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Summary and Conclusion;

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The computed tomography (CT) scanner remains an instructive case study which illuminates both the process of innovation and Federal policies toward medical technologies. Although the CT scanner is not in itself a major health policy issue, it can be used to understand problems in Federal policies.

The trends in diffusion of CT scanners have been the cause of much controversy. Federal policies have been cautiously developed to curtail the rapid diffusion of medical technologies such as the CT scanner. Critics have leveled a general charge that Government interference is inhibiting the process of innovation— one of the critical signs of a robust, dynamic economy. But it is difficult to ascertain whether the existence of the Health Planning and Resources Development Act itself, the process of review by health systems agencies (HSAs) and approval by State health planning and development agencies (SHPDAs) of applications for large capital expenditures by hospitals under certificate-of-need (CON) provisions of that Act or section 1122 of the Social Security Act, or the standards for CT scanning set in the National Guidelines for Health Planning to assist HSAs and SHPDAs in these functions have influenced the CT scanner diffusion rate. Although one would expect the diffusion and distribution of scanners to be related to Federal policies addressing them, there is really no good evidence available to indicate whether and to what extent any or all of these factors have influenced the diffusion of CT scanners.

Opposition to Federal policies concerning CT scanners has focused on the National Guidelines for Health Planning. For over a year now, the debate between manufacturers, providers, planners, and Federal authorities has honed in on the specific standards set in those guidelines. Although the guidelines have the potential to restrict diffusion and affect the distribution of scanners, diffusion slowed before development of the guidelines (see figure 1 in ch. 2). The standards set in the guidelines became effective only in March 1978. It should also be noted that the standards are advisory rather than mandatory. Scanners installed during 1979 were probably ordered months earlier. The rigor with which the guidelines are applied by HSAs in reviewing CON applications and the extent to which SHPDAs adhere to them in deliberating approval of CON applications are unknown. All these factors make the impact of the guidelines uncertain, It may be that the opposition to the guidelines themselves and the debate over the specific standards for CT scanners in them are based largely on the potential impact that the guidelines may have in the future, rather than on any effect that has been witnessed in the recent past. In addition, the role of the Federal Government in regulating diffusion of medical technology is being questioned.

The impact of CON regulations on the diffusion and distribution of scanners is, in general, currently unknown. (One study that is investigating the correlation between the implementation of State CON laws and the diffusion rate of CT scanners on a State-by-State basis is underway (21).) The manufacturers of CT scanners believe that the guidelines and CON regulations have had an impact. While requests for CT scanners are approved far more often than they are disapproved (74), the effect of the health planning process of discouraging applications must be considered as well. It may well be that the extremely high number of scanners sold in 1975 was induced by the anticipation of the impeding sanctions embodied in the upcoming health planning regulations (15). It also seems likely that a number of scanners were purchased for physicians' offices because of delays in obtaining permission for hospital scanners (15). Thus, the health planning program has partial responsibility for the existing maldistribution of CT scanners (see ch. 2). With the large number of older scanners in place, the health planning process may impede appropriate replacement and upgrading as well.

This discussion suggests a partial alternative explanation regarding the slowdown of the diffusion rate that would be the logical outcome of the intense market activity of 1975. That is that the market for CT scanners may be beginning to reach its limits. It is supported by close inspection of the data on distribution and diffusion of CT scanners to May 1980, when there were 1,471 operating scanners. Analysis of the institutional placement of scanners indicates that more than 80 percent of all large hospitals, or those over 500 beds, now have operational scanners. Even in early 1979, 62 percent of hospitals over 300 beds and 46 percent of those over 200 beds had scanners, A July 1979 presentation by the Technology Marketing Group, Ltd. (66), showed that of 2,250 hospitals with over 100 beds that did not have a scanner, only 23 percent were considering purchase of a scanner, while only 22 percent of the 624 hospitals with scanners were considering purchase of an additional one.

That the slowdown is more a natural phenomenon than a result of Government policy may be supported from a theoretical point of view as well as an empirical one. The cumulative diffusion curve of the installation of CT scanners in the United States is a textbook illustration of **a** theoretical innovation diffusion process (see ch. 2). The logistic curve is a model of that process that holds true of innovations such as automobiles, televisions, and automatic washing machines. Following the introduction of an innovation to the market, a certain percentage of interested parties will purchase it. Through time, this percentage will accumulate until virtually all of those who are expected to purchase will have done so. As more parties of this target group make their purchase, a smaller percentage are left to make theirs, so that over time the rate of diffusion must slow down and eventually level off. This phenomenon may just be manifesting itself in the 1978, 1979, and early 1980 data on CT scanner installations.

In addition to the question of whether or not Federal policies embodied in health planning programs have had an impact on the number of scanners, the question of whether they have had an impact on the distribution of scanners also remains at issue. Questions persist about the effectiveness of health planning laws with respect to the optimal location of scanners. Provisions of the health planning laws do not require CON approval of large expenditures made by private physicians. Currently, about 19 percent of the total number of scanners in this country are located in nonhospital settings. In particular, large urban hospitals typically serving a predominantly indigent clientele and large Veterans Administration hospitals lack scanners. Geographic maldistribution is also evident. Some urban areas have exceptionally high scanner-to-population ratios (the District of Columbia, for example, has 15.9 scanners per million population, and the Los Angeles area has 14.0 scanners per million); but some rural areas have no accessible CT scanner. Health planners have limited tools to assure placement in appropriate sites—their powers are largely negative. This may be the greatest problem with the health planning program.

Although Federal health planning programs may aim to curtail the diffusion of CT scanners, the stance assumed by the Federal Government in its policies toward other stages of development and use of scanners has tended to foster diffusion and widespread use. As noted earlier, Federal policies address all of the four stages in the development and use of medical technologies: R&D, demonstration of efficacy and safety, diffusion, and widespread utilization. In particular, the Federal Government has traditionally been a generous supporter of biomedical R&D. The real boon to diffusion and use of CT, however, has been in the Federal policy area of financing. Through its reimbursement policies, the Federal Government continues to assume an almost open-ended commitment to pay for CT scans. This posture has doubtless played an important role in the rapid acceptance of CT scanners and scanning in medical practice, thereby influencing the rate of diffusion and the aggreate supply of scanners.

Thus, a number of factors have affected CT scanner diffusion, not least of which is the revolutionary nature of the technology itself and its potential for improving diagnosis. The relative

impact of each of these factors will probably never be fully understood.

Although some changes have been made in policies regarding CT scanners since 1978, the underlying programs remain little changed, and the problems identified in OTA's 1978 report (129) remain largely unaddressed. For this reason, the policy alternatives of the 1978 report are reprinted in appendix A. They still seem to have relevance to those interested in improving Federal policies toward medical technologies.