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SID 5 Research Project Final Report

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Project identification

1. Defra Project code: 0F 0186
2. Project title: The use of homeopathic nosodes in the prevention of mastitis within organic dairy herds
3. Contractor organisation(s): University of Bristol
4. Total Defra project costs: £ 259,202
5. Project: start date .... 01 February 2002
   end date .... 01 April 2005

6. It is Defra's intention to publish this form.
Please confirm your agreement to do so. .... **YES** ☒ **NO** ☐

(a) When preparing SID 5s contractors should bear in mind that Defra intends that they be made public. They should be written in a clear and concise manner and represent a full account of the research project which someone not closely associated with the project can follow.
Defra recognises that in a small minority of cases there may be information, such as intellectual property or commercially confidential data, used in or generated by the research project, which should not be disclosed. In these cases, such information should be detailed in a separate annex (not to be published) so that the SID 5 can be placed in the public domain. Where it is impossible to complete the Final Report without including references to any sensitive or confidential data, the information should be included and section (b) completed. NB: only in exceptional circumstances will Defra expect contractors to give a "No" answer.
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(b) If you have answered NO, please explain why the Final report should not be released into public domain

Executive Summary

7. The executive summary must not exceed 2 sides in total of A4 and should be understandable to the intelligent non-scientist. It should cover the main objectives, methods and findings of the research, together with any other significant events and options for new work.

Mastitis is the most significant disease affecting the health, welfare and economic productivity of dairy cattle and is recognised by Defra as a major economic and welfare concern. Research into the efficacy of homeopathic treatments and of management control of mastitis on organic dairy farms have both been identified as research priorities in recent Defra funded reviews of organic dairy farming. This study examined the use of a specific mode of homeopathic treatment in the prevention of mastitis and quantified the effect that the year-round, prophylactic use of nosodes, supplied to the cattle in the drinking water, had on the number of clinical cases of mastitis on somatic cell counts within herds.

Context and background

Organic dairy farming is a significant industry with milk being the largest single organic product in the UK. Organic milk is produced to defined standards which meet the Advisory Committee on Organic Standards (ACOS) criteria. These standards *'emphasise animal welfare and, by avoiding artificial fertilisers, pesticides and other non-natural chemicals, and prohibiting the routine use of antibiotics and other conventional drugs, also ensure care for the environment, and promote the highest standards of food quality and safety'* (Omsco 2005). As part of the management of organic dairy cattle with reduced use of conventional pharmaceutical treatments, many organic farmers use homeopathic and other complementary therapies on their animals.

Mastitis is recognised as the main animal health problem in organic milk production systems (Bennedsgaard *et al* 2003). Whilst mastitis levels appear to be similar to those found in conventional production (Hovi and Roderick, 2000) specific problem areas in mastitis control under organic management standards have been identified.

One of the overall goals of organic animal husbandry is to avoid disease through management, husbandry, breeding and feeding. According to the EC-Regulation No. 1804/1999 governing organic livestock production, animal health management should be based on disease prevention. However, the preventive use of chemically synthesised allopathic medicinal products like dry cow antibiotics is not permitted. In organic units, phytotherapeutic and homeopathic products and trace elements are to be used in preference to antibiotic and prolonged withdrawal periods need to be observed after conventional medicine use. As a consequence of these requirements, organic dairy farmers look for alternatives to conventional therapy and prophylaxis (Hektoen 2004).

Homeopathy is widely used for the treatment of mastitis within UK organic dairy herds and prophylactic use of homeopathic nosodes, either continuously or just during housing, is practised on many organic dairy farms and is thought to offer general protection against mastitis and to reduce somatic cell counts (SCC). Research into the effectiveness of homeopathic treatments was one of the most important research requirements identified in a recent MAFF review of animal health within organic herds (Hovi & Roderick 1999).

The range of homeopathic treatments used on farm today is wide, with treatment practices either focussing on the needs of the individual animal, which is known as constitutional treatment and which employs individual remedies, or aimed at groups of animals using specific remedies, or 'nosodes', which are considered to be a very specific form of homeopathy - isopathy (*iso* - all the same, *pathy* – treatment/exposure). Unlike specific remedies, nosodes do not account for the individual needs of each animal, but create the potential for protective treatment for a herd or group, they are generally applied in drinking water, and may be used on individual animals, usually by vulval spray.

Benefit for the sector and for Defra

Mastitis is the most significant disease affecting the health, welfare and economic productivity of dairy cattle, and management and control of mastitis is an important facet of practical dairy herd management. Mastitis is recognised by Defra as a major economic and welfare problem in dairy cattle. Research into the efficacy of homeopathic treatments and of management control of mastitis on organic dairy farms have both been identified as research priorities in recent Defra funded reviews of organic dairy farming.

The Study

Ninety-six farms participated in a double-blind trial to compare a homeopathic nosode and an inactive control treatment (carrier alone). Treatments were at the farm level and took place over a period of 12 months or 24 months (some farms were swapped to the opposite treatment during a second year). The treatments were randomised to each farm by a third party. During the trial, where available, records were collected of farm monthly bulk tank somatic cell count (BMSSC), a monthly cell count based on National Milk Recording data (NMR) and the annual number of cases of mastitis as recorded by the farmer. Additional farm level data were collected and their relationship to the level of mastitis on the farms investigated.

Objectives of the Study

The study described in this report explores the use of a specific mode of homeopathic treatment, a nosode, in the prevention of mastitis and quantifies the effect that the year-round, prophylactic use of nosodes, supplied to the cattle in the drinking water, had in reducing the number of clinical cases of mastitis and also quantifying any effect that the use of a nosode has on somatic cell counts within herds.

- To quantify the effectiveness of the prophylactic use of homeopathic nosodes for the treatment of mastitis in reducing the incidence of clinical mastitis and the concentration of somatic cells in milk.
- To survey management practices on organically managed farms.
- To investigate associations between the homeopathic treatment, farm management practice and the incidence of different types of mastitis and to provide guidance for mastitis control in organic dairy herds.

Materials and methods

In testing the efficacy of a homeopathic nosode it was determined that the study should:

- Look at a nosode already being commonly used and commercially available.
- Not ask for new recording systems to be used for data collection but to use the existing systems which are in place.
- Not interfere in the 'normal' practises carried out by the farms, by, for example, repeated prompting of farmers to carry out treatments, or ask them to adopt prescribed ways for describing, recording or treating mastitis.

There are three commonly used measures of the udder health of milking cows:

a) The bulk tank milk somatic cell count (BMSCC, commonly referred to as SCC) gives a count (in 000's cells / ml) of white cells and desquamated cells shed by the udder. The BMSCC is not an accurate indicator for the presence of clinical mastitis, but may give information on sub-clinical (undetected) mastitis.

b) Somatic cell counts for individual cows from farms which subscribe to commercial milk recording services (ICSCC).
c) The number of cases of mastitis. The incidence rate for clinical mastitis (IRCM) is the number of distinct cases of mastitis in 100 cows in a year.

The response variables that were measured were:

- Farmers' own record of mastitis cases.
- Bulk milk SCC.
- Individual cow somatic cell records (ICSCC) if the farms were on a milk recording service.
- Farmer's opinion of his/her success in controlling mastitis.
- A large number of variables, recorded using a questionnaire at the farm visits, which could influence mastitis and the effectiveness of the treatment.

After visiting a number of homeopathic pharmacies, an agreement was made with Crossgates homeopathic pharmacy[1], and Freemans Homeopathic Pharmacy[2] (Appendix D) to make the individual herd specific nosode remedies for the farms. The trial was double-blinded, with blinding carried out by the creation of a randomly generated list of A and B's. As each new farm was recruited, it was allocated to the next A or B in the sequence, the farms being allocated to either nosode treatment or control, one by one, in chronological order.

Articles were written in the organic press, Organic Farming, and The Turning Worm, inviting farms to take part in the study. It was clear that farms should only join the study voluntarily and would not be 'cold called' or pressurised to join. One hundred and four farms responded to the call, and 96 of these farms went on to take part in the study. The 8 farms which declined to take part either went out of milk production before the study started, or changed their minds about inclusion in the trial before the start of the study. The 96 farms were visited and the study introduced. Farmers were issued with a kit to collect milk from high cell count cows for preparation as a nosode. An 80 part questionnaire (Appendix A) was used to gather the information needed to understand the possible factors that may influence mastitis. During visits the farmers were also asked whether they were willing to fill in a self assessment of their personality type.

Number of farms recruited	= 96
Total farms completing the study period	= 88
Number of farm years followed	= 206
Average herd size	= 101 cows
Number of cows followed in the study	= 9,680
Number of cows receiving remedy (R)	= 4,734
Number of cows receiving control (P)	= 4,946
Total cow years followed	= 21,580 cow years (Some farms two years, some 3 years)
Farms lost during study	= 8 (due to sale of the herd, or going out of milk production and into, for example, heifer rearing)

Results

The data collected were subject to a number of different analyses:-
1. A test for an effect of the homeopathic nosode in reducing the cell count in milk.
2. A test for an effect of the homeopathic nosode in reducing the annual cases of mastitis.
3. An analysis to identify risk factors associated with increased cell count in milk.
4. An analysis to identify risk factors associated with higher levels of mastitis.

No effect of nosode in reducing either the incidence of cases of mastitis or the somatic cell counts in the milk were detected.

The following risk factors were found to be associated with composite cell counts:-
- A decrease in cell count with increased culling of high cell count cows
- A decrease in cell count for farms which use complementary therapies on dry cows
- A decrease in cell count for farms which use dry cow therapy, including teat sealants, on dry cows
- An increased cell count for farms which did not pre-wipe before milking or pre-wiped the teats with a cloth before milking
- An increase in cell count for farms which pre-wipe only the udders of cows which are visibly dirty before milking

The following risk factors were found to be associated with the number of cases of mastitis:-

- Increasing herd yield is associated with increased mastitis case numbers
- Increased calving of cows indoors in a calving box was associated with increased numbers of mastitis cases
- Use of an in line clot filer was associated with reduced numbers of mastitis cases
- Having an abreast parlour (as opposed to a herringbone or rotary parlour) was associated with a reduced numbers of mastitis cases

The extent to which the objectives set have been achieved

The effectiveness of homeopathic nosodes in treating mastitis and lowering cell count is quantified and described (Objective 1) and the survey results of management practices on organically managed dairy farms are described (Objective 2). Additionally, the associations between homeopathic treatment, farm management practices, mastitis incidence and cell count are quantified (Objective 4) and management controls which show a reduction in mastitis cases or cell counts are identified as risk factors and described in the report (Objective 5).

Conclusions

- There was no significant effect of the herd specific nosode on either the cell count of milk or the number of cases of mastitis.
- That there were strong 'within farm' correlations of cell count and cases i.e. between farms, farms tend to stay at the same level of cases and average cell count from year to year.
- That there was a characteristic pattern of seasonal change in cell counts (this is already widely recognised).
- The study provides useful and interesting statistics on organic dairy farm production.
- The study identified an association between decreased cell count and culling for high cell count, the use of complementary dry cow therapy and the use of traditional dry cow therapy.
- The study identified an association between increased cell count and not pre-wiping the udder, pre-wiping using a cloth and only pre-wiping dirty cows.
- The study identified an association between higher numbers of mastitis cases and higher average yield and also with higher percentage of cows calving in a calving box.
- An association was identified between decreased numbers of mastitis cases and the use of an in-line clot filter and also with farms with an abreast parlour (rather than a herring-bone parlour).
- Eighty five per cent of farmers in the survey responded that they did believe in non-conventional remedies, and 62 per cent of farmers responded that they used non-conventional remedies on their own family.

Project Report to Defra

8. As a guide this report should be no longer than 20 sides of A4. This report is to provide Defra with details of the outputs of the research project for internal purposes; to meet the terms of the contract; and to allow Defra to publish details of the outputs to meet Environmental Information Regulation or Freedom of Information obligations. This short report to Defra does not preclude contractors from also seeking to publish a full, formal scientific report/paper in an appropriate scientific or other journal/publication. Indeed, Defra actively encourages such publications as part of the contract terms. The report to Defra should include:

- the scientific objectives as set out in the contract;
- the extent to which the objectives set out in the contract have been met;
- details of methods used and the results obtained, including statistical analysis (if appropriate);
- a discussion of the results and their reliability;
- the main implications of the findings;
- possible future work; and
- any action resulting from the research (e.g. IP, Knowledge Transfer).

The Ojectives as set out in CSG7

01 To quantify the effectiveness of the prophylactic use of homeopathic nosodes for the treatment of mastitis in reducing the incidence of clinical mastitis and the concentration of somatic cells in milk.

02 To survey management practices on organically managed farms.

03* To provide information of the causal agents of mastitis found in organically managed herds for use in this project and for use by other workers in the field.

04 Using the data from Objectives 02 and 03*, to investigate associations between the homeopathic treatment, farm management practice and the incidence of different types of mastitis.

05 To provide a standard protocol on management and target setting for mastitis control in organic dairy herds based on the data obtained from the study.

The Extent to which these objectives have been met

Objectives 01 has been met and the results are described below. The effectiveness of homeopathic nosodes in treating mastitis and lowering cell count is quantified.

Objective 02 has been met and the survey results of management practices on organically managed dairy farms are described below.

The asterisked, optional Objective 03 in the proposal was not taken up by Defra.

Objective 04 has been met and the results are described below. The associations between homeopathic treatment, farm management practices, mastitis incidence and cell count are quantified.

Objective 05 A number of risk factors have been identified in this study. In liaison with Defra, guidance on management and target setting for organic dairy farmers, based on these risk factors, could be made available in a form for the internet and for distribution. The risk factors identified are very much in line with present recommendations for dairy farms in general (see the Introduction, below, which outlines the 'Five Point Plan').

Further Work

In view of the current interest in sustainable farming issues particularly in the improvement of animal health and welfare in sustainable systems, development and improvement of sustainable livestock husbandry systems and improved environmental management of livestock systems, the risk factors identified in this study, in conjunction with other potential risk factors in organic dairy production, merit further study by means of controlled experimental trials.

Actions resulting from the work

With Defra's permission we would wish to publish the findings of this study in the relevant scientific and industry journals.
With Defra's permission we would like to send an abstracted form of this report to the farmers who contributed to the study.

Report - The use of homeopathic nosodes in the prevention of mastitis within organic dairy herds DEFRA OF 0186

INTRODUCTION

The use of homeopathic remedies was first outlined by Hippocrates (400 BC) and developed into the forms recognised today by a German doctor Friedrich Samuel Hahnemann (1755 – 1843). Hahnemann first experimented with cinchona bark (quinine) and found that 'Like cures like'. Homeopathic treatments have been widely used in animals since Hahnemann, and, in dairy cattle, are used by many farmers as a part of their efforts to control mastitis, which, (alongside lameness and foot problems), is a very significant animal disease and welfare problem as well as a cause of lost productivity.

In general, the 'udder health' of the UK national dairy herd (both conventional and organic) has improved dramatically over the last 20 years. In 1986, the average Bulk Milk Somatic Cell Count (BMSCC) was 352 ('000 cells/ml). By 2000, the average had been brought down to 165 ('000 cells/ml) by a combination of pressure from milk purchasers for improved quality in the product they purchased, control measures such as the NIRD - Five Point Plan (Hygienic teat management - combined with sound housing management, Prompt treatment of clinical mastitis, Dry cow therapy, Culling chronically affected cows, Correct maintenance of the milking machine). The average incidence rate for clinical mastitis (IRCM) in the UK is, between 38 cases/100 cows/yr (Berry, 1998) and 43 cases per 100 cows/yr (Kossaibati, 1998).

Changes in the genetic 'type' of cow, and concentration on control of specific mastitis causing organisms including *Staph aureus, Strep Uberis, Strep dysgalactiae, Strep agalactiae* and coagulase negative Staphylococci, and, less commonly *Corynebacterium bovis* have also contributed to this reduction in the National BMSCC. The benefits of reducing the cell count of milk are that this may reduce cross infection between cows at milking and hence reduce the incidence of clinical mastitis, may improve the quality and food safety of milk, and also maximises the price through bonuses or penalties paid on the basis of somatic cell count. There is a well established relationship between the time of year and average BMSCC's, and older cows tend toward higher cell counts (and so herds with a higher proportion of older cows tend toward higher BMSCC's. There is also a difference in the average BMSCC between the morning milking and the evening milking in many herds.

When dairy farms convert to organic production, they are encouraged;

'*to sustain animals in good health by the adoption of effective management practices, including high standards for animal welfare, appropriate diets and good stockmanship'* (Soil Association Standards)

and to reduce the use of conventional (allopathic) pharmaceutical veterinary treatments, as much as is possible, without compromising the welfare of their animals. There is significant pressure from the WHO (World Health Organisation) to reduce the use of prophylactic antibiotics in food producing animals, and, in the future it is likely that dairy farmers will increasingly be required to justify the use of both milking cow and dry cow antibiotics.

In organically farmed dairy cows, management practices which are promoted (permitted or recommended) in organic standards to control mastitis include;

- Recommended - Frequent stripping, cold water treatments, licensed herbal udder creams
- Permitted – Homeopathic treatments including nosodes for prevention and *Antibiotics – in clinical cases where no other remedy would be effective.*

On many farms, udder liniments are very commonly used, cold water washing and repeated stripping is sometimes used by some farms to treat individual cases of clinical mastitis, and some farms use homoeopathic remedies to treat individual cases of mastitis, nosodes to prevent mastitis, and much less commonly, herbal remedies for treating mastitis in individual animals. Almost all farms do have to use allopathic treatments (intra-mammary antibiotics, parenteral antibiotics and anti-inflammatory agents) on occasion to treat individual sick animals, and this is permitted within the organic standards to ensure that the welfare of animals is not threatened if conventional treatments appear to the most appropriate route to a cure.

The range of homeopathic treatments used on farm today is wide, with treatment practices either focussing on the needs of the individual animal (which is known as constitutional treatment), using individual remedies tailored to each animals needs. Sometimes groups of animals are treated using specific remedies or nosodes. Sometimes the treatments are given with advice from a homeopathic vet or a homeopathic pharmacy, and sometimes the treatments are given after the farmer has researched their use from guides, books or *materia medica*. Some farmers become very proficient in choosing and using remedies, whilst others use the information provided in guides and do not progress to a 'complex' understanding of the use of these remedies.

There are three commonly used measures of the udder health of milking cows.

a) The bulk milk somatic cell count (BMSCC, commonly referred to as SCC) gives a count (in 000's cells / ml) of white cells and desquamated cells shed by the udder. If the udder is not under challenge by mastitis causing organisms, then a low but constant population of cells are shed and the SCC will be low. Young animals also have a lower mean SCC than older animals. However, with inflammation, disease (mastitis), or immediately post calving, the SCC is raised. Milk from the bulk tank is sampled routinely by the milk purchaser as part of their quality assessment procedures, and also as a basis for quality payments to the farmer. This bulk milk somatic cell count (BMSCC) information is of some value to the farmer in monitoring the udder health of his cows. However, because farmers usually remove the milk of individual high cell count cows (either by not milking them, or by diverting the milk from these cows to waste, or to feed calves), the BMSCC is not an accurate indicator for the presence of clinical mastitis, but may give information on subclinical (undetected) mastitis.
b) Somatic cell counts for individual cows for farms which subscribe to commercial milk recording services (ICSCC).
c) The number of cases of mastitis. The incidence rate for clinical mastitis (IRCM) is the number of distinct cases of mastitis in 100 cows in a year.

Farmers use a variety of recording systems for the incidence of disease, including mastitis, and do not have uniform recording systems for disease incidence or for the success or failure of their treatments. Some very effective computerised systems do exist, such as Interherd™, which can provide detailed information on a number of herd measures, including mastitis. These rely on the farmer subscription to a recording programme such as the National Milk recording scheme which provides management information on individual cow's performance in terms of milk parameters, including individual cow cell counts, yield and fertility.

Farmers who are not on recording schemes for individual cell count can use methods such as stripping on to the floor or into a strip cup (visual examination of raw milk), the California milk test (CMT) which causes visible agglutination of somatic cells, milk conductivity testers, or in line clot filters, to detect mastitic milk. If they are able to detect them, most farms keep the milk of high cell count cows out of the bulk tank to control their BMSCC. For farms which can identify the cell counts of individual cows through milk recording, this information, along with the incidence rate for clinical mastitis for the cow is used as a factor when deciding whether to keep the cow in the milking herd, or to cull it. There has also been a certain amount of selection of breeds of dairy cows with a reputation for low mastitis incidence, for example Swedish Red or British Holstein.

What is a nosode?

Nosodes are considered to be a very specific form of homeopathy - isopathy
(*iso* - all the same, *pathy* – treatment/exposure)

Like other homeopathic remedies, a nosode follows the principle of 'like curing like'. Nosodes are usually used to treat groups of animals, and a mastitis nosode uses milk collected from high cell count animals of the herd to be treated, along with a general sample from healthy herd members. Some established nosodes can be bought 'off the shelf' i.e. they are not created from the milk of the cows they will treat, but are made originally from the milk of another herd of cows (such as Ainsworths Udder Care & Udder Health). Relative to dry cow or blanket antibiotic therapy, the use of a nosode is usually less expensive, however, nosode remedies can cost significant amounts (up to £400 per year for a 100 cow herd).

When the original samples have been collected, a series of dilutions are made – a dilution of 1 in 100 is known as a Centesimal (C). Between each dilution the mixture is succussed - energetically shaken, and the energetic properties of the remedy are believed to be acquired during this process
An example – a common potentisation = 30 C

This = 30 x 1 in 100 dilutions, or 1 in 10^{29}
A 6C, 30C and 200C potentised nosode is commonly made by a homeopathic pharmacy, and this service – manfacture of herd specific nosodes made from high cell count milk from the herd to be treated, is available as a commercial process from a number of well recognised homeopathic pharmacies, and is also performed by a number of individual homeopathic practitioners in the UK.

- Unlike specific remedies, nosodes do not account for the individual needs of each animal, but create the potential for protective treatment for a herd or group
- Nosodes are generally applied in drinking water, and may be used on individual animals, usually by vulval spray.
- Nosodes are very widely used in organic dairy farms in this country - in this study, 70% of the farms have used in the past, or are at present using, mastitis nosodes.

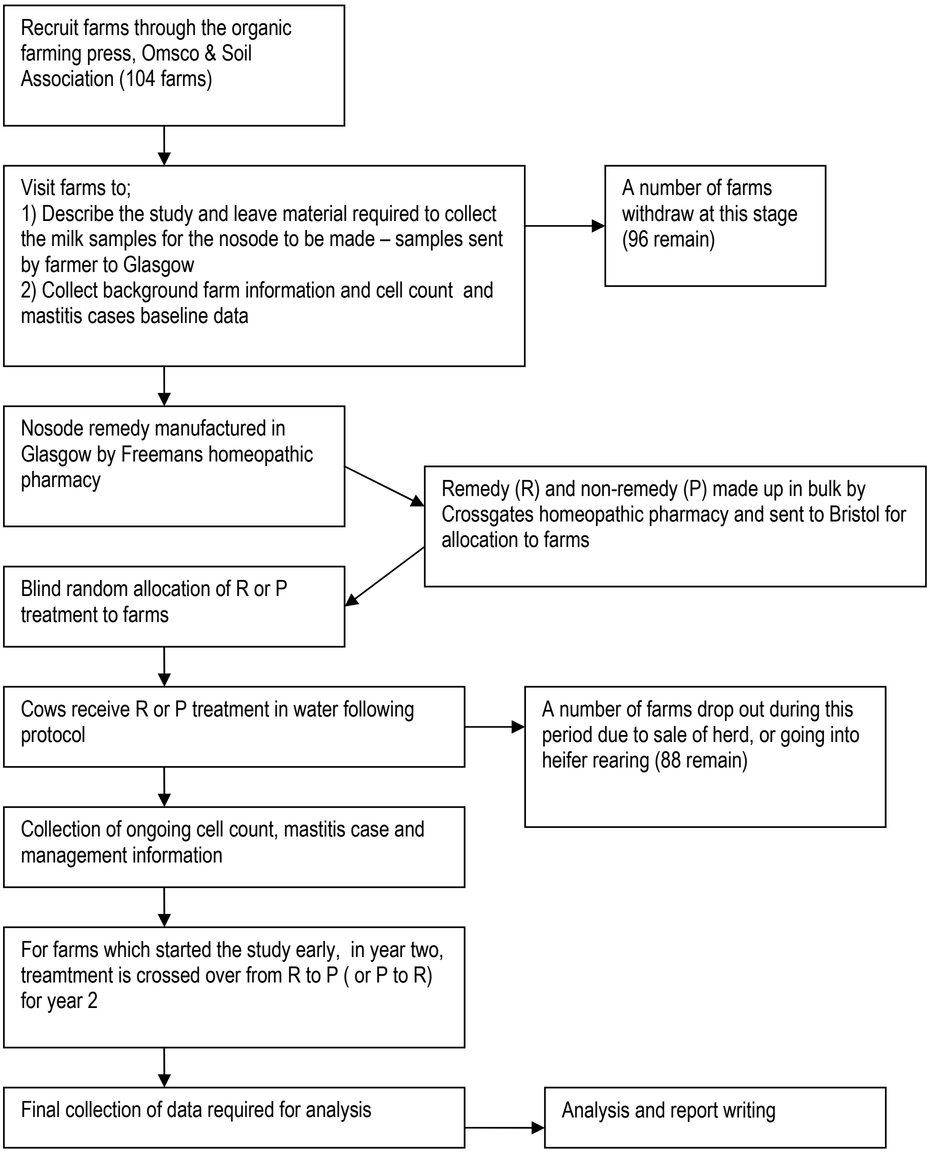
Farmers store and use nosodes and individual homeopathic remedies in a variety of ways. Many make up a plastic box containing the remedies they commonly use, and have this box available in the parlour or in the drugs cabinet. Some photographs of real examples of remedy 'kits' and guidance, as created by a farmer, are provided in figure 1.

Figure 1. Farmers created their own systems for using homeopathic remedies, often making up kits which can be used day to day in the parlour or in the yard.

Farmer created guide to the use of remedies.	Remedy box, with a wide range of individual remedies.	Daily use dilutions in spray bottles for application to individual cows.
		

Objectives

To quantify the effectiveness of the prophylactic use of homeopathic nosodes for the treatment of mastitis in reducing the incidence of clinical cases. An outline of the recruitment, treatments and analysis of the farms is produced below.



MATERIALS AND METHODS

At the inception of the study, a number of homeopathic practitioners were consulted. They suggested that; there should be clear presence of a disease to investigate, that the disease should be of significant incidence, that the disease should be easily identifiable, and that it should be possible to deliver the medication to the animals effectively. Additionally, they considered it important that adequate recording should be possible, that the disease should be amenable to treatment with a single or very limited number of remedies and that confounding factors should be recognised.

Mastitis is a common disease problem, which leads to motivation to 'understand it', but it is one of the most complex disease, with multiple causative agents and aetiologies. This means that studies in the complex area of the interaction between mastitis and, for example, homeopathic treatments can be subject to difficulties. In efforts to reduce the confounding effects that might occur if prescriptive recording and descriptive techniques are introduced to established animal systems, it was determined that the study should;

- Use a treatment which was already being commonly used and which was commercially available.
- Use the existing systems for recording disease which were already in place on the farms.
- Avoid interference in the 'normal' practises carried out by the farms, by, for example, repeated prompting of farmers to carry out treatments, or by interference in the decisions made on whether to treat animals, and on whether or not to record cases of mastitis.

The response variables that were measured were;

- Farmers own record of mastitis cases
- Bulk milk SCC
- Individual cow somatic cell records (ICSCC) if the farms were on a milk recording service
- Farmers opinion of his/her success in controlling mastitis
- A large number of variables, recorded as a questionnaire (Appendix A) at the farm visits, which could influence the effectiveness of the treatment

Treatment allocation

After visiting a number of homeopathic pharmacies, an agreement was made with Crossgates homeopathic pharmacy[1], and Freemans Homeopathic Pharmacy[2] to make the individual herd specific nosode remedies for the farms. Freemans manufactured the 'mother tincture' the primary remedy which was created from the milk samples supplied by each farm, and Crossgates created the following volume treatments;

- 1l and 500ml containers of 200C nososde – in the winter containing the herd specific remedy alone, and in the summer, containing a 30C fly remedy routinely added to their proprietary summer remedy.
- 10M individual 50ml sprays of the same treatment for application to the vulva or nasal mucosa of individual cows showing clots.

Agreement was reached with the pharmacies to produce equal quantities of remedy and of a non remedy control in identical containers, with identical batch numbers, distinguishable only by a temporary label which was removed at the 'blinding' stage.

Figure 2. Examples of the remedy presented as a 1 litre bottle of 200C with a pump for inclusion in water troughs, and a 10M spray for application to the vulva or to the nasal mucosa.

Blinding was carried out by the creation of a randomly generated list of A and B's. As each new farm was recruited, it was allocated to the next A or B in the sequence and the farms were allocated one by one in chronological order.

Recruitment of farms

Articles were written in the organic press, Organic farming and The Turning Worm, inviting farms to take part in the study. It was clear that farms should only join the study voluntarily and would not be 'cold called' or pressurised to join. One hundred and four farms responded to the call, and 96 of these farms went on to take part in the study.

The farms were visited and the study introduced. Farms who wanted to contribute to the study were issued with a kit to collect milk from high cell count cows. The farmers collected 15ml milk samples from 10 to 20% of their herd, selecting any cows which they knew to have recently had high cell counts, to be freshly calved, or cows known to be susceptible to repeat cases of mastitis. These samples were combined in a clean container, and 10ml of this pooled sample was posted to the homeopathic pharmacy. The sample was used to create the mother tincture, the origin of the herd specific nosode remedy. The pharmacy created the remedies using their established commercial process. The clear intention of this study was to use commercially available homeopathic products without any modification.

An 80 part questionnaire was used to gather the information needed to assess the possible compounding factors that may influence mastitis. The questionnaire can be found in appendix A.

In summary, 9670 cows were exposed to the study, and the number of farms, and the number of years combined gives a combined study group size of 206 farm years, 21,580 cow years.

Instructions for use of the treatments

When the farmers received their treatments, they were instructed;

> 3 pumps into every trough - Daily for the first week
> Twice a week in the second week
> Once a week thereafter
>
> Record your mastitis cases and other treatments as you always have

A typical pack of bulk treatment (1l or 500ml bottles or 200C treatment, and an individual 50ml spray of 10M treatment) can be seen in Figure 2.

In each year, the balance of farms receiving remedy (R) and non remedy (P) were as follows (Table 3);

Table 3. Distribution of remedy (R) and non remedy (P) in the three years of the study.

Year	% farms receiving R	% farms receiving P	% farms changing – R to P or P to R
0 (control year)	0	0	0
1	48% (42)	49% (43)	3% (2)
2	43 %(9)	52% (11)	5% (1)

A distinct policy of non interference was adopted. The concern was that repeated prompting of farmers to use the remedy, and advice giving, would modify the usual behaviour of the farmers. It was the clear intention to allow farmers to choose to use the remedy in ways which were natural to their normal working patterns.

RESULTS

The results from this study break down into three areas;

A) Descriptive statistics – which contain much 'outline' information on the organic dairy farms in the study group.
B) An analysis of the efficacy of the nosode treatment in reducing the cell count of each farm and cases of mastitis.
C) An analysis of the risk factors for increased cell count and cases of mastitis – the wide range of practices, farm conditions, operating procedures and attitudes which can influence the management and health and welfare of the cows

A) DESCRIPTIVE STATISTICS

Group statistics

Number of farms recruited	= 96
Total farms completing the study period	= 88
Number of farm years followed	= 206
Average herd size	= 101 cows
Number of cows followed in the study	= 9,680
Number of cows receiving remedy (R)	= 4,734
Number of cows receiving control (P)	= 4,946
Total cow years followed	= 21,580 cow years (Some farms two years, some 3 years)
Farms lost during study	= 8 (due to sale of the herd, or going out of milk production and into, for example, heifer rearing)

Treatment statistics

Winter - 200C Herd specific remedy	= 300 litres used
Summer - 200C Herd specific remedy + fly remedy	= 325 litres used
10M individual sprays used	= 236 (11.8 litres used)
Average cost to treat a farm with the remedies above for each year of the study	= £241.50

Basic statistics for the farms taking part in the study

A summary of the statistics resulting from the farm questionnaire can be found in Appendix A.

Voluntary personality type for farmers

During visits the farmers were asked whether they were willing to fill in a self assessment of their personality type. For those who were willing (the majority were) the 'average' values for these self filled descriptions are tabulated below. The simple representation of the 'average' profiles for farmers on farms receiving remedy (R) and those not receiving remedy (P) are tabulated in the tables tables contained in Appendix B. The rationale for requesting this voluntary information was to form the basis of an analysis of the following questions;

a) *Were there unforeseen differences between the farmer personalities between the control and treated farms?*

The 'average' personality profile for farmers in both treated and control farms are very similar. The average score for each trait was the same except in the following categories 'conscientious', 'shy', 'practical' - which differed by one score (See tables 5 & 6).

b) *Did farmer personality act as a significant factor in udder health?*

The personality 'traits' were explored by adding them as possible risk factors to the risk factor models described below for composite cell count and mastitis cases. The same criteria as described below were used to fit a model.

- Of all the traits, self scoring high levels of 'emotional stability' (see tables 5, 6, 7 for question structure) was a risk factor for both composite cell count (F=4.292, P=0.043) and mastitis cases (F=7.012, P=0.011). Those scoring themselves as less emotionally stable were associated with farms with both lower composite cell count and clinical mastitis cases.
- High levels of 'self sufficiency' were linked with increased cell count (F=12.454, P=0.001), but were not associated with mastitis cases.
- High levels of 'shrewdness' was linked with reduced cell count (F=3.38, P=0.071), but was not associated with mastitis cases.

B) & C) ANALYSIS OF THE EFFECTS OF THE NOSODE TREATMENT AND ANALYSIS OF RISK FACTORS

Recap of Study Design
Ninety-six farms participated in a double-blind trial to compare a homeopathic nosode and an inactive control treatment (carrier alone). Treatments were at the farm level and took place over a period of 12 months and 24 months. The treatments were randomised to each farm by a third party. During the trial, where available, records were collected of farm monthly bulk tank somatic cell count (BMSSC), a monthly cell count based on National Milk Recording data (NMR) and the annual number of cases of mastitis as recorded by the farmer. Records of these variables for the year preceding the trial were also available and these were used in some analyses as covariates to reduce between farm variability and so increase the sensitivity of the trial to any effects of treatment.

Ninety six farms took part in the first year of the study, and 14 of the farms were retained in the trial for a further 12 months after the treatment on each of these farms had been crossed over to the alternative treatment. This provided a total of 206 farm years followed, including the lead-in year.

In order to also study risk factors associated with higher cell count farms, and with higher incidence of mastitis, a comprehensive survey questionnaire was completed for each farm (Appendix A).

The data collected were subject to a number of different analyses:-

1. A test for an effect of the homeopathic nosode in reducing the cell count in milk.
2. A test for an effect of the homeopathic nosode in reducing the annual cases of mastitis.
3. An analysis to identify risk factors associated with increased cell count in milk.
4. An analysis to identify risk factors associated with higher levels of mastitis.

The approach to each of these analyses is given in detail, below.

1. To test for an effect of the homeopathic nosode in reducing cell count in milk

Methods

Table 8 summarises the NMR and SCC data collected. In order to use the available data to the full the SSC and NMR data were combined to produce one variable as a measure of monthly cell count for each farm. This was achieved by first taking $\log_{10}$ of all counts. The $\log_{10}$ SSC cell counts within each month were then normalised (converted to z - scores) and similarly, the monthly NMR cell counts within each month. As NMR measurements are considered to be a more accurate reflection of cell count the normalised monthly NMR data were used primarily but where these were not available the normalised SSC data were substituted. The new variable was named combined cell count (CCC).

The response variable, monthly CCC, was modelled as repeated measurements within farm using the software package MLwiN version 2.00 (Institute of Education, London). The monthly CCC for the preceding year was entered into the model as a covariate and a sinusoidal curve with a 12 month period was also fitted as cell counts are known to follow a seasonal pattern. The approach taken to modelling the crossed-over treatments was that given by Senn (2002) in which treatment and period, alone, are modelled.

Table 8 Breakdown of type of cell count available for each farm.

		NMR cell count available	
		Yes	No
SCC available	Yes	42	40
	No	6	0

Results

The parameter estimates for the fitted model are shown in the MLwiN output in Figure 3. The residuals from the model at both the farm and the monthly CCC level were examined using a Q-Q plot and were satisfactorily normally distributed and homogeneous. A similar model was fitted to SCC data alone and NMR data alone. All three models were in general agreement. Figure 4 shows the monthly farm CCCs by farm and treatment plotted against time on treatment for years one and two of the trial. The values on the graph are seasonally adjusted (Sin and Cos in Figure 3) and adjusted for the cell counts in the year preceding the trial (CovCCC in Figure 3). In Figure 4 the nosode treatment is shown in blue and the control treatment in red.

Figure 3 The output from MLwiN (Rasbash 2000) detailing the model used to analyse the affect of the nosode on farm monthly averaged cell count.

$$\mathrm{CCC}_{ij} \sim \mathrm{N}(XB, \Omega)$$

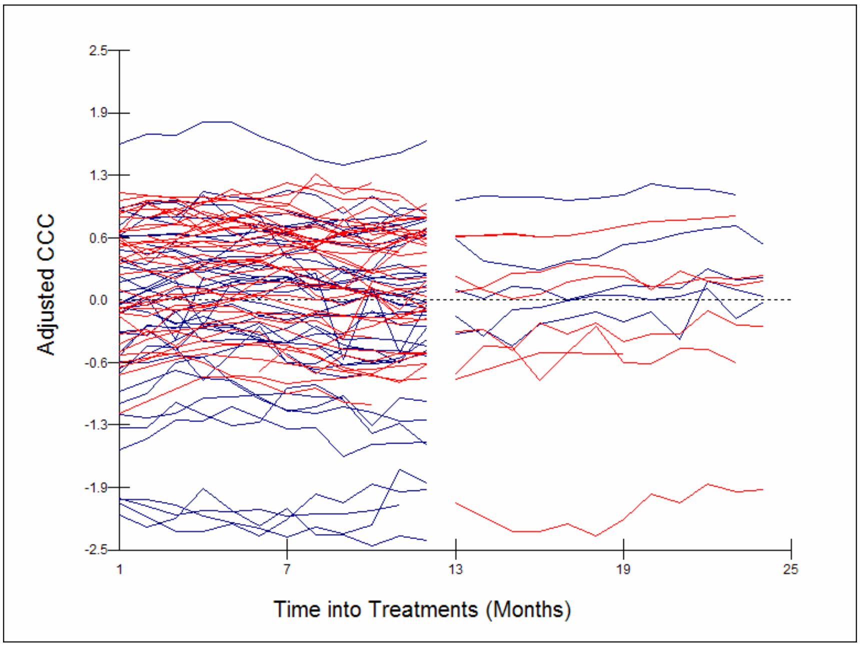
$$\mathrm{CCC}_{ij} = \beta_{0ij}\mathrm{Const} + 0.163(0.032)\mathrm{CovCCC}_{ij} + -0.089(0.028)\mathrm{Sin}_{ij} + -0.055(0.028)\mathrm{Cos}_{ij} + 0.012(0.069)\mathrm{Nosode}_{ij} + -0.035(0.074)\mathrm{Year\_2}_{ij}$$

$$\beta_{0ij} = 0.026(0.088) + u_{0j} + e_{0ij}$$

$$\left[u_{0j}\right] \sim \mathrm{N}(0,\ \Omega_u) \ :\ \Omega_u = \left[0.487(0.082)\right]$$

$$\left[e_{0ij}\right] \sim \mathrm{N}(0,\ \Omega_e) \ :\ \Omega_e = \left[0.378(0.018)\right]$$

Figure 4 Monthly farm marginal mean CCCs plotted against 'time on treatment' for year one and year two. The CCCs are seasonally and covariate adjusted at the level of month. Farms on the nosode treatments are shown as blue and those on control treatments as red.

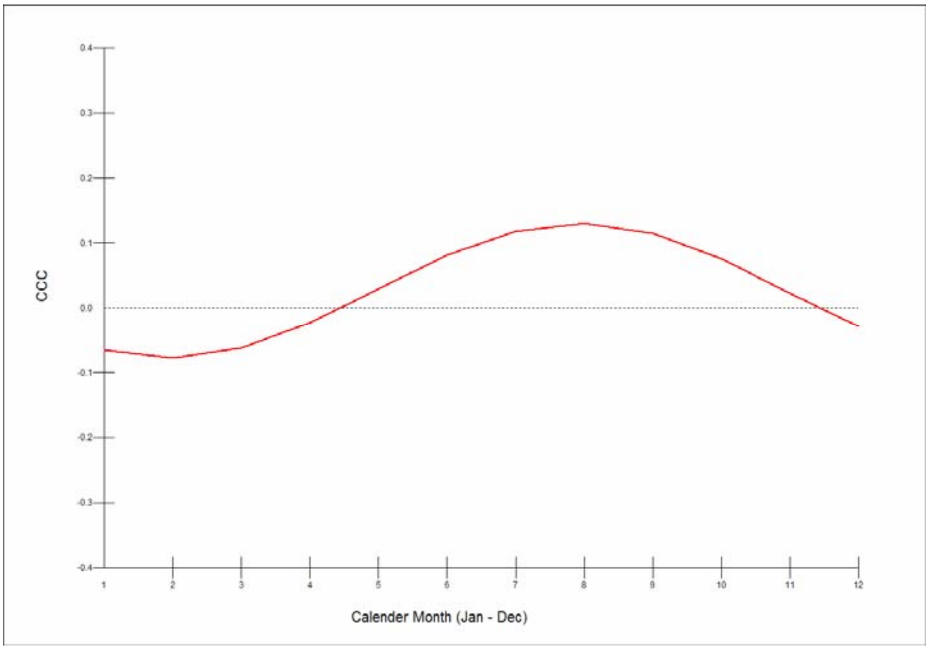


The significance of the parameter estimates are shown in Table 9. The constant in the model was not significantly different from zero. This would be expected as the data had been centred. CovCCC, the covariate of monthly cell counts from the year preceding the trial was highly significant indicating that cell counts over time within each farm were strongly correlated. It's inclusion in the model thus helped reduce between farm variation and increased the sensitivity of the analysis to any effect of nosode. The fitted seasonal effect was also significant (Sin and Cos) indicating that the seasonal changes in cell count could be approximated by a sinusoidal curve. The fitted curve is shown in Figure 5 and shows that the overall minimum cell count would be expected in approximately February and the overall maximum in approximately August. There was no significant effect of nosode on cell count and no significant difference in overall cell count between the first and second years of the trial. The variance components from the model (Fig 3) indicate that 56 per cent of the variability in cell counts was at the farm level (0.487/0.865) and 44 per cent at the level of the monthly measurements (0.378/0.865).

Table 9 The parameter estimates from the model of the effect of nosode on cell count, with their standard error and significance. (Const = Model constant, CovCCC = combined average NMR/bulk cell count in the pre-trial year (transformed), Sin and Cos = parameters to model the seasonal changes in cell count, Nosode = effect of the nosode treatment, Year 2 = the overall difference in average cell count between years).

	Parameter est.	SE	P	
Const	0.026	0.088	0.768	NS
CovCCC	0.163	0.032	3.52E-07	***
Sin	-0.089	0.028	0.001	***
Cos	-0.055	0.028	0.049	*
Nosode	0.012	0.069	0.862	NS
Year 2	-0.035	0.074	0.636	NS

Figure 5 The fitted seasonal trend line is shown in red. The minimum occurs in February and the maximum in August.



The model was used to assess the sensitivity of the study to detect a difference between the control and nosode treatment. Using the standard error of the nosode parameter estimate and evaluating the model at the farm average NMR cell count of 226.2 (which gives a $\log_{10}$ value of 2.255 with standard error 0.2275) gives an estimate for the control treatment of approximately 227 counts. The estimate of the cell count for the nosode treatment was then approximately 228 counts with a 95% confidence interval of 213 counts to 245 counts. Note that the confidence interval is not symmetric due to the log transformation and that cell counts are reported in thousands.

2. To test for an effect of the homeopathic nosode in reducing the annual cases of mastitis.

Method

An annual count of the number of cases of mastitis on each farm was collected. The number of farms for which usable data were available was 84 from the first year of the trial and 13 from the second year, in which treatments were crossed over. The number of cases as a proportion of the herd size was used for the analysis. The data were first transformed by taking the arcsine of the square root of the proportion in order to remove heterogeneity in the variance and the variable was named TProp. A count of mastitis cases for the year preceding the trial was also available for these farms and this was used as a covariate (CovTProp). A multilevel model was fitted with the repeated measure within farm using MLwiN v2.00 (Institute of

Education, London). The approach taken to modelling the crossed-over treatments was that given by Senn (2002) in which treatment and period, alone, are modelled.

Results

The parameter estimates for the fitted model are shown as the MLwiN output in Figure 6. The residuals from the model were examined using a Q-Q plot and were satisfactorily normally distributed and homogeneous.

Figure 6 The output from MLwiN detailing the model used to analyse the affect of nosode on the proportion of cases of mastitis in a herd (Rasbash 2000).

$$\text{TProp}_{ij} \sim \text{N}(XB, \Omega)$$

$$\text{TProp}_{ij} = \beta_{0ij}\text{Const} + 0.6235(0.0793)\text{CovTProp}_j + 0.0002(0.0002)\text{Herdsize}_j + 0.0200(0.0235)\text{Nosode}_{ij} + 0.0778(0.0331)\text{Year\_2}_{ij}$$

$$\beta_{0ij} = 0.1574(0.0507) + u_{0j} + e_{0ij}$$

$$\left[u_{0j}\right] \sim \text{N}(0,\ \Omega_u) \ :\ \Omega_u = \left[0.0061(0.0037)\right]$$

$$\left[e_{0ij}\right] \sim \text{N}(0,\ \Omega_e) \ :\ \Omega_e = \left[0.0093(0.0034)\right]$$

The significance of the parameter estimates are shown in Table 10. The number of cases in the year preceding the trial as a proportion of the herd (CovTProp) was significant as a covariate. This indicates that the proportion of cases within a farm was correlated across years. The inclusion of this covariate will have increased the sensitivity of the analysis to any effect of nosode. There was no effect of herd size on the proportion of cases and no effect of nosode on the proportion of cases. There was a significant increase in the proportion of cases in year two. The overall proportion of cases in the year preceding the trial was 0.27 (0.015) and the overall proportion in the first year of the trial 0.25 (0.014). For the farms which were crossed, alone, the proportion of cases in the first year of the trial over was 0.26 (0.042) and in the second year 0.33 (0.051). Of these farms, 10 showed an increase in cases, two a decrease and one no change.

Table 10 The parameter estimates from the model of the effect of nosode on cases of mastitis, with their standard error and significance (Const = Model constant, CovTProp = proportion of cases in the herd in the pre-trial year (transformed), Herdsize = average number of cows in herd, Nosode = effect of the nosode treatment, Year 2 = the overall difference in cases between years).

	Parameter est.	SE	P	
Const	0.1574	0.0507	0.002	**
CovTProp	0.6235	0.0793	3.76E-15	***
Herdsize	0.0002	0.0002	0.317	NS
Nosode	0.02	0.0235	0.395	NS
Year 2	0.0778	0.0331	0.019	*

The model was used to assess the sensitivity of the study to detect a difference between the control and nosode treatment in terms of cow cases. Using the standard error of the nosode parameter estimate and evaluating the model at the farm average pre-trial year (CovTProp) of 28.6 cases per 100 cows per year (incident rate of clinical mastitis (IRCM)) and the average herd size of 108.5 cows, the estimated IRCM of the herd as cases under the control treatment was 28.9. The estimated IRCM under the nosode treatment was 30.8 with a 95 per cent confidence interval from 28.6 to 33.0.

3. Analysis to identify risk factors associated with increased cell count in milk.

Methods

As all the risk factors were farm level factors, a single response measure for each farm was calculated. Because in the previous analysis no effects of period or treatment were identified, where available, data across all three years were used to construct a single measure of cell count for a farm. In a similar manner to analysis 1, the monthly SCC counts and NMR counts were normalised before being combined into a single index in which the NMR measurements took precedence over the SCC measurements. The normalised value, averaged across the months, was then used as the measure of cell count for a farm. On this occasion it was not necessary to transform the raw counts to normalise the residuals from the model (a $\log_{10}$ transformation was not required).

The initial screening and construction of the GLMs was carried out using the software package SPSS v12.02 (SPSS Inc.). All of the farm level variables were screened for a linear or additive association with farm averaged cell count (FACC). Variables which showed a significant association with FACC, where $P \leq 0.10$, were retained for further analysis using general linear models (GLM). Models were fitted using both a stepwise forward method and backward elimination. Variables were retained in the model if they remained significant or if their removal affected the parameter estimates of other variables in the model. Variables that had been dropped from the model were reintroduced into the final model, one at a time, and retained if they became significant.

Results

The variables retained in the final model are shown in the analysis of variance table with the parameter estimates below (Tables 11 and 12). The errors from the model were satisfactorily normally distributed and homogeneous. R Squared for this model was 0.21 with an adjusted R Squared of 0.16. The low R squared value of 0.16 shows that only 16 per cent of the variation in farm average cell counts is explained by the model. Two variables with $0.05 < P < 0.10$ have been retained in the model as their presence affects the significance of other variables in the model. The parameter estimates indicate that farms with a high percentage of cows culled because of high cell counts were associated with lower annual average cell count as were farms that used either traditional dry cow therapy or a complementary dry cow therapy. Higher annual average farm cell counts were associated with farms that only pre-wiped cows which were dirty, did not pre-wipe at all or used a cloth to pre-wipe udders.

Tables 11 and 12 The analysis of variance table and parameter estimates, their standard error and upper and lower confidence interval for the final model of risk factors for cell counts.

Source	df	F	P
Corrected Model	5	3.71	0.005
Intercept	1	8.75	0.004
Cows culled high %	1	3.23	0.077
No pre-wipe or use cloth	1	3.88	0.053
Only pre-wipe dirty	1	4.03	0.049
Complementary DCT	1	2.87	0.095
Dry Cow Therapy	1	4.10	0.047

Parameter	B	SE	t	P	LCI	UCI
Intercept	0.006	0.1508	0.04	0.969	-0.295	0.307
Cows culled high %	-0.054	0.0301	-1.80	0.077	-0.114	0.006
No pre-wipe or use cloth	0.376	0.1911	1.97	0.053	-0.005	0.758
Only pre-wipe dirty	0.314	0.1562	2.01	0.049	0.002	0.625
Complementary DCT	-0.310	0.1830	-1.69	0.095	-0.675	0.055
Dry Cow Therapy	-0.326	0.1609	-2.03	0.047	-0.647	-0.005

4. Analysis to identify risk factors associated with higher annual numbers of mastitis cases

Methods

Both the risk factors and the response variable were measured at the level of farm. The response variable used in the analysis was the proportion of cases in the herd averaged over the year preceding the trial and the first year of the trial. These proportions were transformed by taking the arcsine of the square root in order to remove heterogeneity in the variance and the variable named TAvProp. Data for the second year of the trial were not included as the subset of farms that were carried into the second year of the trial had shown an increase in cases.

The initial screening and construction of the GLMs was carried out using the software package SPSS v12.02 (SPSS Inc.). All of the farm level variables were screened for a linear or additive association with TAvProp. Variables which showed a significant association, where $P \leq 0.10$, were retained for further analysis using general linear models (GLM). Models were fitted using both a stepwise forward method and backward elimination. Variables were retained in the model if they remained significant or if their removal affected the parameter estimates of other variables in the model. Variables that had been dropped from the model were reintroduced into the final model, one at a time, and retained if they became significant.

Results

The variables retained in the final model are shown in the analysis of variance table with the parameter estimates below (Tables 13 and 14). A Q-Q plot of the errors from the model showed them to be satisfactorily normally distributed and homogeneous. R Squared for this model was 0.38 with an adjusted R Squared of 0.34. The parameter estimates indicate that higher farm average yield was a risk factor for mastitis, as was increased percentage of cows calving in a box. Using an in-line clot filter and having an abreast parlour, rather than a herring-bone parlour, were both associated with a lower proportion of mastitis cases on a farm.

Tables 13 and 14 The analysis of variance table and parameter estimates, their standard error and upper and lower confidence interval for the final model of risk factors for cases of mastitis as a proportion of herd.

Source	df	F	P
Corrected Model	4	8.73	0.000
Intercept	1	8.05	0.006
Average Yield	1	4.49	0.038
Inline Filter	1	5.16	0.027
Calve in Box %	1	9.36	0.003
Abreast Parlour	1	4.23	0.044

Parameter	B	Std. Error	t	Sig.	LCI	UCI
Intercept	0.3003	0.09321	3.22	0.002	0.1137	0.4869
Average Yield	1.33E-5	0.00001	2.12	0.038	0.0000	0.0001
Inline Filter	-0.0772	0.03399	-2.27	0.027	-0.1453	-0.0092
Calve in Box %	0.0019	0.00063	3.06	0.003	0.0007	0.0032
Abreast Parlour	-0.0881	0.04287	-2.06	0.044	-0.1740	-0.0023

DISCUSSION

Questionnaire

The results of the questions asked during the farm visits provide basic statistics for the farms studied. The ‘average’ farm in the study (of course there is no average farm) has been converted to organic production for nearly six years, has 109 cows, produces 5900 litres of milk per cow/year (national average 6,609 litres/yr (Milk Development Council datum 2004)), has Black and White Friesian/ Holstein cows and milks the cows in a herring bone parlour. The farm replaces just over 20% of its animals each year, calves its young cows first at 27 months of age, takes the calf away from the dam at 2 days of age and has cubicles to house the cows. During milking, more than 60% of milkers wear gloves, and the majority of cows are made to stand in a loafing area for a period after milking before returning to their accommodation. The farmer estimate for the number of cases of mastitis was 23.7 cases/100 cows/yr (the figure calculated from records was 25.8 cases/100 cows/yr, and that taken from recording data was 28.6 cases/100 cows/yr), 84% of farms had removed cows from the herd as a result of mastitis or high cell counts in the last year, and the average farm had a cow die from mastitis about every 5 years. Half of the farmers had some kind of training in complementary therapy use, and 85% said that they had some belief in complementary therapies, with 62% using them on themselves and their families.

These results show the 'average' organic farm in the study group to be a productive unit with milk production figures just below the national average and an incidence rate for clinical mastitis (IRCM) of 28.6 cases/100 cows/yr which is below the average for conventional farms which was recorded as between 38 cases/100 cows/yr (Berry, 1998) and 43 cases per 100 cows/yr (Kossaibati, 1998) in two large scale studies in the late 1990's.

Nosode Trial

No significant effect of the nosode remedy on either somatic cell counts, nor the number of mastitis cases recorded by the farmer was found in this study. The data from the trial suggest that, if it had existed, the study would have been able to detect a difference due to nosode of at least approximately 15 cell counts (000s) and a difference due to nosode of at least approximately 2 cow cases/100 cows/yr. Within the study group, there was good correlation between bulk tank counts (BMSCC) and averaged cow counts from national milk recording (NMR). However, NMR averages are higher than BMSCCs because high cell count milk is excluded from the bulk tank but high cell count cows are still NMR recorded. For this reason the two available measures of cell count were combined as described above so that the model describes deviations which are standardised across types of count. The seasonal trend in cell count identified in the study, with a minimum occurring in approximately February and a maximum in approximately August, is well documented in the literature.

Many of the farmers had previously used nosode therapies for mastitis in the past, and a number were firmly of the opinion that, for them, homeopathic remedies, including nosodes, were of value and had a place in their management of mastitis (and other dairy cow conditions). For these farmers, the results of this study will be a disappointment, whilst for others these results will not be seen as unexpected. The experience of the authors during this study was that many organic dairy farmers had a very intelligent and practical approach to mastitis management, using complementary therapies where they saw them to be appropriate, but not withholding the use of stripping, udder liniments, removal of high cell count animals from the herd, and targeted use of antibiotics when the health and welfare of their animals demanded their use. During the trial a number of farmers were convinced that, for them, the treatment they received was beneficial. This applied both to farmers on nosode treatments and on control treatments. Appendix B contains an example of a letter (anonymised) from one of these farmers.

Risk Factors

For each factor, a question appears in the questionnaire (Appendix A) and the response of the farmers, or the visible finding on the farm, was used to assess the impact on cell count and the number of clinical mastitis cases. Below, the 'question' that was asked for each risk factor which was found to have a significant association with mastitis is used as a heading for a brief commentary on the possible implications of that risk factor.

Risk factors for high cell counts

a) What percentage of the herd was culled due to a high cell count?

For farms which cull significant numbers of cows with high cell counts, there was a significant decrease in cell count. This finding is in agreement with the principles of the five point plan (Cull chronically infected cows) and is considered a fundamental tool in controlling cell count. However, in organic systems, culling of cows, unless essential, is sometimes considered to go against the wider principles of holistic production – i.e. to make every effort to sustain animals in production for a reasonable proportion of their normal lifespan – and culling of cows at 4, 5, 6 or 7 lactations when a cows can sustain milk production until 12 lactations, is seen by many organic farmers as a failing.

b) Did the farmer pre wipe the teats with a cloth, medicated wipe or paper towel before milking?

For farmers who did not wipe the udder before milking, and for those who used a reusable udder cloth, (usually with warm disinfectant containing water), there was a significant positive correlation with composite cell count. This supports the often stated view that a common udder cloth (or no pre wiping) can adversely affect cell count. Many dairy standards prohibit the use of a common udder cloth.

c) Did the farmer pre wipe only cows which are visibly dirty before milking?

For farmers who wipe only the udders of cows which are visibly dirty before milking, a positive correlation with composite cell count exists – i.e. those farmers who only wipe dirty udders appear to have a higher overall composite cell count.

d) Did the farmer use complementary therapies on dry cows?

Some of the farms (17 of 88, 19%) used complementary therapies such as nosodes for ringworm prevention, for dry cow mastitis, for new forest eye and for coughing or lameness, on groups and individual dry cows. For those farms indicating that they did use these therapies on their dry cows, the negative correlation seen supports the supposition that use of complementary therapies during the dry period is associated with decreased composite cell count. The question used to explore this area is a very generalised one, and does not restrict itself to mastitis treatments alone, and so the significant finding in this factor is perhaps difficult to interpret – other than to indicate that the farmers who showed attention to their dry cows, by (in these cases) use of complementary therapies during this period showed a decreased composite cell count.

e) Was dry cow therapy used?

Conventional (allopathic) dry cow therapy was used on some farms, at times, to treat both groups of cows and individual cows with a history of high cell counts. Additionally, around 25% (this varied from season to season, and with the introduction of Orbeseal (Pfizer Animal Health) of the farms used non antibiotic teat sealants during the dry cow period. The negative correlation found supports the supposition that the use of dry cow therapy reduces the composite cell count.

Risk factors for higher numbers of cases of mastitis

a) What was the annual average yield of the herd?

There was a positive correlation between average herd yield and the number of clinical cases of mastitis. This means that high yielding herds had, in general, an increased proportion of mastitis cases. In this study, this finding appeared to be independent of herd size.

b) Was an in-line filter used to detect clots in the milk?

A number of methods for detecting clots and mastitic milk were used by farmers. These included stripping milk onto the floor (or onto a Wellington), into a strip cup, onto the plastic tray of a California milk test where a reagent showed high cell count milk, or into a conductivity meter, which showed changes in milk electrical resistance with changes in milk composition (including cell count).
Many milking systems had visible filters in the milk tube, which the farmer could inspect to detect gross clots. The farmers chose to include, or exclude, milk from the bulk tank in systems which were not ‘direct to line’, and also chose to treat animals showing clots or early signs of mastitis using these tests. The Dairy Products (Hygiene) Regulations 1995 require examination of foremilk before the cluster is put on and milk allowed into the bulk tank. How farmers carry out this examination is linked with their methods for detecting mastitis through examination of milk character and for clots, and by familiarity with individual cow behaviour (reactions to a tender udder, sick cow, position in the milking queue etc.).

Of all the methods described, only the use of the in line filter showed a negative correlation with the number of clinical mastitis cases recorded by the farmer i.e. use of an in line filter appears to have a significant effect in reducing the number of mastitis cases.

c) What percentage of the herd calved in a box?

Farms operated many different calving patterns and systems. Some calved almost exclusively on grass, some calved indoors in yards, and some in dedicated calving pens or boxes – most farms actually used a mixture of these, calving in locations determined by the season and the availability of space. Whether contamination of the udder could occur more readily in a calving box during calving, or whether the use of calving boxes reflected other management practices cannot be determined in this study, however, farms where the cows predominately calved in dedicated calving boxes appeared to be linked with significant increases in composite cell count.

d) Did the farm have an abreast parlour or a herring-bone parlour?

Three main types of milking parlour are found in the UK, herring bone (80%), abreast (17%) and rotary parlour (3%). (In brackets are the percentage of each parlour type found in the farms in this study.) For the two more common types, farms with an abreast parlour, a significant reduction in composite cell count was seen. Whilst many people associated herring bone parlours with updated farms and abreast parlour with traditional milking, in this study, traditional abreast parlours appeared to beneficially affect composite cell count performance.

Comparison between the risk factors found in this study and the 'Five Point Plan'

The existing NIRD Five Point Plan is widely adopted by the UK dairy industry and recommends; Hygienic teat management - combined with sound housing management, Prompt treatment of clinical mastitis, Dry cow therapy, Culling chronically affected cows and Correct maintenance of the milking machine. Because the majority of risk factors that have been identified in the present study are in line with the 'Five Point Plan' it may not be considered appropriate to issue specific additional guidance for organic dairy farms.

Conclusions

The study has identified;

- That there was no significant effect of the herd specific nosode on either the cell counts or the number of cases of mastitis was identified.
- That there were strong 'within farm' correlations of cell count and cases i.e. farms tend to stay at the same level of cases and average cell count from year to year.
- That there was a characteristic pattern of seasonal change in cell counts (this is already widely recognised).
- The study provides useful and interesting statistics on organic dairy farm production.
- The study identified an association between decreased cell count and culling for high cell count, complementary dry cow therapy and traditional dry cow therapy.
- The study identified an association between increased cell count and not pre-wiping the udder, pre-wiping using a cloth and only pre-wiping dirty cows.
- The study identified an association between higher numbers of mastitis cases and higher average yield and also with a higher percentage of cows calving in a calving box.
- The study identified an association between decreased numbers of mastitis cases and the use of an inline clot filter and also with farms with an abreast parlour (rather than a herring-bone parlour).
- Eighty five per cent of farmers in the survey responded that they did believe in non-conventional remedies, and 62 per cent of farmers responded that they used non-conventional remedies on their own family.
- In a 'self scoring' exercise for the type of personality of the farmers in the study, high levels of 'emotional stability' (see tables 5, 6, 7 for question structure) were a risk factor for both composite cell count (F=4.292, P=0.043) and mastitis cases (F=7.012, P=0.011). Those scoring themselves as less emotionally stable were associated with farms with both lower composite cell count and clinical mastitis cases.
- High levels of 'self sufficiency' were linked with increased cell count (F=12.454, P=0.001), but were not associated with reduced or increased numbers of mastitis cases.
- High levels of 'shrewdness' were linked with reduced cell count (F=3.38, P=0.071), but was not associated with either reduced or increased numbers of mastitis cases.

Acknowledgements We thank all the farmers who, to a greater or lesser degree, and through their interest and enthusiasm for their cows and their dairy business contributed to this study. Thanks also to the staff of Crossgates Homeopathic Pharmacy, and of National Milk Recording.

Appendix A

Table A Summary table of responses to question or factors which can be broken down to single answers. For factors with a number of answers, the correlation table (Table 5) gives values for significance.

Relates to questionnaire question number	Factor	Answer options	Mean	Min	Max	SD
A1b	Average time converted ?		5.7 yr	2 yr	50 yr	6.24 yr
A2	Which certification body are you converted with ?	Soil Association Organic Standard Organic Farmers & Growers	76% 24%			
B1	What stock do you have on the farm at the present time ?	Dairy cows Beef cows	109.76 28.70	9 0	550 320	76.39 64.18
B3	What was the herd average milk yield per cow per year last year?	Litres/yr	5976	2500	9500	1306.36
B4	Age of oldest milking cow ?	Years	9.52	6	14	2.35
B5	What breed are the majority of your dairy cows at the present time?	Friesian/Holstein Ayrshire Channel Island Brown Swiss Norwegian / Swedish Red	89% 2.5% 8% <1% <1% <1%			
B6	Have you changed breed (or, are you in the process of changing breed) in the last 12 months.	Yes (%)	32%	0	1	0.467
B7	How many replacement cows and / or heifers did you introduce during the last 12 months?		21%	0%	50%	9.7
B8	Average age at which heifers are calved? (Months)		26.9	23	33	2.51
C6	What type of housing do you now have for milking cows?	Cubicles Straw yard	74% 26%			
C7	Do you have an automatic scraper system?	Yes (%)	19%	0	1	0.392
C10	Is lime added to the bedding	Yes (%)	46%	0	1	0.499
D6	Did you teat dip during the dry cow period in the last 12 months?	no cows	26%	0	1	0.44
D7	Did you use complementary therapies for groups of dry cows during the last 12 months ?	Yes (%)	20%	0	1	0.40
E2	If you calved cows / heifers in individual pens / boxes: how many pens / boxes did you have? what proportion of cows / heifers calved in them?		 2.7 57.7%	 1 5	 9 100	 2.05 25.24
E4	How soon after birth were calves removed from their mothers? (Days)		2.4	1	4	1.13
G2	Was the plan compiled with veterinary input ?	Yes (%)	58%	0	1	0.49
G3	Is the plan updated ? If so, how often?		71%	0	1	0.45
H1	In the last year have you culled any cows because of mastitis?	Yes (%)	84%	0	1	
H2	Did any cows die from mastitis in the last 12 month period? How many ?	(Average number of cows dying per year from mastitis)	0.23	0	2	0.443

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H3	What is the farmer estimate for the percentage of cows affected ?	% Estimate for mastitis incidence	23.7 (cases/100 cow/yr)	3	60	13.79
H4	From the disease and medicine records kept for certification purposes, and with the farmer adding additional information from other records, medicine records and from memory, the identifiable individual cases for mastitis in the last 12 months.		25.83 (cases/100 cows/yr)	0	70	15.03
I3	Does it have an automatic cluster removal (ACR)?	Yes (%)	48%	0	1	.5
I6	How often do you currently change the liners?	(Months)	7.17	3	12	2.66
I11	What type of milking parlour do you have ?	Abreast Herring bone Rotary	17% 80% 3%			
J1	During the last 12 months how many people regularly milked the cows (i.e. not reliefs)?		1.8	1	5	0.86
J7a	Did the people doing the milking wear gloves? Are disposable gloves used?	Yes (%) Yes (%)	63% 60%	0 0	1 1	0.52 0.49
J7b	Did you keep the cows in a loafing area (standing only) after milking, in the last 12 months?	Yes (%)	66%	0	1	0.47
K3	In the last 12 months did you wash the teats of any cows <u>before</u> milking? Did you dry the teats after washing? What did you use?	Yes (%) Paper towel	25% 60%	0 0	1 1	0.43 0.49
L2	Do you clean the water troughs ?	Yes (%)	49%	0	1	.50
M4	Has the stockperson had any training in complementary medicine use ?	Yes (%)	50%	0	1	.50
M5	Does this person feel that training in homeopathy would be of value ?	Yes (%)	83%	0	1	.44
M6	Does this person 'believe' in non-conventional remedies ?	Yes (%)	85%	0	1	.49
M7	Does this person use complementary therapies on themselves or their family ?	Yes (%)	62%	0	1	.49

Appendix B

Table B1 'Average' values for the personality questions voluntarily self filled by farmers in the group receiving remedy (R).

	-3	-2	-1	0	1	2	3	
Reserved					✓			Outgoing
Less emotionally stable						✓		Emotionally stable
Confident			✓					Lacking confidence
Humble				✓				Assertive
Serious				✓				Happy go lucky
Expedient					✓			Conscientious
Shy				✓				Venturesome
Tough minded				✓				Tender minded
Trusting			✓					Suspicious
Practical				✓				Imaginative
Unpretentious				✓				Shrewd
Traditional					✓			Experimenting
Group dependent						✓		Self sufficient
Independent			✓					Concerned with image

Relaxed			✓					Tense
Less intelligent					✓			Intelligent

Table B2 ‘Average’ values for the personality questions voluntarily self filled by farmers in the group not receiving remedy (P).

	-3	-2	-1	0	1	2	3	
Reserved					✓			Outgoing
Less emotionally stable						✓		Emotionally stable
Confident			✓					Lacking confidence
Humble				✓				Assertive
Serious				✓				Happy go lucky
Expedient						✓		Conscientious
Shy					✓			Venturesome
Tough minded				✓				Tender minded
Trusting			✓					Suspicious
Practical			✓					Imaginative
Unpretentious				✓				Shrewd
Traditional					✓			Experimenting
Group dependent						✓		Self sufficient
Independent			✓					Concerned with image
Relaxed			✓					Tense
Less intelligent					✓			Intelligent

Table B3 ‘Average’ values for the personality questions voluntarily self filled by farmers for all the farms in the study.

	-3	-2	-1	0	1	2	3	
Reserved					✓			Outgoing
Less emotionally stable						✓		Emotionally stable
Confident			✓					Lacking confidence
Humble				✓				Assertive
Serious				✓				Happy go lucky
Expedient					✓			Conscientious
Shy					✓			Venturesome
Tough minded				✓				Tender minded
Trusting			✓					Suspicious
Practical			✓					Imaginative
Unpretentious				✓				Shrewd
Traditional					✓			Experimenting
Group dependent						✓		Self sufficient
Independent			✓					Concerned with image
Relaxed			✓					Tense
Less intelligent					✓			Intelligent

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Appendix D

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References to published material

9. This section should be used to record links (hypertext links where possible) or references to other published material generated by, or relating to this project.

A Bibliography has been included as Appendix C.