

TITLE PAGE

FULL NAME	Wendy C. Jessiman
QUALIFICATIONS	BSc (Nursing Studies) RM, RN
CURRENT POST	Lecturer in Midwifery Studies
CURRENT PLACE OF WORK	University of Stirling Department of Nursing and Midwifery Highland Campus Old Perth Road Inverness IV2 3FG
ADDRESS FOR CORRESPONDENCE	As above
HOME ADDRESS	15 East MacKenzie Park Inverness IV2 3SR
DAYTIME TELEPHONE NUMBER	01463 704345
EVENING TELEPHONE NUMBER	01463 242327
FAX NUMBER	01463 713471
email address	w.c.jessiman@stir.ac.uk
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## Introduction

Few studies have been published by midwives regarding the lotions and lubricants used in vaginal examination and procedures in labour and in the immediate postnatal period. In this article I review published research and present the findings of my own research conducted in 1993. Although seven years ago it describes a range of practices which are as relevant today as they were then.

Ralph Reis provides an interesting summary of the opinions and practice of doctors in the late 19<sup>th</sup> and early 20<sup>th</sup> century.<sup>1</sup> At this time rectal examinations in labour were favoured over vaginal examinations as there was a concern that puerperal infection could be increased by vaginal examination. Reis reports on a series of 609 women who were examined either vaginally (271) or rectally (106). Women were routinely shaved and 'rinsed externally' with sterile water, no antiseptics or douches were used. By recording temperature and 'evidence of definite pelvic infection' in women, he concluded that there were no differences in infection between the groups. However, he stated that the number of vaginal examinations should be limited and that the rectal examination was quicker and easier.

Since the 1950s a variety of practices for cleansing the perineum have been documented. A mixture of lotions have been used including sterile water<sup>2,3</sup>, soap and water,<sup>4,5</sup> and benzalkonium chloride.<sup>6,7</sup> Various studies have shown the use of sterile<sup>2,3,6,7</sup> and non-sterile gloves.<sup>4,5</sup> The use of lubricants is not mentioned. However comparative studies have shown that although

the rectal examination had been regarded as both quick and easy the vaginal examination could be employed without increasing the risk of puerperal infection.<sup>1-7</sup>

From the middle 1960s rectal examination fell into disuse.<sup>8</sup> However, in the 1980s the rectal examination was still employed in Ireland.<sup>8</sup> In 1986 women were asked to report on the levels of discomfort experienced during vaginal or rectal examination.<sup>8</sup> Twenty eight percent of women who were examined rectally described the examination as very uncomfortable compared with 11 per cent examined vaginally. In this study Hibitane Obstetric cream was used as the lubricant for either examination, however, no antiseptic solutions were used.

The effects of Hibitane Obstetric cream were observed in 15 healthy volunteers in a small non-controlled experiment.<sup>9</sup> It was reported that a “few” suffered from vaginal burning. There has been one other report of mild adverse reaction to chlorhexidine containing products used for vaginal examination or vaginal douche.<sup>10</sup> In a randomised controlled trial Burman et al used chlorhexidine lotions in a vaginal douche to examine transmission rates of group B streptococci from mother to baby.<sup>10</sup> Two women (from a total of 2238) experienced “slight vaginal stinging” after two douches and one woman reported “local irritation” for two hours after five douches, so called transient vaginal reactions. Others have reported on delayed and severe reactions to chlorhexidine and cetrimide.<sup>11-13</sup>

Vulval cleansing and the use of lubricants prior to vaginal examinations and procedures is a routine practice, occurring as often as four to six times during the course of each

labour. If this is extrapolated to the whole of the United Kingdom as many as three million cleansing procedures are conducted each year. Since no published studies had demonstrated what was being used by midwives, in 1993 I conducted a telephone survey to identify the lotions and lubricants used by midwives in practice in the UK.

### Telephone survey

Study populations as diverse as elderly patients,<sup>14</sup> intensive care beds<sup>15</sup> and pregnant women<sup>16</sup> have been subject to the telephone survey technique. This survey technique has been found to be effective in obtaining information.<sup>14-16</sup> Similarly, given the geographical dispersion of the sample, the specialised nature of the respondents, and the limited time, the telephone survey was identified as the method of choice to fulfil the purpose of this research.<sup>17</sup> However, obtaining current telephone numbers can take time and respondents may be unwilling to speak on the telephone until they have satisfied themselves of the identity and legitimacy of the researcher.

The purpose of this telephone survey was to gather information on current practice in maternity units in the United Kingdom in relation to the lubricants and lotions used for vaginal examinations and procedures in labour and the immediate postnatal period. Funding for the survey was provided by a Research Scheme set up by Oxford Regional Health Authority and Oxfordshire Health Authority District Research Committee.

Ethics Committee approval was granted by the Central Oxford Research Committee and the University of Reading Ethics Committee.

## Methods

No definitive list of maternity units in the UK was available from the Department of Health, therefore the sampling frame, was constructed using the four sources listed below:

Institute of Manpower Studies;

Royal College of Obstetricians and Gynaecologists;

Royal College of Midwives England, Wales, Scotland and Northern Ireland;

Hospital and Health Services Year Book.

For the purpose of the survey, maternity units were those identified as having maternity beds. This yielded a total of 373 maternity units which included midwife, consultant, General Practitioner (GP) led units, and integrated units. Following consideration of the purpose of this survey and the resources available, a random sample of fifty units was chosen from this list using computer generated random numbers. Units were stratified into either Consultant/Integrated units or General Practitioner/Midwife led units. Thirty five units were chosen from the first category and 15 from the second. This strategy was adopted to ensure that the 50 randomly selected units would represent the different type of units within the countries, not all 373 could be contacted due to time constraints. The

midwife in charge of the labour suite at the time of the telephone call would be asked to complete the questionnaire.

## Pilot

Following critical comment by a panel of experts the questionnaire was revised six times prior to administration at the pilot stage. One maternity unit was randomly selected from the 323 remaining units (50 selected at random for the survey) and three midwives were telephoned and asked for their co-operation during the piloting of the questionnaire. Amendments were subsequently made to the questionnaire. These included writing down all that would be said and ensuring that there was repetition of key phrases in questions.

## The Questionnaire

The questionnaire included an introductory message giving information to the midwife regarding the researchers credibility and the purpose of the survey and an assurance of anonymity that neither the midwife nor the unit would be identified. Midwives were asked questions concerning:

- lotions and lubricants
- gloves and sterile packs
- changes in practice
- suturing
- episiotomy
- maternal and fetal infection

- speculum examination
- their own choice of lotion or
- written policies/verbal directives (agreed lubricant common policy)

An example of the questions:

- Has there been a change in practice with regard to the lotions and lubricants used for vaginal examinations in labour in the last year?
- Does your unit have an written policy at present which states whether sterile or non-sterile gloves are to be used to conduct vaginal examinations in labour ?
- What lotions and lubricants would you use prior to episiotomy ?

Using a Royal College of Midwives mailing list Heads of Midwifery were contacted prior to the data collection period and advised of the forthcoming survey and the possible involvement of midwives in their area.

Conducting the telephone survey

The telephone survey was conducted over a period of three months each questionnaire took three to five minutes to complete depending on the midwife. All midwives were interviewed by myself. Telephone calls were made at a time when telephone call charges were cheaper. In practice this meant weekday evenings after 6pm and at weekends. If the time was inconvenient, permission was sought to telephone again.

Forty two questionnaires were completed in the first telephone call (84%). A total of eight units required a “call-back”. The reasons for this are illustrated in table 1

Insert Table 1

In spite of the fact that Heads of Midwifery were contacted regarding the impending survey only four midwives (8%) said they had “heard something” about a survey from their line manager. Nevertheless the majority of midwives were enthusiastic and co-operative. Once assured of the researcher’s identity no midwife refused to be interviewed.

The questionnaire was completed by one midwife in each of the fifty units surveyed. Generally respondents were able to answer all questions relating to the lotions and lubricants they used. There were occasions when respondents went to check precise constituents of lotions that they used. The telephone survey method allowed for this. Supplementary information was also offered by a number of midwives, examples of this are included in the results

## Results

A summary of the lotions used in the fifty units sampled is displayed in table 2. Antiseptic lotions were used in 80% (40) of the units. These included :cetrimide, Chlorasept, Hibidil, Travasept, Savlon and Savlodil. Only two lubricants were used Hibitane Obstetric cream or a lubricating jelly; Clinijel, KY jelly or Aquagel.



Insert table 2 here

Eight units reported a change in policy in the 12 months prior to the survey (see table 3). Only half of the midwives (4) knew the reason for the change.

Insert table 3 here

In 46 of the units (92%) antiseptic lotions were kept either in warming cabinets or warm water was used to reconstitute the solution. Four units (8%) kept lotions at room temperature. Of the 50 units surveyed, 28 (56%) had written policies regarding the lotions used to cleanse the vulva prior to vaginal examination. The remainder had no written policy but a verbal directive (agreed common policy) which guided practice.

In response to the question “what lotion would you use ?” all midwives said if vulval cleansing were necessary they would use the policy/directive preparation. Not all midwives used these preparations routinely however and one midwife responded that if a women was “allergic” to Salvodil in her unit, sterile normal saline would be used.

### Lubricants

Midwives used either Hibitane Obstetric cream or a lubricant jelly however only 22 units had a written policy relating to lubricants. Generally all midwives responded with a choice of lubricant, lubricating jelly or Hibitane Obstetric cream, one midwife used

Hibitane Obstetric cream alone. When asked what they would choose as a lubricant, nine midwives said they would use Hibitane Obstetric cream. Three midwives added that they would use a jelly lubricant when prostaglandin preparations were inserted vaginally (the question related to the use of lubricants in labour). However, 21 out of 50 midwives stated both lubricants were available as there was a need to be alert to women who might be “allergic” to Hibitane Obstetric cream. This compares with only two out of 41 units which offered an alternative to an antiseptic lotion if any sensitivity was suspected.

#### Gloves

Overall, sterile gloves were used for vaginal examinations in labour with only five exceptions (4 consultant unit and 1 General Practitioner unit). In these five units, non-sterile gloves were used if the membranes were intact, if the membranes had ruptured sterile gloves were used. Ninety per cent of the sample used sterile gloves regardless of the status of the membranes. Thirty two units had a written policy concerning the type of glove to be used.

#### Sterile vaginal examination packs

Two specific clinical situations were outlined; speculum examination at any time, and vaginal examination in labour with known or suspected maternal or fetal infection. Midwives were asked whether they used sterile packs in these instances. Practice did vary (see table 4). Thirty midwives reported that the unit had a written policy which

stated sterile examinations packs must be used, and in 20 units a similar directive guided practice.

Insert table 4 here

### Speculum examination

Five midwives responded that speculum examination was not performed in their units. In all other units sterile gloves were used when conducting this examination. In eight units a lotion not previously identified was used: five used sterile water and three tap water or chlorhexidine.

### Suspected maternal /fetal infection

In cases where there was a known or suspected maternal or fetal infection all midwives used sterile gloves, most used a sterile pack (three midwives said this was not always necessary), only one change of lotion occurred in this situation, a change from the previously used tap water to sterile water.

### Fetal blood sampling

Twenty one units carried out fetal blood sampling (FBS), and the same lotions and lubricants were used for FBS as for vaginal examination when fetal/maternal infection was present in fifteen of the units. There were six exceptions. One unit gave a choice

where one had not existed before, tap water or sterile normal saline. Two changed from tap water to a chlorhexidine solution, two from Hibitane Obstetric cream to lubricating and one midwife did not know what was used in the unit.

#### Lotions used prior to episiotomy and suturing

Of the fifty units surveyed, one midwife reported that the unit did not perform episiotomies. In all but two units the lotion used prior to episiotomy was also used prior to suturing. Two units used tap water prior to episiotomy, however prior to suturing one changed to an antiseptic lotion and the other to sterile normal saline. The lotions used are given in tables 5 and 6.

Insert tables 5 and 6 here

#### Limitations of the survey

The greatest limitation of the survey is the sample size. Only 13% of the maternity units were included and one midwife from each unit completed the questionnaire. However it provides a useful insight into policies and practices. The survey was conducted in 1993 and practice may have changed since this time. However, this 1993 survey was concerned with a wider range of midwifery practices and arguably provides a foundation for work that will be needed to satisfy demands for evidence-based practice.

#### Discussion

The survey identified and described a variety of lotions and lubricants used in midwifery practice. Twelve per cent of units sampled used tap water exclusively for cleansing the vulva prior to vaginal examination in labour. The use of Infacare and ordinary soap and water had not been anticipated. However at the time of the survey two out of eight units identified research conducted in or near to their unit as a reason for a change in practice. Unfortunately none of this research was published.

#### Midwife preferences

Midwives when asked what they would choose to use, used those lotions and lubricants made available to them in the clinical area, only one midwife said she would use a jelly lubricant in preference to Hibitane Obstetric cream. It is interesting to note that only three midwives said they would use jelly preparations if administering vaginal prostaglandin despite evidence to show that Hibitane Obstetric cream should not be used in conjunction with prostaglandin preparations.<sup>18,19</sup>

When the units preferred lotion or lubricant changed from one clinical situation to another, the survey tool was not designed to ask why. This information would have informed the survey, nevertheless it is clear that a great deal of variation existed in practice and between units. Are midwives questioning their practice?

#### The choice of sterile or non-sterile gloves

Only 10 per cent of midwives stated they would use non-sterile gloves in labour if the membranes were intact. Clearly there are cost implications involved in the choice of glove. Midwives, obstetricians and bacteriologists may not agree on the type of gloves used. However, if all practitioners are basing their choice of gloves on the same evidence why is there a variation in practice?

#### Sensitivity to chlorhexidine/cetrimide containing preparations

Forty two percent of midwives responding on behalf of their unit, considered possible adverse reactions (“sensitive”/ “allergic”) to Hibitane Cream as a lubricant and gave an alternative lubricating jelly. As previously stated only two per cent of midwives recognised women may be sensitive to chlorhexidine/cetrimide containing lotions. At the time of the survey Hibitane Obstetric cream was manufactured by ICI Pharmaceuticals. The bottle gave information regarding the use of the product which included a caution advising the practitioner that it should not be used in cases of known sensitivity to chlorhexidine. Zeneca (formerly ICI Pharmaceuticals), who now manufacture Hibitane Obstetric cream, do advise that the cream should not be used when there is a known hypersensitivity to chlorhexidine preparations. However, these reactions are rare. Nevertheless, midwives appear to report the need for alternative lubricants due to the likelihood of sensitivity, as a matter of routine. Midwives may have witnessed in practice what is in the literature at least, a very rare event.

#### Recent published research

In 1996<sup>20</sup> and 1998<sup>21</sup> two published experimental studies considered the effectiveness of lotions used to cleanse the perineum. These studies used antiseptic lotions or tap water to cleanse the perineum. Additionally, one used KY jelly as a lubricant during the trial period<sup>20</sup> and the other used a “vaginal chlorhexidine cream”.<sup>21</sup> The trials also differed in how consent was obtained, the outcome measures, and the duration of the data collection period.<sup>20,21</sup> Both studies concluded that antiseptic lotions did not reduce infection rates in mothers and babies. However these results are not generalisable since in one study<sup>21</sup> the lotion/lubricant groups were determined not solely by random allocation and in the other<sup>20</sup> the sample size was too small. There are other policies, procedures and individual practices which may affect the outcomes. For example the technique used to cleanse the vulva, whether cleansing of the vulva is performed prior to examination, performing a vaginal douche with an antiseptic solution, or the use of chlorhexidine based lubricants.

A quasi-experimental study in Malawi reported in two journals in 1996 and 1997 respectively<sup>22,23</sup> to assess the effect of chlorhexidine solution on the transmission of HIV (human deficiency virus) from mother to baby and maternal and newborn mortality and morbidity, employed a standardised form of cleansing the vulva and vagina.<sup>22,23</sup> The findings suggested that HIV transmission was not affected by the use of the antiseptic preparation, but that neonatal and maternal morbidity as a result of bacterial infections, was reduced.

Only one of the most recent studies was informed by survey data<sup>20</sup>. Prior to the experimental study Sheelagh Calkin randomly selected forty maternity units in the

United Kingdom and asked for details of their policy regarding ‘vaginal swabbing’.<sup>20</sup> The sample included teaching hospitals with over 4000 deliveries a year and rural units with less than 1,000 deliveries a year. From her published paper it is unclear why and how the survey was conducted and how the sample was selected, which raises major questions about the significance of the findings. Nevertheless, it was reported that all units included in the study used a chlorhexidine solution.<sup>20</sup> No unit used tap water. Calkin also reported the results of a randomised controlled trial which compared the use of chlorhexidine and tap water, which concluded that there was no difference in the rate of neonatal and maternal infection when tap water was used to cleanse the vulva.<sup>20</sup>

## Conclusion

To date a range of practice has been demonstrated by the survey in 1993 and latterly by Calkin in 1996. In 1993 tap water was being used by midwives as an alternative to antiseptic lotions. This survey identified the complexities associated with the choice of lotion and lubricant, practice issues that have not been addressed in other published work.

Despite publications since 1993 there is a lack of evidence on which to base midwifery practice. The Cochrane Controlled Trials Register<sup>24</sup> includes information regarding a number of experimental studies which have examined the effect of the use of chlorhexidine cleansing on neonatal infection and to a lesser extent maternal infection. .. However, there is no overwhelming evidence which would guide practice. There has been a call to conduct a large multicentre randomised trial of cleansing in labour to



confirm the effectiveness of the use of antiseptics, and one to complete a systematic review of published work to date.<sup>24,25</sup> Both are required to guide future research initiatives. We do not know what the range of practices are today.

Recent published midwifery research is beginning to question the routine use of antiseptic lotions and lubricants.<sup>20,21</sup> For some time now women have chosen to labour and give birth to their babies in water, contrast this if you will with the same woman who gives birth on land, where antiseptic lotions and lubricants may be used. Are these products really necessary? The evidence to date is contradictory and requires to be reviewed.

The findings of this review suggest that;

1. a variety of lotions are in use and are used in different ways. There is no standard lotion or lubricant in use.
2. variations in practice exist which highlights the need for research into what is effective in practice to ensure optimal comfort and clinical outcome for mother and fetus/baby.
3. midwives choice of product may be influenced by what is provided within the unit.

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Table 1: Call-backs

Reason for call-back	No of units
midwife too busy on the first or subsequent calls	5
wished to verify identity of interviewer and requested a letter be sent to local supervisor of midwives	2
no midwife present	1
Total	8

Table 2 : Lotions used

Lotion Used	Number of Units
Antiseptic Solution [containing chlorhexidine/cetrimide]	40
Tap water (exclusive)	6
Antiseptic solution or tap water	1
Soap and water	1
Infacare and water	1
Sterile normal saline	1
Total	50

Table 3 : Reasons for Changes in practice

Reason for change	from	to	“Type” of Unit
Research	Milton 1:40	Tap water	Integrated
Research	Savlon	Tap water	G.P.
Not Known	Tisept	Sterile N/Saline	Consultant
Not Known	Chlorhexidine 1 litre bottles	Chlorhexidine 100 ml sachets	Consultant
Microbiologist	Routine use Hibitane Obstetric cream	Restricted Use	Consultant
Not Known	Chlorhexidine	Tap Water	Consultant
Not Known	Savlon	Tap Water	G.P.
Financial	Savlon	Tap water	G.P.

Table 4: Adherence to written policies and directives when using sterile packs.

Reason for deviation from policy/directive	Number of Midwives n=9
“only use pack if spontaneous rupture of membranes or performing an amniotomy”	3
“only use a pack where I feel it is necessary”	1
“only use a glove (not a pack) if the membranes are intact”	1
“ I don’t use packs”	1
“ would not choose to use a pack routinely”	2
“ if it is a quick ve (vaginal examination) would not use pack”	1



Table 5: Lotions used Prior to Episiotomy

Prior to Episiotomy	Number of units
Soap and water	1
Sterile normal saline	1
Tap water	5
Antiseptic lotions	42
Total	49

(1 unit did not perform episiotomies)

Table 6: Lotions used Prior to Suturing

Prior to Suturing	Number of units
Infacare and water	1
Sterile normal saline	2
Soap and water	1
Tap water	3
Antiseptic lotions	43
Total	50