

# Observational study of factors associated with return of home sampling kits for sexually transmitted infections requested online in the UK

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# BMJ Open Observational study of factors associated with return of home sampling kits for sexually transmitted infections requested online in the UK

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## ABSTRACT

**Objectives** To investigate factors associated with the return of home sampling kits for sexually transmitted infections (STIs).

**Setting** Online STI testing service offered to the residents of Birmingham and Solihull.

**Participants** All patients requesting STI home sampling kits via the Umbrella sexual health service website between 15 July 2016 and 14 December 2016.

**Interventions** Associations between data collected at online registration and the rate of return of STI home sampling kits within 30 days of request was assessed.

**Results** A total of 5310 kits were requested, of which 3099 (58.4%) were returned to the medical microbiology laboratory. On multivariable analysis, women and men who have sex with men were similarly likely to return their sampling kits (adjusted OR (OR<sub>adj</sub>) 1.06, 95% CI 0.86 to 1.30), while heterosexual men were significantly less likely to return their sampling kits (OR<sub>adj</sub> 0.63, 95% CI 0.55 to 0.72, p<0.001 vs women). Patients reporting symptoms were also less likely to return kits (OR<sub>adj</sub> 0.77, 95% CI 0.67 to 0.89, p=0.001 vs asymptomatic patients). Kits that were delivered to the patient's home, rather than to a clinic or pharmacy (p<0.001), and those requested from less economically deprived neighbourhoods (p=0.029) were significantly more likely to be returned.

**Conclusion** STI self-sampling testing kits delivered to patients' homes are most likely to be returned. Heterosexual men and those from more economically deprived areas are the less likely groups to return the kits. Further research on the barriers to return self-sampling STI testing kits of these subgroups of patients is warranted.

**Trial registration number** Registered with R&D department at University Hospitals Birmingham; CARMS-13551.

## INTRODUCTION

The advent of new technologies has provided opportunities for expansion of screening for sexually transmitted infections (STIs) and HIV in general population. Home sampling kits for STI testing take advantage of the features of nucleic acid amplification tests (NAATs) for the detection of chlamydia and

## Strengths and limitations of this study

- The study showed large numbers of different sex groups tested for chlamydia, gonorrhoea, HIV and syphilis by self-sampling kits delivered to their address of choice.
- Kits delivered to heterosexual men, those with symptoms, neighbourhoods with more socioeconomic deprivation and locations other than the patient's home are the least likely to be returned.
- The study's observational design made it difficult to investigate reason(s) for failure to return sampling kits.
- The findings of the study may help to improve the usage of similar services rolled out by other sexual health departments in the UK.

gonorrhoea. The high sensitivity and specificity of the tests allows for testing of anogenital specimens obtained by self-collecting procedures. New laboratory-based HIV assays can operate on small volume blood samples that can be obtained through a finger prick, and collected in a small blood tube that fits inside a small box or envelope. Specimens for NAAT can be stored at room temperature while being transported to the laboratory.

Home sampling STI and HIV testing provides optimal privacy, and the choice of being tested on any occasion. Because of savings on the cost of clinical overheads, home sampling STI testing services may be more cost-effective compared with traditional services. However, the service is also perceived to have a number of limitations, such as not being able to talk to a doctor about test results.<sup>1</sup> Over the past two decades, several studies have reported on acceptability of home sampling for chlamydia and gonorrhoea testing.<sup>2-6</sup> Studies have also investigated the success of internet-based home sampling services for chlamydia testing.<sup>7,8</sup> In England, 76 842 individuals aged between 15 and 24



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years were tested for chlamydia using internet services in 2015.<sup>9</sup>

Following the tendering process of sexual health services in England, many services are now expected to offer home sampling kits for STI screening. Improving return rates of home sampling kits would improve the cost-effectiveness of these services, while potentially enhancing the success of the services in reducing the incidence of STI.

Studies reporting on the return rates of internet-registered home sampling kits have focused on the use of kits for chlamydia and gonorrhoea testing or on HIV screening, and only on specific sex groups: men who have sex with men (MSM) or women.<sup>7 8 10 11</sup> Limited data currently exist on the return rates of internet-registered home sampling kits for STI and HIV screening in general population.

The aim of this study was to investigate the rate of return of home sampling kits after registration with an online health website in the cities of Birmingham and Solihull, UK. To the best of our knowledge, this is the first report on return rate of home sampling kits offering combined chlamydia, gonorrhoea, HIV and syphilis screening to all patients.

## METHODS

Following the tender of the services by Birmingham and Solihull local governments, the new sexual health service (Umbrella Health) was formed in August 2015. This offers an online service for requesting home sampling kits for STI and HIV, which can be used by any adult residents of Birmingham and Solihull and without the need for direct referral from their general practitioners. The service is promoted online and through a number of local media outlets and venues, including community partnerships and primary care centres. Individuals are encouraged to visit the service's website and request a sampling kit at the time of their convenience.

### Requesting sampling kits

The service allows for individuals' self-registration on Umbrella Health website (<https://umbrellahealth.co.uk/our-services/self-sampling-kits>). When applying for kits, individuals are asked a range of questions relating to sexual orientation, anogenital symptoms and sexual behaviours, in order to identify the appropriate type of sampling kit they should receive. All questions must be answered to complete the application process. Because of the risk of having an STI, individuals who report anogenital symptoms are advised to attend one of several community umbrella health clinics across Birmingham and Solihull. They are still able to request home sampling kits for STI screening.

After registration with the service, the individual can choose to receive their home sampling kits at their address of choice or to collect it from 1 of 66 locations in partnership with Umbrella Health, including 24 local

**Table 1** Contents of the four types of sampling kit

	Female-design A	Female-design B	Male	MSM
Pictorial information and guidance leaflet	✓	✓	✓	✓
Preadressed return envelope	✓	✓	✓	✓
Sterile disposable lancet and tiny blood bottle	✓	✓	✓	✓
Urine sample bottle			✓	✓
Vulvovaginal swab	✓	✓		
Anorectal swab		✓		✓
Throat swab				✓

MSM, men who have sex with men.

pharmacies and 24 community sexual health clinics across Birmingham and Solihull.

### Contents of sampling kits

Depending on the responses given to questions when requesting, there are four different types of sampling kit that can be ordered, which are tailored to the risk profile of the patient. For women, there are two types of kit: 'Design A' is for patients who do not report having engaged in anal sex within the previous 6 months, and 'Design B' is for those who answered yes to this question. Similarly, for men, the standard male kit is dispatched to those who do not report having sex with men within the previous 6 months, with an MSM kit being dispatched otherwise. The contents of the various sampling kits are summarised below and in [table 1](#).

All four of the home sampling kits contain sterile disposable lancets, to obtain finger prick blood samples, which are collected in the included tiny blood bottles. The aim is to collect a minimum of 400 µmL, so that samples can be used for HIV and syphilis serology testing. The female kits also include the swabs and manufacturer's transport media for chlamydia and gonorrhoea testing on an Aptima Combo assay. Both of the female kits include a vulvovaginal swab, with the design B kit additionally including an anorectal swab. The two male kits also include urine sample bottles for urethral testing, while the MSM kit additionally includes anorectal and throat swabs.

All kits contain pictorial information and guidance on how to obtain the appropriate sample for each test. They also hold an envelope preaddressed to the medical microbiology laboratory at Queen Elizabeth Hospital Birmingham. The packaging of the kits complies with Royal Mail standards requiring three layers of packaging. This includes a watertight leakproof container for the sample, packed with enough porous material to absorb all fluids in case of breakage, which is enclosed in a second watertight leakproof container. The two layers of packaging are then enclosed in a third outer package



to protect against external damage during the delivery of the specimens.

### Testing of samples

On receipt of specimens from the home sampling kits, their unique number is entered in the medical microbiology laboratory registry system. Individuals' details are then automatically retrieved from the web-booking database. The specimens are simultaneously registered in the sexual health service's electronic patients' system. The specimens are then processed according to UK medical laboratory standards. Chlamydia and gonorrhoea tests are carried out on an Aptima Combo assay and platform. HIV serology is carried out on Abbott's fourth-generation ELISA HIV assay, and the enzyme-linked immunosorbent assay for IgG against treponemal antibodies assay is used for syphilis screening.

Patients were informed of their test results by a text message to their mobile phones within 1 hour of their authorisation by the laboratory.

### Study design

This was service evaluation study of factors associated with return of STI sampling kits within 30 days of their online request through the Umbrella Health website. The analysis was based on anonymised retrospective data and, as such, we did not seek ethics committee approval.

### Data collection

Data were collected on patients requesting STI and HIV sampling kits from Umbrella Health website between 15 July 2016 and 14 December 2016. Information on patients' demography and responses to questions relating to drug usage, sexual history and symptoms were recorded. Since all of these questions needed to be completed in order to request a sampling kit, complete data were available for all of these factors.

The final question of the online registration was in two parts, first asking if the patient had a history of unprotected sex with someone born or raised outside of a list of 16 countries. A negative response to this revealed the second part of the question, asking whether the patient was born or raised outside of the countries listed. The 16 countries in the list were: Austria, Belgium, Czech Republic, Denmark, Faroe Islands, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Sweden, Switzerland and the UK (which will be subsequently referred to the 'Northern EU' for brevity). We consider these 16 Northern European countries to have low overall prevalence of hepatitis B infection. Individuals that were born and raised, or have sex with partners from outside the Northern EU may be at increased risk of hepatitis B infection. Hence, in accordance with National Institute for Health and Care Excellence guidelines, the website advises those individuals to attend one of Umbrella Health clinics for hepatitis B screening and vaccination.<sup>12</sup>

Temporal factors relating to the day and time that the request for sampling kits was placed were also collected automatically by the website. All individuals were required to provide a postcode, which was converted to a 2015 Index of Multiple Deprivation Score (IMD), based on the data from the Department for Communities and Local Government.<sup>13</sup> For 39 cases, the given postcodes were not available in the IMD database, hence these cases were excluded from the analysis of IMD score.

The medical microbiology laboratory system was then interrogated to identify which of the individuals requesting sampling kits actually returned samples.

### Statistical analysis

Initially, the proportions of STI sampling kits where a sample was returned were compared across the factors using  $\chi^2$  tests or Mann-Whitney tests, as appropriate. Continuous variables were expressed as medians and IQRs. For some of the questions in online registration, a different set of answers was displayed, depending on the gender of the respondent. In these cases, the analyses were performed separately for men and women, with the small number of transgender respondents excluded.

A multivariable binary logistic regression model was then produced, to identify significant independent predictors of the return of samples. The transgender respondents were also excluded from this analysis, due to the small number of cases, as were those cases where the IMD score was unavailable. A forwards stepwise approach was used to select factors for inclusion in the model.

All analyses were performed using IBM SPSS V.22 (IBM Corp), with  $p < 0.05$  deemed to be indicative of statistical significance throughout.

## RESULTS

Between the 15 July 2016 and the 14 October 2016, a total of 5310 kits were requested, of which 3099 (58.4%) were returned to the medical microbiology laboratory. The age distributions were similar in the groups of patients who did and did not return sampling kits, with a median of 24 years (IQR: 20–28) for both ( $p = 0.100$ ). Associations between other factors and the return rate of kits are reported in [table 2a,b](#).

On univariable analysis, women were found to be significantly more likely than men to return sampling kits (61.2% vs 53.1%,  $p < 0.001$ ). There was also a small group of 10 transgender respondents, who were the least likely to return kits, with only 10% ( $n = 1$ ) doing so. Analysis of gender was then further broken down by the type of kit requested. Women were found to have similar rates of kit return, regardless of whether or not they reported having receptive anal sex (61.3% vs 59.6% for design A vs design B,  $p = 0.572$ ). Of the male respondents, those requesting an MSM kit had a similar rate of kit return to females, at 62.5% ( $p = 0.416$ ). However, heterosexual men were significantly less likely to return kits ( $p < 0.001$ ), with only 49.6% doing so.

**Table 2a** Comparisons of the rates of samples received by temporal factors and survey responses

	STI kits	Samples received	p-Value
Day of request			0.059
Monday	936	550 (58.8%)	
Tuesday	882	510 (57.8%)	
Wednesday	888	518 (58.3%)	
Thursday	814	454 (55.8%)	
Friday	738	435 (58.9%)	
Saturday	466	257 (55.2%)	
Sunday	586	375 (64.0%)	
Time of day			0.665
8:00–12:59	1437	858 (59.7%)	
13:00–17:59	1702	980 (57.6%)	
18:00–22:59	1407	818 (58.1%)	
23:00–7:59	764	443 (58.0%)	
Gender			<0.001*
Female	3513	2149 (61.2%)	
Male	1787	949 (53.1%)	
Transgender (female to male)	3	0 (0.0%)	
Transgender (male to female)	7	1 (14.3%)	
Place of kit collection/delivery			<0.001
Home	4115	2495 (60.6%)	
Clinic	633	357 (56.4%)	
Pharmacy	562	247 (44.0%)	
History of sex with someone with infections in the last 6 months			0.085
None of these infections	4747	2782 (58.6%)	
Chlamydia or NSU	469	267 (56.9%)	
Gonorrhoea	52	35 (67.3%)	
Hepatitis B or C	12	4 (33.3%)	
HIV	11	5 (45.5%)	
Syphilis	8	2 (25.0%)	
Trichomoniasis	10	4 (40.0%)	
Country of birth questions†			0.031
Neither option	4407	2605 (59.1%)	
Unprotected sex with someone born outside Northern EU	715	398 (55.7%)	
Respondent born outside Northern EU	187	96 (51.3%)	
2015 IMD rank‡			0.007
<5000	1855	1039 (56.0%)	
5000–14999	2095	1239 (59.1%)	
15000+	1321	798 (60.4%)	

Continued

**Table 2a** Continued

	STI kits	Samples received	p-Value
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p Values are from  $\chi^2$  tests, unless stated otherwise, and bolded p values are significant at  $p < 0.05$ .

\*A comparison of male versus female (excluding transgender) was also significant at  $p < 0.001$ .

†Combines the questions: 'Do you have a history of unprotected sex with someone born or raised outside any of the countries listed?' and 'Were you born outside of the countries listed?', as the latter is only asked if an answer of 'No' is given to the former.

‡Excludes the  $n=39$  with for whom the IMD was not available, and p value is from a Mann-Whitney test, treating the IMD rank as continuous.

IMD, Index of Multiple Deprivation Score; STI, sexually transmitted infection.

Analysis of the deprivation score IMD 2015 of the area from which the kits were requested found that those who returned kits gave postcodes which were in significantly less deprived areas, with a median IMD rank of 9444 (IQR: 2907–15 387) compared with 8574 (IQR: 2546–14 338) for areas that did not return the kits ( $p=0.007$ ). In addition, the place of delivery of the sampling kits was also significantly associated with their return ( $p < 0.001$ ), with the greatest rate of return observed in those kits delivered to the patient's homes (60.6%) and the lowest rate in those delivered to pharmacies (44.0%). Neither the day of the week ( $p=0.059$ ), nor the time of day ( $p=0.665$ ) that the request was made were found to be significantly predictive of whether a kit would be returned.

A significant association with the questions about countries of birth of the patient and their sexual partners was detected ( $p=0.031$ ), with patients born within and with partners within UK/Northern EU having the highest rate of return of the samples (59.1%) and those born outside the Northern EU having the lowest rate (51.3%). In addition, asymptomatic patients were found to be more likely to return their sampling kits compared with those with symptoms, regardless of gender ( $p=0.020$  for women,  $p=0.010$  for men). However, the rate of return of the samples did not differ significantly with the history of sex with someone with STI ( $p=0.085$ ).

A multivariable analysis was then performed, to identify independent predictors of the return of samples, which returned results that were consistent with the univariable analysis (table 3). The type of kit requested was found to be significantly predictive of the return of samples ( $p < 0.001$ ). The rates of return were similar for women without or with history of anal sex (adjusted OR ( $OR_{adj}$ ) 0.96, 95% CI 0.74 to 1.24,  $p=0.736$ ) and the male MSM kit ( $OR_{adj}$  1.06, 95% CI 0.86 to 1.30,  $p=0.593$ ). However, patients requesting the heterosexual male STI kit were significantly less likely to return samples than those requesting the other kit types ( $OR_{adj}$  0.63, 95% CI 0.55 to 0.72,  $p < 0.001$  vs women without history of anal sex).

The place of delivery of the sampling kits was also a significant independent predictor of the return of

**Table 2b** Comparisons of the rates of samples received by gender-specific questions

	Female			Male		
	STI kits	Sample received	p Value	STI kits	Sample received	p Value
Kit type*			0.572			<0.001
Female-design A	3246	1990 (61.3%)		†	–	
Female-design B	267	159 (59.6%)		†	–	
Male STI	†	–		1325	657 (49.6%)	
MSM STI	†	–		462	292 (63.2%)	
Symptoms			<b>0.020</b>			<b>0.010</b>
I don't have any of these symptoms	2769	1723 (62.2%)		1424	781 (54.8%)	
Deep pain during sex	151	83 (55.0%)		†	–	
Ongoing lower abdominal pain	215	132 (61.4%)		†	–	
Pain when you pass urine	299	174 (58.2%)		146	75 (51.4%)	
Sores, ulcers or cuts on your genitals or around your anus	79	37 (46.8%)		46	20 (43.5%)	
Pain in your testicles	†	–		73	36 (49.3%)	
Unusual discharge from penis or anus	†	–		98	37 (37.8%)	
Sexual and drug taking behaviour (in the last 6 months)			0.736			<0.001
None of these statements apply to me	2961	1810 (61.1%)		1300	644 (49.5%)	
I've had anal sex with a man	213	126 (59.2%)		†	–	
I've had sex with six or more men	301	186 (61.8%)		12	5 (41.7%)	
I've used amyl nitrate (poppers)	11	8 (72.7%)		5	1 (20.0%)	
I've used methamphetamines	27	19 (70.4%)		23	13 (56.5%)	
I've had sex with other men	†	–		438	279 (63.7%)	
I've had receptive anal sex (I was the bottom) with a man	†	–		9	7 (77.8%)	

Excludes the transgender respondents (n=10). p-values are from  $\chi^2$  tests, and bold p values are significant at  $p < 0.05$ .

\*Female-design B is for respondents reporting a history of receptive anal sex.

†Not applicable to the specified gender.

MSM, men who have sex with men; STI, sexually transmitted infection.

samples ( $p < 0.001$ ), with those delivered to the pharmacy the least likely to be returned ( $OR_{adj}$  0.53, 95% CI 0.44 to 0.63,  $p < 0.001$  vs home). Patients reporting symptoms were also less likely to return kits, ( $OR_{adj}$  0.77, 95% CI 0.67 to 0.89,  $p = 0.001$  vs asymptomatic patients).

Decreasing deprivation was associated with an increased chance of the return of kits. For each increase of 10 000 ranks in the IMD score (ie, becoming less deprived), the likelihood of kits being returned increased, with an  $OR_{adj}$  of 1.08 (95% CI 1.01 to 1.15,  $p = 0.029$ ).

## DISCUSSION

We identified a number of factors associated with return of STI and HIV sampling kits. Kits requested by heterosexual men, those with genitourinary symptoms and kits delivered to neighbourhoods with higher socioeconomic deprivation and to locations other than the patient's home were all found to have significantly lower rates of return.

Little comparable evidence for an online service for STI and HIV testing of all sex groups is currently available. Most studies report on home sampling services for HIV or chlamydia testing. In an earlier population study on uptake of postal screening for chlamydia, 25% (95% CI 21.7% to 28.6%) of 14 382 randomly selected men and women returned their sampling kits.<sup>14</sup> An online HIV home sampling service for MSM reported 55% of 10 323 men returned their sampling kits, a rate comparable with that for MSM in our study.<sup>10</sup> In an earlier study on the uptake of home sampling of vaginal chlamydia testing, 31% (350/1139) of the kits requested via email were returned.<sup>7</sup> A study on home sampling kits for STI testing of 433 HIV negative MSM reported a return rate of 47%.<sup>11</sup>

Chlamydia trachomatis Online surveys of target populations for home STI and HIV testing have identified some factors associated with the use of the service and return of the sampling kits. In a survey of 7938 MSM, those who identified themselves as gay or bisexual were more likely to use home sampling testing than men who identified

**Table 3** Multivariable analysis of return of samples

	OR <sub>adj</sub> (95% CI)	p Value
Kit type*		<0.001
Female-design A	–	–
Female-design B	0.96 (0.74 to 1.24)	0.736
Male STI	0.63 (0.55 to 0.72)	<0.001
MSM STI	1.06 (0.86 to 1.30)	0.593
Place of delivery		<0.001
Home	–	–
Clinic	0.84 (0.71 to 1.00)	0.048
Pharmacy	0.53 (0.44 to 0.63)	<0.001
Any symptoms reported	0.77 (0.67 to 0.89)	<0.001
2015 IMD rank (x10 000)†	1.08 (1.01 to 1.15)	0.029

Results are from a multivariable binary logistic regression model, using a forwards stepwise approach. All factors in [table 2a,b](#) were considered for inclusion, as well as patient age. The questions regarding sexual infections, symptoms and statements about sexual and drug history were dichotomised into yes/no responses. The 10 transgender respondents and the 39 cases where the IMD was not available were excluded. Bold p values are significant at p<0.05.

\*Female-design B is for respondents reporting a history of receptive anal sex.

†The OR represents the increase in the odds of sample return associated with an increase of 10 000 ranks of the IMD.

IMD, Index of Multiple Deprivation Score; MSM, men who have sex with men; OR<sub>adj</sub>, adjusted odds ratio; STI, sexually transmitted infection.

as straight/other men.<sup>1</sup> Other surveys have identified level of education, level of income, ethnicity and age as predictor of return of the sampling kits.<sup>15–18</sup> Some of these findings have not been supported by other surveys.<sup>1</sup>

In our study, sampling kits collected from pharmacies were less likely to be returned. This may be secondary to individuals' difficulties with securing a venue where they can obtain their specimens in a confidential manner. Rates of return were also found to be lower in patients with genitourinary symptoms. We hypothesise that this may have been due to patients deciding to attend our sexual health clinics, rather than return their sampling kits, as this is the advice we offer to the patients on our website.

We found that heterosexual men and those from neighbourhoods with higher socioeconomic deprivation were less likely to return their sampling kits. As these are populations at risk of STI and HIV,<sup>19</sup> increasing the return rate of sampling kits from these populations is a priority for our service. However, based on the data available from the surveys, we were not able to hypothesise as to why these groups were less likely to return their samples and, as such, are not able to propose changes to the service to improve sample return.

We suspect improving the process of obtaining specimens would improve the return of the testing kits. We aim to survey patients who do not return their STI sampling

kits to understand their reasons for non-return of the testing kits better.

Our study suffered from a number of limitations, the main one being that, in patients who did not return their sampling kits, the rationale behind this decision was not known. This additional information may have been highly valuable in explaining the observed differences between subgroups (eg, heterosexual men vs MSM) and identifying areas in which the service and, hence, the return rate of kits could be improved. As a result, a questionnaire targeted at those patients who did not return their kits would make for interesting further work in this area. However, the response rates to such questionnaires is likely to be poor, especially since the majority of patients of interest are likely to be non-responders, on account of the fact that they did not return their sampling kits. Consequently, such a study may be hampered by selection bias and a small sample size.

In this study, we assumed all requested kits were delivered to the patients but, since proof of delivery was not recorded, we do not know how many of the sampling kits were actually received. The number of kits lost in transit would be expected to be minimal. However, since the service was free, a number of online requests for the sampling kits may have not been genuine and may have used false delivery addresses, which would likely have resulted in the unwitting recipient disposing of the kit.

The study also only focused on whether or not the kits were returned, and did not consider the quality or quantity of the samples themselves. As such, it is likely that a proportion of those kits returned contained incomplete or inadequate specimens on which the full range of STI and HIV sampling could not be performed. Further assessment of the factors associated with the return of incomplete samples may have yielded useful results. However, anonymised data relating to the samples were not available, hence this was outside the scope of this service evaluation.

Home sampling for STI and HIV testing is rapidly becoming a standard of care. Return of samples for testing is crucial for the success of the service. We identified a number of factors that were associated with non-return of the sampling kits. Further research into the subgroups of patients with the lowest return rates may identify the reasons behind this and changes to the service that could improve the rate of return and, hence, the effectiveness of the programme.

**Contributors** KM researched and proposed the protocol, drafted the manuscript. JH conducted the statistical analysis of the data. KM and JH have contributed to the final version of the manuscript.

**Competing interests** None declared.

**Patient consent** Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

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