‘I’ll just pass you to Customer Service…’
Communication Breakdown Between the Users and Suppliers of Clinical Technology

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Keywords: Human Factors, Healthcare, Incident Reporting, Accident Analysis.

Abstract

New technologies place considerable demands on the clinicians who must learn to operate them. These demands have increased with the growing complexity of more diverse and interconnected systems. New technologies have also altered social and working relationships in many clinical environments. Increasing reliance is placed on the technical staff that must service and maintain new devices. Similarly, a range of devices now enables patients to take a more pro-active role in monitoring and treating their conditions outside traditional clinical environments. These changes in patterns of healthcare provision increase the importance of the support that clinicians, technicians and patients receive from device manufacturers. Similarly, device providers rely upon this increasingly diverse range of end-users to provide them with information about potential problems with the systems that they supply. The following pages use incident reports submitted to the FDA over the last twelve months to illustrate the problems that arise when communication breaks-down between the users and providers of healthcare technology.

Introduction

The demands of learning to operate and maintain healthcare technology can place considerable strain on the relationships between patients, clinicians, technicians and suppliers. Recent mishaps have shown that clinicians may not know whether a device has actually malfunctioned or not. This often results in coping strategies, including switching the machine on and off again to ensure that they get back to a familiar state (Ref. 1, 2). When incidents have been detected, it can also be difficult for technicians to diagnose the causes of any failure. This creates problems because they must understand not only the device characteristics but also the precise manner in which clinical staff were operating the device when the problem arose. Clinical staff can be reluctant to discuss the precise details of coping strategies, especially if they reveal uncertainty about the way in which a device is intended to operate. If technicians cannot diagnose the causes of an adverse event then they must rely upon advice from suppliers who may not have been directly responsible for the development of the device in the first place. They, in turn, must identify potential problems by talking to component suppliers and equipment integrators. At each stage of the process, important information about an adverse event can become confused or lost. Delays inevitably occur and ultimately this can serve to undermine a clinician’s confidence in the devices that they are expected to operate. There is often a feeling that they have become trapped in endless negotiations with customer service departments that delay effective remedies for the problems they experience with particular devices.

National and international regulatory requirements govern the reporting of adverse events involving medical technology (Ref. 3, 4). These regulations identify minimum standards for the dialogue that must take place between regulator and manufacturer or between end-user and regulator following an adverse event. For example, they may specify the maximum time that can pass before any adverse event must be reported to the national monitoring system. These regulations are, however, largely concerned with more serious incidents. Very few regulations say anything about the ‘quality’ of the dialogue that should take place between users and suppliers in the aftermath of lower severity incidents. In consequence, there are tremendous

variations in the mechanisms that suppliers and manufacturers use to respond to user queries about possible device problems. In extreme cases, this can lead to a total breakdown in communication between clinicians and suppliers. In consequence, we may miss many important insights about those mishaps that occur before a particular device injures anyone. This argument can be illustrated by incidents from the Manufacturer and User Facility Device Experience database (MAUDE), maintained by the Centre for Devices and Radiological Health (CDRH) within the US FDA. MAUDE is updated every quarter with voluntary reports of adverse events involving medical devices.

The Clinician's Perspective

Before identifying the communications problems that exacerbate the reporting and analysis of adverse healthcare events, it is important to emphasise that many incidents have relatively clear-cut causes. There is, therefore, little disagreement between clinicians, technicians and suppliers. This is illustrated by a report in which a patient caught their foot between the footplate and the wheel of their chair. The following excerpts preserve the upper case used by the FDA. Lower case is used to denote text that we have introduced to preserve the anonymity of manufacturers, technical support staff and clinicians. The reports have been slightly abridged, however, the original text can be retrieved from the MAUDE system using the text key associated with each account:

> 2 CONSUMERS SHARE SAME CHAIR. USER WAS USING CHAIR WHEN PATIENT CAUGHT THEIR FOOT BETWEEN FOOTPLATE EDGE AND FRONT CASTER... KEEPING FEET ON CHAIRS FOOTPLATE, AND NOT DRAGGING THEM ALONG FLOOR WILL PREVENT ENTRAPMENT. DEALER INSPECTED CHAIR AND FOUND NO PROBLEM. RETURN IS NOT ANTICIPATED AND CHAIR IS STILL IN USE. **(MDR TEXT KEY: 1611331)**

This report is typical of many incidents where user 'error' is diagnosed if initial forensic checks cannot identify any obvious system failures. The causes of the problem were relatively easily identified and there was little adverse comment from the user 'facility' in response to the manufacturers' explanation. In other incidents, clinicians must often respond in a more immediate manner to rectify potential device failures. For instance, the following excerpt described how staff responded to a ventilator failure. The reference to previous similar incidents is instructive of the need to monitor these low severity incidents and act upon them. In other circumstances, the patient in this 'mishap' might not have been so fortunate:

> VENTILATOR IN USE ON PATIENT DEVELOPED BURNING SMELL. PATIENT MOVED AND ANOTHER VENTILATOR USED. NO HARM TO PATIENT AS OF NOW. ROOM CLOSED AND INSPECTED FOR SOURCE OF FIRE/SMELL. EXAM OF VENTILATOR SHOWS FAILURE OF COMPONENTS IN OXYGEN MODULE. THIS IS SECOND TIME THEY HAVE HAD THIS ISSUE WITH THIS MODEL VENTILATOR **(MDR TEXT KEY: 1587033)**

It was relatively easy for clinicians both to detect and mitigate the previous incidents involving the wheel chair and the ventilator. In both cases, their interaction with the supplier was also simplified because that the causes of the incident were relatively straightforward. In the former case, the wheelchair supplier could reiterate guidance on appropriate use of the chair. In the later case, the manufacturer reviewed the quality control procedures on component supply. However, there are other incidents that impose considerable demands upon the clinical staff who must intervene to mitigate their consequences. For example, a clinician found that a ventilator, which had been installed 9 days before, had failed. The patient was manually ventilated until a manufacturers' representative could be contacted by telephone from the operating room:

> THE VENTILATOR ON THE ANESTHESIA FAILED WITH AN ERROR MESSAGE "GAS INLET VALVE FAILURE." PATIENT WAS VENTILATED BY HAND AS PREPARATIONS WERE MADE TO SWAP OUT THE ANESTHESIA MACHINE. the SERVICE REP WAS CONTACTED, HE TELEPHONED INTO OPERATING ROOM. HE WALKED ANESTHESIA ATTENDING THROUGH A SERVICE PROCEDURE TO "BLOW OUT" GAS INLET VALVE. VENTILATOR WORKED AFTER THIS AND FOR REMAINDER OF PROCEDURE. MACHINE WAS TAKEN OUT OF SERVICE AND VALVE IS BEING SENT BACK TO manufacturer. THERE ARE REPORTS OF OTHER RECENT SIMILAR INCIDENTS INVOLVING NEWLY INSTALLED ANESTHESIA MACHINES OF THE SAME MODEL (**MDR TEXT KEY: 1560816)**

Such incidents raise a number of concerns. They include the difficulties associated with talking a clinician through such procedures over a theatre telephone. They also include the observation that similar incidents had previously been reported on this type of device. The informal procedures used to rectify the previous incident are also entirely typical of many adverse healthcare events. Clinicians, technicians and manufacturers cooperate to work-around device problems. This 'fly-fix-fly' approach to medical device development would not be acceptable in many other areas of safety-critical systems development. It is difficult to escape the conclusion that it places patient's wellbeing at risk.

The introduction of more complex hardware and software make it more difficult for clinicians to determine whether or not a device has actually failed. This uncertainty creates problems during subsequent communication with their suppliers. For instance, the following incident report identified a number of problems involving a patient monitor with an in-build medication library. The drug calculator was discovered to round up the second decimal place, which could result in medication errors. The reported cited an example involving nesiritide when 1.5 MG with a volume of 250ML would be displayed as either 6 MCG/ML or 0.01 MG/ML. They argued that this results in almot a doubling of the concentration of the medication. The clinicians contacted the device manufacturer by email, fax, phone calls but the manufacturer did not acknowledge that there was a problem.

> THEIR RESPONSE IS THE NURSING STAFF SHOULD KNOW THE NUMBERS ARE WRONG SINCE MEDICAL STAFF WERE TAUGHT HOW TO CALCULATE MEDICATION. TO ELIMINATE HUMAN ERROR NURSING STAFF IS TAUGHT TO RELY ON THE DRUG CALCULATOR. THE CALCULATOR WILL DISPLAY UP TO 2 TRAILING ZEROS PAST THE DECIMAL POINT. EXAMPLE: 250.00 ML INSTEAD OF 250 ML. THE INDUSTRY HAS RECOGNIZED THIS AS CONTRIBUTING FACTOR IN MEDICATION ERRORS. THIS CAN RESULT IN MEDICAL STAFF READING THE NUMBER WRONG AND DELIVERING THE MEDICATION IMPROPERLY. (**MDR TEXT KEY: 1526689**)

According to the clinicians making the initial report the manufacturer made no direct response to their concerns except to send a nursing specialist to remove some medications for the drug library on the monitors. The clinicians argued that this would not address the 'root cause' of the problem for staff who continued to use the calculator on other medications. The report concluded by observing that no patients had been harmed by this 'problem' and that pro-active measures had been taken to alert hospital staff to this potential hazard. It is important to emphasise that the clinicians' perspective is only one of several points of view that must be considered when analysing any adverse healthcare event. Subsequent reports from the device manufacturer went onto reveal a very different interpretation of the previous incident. They stressed that the drug calculation feature enables users to calculate infusion rates for up to 44 drugs. Up to four of these can be assigned per patient. The resolution on the units used to measure these medications can be configured through a unit manager menu:

> THIS IS THE BEST METHOD TO USE FOR CLINICAL STAFF, AS IT PRE-CONFIGURES THE DRUG CALCULATIONS AND ALLOWS THE SETTINGS TO REFLECT HOW THE DRUGS ARE PREPARED FOR ADMINISTRATION BY THE PHARMACY. THE CUSTOMER WAS TOLD, DRUG CONCENTRATION ROUNDING TO THE NEAREST HUNDREDTHS, COULD BE EASILY ADDRESSED IN THE UNIT MANAGER SETUP, TO REFLECT A HIGHER RESOLUTION (FOR EX. MCG/ML). THEREBY, ADDRESSING ANY CONCERN OF A ROUNDING ISSUE. THE manufacturer HAS REVIEWED THE CUSTOMER'S CONCERN AND HAVE DETERMINED THAT THE "DRUG CALCULATIONS" FEATURE IS FUNCTIONING AS DESIGN. ADDITIONALLY, the manufacturer HAS REVIEWED WITH THE CUSTOMER, THE USER'S ABILITY TO CHANGE UNITS OF MEASURE, TO ACHIEVE THE DESIRED RESOLUTION. THE DEVICE IS PERFORMING AS DESIGNED (**MDR TEXT KEY: 1601404)**

Such incidents are symptomatic of the break down in communication that characterises the relationships between many clinicians and device suppliers. On the one hand it might be argued that clinicians should take more time to read the supporting documentation that accompanies any new device. Equally, however, it might be argued that the manufacturer should assume responsibility for developing such a complex device that clinicians could not easily determine the best way to configure core functionality. This analysis misses many important points. In particular, such incidents represent a learning opportunity for both sides of the dialogue. Clinicians should be prompted to review the documentation supporting the equipment that they use and the manufacturer should assess the usability of the device and their associated training material. As we shall see, however, these insights are often lost when communication breaks down. Clinicians quickly lose sympathy for manufacturers when devices are seen to be unreliable or poorly designed. Conversely, manufacturers exhibit limited sympathy for users who invest insufficient time learning about the functionality offered by new and more complex devices.

The Technician's Perspective

This following incident typifies the increasing number of incident reports that are being submitted by technician rather than clinicians. This reflects their growing importance in patient safety. This report also illustrates the technicians' lack of confidence both in the manufacturer and their device. Even after the representative had reloaded the software, the technician is still concerned about the calibration of the device. Above all, they are concerned that similar incidents may occur in the future without anyone knowing about it:

> DEVICE USED TO CALCULATE VOLUMES OF PATIENT'S ORGANS BASED ON CT SCANS TO HELP ONCOLOGISTS DETERMINE IF PATIENTS ARE APPROPRIATE FOR DRUG OR RADIATION THERAPY. CALLER'S CONCERN: 1. VOLUMES REPORTED ARE SOMETIMES WILDLY DIFFERENT (50%) WITHIN SHORT PERIOD OF TIME. 2. VOLUMES OFTEN DON'T CORRESPOND WITH OTHER CLINICAL EVIDENCE. MANUFACRTURER REP: HAS RELOADED SOFTWARE, BUT CALLER FEELS MANUFACTURER HAS NO MEANS OF CHECKING ACCURACY OF VOLUMES GIVEN, OR ASSURING THAT DEVICE IS WORKING. THERE IS CONCERN THAT PATIENTS ARE BEING TREATED INCORRECTLY WITHOUT ANYONE REALIZING IT. USER WOULD LIKE TO REPORT TO TREATING PHYSICIANS VOLUMES THEY ARE CERTAIN ARE ACCURATE **(MDR TEXT KEY: 1619844)**

The technician's uncertainty in the previous incident can be seen in many of the other reports that are submitted through the MAUDE system. It is difficult to be certain whether this uncertainty can be blamed on the manufacturer or supplier. Technical staff might have raised their concerns when the software upgrade was being installed. Without further information about the circumstances surrounding this incident all that we can be certain of is that this uncertainty and

lack of trust illustrates a break down of communication between the technicians and the technology providers.

The Manufacturers' Perspective

It is important to emphasise that clinicians and healthcare technicians are not the only groups who experience problems with complex systems. Occasionally, MAUSE receives reports like the following that describe problems for suppliers and manufacturers. In this case, the adverse event affected the supplier's representative during a demonstration of the device that they were marketing. The representative temporarily silenced the device alarms and suspended ventilation. However, the unit did not come back on-line in the manner anticipated both by the supplier and his audience:

> WHILE DEMONSTRATING THE DEVICE THE REP PRESSED I/E HOLD BUTTON AND THE UNIT STAYED POWERED ON. THEY NOTICED ALL THREE WAVE FORMS FLAT ON LTM DISPLAY. THEY SAID WHEN THE BUTTON WAS PRESSED THE ALARMS ARE SILENCE FOR 6 SECONDS. IN THIS CASE THE UNIT DIDN'T SWITCH OVER AND STAYED IN THIS POSITION. THE DEVICE DID NOT DELIVER VENTILATION AND DID NOT ALARM IN THIS CONDITION (**MDR TEXT KEY: 1557328)**

Incident reports from manufacturers, suppliers and their representatives are important because they illustrate that these groups continue to exploit the reporting channels established by regulators. The following incident illustrates the difficulty that manufacturers have in first replicating and then diagnosing the causes of the adverse events that are reported to them. The incident began when a medical physicist began to edit a radiation therapy plan. When he reviewed the plan, he found that his changes had not been saved. He repeated them and this time found that the plan had been correctly updated. The manufacturers' customer service branch passed the report to their engineers. Initially, they could not recreate the problem until they found a software problem. The system relied upon a workstation and a remote compute engine (REC):

> The system KEEPS TRACK OF WHICH FILES WERE MODIFILED BY COMPARING TWO FILE ATTRIBUTES: FILE SIZE AND FILE DATE/TIME STAMP. IF THE TIME CLOCK ON THE WORKSTATION DOES NOT MATCH THE TIME CLOCK ON THE REMOTE COMPUTE ENGINE (RCE), IT IS POSSIBLE THAT A MODIFIED FILE COULD BE INCORRECTLY IDENTIFIED AS UNMODIFIED BECAUSE OF THE TIME STAMP ERROR. THIS COULD ONLY OCCUR IF THE PROCESSING TIME TO MODIFY THE FILE IS PRECISELY EQUAL TO THE TIME DIFFERENCE ERROR BETWEEN THE TWO TIME CLOCKS. ALSO, THE FILE MUST REMAIN EXACTLY THE SAME SIZE... NORMAL CLINICAL PRACTICE INVOLVES PRACTITIONER REVIEW OF THE PLAN AS PART OF THE REQUIRED QA PROCESS. HOWEVER, the manufacturer IS AWARE THAT SCRUTINY VARIES AMONG INSTITUTIONS. THEREFORE, the manufacturer CREATED A FIX FOR THIS SOFTWARE. THE FIX CHANGES THE FILE TRANSFER PROCESS BETWEEN THE SYSTEM'S WORKSTATION AND SEVER SUCH THAT THE FILE SIZE AND TIME STAMP ARE NO LONGER EVALUATED, AND ALL FILES ARE TRANSFERRED WHETHER THEY ARE MODIFIED OR NOT. The manufacturer CREATED A CUSTOMER-INSTALLABLE SOFTWARE PATCH TO IMPLEMENT THIS FIX AND SENT IT TO ALL AFFECTED CUSTOMERS. **(MDR TEXT KEY: 1622256)**

This incident illustrates the problem solving and diagnostic skills that support staff and manufacturers must use in order to identify the potential causes of technical failures in complex, healthcare applications. It is unlikely that an end-user would be able to diagnose the symptoms that they observed with the system. Unless manufacturers respond with such detailed explanations the apparent unpredictability of many devices can undermine end-user confidence in them. This incident forms a strong contrast with the previous report about the device used to

calculate the volume of patient's organs from CT scans. In this case, technicians and clinicians can be confident that the manufacturer has identified, explained and responded to the problem. However, in the previous case the technicians were still worried about the reliability of the device given that they had not been told how the changes to the device had been calibrated. Manufacturers are, however, faced with a number of constraints in issuing detailed information about the causes of near-miss incidents and adverse events. Previous paragraphs have already described how many clinicians find it difficult to find the time even to read existing device documentation. There are proprietary concerns that such technical updates may inadvertently release sensitive commercial information about the design of their system. There is also a concern that these explanations will have the opposite of their intended effect. Technicians who were not involved in the original incident may be surprised to learn of the details of potential problems and this may inadvertently undermine their confidence in the system. We have, however, observed that many technical staff are suspicious of the many software updates that they already receive for some devices (Ref. 1 and 2). In these cases, the provision of a more detailed explanation may serve to address their concerns and help to motivate them to install the patch in a timely manner.

The Patient's Perspective

Previous sections have argued that communications often break down between clinicians, suppliers, technicians and manufacturers in the aftermath of adverse events and near misses. Unfortunately, the barriers to effective communication seem particularly difficult when patients must themselves use increasingly complex devices to monitor or treat their own condition. MAUDE reports reveal members of the public struggling with what they perceive to be complex and unreliable devices. Their situation is exacerbated by the fact that they have to live with the consequences of any adverse events. Concern over these adverse consequences creates stress for the patient and can further undermine effective communication between them and clinicians, manufacturers or suppliers. It seems likely that these problems will become increasingly significant as a wider range of devices are issued to patients for use outside conventional clinical settings:

> PATIENT HAD TO VISIT AN EMERGENCY ROOM FIVE TIMES BECAUSE SYSTEM REPORTED PATIENT BLOOD SUGAR AS HIGH WHEN IT WAS NOT. AN EXAMPLE SITED WAS 478 MG/DL, EMERGENCY ROOM SYSTEM (METHOD UNKNOWN) 150 MG/DL. WHILE ON THE PHONE ELECTRONIC CHECKS WERE CONDUCTED. SYSTEM REPORTED SEVERAL ERROR CODES RELATED TO TEST SENSOR PRESENTATION…UPON FURTHER INVESTIGATION CUSTOMER STATED THAT PATIENT COULD SEE SENSORS JAMMED INTO SLOT. REQUEST WAS MADE TO RETURN SYSTEM FOR EVALUATION. IN THE MEANTIME A REPLACEMENT UNIT WAS PROVIDED. (**MDR TEXT KEY: 1195374)**

The patient's sense of frustration with the device can be imagined. This incident also illustrates the problems that manufacturers face in identifying the causes of potential system failures when patients operate devices in widely distributed geographical areas. The method of diagnosing the failure involved the manufacturers' representative proving instructions to the patient over the telephone. This eventually provided access to the necessary error codes that identified the potential system failure. As with previous MAUDE reports, this is not an isolated incident. The patients' sense of frustration with complex medical devices is a recurrent theme in submissions over the last year. The following report describes how a user experienced four 'bolus stopped' error messages on two different versions of the same infusion pump. The patient could not identify any common factors contributing to the problems when they reported the incidents to the manufacturers' help line. It took seven weeks for the patient to elicit a response that was only provoked by a demand for a refund. The company sent out a replacement machine but again the

patient received further ‘bolus stopped’ warnings. Previously the manufacturer had argued that the problem was caused by a loose battery cap or the bumping of the pump. On this occasion they argued that the incident was due to static discharge:

> THEIR SUGGESTION WAS TO KEEP PUMP IN LEATHER CASE-INSTEAD OF PLASTIC HOLSTER … patient PROGRAMMED PUMP FOR 7.5U. PUMP DELIVERED 0.2U THEN ALARMED WITH BOLUS STOPPED. PATIENT PROGRAMMED PUMP FOR 7.3U. PUMP DELIVERED 0.2 MORE THEN ALARMED. PATIENT THEN CHECKED BATTERY LIFE INDICATOR ON PUMP. IT STATED "NORMAL". PATIENT SUSPECTED THAT BATTERY INDICATOR WAS NOT INDICATING BATTERY TOO WEAK TO DELIVER BOLUS BUT STRONG ENOUGH THAT THEIR BASAL'S WERE STILL COMING THROUGH. PATIENT CHANGED BATTERY AND PROGRAMMED AND SUCCESSFULLY DELIVERED 7.1 U BOLUS TO COMPLETE THEIR MEAL BOLUS. PATIENT'S QUESTION TO ENGINEERS IS SINCE BATTERY LIFE INDICATOR IS KNOWN TO BE LESS RELIABLE WITH OTHER BATTERY TYPES, IS IT POSSIBLE THAT ‘BOLUS STOPPED’ ERRORS WERE DUE TO A WEAK -3 WEEK OLD BATTERY? CAN ANYTHING BE DONE IN SOFTWARE TO GIVE USERS MORE INFO REGARDING BATTERY LIFE. PATIENT HAS ALREADY CONTACTED manufacturers HELP LINE. THEY WERE UNABLE TO ANSWER QUESTION. THEY INDICATED THAT BOLUS STOPPED ERROR MIGHT OCCUR IF PUMP WERE BUMPED OR BATTERY CAP WERE LOOSE. NEITHER OF THESE EVENTS OCCURRED DURING 2 BOLUS STOPPED ERRORS PATIENT EXPERIENCED YESTERDAY **(MDR TEXT KEY: 1622511)**

By reviewing the incidents in the MAUDE database, it is possible to reconstruct the dialogue between the patient and the manufacturer over time. For example, the following report describes further failures that continued to affect this user. The number of devices that they had been sent and the reference to the leather case and electrostatic ‘reasons’ for the failures illustrate the problems that end-users face in any dialogue with suppliers and manufacturers. The inherent device complexity can make it difficult for end-users to elicit a satisfactory or convincing explanation about the causes of a mishap. In consequence, there is a danger that individuals will feel they are being ‘fobbed off’ with an excuse rather than a thorough explanation. There is also a danger that manufacturers and suppliers may miss important opportunities to learn about the underlying causes of device problems. These need not simply lie in hardware or software errors but also in the documentation and help systems that are intended to support the end-users of their products:

> REPORTER HAS HAD PROBLEMS SINCE THEY FIRST GOT THIS MODEL. IT CONTINUALLY FAILS FOR "ELECTROSTATIC REASONS". REPORTER JUST HAD A PROBLEM AGAIN THIS EVENING. REPORTER HAS HAD THIS MODEL FOR ALMOST 3 YEARS AND TOMORROW THEY WILL BE SENDING THEM THEIR 5TH PUMP. IT IS WARRANTIED FOR 4 YEARS BUT IF THEY HAVE NO CONFIDENCE IN PUMP IT IS PRETTY USELESS. FIRST THEY CLAIMED THAT IT WAS BECAUSE OF LEATHER CASE AND THEY GAVE THEM A NEW CASE, BUT OBVIOUSLY THAT DIDN'T HELP. REPORTER THINK'S IT IS A PROBLEM WITHIN THE PUMP AND THEY SHOULD FIX THEM OR RECALL THEM AND ISSUE DIFFERENT PUMPS TO USERS. REPORTER IS GETTING VERY FRUSTRATED WITH COMPANY, BECAUSE REPORTER HAS WRITTEN THEM AND SPOKEN WITH SEVERAL OF THEIR REPS AND GETS NOWHERE. SINCE original company WAS PURCHASED it HAS DRASTICALLY CHANGED AND THEY DON'T CARE ABOUT CONSUMER (**MDR TEXT KEY: 1562810)**

Such reports are indicative of communications failures between patients and suppliers or manufacturers. Previous incidents have illustrates similar problems facing clinicians and technicians. These breakdowns stem from a number of factors, including device complexity. It can be difficult for equipment providers to recreate and diagnose the adverse events that are reported to them. Many of the individuals who observe incidents have only a limited understanding of how the devices work. This is particularly true for end-users who are also patients. However, further

problems arise when manufacturers and suppliers do not respond adequately to detailed enquiries about the potential causes of adverse events.

Conclusion

New technologies place considerable demands on the clinicians who must learn to operate them. These demands have increased with the growing complexity of more diverse and interconnected systems. New technologies have also altered social and working relationships in many clinical environments. Increasing reliance is placed on the technical staff that must service and maintain novel devices. The ability of technical staff to meet these demands is, in part, determined by the support that they receive from manufacturers and suppliers. Further changes stem from the introduction of devices that enable patients to monitor and treat their own conditions. Unfortunately, recent mishaps have shown the problems that can arise when information about innovative technologies must be passed from the development labs and suppliers benches to the clinical environments where they are eventually deployed. Patients, clinicians and technicians are often forced into prolonged dialogues with suppliers and manufacturers. From their perspective, it can be difficult for end-users to identify the causes of failures that appear to be random in nature and which can have strong adverse consequences for patient care. From the suppliers' perspective, it can be difficult to elicit the information that is necessary to diagnose the causes in which a failure occurred. Devices may not be configured in the manner defined within the manuals. Similarly, end-users may be unsure about the precise way in which a device was operated immediately before the incident occurred.

Two constructive findings have emerged from our work. The first is that technical and clinical staff must be encouraged to obtain a more complete technical understanding of the devices that they operate. This may require a commitment from hospital management to provide sufficient training time and a commitment from clinicians to safeguard that time for this intended purpose. Unless this is done, we will continue to have 'adverse events' that could have been avoided by correctly configuring the device or that were the result of well-documented device functionality. On the other hand, manufacturers should spend some time monitoring the quality of the technical explanations that are provided to clinicians, technicians and patients. In particular, the credibility of these explanations can be clearly undermined as they are successively revised to account for repeated problems with similar devices.

A number of caveats can be raised about the methodology that was used to inform our argument. Monitoring systems, such as the FDA's MAUDE, often suffer from the problems of underreporting and reporting bias (Ref. 1). In other words, problems between suppliers, manufacturers, clinicians and patients would have to be particularly severe before there is sufficient motivation to file a MAUDE report. Those incidents of communication breakdown that are submitted through the system may be unrepresentative. They focus our attention of a few bad examples rather than the more general experience of positive communication between the parties involved in most device related incidents. A number of techniques can be used to address these criticisms of national reporting schemes. In particular, the FDA uses Sentinel monitoring; a small number of units are studied in greater depth to identify adverse events that are not currently being reported. Such studies have confirmed that there are many further problems in the communication over potential adverse device events than are being submitted through incident reporting schemes (Ref 5). Rather than hiding a mass of more positive experiences, it seems as though systems like MAUDE only represent 'the tip of the iceberg' when they describe the communications breakdowns that occur between suppliers, manufacturers, clinicians and patients.

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Biography

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