Department of Health & Social Care

Review of the action set out in ‘Safer ambulatory syringe drivers’

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Introduction

This note sets out the Department's findings following a review of the action taken in 2010 and subsequently to address safety concerns with certain ambulatory syringe drivers.

It considers:

1. The decision-making process around the 2010 safety alert, including the evidence for action and the timeliness of the decision; and

2. The action that was then taken and how quickly it was completed.

Finally, the review assesses whether there are lessons for current practice and / or areas for further analysis or research. While this review has found that the action taken in 2010 was timely and justified, it has generated further reflections and questions about our collective approach to managing safety issues pertaining to medical devices. This note concludes with a description of further work to be undertaken.

Syringe drivers – function and brief history

The syringe drivers in question are small, lightweight, portable devices powered by batteries. They are primarily used to supply a continuous, steady dose of pain-relieving medication and are far more effective in controlling moderate to severe pain than single injections (which lead to waxing and waning pain). Their portability made them helpful in allowing patients to stay at home and for managing pain overnight, and they have had a very beneficial impact on palliative care from the 1980s onwards. Their successor devices continue to do this to this day and have benefitted many thousands of patients experiencing what would otherwise be unrelenting pain in the last hours and days of their lives.

From that time until early in the 2000s, the market for these devices was dominated by the Graseby MS models both in this country and internationally and during this time they were state of the art.

The Graseby syringe drivers operated by millimetres of syringe length rather than millilitres of solution used to deliver the painkilling drugs. There were 2 types of syringe driver allowing injection at millimetres per hour (MS16 and MS16A) and another which could inject at millimetres per 24 hours (MS26). The syringe drivers were also capable of using either 10ml or 20ml syringes from any manufacturer. The benefit of this was it allowed for complete flexibility in dosing, to ensure patients received exactly what was needed over a given period without the need for syringe changes, particularly when they were at home and asleep. The Patient Safety Team have advised the 24-hour version was developed to meet a clinical need to make smoother adjustments to the rate of travel, because higher

concentrations could be used with the slower rate of delivery, thus extending the time between syringe changes further. It also accommodated patients who were becoming tolerant to the drugs and required more drug to be delivered.

Initial concerns

The predecessor organisation to MHRA (the Medical Devices Agency) published two hazard notices on the Graseby Syringe Drivers in 1994 and 1995. These notices drew attention to the potential for confusion between the two types of syringe drivers which could result in inappropriate infusion rates leading to over-infusion and there had been patient deaths as a result. The notices advised users to use enhanced labelling to ensure that the two types of driver were not confused. These labels were developed by the manufacturer and were colour coded, clearly stating in bold on the control panel whether they were millimetres per hour or per 24 hours.

MHRA have pointed out that 'The notices were not published because the device was considered to be inherently unsafe, but to raise awareness of the risks of confusing the two devices'.

It would be unreasonable to describe the action taken in 1994-5 as falling short of the more extensive action taken in 2010. The contexts were different – critically, there were alternatives coming onto the market at the later date which were not available earlier. These newer devices represented technological advances and replaced the earlier types as the new state of the art. This is a common occurrence with medical devices as advances take place over time. The position taken in 1994-5 would, therefore, appear to constitute a reasonable balance between the benefits of the syringe drivers available to patients at the time and the management of the risks they presented.

The path to the patient safety alert in 2010

The two key agencies with a role in the decisions that led to the 2010 safety alert were the Medicines and Healthcare products Regulatory Agency (MHRA) and the NPSA (National Patient Safety Agency). The role of the MHRA in respect of devices is one of market surveillance aimed at ensuring manufacturers, through the regulatory process, have complied with the Medical Device Directives and met applicable standards of safety and their device performs as intended. The role of the NPSA (and now its successors in the Patient Safety Team in NHSI) was to support the NHS to improve safety, including through identifying causes of harm and by setting out measures for avoiding or mitigating them.

When it comes to medical devices, evidence of harm will often precede an understanding of the key causes and potential mitigations. The key distinction here is between the inherent features of a device and what are called 'human factors', our habits of thought

and functioning which can lead to error and harm in the wrong circumstances. This is not an absolute distinction for the obvious reason that medical devices are designed to be used by humans, and a great deal of work is done in patient safety to ensure pro-safety features are designed in to products and processes. However, it must be recognised state of the art is an iterative process and later versions of a given technology have usually evolved as experience with them have increased. Also, standards with which they are required to comply may have changed. This means what might have been acceptable in the past may no longer be acceptable later.

There are routes for reporting harms on both sides – both MHRA and the NPSA/Patient Safety Team have vigilance processes in place to receive incident reports about problems in care (on the patient safety side it is the National Reporting and Learning System or NRLS). MHRA is able to take a variety of regulatory actions, particularly where a device has developed a patient safety issue, but it must do this within domestic and European law. The threshold for action varies according to the risk posed, but the initial aim is always to bring devices back into compliance and correct a safety issue. This is because all responses need to be proportionate, not least because taking a device off the market can have serious repercussions for overall healthcare delivery, particularly where there are no alternatives. In the early days of these syringe drivers, there were no alternatives.

The vast majority of actions to correct safety issues are taken by manufacturers; MHRA will issue non-statutory guidance (such as medical device alerts) where required and where it is important to highlight particular issues. As the regulatory system is predicated on supporting manufacturers into compliance, formal regulatory action is very rarely needed.

On the patient safety side, the approach taken is more strongly rooted in an understanding of the potential for human error, and on the potential for improving safety through changes in practice (which might include changes in the products used in clinical practice). This can lead, as it did in this case, to some differences of view which are described below.

There appear to have been two key factors that led to the 2010 Rapid Response Report (RRR). These were reports of harm resulting from the use of the syringe drivers and the development of alternative drivers that offered enhanced safety features.

There were two main types of evidence relevant here: domestic reports of problems with the drivers and international action on the same issue.

The 'supporting information' document issued alongside the 2010 Rapid Response Report describes the results of a keyword search of the National Reporting and Learning System (the database for patient safety incidents). Between 1st January 2005 and 30th June 2010 there were 175 errors associated with patient safety incidents involving ambulatory syringe drivers. Not all of these incidents would have been severe, but the review did show eight deaths resulting from over-infusion with four of these occurring in 2009. A large number of

the 175 errors were associated with 'incorrect rate setting' (53) and 'unexplained fast infusion' (42). In a letter sent from MHRA to NPSA on 18th June 2010, MHRA note they had received 'no relevant reports relating to rate confusion since 2005'. This difference is likely to be due to the growing awareness in the NHS of the role of the NPSA and its reporting systems and the tendency to recognise problems with syringe drivers as being about how they are used.

In addition to growing domestic awareness of the risks of the drivers in question, there was also international change. In October 2007, Australia introduced a registration process for medical devices overseen by its Therapeutic Goods Administration (TGA). This meant all companies had to submit documentation to prove their products met appropriate standards. The company manufacturing the Graseby syringe drivers (Smith medical) did not believe the drivers met those required standards and so withdrew them from the Australian market. As a result of this, in November 2007 Palliative Care Australia issued a note on alternative devices and also brokered an agreement with the TGA and Smith Medical to ensure devices already in place would continue to be serviced for five years. It would appear from subsequent guidance issued in Australia the Graseby devices remained in use in some cases in 2015. Similar measures were put in place in New Zealand. This demonstrates a continuing clinical need for such devices and an appreciation of their benefits within the framework of the acceptance of the risks they presented, subject to the mitigations put in place for those risks.

Action in Australia and New Zealand came before action in England's 2010 notice. This raises the question of whether we were comparatively behind the pace. We return to this question once we have described the process as it unfolded in England. As will become clear, the two systems are quite different in the way they operate.

One factor which may have contributed to a later response in England was the development over 2007-8 of the NPSA process for reviewing deaths and severe harm reported to the NRLS database. Following a pilot process, weekly reviews of severe harm incidents began around April 2008. On 27th May 2008, an incident was discussed involving a 24-hour dose of morphine being given through a syringe driver over 2 hours. The action from this meeting was to discuss with the 'evidence-based purchasing group' and MHRA. These discussions occurred, though we have not identified a record of the outcome of those discussions.

In parallel with this work, the NHS Purchasing and Supply Agency Centre for Evidence Based Purchasing issued a 'Buyers' Guide' to Ambulatory Syringe Drivers in December 2008. This guide noted that 'Currently, there are safer alternatives to the MS26/MS16A drivers on the UK market…Adopting safer syringe drivers would require modification of established working protocols and practices in UK palliative care, and a significant amount of re-training for staff'. This serves to illustrate the awareness of the issues, but also the practicalities that needed to be managed to find an alternative to the MS26/16A drivers.

On 1st December 2009, two further incidents were discussed and further work on this issue was put in train. By February 2010, the NPSA response meeting considered two papers. The first, from MHRA, concluded the number of reports relating to the MS16A and MS26 syringe drivers was relatively low compared to other drivers then available and 'MHRA has no reason to contest the CE mark, and as the device is CE marked we feel unable to endorse any restriction relating to their purchase'. The NPSA paper took a different view and explored the publication of a Rapid Response Report to indicate the need to move away from millimetre drivers. The agreed action was to progress work on this report and to discuss it with MHRA.

As this work developed, MHRA remained concerned about the path the NPSA were going down. MHRA's letter of 18th June stated 'MHRA suspect that the alert will be very poorly received by palliative care teams and district nurses…Not least because there will be huge cost implications of replacement…' They go on to say, 'Recommending to the NHS that they don't buy specific products could be seen as a barrier to trade if the devices are legitimately CE marked and lead to infraction proceedings against the UK…In addition if the NPSA effectively bans these products…this would be open to legal challenge'. The letter goes on to add 'We are not suggesting that the NPSA should not take action to resolve the problem but just that they should be aware of these potential difficulties with the action proposed and consult their lawyers about the implications'.

There then followed a consultation process on a draft alert. Of the 16 respondents from the NHS, Royal Colleges, Department of Health, Independent Sector and Industry, 15 agreed that a Rapid Response Report requiring the purchase of safer designs of ambulatory syringe drivers was justified. MHRA did not agree to support this view, remaining consistent with its previous position, because, as they have subsequently noted, it would not have been consistent with their regulatory opinions based on their statutory obligations.

In addition to this work, there was further engagement with a manufacturer of alternative syringe drivers (McKinley Medical) to assess how long it would take to replace the Graseby devices. This fed into the timeframes given in the Rapid Response Report for replacement.

The Rapid Response Report was issued on 16th December 2010 along with a document setting out supporting information. This required providers to put in place a transition plan within a year and to effect a transition to ambulatory syringe drivers with additional safety features 'as soon as locally feasible, and within five years of this RRR'.

We are not aware of any legal challenges that were made to this decision.

Two questions arise from this process – what should we conclude from the differences between NPSA and MHRA on this issue and does the difference in timing between action

in England compared to Australia imply we could have moved more quickly in this country?

On the differences between MHRA and NPSA, it seems clear that these were differences that were honestly held and flowed in part from the respective functions of the organisations. MHRA had a duty to point out there are potentially legal consequences in taking measures which restrict supply of legally available devices. In discussing this case, they have made the additional point that the NHS only has to buy what it feels can safely be used in its organisation. Conflict and disagreement within a system is not necessarily unhealthy, and it seems likely that the Rapid Response Report which emerged from this process of discussion was more robust than it might otherwise have been, though it also seems likely that it might have been issued a little earlier if there had been less consideration of the matter. This case involved a difficult (but far from rare) balancing act between the need to protect patients and maintain services versus attempting to overcome known safety issues, which although were very serious, were not widespread.

This case serves to highlight the inherent challenges in managing safety issues related to medical devices. There is always a balance to be struck between protecting some patients from serious complications while preserving successful treatments for the majority of patients who benefit greatly. Simply stopping a procedure or removing a medical device from use can have serious untoward consequences for those subsequently deprived of treatment. What is essential is the need to maintain a strong and close working relationship across all organisations who are involved in promoting and protecting patient safety to ensure, patients are protected by ensuring risks are reduced to the minimum for all those who need treatment. We should therefore discuss this issue regularly and ensure communications are functioning well and areas of patient safety are examined in detail. In the course of developing this note, we have seen positive reassurance from both MHRA and the Patient Safety Team of joint working and strong relationships; but also, a recognition that the issues surrounding the design of medical devices (the middle ground between devices as things and their use by practitioners) are particularly complex. MHRA has already undertaken work in this area issuing guidance for manufacturers and Notified Bodies who oversee medical devices coming to market. They published advice on human factors in 2017, following wide consultation with stakeholders across those involved in human factors and usability engineering.

There is merit in further work being undertaken to look at the current legal framework for the routine assessment of the design of medical devices and the ability of the NHS to respond to appropriate actions following such assessments. This action should be referred to the DHSC sponsors of MHRA and the Patient Safety Team. This work would need to recognise the considerable work – much of it led by the UK – that has gone into developing the current EU system for regulating medical devices in recent years.

On the differences in timing between action in UK and Australia, we need to consider whether we were behind the pace in this country compared to Australia. While a full comparison of the two decision-making processes would be needed to draw final conclusions, we can make some observations to help with that question. The two regulatory systems differ in many ways, but one feature that stands out is that the Australian system could appear to some to be more willing to take rapid action with respect to devices and then manage the operational consequences subsequently. MHRA advise that this is illusory and is based in the fact the Australian regulatory system is highly reliant on the EU and US regulatory systems and does not have the resources available to it as do the leading global organisations. In particular the Australian Therapeutic Goods Administration does not have a similar organisation to NICE to go to for guidance. The work of Palliative Care Australia to deal with the consequences of the October 2007 decision clearly had to be mobilised quite quickly, but it is clear their different approach did not result in the sudden cessation of use of the syringe drivers their actions might suggest. This was because, as in UK services had to be maintained for patients' benefit. Nevertheless, there are clearly differences of approach between the system which could merit further analysis.

In England, the pattern appeared to be more one of seeking system consensus while also thinking through the practicalities of change. This may have taken longer, but perhaps may have led to UK having a smoother transition into the new arrangements and overall the result was similar. In acknowledging this it should be clear there will often be different ways of achieving the same or similar result, and we need to understand this and be in a position to explain this from the outset of a given course of action. We should also remain open to the possibility that other systems may, even in small aspects of their practice if not their overall approach, be able to teach us things that might improve our own system. This leads to two questions for the MHRA and patient safety sponsor teams to explore further:

1. Is there more that could be done to build on current processes and relationships to ensure that our current regulatory system (covering both device regulation and patient safety) takes sufficient account of international evidence?

2. The way our system manages the trade-off between acting quickly and putting in place clear paths to implementation, and how we understand, explain and learn from real or apparent differences between our system and those in other countries.

In conclusion on the decision to publish the Rapid Response Report (RRR), the decision was evidence-based, balanced timeliness and the need to secure agreement across the system and a path to implementation, and it was clearly set out in the alert.

Implementation of the decision

The RRR notice required organisations to put in place a plan within a year to transition to safer ambulatory syringe drivers within five years. It was disseminated via the Central Alerting System controlled by the Department of Health (it now sits with MHRA). It would have reached all NHS Trusts through this route. Care homes, hospices and private hospitals would have received the message if they had signed up to the system for alerts. The current system of patient safety alerts operated by the Patient Safety Team in NHSI uses CQC's more comprehensive communication networks to get to Care Homes and Hospices when required.

The action for the 2010 RRR was closed which means that action was either completed or deemed not required by those NHS bodies subject to the alert. This means that they had put in place a plan within a year, it does not give us information on whether or how those plans were implemented.

The NPSA did not have any role in following up beyond this point, and it was abolished in 2012, with its functions moving (in the form of the Patient Safety Team) to NHSE (and then NHSI). The Patient Safety Team has continued to monitor incident reports and has worked with CQC to communicate with the service on this issue. In 2013, there was a joint CQC-NHSE communication which reinforced the need to transfer to non-MS syringe drivers by December 2015 and highlighted recent reports of safety issues. This notice showed that between 1st January 2011 and 31st November 2012 there were 23 reports of harm involving syringe drivers, five of which involved incorrect rate setting and one of which was severe (but non-fatal).

CQC have also described to us their approach to looking at syringe drivers as part of their inspection process. This does not provide a full audit of whether there has been full compliance with the move away from MS syringe drivers, but it does provide a number of angles of inquiry to keep providers aware of the issue and to move them to action:

> We look at the general approach to responding to patient safety alerts and guidance in our inspections under KLOE S6, Are lessons learnt and improvements made when things go wrong? Using prompt S6.5, How effective are the arrangements to respond to relevant external safety alerts, recalls, inquiries, investigations or reviews? We might also, where applicable, look at how syringe drivers are being managed within a service. This would include any decisions to rationalise / standardise equipment and training and competency assessment around use of the equipment. We might also look at whether there have been any calculation / administration errors and what investigation and remedial action have been taken and may speak to the chief pharmacist/medication

> safety officer in a hospital setting. Where practice is poor, we will then report on it as a breach.
>
> In some cases we would look at specific safety alerts and CQC's end of life care service level guidance asks inspectors "Are syringe pumps maintained and used in accordance with professional recommendation?"
>
> We are currently trialling an approach to routinely looking at specific safety alerts as part of our inspection process through the never events thematic fieldwork. Following evaluation, we plan to roll this approach out to NHS trusts in the Autumn.

NHS Improvement is leading work through a new National Patient Safety Alert Committee to design, implement and oversee the process for clear and effective communication and compliance with safety-critical mandatory actions to the NHS, designated as nationally credentialed patient safety alerts. It will be chaired by the National Director for Patient Safety with the Chief Inspector of Hospitals for the CQC as deputy chair. The safety alerts subject to CQC inspection where appropriate, as described above, will be drawn from these.

Such alerts will cover all aspects of primary, community and secondary care, including mental health units and learning disability services. They will require concerted action by healthcare providers either at a Board or equivalent organisational level for organisations that do not have Boards (complex alerts that cover a whole organisation and are multi-professional) or sub-board level (alerts that need senior but not multi-professional organisational coordination). Both types will be designed to address life-threatening risks or risks of disability to patients and require action within a specified timescale. It is likely that the syringe driver RRR would have fallen into this category. The aim is to make it easier for trusts, GPs and other NHS providers to understand when they need to coordinate urgent action to protect patients.

Following the recent media reports about syringe drivers, the Patient Safety Team, working with CQC have sought information from NHS providers about whether there are any MS drivers still in use. The review has concluded that no old-style devices have been found with a single exception: a community patient who was using an old-style device for some years to self-administer a medication for a long-term condition and who was reluctant to change to a more modern device, but has now agreed to do so.

In addition, MHRA have followed up reports that the syringe drivers in question were available for sale on eBay. This process has concluded:

1. Over the last 18 months there were roughly 100 of the devices sold;

2. There have not been widespread sales to healthcare institutions: the main purchaser appears to be veterinary practices with a number of research laboratories also being identifiable purchasers;

3. There were a small number of sales to people who appear to be clinicians or have some sort of link to healthcare (e.g. registered owner of a private nursing company);

4. MHRA are working through next steps with eBay and NHSI, including how to contact any purchasers of the syringe drivers with a connection to healthcare.

This would, then, appear to be a case where the right decision was made and then implemented. It is also true that while there was a degree of follow up in the years following the Rapid Response Report, this was not fully systematic as an audit might be. Such a fully systematic approach would probably be disproportionate in most cases of this kind, but it is worth giving further consideration to whether the system could add something to its processes to review issues of this kind a little more thoroughly. In particular, we might ask whether there is sometimes a blind spot in the system about issues we think are settled because an action has been agreed some time before. We should explore whether we need some sort of 'bring forward' system to ensure that issues of this kind are kept under regular review and that the passage of time as well as the historic position or 'line' is considered as a factor in whether further action may be needed. The DHSC Investigations Team should take this forward. Finally, we should ask the sponsor teams to explore with the MHRA and patient safety team in NHSI whether there are other devices that have been rendered obsolete by the introduction of more advanced technology, and what approach should be taken to identifying such technologies and addressing any risks they present.

Conclusion

The 2010 Rapid Response Report appears to have been justified and timely given the evidence available at the time. While the Australian system had taken action earlier, it appears to have taken more precipitate action that then needed to be managed by the system whereas in UK we appear to have taken longer to get to an agreed position with a path to implementation.

While we cannot be sure how quickly the changeover to new drivers took place, there appear to have been plans in place within the deadline of one year and the recent survey of NHS providers indicates that, with one exception there are no drivers of the kind in question in the system now. It is always possible in retrospect to argue for earlier action, but in this case there is no reason to judge the response inadequate, or evidence that implies action should have been taken sooner.

The key point arising from the review is the need to ensure compliance (and the demonstration of compliance) with patient safety alerts, for which the new National Patient Safety Alert Committee will be an important driver. This issue rather than the formulation of the alerts themselves should be the priority. This review has indicated a number of additional follow up actions for the policy / sponsor teams for patient safety and the MHRA:

1. The Department should work with MHRA and the Patient Safety Team to consider whether we have:

    - the right legal framework in place to enable the routine assessment of the safe design of devices within the appropriate legal boundaries of procurement rules; and

    - the ability to ensure the NHS takes and can demonstrate it has taken appropriate action in response to such assessments. This assurance should come from the role of the New Patient Safety Alert Committee which will oversee the process for compliance with patient safety alerts where significant and complex management action is required. It will be announced by MS(C) on Monday 6th August.

2. Given the inherent difficulties in managing safety issues related to medical devices, there should be a regular assessment by the Department of the shared understanding of roles and responsibilities in this area by MHRA and the patient safety team along with others in the system (such as NICE and the NHS Supply Chain) in ensuring devices are procured and used in ways that maximise safety;

3. Explore what more that could be done to build on current processes and relationships to ensure that our current regulatory system (covering both device regulation and patient safety) takes sufficient account of international evidence.

4. Explore the way our system manages the trade-off between acting quickly and putting in place clear paths to implementation, and how we understand, explain and learn from real or apparent differences between our system and those in other countries.

5. We should develop a 'bring forward' system for issues that have a settled course of action or position which needs to play out over a long period of time This would include assessment of how effectively implementation was undertaken.

6. We should proactively consider what other devices there are in the NHS which are obsolescent or obsolete, acknowledging the balance between the cost of replacement programmes and increments in patient safety afforded by newer technology

These actions should be taken forward over the next three months with a further update to Ministers at that point. Ministers will then be able to update Parliament on this work as part of the response to the report of the Gosport Independent Panel planned for October.

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