THE ROLE OF QUANTIFIABLE RISK FACTORS IN A MEDICAL TECHNOLOGY MANAGEMENT PROGRAM

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Our society expects that competence and efficiency will guide the development, application, and support of medical technology. In accord, engineers in hospitals face the challenge every day of managing appropriate medical technology with limited resources. To make the most of their resources and assist in delivering high-quality health care in the most cost-effective manner, the Biomedical Engineering Department at the Texas Children's Hospital in Houston developed a system for quantifying risk and integrated this system into its medical technology management program.

The Purpose of Technology Risk Assessment

An early phase of any technology management program involves an assessment of existing technology.[1] Medical technology assessment has been proposed as one way of improving patient care and wellness by providing that only appropriate technology is used in the health care environment.[2] In addition to providing for technical evaluation and clinical trials of equipment, technology assessment attempts to control negative legal and economic consequences by assessing risk throughout the medical equipment life cycle.

Historically, risk assessment has been of two types—perceived and quantitative. The *perceived* style of risk assessment is routinely "qualitative, informal, intuitive, and generally undocumented."[3] This style is reactive, involving on-the-spot response to risk events or situations in the hospital. The quantitative risk assessment style is "formal, explicit, disciplined, rigorous, generally peer reviewed and always documented."[3]

The famous Lord Kelvin, a British physicist, mathematician, and author of the *Popular Lectures and Addresses*, would have identified the perceived risk assessment style as lacking in knowledge of the process, as described in the following:

> "When you can measure what you are speaking about, and express it in numbers, you know something about it, but, when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meager and unsatisfactory kind: it may be the beginning of knowledge, but you have scarcely in your thoughts, advanced to the stage of science."[4]

In 1991, with Lord Kelvin somewhat in mind, Texas Children's Hospital began to develop a dynamic risk assessment tool[5] that could measure the risk environment of its medical equipment and include as many quantifiable elements of that environment as possible. Parallel goals included the following:

1. To create a method for classifying medical equipment that would ensure the effective deployment of available resources;
2. To provide a comprehensive and accurate

tool for identifying equipment-related technical and clinical training needs;

3. To guide the triage of repair, preventive maintenance (PM), and other service requirements on the basis of their effectiveness at reducing equipment-associated risk;
4. To advance the biomedical engineering program beyond a traditional, reactive risk assessment mode, typically based on failure analysis, to a more quantitative and proactive one; and
5. To develop and implement methods to review large amounts of data easily without losing the capacity to identify equipment details and higher-than-acceptable incidences of operator errors, unsuccessful repairs, equipment failures, and so on.

Dynamic Risk Assessment

The original dynamic risk assessment tool (Figure 1, p. 13) consists of four modules, paired by their static and dynamic risk characteristics. The two static components, *equipment function* and *physical risk*, are assigned when the medical equipment is entered into the Biomedical Engineering Equipment Management System database, and this category provides the baseline risk level for the equipment. The *equipment function* measure assigns a level of risk keyed to the equipment's purpose, with life support equipment getting the highest rating because its potential failure would be accompanied by the highest level of risk. The *physical risk* measure represents an estimate of the worst-case effect if the equipment does not perform as expected, with patient death receiving the highest rating. These two modules are classified as static because their values usually remain the same over the life cycle of an item of medical equipment.

The two dynamic risk-factor modules are the maintenance requirements and the risk points. The *maintenance requirement* measure works on the assumption that an increased number of interventions by technicians both indicates and causes risk. For instance, if a defibrillator requires high maintenance, this indicates an incident waiting to happen. In addition, the repeated testing of the equipment shortens the life of high-voltage relays, capacitors, and cables, and moves the equipment closer to failure. The *risk point* measure combines various risk factors such as actual failures, reasons for failure, or poor performance with regard to such criteria as the mean time between failures (MTBFs) or the American Hospital Association's Useful Life standard. The risk point values are assigned much as an insurance company uses empirical data to determine auto insurance premium cost on the basis of gender, age, location, automobile price, and so on.

The output of each of the four modules is algebraically summed, averaged over a six-month period, and rated from 1 (low) to 5 (high) (see Risk Groups section of Figure 1). Because no standard yardstick exists for assessing risk, the tool uses current practices to establish a baseline. Then, a feedback loop (not indicated on the figure) permits the clinical engineer to review equipment that shows an increase in risk over a predetermined period of time. If the engineer confirms an increase in the risk factor, action to reduce that risk is necessary. However, if the system is learning to judge the proper level of risk and "overreacts," a scaling factor reduces sensitivity in the system for that equipment by 5 percent empirically. This scaling factor preserves biomedical resources, as it automatically reduces inspection intensity unless an engineer manually overrides it.

Monitoring Environmental Risk

Technology has a tremendous potential for enhancing the health care environment, but it can also contaminate it. Furthermore, the potential for contamination no longer comes from radiation and chemicals alone. Concerns now also surround the use of high-voltage equipment, electromagnetic compatibility issues, and infection control. Various equipment items have the potential to cause environmental damage, injury or death to patients and hospital personnel, and disruptive interaction with other equipment items.

Therefore, an environmental risk assessment module has been added to the risk assessment tool. Using the equipment function categories developed for the risk management tool (see Static Risk Factors, Figure 1), this module attempts to weight the potential environmental impact of each category of equipment. Thus far, our findings regarding environmental risk are preliminary, and values have not been fully validated. Empirical data will be collected to estimate more accurately whether the current weighting is appropriate.

Monitoring High-Risk Equipment

St. Luke's Episcopal Hospital, Texas Children's Hospital, and the Texas Heart Institute in the Texas

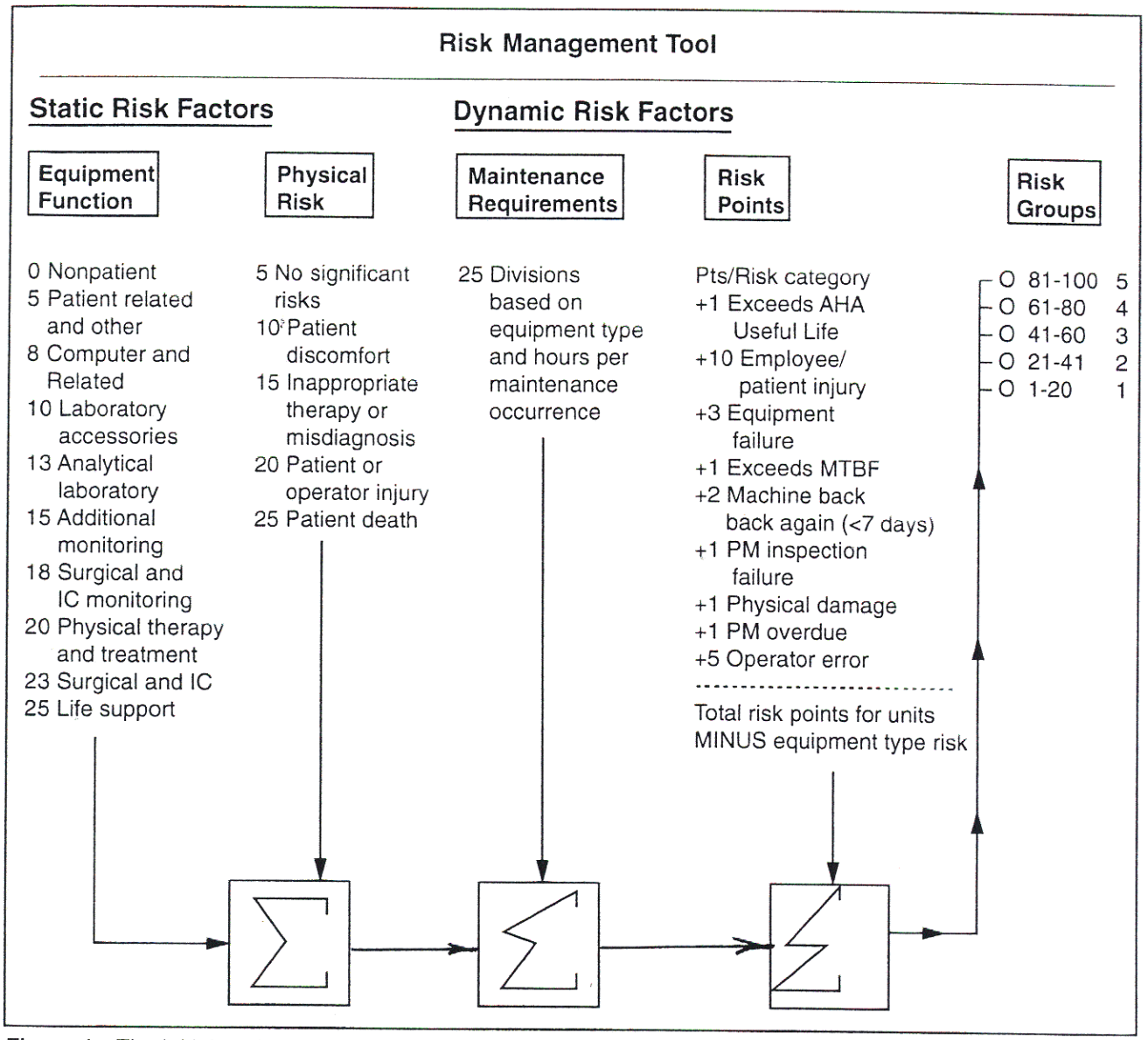

Figure 1. *The initial assignment of risk factors provides a baseline risk level for biomedical equipment.*

Medical Center have a combined medical equipment inventory of close to 20,000 items. Managing this volume of items can be overwhelming for safety, education, or technology assessment groups. Therefore, categories designating high-risk equipment were created from the modules of the risk assessment tool (Figure 2, p. 14). Using these designations, personnel can focus their attention on the equipment with the greatest potential for injury or damage.

Selection is based partly on repair service reports filled out by the technicians. First, an item is only included in the high risk category if a technician has used the "Equipment Failure" code. In addition, each of the static modules must have a value of at least 15. Equipment with these ratings would include, for example, monitoring equipment, defibrillators, dialysis equipment, and electrosurgical units. The critical decision regarding risk, however, is based on whether the failure code "Failed PM" is present. If it is, the equipment was discovered to be out of tolerance or in a failed state during PM—that is, a technician discovered the anomaly during PM, not a clinician who was attempting to use the equipment. This is called a *high-risk soft failure* and is not as serious as when "Failed PM" is not present. If it is not present the problem was detected by the clinician during a clinical procedure. This is called a *high-risk hard failure* and is considered a more hazardous condition.

The strategy is to improve procedures so that we reduce the number of hard failures (clinician-discovered) by having technicians discover equipment problems during PM, and, ultimately, to reduce the total number of failures for high-risk

equipment. As we move toward that goal, we monitor the ratio of hard failures to soft failures and compare the ratios for various equipment categories, identifying strengths and weaknesses in our PM procedures along the way.

To achieve our goals, however, we must also look at the PM program in a more creative light. For example, PM outlined by the manufacturer is geared for the hospital, average usage, and average technical support, with a safety margin factored into the equation. Depending on where a particular institution fits in this definition, PM frequency and content should be reviewed. It may be possible to modify the current PM program to conserve resources in some areas, apply them more effectively in others, and keep equipment failures out of the hands of the clinician. The goal of this process, of course, is to reduce risk to the patient, clinician, and hospital.

One possible PM strategy is a "foreign object detection walk-through"—a military term for having personnel walk across an aircraft carrier deck and seek out objects that would foul aircraft engines. Biomedical Engineering department personnel currently do a morning check of anesthesia equipment, monitors, and lasers in the operating room. And we are considering similar walk-throughs of other high-technology areas of the hospital.

The strategy for determining appropriate PM levels for high-risk equipment is presented in Figure 3 (p. 15). To begin, hospital personnel should focus most resources on the high-risk hard-failure equipment and locations. Second, personnel should decrease PM resource deployment for high-risk equipment not experiencing failure. This change should occur gradually, with personnel continuing to monitor failure rates and risk values. Next, a strategy for reducing all PM resources deployed for low-risk equipment could be considered.

Communicating Risk Assessment Data

Risk assessment data and reports must be formatted in a way that both the clinical engineer and the clinician can understand, and each report should provide only the information needed by any particular department. At Texas Children's Hospital, the clinical engineer's failure analysis report, for example, can sort information by institution, equipment type, and department. Having these records of PM, repairs, failure codes, and high-risk equipment information assists engineers in managing risk for their areas of responsibility. A similar report, which includes statistical thresholds, is pre-

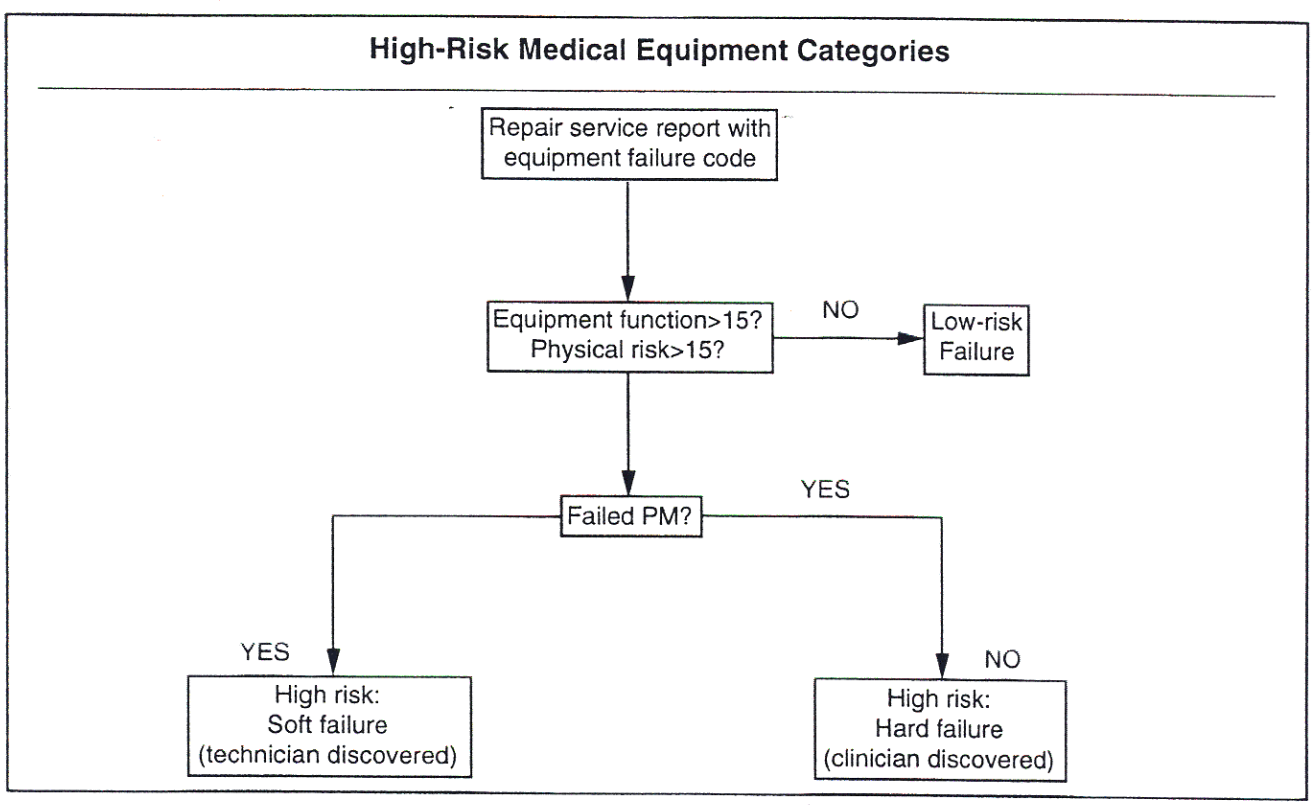

Figure 2. *High-risk medical equipment is that which has the most potential for causing injury or damage.*

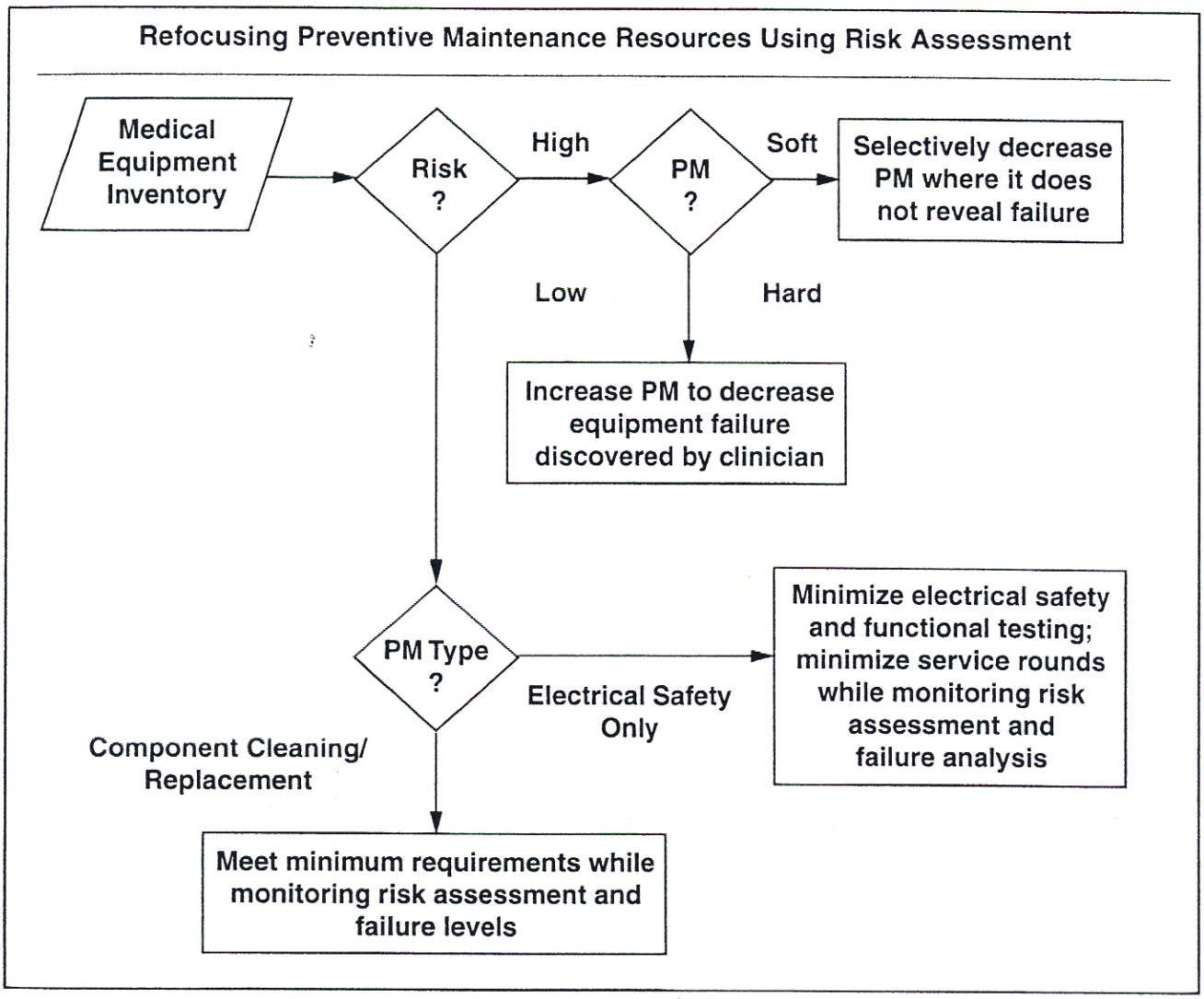

Figure 3. *Preventive maintenance must be focused on high-risk, hard-failure equipment.*

pared for the safety committee's review. Finally, biomedical engineering management receives a report indicating trends for each information category.

Because so much information is generated, it can be difficult to obtain a global view of activities. Thus, a three-dimensional graph is generated for viewing failure analysis codes as a function of department of occurrence and equipment type. This type of graph, which uses information from the risk management tool, is very useful. Moreover, a risk assessment snapshot is taken at six month-intervals, and changes in risk factors are plotted according to department of occurrence and equipment type. If the data indicate a possible risk increase, the medical equipment program can be adjusted before the increased risk leads to equipment failures.

In the same way that the clinical engineer needs both a telescopic and microscopic view of the medical equipment program, the clinical manager requires appropriate information. Properly trained, the clinical manager can use detailed medical equipment reports for equipment and budget planning. This detail is provided in the monthly billing report, which includes a full equipment inventory with equipment cost, depreciated value, cost of lifetime labor and parts, number of repairs, MTBF, placed-in-service date, and date of next PM.

A monthly detailed review of all this information is not practical, however, so an abbreviated graphic presentation was designed. This report (Figure 4, p. 16) enables the clinical manager to identify the medical equipment problem areas quickly for his or her department. The display includes five modules that provide data on equipment malfunction, physical damage, patient/employee injuries, operator error, and maintenance information. (The maintenance information, or maintenance factor, is

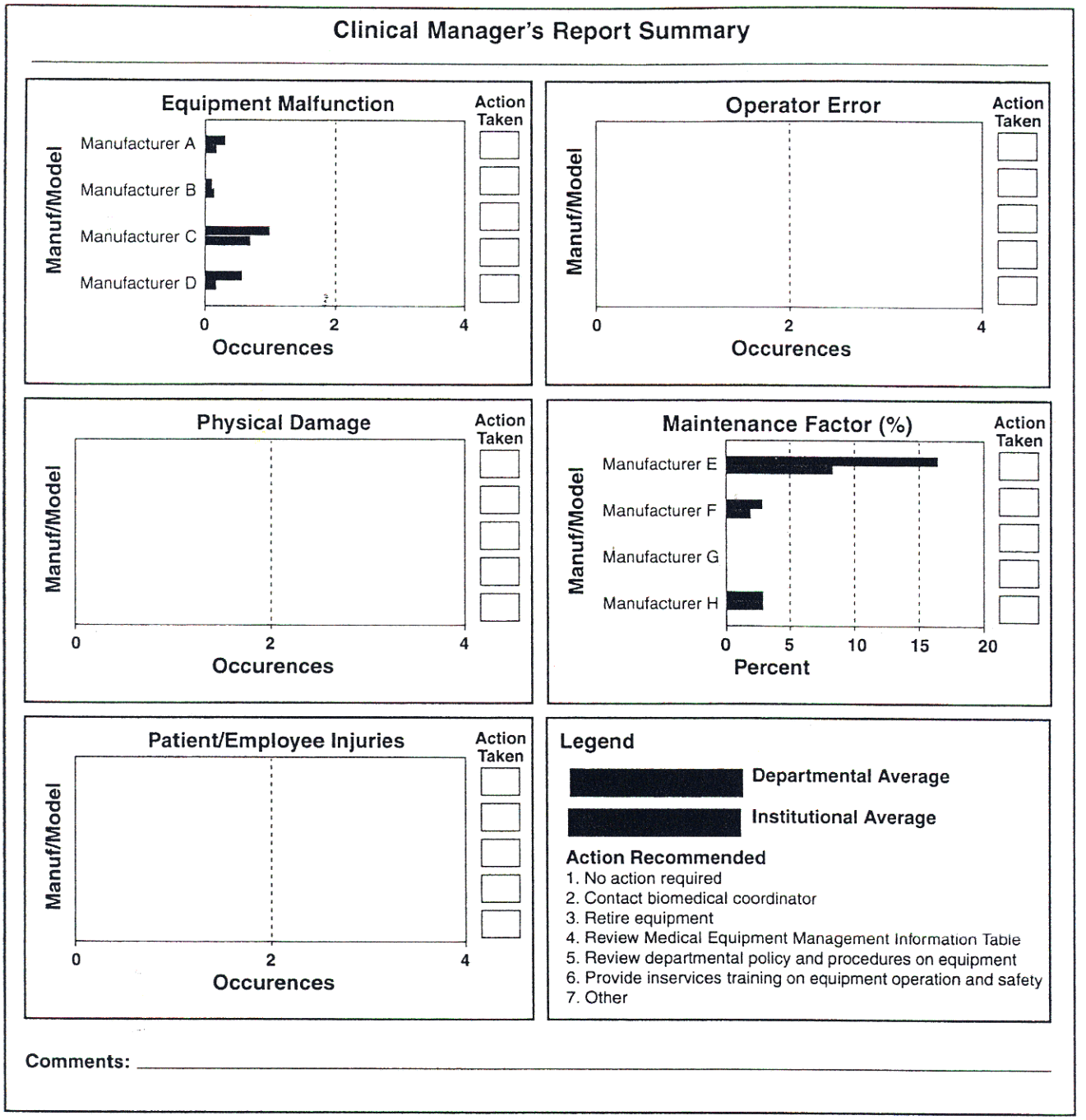

Figure 4. *A summary graphic report helps managers quickly identify equipment problem areas.*

the annual maintenance cost divided by the acquisition cost.) The sixth module includes a list of appropriate actions for the clinician to take.

Each module displays the four equipment items with the greatest activity for that module type. The activity is then averaged over three months, and the departmental average is compared with the institutional average for the same manufacturer and model types. With these data, the clinician can compare, for instance, the average number of equipment failures in his or her department with the institutional average to assess the seriousness of the failure more accurately. Moreover, the biomedical engineering department can monitor the levels of failure and risk for the whole institution.

The clinician reviews the report, indicates an appropriate action, and returns the page to biomedical engineering or another risk management group. Because these report layouts and content resulted from a joint effort of clinicians and biomedical engineering personnel, both groups have been able to use and understand the format.

Optimal Equipment Replacement as a Function of Risk

Purchase Now	Current Year	1Yr	2Yr	3Yr	4Yr	5Yr	6Yr
Equipment Cost	C	0.00	0.00	0.00	C	0.00	0.00
Maintenance Cost	0.00	X	X	X	0.00	X	X
with Risk Factor	0.00	F(X,Y,Z)	F(X,Y,Z)	F(X,Y,Z)	0.00	F(X,Y,Z)	F(X,Y,Z)
Total Cost of Ownership	= C	+ F(X,Y,Z)	+ F(X,Y,Z)	+ F(X,Y,Z)	+ C	+ F(X,Y,Z)	+ F(X,Y,Z)

Purchase in 1 Yr	Current Year	1Yr	2Yr	3Yr	4Yr	5Yr	6Yr
Equipment Cost	0.00	C	0.00	0.00	0.00	C	0.00
Maintenance Cost	X	0.00	X	X	X	0.00	X
with Risk Factor	0.00	0.00	F(X,Y,Z)	F(X,Y,Z)	0.00	0.00	F(X,Y,Z)
Total Cost of Ownership	= F(X,Y,Z)	+ C	+ F(X,Y,Z)	+ F(X,Y,Z)	+ F(X,Y,Z)	+ C	+ F(X,Y,Z)

C = Cost of new equipment X = Maintenance cost Y = Equipment type
Z = Change in risk factor F(X,Y,Z) = Maintenance cost change attributable to increased risk

Figure 5. *Net present value of equipment can be determined more accurately by correlating it with risk factors and maintenance cost.*

Net Present Value and Risk Assessment

Currently, we are attempting to merge our risk assessment information with net present value calculations (Figure 5, p.17) to help our institution plan for capital equipment purchases. The cost of maintaining equipment after the warranty period depends on the manufacturer's required maintenance and the environment of the institution. If the maintenance cost can be correlated with the changing risk factors we detect, then the net present value estimates would be more accurate.

For example, the decision-making process that determines whether a $4,000 infusion pump is to be replaced incorporates quantifiable historical indicators from the equipment maintenance database and derives indicators from the dynamic risk calculations. The review of historical data indicates that the annual maintenance cost has been $285.25 per unit and represents a maintenance factor (annual maintenance cost divided by the acquisition cost) of 7.13 percent. The risk assessment tool calculates that, on the basis of changes in the infusion pump's risk grouping (Figure 1) and an established correlation between maintenance costs and risk, the maintenance factor will increase by 2.0 percent next year—an increase the present maintenance cost would not otherwise suggest.

The predictive tool is of value because the correlation would show a one- to six-month delay between increased risk and the actual increase in maintenance costs. Subsequently, the net present value calculations, F(X,Y,Z), would reflect an annual maintenance cost of $365.20. This is a substantial increase when a purchase of several hundred of these devices is under consideration and may be indicative of purchasing new ones.

Technical Competencies and Risk Assessment

Clinical professionals in the hospitals have employed clinical competency testing for a number of years. Clinical competency means "possessing the knowledge and skills necessary for adequate performance in the clinical area," and competency-based evaluation is intended to facilitate each individual's professional development, enhance accountability and autonomy, benefit the consumer, and promote cost-effective high quality care.[6]

Clinical engineers and technicians can adapt this concept to the development of technical competencies (Figure 6, p. 18). Technical competencies should measure the technician's skills in servicing equipment as well as in assessing the equipment's clinical efficacy, compatibility with other equipment, cost-effectiveness, and risk-related properties. In turn, risk factors for the equipment managed by Technician A could be compared with risk factors for the same type of equipment managed by all technicians in the department. Performance would, become in part a function of the risk management

Technical Competency Checklist

Equipment Type:	**INFUSION PUMPS**
Manufacturer/Model Number:	**GENERAL**
Competency Title:	**PREVENTIVE MAINTENANCE AND REPAIR**
Job Titles to Perform:	**BMET I, BMET II, SENIOR BMET**

Critical Elements	S	U
1. Identifies the hazards of bloodborne pathogens and chemical contaminants as related to this device		
2. Identifies the physiologic applications for this device		
3. Performs preventive maintenance on this device in accordance with Policy No. G11, Procedure No. G11-49		
4. Is able to perform repairs on this device to the component level		
5. Identifies the interaction of this device with other equipment in the clinical environment		
6. Identifies potential hazards related to the interaction of this device with other equipment in the clinical environment		
7. Is able to provide in-service training for clinicians on the operation of this device		
8. Is able to cross-train other biomedical engineering staff in the operation and repair of this service		
9. Is able to diagnose problems specific to this device		
10. Is able to distinguish operator error from equipment malfunction		

Employee Name _____ Title _____

Qualified Observer _____ Title _____

Validation Date _____

Figure 6. *Technical competencies measure the technician's skill in servicing equipment as well as other factors.*

skills of the technician and clinical engineer, and follow-up technical competency testing would become a component of risk management. Ideally, clinical engineers and technicians could become creative partners in risk management for the medical equipment and clinical areas under their responsibility.

Currently, however, at a time when health care resources are under scrutiny, the additional work of administering technical competencies is not practical. If, however, competency training and testing could be administered with a frequency and depth that correspond to the level of risk assessed, the advantages would outweigh the resources expended (Figure 7, page 19). In other words, the greater the associated equipment risk, the more frequent the testing.

As an illustration, a particular physiological monitor was evaluated by the technology-evaluation task force. Following the committee's selection and recommendation, the equipment was approved for use in the hospital. Entered into the biomedical engineering department's equipment master, the monitor reflected a risk group of 3 on the basis of its ge-

neric function and physical risk. However, in a specific clinical environment in the ambulatory unit, the need for greater clinician training was revealed. Specifically, the responsible biomedical engineer manager noticed an increase in operator error and repair redo indicators and advanced the equipment to a risk group of 4. Previously, the clinician was competency tested after initial training and every two years. However, according to Figure 7, competency testing for level 4 equipment occurs annually and is contingent on the specific problem areas identified.

Control Charts and Risk Assessment

Control charts can be used to describe and analyze processes and structures that affect quality of care and services in a health care organization. Such charts are not to be construed as standards or thresholds, however; they describe a process, not its acceptability.[7] The control chart helps the technician monitor failure codes and trends related to them. It can also help monitor the stability of a process. In the classic control chart, process points are plotted between upper and lower control limits based on standard deviations. If readings go outside the limits, indicating that a process is out of control, changes should be made carefully to stabilize the process. Instability can arise from changes made to the risk assessment tool parameters, changes in the medical equipment program made as a result of the risk assessment analysis, or changes in the equipment program process itself.

Conclusion

When a risk assessment tool is developed, quantified, and implemented, myriad applications are possible, from generating elaborate three-dimensional presentations for equipment risk monitoring throughout the institution to implementing a technical competency program for clinical engineers and technicians. An essential ingredient involves correctly formatting the information so that it will be relevant to the professional for whom it is intended. Medical personnel don't have time for complex tables and charts, but they will use information that is relevant and that they can easily apply to improve their daily patient care delivery protocol. And because the accuracy of any risk assessment scheme cannot be measured against any known standards, clinical engineers must continuously update statistical or benchmark references to validate and improve the results of their assessment tools.

Biomedical engineering departments provide the technology-related expertise required for safe and

Technical Competency Testing Intervals According to Risk Calculation

RISK GROUP	TESTING INTERVAL	EQUIPMENT TO BE SELECTED
1	Upon completion of training only	All equipment for which training has been received.
2	Upon completion of training and every 2 years	Equipment that is randomly selected or that has specific problem areas.
3	Upon completion of training and every 2 years	Equipment selected according to frequency of service. Exception: ALL items in Life Support category should be competency tested.
4	Upon completion of training and annually	Equipment selected according to frequency of service. Exception: ALL items in Life Support category should be competency tested.
5	Upon completion of training and annually	All equipment items within this class.

Figure 7. *Technical competency should be retested according to equipment risk.*

efficient integration of clinical interventions at the bedside. Thus, measuring the direct effect of technical program improvements on patient outcomes is difficult. One strategy is to develop, track, and make changes on the basis of performance indicators that measure the *transparency of the medical equipment management program to the clinician and the patient.* In other words, if the program is working well, it should complement the work of clinicians and improve patient comfort and outcomes.

Although medical equipment management is best viewed as a shared responsibility between technician and clinician, new patient-care role design concepts work to minimize the amount of time clinicians spend making service calls for repair, addressing operational errors, and communicating with the biomedical engineering department about equipment status and repeated repairs. In turn, performance parameters built into the risk assessment tool should track repair redos, operator errors, repair turnaround times, service calls, injuries, and other problems that distract the clinician from patient care delivery. A medical equipment management strategy that spans the life cycle of the equipment, builds in a PM program, sets repair priorities, specifies competency testing frequency and scope, and monitors performance using a risk assessment tool will realize a more effective use of resources and will indirectly contribute to improved patient outcomes.

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