

Deriving a clinical prediction rule to target sexual healthcare to women attending British General Practices

Authors: Edelman N.L.^{1,2} Cassell J.A.¹ Mercer C.H.³ Bremner S.A.¹ Jones C.I.¹ Gersten A.⁴
deVisser R.O.⁵

Corresponding author: Natalie Edelman N.Edelman@brighton.ac.uk

1. Brighton & Sussex Medical School
2. University of Brighton
3. University College London
4. Pavilion General Practice
5. University of Sussex

Abstract

Some women attending General Practices (GPs) are at higher risk of unintended pregnancy (RUIP) and sexually transmitted infections (STI) than others. A clinical prediction rule (CPR) may help target resources using psychosocial questions as an acceptable, effective means of assessment. The aim was to derive a CPR that discriminates women who would benefit from sexual health discussion and intervention.

Participants were recruited to a cross-sectional survey from six GPs in a city in South-East England in 2016. On arrival, female patients aged 16-44 were invited to complete a questionnaire that addressed psychosocial factors, and the following self-reported outcomes: 2+ sexual partners in the last year (2PP) and RUIP. For each sexual risk, psychosocial questions were retained from logistic regression modelling which best discriminated women at risk using the C-statistic. Sensitivity and specificity were established in consultation with GP staff.

The final sample comprised N=1238 women. 2PP was predicted by 11 questions including age, binge-drinking weekly, ever having a partner who insulted you often, current smoking, and not cohabiting (C-statistic=0.83, sensitivity=73% and specificity=77%). RUIP was predicted by 5 questions including sexual debut <16 years, and emergency contraception use in the last 6 months (C-statistic=0.70, sensitivity=69% and specificity=57%).

2PP was better discriminated than RUIP but neither to a clinically-useful degree. The finding that different psychosocial factors predicted each outcome has implications for prevention strategies. Further research should investigate causal links between psychosocial factors and sexual risk.

Key words primary care; sexually transmitted infections; women; contraception; sexual behaviour; primary prevention; sexual healthcare; reproductive healthcare;

MAIN TEXT

Introduction

In Britain, General Practices (GP) act as the gatekeeper to specialist secondary services, and are staffed by Practice Nurses and General Practitioners (akin to Family Physicians in the United States). In England 58,969,634 people (approximately 90% of the resident population) are currently registered with a GP (1) from whom they can also obtain a range of interventions directly. Britain's sexual health guidance and policy (2, 3) recommends GPs as sites for provision of sexual health interventions. This widens the availability of testing for sexually transmitted infections (STIs) and contraception; to a broad population who are likely to vary in need for those interventions to a greater degree than those attending specialist contraception and sexual health (CASH) services(4). Without an evidence-based means of targeting these interventions to women in GPs, resources may be wasted offering interventions unnecessarily(5). Opportunities may also be missed to offer STI testing and contraception to high-risk individuals presenting for unrelated problems.

Within CASH clinics, a sexual history is the standard approach to determining appropriate intervention. This is resource-intensive during GP appointments for unrelated concerns and may feel unacceptable to some GP attenders(6, 7), leading to possible under-report (8).Guidance recommends STI screening in GP settings only for target populations such as men who have sex with men, and for symptomatic individuals. The absence of incentives for contraception and chlamydia screening in Britain and elsewhere may further demotivate opportunistic questioning by GP staff, who may struggle to initiate sexual health discussions (9, 10). Interventions to address this have had limited impact (11, 12). Together this evidence

suggests that a brief, acceptable, bespoke tool to target sexual healthcare could benefit GP staff and patients.

Clinical prediction rules (CPRs) identify risk of current or future adverse outcomes in individuals (13) using several patient characteristics(14), to inform decisions about whether to offer interventions (15). Many existing sexual health risk assessment tools and risk scores are CPRs (16). Most comprise sexual behavioural and socio-demographic 'known factors' (17, 18) and focus on STI risk (16). However, no CPRs have been developed to identify women at risk of STIs and/or risk of unintended pregnancy (RUIP) in primary care, and few have used psychosocial questions (16).

Psychosocial factors are increasingly being explored alongside socio-demographic and sexual-behavioural predictors of sexual health, reflecting growing recognition of the need to address the social determinants of sexual health(3). A systematic review and survey analysis identified several psychosocial factors associated with sexual risk in general population surveys of women, which may be usefully deployed as questions in a CPR for women attending GPs (19, 20). That work suggests a psychosocial CPR should focus on identifying women experiencing recent potential *risk* of:

- STI acquisition through multiple partnerships in the last year (the primary outcome in this study)
- RUIP (desire to avoid pregnancy and not consistently using contraception in last six months)
- STI acquisition (through a potentially infected partner)

The latter outcome was included in the hope of identifying a novel population at risk through their partner's behaviour (21). Re-infection from the same partner is believed to be a key factor in the re-infection rates for Chlamydia trachomatis, estimated at 20% (cumulative risk)(22). Together these outcomes facilitate CPR use for primary prevention (contraception

and promotion of condom use) and for secondary prevention (pregnancy and STI testing and treatment).

The aim of this study was to identify the best combination of psychosocial questions to form an acceptable CPR to target sexual health intervention in General Practices to women of reproductive age. To do this we addressed the following research question: What combination of acceptable psychosocial and socio-demographic questions discriminates best those women experiencing multiple partnerships, potential risk of STIs through partner and risk of unintended pregnancy?

Methods

We undertook a cross-sectional quantitative survey across GPs in a city in South-East England between April and September 2016. All female GP attenders aged 16-44 years were eligible to participate: we included women who did not report any male sexual partners in the last year so that we could assess the discriminatory power of the CPR.

Exposures

We identified psychosocial questions for inclusion in the survey questionnaire from a variety of sources based on the findings of preliminary studies (19, 20, 23-28). These are listed in full in Table 1, and included questions on age group and housing tenure (renting or living rent-free versus home ownership) which remained predictive of multiple partnerships after adjustment for psychosocial questions in a preliminary study (20). We chose psychosocial items that were brief and had few response options so that they would be easy to self-score and therefore suitable for self-completion in the CPR. We privileged items that were more common to ensure adequate prediction (i.e. applying the rationale that rarer exposures would lead to the

identification of fewer women). We added a 'prefer not to answer' option to exposures that might be deemed unacceptable in order to measure this.

Outcomes

We developed a model for each of the following outcomes, which were designed to represent recent histories that would warrant sexual health discussion and possible intervention.

1. Report of 2+ male sexual partners in the last year (2PP) - indicating possible need for sexual health advice and STI testing. This outcome was measured using a single item 'In the last year, how many men have you had sexual intercourse with? *By sexual intercourse we mean a man's penis in a woman's vagina, mouth or anus*'.
2. Report of 2PP and/or risk of STI through a male partner (i.e. that the participant perceived that their most recent male sexual partner had had other sexual partners in the last year and had not always used condoms with those other partners).
3. Report of risk of unintended pregnancy in the last six months (RUIP), indicating a possible need for contraception. At the time of development there was no suitable existing measure. Therefore we constructed a composite measure from an item measuring contraception use (29) and an item measuring desire to avoid pregnancy (30), adapting each to report retrospectively on the last six months.

These outcomes were limited to heterosexual experiences on the basis that women who only have sex with other women are at considerably lower risk for STI acquisition than other women (31). Nonetheless, the exclusion criteria did not incorporate women who self-identified as lesbian, as their exclusion from sexual health research is a growing concern as sexual health moves away from a disease-focused biomedical model (32). In addition, evidence suggests that some women who identify as lesbian may also report recent sexual activity with men (31) and may therefore experience the outcomes of interest.

Data collection

Data collection was designed to mimic envisaged delivery of the CPR – in which women self-complete and self-score the CPR during a clinic visit using a paper-and-pencil format. Patient and Public Involvement (PPI) was conducted by consultation with women attending a GP, a Women’s Centre and a Youth Forum (who comment on a range of health services and research) to decide this delivery method and finalise the following approach to data collection.

On arrival, women attending GPs were offered an envelope by research or Reception staff, except visibly-distressed women, those known to have insufficient English language skills, or those who were clearly outside of the eligible age-range. Each envelope contained a pen, participant information sheet (PIS) and a brief questionnaire, comprising potential CPR items and the outcomes of interest. The questionnaire was designed to take five minutes to complete, while awaiting an appointment. This was deemed feasible as a 2016 study of General Practices in the study location found a mean waiting time of 15.6 minutes (K. Maskell, personal communication, November 9, 2017). Participants were instructed to complete the questionnaire anonymously, sitting alone in the waiting area if possible. Consent was implied by completion of the questionnaire. Three questions on the front of the questionnaire were used to screen out ineligible patients (those who had completed the questionnaire previously and/or did not identify as female and/or were outside the eligible age-range were instructed by questionnaire text to seal and return their questionnaire without completing further). The questionnaire and PIS instructed participants to seal their questionnaire in the envelope before returning to staff to be securely returned to the researchers.

Data storage and management

Questionnaires were stored at Brighton & Sussex Medical School for the duration of the study. Data were double-entered by an external company and analysed in a statistical software

dataset - Stata SE v13 (33). Accuracy checks were performed on a random 10% sample and anomalies checked and addressed individually by researchers.

Statistical analysis

Weighting techniques were not applied as pseudo-inclusion probabilities (34) (which approximate the likelihood of study inclusion) could not be calculated. Available case analysis was used because item non-response was low. Bivariate analyses were conducted between psychosocial questions and each outcome. To avoid over-fitting the models, these analyses were only used to exclude from model entry: 1. exposures not associated with any outcomes and 2. exposures reported by less than 10% of respondents. We selected which psychosocial variables to enter into each model and then generated three models, one for each of the outcomes listed above. We used backwards-stepwise multivariable logistic regression as an established methodology for CPR derivation (15, 35, 36).

To assess model performance as a potential set of CPR questions, we used the C-statistic to quantify how well the model discriminated between those with, or without, the sexual risk of interest. The amount of variance explained by each model was assessed using McFadden's pseudo-R squared and calibration using Hosmer-Lemeshow goodness-of-fit test. Bayesian Information Criteria (BIC) were used to compare the parsimony of models. Exposures were not manually removed from the models if the corresponding p-value was >0.05 as CPR derivation is a process of estimation rather than hypothesis testing. This is a recognised statistical approach to clinical prediction modelling (37). For each finalised model the coefficients were used to generate a scoring system for the CPR (38). A cumulative CPR score was then calculated for each participant based on their survey responses. For each model, participants' scores were cross-tabulated against their self-report of that outcome to assess how many participants would be classified as false positive or false negatives using the derived scoring system. Optimal cut-off values for sensitivity and specificity were then selected in a group consultation with five General Practitioners at one of the participating recruitment sites.

A sample size of 1500 was set in order to achieve an anticipated 150 reporting 2PP based on previous analyses (20), sufficient to generate a 10-12 item CPR using the 10 events-per-variable approach (39). 2PP was chosen as the primary outcome of interest as a known broad indicator of sexual risk(40). We ceased data collection at n=1200 when n=150 reporting 2PP had been exceeded.

Results

The final sample comprised n=1238 women. 21.7% (n=269) were aged 16-24 years, 41.8% (n=518) were aged 25-34 years, and 36.4% (n=451) were aged 35-44 years. 69.4% (n=859) reported that they were currently renting or living rent-free and 29.7% (n=368) owned their own home. Figure 1 presents completion rates. We were unable to estimate response rates or investigate reasons for non-participation. Low rates of missing data and 'prefer not to answer' responses indicated that the questions were highly acceptable. Those exposures without the latter category still captured missing data $n \leq 40$, comparable with those exposures that did offer a 'prefer not to answer' option.

The final model identified for '2+ sexual partners in the last year' comprised 11 items (Table 2). The Variance Inflation Factor of 1.21 indicated no multi-collinearity. Therefore no candidate predictors for this model needed to be removed to avoid inflated standard errors. This generated reasonable discriminatory power of $C=0.83$ but low amount of variance explained (McFadden's Pseudo $R^2=0.27$). Good model calibration was indicated by H-L=5.15 ($p=0.74$). Although statistical significance is not the primary concern of modelling for estimation purposes (as in this case), the majority of exposures demonstrated an independent statistically-significant association with the outcome modelled. Through GP consultation a cut-off score of nine or above (range=0-18) was chosen. This afforded a sensitivity of 72.8% and specificity of 76.7%.

The model identified for 'combined risk through multiple partnerships or most recent partner' comprised 11 items (Table 3), similar to those in the model for 2PP. The Variance Inflation Factor was 1.89, therefore no candidate predictors for this model needed to be removed to improve the accuracy of coefficients. It generated reasonable discriminatory power of $C=0.79$ but explained only a small amount of the variance in outcome values (McFadden's Pseudo $R^2=0.21$). $H-L=3.85$ ($p=0.87$) indicated good model calibration and moderate to good level of discrimination (41), only slightly lower than 2PP alone. However, the BIC value was higher for this model (BIC=912) than for 2PP (BIC=762). Through GP consultation a cut-off score of six or above (range=0-17) was chosen. This afforded a sensitivity of 79.2% and specificity of 62.9%.

The model identified for 'risk of unintended pregnancy risk in the last 6 months' (RUIP) is presented in Table 4. The model had $VIF=1.21$ so that no exposures needed to be removed for reasons of multi-collinearity. The model contained only five predictors, within the allowable number for the entered exposures and events, and accordingly had a lower BIC score (BIC=402) than the other models. Although it showed good calibration ($H-L=1.0$, $p=0.96$), the RUIP model demonstrated a lower amount of variance explained (Pseudo- $R^2=0.12$) and lower discriminatory power (C-statistic=0.70) compared to the other models. Nonetheless, this indicates moderate discrimination (on the basis that 0.5 denotes random chance and 1.0 perfect discrimination) (41). Although statistical significance is not the primary concern of modelling for estimation purposes (as in this case), it is noteworthy that only two of the exposures demonstrated an independent statistically-significant association ($p<0.05$) with the outcome modelled. Using the 5 items retained in the UIP model, a score was developed with range 0-11. A cut-off score of three or above optimised sensitivity and specificity, giving a sensitivity of 69.1% and specificity of 56.8% and yielding $n=315$ false positives and $n=52$ false negatives.

The stakeholder consultation indicated that the sensitivity and specificity afforded by the CPR scores were too low for ubiquitous use in General Practices. However, the group felt that further research was warranted to investigate targeted use.

Discussion

Our findings demonstrate that a variety of psychosocial variables are associated with sexual risk among GP-attending women of reproductive age. The results indicate that it is possible to discriminate women attending General Practices who report experiencing multiple male partners and/or risk through partners, to a greater degree than those experiencing RUIP. The findings also suggest that RUIP is predicted by a different profile of psychosocial factors. However, the findings indicate that our CPR does not warrant further validation and evaluation for routine use in GP settings using the particular psychosocial questions that we tested, because the level of discrimination achieved is unlikely to be practical for decision-making in GP settings.

Interestingly, various tools for related issues are already validated for use in General Practices, and may already be used in practice despite large differences in sensitivity and specificity. For example the HITS (Hurt, Insulted, Threatened with harm, Screamed at) domestic violence screening tool has demonstrated 96% sensitivity and 91% specificity in a General Practice setting (28). The AUDIT-C (Alcohol Use Disorders Identification Test of Consumption) demonstrated sensitivity of 73% and specificity of 91% among women attending General Practice (42). This sensitivity was therefore akin to this CPR. However, the specificity of our CPR was much lower, raising concerns among our stakeholders about its routine use in GP environments. Nonetheless, it is important to note that the specificity of our CPR may be lower

in the study than in practice, as women who have been sexually inactive in the last year are likely to decline its use.

Unlike many sexual health tools that are developed without preliminary investigation (16), our CPR included candidate predictor variables selected on the basis of two separate preliminary studies of random probability surveys (19, 20). This survey was conducted on the population for whom the CPR is intended, and in the same setting, using a similar paper-and-pencil self-completion approach. This improves the validity of the dataset and findings, although it is important to note that while the models demonstrate proof-of-concept, they are not validated or evaluated for use by this study.

This survey indicates that age group and housing tenure were socio-demographic factors independently associated with sexual risk, rather than being fully explained by psychosocial items. This mirrors previous studies (20, 43, 44). Our findings concurred with previous research regarding a positive association between sexual risk/morbidity and early sexual debut (20, 45), binge-drinking (45, 46), social support (24), drug use (20, 45, 47) and emotional dissatisfaction (26). However, we found opposite directions of association to previous studies examining self-esteem (48) partner importance (25) and treatment for depression (20). The former two were studies of African-American women, which may account for the differences in direction of association. However the latter finding was from female participants in the National Survey of Sexual Attitudes and Lifestyles-3 (Natsal-3) who were aged 16-44 and who reported sexual activity in the last year. 'Treatment for depression' is a composite of both experiencing depression and accessing treatment for it, which may explain the different direction of association. Alternatively, our contradictory findings may reflect the use of a convenience sample from within an urban clinical setting in South-East England as described below.

The CPR was developed to meet patient delivery preferences and answered a recognised need for brief sexual health assessment using simple self-scoring (49). Low proportions of participants with missing data and reporting 'prefer not to answer' suggests that the questions asked were acceptable. However, if the CPR had been developed for digital delivery, e.g. as a computer-assisted self-interview, this may have resulted in even lower rates of missing data and potentially more accurate reporting of both outcomes and exposures (50). This may have enabled the CPR to achieve higher sensitivity and specificity. Similarly, electronic delivery would have allowed for the development of a more complex and potentially more sensitive scoring system, using a larger number of response options.

In order to tailor the CPR towards primary prevention, the outcomes of interest in this study concerned recent sexual behaviour rather than morbidity. Thus, we could not verify self-report using more objective measures. Recall bias may also have occurred in the self-report of both exposures and outcomes, particularly as the study was cross-sectional and several items in the survey were unvalidated.

The study benefited from having a large sample, ensuring sufficient statistical power to undertake multivariable regression. However, using convenience sampling may have resulted in an under-representation of those reporting sexual risk behaviour and adjunct psychosocial issues, such that sample bias cannot be ruled out. Because brevity and self-completion were key concerns, we were unable to record immigrant or other minority status, and the findings may be biased towards those with stronger English language skills and towards those not experiencing current distress. Nonetheless, it is possible that those who were unable or chose not to participate in the study would be equally unlikely to self-complete the CPR in practice so our findings still anticipate the CPR's performance in practice.

The generalisability of the findings may also be limited by the particular demographics within the city where the study was undertaken. Compared with other geographical areas in the United Kingdom, the population is young, urban, wealthy, University-educated and ethnically homogenous (51). A 2016 survey of the city's General Practices attenders (K. Maskell, personal communication, November 9, 2017) found that 91.6% were White, 87.5% had English as their First Language, 42.4% were educated to degree level, and the mean age was 49.3 years (s.d.=18.9).

Although low sensitivity and specificity suggest that wide-spread delivery of the CPR to all women of reproductive age is not advisable, the CPR may be worthy of further validation and evaluation for targeted use in GP settings to those where poor sexual health is suspected, particularly as a means of generating discussion where adjunct issues such as binge-drinking and intimate partner violence are also a potential cause for concern. In these scenarios the CPR may provide an efficient alternative to clinical decision-making based on either use of socio-demographic data (as a population health approach) or opportunistic, detailed sexual history (as an individual health approach).

Conclusion

Our findings contribute to the broader study of associations between social factors and sexual health. In particular, they indicate that a different set of issues are predictive of RUIP. Further research should take into account how differences in which populations are offered which interventions may affect predictors of sexual risk (e.g. young age may have dropped out of the RUIP model because young women are more likely to be fitted with long acting reversible contraception). Together these findings suggest that further research should be carried out to investigate the role of psychosocial factors both as causal factors in sexual risk and as a means of identifying and differentiating between those experiencing different types of sexual risk.

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