

## Do clinical guidelines improve general practice management and referral of infertile couples?

Carolyn Emslie, Jeremy Grimshaw, Allan Templeton

### Abstract

**Objective**—To evaluate guidelines for general practice management and referral of infertile couples. Guidelines were implemented with a disease specific reminder at the time of consultation (the guidelines were embedded within a structured infertility management sheet for each couple).

**Design**—Pragmatic randomised controlled trial. Participating practices were randomised to a group that received the guidelines and a control group.

**Setting**—82 general practices in Grampian region.

**Subjects**—100 couples referred by general practitioners receiving the guideline and 100 couples referred by control general practitioners.

**Main outcome measure**—Whether the general practitioner had taken a full sexual history and examined and investigated both partners appropriately.

**Results**—Characteristics of patients referred by study and control general practitioners did not differ significantly at baseline. Compliance with the guidelines increased for all targeted activities. General practitioners in the study group were more likely to take a sexual history (for example, couples' use of fertile period, 85% v 69%,  $p < 0.01$ ); examine both partners (female partner, 68% v 52%,  $p < 0.05$ ; male partner 39% v 13%,  $p < 0.01$ ); and investigate both partners (day 21 progesterone, 72% v 41%,  $p < 0.001$ ; semen analysis, 51% v 41%,  $p > 0.05$ ). Improvements were greater when general practitioners used the disease specific reminder.

**Conclusion**—Receiving guidelines led to improvements in the process of care of infertile couples within general practice. This effect was enhanced when the guidelines were embedded in a structured infertility management sheet for each couple.

### Introduction

Infertility is a common problem affecting about 14% of couples.<sup>1,2</sup> Growing awareness of infertility among both the public and professionals has led to an increase in referrals to specialist clinics for advice and management.<sup>2,3</sup> This does not seem to be due to an increase in the underlying incidence of infertility but reflects an increasing proportion of infertile couples seeking help.<sup>2</sup> Ninety per cent of infertile couples seek help from their general practitioners, and about three quarters are referred for specialist care.<sup>2</sup> Although a large increase in the number of referrals is unlikely (unless the underlying incidence of infertility changes), there are wide variations in the management of infertile couples before referral. Basic infertility investigations are simple and easily performed in primary care and can provide reassurance to many couples.

The role of the general practitioner in the continuing management of the infertile couple has recently been emphasised.<sup>4</sup> The recent Effective Health Care report

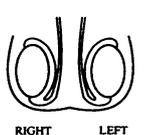
on infertility suggested that guidelines concerning general practice management and referral of couples would be "of value in helping to promote a more homogeneous and effective approach in practice."<sup>5</sup> The Royal College of Obstetricians and Gynaecologists has recently published guidelines for the specialist management of infertility.<sup>6</sup> We report the results of a pragmatic randomised controlled trial of guidelines for general practice management and referral of infertile couples.

### GUIDELINES

The only specialist infertility clinic serving Grampian has detailed guidelines for initial investigation of infertile couples. These were modified during small group discussions between local general practitioners and consultants to produce guidelines for management of infertility in general practice.

The guidelines concerned the history, examination, and investigation of a couple presenting in general practice with infertility, along with indications for early referral. The guidelines were supplied as part of an infertility management pack which included a detailed explanation of the guidelines,<sup>6</sup> a structured infertility management sheet (figure),<sup>6</sup> and semen analysis packs.

2. Male partner		Date .....	Unit No .....	(if known)	♂
Surname .....		Forename .....			
D o B .....		Occupation .....			
Infertility	Primary <input type="checkbox"/>	Secondary <input type="checkbox"/>	Duration .....		
Past medical history		<input type="checkbox"/> Nil	<input type="checkbox"/> Details:		
Recent (6/12) pyrexial illness		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Previous genital pathology (include orchitis, epididymitis, torsion, surgery, injury, maldescent, varicocele)		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Drugs		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Allergies		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Smoking		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Alcohol		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Relevant genetic, family or social history		<input type="checkbox"/> None	<input type="checkbox"/> Details:		
Physical Examination					
Height (cm)	<input type="text"/>	Weight (kg)	<input type="text"/>	B P Sys/Dias	<input type="text"/> / <input type="text"/>
General Examination incl gynaeocomastia		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal - Details:		
Abdominal Exam incl inguinal exam		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal (including scars):		
Urogenital Examination					
Testes	Both palpable <input type="checkbox"/>	<input type="checkbox"/> Non-Palpable			
Site	Both normal <input type="checkbox"/>	<input type="checkbox"/> Abnormal			
Size	Both normal <input type="checkbox"/>	<input type="checkbox"/> Abnormal			
Epididymides	Both normal <input type="checkbox"/>	<input type="checkbox"/> Abnormal			
Vasa deferentia	Both normal <input type="checkbox"/>	<input type="checkbox"/> Abnormal			
Scrotal Swelling	None <input type="checkbox"/>	<input type="checkbox"/> Present			
Varicocele	None <input type="checkbox"/>	<input type="checkbox"/> Present			
Penis	Normal <input type="checkbox"/>	<input type="checkbox"/> Abnormal			



Infertility management sheet: history and examination of male partner

Department of Obstetrics and Gynaecology, University of Aberdeen, Aberdeen AB9 2ZD  
Carolyn Emslie, SOHHD research fellow  
Allan Templeton, professor

Department of General Practice, University of Aberdeen  
Jeremy Grimshaw, Wellcome research fellow

Correspondence to: Carolyn Emslie, St James University Hospital, Leeds LS9 7TF.

The guideline requested that the general practitioner saw and examined any couple presenting with infertility of any duration. If possible, both partners should be seen. A medical history should be obtained with particular attention, in the woman, to any menstrual irregularity, abdominal surgery, or suspected pelvic inflammatory disease, and in the man, to any history of urogenital problems (orchitis, maldescent, torsion, for example) or any systemic illness. A sexual history should be elicited and advice given if necessary. Examination of the woman should aim to detect any underlying endocrine disorder and pelvic pathology, and examination of the man to detect any urogenital pathology not suspected from the history. The male investigation requested by the guidelines was two semen analyses at least three weeks apart. Female investigation consisted of detection of ovulation by estimation of luteal phase progesterone, knowledge of her rubella status, and a full blood count.

#### INFERTILITY MANAGEMENT SHEETS

General practitioners were encouraged to use the infertility management sheet when a couple presented with infertility. The guidelines were embedded in the infertility management sheet, thus avoiding the need for reference to the explanation of the guideline at every consultation, so that general practitioners were prompted to record relevant items of history and examine and investigate couples appropriately as they completed the sheet. The infertility management sheet consisted of two sheets of A4 paper printed on both sides. The front page gave a brief summary of the guidelines and the pointers towards early referral. When the booklet was opened the two inner pages were for details of the history and examination of the woman and the man. The final page was a reminder of investigations to perform and a record of the results. Thus the infertility management sheet provided the general practitioner with a disease specific reminder of the guidelines at the time of consultation.<sup>7</sup>

To facilitate communication, general practitioners were encouraged to send the infertility management sheet instead of a letter if they referred a couple. The completed infertility management sheet gave the medical staff seeing the couple in hospital a complete record of their investigation and treatment to date, so allowing problems to be quickly identified and avoiding unnecessary repetition of investigation.

#### Methods

##### DESIGN

All general practitioners practising in Grampian region were approached to participate in the study. Of the 86 practices, four did not wish to take part and a further nine individual principals declined to participate. The 82 participating practices were randomised to study and control groups stratified for practice location. To reduce the risk of contamination, practices sharing the same premises were allocated to the same group. To reduce the risk of the Hawthorne effect (the beneficial effect on performance of taking part in research),<sup>8</sup> practices allocated to the control group were informed that they would receive the guidelines after the evaluation period.

Couples referred for consideration of reversal of sterilisation (except those sterilised who wished to be considered for in vitro fertilisation) or for ongoing specialist management were excluded as their management would be different from that of couples presenting for the first time.

##### DATA COLLECTION

The study aimed to recruit 100 couples referred by study practices and 100 referred by control practices.

Data collection ran from December 1991 to August 1992. Data concerning couples referred by study general practitioners who used the infertility management sheet (n=36) were abstracted from the sheet. Data concerning couples referred by study general practitioners who did not use the infertility management sheet or by control general practitioners were collected by computer assisted telephone interview.<sup>9</sup> General practitioners were contacted shortly after referral and asked to complete a brief structured telephone interview concerning their management of the referred couple before referral. The interviewer sat in front of a computer terminal, asking questions presented on the screen and entering the respondent's replies directly. Thus data were entered in "real time" during the interview. The data obtained were stored on SIR, a hierarchical database on the University of Aberdeen mainframe computer.

#### ANALYSIS

The data were analysed by SPSS with the  $\chi^2$  test and *t* tests as appropriate. Primary analysis was by intention to treat (all couples referred by study general practitioners were analysed whether they were referred with a completed infertility management sheet or not). A secondary analysis was performed to look at differences in management between those couples in the study group who were referred with completed infertility management sheets and those who were not.

#### Results

##### PATIENT CHARACTERISTICS

One hundred couples were recruited to the study group and 100 to the control group between December 1991 and August 1992. There were no significant differences in the characteristics of couples referred by study and control general practitioners (table I). Sixty four per cent of the study couples had primary infertility compared with 59% in the control group. The main duration of infertility at the time of referral was 25 months in the study group and 23 months in the control referrals. Couples in the study group were referred on average three months after seeing their general practitioner for the first time and couples in the control group after four months.

TABLE I—Characteristics of couples in study. Values are medians (ranges)

	Study couples (n=100)	Control couples (n=100)
Age of female partner (years)	29.4 (17-48)	28.5 (19-45)
Duration of infertility (months)	25.0 (2-120)	23.2 (2-120)
Time from presentation to referral (months)	3.1 (<1-36)	3.8 (<1-17)
% With primary infertility	64%	59%

##### SEXUAL HISTORY

General practitioners in the study group were more likely to have asked about couples' knowledge of the fertile period (85% v 73%,  $p < 0.05$ ) and their use of it (85% v 69%,  $p < 0.01$ ) (table II). Erectile and ejaculatory problems were asked about in 86% of study and 70% of control couples ( $p < 0.01$ ). Study and control general practitioners were equally likely to have asked about dyspareunia (86% v 80%, not significant).

TABLE II—Sexual history obtained

	Study couples (n=100)	Control couples (n=100)	p Value
Knowledge of fertile period	85	73	<0.05
Use of fertile period	85	69	<0.01
Erectile problems	86	70	<0.01
Ejaculatory problems	86	70	<0.01
Dyspareunia	86	80	NS

EXAMINATIONS AND INVESTIGATIONS

General practitioners in the study group were more likely to have examined the female partner (68% v 52%,  $p < 0.05$ ) and to have performed a pelvic examination (67% v 51%,  $p < 0.05$ ) (table III). Thirty seven per cent of women in study couples had a full blood count performed compared with 13% in the control group ( $p < 0.001$ ). Day 21 progesterone levels were assessed in 72% of study couples compared with 41% of control couples ( $p < 0.001$ ). General practitioners were able to report the rubella status of 64% of study women and 25% of control women ( $p < 0.001$ ).

TABLE III—Investigations performed

	Study couples (n=100)	Control couples (n=100)	p Value
Female partner:			
General examination	68	52	<0.05
Pelvic examination	67	51	<0.05
Full blood count	37	13	<0.001
Progesterone	72	41	<0.001
Rubella status	64	25	<0.001
Male partner:			
Registered with GP	75	71	NS
Seen by GP	50	33	<0.05
Genital examination	39	13	<0.001
Semen analysis	51	41	NS

The proportion of men registered with the same practice as their partner was similar in the study and control groups (75% v 71% respectively, not significant), but study general practitioners were more likely to have seen the male partner (50% v 33%,  $p < 0.05$ ) and examined him (39% v 13%,  $p < 0.01$ ). Study and control general practitioners were equally likely to have arranged for semen analysis (51% v 41%, not significant).

EFFECT OF INFERTILITY MANAGEMENT SHEET

Thirty six of the 100 study couples were referred with a completed infertility management sheet. To assess the contribution of the infertility management sheet, a secondary analysis compared the management of study couples referred with and without a completed infertility management sheet with control couples. General practitioners were more likely to use the infertility management sheet when the male partner was registered with the practice (92% v 66%,  $p < 0.005$ ) (table IV).

The comparison of study couples referred without a completed infertility management sheet with control couples gives an indication of the effectiveness of the guidelines without the infertility management sheet. Significant differences in management were observed only for investigations of the female partner. Day 21 progesterone estimations were completed for 59% of study couples referred without a completed infertility management sheet compared with 41% of controls

( $p < 0.05$ ). General practitioners were aware of the rubella status of 52% of study women referred without a completed infertility management sheet and 25% of controls ( $p < 0.001$ ).

The comparison of study couples referred with a completed infertility management sheet with control couples gives an indication of the effectiveness of the guideline if all patients were referred with a completed infertility management sheet. Highly significant differences were seen in all activities indicated by the guideline (table IV).

Discussion

There is increasing interest in the use of guidelines to improve the referral process,<sup>10-13</sup> although there is continuing uncertainty as to how they should be developed and introduced into clinical practice<sup>14</sup> as well as their effectiveness.<sup>15</sup> Grimshaw and Russell recently reviewed 40 evaluations of clinical guidelines and observed improvements in process of care in 37 studies.<sup>7</sup> They proposed a taxonomy for the successful introduction of clinical guidelines based on different strategies for development, dissemination, and implementation.<sup>7</sup> They suggested that the greater the involvement of clinicians in the development of clinical guidelines, the greater the effect of the guidelines in influencing clinical practice. Dissemination strategies ensure that targeted clinicians have adequate access to the guidelines, and the greater the educational component of the dissemination, the greater the effectiveness of the guidelines. Implementation strategies encourage clinicians to adopt the guidelines into their day to day practice. The review suggested that guidelines were more effective if they were implemented with feedback specific to individual patients which was closely associated with the doctor-patient consultation.

USE OF THE GUIDELINES

In the current study, the guidelines were developed by representatives of the clinicians who would use them (a strong development strategy), disseminated by mailing to the targeted clinicians (a weak dissemination strategy), and implemented with the infertility management sheet, a disease specific reminder of the guidelines at the time of consultation (a strong implementation strategy). The study showed clear improvements in the process of care after the introduction of the guidelines. General practitioners receiving the guidelines were more likely to take a detailed sexual history and investigate both the female and male partners appropriately. The guidelines encouraged a more uniform approach to the management of infertile couples in general practice and referral at an appropriate time. (We are aware of at least 15 couples currently being managed in general practice with the infertility management sheet who have not been referred for specialist care.) The infertility management sheet also ensured that the specialist was fully aware of what investigations had been performed in general practice and their results. In future the guidelines could be used in contracting as part of the service specification, with the infertility management sheet providing the mechanism to audit the referral process. This study has looked only at the process of care and these couples are currently being followed through the infertility clinic to detect any differences in outcome.

USE OF THE INFERTILITY MANAGEMENT SHEET

The greatest improvements in process were observed when general practitioners used the infertility management sheet, which prompted compliance with the guideline during the course of the consultation. Similar

TABLE IV—Comparison of management in couples referred using infertility management sheet and those not. Values are percentages (numbers)

	Control couples A (n=100)	Study couples		p Value		
		Management sheet used B (n=36)	Management sheet not used C (n=64)	B v C	C v A	B v A
Female partner:						
Pelvic examination	51	89 (32)	55 (35)	<0.001	NS	<0.001
Progesterone	41	94 (34)	59 (38)	<0.001	<0.05	<0.001
Rubella status	25	86 (31)	52 (33)	<0.001	<0.001	<0.001
Male partner:						
Male registered	71	92 (33)	66 (42)	<0.005	NS	<0.05
Male seen	33	89 (32)	28 (18)	<0.001	NS	<0.001
Genital examination	13	89 (32)	11 (7)	<0.001	NS	<0.001
Semen analysis	41	86 (31)	31 (20)	<0.001	NS	<0.001
Sexual history:						
Use of fertile period	69	94 (34)	80 (51)	<0.05	NS	<0.005
Erectile problems	70	94 (34)	81 (52)	NS	NS	<0.005
Dyspareunia	80	94 (34)	81 (52)	NS	NS	<0.05

improvements in compliance with guidelines were observed when a structured history sheet was used in neonatal<sup>16</sup> and antenatal care.<sup>17</sup> However, the infertility management sheet was used in only a third of couples.

General practitioners were less likely to use the infertility management sheet if the male partner was not registered with the practice. This has implications for the management of infertile couples in primary care. Infertile couples need to be counselled and investigated together. Under the present arrangements it is difficult to provide good quality care if the male partner is registered with another practice. It may be appropriate for a couple registered with different practices to nominate a general practitioner from one practice to coordinate the initial management (and referral, if appropriate) of their infertility.

The use of the infertility management sheet may be improved with a better dissemination strategy including a specific educational initiative which explains the scientific basis of the guidelines and instructs general practitioners in the use of the infertility management sheet. In future, it is likely that clinical guidelines integrated within a computerised medical record will provide similar decision support to the paper based infertility management sheet.<sup>18</sup>

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## Explaining variations in prescribing costs across England

Tony Morton-Jones, Mike Pringle

### Abstract

**Objective**—To derive a predictive model for national prescribing behaviour in terms of basic morbidity and demographic factors.

**Design**—24 demographic, morbidity, and practice factors were entered into a multiple regression analysis to determine the net ingredient cost per patient.

**Setting**—The 90 family health service authorities in England for 1989.

**Results**—For net ingredient cost per patient only two demographic factors (numbers of pensioners and the mobility of the registered population measured by list inflation) and two morbidity related factors (standardised mortality ratios and numbers of prepayment certificates issued) significantly contributed to a multiple regression model. This model explained 81% of the variation in net ingredient cost per registered patient between family health services authorities. The model also enabled a weighting factor of 4.6 (95% confidence interval 3.2 to 6.7) to be derived for the net ingredient cost for elderly patients (compared with the existing prescribing unit factor of 3).

**Conclusions**—The model shows that variations in prescribing costs essentially reflect demand. It also suggests that the current prescribing unit value of 3 for patients aged 65 or more underestimates the extra costs of prescribing for elderly patients.

### Introduction

Prescribing is not uniform across Britain,<sup>1-4</sup> variations existing between prescribers, practices, health authorities, and regions. For 1990-1, for example, the

average annual prescribing costs per patient for the 90 family health services authorities in England ranged from £36.85 to £65.04.<sup>5</sup> Suggested reasons for these variations include the large differences in socio-economic factors, patients' attitudes,<sup>6</sup> and demography across the country, which yield differing levels of health care demand.<sup>7</sup> Unexplained variations in resource use are, however, liable to be interpreted as indicating inefficiency. It is therefore important for primary care needs assessment to explore the relation between prescribing and socioeconomic and demographic features, both in general and in certain therapeutic groups.

It is difficult to assess these links at practice level since local factors, such as the general practitioner's own beliefs about prescribing (which have been shown to be stable and unchanging<sup>8-10</sup>) and differing levels of identification of morbidity, can be distorting. The coarser the level of analysis the less individual prescribing habits affect the overall picture, but the less sensitive the analysis becomes to real local variation in need. Analysis of data aggregated at the level of the family health services authority is a compromise, but it may disguise real differences between, say, inner city and rural components within one authority. Some work with this approach has been reported.<sup>11-13</sup> This paper examines a model to explain the variation in prescribing costs at the level of the family health services authority to establish the extent to which such variations are predictable.

### Methods

We identified 24 factors which might influence prescribing costs. The data for each of these factors

Department of General Practice, Queen's Medical Centre, Nottingham NG2 7UH

Tony Morton-Jones, research fellow  
Mike Pringle, senior lecturer

Correspondence to:  
Dr Morton-Jones.

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