Appendix C
The Medicare Preventive Services Demonstration Projects

Description of the Projects

Authority and Funding

The Health Care Financing Administration (HCFA) is currently supporting six projects whose goal is to demonstrate the costs and effectiveness of providing preventive health services under the Medicare program. These projects provide a mix of health status assessments, immunizations, clinical screening services, and educational services to elderly individuals enrolled in the experimental arms of the projects.

The first of the six ongoing projects, administered by the University of North Carolina, was funded at HCFA's own initiative. HCFA solicited applications for preventive services projects in 1983 (48 FR 36660) and awarded funds to the University of North Carolina and Blue Cross/Blue Shield of Massachusetts in October 1985. The North Carolina study began offering services to the first participants in October 1986, completed recruitment of 2,400 participants in June 1988, and is now in its fourth year of operation. The Massachusetts study was ended after 18 months due to difficulty recruiting beneficiaries (64). The design of this study required participants to be randomized to one of three clinics to receive services, and many of the individuals asked to participate did not understand the purpose of the study or were unwilling to go to a provider other than their usual physician.

The remaining five of the six ongoing demonstration projects have only just begun. Unlike the North Carolina project, these projects were mandated by law (Public Law 99-272, as amended by Public Law 99-509).1 Applications for these projects were solicited in May 1987 (52 FR 20148), and funds were awarded in May 1988 (24). Each project had a 6-month developmental phase prior to recruitment. In addition, in order to carry out the demonstration, each project must receive permission to waive the usual Medicare coverage rules (which do not permit reimbursement for most preventive services) for the duration of the study. These waivers are subject to review by the Office of Management and Budget (OMB), which did not approve them until April 1989. Thus, these five projects could not begin recruiting subjects until May 1, 1989 (24).

Project funding for fiscal year 1989 is approximately $300,000 per study (range $290,000 to $330,000) (24). HCFA will renew funding on a noncompetitive basis each year subject to funding availability and to each project's ability to meet its objectives (52 FR 20148), The five mandated studies are subject to a collective maximum funding amount of *$5.9* million for their administrative costs (Public Law 99-509), which covers items such as researchers' salaries, patient and physician recruitment, and data collection and analysis.

The costs of the actual preventive health services provided under the waivers are not reimbursed from the project research funds and are not subject to any legislated cap. HCFA estimates that the cost of these services will be approximately $150 per person per year (24). These costs are paid out of ordinary part B Medicare funds.

Design

All six demonstration projects share certain similarities in objective and design. In each study, all study participants undergo an extensive health status assessment, performed by a nonphysician. Individuals in the experimental groups are also referred for appropriate screening, immunization, and educational services, with the exact services they receive varying by project and usually depending on their individual medical history and risk status. Control group patients get their usual care.

All studies randomize patients to experimental and control groups, although the groups being compared differ among studies (see table C-l). (In most cases, patients in both groups see their usual provider rather than being randomized to a particular provider.) In addition to examining the costs and effectiveness of preventive services, the projects test alternative methods of payment for these services (e.g., prepayment, fee-for-service) and involve a variety of different settings and health care providers in the provision of the services.

The scope of services provided by the demonstration projects is presented in table C-2. In general:

- *The North Carolina* project, which served as an example for the designs of the later projects, offers a mix of services that are fairly evenly divided between screening and counseling services. This project's design emphasizes a comparison of the effects of the broad components of a prevention program (screening alone, counseling alone, or both together) provided by a subject's usual primary care physician.
- *Seattle* incorporates the preventive services into the scope of care provided to the experimental patients in a health maintenance organization (HMO). This project offers the most comprehensive prevention package. It emphasizes immunization, cancer screen-

[1]The law specified that the demonstration projects must be administered by "accredited public or private nonprofit schools of public health or preventive medicine departments accredited by the Council on Education for Public Health' (Public Law 99-272). Thirty-four programs-twenty-four schools of public health and ten programs in community health/preventive medicine—meet these requirements (18). Eleven of them submitted proposals, and five of those proposals were funded (64).

Table C-1—Design of Medicare Preventive Services Demonstration Projects

Location	Raleigh-Durham, NC	Seattle, WA	San Diego, CA	Los Angeles, CA	Baltimore, MD	Pittsburgh, PA area
Directing organization	University of North Carolina	University of Washington	San Diego State University	University of California	Johns Hopkins University	University of Pittsburgh
Service provider	Physicians' offices, clinics	Group Health of Puget Sound (HMO)	Project team personnel, in conjunction with Secure Horizons (HMO)	Health prevention clinic staff/allied health professions	Beneficiary's usual care provider	Rural hospitals, clinics, physicians' offices
Number of providing sites	13	4	5 health assessment sites; 5 screening sites; approximately 11 health promotion sites in the community	1	Many	Many
Sample pool	Elderly patients of participating practices	Elderly HMO enrollees	Elderly **HMO enrollees**	Elderly patients of participating physicians	Efderly Medicare beneficiaries in local area	Elderly Medicare beneficiaries in local area
Sample size(total participants)	2,538	2,250'	2,400'	1,800[a]	4,400'	4,500'
Control group	958	1,125a	1,200[a]	900'	2,200'	1 ,500'
Experimental group(s)	Screening only (307)	Receive services (1,625)	Receive services (1 ,200)	Receive services (900)	Receive services at usual source of care (2,200)	Receive preventive services from clinic(2,000)
	Health promotion only (317)					Receive services from private physician (2,000)
	Both screening and promotion (900)					

[a]Antlcipated sample size as of November 1989 (recruitment still ongoing).

SOURCE: Office of Technology Assessment, 1990. (Information from project proposals and personal communication with project and HCFA personnel. See references.)

Table C-2—Preventive Services Offered in the Medicare Demonstration Projects

Service	Raleigh-Durham, NC	Seattle, WA	San Diego, CA	Los Angeles, CA	Baltimore, MD	Pittsburgh, PA
Immunizations:						
Influenza	x	x	x	[b]	x	x
Diphtheria/tetanus		x	x	[b]	x	
General clinical screening:						
Risk assessment review	x	x	x	x	x	x
Height/weight	x	x	x	x	x	x
Blood pressure	x	x	x	x	x	x
Dental exam				x	x	
Vision screen	x	x	x	x	x	x
Heariscreen	x	x	x	x	x	x
Other history/physical at physician's discretion	x	x	x	x	x	x
Laboratory tests:						
Hematocrit	x	x	x			x
Cholesterol (fingerstick)		x				x
Blood sugar (fingerstick)						x
Urinalysis	x			x		x
Mean cell volume						
Creatinine						x
Thyroid (TSH)						
Cancer screening:						
Physical breast exam	x	x		[b]	x	
Fecal occult blood	x	x			x	
Digital rectal exam	x	x			x	
Pap smear	x	x			x	
Pelvic exam		x			x	
Mammography				[b]		
Counseling services:						
Diet/nutrition	x	x	x	x	x	x
Stress reduction	x	x	x	x	x	
Exercise	x	x	x	x	x	
Sleep regulation		x	x	x	x	
Injury prevention	x	x	x	x	x	x
Drug/alcohol abuse prevention	x	x	x	x	x	x
Mental disorder prevention		x	x	x		x
Self-care/medication use	x	x	x	x	x	x
Smoking reduction/cessation	x	x	x	x	x	x
Life planning	x	x	x	x		
Breast self-exam		x	x			
Health care utilization		x				
Disease-specific education		x				x

[a] All ***demonstration*** projects include an assessment of immunization history and administration of or referral for pneumococcal pneumonia vaccine, if appropriate. This vaccine is already a Medicare-covered service.
[b] UCLA is referring patients to their physicians for these services, as appropriate.

SOURCE: Office of Technology Assessment, 1990. (Data from project proposals and personal communications with project HCFA personnel. See references.)

ing, and extensive organized counseling sessions, but it offers only one laboratory screening test. Control and experimental patients in this study are stratified according to their usual level of health care utilization.

- *San Diego also stresses* immunization and uses a specific, privately owned education program for the counseling segment of the protocol. It is the only project that includes a thyroid screening test. All clinical screening in this project is provided by two physicians and other supporting members of the project team.
- *The Los Angeles* project is the only site offering comprehensive dental screening and services in its package of preventive services. All services are provided at a single centralized health prevention clinic. Physician involvement is minimal and centers on a review of the risk assessment results with the patient, with followup services provided at the physicians' and patients' discretion.
- The *Pittsburgh* project emphasizes disease-specific screening and counseling, particularly for hypertension and diabetes. Services are provided through rural physicians and health clinics, with two experi-

mental groups that differ according to the settings in which subjects receive the screening and counseling services.

- Finally, the *Baltimore* project includes a moderately comprehensive array of services; unlike the Pittsburgh project, however, the setting is always the one in which subjects receive their usual care. This project differs from the others in that all counseling is provided by physicians during the office visit.

Reimbursement for the services received by experimental subjects is, with only one exception, based on a pre-set fee for a specified package of waivered services. In Seattle and San Diego, the two sites at which services are provided by pre-paid health plans, the package includes all services; these sites receive annual per-enrollee cavitation payments. At the Baltimore and North Carolina sites, payment is also based on annual rates per enrollee. The North Carolina payment is made in two parts, one for screening services and one for health promotion services. The Baltimore payment is an inclusive rate for ail services, but there can be an additional payment for an optional follow-up counseling visit. In the Los Angeles program, where all reimbursed services under the waiver are provided at a single site, the provider is reimbursed a set fee per visit for all clinical and counseling services provided in that visit.

The exceptional program is Pittsburgh, where there are two randomized experimental groups. Subjects authorized to receive services through a clinic or hospital are covered through a single capitated amount (per enrollee per year for all services) paid to the provider. Subjects authorized to receive services from private physicians are covered through a fixed fee for each service (e.g., a pre-set amount paid to the physician for providing counseling regarding hypertension). Physicians may, at their option, refer subjects to clinics for some counseling services; in this case, the clinic is reimbursed for the individual service.

Evaluation Plans

The law mandating the five demonstration projects required the Secretary of the Department of Health and Human Services (DHHS) to submit a preliminary report to the Congress by April 7, 1989, regarding their status. That report has been submitted. Public Law 99-272 also required the Secretary to submit an evaluation of these projects to Congress by April 7, 1991. This evaluation is to include:

- an assessment of the short- and long-term costs and benefits of providing these services to Medicare beneficiaries,
- an assessment of how these services might be financed under Medicare, and
- a recommendation to Congress regarding "appropriate legislative changes to incorporate payment for cost-effective preventive health services into the Medicare program" (Public Law 99-272).

The evaluation report due April 7, 1991 will include the results of the North Carolina project as well as latest results of the five mandated projects (24).

The five demonstration projects, awarded in April 1988, were scheduled for 6 months of planning, 2 years of service provision, and 18 months of evaluation. The five projects began delivering services in the spring of 1989. Consequently, unless it is delayed, the report planned for the spring of 1991 can only give interim results of the five projects.

Each project is required to evaluate itself and report the results of its experiment. In addition, HCFA will undertake a cross-cutting evaluation of the projects. The primary experimental outcomes to be evaluated include:

- utilization of preventive services by the experimental groups;
- costs of providing the preventive services and any associated treatment;
- changes over time in health status measures of experimental patients (e.g., improved functional status, improved self-assessment of well-being, lower weight, lower cholesterol level); and
- changes in utilization of other (nonexperimental) health care services (e.g., number of hospital days in general, changes in hospital days associated with specific diseases).

Abt Associates, under contract to HCFA, will work with the individual projects to ensure comparability of reporting of results among projects. In addition, this contractor will monitor the Medicare claims of a sample of individuals outside of the five projects in order to assess the impact of background trends in health care utilization and cost (51).

Evaluation Issues

Ability To Achieve **Results**

The ultimate goal of all six projects is to demonstrate the costs and effectiveness of providing preventive health services to elderly Medicare beneficiaries. All projects hope to show both better health status and a trend towards lower Medicare costs as a result of providing these services. Unfortunately, the only project with a realistic chance of yielding confident results on costs and health outcomes is the North Carolina study. The other five projects are likely to be most successful in providing information on the feasibility of providing services and the utilization of these services by the elderly under various conditions.

The difficulty in obtaining meaningful results regarding costs and effectiveness from the demonstration projects is due to the fact that only the North Carolina project will likely have at least 2 full years of data on all participants in the project by the beginning of 1991, when HCFA will be composing its evaluation. It is highly unlikely that any of the other five projects will be able to show any significant trends towards lower costs by 1991, even if cost savings might eventually accrue as a result of lower utilization. It is possible that some improvements in hospital bed-days for certain diseases (e.g., influenza), fictional ability, and self-assessed quality of life might occur within the short time that exists, but the failure to find an effect would not be surprising even if an effect exists. Thus, a lack of evidence of lower costs and improved outcomes could mean that the projects did not run long enough for the effects (e.g., improved functional status) to manifest themselves in individual patients in the experimental group. HCFA has no funds budgeted at this time for long-term followup of Medicare claims of study subjects.

The short time frame for service provision and data collection of the five mandated projects at the time of the April 1991 mandated report to Congress can be traced to two factors that contributed to a delay in initiating the projects. First, the process of soliciting applications, preparing and submitting proposals, and evaluating the proposals and awarding funds occupied nearly 2 of the 5 years allotted in the law. Second, the five projects required waivers of the usual Medicare coverage rules; those waivers must be approved not only by HCFA but by the Office of Management and Budget (OMB), which evaluates them as part of the budget process. The waiver process thus added an extra administrative step to startup time.

Design Issues

The design of the demonstration projects presents a number of conceptual problems common to many experiments conducted in the community setting. The most obvious of these is the difficulty of distinguishing between the care received by control and experimental groups. There is no limit to the services that individuals in the control groups receive; they may request and receive all of the same clinical services provided to the experimental group, as long as they pay the costs themselves. Furthermore, in most cases the same physicians (and nonphysician examiners) will be seeing both experimental and control patients. The physicians and associated office personnel may change their own behavior as a result of the project, suggesting or providing more preventive services as part of the "usual care" they provide to the control groups.

The potential similarities between control and experimental groups could make an observed lack of difference in outcomes difficult to interpret. Such a result could have any of three explanations:

1. that the preventive services provided to the experimental groups had no effect on health outcomes,
2. that the provision of enhanced services to one group leads health care providers to alter their behavior and provide enhanced services to the remainder of the population, or
3. that the "enhanced" services provided to the experimental group did not in fact differ from the usual care physicians provide to their patients.

If an effect is found, the design issues will center on what components of the enhanced service package produced the effect. Some of these components are tested explicitly within the design of individual projects. Pittsburgh, for example, is testing the comparative effects of providing services through a centralized clinic v. through private physicians' offices. North Carolina is comparing the relative effects of providing clinical screening only, health promotion only, and both components. In this case, however, it is unlikely that the sample size will permit detailed comparisons of the effectiveness of different components among groups. Significant results will most likely be obtained only for combined screening and health promotion/no screening comparisons.

The individual effects of other components, however, will be more difficult to identify. For example, the role of the health status assessment, what it covers, and how it is administered are slightly different in each project. In addition, some projects offer an opportunity for physicians to add to the information provided in this assessment by conducting their own patient history, while others do not. It is uncertain how much the assessments and clinical screening services in the project protocols duplicate or replace a standard "history and physical exam, ' what extra information they provide, and what aspects they may miss. Finally, the type and manner of services provided as a result of the information provided by the patient in the assessment differ among the projects. This diversity permits a wide variety of possible combinations to be tested, but it also increases the difficulty of determining which components contribute to the effectiveness of disease prevention, and which do not.

Implementation Issues

The demonstration projects are artificial settings in which certain services are packaged, promoted, and provided. Whatever the results of the demonstrations themselves, a major issue to be faced is whether those results will be applicable to ordinary circumstances in the general medical community, where providers will lack special preparation, intensive monitoring, and ties to

academic research centers. This problem is, of course, inherent in many experiments in medical care. A reasonable expectation is that the project outcomes will provide a maximum estimate for what can be expected to occur under ordinary conditions, where efforts to recruit and retain patients do not at present exist. In addition, the projects should provide important information about the circumstances under which participation and utilization is better or worse.

The failed Massachusetts demonstration project has already provided some indication of potential feasibility problems. In this project, a random sample of Medicare beneficiaries was to receive services at specified sites that were not linked in any way with the site where they received their usual medical care. After 18 months the project had not succeeded in recruiting enough patients to enable it to proceed, and a followup survey suggested that most individuals were unwilling to change providers, even temporarily, in order to receive preventive services. Two projects—the Los Angeles project, which uses a central service site, and the Pittsburgh project, which has experimental groups randomized either to a usual care physician or to a designated clinic site—will be testing this hypothesis further. Even if these projects do succeed in encouraging participants to receive care at sites other than their usual providers, it will still be uncertain whether beneficiaries under ordinary conditions would do so.

Other areas in which translating project protocols to real-world circumstances may be difficult are the use of project interviewers to perform health status assessment in all projects, and the use of special training for nurses and physicians performing counseling. To duplicate these features of the demonstration projects, physicians in private practice might need to hire additional staff or coordinate with outside organizations to provide services such as extensive risk assessment and counseling.

Finally, there is some self-selection on the part of physicians participating in the projects. These physicians may be more willing than others to adjust their style of practice to include (or exclude) specified preventive services for the elderly. Whether Medicare coverage of specified preventive services will itself encourage the same level of utilization as provision of those services in an experimental setting is a question that can be answered only after the fact.