



Veterinary
Medicines
Directorate

Microchip Adverse Event Reporting Scheme

Review

From voluntary to compulsory reporting
April 2014 to December 2015

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[Executive Summary](#)

Between the launch of the Microchip Adverse Event Reporting Scheme in April 2014 and the end of December 2015, the Veterinary Medicines Directorate received 1420 microchip reports. Overall, 61 reports described a reaction, 630 microchip failure and 729 migration. More than 75% of reports were submitted by vets and the majority of reports (84.2%) involved dogs. As the VMD does not currently receive microchip sales information, and therefore cannot estimate the number of animals that have been microchipped, calculating the risk of adverse events is not possible at this time. However, given that there are an estimated 8.5 million dogs and 7.5 million cats in the UK¹ and considering the low number of reports received in 2015 despite the high uptake of microchipping following the new legislation, the risk of an animal experiencing an adverse event is likely to be very low.

¹ Pet Foods Manufacturing Association (PFMA) Annual Report 2016
www.pfma.org.uk/statistics

Introduction

The Veterinary Medicines Directorate (VMD) launched its Microchip Adverse Event Reporting Scheme in April 2014, replacing the scheme previously run by the British Small Animal Veterinary Association (BSAVA).

Although we do not regulate the animal microchip market in the same way that we assure the quality, safety and effectiveness of veterinary medicines, we agreed to take on this work as:

- we already had an effective system in place for collecting and monitoring reports of adverse events following the use of veterinary medicines. This process is known as pharmacovigilance, and we publish a [review](#)² of findings from this work separately.
- it supports the Government's new [legislation](#)³, which was first announced in February 2013, making it a legal requirement for all dogs in England to be microchipped from April 6 2016.

Although at that time the planned legislation only related to England, we launched the scheme on a UK-wide basis. The [Welsh](#)⁴ and [Scottish Governments](#)⁵ have subsequently introduced similar legislation requiring all dogs to be microchipped from this same date. Microchipping of dogs has been compulsory in [Northern Ireland](#)⁶ since April 2012.

Reporting adverse events following microchipping of dogs has been a legal requirement in England since February 2015 and in Scotland and Wales since April 2016.

Although there is no legal obligation to report adverse events following microchipping of other animals, you can report problems occurring in any species following microchipping. You must submit your reports using our dedicated and interactive [online reporting form](#)⁷. Separate forms for reporting adverse events following use of veterinary medicines are available via the same link, so make sure you select the right one. Full details of the scheme can be found in our [leaflet](#)⁸.

Please note that the VMD is not responsible for any of these pieces of legislation; we only monitor reports of adverse events following microchipping. All questions relating to any other aspects of microchipping policy should be directed to the relevant authority, details of which can be found in the Useful Contacts section at the end of this report.

² Veterinary Pharmacovigilance in the United Kingdom – Annual Review 2014

www.gov.uk/government/publications/veterinary-medicines-pharmacovigilance-annual-review-2014

³ Microchipping of Dogs (England) Regulations 2015

www.legislation.gov.uk/ukxi/2015/108/contents/made

⁴ The Microchipping of Dogs (Wales) Regulations 2015

www.legislation.gov.uk/wsi/2015/1990/contents/made

⁵ Microchipping of Dogs (Scotland) Regulations 2016

www.legislation.gov.uk/ssi/2016/58/contents/made

⁶ Dogs (Amendment) Act (NI) 2011

www.legislation.gov.uk/nia/2011/9/contents/enacted

⁷ Report a problem with an animal medicine or microchip (search Gov.uk for 'microchip problem')

www.gov.uk/report-veterinary-medicine-problem

⁸ Microchip adverse event reporting scheme

www.gov.uk/government/publications/microchip-adverse-event-reporting-scheme

Who sent the reports

Figure 1 shows that vets submitted the majority of the reports to us. Vet nurses and other practice staff accounted for another significant proportion of the reports. Although it is not a requirement for vets to routinely scan dogs, it is obvious many often do, either to confirm the identity of the dog before pet passport vaccinations or other treatment, or for other reasons. Unless there is an obvious reaction, it is less likely that owners would be aware of most microchip problems.

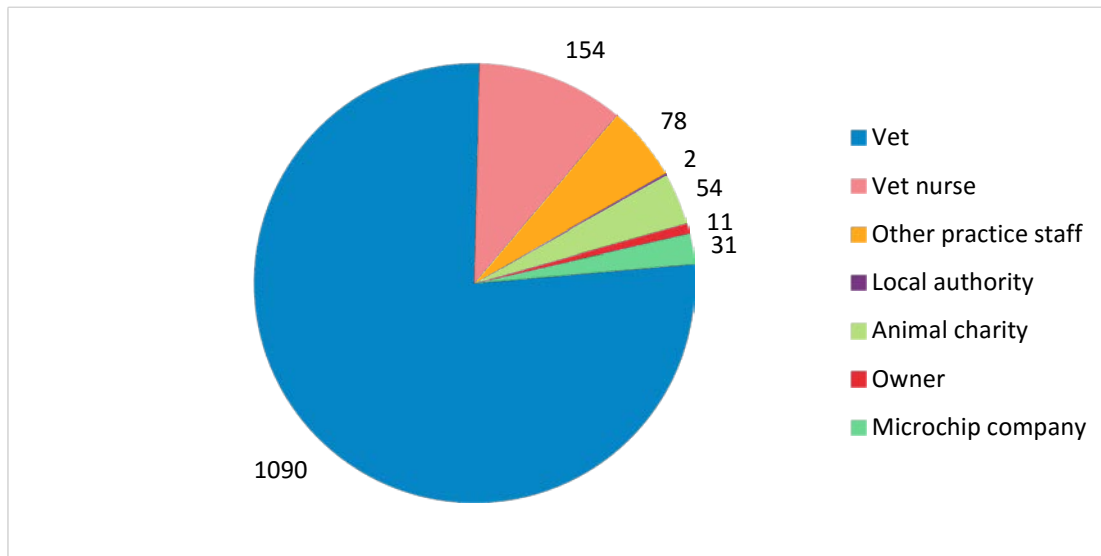


Figure 1 Number of reports by profession, organisation type or relationship to animal

Species

Figure 2 shows the number of reports received per species; 'Other' includes four rabbits, a horse and a tortoise. Most reports received involved a dog; which is unsurprising, given the new legislation. However, the scheme is not exclusively for dogs and adverse events occurring in any species can be reported.

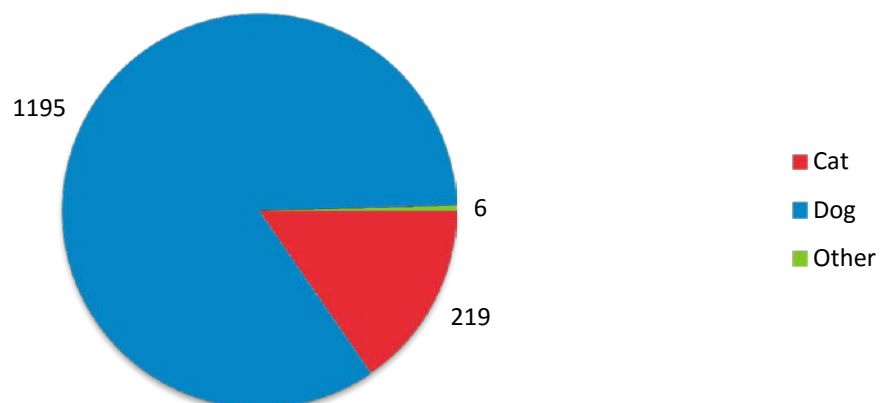


Figure 2 Number of adverse event reports by species

Types of microchip adverse events

The type of adverse events that can be reported are:

- **Reaction**
- **Failure**
- **Migration**

Reaction

A reaction has occurred when any unwanted signs or symptoms (apart from transient pain or bleeding) are observed following microchipping. These may occur at the time of implantation, within a short period of time, or after several weeks, months or even years.

Failure

A failure is when a microchip has not been detected following a full body scan with a **working** scanner (if in doubt check with another chip and change the batteries).

You are only obliged to report a microchip failure if you have firm evidence that the dog has been chipped (ie registration paperwork or clinical records). In order to determine whether a chip has definitely failed, you should try to confirm that it is still present in the animal, either by palpation or imaging.

Failure is a matter for concern, as it means a dog cannot be identified if lost, may have to be quarantined on arrival in a new country and may involve further expense to have the animal rechipped.

Migration

In 1999, the World Small Animal Veterinary Association (WSAVA) produced a [list](#)⁹ of recommended implantation sites for different species, which also gives useful tips on scanning. In the UK and Ireland, microchips for dogs, cats, rabbits and ferrets are implanted subcutaneously on the dorsal midline just cranial to the shoulder blades.

A microchip is judged to have migrated if it has moved a significant distance from the original implant site. For dogs, we advise that the final location should be outside of the pink areas indicated in the diagram provided in the BSAVA [guidance](#)¹⁰. This makes allowance for a small amount of movement, as well as the possibility of the animal being chipped in the site recommended in other countries. Microchips positioned in the areas shown in figure 3, do not need to be reported as migrations and reports of this nature will normally be assessed as being of unlikely significance.

⁹ Veterinary List of Recommended Microchip Implantation site (WSAVA) 1999
www.wsava.org/sites/default/files/Veterinary%20List%20of%20Recommended%20Microchip%20Implantation%20Sites%20%20.pdf

¹⁰ Compulsory Microchipping of Dogs Regulations in the UK (BSAVA, March 2016)
www.bsava.com/Portals/4/knowledgevault/resources/files/Compulsory%20Microchipping%20of%20Dogs%20Regulations_Guidance_BSAVA_Jan2016%20AL_Defra_pc%20comments_IM.pdf

Reporting – not required in shaded area

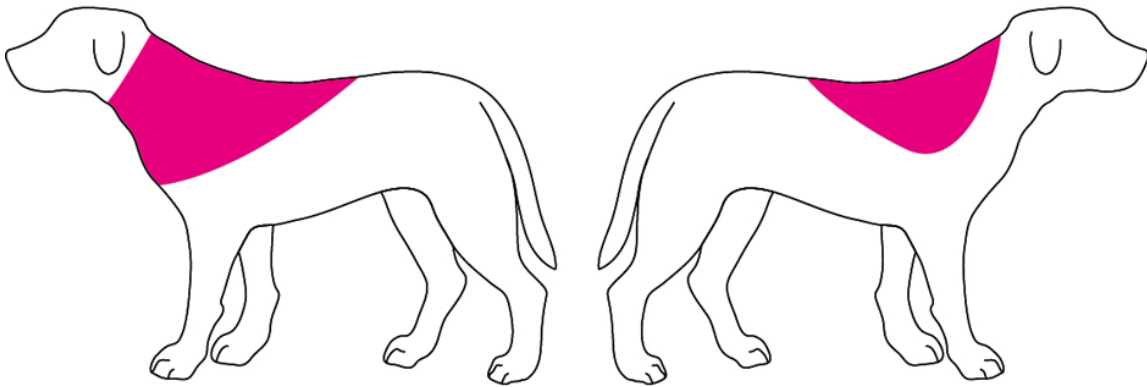


Figure 3 Areas which are discounted as a microchip migration (courtesy of BSAVA)

For cats, rabbits and ferrets we would ask that you consider the diagrams above (taking into account the differing anatomy) to determine whether a migration has occurred but remember it is not a legal requirement to report for these species. For all other species (apart from goats) microchipping is considered an act of veterinary surgery due to the implantation sites used which should make migration highly unlikely.

Migration may be detected by any combination of the following techniques (in order of increasing reliability):

- feeling the position of the chip (palpation)
- scanning with a microchip reader
- seeing its position using imaging, such as x-ray or ultrasound.

The new position of the microchip should be described as fully as possible in a migration report, eg 'left shoulder' is insufficiently detailed to determine whether the final location is inside or outside the area of interest. Due to the differing scan patterns and ranges of different scanners, accurately pinpointing the location of the chip may be difficult.

Incidents involving more than one type of event

Some incidents will involve more than one type of event, eg migration and failure or reaction and migration. You should report any incident involving a reaction as a "reaction". You should mention any associated failure or migration in the description of the reaction. If a microchip cannot be detected by scanning, but can be felt or has been seen by imaging to have moved from the site of implantation, you should report this as a failure.

If the animal was given a veterinary medicine (eg vaccine) at the same time as implantation and a reaction occurs, you can note this within your description of the microchip reaction. However, if you suspect that the medicine is responsible for the signs observed, you should report this to the company marketing the product (the Marketing Authorisation Holder) or to the VMD using the appropriate [form](#)⁶.

Where the reports came from

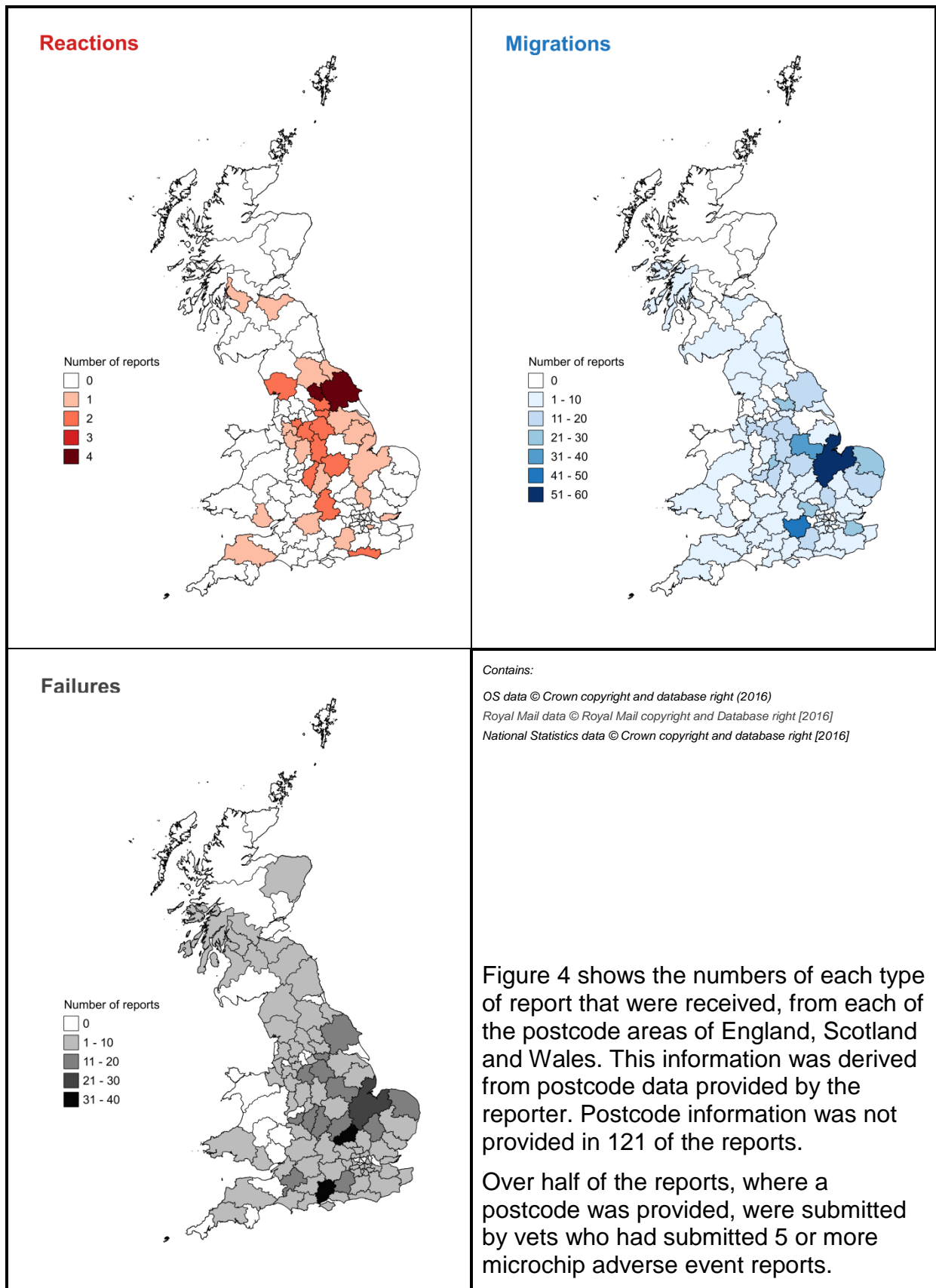


Figure 4 Number of reports by report type in each postcode area (if postcode is known)

Overview of Reports

In the period up to 31 December 2015, 1,420 reports concerning adverse events following microchipping were received. Only 28 of these were received between April and December in 2014 which is why we delayed writing this first annual report.

Figure 5 shows the total number of reports received each month, from April 2014 to December 2015.

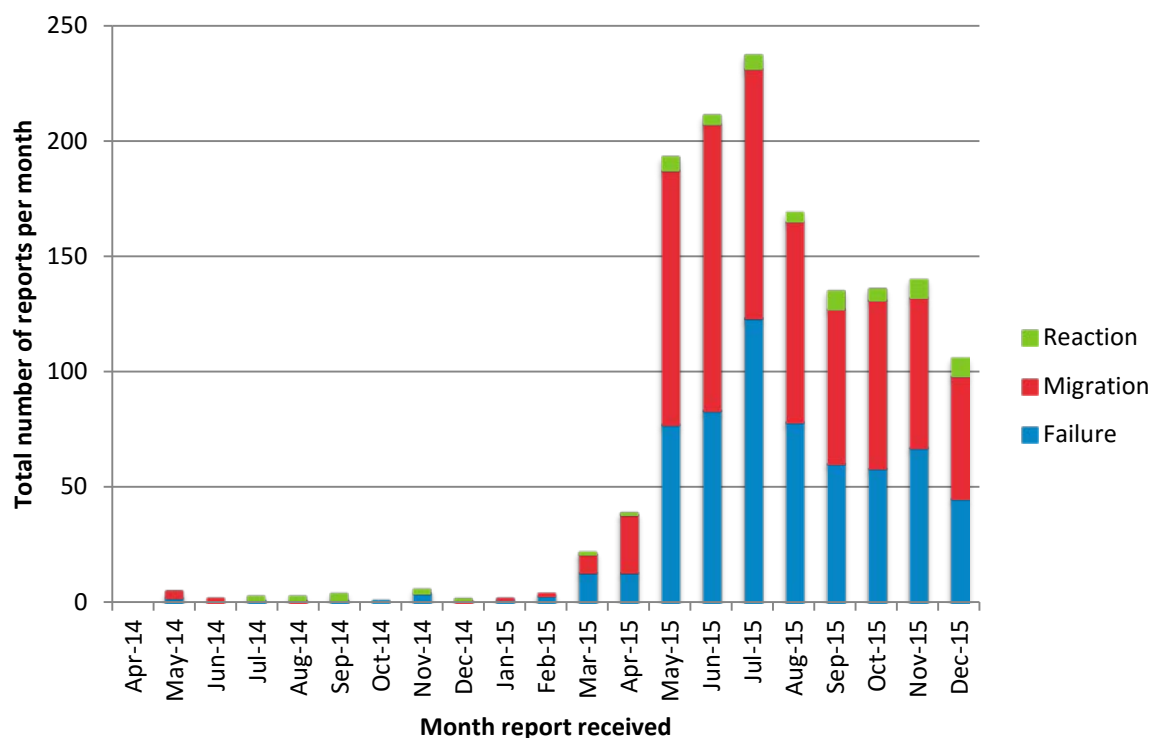


Figure 5 Number of reports received per month

A noticeable increase in the monthly rate of reporting was seen following the introduction of compulsory reporting in February 2015. However, after the initial surge (which included historic reports), the number of reports received each month became lower and more consistent.

This figure also shows the proportion of event type in each month's reports. Over the period, reactions accounted for only 4.3% of reports received, with 51.3% being migrations and 44.4% being failures.

Fifty five of the reports resulted from historical events occurring in 2013 or earlier; 45 of these reports described migration and 10 were failure. All of these historical reports related to dogs, except one which related to a cat.

Overall, 61 reports described a reaction, 630 microchip failure and 729 migration.

Reactions¹¹

Of 61 reports describing a reaction following microchip implantation, 39 (64%) occurred in dogs, 21 (34%) in cats and 1 in a rabbit.

¹¹ See Glossary of clinical terms (page 15)

Rabbit

The rabbit developed an abscess at the implant site, which became necrotic with a mucopurulent discharge. The time from implantation was unknown.

Dog

Thirty-five of the 39 dog reports described the development of implant site lumps, masses or swellings. In some cases, these were identified as abscesses (5 cases), seroma (3), lipoma (2) or haematoma (1). In 3 cases, calcification was observed around or near the site of the microchip. Discharge from abscesses and other swellings were described in 8 cases. In 10 cases, antibiotics were administered to treat infection at the implantation site.

In 8 cases, the removal or loss of the microchip was described. In one of these, the microchip was found protruding from the skin and pulled out by hand, but no other signs were reported. In another, a dog removed the chip whilst scratching at a swelling. In the remaining cases, the chip was either removed surgically, together with associated swellings or was expelled as part of an inflammatory reaction.

The time taken for these lumps and swellings to develop was unknown in 5 cases, but in the others, the time varied from immediately to more than 6 years.

In two cases, scarring at the site of implantation was observed.

In the final case, no actual reaction was reported; a puppy had been microchipped twice by the breeder.

Five reports included details of vaccinations given either before, or at the same time as, a microchip was implanted. Table 1 summarises these cases.

Reaction observed	Time to reaction (post-implantation)	Time of vaccination (relative to implantation)
Soft tissue swelling, migration	3 weeks	2 weeks prior and on same day
Small swelling	10 days	On same day
Microchip protruding from skin	Greater than 1 year	On same day
Hard lump	1 week	2 weeks prior
Seroma	2 weeks	On same day

Table 1 Summary of reactions associated with vaccination in dogs

Cat

Of the 21 reports associated with cats, 11 described the development of lumps, swellings or a mass. In one of these cases, the microchip was surgically removed with the mass. The cat was re-chipped 2 months later, and another mass rapidly developed. This was also removed with its associated chip. In another, the microchip was expelled through the skin, together with a mucopurulent discharge.

Two other reactions that occurred were a local infection, requiring treatment, and dermatitis that developed due to the cat scratching the implantation site.

Remember; if a report mentions a medicinal product, that was used at the same time and may have caused the reaction, report it to the Marketing Authorisation Holder or the VMD using the appropriate form.

There were five reports that described equipment problems. In three of these cases, the rod of the implanter partially inserted into the cat, but it was possible to remove it easily. In the other two cases, the rod of the implanter was fully implanted; in one case the rod was removed as the cat was already under general anaesthetic for another procedure. It is not known if the rod was removed in the other case. These reports were not all linked to a particular manufacturer.

If equipment problems become apparent prior to implantation (eg the chip falls out of the gun) this is not an adverse event. The chip/equipment should not be used and should be reported to the manufacturer of the chip and/or implanting device as a product defect. Once a chip has entered the animal this becomes reportable as an implantation reaction.

A reaction involving inflammation and infection may have been due to a bite, but the chip had moved and medical treatment was required for the infection.

The final cat case appeared to be a simple adverse event describing an anaphylactic reaction following vaccination. No mention of chip implantation was made.

When reporting either medicine or microchip adverse events, make sure you use the correct form. If you submit a report using the incorrect form, you will be asked to resubmit the report.

Table 2 summarises the cases in which vaccination may have been involved in the reaction that occurred.

Reaction observed	Time to reaction (post-implantation)	Time of vaccination (relative to implantation)
Inflammatory reaction; chip expelled through skin	2 weeks	On same day
Lump between shoulder blades	4 weeks	2 weeks post
Fibrous area	1 month	On same day
Lump around chip	2 weeks	On same day

Table 2 Summary of reactions in cats associated with vaccination

Figure 6 shows the distribution of times to onset of reactions for dogs, cats and the rabbit.

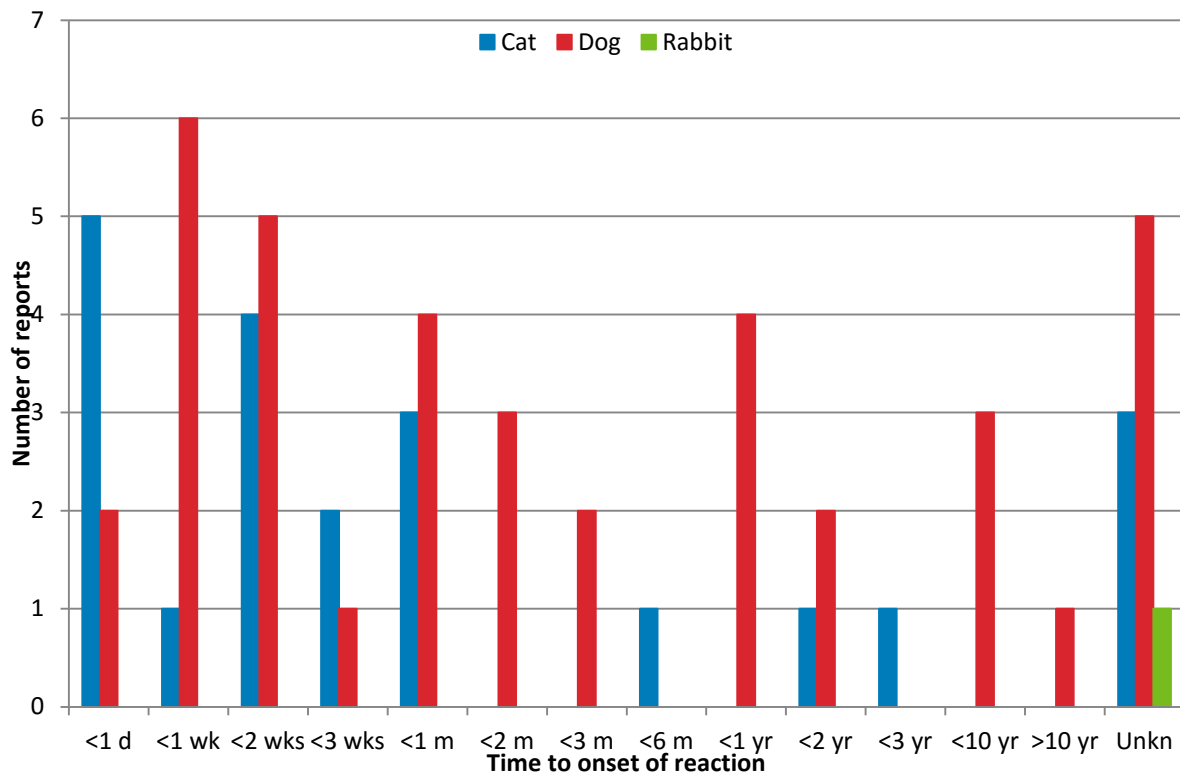


Figure 6 Time to reaction for cats, dogs and a rabbit (Unkn = unknown)

Failures

Before reporting a failure to scan, it is important to ensure that the scanner used is working. It is also important to be sure that the chip being scanned is actually present. This can be done by feeling the chip under the skin or imaging it by x-ray or ultrasound. Microchip failure is not likely to be species specific.

It is important to remember that certain microchips cannot be read by the currently approved UK scanners. These are not true failures; but in such cases involving dogs, it will be necessary to have the dog rechipped, as all dogs must be microchipped with a compliant device.

Of the 630 failure reports received, 482 (77%) occurred in dogs, 145 (23%) in cats, 2 in rabbits and 1 in a horse.

Details of failure reports are summarised, as follows:

- In 5 cases the scanner was not working, and the presence of the chip was not confirmed by another means
- In 33 cases, the scanner was working, but a full body scan was not done, or the reporter did not know whether one had been done. In 2 of these cases, the chip position was confirmed by palpation
- In 538 cases, the scanner was working, a full body scan was done, but the presence of a chip was not confirmed by another means
- In 51 cases, the scanner was working, a full body scan was done, and the presence of the chip was confirmed by palpation or imaging

- In the final 3 cases, the scanner was working, a full body scan was done and the presence of the chip was confirmed by palpation and imaging.

Only in the 56 (<9%) cases in which the presence of the chip was confirmed, can they be truly regarded as chip failures. However, in all but 6 of the remaining 574 cases, some information relating to the identification of the microchip was provided, indicating that records exist that establish a chip was implanted at some time. (For two of these, the microchip number provided was not that of a compliant chip.) Nevertheless, without physical evidence of a microchip's presence, it is not possible to say whether these cases were indeed failures or whether the microchip had migrated out through the skin at some time since implantation.

Implantation dates were not provided for 17 of the 56 cases positively identified as failures. For the remaining 39, the most common period to the detection of failure was 3- 4 years after implantation. Two cases were reported to have occurred on the day of implantation. The longest period was 7 years.

Please note that we will not notify microchip database companies of the failure reports we receive. You are responsible for updating the database that holds your animal's microchip details if the microchip fails or migrates out of the body and needs to be replaced.

Migrations

Of the 729 migration reports received, 674 (92%) occurred in dogs, with 53 (7%) in cats and 1 each in a tortoise and a rabbit.

Almost 300 cases (272 dogs, 19 cats, 1 rabbit) reported as migrations were assessed as being unlikely to be migrations. In most cases, the chip location was within the neck/scapula/shoulder area. In 3 cases involving 1 cat and 2 dogs, the chip fell out immediately after implantation.

In 123 of the dog and 12 of the cat reports the information provided was insufficient to fully assess the extent of migration.

The remaining 302 reports (279 dogs, 22 cats, 1 tortoise) appear to be true migrations. In the case of the tortoise, the microchip was poking out of the skin. In 6 cat cases, the microchip either exited through the skin or its absence was confirmed by imaging. There were also 6 similar cases in dogs.

Note: When microchipping under general anaesthetic it is best practice to have the animal in sternal recumbency, this reduces the risk of migration.

Figure 7 shows the distribution of times to detection of migrations for dogs, cats and the tortoise. For cats, migrations were most often detected within 1 year of implantation, but some were detected between 5 and 10 years later. For dogs, migrations were most often detected between 6 months and a year after implantation, with others being detected over 10 years later.

Apart from those cases in which the chip migrated out through the skin, the furthest migration reported was to the left groin of a dog.

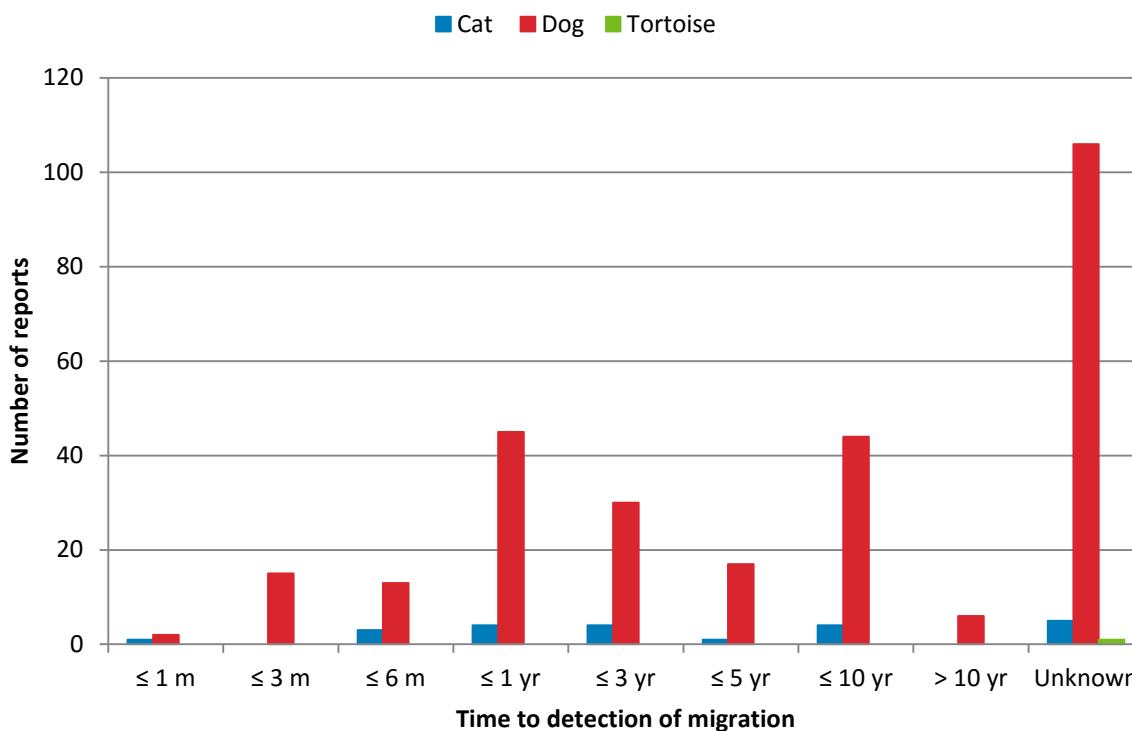


Figure 7 Time to detection of migration for cats, dogs and a tortoise

Incomplete information

There is a wide variety of missing information in the reports received:

- in 105 reports, the microchip number was incomplete or was unknown
- in 629 of the reports the manufacturer name was not provided or was declared unknown or unsure. In a further 271 reports, a database, brand or implanter organisation name was provided instead of the manufacturer
- 308 of 729 migration reports were not clear in the location of the migration eg 'right/left shoulder' covers areas of the animal both inside and outside the pink areas in figure 2
- 468 reports did not include an implantation date

All of this information helps the VMD collate the reports, spot trends and provide reliable advice to microchipping companies, vets and owners to resolve any problems. Given that there are a large number of microchip manufacturers, brand names, implanter organisations and databases, it is no surprise that there is confusion in supplying the required information.

We are working to improve the microchip adverse event reporting form to make it easier to provide information.

In the future we also plan to collect sales information from each of the manufacturers to help us interpret the number of reports we receive.

Conclusions

Between April 2014 and December 2015, the VMD received nearly 1,500 reports describing microchip related adverse events. As reporting a microchip reaction in dogs is compulsory, it is not surprising that the majority of reports involved dogs. The number of reports of failures and migrations were comparable, and far exceeded those of adverse reactions following microchip implantation. In the next year, with the introduction of clearer guidance, it is hoped that the number of 'unlikely' migration reports will decrease.

As the VMD does not currently receive sales information, and cannot estimate the number of animals that have been microchipped, calculating an accurate risk of such adverse events is not possible at this time. However, considering that there are an estimated 8.5 million dogs and 7.5 million cats in the UK¹² the likelihood of an animal experiencing an adverse event is very low.

This report has highlighted some of the data gaps and the reasons why providing as much information as possible is necessary for the VMD to identify specific problems. The authors would like to encourage reporters to provide as much information as possible, especially when reporting reactions and migrations. This will enable a more in-depth analysis and highlight potential problems sooner.

¹² Pet Foods Manufacturing Association (PFMA) Annual Report 2016
www.pfma.org.uk/statistics

Useful contacts

You must remember to update your details associated with your pet's microchip if, for instance, you move home. If you cannot remember which database the microchip was registered with, do not worry. Any of the databases listed below will direct you to the correct one. All databases know the status of each microchip registration, but only the one you registered with will have your personal details.

UK microchip databases¹³

[Anibase](#) 01904 487600

[Pet Protect](#) 0800 0778558

[PetIdentity UK](#) 0800 975 1960

[Pettrac](#) 0800 6529977

[PetLog](#) 01296 336 579

[Smartrac](#) 0844 5420999

Government helplines

The following helplines are for queries about microchipping policy, other than adverse events. You can contact them, as follows:

England	Defra	Telephone: 03459 335577 Email: defra.helpline@defra.gsi.gov.uk
Wales	Welsh Government	Telephone: 0300 0604400 Email: CustomerHelp@Wales.GSI.Gov.UK
Scotland	Scottish Government	Email: Animal.Health@gov.scot

Also, for queries related to reporting reactions, migrations and failures after microchipping, you can contact the VMD Pharmacovigilance team:

Telephone: 01932 338427 Email: postmaster@vmd.defra.gsi.gov.uk

Glossary of clinical terms

Clinical term	Meaning	Clinical term	Meaning
Anaphylactic reaction	A serious, possibly life-threatening allergic reaction	Lipoma	A non-cancerous (benign) fatty lump that grows under the skin
Calcification	Accumulation of calcium in body tissue, causing hardening	Mucopurulent	Containing mucus and pus
Dermatitis	Skin inflammation	Necrotic	Dead tissue
Haematoma	A solid swelling of clotted blood within the tissues	Seroma	A collection of clear body fluid

¹³ Don't forget to update your details - and stay together forever
www.dogstrust.org.uk/help-advice/microchipping/update-your-details



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