sales of the *Informed Choice* leaflets to control maternity units participating in the research until the end of the intervention period.

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Use of evidence based leaflets to promote informed choice in maternity care: randomised controlled trial in everyday practice

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ELPS

The full version of this article appears on bmj.com

Abstract

Objective To assess the effect of leaflets on promoting informed choice in women using maternity services.
Design Cluster trial, with maternity units randomised to use leaflets (intervention units) or offer usual care (control units). Data collected through postal questionnaires.
Setting 13 maternity units in Wales.
Participants Four separate samples of women using maternity services. Antenatal samples: women reaching 28 weeks' gestation before (n=1386) and after (n=1778) the intervention. Postnatal samples: women at eight weeks after delivery before (n=1741) and after (n=1547) the intervention.
Intervention Provision of 10 pairs of *Informed Choice* leaflets for service users and midwives and a training session for staff in their use.
Main outcome measures Change in the proportion of women who reported exercising informed choice. Secondary outcomes: changes in women's knowledge; satisfaction with information, choice, and discussion; and possible consequences of informed choice.
Results There was no change in the proportion of women who reported that they exercised informed choice in the intervention units compared with the control units for either antenatal or postnatal women. There was a small increase in satisfaction with information in the antenatal samples in the intervention units compared with the control units (odds ratio 1.40, 95% confidence interval 1.05 to 1.88). Only three quarters of women in the intervention units reported being given at least one of the leaflets, indicating problems with the implementation of the intervention.
Conclusion In everyday practice, evidence based leaflets were not effective in promoting informed choice in women using maternity services.

Introduction

There is a growing consensus that people should be informed about, and able to influence, decisions about their own health care.[1 2] Decision aids, which present the options available to patients with evidence from research on their effects, can help people to participate in decisions about their care.[3] Midwives Information and Resource Service (MIDIRS) and the NHS Centre for Reviews and Dissemination have produced a set of 10 leaflets on informed choice in maternity care. The leaflets summarise evidence on 10 decisions that women face in pregnancy and childbirth to encourage

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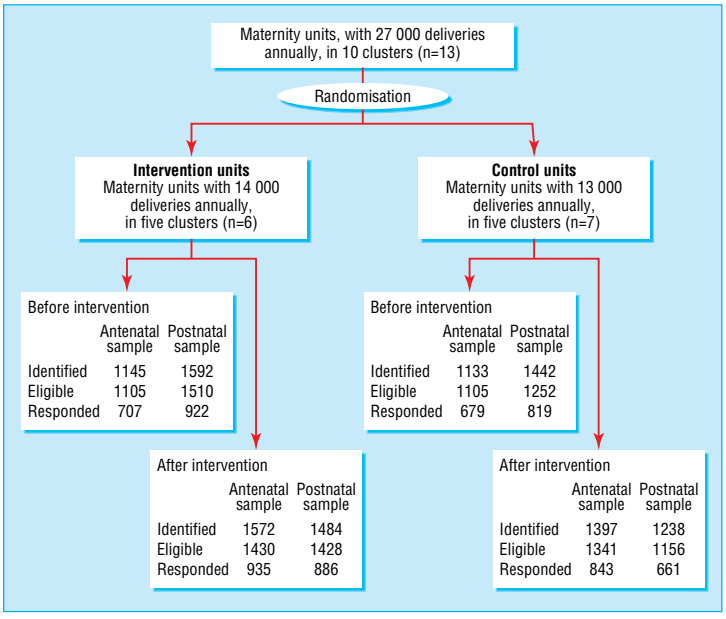
The intervention

- Ten pairs of *Informed Choice* leaflets:
- Support in labour
- Listening to your baby's heartbeat during labour
- Ultrasound scans—should you have one?
- Alcohol and pregnancy
- Positions in labour and delivery
- Epidurals for pain relief in labour
- Feeding your baby—breast or bottle?
- Looking for Down's syndrome and spina bifida in pregnancy
- Breech baby: What are your choices?
- Where will you have your baby – hospital or home?
- Leaflets were in pairs—a women's leaflet, designed to be accessible and give information about the benefits and risks of options available, and a more detailed professionals' leaflet, with references for the research on which it is based, which could be accessed by women through the midwife. The leaflets were designed to be given by health professionals to women at different stages of pregnancy
- Each intervention unit received sets of leaflets in May 1998 for an eight month period. A two hour training session was provided for staff. Training material was left with managers for cascade training
- Women in the intervention arm of the trial received the leaflets relevant to early pregnancy at their first booking appointment (10-12 weeks' gestation) and the other leaflets at 34-36 weeks' gestation

their involvement in decisions about their own care. Many maternity units buy the leaflets, yet little is known about their effectiveness.

We investigated whether the leaflets promoted informed choice and led to increased levels of knowledge, satisfaction with information, satisfaction with the way choices were made, and discussion with health professionals. We also examined whether they changed the actions women took or the services they used.



Study design

Methods

We tested the hypotheses in a cluster randomised controlled trial, with maternity units as clusters, in everyday practice. Qualitative research was undertaken alongside the trial to explore the use of the leaflets in practice and is reported separately.[4]

We randomised maternity units rather than individual women because of the risk of women sharing the leaflets in an individual level trial. Units were included if they had not already purchased the leaflets and had over 1000 deliveries annually. Twelve of the 15 large maternity units in Wales had not already purchased the leaflets and agreed to participate in the study. We also included a small unit under the managerial control of one of the 12 larger units. Maternity units were grouped into 10 clusters because some shared management or clinicians. Clusters were paired on the basis of their annual numbers of deliveries to ensure balance in the two arms of the trial. Members of pairs were randomly assigned by tossing a coin to receive the set of leaflets (five intervention units) or to continue with usual care (five control units). The intervention is described in the box.

Participants

We identified two samples of women. The first sample was all women who reached 28 weeks' gestation during a six week period (antenatal sample). The second sample was all women who delivered during a six week period (postnatal sample).

We identified antenatal and postnatal samples before the introduction of the leaflets and again nine months after they were introduced. We assessed outcomes using a postal questionnaire sent to women in these four different samples (figure). Women in the antenatal samples received the questionnaire at 28 weeks' gestation, and women in the postnatal samples received the questionnaire eight weeks after delivering their babies. Up to two reminders were sent at intervals of three weeks. The second reminder for the women in the antenatal samples was a shorter questionnaire that covered only key questions.

Outcome measures

The primary outcome was the proportion of women who answered "yes" to the question "Have you had enough information and discussion with midwives or doctors to make a choice together about all the things that happened during maternity care?" with the options "yes," "partly," "no," "there was no choice," and "did not apply." As informed choice is a difficult concept to measure[2] we also asked women about the role they took when choices were made, with six options ranging from "active" to "passive."[5]

Secondary outcomes were the "components" and the "consequences" of informed choice. The components measured were women's levels of knowledge of the 10 topics covered by the leaflets; satisfaction with information and with how choices had been made; and views of whether they had had sufficient discussion with health professionals. The consequences measured were the actions taken or services used by women. We also collected data on sociodemographic factors, parity, and women's preferences for involvement in decision making.[5]

Table 1 Informed choice and components of informed choice. Figures are numbers (percentage) of women unless stated otherwise

Measure	Intervention			Control			Unadjusted odds ratio (95% CI)	Adjusted* odds ratio (95% CI)
	Before	After	Change in %	Before	After	Change in %		
Antenatal								
Reporting yes to overall informed choice	357/689 (52)	532/917 (58)	6	373/663 (56)	477/820 (58)	2	1.10 (0.63 to 1.92)	1.15 (0.65 to 2.06)
Reporting "active" decision making role†	483/604 (80)	695/808 (86)	6	492/602 (82)	613/723 (85)	3	1.22 (0.59 to 2.51)	1.13 (0.47 to 2.74)
Satisfied with amount of information†	388/604 (64)	579/812 (71)	7	427/607 (70)	528/729 (72)	2	1.30 (0.96 to 1.75)	1.40 (1.05 to 1.88)‡
Satisfied with way choices were made†	416/601 (69)	612/815 (75)	6	455/608 (75)	549/722 (76)	1	1.22 (0.76 to 1.93)	1.25 (0.77 to 2.02)
Enough discussion	396/692 (57)	598/921 (65)	8	413/663 (62)	520/827 (63)	1	1.28 (0.80 to 2.07)	1.32 (0.82 to 2.14)
Postnatal								
Reporting yes to overall informed choice	499/887 (56)	500/848 (59)	3	406/788 (51)	358/637 (56)	5	0.90 (0.61 to 1.33)	0.90 (0.59 to 1.37)
Reporting "active" decision making role	664/901 (74)	638/866 (74)	0	559/797 (70)	463/647 (72)	2	0.89 (0.57 to 1.39)	0.99 (0.68 to 1.44)
Satisfied with amount of information	619/891 (70)	635/855 (74)	4	536/780 (69)	458/637 (72)	3	1.09 (0.76 to 1.57)	1.07 (0.73 to 1.57)
Satisfied with way choices were made	683/886 (77)	656/855 (77)	0	600/780 (77)	502/633 (79)	2	0.77 (0.40 to 1.48)	0.78 (0.40 to 1.54)
Enough discussion	570/883 (65)	548/847 (65)	0	481/774 (62)	414/636 (65)	3	0.86 (0.56 to 1.32)	0.82 (0.54 to 1.26)

*Adjusted for woman's age, age at leaving full time education, parity, and decision style preference.
†Not included in short questionnaire sent as second reminder to antenatal sample.
‡P<0.05.

Results

Participants—The overall response rate to the questionnaires was 64% (6452/10 070). Response rates were lower in women with manual occupations and from ethnic minorities but did not differ by type of delivery, type of pain relief, parity, or age.[6]

Impact on informed choice—Before the intervention about half of women in both intervention and control units reported exercising informed choice "overall" in their maternity care. After the intervention, this proportion increased slightly in both groups but with no significant difference in the change between groups (table 1). Results were similar for the proportion of women reporting active involvement in decision making. In the antenatal samples there were increases in knowledge, discussion, and satisfaction with information and with the way choices were made in intervention units. They were not significant, however, with the exception of satisfaction with information. There was only one change in postnatal samples, with an increase of 0.24 points on a 10 point knowledge score, which was no longer significant after adjustment for covariates.

Consequences of informed choice—Given that there was no change in the proportion of women who reported that they exercised informed choice we would not expect changes in choices made. The one significant difference, which was in the proportion of women having screening tests for Down's syndrome and spina bifida, was due in part to an increase in reported uptake in the control units.

Uptake of leaflets—During the intervention period there was a significant increase in the proportion of women who reported that they had been given any of the *Informed Choice* leaflets in the intervention units compared with the control units, which showed little change (table 2). However, it was difficult to assess the uptake of the intervention leaflets with any precision. A large minority of women in the intervention units (44%) reported that they had been given at least one of the *Informed Choice* leaflets before the intervention had taken place (table 2). It is possible that a few *Informed Choice* leaflets were distributed in all the maternity units before the trial. However, most of this reported use probably relates to leaflets other than those under study because women had difficulty in distinguishing the intervention leaflets from other leaflets available in the maternity units.

Discussion

In this randomised controlled trial the use of *Informed Choice* leaflets did not change the proportion of women who reported exercising informed choice, or components or consequences of informed choice, in maternity care. This is surprising as a recent systematic review concluded that decision aids improve knowledge and increase the proportion of people who assume a more active role in decision making.[3]

Limitations in design

Possible limitations of this study are response bias, poor definition of "informed choice," and lack of power. The response rate of 64% may have introduced some bias, with under-representation of non-white women and women with manual occupations in both intervention and control groups.

The question used to measure informed choice may have been insensitive. However, we used two different questions and neither showed change. Although we recruited fewer women than planned, the analysis for postnatal women was adequately powered due to a smaller intraclass correlation coefficient than estimated for the sample size calculation. The analysis for antenatal women had a power of about 65%. However, observed changes were small, and, although low power can explain the lack of significance, it cannot explain the size of the observed effect. Overall, it is unlikely that the study failed to detect any important change.

Table 2 Proportion of women who said they had received any *Informed Choice* leaflet before and after intervention. Figures are numbers (percentage) of women

	Before	After	Change in %
Antenatal			
All	580/1241 (47)	1048/1570 (67)	20
Intervention	266/619 (43)	598/827 (72)	29
Control	314/622 (50)	450/743 (61)	10
Postnatal			
All	760/1741 (44)	977/1547 (63)	19
Intervention	405/922 (44)	665/886 (75)	31
Control	355/819 (43)	312/661 (47)	4

What is already known on this topic

Decision aids can help patients to participate in their care

Ten evidence based leaflets (*Informed Choice*) are used by maternity services in the United Kingdom to promote informed choice in women using these services

What this paper adds

The leaflets did not help to promote informed choice in maternity care

Decision aids may not be effective in the real world

Practicality and quality of implementation

We carried out this trial in everyday practice. We included thousands of women who might have received the 10 leaflets, but only 70% reported receiving one of them. Studies reported in the systematic review of decision aids were explanatory trials, with the implicit assumption that all patients received the intervention.[3] One conclusion might be that the systematic review showed that decision aids can be effective under certain circumstances but that our study showed that they are not necessarily effective in the real world.[7] The pragmatic nature of our design may have affected the outcome, but that outcome represents a true picture of the impact of introducing the leaflets into routine practice.

We thank midwives, managers, and administrative staff in the maternity units in Wales (unnamed to ensure confidentiality of participating units), who worked so hard to help us with data collection. We thank the thousands of women who completed our questionnaires at such an important time in their lives.

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Trends in demand for emergency ambulance services in Wiltshire over nine years: observational study

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Demand for emergency medical services in the United Kingdom is rising.[1] Research into the type of patients transported by emergency ambulances and the severity of their illness has tended to focus on identifying people who use the service inappropriately rather than factors influencing demand, and our understanding of the increase in demand is poor.[2 3]

In Wiltshire, a largely rural county in the south west of England, the number of emergency transports of patients increased from 11 268 in 1988 to 16 814 in 1996, a crude increase of 49%.[4] This increase is often attributed to general practitioners redirecting patients with urgent problems to the ambulance service, particularly out of surgery hours. Over the same period, however, urgent transports booked by general practitioners rather than in response to a 999 call rose from 9982 to 13 951 (40%). We examined the reasons for this rise.

Methods and results

We conducted a retrospective analysis of emergency ambulance despatches using a random sample of records held by Wiltshire Ambulance Service NHS Trust. From each year in nine years' records (1988-96) we sampled 14 days, stratified by season, providing a dataset of 126 days of calls. Data were drawn from AS1 forms (completed by call takers) and from patient report forms (completed by paramedics). We used the system of call classification used by the trust to categorise data on the nature of incidents for analysis. We used indirect age standardisation based on the year with the most complete age data (1994) to account for demographic changes over the nine years (see methodological supplement on bmj.com). We calculated significance of trends with EpiInfo 6.03, using χ^2 for trend.

Our sample contained details of 6100 calls relating to 5821 incidents. For 1225 (21%) of these, patient report forms rather than AS1 forms had been filled in. The table shows the numbers of vehicles despatched, incidents, and patients transported in each year.

A 72% increase in incidents attended over nine years reduced to 53% after standardisation for age. The proportion of incidents in response to a call from a general practitioner, or incidents where one was present, remained fairly constant over the study period, whereas the proportion of calls made by patients and relatives rose from 11.8% to 20.1% (see tables A and B on bmj.com). Calls from other emergency services peaked in 1990. The category showing an increase out of line with that seen overall was "sudden illness at

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Extra tables and a methodological supplement appear on bmj.com