

Independent nurse medication provision: a mixed method study assessing impact on patients' experience, processes, and costs in sexual health clinics

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TITLE

Independent nurse medication provision: a mixed method study assessing impact on patients' experience, processes, and costs in sexual health clinics

ABSTRACT

Background: Local services within the United Kingdom National Health Service enable autonomous provision of medication by nurses, by supporting individual nurses to gain prescribing qualifications or by introducing local patient group directions.

Aim: To compare nurse prescribing and patient group directions regarding clinic processes, patients' experiences, and costs from the perspectives of providers, nurses, and patients.

Design: Mixed methods, comparative case study in five urban sexual health services in the United Kingdom.

Methods: Data were collected from nurse prescribers, patient group direction users and their patients July 2015 to December 2016. Nurse questionnaires explored training funding and methods. Nurses recorded consultation durations and support from other professionals in clinical diaries. Patient notes were reviewed to explore medication provision, appropriateness and safety; errors were judged by an expert panel. Patients completed satisfaction questionnaires about consultations and information about medications.

Results: Twenty-eight nurse prescribers and 67 patient group directions users took part; records of 1,682 consultations were reviewed, with 1,357 medications prescribed and 98.5% therapeutically appropriate. Most medication decisions were deemed safe (96.0% nurse prescribers, 98.7% patient group directions, $p=0.55$). Errors were predominantly minor (55.6% nurse prescribers, 62.4% patient group directions) and related to documentation omissions (78.0%); no patients were harmed. Consultation durations and unplanned re-consultations were similar for both groups. Nurse prescribers sought assistance from colleagues less frequently ($p<0.001$) but spent longer discussing cases. Nurse prescribing training required more resources and cost for providers and nurses, compared to patient group directions. Nurse prescribers were on higher salary-bands. Patient satisfaction was high in both groups (>96%).

Conclusions: Nurse medication provision by both nurse prescribers and patient group direction users is safe and associated with high patient satisfaction; effects on clinic processes and costs are similar. Undertaking the prescribing qualification involves independent study but may bring longer term career progression to nurses.

Keywords

- Nurse/ non-medical prescribing
- Sexual health
- Patient group directions/ medication directives
- Cost consequence
- Health resources

INTRODUCTION

Nurses can independently provide medication without a prescription from a medical doctor in countries including Australia, Canada, China, Ireland, Spain, New Zealand, Norway, South Africa, Sweden, Netherlands, and USA (Kroezen et al., 2011; Gielen et al., 2014; Ling et al., 2018). The United Kingdom (UK) is considered world-leading with regards to medication provision by nurses (Kroezen et al., 2012). This ability for nurses to provide medication enables greater flexibility in service planning and has the potential to affect patient outcomes as well as processes and costs (Nursing & Midwifery Council (NMC), 2006; UK Department of Health (DH), 2006). Internationally, nurses' scope of prescribing practice varies considerably ranging from a restricted formulary to prescribing powers comparable to doctors (Gielen et al., 2014). The study reported in this paper compared two different models of independent medication delivery by nurses in the UK National Health Service (NHS): patient group directions and independent nurse prescribing.

BACKGROUND

Patient group directions are local agreements, introduced in 2000 (DH, 2000), that enable nurses to supply and/or administer certain medications within a specified scope. Patient group directions can be used by larger numbers of nurses deemed competent locally but involve time by senior members of local services to set them up. Once agreed, training is usually delivered to nurses by the provider organisation (National Institute for Health and Care Excellence (NICE), 2013).

From 2001, UK nurses have had increasing powers to prescribe independently, outside of patient group directions, (referred to hereafter at 'nurse prescribing') (Great Britain. *Health & Social Care Act 2001*; DH, 2006). Nurses who successfully complete an accredited prescribing course are now able to provide almost all medications within their clinical competence (*The Human Medicines Regulations 2012* Statutory Instrument 2012/1916). At the time of this study, the UK regulatory body, the NMC, required that nurse prescribing training was at degree level or above, over a minimum of 26 days, with a further 12 days (7.5 hours/day) of clinical practice supervised locally by a 'designated medical practitioner' (NMC, 2006; NMC, 2015). Since the present study, 'designated medical practitioners' have been replaced with 'designated prescribing practitioners' which also allows experienced nurse and pharmacist prescribers to act as clinical supervisors (NMC, 2018).

THE STUDY

Aims

The aim of this paper is to compare the implications of patient group directions and nurse prescribing for provision of medications in sexual health clinics from the perspectives of local NHS services, individual nurses, and patients. The study investigated training and governance, clinic processes, patients' experiences, and costs, to provide an overview of relevant factors.

Design, Setting and Participants

The study used mixed methods and a comparative case study design. It was set in five geographically spread urban-based specialist sexual health services (three in England, one in Wales, one in Scotland). Patient group directions and/or nurse prescribing were fully established in each service. Participants were sexual health nurses who managed patients using patient group directions or nurse prescribing, and their patients. To facilitate nurse recruitment and staff awareness, the study was presented to staff at local site meetings.

Data collection

Factors of interest in the comparison of patient group directions and nurse prescribing were identified from an initial literature review and discussion amongst investigators. Those pertinent from the NHS perspective were: (i) training, set-up and governance costs; (ii) clinic processes, including: medication provision, errors and appropriateness; consultation lengths; impact on the workload of other professionals; rates of unplanned repeat attendances for the index condition, and (iii) patient experiences. From the nurse's perspective, embarking on prescribing training may incur personal time to study and out-of-pocket expenses, but may generate benefits in terms of career progression and job satisfaction. Patient group direction training is usually delivered in work time ('on-the-job').

Data were collected sequentially between July 2015 and December 2016 using nurse questionnaires, nurse diaries, patient notes reviews and patient questionnaires at each site. Costs (British pounds, 2016) were attributed to the resources, where possible. Data sources are summarised in Table A and described further below. Synthesis was largely narrative. Detailed findings regarding medication safety/appropriateness (Black et al., 2020a) and patient experiences (Black et al., 2020b) are published elsewhere.

NHS perspective

(i) Training and governance for patient group directions and nurse prescribing

The resource implications of developing and implementing patient group directions were assessed by observing the process of writing one local patient group direction for a contraceptive implant and updating a group of other directions (also contraceptives). Each step was logged and senior staff contributing to the process asked to report the time involved. Being a local policy, patient group direction training is delivered in work time and staff time implications were not gathered in detail.

Regarding local sponsorship of nurse prescribing courses, nurses at each site who had completed training were asked to report on courses attended and clinical support received (role and hours of designated medical supervisors) by means of a questionnaire (further details below). Course fees were obtained from the websites of universities reported by questionnaire respondents.

Clinic processes

Medication, errors and appropriateness: Data were obtained for four categories of patient presentations (consultations): when patient group direction users did/did not provide medications, and when nurse prescribers did/did not provide medications. A sample size of 344 consultations for each category was calculated as required to enable a comparison of the appropriateness of prescribing by patient group direction users and nurse prescribers with 99% power at the 5% significance level. Using data from Black (2012), it was assumed 98% of consultations from nurse prescribers would be appropriate, compared with 89% of patient group direction users.

Patient attendance lists at each site were used to identify clinical notes of patients managed by patient group direction users and nurse prescribers over a six-month period. Quotas for presentations were set for sites based on the number of nurse prescribers or patient group direction users in each site and notes randomly selected using Microsoft Excel®, until the sample size of 344 had been achieved for all four categories.

Details of all medications delivered and the documentation on the prescriptions were extracted from notes onto a standardised proforma. Medication provision by nurse prescribers and patient group direction users was compared. The researcher (AB) identified any potential issues with medication

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3 provision, or lack of, based on Dornan et al.'s (2009) prescribing error classifications. Appropriateness
4 of medications delivered and decisions not to provided medications was assessed using the ten-item
5 Medication Appropriateness Index (Hanlon et al., 1992), national guidance (BASHH, 2016; FRS
6 2016) and clinical judgement. Use of patient group directions was assessed against local guidance. Items
7 in the Index covered: indication for the drug, effectiveness for the condition, dosage, directions,
8 interactions, reactions, cost; scoring ranges from 0 (appropriate) to 18 (inappropriate) with the cut-off
9 for appropriateness set at 3. All errors were confirmed with a prescribing representative at each site,
10 and any disagreements resolved locally. A project-specific error categorisation was created by the
11 research team based on the error types observed in the data. This included potential of drug interactions,
12 absence of risk assessment, omission of prescription documentation, instances of under/ over/ wrong
13 prescribing and inappropriate use of patient group directions. Error rates per consultation were
14 calculated. An expert clinical panel, comprising two consultant physicians, two nurse prescribers and a
15 pharmacist, was convened to assess the severity of errors using a validated, reliable scoring tool (Dean
16 and Barber, 1999). Each judge scored each error on a scale of zero (no harm) to ten (death). Errors
17 were classified as minor (score 0-2), moderate (3-6), severe (7-10), and the mean score calculated. As
18 part of this process, the panel identified any consultations where they considered the medication
19 provided was not safe. Any disagreements were resolved by discussion. Further information on the
20 methods for identifying and rating medication errors is provided in Black (2020a).

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26 *Consultation duration:* Data on consultation length were gathered from clinical diaries completed for
27 two weeks by nurses in the study as the electronic patient record consultation start and stop times (i.e.,
28 consultation durations) were not available at most sites. Mean consultation durations were calculated
29 and compared for nurse prescribers and patient group direction users, distinguishing new from follow-
30 up consultations.

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33 *Workload of other professionals:* The impact of nurse delivery of medications on the workloads of other
34 health professionals (e.g. nurses obtaining prescriptions or clinical advice from doctors) was also based
35 on data collected through the clinical diaries. Participants were prompted to record episodes of
36 professional support required, the role of the person they sought support from, and duration spent
37 supporting them. Mean support durations were calculated and compared.

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40 *Unplanned re-consultations:* Unplanned re-consultations for the index condition were obtained from
41 clinical records and compared between nurse prescribers and patient group direction users as a measure
42 of the effectiveness of the initial treatment received.

43 (ii) Patient experience

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45 During the two-week period when nurses were completing clinical diaries, they invited patients
46 provided with medications to complete a patient experience questionnaire. Patients returned completed
47 surveys in a collection box before leaving the clinic. Patients predominantly managed by another health
48 professional or those deemed vulnerable (e.g. under 16, sexual assault victims) were excluded. The
49 questionnaire included five items from the validated patient satisfaction survey for sexual health clinic
50 attendees (Weston 2010) and 16 items in two domains (action and usage of medications, and potential
51 problems of medicines) from the Satisfaction with Information about Medications Scale (Horne et al
52 2001). Each item is scored 0 (negative) or 1 (positive) and summed to obtain domain scores, range 0 to
53 8 (highest satisfaction),
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56 Nurse perspectives

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58 Questionnaires were distributed to nurses (both groups) in each site to capture information on the
59 training received. They indicated their motivations for training for independent delivery of medications
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3 from a series of statements (e.g. improving job satisfaction, patient experience and clinical skills).
4 Background information was gathered on gender, age, nurse banding/ grade, prior qualifications and
5 clinical experience. Nurse prescribers reported the prescribing course they had attended and who funded
6 them. Respondents in each group were asked about study leave provided, personal time devoted to
7 studying, and out-of-pocket expenses for travel and purchase of learning resources for training. Any
8 potential career advantages were estimated by comparing current seniority bandings of nurse prescribers
9 in the study with those of nurses using patient group directions.
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12 **Ethical considerations**

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14 A favourable ethical opinion was obtained for the study from Wales Research Ethics Committee 4,
15 reference 15/WA/0120. Participation was voluntary, except for the clinical notes review (as approved
16 by the ethics committee). All identifying data were anonymised. Nurse participants could withdraw at
17 any time without giving a reason.
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20 **Data analysis/ synthesis**

21 Data gathered on the various factors were synthesised using a cost-consequences balance sheet, or
22 through descriptive narrative to enable a comparison of patient group directions versus nurse
23 prescribing. A cost-consequences framework permits comparisons in the context of multiple influences,
24 perspectives and effects (Mauskoff et al., 1998), and supports the inclusion of non-health related factors
25 and processes of care, providing a broad and comprehensive consideration in the context of service
26 delivery interventions (Drummond et al., 2015; Sutton et al., 2018). Data are presented as non-
27 aggregated information so that healthcare systems, organisations and individuals can review specific
28 aspects of the same dataset to determine whether the issues under consideration are likely to be
29 economically beneficial from their perspective.
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33 **Statistical methods**

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35 Data were analysed using Statistical Package for Social Sciences (SPSS) version 24.0 (IBM Corp,
36 2016), Microsoft Access® and Microsoft Excel®. Data are presented, where appropriate, using the
37 mean (standard deviation), range, median and frequencies (percentages). The chi-squared test was used
38 to compare differences in proportions between nurse prescribers and patient group direction users, or
39 the Fisher's Exact Test if any expected cell values were <5 (Field, 2009). Group means were compared
40 using the Independent Samples t Test.
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43 Consultation lengths were compared between nurse prescribers and patient group direction users
44 distinguishing between new and follow up consultations, and between consultations where medications
45 were or were not provided.
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47 Costs were estimated in British pounds (2016) for items where differences were observed between nurse
48 prescribers and patient group direction users. Hours spent by staff involved in patient group direction
49 governance and as designated medical practitioners were valued according to national salary tariffs
50 (Curtis and Burns, 2016) inclusive of on-costs and overheads. Medications prescribed were costed
51 based on the British National Formulary (2016) prices. Wrong- and over-prescribing were taken as an
52 indication of wastage and the cost of 'wasted' medication estimated. For under-prescribing, the
53 medications that should have been prescribed were identified and costs included.
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57 **RESULTS**

58 **NHS perspective**

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(i) *Training and governance for nurse prescribers and patient group direction users*

Twenty-six of 28 (93%) nurse prescribers recruited across the five sites returned staff questionnaires. The fees of 25 nurse prescribers (at 10 different universities) were paid in full by employers or health education grants, ranging from £900 to £3,555 (mean £1,695, from data available for 2016). Consultant level doctors were the most frequently reported designated medical practitioner (20 of 26 nurses), with Registrars and Associate Specialists supporting the others. Support ranged from 2 to 12 days. Ten nurses reported additional support from nurse practitioners (1 to 3 days). Including all clinical supervision, a mean of 7.4 days (range 2 to 13.7) was provided to each nurse prescriber during training. This would equate to a cost to the NHS of £6,451 (weighted mean, range £1,283 to £11,138) per nurse prescribing student but would not apply if the supervision was provided alongside normal clinical duties. Respondents (24 of 26 nurses) reported a mean of 20.1 employer-funded study days (range 1 to 31) with nurses in higher bands reported receiving more study leave (Supplementary tables 1- 3).

The process for patient group direction creation, approval, and implementation followed National Institute for Health and Care Excellence guidance (NICE, 2013), summarised in Figure 1. The process for the creation of a new contraceptive patient group direction, including drafting by a senior nurse and review and committee approval involving another senior nurse and a consultant doctor involved a total of 13.8 hours (time cost to the employer of £912); the updating of a patient group direction for individual contraceptives (same staff) took 4.0 hours (£276) (Supplementary table 4).

Thirty-five of 67 (52.2%) patient group direction users recruited across the five sites returned staff questionnaires. Twenty-nine of 35 (82.9%) respondents reported how they were trained to become competent to use patient group directions. A variety of methods (often hybrid) were reported including classroom teaching (23), one-to-one instruction (11), self-directed learning (20) and e-learning (10). (Supplementary table 5). While there was no requirement for the NHS to provide study days for patient group direction training, 30 respondents identified a mean of 6.4 study hours (0.9 days); 16 respondents reported no study time and one reported 85 hours. As with nurse prescribers, more senior patient group direction users reported a larger amount of study leave than those in junior bands (Supplementary table 6).

(ii) *Clinic processes*

Medication, errors and appropriateness: A total of 1,682 presentations were reviewed to achieve the sample size of 344 in each of the four categories (nurse prescriber consultations with and without medication delivery; patient group direction user consultations with and without medication delivery). Presentations to nurse prescribers in which no medications were delivered were the least frequent category of consultation, and resource constraints meant data collection had to stop when only 326 records of this sort of consultations had been identified. The remaining 18 consultations were therefore sourced from nurse diaries collected at dates outside the six-month period covered by the record review (thus avoiding double counting) (Table B).

A total of 1,357 medications were provided in the 879 (52.3%) presentations involving medication provision. Nurse prescribers delivered 620 medications from 399 consultations (1.55 per consultation); patient group direction users delivered 737 medications from 480 consultations (1.54 per consultation). The most frequently prescribed medications were antibiotics (n=486, 35.8%) and local anaesthetics (n=156, 11.5%); vaccinations, wart treatment, contraceptives (short and long acting) and antifungals each accounted for between 8 and 9% of all prescriptions. The overall mean costs of medication per patient was higher for nurse prescribers than for patient group direction users (£19.00 vs £11.25 respectively), reflecting a more complex case load and higher rates of prescribing of HIV-related drugs.

Both nurse prescribers and patient group directions users consistently provided appropriate medication choices. Overall, medication was determined to be therapeutically effective in 1,336 (98.5%) of 1,357 cases. Including consultations when medications were not provided, the proportion that were appropriate was lower for nurse prescribers (714/743, 96.1%) than for patient group direction users (883/939, 94.0%) (Fisher's Exact $p < 0.001$); the mean Medication Appropriateness Index was similar (0.9 (SD=2.3) vs 0.8 (SD=2.0); $t = 1.032$ (df=1239.6), $p = 0.302$). The main reason for medication provision to be deemed 'inappropriate' related to inadequate clinical documentation. Patient group direction users also made inappropriate use of the directions in a small number of cases.

From the 1,682 presentations (i.e., with and without medication prescribing), a total of 1,844 individual medication errors were identified (including inappropriate medications). There were 879 errors across 743 nurse prescriber consultation, and 965 errors across 939 patient group direction user presentations, an average 1.18 and 1.03 errors per consultation, respectively (chi-square $p = 0.001$). Errors most frequently related to documentation omissions (1,439, 78.0%). Patient group direction users were more likely to make medication risk assessment errors than nurse prescribers. Most errors were categorised by the expert panel as being minor (nurse prescribers, 55.6%; patient group directions, 62.4%). The rates for wrong, over and under provision of medications, and their associated costs, were similar for nurse prescribers and patient group direction users (Table B). Overall, 713 of 743 (96.0%) of all nurse prescriber medication decisions were considered safe, as were 927 of 939 (98.7%) of patient group directions decisions (Fisher's Exact, $p = 0.55$). For more details see Black et al. (2020a).

Consultation duration: Overall the mean (SD) consultation duration (minutes) was longer for nurse prescribers than patient group direction users (24.9 (12.9) vs. 22.8 (13.9)). New consultations, however, were longer than follow ups for both nurse prescribers and patient group direction users, but with no significant differences between the groups: new, 27.2 (13.0) vs. 25.7 (15.1), $p = 0.15$; follow-up 19.5 (10.9) vs. 19.4 (12.0), $p = 0.74$. Length of consultations was also longer when medications were provided, rather than not: with medications 25.7 (12.7) vs 23.3 (14.2); without medications 23.3 (13.1) vs. 22.1 (13.3).

Workload of other professionals: Nurse prescribers sought advice from professional colleagues about medication delivery less frequently than patient group direction users (95 of 737, 12.9% vs. 152 of 539, 25.6% of all consultations respectively, $p < 0.001$) but the time they spent with colleagues was longer (mean (SD) 11.0 (11.7) vs. 8.2 (6.9) minutes). Advice was sought mostly from doctors (81% of nurse prescriber enquiries; 85% of patient group direction user enquiries). They also approached pharmacists (9; 2%) and nurses (6, 10%). The weighted mean time cost of the other professionals providing advice was £10.41 (nurse prescribers) and £9.39 (patient group direction users).

Unplanned re-consultations: Patients returned to the clinic after 306 of the 1,682 (18.2%) of index consultations; this involved 145 (19.5%) of 743 patients of nurse prescribers and 161 (17.1%) of 939 patients of patient group direction users ($p = 0.21$), involving 400 specific reasons (200 in both groups). The reasons why patients returned were also similar in both groups. Re-consultations were mostly attributable to patients' behaviour (17%). No instances were judged to have been potentially avoidable by the nurse in the original consultation.

(iii) Patient experiences

A total of 393 (48.6%) of a potential 808 eligible patients were given a patient questionnaire after their consultation with the nurse and 380 of 393 (96.7%) were returned (nurse prescribers 180 of 198 (90.9%), patient group directions 173 of 195 (88.7%)) Consultation satisfaction rates were above 96% for both nurse prescribers and patient group direction users for all five questions (friendliness/approachability of the nurse; confidence/trust in the nurse; information provided (two items); perceived

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3 skills of the nurse). Scores on the Satisfaction with Information about Medications Scale were also
4 high and similar between groups. Nurse prescribers and patient group direction users scored 6.9 and 7.1
5 out of 8 respectively ($p=0.34$) on the action and usage of medicines domain (medications' name,
6 purpose, what it does, how it works, duration to act, understanding if medication is working, treatment
7 duration and obtaining further supplies). Both groups scored 6.4 out of 8 ($p=0.98$) on the potential
8 problems of medicines domain (side effects (risks and how to manage them), interactions with other
9 medicines and alcohol, drowsiness, ability to have sex and what to do if doses are missed). Overall
10 mean scores were 13.3 (nurse prescribers) and 13.5 (patient group direction users), maximum 16. For
11 further information see Black et al. (2020b).
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14 **Nurse perspective**

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16 Nurses responding to the questionnaire were mostly female (25 of 26 nurse prescribers and 34 of 35
17 patient group direction users). The mean years of clinical experience was 19 in both groups (range 6 to
18 35 years for nurse prescribers, and 3 to 45 years for patient group direction users).
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21 *Loss of personal time:* Twenty-one (of 26) nurse prescriber respondents reported spending a mean of
22 26.3 (SD=13.9) days (range 8 to 60 days) of personal time studying for nurse prescriber qualifications,
23 additional to employer-provided study days (based on 7.5 hours per day). By comparison, 26 of 35
24 patient group direction users who answered the question reported spending a mean of 1.6 (SD=2.8) days
25 of personal time undertaking training, but most reported no days.
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28 *Out-of-pocket expenses during training:* Twenty-two nurse prescribers and 21 patient group direction
29 users answered questions relating to out-of-pocket expenses. Predominantly across both nurse
30 prescribers and patient group direction users there were no additional out-of-pocket expenses reported.
31 Across all categories of expenditure, including books and travel, nurse prescribers reported spending a
32 mean of £32.02 (SD= £46.09; median £20) compared to a mean of £1.49 (SD=£6.05; median £0) by
33 patient group direction users.
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36 *Nurses' benefits:* Twenty-six nurse prescribers and 35 patient group direction users provided responses
37 on motivations for providing medications independently. Nurse prescribers were predominantly
38 motivated by a desire to enhance their clinical skills and job satisfaction and improve the patient
39 experience (over 90% agreeing with these statements). While these motivations were also important
40 for patient group direction users (over 80% agreed), the main influencing factor for this group ($n=30$,
41 85.7%) was fulfilling the expectation of their employer ($n=16$, 61.5% of nurse prescribers) Table C.
42 Nurse prescribers tended to be more senior and in higher salary-bands than patient group direction users;
43 18 (69.2%) of 26 nurse prescribers salary-band 7 or 8, annual salary (in 2018) above £40,000 whilst 29
44 of 35 (82.9%) patient group direction users were salary-band 5 or 6, annual salary in the range £26,000
45 to £32,000). Although the ability to prescribe cannot be confirmed as the causal factor (as prescribing
46 may be expected of senior nurses), it does suggest nurse prescribers are likely to gain higher lifetime
47 financial benefits compared to patient group direction users.
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50 **Synthesis**

51 Findings are summarised in Table D and discussed below.
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54 **DISCUSSION**

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56 While some studies have compared nurse prescribing with medical prescribing, a unique feature of this
57 study is that it compares two alternative ways in which nurses independently provide medications.
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3 Although largely descriptive, the cost-consequence approach provides a framework to summarise the
4 differences between nurse prescribers and patient group direction users. Although the training and
5 governance arrangements differ, the study found little or no difference between nurse prescribing and
6 use of patient group directions in clinic processes or patients' experiences.
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8 *Training and governance for nurse prescribing and patient group directions*

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10 Establishing nurses' independent medication provision, either through use of patient group directions
11 or independent prescribing, allows greater flexibility in the delivery of care to patients. Local services
12 must balance the resource implications of adopting these approaches in the context of current budgets,
13 the nature and size of the service and the expected longer-term benefits. Introducing a new patient group
14 direction has the advantage that it can be applied in practice (after training) by all nurses. When
15 directions relate to commonly presenting conditions, they offer potential efficiencies and savings.
16 Nurses with prescribing qualifications have wider scope of practice but may be more expensive to hire
17 or keep in post.
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21 Nurses in our study who had completed the prescribing qualification tended to be more senior than
22 patient group direction users. We do not know if gaining the qualification led to promotion or if only
23 more senior nurses were expected, or allowed, to become prescribers by their employer. The nurse
24 prescribers in higher salary-bands, however, enjoy the benefits of higher lifetime earnings which more
25 than offset any personal costs incurred during training. Higher salaries for nurse prescribers compared
26 to those who could not prescribe was also found in other literature, although the reasons underlying this
27 remained somewhat speculative (Kroezen et al., 2012; Courtenay et al., 2015; Creedon et al., 2015).
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29
30 A significant portion of the immediate costs for services of sponsoring a nurse to undertake a university
31 prescribing qualification is their supervision during training. Questionnaire responses identified a mean
32 of 7.4 days supervision (mostly by medical colleagues) as opposed to the NMC's expected 12 days
33 (NMC, 2015). Nurse prescribing students, however, are expected to be competent autonomous
34 practitioners before starting the university training (NMC, 2015) and much of the designated medical
35 practitioner supervision is often provided alongside normal clinical duties, with support and advice
36 being available as required. Moreover, with the NMC's (2018) move to 'prescribing practitioners,
37 compared to reliance purely on medical colleagues, supervision costs could, perhaps, prove to be less
38 expensive. Future nurses will also be trained and prepared for prescribing roles as an integral component
39 of their undergraduate training (NMC, 2018). With regards to study leave, while it is not mandatory for
40 the NHS to fully fund the 26 required study days, most sites in this study did.
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42 *Clinic processes*

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45 Compared to patient group direction users, nurse prescribers delivered a wider range of medication,
46 including HIV drugs, reflecting their broader scope of practice and ability to manage more complex
47 patients. Patient group direction users sought professional support from colleagues more frequently than
48 nurse prescribers, but the queries tended to be resolved more quickly. Excellent patient satisfaction with
49 consultations and information provision around medication was recorded for both groups. Consultation
50 duration was longer when the appointment was for a new issue (rather than a follow up) and when
51 medications were prescribed but were similar for both groups of nurses.
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54 We found that both nurse prescribers and patient group direction users made safe and appropriate
55 medication choices with regards to patients' requirements and national guidelines. Unexpected re-
56 consultations were similar and for unavoidable reasons such as positive test results, exacerbations of
57 symptoms, medication reactions or completely new issues unrelated to the index consultation. Slightly
58 higher error rates per consultation were recorded by nurse prescribers (1.18) than by nurses using patient
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3 group directions (1.03), but errors were predominantly judged minor and often attributed to
4 documentation omissions. No patients were known to have been harmed from any errors identified.
5 One strength of this study is that it explored medication errors for patients who did not receive
6 medications, i.e., potential of under-prescribing, whilst other large prescribing studies focus specifically
7 on circumstances in which medication was provided (Dorman et al., 2009; Avery et al., 2012). This
8 study also confirmed prior findings that sexual health nurses frequently provided medications (in
9 approximately 50% of consultations) (Black 2012, Black et al., 2020a). Such frequent, appropriate, and
10 safe medication delivery indicates the benefits from investment in nurse training and governance around
11 medications.
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14 *Individual nurses*

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16 Nurse prescribers reported spending personal leisure time in completing prescribing training. This was
17 not found, or expected, in the patient group direction user cohort who reported they were delivering
18 medications largely to fulfil the expectations of their employers. Nurses with prescribing qualifications
19 in this study, as well as in other studies (Kroezen et al., 2012; Courtenay et al., 2015; Creedon et al.,
20 2015), make a personal commitment and express motivations associated with improving knowledge,
21 skills and job satisfaction.
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24 **Limitations**

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26 The study took place in sexual health clinics, which limits the findings' generalisability outside of this
27 setting. Further research across a wider range of clinical specialties is required. The process of data
28 extraction and analysis from clinic records and nurse diaries was methodical and the samples involved
29 were large. However, the questionnaire response rate was lower and responses to some questions which
30 required long term recall could have been inaccurate. In addition, nurses may have been selective in
31 which patients they asked to complete satisfaction questionnaires.
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34 **CONCLUSION**

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36 Both nurse prescribing and patient group directions are beneficial from the perspectives of the health
37 service, nurses, and patients, offering convenient, safe, and effective access to medications, enhanced
38 service delivery, and improved use of staff skills and, high levels of patient satisfaction. Nurse
39 prescribing offers greater autonomy and reduced reliance on professional colleagues. Differences exist
40 in training and governance and in scope of practice that affect local services, and which may influence
41 decision making around which approach they might adopt in the context of their particular goals,
42 caseloads, staffing profiles and resources.
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45 **Anonymised conflict of interest statement:**

46 All authors declare that they have no conflict of interest.
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Table A: Components and data sources

Perspective	Component	Nurse Prescribing	Patient Group Direction	Data source
NHS	Training and governance	HEI course	Not applicable	Staff questionnaires.
		Senior staff supervision time		
		Study time and back fill		Patient Group Directions development by observation
		Not applicable		
	Clinic processes	Medication delivery, errors, appropriateness, safety	Review of clinic records	
		Consultation duration	Nurse diaries	
		Impact on workload of other professionals	Nurse diaries, clinical records	
		Unplanned repeat consultation for index condition	Review of clinic records	
Patients	Patient experience	Consultation experience	Patient questionnaire	
		Satisfaction with information about medicines		
Nurse (costs)	Training	Personal study time and loss of leisure	Staff questionnaires	
		Out-of-pocket expenses, e.g. travel, materials		
Nurse (benefits)	Prospects	Promotion prospects, lifetime earnings		
		Subjective benefits, job satisfaction		

PGDs= patient group directions; NHS= National Health Service; HEI= Higher Education Institute



Table B: Medication analysis from clinical notes review

Summary statistics	Nurse prescribers			Patient group directions			All
	Medications given	Medications not given	Total	Medications given	Medications not given	Total	Total
Number of presentations/ consultations	399	344 [†]	743	480	459	939	1682
Number of individual drugs	620		620	737		737	1357
Number of drugs per consultation	1.55		1.55	1.54		1.54	1.54
Number of individual errors			879			965	1844
Errors per presentation / consultation			1.18			1.03	1.10
Medication provision errors [‡]	Nurse prescribers (N=879)			Patient group directions (N=965)			Both (% of total)
	Minor	Moderate	Severe	Minor	Moderate	Severe	
Drug interactions not documented	0	2	1	1	6	0	10 (0.5%)
Inappropriate patient group direction use	0	0	0	34	29	0	63 (3.4%)
Medication risk assessment	10	67	0	35	115	2	229 (12.4%)
Prescription documentation omission	458	292	0	514	175	0	1,439 (78.0%)
Under, over, wrong prescribing [‡]	21	27	1	18	36	0	103 (5.6%)
TOTAL (% of all errors)	489 (55.6%)	388 (44.1%)	2 (0.2%)	602 (62.4%)	361 (37.4%)	2 (0.2%)	1844 (100.0%)

[†] 18 consultations taken from nurse diaries [‡]103 related to under, over and wrong prescribing. Nurse prescribers, 24 drugs were considered wrong or overprescribed; 25 instances where drugs were not prescribed but deemed warranted (total cost £324). Patient group direction users, 35 drugs were considered wrong or overprescribed; 19 drugs were not prescribed and deemed warranted (total cost £289).

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Table C: Nurses' motivation for independently providing medications

Training motivation	Nurse prescribers (n=26)		Patient group directions (n=35)	
	n	%	n	%
Enhance clinical skills	24	92.3	29	82.9
Improve patient experience	24	92.3	28	80.0
Expectations of employer	16	61.5	30	85.7
Increase knowledge of medications / pharmacology	20	76.9	22	62.9
Facilitate service delivery	20	76.9	26	74.3
Improve job satisfaction	24	92.3	29	82.9
Remove existing restrictions to medication delivery	21	80.8	24	68.6
Obtain academic credits	10	38.5	N/A	

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Table D: Costs and consequences synthesis and summary

Perspective	Item	Nurse prescribers	Patient Group Directions	Balance / comment
NHS: costs and outcomes for services	Resource implications and costs for local services/ employers	Local employers pay fees to enable nurses to attend university courses to gain a nurse prescribing qualification. Service senior staff provide up to 12 days of on-the-job supervision to nurses in training.	Local employers design, approve and implement patient group directions for individual medications, including training of local nurses. Patient group directions are revalidated every three years.	Local services incur costs when designing and implementing patient group directions and supporting nurses to undertake nurse prescribing courses. Once trained, both patient group direction users and nurse prescribers provide medications to large numbers of patients over many years. Unlike nurse prescribers, the scope of practice of patient group directions users is limited.
	Service level outcomes	1.55 medications prescribed per consultation; 96.1% appropriateness; 96.0% safety. 1.18 errors per consultation; 55.6% minor.	1.54 medications prescribed per consultation; 94.0% appropriateness; 99.7% safety. 1.03 errors per consultation; 62.4% minor.	Patient group direction users had higher proportion of inappropriate consultations (p<0.001), but a lower error rate (p=0.001). No significant difference in safety (high for both groups).
		Mean (SD) consultation durations (minutes): overall 24.9 (12.9); new vs follow-up: 27.3 (13.0) vs 19.6 (10.8); when medication given vs not given: 25.7 (12.7) vs. 23.3 (13.1).	Mean (SD) consultation durations (minutes): overall: 22.8 (13.9); new vs follow-up 25.7 (15.1) vs 19.4 (12.0); when medication given vs not given: 23.3 (14.2) vs. 22.1 (13.3).	Being a new (not follow up) consultation and providing medications added to consultation length for both groups of nurses but no difference between nurse prescribers and patient group direction users.
		Nurse prescribers sought advice from other health professionals in 13% of consultations, mean 11 minutes	Patient group direction users sought advice from other health professionals in 26% of consultations, mean 8 minutes	Nurse prescribers sought support from colleagues less than patient group direction users but for longer durations when they did.
		19.5% unplanned re-consultation rate; none judged potentially unavoidable	17.1% unplanned re-consultation rate; none judged potentially unavoidable	Unplanned re-consultation rates of patient of nurse prescribers and patient group direction users were similar and related to: new clinical issues/ positive test (50%), symptom exacerbations / medication side effects (29%), behaviour (17%).
Patients	Patient level outcomes	Over 96% satisfaction with nurse consultation. Mean score of 13.3 (out of 16) in satisfaction with information around medications	Over 96% satisfaction with nurse consultation. Mean score of 13.5 (out of 16) in satisfaction with information around medications	No differences were observed between patients of nurse prescribers and patients of patient group direction users in satisfaction with consultations or in information provision related to medications.
Nurses	Training costs	Nurses spent an average of 26 days of their own time for studying and £32 on travel and materials costs	Training in patient group directions incurred virtually no personal time or expenditure for most nurses	Nurses undertaking university prescribing courses reported giving up leisure time to study and incurring small out-of-pocket expenditures on travel and books, but they were more likely to be employed in more senior positions with higher remuneration than patient group direction users. Nurse prescribers were motivated by the aims of enhancing the patient experience and improving their clinical skills and job satisfaction. Patient group direction users are more likely to be involved in prescribing in response to an expectation by their employer.
	Prospects	70% of nurse prescribers were salary bands 7 or 8.	83% of nurses using patient group directions were salary bands 5 or 6	

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SUPPLEMENTARY TABLES

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Supplementary Table 1: Clinical supervision during training reported by nurse prescribers responding to the questionnaire

Participant (n=26)	Designated Medical Practitioner (n=26) (7.5hour days)				Other supervision (n=14 from the 26 respondents) (7.5 hour days)					Overall clinical supervision
	Consultant	Associate Specialist	Registrar	Total	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total	
1	5			5						5
2	11			11						11
3	8			8			✓			8+
4	4.5			4.5				1.5	1.5	6
5	4.5			4.5						4.5
6	8			8						8
7	8			8						8
8	11			11		✓				11+
9			8	8						8
10			11	11						11
11	11			11						11
12	11			11			✓	✓		11+
13	2			2	1.5				1.5	3.5
14	2			2						2
15			8	8						8
16	8			8		2.7	3		5.7	13.7
17			2	2			1		1	3
18		5		5						5
19	2			2						2
20	11			11						11
21	5			5		1	2	1	4	9
22	5			5			1.5		1.5	6.5
23	5			5						5

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Participant (n=26)	Designated Medical Practitioner (n=26) (7.5hour days)				Other supervision (n=14 from the 26 respondents) (7.5 hour days)					Overall clinical supervision
	Consultant	Associate Specialist	Registrar	Total	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total	
24		✓		N/A						N/A
25	✓			N/A		✓	✓		N/A	N/A
26	✓			N/A						N/A

✓ = Support from professional group obtained, but no duration reported by participants. + = time on top of this entry, but no additional duration provided by respondent. N/A= unable to ascertain duration.

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Supplementary Table 2: Hours and cost of senior staff supervision time during nurse prescriber training, as reported by nurse questionnaires

Measure [†]	Amount of clinical supervision provided during nurse prescribing training where a duration was provided (n=23/26, 88.5%)									Overall clinical supervision total
	Designated Medical Practitioner (n=23/26)				Other supervision (n=10/14 from the 26 respondents)					
	Consultant	Associate Specialist	Registrar	Total [‡]	Associate Specialist	Registrar	Nurse Practitioner	Pharmacist	Total [¶]	
Mean (days)	6.8	5.0	7.3	6.8	1.5	1.9	1.9	1.3	2.5	7.4
SD	3.3	0.0	3.8	3.3	0.0	1.2	0.9	0.4	1.9	3.3
Range	2 to 11 [§]	5	2 to 11 [§]	2 to 11	1.5	1 to 2.7	1 to 3	1 to 1.5	1 to 5.7	1 to 13.7 [§]
Unit cost (/day) [‡]	£1,012.50	£960.00	£442.50	£904.86 (221.84)	£960.00	£442.50	£397.50	£465.00	£486.18 (180.43)	£863.71 (251.00)
Mean cost	£6,885.00	£4,800.00	£3,230.25	£6,153.05	£1,440.00	£840.75	£755.25	£604.50	£1,215.45	£6,391.45

[†]Missing durations entries (n=3/26) not included in this dataset. [‡]Cost calculations: daily cost = [hourly cost] x7.5, mean costs= unit costs/day x total mean supervised days for each section. Hourly costs: Cost of specialist training support was obtained from 'Hospital-based health care staff' in Curtis & Burns (2016); page 191 for doctors: consultant doctor £135/hour; registrar £59/hour; associate specialist £128/hour. Page 188 for nurse practitioner band 7 nurse £53/hour; pharmacist Band 8 £62/hour (pharmacist was considered as Band 8 hospital nurse). [§]where range given mid-point used: 0 to 3 was considered 2 days; 10 or over considered 11 days (full DMP supervision is 12 days; this range considered as 10-12). Overall supervision includes DMP time and additional supervision so overall range increases. [¶]Total and total costs are weighted based on full data set (i.e. not a mean of means). SD= standard deviation

Supplementary Table 3: Study time (days) during nurse prescriber training reported by nurse respondents to questionnaire

Salary band	Responses (n)	Units (£) [†]	Study days				
			Measure	Range	Mean [†]	Standard Deviation	Total
6	7	£44/hr £330/day	n	3 to 26	16.7	9.4	117
			£	£990 to £8,580	£5,511.00	n/a	£38,610.00
7	12	£53/hr £397.50/day	n	1 to 31	19.6	9.2	235
			£	£397.50 to £12,322.50	£7,791.00	n/a	£93,412.50
8	5	£62/hr £465.50/day	n	26	26	0	130
			£	£12,103	£12,103.00	n/a	£60,515.00
All reported [‡]	24	£394.50/day	n	1 to 31	20.1	8.6	482
			£	£394.50 to £12,229.50	£7,929.45	n/a	£192,537.50

[†]Day cost= hourly costx7.5. Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 5 nurse £35/hour, Band 6 nurse £44/hour, Band 7 £53/hour, Band 8 nurse £62/hour. [‡]All means calculated from full relevant dataset (i.e. not based on mean of means).

Supplementary Table 4: Time to write and obtain committee approval for patient group directions based on observation log

Resource	Write patient group direction		Update patient group direction [†]	
	Hours	Cost [‡]	Hour	Cost [‡]
Time to write patient group directions				
Primary patient group direction author (Band 8 nurse/ researcher)	5.1	£316.20	1.3	£80.60
Consultant doctor	0.8	£108.00	0.1	£13.50
Combined resource from department's Band 8 team (2x nurses)	1.8	£111.60	0.2	£12.40
Total	7.8	£535.80	1.7	£106.50
Committee time to approve patient group directions				
Lead pharmacist (Band 8)	0.5	£31.00	0.2	£12.40
Lead directorate nurse (Band 9)	0.5	£61.00	0.2	£24.40
Lead directorate clinician (consultant doctor)	0.5	£67.50	0.2	£27.00
Non-medical prescribing committee (x7 Band 8 nurses)	3.5	£217.00	1.7	£105.40
Total	5.0	£376.50	2.3	£169.20
Overall total to write and approve	13.8	£912.30	4.0	£275.70

[†]The total time to update a suite of nine patient group directions was divided by nine to give an approximate time to update each individual patient group direction. [‡]Duration to write patient group directions were approximations based on the researcher's log or estimations. Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 8 nurse £62/hour (and pharmacist was considered as Band 8 hospital nurse), and Band 9 nurse £122/hour, page 191 for doctors £135/hour.

Supplementary Table 5: Formal Patient Group Direction training resources

Category of Patient Group Direction training reported [†]	Responses from formal PGD teaching (n=29)		Number of PGD trainees in group				Training hours					
			Responses		Range (persons)	Mean	SD	Responses		Range (hrs)	Mean (hrs)	SD
	n	%	n	%				n	%			
Class teaching	23	79.3	14	60.9	1 to 30	10.9	7.8	14	60.9	0.5 to 30	5.2	8.6
Question & answer	20	69.0	7	35.0	1 to 15	9.1	4.7	5	25.0	0.5 to 8	2.7	3.0
Workshops	6	20.7	3	50.0	5 to 13	8.5	3.8	2	33.3	1 to 2	1.5	0.7
Self-directed learning	20	69.0					7	35.0	2.5 to 15	6.9	5.1	
e-learning	10	34.5					4	40.0	1 to 5	2.1	1.9	
One-to-one training	11	37.9					4	36.4	1 to 20	7.0	8.8	

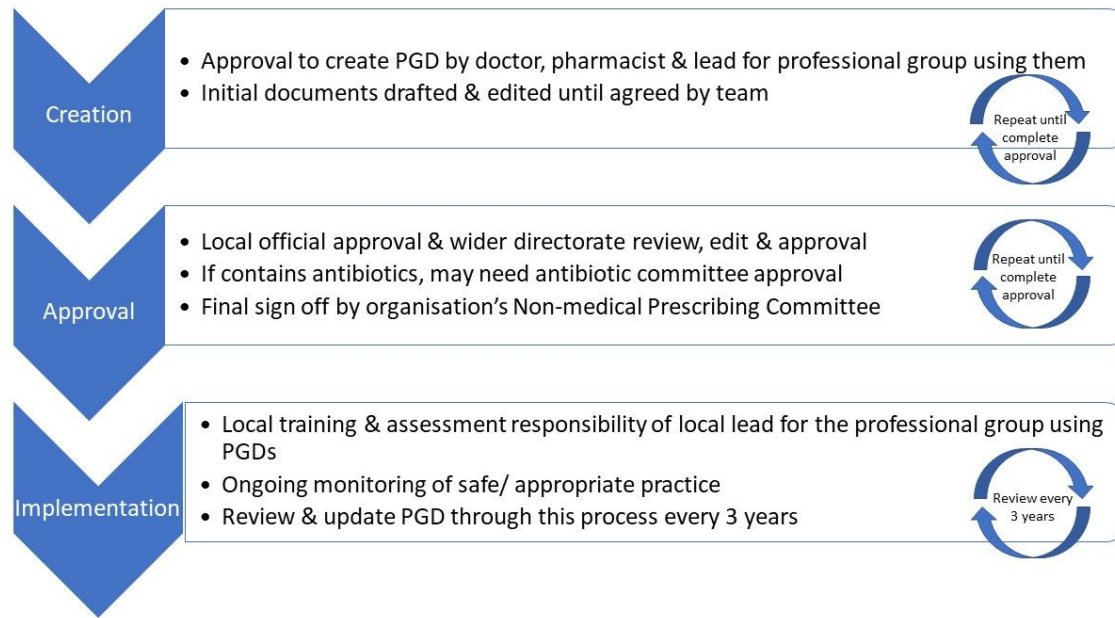
[†] Respondents may have had multiple methods of patient group direction training. Calculations based on completed entries in the staff questionnaires; mid-points used when a range given. Skewed results as a large amount of training involved lone training or classroom teaching with multiple students (i.e. e-learning 10 respondents reported lone personal training, whereas two respondents detailed classroom teaching with 30 students undertaking a contraception course which involved patient group directions as one part of a larger syllabus). Interquartile range not used due to small sample size and need to capture all variations of patient group directions training. Trainers' costs not included, or time taken to design training packages (as unable to calculate from data collected). PGD= patient group direction; SD= standard Deviation

Supplementary Table 6: Professional study time (hours) during training reported by patient group direction users responding to questionnaire

Band	Responses (n)	Units (£) [†]	Study hours (hours)						
			Measure	Range	Mean [†]	SD	Median	Mode	Total
5	4	£35/hr	n	0 to 15	4.3	7.2	1	0	17
			£	£0 to £525	£150.50	£252.00	£35.00	£0.00	£595.00
6	21	£44/hr	n	0 to 11.3	2.1	2.9	0	0	44.3
			£	£0 to £497.20	£92.40	£127.60	£0.00	£0.00	£1949.20
7	5	£53/hr	n	0 to 85.2	26	38.4	0	0	130.2
			£	£0 to £4,515.60	£1,378.00	£2,035.20	£0.00	£0.00	£6,900.60
All reported [‡]	30	£44.30/hr	n	0 to 85.2	6.4	17.2	0	0	191.5
			£	£0 to £3,774.36	£283.52	£761.96	£0.00	£0.00	£8,483.45

[†] Costs were based on from 'Hospital-based health care staff' in Curtis & Burns (2016); page 188 for Band 5 nurse £35/hour, Band 6 nurse £44/hour, Band 7 £53/hour. This includes data from a university contraception training module that was not specific to patient group directions but did facilitate delivery of contraception through patient group directions. [‡]All results calculated and weighted from full relevant dataset (i.e. not based on mean of means). SD= standard deviation.

Figure 1: Patient Group Direction (PGD) approval process (based on National Institute for Health and Care Excellence guidance (2013))



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