Significant Event Audit Case Example: Informed consent

Section A: Case example on the six stages of a significant event audit

A Significant Event Audit (SEA) is a quality improvement technique. It is a retrospective audit, which looks at one case in detail from beginning to end to either increase the likelihood of repeating outcomes that went well or to decrease the likelihood of repeating outcomes that went badly. SEAs may result in further development of guidelines, protocols or checklists and may result in the need for additional clinical audits (process/ structure or outcome). SEAs are conducted by bringing your team and the relevant case notes together to discuss the event. It is important that the event is discussed without any blame – allowing team members to provide honest and constructive feedback on how they contributed to the care process. An SEA is completed in 6 stages. The following points will take you through the steps that this practice took to put an SEA into practise.

1. Identify the significant event

Create a brief description of the event, context and outcome to be discussed in the meeting.

A patient, that had been dispensed gabapentin, passed away. Although unrelated, the owner had not been made aware that gabapentin had been dispensed off-licence and had sought legal action.

2. Collect all the relevant information

Gather all relevant information, such as case files and staff accounts etc., which contribute to the case.

A significant event audit was completed. Information was collected from the team members involved with the patient; the team members working on site; the patient's records and the owner.

3. The meeting and analysis

In a team discussion regarding the event, analyse the event and its causes to suggest where changes can be made. Indicate changes that could aid in achieving the desired outcome. It is important to ensure this meeting provides an environment where all staff members are encouraged to speak freely and honestly, for example by using The 5 whys strategy or root cause analysis, plus identifying contributory factors. Any discussion should be kind and constructive.

A meeting was led by the clinical director. The results of the meeting were split into factors that affected the overall results. These were system, human, patient, owner, communication and other. This helps to create a blame-free meeting, looking at all contributions and getting input from all member of the team.

4. Decide what changes need to be made

Confirm which changes should be made, and make a prediction on the effect this will have. It may be that no change is required or there is only a need to disseminate the findings. Where changes are made, they could be in the form of checklists, guidelines or protocols. Following the meeting, a final report detailing the key points raised in stages 1-4 should be written.

There was no clear protocol for the use of unauthorised medications, and the veterinary surgeon that had dispensed the tablets was not aware of the UK medicines regulations or the cascade.

5. Implement the changes

Develop an action plan. What needs to be done by whom, when and how? Ensure the whole practice team is aware of the changes and what role they play in implementing them. Monitor the changes once implemented and set a time to review them. The length of time required for monitoring will be dependent on the event.

Further training on the UK VMR and the cascade was given to all team members.

6. Review the changes

The team should sit down together to review the changes and discuss what went well and what didn't. You could also share what you have found with clients and the profession. Further audit may be required to monitor the change.

A process audit of the consent forms for human POM will be completed in three months' time.

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Section B: Significant event audit after a failure to obtain informed consent

QI Vets
PATIENT OUTCOMES FIRST

Title:	Significant event audit for obtaining informed consent
Date of significant event:	08/11/2018
Date of meeting:	20/03/2019
Meeting lead:	Khalid
Team members present	The whole practice team; Vets, RVNs, ACAs & Receptionists

What happened?

Boris, a 15 year old Jack Russell, had become very stiff on his back end and was having trouble getting out of his basket. His owner, Mr Murray hadn't taken Boris to the vets for quite a while but he took him in to QI vets. Serena, the vet who examined Boris, found he had severe hind limb pain on extension of his hips and recommended radiographs. Mr Murray did not want to have Boris anaesthetised and was reluctant to spend money on x-rays. He asked if there were some tablets he could give Boris instead. He asked for it not to be meloxicam, as he thought Boris had that before about 4 years ago and was very sick afterwards. Serena prescribed gabapentin.

Nothing more was heard about Boris until a solicitor's letter arrived 3 months later. Boris had died 10 days after starting the medication and Mr Murray thought that gabapentin, a human drug, had killed his dog. He stated he had not been made aware that it was not authorised for dogs. He was asking for compensation and was intending to complain to RCVS too.

At the SEA meeting we found out the following

Serena said she felt pressured by Mr Murray as he didn't want any investigations. She was worried that Boris needed effective pain relief and did not think Mr Murray would bring Boris back so wanted to give him something quite strong from the start. The previous records were not available as the PMS system had been changed, and only the last three years of notes were accessible with the new system. Serena said she was unfamiliar with the cascade as it did not apply in quite the same way in Italy. She was also unsure which medicines were not authorised. In the letter, Mr Murray said he was suspicious when he read the patient leaflet with the medicine and it mentioned driving and operating heavy machinery. He had then googled gabapentin. The practice did not give any other information out with the medicine. On checking through the records it was also discovered that the label did not have Serena's name or initials on it as the vet responsible for prescribing under the cascade.

Why did it happen?

System factors:	· The practice did not have a protocol for use of unauthorised medicines · The consent forms for unauthorised medicines were not easily accessible. · Human medicines were not clearly identified in dispensary. · Previous clinical records from 4 years ago were not readily available as PMS changed when practice was sold 3 years before.
Human factors:	· Serena qualified in Italy and had only been in the UK for 6 months at the time of the complaint. · Serena was not aware of UK medicines regulations or the cascade.
Patient factors:	· None
Owner factors:	· The owner read the leaflet in the pack, which stated, 'no drinking alcohol or operating heavy machinery' so he realised gabapentin was a human drug. He then looked it up on google.
Communication factors:	· No communication either verbally or in writing about unauthorised medications.
Other:	· None ·

What has been learned?

All the other vets sympathised with Serena as although they knew what they should be doing there was no clear practice protocol and in a busy evening surgery it was very easy to forget. They also stated they could never find the consent forms either.

One of the nurses, Clare, mentioned that in her old practice they had used the BSAVA patient information leaflets for unauthorised medicines which explained their use in dogs and cats to owners.
Boris had been prescribed 90 days of gabapentin.

The practice manager, Helen, who had just been on a dispensing course said that as it is a Schedule 3 controlled drug it is best practice to only prescribe or dispense 28 days at a time. The team did not know that gabapentin is now a Schedule 3 controlled drug and therefore subject to special prescription writing requirements.

What has been changed?

CPD/training required:	· CPD for Serena on UK Veterinary Medicines Regulation. · Training for the whole team on cascade use. · Training for the whole team on the practice unauthorised medicine protocol. · Training for whole team on informed consent and use of consent forms. · Training for whole team on controlled drugs.

New or updated protocols/checklists/guidelines:	· Unauthorised medicine protocol. · PMS to automatically prompt to use consent form when dispensing human POM. · PMS to automatically generate consent form. · PMS to automatically generate correct label. · BSAVA client information leaflets to be used to give animal specific advice on gabapentin and other unauthorised medicines. · BSAVA patient information leaflets to be automatically generated when dispensing human POM.
Further audit required?	· Process audit of use of consent forms for human POM.
Other:	· Information bullet points from CPD courses to be presented to rest of team at practice meetings or on the intranet. · Whole corporate group to look at induction of overseas vets and training on UK VMR.

Follow-up date

Today's date: 20/03/2019

Review date: 22/04/2019

Signature: