, with a strong and positive association for teenagers and women over 40. A statistically significant and increasing percentage of consultations were accompanied by further sexual health advice ($r=0.7$, $p<0.01$).

Conclusions

Access to EC through CPs is contributing to reducing teenage conceptions and termination rates. However, action is needed to increase contraception use in all age groups. Reduced availability of CP services on Sundays is a barrier to timely EC access. Findings support an expanded role for community pharmacists in provision of regular contraception.

Key messages

- The Community Pharmacy EC service helps meet the EC needs of women of any age, despite originally being targeted at teenagers.
- The reasons for attending an EC consultation vary with age, and age-targeted actions are needed to increase awareness of contraception use in all age groups.
- Results support expansion of the role of the community pharmacists to include provision of regular contraception.

Introduction

Emergency contraception (EC) is used to prevent pregnancy following unprotected sexual intercourse (UPSI) or contraceptive failure. In the United Kingdom (UK) two methods of EC are in common use: insertion of an intrauterine device (IUD) within five days of UPSI; and the administration of an emergency contraceptive pill. (1) Two types of licensed EC pill are currently available. Preparations containing levonorgestrel, licensed for use up to 72 hours following UPSI, have been available since 2000, whereas ulipristal acetate 30mg tablet (EllaOne®), for use within 120 hours of UPSI, has been available since 2009. (2,3) Initially EC pills were licensed in the UK as prescription only medicines (POMs), requiring a prescription from general practitioners (GPs), or supplied by family planning or accident and emergency services.

In the early 2000s, in an attempt to improve access to EC, NHS bodies across the UK, began making provision for POM levonorgestrel to be supplied from community pharmacies (CPs) without prescription using patient group directions (PGDs). (4) Subsequently, levonorgestrel was reclassified as a pharmacy medicine, to allow it to be sold 'over-the-counter' (OTC) from CPs. However, the high cost of OTC relative to POM preparations, and licensing restrictions which prevented pharmacists selling EC to girls under 16, remained barriers to wider access and NHS funded PGD schemes persisted. (5)

In 2011, the Welsh Government directed local health boards to commission a national EC service from CPs allowing levonorgestrel to be obtained by women and girls from the age of 13 free of charge under a PGD. (6) In April 2015, the service was extended to allow ulipristal acetate to be supplied between 72 and 120 hours after UPSI. The arrangements aimed to widen access to EC and increase the provision of sexual health advice amongst sexually active women. By 2017, 76% of CPs in Wales (544/716) were providing the service. (7)

Most previous research has focused on OTC sales of EC, rather than supply under a PGD (8-12). In general, studies have been small scale evaluations of pilot schemes, they have however, consistently identified pharmacy services promote access to EC and are highly acceptable to service users, with many reporting CPs as the preferred route of access. There has to date been no large scale, longitudinal evaluation of EC provision by CPs to explore whether the benefits identified in smaller studies are maintained over time. The aim of this study was twofold: first to describe the CP EC use in Wales between 2012 and 2017, and secondly to investigate changes in the pattern of EC use over time.

Methods

Figure 1 presents an overview of the study methodology. (13)

Study design and setting

Secondary analyses of data from all NHS funded EC consultations taking place in CPs in Wales between 1 August 2012 and 31 July 2017 (n = 181,359) was undertaken. Data were obtained from the NHS Wales Shared Services Partnership from details of EC service consultations, submitted by CPs for reimbursement. Data contained standardised clinical and demographic information, in the form of pre-defined responses recorded by pharmacists.

As there were no identifiers that could link the information to an individual in the data set, this study required no ethical approval. (14)

Measures

Our primary outcome was the number of CP EC consultations over time. Secondary outcomes were consultation outcome (i.e. EC supplied or not, levonorgestrel versus ulipristal acetate); the rate of EC use by age group; EC access by day of week; time since UPSI; reason for requesting EC and regular use of contraception by service users, defined in the service specification as the use of any form of prescribed contraception including oral contraception, contraceptive patch, long acting reversible contraception, or intrauterine device or system; and how these changed over time.

Statistical analyses

Data were exported to IBM SPSS® v23 for analysis; a random 10% manual validation check was conducted independently by two researchers for quality assurance of the data transfer process. No discrepancies were identified. Secondary data analysis was carried out using Microsoft Excel® and IBM SPSS® v23 to obtain descriptive statistics and undertake more detailed statistical comparisons. Scatter plots and line graphs with 95% confidence intervals were used to assess linearity between time and EC service use as well as outcomes. Pearson's chi-squared tests were used to determine if there were any statistically significant associations between variables ($p<0.05$), and the distribution of standardized residuals (z-scores) to determine the strength of the associations.

Patient Involvement

Patients were not involved in the design or conduct of this study.

Results

Overall characteristics of the population using the EC service for all 181,359 recorded consultations between 1 August 2012 and 31 July 2017 are presented in Table 1. There was evidence of a decline in the absolute number of EC requests over the study period ($r = -0.41$, $p = 0.001$) (Supplementary Figure 1). The median age of service users was 25, range 13-59, interquartile range 19-30 (data available for n=175,460 consultations). After age data were standardized per age group population using data for estimated population in Wales (15), the highest rate of consultations was noted for 16-19-year-olds (at 5.5 consultations per 100 population) (Table 2).

Table 1 Overall characteristics of the population using the community pharmacy Emergency Contraception (EC) service during the 5-year study period 1st August 2012 – 31st July 2017 (total consultations n=181,359).

		2012-13		2013-14		2014-15		2015-16		2016-17		Total	
		n	(%)*	n	(%)*	n	(%)*	n	(%)*	n	(%)*	n	(%)*
Age group	13-15	1,312	(3.5)	1,223	(3.3)	883	(2.5)	878	(2.5)	786	(2.2)	5,082	(2.8)
	16-19	8,807	(23.8)	8,958	(23.9)	8,064	(22.6)	7,849	(22.0)	6,806	(19.2)	40,484	(22.3)
	20-24	11,342	(30.6)	11,219	(29.9)	10,438	(29.3)	10,042	(28.1)	8,754	(24.7)	51,795	(28.6)
	25-29	6,722	(18.1)	6,844	(18.3)	6,912	(19.4)	6,843	(19.2)	6,264	(17.6)	33,585	(18.5)
	30-39	6,573	(17.7)	6,835	(18.3)	6,945	(19.5)	6,935	(19.4)	6,692	(18.8)	33,980	(18.7)
	40+	2,142	(5.8)	2,147	(5.7)	2,213	(6.2)	2,116	(5.9)	1,916	(5.4)	10,534	(5.8)
	Not recorded	180	(0.5)	190	(0.5)	162	(0.5)	1,069	(3.0)	4,298	(12.1)	5,899	(3.3)
Regular contraception use	Yes	16,376	(44.2)	15,500	(41.4)	14,049	(39.4)	13,190	(36.9)	12,029	(33.9)	71,144	(39.2)
	No	20,702	(55.8)	21,916	(58.6)	21,568	(60.6)	22,542	(63.1)	23,487	(66.1)	110,215	(60.8)
Reason for EC request	Failure of barrier contraception	16,983	(45.8)	16,505	(44.1)	15,160	(42.6)	14,677	(41.1)	13,448	(37.9)	76,773	(42.3)
	No contraception used	17,093	(46.1)	17,878	(47.8)	17,282	(48.5)	17,141	(48.0)	17,642	(49.7)	87,036	(47.9)
	Missed contraception	3,002	(8.1)	3,033	(8.1)	3,175	(8.9)	3,904	(10.9)	3,667	(10.3)	16,781	(9.3)
	Other	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.0)	759	(2.1)	769	(0.4)
Time since UnProtected Sexual Intercourse (UPSI)	0-24	25,894	(69.8)	25,851	(69.1)	24,107	(67.7)	23,561	(65.9)	23,038	(64.9)	122,451	(67.5)
	25-48	8,955	(24.2)	9,045	(24.2)	8,871	(24.9)	8,917	(25.0)	8,754	(24.6)	44,542	(24.6)
	49+	2,229	(6.0)	2,520	(6.7)	2,639	(7.4)	3,254	(9.1)	3,724	(10.5)	14,366	(6.4)
Medication provided *(EllaOne ® included in service since April 2015)*	Levonorgestrel 1.5mg tablet (Levonelle®)	36,090	(97.3)	36,426	(97.4)	34,599	(97.1)	34,269	(95.9)	34,012	(95.8)	175,396	(96.7)
	Ulipristal Acetate 30mg Tablet (EllaOne®)	-	-	-	-	188	(0.5)	726	(2.0)	877	(2.5)	1,791	(0.9)
	No medication supplied	988	(2.7)	990	(2.6)	830	(2.3)	737	(2.1)	627	(1.8)	4,172	(2.4)
Referral to another agency *(data available since April 2015)*	Sexual health clinic	-	-	-	-	1,545	(17.8)	6,057	(17.0)	6,802	(19.2)	14,404	(18.0)
	General Practitioner (GP)	-	-	-	-	1,043	(12.0)	4,772	(13.4)	4,684	(13.2)	10,499	(13.1)
	Out of hours (OOH)	-	-	-	-	0	(0.0)	0	(0.0)	26	(0.1)	26	-
	Another pharmacy	-	-	-	-	0	(0.0)	1	(0.0)	24	(0.1)	25	-
	Accident & Emergency (A&E)	-	-	-	-	0	(0.0)	0	(0.0)	2	(0.0)	2	-
	No referral	-	-	-	-	6,080	(70.1)	24,902	(69.7)	23,978	(67.5)	54,960	(68.8)
	Total											79,916	
Further sexual health and contraception information provided	Yes	28,758	(77.6)	29,470	(78.8)	27,401	(76.9)	28,526	(79.8)	29,396	(82.8)	143,551	(79.2)
	No	8,320	(22.4)	7,946	(21.2)	8,216	(23.1)	7,206	(20.2)	6,120	(17.2)	37,808	(20.8)

* Overall percentages may not add to 100 due to rounding

Table 2: Rate of consultations per age group, when numbers were standardized using data for estimated population in Wales (15) (data available for 2012-16).

Age group	Average population	Average number of users per year	Rate (users/100 population)
13-15	103,855	1,074	1.0
16-19	153,323	8,420	5.5
20-24	211,100	10,760	5.1
25-29	200,900	6,830	3.4
30-39	358,000	6,822	1.9
40+	818,100	2,155	0.3

Day and time after UPSI EC service was accessed

There was a statistically significant difference on number of consultations with day of week (Kruskal Wallis test, p<0.001, CI 95%). More than a quarter of the consultations were conducted on a Monday (25.8%) and just under a quarter of consultations (24.6%) during the weekend (Figure 2). An association was observed between the time since UPSI and the day on which the service was accessed ($X^2(18) = 16292.327$, p<0.001). Consultations within 25-48 hours of UPSI were more likely to happen on Mondays and Tuesdays, and for 49-120 hours since UPSI on Mondays, Tuesdays and Wednesdays (Supplementary Table 1). In the 5-year period, more than two thirds of requests made through the EC service took place within 24 hours of UPSI (67.5%). Requests made more than 49 hours after UPSI increased from 6.0% to 10.5% of total annual consultations.

Reasons for requesting EC

Over the 5-year period, almost half (47.9%) of requests made through the EC service were because no contraception had been used. EC requests resulting from barrier contraception failure decreased from 45.8% to 37.9% over the study period (Table 1), p-value for trend 0.002 (Figure 3). A statistically significant association was found between EC request reasons and the age group of EC service users ($X^2(15) = 989.271$, p<0.001). There was a strong negative association between EC requests due to barrier contraception failure and patients aged 24 or under, and a strong positive association for those aged over 25. A strong positive association was observed for no contraception use and teenagers, and reporting of missed contraceptive pills and women between 20-29 years old (Supplementary Table 2).

Regular contraception use

Over the 5-years, the percentage of consultations conducted with patients who used regular contraception decreased from 44.2% to 33.9% (Table 1), p-value for trend <0.001 (Supplementary Figure 3). A statistically significant association was found between regular contraception use and the age group of EC service users ($X^2(5) = 724.655$, p<0.001). Teenagers and women over 40 were more likely to not use regular contraception (Supplementary Table 3).

Service outcomes

Levonorgestrel was supplied in 96.7% of the consultations; 2.4% of consultations resulted in no medication being supplied (Table 1). Since 2015, levonorgestrel and ulipristal were supplied in 95.8% and 2.2% of consultations respectively. The proportion of ulipristal supplies was similar to the rate of late presentations (2.2% and 1.5% respectively). Only 0.1% of users (n=187) failed to access the service within 120 hours following UPSI. No data was available to identify reasons for delayed access.

Further sexual health and contraception counselling was provided in 79.2% and referral to another agency in 31.3% of EC consultations; both increased with time (Pearson's correlation r=0.7, p<0.001 and r=0.56, p=0.002 respectively, supplementary Figures 4 and 5).

Discussion

This study describes long term trends in the use of CP EC services using data from all NHS funded EC consultations in CPs in Wales over a five year period, and provides the first insight into the changing pattern of CP EC service use over time. We found substantial numbers of EC consultations took place in CPs in each year of the study but with indications that numbers of consultations were declining over time. By the end of year five, the annual number of consultations was 4.2% lower than at the end of year one. However, data indicate the decline took place between years two and three with little change in consultation numbers in the most recent three year period. Previous studies report concern of an increasing demand for EC when introducing a PGD (11); we found no evidence to support concerns that routine access to EC from CP leads to increased use over time. Over 97% of consultations resulted in the supply of EC. A small reduction in the proportion of consultations resulting in supply of levonorgestrel was observed following the inclusion of ulipristal acetate, as a treatment option for service users presenting more than 72 hours following UPSI, in April 2015.

Most EC consultations took place with 20-24 year-olds, however use in this group represented less than 30% of all EC consultations with the service accessed by large numbers of service users of all ages . This suggests the service is helping meet the sexual health needs of many women regardless of age. Despite a lower number and proportion of consultations amongst 16-19-year-olds, age standardized rates demonstrate this group were the most frequent users of the CP service over the study period. This finding supports the role of the CP EC service as part of a wider teenage pregnancy strategy. Access to free of charge EC, which is especially relevant to young users, may have contributed to uptake. (10) Despite use being high in teenagers aged 16-19, in teenagers aged 13-15 it was very low; this must be interpreted carefully as age may have been deliberately concealed due to negative societal perceptions of sexual intercourse in those under the legal age of consent.

Access to EC from CPs has coincided with decreased rates of abortion (16) and live births to teenage mothers in Wales. (17) Whilst the rate of abortions in the 20-24-year-old age group has decreased (16), it remains higher than in other age groups, following the same pattern as the number of EC consultations during the study period. This may suggest this group who would have been teenagers at the start of the study period and were the target of measures to improve availability of EC, continue to use EC as a means of contraception in later life. Further work may be required to promote routine contraception amongst this age group.

Around 25% of all EC consultations occurred on a Monday, with Tuesday and Saturday (at ~15%) the next most popular days. The lowest proportion of consultations was observed on Sunday (9.5%). This, alongside the finding that girls and women using the CP EC service on Monday, Tuesday and Wednesday were more likely to have had UPSI more than 48 hours earlier, suggest poorer access to EC over the weekend. Prompt access is of clinical significance, as the sooner EC is taken the more effective it is. (1) Previous studies found that access was a barrier to EC use and that the longer opening hours, weekend openings and more accessible locations of pharmacies allowed most users to access EC within 24

hours, (9,12, 18,19) our study demonstrates that there remain barriers to access on Sunday. Possible reason for this are fewer pharmacies being open and shorter opening times amongst those pharmacies that are open. A focussed review of accessibility of EC service on Sunday would be beneficial for service commissioners, to explore whether other determinants, for example the absence of a pharmacist accredited to provide the EC service, contributed to this finding.

The reasons for requesting EC differ with age. Women under 19 and over 40 were more likely not to use regular contraception although we found differences between these groups in relation to UPSI. In general, those under 19 were more likely to report not using any form of contraception; those over 40 were more likely to report failure of barrier contraception. Our data indicate women aged 20-29 were most likely to use regular contraception, requesting EC because they missed doses. Reasons older women are not using regular contraception may be attributable to physiological changes such as the menopause, or perceived lack of need after having children. (20) Trip *et al* found that younger users may be less likely to use regular contraception due to a lack of ability to find suitable contraception. (21) Firman *et al* explored the impact of nature and duration of relationship on preferred method of contraception and established that barrier methods were higher in short-term relationships among younger population. (22) Pregnancy 'risk' perception and personal invulnerability may be potential factors influencing the use/non-use of contraception during sexual intercourse. (23,24) A large study amongst young people in Britain aged 16-24 highlighted the need for more information on 'safer' sex, contraception/birth control, correct condom uses and sexually transmitted infection. (25) Geary *et al* reported that young people favour obtaining sexual information and contraception from a healthcare rather than an online source. (26f) Findings of this study support the expressed need for improved sex education in schools alongside greater involvement from healthcare professionals to raise awareness on contraception use.

This is the largest ever study of CP provided EC services and the first to examine changes in service use over time. The study size and duration mean our results are likely to be generalizable. Restrictions on information recorded in consultations (including data format) and tracing missing information were limitations. However, we accounted for the small number of consultations missing information on age of users and hence it is unlikely that this affects the results. A degree of self-reporting bias from some service users should be considered due to the sensitivity of the topic. The inability to identify repeat EC service users prevented quantification of the actual number of women using the EC service and investigation of changes in contraceptive behaviour over time. Data linkage to enable anonymised identification of multiple consultations by service users should be considered to improve future analyses.

This study suggests improved access to EC, as part of the multifaceted approach set out in Wales' sexual health action plan of 2010 (27) is contributing to a positive and sustained effect towards the root causes of teenage pregnancy. The finding that provision of further sexual health and contraception counselling by pharmacists increased over the study period, in line with the original aims of the EC service, adds further support for extending the role of CPs. Our findings support CP extended roles, for example in the provision of routine oral contraception, as described in the 2017-18 report on sexual health in Wales (28) and reinforced by Parsons *et al* (29) and the results of the third National Survey of Sexual Attitudes and Lifestyles (30).

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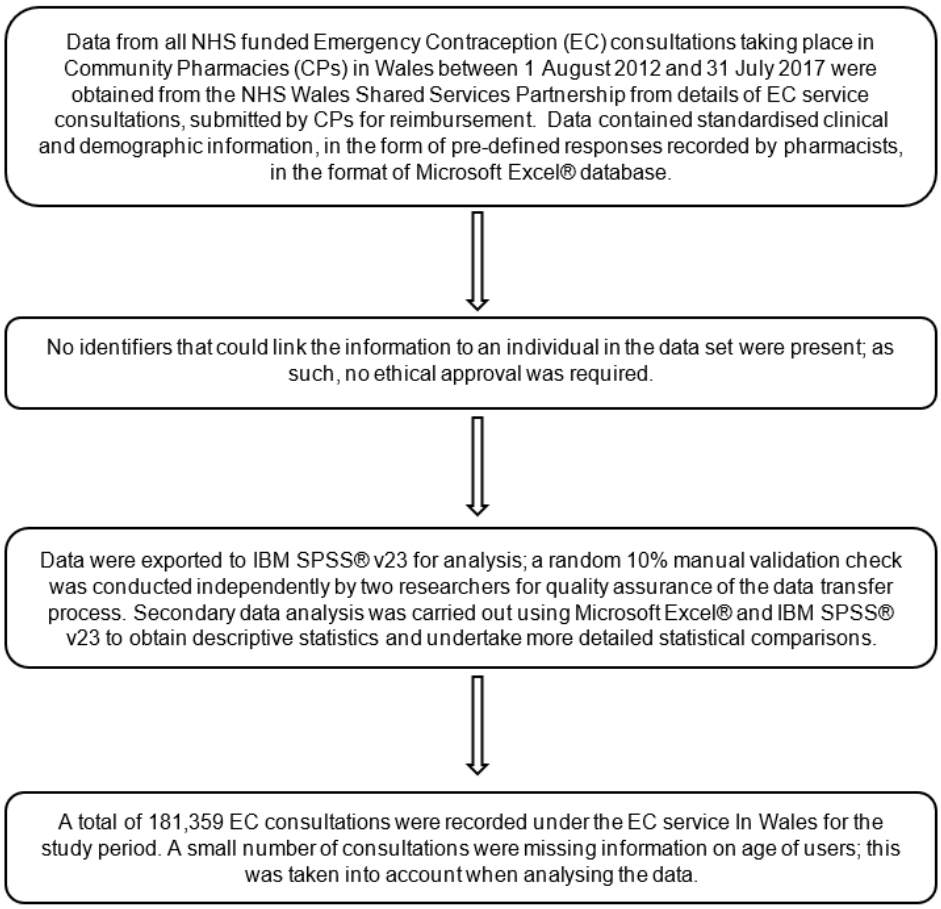
Figure 1: A flowchart illustrating the study methodology, in accordance with RECORD guidelines (13)

Figure 2: A graph illustrating the percentage (%) of consultations that took place within the stated time frames after UnProtected Sexual Intercourse (UPSI) for each day of the week (information available for n = 181,172). The proportion of consultations for the different days of the week is presented in brackets.

Figure 3: A graph illustrating the numbers of consultations for the different reasons Emergency Contraception (EC) was requested, per reporting period (information available for n = 181,359). P-values for trend lines have been calculated with 95% confidence intervals.



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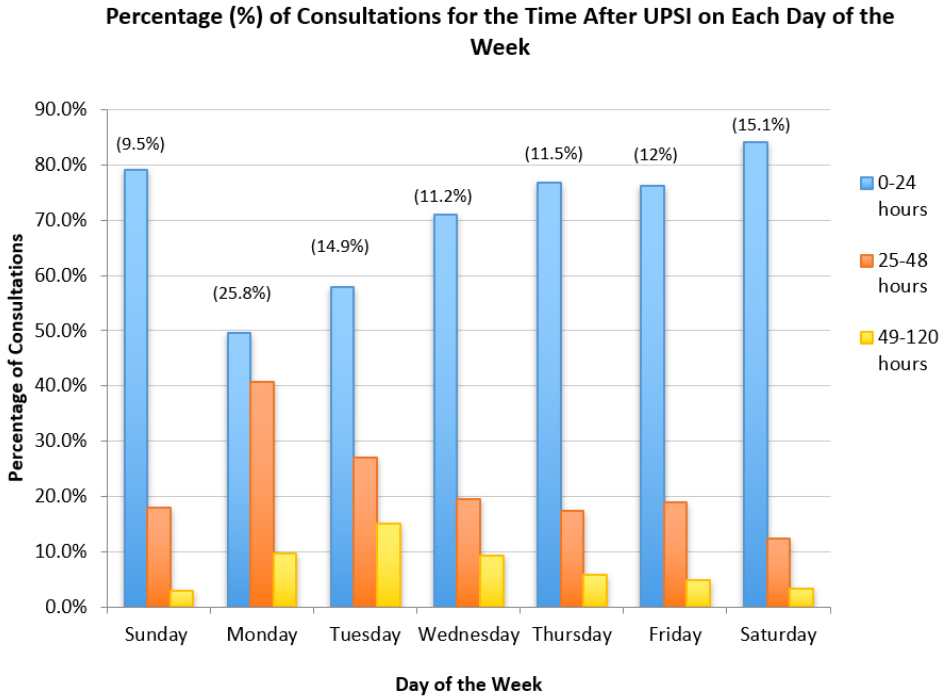

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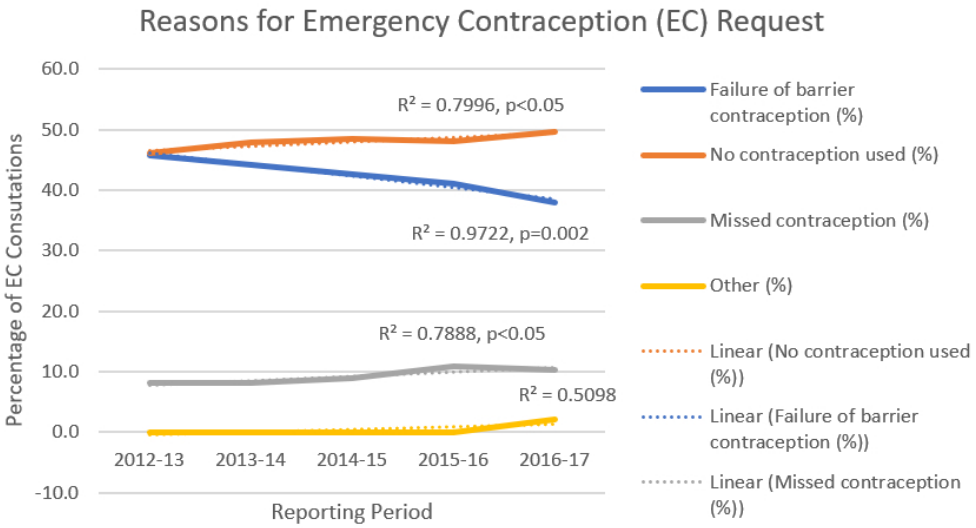

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Supplementary Table 1: Z-scores from cross-tabulation between day of Emergency Contraception (EC) request and time since UnProtected Sexual Intercourse (UPSI)

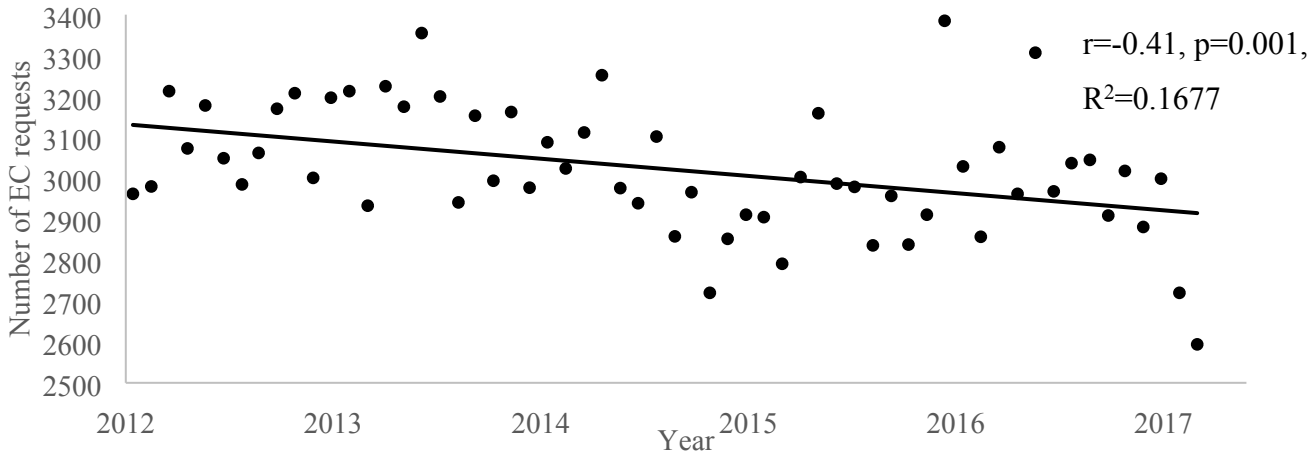
Day of EC request	Time Since UPSI			
	0-24h	**25-48h**	**49-120h**	**120+h**
Sunday	18.4	-17.4	-22.8	-2.5
Monday	-47.6	71.0	14.1	-1.1
Tuesday	-19.2	8.0	42.4	-.9
Wednesday	6.0	-14.5	7.9	.7
Thursday	16.3	-21.2	-10.5	1.0
Friday	15.5	-16.9	-16.0	2.2
Saturday	33.5	-41.0	-26.0	.9

Supplementary Table 2: Z-scores from cross-tabulation of reason for Emergency Contraception (EC) request and age group of users accessing the EC service

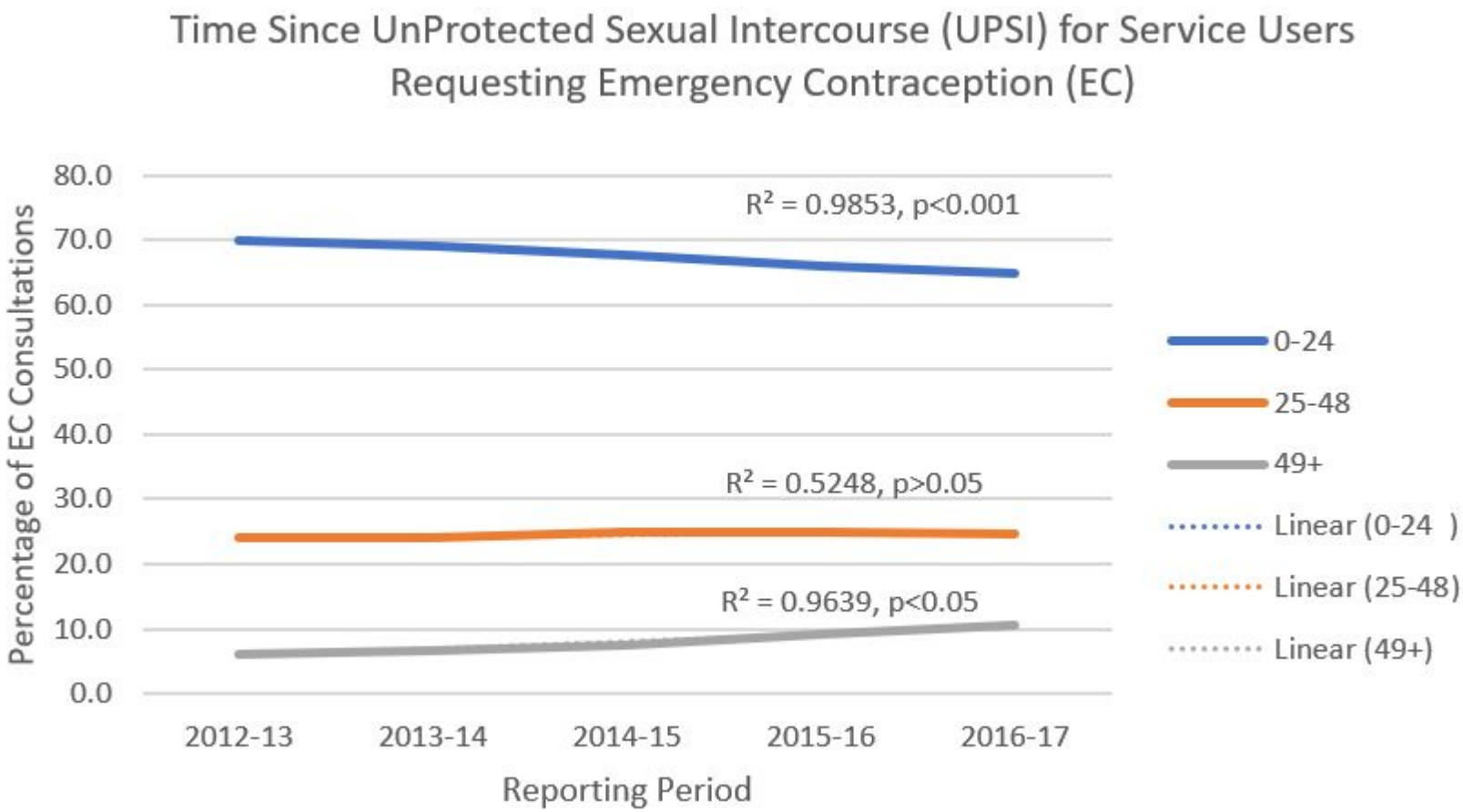
		Age group (years)					
		13-15	**16-19**	**20-24**	**25-29**	**30-39**	**40+**
Reason for EC Request	Barrier contraception failure	-4.7	-10.3	-3.0	2.8	9.6	8.0
	No contraception used	10.0	9.5	-1.4	-4.4	-6.8	-2.6
	Missed pill	-12.3	.5	9.7	4.1	-5.5	-11.2

Supplementary Table 3: Z-scores from cross-tabulation between regular contraception use and age group of users accessing the Emergency Contraception service

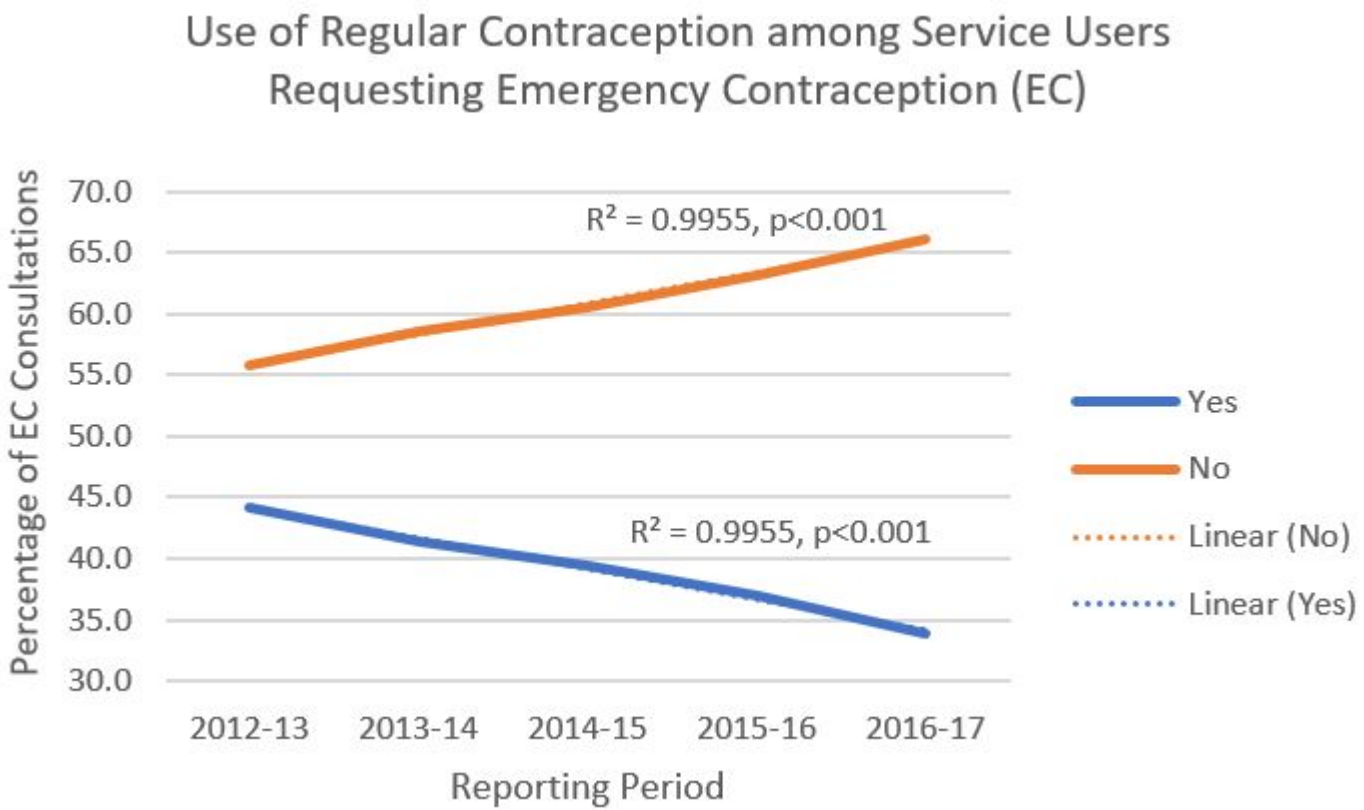
Using Regular Contraception	Age group (years)					
	13-15	**16-19**	**20-24**	**25-29**	**30-39**	**40+**
No	13.2	2.3	-6.6	-4.3	1.0	6.6
Yes	-16.4	-2.8	8.1	5.3	-1.3	-8.2



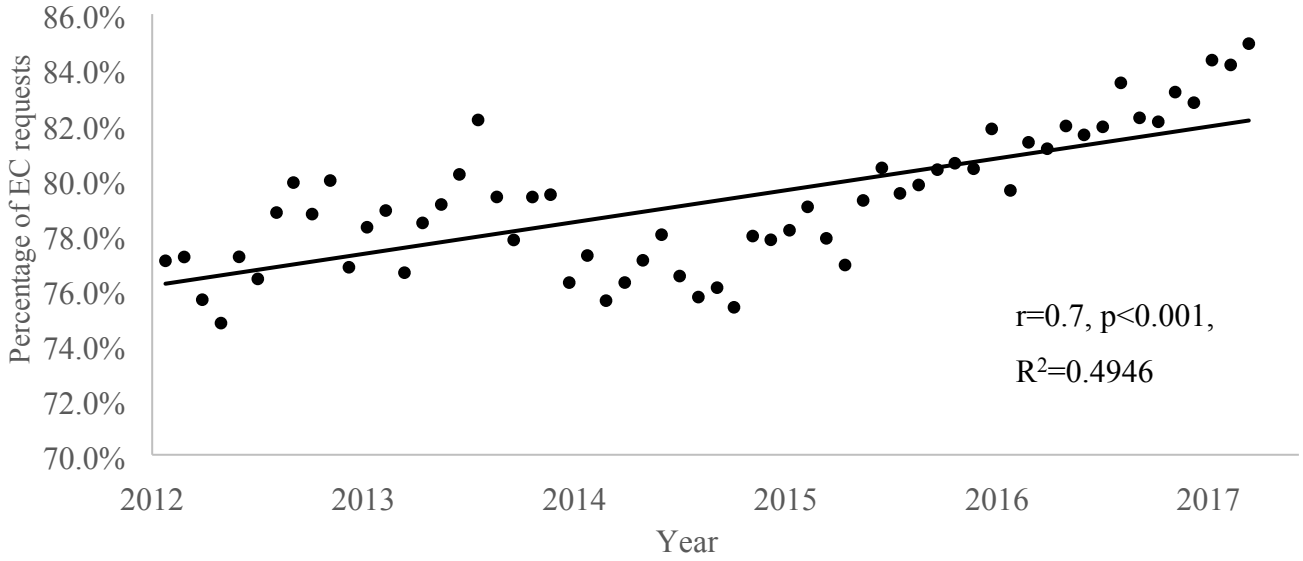
Supplementary Figure 1: Relationship between time and absolute number of requests made through the EC service in Wales



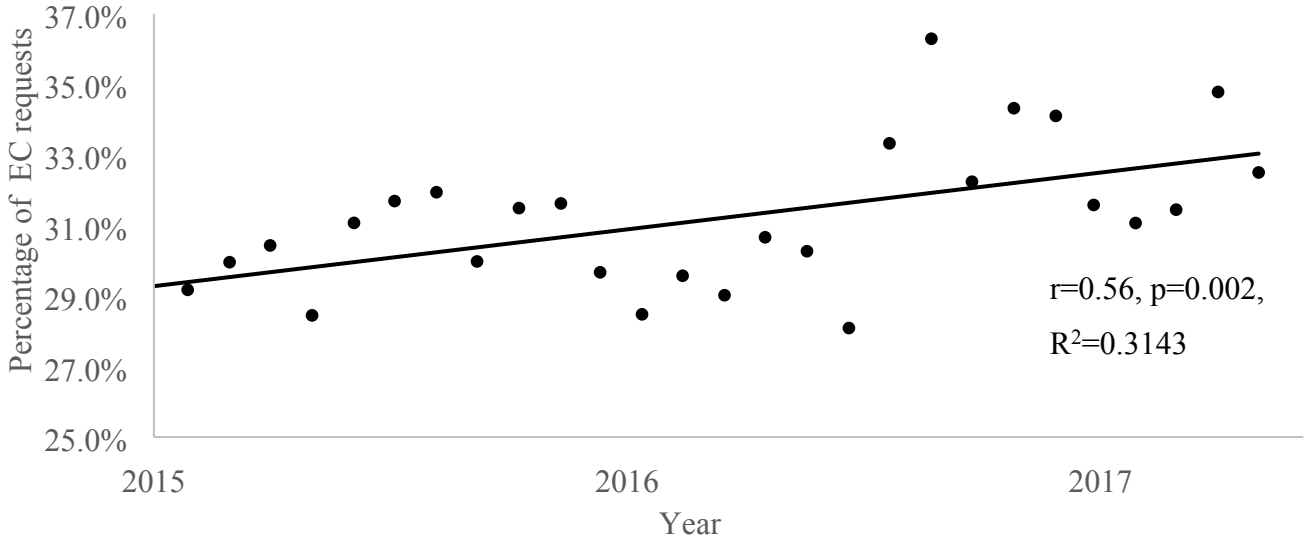
Supplementary Figure 2: A graph illustrating the proportion (%) of yearly consultations for three time periods since UnProtected Sexual Intercourse (UPSI) (information available for n = 181,359 consultations) against the reporting period. P-values for trend lines have been calculated with 95% confidence intervals.



Supplementary Figure 3: A graph illustrating the proportion (%) of yearly consultations where regular contraception was used (information available for n = 181,359 consultations). P-values for trend lines have been calculated with 95% confidence intervals.



Supplementary Figure 4: Relationship between time and the percentage of EC requests involving further sexual health and contraception counselling from pharmacists during consultations



Supplementary Figure 5: Relationship between time and percentage of requests made through the EC service in Wales referred to another agency (sexual health clinic, GP, out of hours, another pharmacy or A&E), from April 2015 since the information started being recorded