Appendix F.—Sources of Data on Aggregate Measures of Technological Change

Research and Development Data

The level of ongoing research and development (R&D) activity can be measured in terms of research spending, number of research projects, or personnel involved. In the private sector, two sources of data on industrial R&D inputs are the National Science Foundation's (NSF) annual survey of industrial R&D and data on the size of venture capital investment in various areas. Unfortunately, the validity of either of these sources of data as an estimate of R&D on medical technology is limited.

Industrial R&D Data

For two reasons, it is difficult to identify and quantify industrial R&D activities specifically related to medical technologies. First, most basic and some applied research lays the scientific foundation for a wide range of future products and processes, without being specifically attributable to a single or even a class of medical technologies. Second, the R&D data that are published are usually too aggregated to be useful in identifying specific trends.

The most readily available source of health industry R&D estimates is the NSF's annual survey of industrial firms (308), Firms are categorized for the survey by primary manufacturing product, represented by Standard Industrial Classification (SIC) codes (see table F-1). However, many firms develop and manufacture a variety of different products, not necessarily all of the same type or even all relating to a single field such as health care. Because the NSF estimates are for company-wide R&D, they overestimate R&D in a specific product area when companies whose primary line of business is in that SIC category conduct R&D in other product categories. They underestimate it when R&D for that product is conducted by firms classified in other SIC codes (308). The balance of over- or underestimation probably varies depending on the type of technology. For instance, many medical devices firms are owned by large multiproduct firms; thus, the balance is likely to be toward underestimation of industrial R&D on medical devices. '

Table F-1.—Selected Four-Digit Standard Industrial Classification (SIC) Codes for Health Care Products

SIC code	Products
3693	**X-ray and electromedical equipment**
3841	**Surgical and medical instruments**
3842	**Orthopedic, prosthetic, and surgical appliances and supplies**
3843	**Dental equipment and supplies**
3851	**Opthalmic goods**
2831	**Biological products, including** vaccines and blood derivatives
2833	Medicinal chemicals and botanical products
2834	Pharmaceutical preparations

SOURCE U S Executive Office of the President, Office of Management and Budget, *Standard Industrial Classification Manual,* Washington, DC, 1972

Venture Capital Investment Data

Venture capital has become a very important source of financing for many small and new firms and often funds investments in the development of new medical products (308). Analyzing data on the amount of venture capital invested in medical manufacturing firms is one way of assessing the level of private support for medical R&D. As a measure of innovation, however, such data are seriously flawed. The data themselves are limited in scope and specificity, and venture capital investments include investments in product commercialization and industrial expansion that do not necessarily contribute to R&D.

There are two sources of data on financial capital investment: 1) the Internal Revenue Service (IRS); and 2) private sources such as Venture Economics, Inc., a research and consulting division of Capital Publishing Corp. The IRS collects information on the sources of financial capital for firms in specific categories. (For example, IRS category 3698, "other electrical, " includes X-ray and electromedical devices.) However, the IRS categories in which firms producing medical products are classified include a substantial number of firms not engaged in the production of drugs and devices, and the data pertain to the financing of all activities in these fields, not just the financing of R&D.

Venture Economics, Inc., maintains an extensive database on the U.S. venture capital industry (371). Information on manufacturers that have received venture capital financing can be retrieved according to product category, such as medical imaging or industrial products. Although the investments recorded do not account for all venture capital investments, they do include a high proportion of those in the last few

'A further problem is that NSF's estimates of company-wide expenditures for applied R&D are subdivided into general product categories such as "professional and scientific instruments" and "other electrical machinery equipment and supplies. " These categories are too broad to allow the extraction of applied R&D expenditures that pertain specifically to medical technologies. Basic research expenditures are collected for the company as a whole and are not broken down by product class (308).

years and offer a representative picture of venture capital investment activity.

Data on New Product Introductions

The most useful sources of data on new medical product introductions are the U.S. Patent and Trademark Office and the Food and Drug Administration (FDA). Like the data sources on R&D, they suffer from several problems. Data from the various sources tend to be incomparable, redundant, or incomplete; and they usually do not measure new techniques, small but important modifications, or new or unconventional ways of using old products.

Patent Data

The U.S. Patent and Trademark Office classifies patents into 400 to 500 functional categories. FDA has recategorized the patent classes according to its own definitions (308). Thus, data on patent applications can be compared with the FDA-designated categories to yield information on the annual numbers of patent applications for medical products.

Patent data are somewhat untimely, however, because the delay between the application for and issuance of a patent currently averages more than 2 years. In addition, patent data suffer as a measure of new product introduction because they do not distinguish between products that are marketed and those that are not, Furthermore, not all new products (or modifications of old products) are patented. Many firms depend on trade secrets and rapid changes in technology and design to protect their products and profits, rather **than** relying on the patent process (220).

Food and Drug Administration Data

No single FDA file can produce a listing of all new medical drugs and devices. Several separate databases can provide relevant information and might be merged to provide more useful and comprehensive information. The most applicable data files are the following:

- *510k Registry.* —Whenever a manufacturer wishes to market a new medical device, or an old device with new features or uses, it is required by section 510(k) of the 1976 Medical Device Amendments to notify FDA. If the device is found by FDA to be "substantially equivalent" to a preenactment device, it may be marketed without further proof of safety and efficacy. If not, further proof may be required, depending on whether FDA classifies the device as Class I, Class II, or Class III.[2]

FDA maintains a file of all active 510k applications to track their progress through the system. As a comprehensive measure of new devices, this database suffers some drawbacks. For instance, if a new device is accepted as "substantially equivalent" to a previous device, it may be listed under the product code of the old device even if it has some major technological differences. Thus, a listing of all new products in the database would not necessarily produce a comprehensive list of all new devices. More important, there is no way to distinguish between minor modifications and significant new products.

- *Premarket Approval Application* (PMAA) *T'racking File.* —Devices that are not found "substantially equivalent" and present a potentially high risk are categorized as Class III devices and require FDA approval before being marketed. Applications for premarket approval are submitted by manufacturers showing the results of clinical trials and other safety and efficacy information that FDA requires. A PMAA tracking file at FDA lists all devices in this category, but the file does not discriminate between devices actually marketed and those that are not. To obtain a list of Class III devices being marketed, the PMAA tracking file must be matched with the device registration file (see below).
- *Device Registration* File.–Each manufacturer of medical devices must report annually to FDA the devices being manufactured by that firm. This file contains all medical devices being manufactured in the United States, but it does not distinguish between new and old devices.
- New *Drug Evaluation Files.* —The FDA Office of Drugs' New Drug Evaluation database contains information on all new drugs that have been approved for marketing by FDA, both prescription and over-the-counter. Its analog, the Abbreviated New Drug Application file, contains information on "me-too" drugs that are not chemically new but have been approved for marketing by a new manufacturer. Neither file, however, records whether a drug is actually being marketed at present.
- *Drug Registration and Listing.* —This file contains information on the current marketing status of all prescription drugs, updated through an annual compliance report by manufacturers. New drugs listed by a manufacturer in this file can be crosshatched with the New Drug Evaluation file, but the process is a tedious one. There is an equivalent database for over-the-counter drugs, but it is not updated regularly and is currently about 2 years behind.

[2]Of more than 17,000 510(k) notifications of intent to market a new medical device that were received by FDA for fiscal years 1977-1981, only approximately 300 were found to be not substantially equivalent (308).

Appendix G— PROs' Quality-of-Care Role in PPS[1]

The Utilization and Quality Control Peer Review Organization (PRO) program was established by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) as a direct successor to the Professional Standards Review Organization (PSRO) program; it was modified the following year by the Social Security Amendments (Public Law 98-21) that inaugurated Medicare's prospective payment system (PPS) for inpatient hospital services.

PROS, which are administered by the Health Care Financing Administration (HCFA), have substantial responsibilities for containing costs by reviewing hospital behavior in response to PPS incentives; they are also expected to carry out quality-of-care review.

Expectations of and tasks assigned to PROS derive in part from the history of peer review efforts going back a generation to the development of Foundations for Medical Care and the Experimental Medical Care Review Organization program.

The PSRO program, established by 1972 legislation and charged with both containing costs and assuring quality in the Medicare and Medicaid programs (121, 272), set the stage for PROS. The members of PSROs were to ensure that institutional services provided through the Medicare and Medicaid programs were medically necessary, of a quality that met locally determined professional standards, and provided at the most economical level consistent with quality of care (304).

Ultimately, the PSRO program proved a disappointment. Results of several evaluations of its cost-effectiveness were ambiguous (11,128,293,294,296,314, 321). PSROs may have saved about as much money as the PSRO program cost to run, but they certainly did not meet expectations of Congress, the Administration, and others in the cost-containment area.

PSROs had demonstrably positive effects on quality of care, although these were difficult to assess in a cost-benefit framework. Quality assurance methods improved during the PSRO era. Changing attitudes of the medical community during the 1970s and early 1980s, which saw many more physicians willing to band together in the interests of assessing and improving the quality of medical care, were attributable in part to the spread and activity of the PSRO program.

Disenchantment with the PSRO program, especially because of its inability to curb costs, led two Administrations to try to abolish the program. Congress, on the other hand, recognized potential quality impacts and decided to establish the PRO program at the same time that it initiated major changes in the financing structure of the Medicare program. The PRO program differs from the PSRO program in many ways. For instance, individual PROS are awarded competitively bid contracts, not grants as with PSROs. Furthermore, in an extension of a process initiated in the last days of the PSRO program, PROS must negotiate with HCFA a wide variety of numerical objectives for curtailing the use of inpatient care and maintaining or improving quality of care; PROS are to be evaluated in part according to how well they meet or exceed those objectives.

Table G-1 lists the requirements of PROS. Most PRO activities focus on hospital admissions and the use of invasive procedures, largely for cost-containment purposes. Five objectives required of PROS relate to quality of care: 1) reducing unnecessary hospital readmission due to previously substandard care; 2) assuring provision of medical services which, if not given, would have significant potential for causing serious patient complications; 3) "reducing the risk of mortality associated with selected procedures and/or conditions requiring hospitalization"[2] 4) reducing unnecessary surgery; and 5) reducing avoidable postoperative or other complications.

Several required activities involving admissions review have stringent numerical objectives, as do all five quality-of-care areas. Over a 2-year period, to meet their stated admissions objectives the PROS must eliminate 1.25 million admissions, just under 5 percent of total Medicare admissions in 1982 (239). It is possible that under such stringent numerical objectives, quality of care and access to inpatient care could decline.

The required quality objectives for the first 2-year contract period, which are common to all PRO contracts, were defined by HCFA. Within them, however, PROS were given flexibility to identify local problems and devise local approaches to solve them. The actual quantitative objectives were developed during contract negotiations with HCFA. The presumed gain in accountability through contracting and specifying numerical objectives is regarded as an improvement in management capabilities for HCFA relative to what was possible in the PSRO program.

Specific examples of PRO objectives in each quality area are presented in box G-A. Several PROS have objectives concerning the same diagnoses, but they do not have the same numerical goals or procedures to

[1]This appendix is based on a contract paper prepared for OTA by K.N. Lohr, entitled "Peer Review Organizations (PROS). Quality Assurance in Medicare" (185). That paper is available from the National Technical Information Service.

[2]This objective has recently been changed by HCFA from the controversial phrase, "decreasing avoidable deaths."

Table G-1 .—Major PRO Requirements

Hospital admission objectives:
- Reduce admissions for procedures that could be performed effectively and safely in an ambulatory surgical setting or on an outpatient basis.
- Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific DRGs.
- Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.

Other hospital admission and utilization reviews:
- Review "(before admission or before procedure) every elective case for 5 procedure-related DRGs (from a State-specific list of the top 20 procedures or procedure-specific DRGs for 1982).
- Review admissions occurring within 7 days of a discharge and deny all claims for inappropriate admissions.
- Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary.
- Review transfers from a PPS hospital to other hospitals or to specific PPS-exempt special unit or swing beds.
- Perform Admission Pattern Monitoring.
- Perform additional admission-related reviews in three distinct areas, including cases with specific principal diagnoses.
- Review admissions to and days of care in non-PPS hospitals or units.
- Carry out various other tasks relating to review and monitoring of hospital denials and notices of non coverage.

Quality of care objectives:
- Reduce unnecessary hospital readmission resulting from substandard care provided during the prior admission,
- Assure the provision of medical services which, when not performed, have "significant potential" (occurrence in 5 percent or more of cases) for causing "serious patient complications. "
- Reduce the risk of mortality associated with selected procedures and/or conditions requiring hospitalization.[a]
- Reduce unnecessary surgery or other invasive procedures.
- Reduce avoidable postoperative or other complications.

Other reviews:
- DRG validation.
- Review every case involving day and/or cost outliers for necessity and appropriateness of admission and subsequent care.
- Carry out special sets of reviews on DRGs #462 and #468.
- Monitor denial notices that hospitals issue to Medicare beneficiaries to ensure that they do not mislead the patient (or family) or misstate the hospitals' authority or responsibility as to decisions to terminate care.
- Monitor hospitals' compliance with the physician attestation requirements.

[a]!S objective was formerly "reduce avoidable deaths " it was changed by the Health Care Financing Administrationin 1985

SOURCE: K N Lohr, "Peer Review Organ izations (PROS) Quality Assurance in Medic are," prepared for Off Ice of Technology Assessment, U S Congress, Washington, DC July 1, 1985

meet those goals (380). Most quality objectives set by PROS for the first contract period concern problems that predated PPS and DRG-based payment. Whether the specific problems identified by the PROS persist in the PPS era or are supplanted by different problems, and whether the general areas of concern specified by HCFA are the crucial ones for PPS, remain open to question. One mark of the PROS' commitment to quality assurance, however, is that many took on more than just the five required objectives. The problems inherent in PRO quality activities have been noted by various observers, but PROS have a number of strengths as well. The more important limitations and strengths of quality assurance in the PRO program are listed in table G-2.

Some critics claim that the current quality objectives defined by HCFA are rather narrow and rigid. They

Table G-2.—Important Limitations and Strengths of Quality Assurance in the PRO Program

Limitations:
- Quality objectives are seen as rather rigid and narrow.
- Considerable ambiguity persists about program evaluation procedures and the weight to be given to quality assurance.
- If PPS has its intended effects on hospital use, questions about quality of care may arise for other providers (nursing homes, outpatient settings), but PROS do not have the mandate or the funding to carry out quality assurance activities in those areas.
- Many of the mandatory review tasks are also new activities (e.g., outlier review, DRG validation); getting them underway in a timely, effective manner may force PROS to skimp on quality review in the first year or so.
- Questions are raised that third-party payer organizations, such as fiscal intermediaries and insurers, are not as well equipped or disposed to emphasize quality concerns as are the PROS established by nonpayer organizations.
- Critics perceive the quality objectives (as well as objectives for admissions and invasive procedures) as quotas for limiting Medicare hospitalizations irrespective of whether the admission is appropriate or not.

Strengths:
- Several PROS formed by strong statewide PSROs (or amalgams of regional PSROs within a State) have a great deal of quality assurance experience.
- Many PROS are sufficiently committed to quality assurance efforts that they have taken on more than the required number (5) of quality objectives.
- All but 1 of the 54 PROS is a physician-sponsored (or physician-access) PRO; the 1 fiscal-intermediary PRO was organized by Blue Cross (of Idaho).
- Potential resources are broad: some PROS have substantial private review experience; some are independently developing analytic and research capabilities that might be applied to quality assurance.
- Medical record data are essential to comprehensive quality assurance, PROS are currently handling records from 30 to 40 percent of all Medicare admissions.

SOURCE K N Lohr, "Peer Review Organizations (PROS) Quality Assurance in Medicare, " prepared for Office of Technology Assessment, U S Congress, Washington DC, July 1, 1985

Box G-A —Specific Examples of PRO Objectives in Quality of Care

- **Reduce Unnecessary Readmissions Due to Substandard Care The South Carolina Medical Care Foundation detailed the following goals for this quality objective: "to reduce hospital readmission resulting from substandard care provided during the prior admissions from 1,543 cases (17 percent) to 908 (10 percent)." The numerical goals for this objective were based on data for the first quarter of fiscal year 1984 (i.e., the first PPS year). Of a total of more than 33,000 Medicare discharges, about 2 percent resulted in readmission; of these, about 17 percent were attributable to premature discharge. Similar findings were cited from Alabama. The South Carolina PRO concluded that with its retrospective quality review and other procedures, it would be able to reduce the 17-percent figure to 10 percent.**
- **Assure Provision of Necessary Medical Services. The objective statement of the Utah PRO for this quality area was "to assure the provision of necessary medical services through improvement in measuring baseline renal function, calculating appropriate dosage, and monitoring serum concentration levels during the usage of aminogiycosides." Aminoglycosides are powerful antibiotics; their concomitant risks and a relatively narrow range between effective and possibly toxic levels require that dosage levels be calculated carefully and that use is monitored closely (see ref. 28). Although the PRO could not precisely specify numerical goals, it was able to estimate that about half of all Medicare patients receiving aminoglycosides during hospitalizations were inadequately monitored. It proposed, therefore, to cut the rate of noncompliance with explicit monitoring criteria by so percent in the first year of the contract and by another 40 percent in the second year.**
- **Reduce Avoidable Deaths.* The New York PRO will pursue the following goal in this area: "to reduce by 514 the number of avoidable deaths with the diagnosis of pneumococcal, aspiration, or bacterial pneumonia." Information from New *York* State and three PSRO-area studies from the 1982-84 period showed that about 20 percent of patients of Medicare age admitted with the principal diagnosis of pneumococcal, bacterial, or aspiration pneumonia died; about 25 percent of these deaths were found to be preventable. Assuming that about 1,02$ patients admitted per year with these diagnoses would die, then about 257 deaths can be expected to be avoidable (0.25 X 1,028 deaths). Because the objective covers 2 years, the total number of avoidable deaths to be reduced is 514,**
- **Reduce Unnecessary Surgery or Other Invasive Procedures. In West Virginia, the PRO proposed to reduce by 528 cases the incidence of unnecessary surgery or other invasive procedures, with special reference to selected gastrointestinal procedures (esophagoscopy, gastroscopy, small bowel endoscopy, fiberop tic colonoscopy, large bowel endoscopy, and proctosigmoidoscopy). Factors that prompted this objective included a significant rise in gastrointestinal endoscopies, often in patients with at best minimal indications and frequently without prior X-ray studies that are usually considered critical diagnostic services. In perhaps as many as one-quarter of patients receiving such gastrointestinal procedures, the principal diagnoses were inappropriate or the procedure was otherwise apparently not indicated.**
- **Reduce Avoidable Postoperative or Other Complications. The Connecticut PRO proposed to reduce by 30 percent the number of postoperative urinary tract infections of indwelling catheters for patients r& ceiving six procedures (abdominal hysterectomy, disc excision, total hip replacement, bowel resection, cholecystectomy, and repair of hip fracture). The estimated reduction of 237 infections is to be accomplished over 2 years. The goal was based on chart review in one of the State's PSRO areas which showed an $.3-percent incidence of such infections. Data will be collected by retropective chart review. Interventions range from written communications to physician sanctions.**

● This objective is now "reduce the risk of mortality associated with selected procedures and/or conditions requiring hospitalization," It was changed by the Health Care Financing Administration

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau *Peer Review Organization Objectives: A Synopsis*, vol. 1, September 1984, cited in K.N., Lohr, "Peer Review Organizations (PROs): Quality Assurance in Medicare," prepared for Office of Technology Assessment, U.S. Congress, Washington, DC, July 1, 1985.

do not concern negative patient outcomes that fall short of death or major complications unless care was so poor that it necessitated a second admission, and they leave little room for modification if problems appear less serious than originally believed or if new problems surface.

Explicit criteria by which PROS' contract performance will be evaluated had not been issued (as of August 1985). HCFA has said that PROS' performance will be reviewed basically in terms of: 1) fulfilling numerical admissions and quality objectives, and 2) dollar benefits to the Federal Government (330). The relative weights to be given to meeting quality objectives, meeting admissions objectives, or adequately carrying out other tasks such as DRG validation or Admission Pattern Monitoring have not yet been made clear. Admissions objectives and other activities related directly to PPS could therefore take priority over quality objectives.[3]

PROS are not authorized by Medicare to review the quality of care delivered by nonhospital providers. Home health agencies and long-term-care facilities are of particular concern: If PPS has the expected effects on hospital use, caseloads for these long-term care providers will grow and patients will be on average sicker. The quality of some nursing home care has been questioned (158,373), and the methods to evaluate such care are still poorly developed (257,395).

Medicare beneficiaries have a great deal to lose if the quality of care in these settings is not monitored aggressively. The capacity for at least some PROS, especially those developed from strong PSROs, to take on such work is not in question. It seems unlikely that a second or complementary PRO program would be developed to take on such review, and it is not feasible for PROS to do so at their present funding and staffing levels.

PROS also do not have quality assurance responsibilities in nonacute or ambulatory care settings. As hospitals adapt to PPS by moving some services to the outpatient sector, a question that arises whether patients are more helped or harmed by the provision of care in such a wholly different way.[4] The validity of quality assurance efforts on behalf of Medicare beneficiaries can be questioned if the responsibility of the PROS stops at the hospital door. Again, at least a few PROS are probably capable at present of designing and implementing an effective ambulatory care review effort but not without additional resources and an explicit mandate to do so. HCFA is hoping to test quality review in nonacute and ambulatory settings by the start of fiscal year 1986 (78).

Whether PRO funding will prove adequate pervades the entire issue. PROS have a sizable budget—$339 million for the first 2-year cycle—but it is small in proportion to the $100+ billions that may be spent by Medicare just for hospital care in the equivalent 2 years. Furthermore, the portion of the PRO budgets directed to quality assurance may also be small because of the large number of other required functions and the uncertainty about the importance that will be placed on quality of care when contract performance is evaluated. If even as much as 25 percent of PRO budgets were spent for quality review, a miniscule proportion of the amount spent on inpatient care would be going for quality assurance. The interrelated effects of quality and admissions objectives further complicate the funding issue.

[3] On June 17, 1985, HCFA signed a contract with Systemetrics to be the "SuperPRO." The SuperPRO's three major responsibilities are to: 1) review PRO admission and DRG validation criteria; 2) replicate PRO reviews and compare them on a large sample of cases, and 3) identify quality issues not identified by the PROs. Results of the SuperPRO's monitoring activities will be available to HCFA for routine assistance to PROS and for contract purposes.

[4] The fact that the elderly will face increased out-of-pocket costs as a result of shifts in the site of care to the outpatient sector itself has quality-of-care ramifications, if Medicare patients do not obtain appropriate types or levels of care because of such financial barriers.