

## Original Article

# A Comparative Study of the Cost and Uptake of Community Pharmacy "Stop Smoking and Emergency Contraception" Services from the Perspective of the National Health Service

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ABSTRACT

**Objective:** The objective was to explore if the community pharmacy (CP) stop smoking service (SSS) and emergency hormonal contraception patient group direction (EHC PGD) meet the needs of the English population and are cost-effective. **Methods:** This research was completed over 2 years. Public health resources provided details of CPs and provision of SSS and EHC PGD. Questionnaires were sent to smoking cessation/sexual health leads in local authorities to obtain information not available elsewhere. Questionnaires inquired about CP payment for provision of SSS and EHC PGD, overhead costs, successful outcomes, and validation methods. Quit rates at 4-weeks, 52-weeks, and lifetime determined SSS effectiveness. The effectiveness of EHC PGD was based on the probability of unintended pregnancy with/without levonorgestrel. Incremental cost-effectiveness ratio and cost of quality-adjusted life years (QALYs) gained were calculated. Descriptive statistics were determined. *A priori* of less than 0.05 ( $P < 0.05$ ) was significant. **Findings:** SSS provision and uptake did not match local needs (smoking prevalence) even though increased CP SSS provision correlated with increased SSS success. Similarly, the need (based on teenage pregnancy rates) for EHC PGD did not correlate with the rate of CP provision but only with the uptake. Nevertheless, the provision of SSS and EHC PGD from CPs was cost-effective from an NHS perspective. Various assumptions were tested, but in all cases fell well below NICE QALY recommendations for cost-effectiveness. **Conclusion:** Provision of SSS and EHC PGD from CP does not meet the needs of the population even though the delivery of these services is cost-effective.

**KEYWORDS:** Community pharmacy, cost-effectiveness, emergency hormonal contraception, National Health Service, smoking cessation

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## INTRODUCTION

English community pharmacy (CP) public health services are commissioned by local authorities (LAs) based on the needs of the local population, which are determined from resources, such as pharmaceutical needs assessments (PNAs).<sup>[1]</sup> The PNA assesses local needs and current provision of services, and then identifies any gaps that could be filled. It also considers if there is a need for any services that would improve the provision of or access to health services for vulnerable patient groups.<sup>[2]</sup> However, even if a PNA does identify a gap in the delivery of pharmaceutical services,

this does not mean that the service will definitely be commissioned.<sup>[3]</sup> NHS England takes into account the findings of the PNA alongside other evidence before making any commissioning decisions.

While there are now a range of pharmaceutical health services available, a cross-sectional study<sup>[4]</sup> from 2017

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highlighted that four services were commissioned by over 90% of LAs in England: EHC, smoking cessation, supervised consumption of methadone or other opiates and needle and syringe programs (NSPs). The focus of this study will be on the stop smoking service (SSS) and the levonorgestrel emergency hormonal contraception (EHC) patient group direction (EHC PGD). A PGD is a legal document that allows CPs, as well as other health-care professionals (HCPs), to supply medicines to groups of patients with certain health conditions or public health needs.<sup>[5]</sup> Often, as is the case with nicotine replacement therapy (NRT) in SSS and levonorgestrel in EHC, the supplied medicines may also be available to buy over the counter, however, an NHS PGD allows the CP to supply the medicine without charge to any patient who meets the PGD inclusion criteria. This can reduce health inequalities in terms of ability to pay for the medication.

While smoking prevalence has more than halved since the 1970s (46% of adults smoked in 1974 vs. 19% of adults in 2016), there are still more than 9.6 million smokers in the UK today.<sup>[6]</sup> Worldwide, 3.2 million people died in 2015 from chronic obstructive pulmonary disease, a condition for which smoking is the main risk factor.<sup>[7]</sup> Reviews of the cost-effectiveness of addiction interventions, such as those for alcohol dependence,<sup>[8]</sup> demonstrate the high costs that these can place on the health-care system. Interventions targeted at smoking-related diseases are no different but the potential cost-savings for the NHS are upward of £50 million (€61 million; US\$80 million) every week if smoking among the general population can be reduced.<sup>[9]</sup>

In 2000, the NHS SSS was first launched. The national strategy for smoking cessation in England<sup>[10]</sup> detailed the need for HCPs to deliver opportunistic smoking cessation interventions. These would involve HCPs receiving appropriate training, offering smoking cessation support to smokers on a weekly basis for at least 4 weeks postquit and keeping appropriate records of interventions. Those who met the listed criteria for the intervention would be paid a fee for delivering the service.

Monitoring is also important and requires keeping records of how many people set a quit date and what products they are supplied, as well as documenting 4-week quit successes. Clients need to demonstrate that they have successfully quit by having an exhaled carbon monoxide (CO) level of <10 parts per million. This is measured using a validated CO monitor.<sup>[11]</sup>

Studies have shown that one-to-one support with a HCP and varenicline results in 4-week quit rate of 52%, versus 37% when varenicline is used alone and 74%

when varenicline is used alongside group support.<sup>[12-15]</sup> More recent findings from 2014/2015 noted that nearly 152,000 people in England managed to quit smoking through the use of nicotine-containing products.<sup>[16]</sup> This term refers mainly to e-cigarettes and accounted for 65% of all quitters during this period. While the use of e-cigarettes is popular among the general public, concerns about their regulation mean that HCPs need to use their professional judgment when recommending these alternatives.<sup>[17]</sup>

A link between smoking and deprivation has been identified in an analysis by the Office for National Statistics (ONS).<sup>[18]</sup> This analysis supports the strategy taken in previous guidance, published by the Department of Health in 2011, which stated that the SSS should be focused on areas with the highest levels of deprivation and the highest percentage of Black and minority ethnicities (BME), to overcome health inequalities.<sup>[11]</sup>

Looking specifically at the pharmacy SSS, 51,534 smokers in the UK set a quit date through pharmacy from April to December 2015.<sup>[19]</sup> This represented 19.3% of all smokers who set a quit date through the NHS SSS. A total of 23,824 smokers successfully quit at 4-week follow-up giving a percentage quit rate of 46%.

Systematic reviews<sup>[20,21]</sup> from 2016 highlighted that CP-delivered smoking cessation interventions are both effective and cost-effective. In addition, a number of studies from 2009 and 2011 looking at the cost-effectiveness of pharmacy SSS, identified incremental cost per quality-adjusted life year (QALY) of between £2600 (€3171; US\$5073)<sup>[22]</sup> and £4400 (€5366; US\$8585)<sup>[23]</sup> for pharmacy stop smoking services, respectively. Although pharmacy provides cost-effective stop smoking interventions for the NHS, over 80% of smokers do not choose pharmacy to help them quit and 54% of smokers fail to quit successfully through pharmacy.<sup>[24]</sup> Therefore, this research aims to see if the uptake and success of CP SSS has changed.

Teenage pregnancy is associated with lower socioeconomic status and poor educational background.<sup>[25]</sup>

A 10-year strategy to halve under-18 pregnancy rates in England was launched by the government in 1999.<sup>[26]</sup> It recommended using a multifaceted approach to improve young people's access to effective contraception. Latest figures from the ONS looking at conceptions in England and Wales noted that rates of teenage pregnancy are on the decline.<sup>[27]</sup> In 2014, the under-18 conception rate was 23 conceptions per 1000 women. This figure is 6.5% down from 2013 and down from 1971 when it was 55 conceptions per thousand.<sup>[27]</sup>

To tackle teenage pregnancy, the progestogen-only (levonorgestrel) form of EHC became available from various sources, including pharmacies, in 2000. Women could obtain EHC from community pharmacies under a PGD without having to visit their general practitioner.<sup>[28]</sup> In order to ensure that the most vulnerable in the society have access to emergency contraception, wherever and whenever they need it, the latest guidance from NICE on contraception services for under 25s<sup>[29]</sup> states that commissioners need to map out local needs against service delivery. A qualitative study<sup>[30]</sup> on pharmacist perspectives of the EHC PGD noted that respondents felt that the service improved access to emergency contraception for some patients.

The literature is limited on the cost-effectiveness of obtaining EHC from a CP, however, one study conducted in America<sup>[31]</sup> noted that it not only reduced the number of unintended pregnancies but also saved costs. Figures from the study indicated that \$48 and \$158 could be saved per unintended pregnancy cost among those who had unprotected sex for public and private payers, respectively. This study was carried out in 2001 and used a different form of emergency contraception than that used in the UK, therefore, the results may not be fully translatable. Another study by Gross *et al.*<sup>[32]</sup> pointed out that offering EHC from a CP had resulted in cost savings simply because it had lowered the cost of supplying the drug. The rationale was that visits to pharmacies were less expensive than visits to GPs or hospital emergency units, so costs would be reduced.

While CPs can sell products for public health, in order to deliver public health services “free at the point of care,” these must be commissioned by LAs (formally primary care trusts (PCTs)) to receive NHS funding. PCTs will be referred to as LAs from this point forward to reflect the current commissioning of English NHS public health services. This study aimed to determine whether the CP delivery of SSS and the EHC PGD using levonorgestrel in England met the needs of the population within their localities. A further aim was to explore whether these CP services were cost-effective.

## METHODS

This research project was split into two parts, over a period of 2 years starting from November 2012. The authors have reported the findings of the study following the Consolidated Health Economic Evaluation Reporting Standards statement.<sup>[33]</sup> In addition, while this study was conducted before the publication of the review article by Elliott *et al.*,<sup>[34]</sup> the authors believe that they have addressed many of the methodological considerations that the review article suggested for economic

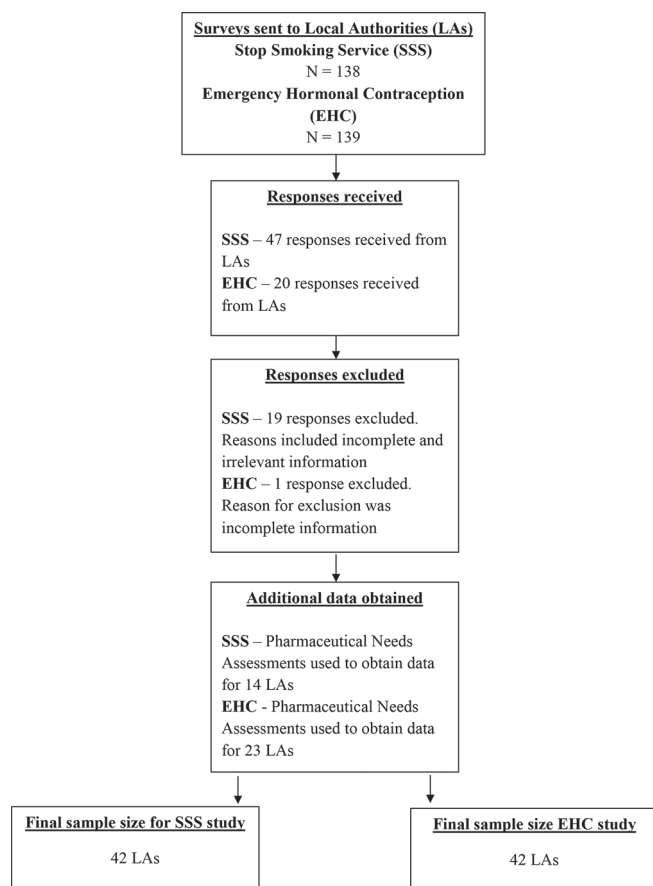
evaluations of pharmacist interventions. Unless stated otherwise, costs within this research article are quoted in Pound Sterling, and date from the time when all the research data had been collected, which was November 2014. An exchange rate of £1 to US\$1.60 and £1 to €1.22 has been used.

Part 1 of this study explored the CP SSS and part 2 explored EHC PGD. For both parts, the details of community pharmacies within each locality and the provision of CP SSS and EHC PGD were identified through the PNAs. Details of the demographics of each LA were obtained from the Office of National Statistics. Other sources used were the Health and Social Care Information Centre, to obtain information about the number of smokers who set a quit date through all providers and the number of smokers who proved to be nonsmokers at 4-week follow-up, and Public Health England, for teenage pregnancy rates for each LA.<sup>[35-37]</sup>

## Sample population

Out of 151 LAs, data on the prevalence of smoking (needs) and CPs providing CP SSS were available for only 138 LAs. Questionnaires were sent to the public health leads within these LAs and the remaining LAs were excluded from the study. Information regarding teenage pregnancy rates (the measure of needs for EHC) could not be identified for 12 LAs, therefore, these were excluded for the EHC PGD arm of the study, and questionnaires were sent to the public health leads of the remaining 139 LAs. The questionnaires sought information that was not available in published resources. This included CP payment for provision of the SSS and EHC PGD services, overhead costs of running each service, the number of service users, those who obtained a successful outcome, and any validation methods used to confirm the success of a service.

A minimum recommend sample size was calculated using Raosoft sample size calculator,<sup>[38]</sup> at a 95% confidence interval and 5% margin of error. For both the CP SSS arm and the EHC PGD arm, the minimum sample size calculated was 95 responses. Of 138 questionnaires sent, 47 (34%) responses were received relating to SSS, of which 19 were excluded as they contained incomplete information. Twenty (14.4%) responses (out of the 139 sent) were received relating to the EHC PGD, of which one was excluded as it contained incomplete information. To compensate for the low response rate, PNA reports for all LAs were investigated. Out of these, PNA reports from 14 and 23 LAs provided information on uptake and cost data for CP SSS and the EHC PGD, respectively. The final sample size for both services was, thus, 42, as shown in Figure 1.



**Figure 1:** Local authority response to surveys and sources of additional data collection

### Sample local authorities versus nonrespondent local authorities-stop smoking service

To confirm whether the 42 LAs were representative of all LAs, the two independent sample *t*-test was applied to test the difference between the two groups (sample and nonsample respondent LAs) in terms of the prevalence of smoking adults, total quit rate, and the weighted CP provision of SSS per 25,000 population as they were normally distributed. The Mann–Whitney test was applied to the rest of the variables (deprivation score, total reach, total success, ethnic minority proportion, adult males, and CP provision of SSS as percentage) as they were not normally distributed [Table 1a].

As a result, the sample was deemed to be representative of the nonrespondent LAs in terms of prevalence of smoking, deprivation, ethnic minority proportion, adult male proportion, total reach, and total success and quit rate. However, it was not representative in terms of pharmacy provision of SSS (per 25,000 population and as percentages). This suggests that any outcome measure that is positively correlated with CP provision of SSS is expected to be higher in nonrespondent LAs than in the sample, and vice versa.

### Sample local authorities versus nonrespondent local authorities-emergency hormonal contraception patient group direction

Similarly, to compare if the 42 LAs were representative of all LAs, the Mann–Whitney test was used to compare the sample and the rest of the LAs for the EHC PGD [Table 1b]. This showed that the median teenage pregnancy rate and median deprivation score were higher in the sample than the rest of the LAs. However, there was no significant difference in any of the other variables (females under 16 as a percentage of total females under 60, BME females, CPs per 10,000 females under 60 and CPs providing EHC). This indicated that even though there was a higher need for EHC service in the sample when compared to the rest of the LAs, there was no difference in terms of CPs EHC provision.

### Ethical approval

Each questionnaire was submitted to the Science, Engineering and Computing Ethics Committee at Kingston University in June 2012 to obtain ethical approval to conduct the survey. The Ethics Committee approved the EHC questionnaire and the SSS questionnaire on August 2, 2012 (approval code 1112/63).

### Perspective

For this study, the perspective of the NHS was considered, following NICE cost per QALY gained guidance. For both arms of this study, patient-level data were not obtained from LAs as the authors wanted to gain a holistic overview of the uptake of these services. The decision tree that commissioners use to determine if a service is worth delivering focuses firstly on local needs within the LA. If there is an unmet need and a service is cost-effective, then that service should be funded.<sup>[39]</sup>

### Outcome measures – Needs, reach, and success – stop smoking service

The outcome measures for CP SSS included: total reach out of needs, total success out of needs, quit rates, pharmacy reach and success out of needs, and pharmacy share in success. Quit rates at 4 weeks, 52 weeks, and at lifetime were used to determine the effectiveness of SSS. NICE guidelines state that LAs need to treat 5% of their local smokers and to achieve at least a 35% quit rate as is confirmed by a CO-validation method.<sup>[40]</sup> CO-validation is a method of distinguishing smokers from nonsmokers by measuring the levels of CO, which indicates that a person has not smoked within, at least, the last 8 h.<sup>[41]</sup> The population subgroups analyzed were minority ethnicities, as well as differences related to levels of deprivation and gender.

**Table 1a: Comparison of variables between respondent local authorities (sample) and nonrespondents for the community pharmacy stop smoking service**

Variable	Sample LAs (%)	Nonrespondent LAs (%)	P
The prevalence of smoking adults - mean	23.26	22.8	0.6
The total quit rate - mean	49.3	50.2	0.59
The CP provision of SSS per 25,000 population - mean	2.7	3.4	0.005
The deprivation score - median	23.2	22.5	0.8
Total reach - median	8.3	7.9	0.37
Total success - median	4.03	3.8	0.29
Ethnic minority proportion - median	7.7	10.3	0.1
Adult males - median	52.5	52.5	0.97
The CP provision of SSS as percentage	55.1	67.5	0.049

P<0.05 taken as significant. Sample=Responses to questionnaires from public health leads of LAs, LA=Local authority, CP=Community pharmacy

**Table 1b: Comparison of variables between respondent local authorities (sample) and nonrespondents for community pharmacy emergency hormonal contraceptive patient group direction**

Variable	Sample median	Rest of LAs median	P
Needs			
Teenage pregnancy rate (conception rate per 1000 females [15-17 year olds only])	48.5	41.02	0.035
Demographic factors			
Deprivation (index of multiple deprivations)	26.00	20.54	0.002
Female under 16 years (%) (out of total females under 60)	24.18	24.03	0.66
Female under 60 years as BME <sup>a</sup> (%)	8.04	8.94	0.88
Female under 16 years as BME <sup>a</sup> (%)	7.27	8.28	0.903
Female (16-59) as BME <sup>a</sup> (%)	8.44	9.38	0.916
Pharmacy provision factors			
CPs per 10,000 female under 60	5.61	5.48	0.499
CPs providing EHC per 10,000	3.04	2.73	0.157
CPs providing EHC (%)	54.15	49.00	0.151

<sup>a</sup>BME %: The percentage of Asians, Blacks and Chinese or other ethnicities out of total population. P<0.05 taken as significant. CP=Community pharmacy, EHC PGD=Emergency hormonal contraception patient group direction, LA=Local authority, Sample=Responses to questionnaires from public health leads of LAs, BME=Black and minority ethnic

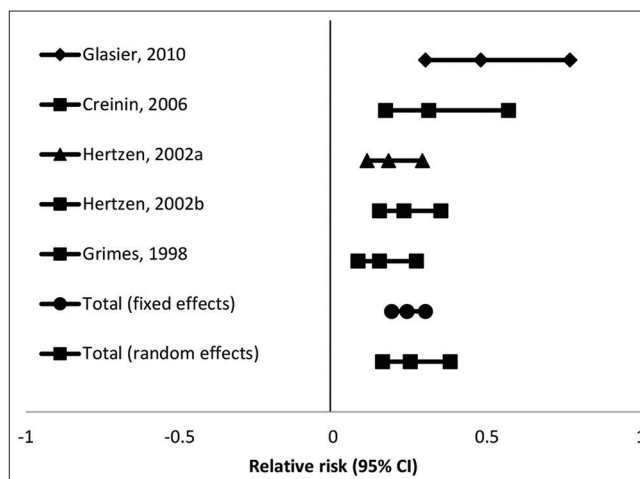
**Outcomes measures – needs, reach, access, and success – emergency hormonal contraception (levonorgestrel) patient group direction**

The outcome measures for EHC PGD were: need for EHC, as well as the provision and uptake of EHC through CP. The effectiveness of EHC was estimated based on the outcomes from four RCT that tested the observed pregnancy rates for women who used levonorgestrel within 120 h of unprotected sexual intercourse [Tables 2, 3 and Figure 2]. The probability of an unintended pregnancy with or without levonorgestrel EHC is 1.72% and 7.1%, respectively.<sup>[42-45]</sup> The population subgroups analyzed were minority ethnicities, as well as differences related to levels of deprivation and age.

**Cost outcomes**

For both CP SSS and EHC PGD, cost-utility analysis was carried out. The incremental cost effectiveness ratio (ICER) was calculated using the following equation:

$$\text{Incremental cost per effective service outcome} = (C1 - C2)/(P1 - P2)$$



**Figure 2:** Forest plot of observed pregnancies using levonorgestrel versus expected pregnancies with no intervention

Where C1 = cost of CP service; C2 = cost of no intervention; P1 = probability of success; and P2 = probability of unsuccessful outcome

**Table 2: Summary of four randomized controlled trials, used in a meta-analysis, to determine the chances of getting pregnant following the use of emergency hormonal contraception**

Study	Methods	Location	Time UI (frequency of UI)	Results (no. of pregnancies)	
				Intervention (observed)	No intervention (expected)
Glasier <i>et al.</i> , 2010 <sup>[42]</sup>	RCT. One dose 1.5 mg levonorgestrel	UK, Ireland and USA	Within 120-h (one or more)	25/958	52/958
Creinin <i>et al.</i> , 2006 <sup>[43]</sup>	RCT. Two doses of levonorgestrel 0.75 mg 12 h apart	USA	Within 72-h (one or more)	13/774	42/774
Hertzen <i>et al.</i> , 2002 <sup>[44]</sup>	RCT. A) One dose 1.5 mg levonorgestrel B) Two doses levonorgestrel 0.75 mg 12 h apart	10 countries	Within 120-h (one)	20/1356 24/1356	111/1356 106/1356
Grimes <i>et al.</i> , 1998 <sup>[45]</sup>	RCT. Two doses of levonorgestrel 0.75 mg, 12 h apart	21 countries	Within 72-h (one)	11/976	75/976
Total				93/5420 (1.72%)	386/5420 (7.1%)

RCT=Randomized controlled trial, UI=Unprotected intercourse

**Table 3: Summary of literature - observed pregnancies using levonorgestrel versus expected pregnancies with no intervention**

Study	Levonorgestrel	No intervention	Relative risk (95% CI)
Glasier, 2010	25/958	52/958	0.48 (0.30-0.77)
Creinin, 2006	13/774	42/774	0.31 (0.17-0.57)
Hertzen, 2002a	20/1356	111/1356	0.18 (0.11-0.29)
Hertzen, 2002b	24/1356	106/1356	0.23 (0.15-0.35)
Grimes, 1998	11/976	75/976	0.15 (0.08-0.27)
Total (fixed effects)	93/5420	386/5420	0.24 (0.19-0.30)
Total (random effects)	93/5420	386/5420	0.25 (0.16-0.38)

CI=Confidence interval

For CP SSS, the incremental cost per quitter was calculated based on a 4-week period. An assumption of 10% CO-validated self-quit was assumed at 4 weeks and 2.5% at 52 weeks.<sup>[46,47]</sup> The assumption of 75% relapse rate (average of 78.2% and 72% quoted by Bauld *et al.*<sup>[48,49]</sup>) was applied between 4 weeks and 52 weeks for both intervened quit and self-quit.<sup>[50,51]</sup> An additional 35% relapse rate was applied between 52 weeks and lifetime.<sup>[51,52]</sup>

For EHC PGD, the probability and costs of the different outcomes of pregnancy were obtained from Montouchet and Trussell.<sup>[53]</sup> The costs of intervention (EHC through CPs) included costs of consultation (payment to CPs), costs of medication, and costs of unintended pregnancy (£1016; €1239; US\$1982).<sup>[53]</sup> The consultation and medication costs were based on answers from the questionnaires.

### Sensitivity analysis

For each of the outcome measures where assumptions have been made, a lower value and upper value were applied to test the uncertainty. Five and four different scenarios were used to test uncertainty in the SSS and EHC PGD, respectively.

For SSS, the first two scenarios dealt with the CO-validated quit rate, where in the first scenario, it

was assumed that the quit rate went down from 10% to 5%, while in the second scenario, it was assumed that it went up to 15%. The third scenario dealt with the self-reported validation results. The fourth scenario assumed a supply of NRT for 8 weeks for a smoker who succeeded in quitting smoking after 4-week follow-up, as in the case of Cumbria LA.<sup>[54]</sup> The fifth scenario assumed 4-week supply of NRT for a smoker who was lost to follow-up.

For EHC PGD, in order to overcome uncertainty in calculating the incremental cost-effectiveness ratio, a sensitivity analysis was applied to the costs and benefits of EHC intervention in comparison to no intervention. As the costs of intervention (consultation and medication) varied across different LAs, and the median was used to calculate the incremental cost, the lowest costs of intervention were used in the first scenario and the highest costs were used in the second scenario. The third and fourth scenarios were related to the probability of getting pregnant using EHC versus no intervention. The third scenario used the results of Glasier *et al.*,<sup>[42]</sup> which had the highest relative risk ratio (0.48) in Figure 2. The fourth scenario used the results of Grimes *et al.*,<sup>[45]</sup> which had the lowest risk relative ratio [Figure 2].

### Calculation of cost per quality-adjusted life years – stop smoking service

Previous studies reported the value of discounted QALYs per lifetime quitter as 1.98<sup>[55]</sup> and as 1.98 for female and 1.97 for male.<sup>[56]</sup> These two values for females and males were weighted against the proportion of adult males (52.5%) and the proportion of adult females (47.5%) in the sample population, the resulted value was 1.975. As a result, 1.98 was applied. As this QALY value was quoted in the literature, an EQ5D measurement<sup>[57]</sup> was not taken. No discount rate was used for costs per QALY gained for lifetime quitter.

The costs per QALY gained for lifetime quitter was calculated using the following equation:

Cost per QALY gained = incremental cost per lifetime quitter

QALYs gained for lifetime quitter (1.98).

### Statistical procedures

Descriptive statistical measures were carried out on the explanatory variable and outcome measures, such as median, lower quartile, upper quartile, and range. The normality of distribution was tested using Shapiro–Wilk test. Uni-variable correlation between two variables was tested using Spearman's correlation coefficient in case of nonnormal distribution and Pearson's correlation coefficient in case of normal distribution at 95% confidence level. *A priori* level of less than 0.05 ( $P < 0.05$ ) was set as level of significance.

## RESULTS

### Provision, reach, and success of the stop smoking service

#### Published data

The prevalence of smoking adults varied across different LAs with a median of 22.4%, and a range of 12% to 36% [Table 4a]. Smoking prevalence did not statistically correlate with being male or being from an ethnic minority ( $P = 0.45$  and  $0.8$ , respectively). However, a higher prevalence of smoking was associated with higher deprivation ( $P < 0.001$ ). The median LA SSS total reach out of needs was 7.9% (above the 5% target) [Table 4a]. The median CO-validated quit rate was 34.2%. Sixty-one LAs failed the recommended 35% CO-validated quit rate.

Higher concentrations of CPs were seen in more deprived LAs, those with a higher prevalence of smoking adults, and those with higher ethnic minority proportion (rho was 0.63, 0.34, and 0.18, respectively, with  $P < 0.001$  in the first two cases and  $P = 0.034$  in the latter case). The median pharmacy provision of SSS was 62.9% with a lower quartile of 39.1% and upper quartile

of 76.8% [Table 4a]. There was no correlation between smoking prevalence and CP SSS provision ( $P = 0.67$ ). However, in more deprived LAs and in those with high ethnic minority proportion, there was a slightly higher number of CPs per 25,000 population which offered SSS (rho of 0.27 and 0.36 with  $P = 0.001$  and  $P < 0.001$ , respectively).

#### Sample

The sample analysis showed wide variations in terms of the percentage setters (someone who has set a quit date) and the percentage quitters through CPs out of total smokers in an LA. In terms of number of setters and quitters per each pharmacy per year, the median number was 15 setters with a range from 2 to 116 setters and 6 quitters with a range from 1 to 42 quitters [Table 4b].

The CP uptake measures did not correlate with the prevalence of smoking, the deprivation, the ethnicity, or the gender factors. However, smoking adults were responsible for 40% of the number of setters and for 31% of the number of quitters per pharmacy per year ( $P = 0.01$  and  $0.046$ , respectively). This means that in LAs with higher prevalence of smoking adults, there are a higher number of smokers who set a quit date and higher numbers of smokers who quit smoking per pharmacy. Furthermore, the level of CP provision correlated with quit smoking success ( $P = 0.01$ ). This means that any increase in CPs' provision of the SSS will encounter an increase in the uptake of the service, and this will be reflected in quit smoking success.

The association between pharmacy quit rate and demographic factors was assessed. The higher the prevalence of smoking adults and the higher the deprivation scores, the lower the quit rate ( $R = -0.61$  and  $R = -0.58$ , respectively), with  $P < 0.01$  in both cases.

#### Costs and incremental cost per quitter for stop smoking service

Two out of the 28 questionnaire responses received did not provide payment information for SSS provision. As a result, the final sample was 26 LAs. Three responses mentioned that they only use self-declaration to validate quit smoking, the results of those were included in the sensitivity analysis. Therefore, the final sample was 23 responses.

Payments for providing SSS varied across the different LAs [Table 5]. The median cost per quitter excluding NRT reimbursement was £71.30 (€87; US\$139), with a range from £23.80 (€29; US\$46) to £602.50 (€735; US\$1176). Upon consideration of NRT, the median cost per quitter was £116.70 (€142; US\$228), with a range from £65.20 (€76; US\$127) to £649.20 (€792; US\$1267).

**Table 4a: Demographic, service delivery and pharmacy factors from published data - stop smoking service**

Variable	Median/ mean	LQ	UQ	Minimum-maximum
Prevalence of smoking adults (%)	22.4	19.3	26.7	12.0-36.0
Smokers who set a quit through all providers out of total smokers within a local authority (%)	7.9	6.7	9.7	2.5-33.9
Smokers who quit after 4-week follow-up out of total smokers within a local authority (%)	3.9	3.4	4.8	1.2-17.1
Self-reported quit rate after 4-week follow-up out of total smokers who set a quit date (%)	49.9	44.1	56.8	31.1-69.8
CO-validated quit rate after 4-week follow-up out of total smokers who set a quit date (%)	34.2	28.2	40.8	2.7-58.3
Deprivation score IMD <sup>a</sup>	23.0	16.4	29.3	8.8-43.5
Ethnicity minority population (%)	9.1	5.4	16.2	2.0-52.3
Male population (%)	52.5	52.1	53.0	49.8-53.9
CPs offering SSS out of total CPs within local authority (%)	62.9	39.1	76.8	8.0-100.0
CPs offering SSS per 25,000 population ( <i>n</i> )	3.2	2.1	4.3	0.0-7.0

CP=Community pharmacy, SSS=Stop smoking service, IMD=Index of Multiple Deprivation, LQ=Lower quartile, UQ=Upper quartile, CO=CO-validated=Confirmation of smoking quit using a carbon monoxide monitor

**Table 4b: Demographic, service delivery and pharmacy factors for the sample - stop smoking service**

Variable	Median/ mean	LQ	UQ	Minimum-maximum
Prevalence of smoking adults (%)	22.7	19.3	26.9	14.9-35.2
Deprivation score (IMD) <sup>a</sup>	23.3	15.3	28.8	8.8-43.5
Ethnic minority proportion (%)	7.7	5	11	2-38.6
Adult male proportion (%)	52.5	52	53.1	49.8-53.5
Smokers who set a quit through all providers out of total smokers within a local authority (%)	8.3	6.9	10.7	4-16
Smokers who quit after 4-week follow-up out of total smokers within a local authority (%)	4.0	3.5	5	2-7
CO-validated quit rate after 4-week follow-up out of total smokers who set a quit date (%)	49.2	43.7	54.1	33.1-67
Smokers who set a quit through CPs out of total smokers within a local authority (%)	1.3	0.5	2.9	0.1-6.7
Pharmacy share in reach (%)	12	3.5	23.2	0.6-53.3
Pharmacy success out of needs (%)	0.4	0.2	1.4	0.03-2.9
Pharmacy share in success (%)	9.8	3.4	24.9	0.7-49.2
Pharmacy quit rate (%)	44.5	39.4	49.4	30.7-64.5
Setter per pharmacy per year ( <i>n</i> )	15	8	43	2-116
Quitters per pharmacy per year ( <i>n</i> )	6	3	18	1-42
CPs offering SSS out of total CPs within local authority (%)	55.1	35.4	70.6	14.8-100
CPs offering SSS per 25,000 population ( <i>n</i> )	2.7	1.8	3.4	1-5

CP=Community pharmacy, SSS=Stop smoking service, CO-validated=Confirmation of smoking quit using a carbon monoxide monitor, IMD=Index of multiple deprivation, LQ=Lower quartile, UQ=Upper quartile

The incremental cost per quitter at 4 weeks, 52 weeks, and at lifetime was calculated by adding the cost of payments to the pharmacy, overhead costs per client, and costs of NRT reimbursement [Table 5]. The baseline incremental cost per quitter at 4 weeks was £486.40 (€593; US\$949), the median cost at 52 weeks was £1,945.40 (€2372; US\$3796), and the median cost at lifetime was £2,993 (€3650; US\$5840). In order to reduce uncertainty, five different scenarios were tested, and the incremental cost per quitter at 4 weeks was calculated [Table 5]. The costs ranged from £310 (€378; US\$605) and £614.40 (€749; US\$1199).

#### Costs of quality-adjusted life years gained for lifetime quitter

The median cost per QALY gained for lifetime quitter was £1,511 (€1843; US\$2948), with a range from £684.30 (€835; US\$1335) to £7,824.40 (€9542; US\$15267).

#### Provision, reach, and success of the emergency hormonal contraception patient group direction

##### Published data

The teenage pregnancy rates among LAs ranged from 22.1 to 74.8/1000, with a median of 43.2 [Table 6a].

LAs with teenage pregnancy rates in the bottom quartile were among the most affluent in England and those with the highest rates were the most deprived LAs. The median CP provision of EHC PGD was 52.3%, with a range from 5.3% to 90% [Table 6a]. Of the 33 LAs that have a CP EHC PGD provision higher than the upper quartile (65.1%), the highest four had a moderate teenage pregnancy rate. No outliers were identified in terms of needs, demographic factors, or CP provision factors.

Higher teenage pregnancy rates were strongly correlated with deprivation ( $\rho = 0.83$ ,  $P < 0.001$ ). There was



**Table 5: Summary description of service uptake, payments, and costs**

Variable	Median	LQ	UQ	Minimum-maximum
Stop smoking service				
Setters through CPs per LA ( <i>n</i> )	532	180	984	31-5270
Quitters (at 4 weeks) through CPs per LA ( <i>n</i> )	235	90	503	20-2573
Quit rate (%)	47.9	39.9	53	34-76
Total cost for provision of SSS from CPs excluding NRT reimbursement (£)	71.3 (€87; US\$139)	37.9	143.8	23.8-602.5
Total cost for provision of SSS from CPs including NRT reimbursement (£)	116.7 (€142; US\$228)	83.4	188.8	65.2-649.2
<b>Incremental cost per quitter</b>	<b>Median</b>	<b>LQ</b>	<b>UQ</b>	<b>Minimum-maximum</b>
At 4 weeks (£)	486.4 (€593; US\$949)	298.6	486.4	220.2-2517.5
At 52 weeks (£)	1945.4 (€2372; US\$3796)	1,835.4	5,173.5	889.7-9,189.1
At lifetime (£)	2993 (€3650; US\$5840)	1,193	3,362.7	1355-15,492
<b>Scenarios</b>	<b>Median incremental cost per quitter at 4 weeks (£)</b>			
Scenario 1 CO-validated quit went down from 10% to 5%	402.5 (€491; US\$644)			
Scenario 2 CO-validated quit went up from 10% to 15%	614.4 (€749; US\$1199)			
Scenario 3 Self-reported validation considered	310 (€378; US\$605)			
Scenario 4 supply of NRT for 8 weeks for smoker who quit after 4-week follow up	433.6 (€529; US\$694)			
Scenario 5 supply of NRT for 4 weeks then lost to follow up	499 (€609; US\$798)			

Median incremental cost per quitter in a CP SSS at 4-weeks, 52-weeks and at lifetime and the results of the use of different scenarios to reduce uncertainty. CP SSS=Community pharmacy stop smoking service, LQ=Lower quartile, UQ=Upper quartile, NRT=Nicotine replacement therapy, CO-validated=Confirmation of smoking quit using a carbon monoxide monitor, LA=Local authority

**Table 6a: Demographic, service delivery, and pharmacy factors from published data - emergency hormonal contraception patient group direction**

Variable	Median/mean	LQ	UQ	Minimum-maximum
Teenage pregnancy rate (conception rate per 1000 15-17-year-old females only) ( <i>n</i> )	43.2	34.1	52.4	22.1-74.8
Deprivation score (index of multiple deprivations)	23.2	16.4	29.5	8.8-43.5
Females under 16 years out of total females under 60 years old (%)	24.1	22.9	24.8	15.1-29.2
Females under 60 years of BME background out of the total population (%)	8.9	4.9	18.8	1.8-53.8
Females under 16 years of BME background out of the total population (%)	7.8	4.2	18.6	1.4-5.6
Females 16-59 years of BME background out of the total population (%)	9	4.9	19.2	1.9-52.9
CPs per 10,000 females under 60 years ( <i>n</i> )	5.5	4.9	6.2	3.7-12.5
CPs providing EHC per 10,000 females under 60 years ( <i>n</i> )	2.8	1.9	3.5	0.3-5.7
CPs providing EHC out of total CPs within local authority	52.3	34.5	65.1	5.3-90

CPs=Community pharmacy, EHC PGD=Community pharmacy emergency hormonal contraception patient group direction, LQ=Lower quartile, UQ=Upper quartile, BME=Black and minority ethnic

only a weak correlation between the percentage of Black and minority ethnicity (BME) teenagers under 16 and pregnancy rates in an LA ( $\rho = 0.2, P = 0.02$ ). Although there was a greater concentration of CPs in the LAs with greater needs ( $\rho = 0.4, P < 0.001$ ), this did not translate into an improved provision of EHC PGD through CPs ( $\rho = 0.002, P = 0.99$ ).

**Sample**

There was a wide variation in the uptake of the EHC PGD through different LAs [Table 6b], with a range from 10 to 833 clients with a median of 159 clients per month. When the uptake per month was divided by number of CPs within an LA, the median number of clients per month per CP was 5 clients, with a range from 1 to 86 [Table 6b]. All of the uptake variables were log<sub>10</sub>

transformed to make them closer to normal distribution. The uptake factors were measured per calendar month and per calendar month per CP. There was no significant correlation between needs (teenage pregnancy rates) and uptake per calendar month. When the uptake was weighted against number of CPs that were offering the EHC PGD, the uptake correlated significantly with the provision with  $R = 0.36 (P = 0.02)$ . This suggests that CPs in LAs with higher needs had to deal with higher number of clients per month to meet their local needs as the CPs EHC PGD provision did not match the needs.

**Incremental cost-effectiveness ratio of emergency hormonal contraception in comparison to no intervention**

The cost of consultation was available for 15 LAs and ranged from £10 (€12.20; US\$19.51) to £15.50 (€18.90;

**Table 6b: Demographic, service delivery, and pharmacy factors for the sample - community pharmacy emergency hormonal contraception patient group direction**

Variable	Median/ mean	LQ	UQ	Minimum-Maximum
Teenage pregnancy rate (conception rate per 1000 15-17-year-old females only) ( <i>n</i> )	48.5	38.5	53.9	25.4-68.5
Deprivation score (Index of Multiple Deprivations)	26.0	21.1	33.9	11.3-43.5
Females under 16 years out of total females under 60 years old (%)	24.2	23	24.8	19.4-29.2
Females under 60 years of BME background out of the total population (%)	8.0	4.5	23.3	2.5-46.4
Females under 16 years of BME background out of the total population (%)	7.3	4.2	21.8	2.2-55.3
Females 16-59 years of BME background out of the total population (%)	8.4	4.5	23	2.4-46.1
Clients who accessed EHC service during 2009/2010 per calendar month ( <i>n</i> )	159	66	303	10-833
Clients who were issued with EHC medication during 2009/2010 per calendar month ( <i>n</i> )	155	62	291	10-803
Clients who accessed EHC/month per CPs which were offering EHC ( <i>n</i> )	5	3	8	1-86
Clients who were issued with EHC medication/month per CPs which were offering EHC ( <i>n</i> )	5	3	7	1-84
Clients who accessed EHC per calendar month per female aged 15-24 years old ( <i>n</i> )	9	4	14	1-45

CPs=Community pharmacy, EHC PGD=Community pharmacy emergency hormonal contraception patient group direction, LQ=Lower quartile, UQ=Upper quartile, BME=Black and minority ethnic

US\$30.24), with a median of £12.50 (€15.24; US\$24.39). The cost of medication ranged from £5.20 (€6.34; US\$10.15) to £6 (€7.32; US\$11.71), with a median of £5.37 (€6.55; US\$10.48). The median cost per client was £17.68 (€21.56; US\$34.50) ranging from £15.78 (€19.24; US\$30.79) to £20.57 (€25.09; US\$40.14) [Table 7]. The ICER for EHC intervention in comparison to no intervention had a negative value of 688.7 [Table 7], indicating cost-effectiveness. As stated in the method, four scenarios were tested as part of the sensitivity analysis [Table 7]. The results indicate that provision of EHC through CPs would save at least £384.29 (€468.65; US\$749.83) for the NHS.

## DISCUSSION

This study has shown a higher prevalence of smoking being associated with higher deprivation. Furthermore, despite all the progress that have been made in reducing teenage pregnancy rates in England, following the government plan which was set in 1999, the rates of teenage pregnancies were found to be still highly associated with deprivation at LA level, which agrees with Conrad's findings.<sup>[58]</sup> Therefore, although this study was based in a high-income country, its findings may also be of interest to low/middle-income countries (LMICs) who are looking for cost-effective ways to reduce the incidence of noncommunicable diseases (NCDs).<sup>[59]</sup>

This study provides updated evidence on the success of the SSS through all providers with a focus on CP provision. Although there is a high intention to quit smoking among UK smokers (77% UK smokers intend to quit smoking<sup>[60]</sup>), the SSS was only able to reach 7.9% of total smokers. This can be explained by the fact that more than half of the UK smokers try to quit smoking without using any treatment and only 6% out

of those who tried to quit smoking used NHS SSS.<sup>[61]</sup> However, this study finds that the SSS in total failed to help 5% or more of UK smokers to quit smoking as per NICE guidelines as the median success out of needs was only 3.9%.<sup>[40]</sup> Of those who set a quit date, 49.9% self-reported quitting smoking with 68.5% of those having their successful quit confirmed through the CO-validated method. This represented 34.2% of total setters, a lower figure than the 35% CO-validated quit rate that was recommended by the government.<sup>[40]</sup>

There is a higher concentration of CPs per 25,000 population in more deprived areas and in areas with a higher proportion of ethnic minorities where smoking is more prevalent. The SSS was initially piloted to reach more deprived smokers to reduce health inequalities.<sup>[62,63]</sup> Our results showed that SSS reach is higher in deprived areas. This finding echoes that of Bauld *et al.*<sup>[62]</sup> and West *et al.*<sup>[35]</sup> Quit setting rates, however, did not translate into higher quit rates for smokers of lower socioeconomic status (SES). In fact, those from higher SES were more likely to successfully quit smoking, a theme also identified in other studies.<sup>[64,65]</sup> This indicates that to improve the outcomes for those from lower SES, factors that force setters to resume smoking in more deprived LAs should be identified and work should be done to overcome these.

Overall, CP SSS provision per 25,000 population correlated significantly with deprivation and ethnic minority proportion but did not correlate with the prevalence of smoking adults (needs). Therefore, CPs in LAs with higher needs had to deal with a higher number of smokers who set a quit date per year ( $\rho = 0.4$ ). Although quit rates through CPs were negatively correlated with needs, community pharmacies in LAs with higher needs achieved a higher number of quitters

**Table 7: Summary description of the emergency hormonal contraception patient group direction service uptake, payments, and costs**

	EHC intervention	No intervention		
Cost of consultation and medication (£) <sup>Δ</sup>	17.68 (€21.56; US\$34.50)		No cost	
Cost of unintended pregnancy (£)*	17.27 (€21.06; US\$33.70)		72.14 (€88; US\$141)	
Total cost (£)	34.95 (€43; US\$68)		72.14 (€88; US\$141)	
Difference in pregnancy rate (%) <sup>†</sup>			5.4%	
ICER			-688.7	
Scenario	EHC intervention	No intervention	Difference in pregnancy rates (%)	ICER
First scenario				
Cost of intervention	£15.78	No costs		
Unintended pregnancy cost	£17.27	£72.14	5.4	-723.89
Total costs	£33.05	£72.14		
Second scenario				
Cost of intervention	£20.57	No costs		
Unintended pregnancy cost	£17.27	£72.14	5.4	-635.19
Total costs	37.84	£72.14		
Third scenario <sup>‡</sup>				
Cost of intervention	£17.68	No costs		
Unintended pregnancy cost	£26.42	£54.86	2.8	-384.29
Total costs	£44.1	£54.86		
Fourth scenario <sup>#</sup>				
Cost of intervention	£17.68	No costs		
Unintended pregnancy cost	£11.48	£78.03	6.55	-746.11
Total costs	£29.16	£78.03		

\*Cost of unintended pregnancy is probability of getting pregnant x cost of unintended pregnancy (£1016)=1.7% × £1016 in the case of EHC intervention; 7.1% × £1016 in the case of no intervention, <sup>†</sup>Difference in pregnancy rate equals the probability of not-getting pregnant using EHC (100%-1.7%=98.3%) minus the probably of not-getting pregnant with no intervention (100%-7.1%=92.9%), <sup>‡</sup>2.6% chance of pregnancy with intervention versus 5.4% chance of pregnancy with no intervention, <sup>#</sup>1.13% chance of pregnancy with intervention versus 7.68% chance of pregnancy with no intervention. <sup>Δ</sup>Total cost of consultation=Cost per consultation x number accessed EHC, <sup>Δ</sup>Total cost of medication=Cost per medication x number received EHC, <sup>Δ</sup>Total cost per client=Total cost of consultation + total cost of medication number of clients who accessed EHC service. EHC PGD=Emergency hormonal contraception patient group direction, ICER=Incremental cost effectiveness ratio

per pharmacy per year with rho of 0.31 and P of 0.046. Thus, an increase in CP provision of SSS will potentially result in higher reach of SSS and higher success of SSS out of needs. This suggests that to improve the uptake of SSS and to avoid the increase in workload related to SSS, an increase in SSS provision through CPs should be considered.

Similarly, although there is a higher concentration of CPs in LAs with higher rates of teenage pregnancy, this was not translated into a higher number of CPs offering the EHC PGD, so the provision did not match the needs. This contradicts the action plan set up by the government in its White paper, “Pharmacy in England – building on strengths – delivering the future” to improve access to contraceptive services through CPs.<sup>[66]</sup> A higher uptake of EHC PGD from CPs was noted in LAs with higher teenage pregnancy rates; however, this did not correlate with needs. However, as expected, the overall uptake of EHC correlated with the level of provision (R = 0.51, P = 0.001).

In terms of the cost-effectiveness of CP SSS, the median cost per participant was £116.7 (€142.32; US\$227.71),

which resulted in £486.4 (€593.17; US\$949.07) median incremental cost per quitter at 4 weeks. This is similar to that reported by Cramp *et al.*<sup>[67]</sup> A previous Glasgow study reported £53.31 (€65.01; US\$104.02) as the cost per participant and £772 (€941.46; US\$1506.34) as incremental cost per quitter at 4 weeks (based on 2007 prices).<sup>[23]</sup> Although the cost per participant was lower, the CO-validated quit rate in this study was almost twice that identified in Boyd and Briggs study.<sup>[23]</sup>

When looking at cost per QALY gained, the median cost was £1539 (€1876.83; US\$3002.93) with a range from £695 (€847.56; US\$1356.10) to £7891 (€9623; US\$15397). NICE gives a cost-effectiveness figure of £20k (€24k; US\$39k) to £30k(€37k; US\$59k) per QALY gained,<sup>[68]</sup> this, however, is not specific to CP. The intervention is below £20,000 (€24,000; US\$39,000), thus demonstrating that the provision of CP SSS is cost effective.

From a cost-effectiveness perspective, the EHC PGD was also cost-effective when compared to no intervention based on using median costs of intervention and the

mean effectiveness of EHC versus no intervention from the meta-analysis conducted. Furthermore, the sensitivity analysis showed that the EHC PGD was still cost-effective, even if the higher cost of intervention was used and when the difference in probability in getting pregnant following unprotected sexual intercourse of EHC versus no intervention<sup>[42]</sup> was taken into consideration.

Marcianti *et al.*<sup>[31]</sup> found that the ICER for obtaining EHC from pharmacies over other venues was £33 (€40; US\$64) from public payer perspective and £109 (€133; US\$213) from private payer perspective over a period of 9 months. On the other hand, Trussell *et al.*<sup>[69]</sup> found that the ICER of levonorgestrel intrauterine system is \$930 when compared to no method. This study identified that the ICER per one prevented unintended pregnancy was £688.7 (€840; US\$1344).

While teenage maternal health is generally high in high-income countries, those from LMICs are at risk of morbidity and mortality associated with pregnancy.<sup>[70]</sup> Strategies used in high-income countries, such as the UK, to reduce teenage pregnancy rates may also prove useful in LMICs to improve teenage maternal and reproductive health, while at the same time being cost-effective for the providers.

Future research into the cost-effectiveness of CP public health services should look at whether CPs are satisfied with the level of payment for service delivery and if this payment appropriately covers the costs of service delivery. In addition, it would be important to consider whether external challenges and pressures, such as government funding cuts, affect CPs ability to deliver public health services.

The study had a low response rate that did not meet the minimum sample size calculated by the sample size calculator. However, to overcome this low response rate, the sample was weighted against nonrespondent LAs as was recommended by Brick and Kalton.<sup>[71]</sup> In the case of the cost analysis, several measures were not given by the respondent LAs exactly. Thus, a sensitivity analysis was conducted to overcome this problem.

As the study was carried out, there have been changes to the options the public have available to them to help them quit smoking and to prevent unwanted pregnancies. Electronic cigarettes are changing the way smokers choose to quit. Ulipristal is a new form of EHC. It is more effective than levonorgestrel with a 1.8% failure probability for ulipristal versus 2.6% for levonorgestrel.<sup>[42]</sup> Thomas *et al.*<sup>[72]</sup> found that using ulipristal rather than levonorgestrel within 120 h following unprotected intercourse would save

the NHS £311 in terms of preventing one unintended pregnancy. In addition, prices quoted in this article are from 2014, as such, currency rates at the time of publication may need to be considered.

The CP SSS arm of this study assumed the value of QALY per lifetime quitter from the literature. As such the measurement of consequences for cost-utility analysis was not derived from the study population. In addition, this study was concerned with the perspective of the NHS. As such, it did not consider the wider potential benefits of the CP SSS and the EHC PGD outside of the health sector. In relation to the EHC PGD, for example, a reduction in pregnancy rates may also have a long-term impact on the education sector.

Ten years since the introduction of the NHS SSS, smoking prevalence is still highly correlated with deprivation. There is also a strong correlation between needs and deprivation in the case of the EHC PGD. The CP SSS provision did not match with the needs, despite the fact that there was a higher concentration of CPs in more deprived areas. Similarly, the provision of EHC PGD did not match with the needs, however, it did match with the uptake. If the CP SSS provision increases, the total reach and total success of SSS through CPs will increase. An increase in CP EHC PGD provision would also result in higher uptake of the service. Both services were found to be cost-effective and thus provide a convenient and accessible source for help, however, their provision does not match the needs of the population. Future work should investigate the wider impact of public health services outside of the NHS and the factors that influence CP provision of public health services.

## AUTHORS' CONTRIBUTION

Wail Chalati, John Fletcher, and Reem Kayyali conceived and designed the study. Wail Chalati collected and analyzed the data for the study. Philip Crilly interpreted the data from the study and drafted the paper. Philip Crilly, Wail Chalati, John Fletcher, and Reem Kayyali reviewed and approved the final version of the manuscript for publication.

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## Conflicts of interest

There are no conflicts of interest.

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