



Audit of the CCS2005
Study

Key words: planning, working group, well-trained small team, clarity and simplicity, inter-department communication,

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Executive Summary

The CCS2005 project is a one-year case – control study, which aims to identify herd, based risk factors associated with Bovine TB (bTB). This project follows on from a previous case-control study (TB99), which ran from late 1998 until the end of 2004.

Two previous audits of the TB99 study were carried out, one in 2003⁽¹⁾ and another one in 2005⁽²⁾.

The first report looked at the whole project process from source data collection in the field to final data entry onto the database. The first audit report recommended that major changes should be made to the questionnaire, and it highlighted other areas of concern, such as the high number of people who had collected data.

The second audit report concentrated mainly on assessing the implementation of activities following the Auditor's recommendations and the Government's response to the 2003 report. The conclusion of the second report was that:

“Overall, the Auditor found a great deal of improvement in terms of team spirit, training, handling the questionnaire on the farms as well as in terms of documentation.

All the above-mentioned improvements constitute a good basis for the quality of the data collected in the new Case Control Study 2005 (CCS2005)”.

The present audit once more assessed the whole process from design and implementation of the questionnaire to its data management. Throughout the audit all people involved in the project gave their full support to the audit activities.

A major failing of the previous TB99 project was that it had failed to deliver in terms of collecting the required number of control forms. For the CCS2005 project the target number of completed forms (both cases and controls) has been met on time. All members of the project team, and in particular the field staff who collected the data, should be congratulated on this effort.

The Auditor has been impressed by the professionalism and dedication throughout all the stages of the study, from the planning phase to the training, the completion of the questionnaire in the field, the collection of the data and the data management.

All the auditor's recommendations from the two previous audit reports had been considered and with the exception of one, an overall responsible person, were all implemented. The overall responsible person was not appointed, as a DEFRA project manager would not have had authority over staff from other organizations. Nevertheless the idea of the recommendation was followed by appointing a CCS2005 working group. This group consisted of a representative of each department involved in the project. Prior to the implementation of its activities a number of program planning documents were created by the Defra project manager to enable effective management of the project when it started. The group was responsible for the study design and the design of the questionnaire. The questionnaire design concentrated on key questions derived from the experience of TB99, and on creating a simple, more user friendly and shorter questionnaire. The questionnaire was annotated and extensive explanations written down to describe how to complete it.

Four Animal Health Divisional Offices (AHDO's) were selected for carrying out the trial. The staff within each ADHO was identified, with the auditor's recommendation to keep the team small being followed.

Once the questionnaire had been designed a pilot study was undertaken to assess the feasibility of the completion of the questionnaire in the field, both in terms of the time and the ease with which it was completed. All team members from the four AHDOs, and a number of ADAS consultants, were provided with suitable training encompassing all relevant aspects of the project before the study went live through the provision of one-day training sessions.

The auditor accompanied field staff on one farm visit. The interview went well and smoothly, with the questions being clearly explained by the interviewer. The farmer had ample time to answer the questions and in no instance did the Officer influence him in his answers.

The CCS2005 AHDO's teams were well organized and each member of the team knew what their role and function was within the project. The atmosphere in both AHDOs visited was very good and there was a good team spirit.

At the VLA the recommendations made by the Auditor have been implemented, are well documented and self-explanatory. A quality control document is in place.

Communication between all parties appears to have been excellent, with daily contact between the AHDOs and the VLA and monthly teleconferences between AHDOs, the VLA and other members of the team. The AHDOs' responsible person and his assistant were fully dedicated to the trial and together with the AHDO teams were a major factor in the success of the CCS2005 trial. The other key contributors were the team in the VLA, who gave their constant support to the AHDOs. Finally thanks to the dedication of the CCS2005 working group the project ran smoothly, on time and with high data quality standards.

The auditor makes two recommendations to DEFRA. First, it should capitalise on the expertise acquired by the different groups within this team as well as on the lessons learnt throughout the years on how to plan, design, run and analyse a trial. Secondly, that because the targets in terms of data collection were met and because the quality of the data is of the highest standard that it should consider prioritizing the analysis of the CCS2005 data.

Table 1 The number of cases and controls allocated to and received from each AHDO

<i>AHO</i>	<i>Cases</i>						<i>Controls</i>				
	<i>Target</i>	<i>Sent out</i>	<i>Accepted</i>	<i>Refused</i>	<i>Not considered</i>	<i>Received</i>	<i>Target</i>	<i>Possible</i>	<i>Rejected</i>	<i>Accepted</i>	<i>Received</i>
CARLISLE	27	39	27	12	0	27	54	54	132	54	54
CARMARTHEN	125	356	125	115	116	125	250	250	279	250	250
STAFFORD	125	269	125	71	73	125	250	250	308	250	250
TAUNTON	125	187	125	12	50	125	250	250	165	250	250
TOTAL	402	851	402	210	239	402 *	804	804	884	804	804 *

** 402 cases and 804 controls were received where the case and controls where matched pairs. 6 further questionnaires were received where this was not the case, meaning that 1212 questionnaires were received in total. Other tables in this report are based on all 1212 questionnaires received.*

1. Introduction

The Krebs report of 1997⁽³⁾ highlighted the lack of epidemiological data collected at TB herd breakdowns. In response to the report DEFRA initiated the TB99 case control study in late 1998. The TB99 study continued in various forms until 2005, when it was re-launched as the Case Control Study 2005 (CCS2005)

The Independent Scientific Group (ISG), appointed to advise DEFRA on the running of the Randomised Badger Culling Trial (RBCT) and other aspects of TB policy, wishes to see all aspects of the RBCT audited. As such, the audit of the CCS2005 questionnaire forms part of the wider audit of the whole RBCT. Two previous audits have taken place of the TB99 study in 2003 and 2004 and have led to two audit reports^{(1) (2)}.

2. Background and Rationale

The CCS2005 is aimed at evaluating herd-based risk factors associated with the occurrence of bovine TB (BTB).

The CCS2005 study, which was launched in February 2005, replaces the earlier TB99 study. The questionnaire has been completely re-designed in the light of the lessons learnt from TB99 and from the analysis of TB99 data. The lessons learnt are covered in more detail in this report, but include shortening and simplifying the questionnaire and ensuring that all questions require an answer. Previous analysis of TB99 had shown certain variables not to be significant as a risk factor (e.g. herd health and testing history of animals slaughtered), and these have been dropped. Other questions, which proved to be significant, have been expanded (e.g. Cattle accommodation).

The study design of CCS2005 is also significantly different from that of TB99, which as a case-control study had been confined to the RBCT areas. CCS2005 operates in 4 animal health regions: Taunton (covering Somerset and Dorset), Stafford (covering Staffordshire, Cheshire and Derbyshire), Carmarthen (Dyfed), and Carlisle (covering Cumbria). Although being in a trial area does not preclude a farm from being in the

study, the majority will exist outside trial areas.

The study design aims to include farms that exist in medium to low BTB prevalence areas (Taunton and Carlisle), as well as high prevalence areas outside of trial areas (Stafford and Carmarthen).

The reason for expanding the study outside of trial areas was to gain knowledge in these areas and also to tackle the problem of a lack of control farms that was occurring in the later years under the TB99 study.

The study was designed to last one year (2005). It was launched on 7th February 2005, and continued until the end of February 2006. The target number of cases for the study was calculated by power analysis and was for Taunton, Stafford, and Carmarthen AHDOs 125 cases, with two controls for each case (250), giving a grand total of 375 cases and 750 controls. The VLA randomly allocated cases and controls. Because Carlisle AHDO was unlikely to have a large number of herd breakdowns during the study period, it was agreed that they would attempt to include all herd breakdowns in their region as cases, along with 2 controls for each of these cases.

2.1 The rationale behind the audit:

The rationale is to have reasonable assurance that the conclusions or recommendations made at the end of the trial are based on the analysis of data collected which is as complete, accurate and reliable as possible.

3. Material and Methods

3.1 Material

All pertinent material was made available to the Auditor including the content of the training sessions, minutes of CCS2005 working group, minutes of teleconferences and quality control documents.

3.2 Method

3.2.1 Implementation of auditor's recommendations and processes in place

The Auditor assessed

- The implementation of the recommendations made in her previous report including the government reply.
- The processes in place to ensure the proper completion of the questionnaires in terms of both quantity and quality (including query handling).

The VLA was visited on several occasions. Interviews of the VLA's CCS2005 project manager; the database developer and all administrative staff involved in the project took place. Quality control documents and data validation programs were reviewed. A number of CCS2005 questionnaires were checked.

Two AHDOs were visited as well as one farm. Interviews took place, the team took the auditor through the whole process from farm selection to completion of questionnaire, its review, answering queries and keeping track of all events. Study documents were reviewed. At the farm the AHDO representative completed the questionnaire with the farmer in front of the Auditor.

3.2.2 Attendance to training sessions and working group meetings

The auditor attended two training sessions as well as two working group meetings.

4. Findings

The findings are reported per topic with each topic relating to the recommendations made in the two previous audit reports.

4.1 Prior to study start: planning stages

4.1.1 CCS2005 working party

Previous audit recommendation

"For future projects the auditor recommends that the question of project management be fully considered during the planning stages".

Auditor's comment

An overall project manager responsible for all aspects of the day to day running of the trial was never appointed, because a Defra project manager would not have had any authority over staff from the SVS, ADAS and VLA. The spirit of the recommendation, however, was met through the CCS2005 Working Group, the members of which took joint responsibility for project management. The involvement of a responsible person from each department in this working group contributed greatly to the success of the project. The auditor is pleased to see that following her recommendations a team approach was used.

A working group was created to redesign the TB99 form. This group was representative of all the interested parties and involved representatives from the SVS (responsible for farm visits), a representative from the VLA (responsible for data management), representatives from the ISG (responsible for data analysis) and representatives from Defra (responsible for project management).

Name	Organisation	Role
Steve Coleman	DEFRA	CCS2005 project manager to working group section
Professor George Gettingby	ISG / Strathclyde University	Statistical consultancy and chair of the working group
Tom Johnson	ISG / Imperial College	Analysis of CCS2005 data
Andy Mitchell	VLA	Project manager for VLA CCS2005 database project
Peter Crea	SVS	Project manager for SVS field work

Although the group's main task was to design the CCS2005 questionnaire a number of program planning documents were also drawn up by the Defra project manager to enable effective management of the project when it started. These included a project initiation document, risk register, mission statement and a flow diagram of work dependencies and communication lines. The ISG statistician designed the initial version of the questionnaire, but all subsequent versions were the result of input from all members of the group. Towards the end of the process of questionnaire design, the form was tested in a pilot study of eight farms.

The auditor attended one meeting of the working group prior to the start of the study. She felt that the meetings were well structured and fulfilled their functions of reporting progress, and assessing quality and other issues. Solutions were found within the team and subsequently discussed within each of the member's departments.

4.2 Documentation, communication and coordination

4.2.1 Design, quality of the Farm Management Questionnaire (FMQ)

Previous audit recommendation

“The questionnaire should be modified to be simpler and shorter, that the instructions and the questionnaire should match.” Defra had agreed with these points

Furthermore, there was anecdotal evidence that the TB99 form was taking around two hours to complete; the auditor had recommended that they should be aiming for a form that would take around one hour to complete.

A new, more concise and more user-friendly questionnaire (the FMQ) has been developed, which all the interested parties seem satisfied with. Prior to its finalization it was tested in Taunton AHDO.

Auditor's comments:

Although she never contributed to its design, the Auditor had a chance to review it at regular intervals. In particular the issue of 'potential missing data' seems to have been addressed with all questions in the new questionnaire requiring an answer. Also, many of the instructions relating to the form are integrated into the form itself, rather than being in a separate document.

Table 2 shows the average time taken for the CCS2005 interview. The average time taken varies (depending on the AHDO) between an hour and an hour and twenty minutes. These times mean that the farmer's attention can be maintained for the period of the interview.

Table 2 Average time taken for CCS2005 completion by AHDO

AHDO	Average Time per Questionnaire / minutes
Carlisle	63
Stafford	84
Taunton	61
Carmarthen	84

Auditor's comments

The auditor is pleased that a new questionnaire was designed which also took into consideration her recommendations. This is a simple questionnaire, asking key questions. Questions are phrased in such a way that there is no room for misunderstanding. The questionnaire is reasonably short. The display of the questions and their answers is easy to follow. The questionnaire is annotated and extensive description on how to complete it is given for each set of questions. On average the questionnaire takes just over an hour to complete.

Therefore the auditor feels that all her recommendations were taken into

consideration and acted upon.

Work on the database could only commence once the questionnaire design was complete. The time period between the questionnaire being finalized and running the pilot study was not sufficient to have the database ready for the piloting of the questionnaire in the field. It would have been ideal to be able to enter the data from the pilot run onto the CCS2005 database.

One criticism therefore is that although the questionnaire was tested in the field, the data processing stages were not.

4.2.2 Identification of the AHDOs and the AHDO's team

The identification of the regions where the CCS2005 study should take place was also part of the remit of the working group. The four regions were identified by the group as likely to satisfy the requirements of providing areas of high, medium and low prevalence and also of providing sufficient numbers of cases and controls in one year. Once the four areas had been identified and their involvement agreed, the SVS identified staff (both administrative and field) to take on the project.

4.2.3 Training sessions

The working party stipulated that all staff involved in the CCS2005 project should attend a CCS2005 training session.

The auditor attended two training sessions. The courses were given by speakers from all departments involved. First, the background to the CCS2005 was described to set the scene. Then a detailed introduction to the FMQ followed, given by the AHDO project management. Administrative spreadsheets, procedures and desk instructions were presented by the AHDO project management and by the VLA project manager.

A practical exercise followed where the course participants were asked to complete some part of the FMQ.

In addition an evaluation form was given to the participants asking them whether they felt that the course had met their objectives and how useful and interesting it had been.

Auditor's comments:

These sessions were extremely well prepared. They were very interactive. They covered all aspects of the study. Each participant left with a very comprehensive folder which included written instructions, all slides presented at the course, an example of a FMQ spreadsheet, questions and answers, risks linked to the project etc. The training covered all aspects of the study, it made people realize that they were part of a broad project and that each of their contributions was of the utmost importance. They understood the importance of each aspect of the trial from data collection to data cleaning and to analysis, and also, not only what was being asked from them but also why, which is very important when dealing with unexpected situations.

4.3 In-study

4.3.1 CCS2005 working group

In-study the working group's main tasks have been to coordinate and ensure the proper running of the trial in terms of quantity, quality and proper timing, as well as to address and try to resolve any issues. They met at regular intervals and minutes of their meetings are available. The auditor attended one session in July 2005.

As in any project of this size, various issues came up during the year. One such issue involved the issuing of controls by the VLA to the AHDOs. The issue was that there had been a misunderstanding of the way control allocation would work. The procedures used by the VLA meant that controls were issued individually and they required notification of the result of the control allocation before they could allocate the next control. This caused a very major backlog of control allocations. The solution started on 25/04/05 nearly 3 months into the project.

Auditors comments:

Potentially this misunderstanding could have had serious consequences for the trial in terms of recruiting the required number of controls. However, because there was good communication between all parties and because the working group was meeting at regular intervals a solution was found relatively quickly, with the VLA being able to modify their control allocation procedures so that controls were allocated in batches, and an agreed, achievable yet challenging target set for the shortfall, that had built up, to be caught up

4.3.2 General communication and documentation

All aspects of the trial are well documented in the AHDOs as well as in the VLA.

Recommendations from previous audit reports

"It is important for the quality of the project and for the motivation of the staff, to give regular feed-back not only about TB99 activities within their own AHDOs but also about the whole TB99 project".

Regular monthly teleconferences took place between the four AHDOs and the VLA. According to the participants these were very useful. They helped identify issues and how to solve them; they also helped staff feel less isolated, as well as understanding that they were not alone when, or if, they had problems.

Contacts with the VLA were on an almost daily basis and a great part of the success of the project was due to the dedication of the VLA administrative and data management team.

Auditor's comments:

In this study communication between all parties worked very well and this represents an important part of the success of the study. Here also all the auditor's recommendations were taken into account.

4.3.3 The AHDOs

The contributions of the four Animal Health Divisional Offices (AHDOs) involved in the study were reviewed in terms of the number of queries raised by their questionnaires, the reasons they had given for not accepting a control and the number of Officers filling out questionnaires. A number of printouts were also generated which constituted the basis for some of the discussions in the AHDOs.

Two AHDOs were visited.

Auditor's comments:

The auditor was impressed by the dedication of the teams in the AHDOs. She was pleased to see that as opposed to her previous audits only a small team (mainly Animal Health Officer field staff) went out to interview farmers and complete the questionnaire.

4.3.3.1 Completion of the CCS2005 FMQ

Recommendations from the 2003 audit.

“Possibly too many people are going out to the farms (on average 25 to 30 persons in each AHDO have gone to visit farmers at least once). It would be better to have as few interviewers as possible, but well trained and capable to follow the cases including correcting the questionnaire if needed”

It had also been noted that some interviewers were insufficiently neutral.

DEFRA had agreed with these points.

In the Auditor's 2004 report a great improvement had been noted in terms of how to handle the interviews. Nevertheless there were still far too many interviewers.

In the CCS2005 FMQ the number of staff having gone out to the farms has dropped drastically as can be seen in the comparison between the 2005 figures (table 3) and the 2004 figures shown in table 4.

Table 3 Average number of forms completed per officer in 2005

<i>AHDO Name</i>	<i>Year</i>	<i>Total CCS2005</i>	<i>Total Officers</i>	<i>Average No. of forms completed per officer</i>
Carlisle	2005	81	3	27
Stafford	2005	375	13	28.8
Taunton	2005	375	10	37.5
Carmarthen	2005	381	9	42.3

Table 4 Average number of forms completed per officer in 2003 and 2004

<i>Ahdo Name</i>	<i>Year</i>	<i>Total TB99s</i>	<i>Total Officers</i>	<i>Average No. of forms completed per officer</i>
EXETER	03	188	24	7.83
EXETER	04	44	14	3.14
GLOUCESTER	03	154	34	4.53
GLOUCESTER	04	94	21	4.48
STAFFORD	03	69	15	4.60
TRURO	03	199	22	9.05
TRURO	04	17	8	2.13
WORCESTER	03	121	13	9.31
WORCESTER	04	71	12	5.92

4.3.3.2 Processing of CCS2005 questionnaires and tracking procedures

Recommendations from previous audit reports

" It seems that each office has a different system in place to track the TB99 process and it might be worthwhile thinking of a uniform system for all AHDO's especially also in the light of new areas filling in the questionnaire (It is planned to have a uniform TB99 administrative tracking system in place for the CCS2005 study)".

A unique system of FMQ tracking spreadsheets has been in place in this study and it worked well according to all persons interviewed.

4.3.3.3. Queries

Recommendations from previous audit reports

"The Auditor reiterates what she had been saying in her earlier audit report and that is that one way to improve the quality of the data in the questionnaire is to have a quick turn-over of queries. Apart from answering the query and therefore cleaning the database, this has an educational effect. It helps to avoid repeating the same mistakes time after time (provided the queries are relevant)."

The answering of queries and their quick turnover was much improved for the CCS2005 project.

Table 5 shows that 42 % of all questionnaires did not generate any queries; this is a remarkably high figure. The auditor checked 10 questionnaires that had raised no queries and could not find any data that should have raised queries. The high percentage of forms not raising any queries is an indication that the data quality for CCS2005 is high.

Table 5 Number of queries raised per form

<i>Number of queries</i>	<i>Number of forms</i>
0	511
1	385
2	176
3	70
4	24
5	19
6	12
7	8
8	4
9	1
10	0
11	1
12	1

Table 6 shows the 'educational effect' of having a quick turnover of queries. The VLA sent queries out once a month and there was agreement that all queries would be answered within the month. Because of this quick turnover of queries there was a 'learning process' throughout the life of the trial and a consequent drop off in the number of queries raised over time.

Table 6 Number of queries raised per month

<i>Month</i>	<i>Year</i>	<i>No. FMQs</i>	<i>No. Queries</i>	<i>Queries / form</i>
2	2005	15	60	4.0
3	2005	68	187	2.75
4	2005	69	113	1.64
5	2005	84	99	1.18
6	2005	124	174	1.40
7	2005	152	199	1.31
8	2005	135	112	0.83
9	2005	105	76	0.72
10	2005	67	46	0.69
11	2005	107	92	0.86
12	2005	74	39	0.53
1	2006	98	49	0.50
2	2006	95	74	0.78
3	2006	17	10	0.59

The querying process

The following extract from a document written by the VLA administrative team describes how the querying process worked.

"A query program was written within the CCS2005 data entry program that allowed those entering data to write a query on any field of input, with the exception of the initial login screen. If a query arose while logging in a form the administrator contacted the SVS office by phone or email.

Table 7 shows the questions that raised twenty or more queries at the data entry stage.

Table 7: Questions raising over 20 or more queries

<i>Question</i>	<i>No. of Queries Raised</i>
10.1 CPHH	362
4.2 Reactors no. weeks	59
3.1 a) If Yes, may we have access to them?	52
8.1 Fertiliser type	42
12.1 Where on the farm?	41
3.2 OS map ref	41
4.2 Cattle type	40
12.5 b) Deer?	40
3.2 Type(s) of cattle kept on premises	37
12.1 Found dead on farm?	34
8.2 What was the minimum time between spreading of fertiliser and cattle grazing the land or grass being cut for forage?	29
3.2 CPH No	29
2.3 Typical number of animals in group	27
4.2 No of weeks	27
6.2 Cattle type	26
12.1 Laboratory confirmed M. bovis?	24
6.2 Was this feed provided for reactors?	23
3.1 Are there IACS maps available that cover all the farms premises?	22
13.1 Is there contact with any cattle?	20
5.2 Cattle type	20

Table 7 shows the disproportionate number of queries raised by question 10.1, which asks for the CPHH of the farmer's neighbours. The CPHH of neighbours is not usually known to the CCS05 farmer. He may know his neighbours CPH, but not the details of his neighbour's herds. Question 10.1 obviously posed practical difficulties and perhaps its

usefulness should have been reviewed at an early stage of the project.

In Carmarthen

From Carmarthen AHDO:

The Divisional Veterinary Manager (DVM), Animal Health Officers (AHOs), and Senior Animal Health Officer (SAHO), an Executive Officer (EO), and two Administrative Officers (AOs).

From elsewhere:

The SVS CCS2005 Project Manager VA, the DEFRA project Manager and the Auditor.

At the time of the audit visit at the end of July 2005 Carmarthen had the largest shortfall. Nevertheless by the end of September i.e. 2 months later they had caught up with their delays as promised in July 2005.

Tables 8 –10 show the situation at Carmarthen with respect to the number of staff completing questionnaires (table 8), the number of queries raised per questionnaire (table 9) and the reason for rejection of controls (table 10)

Table 8 Number of forms completed by officers in Carmarthen

<i>Officer</i>	<i>Number of forms completed</i>
Officer1	1
Officer2	8
Officer3	13
Officer4	31
Officer5	39
Officer6	46
Officer7	49
Officer8	54
Officer9	140
Total	381

Table 9 Number of queries raised per form in Carmarthen

<i>Number of Queries</i>	<i>Number of Forms</i>	<i>% of Forms</i>
0	203	53.28
1	107	28.08
2	46	12.07
3	18	4.72
4	2	0.52
5	3	0.79
6	1	0.26
7	1	0.26
Total	381	100

Table 10 Control rejection reasons for Carmarthen

<i>Rejection Reason</i>	<i>Number</i>
Does not want to take part	134
Rejected	149
Total rejections	283

On the farm

The Auditor accompanied one Animal health officer (AHO) onto the farm. The interviewer explained to the farmer why he was asking each question. He then gave ample time to the farmer to answer the questions. He did not prompt any answers and the data recorded on the questionnaire reflects accurately the data the farmer wanted to have recorded.

Auditor's comments

The Auditor feels that the interview went well and that it was carried out in a professional way. All questions were addressed and the answers provided by the farmer were given to the best of his knowledge. The farmer was very cooperative.

Audit findings, comments and recommendations:

The auditor felt that all aspects of the FMQ process were in place.

The only issue raised was the fact that there was no audit trail for query answers and FMQ corrections. In the VLA there is no way to know which officer has corrected queries.

Although each office has his own electronic records, any post farmer's visit, any correction or alteration to the original FMQ or to the database should be dated and initialed allowing an audit trail at anytime (at present and in the future).

In Taunton

An Executive Officer (EO), an Administrative Officer (AO) and two Animal Health Officers (AHOs).

From elsewhere:

The SVS CCS2005 Project Manager VA and the Auditor.

Tables 11 –13 show the situation at Taunton with respect to the number of staff completing questionnaires (table 11), the number of queries raised per questionnaire (table 12) and the reason for rejection of controls (table 13)

Table 11 Number of forms completed per Officer in Taunton

Officer	Number of forms completed
Officer1 (ADAS)	7
Officer2	25
Officer3 (ADAS)	34
Officer4	34
Officer5	35
Officer6	37
Officer7	39
Officer8	52
Officer9 (ADAS)	56
Officer10 (ADAS)	56
Total	375

Table 12 Number of queries raised per form in Taunton

Number of Queries	Number of forms	% of forms
0	141	37.60
1	146	38.93
2	55	14.67
3	20	5.33
4	8	2.13
5	3	0.80
6	2	0.53
Total	375	100

Table 13 Control rejection reasons for Taunton

Rejection Reason	Number
<i>Does not want to take part</i>	66
<i>Rejected</i>	99
Total rejections	165

Queries/ Audit procedures

Queries are allocated to the case VO. The Lead VO showed his audit procedures, how he is checking the Questionnaire and how queries are passed to him if there is a problem.

Auditor's comments

*The Lead VO assessed the quality of the data on the Questionnaire
The Auditor was impressed by the motivation of the staff, by their excellent organization and by the quality of the work produced.*

The only issue raised in Taunton was the fact that the AHDO did not have the authority or control over the quality of the data provided by the Agricultural Development and Advisory Staff (ADAS). Reservations over the quality of ADAS data existed, because of the high turnover of ADAS staff. At some stage ADAS had changed its project manager, staff had left and other staff had joined. The role of ADAS is covered in 4.3.5.

General comments:

The auditor was impressed by the dedication of the teams in both the AHDOs visited. The success of this trial is in a great part due to them.

The auditor wants to acknowledge the contribution of the SVS CCS2005 project manager and his colleagues without whom this project would not have reached the level of quality it did.

4.3.4 In the VLA

The VLA was visited on several occasions. These visits were to assess the quality of the current CCS2005 data and also to follow up the audit recommendations specific to the VLA from previous audit reports.

Previous Audit recommendations had been:

4.3.4.1 Logging changes to the database

Previous audit recommendation

The Auditor recommends that any changes made to the database during the lifetime of the new CCS2005 study should be logged in a similar manner to the TB99 study.

This had been done. Any changes made to the CCS2005 database during the project year have been logged in the module mdChanges within the Access database VLA25:\TB99\Version2005\forms\TB99_2005_FrontEnd.

4.3.4.2 Computer based administrative queries

Previous audit recommendation

The Auditor recommends that the computer-based checks should be expanded for the new CCS2005 study to include more non-control checks.

A separate database was developed to record any data entry queries in a similar manner to that used for the TB99 study. Not only does this method provide a useful method for recording and sending out queries, it provides an efficient way of monitoring problems e.g. it is easy to highlight questions that are raising a disproportionate number of queries. The data recorded has been used extensively in this report

4.3.4.3 Validation constants

Previous audit recommendation

The Auditor recommends that a list of the validation constants for the new CCS2005 study should again form part of the VLA's new CCS2005 QC document.

A list of validation (or boundary) constants has been kept and is located at VLA25:\TB99\Version2005\forms\Docs\ValidationConstants

4.3.4.4. Control allocation

Previous audit recommendation

The changes over the years in the way controls were selected and allocated are now summarized in a clear document. This process should be continued for CCS2005.

The VLA's CCS2005 quality control document describes accurately the way in which control allocation works. There was a change in the way control allocation was

administered after a few months. On the 25 of April 2005 the new system started. However the document only describes the method in operation for the majority of the study.

Tables 10 and 13 highlight the high number of control rejections. The reasons for control rejection were only recorded at the VLA as being of two types: 'Control rejected' – meaning the AHDO did not believe it satisfied the criteria required or 'farmer did not want to take part'. In fact some of the AHDOs did record more detail on control rejection, but this was never standardized across all the AHDOs.

Auditor's comments

The auditor recommends that for any future trials more detail on the reasons for refusing to participate should be recorded.

4.3.4.4 "Empty fields" in the database.

Previous audits had highlighted the issue of empty or null fields in the database and the difficulty in their interpretation. For instance should they be interpreted as missing or not applicable. The design of the current questionnaire is much better with respect to this issue, with the vast majority of questions requiring an answer.

For any fields that can still potentially be left blank there is a section in the VLA quality control manual that describes their interpretation.

4.3.4.5 Computer based administrative queries

Previous audit recommendation

The Auditor recommends that the computer-based checks should be expanded for the new CCS2005 study to include more non-control checks.

A series of administrative queries have been developed to aid the administration of the project, these queries include both control and non-control queries. For example lists were generated where both controls and cases had been accepted by the AHDO and the forms not received after a set number of weeks

4.3.4.6 Data Entry Procedures

Previous audit recommendation

"Data entry procedures should be documented".

The data entry procedures are documented in the VLA's quality control document.

4.3.4.7 Interviews of VLA staff

As part of the audit process in the VLA, the auditor asked the VLA administrative team, who were involved in the project on a day to day basis, about what they thought were the positive and negative points of the study and what possible improvements could have been made. They made the following comments:

Negatives

1. Section 10.1 caused the highest number of queries. Steps were taken to improve the quality of form filling by the SVS and subsequent data entry by VLA.
2. One office encountered problems carrying out farm visits in good time. By August a backlog had developed of cases and controls that had been accepted by them but for which the farm visits had not taken place. This problem was highlighted by the regular reports sent by VLA to the SVS project manager (P Crea) and he ensured that steps were taken to deal with the backlog. By the end of 2005 all the offices were up to date.

Positives

1. There was an excellent rapport between the VLA and SVS admin teams, which greatly aided the smooth running of the project.
2. Training sessions of the SVS by VLA helped to establish contact between the two prior to the start of the project and subsequent phone conferences and

meetings highlighted problems that were then dealt with rapidly.

3. The number of data entry queries submitted by VLA to the SVS declined steadily during the 12 months spanned by the project. That this occurred was largely due to the regular meetings and the good rapport between the two.
4. The CCS2005 form was, in general, well laid out offering few opportunities for misinterpretation; this made data entry smoother and faster.

Improvements

1. If there had been time, a very small pilot project would have highlighted the problem with section 10.1 and perhaps shown the SVS that the initial control allocation program was too limited given the number of cases and controls allocated each month. As it was, the program was quickly re-written by VLA.

As can be seen from the above points, in general the VLA team was very positive about the project, with the list of positive points outnumbering the negative ones.

The success of the data management part of the project was in no small part due to the dedication of the VLA administrative and programming data management team.

4.3.5 The role of ADAS

A total of 200 questionnaires in the CCS2005 study were completed by ADAS– see table 14

As mentioned previously, one of the issues raised by SVS staff had been the role of ADAS and the fact that the SVS had no control over the quality of data they provided. Although the auditor did not interview any ADAS staff as part of this audit, the following graphs and tables analyse their contribution.

Probably the easiest way to see if there was a difference in the quality of the data provided by the two organizations is to look at the number of queries raised per form. This is shown in Table 15 and Figure 1.

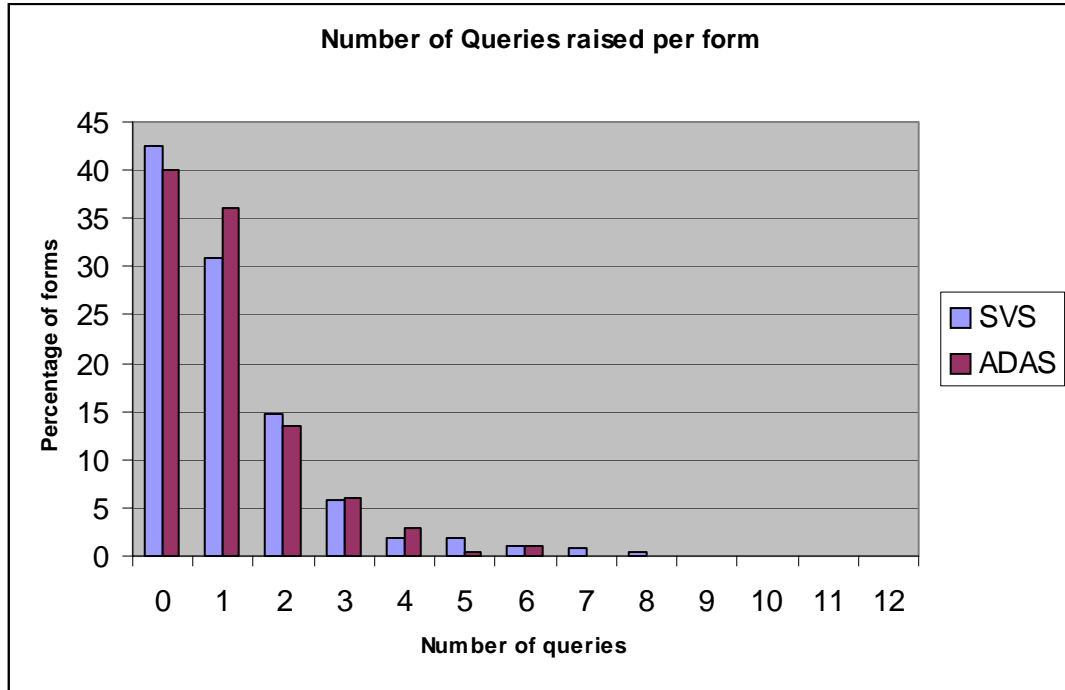
Table 14 The number of questionnaires completed by ADAS and SVS staff

<i>Organisation</i>	<i>Type</i>	<i>Total</i>
ADAS	Case	59
ADAS	Control	141
SVS	Case	343
SVS	Control	669

Table 15 The number of queries per form for SVS and ADAS

<i>No. of Queries</i>	<i>SVS – No. of forms</i>	<i>ADAS – No. of forms</i>
0	431	80
1	313	72
2	149	27
3	58	12
4	18	6
5	18	1
6	10	2
7	8	0
8	4	0
9	1	0
10	0	0
11	1	0
12	1	0

Figure 1 The percentage of forms raising queries for SVS and ADAS



Auditor's comments:

Table 14 and figure 1 show that the distribution of the number of queries raised at data entry for the two organizations is very similar.

One further measure of data quality is the time it took for the interview to take place and the form to be returned to the VLA, once the case or control had been allocated. These are likely to be a measure of quality because ideally (for cases) the interview should take place as near as possible to the breakdown date. Tables 16 and 17 give these times for cases and controls respectively.

Table 16 Time from case breakdown to visit date and form return date

	<i>Breakdown - Farm visit (days)</i>	<i>Breakdown - VLA receive form</i>
ADAS	65.6	86.4
SVS	61.2	77.2

Table 17 Time from control acceptance to farm visit and form return

	Accept to farm visit	Accept to return to VLA
ADAS	29.6	46.3
SVS	25.6	41.0

Although, for both cases and controls, ADAS took longer to visit the farm and return the completed form, the differences are a matter of a few days.

Auditor's comments:

The auditor does not feel that these differences would have had a negative effect on data quality.

Nevertheless the concern raised in Taunton needs to be considered for future trials when using external resources. It is important to define who has overall responsibility for quality control at the source where the collection of data takes place, especially if issues arise.

5. Conclusions

The auditor is pleased that the majority of her previous audit recommendations were implemented. These included a simplified FMQ, training for all staff, better communication between team members and smaller but well trained teams.

The one audit recommendation that was not implemented was the appointment of an overall project manager, responsible for the day to day running of the project. Despite this the project has run smoothly largely due to the small working group

where each member had specific project responsibilities

The auditor was impressed by the dedication of the whole team and by the quality standards achieved.

She would like to recommend DEFRA to capitalize on the expertise gained in all departments.

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