steps to implement the recommendations of the select committee. One result was the introduction by Anderson and others of a bill to encourage river-basin planning. The Eisenhower administration had backed a bill on the same subject, and the new proposal was accepted by the Kennedy administration as part of its program.

Stiff opposition developed among groups suspicious of federal meddling in the affairs of the states. The Army Corps of Engineers was less than delighted with the prospect of infringement of its own considerable authority in planning for rivers and harbors, and the Engineers' influential friends came out against the bill (S. 1111).

Advocates of the measure persevered, however, and 2 years of discussion and revision produced a viable bill. Key to the compromise was a guarantee of authority of the states. Water rights problems between the states were not to be affected, nor were existing agencies to be disturbed. Provisions for a new kind of mixed federal-state river-basin planning commission also helped gain acceptance for the proposal.

Funds for Planning

The outcome is a bill which provides $5 million a year for 10 years for comprehensive planning and grant authorization. The Senate has passed its version of the bill, and the House version, which differs in only a few details, was favorably reported by the Interior Committee on Tuesday.

The spirit of compromise engendered on the river-basin planning bill smoothed the way for the Water Resources Research Act. Another Anderson bill, the water research measure was patterned on the venerable statute which created the agricultural experiment stations back in the 1880's. From the beginning the proposal had the built-in support of the land-grant colleges and state universities, which were designated its chief beneficiaries.

The bill was designed to achieve the double purpose of increasing water research through establishment of the new centers and increasing the number of water researchers by financing graduate study through the assistantships accessory to university grants and contracts. The bill provides $75,000 in fiscal 1965 for each state (rising to $100,000 a year in the fourth year and after) for establishment or expansion of water research "institutes" at land-grant institutions, or their state-designated equivalents.

In the second major title, the bill authorizes $1 million a year for 10 years for additional water research programs in institutions not covered by the first title. Not only private colleges and universities but foundations, private research firms, and state and local governments are eligible. The bill is to be administered by the Secretary of the Interior, and an Office of Water Resources Research has been set up in the Interior Department to oversee the new program of grants and contracts to universities and other research institutions. Acting director of the office is John C. Calhoun, Jr., science adviser to the Secretary of the Interior.

President Johnson, in signing the bill into law, voiced disapproval of one feature of title II which requires the Secretary to submit proposed grants, contracts, and other arrangements to the House and Senate—in effect, the two Interior committees—for approval. Johnson objected on the grounds that the provision "violates the spirit of the constitutional requirement of separation of power between the Executive and Legislative branches," and also because it would invite delay. He asked Congress to amend the act.

The bill was signed in July after passing through the legislative mill without serious difficulty. Agency support for the measure seems in some quarters to have amounted to faint praise. For there were some misgivings in the agencies about the effect on in-house research because of a possible diversion of funds for water research and of a drain on research manpower.

Passage of the bill does raise the question of whether the creation of 50 centers of water research will result in a harmful dispersion of talent. Although the bill permits states to combine funds to build centers for two or more states and interstate cooperation is encouraged, observers say these joint efforts are unlikely to materialize in very many cases.

A current shortage of hydroscientists was recognized in the Senate report on the bill, which noted, "we cannot vastly increase water research speedily if we would. The needed hydroscientists are not available. Experts in related fields must be recruited to specialize in the water field. Greatly increased numbers of the presently sharply limited cadre of hydrologists, hydroengineers, and hydroscientists of many disciplines must be trained to staff an adequate national research effort."

The clear alternative to distributing research centers on a basis of equal shares was federal support of extramural research in a few "centers of excellence." A general program was chosen because water problems are both widespread and diverse, and because it seems to offer a hope of training or converting more water researchers. This alternative also avoids the problem of locational politics, or at least transfers it to the states. A few research centers might well have been located in deference to the wishes of influential legislators, a not unheard of practice.

The water research bill, all in all, offers some interesting examples of the various kinds of politics which affect science legislation. The episode provides a fairly typical instance of how the federal government, when confronted with a particular problem involving a shortage of scientific and technical manpower, moves to establish a "need" and then prescribe the remedy. The form of the new water research bill constitutes one means of avoiding the old pork barrel approach in locating new research facilities. And the delay caused by the failure of coordination among the agencies encouraged Congress to keep the initiative.

—JOHN WALSH

Medical Ethics: British Unit Offers Guidelines for Research Involving Human Subjects

Concern over the ethical dilemmas which the growth of medical research poses for the investigator has been growing in Britain, as well as in this country. In the annual report of Britain's Medical Research Council to Parliament for 1962–1963 (published in July 1964), the Council issued a thoughtful statement entitled "Responsibility in Investigation on Human Subjects." Coming from an institution which supports most medical research in Britain (and which is roughly comparable in scope and stature to our National Institutes of Health), the statement is particularly significant. The Council clearly intends that the work under its jurisdiction should meet the ethical standards it outlines.

The following are major excerpts from the statement.

. . . A distinction may legitimately be drawn between procedures undertaken as part of patient-care which are intended to contribute to the benefit of

the individual patient, by treatment, prevention or assessment, and those procedures which are undertaken either on patients or on healthy subjects solely for the purpose of contributing to medical knowledge and are not themselves designed to benefit the particular individual on whom they are performed. The former fall within the ambit of patient-care and are governed by the ordinary rules of professional conduct in medicine; the latter fall within the ambit of investigations on volunteers.

Important considerations flow from this distinction.

Procedures contributing to the benefit of the individual. In the case of procedures directly connected with the management of the condition in the particular individual, the relationship is essentially that between doctor and patient. Implicit in this relationship is the willingness on the part of the subject to be guided by the judgment of his medical attendant. Provided, therefore, that the medical attendant is satisfied that there are reasonable grounds for believing that a particular new procedure will contribute to the benefit of that particular patient, either by treatment, prevention or increased understanding of his case, he may assume the patient's consent to the same extent as he would were the procedure entirely established practice. It is axiomatic that no two patients are alike and that the medical attendant must be at liberty to vary his procedures according to his judgment of what is in his patients' best interests. The question of novelty is only relevant to the extent that in reaching a decision to use a novel procedure the doctor, being unable to fortify his judgment by previous experience, must exercise special care. That it is both considerate and prudent to obtain the patient's agreement before using a novel procedure is no more than a requirement of good medical practice.

The second important consideration that follows from this distinction is that it is clearly within the competence of a parent or guardian of a child to give permission for procedures intended to benefit that child when he is not old or intelligent enough to be able himself to give a valid consent.

A category of investigation that has occasionally raised questions in the minds of investigators is that in which a new preventive, such as a vaccine, is tried. Necessarily, preventives are given to people who are not, at the moment, suffering from the relevant illness. But the ethical and legal considerations are the same as those that govern the introduction of a new treatment. The intention is to benefit an individual by protecting him against a future hazard; and it is a matter of professional judgment whether the procedure in question offers a better chance of doing so than previously existing measures.

In general, therefore, the propriety of procedures intended to benefit the individual—whether these are directed to treatment, to prevention or to assessment—are determined by the same considerations as govern the care of patients. At the frontiers of knowledge, however, where not only are many procedures novel but their value in the particular instance may be debatable, it is wise, if any doubt exists, to obtain the opinion of experienced colleagues on the desirability of the projected procedure.

Control subjects in investigations of treatment or prevention. Over recent years, the development of treatment and prevention has been greatly advanced by the method of the controlled clinical trial. Instead of waiting, as in the past, on the slow accumulation of general experience to determine the relative advantages and disadvantages of any particular measure, it is now often possible to put the question to the test under conditions which will not only yield a speedy and more precise answer, but also limit the risk of untoward effects remaining undetected. Such trials are, however, only feasible when it is possible to compare suitable groups of patients and only permissible when there is a genuine doubt within the profession as to which of two treatments or preventive regimes is the better. In these circumstances it is justifiable to give to a proportion of the patients the novel procedure on the understanding that the remainder receive the procedure previously accepted as the best. In the case when no effective treatment has previously been devised then the situation should be fully explained to the participants and their true consent obtained.

Such controlled trials may raise ethical points which may be of some difficulty. In general, the patients participating in them should be told frankly that two different procedures are being assessed and their co-operation invited. Occasionally, however, to do so is contra-indicated. For example, to awaken patients with a possibly fatal illness to the existence of such doubts about effective treatment may not always be in their best interest; or suspicion may have arisen as to whether a particular treatment has any effect apart from suggestion and it may be necessary to introduce a placebo into part of the trial to determine this. Because of these and similar difficulties, it is the firm opinion of the Council that controlled clinical trials should always be planned and supervised by a group of investigators and never by an individual alone. It goes without question that any doctor taking part in such a collective controlled trial is under an obligation to withdraw a patient from the trial, and to institute any treatment he considers necessary, should this in his personal opinion, be in the better interests of the patient.

Procedures not of direct benefit to the individual. The preceding considerations cover the majority of clinical investigations. There remains, however, a large and important field of investigations on human subjects which aims to provide normal values and their variation so that abnormal values can be recognized. This involves both ill persons and "healthy" persons, whether the latter are entirely healthy or patients suffering from a condition that has no relevance to the investigation. In regard to persons with a particular illness, such as metabolic defect, it may be necessary to know the range of abnormality compatible with the activities of normal life or the reaction of such persons to some change in circumstances such as an alteration in diet. Similarly it may be necessary to have a clear understanding of the range of a normal function and its reaction to changes in circumstances in entirely healthy persons. The common feature of this type of investigation is that it is of no direct benefit to the particular individual and that, in consequence, if he is to submit to it he must volunteer in the full sense of the word.

It should be clearly understood that the possibility or probability that a particular investigation will be of benefit to humanity or to posterity would afford no defence in the event of legal proceedings. The individual has rights that the law protects and nobody can infringe those rights for the public good. In investigations of this type it is, therefore, always necessary to ensure that the true consent of the subject is explicitly obtained.

By true consent is meant consent freely given with proper understanding

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of the nature and consequences of what is proposed. Assumed consent or consent obtained by undue influence is valueless and, in this latter respect, particular care is necessary when the volunteer stands in special relationship to the investigator as in the case of a patient to his doctor, or a student to his teacher.

The need for obtaining evidence of consent in this type of investigation has been generally recognized, but there are some misunderstandings as to what constitutes such evidence. In general, the investigator should obtain the consent himself in the presence of another person. Written consent unaccompanied by other evidence that an explanation has been given, understood and accepted is of little value.

The situation in respect of minors and mentally subnormal or mentally disordered persons is of particular difficulty. . . .

Investigations that are of no direct benefit to the individual require, therefore, that his true consent to them shall be explicitly obtained. After adequate explanation, the consent of an adult of sound mind and understanding can be relied upon to be true consent. In the case of children and young persons the question whether purported consent was true consent would in each case depend upon facts such as the age, intelligence, situation and character of the subject and the nature of the investigation. When the subject is below the age of 12 years, information requiring the performance of any procedure involving his body would need to be obtained incidentally to and without altering the nature of a procedure intended for his individual benefit.

Professional discipline. All who have been concerned with medical research are aware of the impossibility of formulating any detailed code of rules which will ensure that irreproachability of practice which alone will suffice where investigations on human beings are concerned. The law lays down a minimum code in matters of professional negligence and the doctrine of assault. But this is not enough. Owing to the special relationship of trust that exists between a patient and his doctor, most patients will consent to any proposal that is made. Further, the considerations involved in a novel procedure are nearly always so technical as to prevent their being adequately understood by one who is not himself an expert. It must, therefore, be frankly recognized that, for practical purposes, an inescapable moral responsibility rests with the doctor concerned for determining what investigations are, or are not, proposed to a particular patient or volunteer. Nevertheless, moral codes are formulated by man and if, in the ever-changing circumstances of medical advance, their relevance is to be maintained, it is to the profession itself that we must look, and in particular to the heads of departments, the specialized Societies and the editors of medical and scientific journals.

In the opinion of the Council, the head of a department where investigations on human subjects take place has an inescapable responsibility for ensuring that practice by those under his direction is irreproachable.

In the same way the Council feel that, as a matter of policy, bodies like themselves that support medical research should do everything in their power to ensure that the practice of all workers whom they support shall be unexceptionable and known to be so.

So specialized has medical knowledge now become that the profession in general can rarely deal adequately with individual problems. In regard to any particular type of investigation, only a small group of experienced men who have specialized in this branch of knowledge are likely to be competent to pass an opinion on the justification for undertaking any particular procedure. But in every branch of medicine specialized scientific societies exist. It is upon these that the profession in general must mainly rely for the creation and maintenance of that body of precedents which shall guide individual investigators in case of doubt, and for the critical discussion of the communications presented to them on which the formation of the necessary climate of opinion depends.

Finally, it is the Council's opinion that any account of investigations on human subjects should make clear that the appropriate requirements have been fulfilled and, further, that no paper should be accepted for publication if there are any doubts that such is the case.

The progress of medical knowledge has depended, and will continue to depend, in no small measure upon the confidence which the public has in those who carry out investigations on human subjects, be these healthy or sick. Only in so far as it is known that

such investigations are submitted to the highest ethical scrutiny and self-discipline will this confidence be maintained. Mistaken, or misunderstood, investigations could do incalculable harm to medical progress. It is our collective duty as a profession to see that this does not happen and so to continue to deserve the confidence that we now enjoy.

Announcements

A graduate program leading to the master's and doctor's degrees in **materials science** has been established at the University of Virginia. The curriculum, open to persons holding a bachelor's degree in engineering or science, will center on the quantum mechanics of solids, crystal structure of materials, and the theory of lattice defects. Experimental research will concentrate on work with electron microscopes, x-ray diffractometers, and high and low energy electron diffraction apparatus. A training and research program in medical and dental materials is also being established, supported by an NIH grant. Information on the new programs is available from H. G. F. Wilsdorf, Department of Materials Science, University of Virginia, Charlottesville.

The National Bureau of Standards' Institute for Basic Standards is starting a four-phase program to establish **standards for radar equipment**. The work is being done at the Boulder, Colorado, laboratories, for the Defense Department's Advanced Research Projects Agency. The program will concentrate on exploratory research and on technical requirements in measurements of radar power, noise, and antenna patterns. Additional information is available from J. M. Richardson, chief of the Radio Standards Laboratory, NBS, Boulder.

Meeting Notes

Papers on **theoretical and experimental physics** are invited for presentation at the American Physical Society meeting 21–23 December in Berkeley, California. Persons giving papers may be members of the society or nonmembers whose papers are sponsored by members. Deadline for receipt of abstracts: *16 October*. (W. Whaling, California Institute of Technology, 1201 E. California St., Pasadena)