

Improving Medication Security

**An evaluation of the cost effectiveness of the Drug
Guardian Device: a pilot study**

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Improving Medication Security**

The Drug Guardian: a pilot study

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Executive Summary and recommendations

Introduction

Medication that is stored in hospitals, care or nursing homes, GP surgeries or pharmacies must be handled, safely kept, dispensed and disposed of securely in accordance with part 4, section 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 in order to protect the service users and staff. Since 2014, the revised standards require the service provider to ensure the “proper and safe management of medicines.” In order to ensure that service providers comply with legislation, the Care and Quality Commission (CQC) perform routine health inspections of these institutions. Trusts must comply by ensuring that all drug enclosures, such as drug trolleys or controlled drug cupboards, when not in use, must be locked away in order to safely store medication. Drug enclosures must never be left open *and* unattended, and when open, the drug enclosure must be in constant supervision by an authorised member of staff.

Although the practice of leaving drug trolleys or controlled drugs (CD) cupboards open and unattended should never happen, it is in reality difficult to achieve and the CQC inspections frequently report failings in hospitals during their inspections. In 2012 the CQC reported the results of 14,000 inspections of service providers in the UK and found that 14% of hospitals, 20% of nursing homes and 16% of residential homes were non-compliant with the management of medicines standard. Since this report a further 6 hospitals, 10 care homes, 1 nursing home and 1 GP practice have been issued with formal warnings, due to failures in the safekeeping of medication, all of which must be addressed by the next inspection.

Clinical staff do not leave drug enclosures unattended purposefully and are aware they should not do this, however, the nature of their job does not always allow them to fully comply with guidelines. The problem normally occurs due to distraction during ward drug rounds. However, leaving drug enclosures open and unattended leaves medication vulnerable to theft or tampering by any person in the vicinity, therefore any clinical staff found to not be fully compliant guidelines may be subject to investigation, suspension and be found to be solely responsible for any clinical incidents.

Theft or tampering of medication is often opportunistic and usually occurs when drug enclosures are left open and unattended. This not only poses major risks for patients, but also damages the credibility of health care and undermines public trust in the profession. Any patient, member of public or hospital worker given the right opportunity could steal or tamper with medications, however it is often clinical staff, who have easy access to drugs, that are found to be at fault. Incidents of theft are common; in a survey of the hospital security departments in the East of England 71% stated that the frequency of missing drugs is increasing year on year. The costs of investigating these incidents can range from £5,000 to the £500,000 spent at Stepping Hill Hospital, after their recent incident: where a member of nursing staff purposely tampered with insulin infusions and has been charged with the murder of 5 patients and causing

grievous harm to more than 20 patients. This problem is not confined to the UK, and has been widely reported in institutions in the USA with significant patient consequences and litigation costs.

The Drug Guardian is a device designed to prevent these problems. It is a self contained, battery powered, retrofittable device which contains a light sensor, motion detector, crescendo buzzer and camera. When the device is fitted inside the drug enclosure, it monitors the drug round activity. As long as the nurse correctly attends the drug enclosure, the device remains inconspicuous. However, if the nurse leaves the drug enclosure open and unattended for more than a given time frame a crescendo alarm begins, reminding the nurse to re-attend. If this is not done promptly, noise becomes more persistent and louder in volume until the drug enclosure has been correctly re-attended or closed. The Drug Guardian acts as a behavioural modifier, alerting staff to errors and modifying subsequent behaviour by learned operant conditioning, rather than via education or training courses. The device collects drug round activity data and takes photographs of anyone in attendance of the device, acting as a deterrent and identifies any criminal activity.

Study Aims

The aims of the study were to:

1. To improve drug stewardship to ensure compliance with the Health and Social Care Act 2008, Regulations 2010, relating to the safe keeping of medicines, by means of the Drug Guardian device to preventing drug trolleys or controlled drug cupboards being left open and unattended in 6 Trusts in the East of England;
2. Assess the cost effectiveness of using the Drug Guardian;
3. Understand any barriers to adoption of the Drug Guardian.

Proof of concept studies

Three studies were performed at the Queen Elizabeth Hospital in order to test the device, with the approval of the security lead and nursing director.

Pre-baseline pilot study: Drug Guardians were installed on general ward drug trolleys, with the alarm disabled to monitor normal activity. It was found that drug trolleys were left open and unattended on average 14 times a day, with each episode lasting on average 2 minutes. When the alarm was activated, the number of episodes fell markedly to 3 episodes over a two week period.

Stealth study: It was found that 60% of the time non-nursing staff were able to gain easy access to medication inside drug trolleys during routine ward drug rounds, without being detected by the nurse conducting the ward round.

Theft study: It was found that 100% of the time, a consultant was able to gain access and 'steal' controlled medication without being detected by operating theatre staff. Where staff only discovered discrepancies during evening stock checks and were unable to identify the culprit amongst the entire theatre staff,

the Drug Guardian was able to clearly identify the perpetrator in the act each time.

Implementation studies.

During the implementation study, Trusts asked for the Drug Guardian cameras to be turned off, as they felt this was not appropriate for the study. Therefore the data collected simply recorded the time that the drug enclosure was left open and unattended.

6 Trusts participated in the study. These were the Queen Elizabeth Hospital, Colchester General Hospital, Hinchingsbrooke Hospital, Ipswich Hospital, East and North Hertfordshire Hospital and the James Paget Hospital. Most Trusts decided to place the Drug Guardians inside their controlled drug (CD) cupboards. Devices were placed in general ward drug trolleys, general ward CD cupboards, accident and emergency departments, operating theatres, maternity and ambulance service CD cupboards.

Across the region, during the baseline period, the total time that the drug enclosures were left open and unattended during the baseline study period was 503048 seconds (8384.13 minutes), which is 7.99 minutes per day. In the alarm period the total time drug enclosures were left open and unattended for 27590 seconds (459.83mins), which is 0.36 minutes (or 22 seconds) per day. This is a 95.5% improvement in correct attendance without the need for teaching or training.

Study Incidents

During a visit to a hospital by the study team, 1 department mentioned that the Drug Guardian was not working. We asked the nurse to step aside and leave the drug enclosure open whilst we watched to see if the device was working. After the set period, the device started alarming and working normally. This incident shows that the nurses had simply learnt to change their behaviour accordingly without realising that they had done so. This effect was seen in a number of different wards and hospitals during the study period and with only 40 Drug Guardians implemented in total.

During the study, 1 hospital contacted the study team urgently asking for the data prior to completion particularly requesting the photographs. They were reminded that they requested the camera to be turned off during the study period. It was discovered that, as the notices inside the drug enclosure informed staff members that the camera for the device had been turned off, a perpetrator continued to steal medication from the CD cupboard. This not only highlights the frequency of incidents of theft, even during the study period, but also the need for the camera to act as a deterrent.

Regional survey

A survey of the security leads of all acute Trusts was conducted as part of the study, in order to determine scale of the problem of drug thefts and tampering within the region.

For incidents, that could be resolved internally, it was found on average that staff spent between 20 hours to 5 days investigating minor incidents of drug theft or tampering. For criminal offences, this increased to an average of 10 days. Cases which have led to court, have resulted in loss of job, criminal sentencing and disciplinary hearings with staff member's professional regulatory body.

In terms of drug theft, 71% of hospital security leads thought the problem was increasing on a yearly basis.

Cost effectiveness

An independent cost analysis of the drug guardian was commissioned for this study.

The function of the Drug Guardian is to help hospitals and support staff in complying with the CQC guidance of never leaving drug trolleys open and unattended and to act as a deterrent to theft and tampering of medication.

The former is difficult to measure in terms of cost neutrality as these costs are in terms of ensuring patient safety, protection and support of staff in their clinical work and even the loss of public confidence and reputation of the Trust, if it is failed on a CQC inspection.

The later can be measured in terms of preventing the cost of investigations into theft or tampering of medication. Data from the six East of England study Trusts shows an annual average of 10-12 incidents involving missing medication. Calculating the frequency of investigations it was estimated that investigation costs in the Trusts surveyed ranged from £14,400 to £57,400 per year. These costs range from ward level investigation to internal disciplinary hearings and are for non-medical staff. These costs are substantially higher when doctors are involved. On going pharmacy reconciliation and monitoring of medication may cost £18,000-£35,000 per annum, depending on the level of resources required. Estimates of the cost of loss of medication at a prudent guess can be made as £5000 per year. Adding these three elements together implies a total cost of approximately £37,400 – £97,400 per annum for the size of trusts seen in this study and will be considerably higher for larger hospitals.

At a cost of £10 per unit per month, 1.6 investigations per Trust would need to be prevented for the devices to be cost neutral; at a cost of £50 per device per month, 7.9 investigations per Trust would need to be prevented for cost-neutrality. If one considers the annual average number of incidents investigations per trust was quoted as 10-12, for many Trusts cost neutrality is achievable, even at a cost of £50 per device per month.

Importantly, the Drug Guardian has the ability to be able to demonstrate good practice in relation to medicines management during CQC inspections, which is highly valuable to Trusts in ensuring patient safety.

Barriers to adoption

The Drug Guardian was well received during the study period and beyond. The Drug Guardian study was well supported in all participating Trusts by the nursing directors, chief pharmacists and security leads. All have been keenly interested in the results, and some have asked to continue to use the devices after the study period. Nationally, the Drug Guardian has been supported by NHS Protect, the NHS England security organisation which safeguards the NHS from crime. The regional and national leads have taken a keen interest in the device and the results, as drug theft and tampering is nationally a difficult problem to manage.

When new practice is introduced, in any environment, there are often a number of barriers preventing its introduction, such as senior support, resistance from staff or cost of new technology. The Drug Guardian works to protect the staff using the device, helps hospitals in their management of CQC requirements and helps security leads, chief pharmacists and the management team in their daily task of preventing fraud in the NHS. The device is also easy to install, requires no training but simply an explanation of what the Drug Guardian does and unobtrusively collects and stores the data required. Therefore the introduction of this device in the NHS has been extremely successful with new Trusts coming forward, on completion of the study period, asking for the device.

Conclusions

We are grateful to the EAHSN for funding this study, and believe the EAHSN has made a tangible difference to the improvement of medicines management in the region.

The Drug Guardian recognises when a drug enclosure has been opened and left unattended, creating an audit trail of persons who have had access to the drugs stored within it. The aim of the device is therefore to support staff in their safe management of medicines, by alerting them rapidly to any open trolleys or cupboards and acting as a learning tool.

In this study we have proved that the Drug Guardian is a solution to non-compliance with Care Quality Commission (CQC) guidelines with regards to drug cabinet and trolley management. The Drug Guardian can make medication management safer, acts as a deterrent to theft and tampering saving costly investigations, improves patient care and gives healthcare staff peace of mind and facilitates compliance with UK law.

The support for the Drug Guardian from NHS Protect, Trust managers and staff shows that we have identified a credible solution to the problem, which can now be spread into other areas where controlled and other high-risk drugs are stored and administered such as the ambulance services or care homes.

Background

Medication that is stored in hospitals, care or nursing homes, GP surgeries or pharmacies must be handled, safely kept, dispensed and disposed of securely in accordance with part 4, section 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 in order to protect the service users and staff.¹ Since 2014, the revised standards require the service provider to ensure the “proper and safe management of medicines.”² In order to ensure that service providers comply with legislation, the Care and Quality Commission (CQC) perform routine health inspections of these institutions.

In hospitals, controlled drugs (CD, sedative or opiate based medication) are stored on the wards and operating theatres in locked cupboards. Non-controlled medications are stored in drug trolleys on the wards. These trolleys can be moved around the ward bays by the nursing staff during drug dispensing ward rounds, figure 1.



Figure 1: (A) a controlled drugs cupboard, (B) a ward drug trolley

When not in use, both CD cupboards and drug trolleys must be locked away in order to safely store medication. The CQC, state that staff must never leave CD cupboards or drug trolleys open *and* unattended.³ When the cupboard is opened, the CD cupboard or the drug trolley must be in constant supervision by an authorised member of staff and the CQC best practice recommendations are to lock the trolley whenever the operator steps away from it.³

Although the practice of leaving drug trolleys or CD cupboards open and unattended should never happen, it is in reality difficult to achieve and the CQC inspections frequently report failings in hospitals during their inspections. In 2012 the CQC reported the results of 14,000 inspection of services providers in the UK and found that 14% of hospitals, 20% of nursing homes and 16% of

residential homes were non-compliant with the management of medicines standard.⁴ Since this report a further 6 hospitals, 10 care homes, 1 nursing home and 1 GP practice have been issued with formal warnings, due to failures in the safekeeping of medication, all of which must be addressed by the next inspection.⁵

It is however, acknowledged that trolleys are not left unattended purposefully and normally occurs due to distraction during drug rounds. Nurses are aware that trolleys should not be left open and unattended, however, the nature of their job does not always allow them to fully comply with guidelines. Distractions are typically from patients, health care staff, the telephone etc. and it is difficult to ignore the distractions and sometimes unsafe if for example a patient is suddenly taken ill, and remember to securely close the drug trolley or cupboard. One study highlighted that nurses were interrupted on average 26 times during a drug administration round.⁶ Due to surrounding environmental factors, ensuring that the drug trolley is never left open and unattended is a difficult problem to address. However, it is vitally important for the nurse to attend the drug trolley or CD cupboard correctly. If any medication is lost, stolen or tampered with, the responsibility for this lies exclusively with the nurse in charge of the drug enclosure keys during that shift, whether or not they are the perpetrators of the medication mismanagement. Leaving drug trolleys or CD cupboards open and unattended leaves medication vulnerable to theft or tampering by any person in the vicinity, therefore any clinical staff found to not be fully compliant with these guidelines, may be subject to investigation which may lead to suspension.

Theft or tampering of medication is often opportunistic and usually occurs when drug enclosures are left open and unattended. This not only poses major risks for patients, but also damages the credibility of health care and undermines public trust in the profession. Any patient, member of public or hospital worker given the right opportunity could steal or tamper with medications. However, theft of medication is often found to be by healthcare staff who have easy access to the drug enclosures. In disciplinary hearings for both the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC), in cases of drug theft, a standard defence or justification is often that "everybody does it." The public arrest of a member of nursing staff during the Stepping Hill Hospital, Stockport investigations illustrates this issue, where the nurse was found to be stealing painkillers, including opiates and antibiotics for herself and for a relative.⁷ There are several publically documented cases, however there are many more incidents where drug theft is dealt with internally or simply remains undetected.

The incidents of theft are common; in a survey of the hospital security departments in the East of England, 71% stated that the frequency of missing drugs is increasing year on year. The costs of investigating these incidents can range from £5,000 to the £500,000 spent at Stepping Hill Hospital, after their recent incident: where a member of nursing staff purposely tampered with insulin infusions and has been charged with the murder of 5 patients and causing grievous harm to more than 20 patients. The costs of investigation medication theft range extensively from the price of medication to criminal investigations, involving the police and covert CCTV cameras to catch perpetrators. Often, once

perpetrators are caught, this can lead to suspension or dismissal, and mounting costs for the hospital and the NHS. This problem is not confined to the UK, and has been widely reported in institutions in the USA with significant patient consequences and litigation costs.⁸

The correct management and security of drug trolleys and CD cupboards is therefore an important area for hospitals to address, and are areas that are subject to inspection. However, ensuring that the storage of drugs safely is a difficult problem to solve, due to the busy clinical environment. It is impossible to simply ask nurses to do this correctly or work better, as this does not change or improve practice.

Drug Guardian

In recognition of these problems the Drug Guardian has been developed in an attempt to eliminate these risks for drug enclosures, figure 2.



Figure 2: The Drug Guardian

This device is self contained, battery powered and retrofittable into any location. It has a light sensor, a motion detector, a crescendo buzzer and a camera. When the device is fitted inside the CD cupboard or drug trolley, it detects light when the trolley or cupboard is opened. As long as the nurse correctly attends the CD cupboard or drug trolley, the device remains silent. However, when a nurse opens the trolley and leaves it for more than a given time frame, e.g. 40 seconds a slow crescendo alarm begins. Initially the alarm sounds softly, reminding the nurse to re-attend, if however they do not re-attend promptly, the noise becomes more persistent and louder in volume until the CD cupboard or drug trolley is correctly re-attended or closed. Once this happens, the device resets and the cycle starts again. When the drug enclosure is correctly attended during a properly run drug round, the device remains silent and is not inconvenient to the user in any way.

Whilst the device is open it collects data, including the length of time the drug enclosure has been open for, the number of times the alarm has been activated and how long the alarm has been activated for. The camera takes photographs of any person attending the trolley. This can be set to be taken over various time periods and the photographs are time and date stamped. The box is able to collect and record large amounts of data, which can be processed to audit behaviour and identify any source of criminal or poor practice activity. The data is stored on the device on an encrypted data card. Nursing staff are also

protected by retrospective identification of security breaches when tampering or theft is detected.

The Drug Guardian acts as a behavioural modifier. It directly alerts staff to errors and modifies their subsequent behaviour by learned operant conditioning, rather than via education or training courses. It has been designed to be placed in the drug cupboard or trolley and fit into the daily working routine, with no inconvenience to staff or disturbance to patients. It also, therefore, requires minimal workforce training and most staff will never notice the device is in place as they are carrying out their duties around the medication trolley/cabinet correctly, as standard practice, already. We also believe that the camera will act as a deterrent, all but eliminating tampering and drug theft from the device location.

The aim of the device is therefore to support staff in their safe management of medicines, with minimal interference to their normal daily work.

Study Aims

The aims of the study were to:

1. To improve drug stewardship to ensure compliance with the Health and Social Care Act 2008, Regulations 2010, relating to the safe keeping of medicines, by means of the Drug Guardian device to preventing drug trolleys or controlled drug cupboards being left open and unattended in 6 Trusts in the East of England;
2. Assess the cost effectiveness of using the Drug Guardian;
3. Understand any barriers to adoption of the Drug Guardian.

Methods

Proof of concept studies

All studies were performed at the Queen Elizabeth Hospital, having informed the head of security and the nursing director.

1. A Pre-pilot baseline study

Drug Guardians were installed in drug trolleys in a surgical assessment unit. The alarm function was disabled, the devices simply recorded the normal activity. Nurses were educated on the risks of leaving the drug trolley open and unattended according to the CQC guidelines. The devices monitored staff's behaviour after education (alarm function off). Fully functional devices were then placed inside the drug trolley, the alarm function was activated, and would turn on if the drug trolley was unattended for more than 45 seconds.

2. Stealth study

A stealth study was performed to determine the ease of access to drug trolleys for a non-ward member of staff during normal drug rounds. During normal drug

rounds on general wards, two critical care nurses attempted to substitute one medication for an identical version in the drug trolley.

3. Theft study

This study attempted to determine the ease of access to morphine from controlled drug cupboards in operating theatres. Drug Guardians were placed in all operating theatre CD cupboard enclosures with the camera turned on. One consultant attempted to 'steal' morphine from the cupboard without being detected by the operating department practitioners (ODP).

Implementation Study

1. Preparation

It was necessary for hospital management to support the study in order to trial the Drug Guardians in their hospitals. Therefore the Chief Executive, Nursing Director and head of security for each acute Trust in the region were contacted and the study was explained. The regional local security management systems (LSMS) meeting were attended and the device was discussed with the acute Trust's security leads. Discussions were also started with NHS Protect, the NHS England security organisation which safeguards the NHS from crime, in order to inform them of the product and seek their advice on the device and this project. A research fellow, research nurse and data collector/analyst were hired to conduct the project.

2. Baseline data collection

6 Trusts were each given 5 Drug Guardians, and were asked to place these inside a CD cupboard or drug trolley of their choice over a 4 month period. The devices had the alarm function turned off and were set to record normal activity.

The data recorded was:

- the total time the drug enclosure was open;
- the total time the drug enclosure was left open and unattended.

The principal study lead designed a data analysis programme in order to easily covert the data into a layman's format. This permitted the research team to easily analyse the data. A poster was placed inside the cupboard or drug trolley door informing staff that the Drug Guardian was a new security device being trialled in their hospital. Hospital staff were informed that the camera was turned off, as Trusts felt it would not be appropriate to have the camera on during a research study.

3. Alarm data collection

After 4 months, the alarm on the Drug Guardian was turned on. The Drug Guardians were placed back inside the CD cupboards or trolleys in the same locations, so a behavioural comparison could be made. Data was recorded over a 2 month period as described in the baseline period. As with baseline data recording the camera was turned off.

Regional survey

A survey of the security leads of all acute Trusts was conducted as part of the study, in order to determine scale of the problem of drug thefts and tampering within the region.

Health Economic Analysis

A health economic evaluation was performed in order to determine to cost effectiveness of introducing the Drug Guardian devices into hospitals.

Results

Proof of concept studies

All studies were performed at the Queen Elizabeth Hospital, having informed the head of security and the nursing director.

1. A Pre-pilot baseline study

Drug Guardians were installed in drug trolleys in a surgical assessment unit. The alarm function was disabled and the devices simply recorded the normal activity. It was found that drug trolleys were left open and unattended on average 14 times a day, with each episode lasting on average 2 minutes. Staff were then educated on the risks of leaving the drug trolley open and unattended, however this resulted in 13 episodes of leaving the drug trolleys open and unattended. Once the alarm function was activated, where the Drug Guardian would alarm if unattended for more than 45 seconds, the number of episodes fell markedly to 3 episodes over a two week period.

2. Stealth study

The stealth study was performed to determine the ease of access to drug trolleys for a non-ward member of staff during normal drug rounds. During normal drug rounds on general wards, two critical care nurses attempted to substitute one medication for an identical version (new and sealed version). It was found that 60% of the time the nurses were able to replace like for like medication, during a normal drug round without being detected. This highlights that any person could replace a genuine medication with one that had potentially been tampered with, without the staff performing the drug round noticing any dishonest behaviour.

3. Theft study

The theft study attempted to determine the ease of access to morphine from controlled drug cupboards in operating theatres. Drug Guardians were placed in all operating theatre CD cupboard enclosures, with the camera turned on. One consultant attempted to 'steal' morphine from the cupboard without being detected by the ODPs. The consultant was able to 'steal' morphine from the cupboard on every attempt, without being detected by the ODPs. The ODPs discovered discrepancies during evening stock checks but were unable to identify the culprit amongst the entire theatre staff, however the Drug Guardian was able to accurately identify the perpetrator in the act every time.

Implementation study

During the implementation study, Trusts asked for the Drug Guardian cameras to be turned off, as they felt this was not appropriate for a research study.

Therefore the data collected simply recorded the time that the drug enclosure was left open and unattended.

6 Trusts participated in the study. These were the Queen Elizabeth Hospital, Colchester General Hospital, Hinchingsbrooke Hospital, Ipswich Hospital, East and North Hertfordshire Hospital, the James Paget Hospital.

Most Trusts decided to place the Drug Guardians inside their CD cupboards. 29 Drug Guardians were used in the baseline and alarm study periods. However, some data collected was erroneous and was discarded. Therefore in the baseline period, there were 17 Drug Guardians in CD Cupboards and 3 in drug trolleys. In the alarm period there were 18 Drug Guardians in CD Cupboards and 5 in drug trolleys. Drug Guardians were located in general wards drug trolleys, general ward CD cupboards, accident and emergency departments CD cupboards, operating theatres CD cupboards, maternity CD cupboards and ambulance service CD cupboards.

Data collection was conducted between December 2014 and July 2015. There were a total of 1049 days of data in the baseline period and 1247 days of data in the alarm period, where the alarm was set to be activated at 40 seconds.

Across the region, the total time that the drug enclosures were left open and unattended during the baseline study period was 503048 seconds (8384.13 minutes), which is 7.99 minutes per day. In the alarm period the total time drug enclosures were left open and unattended for 27590 seconds (459.83mins), which is 0.36 minutes (or 22 seconds) per day. This is a 95.5% improvement in behaviour without the need for teaching or training.

When individual Trust data is analysed, the results and percentage improvement were similar to the combined regional results, table 1, figure 3. This result is also seen when the data for CD cupboards or Drug Trolley is analysed separately, table 2, figure 4. This shows that the same problem is seen across different hospitals and that the device has the same improvement effect across different hospitals, different wards and different drug enclosures.

Table 1: Showing the average time the drug enclosures were left open and unattended per day by Trust

Trust	Average time the drug enclosure was left open and unattended per day (mins)		% Improvement
	Baseline	Alarm on	
(A) Colchester	1.81	0.03	98.38
(B) Hinchingsbrooke	15.63	1.78	88.59
(C) Ipswich	39.88	1.87	95.31
(D) JPH	3.03	0.19	93.58
(E) East and North Herts	15.96	0.53	96.71
(F) QEH	6.89	0.37	94.67

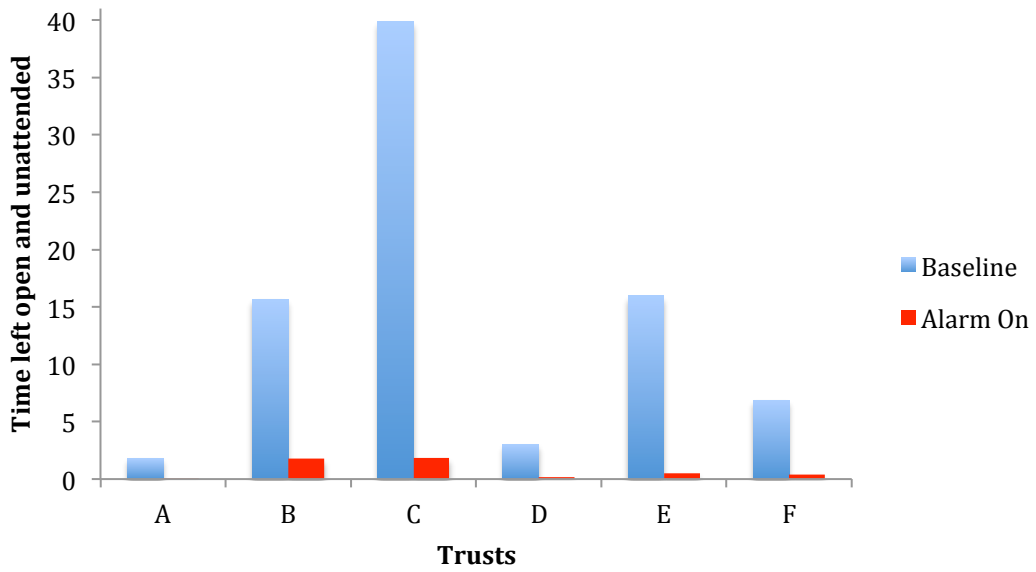


Figure 3: Showing the average time the drug enclosures were left open and unattended per day by Trust

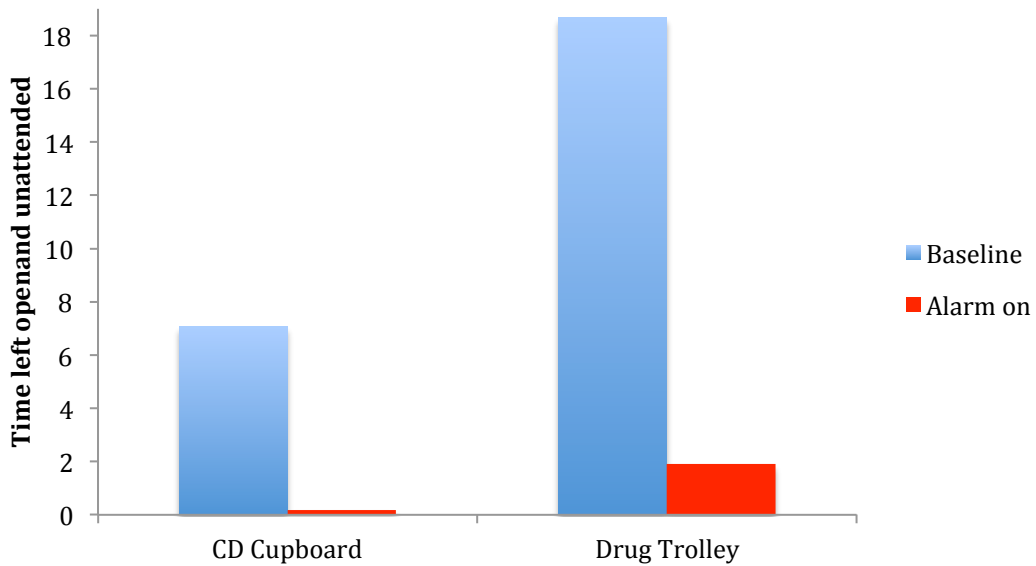


Figure 4: Showing the average time the drug enclosures were left open and unattended per day

Table 2: Showing the average time the drug enclosures were left open and unattended per day

Drug Enclosure	Average time the drug enclosure was left open and unattended per day (mins)		% Improvement
	Baseline	Alarm on	
CD Cupboard	7.06	0.17	97.55
Drug Trolley	18.67	1.90	89.79

Study incidents

During a visit to a hospital by the study team, 1 department mentioned that the Drug Guardian was not working. We asked the nurse to step aside and leave the drug enclosure open whilst we watched to see if the device was working. After the set period, the device started alarming and working normally. This incident shows that the nurses had simply learnt to change their behaviour accordingly without realising that they had done so. This effect was seen in a number of different wards and hospitals during the study period and with only 40 Drug Guardians implemented in total.

During the study, 1 hospital contacted the study team urgently asking for the data prior to completion particularly requesting the photographs. They were reminded that they requested the camera to be turned off during the study period. It was discovered that, as the notices inside the drug enclosure informed staff members that the camera for the device had been turned off, a perpetrator continued to steal medication from the CD cupboard. This not only highlights the frequency of incidents of theft, even during the study period, but also the need for the camera to act as a deterrent.

Regional Survey

A survey of the security leads of all acute Trusts was conducted as part of the study, in order to determine scale of the problem of drug thefts and tampering within the region. 7 acute Trusts in the region replied to the survey.

For incidents, that could be resolved internally, it was found on average that staff spent between 20 hours to 5 days investigating minor incidents of drug theft or tampering. Typically it was found that 2 members of staff were involved in investigating these incidents and staff members were often ward managers or senior nurses of band 7 or above.

In incidents involving missing or stolen drugs which progressed to a trial (both disciplinary hearing or criminal court), Trusts had spent up to 10 days of time on both the investigation and the hearing. Typically this has involved at least 4 members of staff, including the head of security, head of pharmacy, the ward matron and the police. Cases which have led to court have resulted in loss of job, criminal sentencing and disciplinary hearings with the staff member's regulating professional body.

Survey responses indicate that in some Trusts there are up to 45 incidents of 'lost' potentially stolen medication a year, and if any cases involve controlled drugs this must be investigated by the head of security. There are typically 2 incidents a year per Trust that lead to disciplinary hearings and in order to investigate the incidents Trusts spend between £500 - £1,500 on extra CCTV recording alone. This is in addition to the time and staff numbers required to conduct the investigation.

There is also a significant impact on all of the ward staff when an investigation is underway. The responses indicate that all staff feel as though they are under suspicion when allegations of theft from a ward have been made. Staff morale is particularly low during these periods, with high levels of anxiety.

In terms of drug theft, 71% of respondents think the problem is increasing on a yearly basis.

Health Economic Analysis

A report on the costs and incidence of drug theft and drug tampering and cost-effectiveness of Drug Guardian Preventative Device.

Independently commissioned from Anna Crispe, a Health Economist.

Introduction

This report describes the work undertaken within an East Anglian Academic Health Science Network project to test a prototype device designed by a team at the Queen Elizabeth Hospital King's Lynn NHS Foundation Trust. The device, known as the "Drug Guardian", is designed to be located in drug trolleys and cupboards. It sounds an alert when the trolley or cupboard door is left open in excess of a set time, and can also take a date and time stamped photograph of whoever has opened it. It is designed to ensure that drug trolleys and cupboards are not left open and unattended, in line with Care Quality Commission guidance on the safe management of medicines, and also to provide a clear audit trail should an incident involving missing or unaccounted for drugs occur.

To inform the study, a literature review was completed on the incidence, harm and costs of drug losses and tampering, and Trusts taking part in the pilot were surveyed about their experiences of these events. A costing model was developed, on the basis of information from Trust incident reports and survey responses, setting out the costs of investigating incidents involving unaccounted for drugs. Work was undertaken with the pilot Trusts to ascertain the cost of drug losses each year, a figure which proved impossible to calculate but was agreed by all to be greater than zero, and in some cases, was felt to be substantial. These losses, together with the costs of investigations, were modelled in relation to the possible costs of the Drug Guardian; however, as this project is still only at the pilot stage the reported findings are in relation to cost neutrality and are based on estimated costs of the Drug Guardian.

Purpose of the Drug Guardian

Drug cabinets and trolleys are used in hospitals, in wards and other areas such as operating theatres, to securely store medication. Nurses and other staff access the trolley or cabinet when the medication is required by patients, typically during a "drug round". On a ward, it is the responsibility of the nurse in charge of each shift to keep the contents secure, and they are the sole key-holder. During a ward drug round the trolley is unlocked and pushed around the ward to each patient. While nursing staff are aware that drug trolleys shouldn't be left open and unattended, but during busy ward rounds this can happen, presenting

opportunities for theft or tampering. These actions can both have serious consequences, which are explored further below.

The Drug Guardian device recognises when a trolley or cabinet has been opened and left unattended, for example for 45 seconds (the time is adjustable). The Drug Guardian then sounds an alarm, increasing in volume, until someone returns to it. In time, it will also incorporate a digital camera, which will record images of the person opening the cupboard or trolley, and further images taken while the cabinet or trolley remains open, adding to the audit trail of who has had access to the drugs stored within it. The aim of the device is therefore to support staff in their safe management of medicines, by alerting them rapidly to any open trolleys or cupboards, and acting as a learning tool – initial trial use at Queen Elizabeth Hospital King's Lynn indicated that nurses quickly adapted their behaviour to prevent the alarm sounding, thereby substantially increasing the safe storage of medicines in patient areas. The device clearly also has potential to improve patients and staff safety in many other parts of the health and care system in addition to hospitals where controlled and other high-risk drugs are stored and administered, including ambulance services, and care homes.

The problem of drug losses and fraud

The loss or theft of drugs, also known as “drug diversion” in the US, presents multiple potentially serious problems, which can affect healthcare providers and staff, patients and their relatives. While the proportion of drugs dispensed in the hospital setting is relatively small, the way that drugs are stored, dispensed and used in that setting presents many opportunities for fraud. Fraud in this context may range from the pilfering of relatively safe non-prescription items, such as paracetamol, for self or family use; to theft or tampering to secure controlled drugs for personal use by addicted healthcare workers; to theft of drugs for black market resale; right up to theft or tampering with the apparent express intention of causing serious patient harm.

A literature search on drug theft from healthcare facilities reveals articles going back well over 30 years – clearly this is not a new problem. An American survey in 1981 stated that 64% of hospital pharmacy directors reported actual or suspected drug pilfering in the previous year,⁹ and more recent data, again from America, suggests that either the frequency of pilfering or reporting is increasing, with an incidence of 1.3 reports per month of controlled substances being lost or stolen in 2006, and 4.3 reports in 2010.⁸ Survey data gathered from acute Trusts across the East of England for this study indicates that 71% of them reported that the frequency of missing drugs is increasing year on year.

It appears that most incidences of drug theft or diversion are committed by staff, although examples from patients and their relatives are not unknown. Consultant Anaesthetists at the Mayo Clinic have recently published their efforts to understand and investigate the problem, and found 6 serious incidences in their organisation between 2010 and 2012.¹⁰ These included:

- a patient's relative removing the patient's fentanyl patch, presumably for their own use, having asked to assist in bathing their loved one;

- a patient who stole a nurse's PCA pump key and altered the pump settings so that the entire opioid dose was delivered in a very short time, only tolerated by the patient due to their pre-existing addiction;
- a nurse with a secret pocket sewn into her top in which she hid fentanyl syringes, substituting them for normal saline which she injected into the patients, denying them pain relief during their procedure;
- a radiology technician who changed the needles of fentanyl syringes drawn up for use in the interventional radiology suite, injected himself and then refilled the syringes with normal saline before changing the needle back and injecting the patient, infecting 5 patients with hepatitis C;
- a nurse breaking into sharps containers, transferring the contents into plastic bags before taking them home and sorting through them to extract discarded controlled drugs, then returning the bags to the hospital with dirty needles protruding from them, putting colleagues at risk;
- a night nurse searching through sharps bins for fentanyl which he then consolidated from used syringes and injected himself with.

Clearly the Mayo Clinic, with 55,000 employees, is a much larger institution than many NHS organisations, but all these incidents could happen in this country. While the availability of the Drug Guardian in drug cupboards and trolleys would not have prevented all these instances, it helps to support a culture which takes drug theft and diversion seriously, and aims to protect innocent staff from the effects of these events.

While some of these examples are extreme, and clearly resulted in serious harm to staff and patients, less dramatic theft and/or tampering in a routine clinical environment is relatively easy to do, and difficult to detect. A study was undertaken at one of the pilot Trusts in the East of England where a designated senior doctor attempted to 'steal' controlled drugs from drug cupboards at different times of the day on 6 different occasions – the Drug Guardian detected all these attempts, and took a photo from which the culprit could be easily identified on every occasion, while no staff on duty noticed that there was a problem.¹¹ This example illustrates why the safety and security of medicines requires constant vigilance.

Another reason why drug theft and misappropriation may be so prevalent is that it may not be reported. We have already seen that the incidence of pilfering may be relatively high, a claim also made by the nurse initially accused of the saline tampering that led to the death of 3 patients at Stepping Hill Hospital, Stockport, Greater Manchester in June-July 2011, although this was only supported by limited evidence from the wider enquiry.¹² In one study which surveyed almost 3,000 doctors in the US, 33% of them who knew that a colleague was impaired by drug use did not report that colleague.¹³ The reasons for this may be complex – wishing to support a colleague in difficulty, perhaps a feeling that a colleague can in some way handle the risks involved, or perhaps not wanting to speak out – but given the harm which can result, examples of which have already been discussed, this finding gives further impetus to the need for clear structural and systematic monitoring of high risk areas and processes, something which the Drug Guardian can contribute to. It is also interesting to note that in a hospital in

New Hampshire where a Hepatitis C infected healthcare worker passed on the virus to over 20 patients by tampering with fentanyl syringes, the hospital is now suing individual staff on the basis that they failed to intervene when faced with earlier evidence of opioid abuse by the infected colleague.⁸ While the UK has a different legal culture to the US, it is clear that regulatory or criminal sanctions could equally apply here in a similar situation.

We have already seen some examples of drug theft or tampering leading to serious harm to individual patients, which can occur through the abuse of controlled and non-controlled substances. Sometimes the harm can be widespread. The criminal proceedings into the saline tampering at Stepping Hill Hospital are still ongoing, with a nurse now charged with three counts of murder and 18 counts of grievous bodily harm. A review of CDC data in the USA between 2000 and 2013 highlights 6 disease outbreaks stemming from drug theft or tampering by healthcare workers in hospital settings; in total these incidents resulted in 34 gram-negative bacteraemias, 84 cases of hepatitis C infection; and almost 30,000 patients having to be recalled for blood-borne virus testing. Given that these headline cases are likely to represent only a tiny fraction of the incidents of drug theft or tampering, it is no surprise that there are stringent regulatory requirements applying to the handling, administration and storage of medicines.

In England, this regulatory effort is led by the Care Quality Commission, who have the responsibility, in partnership with others including NHS England, to oversee the regulations regarding controlled drugs, and are also the Regulator for health and social care providers, including hospitals, primary care, residential and nursing homes and ambulance services.

The CQC follow a regulatory framework set out in Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, known as the Essential Standards of Quality and Care. Medicines Management features in Outcome 9, which requires that “The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity”. From April 2015, a revised set of regulatory standards (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) will come into place, which requires that “where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;” and “the proper and safe management of medicines”.

The safe management and storage of medicines has been problematic for many health and social care providers. In 2012, the CQC reported that 14% of hospitals were non-compliant with the management of medicines standard.⁴ 1 in 5 nursing homes and 16% of residential homes were also non-compliant, the highest reason for non-compliance in both these sectors. Recent evidence suggests problems are continuing; a care home in Suffolk was issued with a formal CQC warning in relation to this standard in August 2013, with the manager

commenting “The CQC were happy with the way drugs were being administered. Their complaint was more about the safekeeping of drugs and how they are housed.”¹⁴ The North East Ambulance Service NHS Foundation Trust was required by the CQC in May 2014 to take action in respect of the finding that “some medicines were not always kept safely or securely in ambulance stations.”¹⁵ The CQC standards mean that drug trolleys or cupboards should never be left open and unattended, but in practice, on a busy ward-based drug round, this can be extremely difficult to comply with.

The CQC are taking positive action to understand and assist in the prevention of controlled drug fraud. For the first time in England, they are starting to collate and publish data on all incidents of controlled drug theft or loss across the country, and intend to use the trend information revealed by this to inform future efforts to improve controlled drug security.

The Direct Costs of Drug Fraud/Diversion

It has been shown that drug fraud can occur in many settings, can be perpetrated by a range of staff, and may be less of a rare occurrence than initially supposed. In this section the various direct and indirect costs which may arise from drug fraud are considered, using data from the literature and the study.

a) Direct costs – Value of Drugs

In many cases, the value of the drugs stolen or unaccounted for may not be particularly high, and in many cases it is only the value of unaccounted for controlled drugs which is costed. Data from FOI requests in relation to controlled drugs responded to by 3 NHS hospitals and a Health Board, and covering 9 separate years indicates an average annual cost of missing/unaccounted for controlled drugs of £105.09, or £29.07 if one outlying very high yearly loss (£713.20) is excluded from the mean.¹⁶

However, if wider drug losses are considered, the costs may be considerably higher. Queen Elizabeth Hospital King’s Lynn, a hospital with 488 beds, estimate a total annual cost of all drug theft/loss to be at least £15,000, or £30.75 per bed (according the security lead). While this estimate appears quite high, it has not been possible for either security or pharmacy leaders across the region to corroborate it as either too high or too low, as this data is not available within NHS Trusts. For the purposes of the model in this study, two figures of £5,000 per year and £15,000 per year have been adopted (approximately £8.50 per bed per year, and £25.50 per bed per year), and these levels could be adjusted to produce different scenarios if required. Across the 6 Trusts in the pilot study therefore, total annual drug losses ranging from approximately £30k per year to approximately £90k per year have been assumed.

b) Direct costs - Monitoring systems and framework

All Trusts will have in place extensive policies and regulations around the storage, management, dispensing and administration and handling of returns and waste, as well as separate policies and arrangements for controlled drugs, which will be audited and reviewed regularly. The cost of much of this work will typically be borne by the pharmacy team. With hospital pharmacists costing an

estimated £47 per hour, it can easily be seen that spending 1-2 days per week on this activity would lead to annual opportunity costs of £18-35k.¹⁷

c) Investigative time / surveillance

The FOI reports referred to above indicate an average of 8 incidents per year involving controlled drugs which required formal investigation. In addition to this, it is likely that a number of incidents will occur each year involving non-controlled drugs, for example insulin, that will also require full investigation. Data from the six East of England study Trusts shows an annual average of 10-12 incidents involving missing drugs, with one Trust reporting 32 incidents per year. Again, for some of these Trusts this only covers unaccounted for controlled drugs, as these are required to be reported; the actual figures when all unaccounted for drugs are considered may be considerably higher.

Using the 2013 unit costs from the Personal and Social Services Research Unit,¹⁷ a cost can be developed for such an investigation. The pilot Trusts were surveyed about the resource implications of such investigations, and their comments and datix incident returns suggest that on average, the first level investigation typically requires up to 1 day of staff time in total, split between staff nurses double checking the error, a ward pharmacist doing an initial investigation and a band 7 ward manager or night nurse practitioner following up the initial findings and making decisions about next steps.

A proportion of these initial local investigations will then progress to a more formal stage – data from the study Trusts indicates that this could be anywhere between 4% and 30% of the initial investigations. This more formal stage typically involves ward staff providing statements, and may also involve the installation of CCTV surveillance equipment, which requires considerable input from the local Security Management Specialist. This equipment and the associated security staff time is estimated to cost approximately £3,163, based on survey responses from study Trusts.

If there are grounds for disciplinary action, a member of staff may be suspended on full pay while investigations proceed, perhaps for three weeks, requiring additional cover to prevent the ward being short-staffed in the meantime. If indicated, preparation for and completion of a formal hearing is likely to require 2 further days of ward manager band 7 time, in addition to two days of HR management time (band 7) and a day of senior management time (8B). Feedback from Trusts also indicated that there may be considerable support from Occupational Health at this stage, to try and assist staff in returning to work where appropriate. Should the outcome of that hearing be a recommendation of dismissal, a further dismissal hearing will be required, with further time from HR, the band 7 senior nurse, and a more senior manager (at least Band 9, usually a Director).

Using this simple estimate of costs, it can be seen that total staff costs of £22,240 are incurred by the Trust if an incident results in a dismissal; £347 on the initial investigation; £4,239 on a more formal local investigation; £14,311 on any staff suspension and subsequent disciplinary hearing, and a further £3,690 on the dismissal hearing. Some of these costs will be additional cash costs (e.g. agency

nursing cover for a suspended staff member), while most are opportunity costs (no impact on overall spending, but staff are required to spend their time conducting investigations rather than caring for patients, or completing other tasks such as training or audit).

If the investigation includes doctors, and continues all the way through to a dismissal hearing, the estimated investigation costs are higher at £33,516. In reality, investigations may not proceed to a hearing, or, conversely, may be far more complex than this model suggests. The Police investigation into the drug tampering at Stepping Hill Hospital, Greater Manchester involved interviewing more than 800 members of Trust staff in the year following the incident, with Greater Manchester Police spending £0.5 million in the first four months of the investigation, and the Trust incurring costs of at least £100,000 on security, legal, police liaison and incident management (excluding staff opportunity cost time) in the same timeframe.^{18,19}

d) Direct costs - Harm to patients

We have already seen a number of examples where patients either died, or were severely harmed, as a result of drug theft or tampering, in both the US and UK. While the probability of such events occurring is clearly low, when they do occur they can be devastating for the individual and their family. Quantifying the effects of patients requires clearer data on the frequency and impact of drug fraud on patient's costs in the widest sense (including loss of utility, loss of earnings etc.), which is outside the scope of this pilot assessment, but is potentially extremely high.

e) Regulatory / legal issues – CQC compliance

The costs of compliance with regulatory and legal frameworks can be considerable; however, the costs of non-compliance may be much higher once the poor patient outcomes, increased risks to patients, staff and visitors, possible loss of business due to patients or residents choosing to be treated elsewhere, and the negative impact on staff morale and organisational reputation are taken into account. Given that the incidence of regulatory failure in medicines management has been so high in both the health and care sectors in the UK, some investment in improving the safety of medicines storage and management, along with the greater staff awareness of the issue that this investment would bring, may prove to be highly cost-effective.

f) Direct Costs – Summary

We have therefore seen that for a 500 bedded UK hospital, the direct cost of missing or stolen drugs may be up to £15,000 annually, although we have also modelled a prudent scenario of £5,000 for this study. Based on the cost model described above, and on the frequency of investigations and the number of those investigations proceeding to a formal stage reported by the study Trusts, it is estimated that investigation costs in the Trusts surveyed range from £14,400 to £57,400 per year. These costs are higher where doctors are involved. On going pharmacy reconciliation and monitoring may cost £18,000 -£35,000 per annum, depending on the level of resource required. Adding these three elements together in total implies a total cost of or approximately £37,400 – £97,400 per

annum for the study Trusts, which have between 304 and 657 beds; costs for larger Trusts may be proportionately higher.

The Indirect Costs of Drug Fraud/Diversion

In addition to the direct or opportunity costs we have considered above, there may also be further indirect impacts from drug fraud. The Chartered Institute of Personnel and Development's 2007 report "Tackling Staff Fraud and Dishonesty" notes that "staff fraud can disrupt the normal daily routines of other employees and ... have a negative impact with respect to morale and Trust... Speculation and the grapevine can lead to misinformation and unsubstantiated rumours and gossip circulating within departments. Team spirit and morale can be harmed if staff are shocked and unsettled by co-workers being dismissed, arrested... or prosecuted. Occurrences of staff fraud can also create a culture of mistrust and suspicion." It is possible to speculate that in a high-risk area such as acute healthcare, where teamwork and Trust are perhaps even more important than in other settings, the corresponding impact of such an event may be considerable. Survey responses from the study Trusts corroborated these views, with Trusts commenting that *"missing drugs put all staff under suspicion; staff morale is affected by such allegations"*; and *"there was a significant reduction in staff morale while a major investigation was going on, as all of the staff members felt they were under investigation"*; and *"staff all feel implicated"*; and *"staff were suspecting each other"*; and *"there was a definite impact on clinical teams – the lack of Trust and increased suspicion adversely affects teamwork"*; and *"during an investigation there is expected to be significant effects on morale and sickness."* One Trust who successfully prosecuted someone for drug theft said there was *"staff anxiety prior to the member of staff being identified, but relief afterwards that it was resolved. It raised awareness of the possibility of theft and the procedure to follow if suspicious"*.

Institutional reputation is also a precious, hard-won commodity, which will almost inevitably be damaged by a serious drug fraud, particularly if patient safety is compromised. The indirect costs of drug mishandling or fraud to an institutions' reputation may be severe and long-lasting, as attested to by the media coverage of the Stepping Hill tampering incident, still unresolved more than three years after the events occurred. While the institution may have acted impeccably in response to an issue, it is inevitably tarnished by the actions of its member of staff, and by the fact that it failed to protect its patients.

In addition, there are of course wider costs to both the individual found guilty of a drug fraud, and to society. The PSSRU Unit Costs for 2014 indicate that training a nurse costs £79,172, while training a doctor to registrar level costs £441,219, and to Consultant level £726,551. Clearly, being found unfit to practice turns this sizeable investment by society into a cost burden. Such an individual would find it impossible to work in their trained occupation in the future. The sentences handed down for patient safety incidents resulting from drug fraud in America have become noticeably tougher in recent years, perhaps reflecting a change in attitude towards this sort of crime. A recent review of cases noted that an episode of hepatitis C infection caused by a drug diverting healthcare worker in

2006 resulted in a 41 month prison sentence; the latest episode in 2012 resulted in a 39 year sentence, incurring yet more societal costs.⁸

Cost Effectiveness of the Drug Guardian

Using the analysis of direct costs associated with drug loss or theft set out above, and data from the 6 pilot Trusts and other Trusts within the Eastern Academic Health Science Network area, a simple model has been constructed to review the likely cost-effectiveness of using the Drug Guardian.

The model could be used to calculate two types of cost saving. The first is the cost of drug losses and the second is the cost of an investigation into missing medication. In terms of lost or stolen drugs none of the Trusts in the study were able to clarify the cost of their drug losses, where estimates of between greater than zero to substantial were given. This model estimated losses of between £5k-£15k per annum, however as this guess is without substantial evidence and the use of the Drug Guardian will not necessarily prevent lost medication, but prevent the incidence of investigations, the model concentrates on the cost of the investigation. An evidence-based approach to estimating the costs of an investigation into missing drugs centred on medical or non-medical personnel, and the costs of a disciplinary hearing subsequent to a small proportion of those initial investigations; reports of the numbers of investigations conducted annually by Trusts in the study; and local Trust's estimates of the proportion of those investigations which proceed as far as a disciplinary hearing. The model also estimates the costs of additional camera surveillance, again based on data from local Trusts. The model assumes a range of costs for the Drug Guardian of £10, £30 or £50 per Drug Guardian per month, on a lease basis. The model assumes that none of the investigations result in criminal proceedings or local disciplinary action greater than a hearing, as the frequency of this type of very serious incident is low and the costs are highly variable, making it difficult to establish robust modelling assumptions.

Pilot Trusts have provided detail on the number of wards, operating theatres and emergency departments in their Trusts. Two scenarios have been modelled; both scenarios assume that every Operating Theatre controlled drugs cupboard and each Emergency Department controlled drugs cupboard will have a Drug Guardian. One scenario then assumes that each ward will have three Drug Guardians (two in the drug trolleys and one in the controlled drugs cupboard), and the second scenario assumes that each ward will only have one Drug Guardian, in the controlled drugs cupboard.

Assuming each ward has three Drug Guardians at a cost of £10 per device per month, it can be seen that the Drug Guardians, will, on average, be offset cost-neutral if they prevent 3.3 investigations each year per Trust. The exact figure may vary between Trusts.

Considering the alternative scenario, where Drug Guardians are only deployed in higher risk areas (controlled drugs cupboards), the costs of the Guardians can be offset in full by reducing the numbers of investigations required, and hence the

resources involved in conducting them. At a cost of £10 per unit per month, 1.6 investigations per Trust would need to be prevented for the devices to be cost neutral; at a cost of £50 per device per month, 7.9 investigations per Trust would need to be prevented for cost-neutrality. If one considers the average number of incidents investigations per trust was quoted as 10-12, for many Trusts cost neutrality is achievable, even at a cost of £50 per device per month.

It is worth noting that the value of being able to demonstrate good practice in relation to medicines management, and the deterrent effect provided by the Drug Guardians, are not factored into these estimates. These factors are likely to be very valuable to Trusts in ensuring patient safety, and in relation to their CQC inspections.

Of course, while the cost of lost or stolen drugs is a real cost and a cash loss, the cost of staff time on investigations or disciplinary hearings is an opportunity cost – time that staff cannot spend on patient care, training, audit or any other productive activity. However, including these opportunity costs seems reasonable given the current context of tightly controlled staffing budgets and the need to demonstrate safe staffing levels on a daily basis.

Conclusion

While use of the Drug Guardian cannot prevent every premeditated malicious action involving drugs that might be carried out in a hospital environment, it can clearly make a contribution to improving the safety culture around the management of drugs, in ward, operating theatre and emergency department settings. It supports staff to systematically adopt behaviour which is in line with regulatory requirements through the use of a simple and non-intrusive device. This approach is clearly aligned to the recent consultation by NHS England concerning the revised framework for Never Events, which includes a new focus on the need for strong organisational barriers to support staff and prevent incidents and near-misses.

Detailed assessment of the cost-effectiveness of the Drug Guardian depends on an accurate assessment of the costs of missing or stolen drugs, and the resources dedicated to investigating and resolving these issues. While the study is only at a pilot phase at the moment, and costs and assumptions may change, local data suggests that the Drug Guardians could be offset- cost neutral, through prevention of drug losses and investigation costs. These assessments do not take into account further possible wider benefits, which may include reduced harm to patients, improved regulatory compliance, improved staff morale and a stronger institutional reputation.

Problems encountered during the study

There were significant delays in the project due to technical problems with the manufacturer commissioned to produce the initial 100 units. The contract with the manufacturer had to be terminated and there were further delays whilst a new supplier was found. Health Enterprise East were very helpful in providing the legal advice required to get the project smoothly back on track. The delays

were time consuming and costly. Ultimately 40 units were manufactured and these devices were used in study sites. Lessons from this incident were learnt. The Drug Guardian is now being manufactured in Singapore, to the specifications required with adaptations from the feedback received.

Adoption in the NHS

Adoption

The Drug Guardian was well received during the study period and beyond. During the study period the main advantage for study leads in the Trusts was that the device collected all of the data for them. This ensured very accurate and robust daily data collection.

When introducing devices such as these or any new change of practice, there is often suspicion. Indeed, many nurses felt that they were being watched and did not like the idea of a camera inside the drug enclosure. However, by explaining to the nurses the purpose of the device and its role in protecting them and patients, by ensuring the cupboard was always closed and that the camera would protect them if a theft incident occurred, actually changed their opinion of the Drug Guardian and they wanted the device in their cupboards.

The Drug Guardian study was well supported in all participating Trusts by the nursing directors, pharmacy and security leads. All have been keenly interested in the results, and some have asked to purchase the devices after the study period.

Nationally, the Drug Guardian has been supported by NHS Protect, the NHS England security organisation which safeguards the NHS from crime. The regional and national leads have taken a keen interest in the device and the results, as drug theft and tampering is nationally a difficult problem to manage.

Changing Behaviour

When new practice is introduced, in any environment, there are often a number of barriers preventing its introduction, such as senior support, resistance from staff or the cost of new technology. The Drug Guardian works to protect the staff using the device, helps hospitals in their management of CQC requirements and helps security leads in their daily task of preventing fraud in the NHS. The device is also easy to install, requires no training but simply an explanation of what the device does and unobtrusively collects and stores the data required. Therefore the introduction of this device in the NHS has been extremely successful with new sites coming forward, on completion of the study period, asking for the device.

Feedback

The feedback from staff using the device has been incredibly helpful in the development of the Drug Guardian.

“staff are much more aware not to leave the drug trolley open and unattended”

“I had forgotten all about the Drug Guardian being in the trolley until it sounded, so it definitely works”

Staff felt that the pitch and volume of the alarm was suitable, and did not affect patients when they were sleeping.

Staff also felt the motion detector should be more sensitive, so that they had the freedom to move around the trolley.

Next steps

Based on the feedback, we will be making some changes to the device which are:

1. manufacture a secure docking system which can be fastened to the drug cabinet and holds the Drug Guardian;
2. a very wide angle camera lens;
3. a more sensitive motion detector;
4. large storage and battery capacity.

Conclusions

The Drug Guardian has been developed at the Queen Elizabeth Hospital King's Lynn NHS Foundation Trust. It is a security unit which can be retrofitted into drug trolleys or controlled drug cabinets in order to help hospitals comply with the CQC guidelines of never leaving drug enclosures open and unattended and deterring the theft and/or tampering of medication.

The Drug Guardian recognises when a drug enclosure has been opened and left unattended, creating an audit trail of who has had access to the drugs stored within it. The aim of the device is therefore to support staff in their safe management of medicines, by alerting them rapidly to any open trolleys or cupboards, and acting as a learning tool.

In this study we have proved that the Drug Guardian is a solution to non-compliance with Care Quality Commission (CQC) guidelines regarding to drug cabinet and trolley management. The Drug Guardian can make medication management safer, acts as a deterrent to theft and tampering saving costly investigations, improves patient care and gives healthcare staff peace of mind, whilst facilitating compliance with UK law.

The support for the device from NHS Protect, Trust managers and staff shows that we have identified a credible solution to the problem, which can now be spread into other areas where controlled and other high-risk drugs are stored and administered such as the ambulance services or care homes.

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Conflicts of Interests

Dr Young is now a shareholder and advising on designing and manufacturing a commercial device.

Appendix

1. Promotion of Work: Awards, Publications and Presentations

This research has been presented at international, national and regional conferences in order to promote the work.

Awards

2014 Winner, NHS Innovation Competition, Health Enterprise East

Publications

Hodge E, Pearson D, Moondi P, Mariyaselvam M, Gibson J, Young P, Blunt M. Drug trolley surveillance alarms have a role in improving patient safety. *Nursing Times* 2015; 11(40):20-21

Mariyaselvam M, Pearson D, Moondi P, Young P. The Limpet controlled drug cabinet alarm and camera *Critical Care* 2014, 18 Suppl 1:P2

Presentations, oral and poster:

International:

The International Symposium on Intensive Care and Emergency Medicine, Brussels, March 2014.

National:

The Patient Safety Congress, Liverpool, May 2014

CARE Conference, Warwick, June 2014

The Kent Surrey and Sussex Eastern Academic Health Science Network Exposition, London, January 2015.

Regional

The LSMS Regional Security Meeting, Hinchinbrooke, March 2014
The East Anglia Intensive Care Group, Bury St Edmunds, May 2014.
The East Anglia Intensive Care Group, Bury St Edmunds, November 2014
The LSMS Regional Security Meeting, Hinchinbrooke, December 2014
The Regional Controlled Drug Conference, Stansted, January 2015

Exhibition stands

The Clinical Human Factors Group, Human Factors, Design and Safety Equipment Conference, Birmingham, March 2014

CARE conference, Warwick, June 2014

The International Quality and Patient Safety Forum in Health, Paris 2014

The Patient Safety Congress, Liverpool, May 2014

Kent Surrey Sussex AHSN, Exposition, London, January 2015

Medtec UK, Health Care Technologies, London, March 2015,

Medtech Europe, Health Care Technologies, Stuttgart, Germany, April 2015

Innovation Scouts Network, Health Enterprise East, Cambridge, May 2015

NHS Confederation Conference, Liverpool, June, 2015

The Patient Safety Congress, Birmingham, July 2015

A drug trolley surveillance device can improve the security of medications for ward administration by sounding an alarm if a drug trolley is left unattended

Using an alarm to improve drug trolley safety

In this article...

- › Incidence of tampering and theft from drug trolleys
- › Trial of a drug trolley alarm device
- › Outcomes of introducing the alarm device

Authors Emily Hodges is critical care clinical governance nurse; Darcy Pearson, Parvez Moondi, John Gibson, Mark Blunt and Peter Young are critical care consultants; Maryanne Mariyaselvam is critical care research fellow; all at Queen Elizabeth Hospital, King's Lynn.

Abstract Hodges E et al (2015) Using an alarm to improve drug trolley safety. *Nursing Times*; 111: 40, 20-21.

Leaving drug trolleys unlocked and unattended during drug rounds creates opportunities for drug theft and tampering. A new device was developed by our trust to detect when an open drug trolley is left unattended; it then sounds an alarm to remind staff to return to the trolley. This article describes use of the alarm on general hospital wards in one trust in the east of England. When the alarm was installed into drug trolleys on a hospital ward, it reduced the number of times unlocked trolleys were left unattended. The drug trolley alarm successfully changed the behaviour of staff on drug rounds and, in so doing, improved patient safety.

Reported cases of theft and tampering with medicines are helping to raise awareness of the need to improve drug stewardship on hospital wards to maintain patient safety. Besides posing a risk to patients, these incidents damage the credibility of carers and undermine public trust in the nursing profession.

Recent cases include the well-publicised case of a staff nurse from Stepping Hill Hospital, Stockport, who admitted to stealing painkillers, including opioids, and antibiotics. During her Nursing and

Midwifery Council fitness-to-practise hearing she claimed that members of staff regularly took medications (NMC, 2013a). There have been several other cases of drug theft by nurses that have resulted in disciplinary action (NMC, 2013b; 2009).

While the cases mentioned above are publicly documented, it is highly likely that in many others drug theft is dealt with in-house or simply remains undetected. Hospital workers are often presented with opportunities when they could steal or tamper with medications without being detected, particularly when drug trolleys are left open and unattended.

Despite alternatives being available, drug trolleys are still used for securing medications in clinical areas. The Care Quality Commission inspects UK health-care providers to ensure they comply with Health and Social Care Act 2008 regulations on the safekeeping of medicines (CQC, 2010). In NHS hospitals it is mandatory for drug trolleys to be closely supervised when they are open; best practice is arguably for staff members to lock trolleys whenever they step away from them. However, given the many distractions experienced by nurses during drug rounds it is unsurprising that, in practice, this is often not the case.

This article describes an innovation in our trust – use of a device known as a Drug Guardian. This device allows us to:

- » Measure and improve the security of medications for ward administration;
- » Reduce opportunities for drug theft and tampering by using.

The device

At the start of the project we enlisted an electronic engineer to develop a device

5 key points

1 Leaving drug trolleys unlocked and unattended on the ward gives opportunities for drug theft and tampering

2 Drug safety lapses are typically due to the distractions nurses experience during drug rounds

3 Educating nurses about safety and devices to monitor when an open trolley is left unattended can help cut the risk of drug errors and theft

4 Combining the device with a drug trolley alarm that reminds staff to return to an unattended trolley cuts the risk further

5 Adding a camera to the device may help to identify those who commit drug theft and tampering



Unattended trolleys can lead to drug theft

BOX 1. HOW THE DRUG GUARDIAN WORKS

The Drug Guardian is a small black box with a light-sensitive photocell that activates the device when the drug trolley is opened. An infrared sensor continually senses movement – such as a nurse in attendance – within the proximity of the trolley. If no movement is detected for 45 seconds the device emits a quiet intermittent alarm, which continues with increasing volume and frequency until it eventually becomes continuous. The alarm switches off when movement is detected or the trolley is closed.



The Drug Guardian (above) is fitted directly to the drugs trolley (below)



that could be fitted onto ward drug trolleys and would:

- » Measure when the trolley is left open and unattended;
- » Alert staff of the non-attendance with an alarm.

Box 1 gives a brief outline of how the Drug Guardian device works.

Collecting data

The Drug Guardian was fitted in the drug trolleys on general wards within the trust and used to collect data on the frequency and duration of episodes when the trolley was left open and unattended. The trolleys were considered to be unattended if no movement was detected for more than two minutes.

Data was collected in three phases:

- » Phase 1 – the devices were installed with the alarm function disabled to collect baseline information. Staff were not told about the role of the device so their normal behaviour could be observed;
- » Phase 2 – Ward staff were educated on the risks of leaving the trolley unattended, the CQC's recommendations regarding medicines management and the role of the device. The devices were then used on the ward with the alarm disabled as before;

- » Phase 3 – Fully functional devices were placed on the ward, with alarms that activated if the trolley was unattended for more than 45 seconds.

Results

During phase 1, drug trolleys were found to be left open without a nurse in attendance an average of 14 times per day. Each episode lasted, on average, three minutes – this means that for around 45 minutes every day there was an opportunity for drug theft or tampering.

Once staff had been educated about the device, the average number of episodes when a trolley was left unattended fell to fewer than two per day, amounting to 13 over one week of data collection. After installing fully operational drug trolley alarms, this decreased dramatically to three episodes over a two-week period.

Discussion

Wards are busy and often stressful places to work, presenting nurses with constant distractions and demands. Our trust has a policy that nurses on drug rounds should not be interrupted unless absolutely necessary; this allows them to concentrate fully on the task and minimise errors in drug administration. In spite of this, the first phase of our study confirmed that open

drug trolleys were being left unsupervised for a significant period of time each day.

Trolleys were considered to be abandoned only after two minutes had passed, to allow staff time to leave the trolley, move to the bedside and administer the patient's medication. In the first phase of the study there were, on average, 14 occasions each day when more than two minutes elapsed without the staff member returning to resume responsibility for the trolley. Removing or tampering with medication may only take a few seconds, so this posed a considerable safety risk.

Although staff education on the role of the drug trolley device and why it was needed improved trolley attendance, there were still 13 episodes of trolleys being abandoned over a one-week period. However, once the alarm function of the device was enabled, the number of episodes reduced to three during a two-week period.

The ability of the drug trolley alarm to change people's behaviour is known as "operant conditioning". This is a learning process in which the changes in an individual's behaviour arise from the consequences of that behaviour. In this case, the consequence of trolley abandonment is an alarm that alerts the staff member to the error. This causes staff to modify their behaviour so trolley abandonment becomes an infrequent event.

Conclusion

Having shown the ability of the device to modify behaviour and improve the security of medications for ward administration, the Drug Guardian has been further enhanced by adding a panoramic camera. We are now carrying out further studies to investigate how the device might help us identify perpetrators of drug theft and tampering. The alarm-only model is currently beginning to be rolled out for use across the trust. **NT**

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For more on this topic go online...

- » Reducing nurse medicine administration errors
- » [Bit.ly/NTDrugAdminErrors](http://bit.ly/NTDrugAdminErrors)

