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Evolving Approaches to Management of Quality in Clinical Microbiology

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HISTORY

Quality management (QM) in microbiology has evolved through several phases over the last 25 years. Although government agencies might claim to have taken the initiative, the College of American Pathologists (CAP) had established a proficiency testing and laboratory accreditation program many years before legislation was enacted to empower the government to require participation in proficiency testing and inspection programs. Initially, the focus was entirely on proficiency testing and internal quality control. The CAP broadened QM to encompass quality assurance, which they defined as a more patient-care-oriented approach apart from quality control, which they believed applied specifically to internal laboratory monitoring. Quality assurance, as such, was never incorporated into government regulations or guidelines. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) moved progressively into quality assurance issues, however. In the 1990s, the JCAHO began to shift the emphasis to continuous quality improvement (CQI) or total quality management, an industrial approach which has not been incorporated into government accreditation programs. The JCAHO has required participation of staff in training in CQI and is requiring increasing analysis of indicator data. The CAP Laboratory Accreditation Program has been less specific about introduction of these measures.

Until 1960, monitoring of the quantitative variation and accuracy of analytical measurements in clinical chemistry was the predominant QM activity in clinical laboratories, and the process did not seem to have much application to the microbiology laboratory. By 1965, R. C. Bartlett had introduced a system of monitors on the performance of personnel, equipment, and materials within the microbiology laboratory at Hartford Hospital, and he described the program at the annual meeting of the American Society for Microbiology in 1967 (13). He conducted a series of workshops under the auspices of the American Society of Clinical Pathologists (ASCP) describing these procedures and the observations of his staff (33). In addition, he urged that improving the quality of patient care would require a broader approach, including monitoring and control of the quality of specimens submitted to the laboratory, physician ordering practices, and interpretation and use of laboratory reports. The expansion of QM into these areas was inhibited at the time by the traditional attitude of practicing clinicians. Physicians were not receptive to the role of the laboratory in monitoring either the rationale behind ordering or the appropriateness of submission of specimens and their quality. This made it difficult or impossible to introduce these practices into most hospitals, including our own, during the 1960s.

Harding may have been the first to publish recommendations for quality control in microbiology in 1967 (97). During the same year, Petersdorf and Sherris discussed the quality control aspects of improving in vitro testing for antibiotic susceptibility (170). Branson addressed approaches to solving problems and errors in microbiology in 1966 (54). Between 1967 and 1973, a number of publications describing basic quality control programs in microbiology appeared (11, 12, 90, 95, 130, 145, 185, 196, 243).

In the late 1960s, the growing threat of a multiplicity of regulatory agencies, each establishing somewhat different standards, rules, and regulations, began to emerge. Eilers proposed at that time that laboratorians, government, and suppliers work together to create voluntary consensus standards (78). This resulted in the formation of the National Committee for Clinical Laboratory Standards (NCCLS). Clinical relevance was established as an early criterion for evaluating new standards.

In 1972, the NCCLS published recommendations for quality control of disk susceptibility tests (10). Prior to that time, acceptable target zone diameters for various antibiotics had been established by the Food and Drug Administration (FDA) working in collaboration with John Sherris at the University of Washington. In 1973, Nagel and Kunz challenged the need for quality assessment of performance of commercially prepared culture media. In their experience, no deficiencies that would have been detected only by monitoring with stock cultures had occurred. The only defects that had been observed were grossly visible upon inspection of the media, e.g., cracking resulting from freezing or drying (155). Porres emphasized the value of comparing results with a reference laboratory for detection of errors (174, 175). His program made extensive use of blind unknown specimens.

In 1974, one of us (R.C.B.) described the accumulated experience with quality control in the microbiology laboratory at Hartford Hospital (15). This included experience with monitoring of media, biochemical reagents, equipment, and personnel performance. Also addressed were related issues including cost implications, the need for more efficient laboratory management (including workload assessment), space planning, and control of the appropriateness of specimen submissions (including evaluation of the quality of specimens). The extent of work performed on specimens and the amount of information reported and its influence on medical decision making were discussed. Ellis at the Centers for Disease Control (CDC) published a manual on quality control procedures for microbiology laboratories in 1974 (79). Marks described quality control of susceptibility testing of mycobacteria in 1975 (146). Lamanna reviewed quality control efforts in clinical microbiology in Italy in 1977 (130).

In 1976, the third in the American Society for Microbiology (ASM) Cumitech series addressed quality control (51). It focused on internal laboratory process and reflected largely the regulations which followed the Clinical Laboratory Improvement Act of 1967 (CLIA 67). The relative cost effectiveness of control procedures was not addressed. In 1980, Wood and Durham recommended an approach to establishing the reproducibility of serologic tests (242). Reynolds described an approach to quality testing of media by preparation of metabolite suspensions, which obviated the need for use of live cultures (180).

Gruft described moderate variations in the results achieved by proficiency testing participants, using various acid-fast-staining techniques for mycobacteria (94). Hoke and associates drew attention to the problem of false-positive Gram stains for gram-negative rods in transport media in 1979 (101). Martin provided an overall description of quality control activity in microbiology in Great Britain in which the scope was somewhat broadened to include evaluation of the quality of specimens, including a proposal for preparation of standardized suspensions of cells for preparation of smears to help standardize interpretation of Gram stains (148). He also emphasized the need for standardization of procedures. Petersen described a procedure for monitoring smears and cultures for mycobacteria which would aid in the detection of error in both the preparation of smears and their interpretation and the performance of culture media (171).

Numerous publications regarding quality assurance of microbiology performed in doctors' offices appeared in 1986

(41, 45, 63, 64, 84, 85, 173, 233). This subject will not be reviewed here.

Steward and Koepke published a manual broadly reviewing basic quality assurance practices in clinical laboratories in 1987 (208). This manual introduced no new approaches in clinical microbiology but reaffirmed previously recommended practices. Belyus et al. (46) may have been the first to make reference to the publications of Phillip Crosby (65), one of the emerging proponents of the new and growing practice of continuous quality improvement in industry. They also made reference to the publications of Westgard, who had addressed quality improvement concepts as they apply to laboratory quality control (231).

Kiehlbauch and associates addressed quality control of commercial automated antibiotic susceptibility testing systems (122). They recommended that the NCCLS develop some recommendations to deal with these systems, because the recommendations applicable to disk and microdilution testing were not conveniently adaptable.

Valenstein and Emancipator addressed the turnaround time (TAT) for reporting results of a variety of laboratory specimens, including urine cultures, in 1989 (220). The model TAT for negative urine cultures was 24 h. They gave some attention to the question of defining acceptable TATs. Perry and Miller described the use of a control slide for monitoring direct staining of fungi in smears (167). Manuselis et al. described six major steps for a quality assurance program in clinical microbiology (145). They emphasized the importance of evaluating the effectiveness of corrective action. Up-to-date and comprehensive descriptions of quality control in microbiology were published by Braunstein, Miller and Wentworth, and Weissfeld and Bartlett (55, 150, 230). The recommendations appearing in Cumitech 3 (51) were updated in Cumitech 3A in 1990 (7). As in the previous publication, more emphasis was placed on conventional quality control procedures than on monitoring of indicators and more patient-care-directed aspects of QM. Most recently, Sewell outlined in detail recommendations for QM activities in clinical microbiology which included many practical suggestions for monitoring indicators that seem to have relevance to health care outcome (192).

Advent of Government Regulation

The Social Security Act of 1965 (Public Law 89-97) on 30 July 1965 established a system for the payment of benefits for medical care for several categories of individuals, including the indigent, the financially needy, dependent children, and the disabled. The Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services (DHHS) was given primary responsibility for administration of the Medicare program (Title XVIII) and for the provision of assistance to the states for the administration of the Medicaid program (Title XIX).

The Social Security Act of 1965 forbade Medicare to establish higher standards for hospitals than those imposed by the voluntary accreditation organizations. This was modified by the passage of the Social Security Act of 1972 (Public Law 92-603), which permitted DHHS to set higher standards. This would require voluntary organizations to meet or exceed DHHS standards in order for them to retain "deemed status," which meant that their accreditation process would be acceptable as equivalent to inspection and accreditation by the HCFA or state agencies functioning on behalf of the HCFA. The problem was intensified by the availability of only 150 surveyors (state and federal) with approximately 12,000 facilities to be surveyed annually. The survey burden was reduced by almost one-half by acceptance of JCAHO inspection and accreditation by the HCFA as equivalent to, or granting, deemed status. But in states with licensure laws that did not enable allocating deemed status to the JCAHO, the facilities needed to be separately surveyed for state licensure purposes.

In 1966, attention was focused on evidence of widespread deficiencies in the performance of tests in the nation's clinical laboratories. Numerous incidents were reported in the press, and these were used by the CDC to give support to passage of regulations to govern clinical laboratories and assess their performance through proficiency testing. It was reported that a laboratorian had confused nonpathogenic diphtheroids with *Corynebacterium diphtheriae* and that all of the children in an orphanage had been unnecessarily immunized.

A small boy was bitten by a rat used in a school demonstration; the rat was then killed and examined for rabies. The local laboratory reported that the brain was positive for this disease. By the time these specimens were submitted to the CDC for confirmation and a negative report had been returned to the attending physician, the boy had received 12 inoculations of rabies vaccine, which resulted in a febrile reaction and severe discomfort.

In another incident, a man with a fungal infection was misdiagnosed because of laboratory error. He was medically and surgically mistreated over a period of 30 years before the error was recognized.

A young mother of two children was diagnosed on the basis of laboratory tests as having pulmonary tuberculosis and was confined to a sanatorium. Subsequent studies in the sanatorium proved that she did not have tuberculosis, and the woman was released.

A hospital laboratory failed to correctly identify one-third of 47 *Shigella*-positive stool specimens. Many patients were deprived of therapy and suffered prolonged, severe illnesses.

Specimens from 33 suspected cases of malaria were submitted to the CDC for confirmation. These specimens had been diagnosed as positive, and the patients had been treated for malaria. The CDC found that all of the specimens were negative for malaria. Specimens of bone marrow had been removed 8 times from one patient and blood had been drawn 12 times for smears and a serologic test. The patient was treated for malaria in spite of not having the disease.

The studies of laboratory performance in New York City, which were published by Shaeffer in 1966, contributed further to the perceived magnitude of the problem of incompetence in clinical laboratories (186). As a result of concern over such incidents, Congress passed CLIA 67. It applied only to laboratories in interstate commerce. The legislation focused attention on internal laboratory error, but the regulations that ensued did not address any QM issues external to the laboratory. With subsequent adoption of the regulations by the HCFA, and continuing to the most recent set of regulations resulting from passage of CLIA 88, the focus has continued to be on internal laboratory processes. The regulations addressed internal quality control activity, proficiency testing, and personnel standards.

CLIA 67 mandated equivalency for the CAP Laboratory Accreditation Program if it enforced standards at least as stringent as those to be developed by government. It was not until July 1969 that CLIA 67 was finally implemented and the CAP was duly recognized as adequate to establish compliance with standards. As a further step in bringing government, the CAP, and the JCAHO closer together, CAP was

able in 1967 to convince the JCAHO to adopt CAP standards rather than develop an independent set of standards.

The CDC conducted proficiency testing of laboratories in interstate commerce subsequent to passage of CLIA 67. Medicare established the same standards for hospital and independent laboratories and initially required that they successfully participate in a proficiency testing program operated by the CDC. There was a specific grading scheme in the regulations for the CDC proficiency testing program. In 1986, the CDC stopped offering their program and approved the CAP program, but the grading criteria remained the same. The chaotic and conflicting state of these regulations was reviewed by Hammond (96). He referred to the interagency agreement signed in 1979 to consolidate administration of the Medicare and CLIA laboratory programs within HCFA. In 1980, a notice was published in the *Federal Register* that the HCFA and the Public Health Service FDA had signed a memorandum of understanding covering a number of areas, including hepatitis and syphilis testing (81). Thus, facilities were no longer required to be surveyed and certified by the HCFA even though they had been accredited by the JCAHO.

Despite the passage of CLIA 67, there was continued concern about the quality of laboratory work. In the report of its Forward Plan for Health FY 1978–82, the DHHS reported that ". . . the accuracy and precision of laboratory results continues to be a national problem with error rates ranging from 8 to 25%" (218). The effectiveness of CLIA 67 was blunted by a restriction of its application to laboratories in interstate commerce. This restriction was extended only to other laboratories being reimbursed through Medicare or Medicaid by an interagency agreement in 1981. Also, the regulations did not apply to at least 50,000 laboratories operating in physicians' offices. This omission led to submission of CLIA 79 by Senator Jacob Javits, who said, "I believe that every person is entitled to protection from inaccurate and unreliable results because of a failure of laboratories to observe basic quality standards and procedures. Every person is entitled to have professionally qualified persons perform this vital work. Until this Bill is enacted into law, I believe that essential medical laboratory improvement to cover those who should be covered remains illusory" (109). CLIA 79 might have helped to eliminate the duplicity of regulatory standards that were developing and establish uniform personnel standards applicable to all laboratories including those in physicians' offices. The Bill failed to pass because of increasing concern over government overregulation in general. At that point also, an interagency agreement was developed between the HCFA and the CDC to enable the HCFA to assume the primary role of administering interstate laboratory regulations through state Medicare agencies (137).

CLIA 88. Despite efforts to improve laboratory performance, there were continued media reports of inaccuracies that generated headlines (60, 225). An amendment to CLIA 67 was finally passed in 1988; it has been referred to generally as CLIA 88. The subsequently published regulations provoked 50,000 comment letters from interested parties. Proposed regulations for proficiency testing would have created the risk that many laboratories might lose their accreditation for certain testing as a result of a limited number of failures. Most provocative were proposals that would lower the standards for most categories of laboratory workers. At the same time, standards would be raised for supervisors in many independent laboratories where experienced and competent workers without bachelor's degrees could not qualify. Laboratories would receive five proficiency testing samples for every two that they had received previously. Initially, a failure in any single microbiologic test would cause loss of certification for the entire discipline. Subsequently, this was modified so that certification would be lost only if two consecutive proficiency tests were failed or two of three were failed. CLIA 88 did not include assurance that the CAP and the JCAHO would continue to enjoy deemed status. A formal request from the CAP and the JCAHO to the HCFA was made a requirement. Such a request was made, but so far the deemed status has not been awarded.

The final rule was published in the *Federal Register* in 1992 (81). The CLIA statute specifically states that the "risk and consequences of erroneous results" be considered in setting personnel standards. This statement was omitted from the final rule. Tests were placed into three categories: a waivered category, a moderately complex category, and a complex category. A number of tests were shifted from the waivered category to the moderately complex category in the final regulations. Unfortunately, the personnel qualifications necessary to perform the testing were reduced. The final rule states that high school graduates with no formal laboratory training will have to obtain an associate degree to perform highly complex tests after 1997. Most laboratory scientists agree that a baccalaureate degree should be required for performance of highly complex tests and that general supervisors in laboratories performing highly complex tests should have a baccalaureate degree.

The rule was faulted for not placing workup of cultures in the high-complexity category along with all microscopic evaluations. The ASM urged the HCFA to complete studies on the relationship between proficiency testing and quality laboratory testing as soon as possible to refine proficiency testing programs. The period of 6 months for suspension of certification was considered excessive. The rule required the name of the ordering physician on the requisition slip and persisted in requiring daily quality control requirements in bacteriology despite the recommendation for weekly controls by the NCCLS. The same criticism was applied by ASM to test kits or strips used for organism identification in mycology. It seemed a step backward for the rule to allow laboratories to use manufacturer's package inserts in laboratory procedures.

Quality control. The rule added the need for daily checks on tests for β-lactamase, the flagella stain, and tests for identification of mycobacteria. Other staining procedures must be monitored weekly along with X and V disks. Antisera can be monitored on a monthly basis. Slides and photographs must be available in parasitology, and workers cannot depend only on published materials. The trichrome stain must be evaluated with control organisms monthly. Positive and negative controls must be applied to all cell lines in virology. The ocular micrometer must be calibrated before use. Media and disks used for susceptibility testing must be checked before or concurrent with use on a daily basis. For proficiency testing, the rule requires that at least 50% of the samples be mixtures of the principal pathogenic organism and normal flora. Other mixtures of organisms from which the laboratory must identify all isolates can be distributed. The types of organisms that might be included are *Bacteroides fragilis* group, *Clostridium perfringens*, *Peptostreptococcus anaerobius*, *Enterobacteriaceae*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Salmonella typhimurium*, *Serratia marcescens*, *Shigella sonnei*, *Yersinia*

enterocolitica, *Listeria monocytogenes*, *Corynebacterium jeikeium*, *Staphylococcus aureus*, *Streptococcus* group A, *Streptococcus* group B, *Streptococcus* group D (*Streptococcus bovis* and *Enterococcus* spp.), *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Haemophilus influenzae* type B, and *Pseudomonas aeruginosa*. In mycology, the following might be included: *Candida albicans*, *Candida* spp., *Cryptococcus neoformans*, *Sporothrix schenckii*, *Exophiala jeanselmei*, *Fonsecaea pedrosoi*, *Microsporum* sp., *Acremonium* sp., *Trichophyton* sp., *Aspergillus fumigatus*, *Nocardia* sp., *Blastomyces dermatitidis*, and zygomycetes. Parasitology specimens that might be included are *Enterobius vermicularis*, *Ascaris lumbricoides*, *Entamoeba histolytica*, *Strongyloides stercoralis*, *Trichuris trichiura*, *Diphyllobothrium latum*, *Cryptosporidium* sp., *Plasmodium falciparum*, *Entamoeba coli*, *Giardia lamblia*, *Endolimax nana*, *Dientamoeba fragilis*, *Iodamoeba butschli*, *Chilomastix mesnili*, and hookworm.

According to CLIA 88, there will be a phase-in period for quality control requirements for moderately complex laboratories. During that time, the FDA will examine manufacturers' quality control requirements. In the meantime, laboratories may use the instructions provided by the manufacturer. Proficiency testing for moderately and highly complex laboratories will be on a trimester basis.

Personnel requirements. For laboratories performing only moderately complex tests, the director may be a physician with a minimum of 1 year of experience directing a laboratory. Other qualified individuals would be persons with a master's or baccalaureate degree, 1 or 2 years of laboratory training and experience, or 1 or 2 years of supervisory experience. It might be possible for nurses and other allied health professionals not trained in medical technology to serve as laboratory directors. In these instances, there must be a technical consultant responsible for technical and scientific oversight of each specialty and subspecialty area of the laboratory. A clinical consultant who serves as a liaison between the laboratory and its clients is required. This must be a physician or board-certified doctoral scientist. Testing personnel may have a minimum of a high school degree. Laboratories performing highly complex tests may be directed by a physician with the same qualifications described previously for moderately complex laboratories. There must be a technical supervisor for each specialty or subspecialty. This person must, at a minimum, have a B.S. degree with 4 years of laboratory experience. A general supervisor who, at a minimum, must have an associate degree plus 2 years of laboratory training or experience also is required. A clinical consultant must be available as described above for moderately complex laboratories. Testing personnel require a minimum of a high school degree, but by September 1997 they must have an associate degree in either laboratory science or medical laboratory technology.

The regulations went into effect on 1 September 1992. Compliance with proficiency testing began in January 1993, but sanctions will not be enforced until 1 January 1994. Moderately complex laboratories need apply only limited quality control until September 1994, at which time they must either follow manufacturers' instructions approved by the FDA or comply with quality control requirements in the CLIA 88 regulations. Highly complex laboratories must follow the CLIA 88 regulations until September 1994, at which time they may follow FDA-approved procedures as an alternative.

Proficiency Testing

Proficiency testing had been shown to be a valuable tool for recognizing deficient laboratory performance long before passage of CLIA 67. In the mid-1940s, Sunderman and others operating clinical laboratories in Philadelphia, Pa., became concerned over incidents in which physicians had divided samples of blood and obtained substantially different results from different laboratories (210). Under the auspices of the Philadelphia County Medical Society, the first proficiency testing program was initiated. This program was so revealing of inadequacies that it became the impetus for organization of the CAP in 1946. The first microbiology survey was conducted by the CAP in 1959 and involved 600 laboratories. Following CLIA 67, and later with passage of the Medicare Act and creation of the HCFA, the role of these organizations in conducting proficiency testing was expanded.

Experience with proficiency testing in microbiology. Proficiency testing was made a regulatory requirement in the 1960s by a number of state health departments, including those of New York and Connecticut. Schaeffer et al. reported in 1970 that bacteriology laboratories participating in workshops had shown an improvement in proficiency test performance (188). Smith reported on the CAP proficiency testing program in parasitology in 1974 and indicated that participants were having moderate difficulty identifying *Giardia lamblia* cysts and hookworm, *Paragonimus*, and schistosome ova (197).

By 1973, 70% of laboratories performing microbiology were participating in proficiency testing programs (147). Between 1970 and 1974, Dolan (70), Gavan and King (88, 89), and Sommers (204) reported that the performance in microbiology of 80% of participating laboratories had been satisfactory. Over 85% of laboratories were using standardized methods for susceptibility testing. Tillett and Crone described the performance of British laboratories participating in a proficiency testing program in 1976 (215). Black and Dorse described the use of blind unknown specimens in a regional quality control program conducted in Canada in 1976 (49, 50). They described the substantially greater yield of information regarding substandard practices when blind unknown specimens were submitted to laboratories as simulated clinical specimens.

Wilson and associates in 1977 reviewed the improvement in proficiency testing performance in New York City laboratories between 1964 and 1974 (234). The number of laboratories obtaining excellent scores increased from 30 to 40% at the beginning of that period to 50 to 60%. The program was thought to be instrumental in substantially improving laboratory performance because of better communication, workshops, and greater educational activity overall.

Estevez reported on the successful use of blind unknown specimens in 1980 (80). In 1979, Taylor and associates remarked on the ability of proficiency testing in immunology to compare the accuracy of different methods and enable collection of information on the variety of procedures used in different laboratories (212). Subsequently, collection of this type of information in proficiency testing programs would prove to be a powerful tool for contributing towards standardization of laboratory testing methods with the highest degree of accuracy (211).

Knowles and Gilmore reported in 1981 that participants in the CAP proficiency testing program had reported fewer antimicrobial susceptibility determinations showing variation outside the control limits than had been reported previ-

ously (123). Jones et al. reviewed proficiency testing performance in antimicrobial susceptibility testing in 1982 (115). They observed that performance had now routinely exceeded over 95% correct results for all antimicrobial agents. A recommendation which was reiterated in updated standards published by the NCCLS was that the previous requirement for daily controls be modified to the use of weekly controls as long as no changes were made in procedures and no increase in deficiencies was detected (156). Jones estimated that the cost savings would be between 400,000 and 2 million dollars annually. At the same time, Smith reviewed performance in parasitology proficiency testing conducted by the CAP (198). Although performance had improved, participants were still having difficulty identifying protozoa in formalin-fixed fecal material and permanently stained slides. Fuchs and Dolan reported at the same time that there had been a slight but discrete improvement in performance in mycology proficiency testing (87).

Whitby and associates reviewed performance in proficiency testing in Canada in 1982 (232). Sixty-eight percent of laboratories achieved a score of 70% or higher. Snell et al. reported in 1982 on proficiency testing of antibiotic susceptibility testing in the United Kingdom (201). Lack of standardization and performance factors contributing to error were identified. In general, standards of practice were not comparable to those observed in the CAP proficiency testing program reports. Snell et al. reviewed the proficiency testing program in use in the United Kingdom in 1982 (202). The program was confidential, and its main role was described as educational since it included no threat of punitive action.

The Italian experience in proficiency testing in microbiology was reported by Orsi et al. (163). Unlike the reports on proficiency testing in the United Kingdom, the data from Italy displayed evidence of improvement in performance. Ackerman and Pritchard described the experience with proficiency testing in Australia in 1984 (1). As with programs in use in the United Kingdom, the activity was considered primarily educational. Snell reviewed the status of proficiency testing in microbiology in the United Kingdom in 1985 (199). The program continued to emphasize its educational features. No data that revealed any improvements in performance were presented. Lassen and Sandven described the proficiency testing program being conducted in Norway (132).

Jones and associates in 1983 reaffirmed their recommendations that daily quality control of antimicrobial susceptibility testing might not be necessary (114). Accuracy of participants in the comprehensive survey had reached 97.5% and was lowest only in the basic survey subscribers at 93.7%. In another report, Jones and associates stated that correct categorization of penicillin-resistant *Streptococcus pneumoniae* had increased from 15% in 1981 to 78% in 1982 largely as a result of the recommended use of the 1-μg oxacillin disk (116). Recognition of methicillin-resistant *Staphylococcus aureus* was correct for 96.8% of participants. The problems with such recognition by automated systems were noted. Use of chromogenic cephalosporins showed the lowest error rate for detection of β-lactamase, and their use was recommended over other techniques. Jones and Edson further updated observations with proficiency testing of antibiotic susceptibility testing in 1985 (113).

Griffin et al. reported on experience with the CDC proficiency testing program between 1980 and 1985 (91). Participants experienced the least difficulty with gram-positive and gram-negative cocci and greater difficulty with anaerobes, gram-positive bacilli, and miscellaneous gram-negative bacteria. Earlier, Griffin and associates reported that performance in the CDC proficiency testing program was best for laboratories processing large volumes of specimens (92). They recommended that laboratories processing small volumes limit their work to procedures for which they could demonstrate satisfactory performance.

Pritchard described the experience with proficiency testing in Australia in 1987 (176). He emphasized the problems of preparation and distribution of specimens for transport over extended distances and the need to evaluate the ability of the laboratory to isolate organisms in pure culture from mixtures of strains. He also commented on laboratory safety issues, there having been several cases of laboratory-acquired shigellosis as a result of participation in the program. In 1986, Snell et al. reported on experience with the United Kingdom proficiency testing program (203). They remarked that it was difficult to demonstrate improvement in performance because of changes in scoring criteria. They lamented the numbers of laboratories that demonstrated recurrent errors. The same authors reported significant errors in proficiency tests of *Haemophilus influenzae* as a result of the use of improper media and susceptibility testing materials.

Laessig et al. reviewed the history of proficiency testing in 1986 and in 1988 (77, 128, 129). The percentage of correct results increased from 54% in 1974 to 70% in 1983. Snell and Brown reported on the United Kingdom proficiency testing with *Neisseria gonorrhoeae* (200). A low but significant error rate for detection of penicillin-resistant strains was observed as well as false-negative tests for β-lactamase resulting from the use of acidometric methods. Lassen and Sandven reported again on proficiency testing in Norway in 1988 (133). Jones, Edson, and associates reported that participants in the CAP bacteriology and comprehensive surveys more often correctly identified *Neisseria gonorrhoeae* and its antimicrobial susceptibility than participants in the basic survey (117). Submission of samples in mixed culture also decreased the accuracy rate. Disk diffusion and β-lactamase testing were more accurate than dilution methods for detection of penicillin resistance.

Schalla and associates reported in 1990 on the CDC performance evaluation program for human immunodeficiency virus type 1 antibody testing (189). An interesting feature of the program was not only evaluation of testing but formulation of the clinical question leading to testing, collection and management of specimens, technology and methodology development and transfer, validation and reporting of results, and finally, interpretation and application of results. On the basis of this model, it would be useful to develop means for proficiency testing of other analytical procedures in which a broader range of processes is examined to assess their effect on the quality of health care.

Perry et al. reported on mycology proficiency testing in the United Kingdom in 1988 (168). The focus was on the standardization of methods, with no report of improvements in performance over time, as is typical of other publications from the United Kingdom.

Jones and associates updated results of antimicrobial susceptibility testing in the proficiency testing program of the CAP in 1991 (118). Accuracy of disk testing had increased to 98.2%, and that of dilution testing had increased to 96.1%. Seventy percent of laboratories had switched to weekly monitoring. Problems continued to exist among anaerobic methods and procedures for fastidious organisms. Lanyi and Czirok described the experience with proficiency testing in microbiology in Hungary in 1990 (131). Fifty

percent of laboratories attained a score of 50% or greater, and only 5% (one hospital laboratory) achieved a score of 90% or better.

Roberts-Thompson et al. described proficiency testing in Australia in 1991 (181). Unique was the participation of laboratories from a wide geographic area. A wide range in the quality of performance was observed.

Reactions. In 1975, one of us (R.C.B.) became concerned that proficiency testing was encouraging clinically inappropriate laboratory practices. The distribution of specimens labeled as "urine" containing as many as three different pathogens was encouraging laboratories to identify and report such isolations with antimicrobial susceptibility test results from clinical specimens despite the fact that specimens with this composition were most likely contaminated. Subsequent studies performed in our laboratory showed that mixtures of pathogens in urine specimens are not found in sequentially collected specimens in 85% of instances (40). These concerns led to the formation of a committee within the state of Connecticut whose charge would be to develop recommendations for medically relevant microbiology laboratory practices. At the same time, an effort would be made to control the distribution of proficiency testing specimens that might contribute to inappropriate laboratory practice (36). In 1974, Cicchetti et al. reacted to the numbers of proficiency testing specimens being distributed in syphilis serology by the Connecticut State Department of Health (61). They showed with statistical methods that the number could be reduced to one-third and continue to establish the ability of the participating laboratories to correctly perform these tests.

MacLowry expressed concern about proficiency testing in 1991 (141). He reviewed the evolution of proficiency testing from an educational program to one of assessing quality of performance with punitive implications. He referred to the specific list of organisms in the federal regulations (see p. 16) that are pathogenic at certain body sites and which laboratories must be able to identify to the species level from mixed cultures. MacLowry expressed concern that the CAP program might be required to demonstrate the ability to identify to species isolates such as viridans streptococci from mixtures of other organisms such as enteric bacteria and staphylococci from simulated sputum specimens. MacLowry raised concern that such an instance would be a departure from medical relevance and purely an exercise in technological capability that might encourage laboratory workers to engage in similarly nonuseful practices with clinical specimens.

In a letter to the *Journal of the American Medical Association*, Peddecord (165) responded to a previous publication by Lunz et al. (140) regarding correlations between the quality of work performed based on proficiency testing and the qualifications of laboratory personnel. He questioned whether the study established with statistical legitimacy the relationship between a higher percentage of ASCP-certified technologists in the workplace and better performance. In a response to this letter, Lunz commented that nonparametric statistical methods used had established the relationship between certified medical technologists and the level of performance (139). In 1988, Howanitz (102) referred to studies conducted by Schaeffer (186) and Schaeffer et al. (187, 188) between 1966 and 1970 in which performance in proficiency testing in bacteriology was better for laboratories directed by pathologists certified in anatomic and clinical pathology than in laboratories directed by physicians with other qualifications. He also referred to the work of Kenney, who in 1984 had shown no difference in the level of proficiency testing performance in laboratories directed by pathologists, doctoral scientist directors, nondoctoral directors, or other categories of physicians and laboratory directors (121). Studies performed by Howanitz showed that microbiology laboratories directed by Ph.D.s performed better than those directed by nondoctoral scientists (102).

Neff and Speicher reported on the correlation between performance in proficiency testing and other characteristics of clinical laboratories (158). Increasing size was related to improved performance in microbiology. Performance was better in laboratories when state laboratories had offered educational assistance. Improved performance was sustained when supervisors were technologists but not when supervisors did not have technical training. Performance was related to the proportion of ASCP-registered technologists. They concluded that mistakes in the preanalytic and postanalytic steps of the testing process were more likely to alter the outcome of patient testing than variability in the analysis step. They found only two studies that documented the frequency of mistakes in the preanalytic and postanalytic steps of laboratory testing, neither of which, they thought, threw any light on what consequences these mistakes may have on patient care. They concluded that much more research would be needed to establish the relationship between error in testing and the effect on health care. They reported that the CDC had contracted for a comprehensive research design and implementation plan to evaluate the impact of CLIA 88 on laboratory testing. It is hoped that the study will broadly address the patient care impact of errors in both the preanalytic and the postanalytic, as well as the analytic, steps of testing.

Critical Reassessment of QM

Role of professional societies. The growth of federal regulatory activity and the role of professional societies have been well described elsewhere (52, 69, 73, 75, 76, 96, 137, 160). The Laboratory Accreditation Program of the CAP was introduced in 1961, 6 years prior to passage of CLIA 67. In 1973, CAP was inspecting 2,188 laboratories. At the same time, over 7,000 laboratories were approved by Medicare or licensed by state programs (147).

In 1978, the American Public Health Association published a book that contained several chapters on quality control in clinical microbiology with many contributors from the microbiologic community (31, 68, 191). This book addressed not only cost-effective quality control practices but the need to address the quality and appropriateness of specimen submissions.

In 1979, the CAP conducted a conference entitled Clinical Relevance in Microbiology. The conference and proceedings greatly broadened the numbers of issues and recommendations for more cost-effective practices (20). One of us (R.C.B.) introduced an approach to allocating the cost of quality control among the number of deficient operations detected. This enabled a ranking in descending order of cost which would provide a logical approach to setting priorities for quality control. When no deficiencies had been detected over extended periods of surveillance, the cost for preventing a deficiency was theoretically infinite. These observations challenged the appropriateness of quality control requirements stipulated by CLIA 67. Depending on the method used, many biochemical tests had shown no deficiencies after 50 or 100 surveillance determinations conducted over an extended period of time. Similarly, clarifica-

tion of the sensitivity and specificity of serologic reagents for each use was not found worthwhile. The CLIA 67 requirement that the Gram stain be tested with known gram-positive and gram-negative organisms was condemned as a useless procedure.

The expanding recognition of the doubtful cost effectiveness of many of the controls required by the federal regulations led to modifications in many of the CAP requirements and also a tempering of the instructions given to inspectors by the CDC and HCFA. For example, the federal regulation stated that all reagents must be monitored each time they are used. Those responsible for preparation of guidelines for use by inspectors recognized the important observations and recommendations of the Subcommittee on Antimicrobial Susceptibility Testing of the NCCLS which recommended that daily controls no longer be required after a series of consecutive observations had shown acceptable results (157). Thus, without any change in the federal regulations, the implementation gradually became modified in accord with observation and careful statistical assessment of the variability observed in practice. A chapter on quality control in the third edition of the ASM *Manual of Clinical Microbiology* in 1980 questioned the appropriateness of the CLIA 67-mandated quality control procedures and provided tables and recommendations for modifications in the frequencies of conducting these procedures (18). The chapter also introduced the need for recognition of issues beyond that of internal process control, such as the appropriateness and quality of specimen submissions. The recommendations were updated further in 1991 (99).

In 1983, the ASCP published a manual on clinical laboratory decision making similarly intended to influence physician use of laboratory services (26). This included a detailed discussion of the usefulness of the extent of work performed, transport problems, the use of the direct smear, aspects of anaerobic infection, and culture and handling of specimens from various body sites. Also included was a detailed assessment of indications for antimicrobial susceptibility testing and reporting of results. In 1985, the CAP conducted a conference on the role of the clinical microbiology laboratory in cost-effective health care. This consisted of a broad reassessment of the appropriateness of practices in all areas of clinical microbiology and provided a very sound basis of support for introduction of more cost-effective practices (27).

Both the CAP and the JCAHO began to introduce broader requirements in their inspection and accreditation procedures that went beyond the intralaboratory controls mandated by the federal regulations. The result was introduction of requirements for monitoring the accuracy of transcription of doctor's orders, control of delay in transport, and assessment of the quality of specimens. Because of accumulating concern about unnecessary quality control of commercially prepared, ready-to-use culture media, the NCCLS established a subcommittee to develop cost-effective recommendations for quality assurance of culture media. The Proposed Standard was published in 1985 and the Approved Standard was finalized in 1990 (157). On the basis of surveys conducted by the CAP of about 350,000 lots of media, it was apparent that only media for the isolation of pathogenic *Neisseria* spp. and *Campylobacter* spp. required retesting by users. Guidelines were provided for the manufacturers for testing of most of the other commonly used media. Thus, purchasers of those common types of media would not be required to retest them if the NCCLS-recommended procedures had been conducted and satisfactory performance had been established by the manufacturer. Users who purchased other, less common types of media for which the subcommittee did not establish guidelines for testing would be required to conduct their own quality control to establish appropriate performance. Shanholtzer and Peterson reported that they had noted deficiencies in a number of common types of media that were exempted by the NCCLS recommendation from continued user quality control (193). Despite their report, there appears to be acceptance of the subcommittee's recommendations by the HCFA and CAP.

Sullivan reported on the complexity of factors contributing to the performance of culture media (209). He hoped that the recommendations of the NCCLS would not lead to neglect of both the quality of media and improvement in methods for assessing its performance.

Wong and Nelson (239) remarked on the studies of Finn et al. (84) in which it was reported that 73% of physician orders were judged inappropriate. Wong and Nelson also commented on the "plethora" of quality indicator data being induced by institutions seeking to comply with JCAHO standards.

Reactions of pathologists and laboratory scientists. Woo et al. questioned how much of the improvement in laboratory performance could be ascribed primarily to proficiency testing and how much was a result of advances in instrumentation, availability of specialized reagents, entry of better-qualified personnel, improved data handling, and improved sensitivity, specificity, and precision (241). They questioned whether expansion and increased cost of proficiency testing programs would be truly cost-effective in terms of health care benefit. They gave attention to the issue of clinical use of laboratory data and the need to reexamine whether variations in precision and accuracy that might be considered unacceptable for proficiency testing purposes might not in fact have any significant bearing on patient care. Most of this discussion related to analytical chemistry, but the issue is perhaps more relevant to clinical microbiology.

Howie, in the president's address to the Association of Clinical Pathologists in 1970, expressed what he thought "medical microbiology" ought to be and to become if it is properly to serve the patient, the community, and the body of medicine (107). He emphasized the consultative role of the microbiologist in providing rapid interpretation of Gram stain data. He stated that consultation was an essential function of the microbiology laboratory: "Otherwise they will be submerged under a rapidly rising tide of ill considered requests leading to diminishingly useful reports which may not be understood even if read" (107).

In 1974, Bartlett drew attention to the need for more cost-effective and clinically relevant microbiologic practices and a broader approach to quality assurance (14). This included submission of inappropriate specimens and specimens of poor quality. The concept of evaluating sputum on the basis of the relative numbers of squamous cells and neutrophils was introduced. Shortly thereafter, Murray and Washington (154) and Van Scoy (221) reported on the procedure. In 1977, Heineman et al. reaffirmed the need for evaluation of the quality of sputum specimens (100). Various other approaches were reviewed by Bartlett et al. in Cumitech 7 in 1978 (32). More recent comparative studies of methods for sputum evaluation were reported by Mizrachi and Valenstein (151), Lentino and Lucks (135), and Wong et al. (240).

In 1975, various aspects of quality control in clinical microbiology were addressed at a seminar conducted by the Eastern Pennsylvania branch of ASM (16). The question of

the cost-effectiveness of the quality control effort was gaining increasing attention. In 1977, Bartlett described in some depth what he perceived to be appropriate and cost-effective processing and reporting strategies (17). The concept of cost-effectiveness was poorly understood at that time and still required elaboration by Doubilet et al. as late as 1986 (74).

Paris described efforts in the New York City Medicaid system to monitor utilization of laboratory testing and attempt to control rising costs (164). The program disallowed reimbursement of laboratories for tests deemed medically unnecessary. This led to a legal conflict in which it was held that the laboratories could not be denied reimbursement for tests ordered by health care professionals. It was clear that refusing reimbursement of laboratories was not an effective way to control physician test utilization. Carlson reported in 1977 that laboratory improvement programs might represent 10 to 15% of the operating cost of laboratories (58). He suggested that publicly supported programs were more expensive than those conducted by professional organizations and that the charges for publicly supported programs were misleadingly low in that the true cost was supported by public taxation.

Skendzel assessed the use of laboratory tests by physicians in 1978 and found that 80% of test requests were clinically justified (195). In 1979, Nyiendo and Kilbourn expressed the need for standardization of the numbers of colonies to be assessed as potential enteric pathogens in stool specimens and concluded that it was not cost-effective to evaluate more than two colonies of identical morphologic appearance (160). The same conclusions were applied to urine specimens. For assessment of carriers of enteric pathogens in stool, at least 16 colonies would need to be evaluated. In 1979, Barr drew attention to the need to give more consideration to the clinical benefit of the extent of workup which was being applied to some specimens (9).

In 1979, Bartlett et al. described a program for staining and evaluation of replicate smears for purposes of monitoring the interpretive skills of medical technologists (39). In 1980, Bartlett and Rutz described a detailed cost analysis of the effect of applying control to the assessment of the quality and extent of work performed on specimens of lower respiratory tract secretions, wound exudate, cervicovaginal exudate, and urine (37). The labor expended on these specimens was reduced by 19% through the control measures. This represented a total cost reduction of $42,000 per year.

There was growing concern among the clinical laboratory community that many of the controls required by federal regulations were time-consuming and costly to perform and did not yield a commensurate patient care benefit. In some cases it was apparent that thousands of dollars of expense might be incurred for detection and prevention of a single deficiency. In the minds of most informed laboratory scientists, this far exceeded the probable patient care benefit of the procedure.

In 1982, Bartlett et al. reported on an extensive evaluation of quality control practices in their laboratory (38). One hundred eleven surveillance procedures applied to 54 different operations were evaluated. One hundred of these had been performed in the laboratory between 1965 and 1980. Ninety-one of the procedures had been conducted at least 50 times. Sixty-seven percent of the CLIA-mandated procedures detected deficiencies at one time or another for a mean deficiency rate of 3.5%. Eight control procedures not mandated by CLIA which these authors introduced consistently displayed deficiencies with a mean frequency of 8.8%. Termination of quality control procedures required by CLIA which had not yielded deficiencies in this laboratory would have reduced cost by about $3,000 per year. Another $2,000 of saving was projected through application of certain surveillance procedures only to new lots of media and not each batch. The quality control program had constituted 5% of the total cost for operating the laboratory.

In 1982, Bartlett reported in a three-part series recommendations for making optimum use of the microbiology laboratory. This included assessment of appropriate specimen submissions and evaluation of specimen quality (21–23). Limitations in the processing and production of useful information from urine, respiratory, wound, and cervicovaginal exudate specimens were discussed. Also reviewed were appropriate performance and reporting of antimicrobial susceptibility test results. In 1982, Bartlett reviewed reporting practices that would optimize effective handling of specimens and requests for consultations from physicians for processing of specimens of questionable value (25). The report included an assessment of the predictive value of the Gram stain relative to culture for identification of pathogens. Limitations of workload accounting in microbiology were addressed along with suggestions for space planning. In 1980, the Council on Scientific Affairs of the American Medical Association published a manual intended to provide guidance to clinicians in the more discriminating use of laboratory services (19). This manual included a discussion of microbiology, parasitology, and antimicrobial susceptibility testing.

Merrick reviewed in 1982 features of a microbiology quality control program which would include guidelines for quality assurance of specimens (149). This included specimen labeling and transportation, monitoring of the adequacy and appropriateness of specimen submissions, and evaluation by direct microscopy. He included recommendations that would improve handling of specimens from the female genital tract, feces, and wound cultures.

Wong and Lincoln reviewed irrational test ordering practices in 1983, recommending that algorithms be constructed to replace what they called folkloric protocols (238). They illustrated the problem with illogical and inconsistent test ordering protocols for hepatitis. Lachner (127), Speicher and Smith (206), and Wong (237) addressed the need to apply scientific methods to establishing probabilities that would justify test ordering.

Isenberg addressed the compromises to be made between academically complete microbiologic assessment of specimens and the extent of work that could be justified to provide cost-effective information for patient care (108). He questioned whether increased emphasis on medically relevant practices would significantly contribute to reduced health care costs and quoted a personal communication from Ferraro claiming that only 1% of the Diagnostic Related Group (DRG) dollar was being consumed by microbiology services. Ferraro emphasized the importance of reducing labor and supply costs and introducing rapid methods selectively to control laboratory cost (82, 83). Washington also addressed this point and reviewed other aspects of more cost-effective microbiology laboratory use, including evaluation of the quality of specimens (227). He reviewed the increasingly available numbers and types of screening tests and questioned whether the predictive value was good enough to assume that the results could be accepted as reliable rapid methods for influencing diagnosis and treatment. He emphasized the need for discriminant antibiotic reporting that would not encourage the use of newer, more

expensive agents when older drugs would suffice. Also, he suggested that the cost of identification and susceptibility testing of large numbers of isolates from mixed infections, especially anaerobic infections, could not be justified.

Winkelman (235) and Woo et al. (241) addressed the issue of the cost of quality control. They grappled with the definition of the term cost-effectiveness. They referred to the previous work of Tydeman et al. (in 1981), who had found that the time spent on quality control activity was relatively constant such that it would constitute a larger percentage of total activity in smaller laboratories (217). Up to 30% of laboratory budgets in large laboratories were thought to be expended on quality control. Woo et al. (241) also provided clear definitions of cost-effectiveness and made reference to changing practices that had reduced cost and improved the health care benefit of quality control activity. In a report based on a survey of laboratory management data, Bartlett found that time spent on quality control activity in microbiology varied from 5% in laboratories with 15 or more employees to 20% in laboratories with fewer than 5 employees (24). Bachner also addressed economic implications of quality control activity and readdressed the need to apply controls to all phases of the cycle of ordering, collecting, and transporting specimens and interpreting reported results (8). He expressed that these phases of testing had "not received a great deal of attention" but that they had considerable potential for "producing harm to the patient." Bachner also addressed the problem being presented by the trend toward point-of-care testing.

Von Seggern described an antibiotic-monitoring service that saved over $100,000 a year by replacing the use of expensive third-generation cephalosporin antibiotics with the use of more economical therapy. Pharmacists called physicians with recommendations on the basis of specific in vitro susceptibility test results (223). Campo and Mylotte examined the use of microbiologic reports by physicians in prescribing antimicrobial agents (56). They found no significant difference in the proportion of treatment regimens that were considered appropriate before and after culture results were known.

In 1988, Watts discussed nine steps involved in the generation and application of test results in diagnosis and treatment (229). He discussed factors leading to physician ordering of tests and issues that affect the predictive value. He recommended greater use of establishing the pretest probability of disease and supported such guidelines as had been developed by the American College of Physicians (169). Cunha et al. reported on cost-effective utilization of microbiology data (66). Although attention usually has been focused on overutilization problems, underutilization also has been given attention. Bates and several of his associates (42–44) and Makadon et al. (142) have reported on underutilization of blood cultures, and Kramer et al. described delay in the diagnosis of tuberculosis in patients with human immunodeficiency virus infection because of lack of recognition of the risk of tuberculosis in these patients (125).

Voldish summarized the requirements of CLIA 88 for quality assurance in physician office laboratories (222). Pedler and Bint (166) reported on a survey of users' attitudes toward microbiology laboratory services which they viewed as a logical extension of quality assurance activity. They discovered expected objection to the gatekeeping activity imposed on obtaining service after regular working hours. Forty percent of respondents thought that the numbers of specimens submitted could be reduced, especially urine specimens. Bates and Lee described an algorithm for interpretation of the significance of positive blood cultures (44).

Koepke and Klee discussed the expanding use of indicators of outcome in quality assurance programs (124). They recommended that these be divided into four types, including data reliability, laboratory management, clinical utilization, and pathologist credentials. In an issue of the *Archives of Pathology and Laboratory Medicine* which was totally devoted to reporting the proceedings of a quality management symposium conducted by the CAP in 1990, Bartlett reported on the trend in QM toward introduction of quality improvement practices that would represent a substantial departure from previous QM styles (30). Previously, Berwick had addressed the need for continuous improvement in health care (47).

Expansion of QM Objectives

A broader approach to quality assurance was being applied to many aspects of health care by Donabedian in the 1960s (71, 72). It was not until the 1980s, however, that the classification of QM into categories of structure, process, and outcome became more widely understood. These concepts were widely espoused in education programs conducted by the CAP and the ASCP. Structure is the basis for any QM program. Structure consists of the buildings, personnel, standards, equipment, and reimbursement that assures the basic capability to provide quality care. Process is the action taken by all health care personnel in the course of providing patient care. Outcome is the ultimate benefit derived by the patient from exposure to the health care system. This could be increased longevity or quality of life in its ultimate sense. Studies of the benefit of such procedures as coronary bypass surgery in terms of long-term outcome have been conducted. It would seem clear that it would be very expensive and time-consuming to assess alternative modes of laboratory process in terms of long-term outcome. Not the least of the limitations would be the fact that no decisions could be made until patients had been followed for 5 to 10 years. The pressures for cost containment simply do not allow that type of time frame for decision making. A more immediate approach to assessing outcome would be a comparison of the length of stay or various aspects of morbidity. Alternative methods of testing or reporting may affect other treatments or interventions and the quality and cost of care. These approaches still present limitations in the amount of time and expense that can be applied to a comparison of alternative approaches to process. Time not normally available to personnel primarily committed to production must be provided. Specially trained personnel are required, and a carefully designed approach to comparison of matched populations of patients must be used. For example, we conducted a study of the effects of recommending antimicrobial therapy as a part of the microbiology laboratory report to assess whether use of the recommended therapy resulted in a better outcome than was obtained when the recommendations were not followed. After considerable expenditure of time and money, including the support of a full-time nurse research specialist, it was ultimately proved statistically inconclusive that use of the recommended therapy had any effect on the outcome (35).

The JCAHO began to introduce the requirement for monitoring of indicators in 1985 (111). An indicator was defined by the JCAHO as an aspect of process that may have a significant effect on outcome. The JCAHO has established 8 to 12 indicators to be monitored in anesthesia, obstetrics and

gynecology, cardiovascular medicine, oncology, and trauma. All of them are being subject to beta testing to determine with statistical confidence their relevance to outcome. So far, no laboratory indicator has been subject to sufficient testing to establish that it has relevance to outcome. In the meantime, laboratory scientists and pathologists should implement monitoring of at least two indicators to meet 1992 JCAHO accreditation requirements. The monitoring should enable observation of trends within the institution, the effect that various interventions have on the indicator, and comparison with data collected from similar monitoring in other institutions. The CAP Q-Probe program is an example of a focused application of an indicator to an aspect of process. It may be repeated with any frequency but differs from continuous monitoring. Howanitz and Steindel reported on experience with the CAP Q-Probe program (104, 105). Microbiology applications demonstrated a median TAT of 45 min for the Gram stain of a stat spinal fluid sample. More recent applications include a reduction of the percentage of single blood cultures and evaluation and improvement of the quality of sputum specimens. Also assessed is the mechanism for detection of errors and the percent detected (103, 224).

We are presented with the risk of becoming engaged in excessive expenditure of time and expense on monitoring of laboratory indicators, many of which ultimately may be proven to have no impact on outcome. We could repeat the experience of the 1960s and 1970s when numerous quality controls were required and religiously performed only to be found not to detect deficiencies or to be of no value in assessing the impact of laboratory service on the quality of patient care. Beyond the Q-Probe program, there is a need for systematic and well-conceived studies that will establish which indicators are most cost-effective for continued monitoring.

Practice guidelines and benchmarking. Laboratorians may expect to become more involved in the preparation of practice guidelines, and clinicians may find that such guidelines will more clearly define appropriate use of laboratory tests (136). Problems of both overutilization and underutilization need to be addressed. The JCAHO recently has added the option that practice guidelines may be among the indicators used to monitor the quality of care in accredited hospitals (112). The term benchmarking applies to a comparison of hospital or laboratory performance versus those of other institutions or laboratories. Indicator data may be collected to enable benchmarking (162).

Moving Toward Quality Improvement

Another approach to QM is embodied in the industrial term CQI (47, 65, 119, 120, 226, 231). This approach to QM completely restructures classical approaches to management authority and accountability of personnel. Emphasis is placed on training and doing things correctly the first time instead of using an elaborate monitoring program to detect deficiencies and correct them. The customer orientation of CQI is somewhat foreign to health care, where it has been unclear whether the patient, the doctor, or the payer is really the customer. In CQI, everyone in an organization is a supplier to some and a customer of others. This relationship is carefully examined in a CQI program which recognizes that most errors occur in the process of handing off the train of responsibility between steps in carrying out the function of the organization. Careless attitudes of workers toward one another in any system in which the outcome is dependent upon a large series of processing steps lead to delay and poor quality. CQI has been effective in establishing the high quality of Japanese automotive, electronic, and optical products as well as placing them in a competitive price position. American industry is now widely introducing CQI and is beginning to place pressure on health care organizations to do the same. Pedler and Bint have explored the usefulness of surveying user's (customer's) attitudes about microbiology laboratory services (166). JCAHO is introducing specific requirements that will foster introduction of CQI in health care organizations. It may be anticipated that as industries bear an increasing share of the burden to finance health care cost, they will bring great pressure to bear on health care organizations to introduce CQI to improve quality and control the expense.

CURRENT APPROACHES TO QM

Organizational Structure for QM

The preceding pages have reviewed the history and evolution of thinking about approaches to QM over the last 30 years. The remainder of this report will consist of a review of current QM practices in clinical microbiology. Although the director should bear primary responsibility for management of quality, a committee composed of the director and others in the department who have been delegated responsibility for QM usually is established. In our laboratory, the director expends about 5% of time on QM. About 2% of the time of personnel in the laboratory is allocated to QM. Previously, Bartlett reported that the percentage of time allocated to QM activity in laboratories ranged from 4 to 10%, with the larger percentage being observed in the smallest laboratories (24). Some laboratories may find it necessary to obtain research funds to support staff to conduct studies to establish the usefulness of newer unestablished QM functions.

A committee can establish what will be monitored, the frequency of observation, and the acceptable range of results. Kardex files are convenient for keeping track of items to be monitored, acceptable results, and the observations that are made, along with the corrective action. Computers can be programmed to provide the same documentation. It will be useful to classify the data collected into four groups: (i) surveillance that is not performed or is performed late, (ii) deficiencies detected, (iii) corrective action, and (iv) evidence that previously applied corrective action was not effective in preventing recurrence of a deficiency. These data may be reviewed by the committee and recommendations may be made for corrective action. In our experience, it is best to focus on failure to apply corrective action or corrective action that has been repeatedly applied but fails to prevent future errors. Typically, a report is prepared by the director of the microbiology division to be sent to the director of the Department of Pathology and Laboratory Medicine for review and comment and forwarding to the hospital QM committee.

An occurrence that does not follow a standard procedure is documented in most laboratories and is usually called an incident report. These include safety infractions and injuries. Incident reports provide another set of observations independent of systematic surveillance. We have grouped incidents as follows.

A. Source of error
   1. Physicians
   2. Nursing unit personnel

3. Department of Pathology (nonmicrobiology) personnel
4. Outside laboratory personnel
5. Division of Microbiology personnel

B. Type of occurrence
1. Ordering
2. Processing of requests
3. Collection of microbiology specimens
4. Collection of nonmicrobiology specimens
5. Transport of microbiology specimens
6. Transport of nonmicrobiology specimens
7. Initial processing
8. Testing
9. Reporting
10. Interpretation
11. Diagnosis and treatment

We have established a means of collecting commendations for outstanding performance that are the opposite of incident reports. These recognize personnel for exceptional performance.

CQI

Problems are identified and CQI teams are established to identify causes, develop alternatives, and propose solutions. CQI teams in our laboratory have addressed such problems as the increasing number of incidents on the processing bench and improved orientation for new employees, including the development of an orientation manual.

The team is composed of representatives from all involved groups: the director, the manager, supervisors, technologists (full-time and part-time, day and evening) for each section, and a clerk. The active participation of all involved groups in the decision to obtain the solution helps to maintain their involvement and cooperation in the implementation phase. The process has been reviewed in detail by Berwick. It requires skillful facilitation by persons trained in CQI technique, "brainstorming," flowcharting, statistical analysis, and monitoring of corrective action (48).

CQI places emphasis on meeting the expectations of customers. Although this has been surprisingly neglected in the past, Lee and McLean in 1977 (134) and Ackerman et al. (1–3), both in Australia, reported on efforts to analyze how clinicians interpreted laboratory reports. The information was used to make improvements in reporting. Similar customer-oriented studies were reported by Pedler and Bint (166) and Phillips et al. (172).

Expanding the Spectrum of Observations and Corrective Action

In the mid 1970s, we and others began to expand QM to a far broader aspect of process than had been applied previously. The spectrum of activities began with monitoring the appropriateness of ordering testing of various types of specimens by physicians (15). This included monitoring both inappropriate requests for processing and specimens that were inappropriate for the processing that was requested. The potential to significantly improve patient care and reduce cost has not gone unquestioned. A large reduction in testing volume is required before actual decreases in laboratory costs occur because of the large amount of fixed cost involved in the operation of hospital laboratories (236). Hartley et al. concluded that control efforts would be worthwhile only if the cost of the test exceeded $100 (98). There is a profound conviction among the members of our infectious disease service that control of specimen submission, the quality of specimens, and the relevance to infection of the information reported have a direct bearing on errors in diagnosis and treatment, morbidity, the cost of therapy, and the length of stay. We have actually wondered whether the greater saving from application of controls to specimen submission and processing might be in patient care rather than in the laboratory itself.

We addressed unnecessary duplication and excessive frequency of orders and transport problems such as lack of time of collection, excessive transport time, use of improper and leaky containers, and incomplete or conflicting labeling. We established methods to assess the quality of sputum and other types of specimens when received in the laboratory. Others also have addressed the usefulness of processing specimens of sputum, feces, and spinal fluid depending on the quality of these specimens and the tests requested (4, 53, 135, 153, 183, 194, 221, 240, 246). Numerous studies have been reported by others, and these have been reviewed by Robinson (182). The converse problem, that of underutilization, should not be ignored.

Physician Ordering

Beginning about 1968, Bartlett introduced the practice of requesting consultations from physicians with him, a pathology resident assigned to microbiology, or a fellow before certain types of specimens would be processed. These tests included culture of mouth, bowel content, vomitus, lochia, colostomy drainage, decubitus ulcers, perirectal abscesses, pilonidal sinuses and abscesses, Foley catheter tips, periurethral catheter-associated exudate, inanimate objects (not approved by the infection control committee), cervical or vaginal specimens without specification of the clinical condition (vaginitis, endometritis, surgical wound, or sexually transmitted disease), and stool for culture and for parasites from patients hospitalized for more than 5 days. The consultation requested more clinical information to justify processing. The number of consultations requested in 1986, the number of clinician requests received, and the number for which processing was completed are displayed in Table 1. Consultations also were requested for processing contaminated respiratory or wound exudate specimens (on the basis of the presence of squamous epithelial cells) and for processing specimens when the smear displayed a large number of bacterial morphotypes (suggesting that a mixed culture would occur). Also included were specimens of exudate containing two or more isolates not all of which were observed in the direct Gram-stained smear. When more than three isolates were found in any specimen, regardless of quality, consultation was requested for complete processing. When atypical isolates not readily identifiable were isolated from sites open to contamination and colonization, consultation was requested. Urine specimens containing less than 10^5 bacteria per ml may be associated with infection, but consultation to determine the value of complete identification and susceptibility testing was requested. Consultation was requested to determine whether recollectible specimens should be processed or be recollected when no time of collection was recorded or when the transit time exceeded 2 h. Specimens received at night, for which consultation with the resident is required for processing, were held if the resident had not been consulted and another request for

TABLE 1. Results of requests for physician consultation before processing specimens or cultures,[a] Hartford Hospital, 1986

Reason consultation requested for further processing	No. of requests	No. of clinician responses	Processing completed (no. of specimens)
Clinical information needed	46	10	5
Contaminated sputum	775	10	4
Contaminated wound exudate	100	5	2
Smear suggests mixed culture	274	20	5
Mixed culture, incomplete ID[b]	274	3	1
More than three isolates	300	10	5
Atypical isolate	456	18	10
$<10^5$ bacteria/ml, urine	1,278	8	4
No time of collection	183	136	70
Delay >2 h	46	30	25
Received at night	137	20	15
Mixed urine culture	5,475	91	50
Duplicate specimen	137	3	2
ID or AST[c] not repeated	228	1	1
Total no. (%)	9,709 (10.1)[d]	365 (3.6)[e]	199 (56)[f]

[a] Total specimens, 96,000.
[b] ID, identification.
[c] AST, antimicrobial susceptibility testing.
[d] Percentage of total specimens.
[e] Percentage of clinician responses.
[f] Percentage of responses resulting in complete processing..

consultation was issued. Urine cultures containing more than one isolate in numbers exceeding 10^5/ml were considered most likely contaminated, and consultation was requested for processing. In the meantime, the specimens were held at 4°C and were discarded after 1 week if no consultation was initiated by the clinician. Duplicate specimens were not processed without consultation. Complete identification was not performed on isolates appearing identical in daily sequentially submitted specimens, but consultation was requested to determine whether this was needed. Similarly, susceptibility testing was performed on only the fifth day when the same isolate was observed in sequentially submitted specimens unless the requested consultation resulted in a justifiable request for more frequent testing. Thomson et al. found it necessary to repeat testing of daily sequential isolates of coagulase-negative staphylococci and *Pseudomonas aeruginosa*, but an elapse of 3 days between sequential isolates of members of the *Enterobacteriaceae* and *Staphylococcus aureus* was acceptable (213). Consultation also was requested for culture of spinal fluid for mycobacteria or fungi when the fluid contained no cells. During 1986, requests were issued for consultation regarding further processing for 10.1% of all specimens. Requests were received from physicians 3.6% of the time for further processing. Further processing was conducted 56% of the time (Table 1). In the majority of cases when such calls were received, it was possible to convince physicians that the processing of specimens would not produce useful information. Sometimes it was agreed to inoculate the cultures and discuss the results the next day. Invariably, clinicians would agree on the next day that no further processing was indicated. Systematic studies to determine whether the requests for such consultations had any effect on the frequency of subsequent submission of poor-quality specimens were not conducted.

An interactive computer-based ordering system also could contribute substantially to control of these problems. A list of specimens of inappropriate types could be provided on a test selection screen, and a response could be automatically provided that such specimens are not appropriate and that consultation with the microbiologists or pathologist is indicated. The system would not accept such a submission. Clearly, some physicians would attempt to subvert the process by submitting the same specimen under an acceptable name. A truly sophisticated system would be able to detect the fact that a previous attempt had been made to submit the specimen under an inappropriate name. Subsequent isolated efforts to submit specimens of inappropriate types using appropriate names could not be as easily detected. The system could provide a message when duplicate or daily sequential submissions are attempted. An interface with a computerized medical record or pharmacy system could enable further checks on inappropriate submission. Future pressures for cost containment should easily provide justification for development and implementation of such systems. This will require physicians to order all laboratory testing directly without the intermediary of an order book and a unit secretary. Presently, most physicians would view this method as a nuisance. An interactive ordering system also could provide much assistance to the ordering physician such as suggestions for tests not considered for a given set of alternative diagnoses and rapid summaries of previous testing in a graphic display. It will be necessary to gain the support of physicians in the use of an interactive ordering system.

Urine cultures. Urine specimens for culture represent the largest-volume specimen type received in most laboratories. Specimens are easily collected by a noninvasive process, and this leads to a substantial potential for overordering. Manek and Rees examined the usefulness of culturing urine from patients with indwelling catheters (144). They found that results were only occasionally instrumental in affecting diagnosis or treatment, and they recommended that cultures be performed only in the presence of fever or septicemia and that this be marked on the request slip. Damron et al. (67) criticized the incomplete isolation and identification of mixtures of species present in urine from patients with indwelling catheters in nursing homes. In a letter to the editor, Bartlett suggested that it might be more cost-effective to establish profiles of common organisms and their antimicrobial resistance in individual homes to guide therapy in such patients (29). Worman remarked in 1987 on the excessive ordering of urine cultures from patients with no signs or symptoms of urinary tract infection (245). We are not aware of reports of other efforts to actually control the number of urine specimens submitted for culture.

An algorithm for criteria to support the ordering of a urine culture was established in our region in a program initiated by a peer review organization under contract with Medicare in 1983. The criteria were reviewed and approved by a panel of infectious disease physicians and urologists. The intent was to review patient records and detect instances in which urine cultures were ordered but were not justifiable on the basis of the criteria. Studies were conducted among six hospitals in the greater Hartford, Conn., area. About 50% of the urine culture orders did not appear to be supported by the criteria. The chief executives of the hospitals were notified of the observation and were asked to implement corrective action. It was indicated that the review would be repeated in 6 months. When this was brought to the attention of several committees in our hospital, there was no immediate suggestion for feasible corrective action. After 6 months, the study was repeated by the peer review organization and

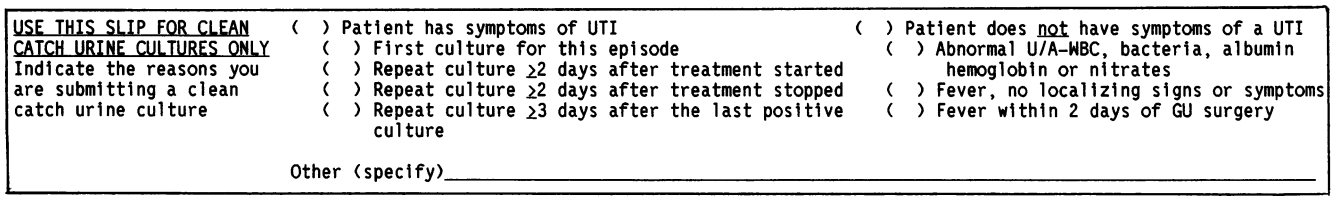

FIG. 1. Questionnaire attached to requisition slips for submission of urine specimens for culture. The questionnaire requests identification of clinical criteria to support the submission. UTI, urinary tract infection; WBC, leukocytes; GU, genitourinary.

the same frequency of orders that could not be supported by the criteria was found. Corrective action again was requested of the chief executive officers of the institutions involved. Nothing specific was done, and the peer review organization turned their attention to other matters.

One of us (R.C.B.) decided to conduct a study of this problem in our hospital in 1984. We reviewed the criteria with full-time members of the medical staff responsible for direct supervision of house staff, infectious disease staff, and house staff from the Department of Medicine. There was unanimous agreement that the criteria were appropriate. We indicated to house staff that urine specimens for culture would be refrigerated and that the medical record would be reviewed to determine adequate criteria to support the request. A number of cases in which the criteria could not be found were quickly detected, and the house staff were called by one of us (R.C.B.) to further assess criteria to justify the order. In several cases it was apparent that the criteria were not met, but in most instances the reaction of the house officer was that, in his judgment, the specimen should be processed. There ensued a widespread reaction of indignation among house staff in the Department of Medicine that created such an unfavorable climate that one of the authors (R.C.B.) offered to terminate the project. The project did not function long enough to show any change in the number of urine culture submissions.

Four years later, in 1988, the project was reinstituted with the same criteria. The criteria were again reviewed with staff in the Department of Medicine, infectious disease physicians, and medical house staff. A questionnaire was attached to requisition slips used for submission of urine for culture from medical care units (Fig. 1). Specimens received without completed questionnaires were not processed, and the patient care units were notified that resubmission would be required. Subsequently, 300 specimens were processed from medical care units. No questionnaire was received for 84 specimens and repeat submissions were requested. For the 214 specimens that were accompanied by questionnaires, the appropriateness of the request was confirmed by chart review for all but 26 specimens. Review with the physician by the nurse coordinator established that the criteria existed for 15 of these but they had not been documented in the medical record. Only 11 cases (5%) in which the appropriate criteria were not documented by chart review or interview with the physician were detected. Bartlett was unable to obtain the support of the staff physicians assigned to supervision of the house staff to review the appropriateness of the orders in these 11 cases. They indicated that internal quality assurance measures adopted by the Department of Medicine had preempted available time for such an activity.

We concluded from this study that agreed-upon criteria to support urine culture requests might be missing from 12% of patient charts and that house staff should appreciate that more complete documentation should be provided. We suggested that additional external surveys of ordering practices could be anticipated and that corrective action introduced by third-party payers might adversely affect reimbursement.

Studies of this type should be conducted in other institutions because the criteria for collection of urine cultures are basic and relatively uncontroversial. A successful outcome will depend on an institution-wide commitment to such a project, including the support of the directors of clinical as well as laboratory services. House staff who order urine cultures inappropriately more often than others should be educated and be subject to a penalty if their practices do not improve.

Another benefit of this project has been the adjustment of the house staff to the need to complete a questionnaire justifying ordering of a laboratory test. Clearly a more receptive response was shown in 1988 than the one we experienced in 1984. Although house staff have been reluctant at times to complete the questionnaire, and often have expected nursing personnel to answer the questions, we believe this is a useful precedent for future studies of laboratory utilization in our hospital.

A crude cost analysis was conducted to determine whether an ongoing program of this type would reduce the cost of processing urine culture specimens including the cost of completing the questionnaires and reviewing the justification. One plan would require physicians to continue to complete the questionnaires. The specimens would be held in the laboratory and would not be processed until the appropriateness review had been completed. This would have to be done in no more than 1 hour so that significant delay in diagnosis and treatment would not result.

There would be a substantial added cost over simply processing all specimens without screening for appropriateness. We thought that the added cost might be less if specimens were not collected until the review process had been completed. This would require educating unit secretaries not to process orders until the review had been completed and the appropriateness of the order had been established. Also, an additional step, requiring the secretary to notify the laboratory that a culture had been ordered, would be added.

We found that at least 50% of the orders would have to be inappropriate for either plan to break even. We conclude that the review process will be cost-effective only when applied to a test which is substantially more expensive to perform than a urine culture or when there is a very high percentage of inappropriate requests.

Blood cultures. Bates et al. (42–44), Makadon et al. (142), Sox (205), and Neu (159) have reported on the use of blood cultures by clinicians. Makadon et al. reported a failure to discriminate which patients should be cultured because those with evidence of septicemia were not cultured about 10% of the time whereas patients with marginal evidence of

septicemia often were unnecessarily cultured (142). Gross et al. reported on unnecessary ordering of blood cultures and reduced the volume by one-half with an annual saving of over $8,000 (93). Collection of single cultures continues to be a problem (190). Blood culture systems have improved in sensitivity, but manufacturers have taken advantage of this by progressively reducing the volume of broth in culture bottles and sample size of blood collected. A range of recommended numbers of blood culture collections and volume of blood to be collected from patients suspected of bacteremia is found in the publications of various authorities. Aronson and Bor recommended two to three collections of at least 10 ml each for a total of 20 to 30 ml (6). Reller et al. recommended in Cumitech 1A that two 10- to 20-ml collections be made over a period of 24 h for a total of 20 to 40 ml (179). Washington and Ilstrup found a 38% increase in positive cultures when 20 ml was collected instead of 10 ml and that a 61% increase occurred when 30 ml was collected (228). Arpi et al. found 17% more positive cultures when 13 to 16 ml was collected versus 6.5 to 8 ml (5). Most authors also recommended that the total blood volume be collected either by two separate venipunctures at one bedside visit or with three separate venipunctures, the third being encountered at a later separate bedside visit.

We investigated the numbers of collections and volume of blood collected at Hartford Hospital. The Bactec NR660 system was in use. Each collection consisted of submission of one aerobic broth (7A) and one anaerobic broth (8A) bottle, each containing 30 ml of broth. Each bottle was supposed to be inoculated with 5 ml of blood. The hemoglobin concentration of the mixture of blood and broth in the bottles was determined for patients whose peripheral blood hemoglobin concentration had been tested on the same day that the blood cultures had been collected. The following formula was used to determine the amount of blood inoculated into each bottle: amount of blood = $30R/1 - R$, where R is bottle hemoglobin concentration/patient's peripheral blood hemoglobin concentration.

We intended to determine the cost of collecting additional blood for culture and relate this to any increase in detection of clinically septic episodes (CSE). A CSE was defined as a period during which blood specimens were collected that was separated by at least 24 h from another period of blood culture collections. Also, we would determine the delay in making additional collections and the potential impact on initiating treatment. Twenty-four bottles were sampled at random for hemoglobin concentration during February 1991. The mean volume of blood inoculated was 3.85 ml, with a range of 2 to 6.2 ml. For CSE during July, August, and September 1990, only one collection was conducted during 20%, double collections during 67%, and triple collections during 13% of episodes (Fig. 2). Thus, 20% of patients had only 7.7 ml of blood collected per CSE, and the majority of patients had a total of 15.4 ml of blood collected.

We decided that an insufficient number of collections and/or total volume of blood was being collected and that an attempt should be made to modify blood culture ordering through educational conferences and a laboratory newsletter. Consideration was given to authorizing three collections regardless of how many were ordered. This idea was rejected by medical staff representatives, who thought that the number of specimens to be collected should be dictated by the clinician.

Between 1 January and 31 May 1990, charts were reviewed for 293 patients who had CSE. No order was found for 25% of the blood cultures that were collected. In another

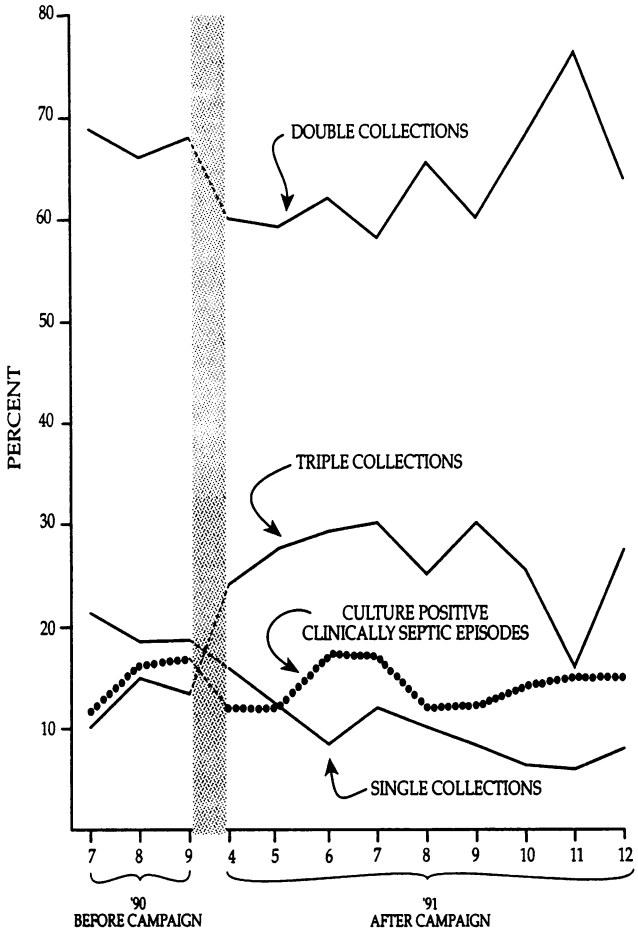

FIG. 2. A decline in single blood culture collections and an increase in triple blood culture collections occurred after an educational campaign was conducted at Hartford Hospital.

20% the signature of the ordering physician was illegible. Letters were sent to the ordering physician for 160 patients who had only one or two collections, including a reprint of the newsletter article recommending that three collections would optimize detection of bacteremia and inquiring why only one or two collections had been conducted. Sixty-nine responses were received. Most thought that one or two collections were enough. Some responded that therapy had to be initiated before additional cultures could be collected. A cartoon printed on pink paper was posted on all nursing units urging triple collections. This type of display to attract attention to important issues had previously proven effective. Despite these educational efforts, house staff and attending staff queried at random frequently responded that they had heard or read nothing about recommendations for blood culture collections.

Blood culture collections were monitored between April and December 1990 to determine whether blood culture collection practices had changed (Fig. 2). An increase in triple collections from 13 to 26% was significant, as was a decrease in single collections from 20 to 10% ($P < 0.05$). There was no change in the percentage of culture-positive CSE. The overall number of CSE increased, as did the numbers of blood specimens collected during the period of the study.

TABLE 2. Costs for collecting one, two, and three blood specimens for culture

Expense	No. of collections					
	1		2		3	
	Time (min)	Cost[a]	Time (min)	Cost	Time (min)	Cost
Labor						
Collection	12.5	$3.40	13.5	$3.65	23	$6.80
Processing	8.6	$2.34	17.2	$4.68	25.8	$7.02
Broth bottles		$2.16		$4.32		$6.48
Total cost ($)		$7.90		$12.65		$20.30

[a] Labor cost, $0.27/min ($16.33/h).

The variable cost for collecting and processing blood cultures was determined and is displayed in Table 2.

During the entire period of this study, of 1,931 CSE in which a third collection was made, only 87 positive cultures were obtained. Review of the medical records of these patients indicated that in 48 instances the culture result altered management and was considered clinically significant. The cost for detection was as follows: $20.30 × 1931/48 = $816.65.

The delay in conducting the third collection was determined for 42 CSE during which there were three collections (Table 3). In 13 instances, the time given by the phlebotomist was the same for all three collections (31%). For another 13 episodes, the third collection was within 15 min of the first two collections (31%). By 1 h, the third collection had been conducted in 28 instances (67%), and by 5 h it had been conducted in 37 instances (88%).

Insufficient blood was being collected in our hospital for detection of bacteremia based on published recommendations. An educational campaign was successful in increasing the number of collections and the volume of blood collected. The effect of the campaign persisted for at least 6 months after the educational effort was terminated. Although there was no increase in the percentage of culture-positive CSE, 48 of 87 CSE in which only the third collection was culture positive were of diagnostic and therapeutic significance. We believe that these results support the need for the increased number of collections and volume of blood collected. A substantial increase in the number of suspected CSE occurred during the period of this study. There is a general sense in our hospital that an increasing number of patients is predisposed to septicemia. This heightened awareness may have led to increased ordering of blood cultures for patients with a more marginal risk of septicemia. This could have offset the increase that might otherwise have occurred in the total number of culture-positive CSE resulting from the increased use of triple collections. The use of an algorithm may improve the appropriate use of blood culture and deserves further investigation and potential implementation as a means of improving cost-effective use of the procedure. There were no physicians' orders for 25% of blood cultures. These were either collected by house staff who forgot to write an order or initiated by nursing staff as a part of a comprehensive protocol for managing patients with signs and symptoms of sepsis. These are recognized problems independent of the objective of this study.

TABLE 3. Delay in collecting third blood specimen for clinically significant bacteremic episodes

Delay (h)	No. of episodes	%	Cumulative %
0	13	31.0	31
0.25	13	31.0	62
1	2	4.8	67
2	2	4.8	72
3	5	12.0	84
4	1	2.4	86
5	1	2.4	88
9	2	4.8	93
15	1	2.4	96
23	2	4.8	100

We could not demonstrate whether the $817 expended to detect the etiology of a bacteremic episode produced a commensurate saving in patient care. It would seem a small expense in consideration of the cost of antimicrobial therapy, especially if directed at bacteremia without isolation of a specific organism. Most of the time the third collection was made with little delay so that initiation of therapy was not prolonged. Anecdotally, when the third collection was delayed by more than 1 h, it turned out that immediate initiation of therapy had not been clinically indicated. In no instance was therapy initiated before the third blood culture collection.

Establishing the bacterial etiology of bacteremia greatly increases reimbursement based on DRGs. The reimbursement for urosepsis is $2,611, that for urosepsis with septicemia is $4,035, and that for septicemia with *E. coli* is $6,148. Cost-effective utilization of laboratory testing may include increased use as illustrated in this report, not always a decrease in utilization. Similar results were reported by Thomson et al. (214).

Duplication and daily sequential submission. A number of factors may contribute to submission of duplicate specimens for testing on the same day or excessive testing on sequential days. More than one physician is frequently involved with management, and redundant orders may be written. If there is doubt that a specimen has been submitted, it is sometimes easier to order and collect another. Anxiety over the progress of the patient understandably may contribute to unnecessary daily collections, but the true indications for daily collection are exceedingly rare except for blood culture collections. Collection of a better-quality specimen should not be viewed as duplication, although, as will be reviewed later, recollection of poor-quality specimens more often results in submission of another poor-quality specimen than a good-quality specimen. A decision may be made to collect a specimen by a more invasive procedure on the same day or on a sequential day following collection of a specimen by a more superficial procedure. This often yields a specimen which is less likely to be contaminated and is more likely to yield the pathogens involved in an infection. None of these should be considered inappropriate submissions. Ordering by persons other than physicians can contribute to the problem. Frequently, medical students and nurses (including nurse practitioners) are given authority to collect and submit specimens. Often the submission is supposed to be countersigned by a physician. Often the countersigning is forgotten. Laboratory information systems (LIS) should be introduced to monitor the frequency of duplicate submissions and daily sequential submissions for common specimen types such as sputum and urine. The LIS can issue a request for consultation with the microbiologist when duplicate submissions of specimens other than blood are received or when more than

TABLE 4. Duplicate submission of specimens before and after educational campaign

Specimen type	No. (%) of duplicate submissions	
	Sept. 1990[a]	Apr. 1991[b]
Urine, straight catheter	2 (0.8)	8 (3.0)
Urine, clean catch	8 (1.5)	6 (1.3)
Urine, closed catheter	4 (0.8)	16 (4.5)
Sputum, expectorated	20 (12.4)	4 (2.5)
Tracheal aspirate	8 (3.5)	4 (1.7)
Stool	10 (12.7)	4 (5.9)
Wound exudate	6 (2.4)	2 (1.0)
Total	58 (3.0)	44 (2.9)

[a] Total specimens, 1,943.
[b] Total specimens, 1,537.

three blood specimens for culture are received in one day. This also could be applied to daily sequential submissions. We are not aware that any LIS currently available performs these functions. The LIS can provide printed tables of duplicate and daily sequential submissions by listing the ordering physician and patient care unit. We collected data on the submission of duplicate specimens and daily sequential submission of specimens of urine collected by clean catch and from closed drainage systems, respiratory secretions collected by expectoration, stool, and wound exudate. Our staff has been informed that the duplicate specimen of these types will not be processed without consultation. Detecting duplicate specimens is not an automatic feature of our LIS. The technologist must observe that two or more duplicate specimens submitted on the previous day have been processed. Further work is performed on only one, although technologists sometimes overlook the duplication and report work on duplicate specimens. We receive calls from clinicians for about 2% of requests for consultation for processing duplicate specimens.

The number and percentage of different types of specimens representing duplicate submissions for the months of September 1990 and April 1991 are shown in Table 4. Table 5 shows the daily sequential submissions of different types of specimens for September 1990 and April 1991. An educational campaign was conducted between September 1990 and April 1991 by reviewing the problem at two educational conferences attended by a minimum of 24 house officers. In addition, the issue was addressed in a laboratory newsletter distributed to all medical and house staff. We identified 101 occasions on which duplicate or daily sequential submissions occurred. The laboratory had requested consultation for processing of the duplicate specimens, but no response to the request had been received in any of these cases. We sent letters to the physicians in 50 of these instances to determine the rationale for the submissions. For the other 51 instances, there was no order ($n = 36$), the order was illegible ($n = 3$), or the patient had been discharged and we elected not to attempt to pursue the ordering rationale ($n = 12$). The letter provided a brief summary of our concern about duplicate and sequential submissions and asked whether the submission had been ordered intentionally and/or was medically indicated. Seventeen responses were received, and in practically all instances ($n = 13$) the response indicated that the order had been both intentional and medically indicated. (The remaining responses were negative to the questions of whether orders were intentional [$n = 1$] and clinically needed [$n = 2$] or there were no responses to the questions in three and two instances, respectively.) This was despite the fact that in no instance had physicians responded to our request for consultation for processing the duplicate specimens at the time they were received. We did not aggressively pursue the nonresponding physicians to determine whether a similar opinion would have been expressed. The number of duplicates decreased somewhat between September 1990 and April 1991, but the change was not statistically significant by the χ^2 square test (Table 4). Increases in duplicate submission of some types of urine specimens actually occurred. The submission of daily sequential specimens decreased significantly, however, for all types of specimens except tracheal aspirate ($P < 0.0001$) (Table 5).

TABLE 5. Daily sequential submission of specimens before and after educational campaign

Specimen type	No. (%) of daily sequential submissions	
	Sept. 1990[a]	Apr. 1991[b]
Urine, straight catheter	18 (7.3)	6 (2.3)
Urine, clean catch	42 (7.8)	22 (4.8)
Urine, closed catheter	74 (17.0)	22 (6.2)
Sputum, expectorated	15 (9.3)	2 (1.3)
Tracheal aspirate	20 (8.9)	34 (14.7)
Stool	14 (12.6)	8 (11.8)
Wound exudate	26 (10.5)	6 (3.0)
Total	209[c] (10.8)	100[c] (6.5)

[a] Total specimens, 1,943.
[b] Total specimens, 1,537.
[c] $P < 0.0001$.

Contrary to the previously described activity encouraging more blood culture collections (see above), submission of duplicate specimens on the same day for most specimens of respiratory or wound exudate, urine, and other body fluids does not seem clinically indicated without consultation. Thus, the annual cost of $4,935 for processing duplicate specimen submissions in 1990 (Table 6) would appear to be medically unnecessary. More controversy may surround indications for daily sequential submission of specimens. No doubt these are necessary for patients whose clinical picture is changing rapidly, but in many instances these submissions represent excessive utilization. One letter of response indicated that . . . "it is the policy to collect sputum specimens every three days." We know of no published clinical support for such a routine practice. We believe that almost all of the sequential closed-catheter and stool submissions were of questionable clinical value. The clinical indications for the others would have to be assessed by chart review, possibly by one or more members of a review committee.

The cost of these resubmissions was investigated. The direct cost for processing urine specimens is very low. The charge for all specimens is about three times the direct cost (Table 7). Charges reflect not only allocation of costs from other hospital departments but cost shifting. The true cost to the institution lies somewhere in between these values. If testing is eliminated, fixed costs remain unchanged, but the smaller numbers of tests reduce the base for recovery of costs from other cost centers. The complexity of accomplishing true cost reductions by decreasing test utilization has been discussed earlier in this report.

Table 6 illustrates the additional cost and charges that result from the duplicate and daily sequential submissions. Using values for September 1990, the overall direct cost

TABLE 6. Annual costs and charges for duplicate and daily sequential submissions, Hartford Hospital

Specimen type	1990[a]		1991[b]	
	Cost	Charges	Cost	Charges
Duplicate	$4,935	$33,408	$2,711	$12,672
Daily sequential	$12,838	$60,192	$7,383	$28,800
Total	$17,773	$93,600	$10,094	$41,472

[a] Calculations made on basis of costs and charges in September 1990.
[b] Calculations made on basis of costs and charges in April 1991.

calculated for 1990 was $17,773 and the annual charges were $93,600. The decrease in duplicate and sequential submissions in April 1991 reduced these calculated annual costs and charges substantially.

Transcription of Orders

For a time the CAP Laboratory Accreditation Program checklist required that the laboratory monitor accurate transcription of physicians' orders onto laboratory request slips. This effort would involve matching laboratory request slips at random with physicians' orders to determine the frequency of errors in transcription. Although we have not conducted such surveillance, we have had a related experience involving transcription of orders. We instituted screening tests for both urine culture and urinalysis (urinalysis is performed in microbiology at Hartford Hospital). The complete procedure would be performed only when the screening test was positive. If the physician ordered the conventional "urine culture" or "urinalysis," a screening test would be performed. If physicians wanted a complete culture or urinalysis performed regardless of screening test results, they were instructed to order "Diagnostic culture" or "Diagnostic urinalysis." When physicians forgot to use the latter terminology but wished that the laboratory had performed the complete test, many of them instructed secretaries on patient care units who were responsible for filling out laboratory requisitions to request "Diagnostic culture" or "Diagnostic urinalysis" routinely regardless of what they had written in the order book. Review of 100 requisitions received for "Diagnostic" tests revealed that in the majority of instances the physician had written simply for "urine culture" or "urinalysis" in the order book. We undertook an in-service education program with the secretaries regarding accurate transcription of orders and attempted to educate physicians regarding the cost containment aspects of the use of screening tests and their predictive value. The problem gradually disappeared as physicians became accustomed to having the screening tests performed.

TABLE 7. Costs and charges for selected specimens, Hartford Hospital

Specimen	Cost	Charge
Urine, straight catheter	$3.35	$24
Urine, clean catch	$3.35	$24
Urine, closed catheter	$3.35	$24
Sputum, expectorated	$8.28	$24
Tracheal aspirate	$8.28	$24
Stool	$8.28	$24
Wound exudate	$8.28	$24

Specimen Collection and Transport

A CAP requirement is that the laboratory be responsible for written procedures for the collection of specimens by patient care unit personnel. The existence and accuracy of such documents should be monitored. We are not aware of studies of the accuracy of such transcription. Further attention will be given to this problem in the discussion below regarding the quality of specimens.

In our hospital, all microbiology specimens must display a collection time on the request slip, and no more than a 2-h delay in transit is accepted. The rationale for this is based in part on studies that were reported by Jefferson et al. (110). When this does not occur, a request for consultation for processing or submission of another specimen is issued. We have not found reports of attempts to control collection time. We have monitored the frequency of specimens with no collection time indicated and also those that displayed no collection time but were processed without request for consultation or resubmission because the omission was not observed in the laboratory. The number of such occurrences ranged from 1 to 15 per quarter, with a mean of 6. The problem peaked during the first quarter of 1989 and 1990 and declined for the rest of the year after the matter was reviewed at meetings in the microbiology laboratory. A more sophisticated computer reporting system would have prevented the processing of these specimens. Monitoring has also included the numbers of specimens with delays exceeding 2 h. During the last 5 years, over 90% of specimens have been received within 2 h. When clusters of longer delays occur, the matter is reviewed with the patient care unit supervisor. The most common problem unit in our experience has been the operating room, where specimens collected during surgery are more often delayed in transmission than those from any other patient care unit.

A survey was conducted over a 6-month period between February and June 1990 to determine how often specimens were received from various nursing units without a time of collection. A range of 0 to 19 incidents was observed per quarter, with a mean of 5. There was a steady decline after the first quarter of 1989, probably resulting from continuous in-service emphasis among patient care unit personnel. However, only 11 of 27 patient care units were implicated. An exact denominator to determine what percentage of all specimens submitted the data represented was not available, but the total number of specimens was probably in the range of 30,000. The data suggest that less than 1 in every 1,000 specimens is submitted without a collection time. Despite this small number, we conducted an in-service education session on the units that submitted the largest number in the first survey. Six months later, a marked reduction was observed for such submissions from that unit, but the total showed an increase of 30%. Four units showed an increase and another four units showed a decrease in the number of submissions without a collection time. This does not appear to be enough of a problem in our hospital to warrant continued monitoring, but it may require study and corrective action in other hospitals. If adherence to the requirement for submission of collection time is not monitored at least intermittently, there is a chance that the practice could deteriorate, risking loss of specimen quality and requiring a major educational effort to correct.

Numerous opportunities for error exist in the transportation of microbiology specimens to the laboratory. Improper containers may be used, containers may leak, adherence to universal precautions may be violated, time of collection

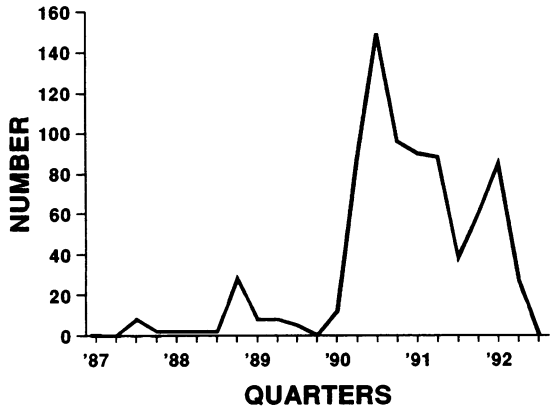

FIG. 3. The number of incidents of delay in transit of specimens, use of inappropriate and leaky containers, and improper labeling of specimens increased abruptly in 1990 at Hartford Hospital. Action taken later in both 1990 and 1991, including in-service education by a laboratory-nursing service liaison committee, corrected the problem.

may not be given, or the transit time may exceed an established limit. There may be errors in labelling both requisition slips and specimen containers. Errors in any of these cases in our hospital typically result in the generation of an incident report. Monitoring the frequency of such errors also constitutes a useful indicator of probable outcome. A marked increase in such incidents occurred in our hospital in the beginning of 1990. This problem and the data displayed in Fig. 3 were referred to a laboratory nursing service liaison committee for discussion and corrective action. In-service programs were conducted during the latter part of 1990 and the beginning of 1991. It appeared that the problem was trending downward until another upward spike occurred at the beginning of 1992. Again, the liaison committee was consulted and in-service programs were resumed. We have not attempted to estimate the cost of the intervention and whether the reduction in collection incidents justifies that cost or reflects a commensurate increase in patient care benefit. Empirically, we believe that this is an effective monitoring and QM procedure.

Evaluation of Quality of Specimens

On the basis of Gram-stained direct smear. The Q score is a reflection of the relative numbers of neutrophils and squamous cells seen in the direct smear. There are numerous reports of methods for quantifying these cells and of comparisons between different systems (15, 28, 32, 62, 135, 154, 219, 240). Some type of evaluation procedure was being used in two-thirds of laboratories in 1978 (62). Neutropenic patients may not demonstrate neutrophils in sputum smears despite pneumonitis. If any squamous cells are found in specimens from such patients, the specimen is likely to yield growth of colonizing bacteria that are unrelated to infection. Therefore, most quality evaluation systems may be applied appropriately to specimens from these patients. We do not culture specimens yielding quality scores of zero or less. A message requesting resubmission is sent both by phone and in writing to the patient care site. The specimen may be held for 7 days pending any justifiable request for processing. The examination of the smear should include a search for bacteria and reporting of the types only when neutrophils are seen and there are few squamous cells.

Q-score reproducibility. Beginning in 1986, we determined the percent agreement among the numbers of squamous cells, neutrophils, and the Q score for sputum and wound exudates in the technologist's original report with the results of a randomly selected repeat interpretation conducted by doctorate and supervisory staff. The results ranged from 80 to 90% in 1986 to a gradual decline into the range of 80 to 85% in 1990. Enumeration of squamous cells and neutrophils and a resultant Q score can be established with a high degree of accuracy and reproducibility.

Sources of Poor-Quality Specimens

Lower respiratory tract. A survey of the number of contaminated sputum specimens submitted from patient care units over the period 1 July to 29 September 1990 was conducted. Contaminated specimens were defined as those containing more than 25 squamous cells per ×10 field and <10 leukocytes per ×10 field. No written procedure was found in the nursing procedure manual for collection of respiratory tract secretion specimens. These were written by our nurse coordinator and were submitted to the nursing service for incorporation into their procedure manual. In addition, procedures were written by our nurse coordinator for collection of tracheal aspirates from both intubated and nonintubated patients. After the procedures were approved and distributed by nursing staff, our nurse coordinator conducted in-service education in proper collection. Subsequently, another survey was conducted to assess improvement.

Surveys of the quality of sputum specimens submitted were conducted for the 37 patient care units in our hospital over five quarters during 1990 and 1991. During the first two quarters, the data included tracheal aspirates. The mean percentages of poor-quality specimens submitted were 8 and 7% for these periods. The range was 0 to 40%. The means for the first three quarters of 1991 were 25, 25, and 24%, respectively, with a range of 0 to 100%. These data included only expectorated sputum specimens. In-service education was conducted on three units displaying the largest percentage of poor-quality specimens during the second period; no decrease occurred subsequently. Flournoy et al. reported on surveillance of sputum quality in a Veterans Administration medical center. They found specimens of the best quality to be collected from patients in intensive care units. A wide range in the acceptability rate of specimens, extending from 70% to as low as 30%, was observed (86).

Wound exudate. Of 775 wound exudate specimens reviewed, only 5 were contaminated by squamous cells, for an incidence of 0.6%. This low incidence was unexpected and indicated that technique for collection of wound exudate was very good and required no corrective action.

Patient care unit sources of poor-quality sputum specimens and clean-catch urine specimens that yield mixed cultures are monitored quarterly in our laboratory. The percentage of poor-quality sputum specimens and that of clean-catch urine specimens yielding mixed cultures are calculated at the end of each quarter. This is used as a guide in conducting in-service education on nursing units.

Resubmitted specimens. We were interested in whether resubmission of wound exudate or sputum adjudged of poor quality on the first submission produced a second specimen of better quality. Table 8 indicates that 16 of the 38 resubmitted poor-quality sputum specimens and 10 of the 14

TABLE 8. Specimen quality[a] in sequential submissions

Type of specimen	Quality level	No. of second specimens of given quality				
		Q0	Q1	Q2	Q3	Total
Sputum	Q0	16	7	8	7	38
	Q1	7	8	9	13	37
	Q2	2	13	13	17	45
	Q3	4	8	16	97	125
	Total	29	36	46	134	245
Wound exudate	Q0	10	2	1	1	14
	Q1			1	1	2
	Q2			3	3	6
	Q3	1		1	15	17
	Total	11	2	6	20	39

[a] Values for squamous cells and neutrophils: 1 to 10 squamous cells per ×10 field = −1; 11 to 25/×10 field = −2; >25/×10 field = −3; 1 to 10 neutrophils per ×10 field = +1; 11 to 25/×10 field = +2; >25/×10 field = +3.

resubmitted poor-quality wound exudate specimens were again of poor quality. Conversely, the majority of good-quality sputum specimens (97 of 125) and wound exudate specimens (15 of 17) were of good quality on resubmission. These observations suggest that specimen quality is reproducible, good or bad, and that little is accomplished by resubmitting specimens that are of poor quality to begin with. It might be effective to recommend that physicians review clinical signs and symptoms of infection before perpetuating the effort to recollect specimens when poor-quality specimens are obtained. Reimer and Carroll reported that most of the patients from whom poor-quality sputum specimens were obtained had minimal clinical evidence of pneumonia (178).

Self-Assessment of Accuracy of Smear Interpretation

Beginning in 1987, we prepared sets of direct Gram-stained smears for which the culture results were known. It has been the practice in our laboratory to differentiate types of gram-negative rods into three categories: *Pseudomonas aeruginosa*, enteric bacilli, and small pleomorphic coccobacilli suggestive of *Haemophilus influenzae* or *Bacteroides* species. When gram-positive cocci are seen, the report "suggests" the presence of streptococci or staphylococci. Large gram-positive rods are reported as "*Bacillus* or *Clostridium* species," and small gram-positive rods are reported as "*Corynebacterium*." The intent was to determine how well technologists could suggest the appropriate organism category from the direct Gram-stained smears. Accuracy of identification of *Pseudomonas aeruginosa* was 60% for the first survey conducted in 1987 but improved progressively to over 80% in 1988 and 1989 until a decline was observed in 1990. We believe this correlated with an increase in the number of untrained personnel and indicated a greater need for in-service education in interpretation of Gram-stained smears. Enteric bacilli are easier to categorize correctly, and the accuracy for these ranged from 80 to 100% throughout the period of the survey. Accuracy of identification of the "*Bacteroides-Haemophilus*" group also has remained in the 90 to 100% range since 1987. Accuracy of identification of staphylococci has never been less than 80% and usually has been in the 90 to 100% range. *Streptococcus pneumoniae* in sputum specimens had been correctly recognized 80 to 100% of the time during most of the survey but fell to 50% early in 1990. This was during a period of intensive training of new employees. The accuracy reached 90 to 100% later in 1990. *Neisseria* sp. recognition always has fallen in the 95 to 100% range but dropped to 50% early in 1988 and resulted in more intensive in-service emphasis on recognition of this group of organisms. There have been insufficient numbers of slides containing *Clostridium*, *Bacillus*, and *Corynebacterium* species and others to assess any trend in the accuracy of their identification.

Gram-stained smears from specimens from which the same morphotype of organism is grown in culture are collected in our laboratory. During each quarter a study set of five to eight slides is reviewed by all technologists responsible for reading and reporting Gram-stained smears. For each slide, results are tallied and the percent accuracy is calculated, assuming that the culture results are correct. The study set is available for the technologists to reexamine.

Predictive Value of Smear Interpretation

Beginning in 1986, we correlated the results of reports of organism categories in direct smears of randomly selected specimens with the results of cultures from the same specimens. The technologists' results for neutrophils and squamous cells, Q score, and organism categories were compared with the blind examination of the same smears by senior staff. The numbers of false-positives, false-negatives, and true-positives for both the technical and the senior staff were determined. It was not possible to calculate true predictive value data for several reasons. Some smears contained no bacteria and others contained three or more categories. A true-positive was defined as a Gram stain identification category that agreed with the organism that was isolated. A false-positive result was the reporting of a category of bacteria that was not isolated in culture. A false-negative result was the failure to observe in the smear a category of bacteria that was isolated in culture. We could not calculate the actual number of true-negative observations. Thus, an index representing the numbers of true results divided by the number of false results (true-positives/false-positives plus false-negatives) was derived. The analysis was applied to respiratory secretions and wound exudates. Approximately four of each were selected at random per week.

Discrepancies in Gram stain interpretation and culture results were reviewed by the supervisor with individual technologists when these were detected. Similarly, discrepancies in interpretation by doctoral or supervisory staff and the original report of the technologist were reviewed with the technologist involved. The trend of the "true result" index since 1986 has been progressively upward, ranging from 0.5 during 1986 and 1987 to 1 to 2 in 1989 to 1990. The accuracy of the doctorate and supervisory staff has been monitored in parallel with the accuracy of technologists' interpretations. Generally, the two groups have shown slow but steady improvement in accuracy. Occasionally, there would be conspicuous differences in the accuracy of technologist interpretations for certain categories of bacteria in the smears compared with the results of interpretations by doctorate staff and supervisors. Although these differences probably were not of statistical significance, they provided a basis for some friendly competition between the technologists and the doctorate and supervisory staff. It was especially good for morale when the accuracy of the technolo-

gists' performance appeared to exceed that of the doctorate and supervisory staff.

Detection of Contaminated Specimens Based on Culture

A survey of the number of contaminated clean-catch urine specimens submitted during five quarters in 1990 and 1991 was conducted. The existing nursing procedure for clean-catch urine collection was antiquated and cumbersome. Our nurse coordinator recommended changes in the procedure (which were implemented) as well as modifications in the materials used which should have made it more convenient and less time-consuming for unit personnel to properly collect specimens.

Contamination was defined as two or more species present in numbers of $\geq 10^4$ to 10^5/ml. The percentage of contaminated specimens decreased from 27 and 30% during the first two quarters to 24, 22, and 23% during the last three quarters. This trend downward was found statistically significant by the chi-square test ($P < 0.0001$). The percentage of contaminated specimens ranged from 0 to 100% on different patient care units. In-service education was conducted by the nurse coordinator during the beginning of the third quarter. Intensive sessions were held on six units with a history of submitting the highest percentage of contaminated specimens. Four of the six units educated showed a decrease in the numbers of contaminated specimens during the next quarter. Three of the units continued to submit fewer contaminated specimens for two consecutive quarters. One of the units continued to submit large numbers of contaminated specimens. Revision of instructions for patients and nursing personnel and updating of collection materials in conjunction with an in-service education program conducted by a nurse under the direction of laboratory staff was successful in improving the quality of clean-catch urine specimens and should be a recommended QM practice in all hospitals.

Cost of Recollection of Poor-Quality Specimens

Some microbiologists believe intuitively that it is too costly to request recollection of poor-quality specimens, both for the patient care service and for the laboratory. The potential for reduction in laboratory cost resulting from elimination of unnecessary testing or testing of poor-quality specimens was discussed earlier in this report. We have not found reports comparing the cost of processing all specimens with the cost that results from use of controls that require recollection of poor-quality specimens. It has been our judgment, and the collective opinion of physicians on our infectious disease service, that the saving in the cost and quality of care justifies the cost of the control procedures, including recollection of poor-quality specimens. The saving results from reduced errors in diagnosis and treatment, reduction in morbidity, and reduced length of stay. A one-month sample of both sputum and urine specimens was assessed to determine the cost of our program. The number of specimens found acceptable for culture was determined, as was the number that were reported to floors with requests for recollection or consultation for processing. The cost of recollection on nursing units was calculated. The cost of processing a specimen with complete identification and susceptibility testing of isolates, as well as the cost of providing an abbreviated report based on the gross morphology of growth on the culture plates, was determined. This project was conducted in conjunction with the management engineering department at Hartford Hospital. A complete copy of the cost accounting is available.

The direct cost of processing sputum specimens with controls on processing was $8.57, and that without controls was $9.29. Controlled processing was less costly by $0.72 per specimen ($9.29 to $8.57). The cost for processing urine specimens with controls was $3.20 versus a cost of $3.23 without controls.

The cost for processing urine specimens with and without controls was about the same despite the added cost for requesting recollection and conducting recollections on the nursing units. The main reason for the reduced cost, despite the added expense for the controls and recollection, is the reduction in the overall numbers of isolates that are subject to complete identification and antimicrobial susceptibility testing. The poor-quality specimens contain a larger number of isolates on the average than the good-quality specimens. The study confirms that the use of controls does not impose an added cost on the laboratory. Other studies should be conducted to determine the impact on patient care of processing these and other types of specimens with and without controls. We believe that controlled processing of specimens is an important contribution of the clinical laboratory to more cost-effective health care. It should be widely promoted in educational programs fostering improved laboratory practices and should increasingly be the expectation of regulatory agencies assessing laboratories for high-quality performance.

Intralaboratory Process

Errors in processing. Early in 1991, an average of 20 incidents per quarter occurred in which specimens were improperly processed. This represented only about one every 4 days, but each occurrence was frustrating and annoying to clinicians. Examples included failure to conduct all of the tests that were requested, failure to inoculate all of the media that were required for the tests that were requested, performance of the wrong test, etc. Here no benchmark or a threshold seems acceptable, and zero error is the goal. Later in 1991, a quality improvement team was established to examine in critical detail all of the steps involved in processing of specimens. The activity was flow charted, and its complexity was far greater than anyone had appreciated. Many aspects of the pathway were revised especially to reduce the numbers of "handoffs," an expression used by Berwick to describe the continuity of process as it passes from one person to another (48). Later in 1991, the number of such incidents had become reduced to one-third of that observed early in 1991.

Monitoring the performance of personnel, equipment, and reagents. The organizational approach for establishing items to be monitored, the frequency of such monitoring, and the recording of observations was reviewed at the beginning of this section. Table 9 lists the items that were scheduled for surveillance but for which the surveillance was delayed or did not occur on some occasions. Surveillance was delayed or overlooked for 36 (42%) of the 85 items scheduled for surveillance. The percentage of these oversights of the total number of scheduled surveillances was small, 0.8%, but such oversights affect so many items that it is as important to monitor these delays or omissions in surveillance as it is to detect the deficiencies themselves. Delayed or omitted monitoring most commonly reflected failure to clean equipment, including refrigerators, centrifuges, laminar flow cabinets, and a balance. Failure to calibrate pipettes was common, as

TABLE 9. Items scheduled for monitoring but not monitored or monitored late, Hartford Hospital Microbiology Laboratory, 1986–1992

Item	No. of components	Scheduled frequency[a]	Function monitored	Total no. of surveillances scheduled	No. (%) of surveillances not done or done late
Equipment					
Yellow iris	1	d	Run controls, maintenance	8,382	214 (3)
Room temp	2	d	68°F (±5) (20°C)	3,650	42 (1)
Incubator CO_2	2	w	5% (±2)	520	6 (1)
CO_2 tank	2	d	Content	4,380	89 (2)
Automated ELISA[b]	3	D	Clean	4,380	2 (0.04)
Automated ELISA	3	D	Conduct maintenance	4,380	27 (0.6)
Pipettor	1	w	Check vol dispensed	260	8 (3)
Roller drum	2	w	Check rotation	520	1 (0.2)
Laminar flow	5	d	Check flow dial	8,380	128 (2)
Laminar flow	5	w	Clean	1,197	60 (5)
Incubator	12	m	Clean	1,152	98 (0.7)
Refrigerators	8	2y	Clean	96	29 (30)
Freezers	5	m	Clean	336	41 (12)
Centrifuges	9	w	Clean	234	38 (16)
Microscopes	16	d	Clean	8,030	207 (3)
Anaerobic chamber	1	d	Conduct maintenance	8,160	52 (0.6)
Pipettes	1	2y	Calibrate	4	1 (25)
Bactec	2	d	Conduct maintenance	2,190	121 (6)
Autoclaves	2	d	Date record	3,120	20 (0.6)
Hot air oven	1	d	Date record	1,560	5 (0.3)
Balance	2	y	Clean	12	3 (25)
Spore test	1	m	Determine killing	144	2 (1)
Personnel functions (blind unknowns)	6	d	Obtain expected result	6,738	22 (0.3)
Reagent					
MIC trays	50	w	Obtain target MICs	15,600	127 (0.8)
MIC tubes	4	w	Obtain target MICs	1,248	18 (1)
Tissue culture	14	m	Check appearance, viability, contamination	8,400	35 (0.4)
Tissue culture media	2	w	Record results	208	3 (1)
Catalase	1	d	Expected reactivity	1,460	11 (0.8)
Indole	1	d	Expected reactivity	2,190	32 (2)
Oxidase	1	d	Expected reactivity	2,190	33 (2)
Coagulase	1	d	Expected reactivity	1,460	7 (0.5)
Bile solubility	1	w	Expected reactivity	312	3 (1)
Yeast kit	1	2y	Identify stock cultures	60	2 (3)
Gram stain	8	m	Identify cells and bacteria	576	75 (13)
Gram stain reagent check	1	w	Proper staining of bacteria	104	5 (5)
Antigens/antisera	18	4y[c]	Expected reactivity/specificity	360	2 (0.6)
Total					1,575 (0.8)

[a] d, daily; w, weekly; m, monthly; y, yearly; 2y, twice yearly, etc.
[b] ELISA, enzyme-linked immunosorbent assay.
[c] Frequency estimated. Actually performed on each new lot.

were failures of day shift personnel to evaluate proper interpretation of the Gram stain and urine sediments by personnel on a second shift. Items subject to surveillance that were always monitored on schedule are not listed in Table 9.

The number of deficiencies that occur would seem to be the most obvious indicator to monitor, but this is paradoxical. A low frequency of deficiencies suggests that the laboratory is very well run and that errors and deficiencies rarely occur. On the other hand, it may indicate that little monitoring is being conducted. One should look with suspicion on areas where deficiencies never seem to occur. As an element of managerial style, one of us (R.C.B.) likes to applaud personnel who detect deficiencies! His concern is much more with delays or failure to conduct surveillance, failure to apply corrective action, or failure to apply corrective action that prevents recurrence of a deficiency. The last of these is the most insidious. Personnel often record corrective action as "reviewed the problem with the technologist." Very often this will not correct the problem. Why was the error made and what specifically can be proposed to prevent recurrence? The most useful discussion that takes place at our QM meetings relates to review of corrective action that could have been predicted to be ineffective. All of these parameters are reviewed in meetings with our personnel to enable a complete perspective on QM to be presented.

Table 10 lists items that were monitored, the frequency of the monitoring, the number of surveillances that occurred, the detection of deficiencies, and the corrective action that was taken between 1986 and 1992. This review does not contain data collected prior to that date because a major change was made in the approach to collection and display of

data at that time. The process has entailed the monitoring of some 85 items. Some of the items listed included a number of components such as 12 incubators, 16 microscopes, 20 procedure books, etc., so that the actual number of units subject to surveillance was substantially higher. We have conducted 185,905 surveillances since 1985 and detected some 2,493 deficiencies for a deficiency rate of 1.3%. Sixty-six (78%) of the items demonstrated deficiencies. The items associated with the highest deficiency rates were failure to keep procedure books updated (17%), errors in the interpretation of Gram-stained smears by personnel on a second shift (15%), problems with controls for yeast identification (15%), malfunction in an automated urinalysis instrument (11%), and problems with a few types of media (casein, tyrosine, xanthine, Sabouraud agar, and VCNT medium). Our observations confirm the widely held empirical assumption that control results that exceed acceptable limits almost always reflect faulty control materials, not the reagents or equipment used in the procedure. Next most commonly, it reflects improper performance of the procedure, as was often the case in setting up proper inocula for antimicrobial susceptibility testing. But the performance characteristics of the reagents themselves or of culture media and equipment were rarely if ever responsible for the deficiencies appearing in quality control procedures.

Examination of Fig. 4 to 7 reveals some events that have occurred in QM in our laboratory over the last 5 years. Deficiencies peaked in the third quarter of 1987 when equilibration of inocula for antimicrobial susceptibility testing repeatedly exceeded control limits (Fig. 4). The peak in 1988 was caused by deficient media being received from a commercial supplier. The gradual upward trend between 1989 and 1992 reflected more attentive surveillance being applied to numerous operations. We do not believe that it represented a deterioration in the quality of performance.

Ineffective corrective action also peaked in the third quarter of 1987 when efforts to correct the deficiencies in equilibration of inocula for antimicrobial susceptibility testing were ineffective (Fig. 5). The second peak in 1988 was caused by shipments of defective media despite our complaints to the supplier. The problem was corrected by changing our medium vendor. The peak in 1991 was caused by a defective refrigerator which would not maintain an acceptable temperature range despite notification of our engineering department and their repeated efforts to improve its performance. The data confirming the ineffectiveness of correction action in such a case help to provide justification for the expense associated with the replacement of such a deficient piece of equipment.

Surveillance conducted late or not at all peaked in the fourth quarter of 1987 during the absence of a supervisor (Fig. 6). Failure to take corrective action on deficiencies that were detected also peaked at the same time (Fig. 7). Both were a reflection of a supervisor having been placed on a leave of absence without adequate delegation of responsibility to remaining senior personnel to assure perpetuation of QM functions. As soon as the problem was identified, administrative measures were taken to assign responsibility to appropriate remaining personnel. This corrected the problem, as is reflected in the downward trends shown in both Fig. 6 and 7. It is important not to apply undue significance to fluctuations in such data.

Revision of reports. Computer printouts are received from the Data Systems Department daily. Tuesday through Friday, the bacteriology technologists review the list for any preliminary reports not rendered within 2 days or no final reports within 5 days. The report is brought up to date when possible. For each quarter, the average number of delayed reports per day is reported to the QM coordinator.

The computer reporting system in use enables revision of reports. The revised version is printed below the previous version, and a message is printed indicating that the previous version has been revised. Daily computer-generated patient reports are screened by the microbiology clerks. Revised reports are separated and given to the bacteriology supervisor. The reports are reviewed by the supervisor and/or technologist and are coded according to the type of revision. The number of revised reports per day and the percentage of total reports are calculated, and these data are reported to the QM committee.

All reports containing such revisions are reviewed by the clinical coordinator, and the number and types of revisions are tabulated. Between 1986 and 1992, there was a mean of 2.4 revisions per day. A mean of 0.31 revision per day was unnecessary. These represented misuse of the reporting system procedure by the technologist such that an improper report was issued before it could be corrected. The error was detected on review of the report by a supervisor, and the technologist causing the incorrect report was required to revise it. The total number of revisions as well as the number of unnecessary revisions were above the mean value of 2.4 for 1986 to 1989 and below the mean for 1990 to 1992. Of special interest were the number of incorrect antibiotic susceptibility results reported. A mean of 0.35 such errors was made per day between 1986 and 1992, but the numbers were above that mean between 1986 and 1989 and below it during 1990 and 1992. The trend reflects educational effort to reduce revisions. The data provide positive reinforcement for personnel.

The need for a systematic method for monitoring errors in reporting has been addressed by the CAP Q-Probe program (106). A huge range in frequency of error was observed. Systematic methods must be introduced to detect errors. It is likely that most laboratories that perceive their rates of reporting error to be low have unrecognized significant error reporting rates.

TAT. An arbitrary goal was set to establish 30 min as the maximum time allowable for returning a report to the patient care unit after receiving specimens for stat urinalysis or stat Gram stain of a direct smear. (Urinalysis is performed in microbiology at Hartford Hospital.) TAT increased for urinalysis during 1991 (Table 11). This was a reflection of a large amount of downtime on an automated instrument in use for urinalysis that had greatly facilitated rapid reporting of urinalysis results. Declines in Gram stain TAT have been addressed in section meetings, but the problem is recurrent.

One of the few automated quality assurance aids provided by our computer reporting system has been the preparation of lists for accessions for which no preliminary report has been rendered within 2 days and no final report within 5 days. Between 1986 and 1992, delayed preliminary reports averaged 2.1 per day for each quarter, with a range of 1.3 to 4.1. The most recent data show a worsening of delay in preliminary reports, with the mean for the last four quarters at 3.3 per day. We have not viewed this as a serious problem. Most of these instances were considered unavoidable on review, and the number in itself is not alarming.

The number of reports not final within 5 days has been viewed as more serious and has gained more attention. The mean for such delays was 2.1 per day for the period 1986 through 1992. The mean was higher than 2.1 prior to 1989 and lower than 2.1 during the last 2 years. Rogers et al.

TABLE 10. Items monitored in Hartford Hospital Microbiology Laboratory, 1986–1992

Item	No. of components	Scheduled frequency[a]	Function monitored	Total no. of surveillances conducted	No. (%) of deficiencies observed	Most common problem	Corrective action
Equipment							
Densitometer	1	w	Calibration	104	1 (1)	Out of range	Recalibrate
Yellow IRIS[b]	1	d	Focus, dipstick reactions	1,080	123 (11)	Focus, dipstick reactions	Replace camera, dipstick controls
Water bath	3	w	Temp	312	20 (6)	Temp off	Adjust thermostat
Temp block	1	w	Temp	624	8 (1)	Temp off	Adjust thermostat
Room temp	2	d	68°F (±5) (20°C)	3,600	79 (2)	Out of range	Call engineering
Incubator CO_2	1	w	5% (±2%)	514	1 (0.2)	Tank leak	Replace tank
CO_2 tank	1	d	Content	4,291	4 (0.1)	Low content	Replace tank
Central alarm	1	2d	Operating	4,380	21 (0.5)	Battery, printer	Replace parts
Rotator	2	2w	Rotations per min	624	24 (4)	Out of range	Recalibrate
Automated ELISA[c]	3	w	Temp standardization	468	5 (1)	Out of range	Recalibrate
Pipettor	1	w	Vol dispensed	252	14 (5)	Out of range	Recalibrate
Roller drum	2	w	Check rotation	519	5 (1)	Out of range	Repair motor
Incubators	12	d	Check temp	18,997	174 (0.9)	Out of range	Adjust thermostat
Refrigerators	8	d	Check temp	16,936	180 (1)	Door left open	Keep door closed
Freezers	5	d	Check temp	9,480	57 (0.6)	Temp high	Defrost
Centrifuges	9	4y	Check rpm	216	3 (1)	Out of range	Recalibrate
Microdiluter	1	d	Vol dispensed	360	6 (2)	Out of range	Replace
pH meter	2	w	Calibration	260	1 (0.4)	Out of range	Replace electrode
Microscopes	16	d	Performance	8,030	8 (0.01)	Not focusing	Schedule maintenance
Anaerobic chamber	1	d	Routine maintenance	8,108	44 (0.5)	Leaks	Seal leaks
Pipettes	1	2y	Calibrate	4	0 (0)	Out of range	Replace
Bactec	2	d	Performance tests	2,069	71 (3)	Contamination	Replace needles
Autoclaves	2	d	Operation	3,120	15 (0.5)	Vacuum leak	Repair
Hot air	1	d	Operation	1,560	5 (0.3)	Out of range	Adjust thermostat
Balance	2	w	Calibrate	624	0 (0)	None found	
Spore test	2	m	Killing	142	0 (0)	None found	
Personnel functions							
Procedure books	20	y	Update	120	20 (17)	Not updated	Set higher priority
AST colony counts (MICs)	7	w	1×10^5–9×10^5	1,820	20 (1)	Out of range	Review procedure, repeat
AST colony counts (Vitek)	40	d	1×10^8–5×10^8	14,600	72 (0.5)	Improper prepn	Replace densitometer
Proficiency testing	20	4y	Performance	2,400	23 (1)	Unsatisfactory performance	Review processing, conduct in-service
Blind unknowns	6	d	Performance	6,716	377 (6)	Unsatisfactory performance	Review processing, conduct in-service
Gram stain reading	8	m	Bacteria, cell identification, second shift	501	74 (15)	Wrong interpretation	Review processing, conduct in-service
Reagents							
MIC trays	50	w	Obtain target MICs	15,600	127 (0.8)	Contamination	Repeat
AMS cards	50	w	Obtain target MICs	15,473	468 (3)	Out of range	Repeat test
MIC tubes	4	w	Obtain target MICs	1,230	18 (1)	Out of range	Repeat test
Cell cultures	14	w	Appearance, viability, contamination	8,365	46 (0.5)	Rounded cells, contamination	Replace cells
Positive and negative controls (*Clostridium difficile*, etc.)	3	d	Sensitivity, specificity	975	4 (0.4)	Nonviable	Replace controls, contamination
Cell culture media	2	w	Appearance, sterility	205	0 (0)	None found	
Aspergillus sp.	1	m	Growth at 47°C	72	6 (8)	No growth	Replace control
Hair penetration	1	4y	Penetration	24	1 (4)	No penetration	Replace control
Catalase	1	d	Reactivity	1,449	2 (0.1)	Nonreactive	Replace control
Indole	1	d	Reactivity	2,158	3 (0.1)	Nonreactive	Replace control
Oxidase	1	d	Reactivity	2,157	31 (1)	Nonreactive	Replace control
Coagulase	1	d	Reactivity	1,453	1 (0.1)	Nonreactive	Replace controls
Bile solubility	1	w	Reactivity	309	6 (2)	Nonreactive	Replace controls
Yeast kit	1	2y	Identification	52	8 (15)	Nonreactive, wrong identification	Replace controls
AMS cards	48	w	Obtain target MICs	14,976	228 (2)	Target not met	Result not reported
Gram stain reagent check	1	w	Proper staining of bacteria, identification	99	0 (0)	None found	Repeat with MICs

Continued on following page

TABLE 10—*Continued*

Item	No. of components	Scheduled frequency[a]	Function monitored	Total no. of surveillances conducted	No. (%) of deficiencies observed	Most common problem	Corrective action
Antigens/antisera	18	4y[d]	Reactivity/specificity	358	15 (4)	Out of range	Repeat
Control stocks	27	3y	Performance	486	0 (0)	None found	
Media[e]							
Sabouraud with chloramphenicol	1	2md	Inspect quality, pH	144	2 (1)	Contamination	Replace
Mueller-Hinton[f]	1	y	Ca + Mg concn	6	0 (0)	None found	
6.5% saline[f]	4	m	Growth of *Enterococcus* spp.	288	0 (0)	None found	
TCBS	4	2y	Growth of vibrios, pH	48	0 (0)	None found	
TSI	4	m	Correct reaction, pH	288	0 (0)	None found	
Urea	4	m	Correct reaction, pH	288	0 (0)	None found	
Sabouraud	1	m	Inspect quality, pH	72	5 (7)	Contamination	Replace
Potato dextrose	1	6y	Pigment product, pH	36	1 (3)	pH too low	Replace
Mycosel	1	m	Inspect quality, pH	72	1 (1)	Contamination	Replace
Oxacillin	1	w	MRSA[g] resistant	36	1 (3)	False susceptibility	Replace control
Brain heart agar	2	m	Growth of *Cryptococcus neoformans*	144	3 (2)	Contamination	Replace
Brain heart broth	2	6y	Growth of *Cryptococcus neoformans*	72	0 (0)	None found	
XLD	1	m	Inspect appearance, pH	72	3 (4)	None	
Anaerobic BAP	1	w	Inspect appearance, pH	312	10 (3)	pH	Replace
CNA	1	w	Inspect appearance, pH	312	4 (1)	Too soft	Replace
Blood agar	1	w	Inspect appearance, pH	312	3 (1)	pH	Replace
Anaerobic NV/KV	5	w	Growth of *Bacteroides fragilis*, pH	360	5 (1)	No growth	Replace control
TSA	3	m	Growth of control, pH	216	1 (0.4)	No growth	Replace control
BAP/MacConkey	1	w	Inspect quality, pH	312	10 (3)	pH	Replace
Casein	3	y	Correct reaction, pH	18	1 (6)	False-negative	Replace control
Xanthine	3	y	Correct reaction, pH	18	1 (6)	False-negative	Replace control
Tyrosine	3	y	Correct reaction, pH	18	1 (6)	pH too low	Replace
Anaerobic CNA	4	w	Growth of anaerobic controls	1,248	9 (0.7)	pH, dry, contamination	Replace
Skirrow's	5	m	Growth of *Campylobacter* sp.	360	2 (0.6)	No growth	Replace control
CYE	2	m	Growth of *Legionella* sp.	144	2 (1)	Poor growth	Replace control
Chocolate agar	3	w	Growth of *Haemophilus influenzae*, *Neisseria gonorrhoeae*	936	5 (0.5)	Poor growth	Replace control
CIN	5	m	Growth of *Yersinia* sp.	360	0 (0)	None found	
Glucose OF	3	3y	Oxidation-fermentation	54	1 (2)	Media too soft	Replace
Indole nitrate	6	4	Correct reactions	144	0 (0)	None found	
VCNT	3	2m	Growth of *N. gonorrhoeae*	72	6 (8)	No growth	Replace control
Miles[f]	5	6y	Growth of *Salmonella* and *Shigella* spp.	360	0 (0)	None found	
CYE selective	2	m	Growth of *Legionella* sp.	72	0 (0)	None found	
Brucella agar	5	m	Growth of *Brucella* sp.	180	0 (0)	None found	
TOC agar	4	m	Germ tube, chlamydospores	288	0 (0)	None found	
Yersinia[f]	3	44	Growth of *Yersinia* sp.	36	0 (0)	None found	
Total				185,905	2493 (1.3)		

[a] w, weekly; d, daily; m, monthly; y, yearly; 2d, twice daily, etc.
[b] Automated urinalysis instrument (International Remote Imaging Systems, Chatsworth, Calif.). Urinalysis is performed in microbiology at Hartford Hospital.
[c] ELISA, enzyme-linked immunosorbent assay.
[d] Estimated frequency. Surveillance actually conducted on all new lots of antigens and antisera and media.
[e] TCBS; TSI, triple sugar iron; BAP, blood agar plate; CNA, colistin-nalidixic acid; NV[T]/KV, neomycin-vancomycin/kanamycin-vancomycin; TSA, tryptic soy agar; CYE, charcoal-yeast extract; CIN, cefsulodin-irgasan-novobiocin; VCNT, vancomycin-colistin-nystatin-trimethoprim; TOC, Tween-oxgall-caffeic acid.
[f] Made in-house; other media purchased ready to use.
[g] MRSA, methicillin-resistant *Staphylococcus aureus*.

reported a mean TAT for bacteriology reports of 36 h from the time specimens are received to the time the report is issued. TAT from time of collection to reporting was 51.5 h (184).

Reports rendered on or after discharge of patient. Microbiologists may be astonished at the number of reports rendered on or after the day of patient discharge that are not seen by the patient's physician until the discharge summary

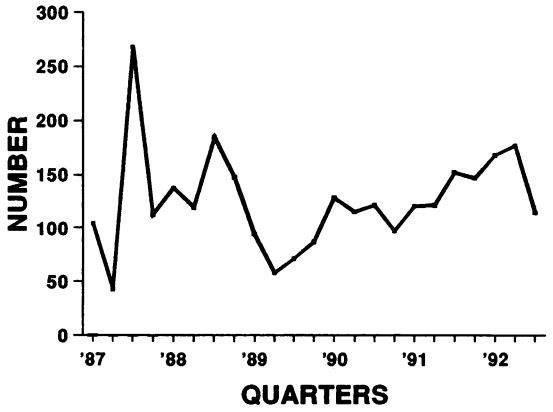

FIG. 4. Deficiencies peaked in the third quarter of 1987 when equilibration of inocula for antimicrobial susceptibility testing repeatedly exceeded control limits. The peak in 1988 was caused by deficient media being received from a commercial supplier. The gradual upward trend between 1989 and 1992 reflected more attentive surveillance.

is dictated. We are aware of a number of cases in which patients with significant infections were readmitted because the infections were not recognized at the time of discharge. We investigated this problem and discovered that 722 of 1,001 reports contained potentially significant information. We queried physicians about these reports. Responses were received only in 674 instances, but among these there was an indication that 90 of the reports (12.4%) contained significant information that could have affected discharge or management of the patient (34) (Table 12). As a result, it was possible to gain a higher priority for a change in the LIS. The change allowed for a copy of the report and a letter to be automatically generated and sent to the physician of record whenever a report was rendered on or after the day of discharge.

Placement of reports in the medical record. The laboratory is responsible for monitoring proper placement of reports in the medical record. We have conducted no systematic

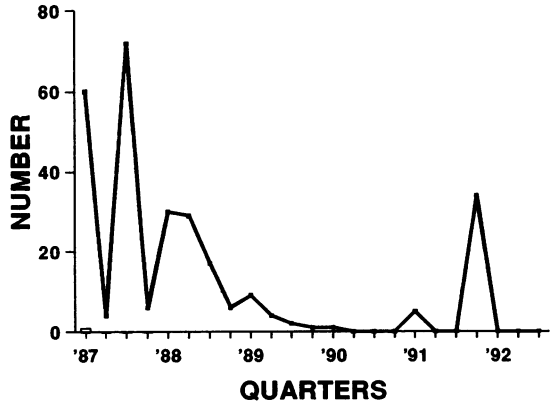

FIG. 5. Ineffective corrective action peaked in the third quarter of 1987 when efforts to correct the deficiencies in equilibration of inocula for antimicrobial susceptibility testing were ineffective. A second peak in 1988 was caused by shipments of defective media despite complaints to suppliers. The peak in 1991 was caused by a defective refrigerator despite efforts of the engineering department to repair the equipment.

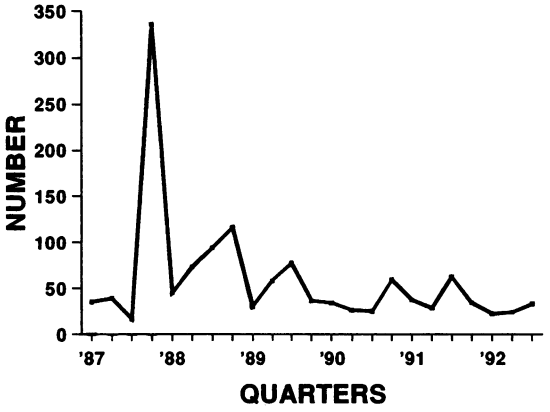

FIG. 6. Surveillance conducted late or not at all peaked in the fourth quarter of 1987 during the absence of a supervisor.

surveillance of this activity. The most frequent observation relevant to the microbiology laboratory is failure of unit secretaries to discard cumulative printed computer reports before replacing them with newer versions. Physicians may review older versions of hard copies and fail to note more recently reported information. One reason for our neglect of this problem is recognition that physicians depend almost entirely on review of reports on video display terminals rather than on hard copies in the medical record.

Continuing Education Activity

We began monitoring education and training in 1991. During that year, the percentage of total hours consumed by training increased from 4 to 8%. The percentage of hours consumed by intramural or extramural education programs did not exceed 1%. For the majority of employees continuing education or training time consisted of <1% of the hours worked. Only about five employees expended 1 to 5% of their time on education and training, and another two or three employees spent 6 to 10% of their time on education and training. Reflecting the increase in training of new employees, there was an increase of one to six employees during the course of the year 1991 who expended more than 25% of their time on training. We believe that both training time for new employees and the amount of time spent on

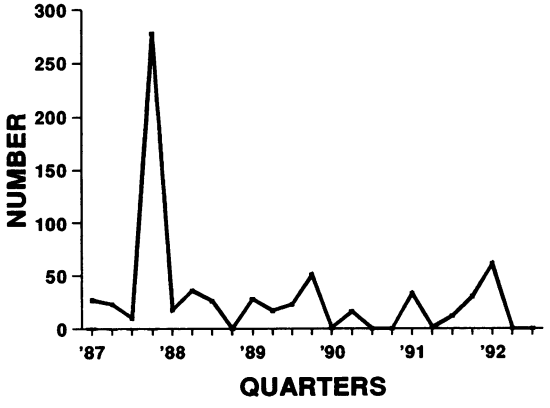

FIG. 7. Failure to take corrective action peaked in the fourth quarter of 1987 during the absence of a supervisor.

TABLE 11. Results for stat urinalysis and Gram stain reported with delay not exceeding 30 min

Test	% Results for given quarter											
	1990				1991				1992			
	1	2	3	4	1	2	3	4	1	2	3	4
Urinalysis	—[a]	79	55	44	60	67	27	—	78	52	79	—
Gram smear	—	38	67	—	20	56	71	70	60	23	28	—

[a] —, no data for these quarters.

continuing education should be expanded for experienced employees. Over a period of time, it is our objective to find the majority of employees expending at least 5% of their time on education. The introduction of CQI should stimulate a substantial increase in the amount of time spent on training and continuing education. Application of CQI in industry has demonstrated that ample training has substantially reduced errors and thus the amount of time required for monitoring and detection of errors.

Commendable Performance

In 1989, one of our technologists remarked that there ought to be a system for recognizing commendable performance instead of documenting only instances of unacceptable performance. A program was developed which would enable any employee to record and publicize the commendable performance of another. It was enthusiastically received. Not only were employees commending each other, but subordinates were commending their supervisors. One of us (R.C.B.) was commended by a technologist for reading a malaria smear so she could leave work on schedule. One hundred ninety-nine commendable reports were turned in between 1989 and 1992, with an average of 13 per quarter. The largest number was reported during 1990, 29 per quarter, a year during which the concept and the psychological reward were being emphasized. Subsequently, the practice declined. It requires continual fostering by senior staff.

Clinical Use of Reported Information

Monitoring the use of reported information may be the best indicator of health care outcome. This enables a comparison of the cost-effectiveness of conventional versus rapid methods of analysis and reporting. Trenholme et al. described the effect of improving therapy of bacteremic patients when rapid identification and antimicrobial susceptibility testing results obtained with the AutoMicrobic system (AMS; Vitek Systems, Inc., Hazelwood, Mo.) were reported compared with the more delayed reports resulting from the use of conventional methods (216). Although we use the AMS instrument, we have found that the results are produced in an intermittent manner by the instrument during the evening shift. This shift is staffed primarily to provide emergency services, and the handling of AMS results made inefficient use of technician time. We found little anecdotal evidence that clinicians were looking for this information by querying the LIS during the evening or night preceding the day on which the results are normally reported. A significant difference in our experience and that of Trenholme et al. may be in the extent to which the activity was organized and how well clinicians were apprised of the availability of the information. There is an urgent need to conduct studies of the impact of rapid testing and reporting and various alternative reporting formats, including the reporting of interpretive information. Our experience has focused on the effect of reporting practices on antimicrobial agent use. Interpretive reporting has been addressed by Lundberg (138) and Speicher and Smith (207).

TABLE 12. Follow-up on 1,001 patient reports rendered on or after the day of discharge

Report	No. (%)
Not considered clinically significant	279 (28)
Considered significant	
Letters sent to physicians	722 (72)
Replies	674
Physician had been aware of report	314
Physician had not been aware of report	360
Information would have altered discharge planning or treatment	90
Information would not have altered discharge planning or treatment	270

Cost-effective use of antibiotics has been the subject of a number of publications (126, 152, 177). Cannon et al. reported that only 51.7% of physicians were aware of the susceptibility testing results 72 h after reports were charted (57). Maki and Schuna reported that antibiotic therapy was inappropriate 35% of the time in a university teaching hospital (143). In another study, Castle and coworkers found that 39% of antibiotic use was inappropriate (59). Moleski described a surveillance program to monitor and influence antibiotic use (152). In other institutions, computerized monitoring programs have been implemented through pharmacy departments to help facilitate delivery of information from the laboratory to the physician and assist physicians in choosing the most appropriate treatment. Some programs have employed computerized monitoring to identify inappropriate antibiotic use (169, 223). In these cases, pharmacists were aware of discrepancies between in vitro susceptibility results and the antibiotics that were ordered. The physicians were contacted and informed of the results, and recommendations were provided for appropriate antibiotic use. An evolving trend in our hospital, and in many others, is the role of clinical pharmacists as consultants and participants on clinical rounds to improve appropriate use of antimicrobial agents.

We conducted a study of the continued use of antimicrobial agents despite laboratory reporting of in vitro resistance. We are not aware of the implementation of any similar programs that use the microbiology laboratory as a base. We have access to a computer display of antimicrobial therapy being given to hospitalized patients in our institution through video display terminals in the laboratory. We established a study to compare in vitro susceptibility results with the therapy being given. The physician was called when in vitro resistance to drugs being given to patients was observed. A control group of patients whose clinicians would not be called would enable us to determine the effectiveness of the activity.

Specimens for culture were processed by conventional methods within 2 h of collection (day 1). On day 2, isolates were tested for antimicrobial susceptibility by the AMS. Results of tests were entered on day 3 into a computerized LIS by noon. These results were immediately retrievable by clinicians on LIS terminals on each patient care unit. Hard copies of these reports were printed and distributed to patient care units within a few hours after midnight on day 4.

TABLE 13. Effect of calling physicians to report in vitro resistance to drugs being used for therapy

Action	No. (%) of patients	
	Control group	Study group
Changed to appropriate therapy		
Same day	1	2
24 h	7	11
48 h	4	0
Subtotal	12 (50)	13 (87)
Remained on inappropriate therapy	9 (38)	0 (0)
Died within 24 h	1	1
All antimicrobial therapy discontinued	2	1
Total no. of patients	24	15

Pediatric patients and patients being seen in consultation by the infectious disease service were excluded from the study.

Reports were divided into two groups on the basis of the last digit of the hospital identification number. Those which ended with an odd number were placed in the control group and those which ended with an even number were placed in a study group.

Data displayed in a computerized pharmacy prescription processing program were reviewed, and the therapy was compared with the in vitro test results. Patients who were found to be on appropriate therapy were excluded from the study.

If therapy was inappropriate, physicians caring for study patients were contacted by telephone and informed of the bacteriology report and the susceptibility testing results. The current antimicrobial therapy was confirmed and discussed during the conversation. The physician did not know that the telephone call was part of a study. Physicians were not called regarding inappropriate therapy of control patients.

The pharmacy program was queried at 24 and 48 h to determine changes in therapy in both the control and study groups. Data were gathered over a 4-month period extending from February through May 1990. During this time, we entered 15 patients in the study group and 24 patients in the control group (Table 13). The numbers were unequal because more patients were excluded from the study group for the reasons previously mentioned. Of the 15 patients in the study group, therapy was changed to an appropriate drug on the same day for 2 patients and within 24 h for another 11 patients for a total of 13 (87%). There were no patients in the study group who continued on inappropriate therapy after 24 h. One patient died within 24 h. The death was unrelated to antimicrobial therapy. All antimicrobial therapy was discontinued for another patient.

Of the 24 patients in the control group, therapy was changed on the same day for only 1, within 24 h for 7, and within 48 h for another 4 patients. One patient died; the cause appeared unrelated to antimicrobial therapy. All antibiotic therapy was discontinued for two patients. Thus, at 48 h, the therapy had been changed to an appropriate drug for only 12 (50%) of the 24 patients in the control group. Nine of the 24 patients (38%) in the control group remained on inappropriate therapy after 48 h. None of the 15 patients in the study group remained on inappropriate therapy after 48 h. These differences were found to be statistically significant based on a χ^2 analysis ($P < 0.05$).

Systematic and ongoing monitoring of antibiotic usage is required by the JCAHO. Most hospitals today have surveillance programs to monitor antibiotic usage. These programs have been implemented through recommendations for formulary restrictions, chart reviews, and educational seminars for staff and residents (126, 152, 177).

This study suggests that clinicians usually will change to appropriate therapy when they are made aware of in vitro resistance. We do not know why inappropriate therapy continues to be used for many patients when this information is not presented directly to clinicians. It is possible that they do not look at bacteriology reports when patients are doing well clinically. We did not examine the clinical courses of the patients in the control group to see whether the patients whose therapy was changed appeared sicker or less responsive to the initial therapy than the patients whose therapy was not changed. Also, we did not attempt to determine any differences in the outcome between the patients whose therapy was changed and those whose therapy was not changed. This would be desirable if the cost of a continuous ongoing service to notify clinicians of in vitro resistance is to be justified. On empirical grounds, it would seem desirable for patients to be on appropriate therapy, but the cost of such a program might have to be supported by evidence that inappropriate therapy yields a greater cost as a result of extended hospitalization or added morbidity. In this study, a physician called the clinician to inform him (her) of the results. We do not know whether the activity would have produced the same results if the clinician had been called by a technologist or a clerk. This would reduce the cost of the activity. Another approach that would reduce the cost further would be to print a unique report that would be delivered directly to the physician's mailbox or office. This could add delay to the process and might be less effective. All of these approaches deserve investigation.

Our findings support those of prior studies that suggest that alerting physicians of in vitro susceptibility data does facilitate clinically indicated alterations in therapy.

In another study, we evaluated the effect of reporting recommendations for antimicrobial therapy in the bacteriology report in addition to the usual in vitro susceptibility test results (35). The recommendation was based on an algorithm developed by the infectious disease division and consisted of a recommendation for a single oral and a single parenteral antimicrobial agent along with a recommended dose. The recommendations were used on only 13% of patient days of treatment. Multiple reasons were given. There is more than one alternative approach to the treatment of most infections. Physicians wrote orders for therapy at the same time orders for collection of sputum specimens were written. Although laboratory reports of the examination of the Gram-stained smear along with the recommendation for therapy based on that smear were retrievable on LIS terminals on patient care floors within 30 min, this was still too late to constitute a basis for ordering antimicrobial therapy. Physicians did not review the bacteriology report in many cases when patients were doing well on the treatment originally ordered. Thus, in vitro resistance or departures from the recommended therapy were not appreciated.

CONCLUSIONS

QM in clinical microbiology began in the 1960s. Both government and professional societies introduced programs for proficiency testing and laboratory inspection and accreditation. Many laboratory scientists and pathologists were independently active and creative in expanding efforts to

monitor and improve practices. The initial emphasis was placed on intralaboratory process. Later, attention was shifted to physician ordering, specimen collection, reporting, and use of information. QM in the laboratory depends in large part on the monitoring of indicators that provide some evidence of how laboratory resources are being used and how the information benefits patient care. We have applied a substantial number of these indicators in our laboratory, but none has been proven with statistical validity to correlate with an improved patient care outcome. Such studies need to be conducted, possibly under the auspices of the JCAHO, which is conducting studies of indicators in use in obstetrics and gynecology, emergency medicine, etc. Current JCAHO requirements dictate that two indicators be subject to evaluation by each hospital department. A dozen or more indicators have been described in this report, any two of which would meet that requirement. It would be up to individual laboratory directors to assess the relative usefulness and potential cost-effectiveness of introducing monitoring of one or more of these indicators in their own laboratories.

Monitoring of process (classical quality control) in our laboratory has not consumed an inordinate amount of personnel time. Failure to perform surveillance, or delays in its performance, are problems as important as the detection of the deficiencies themselves and require constant attention. Most functions of personnel, equipment, and reagents display deficiencies, albeit in low frequency. Many of the deficiencies detected turn out to be errors in performance of the control procedures or defects in control materials. Despite these annoyances, currently conducted monitoring of aspects of process appears to be worthwhile in our laboratory.

Much of what we have accomplished in our laboratory at Hartford Hospital has been supported by funds from research grants which have supported the half-time services of a nurse coordinator. We have not been able to clearly establish that the cost of the monitoring and continuing educational activity of such a worker can be justified. CQI should be introduced. This will place more emphasis on prevention of errors through more effective training and continuing education and will force a more conscious attention on meeting the expectations of the many customers that must be satisfied by laboratory services, including patients, physicians, third-party payers, and managed-care organizations.

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REFERENCES

1. **Ackerman, V. P., and R. C. Pritchard.** 1984. External quality assurance in microbiology. The programme of the Royal College of Pathologists of Australasia. Pathology **16**:235–239.
2. **Ackerman, V. P., R. C. Pritchard, D. J. Groot Obbink, R. Bradbury, and A. Lee.** 1979. Consumer survey on microbiology reports. Lancet **i**:199–202.
3. **Ackerman, V. P., R. C. Pritchard, D. J. Groot Obbink, R. Bradbury, and A. Lee.** 1980. Reporting practices of microbiology laboratories. J. Clin. Pathol. **33**:830–835.
4. **Albright, R. E., C. B. Graham III, R. H. Christenson, W. A. Schell, M. C. Bledsoe, J. L. Emlet, T. P. Mears, L. B. Reller, and K. A. Schneider.** 1991. Rational testing of cerebrovascular fluid. Am. J. Clin. Pathol. **95**:418–423.
5. **Arpi, M., M. W. Bentzon, J. Jensen, and W. Frederiksen.** 1989. Importance of blood volume cultured in the detection of bacteremia. Eur. J. Clin. Microbiol. Infect. Dis. **8**:838–842.
6. **Aronson, M. D., and D. H. Bor.** 1987. Blood cultures. Ann. Intern. Med. **106**:246–253.
7. **August, M. J., J. A. Hindler, T. W. Huber, and D. L. Sewell.** 1990. Cumitech 3A, Quality control and quality assurance practices in clinical microbiology. Coordinating ed., A. S. Weissfeld. American Society for Microbiology, Washington, D.C.
8. **Bachner, P.** 1986. Quality assurance of the analytic process: pre- and postanalytic variation. Clin. Lab. Med. **6**:613–624.
9. **Barr, J. T.** 1979. Quality laboratory service and cost containment: are the two incompatible? Am. J. Med. Technol. **45**:613–614.
10. **Barry, A. L.** 1972. Performance standards for antimicrobial disc susceptibility tests, as used in clinical laboratories. National Committee for Clinical Laboratory Standards, Los Angeles.
11. **Barry, A. L., and K. L. Bernsohn.** 1968. The role of quality control in the clinical bacteriology laboratory. Am. J. Med. Technol. **34**:195–201.
12. **Barry, A. L., and K. L. Feeney.** 1967. Quality control in bacteriology through media monitoring. Am. J. Med. Technol. **33**:387–393.
13. **Bartlett, R. C.** 1967. Experience with a quality control program in a clinical laboratory. Presented at the Annual Meeting of the American Society for Microbiology, New York.
14. **Bartlett, R. C.** 1974. A plea for clinical relevance in medical microbiology. Am. J. Clin. Pathol. **61**:867–872.
15. **Bartlett, R. C.** 1974. Medical microbiology: quality, cost and clinical relevance. Wiley Interscience, New York.
16. **Bartlett, R. C.** 1975. Can we afford the price of quality?, p. 1–9. *In* J. E. Prier, J. T. Bartola, and H. Friedman (ed.), Quality control in microbiology, University Park Press, Baltimore.
17. **Bartlett, R. C.** 1977. Medical microbiology: how fast to go-how far to go, p. 15–35. *In* V. Lorian (ed.), Significance of medical microbiology in the care of patients. The Williams & Wilkins Co., Baltimore.
18. **Bartlett, R. C.** 1980. Quality control in clinical microbiology, p. 14–24. *In* E. J. Lennette, A. Balows, W. J. Hausler, Jr., and J. P. Truant (ed.), Manual of clinical microbiology, 3rd ed. American Society for Microbiology, Washington, D.C.
19. **Bartlett, R. C.** 1980. Microbiology, parasitology, and antibiotic sensitivity, p. 151–174. *In* R. J. Jones and R. M. Palulonis (ed.), Laboratory tests in medical practice. American Medical Association, Chicago.
20. **Bartlett, R. C.** 1981. Quality control in microbiology, p. 25–38. *In* H. M. Sommers (ed.), Clinical relevance in microbiology. College of American Pathologists, Skokie, Ill.
21. **Bartlett, R. C.** 1982. Making optimum use of the microbiology laboratory. I. Use of the laboratory. JAMA **247**:857–859.
22. **Bartlett, R. C.** 1982. Making optimum use of the microbiology laboratory. II. Urine, respiratory, wound, and cervicovaginal exudate. JAMA **247**:1336–1338.
23. **Bartlett, R. C.** 1982. Making optimum use of the microbiology laboratory. III. Aids of antimicrobial therapy. JAMA **247**: 1868–1871.
24. **Bartlett, R. C.** 1982. Results of the survey of microbiology laboratory management: summary and comments. Clin. Microbiol. Newsl. **4**:97–101.
25. **Bartlett, R. C.** 1982. Medical microbiology: how fast to go-how far to go in 1982, p. 12–44. *In* V. Lorian (ed.), Significance of medical microbiology in the care of patients, 2nd ed. The Williams & Wilkins Co., Baltimore.
26. **Bartlett, R. C.** 1983. Use of the microbiology laboratory, p. 251–268. *In* G. D. Lundberg (ed.), Using the clinical laboratory in medical decision-making. American Society of Clinical Pathologists Press, Chicago.

27. **Bartlett, R. C.** 1985. Quality control in microbiology, p. 537–550. *In* J. W. Smith (ed.), The role of clinical microbiology in cost-effective health care. College of American Pathologists, Skokie, Ill.
28. **Bartlett, R. C.** 1985. Cost containment in microbiology. Clin. Lab. Med. **5**:761–792.
29. **Bartlett, R. C.** 1987. Bacteriologic surveillance of long-term-catheterized patients. J. Clin. Microbiol. **25**:464–465. (Letter.)
30. **Bartlett, R. C.** 1990. Trends in quality management. Arch. Pathol. Lab. Med. **114**:1126–1130.
31. **Bartlett, R. C., V. D. Allen, D. J. Blazevic, C. T. Dolan, V. R. Dowell, T. L. Gavan, S. L. Inhorn, G. L. Lombard, J. M. Matsen, D. M. Melvin, H. M. Sommers, M. T. Suggs, and B. S. West.** 1978. Clinical microbiology, p. 871–1005. *In* S. L. Inhorn (ed.), Quality assurance practices for health laboratories. American Public Health Association, Washington, D.C.
32. **Bartlett, J. G., N. S. Brewer, K. J. Ryan, and J. A. Washington, II (ed.).** 1978. Cumitech 7, Laboratory diagnosis of lower respiratory tract infections. American Society for Microbiology, Washington, D.C.
33. **Bartlett, R. C., W. R. Irving, and C. Rutz.** 1968. Quality control in clinical microbiology. American Society of Clinical Pathologists Commission on Continuing Education, Chicago.
34. **Bartlett, R. C., and S. Lobel.** 1991. Laboratory reports issued on or after discharge date. J. Am. Med. Rec. Assoc. **62**:1–2.
35. **Bartlett, R. C., R. D. Quintiliani, C. H. Nightingale, D. Platt, H. Crowe, R. Grotz, R. Orlando, C. Strycharz, J. Tetreault, and T. Lerer.** 1991. Effect of including recommendations for antimicrobial therapy in microbiology laboratory reports. Diagn. Microbiol. Infect. Dis. **14**:157–166.
36. **Bartlett, R. C., J. Redys, C. Fitzgerald, G. Thornton, R. Maggio, A. von Graevenitz, D. Miller, W. Vincent, and R. Quintiliani.** 1975. Report of the Ad Hoc Committee on Medical Microbiology Laboratory Utilization. State of Connecticut, Department of Health. Conn. Med. **39**:499–505.
37. **Bartlett, R. C., and C. Rutz.** 1980. Processing control and cost in bacteriology. Am. J. Clin. Pathol. **74**:287–296.
38. **Bartlett, R. C., C. A. Rutz, and N. Konopacki.** 1982. Cost effectiveness of quality control in bacteriology. Am. J. Clin. Pathol. **77**:184–190.
39. **Bartlett, R. C., J. Tetreault, and J. Evers.** 1979. Quality assurance of gram stained direct smears. Am. J. Clin. Pathol. **72**:984–990.
40. **Bartlett, R. C., and N. Treiber.** 1984. Clinical significance of mixed urine cultures. Am. J. Clin. Pathol. **82**:319–322.
41. **Bartola, J.** 1986. Painless office laboratory regulation. Primary care. Clinics in Office Practice, vol. 13, p. 605–615.
42. **Bates, D. W., E. F. Cook, L. Goldman, and T. H. Lee.** 1990. Predicting bacteremia in hospitalized patients. A prospectively validated model. Ann. Intern. Med. **113**:495–500.
43. **Bates, D. W., L. Goldman, and T. H. Lee.** 1991. Contaminant blood cultures and resource utilization. JAMA **265**:365–369.
44. **Bates, D. W., and T. H. Lee.** 1992. Rapid classification of positive blood cultures. The true consequences of false-positive results. JAMA **267**:1962–1966.
45. **Belsey, R., and D. M. Baer.** 1986. Proficiency of office microbiology testing. Clin. Lab. Med. **6**:345–354.
46. **Belyus, P. S., T. E. Burgess, and P. R. Walsh.** 1986. Quality assurance in a large reference laboratory. Clin. Lab. Med. **6**:745–754.
47. **Berwick, D. M.** 1988. Sounding board: continuous improvement as an ideal in health care. N. Engl. J. Med. **320**:53–56.
48. **Berwick, D. M.** 1990. Improving health care quality 1990. The National Demonstration Project, Brookline, Mass.
49. **Black, W. A., and S. E. Dorse.** 1976. A regional quality control program in microbiology. I. Administrative aspects. Am. J. Clin. Pathol. **66**:401–406.
50. **Black, W. A., and S. E. Dorse.** 1976. A regional quality control program in microbiology. II. Advantages of simulated clinical specimens. Am. J. Clin. Pathol. **66**:407–415.
51. **Blazevic, D. J., C. T. Hall, and M. E. Wilson.** 1976. Cumitech 3, Practical quality control procedures for the clinical microbiology laboratory. Coordinating ed., A. Balows, American Society for Microbiology, Washington, D.C.
52. **Boone, D. J.** 1988. Evaluating laboratory performance. Arch. Pathol. Lab. Med. **112**:354–356.
53. **Bowman, R. A., J. M. Bowman, S. A. Arrow, and T. V. Riley.** 1992. Selective criteria for the microbiological examination of faecal specimens. J. Clin. Pathol. **45**:838–839.
54. **Branson, D.** 1966. Problems and errors in the clinical microbiology laboratory. Am. J. Med. Technol. **32**:349–357.
55. **Braunstein, H.** 1986. Quality control in microbiology: a review and bibliography. Clin. Lab. Med. **6**:649–675.
56. **Campo, L., and J. M. Mylotte.** 1988. Use of microbiology reports by physicians in prescribing antimicrobial agents. Am. J. Med. Sci. **296**:392–398.
57. **Cannon, W. H., D. C. Hale, and J. M. Matsen.** 1980. Physician awareness of and response to antimicrobial susceptibility data in a university medical center. Program Abstr. 20th Intersci. Conf. Antimicrob. Agents Chemother., abstr. 396.
58. **Carlson, D. J.** 1977. Cost effectiveness of laboratory improvement programs: the viewpoint from the private sector. Health Lab. Sci. **14**:199–205.
59. **Castle, M., C. M. Wilfert, T. R. Cate, and S. Osterhout.** 1977. Antibiotic use at Duke University Medical Center. JAMA **237**:2819–2822.
60. **CBS Nightly News.** 20 July 1987.
61. **Cicchetti, D. V., P. Keitges, and R. N. Barnett.** 1974. How many is enough? A statistical study of proficiency testing of syphilis serology specimens. Health Lab. Sci. **11**:299–305.
62. **Clinical Microbiology Newsletter.** 1979. Results of the sputum questionnaire. Clin. Microbiol. Newsl. **1**:1–5.
63. **Crane, S. C.** 1987. Regulatory considerations in the establishment and expansion of office-based laboratories. Med. Clin. North Am. **71**:733–749.
64. **Crawley, R., R. Belsey, D. Brock, and D. M. Baer.** 1986. Regulation of physicians' office laboratories. JAMA **255**:374–382.
65. **Crosby, P. B.** 1979. Quality is free. McGraw-Hill Book Co., New York.
66. **Cunha, B. A., I. Gurevich, and P. Tafuro.** 1986. Cost-effective utilization of microbiology data. Hosp. Physician **22**:19–21.
67. **Damron, D. J., J. W. Warren, G. R. Chippendale, and J. W. Tenney.** 1986. Do clinical microbiology laboratories report complete bacteriology in urine from patients with long-term urinary catheters? J. Clin. Microbiol. **24**:400–404.
68. **Deodhar, S. D., W. E. Braun, L. P. Cawley, P. W. Keitges, R. M. Nakamura, G. M. Penn, G. Reynoso, and E. S. Tucker, III.** 1978. Immunology, p. 745–786. *In* S. L. Inhorn (ed.), Quality assurance practices for health laboratories. American Public Health Association, Washington, D.C.
69. **Derman, H., and D. B. Dorsey.** 1991. The pathology of regulation. Clin. Lab. Med. **11**:793–802.
70. **Dolan, T.** 1974. A summary of the 1972 mycology proficiency testing survey of the College of American Pathologists. Am. J. Clin. Pathol. **61**:990–993.
71. **Donabedian, A.** 1966. Evaluating the quality of medical care. Milbank Mem. Fund Q. **44**:166–203.
72. **Donabedian, A.** 1988. The quality of care: how can it be assessed? JAMA **260**:1743–1748.
73. **Dorsey, D. B.** 1989. Evolving concepts of quality in laboratory practice. Arch. Pathol. Lab. Med. **113**:1329–1334.
74. **Doubilet, P., M. C. Weinstein, and B. J. McNeil.** 1986. Occasional notes. Use and misuse of the term "cost effective" in medicine. N. Engl. J. Med. **314**:253–256.
75. **Duckworth, J. K.** 1988. Proficiency testing. Its role in a voluntary clinical laboratory accreditation program. Arch. Pathol. Lab. Med. **112**:346–348.
76. **Edinger, S. E.** 1988. The Medicare and Clinical Laboratories Improvement Act of 1967. Proficiency testing requirements and its relationship to the private sector. Arch. Pathol. Lab. Med. **112**:357–362.
77. **Ehrmeyer, S. S., and R. H. Laessig.** 1988. An evaluation of the ability of proficiency testing programs to determine intralaboratory performance. Peer group statistics vs clinical usefulness limits. Arch. Pathol. Lab. Med. **112**:444–448.

78. **Eilers, R. J.** 1969. Total quality control for the medical laboratory. South. Med. J. **62**:1362–1365.
79. **Ellis, R. J.** 1974. Quality control procedures for microbiological laboratories, 1st ed. Center for Disease Control, Atlanta.
80. **Estevez, E. G.** 1980. A program of in-house proficiency testing in clinical microbiology. Am. J. Med. Technol. **46**:102–105.
81. **Federal Register.** 1992. Fed. Regist. **57**:7002–7288.
82. **Ferraro, M. J.** 1985. Cost-effectiveness in the microbiology laboratory in view of hospital incentives under prospective reimbursement. *In* J. W. Smith (ed.), The role of clinical microbiology in cost effective health care. College of American Pathologists. Skokie, IL.
83. **Ferraro, M. J.** 1985. Potential impact of rapid microbiology tests in the prospective payment era. Diagn. Microbiol. Infect. Dis. **3**:65S–71S.
84. **Finn, A. F., P. N. Valenstein, and D. Burke.** 1988. Alteration of physicians' orders by nonphysicians. JAMA **259**:2549–2552.
85. **Fischer, P. M., L. A. Addison, E. W. Koneman, and J. Crowley.** 1986. Education and the physician's office laboratory. JAMA **255**:1464–1467.
86. **Flournoy, D. J., S. K. Darter, C. K. Murray, and R. Catlett.** 1990. The influence of patient location and physician on sputum adequacy in a Veterans Administration medical center. Laboratory Medicine **21**:653–657.
87. **Fuchs, P. C., and C. T. Dolan.** 1981. Summary and analysis of the mycology proficiency testing survey results of the College of American Pathologists. 1976–1979. Am. J. Clin. Pathol. **76**(Suppl.):538–543.
88. **Gavan, T. L.** 1974. A summary of the bacteriology portion of the 1972 basic, comprehensive and special College of American Pathologists (CAP) quality evaluation program. Am. J. Clin. Pathol. **61**:971–979.
89. **Gavan, T. L., and J. W. King.** 1970. An evaluation of the microbiology portions of the 1969 basic, comprehensive, and special College of American Pathologists proficiency testing surveys. Am. J. Clin. Pathol. **54**(Suppl.):514–520.
90. **Glasser, L., G. S. Bosley, and J. R. Boring.** 1971. A systematic program of quality control in clinical microbiology. Am. J. Clin. Pathol. **56**:379–383.
91. **Griffin, C. W., E. C. Cook, and M. A. Mehaffey.** 1986. Centers for Disease Control performance evaluation program in bacteriology: 1980 to 1985 review. J. Clin. Microbiol. **24**:1004–1012.
92. **Griffin, C. W., M. A. Mehaffey, E. C. Cook, S. O. Blumer, and P. A. Podeszwik.** 1986. Relationship between performance in three of the Centers for Disease Control microbiology proficiency testing programs and the number of actual patient specimens tested by participating laboratories. J. Clin. Microbiol. **23**:246–250.
93. **Gross, P. A., C. L. Van Antwerpen, W. A. Hess, and K. A. Reilly.** 1988. Use and abuse of blood cultures: program to limit use. Am. J. Infect. Control **16**:114–117.
94. **Gruft, H.** 1978. Evaluation of mycobacteriology laboratories: the acid-fast smear. Health Lab. Sci. **15**:215–220.
95. **Halstead, E. G., R. A. Quevedo, and W. H. Gingerich.** 1971. A quality control program for the bacteriology laboratory. Am. J. Technol. **37**:15–20.
96. **Hammond, H. C.** 1988. Federal regulation of clinical laboratories. Arch. Pathol. Lab. Med. **112**:363–367.
97. **Harding, H. B.** 1967. Quality control in bacteriology, parts I and II. Hosp. Top. **43**:78–85.
98. **Hartley, R. M., M. A. Markowitz, and A. L. Komaroff.** 1989. The expense of testing in a teaching hospital: the predominant role of high-cost tests. Am. J. Public Health **79**:1389–1391.
99. **Hausler, W. J., K. L. Herrmann, H. D. Isenberg, and H. J. Shadomy (ed.).** 1991. Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
100. **Heineman, H. S., J. K. Chawla, and W. M. Lofton.** 1977. Misinformation from sputum cultures without microscopic examination. J. Clin. Microbiol. **6**:518–527.
101. **Hoke, C. H., Jr., J. M. Batt, S. Mirrett, R. L. Cox, and L. B. Reller.** 1979. False-positive gram-stained smears. JAMA **241**: 478–480.
102. **Howanitz, P. J.** 1988. Use of proficiency test performance to determine clinical laboratory director qualifications. Arch. Pathol. Lab. Med. **112**:349–353.
103. **Howanitz, P., and K. Walker.** 1990. Reporting error, data analysis and critique. Publication 90-15. College of American Pathologists. Northfield, Ill.
104. **Howanitz, P. J.** 1990. Quality assurance measurements in departments of pathology and laboratory medicine. Arch. Pathol. Lab. Med. **114**:1131–1135.
105. **Howanitz, P. J., and S. J. Steindel.** 1991. Intralaboratory performance and laboratorians' expectations for stat turnaround times. Arch. Pathol. Lab. Med. **115**:977–983.
106. **Howanitz, P. J., K. Walker, and P. Bachner.** 1992. Quantification of errors in laboratory reports. Arch. Pathol. Lab. Med. **116**:694–700.
107. **Howie, J.** 1972. Medical microbiology for patient and community. J. Clin. Pathol. **25**:921–926.
108. **Isenberg, H. D.** 1985. Is cost effective ordering of microbiology tests for infection control possible? Infect. Control **6**:425–427.
109. **Javits, J.** 1979. Congressional record, vol. 125, p. 865. Washington, D.C.
110. **Jefferson, H., H. P. Dalton, M. R. Escobar, and M. J. Allison.** 1975. Transportation delay and the microbiological quality of clinical specimens. Am. J. Clin. Pathol. **64**:689–693.
111. **Joint Commission on Accreditation of Healthcare Organizations.** 1985. Standards for accreditation of healthcare organizations. Joint Commission on Accreditation of Healthcare Organizations, Chicago.
112. **Joint Commission on Accreditation of Healthcare Organizations.** 1993. Accreditation manual for hospitals, p. 143. Joint Commission on Accreditation of Health Care Organizations, Chicago.
113. **Jones, R. N., and D. C. Edson.** 1985. Antibiotic susceptibility testing accuracy. Review of the College of American Pathologists microbiology survey, 1972–1983. Arch. Pathol. Lab. Med. **109**:595–601.
114. **Jones, R. N., D. C. Edson, B. F. Gilmore, and the CAP Microbiology Resource Committee.** 1983. Contemporary quality control practices for antimicrobial susceptibility tests: a report from the microbiology portion of the College of American Pathologists (CAP) surveys program. Am. J. Clin. Pathol. **80**(Suppl. 4):622–625.
115. **Jones, R. N., D. C. Edson, and J. V. Marymount.** 1982. Evaluations of antimicrobial susceptibility test proficiency by the College of American Pathologists survey program. Am. J. Clin. Pathol. **78**:168–172.
116. **Jones, R. N., D. C. Edson, and the CAP Microbiology Resource Committee.** 1983. Special topics in antimicrobial susceptibility testing: test accuracy against methicillin-resistant *Staphylococcus aureus*, *Pneumococci*, and the sensitivity of β-lactamase methods. Am. J. Clin. Pathol. **80**(Suppl. 4):609–614.
117. **Jones, R. N., D. C. Edson, and the Microbiology Resource Committee of the College of American Pathologists.** 1988. The identification and antimicrobial susceptibility testing of *Neisseria gonorrhoeae*, 1980–1987. Results from the College of American Pathologists microbiology surveys program. Arch. Pathol. Lab. Med. **112**:485–488.
118. **Jones, R. N., D. C. Edson, and the Microbiology Resource Committee of the College of American Pathologists.** 1991. Antimicrobial susceptibility testing trends and accuracy in the United States. A review of the College of American Pathologists microbiology surveys, 1972–1989. Arch. Pathol. Lab. Med. **115**:429–436.
119. **Juran, J. M.** 1988. Juran on planning for quality. The Free Press, New York.
120. **Juran, J. M., and F. M. Fryna.** 1988. Juran's quality control handbook, 4th ed., p. 22–31. McGraw-Hill, New York.
121. **Kenney, M. L.** 1984. Laboratory quality and director qualifications: assessment of medicare requirements that directors of independent clinical laboratories possess earned doctorates. Thesis. School of Public Health, University of California, Berkeley.
122. **Kiehlbauch, J., J. M. Kendle, and L. G. Carlson.** 1989. Automated antibiotic susceptibility testing: comparative evaluation

of four commercial systems and present state. Clin. Lab. Med. **9**:319–340.
123. **Knowles, R. C., and B. F. Gilmore.** 1981. Quality control of agar diffusion susceptibility tests. Am. J. Clin. Pathol. **76**(Suppl. 4):590–596.
124. **Koepke, J. A., and G. G. Klee.** 1990. The process of quality assurance. Quality indicators in clinical pathology. Arch. Pathol. Lab. Med. **114**:1136–1139.
125. **Kramer, F., T. Modilevsky, A. R. Waliany, J. M. Leedom, and P. F. Barnes.** 1990. Delayed diagnosis of tuberculosis in patients with human immunodeficiency virus infection. Am. J. Med. **89**:451–456.
126. **Kunin, C. M.** 1985. The responsibility of the infectious disease community for the optimal use of antimicrobial agents. J. Infect. Dis. **151**:388–398.
127. **Lachner, D. A.** 1987. Predictive value derived from likelihood ratios: a superior technique to interpret quantitative laboratory results. Am. J. Clin. Pathol. **87**:673–676.
128. **Laessig, R. H., and S. S. Ehrmeyer.** 1988. Proficiency testing programs—promises, progress, and problems. A 40-year prospective. Arch. Pathol. Lab. Med. **112**:329–333.
129. **Laessig, R. H., S. S. Ehrmeyer, and D. J. Hassemer.** 1986. Quality control and quality assurance. Clin. Lab. Med. **6**:317–327.
130. **Lamanna, A.** 1977. Control of quality in microbiology. Ann. Sclavo **19**:610–621.
131. **Lanyi, B., and E. Czirok.** 1990. Bacteriological proficiency testing in Hungarian clinical microbiology laboratories. Acta Microbiol. Hung. **37**:379–392.
132. **Lassen, J., and P. Sandven.** 1986. External quality assessment for clinical microbiology in Norway 1985. NIPH Ann. (Oslo) **9**:23–31.
133. **Lassen, J., and P. Sandven.** 1988. External quality assessment for clinical microbiology in Norway 1986–87. NIPH Ann. (Oslo) **11**:29–41.
134. **Lee, A., and S. McLean.** 1977. The laboratory report: a problem in communication between clinician and microbiologist? Med. J. Aust. **2**:858–860.
135. **Lentino, J. R., and D. A. Lucks.** 1987. Nonvalue of sputum culture in the management of lower respiratory tract infections. J. Clin. Microbiol. **25**:758–762.
136. **Lomas, J., G. M. Anderson, K. Domnick-Pierre, E. Vayda, M. W. Enkin, and W. J. Hannah.** 1989. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. N. Engl. J. Med. **321**:1306–1311.
137. **Longberry, J., and G. A. DelPolito.** 1981. The clinical laboratory improvement act: a retrospective view. Am. J. Med. Technol. **47**:205–207.
138. **Lundberg, G. M.** 1980. The reporting of laboratory data interpretations: to omit or commit? JAMA **243**:1554–1555. (Letter.)
139. **Lunz, M. E.** 1988. The quality of laboratory staff and the accuracy of results. JAMA **259**:44. (Letter.)
140. **Lunz, M. E., B. M. Castleberry, K. James, and J. Stahl.** 1987. The impact of the quality of laboratory staff on the accuracy of laboratory results. JAMA **258**:361–363.
141. **MacLowry, J. D.** 1991. Concerns and problems related to proficiency testing in microbiology: a CAP perspective. Clin. Microbiol. Newsl. **13**:133–135. (Editorial.)
142. **Makadon, H. J., D. Bor, G. Friedland, P. Dasse, A. L. Komaroff, and M. D. Aronson.** Febrile inpatients: house officers' use of blood cultures. J. Gen. Intern. Med. **2**:293–297.
143. **Maki, D. G., and A. A. Schuna.** 1978. A study of antimicrobial misuse in a university hospital. Am. J. Med. Sci. **275**:271–282.
144. **Manek, N., and E. N. Rees.** 1992. Audit of catheter urine culture requests. J. Clin. Pathol. **45**:79.
145. **Manuselis, G., M. Rausch, and P. Wilson.** 1989. Quality assurance in clinical microbiology. Clin. Lab. Sci. **2**:34–36.
146. **Marks, J.** 1975. Notes on the organization of tuberculosis bacteriology and its quality control. Tubercle **56**:219–226.
147. **Martens, V. E.** 1973. The I & A commission: is it worth it? Bull. Coll. Am. Pathol. **1973**:391–392.
148. **Martin, R. J.** 1983. Quality assurance and clinical microbiology. Med. Lab. Sci. **40**:269–274.
149. **Merrick, T. A.** 1982. Specimen quality assurance for the microbiology laboratory. Lab. Med. **13**:498–505.
150. **Miller, J. M., and B. B. Wentworth.** 1985. Methods for quality control in diagnostic microbiology. American Public Health Association, Washington, D.C.
151. **Mizrachi, H. H., and P. N. Valenstein.** 1987. Randomized trial interpreting sputum quality in a clinical laboratory. J. Clin. Microbiol. **25**:2327–2329.
152. **Moleski, R. J.** 1986. Role of infectious disease specialist in containing costs of antibiotics in the hospital. Rev. Infect. Dis. **8**:488–493.
153. **Morris, A. J., M. L. Wilson, and L. B. Reller.** 1992. Application of rejection criteria for stool ovum and parasite examinations. J. Clin. Microbiol. **30**:3213–3216.
154. **Murray, P. R., and J. A. Washington, II.** 1975. Microscopic and bacteriologic analysis of expectorated sputum. Mayo Clin. Proc. **50**:339–344.
155. **Nagel, J. C., and L. J. Kunz.** 1973. Needless retesting of quality assured, commercially prepared culture media. Appl. Microbiol. **26**:31–37.
156. **National Committee for Clinical Laboratory Standards.** 1983. Performance standards for antimicrobial disc susceptibility tests, 2nd ed. National Committee for Clinical Laboratory Standards, Villanova, Pa.
157. **National Committee for Clinical Laboratory Standards.** 1987. Quality assurance standards for commercially prepared microbiologic culture media (approved standard). National Committee for Clinical Laboratory Standards, Villanova, Pa.
158. **Neff, J. C., and C. E. Speicher.** 1992. More misguided regulation, or a promise of quality? Arch. Pathol. Lab. Med. **116**: 679–680.
159. **Neu, H. C.** 1986. Cost effective blood cultures—is it possible or impossible to modify behavior? Infect. Control **7**:32–33.
160. **Nyiendo, J., and J. P. Kilbourn.** 1979. Cost-effective clinical microbiology. Am. J. Med. Technol. **45**:393–396. (Letter.)
161. **O'Connor, M.** 1989. How to evaluate medical laboratories, p. 103–110. Proc. 103rd Annu. Meet. Med. Sect. Am. Council Life Insurance.
162. **O'Dell, C.** 1993. Building on received wisdom. Healthcare Forum J. **36**:17–21.
163. **Orsi, A., E. DeMayo, and F. Morganetti.** 1984. The Italian experience of quality control in microbiology. Quad. Sclavo Diagn. Clin. Lab. **20**:203–211.
164. **Paris, M.** 1976. Cost and quality control of laboratory services: the New York City medicaid centralized laboratory proposal. Med. Care **14**:777–793.
165. **Peddecord, K. M.** 1988. The quality of laboratory staff and the accuracy of results. JAMA **259**:44. (Letter.)
166. **Pedler, S. J., and A. J. Bint.** 1991. Survey of users' attitudes to their local microbiology laboratory. J. Clin. Pathol. **44**:6–9.
167. **Perry, J. L., and G. R. Miller.** 1989. Quality control slide for potassium hydroxide and cellufluor fungal preparations. J. Clin. Microbiol. **27**:1411–1412.
168. **Perry, S. F., C. K. Campbell, and J. J. S. Snell.** 1988. Mycology quality assessment: United Kingdom national scheme. J. Clin. Pathol. **42**:531–535.
169. **Pestotnik, S. L., R. S. Evans, J. P. Burke, R. M. Gardner, and D. C. Classen.** 1990. Therapeutic antibiotic monitoring: surveillance using a computerized expert system. Am. J. Med. **88**:43–48.
170. **Petersdorf, R. G., and J. C. Sherris.** 1965. Methods and significance of in vitro testing of bacterial sensitivity to drugs. Am. J. Med. **35**:766–779.
171. **Petersen, K. F.** 1983. Methods for internal quality control in the mycobacteriology laboratory. Zentralbl. Bakteriol. Hyg. Abt. 1 Orig. Reihe A **255**:503–510.
172. **Phillips, G., B. W. Senior, and E. McEwan.** 1991. Use of telephone enquiries to a microbiology laboratory as a proxy measure of reporting efficiency. J. Clin. Pathol. **45**:250–253.
173. **Pitts, S. R.** 1986. Quality assurance for office laboratories. JAMA **256**:211. (Letter.)
174. **Porres, J. M.** 1974. Quality control in microbiology. I. Utiliza-

tion of reference laboratory data. Am. J. Clin. Pathol. **62**:407–411.
175. **Porres, J. M.** 1974. Quality control in microbiology. II. The need for standards. Am. J. Clin. Pathol. **62**:412–419.
176. **Pritchard, R. C.** 1987. A medical microbiology quality assurance program. Malays. J. Pathol. **9**:9–11.
177. **Quintiliani, R., B. W. Cooper, L. L. Briceland, and C. H. Nightingale.** 1987. Economic impact of streamlining antibiotic administration. Am. J. Med. **82**:391–394.
178. **Reimer, L., and K. Carroll.** 1991. Utility of sputum Gram stains in rejecting unnecessary specimens. Program Abstr. 31st Intersci. Conf. Antimicrob. Agents Chemother., abstr. 1173.
179. **Reller, L., P. R. Murray, and J. D. MacLowry.** 1982. Cumitech 1A, Blood cultures. American Society for Microbiology, Washington, D.C.
180. **Reynolds, S. M.** 1982. Nonmicrobial alternative to reagent quality control testing. J. Clin. Microbiol. **16**:836–839.
181. **Roberts-Thomson, P., R. McEvoy, R. Gale, S. Jovanovich, and J. Bradley.** 1991. Quality assurance of immunodiagnostic tests in Australasia. Pathology **23**:125–129.
182. **Robinson, A.** Unpublished data.
183. **Rodewald, L. E., K. A. Woodin, P. G. Szilagyi, D. A. Arvan, R. F. Raubertas, and K. R. Powell.** 1991. Relevance of common tests of cerebrospinal fluid in screening for bacterial meningitis. J. Pediatr. **119**:363–369.
184. **Rogers, S., M. J. Bywater, and D. S. Reeves.** 1990. Audit of turn-around times in a microbiology laboratory. J. Clin. Pathol. **44**:257–258.
185. **Russell, R. L., R. S. Yoshimori, T. F. Rhodes, J. W. Reynolds, and E. R. Jennings.** 1969. A quality control program for clinical microbiology. Am. J. Clin. Pathol. **52**:489–494.
186. **Schaeffer, M.** 1966. Health department's role in improving operations of clinical laboratories. Public Health Rep. **81**:71.
187. **Schaeffer, M., D. Widlock, S. Blatt, and M. E. Wilson.** 1967. Clinical laboratory improvement program in New York City. I. Methods of evaluation and results of performance tests. Health Lab. Sci. **4**:72–89.
188. **Schaeffer, M., D. Widlock, P. S. May, S. Blatt, and M. E. Wilson.** 1970. The clinical laboratory improvement program in New York City. II. Progress after five years of experience. Health Lab. Sci. **7**:242–255.
189. **Schalla, W. O., T. L. Hearn, R. N. Taylor, E. Eavenson, R. O. Valdiserri, and J. D. K. Essien.** 1990. CDC's model performance evaluation program: assessment of the quality of laboratory performance for HIV-1 antibody testing. Public Health Rep. **105**:167–171.
190. **Schifman, R. B., C. L. Strand, E. Braun, A. Louis-Charles, R. P. Spark, and M. L. Fried.** 1991. Solitary blood cultures as a quality assurance indicator. Quality Assurance Utilization Rev. **6**:132–137.
191. **Schmidt, N. M., V. V. Hamparian, G. E. Sather, and Y. W. Wong.** 1978. Virology, p. 1097–1144. *In* S. L. Inhorn (ed.), Quality assurance practices for health laboratories. American Public Health Association, Washington, D.C.
192. **Sewell, D. L.** 1992. Quality assurance, quality control, laboratory records and water quality. *In* H. D. Isenberg (ed.), Clinical microbiology procedures handbook. American Society for Microbiology, Washington, D.C.
193. **Shanholtzer, C. J., and L. R. Peterson.** 1986. Laboratory quality assurance testing of microbiologic media from commercial sources. Am. J. Clin. Pathol. **88**:210–215.
194. **Siegel, D. L., P. H. Edelstein, and I. Nachamkin.** 1990. Inappropriate testing for diarrheal diseases in the hospital. JAMA **263**:979–982.
195. **Skendzel, L. P.** 1978. How physicians use laboratory tests. JAMA **239**:1077–1080.
196. **Smith, J. P., and C. Sandlin.** 1969. Quality control in bacteriology. Am. J. Med. Technol. **35**:531–539.
197. **Smith, J. W.** 1974. Parasitology proficiency testing in the quality evaluation programs of the College of American Pathologists. Am. J. Clin. Pathol. **61**:994–998.
198. **Smith, J. W.** 1979. Identification of fecal parasites in the special parasitology survey of the College of American Pathologists. Am. J. Clin. Pathol. **72**(Suppl. 2):371–373.
199. **Snell, J. J. S.** 1985. United Kingdom national external quality assessment scheme for microbiology. Eur. J. Clin. Microbiol. **4**:464–467. (Editorial.)
200. **Snell, J. J. S., and D. F. J. Brown.** 1988. Antimicrobial susceptibility testing of *Neisseria gonorrhoeae*: a trial organized as part of the United Kingdom national external quality assessment scheme for microbiology. J. Clin. Pathol. **41**:97–102.
201. **Snell, J. J. S., D. F. J. Brown, and P. S. Gardner.** 1982. An antibiotic susceptibility testing trial organised as part of the United Kingdom national external microbiological quality assessment scheme. J. Clin. Pathol. **35**:1169–1176.
202. **Snell, J. J. S., J. V. DeMello, and P. S. Gardner.** 1982. The United Kingdom national microbiological quality assessment scheme. J. Clin. Pathol. **35**:82–93.
203. **Snell, J. J. S., J. V. DeMello, and T. J. Phua.** 1986. Errors in bacteriological techniques: results from the United Kingdom national external quality assessment scheme for microbiology. Med. Lab. Sci. **43**:344–355.
204. **Sommers, H. M.** 1974. Mycobacterial proficiency testing in the quality evaluation programs of the College of American Pathologists. Am. J. Clin. Pathol. **61**(Suppl.):980–989.
205. **Sox, H. C.** 1987. Common diagnostic tests used in interpretation. American College of Physicians.
206. **Speicher, C. E., and J. W. Smith.** 1985. Helping physicians use laboratory tests. Clin. Lab. Med. **5**:653–664.
207. **Speicher, C. E., and J. W. Smith, Jr.** 1980. Interpretive reporting in clinical pathology. JAMA **243**:1556–1560.
208. **Stewart, C. E., and J. A. Koepke.** 1987. Quality assurance in microbiology and serology, p. 227. *In* Basic quality assurance practices. J. B. Lippincott Co., Philadelphia.
209. **Sullivan, N. M.** 1992. Culture media development: nutritional growth and metabolite requirements as affected by other factors. Clin. Microbiol. Newsl. **14**:9–14.
210. **Sunderman, F. W.** 1991. Forty-five years of proficiency testing. Ann. Clin. Lab. Sci. **21**:143–144. (Editorial.)
211. **Taylor, R. N., and K. M. Fulford.** 1981. Assessment of laboratory improvements by the Center for Disease Control diagnostic immunology proficiency testing program. J. Clin. Microbiol. **13**:356–368.
212. **Taylor, R. N., Y. A. Huong, K. M. Fulford, V. A. Przybyszewski, and T. L. Hearn.** 1979. Quality control for immunologic tests. Centers for Disease Control, Atlanta.
213. **Thomson, R. B., Jr., T. M. File, Jr., and R. A. Burgoon.** 1989. Repeat antimicrobial susceptibility testing of identical isolates. J. Clin. Microbiol. **27**:1108–1111.
214. **Thomson, R. B., Jr., T. M. File, Jr., J. S. Tan, and B. L. Evans.** 1987. Yield, clinical significance, and cost of a combination BACTEC plus Septi-Chek blood culture system. J. Clin. Microbiol. **25**:819–823.
215. **Tillett, H. E., and P. B. Crone.** 1976. Quality control of the isolation rate of pathogens in medical microbiology laboratories. J. Hyg. **77**:359–367.
216. **Trenholme, G. M., R. L. Kaplan, P. H. Karakusis, T. Stine, J. Fuhrer, W. Landau, and S. Levin.** 1989. Clinical impact of rapid identification and susceptibility testing of bacterial blood culture isolates. J. Clin. Microbiol. **27**:1342–1345.
217. **Tydeman, J., J. I. Morrison, D. F. Hardwick, and P. A. Cassidy.** 1981. The cost of quality control procedures in the clinical laboratory. Am. J. Clin. Pathol. **77**:528–533.
218. **U.S. Public Health Service.** 1977. Forward Plan for Health FY 1978–82. U.S. Public Health Service, Department of Health, Education and Welfare, Washington, D.C.
219. **Valenstein, P., A. Leiken, and C. Lehmann.** 1988. Test-ordering by multiple physicians increases unnecessary laboratory examinations. Arch. Pathol. Lab. Med. **112**:238–241.
220. **Valenstein, P. N., and K. Emancipator.** 1989. Sensitivity, specificity, and reproducibility of four measures of laboratory turnaround time. Am. J. Clin. Pathol. **91**:452–457.
221. **Van Scoy, R. E.** 1977. Bacterial sputum cultures—a clinician's viewpoint. Mayo Clin. Proc. **52**:39–41.
222. **Voldish, K. L.** 1991. Physician office laboratory quality assur-

ance. N. J. Med. **88:**353–354.
223. **Von Seggern, R. L.** 1987. Culture and antibiotic monitoring service in a community hospital. Am. J. Hosp. Pharm. **44:** 1358–1362.
224. **Walker, K., and P. Howanitz.** 1989. Reporting error, data analysis and critique. Publication 89-02. College of American Pathologists. Northfield, Ill.
225. **Wall Street Journal.** 1987 February 2, p. 1, 19.
226. **Walton, M.** 1986. The Deming management approach. Dodd, Mead & Co., New York.
227. **Washington, J. A., II.** 1985. The clinical microbiology laboratory. Am. J. Med. **78**(Suppl. 6B):8–16.
228. **Washington, J. A., II, and D. M. Ilstrup.** 1986. Blood cultures: issues and controversies. Rev. Infect. Dis. **8:**792–802.
229. **Watts, N. B.** 1988. Medical relevance of laboratory tests. Arch. Pathol. Lab. Med. **112:**379–382.
230. **Weissfeld, A. S., and R. C. Bartlett.** 1987. Quality control, p. 35. *In* B. J. Howard, J. Klaas, A. S. Weissfeld, and R. C. Tilton (ed.), Clinical and pathogenic microbiology. The C. V. Mosby Co., St. Louis.
231. **Westgard, J. O.** 1987. What is quality?, p. 118–131. *In* S. L. Inhorn and B. V. Addison (ed.), Proceedings of the 1986 Institute on Clinical Issues in Health Laboratory Practice: managing the quality of laboratory test results in a changing health care environment. DuPont Co., Wilmington, Del.
232. **Whitby, J. L., W. A. Black, H. Richardson, and D. E. Wood.** 1982. System for laboratory proficiency testing in bacteriology: organisation and impact on microbiology laboratories in health care facilities funded by the Ontario government. J. Clin. Pathol. **35:**94–100.
233. **Wilderman, R. F., and K. A. Schneider.** 1986. Regulatory and legal influences on physicians' office laboratories. JAMA **256:** 252–253.
234. **Wilson, M. E., Y. C. Faur, S. Schaeffler, I. Weitzman, M. H. Weisburd, and M. Schaeffer.** 1977. Proficiency testing in clinical microbiology: the New York City program. Mt. Sinai J. Med. **44:**142–163.
235. **Winkelman, J. W.** 1984. Less utilization of the clinical laboratory produces disproportionately small true cost reductions. Hum. Pathol. **15:**499–501.
236. **Winkelman, J. W.** 1985. Quantitative analysis of cost-savings strategies in the clinical laboratory. Clin. Lab. Med. **5:**635–652.
237. **Wong, E. T.** 1985. Cost-effective use of laboratory tests: a joint responsibility of clinicians and laboratorians. Clin. Lab. Med. **5:**665–672.
238. **Wong, E. T., and T. L. Lincoln.** 1983. Ready! Fire!. . .Aim! JAMA **250:**2510–2513.
239. **Wong, E. T., and J. M. Nelson.** 1988. Quality assurance in the clinical laboratory. JAMA **259:**2584–2585. (Editorial.)
240. **Wong, L. K., A. L. Barry, and S. M. Horgan.** 1982. Comparison of six different criteria for judging the acceptability of sputum specimens. J. Clin. Microbiol. **16:**627–631.
241. **Woo, J., R. S. Schifreen, and J. W. Winkelman.** 1986. Controlling the cost of quality control. Clin. Lab. Med. **6:**755–786.
242. **Wood, R. J., and T. M. Durham.** 1980. Reproducibility of serological titers. J. Clin. Microbiol. **11:**541–545.
243. **Woods, D., and J. F. Byers.** 1973. Quality control recording methods in microbiology. Am. J. Med. Technol. **39:**79–85.
244. **Woodward, R. S.** 1987. Antibiotic cost savings from formulary restrictions and physician monitoring in a medical-school-affiliated hospital. Am. J. Med. **83:**817–823.
245. **Worman, H. J.** 1987. Excessive use of urine cultures for inpatients. Ann. Intern. Med. **107:**115. (Letter.)
246. **Yannelli, B., I. Gurevich, P. E. Schoch, and B. A. Cunha.** 1988. Yield of stool cultures, ova and parasite tests, and *Clostridium difficile* determinations in nosocomial diarrheas. Am. J. Infect. Control. **16:**246–249.